CRANFIELD UNIVERSITY

KATARZYNA E. PANIKOWSKA

Service-oriented Design of Microfluidic Devices

SCHOOL OF APPLIED SCIENCES

PhD Thesis

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Academic Year 2010-2011

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January 2011

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Abstract

Microfluidics is a relatively new and, with an estimation of the market for these devices exceeding $ 3 billion in 2014, it is considered a profitable domain. Constant development of new technologies and growing demand for more versatile products cause increasing complexity in this area. To address this, the current trends for the domain include automation, standardisation and customisation. At the same time, the society is moving from product types offering to services. Due to the customisation trend this transition appears beneficial for microfluidics. Taking advantage of these opportunities, an investigation of microfluidic design has been undertaken to address the issues at their origins.

The literature review showed a lack of a general design methodology applicable for all microfluidic devices, identified existing approaches as technology driven and the domain as unique in terms of design. Also, it highlighted a number of automation and standardisation attempts in the area. In addition, microfluidics shows limited customer and service-orientation. Meanwhile, an investigation of complexity and its implications in microfluidics narrowed the study to sub-section interactions, which allowed standardisation and automation without compromising customisation.

In response to these gaps, an aim of the research is to develop a guideline for service-oriented design of microfluidic devices that can deal with sub-section interactions. This research reviews: existing methodologies for design in micro-scale, their applicability to the domain, microfluidic practitioners' approach to design, state of service-thinking and services in the area and how sub-section interactions are dealt with for these devices.

The developed guideline and design enablers present a proposal for a general process for the design of microfluidics. The solution attempts to tackle the issue of sub-section interactions and brings the domain one step towards an 'experience economy' by incorporating service-considerations into the design process. The usefulness of this contribution has been confirmed by a variety of methods and numerous sources including experts in the field.

Acknowledgements

I would like to thank the Innovative Manufacturing Research Centre (IMRC) at Cranfield and Engineering and Physical Sciences Research Council (EPSRC) for their funding and support. Also, I would like to thank my supervisors: Dr Ashutosh Tiwari and Dr Jeffrey R. Alcock, who provided advice, support and guidance in the completion of this research project. Moreover, I would like to express my gratitude to participants of the research from industry and academia for their contribution and effort.

My special appreciation goes to:

- Dulan Mudalige, whom I feel honoured to know as a friend.
- Krzysiu, Eliza, Ela, Kasia and Marta for trusting in my decisions, sometimes more than I did.
- Joanna Zawadzka, Sarocha Phumbua, Kay Godain and Catia Sousa for good and interesting times, with a hope we will have more.
- Leigh Kirkwood, Rob Evans and Robert Sawko for enlightening me about the world and its mysteries – constantly broadening my horizons.
- And everybody who helped to dance my worries away.

I owe my deepest gratitude to my family for motivation and encouragement. They provided me with inspiration to work and to overcome any difficulty, not only over the past three years but in my whole life. It is parents who showed me the importance of knowledge. My appreciation to my Mum and Dad, for believing in me and continuous support. My gratitude to Izabela, who showed me that there are many paths in life and gave me a responsibility, even if I was trying to avoid it at first. I appreciate it now. My thanks to Agnieszka, who is always keen to listen to my worries, even if none of us can find a solution. I am grateful to both my sisters for being there for me and caring. I also would like to thank Marcin and Grzegorz for help and encouragement. To all members of my family: close and far, old and new, always believing in me - I love you all.

Most of all, I would like to thank the Lord for his grace and love. I am wishing for him to grant me serenity, courage and wisdom through my life.

During last three years

"I chewed my nails and I twiddled my thumbs

I was real nervous but it sure was fun".

Therefore,

Thank You All! I am ready for the Next Challenge

List of Publications

Conference papers

Panikowska, K., Tiwari, A. & Alcock, J.R. (2008), "Complexity in Engineering Design and Micro Devices: A Review of Literature", in: *International Conference in Manufacturing Research ICMR'08*, 9-11 September, London, UK, p.505-512.

Panikowska, K., Tiwari, A. & Alcock, J.R. (2009), "Design in the Microfluidic Domain as Compared to Other Domains", in: 17th Conference on Engineering Design ICED'09, 24-27 August, Stanford University, Stanford, CA, USA.

Accepted papers

Panikowska, K., Tiwari, A. & Alcock, J.R. (2011), "Towards Service-orientation – state of service thoughts in the microfluidic domain", accepted to the *International Journal of Advanced Manufacturing Technology*.

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Frequently Used Abbreviations

2D	Two Dimensional
3D	Three Dimensional
ASIC	Application-Specific Integrated Circuit
B2B	Business to Business
B2C	Business to Customer
BIST	Built-In Self-Test
CAD	Computer Aided Design
CFD	Computational Fluid Dynamics
DFR	Design for Reliability
DFS	Design for Service
DFT	Design for Testability
EPSRC	Engineering and Physical Sciences Research Council
FEA	Finite Element Analysis
FEM	Finite Element Method
FPGA	Field-Programmable Gate Array
IMRC	Innovative Manufacturing Research Centre
IP	Intellectual Property
IT	Information Technology
LIFT	Laser Induced Forward Transfer
LOC	Lab-On-a-Chip
MEMS	Microelectromechanical Systems
MINAM	Micro- and NanoManufacturing (European Technology Platform)
MST	Microsystems Technology
NPD	New Product Development

PCR	Polymerase Chain Reaction
PLC	Product Life-Cycle
POC	Point-of-Care
PSS	Product-Service System
R&D	Research and Development
SOA	Service-Oriented Architecture
SOD	Service-Oriented Design
VLSI	Very large Scale Integration

Chapter 1
Introduction

This Chapter presents an overview on the PhD research '*Service-oriented Design of Microfluidic Devices*'. It starts by providing motivation for the research and briefing its background. Next, the research aim and objectives leading towards its realisation are presented. Then, the structure of the thesis is outlined to provide a reader with more detailed description about how the research aim has been addressed.

1.1. Research Motivation

'Service-oriented Design of Microfluidic Devices' PhD is part of a bigger project – 'Designing PSS (Product-Service Systems) for Complex Micro-integrated Devices' involving a number of researchers. This project is sponsored by EPSRC (Engineering and Physical Sciences Research Council) and IMRC (Innovative Manufacturing Research Centre) at Cranfield University.

Although, this project has been undertaken for all micro-integrated devices to investigate PSS opportunity in the micro-world its scope has been narrowed for this PhD. Rationale for this change from academic point of view is presented below. Reasons which motivated the author to this research are: focus on the design aspect as one of the main interests, challenges posed by the novelty of the microfluidic domain, combination of new research areas and opportunity to enhance transferable skills such as time-management and self-motivation.

1.1.1. Why Microfluidics?

In the past ten years research into, and the use of, small-sized devices has rapidly increased, highlighting micro-technology as a strong economic driver in the 21st century. Market research shows not only rapid annual growth in this sector but also

trend predictions for its further development. According to the NEXUS report (2005) commercialised micro-devices with direct customer applications showed the highest potential in terms of market growth and market share. Microfluidics is a part of this market. For details regarding the market drivers for the design of micro-devices and microfluidics in particular see Appendix 1.

"Microfluidics covers the science of fluid behaviours on the micro-/nano-scales and the design engineering, simulation, and fabrication of fluidic devices for the transport, delivery, and handling of fluids in the order of microliters or smaller volumes" *(Bhushan, 2007:523).*

Although, the manipulation of fluid in microfluidic devices takes place in micro-scale their dimensions and volume scale differ in a broad range (see Figure 1-1). Applications areas for these devices include:

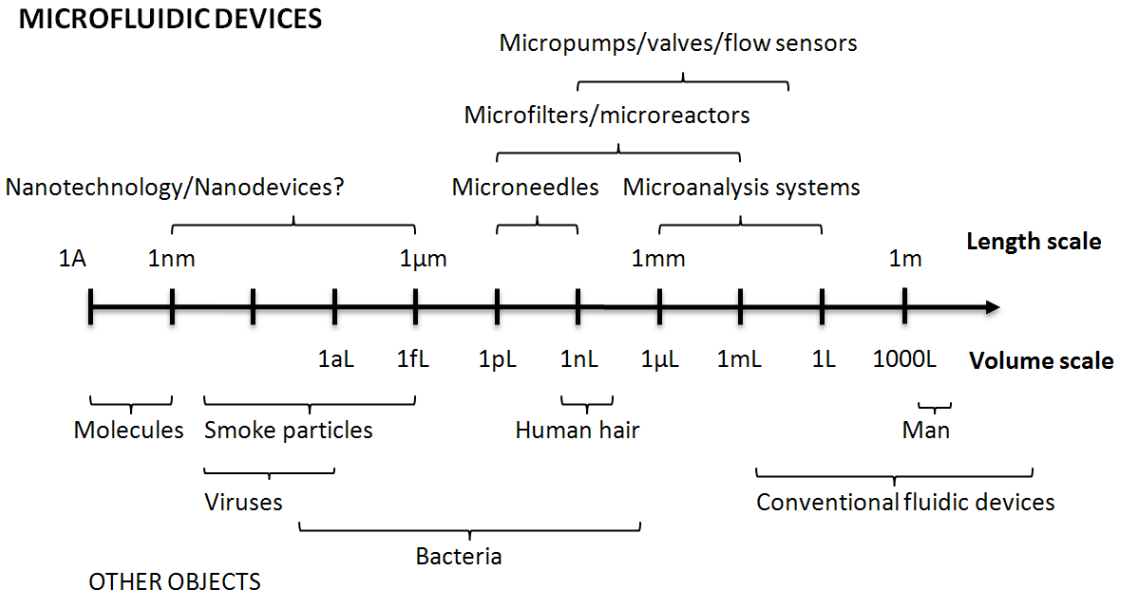


Figure 1-1 Size characteristics of microfluidic devices (Nguyen & Wereley, 2006)

Evaluated for well beyond 10 billion € global turnover includes inkjet printing technology (which is the most mature and commercially successful part of microfluidics market and includes areas of applications such as industrial automation, dispensers, life science, etc.). Therefore, no surprise that this is

considered as "one of the most dynamically emerging disciplines of microtechnology" (Ducrée et al., 2004).

1.1.2. Why Design?

There are different definitions of design, e.g.

- Definition 1:

"Designing is: describing a new possibility, which is expected to allow the achievement of a preferred situation." (Cowie, 1993)

- Definition 2:

"The purpose of design is to produce knowledge about a designed object which can then be used to manufacture the object." (Balazs and Brown, 1994)

- Definition 3:

"Design is an engineering activity that:

  - *Affects almost all area of human life,*
  - *Uses the laws and insights of science,*
  - *Builds upon special experience, and*
  - *Provides the prerequisites for the physical realisation of solution ideas"* (Pahl, Beitz and Wallace, 1996)

- Definition 4:

"Design is the human power to conceive, plan, and realize products that serve human beings in the accomplishment of any individual or collective purpose." (Buchanan, 2001)

All presented definitions possess common factors and all are considered valid for this research. They provide various points of view on what is tried to be achieved by design – obtaining a suitable solution addressing an issue. Therefore, through design

a customer problem can be solved by development of a suitable solution. In microfluidic area this solution is currently a product.

Although, the initial development of microfluidic devices can be dated to late 1980s (Tay, 2003), a work on design methodologies[1] for this area is still relatively immature. In the past, designers have sought to adapt approaches used in other domains. However, due to differences between domains, this adaptation has fallen short of expectations (Albers, Marz & Burkardt, 2003). Moreover, a generic design concept in this area had not been developed (Hardt, 2005).

Research proved that companies with formal NPD (New Product Development) process are more successful (Martin and Horne, 1991). Therefore, development of design methodology for microfluidic devices seems useful for the area.

1.1.3. Why Service-oriented?

Society is shifting towards an 'experience economy' (Tukker, 2004). This transformation could be observed in the 90's in the USA (Wise and Baumgartner, 1999). Researchers identified "that in many manufacturing sectors, revenues from downstream activities represent 10 to 30 times the annual volume of the underlying product sales" (Wise and Baumgartner, 1999). Hence, organisations begin to focus on providing services required for operation and maintenance of products. Motivation for this is relatively new. This motivation is to create a strong relationship with the customer and help to attain the customer loyalty. Increasing profit impact by increasing customer retention has also justified this (Voss, 1992). Moreover, it has allowed to acquire insight into customer needs. It has improved suitability of offerings and helped to satisfied needs faster. However, the movement downstream towards services is not beneficial in case of every company. Supplying

[1] "a specific method, approach and/or set of rules to be followed when solving a given design problem. For example, it may take the form of rules concerning the order of performing certain design tasks, how problems are to be decomposed, or, which particular tools are to be used for a certain task. Typically a company or group will specify a methodology for designers to follow so as to ensure consistent design results." (Sutton & Director, 1996)

services to the customer is a big investment. Hence, it has to have an opportunity of revenue in the future.

Transition towards services has proven as natural in other domains. Preparing microfluidics for future is the main target of this research. Therefore, orienting design towards services can help bridge the gap expected to be faced by this domain.

But how this service-orientation has been defined for this research? No single definition was identified which will express fully meaning of service-orientation. Definitions which were closest to the sought meaning are as follow:

- Definition 1:

  Service-orientation - is a way of thinking in terms of services and service-based development and the outcomes of services (The SOA Definition team of the SOA Working Group, The Open Group, 2006)

- Definition 2:

  Service-oriented Design – is a design which supports human centred development by imagining future lives, creating scenarios of services desired by customers and designing products on basis of this approach (Ueda, 2009)

- Definition 3:

  Service-orientation – is moving towards model of a 'bundle' of products and services, not concentrating on one or the other (Martin & Horne, 1992)

Regarding specifics of the domain to maximise potential benefits from the research, the meaning of service-oriented design in the project has been used as follow:

Service-oriented Design – is a design which supports the development of a 'bundle' of products and services. It incorporates thinking of services, service-based development and is leading towards services as an outcome or part of the outcome.

1.1.4. Why Sub-section Interactions?

Increasing complexity of microfluidics (Chatterjee, 2003) has negative influence on their modelling and micro-architecture in terms of testability and manufacturing cost (Bose, Albonesi & Marculescu, 2003). This research focuses on sub-section interactions in microfluidics. Since direct definition of sub-section interactions could not be found, the development of a suitable definition for this research has been approached, by combining meaning of sub-section[2] and interactions[3], which resulted in following:

Sub-section interactions are understood as relations between modules of the device and their interoperability.

Although researchers are pointing out that micro-scale devices are usually characterised by a high degree of integration of functionalities and components (Tietje & Ratchev, 2007) and that these interactions among parts and sub-sections play a large role in the micro-design process (Albers, Oerding & Deigendesch, 2006), an exhaustive description of this influence and its characteristics were not identified in the literature.

1.2. Research Focus

This research tries to provide an insight on the microfluidic design, service-orientation and methods to deal with sub-section interactions. It investigates the current practice in the domain and tries to address gaps identified.

The research does not try to solve all the problems rising in the area. However, it attempts to enhance work of people and simplify their future tasks.

[2] any of the smaller parts into which a section (a part, subdivision, a piece) may be divided (Collins Dictionary, 2010); a section (one of several parts or pieces that fit with others to constitute a whole object) of a section; a part of a part; i.e., a part of something already divided (Free Dictionary, 2010);
[3] interact – to act on or in close relation to each other (Collins Dictionary, 2010); Interaction - a mutual or reciprocal action or influence (Free Dictionary, 2010)

1.3. Research Aim & Objectives

1.3.1. Research Aim

The research aim is to develop a guideline for service-oriented design of microfluidic devices that can deal with sub-section interactions.

1.3.2. Research Objectives

Objectives are as follow:

1. To understand the state-of-the-art in the service-oriented design of microfluidic devices.
2. To identify the influence of sub-section interactions on the design of microfluidic devices.
3. To identify how service requirements are defined for microfluidic devices.
4. To develop a guideline for service-oriented design of microfluidic devices that can deal with sub-section interactions.
5. To validate the proposed guideline using multiple methods.

1.4. Thesis Structure

To provide the reader with logical information flow from the project realisation, which has been carefully planned and executed according to established methodology (Chapter 3), this thesis has been structured by following an investigation path from initial area investigation to conclusions. This path starts from introduction of the research background and identification of gaps to be addressed, through identification of state-of-the-art practice in the domain, development of the solution addressing selected gaps and its validation. It sums-up with conclusions and recommendations for future research.

This section outlines the thesis structure in terms of its content. It presents issues discussed in each chapter, interconnections between the chapters and their contributions to publications. Thesis structure, presented in Figure 1-2, is as follow.

Chapter 1 – Introduction – presents motivation and background of the research, its scope, aim and objectives and structure of the thesis. The purpose of it is to introduce a reader to the topic and explain rationale behind it.

Chapter 2 – Literature Review – provides an insight into literature in three areas: design of microfluidics, service-orientation and sub-section interactions. It presents the realisation of Objectives 1 and 2 of the research. This chapter intends to expose to the reader current situation in the area from literature point of view. It highlights the gaps in the domain some of which will be addressed by the research.

Chapter 3 – Methodology – details methodological approach developed to execute this research. It includes a review of existing research methodologies and a selection and customisation of methodology to be applied. This chapter introduces a reader to the techniques and tools used in conducting this research as well as the path followed to obtain the outcome – the guideline and design enablers.

Chapter 4 – Microfluidic Design Practice – presents analysis of the current practice in microfluidic domain in terms of design, services and methods to deal with sub-section interactions. It demonstrates the accomplishment of Objectives 1, 2 and 3 of the research. This chapter is uncovering the gap in the practitioners' work that aims to be addressed by this research.

Chapter 5 – The Guideline and Design Enablers – introduces the main contribution of the research – the solution addressing identified gaps in microfluidic design. The solution consists of two elements: the guideline for service-oriented design of microfluidic devices that can deal with sub-section interactions and a set of design enablers. This chapter executes Objective 4 by the exhibition of the guideline and design enablers and intends to present the developed solution and the path used to obtain it.

Chapter 6 – Validation – deals with the testing of the solution presented in Chapter 5. This chapter presents the execution of the last objective – Objective 5. Validation has been performed in multiple manners using comparative analysis with

literature and practitioners work, workshops and structured feedback questionnaires. This chapter intends to evaluate how the presented solution is fulfilling the research aim.

Chapter 7 – Discussion – provides a detailed rationale behind development of the solution (the guideline and design enablers), explores its composition, indicates potential users and how the solution is intended to be utilised, and exposes the main areas addressed. This chapter gives the context of developed solution to the reader underlying its advantages and limitations.

Finally, Chapter 8 – Conclusions and Future Research – presents the contributions of the research to knowledge and draws conclusions based on the work described in this thesis. Moreover, it suggests future research to be undertaken in the domain and possibilities of further enhancement of the presented solutions.

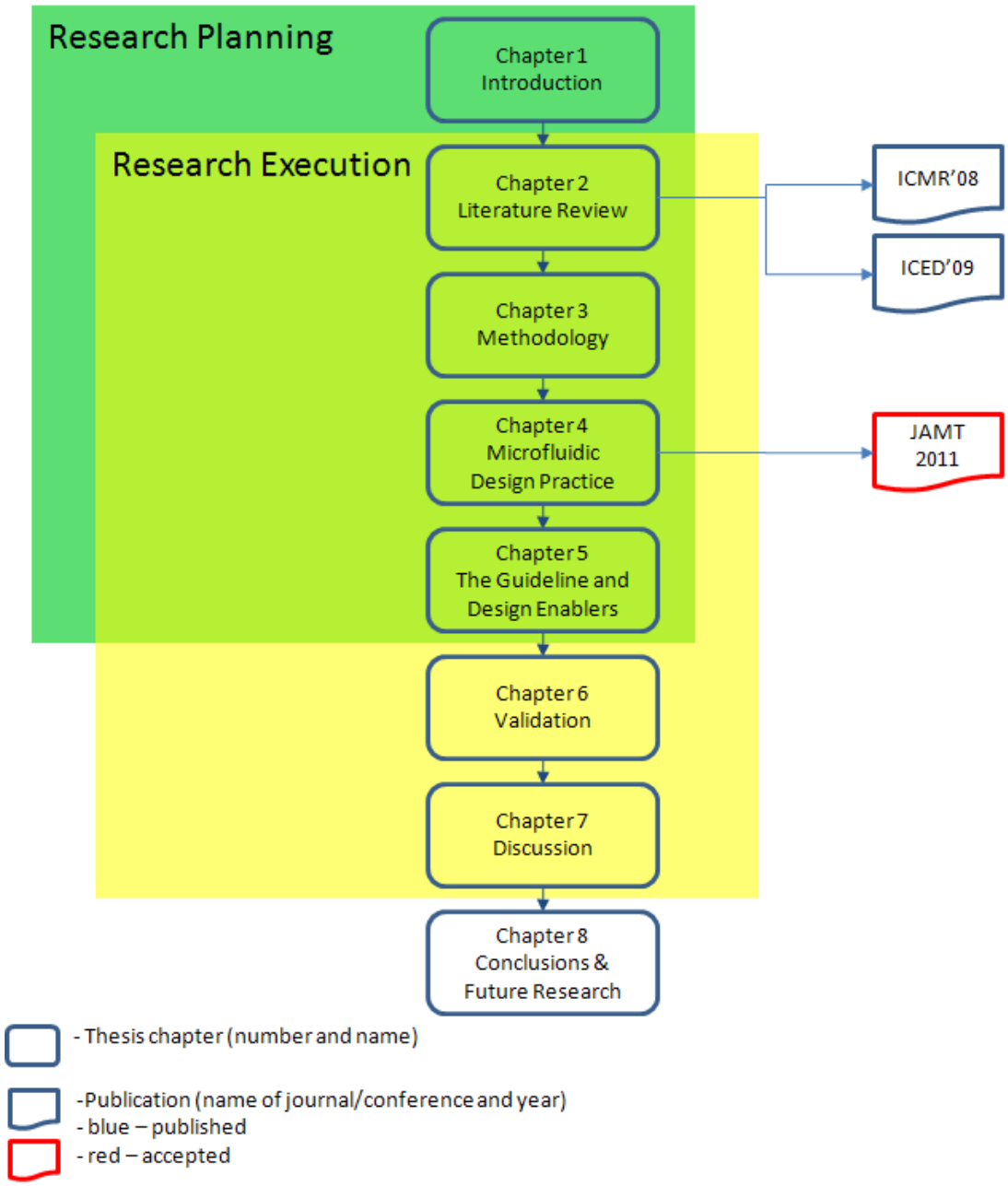


Figure 1-2 Thesis structure

Chapter 2
Literature Review

To understand the characteristics and needs of the area, a literature investigation has been scoped. This chapter presents the state-of-the-art literature in the three domains on the overlap of which the research lies: design methodology, service and sub-section interactions. Selection of these three topics for investigation has been based on (see Section 2.1.2) the identification of microfluidics as an area with high potential for customisation, and hence, stepping into the service future. However, this future could be threatened by the increasing complexity of these devices. An overlap of these areas, if properly addressed, creates the potential to utilise an opportunity presented by a high profit market with minimisation of risk for the future.

First, a review of how microfluidic devices are designed is presented. Due to limited information on design methodologies developed for the domain, the presentation of the literature starts from general design approaches for micro-scale device design, which is followed by design methodologies and models developed for micro-domains, and specifically for microfluidics. Next, the domain dependence of the design process for microfluidics is reviewed. Then, a comparison between identified models for micro-scale device design is presented. Finally, the applicability of the reviewed approaches to microfluidic design, based on the identified domain characteristics, is reviewed.

Second, the level of service-orientation of microfluidic literature is identified. It starts by exploration of the service-type literature in microfluidics and broadens around service-connected design literature which can be applicable in this domain.

Finally, methods applied in the microfluidic domain to deal with complexity are described. This identification starts with an attempt to search for a definition of

complexity for microfluidics and other micro domains. Next, the researchers' views on microfluidics are briefed. Then, methods to tackle sub-section interactions in microfluidics, as one of the crucial aspects of complexity in micro-scale, are reviewed and finalised by a presentation on how modularity is seen in the domain.

2.1. Design of Microfluidics

Design methodology for micro-devices has been the subject of investigation for a decade. Design methodologies specific to the micro-domain have been considered as a necessity, owing to the failure of the successful application of methodologies used for macro-devices. However, in general, the development in methodologies for micro-scale devices has used conventional product development practices as their starting point (Albers, Marz & Burkardt, 2003). Researchers have then initiated developments for the micro-domain by introducing their own methodologies, e.g. based on existing digital and analogue design methodologies (Mukherjee & Fedder, 1998) as well as adapting them from other domains.

Literature regarding the design of micro-devices is usually focused on specific applications types, such as MEMS[4] (Microelectromechanical Systems) (Mukherjee & Fedder, 1997; Fedder, 1999; Swart, 1999; Baidya, Gupta & Mukherjee, 2002; Mukherjee, 2003; McCorquodale et al., 2003), or robotic micro devices (Havlik & Carbone, 2006); on particular devices, e.g. air vehicle (Conn, Burgess & Ling, 2007); or on part of the design process (Bunyan & Ward, 1997) and the tools and techniques used within it (Karam et al., 1997; Senturia, 1998; Gobinath, Cecil, & Powell, 2007).

Due to limited literature on design methodologies for microfluidics, a review of micro-specific design approaches is presented and their applicability for microfluidics discussed. First, the main approaches used for the micro-domain in general, are presented to indicate the structure, or lack of it, in the design processes for micro-scale. Second, design models for the micro-domain in general, developed based on these approaches, are briefed and followed by models created, in particular,

[4] considered as narrower to MST (Microsystems) by focusing on technology including electromechanical elements – for details on nomenclature differences please see McKenna (2000)

for microfluidics. Because of the large number of applications and long history of some of these models and approaches in the macro domain, only literature considering their use for design of micro-scale devices is reviewed. Next, domain dependence of microfluidic design and its characteristics are uncovered. Finally, the applicability of the presented models to microfluidic design is discussed.

2.1.1. Fundamental Approaches to Microsystems Design

Four general approaches were indicated by literature as fundamental for micro-scale domain: unstructured, structured, bottom-up and top-down. Firstly, the unstructured approach is presented and is followed by the structured approach which is derived from it. Next, the bottom-up and top-down methodologies are reviewed.

2.1.1.1. Unstructured and Structured Approach to Design

Unstructured Approach to Design

Commonly used in the development of MEMS is an unstructured design flow (Fedder, 1999). It has mainly been used when an interplay of electronics and micromechanical components takes place in the device. As the name suggests, this approach does not follow any particular methodology and the process of design itself is unstructured and ad-hoc.

Structured Approach to Design

The majority of research regarding a structured approach to design is for application to MEMS development. The main difference between the structured and unstructured approach, is the combination of the different domains, the micromechanics and electronics, into a single flow scoped around the core of the device. In the case of microelectronics, this is the circuit representation. There is no current equivalent for microfluidics.

2.1.1.2. Bottom-up and Top-down Design Flows

A 'bottom-up' design flow and a 'top-down' design flow, applied to micro-scale devices, are less focussed on automation and design tools, and more on the design process itself. These, considered as the two primary design methodologies for MEMS (Liu et al., 2007), are presented below.

Bottom-up Approach

A 'bottom-up' design is an expression used to describe an approach in which the designer goes from structural to system level in design (Feynman, 1986). This approach is considered as natural and referred to as traditional. It starts from individual components, which are separately tested and verified, and is followed by verification of the whole system. It has been commonly used in the design of micro-scale devices, especially at microfluidic chips (Chakrabarty & Su, 2005).

In the bottom-up approach, MST (Microsystems Technology) devices are combined to form modules, which are then combined to obtain the complete system. Verification of the system behaviour, however, is performed at the last stage, which may cause costly redesign efforts.

Top-down Approach

A 'top-down' design is an expression used to describe an approach in which the designer goes from conceptual to detail, from architectural-level to component-level design (Feynman, 1986). It starts at the system-level, with requirements and performance, by development of a block diagram which is simulated and optimised to provide requirements for individual blocks, and later on components. Design is finished at the component-level when all the details are agreed and verified.

McCorquodale et al. (2003) presented a model of a 'top-down' methodology, addressing one of the main issues faced with bottom-up design. It allows for design of large multi-domain systems by consideration of architectural-level and analysis of

implication of component interoperability up front in the design process (Kundert, 2001).

Mukherjee (2003) provided an exhaustive comparison between top-down and bottom-up approaches. He noted the advantages of the top-down approach, but also implied that a bottom-up approach is a barrier for optimisation at the lowest level of the hierarchy (component-level design), and hence, it is not suitable for customisation purposes where reconfiguration of components, possibly by modular structure of device design, can be beneficial.

2.1.2. General Design Models for the Micro-domain

The approaches to design presented above - top-down, bottom-up, unstructured and structured - are only the basis for design flow models and methodologies. In the main, design flows are created as a combination of these approaches (Fedder, 1999). An example is when the top-down approach is used to design a device in micro-scale and the bottom-up approach to verify it.

In this section, design methodologies for the micro-domain are briefed. These models are presented in chronological order based on time when the approach was originated.

VLSI (Very Large Scale Integration)

An approach which can be seen as useful for microfluidic design, is VLSI (Very Large Scale Integration). This process of creation of integrated circuits has benefited from clear separation between fabrication and design over the last 20 years (Wagener et al., 2005).

However, since in micro technology, the structural design greatly depends on the laboratory experience, manufacturing process plan and manufacturing skills, clear separation into device design stage and fabrication stage in the design flow is not recommended (Liu et al., 2007). Iteration incorporated in the design of VSLI in comparison to the MEMS design flow is presented in Figure 2-1.

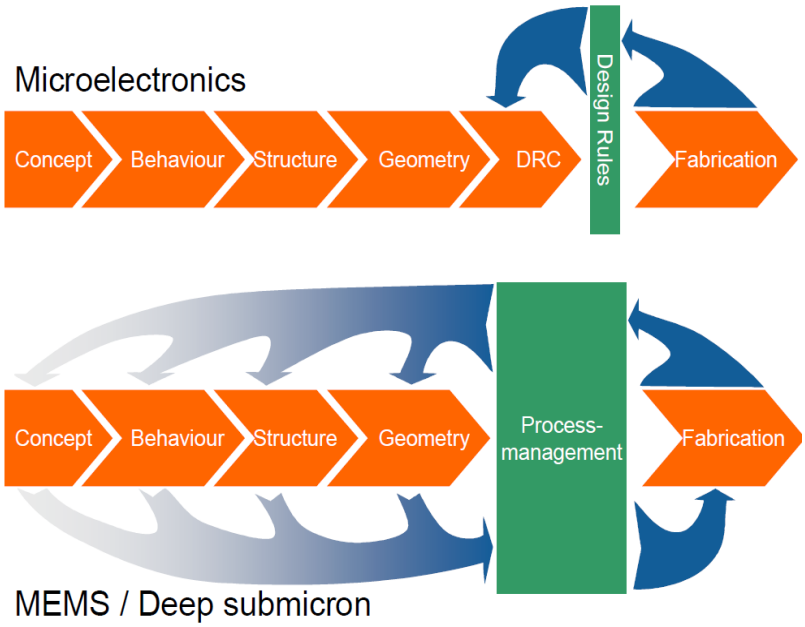


Figure 2-1 Design processes for VSLI and MEMS development (Wagener et al., 2005)

Y-model

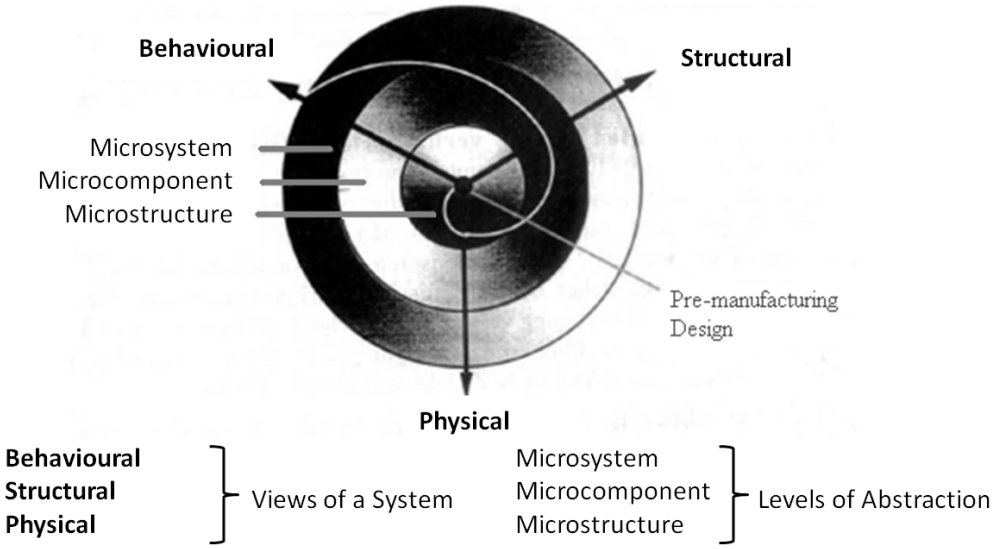


Figure 2-2 Y-shape model (Hahn, 1999)

The 'Y model' was developed by Hahn in 1999 (Hahn, 1999). However, it has a number of precursors. It was originated by Gajski and Khun (1983) as the 'Y-chart', and enhanced by Walker and Thomas (1985) to the 'Y-shaped' model, based on which Hahn developed his model. He replaced previous levels of abstraction

(introduced by Walker and Thomas in 'Y-shaped' model) with system, component and structural levels (see Figure 2-2). Hahn presented a general model of design in comparison to the detailed and microelectronic focused Y-models developed by his precursors. His approach requires not only the object of design to be created but also development of the production sequence in parallel, as presented in Figure 2-2 by the spiral line from the vertex to the behavioural model axis. This incorporation of manufacturing consideration is the main enhancement in comparison to previous Y-models (Wagener & Hahn, 2003).

Hierarchical Model

Another approach which was considered by Albers, Oerding and Deigendesch (2006) as applicable to micro-devices manufactured using mask-based technologies, is what they called a 'hierarchical model'. This model was claimed by them to have been developed by Wagener and Hahn in 1994. However, the author of this review failed to find this particular model in the work of Wagener and Hahn. The model mentioned by Albers, Oerding and Deigendesch (2006) divided complete systems into a number of hierarchical levels with corresponding subsystems and components. Each subsystem was developed and tested separately, and then implemented into the higher hierarchical level until the complete system was achieved. They stated that design flow starts from a definition of requirements and specifications, and is then followed by design, implementation and integration in order to provide a complete description of the system with simultaneous validation and eventual set up and test of prototypes.

Circle Model

The "circle model" is a highly iterative model, employed by Schumer in 1998 as an innovative approach for MEMS development (Schumer, 1998). It comprises of four steps: layout design, process development, verification and process modification, which are arranged in a circle (see Figure 2-3). The shape of the model represents the cyclic, concurrent procedure of designing and redesigning layout and processes. The emphasis on the model is on the concurrent development of the mask layout and

production process. Therefore, it was viewed as suitable for adoption to microstructure design (Albers et al., 2005). A disadvantage of this model is repetition of the cycle until an optimised solution is achieved, which makes it time-consuming and not very intuitive (Popp et al., 2004). However, this model covers the particular sequence of processing steps and parameters suitable for MEMS physical design (Hahn & Brück, 1999). This model, undertaken with a bottom-up design approach, provides a close look at detailing the steps required for the development of an application specific fabrication sequence (Brück et al., 2006). This consideration of the technology aspect has enormous importance in the design of microfluidics.

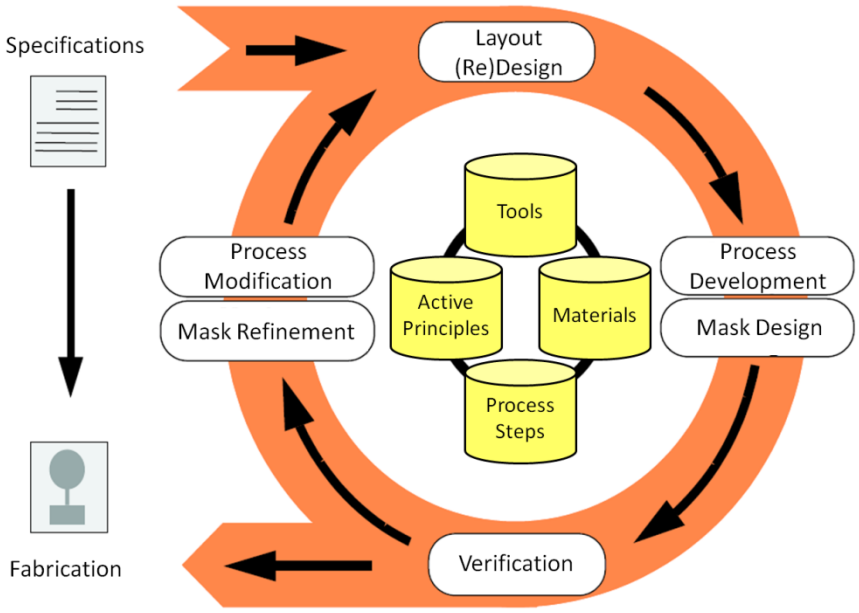


Figure 2-3 Circle model (Schumer, 1998)

Pretzel Model

The 'pretzel model' emphasised (Wagener & Hahn, 2003) parallelism of production planning while designing micro-scale devices. This model used parallelism in developing the behavioural design, focusing on the performance (not on the appearance of the object) and the processing sequence (see Figure 2-4). This simultaneous work is necessary due to issues such as, use of new materials or new combinations of materials. The pretzel model combines specifications and results of the process design. It consists of top-down and bottom-up approaches, and

combination of both (Wagener, Popp & Hahn, 2004). The top-down, behaviour driven (Brück et al., 2006) approach starts by analysis of requirements and transferring them into a schematic arrangement of microstructure components, from which a 3D (Three Dimensional) model is synthesised. This 3D model takes into account the different materials used in the device in which performance is simulated using FEM (Finite Element Methods). Difficulty in obtaining an appropriate process step sequence results in a high number of iterations, and in some cases, when a suitable process is not obtained, in redesign of the 3D model. However, in cases when the process is obtained, the system and its fabrication are sufficiently described (Wagener, Popp & Hahn, 2004).

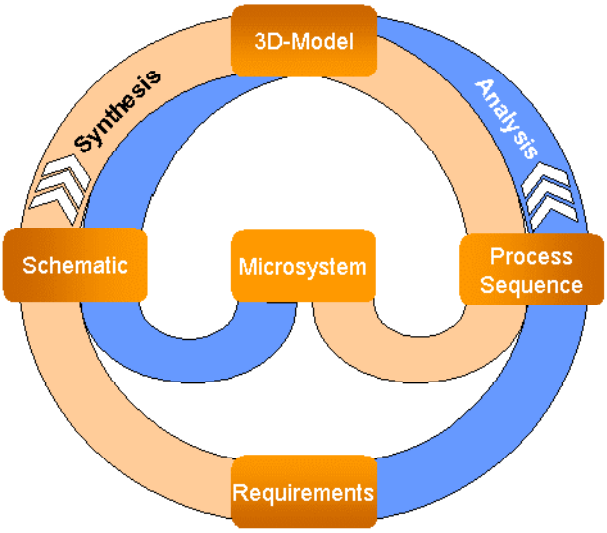


Figure 2-4 Pretzel-model (Wagener & Hahn, 2003)

The bottom-up, process driven approach (Brück et al., 2006), in the context of this model, is understood as the design of a consistent fabrication process capable of coping with a specific class of microstructures. Design and verification of process flow are followed by adoption of new technology since this approach is designated for new technology applications in micro-scale devices (Wagener, Popp & Hahn, 2004).

Most common for design (using the circle model) is a combination of top-down and bottom up approaches. This approach undertakes design of 3D model from two sides - the schematic development with top-down and the process flow with bottom-up -

simultaneously. The iteration in matching these two parts together is undertaken with the circle model (Wagener & Hahn, 2003), as discussed previously.

Sickle Model

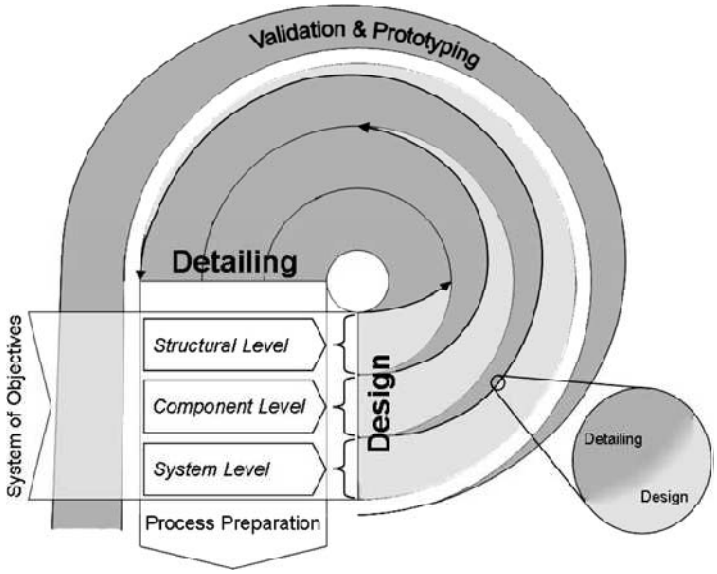


Figure 2-5 Design flow for tool-based microtechnology - sickle model (Albers et al., 2005)

The sickle model was introduced by Albers and Marz in 2005. It is named in accordance with a sickle shaped transition from the design stage to the detailing stage (see Figure 2-5). This model represents design at different levels of abstractions, introduced by centric rings, which are structural, component and system level, where the outer ring, 'system', is the most abstract. The design flow itself runs counter-clockwise, from the conceptual stage, through basic design, to concrete detailed design. This model contains the bottom-up approach from structural to system level, and the top-down approach from conceptual to detail design stage. This representation is visible in Figure 2-5 in a global circle curve. The strong influence of technology is underlined in this model. Manufacturing processes should be decided for the conceptual model at the structural level in order to assure that the final result of design will meet the given specifications. These specifications can be achieved by suboptimal results. In case of the appearance of suboptimal

results, the model is developed in an iterative manner. The model was verified by its creators based on the design of micro planetary gear[5] (Albers et al., 2007).

V-model

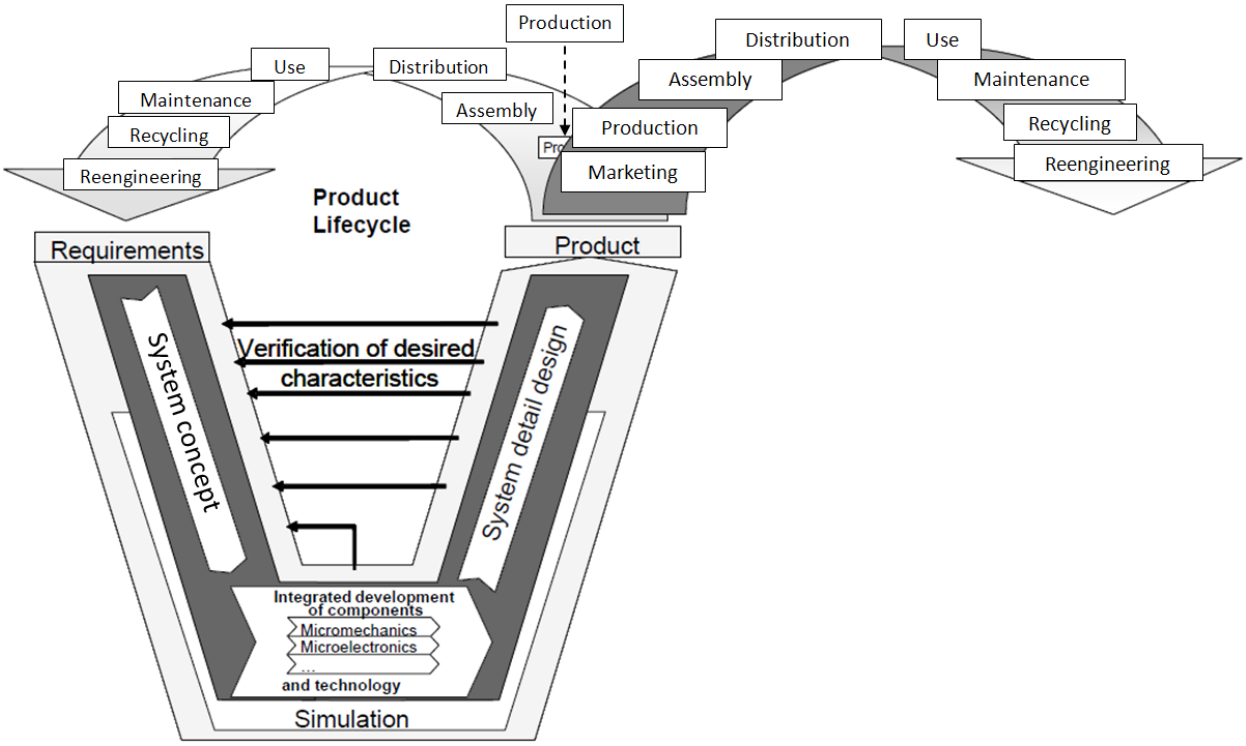


Figure 2-6 V-model MEMS development process (Watty, 2006)

The 'V-model', derived from VDI 2206[6] methodology (Albers, Burkardt & Deigendesch, 2007), and introduced by Watty in 2006 as an approach for mechatronic design, presents the whole development process for MEMS. It is general (Watty, 2006) and starts with the generation of an interdisciplinary system concept (see Figure 2-6). This step is followed by parallel development of the system components and manufacturing technology, which is characteristic of this set of devices. This stage has been identified as crucial to avoid faulty interactions between the components and environment of the system. The concluding system integration verifies products according to given specifications. This iteration has

[5] a system in which one or more of the gear elements (planet) rotates around another gear (sun) (Hillier & Coombes, 2004:293)

[6] Verein Deutscher Ingenieure 2206 – the guideline for mechatronic systems (VDI 2206, 2004)

been stated as a necessity due to the fast changing environment and simultaneous development of the manufacturing technology. These stages of design were placed in the product development process by Watty, to show the incorporation of knowledge and demands from different phases of the product's life. He underlined that this process is general, and needs adaptation and has to be specified for the demands of particular product development, supporting himself by the statement, "well defined and continuous MEMS development process, like the classic process for mechanical tasks, is often not possible."

2.1.3. Design Models Developed for Microfluidics

Several design models have been identified for microfluidics. However, all of them have been focused on restricted types of microfluidic devices and have dealt only with issues particular for them. This high specialisation made these processes inapplicable across the domain. For example, Lin and Chang (2009) presented a design methodology for digital microfluidic biochips focused on pin-count reduction. This methodology is highly driven by technology, presents only the detailed design stage, and is not transferable to other types of devices. Later on, these authors (Lin and Chang, 2010) enhanced their work by cross-contamination awareness; however, claims made about their first model stand.

Similarly, Cortes-Quiroz, Zangeneh and Goto (2009) presented what they named a design methodology for staggered herringbone mixers. Their approach, however, not only is driven by technology but also appears as a 'design optimisation methodology' - and not a 'design methodology'. It starts by definition of the set of experiments or simulations – no indication of how and from where they are obtained – and it is finished by obtaining a set of optimum designs. The approach is considered as part of the design process, and not an end-to-end design process. It is viewed as a presentation of the use of three techniques (DOE (Design of Experiment), FA (Function Approximation technique) and MOGA (Multi-Objective Genetic Algorithm)) for the optimisation of microfluidic geometry with the focus on micromixers; therefore, it is not applicable across the field of microfluidics in terms of general design, but applicable inside the design for calculation and process

automation purposes. Hence, the mentioned approaches will not be included for further considerations.

Only one model has been identified in the literature as developed specifically for the microfluidic domain and showing the potential for application to a variety of devices. Chakrabarty and Su (2005) developed their own 'top-down' methodology for design of biochips (see Figure 2-7). They selected a top-down approach as useful on the system level for the microdomain to speed up the design cycle and reduce human effort.

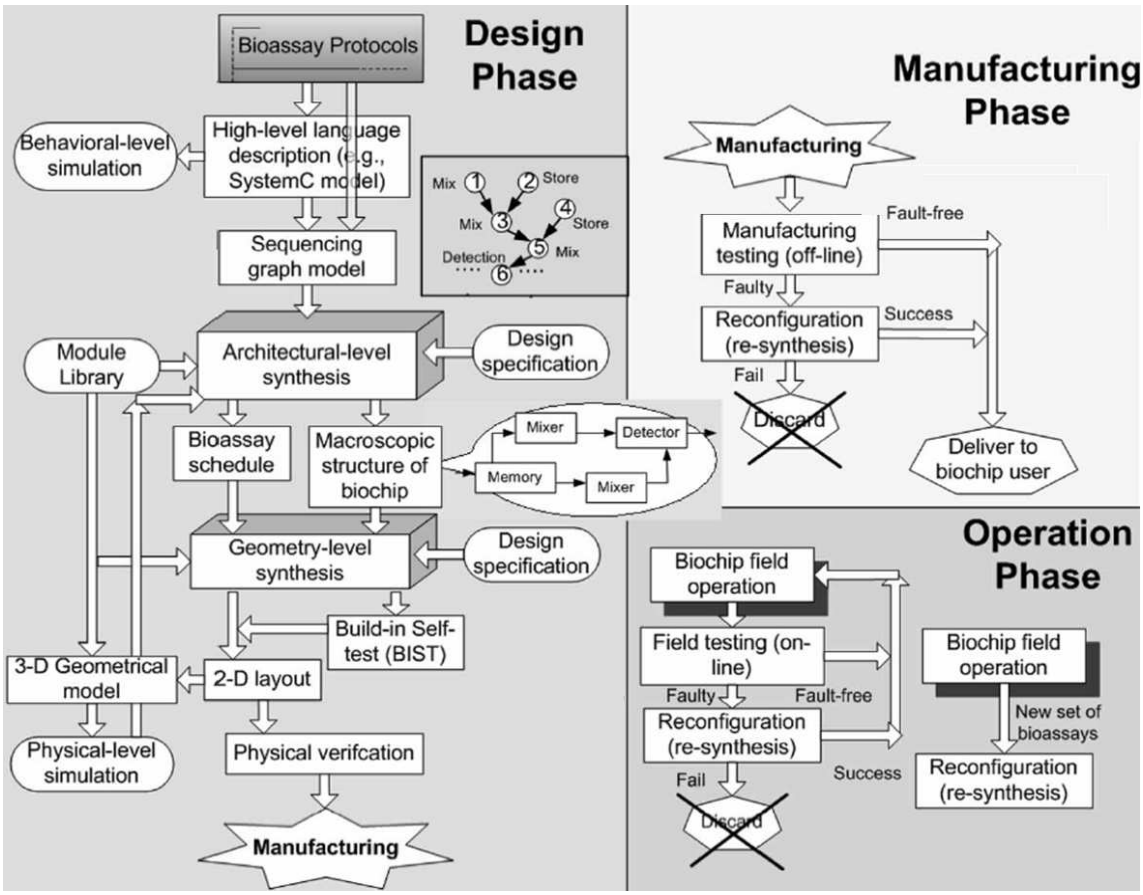


Figure 2-7 Overview of top-down design methodology (Su, Chakrabarty & Fair, 2006)

They claimed that with the aid of design automation tools, this model reduces biochip design complexity and time-to-market. This approach can also be extended to enhance the yield and reliability of biochips in the manufacturing and operational phases, respectively. The authors presented a methodology which combined three

phases: design, manufacturing and operation. All three phases are based on computer software and driven by technology.

This framework is discussed in detail by Chakrabarty and his co-researchers (Chakrabarty & Su, 2005; Chakrabarty & Zeng, 2005; Su, Chakrabarty & Fair, 2006). They underlined that this model allows for physical-level simulation and design verification at the component level, by incorporating detailed information about elements of the device. When the physical verification is accomplished, a digital design of the device can be sent for production.

Chakrabarty and Su (2005) claimed that in comparison to the full custom design - a methodology developed for designing integrated circuits by specifying the layout of each individual transistor and the interconnections between them (Allen, 2005) - and bottom-up design methods, the methodology outlined above not only reduced the design cycle time and redesign efforts, but also increased efficiency by dealing with design-for-testability (DFT) and design-for-reliability (DFR) issues. However, they also underlined the improvements required for this methodology to be effective. In the main, these consist of enhancing the synthesis tools for better quality and accuracy of the simulation and of the design result itself, as well as automation of the design process. They also supported the creation and use of design rules particular for microfluidics to speed up the development of microfluidics.

2.1.4. Domain-dependence of Microfluidic Design

The development of methodologies for the micro-domain has evolved based on the devices' appearance in the market. Methodologies for microelectronics appeared first and were followed by MEMS devices that finally included microfluidics as a separate domain. These methodologies were evolving from one domain to another, which is clearly presented in the example of the Y-model that was derived from microelectronics specific models. This partial adaptation influences the shape of the models, as well as the level and type of information they contain. As presented in Tables 2-1 – 2-5, the differences between domains indicate that each of these areas has unique requirements and direct adoption of these models is not possible.

Therefore, each of the presented models has weaknesses, which are discussed later in this section.

Table 2-1 presents a comparison of micro and macro-scale assembly. Due to the movement of the micro-scale device industry towards increasing complexity of newly developed systems, the creation of modular architectures seems useful. However, to make this possible, assembly issues have to be resolved. Differences between operating forces, precision of positioning and stiffness of elements influence the use of assembly methods in this area. The majority of assembly is done manually to provide required precision and minimise investments in assembly equipment. This lack of automation decreases the possibility of mass production of modular micro-devices.

Table 2-1 Comparison of micro and macro-scale assembly

	Micro-domain	Macro-domain
Assembly main force operating	Van der Waals, electrostatic and surface tension forces (Mukherjee & Fedder, 1997; Chen, 1999; Hardt, 2005)	Gravity (Mukherjee & Fedder, 1997; Hardt, 2005)
Positioning	Submicrometer (Hardt, 2005)	Few hundred micrometers (Hardt, 2005)
Element stiffness and mass for assembly equipment	Low (Mukherjee, 2003)	Vary (Mukherjee, 2003)
Assembly methods	Mainly manual, time consuming, tiresome (Robertson & Lucyszyn, 2001), lack of automation, not reliable and not cost-effective (Baidya, Gupta & Mukherjee, 2002)	Standardised and automated (Baidya, Gupta & Mukherjee, 2002)

Micro domains vary not only from the macro-domain but also from each other in basic characteristics (see Table 2-2). The microfluidic domain differs from other domains in terms of area maturity, which is indicated by differences in the whole design process, as well as in design support and manufacturing. Microfluidics varies in terms of forces operating from other domains as well as from macro-scale fluidic devices. Effects which can be omitted on a macro scale are dominant when fluid dynamic faces the issue of scale. Knowledge about forces operating in microfluidics as well as physical failure mechanisms is still in its infancy. Lack of proper understanding of this area creates difficulties and causes error prone designs.

The size of structures in microfluidics, in comparison to microelectronics, makes it unprofitable to use some manufacturing techniques, such as etching. Also, characteristics, such as the requirement for 3D structures and arbitrary shapes, make it hard to standardise design, modelling and production.

Table 2-2 Microfluidics in comparison to other domains - general characteristics

	Microfluidics	MEMS	Microelectronics	Macro-domain
Area maturity	Low (NEXUS, 2005; Yole Développement, 2007)	Low (Feynman, 1986)	High (Conn, Burgess & Ling, 2007)	Very high (Conn, Burgess & Ling, 2007)
Main operating force(s)	Micro-fluid dynamic (Chakrabarty & Su, 2005; Yole Développement, 2007), viscous forces and Brownian random motion (Kundert , 2001)	Multidomain – mainly mechanical and electronic forces (Feynman, 1986)	Electric forces (Ananthasuresh & Senturia, 1996)	Gravity, an inertial effects (Kundert , 2001), friction (Davies, Rodgers & Montague, 1998)
Physical failure mechanisms	Not well understood (Melin & Quake, 2007)	Understood	Well understood (Vashchenko & Sinkevitch, 2008)	Well understood
Size scale of structures	Tens of microns (Kundert & Chang, 2005)	1 μm to 2 mm (Allen, 2005)	Micron scale or smaller (Kundert & Chang, 2005)	Wide range
Number of dimensions required	3 (Albers et al., 2005)	3 (Hahn, 1999; Albers, Oerding & Deigendesch, 2006)	2.5	3 (Ma, Tor & Britton, 2003)
Arbitrary shapes	Required (Albers, Oerding & Deigendesch, 2006)	Required (Albers, Oerding & Deigendesch, 2006)	Not required (Albers, Oerding & Deigendesch, 2006)	Required (Albers, Oerding & Deigendesch, 2006)
Precision required	High	High (Allen, 2005)	High	Low-high (Childs , 2004; Allen, 2005)
Price per unit	Low (Eberhardt et al., 2003)	Low (Gajski & Khun, 1983)	Low	Low-high (market driven) (Rosenthal, 1992)

In comparison to the macro-domain, where precision in many cases is required and tolerances can be tight, in the micro-scale, dimensions are in the scale of macro-scale tolerances (for microfluidics tens of microns). Due to this, the majority of manufacturing methods start to be costly and the selection of materials for new

devices is constrained. Moreover, price per unit, which a customer expects for a micro-device, creates a requirement for mass production.

Table 2-3 Microfluidics in comparison to other domains – design characteristics

	Microfluidics	MEMS	Microelectronics	Macro-domain
Factor(s) driving the design	Technology (Mehregany & Roy, 1999)	Technology (Feynman, 1986; Antonsson, 1996; Hahn, 1999; McCorquodale et al., 2003; Albers et al., 2005)	Market (Homes et al., 2001) + fabrication	Market (Mehregany & Roy, 1999; Albers et al., 2005; Conn, Burgess & Ling, 2007)
Customer input	Specifications (Chakrabarty & Su, 2005)	Specifications	Specifications	Throughout the process (Rosenthal, 1992)
Specifications	Performance, size and in some cases cost	Performance, size and in some cases cost (Gajski & Khun, 1983)	Detailed in terms of performance, size and cost	Relatively detailed from product and service point of view (Lindbeck, 1995; Childs , 2004; Ulrich & Eppinger, 2008)
Design processes	Not suitable for domain (Walker & Thomas, 1985; Melin & Quake, 2007)	Cover majority of issues (Walker & Thomas, 1985)	Well established, structured (Hubbard, 1996), highly formalised and automated (Antonsson, 1996)	Highly developed, broad selection (Rosenthal, 1992)
Standard element of design	-	No generic elements (Peeters, 1999)	Circuit (Albers, Oerding & Deigendesch, 2006)	N/A
Design rules	Requirement for design rules (Melin & Quake, 2007), not well defined	Difficult to define, however exist (Allen, 2005)	Clearly defined (Albers et al., 2005) , conservative (Antonsson, 1996)	Clearly defined
Link between fabrication and design	Fabrication driven design	Fabrication driven (McCorquodale et al., 2003), lack of separation (Antonsson, 1996)	Clearly separated (Antonsson, 1996)	Mainly separated (Rosenthal, 1992)

Design of microfluidic devices is driven by technology and what is possible to be manufactured (see Table 2-3). Customer input is taken into consideration only in terms of specifications acquired at the beginning of the design process, which are, in

the majority, restricted to future performance, size and, in some cases, cost of the device. Market requirements, other than price, are not taken into consideration. Design processes are not suitable for this domain and design rules themselves, although greatly required, are still not well defined.

Table 2-4 Microfluidics in comparison to other domains - design support

	Microfluidics	MEMS	Microelectronics	Macro-domain
Design support	-	Problem oriented (Schumer, 1998)	Technology oriented (Schumer, 1998)	Broad range (Rosenthal, 1992)
Tools available	Suitable tools not commercially available (Antonsson, 1996; Bunyan & Ward, 1997; Przekwas & Makhijani, 2001; Amin, Thies & Amarasinghe, 2009)	Poor selection (Hahn, 1999), lack of suitable cross-domains tools (Schumer, 1998; McCorquodale et al., 2003; Popp et al., 2004; Albers, Oerding & Deigendesch, 2006), lack of consideration of product development tools (Conn, Burgess & Ling, 2007)	Commercially available (Albers et al., 2005; Albers, Burkardt & Deigendesch, 2007), highly developed (Gobinath, Cecil & Powell, 2007)	Broad selection of multifunctional tools (Lindbeck, 1995; Childs, 1998)
Component libraries	Lack of standard elements (Albers, Oerding & Deigendesch, 2006)	Exist (Crary, 1996), contains many elements inside (Davies, Rodgers & Montague, 1998)	Commonly used (Albers, Oerding & Deigendesch, 2006), (Robertson & Lucyszyn, 2001)	Commonly used (Ma, Tor & Britton, 2003)
Model reusability	No	No (Hahn & Brück, 1999)	Yes (Gobinath, Cecil & Powell, 2007)	Yes
Dimensioning	Lack of empirical basis – need for new strategies for building up working systems (Havlik & Carbone, 2006)			Broad empirical basis (Havlik & Carbone, 2006)

A strong link between fabrication and design characterises microfluidics. A limited selection of materials and manufacturing techniques as well as the high precision required forces designers to incorporate manufacturing considerations at the first stage of design processes. Moreover, these design processes have low adaptability to change and the required devices often create a demand to start from scratch. This is happening due to the uniqueness of device shapes, manufacturing methods,

performance required, and most of all, lack of understanding and knowledge about this domain, which complicates tasks and makes it highly dependent on technology and design support.

Support for design of microfluidics also distinguishes this domain from others (see Table 2-4). There is a lack of proper tools which can address design issues in this area; they are not commercially available and due to lack of proper knowledge about the failure mechanism in the devices, modelling and simulations cannot be fully accurate. There is a lack of standard elements in the design of these devices that makes it difficult to: automate the design process, create component libraries and standardise production. Dimensioning of these devices is an issue due to the fact that measuring equipment is, in many cases, characterised by dimensions equal to the device which is being investigated.

Table 2-5 Microfluidics in comparison to other domains – factors characterising manufacturing

	Microfluidics	MEMS	Microelectronics	Macro-domain
Manufacturing technologies	Relatively new (Kundert & Chang, 2005)	Broad (Fedder, 1996), not fixed (Albers, Oerding & Deigendesch, 2006), novel and in a wide range (Feynman, 1986), diversified (Albers, Burkardt & Deigendesch, 2007)	Fixed (Albers, Oerding & Deigendesch, 2006; Albers, Burkardt & Deigendesch, 2007), standardised (Karam et al., 1997)	Standardised, broad range (Lindbeck, 1995)
Cost of manufacturing equipment	High (Bullema, 2007)	High (Mraz, 2001; Fujita, 2005)	Average-high (Bullema, 2007)	Low-high (Chitale & Gupta, 2004)
Required accuracy of manufacturing methods	High accuracy required in a reproducible and economical way (not possible) (Havlik & Carbone, 2006)			Required accuracy generally possible to obtain (Chitale & Gupta, 2004)
Production scale	High (Keyhani, Banerjee & Hejilao, 2000; Eberhardt et al., 2003)	High	High (Mehregany & Roy, 1999)	Low-high

Microfluidics is a relatively new area in comparison to other micro-domains. Therefore, the manufacturing methods are also relatively new (see Table 2-5).

Although it seems reasonable that manufacturing techniques from other micro-domains should suit the needs of microfluidics, due to issues such as minimal dimensions required (see Table 2-2) or materials to be used, their applicability is questionable - e.g. in terms of profitability. Cost of manufacturing equipment in micro scale is high. Due to low price expectation from micro-scale devices, in the majority, only mass production can justify their use. Due to this fact, many companies use foundries' services (their production lines) to manufacture their own devices. This decreases influence and control on the manufacturing process, and incorporates new constraints. High accuracy, which is required to be provided in a reproducible and economical way, is often not achieved in the high production scale demanded.

2.1.5. Comparison of Reviewed Methodologies

To clearly show the characteristics of the reviewed models, their features have been set out in Tables 2-6 – 2-10. This comparison starts by identification of the model application area and its predecessors (see Table 2-6). This is followed by an indication of which of the four fundamentals approaches, discussed in Section 2.1.1., are incorporated in the models (see Table 2-7); the approaches - structured and top-down, or combination of top-down and bottom-up - are considered as most suitable for microfluidics. Next, the level of details is presented, which makes it clear that the majority of methodologies are high-level and need to be detailed.

Comparison showed that design models designated for the micro-domain present a lack of market orientation and service orientation. There are gaps in terms of proper identification of customer requirements and indication of how this information can be acquired. Specifications included in the design process are very technical. They cover performance, size and sometimes, the only market requirement identified is price. No other suggestions are recognised in terms of specifications or methods for gathering them. The device is aimed to be sold as a product, not as a service itself, and its function is important only in terms of performance.

Table 2-6 Overview of high-level methodologies

	VLSI	Y-model	Hierarchical model	Circle model	Pretzel model	Sickle model	V-model	Top-down
Author(s)	Mead and Conway	Hahn	Wagener and Hahn	Schumer and Brück	Wagener and Hahn	Albers and Marz	Watty	Chakrabarty and Su
Year	1980	1999	1994	1998	2003	2005	2006	2005
Precursors	Medium scale integration	Y-chart (Gajski & Khun, 1983) and Y-shape model (Walker & Thomas, 1985)	-	-	-	-	VDI 2206	-
Developed for	Microelectronics	MEMS development	Not identified	MEMS physical design	MST design	Tool-based micromachining	Mechatronic design	Biochips

Table 2-7 Comparison of reviewed methodologies

	VLSI	Y-model	Hierarchical model	Circle model	Pretzel model	Sickle model	V-model	Top-down
Approach (Top-down, Bottom-up, unstructured, structured)	Top-down in terms of functionality and bottom-up in terms of layout; structured	Bottom-up, roughly structured	Top-down, bottom-up, structured	Bottom-up, roughly structured	Top-down, Bottom-up, Top-down + Bottom-up, roughly structured (when it incorporates circle model)	Top-down + Bottom-up, roughly structured	Top-down, structured	Top-down, highly structured
Level of methodology (amount of details)	General model with detailed design	General	Very general, no model identified	General in terms of steps, requiring detail information	General with initiation of details by incorporation of the circle model at 3D model stage	General	General	Relatively detailed and structured

Service-orientation in design	Not identified	-	-	-	-	-	-	-
Principle of work	Development starts by description of object's function which is followed by logic to leads to separated layout verification, and incorporation of fabrication information	Development of new design starts from microstructure on physical level and is accomplished at microsystem behavioural level	Divided complete systems into a number of hierarchical levels with corresponding subsystems and components; each subsystem is developed and tested and incorporated into higher hierarchical systems till whole system is achieved	Cyclical concurrent procedure of designing ad redesigning	Development of new design starting from requirements, through simultaneously process (analysis) and schematic model (synthesis) development , through 3D model creation, followed by verification of process and design object to obtaining whole microsystem	Sickle transition from conceptual stage, through basic design to concrete detailed design with incorporation of abstraction levels	Iterative development of design object, contains multi-domain elements between the concept and detailed stages	Incorporation of detail information about elements of the device, starts from protocols by incorporation of architectural and geometrical synthesis leading to manufacturing of the object
Levels of abstraction	Can be viewed in terms of operating in three domains: behavioural, structural, geometrical layout	Behavioural, structural and physical	-	-	-	Replace by combination of hierarchical levels with detailing and design phases	-	-
Iteration	Frequently between two connecting stages, rarely	-	Takes place if specifications are not met at any point in	High	In top-down or bottom-up approach, which	Yes	Yes	Loop incorporated into the process

	across design		design		separately incorporate more disadvantages			
Input	System specifications	Not indicated	Specifications and requirements (no indication how to obtain them)	Specifications (no indication how to obtain them)	Requirements (no indication how to obtain them)	System of objectives (no indication how to obtain it)	Requirements (no indication how to obtain them)	Protocols defined by device users
Output	Design ready for fabrication	Design of the device	Design ready for fabrication – eventual test of the prototype	Design ready for fabrication	Microsystem	Design ready for fabrication	Reengineering after product recycling	Design ready for fabrication
Number of steps	6 steps	N/A	N/A	4 main steps	N/A	N/A	Not indicated	14 plus possible iteration
Direction of the design flow	Flow chart, straight forward	From vertex outside on spiral	Flow chart	Circular	Simultaneous from both sides to create pretzel shape	Sickle	Straight forward with iteration at the design stage	Flow chart
Type of methodology (which part of the PLC (Product Life-Cycle) it represents)	Design stage	Hard to indicate – pre-manufacturing design stage	No model identified	Design stage	Design stage	Design stage	PLC, end-to-end	Design stage

Obtaining specifications and requirements are the first stages in all the presented design methodologies. However, none of the researchers discussed how to obtain them and what they include. Although the whole purpose of the design process is to meet specifications, they are not described. They are claimed as often not fulfilled, however, there is also no indication what this mismatch means. Also, it is not clear to what degree they are satisfied, if at all, and what needs to be improved in the devices to make them successful.

Validation and use of methodologies indicates their applicability. Table 2-8 shows that validation of a majority of methodologies was not presented, and models which were verified were examined only by their authors. None of the approaches identified for MEMS and/or microfluidics was widely verified and adopted by the industry, according to the reviewed literature. This is identified as the greatest weakness of the reviewed models, since their usefulness and applicability can be questionable.

Table 2-8 Validation and application of reviewed methodologies

	VLSI	Y-model	Hierarchical model	Circle model	Pretzel model	Sickle model	V-model	Top-down
Validated by (whom)	Widely verified e.g. ITT Intermetall	-	-	-	-	Authors	Author	-
Validated using (how)	e.g. full fabrication of the FPGA (Field-Programmable Gate Array) chip , *Digital TV Systems*	-	-	-	-	Micro planetary gear example	Internally	-
Applied by	Industry and academia	-	-	-	-	-	-	-

The investigated methodologies were compared by some authors (Albers, Burkardt & Deigendesch, 2007) and described by them in terms of pro and cons of their use. In the majority, the methodologies' authors were claiming the usefulness of their own approach, pointing out the weaknesses of others. Table 2-9 summarises the advantages and disadvantages indicated by them.

Table 2-9 Summary of advantages and disadvantages of reviewed methodologies and their applicability to the microfluidic domain

	VLSI	Y-model	Hierarchical model	Circle model	Pretzel model	Sickle model	V-model	Top-down
Advantages	Clear separation of design and production simplifying designers task and automation of the process (Albers, Burkardt & Deigendesch, 2007)	Incorporation of abstraction levels (Albers, Oerding & Deigendesch, 2006), smooth transitions between levels of abstraction	Structured approach (Carley et al., 1996; Albers, Oerding & Deigendesch, 2006)	Strong dependence (Hahn & Brück, 1997) and parallelism (Hahn, Brück & Reusch, 1998; Albers, Oerding & Deigendesch, 2006; Albers, Burkardt & Deigendesch, 2007) between mask layout and process sequence design , allowing to obtain an application specific process step sequence (Brück et al., 2006)	Simultaneous development of behavioural design and process sequence (Wagener & Hahn, 2003; Albers, Oerding & Deigendesch, 2006; Albers, Burkardt & Deigendesch, 2007) that cause reduction of iteration in the design process (Wagener, Popp & Hahn, 2004), focus on technology, incorporation of system behaviour at early stage of design, with the growing knowledge base, the concurrent design becomes increasingly straight forward	Technology driven (Albers, Burkardt & Deigendesch, 2007), brings together benefits of top-down and bottom-up approaches (Albers et al., 2007)	Simultaneous development of design object and production sequence (Watty, 2006), incorporation of multidomain knowledge and demands from different stages of the product's life (Watty, 2006), feedback and verification at every design stage, continuous consideration of specifications during whole design process	Reduce biochip design complexity and time-to-market, enhance yield and system reliability, can be easily modified to support defect tolerance, can deal with DFT and DFR issues efficiently (Chakrabarty & Su, 2005), reduce human effort and enable high volume production (Chakrabarty & Zeng, 2005)

					and efficient (Popp et al., 2004)			
Disadvantages	Separation of the design and fabrication steps makes it impossible to be applied to MEMS (Wagener et al., 2005) and therefore to microfluidics	No feedback loop, no place for change in the process (Wagener & Hahn, 2003), lack of production sequence consideration during object design (Albers, Burkardt & Deigendesch, 2007)	Necessity to push down constraints throughout whole design from the highest level of hierarchy to the lowest one (opposite to bottom-up) (Carley et al., 1996)	Poor design support, no integrated development environment for the physical design is available, only special tools for simulation are commercially available (Wagener et al., 2005), high cycle repetition – time consuming, not very intuitive (Popp et al., 2004)	Lack of adequate support from libraries without which design is hard to handle (Wagener et al., 2002)	No end-to-end framework, indicates main steps to be followed, very general	Very general – steps to be followed are not clearly specified and therefore need adjustments (Watty, 2006), no separation at abstraction levels	Highly dependent on tools, needs design rules (Chakrabarty & Su, 2005), synthesis tool not selected, not clear in main elements

Table 2-10 Advantages and disadvantages of models for use in the microfluidic domain

	VLSI	Y-model	Hierarchical model	Circle model	Pretzel model	Sickle model	V-model	Top-down
Advantages	Technology driven, widely verified	Fabrication consideration during design, divide design on levels, technology driven	Top-down approach, structured, formalised	Fabrication consideration during design, incorporates verification, incorporates possible iteration	Connecting top-down with bottom-up approaches, fabrication consideration during design, can be made more detailed by incorporation of the circle model	Connecting top-down with bottom-up approaches, fabrication consideration during design, technology driven, divided in levels, interoperability of levels, provides flexibility, verification throughout the design	Top-down approach, fabrication consideration during design, technology driven, represents whole PLC, incorporates iteration, incorporates cross-domain verification, continuous consideration of specifications during design process	Most structured and detailed approach, can deal with DFT and DFR issues, technology driven, separation in levels, indicates how to obtain input data for the design process, end –to-end framework, top-down approach to design
Disadvantages	Clear separation of design and fabrication stages, which is not possible for microfluidics, iteration only in the last phase of	Lack of verification stages, no end-to-end framework, not detailed, vague structure, no input indication, bottom-up	Bottom-up approach, not properly presented – original source of the model not found, general	Vague representation, general – not many details, no indication how to obtain specifications, not divided in levels, highly iterative, bottom-up, not	Very high-level, tool dependent, not divided in levels, requires high specialisation from designers, no indication how to obtain	General – steps are only indicated, not widely verified, no end-to-end framework, lack of indication how to obtain specifications, not highly	General, steps to be followed are not clearly specified, not divided into levels	Lack of detailed information about synthesis tool which is core of this model, requires specific tools, suitable tools not

	design, no fabrication consideration during design, not divided in levels, no separate verification stage			widely verified	specifications, not widely verified	structured		commercially available, not widely verified, lack of details about input protocols

The reviewed methodologies differ in their applicability to be used for customised microfluidics. As presented in this section, the advantages/ disadvantages are categorised based on the author's judgement regarding observed patterns in literature. A summary of these findings is presented in Table 2-10.

It can be observed that not all of the methodologies show equal potential to be applied to the design of customised microfluidic devices. Three of them have been identified as presenting high applicability: sickle model, V-model and top-down model presented by Chakrabarty and Su (2005). Only two of these three, the 'sickle model' and the 'top-down model' show a limited potential to meet current requirements of the domain. However, none of them was widely verified, which imposed a requirement to investigate which design methodologies and models were used in the microfluidic domain till this day and/or are in use currently. Also, issues, such as how this process is approached and from where data are coming in, and form of specifications and how they are obtained, should be clarified with practical investigations. The methodology used for the proposed investigation is presented in Chapter 3 with practitioners' work in microfluidic design in Section 4.1.

2.2. Service-orientation

An investigation of service-orientation, identified as useful due to customisation forecasts for micro-scale devices (see Section 1.2.1 and Appendix I) and gaps in microfluidic design methodologies literature considering customer's and service requirements, showed not only limited discussions on microfluidic service-orientation but also on surrounding research areas.

2.2.1. Service Literature and Microfluidics

Review of microfluidic literature in terms of services, service thinking and service-orientation of its design showed that product-related services are rarely mentioned and comprehensive elaboration of any topic connected to services was not identified. Product-related services, such as maintenance and repair, have not been discussed in literature for microfluidic devices. They are aimed to be reduced for decreasing the

cost (Pamme, Koyama & Manz, 2003) of the device. However, the term 'maintenance' in microfluidic literature refers to manufacturing equipment for its fabrication (Martinsky, 2003) – or in terms of maintaining the fluid flow or maintaining biological material under analysis, e.g. tissue (Hattersley et al., 2008). 'Repair' of microfluidics is presented in the conventional sense of this word, although, literature shows the possibility of methods used to repair, e.g. LIFT (Laser Induced Forward Transfer) (Germain et al., 2007) rather than describe it in a service form. When discussed together with maintenance, the meaning of repair starts to vary. Also, 'implementation of' and 'training in usage of' microfluidic devices were not elaborated as a service. They were mentioned as the requirement for people's knowledge in operating the device (Fredrickson & Fan, 2004) and in terms of attempting to minimise their requirement (Gascoyne, Satayavivad & Ruchirawat, 2004). Moreover, 'training' has been identified as contributing to successful equipment usage (Russom, et al., 2008) by personnel without prior knowledge in microfluidics, which can be required for new applications to increase adoption rate.

Also, other services have been mentioned in literature as offered by industry; however, they were not elaborated. These services include: microreaction technology development (applied research for government, contract research for industry and 'routine services' – e.g. off the shelf devices and conducting certain experimentation services) (Hessel, Löwe & Stange, 2002), prototyping, manufacturing and custom design services (Clayton, 2005). Moreover, some organisations have been identified as offering software-controlled equipment; therefore, they are considered as also providing suitable software, and maybe, even services such as updates and upgrades. However, this needs to be confirmed.

Due to limited information on the service-orientation of microfluidic domain presented in literature, the investigation was broadened. It has been scoped around the manner in which organisations incorporate services in their offerings in general. This review resulted in identification of a variety of approaches, ranging from the reorganisation of a whole enterprise (Horwitz & Neville, 1996,), e.g. PSS and SOD (Service-Oriented Design) through the change in organisational culture and people's

mindsets to providing services on their own. The degree to which a manufacturing organisation concentrates on services depends on the selected approaches. The most popular service-oriented approaches are: DFS (Design for Service) (Teresco, 1994; Raplee, 1999; Huang, 1996), PSS (Manzini & Vezzoli, 2001, 2002; Morrelli, 2002; Mont, 2002; Oliva & Kallenberg, 2003; Tukker & Tischner, 2005, 2006; Harrison, 2006; Tan & McAloone, 2006; Baines et al., 2007; Wong et al., 2007) and SOD (Quartel, Dijkman & van Sinderen, 2004; Artus, 2006; Dubray, 2006; Liu & He, 2006; Papazoglou & van den Heuvel, 2006; Erl, 2006, 2007a-f; Sorofan, 2008). Also, use of the service nomenclature varies.

The most popular approaches, as mentioned above, have been reviewed in terms of their main characteristics in order to provide an overview of the method, strengths and weaknesses and potential applicability to microfluidic domain. Many of reviewed methods do not present a direct contribution to this research since they are not connected to microfluidics. Therefore, only the potential applicability of the methods for microfluidics is highlighted in this section while the approach overviews are presented in Appendix 2.

None of the most popular service-oriented approaches mentioned is considered as suitable for microfluidics, for various reasons. DFS is restricted to consideration of only one aspect of design (services – mainly maintenance and repair). It has been rejected due to technology dependence of microfluidics and risk of harmful consequences which could occur when neglecting the fabrication aspects. This may lead to more error-prone designs, affecting the fulfilment of the customer and manufacturer demands.

Lack of market orientation of microfluidic design, limited understanding of forces working in these devices and their other specifics cause the creation of systems such as PSS as not profitable in the short term and/or in the current situation. PSS approach is focused on organisational changes rather than on design flow. It considers existing services - mainly maintenance - rather than new ones, at least in the first stages of implementation; this has been identified as limited in the microfluidic domain. At present, the design process for microfluidic devices is not

fully understood. Implementation of PSS at the current stage may encounter many challenges. However, movement towards similar approaches can bring benefits and may simplify any transition in future.

SOD, as a formal approach, is focused on IT (Information Technology) and software development, and only its general principles (Sorofan, 2008) may benefit microfluidics. However, its fundamentals: use of standards, design for reuse, and composition versus creation; are already present, to some extent, in the domain. Therefore, the potential applicability of this approach for the microfluidic domain, in the current situation, is vague.

2.2.2. Design of Services and Products with Services in Mind

Considering the inadequacy of service design methods for microfluidic design, a broader investigation has been undertaken, including design of services and designing of products with services in mind.

Exploration of service design characteristics (intangibility and vagueness) (Holmlid, 2007) led limited applicability of service methods to the microfluidic design process. However, the service characteristics identified have shown potential to be applied in a changed form - design with services in mind. This approach considers not just thinking about the physical products when designing, but taking into consideration features of it enabling future services. It involves thinking about market requirements for functionality and what the customer wants to achieve by using the product. Literature about designing with services in mind was not identified. However, there is a huge amount of documentation discussing a variety of product/service design aspects and issues concerning services themselves. This literature provides basic features which provide an opportunity to enhance microfluidic design. In the design of services, discussion of product and service design dissimilarities allowed the author to view aspects which have to be taken into account when service instead of product is provided. Most importantly, the difference is satisfying needs by providing a service instead of selling a product. It

allows thinking beyond the established methodologies; therefore, it fosters creativity and innovation.

Due to the fact that the design flow incorporating service-orientation (which can be applicable for microfluidic devices) was not seen as well as no direct discussion of services has been identified as present in the domain, an investigation of the services provided for microfluidic products and by microfluidic manufacturers is recommended to ascertain if the literature gap can be addressed by industrial practice. Furthermore, microfluidic design practice in terms of services is being demanded now, which, due to the long presence of the devices in the market, may be more mature.

2.3. Sub-section Interactions

2.3.1. Complexity in Micro-devices

Complexity is an important field of study (Lewin, 1992). However, the word "complexity" is not only hard to define (Heylighen, 1996; Adami, 2002) but also in many areas a precise definition is still not available. Factors that influence this difficulty are the context-dependence and subjectivity of complexity (Edmonds, 1995; Thomson et al., 2005; Suh, 2003). Researchers have made attempts to generate a universal definition of complexity. Resulting from this body of work, "Complexity Theory" has been established as a separate domain of study with diverse applications. Despite this effort, the definition of complexity provided by researchers still varies in different fields (and sometimes even across the same field), showing a discrepancy in terms of meaning, use and quantification.

Since no unique definition of complexity has been identified for microfluidics (see Appendix 3), identification of clarification efforts for this issue across micro-domains has been sought. As a result, several attempts to define complexity were identified in literature. However, it is notable that within the domain of micro-devices, the devices are often stated to be either simple or complex, without a definition of "complexity" or an explanation of where the border between simple and "complex" is.

Within this domain, there are three main methods by which definition of complexity is derived: by creation of a definition by the researcher, by adaptation of someone else's approach or by the identification of characteristics.

Zhou et al. (2001) present an example of the first method. They define complex micro-devices as 'devices composed of parts made from different materials fabricated by various technologies' and claim that this complexity is continuously increasing due to new demands on the market. This definition, created for micro-assembly, is very broad and does not provide sufficient meaning of the word "complexity" for the whole micro-device domain.

The second method, to adopt an approach to complexity and its measurement from the macro scale, was undertaken by Kim (2004, 2006). He applied the "axiomatic" approach to multi-scale system design, with a focus on micro and nano-scale. His work showed the possibility of its quantification. However, this is one of few attempts identified where a definition created for macro-scale was adopted in the micro-scale domain.

Kim states that the use of "functional periodicity[7]" can allow the decrease of overall complexity by transformation of a system with time-dependent combinatorial complexity to a system with time-dependent periodic complexity, which was identified as less faulty. He also claims that by consideration of uncertainty associated with functions, the axiomatic design approach can help in understanding complexity in micro- and nano-assembly. Although he noted that 'information content well characterises the real complexity of tiny product manufacturing,' Kim neither states that the definition of complexity provided by Suh (2003) is suitable for microdevices nor creates his own definition for this domain.

Finally, Albers and Marz (2004) provide an example of the last method. They noted that every micro device is a multitechnology product. They stated that the design of these small devices has to be realised as an integration of technology, process and

[7] repeatability of a set of functional requirements (FRs) of the system, a set can be reinitialised for each period (Suh, 2004)

product development, material sciences and simulation, embracing all these disciplines. They described the process of micro-technology design and manufacturing as very complex, due to the unavailability of proper tools and the high degree of uncertainty of the functionality of products after manufacturing processes. This uncertainty, according to certain definitions of complexity, confirms the high complexity of these devices; however, it does not quantify its level or solve the problem of identifying the sources of complexity.

Although these attempts at a definition of complexity for micro-scale have been identified, the volume of available literature regarding this topic is small. However, several authors have described the necessity to decrease the level of complexity in micro-devices, especially due to the negative influence of complexity on micro-architecture in terms of testability and manufacturing cost (Bose, Albonesi and Marculescu, 2003). At the macro-scale, this impact of complexity (beyond "irreducible complexity[8]") as well as the concept that complexity increases rapidly as the system scale grows (Kim, 2006), have convinced many researchers to attempt to measure and influence it. However, this impact has been measured relative to the prior state and new methods created have not been applied universally owing to the subjectivity of the judgments incorporated in their definition.

2.3.2. Complexity of Microfluidics

A rapid pace of microfluidic research not only expands the range of possible application of the technology but also increases the complexity of these devices (Roco and Bainbridge, 2007). On the way to tackle this issue, researchers focused on very narrow applications and their technological aspects: e.g. integrated AC electro-kinetic pumping for fluid control systems such as pumps and valves in microchannels (Studer et al., 2004), manipulation and separation of particles and cells in continuous flow microfluidics by development of a passive platform (Hsu et al., 2008). However, by addressing one aspect in a highly specialised application, the

[8] idea presented by El-Haik & Yang (1998), considered a universal quality in all objects, level of which may significantly vary. The minimum amount of complexity required for a systems performance – the impossibility of separate parts of the system performing the functions required from the device or performing them inadequately if they are not connected (Colwell, 2005).

general complexity of microfluidics is not considered as tackled. To make this possible, a transferable approach between applications is required.

Goldenberg (2007) pointed out that as a general method to address the complexity of microfluidics, computer modelling and simulation are increasingly being used. However, no indication how this issue is handled by these techniques has been identified. A limited number of methods dealing with complexity in microfluidics have been described in literature. The first method is an introduction of structured design methodology which has been proposed by Su, Chakrabarty and Fair (2006) and is identified as one of several design methodologies developed for microfluidics (see Section 2.1.3). Although the methodology introduced by them shows limitations, the approach proposed is relevant – by structuring the work and introducing synthesis techniques, design automation can be achieved.

The second method is dealing with complexity by combining functionality and material selection. Domachuk at al. (2010) suggested usage of hydrogels[9], their material properties to reduce microfluidics complexity. They identified transition of the stimuli from an aqueous environment into mechanical actions (swelling and contraction) as a potential driving force for molecular processes, by combining function of a sensor and an actuator. The usage of these materials has been investigated by a number of researchers and has shown significant benefits, e.g. devices can be smaller and time-response of their volume transitions faster (Bassetti, Chatterjee & Beebe, 2005), and the use to regulate flow eliminates the need for external power, external control and complex fabrication schemes (Eddington & Beebe, 2004). The potential for exploitation of hydrogels for microfluidics is elaborated by Dong and Jiang (2007), who also point out the challenges of this application: response time for some applications is much above desirable, degradation of mechanical properties and poor robustness while making devices smaller or increasing their porosity (to decrease response time), necessity to thoroughly understand key physical parameters of hydrogels, e.g. thermal diffusivities, specific heats and diffusion coefficients of ions. Moreover, this method

[9] broad range of polymers with high water content (Eddington & Beebe, 2004)

imposes the use of a particular type of material, and therefore, restricts the environment in which the device can be implemented. However, the idea of material selection and combining functionalities as a method to decrease complexity is considered valid and beneficial for the domain.

Another technique is the introduction of a particular prototyping and/or manufacturing method. The work of Narasimhan and Papautsky (2004) is a representation of this approach. They introduced a method for fabricating polymer embossing tools for rapid prototyping of plastic microfluidic devices. By introduction of this tool, they noted a minimisation of complexity in the manufacturing process of microfluidic devices, and a reduction in the time and cost involved. This method decreases complexity of fabrication but not of the device itself. Moreover, it is restricted to a particular type of material used and to a limited technology - tool lifetime, dimensions possible, etc. Therefore, it is considered as a step in the right direction, but it is not transferable across the field.

Most approaches identified in the domain, in which complexity is claimed to be reduced, are taking place through focus on one particular type of microfluidics and introduction of a new design aspect considered as solving a particular issue, e.g. an introduction of a spinning disk platform for microfluidic digital polymerase chain reaction (PCR) (Sundberg et al., 2010). These methods are not transferable across the field.

2.3.3. Sub-section Interactions in Microfluidics Literature

Due to the high number of aspects which are covered by word complexity in the micro-scale device area and the vague description of this word focus on one of its aspects was proposed. Considering forecasts of increasing customisation of microfluidics, focus on sub-section interactions has been selected as showing the potential of creation of modular units, which could be assembled on customer demand. Findings from literature discussing this topic are presented below.

Although researchers are pointing out that micro-scale devices are usually characterised by a high degree of integration of functionalities and components

(Tietje & Ratchev, 2007) and that these interactions among parts and sub-sections play a large role in the micro-design process (Albers, Oerding & Deigendesch, 2006), an exhaustive description of this influence and its characteristics was not identified in the literature.

Only a few methods have been identified in literature through which researchers are dealing with sub-section interactions in microfluidic devices. The closest to design is selection of a monolithic or modular design concept. These approaches present compromises between functionality and size. The monolithic design concept is here represented by a system which consists of a number of sub-units or components, each of which performs only one or a small number of fundamental tasks. The modular design concept is represented by a system which contains multiple identical units that are able to perform all of the required functionalities. The comparison of both concepts presented by Hardt (2005) showed advantages of the monolithic above modular for application in the microfluidic field. According to him, the monolithic design concept allows for different mechanisms of fluid transport to be used in the device, while the modular system allows only for a single choice, and no separate pumping unit is needed in monolithic design. He underlines that these systems are desirable mainly for processing of small droplets, which is the current trend in the market due to the potential of analysis and diagnostics in medical domain.

As can be observed, both concepts, monolithic and modular, presented by Hardt (2005), can be classified as modular designs in the traditional view on modularity. Modular design is conventionally viewed as design of "product architecture consisting of physically detachable units for rapid product development, ease of assembly, services, reuse, recycling and other product life cycle objectives" (Gu, Hashemian & Sosale, 1997). Therefore, the sub-section interactions issue is tackled here by modularity.

Schabmueller et al. (1999) partially introduced an approach to deal with sub-section interactions. Seeking to develop integrated microfluidic systems, they came up with the concept of a microfluidic circuitboard as a physical product that allows the connection of different systems together to create one multifunctional device. This

solution was based on two requirements: connection of discrete fluidic devices and minimal pressure drop within channels. This concept, directly derived from microelectronics, presents planar connections of elements with use of anodic bonding[10]. Advantages of the microfluidic circuitboard, which can be seen as a standard (allows for development of element libraries), is an opportunity to connect diversified devices and develop customised variations of the system by change of the design only in the circuitboard. However, planarity of the device is a problem because of not allowing the creation of a compact system due to the form of the circuitboard and the form of the channels. Also, the necessity of silicon, which is being slowly replaced in this domain, is negatively viewed. Furthermore, the traditional PCB-technique (printed circuit board) is not suitable for complicated devices with small structures, since element-level integration is hardly achievable (Nguyen & Huang, 2001).

Shaikh et al. (2005) claimed that existing microfluidic systems often use a monolithic approach, where all of the elements in the device are integrated into a single chip. In their opinion, this leads to compromised functionality in building the device. Also, the majority of devices are planar, which creates a need for elaborate channel routing to interconnect components. To overcome these issues, they proposed non planar (3D) modular systems. They proposed microfluidic bread-board (FBB) architecture, which allows for flexibility in material choice, rapid turnaround time and low cost and, at the same time, benefits from scale of economy by providing standard parts for nonstandard applications. They also pointed out the weaknesses of this architecture as: increase in dead volume and total channel path length, which can be minimised by proper routing and channel design. Although this system appears to be modular, it still consists of two layers: multifunctional chip (with valves, pumps, mixers and other active elements), which constitutes a

[10] "a method of hermetically and permanently joining glass to silicon without the use of adhesives. The silicon and glass wafers are heated to a temperature (typically in the range 300-5000C depending on the glass type) at which the alkali-metal ions in the glass become mobile. The components are brought into contact and a high voltage applied across them. This causes the alkali cations to migrate from the interface resulting in a depletion layer with high electric field strength. The resulting electrostatic attraction brings the silicon and glass into intimate contact. Further current flow of the oxygen anions from the glass to the silicon results in an anodic reaction at the interface and the result is that the glass becomes bonded to the silicon with a permanent chemical bond." (AML, 2010)

foundation on which a second chip with passive components is mated. This approach was not widely verified, and although it shows potential for reconfiguration and strongly influences sub-sections interactions, it needs comparison with methods currently used in industry in the creation of multifunctional microfluidic devices.

All the introduced approaches are stating advantages of the design of modular microfluidics as a method to deal with sub-section interactions. Therefore, an investigation of how modularity is addressed in microfluidic literature has been considered as value-adding.

2.3.4. Modularity in Microfluidics

A number of researchers underline the movement of microfluidics towards modularity (Fitzgerald, 2003). A majority of this work, however, is not only application driven but also narrowed to a particular device. Some of the broader views identified will be presented below. Castellino (2004) underlined the lack of modularity and standard design techniques as "currently preventing microfluidic technology from becoming commercially viable on a worldwide scale". He stated that every device is custom made due to lack of modularity in chips; components of these devices can only be transferred to other microfluidic technologies conceptually. Moreover, that lack of standardisation, in his opinion, is leading to custom designs. A focus on modularity will benefit both industrial and academic research interests, allowing for greater coordination between research groups and reduced manufacturing costs. Although Castellino's work is focused on system biology, the role of modularity and its importance is valid for the whole domain.

Similarly, the importance of modularity is claimed by Grodzinski et al. (2004). They underline the advantages of modularity, such as flexibility (ease of reconfiguration, selection of optimal material platform for a given chip, tolerance in the variation of fluids volumes) and standardisation of chip-to-chip interfaces. They aimed to achieve the 'plug-and-play' type of microfluidic architecture by standardisation of interfaces through the use of a common board. The other part of their approach

divides system elements into disposable and re-usable, which decreases the cost of the overall solution. The presented approach appears beneficial due to introduction of interface standardisation and possibility to re-use system components; however, it is narrowed down to particular types of devices based on the board design. Development of a set of standard boards could help to overcome this issue.

Miserendino (2007) and Miserendino and Tai (2008) presented modularity in microfluidics as increasing systems' robustness (module exchange) and flexibility in fabrication (modules fabricated using various techniques, combining fabrication of similar modules). They highlighted the necessary trade-off, in comparison to monolithic microfluidics, between mentioned advantages and an additional cost associated (connectors, standardisation, etc.). They focused on module interconnections using silicon microgaskets and O-rings and confirmed superiority of the second.

Interfaces to the macro-environment in microfluidic devices have been identified by Miserendino (2007) as in the scope of interest of many researchers. One of the reviews of macro-to-micro interfaces was presented by Fredrickson and Fan (2004). They summarised the types of connectors as: wells, integrated interconnectors, modular interface and reagent amortisation; and pointed out operating conditions for these types. They highlighted that in microfluidics, "an acceptable interface probably exists for each application and device, but no one solution fits all purposes" - sometimes these connectors require adjustments for a particular application (Grodzinski et al., 2003). Moreover, they listed the enablers for connectors in device design: features to adhere to or align with, agreement of interface dimensions with existing industrial standards and properties of connector's material compatible with the device. This list is followed by the suggestion of desired interface characteristics, such as: ease of assembly, reliability, minimal dead volume, maximum field view, minimal pressure drop for pneumatically driven flow, ability to operate over a range of flow rates and to be automated, and low cost. The mentioned types of connectors will not be elaborated on further; however, characteristics enabling them in design are considered as influencing interfacing, and by this, also sub-section interactions. They show the potential of transferability across various types of microfluidic

devices, although when deciding on them, suitable selection criteria for an application have to be taken into account.

A similar review of interconnection methods from a chip-to-chip point of view has been presented by Igata et al. (2002), who promote a UV (Ultraviolet) adhesive bonding technique. Their review focus on the role of low dead volume required, zero leakage, straightforward fabrication procedures required, and lack of demand for external tubing. Also, they highlighted the possibility of rapid assembly and disassembly, which allows for chip cleaning. Their method has been developed for glass microfluidics and shows limitations for multi-layered microfluidics. Hence, it shows the possibility of standardisation for a limited number of microfluidic devices.

Modularity in microfluidics has been discussed from various aspects, such as: usage of modules in the devices manufactured via different techniques i.e. development of hybrid microfluidic systems (Gärtner et al., 2007), modular architecture (Gilde et al., 2005) or the previously mentioned macro-to-micro interfaces (Fredrickson & Fan, 2004). As can be observed, discussion of modularity is mostly presented based on a particular application and/or a device; for example: a modular assembly for hybrid μTAS (micro total analysis systems) (Wissink, 2000) or a cell pre-concentration and genetic sample preparation (Grodzinski et al., 2003). Therefore, search for a method transferable across the domain, to deal with sub-section interactions based on modularity has been stated as a necessity.

2.4. Research Gap and Summary

High investments and promising future of micro-scale technologies are causing increasing interest in this area. Designers are trying to develop methodologies which will fulfil the requirements that the world can think about. However, these methodologies are still not sufficient for the specific area of microfluidics.

Investigation of design methodologies, which exist in this area, show four major approaches to design: unstructured, which is slowly replaced by structured, top-

down and bottom-up. These approaches have a common aim - to develop universal design flow for all micro-scale devices; however, this is still work in progress since all of the identified methodologies are application specific and show necessity for improvement. Some of the methodologies also show lack of external and wider validation.

Factors which work at micro-scale differ not only from macro-scale but also between micro-domains. Microfluidics is a relatively new area in comparison to microelectronics, or even more recent compared to MEMS, and due to this, it is not so mature. This immaturity is visible in the lack of proper area understanding and sufficient knowledge about it. Components are not standardised and design is not automated, devices require customisation and are highly technology dependent, in terms of design support and manufacturing methods. Design support itself is not sufficient, and manufacturing methods are still under development. All of these issues distinguish microfluidics as a domain that requires a specific design methodology.

Literature regarding design methodologies for micro-devices is technical and mathematical and computer application driven. There is a common focus on the development of specific techniques inside the design process to automate it and speed up the tasks. Many researchers support the development of library catalogues (which allow for the selection of the most commonly used parts) as well as the development of new software tools for modelling and simulation. Due to this technology driven approach, the only requirements which were taken into consideration were size, performance and, in some cases, cost - others were not identified.

Design models showed variations in their potential for application to microfluidic design. Only three of them were viewed as requiring minimal amount of changes to be adopted; however, none of the methods is predicted to be beneficial without adaptation. Models are too general, too vague and indicated as not suitable. They do not fulfil the recent requirements which microfluidics are facing, not to mention future demands.

An investigation of service-orientation, identified as useful due to customisation forecasts for micro-scale devices and gaps in microfluidic design methodology literature on customer and service requirements, showed not only limited discussion on microfluidic service-orientation, but also on surrounding literature areas.

Service-orientation, as relevant to the design of microfluidics, has not been identified. Moreover, articles purely focused on the service potential of the area were not found. Product related services, however, have been mentioned by researchers. These services were only indicated and not elaborated; these included: training, maintenance, repair, implementation, etc. The used terminology, mainly in terms of maintenance, has been identified as referring to chemical and environmental conditions rather than services. Moreover, when mentioned services were identified, they were mostly mentioned with the aim to eliminate them to create self-operating and robust devices.

Services themselves have been indicated as present in the industry by some researchers. They mentioned prototyping, manufacturing and design capabilities as offered most often. Moreover, they pointed out the requirement for software in the control of some microfluidic devices, which creates potential for a service type offering.

The limited volume of literature on service-orientation of microfluidics led to the investigation of service literature in macro scale and the potential of its applicability. Based on the characteristics of the domain identified before, design with services in mind seems to be the most suitable for this area. Moreover, a number of characteristics of services from macro-domain literature have been identified as present in microfluidics, which can simplify its transition towards a service future.

The last topic reviewed has been complexity, leading towards sub-section interactions, which has been identified as increasing in the domain. The word complexity has a broad meaning and has been established as a separate field of study. Also, there is a lack of one definition which can explain its meaning in macro domains as well as in microfluidics. Moreover, complexity is viewed as negatively

influencing the design of these devices. Therefore, the minimisation of complexity has been attempted by a number of methods. Where identified, all of them were application specific and showed limited potential for transferability across the domain.

Since complexity includes many factors and attempts to decrease it have been identified on a device or application basis, narrowing the topics under complexity seemed necessary. Therefore, sub-section interactions, recognised as crucial for microfluidics, are leading to a path for further research. This literature investigation showed that researchers were aiming for standardisation and automation of microfluidics by focusing on interfaces, connectors and modularity to deal with the mentioned issue.

No universal method addressing sub-section interactions has been identified. Moreover, interfaces and modularity have been identified as reviewed from many aspects and with a variety of meanings. Hence, the demand for further investigation has been identified.

Due to the limited volume of literature on the investigated topics (design methodologies, service-orientation and sub-section interactions) for microfluidics and lack of literature on their overlap, an investigation of industrial practice is recommended. It is suggested to focus on future demands from these devices with the aim to gather a real view on the area and make it possible to identify requirements for the development of a suitable methodology and/or filling the gaps in literature by presenting methods which are successful in practice.

Chapter 3
Methodology

To achieve the aim of the research, a systematic approach to it has been adopted. Development of the methodology which will help to reach this target has been stated as a necessity. To assure that the selected approach will be comprehensive, a number of existing methodological approaches have been reviewed across the fields. Below, the developed methodology is presented and supported with literature background.

Rajasekar, Philominathan and Chinnathambi (2006), describing the process of conducting research, underlined, among other crucial aspects of this work, the necessity to "design a methodology for the chosen problem". Development of the suitable methodology and, therefore, selection of a proper approach to the research decide not only the research quality, but in many cases, the reliability of their accomplishments.

To develop a methodology, a review of existing research methods has been undertaken. This chapter first presents the method used for development of the research methodology. Secondly, the existing research approaches are briefed. Next, the selection of the method to be used in the research is presented, with discussion of applicability of reviewed approaches. Afterwards, the method chosen is presented and is followed by the introduction of the applied research methodology.

3.1. Selection and Development of the Research Methodology

Development of the research methodology has been preceded by initial literature study of area characteristics and identification of the research aim and objectives to achieve it. This investigation provided a background for the methodology and

requirements for it. The broad approach to the methodology selection is presented in Figure 3-1.

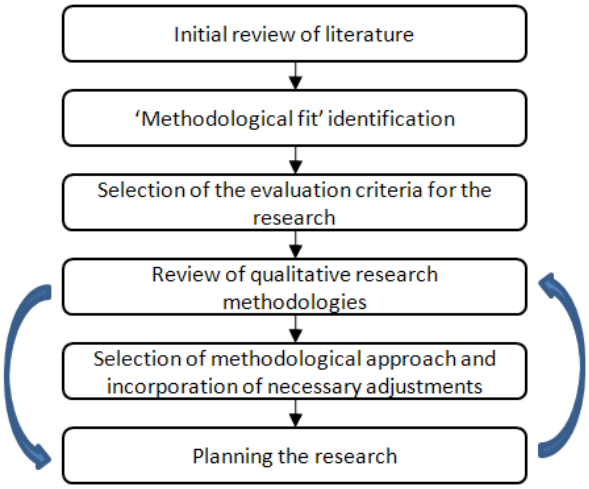


Figure 3-1 Methodology development approach

During development of the approach for this research, a methodological support has been investigated not only in the microfluidic domain, but also in other areas. A concept of 'methodological fit' (Edmondson & Mcmanus, 2007), originated for management field studies and generalised for all research areas, helped to broadly address the issues faced. This concept provides an indication of how to develop a methodological approach based on the maturity of the area. Due to initial literature review findings regarding area immaturity and gaps identified when looking for information, the research has been classified as exploratory. Therefore, data collection and analysis would be performed in a qualitative manner with limited quantifications.

To select a suitable approach for the research, evaluation criteria were needed. These criteria have been established based on the initial literature review. Factors considered during the criteria's development include: microfluidic domain characteristics and investigator knowledge and resources available for the project realisation. The established set of criteria is described in Section 3.1.1.

As a next step, an investigation of existing qualitative research methodologies has been undertaken to provide methodological fit for the conducted research. A number

of qualitative research methodologies have been identified: ethnography, phenomenology, field research, grounded theory, historical research, discourse analysis, symbolic interactionism, etc. As the most popular three methods have been identified and, therefore, briefed (see Section 3.1.2): phenomenology, ethnography, and grounded theory. All of these methods were developed for the social studies. However, their application is viewed as broader than that (Allen, 2003; Jones, Kriflik & Zanko, 2005).

Based on the criteria identified, qualitative research approaches have been evaluated. The optimisation performed is presented in Section 3.1.3. Each of the approaches has been discussed from the perspective of each criterion. Based on the criteria fulfilment, an optimal approach has been selected. Due to the fact that none of the approaches were considered as fully meeting the requirements, an in depth investigation of the selected approach (see Section 3.1.4) was undertaken. This investigation led to review of the approach's applicability from the point of view of conducted research. In this manner, necessary adjustments have been identified to develop a new methodology partially based on the existing formal methods.

Selection of the evaluation criteria, review of qualitative methodologies and optimisation of the approach to be used are presented below. These three steps of the broad methodological approach built to develop the research methodology are presented more descriptively regarding their importance and impact on the further work. Based on this work, an applied research methodology has been developed, and in this manner, research has been planned.

3.1.1. Evaluation Criteria

To allow for selection of the optimal research methodology, a set of criteria has been established. This set of criteria has been developed based on the characteristics of the research domain (microfluidics) that established the aim and objectives, and available time and resources for project realisation. The following criteria have been included:

- Field investigation (Edmondson & McManus, 2007) – methodology should allow for investigation of practitioners' work due to limited literature discussing microfluidic design and its characteristics, as well as sub-section interactions and service-type issues in the domain.
- Objectivity of the study (Crotty, 1998) - results of the research should not be dependent on the respondent from whom information will be obtained, but be universal in the given context (microfluidics).
- Investigation methods not preselected (Edmondson & McManus, 2007) – due to the exploratory character of the research to be conducted, methods which will be used are not recommended to be selected upfront. High uncertainty incorporated in the field and current economical climate do not allow preselection of the investigation method and targeted group individuals/groups.
- Concurrent data collection and analysis (Gerrish & Lacey, 2010) – due to limited amount of time available for the project and time which can be consumed by usage of a variety of data collection approaches, simultaneous data collection and analysis is recommended. Moreover, via this, the lack of first hand design experience in the microfluidic domain of the author will be minimised and further investigation can be scoped better.
- Use of multiple data sources (Thurmond, 2001) – to increase reliability of the data, and by this, of the research results, multiple data collection methods are sought. Due to limited amount of information obtained by initial literature review on the microfluidic design, the probability of obtaining a greater amount of information from other sources is low. Therefore, diversification is recommended, which will allow for viewing the same data from various aspects.
- Lack of previous knowledge about the domain permitted (Cormack, 2000) – the researcher is lacking knowledge about the microfluidic design specifics due to a lack of work experience in the domain. Therefore, a methodology which will allow extraction of information from other sources, and that does not depend on the researcher's previous experience is needed.

Based on these criteria, an optimal research methodology will be selected and, if necessary, adjusted to the research needs.

3.1.2. Qualitative Research Methods

Qualitative methods have been reviewed based on identification ('methodological fit') of an exploratory research as most suitable due to the area characteristics. Methods briefed are just a representation of the qualitative research methods. They are identified as frequently practiced by the researchers (Jones, Kriflik & Zanko, 2005). At this point, a short description of the methods is given, with highlights regarding advantages and disadvantages of their application.

3.1.2.1. Phenomenology

Phenomenology is both a philosophy and a methodology. It is used to explore people's perception rather than to gather a 'picture of what is happening'. This methodology is used to study subjective experiences of one or a couple of individuals on a phenomenon and helps to obtain a rich description of the phenomena and its settings (Groenewald, 2004).

Phenomenology possesses many unique features, but also a number of shortcomings. The main method used for data collection is an interview. This methodology assumes that the participant's view is a 'fact', and the sampling necessary is predetermined by experience of individuals under study (Goulding, 2005).

3.1.2.2. Ethnography

Ethnography originated from anthropology. It is a study of cultural behaviour and interactions within groups, providing insight into their views, actions and nature of habitation (Reeves, Kuper & Hodges, 2008). This methodology is based on data collection through detailed observations and interviews. Interviews are usually conducted in a 'casual' manner (informal and conversational), where the formal part of data collection includes documentary data, such as photographs and diaries, and also some in-depth interviews.

This methodology allows for in-depth understanding of social actions and its subtleties in various contexts uncovers normally 'hidden' facts from the public insights and identifies interconnections in seemingly unlinked issues. It involves multiple data collection methods for a single phenomenon. However, it is also time consuming, labour intensive and creates difficulty in securing repeated access to data sources (Goulding, 2005). It incorporates bias due to lack of required researcher detachment to the investigation in some areas. Moreover, it requires a period of time before data can be analysed due to acclimatisation purposes of the researcher (Jones, Kriflik & Zanko, 2005).

3.1.2.3. Grounded Theory

The grounded theory has been originated by Glaser and Strauss (1967) for social studies. This approach uses comparative methods to derive a theory from qualitative data. It is based on systematic gathering and analysis of data that allow the researcher to obtain substantive or formal theory. A substantive theory is context specific in terms of area of inquiry, and readily modifiable when a formal theory is conceptual and requires further development (Backman & Kyngäs, 1999).

Grounded theory is flexible in terms of data and allows the researcher to look beyond the superficial. However, it has a structured approach to theoretical sampling and saturation of data and theory, which are required before theory development can be claimed (Goulding, 2005). This research requires time and theoretical sensitivity to transfer from data to theory and back (Glaser, 1978). The grounded theory has been developed for social studies, and keeps features of the investigation of the operations and behaviours. It is considered as a time-consuming and long process, especially for novice researchers in the domain (Backman & Kyngäs, 1999). Focus applied by Glaser and Strauss (1967) on use of theoretical sampling and saturation before the development the theory increases the time of the research and requires a number of resources.

3.1.3. Selection of the Optimal Method

The suitability of the above methodologies for the research was investigated. Their appropriateness is briefed in this section and summarised based on selected criteria.

Presented criteria are fulfilled to various degree by the reviewed methodologies. Each of them addresses different requirements and allows approaching of the research from many angles. Table 3-1 presents a short summary of this. In Table 3-1, "x" - indicates that criteria is fulfilled (partially or completely) and "-" – indicates that criteria is not fulfilled.

Table 3-1 Criteria fulfilment by investigated research methodologies

	Phenomenology	Ethnography	Grounded theory
Field investigation	x	x	x
Objectivity of the study	-	x	x
Investigation methods not preselected	-	-	x
Concurrent data collection and analysis	-	-	x
Use of multiple data sources	x	x	x
Lack of previous knowledge about the domain permitted	x	x	x

The aim of the study is to develop a service-oriented methodology for design of microfluidic devices which can deal with sub-section interactions. This requires understanding of how these devices are currently designed and, therefore, investigation of the field and microfluidic designers' work. Therefore, field investigation is needed. It has been identified as allowed, and even considered necessary in all presented methodologies. However, the type of data obtained by this investigation varies.

This research aims not at understanding how designers perceive their work and the reasoning for it, but to gather a real view on the area and design process, as well as what is missing and required. Phenomenology is focused on subjective understanding, while the research aims at obtaining objective characteristics of microfluidic design and the process leading to it. It presents a subjective understanding of the area as facts; therefore, it solely depends on opinions of individuals. Other methods allow obtainment of an objective perspective on people's work and tasks undertaken.

Due to limited knowledge about the domain and about possible sources of information, the investigation method should not be preselected. In both phenomenology and ethnography, limitations regarding methods applied have been identified. Especially in ethnography, observation is considered as crucial and, therefore, preselected. This data collection method for the microfluidic designers' work is considered beneficial. To fully understand how microfluidic devices are designed, observation should be scoped around the whole design process, from identification of requirements, through commercialisation, to the disposal or recycling of the product - or at least until the device is manufactured. To make this investigation general for the field, various types of devices should be investigated as designed by the same individual (team), as well as by various organisations. This observation is considered as impossible to be achieved during the duration of the research due to the fact that design of some devices takes years and some of them are never commercialised. While observation could provide a rich set of information in the study, designers of microfluidic devices were identified as located across the world, and conducting several observations on a daily basis will require investment of human resources which are not available in this research. Benefits from this type of observation are considered by the researcher as minimal in comparison to the costs which will be consumed by it. Phenomenology, similar to grounded theory, does not require preselecting the method used in the investigation. It has been identified as endorsing abstinence from any pre-given framework. However, it restricts the method used from providing deep insight into individuals' views. It is concerned with life experience of people and their points of views rather than stand alone facts. Therefore, it also restricts the size of the sample which can/should be the subject of the study (Groenewald, 2004).

The grounded theory insists on selection of the investigation method based on the data set. The methodology neither imposes the method to be applied nor creates a demand to pre-select it in advance for the whole data collection process. Base on this criterion, grounded theory seems the only suitable approach.

Only grounded theory allows for concurrent data collection and analysis. Ethnography requires sufficient time of observation before any conclusion can be made. It presents separation of data collection and analysis stages (Atkinson, Coffey & Delamont, 2001). Similarly, in phenomenology, data analysis – sometimes named 'explicitation of data' (Groenewald, 2004) – takes place when data collection is accomplished. Therefore, this criterion is also fulfilled only by grounded theory.

All of the techniques encourage usage of a variety of data collection sources. Ethnography, while underlining the benefits of this approach, such as allowing for generation of varying perspectives and context of interests (Arnould & Wallendorf, 1994), highlights shortcomings of data overload and necessity for storage and computing power when conducting data in digital form (Atkinson & Hammersley, 2007). Phenomenology requires investigation of multiple forms of evidence (Jones, Kriflik & Zanko, 2005); however, it limits the size of research samples, which narrows the number of methods possible to be applied. The grounded theory encourages differentiation in data and looks for counterarguments. Multiple data collection methods used in grounded theory aim to increase reliability and construct validity of the research, strengthen grounding of theory by triangulation of evidence, and enhance internal validity and synergistic view of evidence (Pandit, 1996).

The last criterion, which allows a lack of a prior experience in the domain, has been identified as fulfilled by ethnography. In this methodology, the researcher usually does not possess detailed knowledge about the domain when approaching informants (Brewer, 2002). There is no indication if previous knowledge is necessary for usage of the phenomenological approach. However, this approach pursues bracketing (Byrne, 2001) – setting aside preconceived notions – therefore, limited knowledge about the domain is considered beneficial since it minimises risk of assumptions. In grounded theory, the researcher also has to keep aside all the assumptions and preconceptions (Glouding, 2003). However, this does not mean that the researcher needs to be ignorant about the field. Therefore, extensive reading has been attempted to minimise impact of the lack of experience in microfluidics. Based on this criterion, all the investigated methodologies show potential to be applied.

Based on the presented optimisation (see Table 3-1), the grounded theory has been selected as the main research approach. A closer view on this method and its implications are given below.

3.1.4. Grounded Theory

As mentioned previously, the grounded theory was introduced for the first time by Glaser and Strauss (1967) for social studies. It addresses the research where the "need to start gathering data in order to formulate ongoing plans and, perhaps, to discover the nature of the research question" exists (Heath & Cowley, 2004).

Origins:

From the moment the grounded theory was formulated, it evolved in details based on the practical applications in qualitative research. The main diversification which can be observed in its development happened between its founders. Although some researchers claim that a split has been apparent from the beginning, based on the schools which both researchers represented (Strübing, 2007), it was widely acknowledged when Strauss published a guide for applying the grounded theory. Glaser remained faithful to the original concept of the grounded theory (1978, 1992) when Strauss, along with Corbin (1990), re-invented this approach. While Glaser focused on explaining concepts underlying the grounded theory and how to approach it – theoretical sampling, coding, 'memoing' – Strauss tried to present this approach to novel researchers by preparation of the analytical techniques and pathways to follow. Glaser has been underlying creativity of the individual and his/her ability to help theory emerge, while Strauss has been more concerned with validation of the theory and systematic approach. Following publication of Strauss and Corbin's (1990) work on grounded theory, Glaser (1992) recognised it as no longer this approach but 'full conceptual description' of the application area. The main view on both aspects of the grounded theory is common and will be presented. For comparison of both views, please refer to Heath and Cowley (2004) and Strübing (2007).

Method:

This inductive method of investigation works in opposition to the conventional form of qualitative research. It allows the researcher to extract theory without a priori knowledge and is not designed for repetitiveness - which means that two researchers using this same data are not expected to make similar or identical discoveries (Jones, Kriflik & Zanko, 2005). The grounded theory is considered as difficult to be applied by novel researchers (Huehls, 2005) due to its reversed order in comparison to empirical research (see Figure 3-2).

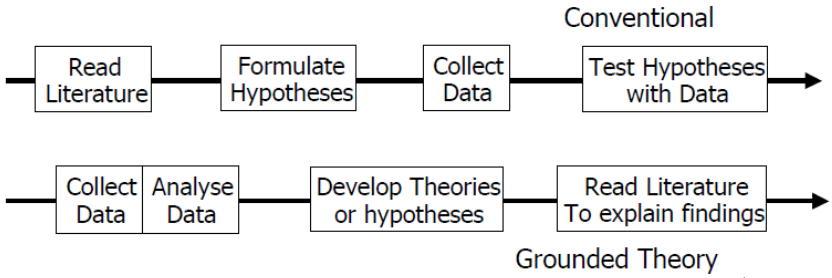


Figure 3-2 Comparison of conventional research methods to grounded theory (Jones, 2005)

Grounded theory aims to evolve a theory directly from the data in order to explain the phenomenon under study using comparative methods. It not only presents, but also explains the topic of the study (Corbin and Strauss, 1990). It is based on systematic collection and analysis of data regarding a particular phenomenon in specific conditions, without a preconceived hypothesis (Strauss and Corbin, 1990). Therefore, this inductive method bonds data collection and analysis by performing them simultaneously.

In the grounded theory, data collection, analysis, obtaining results and reporting do not necessarily follow the chronology of traditional research. Data collection is a starting point of this process; data are analysed to generate theory. The researchers upfront should have as few preconceived ideas about the phenomena as possible to minimise bias. In case of previous experience in the domain, the researcher should keep in mind ideas and assumptions about the situation being studied to increase understanding of the process. The research question is not 'written in stone' - it can change during data collection depending on obtained data. Researchers should note

that withholding from preconceived ideas is not the same as ignorance about the research domain and certain familiarity is a necessity (Heath & Cowley, 2004).

Data are collected using methods such as interviews, observations, written documentation, e.g. diaries and a combination of methods (Corbin & Strauss, 1990). Theoretical sampling is a way in which data are gathered. It creates opportunities for discovering variations among concepts and a deeper exploration of their characteristics. Samples are not predetermined but emerge from the data. The theoretical sampling does not focus on data and suitable data collection methods. It is done for saturation of categories – development of codes. Contrary to this is selective sampling – e.g. key points sampling - which is defended by some researchers in case of restricted research time (Miles & Huberman, 1984; Allan, 2003).

Grounded theory puts focus on simultaneous collection and analysis to allow for selection of methods and sources for further data. Therefore, selected research methods are more suitable for the context than in the case they are decided upfront. Data allows creation of codes and categories (Backman & Kyngäs, 1999). Categories combine grouped codes and, together with developed hypotheses, are compared with the data. This comparative analysis is supported, if possible, by the researcher's experience in the domain as an additional source of data. After comparing features of the data, categories and cases, the researcher continues to explore connections between developed categories. This can be done by axial coding, i.e. study categories according to their context, consequences, causes, conditions, etc. by inductive and deductive thinking.

Gradually, a theory is emerging and, therefore, it should be written down to avoid losing track of the target with the increasing number of ideas generated. Afterwards, the researcher should return to the data regularly to assure connection of ideas to the data and between ideas. In this manner, final categories are obtained. The grounded theory is developed around the core category through coding and analysis, and is verified by saturation, relevance and workability (Glaser & Strauss, 1967).

The analysis process also includes memoing. It is a process of writing a short description of the ideas about codes and their relationships, which appear when coding and analysing. A memo should always be dated, entitled and concise. The length can vary from one sentence to a couple of pages. It should present conceptual thoughts in the first person and be 'sortable' (Miles & Huberman, 1984). These memos help in developing categories and their interrelations, therefore, also the theory.

Presentation of the results should start by discovered theory and the categories. Glaser and Strauss (1967) underlined that developed theory should have the following properties: fitness – underlying basis and characteristics of area from/for which it is developed, corresponds to the reality of the area, data should not be forced to fit it, as theory should not be forced to fit the data which it is referring to; understanding – understandable by the people working in the area and possible to be employed by them to 'engender readiness to use it'; generality – cannot lose aspects of the area by being too abstract, flexible enough to address variety of changing situations and can be applied over a period of time with varying conditions; and control – enable the user a level of control over it, which will make application valuable, enable understanding and analysis of aspects of reality and incorporate necessary changes to control the output. Hence, theory is evaluated based on these properties.

Corbin and Strauss (1990) gave a set of canons and procedures which have to be applied to claim usage of the grounded theory. They are the following:

1. Data collection and analysis are interrelated processes
2. Concepts are the basic units of analysis
3. Categories must be developed and related
4. Sampling in grounded theory proceeds on theoretical grounds
5. Analysis makes use of constant comparisons
6. Patterns and variations must be accounted for
7. Process must be built into the theory
8. Writing is an integral part of performing grounded theory

9. Hypotheses about relationships among categories should be developed and verified as much as possible during the research process
10. A grounded theorist need not work alone
11. Broader structural conditions must be analysed, no matter how microscopic the research is.

This set of procedures, although claimed overly formalistic, provides scope for application of the grounded theory approach, which possesses many benefits and weaknesses. These characteristics are reviewed to provide rationale on how to apply the selected methodology in the most suitable manner for the conducted research.

3.1.5. Applicability of Grounded Theory to the Project

Grounded theory possesses many benefits and shortcomings. This method has been selected based on six criteria. This choice was optimal in comparison to other methods investigated; however, it was noted that grounded theory fulfilled all criteria.

Additional factors which support the decision are as follows:

F1. Making sense of data – the grounded theory allows development of theory from data taking into account empirical observations and evidence (Bamford, 2008) that increase dependability of the output. Strong connection between the data and theory is sought in the conducted research using a number of investigation methods. Data grounded theory allows the researcher to approach generalisation of the research output, at least in the study area that is demanded in the microfluidic – case dependent domain.
F2. Interrelations between categories – analysis of interrelations between categories target the overlapping of the research fields mentioned, which appear not to be strongly connected. To reach the aim of the research, interconnections need to be identified and highlighted.

F3. Oriented towards deriving theory as a process - this fits development of the solution suitable for the area which can help designers since they are using processes on a daily basis.

However, grounded theory also has limitations which discourage its strict application to the presented research. The main limitations imposed are:

L1. Accountability of the data sources - The grounded theory has been mainly applied in the social research context, and there is focus exerted by its authors on the lack of necessity of accountability of the data source (Glaser & Strauss, 1967). In contradiction, due to limited amount of literature identified in the investigated areas and lack of documentation in the research topic (on the overlap of the areas), accountability of data sources is considered crucial to make the research output dependable.

L2. Exploration of the literature – Grounded theory is based on the assumption that the researcher is able to make a conscious decision about data regarding their relevance (Huehls, 2005). To achieve this, the author, due to lack of previous experience in the microfluidic domain, considers exploration of the field a necessity as the first step in the research. In the author's opinion, it is not justified to approach field work in this domain without identification of its basic characteristics and relevant information in the field. It will be difficult to conceptualise from data and make any feasible decisions on data under collection and analysis without sufficient understanding of the domain. The grounded theory leaves literature study at the end of the process to confirm findings and avoid pre-assumptions which can occur. This research starts from literature regarding limited publications identified by initial investigation and seeks deep analysis of this literature before field study will be undertaken to provide better insight in the area. Moreover, this approach is advisable due to uncertainty of experts' participation at the start of this research.

L3. Difficulty in applying the method first time – the grounded theory has been identified as a time-consuming and long process, especially for novice researchers in the domain (Backman & Kyngäs, 1999). Due to the lack of

experience of the author in microfluidic design and that grounded theory approach is also novel for her, this limitation seems significant and is attempted to be minimised by extensive study of the literature on this topic. However, taking into account lack of step by step instructions to be followed in this method, e.g. no prescribed mechanism for how to perform the coding, no clear indication of how many concepts a category should comprise of or when saturation is obtained (Allan, 2003), its application can cause difficulties.

L4. Necessity of not working alone – the grounded theory, as stated in its procedures (Corbin & Strauss, 1990) and in the original framework description (Glaser & Strauss, 1967), needs group work. It is encouraging diversification of points of view by maximising number of people involved to stimulate the thinking process. In this research, the author is the only person conducting the investigation and, although results were discussed with supervisors systematically and experts were contacted during the study – the actual data collection, concept development and analysis were prepared as individual tasks. Moreover, due to lack of literature discussing the topic of the study – connecting services, microfluidic design and sub-section interactions – probability of identification of collaboration possibilities, during the study, with other researchers, was constrained.

Due to the mentioned limitations of the grounded theory, consideration of partial application of this method has been undertaken when applying to this study. Validity of this approach is underlined by other researchers (Goulding, 2005; Bamford, 2008). Therefore, the grounded theory has been applied in the conducted research partially. The methodology developed, incorporating grounded theory characteristics, is presented below.

3.2. Applied Methodology

The developed methodology for the research has been based on conventional research approach and on grounded theory. The author followed what she considers a logical set of actions when planning and executing the research. This section first

presents an overview of the research methodology applied and later details the approach followed during data collection and analysis. Methodologies for the development and validation of the guideline are presented in relevant chapters (Chapter 5 – The Guideline and Design Enablers, Chapter 6 – Validation).

To visualise how criteria, factors stated as advantages of the grounded theory and its limitations from the research point of view have been directly transferred into the methodology development, labelling was used. Criteria, factors and limitations have been labelled with the first letter of a word and a number. They are used in the section below, where appropriate, in square brackets, e.g. when text referred to an aspect of the methodology developed based on the first criterion, it was marked as [C1].

3.2.1. Overview of the Research Methodology

Due to elimination of the pre-selection of data collection methods and simultaneous data collection and analysis, two views on the developed methodology are presented. An early approach – used at the beginning of the research when all methods to be used were not specified, but only type of investigation (literature, field) was established – and the final approach, which identifies all techniques used in the research in a retrospective manner.

Figure 3-3 presents the early approach to the research methodology. Similarity of this methodology to the general approach for the research (Figure 3-4) can be observed. As can be noted, the methodology was developed from the fifth step of the process. The previous four steps have been integrated into the figure to show a full view of how this methodology fits into the project. Therefore, characteristics of grounded theory were incorporated into the research approach starting from the fifth step. Applied aspects of grounded theory include insights in the general methodology, data analysis and solution's validation.

Development of the research methodology has been separated from the research planning due to importance of this step. Planning has been considered here as scheduling and putting in place arrangements to allow for execution of the

methodology. The research methodology application starts, therefore, from the "Research Planning" step which will allow for its implementation.

Figure 3-3 Research Methodology - early approach

The necessity of building the research approach during research realisation [C3] and concurrent data collection and analysis [C4] have been used in the developed methodology [C4]. The limitation of a strict selection of the research methods upfront, when probability of making wrong assumptions and negatively influencing research outcome is high, has been highlighted. Exploration of the field, according to Glaser and Strauss (1967), allows better selection of methods to be used in the research, such as: interviews, survey etc. regarding deeper knowledge about data possible to be obtained and their sources. Fitting with this approach, the concurrent data collection and analysis supports selection of suitable methods, as well as speeds up the research and increases its accuracy. Therefore, this approach has been followed.

The next step of the methodology is the investigation of literature which is in opposition to the grounded theory approach [L2]. Although Glaser (1978) states that

"everything is data", including literature, and recommends its usage during comparative analysis investigation - according to grounded theory (see Figure 3-2), field investigation starts the process of data collection. The author selected literature investigation as the preceding step due to the professional attitude to the possible field investigation. The author supports Allan's (2003) view that "busy people of industry and commerce expect meetings to have an agenda and research projects to be scoped", and that "time and resource constraints prohibit unfocused investigation". Moreover, initial investigation of literature, which allowed scoping of the aim and objectives of the research, showed significant limitations in available literature regarding the topic of investigation. Therefore, deep investigation of the literature has been approached as the first step of data collection and analysis to reveal what exists in the area and provide a first set of data.

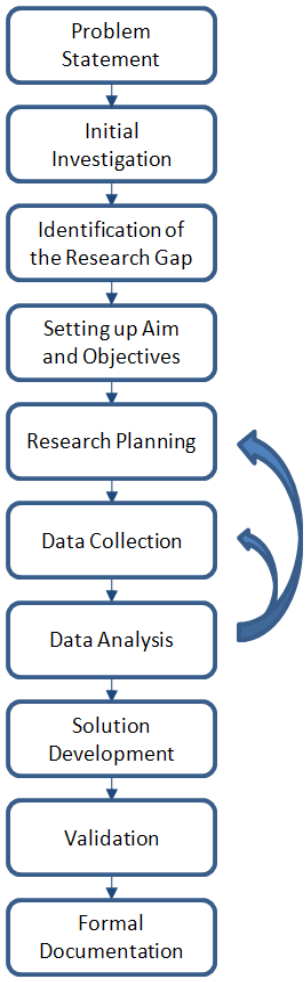


Figure 3-4 Approach for the Research

After that, field investigation has been decided to be a necessity [C1]. The main reason for field investigation is the limited amount of data in literature identified, connected to the main topics. Following the grounded theory approach, methods used in this investigation are not pre-selected, but left to be decided upon till results of data analysis from literature are obtained. All methods selected here are presented in Figure 3-5.

Arrows on both sides of the process (Figure 3-3) indicate evolution of the approach based on data analysis. They represent the fact that methods of data collection, as well as samples, will be decided upon based on the results from systematic analysis. The arrow from the field investigation to the investigation of literature step represents the undertaken constant comparison approach which follows the grounded theory model.

Subsequently, identification of the common gaps from methods of data collection and analysis (literature and field investigations) scope the solution to be developed. The form of the output from analysis will result in identification of the common gaps to be addressed in the domain and a suitable method to do this. The step 'identification of common gaps' aims to summarise results before solution development can start.

The solution development aims to be approached in a systematic manner based on concepts emerging from data [F1]. Although it is presented as one step in the diagram, it is planned to be developed not only in an iterative manner – incorporation of improvements – but also by regular fit-in of information obtained [F2]. This 'one step indication' symbolises the decision on the final shape of the solution when all data has been collected, and 'theory' emerged will scope what is really required.

The last step of the methodology is validation of the developed solution. Also here, as in the research, the method is left to be selected based on the 'theory' which emerges from data. Decision on the validation approach depends on the form of the solution developed.

The final state of the methodology obtained after the research is presented in Figure 3-5. As can be observed, multiple data collection and analysis techniques were used [C5]. The final shape of the solution developed has been decided as a guideline and prepared as a process (F3). Although Figures 3-3 and 3-5 present validation of the solution as one step, a multiple validation approach has been selected to assure the guideline quality.

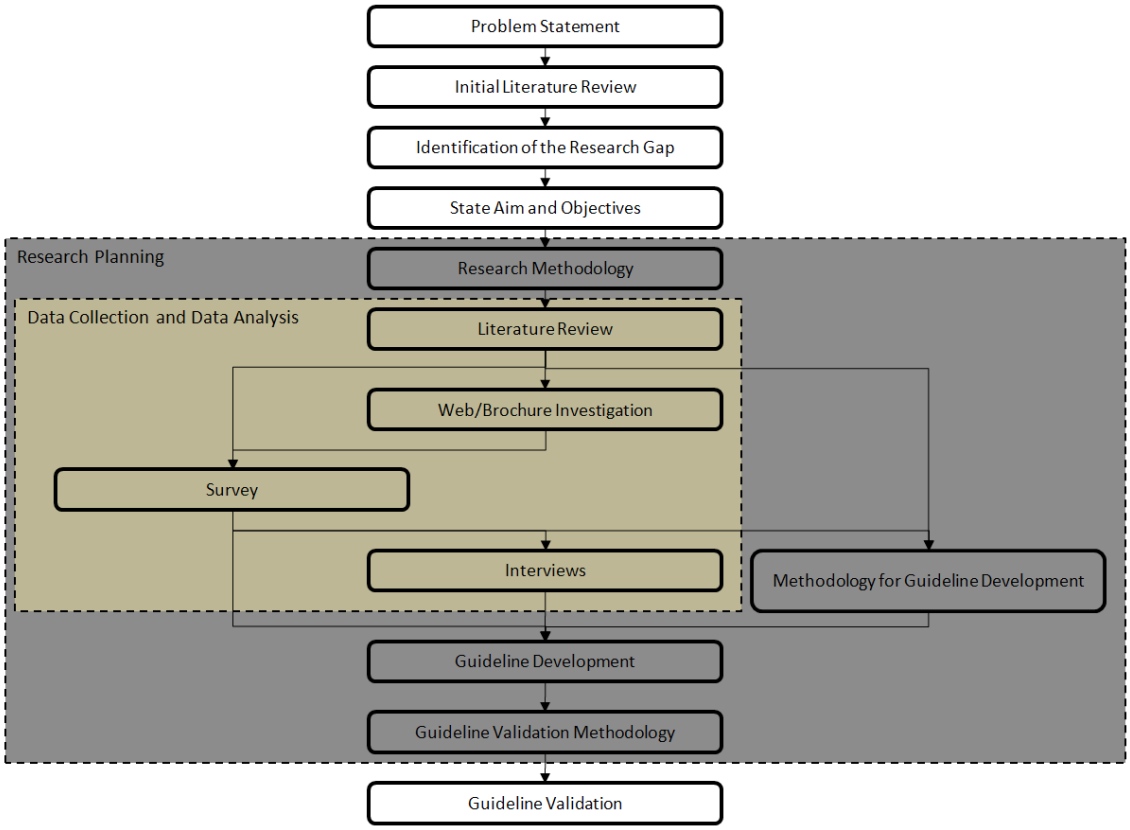


Figure 3-5 Research Methodology – final approach

The methodology followed in the realisation of the indicated stages is detailed in the following parts of this thesis: Data Collection Methodology – Section 3.2.2, Data Analysis Methodology – Section 3.2.3, Solution's Development Methodology – Section 5.1 and Validation Methodology – Section 6.1. A description of techniques used in data collection and analysis has been placed in this chapter to provide the reader with details regarding the applied approach, while other methods have been placed in suitable chapters of the thesis to avoid repetitions.

3.2.2. Data Collection Methodology

Data collection has been approached without preselected methods for the whole process. Selection of each technique used has been a direct result of data analysis from the previous investigation stage. Therefore, the following techniques have been used: literature review, web/brochure investigation, survey and interviews. This section presents the rationale behind selection of the listed techniques and the methodology used in their application.

3.2.2.1. Literature Review

As a first data collection source, a literature review has been selected. It has been decided on as a result of initial investigation undertaken for identification of the research aim and objectives. Section 3.1.5 partially explains the rationale behind selection of this investigation approach. The following reasons can be stated in favour of the choice:

- Lack of author's previous experience in microfluidic design.
- Indication of the lack of direct literature on the subject under investigation and limited information in closely corresponding areas obtained from initial investigation.
- Author's familiarity with conducting literature studies,
- Uncertainty of experts' participation in the research – no industrial sponsors funding this research project.
- Limited resources – due to the need to conduct the investigation solely by the author, this approach presented cost effectiveness.
- Assure originality of the research output - this investigation will allow avoidance of 'reinventing the wheel' by identification of existing approaches and current state of the publications in the domain.
- Identify other people working in this field – due to low probability for direct link between other researchers' work with this research, the relevant areas are targeted in this investigation. It aims at identification of experts in the areas and samples for further data collection.

- Identify methods used by others for similar investigations in the field – by investigation of the techniques successfully applied in the domain, reliability of the research can increase. These techniques can not only provide an indication of what methods can or should not be used, but also how to adjust them for the domain needs.

Investigation of literature has been performed using library electronic resources, catalogue resources, such as books, journal papers, conference papers, and information available from the World Wide Web. Investigation started from the most up-to-date resources and moved backwards in time, depending on the amount of available information on particular topics.

Selection of the references to be used in the literature review was as follows:

1. Journal papers – up-to-date source of information, the accuracy of which is checked before publishing.
2. Conference papers – up-to-date source of information, mainly based on literature and case study research, which prove their reliability; however, control of the presented information is at a lower level.
3. Books – relatively high accuracy of information based on iterative control of data before publishing; however, not up-to-date.
4. World Wide Web – highly up-to-date; however, with the lowest accuracy and accountability of provided information.

Investigation of literature for literature review started in three areas based on the research aim: design methodologies for microfluidic devices, service-orientation of microfluidic devices and sub-section interactions of microfluidic devices. The research was undertaken on many levels. The first level was based on identification of the key aspects of the research aim and formulating keywords from them. This set of keywords included: for design methodology - design of microfluidic devices, design at micro-scale, microfluidics, design methodology; for service-orientation – service-oriented design of microfluidic devices, design of services, design for functionality and services, service-oriented design of products, design with services

in mind; and for interaction issues - sub-section interactions of microfluidic devices, sub-section interactions, dealing with sub-section interactions, interactions between components in microfluidic devices. Investigation of these issues showed gaps in the searched area and led to formulation of the second set of keywords: for design methodology – unstructured design, structured design, top-down design, bottom-up design, design models for microfluidics, microfluidics and technology, macro vs. micro, issue of scale; for service-orientation – PSS, DFS, SOA (Service-Oriented Architecture), movement toward services; and for sub-section interactions – monolithic design, modular design, modularity of microfluidic devices, simplification of microfluidic devices, integration vs. modularity. This process was iterated and included searching for information based on references provided by primary sources and investigation of the originators of the ideas (their other publications, co-workers' publications, publications of their institutions regarding particular topics, etc.).

Literature research was separated into two phases: core literature review – in which all mentioned topics were investigated; and supportive literature research – undergoing till the thesis submission. The supportive literature investigation tried to assure completeness and accuracy of the presented information and originality of the research.

The literature has been analysed systematically, as presented in Section 3.2.3.1. The analysis has been performed as concurrent work with data collection and its results allowed for selection of the approach to be used at the next data collection phase.

3.2.2.2. Web/Brochure Investigation

Investigation of the literature resulted in limited information regarding the state of the service practice in microfluidic domain. Therefore, a view of this state in microfluidics industry has been sought for. To gain it, an investigation of the services provided in this domain by companies has been undertaken. Careful considerations led to the selection of companies' offerings, and an investigation was

carried out based on organisations' websites and their brochures. This approach has been selected for the following reasons:

- Minimal resources required – possibility to apply resources available for the project without any additional costs.
- Information available for the public view – no confidentiality agreement or data disclosure agreements needed.
- No time from the investigated side needed – no time of people from the organisations under investigation required.
- Low risk - limited delay could occur when information has not been provided on the website in words or from download, but will be sent on request.

The additional benefit of this investigation has been an identification of potential participants for further research by review of organisations' prospects and brief familiarisation with their work on microfluidics.

The selection of the companies for research was based on reports regarding the microfluidic market. This allowed the author to choose 38 organisations. The tabularised results are available in Appendix 4.

Data was gathered with a focus on three aspects: products, services and services connected to products. In terms of products, answers to the following questions were acquired: is the organisation offering any microfluidic products; if yes, what types of products does it offer, is there an indication of the service which the device will provide and if it is offered as a functionality of the product itself. In terms of services: does the organisation offer any services; if yes, what services are offered, if they are/can be classified in any manner and are devices themselves offered as services. The last area was an intersection between both aspects: products and services. Scope of this investigation included: are product and service offerings connected, if yes, how; does the organisation provide only services for products, e.g. maintenance and repair, or part of services is offered as a functionality offering. This intersection was aimed at presenting a first insight into the depth of service thinking in the microfluidic domain.

The methodology used for analysis of the gathered data is described in Section 3.2.3.2. Results of this analysis, when compared with the literature review analysis results, led to the selection of the next technique to be used in data collection – survey – which is described in the section below.

3.2.2.3. Survey

Based on the results from previous data collection and analysis phases, further field investigation has been viewed as a necessity. The form of this investigation has been decided on as a survey. Selection was based on several factors:

- To capture current practice of the industry/academia without influencing their view with results obtained from literature (THCU, 1999).
- To target higher number of respondents and obtain more realistic results (THCU, 1999).
- To be cost effective due to the selection of email as a mean of survey (savings in terms of transport) – survey requires minimal investment to develop and administer, and is relatively easy for making generalizations (Bell, 1996, p. 68).
- To establish initial contacts with the microfluidic industry and academic institutes working in the domain.
- To identify participants for follow-up for detailed investigation based on gathered information.

The survey has been performed using a semi-structured questionnaire for industry and academia to allow for comparison of responses. A semi-structured approach has been selected to allow designers to express freely their opinions on some topics, and at the same time, to provide Yes/No answers which will decrease the time required to fill in the document.

This survey has been internally validated due to availability of experts in micro and design methodology domains at the University and cost effectiveness of this approach. After internal validation, the main companies and research institutes in

the microfluidic area were contacted via email and asked to fill-in a short survey. With the aim of establishing good contacts and with respect to the time required from the respondents, only questions viewed as necessary and justified have been incorporated into the survey (Appendix 5.1 explains the rationale behind each question used).

The survey was conducted using a structured questionnaire. This questionnaire has been developed by the author based on literature investigations and results from the initial investigation of companies' offerings from the microfluidic domain. It was evaluated using a piloting session before it was distributed among respondents. The development and the evaluation of the questionnaire are described in Appendix 5.2 with the original questionnaire (Appendix 5.3) and the evaluation form (Appendix 5.4) used during the session.

The piloting session for the questionnaire took place on 17 February 2009 from 11:00 - 12:00 at Cranfield University. It was facilitated by the author. Participants who took part in it as internal experts were: Dr Ashutosh Tiwari (work connected to design) and Dr Jeffrey R. Alcock (work connected to micro-devices). Time estimated for filling in the questionnaire was 15-25 minutes, and time required by participants was on avg. 14 minutes. Filling in the questionnaire was followed by filling in a feedback form. Participants positively evaluated the questionnaire and their feedback has been addressed to improve the questionnaire; the new version is attached in Appendix 5.5.

After evaluation of the questionnaire, small adjustments in the questionnaire were made to make it clearer for respondents. The survey was named "Microfluidics – design, services and modularity" to reflect its three core parts for which information was aimed to be gathered. These sections were: design methodology, service-orientation of products and sub-sections interactions. At the beginning, the section regarding background of the respondents was added to allow for evaluation of their eligibility to provide valuable answers, and at the end, allowing respondents to evaluate the questionnaire and provide additional feedback.

Based on the feedback survey has been structured as follows (section themes and number of questions):

- A – Background 11.
- B - Design Methodology 22.
- C - Service-orientation of Products 5.
- D - Sub-sections Interactions 5.
- E - Questionnaire Evaluation 1.

Average number of questions per section was 11; however, it can be observed that the majority of questions were scoped around design methodologies for microfluidic devices due to the research focus on this area. The questionnaire had 22 open questions, and from 21 closed questions, 19 allowed for explanation of choice to give designers freedom of expression and encourage them to elaborate on the topic.

To distribute the survey, the online software provided by Question Pro[11] was selected. For this, other methods were also considered, such as: personal – rejected due to the small number of potential respondents who can be targeted, time-consuming method and difficult to identify suitable respondents, high cost of transport, international placement of microfluidic companies; traditional mail – long time of delivery (1-2 days to deliver letter to the company in the UK, not including internal mail services to distribute it within the organisation), cost of the method.

Regarding the selected method for survey distribution, the following appearance has been selected to increase the user-friendliness of the questionnaire and ease of its use:

- Survey displayed on multiple pages.
- Survey name and introduction of the survey on first page.
- Name of new section with particular instructions for it on separate pages.

[11] QuestionPro is a web based software for creating and distributing surveys. It consists of an intuitive wizard interface for creating survey questions, tools for distributing survey via email or website, and tools for analysing and viewing results. Survey is built and emailed to a list of potential respondents. QuestionPro takes care of collecting and recording the responses. Results are available in real time. (QuestionPro, 2010)

- Switching between pages with 'Next' button.
- Option to go to the previous page with 'Back' button.
- 'Thank you' page at the end of the questionnaire.
- Bar showing progress in filling the questionnaire placed on the top of every page.
- Maximum number of questions per page: 11 – not too many questions per page to not discourage users, and not all of the questions on one page, allowing to focus on a particular topic at a time (questions categorised).

Additional reasons for this structure were as follows:

- Minimise time required to fill-in questionnaire.
- Questions focused on core issues identified.
- Questions designed based on literature and website findings.
- Background section provided for response evaluation.
- Questions categorised according to the main themes and assigned to sections.
- Evaluation of the questionnaire placed at the end to obtain respondent's view on possible improvements.

Before the survey was placed online, the author familiarised herself with options available by the QuestionPro website for questionnaire. The survey was placed online 09/04/2009 and closed 09/07/2009. The three month duration was considered as sufficient to obtain an optimal number of responses. After one month of the survey presence online, it was updated based on the respondents' feedback (increased explanation of the sub-section interactions and service section) on 09/05/2009.

Potential respondents were contacted via email - 30 companies, 68 research organisations, and via company website (where email was not available) 9 companies. After the survey was updated on 09/05/2009, it was communicated to the microfluidic community by posting a message on the LinkedIn network on 15/05/2009, which is presented in Figure 3- 6.

The survey was closed on 09/07/2009. All responses were stored in an Excel file. The last response was obtained on 7 June 2009, which assured that a large amount of data would not be missed by closure of the survey in July.

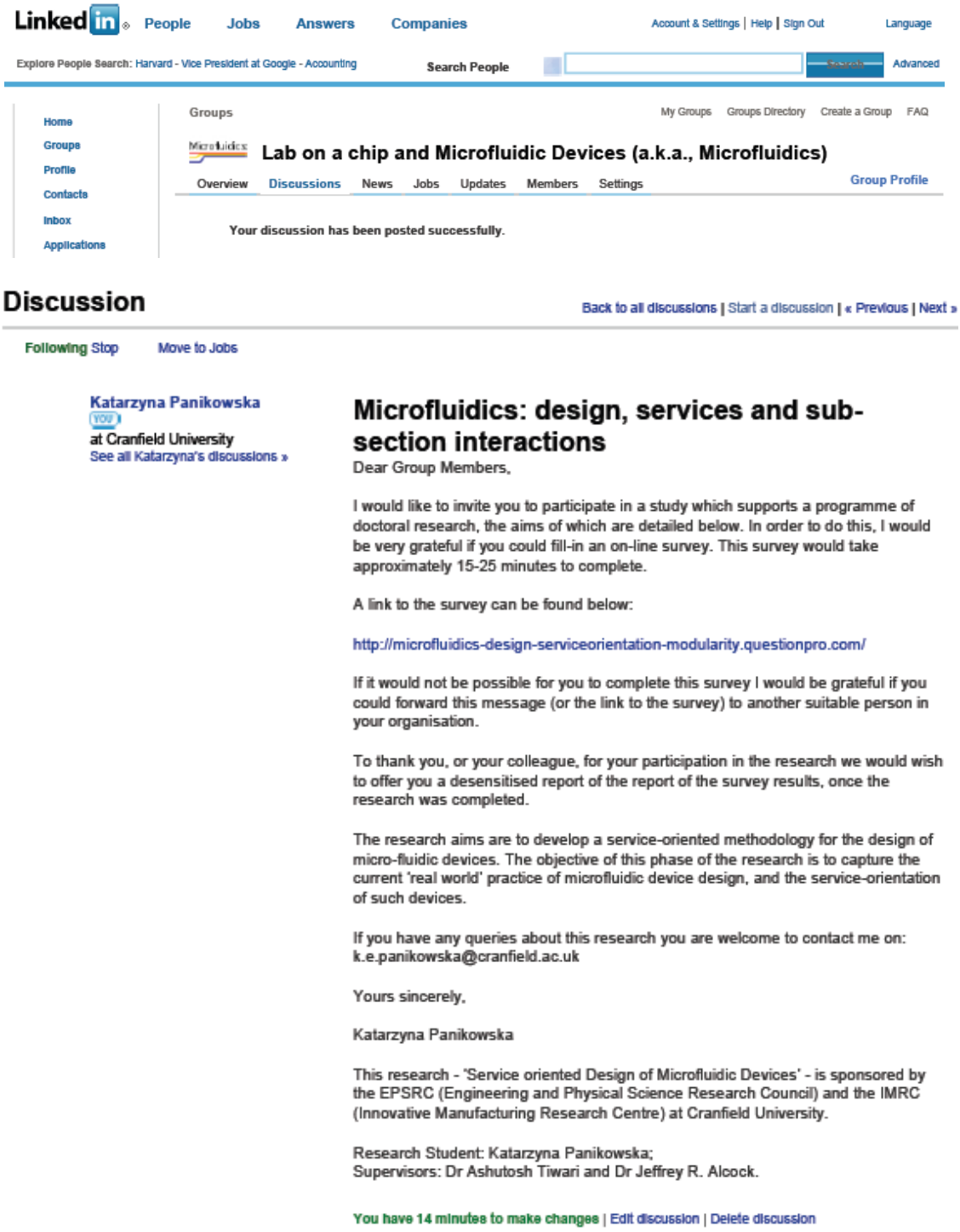


Figure 3-6 Posting of the survey on the LinkedIn network on Microfluidics

The methodology used for analysis of the survey is described in Section 3.2.3.3. Results obtained from this analysis, compared with results from previous analyses, led to selection of the last data collection method – follow-up interviews. Rationale used for selection of this technique and method applied are described in the next section.

3.2.2.4. Interviews

As the last method of data collection, interview was selected. The follow-up interviews were decided to be conducted based on the output from the previous analysis stages. They aimed to clarify questions incorporated into the survey and to investigate issues in detail. The following rationale supports selection of interviews as the preferred tool for the last stage of the field investigation:

- Recommendation of the interviews as main source of data in the grounded theory approach (Glaser & Strauss, 1967).
- Provide an insight and understanding which are required (Gillham, 2000).
- Limited amount of human resources necessary from the author due to limited available sample to be interviewed.
- Possibility to adapt questions when necessary.
- Provide more detailed information than other data collection methods (Boyce & Neale, 2006).
- Allow respondents to feel more comfortable than when filling in the forms (Boyce & Neale, 2006).
- Opportunity to clarify issues and ask additional questions based on responses.
- Opportunity to capture non-verbal clues from respondents based on the body language, face expression and be able to respond to them (clarify issues if respondent struggles to understand the question, make notes of hesitations and uncertainty, etc.).
- Existing author's experience of conducting interviews and skills considered as sufficient for purposes of the project (no training necessary).

Interviews were undertaken both face-to-face and via telephone. Although the face-to-face approach was preferred, due to the geographic limitations, two interviews were conducted by phone. This, in comparison to face-to-face interviews, does not allow for identification of non-verbal clues, but possesses all the mentioned advantages of the method. Both approaches allowed for issue clarification as well as a deeper investigation of issues raised during the interview. Moreover, they allowed for interactions with respondents and identification of their areas of interest in microfluidic design.

The interviews were conducted using semi-structured questionnaires, personalised for each interviewee. These questionnaires have been developed based on the survey responses given by an interviewee in comparison with responses obtained from other respondents. This allowed elimination of irrelevant questions based on previous answers, and by this, minimisation of time for data collection. Moreover, semi-structured questionnaires incorporate a degree of generality. Comparison between answers from various respondents allowed the author to establish a list of issues discussed - commonly and individually. This list has been used as a base when preparing each questionnaire by comparing it with responses given by a potential interviewee in the survey. This allowed the author to fill gaps by preparation of new questions and prepare for future comparison of data between interviews.

A digital recorder has been used during interviews for clarification purposes. Furthermore, it allowed the author to focus on the issues under investigation, maximise amount of data captured and increase effectiveness of data collection. Interview statistics, such as date, time, name of the respondent, position and place, were written by the author, and some of them repeated on the recording for identification purposes. Recording did not eliminate taking notes, but allowed the author to summarise general points raised and write down ideas for new questions for clarification and for further research.

The first interview was performed in the presence of other investigators from the project. This aimed to assure that the author's investigation would be carried out in a professional manner. Other interviews were performed on a one-to-one basis to

increase level of confidence of the interviewees. Data analysis, in all the cases, was carried out in an identical manner.

In total, 16 people were contacted to participate in follow-up interviews. As a result, three face-to-face and two phone interviews were conducted. Interviews were not restricted in time to allow participants to express their opinion freely and investigate issues in depth. Lengths of the interviews varied from 40 minutes to 3 hours. Average duration of the interview has been estimated at 74 minutes.

Analysis of the results from survey and follow-up interviews allowed for comparison of industrial/ academic practice with literature findings, and provided crucial knowledge for the most important step of the research – development of the guideline for service-oriented design of microfluidic devices which can deal with sub-section interactions. The approach to the interview analysis is presented in Section 3.2.3.4.

3.2.3. Data Analysis Methodology

Data analysis was kept in mind during preparation of the data collection stage. Therefore, both are strongly connected to each other. This strong interlink is visible in the research approach, see Figure 3-3. To allow for efficient and effective research, it was decided to carry out the data collection and analysis stages simultaneously. This work was undertaken as soon as the amount of input data allowed for sufficient tentative conclusions. Data obtained from every source were analysed independently before comparison between various sources, and results were incorporated in the next stage of data collection. Details of the analysis approach are given below.

Coding has been integrated as part of the analysis process derived from the grounded theory approach. It has been undertaken not in a numerical manner, due to the problems of losing information when converting text into numbers and difficulty with retrieving them (Miles & Huberman, 1984), but by using qualitative codes (Richards, 2005). Types of the codes used were dependent on the analysis stage and data, and are described here.

3.2.3.1. Analysis of the Literature

Discovery of new categories has been undertaken with the first paper read. Analysis started by coding the information connected to the three main categories identified from the research aim: design methodology for microfluidic devices, services and complexity.

Codes were not predetermined, but developed while reading the text. Data in the literature documentation have been coded descriptively. Descriptive codes are preferably 'single' summarising notations of the attributes of the phenomena (Miles & Huberman, 1984). Examples of used codes are DEF for definition and COMPL for complexity. When a second level of codes was identified as necessary, they were developed as strict, concise and to share common meaning, e.g. COMPL-type for complexity type. Codes were not noted anywhere formally as a list, but used only for the researcher's convenience as abbreviations. They were noted by the researcher on the margins of the paper to simplify later analysis in the context of other documentation.

When a sufficient amount of literature was analysed from a single perspective papers were categorised in an Excel file. Literature was analysed using the Excel spread sheet and papers have been classified according to the topic presented. The first analysis is regarding complexity. Data regarding each paper, considered as relevant, have been noted, i.e. author(s), year, source, volume, issue, pages and title. The topics covered in each paper were marked according to the coded information. Repeatability of the codes allowed development of categories which, for the first stage of the literature analysis, included: general definition of complexity, types of complexity, complexity in design, complexity and factors influencing it, reason for defining complexity and quality of definition. These were high level categories. Some of them have been split into lower level categories, e.g. general definition of complexity included: irreducible complexity, information complexity, Kolmogorov's, system complexity, observer complexity, Löfgren's interpretation and descriptive complexity, Kauffman's number of conflicting constraints, physical, structural, functional, structural hierarchical, functional hierarchical, behavioural,

crude complexity, logical depth, forecasting complexity, computational complexity, Gell-Mann's effective complexity, complexity by design, Intrinsic complexity of multi-disciplinarity, time-independent real, time-independent imaginative and time-dependent complexity. To store coded data under the categories, the codes needed to be revised according to topics. This revision allowed the development of 'topic codes' as the next step in coding (Richards, 2005), which is labelling text according to its subject. Coded data were stored under low level categories.

Categories were placed in the columns of the spreadsheets with literature documentation arranged in rows. This type of storing allowed for fast data recovery and analysis of the data in columns across references. Following this approach, every new document was coded, and when considered relevant, fed into the files.

Following this data analysis, main questions to be answered in the investigated topic were stated. These topics evolved from the main categories and information obtained during the analysis. Also, the requirement for revising codes was identified. Revised codes have been based on the information contained in the statements, phrases etc. These analytical codes represented information and its meaning. This type of coding is not automated, but strongly depends on the researcher and his/her ability to interpret the data (Richards, 2005).

Developed questions were also placed in the spreadsheet in columns and, where identified, followed by categories representing issues to be investigated. For example, the question 'What is the reason for measuring complexity and how can it be done?' had the following categories designated to it: reason, measurement issue, Shannon's equation of entropy, thermodynamical depth, statistical complexity and effective measure of complexity.

As underlined by Glaser and Strauss (1967), development of theory from data can even lead to change in the research question and aim. In this research, investigation of complexity showed a number of issues related to it, which needed to be addressed. Therefore, focus on sub-section interactions has been decided as a complexity feature to narrow the research scope.

Although the above presented investigation of literature has been scoped, the complexity issues which were investigated were more broad and diversified. The second set of developed categories included the following: markets for micro devices, documents flow in design, design process for micro-devices exist/not exist, methodology needs development, methodology is provided, methodology is context specific, design rules for micro-technology/requirements, lack of one meaning for complexity, general definition of complexity, relativity[12] of complexity, subjectivity of complexity, types of complexity, complexity in design, complexity and issue of scale, complexity and issue of elements number, complexity and issue of interrelations, complexity and factors influencing it, effects of complexity, complicated vs. complex, randomness vs. complexity, evolution of complexity, complexity cannot be quantified, measuring complexity, complexity meaning for micro devices, complexity influence on micro-devices, definition of integration, definition of micro-integration, micro-integration vs. complexity, customer needs in micro-devices design, service orientation, service-orientation of micro-devices, services for micro-devices, service-orientation and PSS, definition of a PSS, design of PSS, design process for PSS, applications of PSS, design of PSS vs. design of IPS2 (Industrial Product-Service System), factors influencing PSS, PSS for micro-devices and future belongs to miniaturisation. All these categories have been placed in the Excel spreadsheet in columns, with documentation containing related data in rows. Instead of placing coded data in a descriptive manner, the only indication of the data contained in a paper was marked in appropriate cells. Following this step, a separate file for the final set of categories for the literature research was established and prepared according to the complexity analysis file. This file was fed into the next stages of data collection by identification of the area gaps and providing background knowledge about the problem. Examples of the category on a high level include: factors influencing design in micro-scale, with subcategories such as technology driven approach.

[12] is complexity relative or independent, means always the same or the meaning varies depending on factors (Delorme, 1999)

Other techniques used in initial analysis – before data were stored on the computer – include annotations and ideas storing. Annotations have been made on the documentation and/or photocopies of the literature sources using post-it notes. Ideas, which were not directly connected to the literature analysed, were stored on the post-it notes, in text files and in the research notebook. They were stored as soon as they appeared and revised after reading was accomplished. They were named but not dated. Their length varied from a couple of words to half of the page to assure transfer of the meaning and provide context without interruption in reading with. These ideas and annotations helped in the development of codes and categorisations as well as in the information extraction.

Analysis for each categorisation has been approached, starting from common aspects, followed by similar meanings and finishing with differences. Each of these aspects has been approached by investigating the reasoning behind issues raised, and how this can influence the design process in the microfluidic domain. Results of this analysis allowed for selection of the web/brochure investigation as the next step of data collection, and survey as the following one.

3.2.3.2. Analysis of the Web/Brochure Investigation Results

While data analysis for the literature has been approached broadly in a theoretical sampling manner (data indicated where the investigation would be conducted), web/brochure investigation samples were preselected based on the literature. The method using which this investigation was conducted is described in Section 3.2.2.2.

Initial analysis of the data was performed using the brochures and companies' websites. Specific information was sought. Information searched for was scoped around how microfluidics are offered to the public, what is connected to the product offerings and what other types of offerings companies present.

Data obtained from the web/brochure investigation were stored in a table in a Microsoft Word file. The file was prepared as a table in which categories were placed based on pre-prepared codes. The following information has been stored:

company name, products offered, services offered, services offered for products. These categories were developed based on the data presented by the sources.

Firstly, the table presented the full range of organisation offerings with their description. Secondly, data were filtered according to the offering types in terms of services and products. Then, the way in which services were categorised was revised. A more suitable method of categorisation was identified based on observed patterns. This re-categorisation allowed the author to obtain views on how the services are represented in the companies' offerings in the microfluidic domain. Obtained results were fed into the survey prepared based on the literature review. The methodology used to prepare the survey is described in Section 3.2.2.3.

3.2.3.3. Analysis of the Survey

The analysis of the survey was divided into two parts. The first part of the analysis aimed to confirm the appropriateness of the survey and language used in the questionnaire for data collection in the field. The second part provided core data for the research and was aimed at information which would be used as an input for interviews and the next stage.

A. Analysis of the Survey's Suitability for the Research

The analysis of the survey's suitability for the research, see Figure 3-7, was undertaken after one month of survey's presence online. The survey was conducted for three months: this amount of time was selected as sufficient to gather reliable feedback on the survey, which would allow for any necessary changes and for new respondents to access the improved version of the questionnaire.

The analysis has been undertaken mainly based on the last part of the survey in which respondents were asked for evaluation. This part was prepared to assess the survey and help in improving it. Problems raised by respondents in this section were compared with their answers to questions connected to the relevant issue in the survey. In case of a high number of respondents' suggestions, and contradiction between them, etc., a priority rule was established. This was judged based on

repetitions of the issue. However, due to the low number of suggestions, lack of contradictions between them and the fact that the majority of them were requests for clarifications on nomenclature, this rule did not need to be applied. Therefore, all suggestions have been addressed.

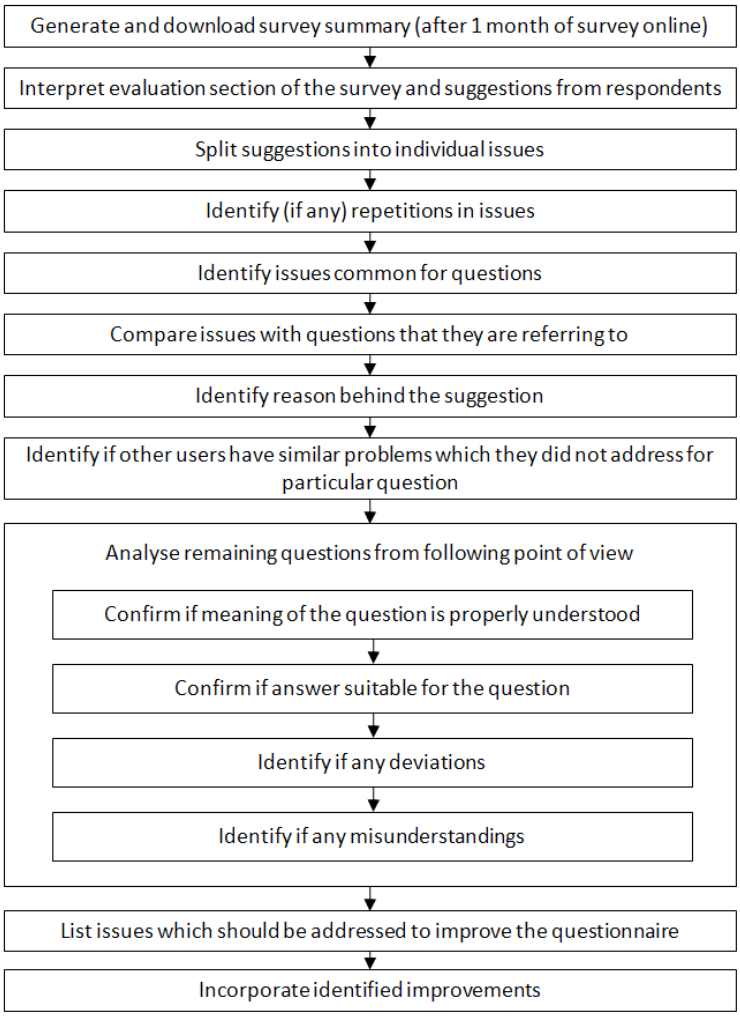


Figure 3-7 Survey's suitability for the research analysis methodology

The remaining analysis was based on accuracy of responses on asked questions. All answers were grouped around questions and studied based on the following points:

- Understand the meaning of the question.
- Given answer suitable for the question.
- If answer deviates – what could be the reason – is it because another sense was indicated by the question or a nearby question?

- Is more than one respondent having problems with answering a particular question?

The analysis has been undertaken following the structure of the questionnaire. These points were used when addressing issues arising in the survey evaluation. As a result of this analysis, small changes were incorporated in the survey. These changes contain additional explanations for respondents to clarify context of words used.

B. Analysis of the Survey Responses

The analysis of survey responses was planned more rigorously. Attention to details was necessary to uncover the meaning behind respondents' answers, their reasoning, and selection of participants for follow up interviews. Analysis was selected to be performed in both a quantitative and qualitative manner, but a qualitative approach was dominant. The survey results analysis methodology is presented in Figure 3-8.

During selection of the website on which the survey would be held, as one of the decision making factors, the possibility of data analysis on a statistical basis was established. This high level analysis of data was allowed by QuestionPro. The provided analysis was in the form of statistical results. Each respondent had a designated identification number for the survey that allowed for their identification when required (assurance that one person, if filling in the questionnaire multiple times would be counted as one respondent, possible contact for follow-up interviews, etc.). Quantitative output was presented in the summary as a number, percentage, and in the graphical form as pie and bar charts.

This basic analysis was generated from unfiltered data (including empty records). To assure that any change in the data would not appear during analysis, it was decided to download the data from the website in raw format (in Excel file), as well as in the form of the report (.pdf format) before any manipulation of the record would be performed. This action was followed by filtering data. To make sure that data was not influenced by the empty records – created when the survey has been

viewed but not undertaken – these records were removed. Lack of influence in empty records removal within the new report generated has been observed. Therefore, study of the generated report was continued in detail.

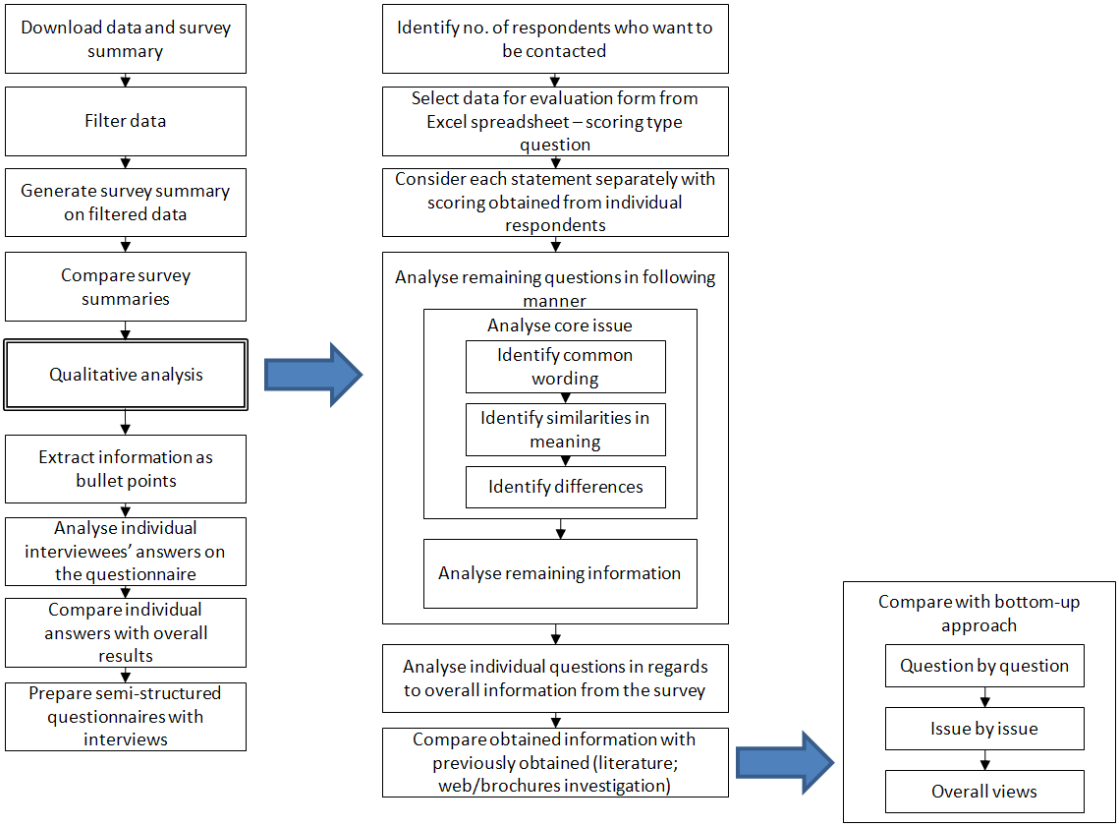


Figure 3-8 Survey results analysis methodology

The prepared report allowed for analysis of the developed open questions without being influenced by the respondents using their survey identification numbers. Data were grouped around prepared questions as a summary of the survey rather than a report. It started with an executive summary of the survey, including its basic statistics: how many times the survey has been viewed, started, completed, number of drop outs and average time to complete the survey, and followed by questionnaire based structure. Open questions were followed by tabled records with participants' answers. Closed questions, depending on their form, were followed by chart, frequency analysis and key analytics, or with all mentioned and a list of open answers. The frequency analysis included an answer count and percentage for each

answer, and in total, where the key analytics constituted of mean, confidence interval at 95%, standard deviation and standard error.

To understand what the reasons behind the given overall statistics were the section regarding evaluation of the questionnaire was analysed upfront. This section was placed in the questionnaire at the end. The mentioned section starts by requesting an email address from the respondents to allow the author to send them a desensitised version of the report as thanks for taking part in the research and/or to request further participation. This allowed the author to instantly identify a number of people who could be keen to take part in a follow up interview. Due to the low number of obtained responses and probability of some participants declining further cooperation, all of them were selected to be contacted. However, contacting participants was postponed until their background and current work could be identified as relevant based on the responses from the first part of the questionnaire.

The analysis of the responses on the first question in the evaluation section was not possible in an effective manner from the summary report. This was due to the website logic behind the selected type of question. Participants were asked to indicate how strongly they agree with particular statements regarding the questionnaire in a scoring manner, with 5 options: strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree. The summary provided prepared answers in percentage form from all responses together, which did not show which answers were selected. Therefore, analysis of the answers was performed on raw data (not filtered, not coded) from the Excel spreadsheet. Each statement was considered separately based on given answers.

The rest of the questions, including open questions from the evaluation section, were possible to be analysed based on the provided summary. The process selected to analyse the open questions was the same in all sections of the questionnaire. First, factors influencing the survey accuracy were taken into consideration. Next, the following approach was selected regarding the core issue in the stated question:

- Looking for common wordings.

- Looking for similarities in meaning.
- Looking for differences.

Looking for Common Wordings

Due to the fact that questions were prepared with a particular issue in mind and scoped in a restricted category, e.g. design methodologies, assumption of familiarity with used terminology seemed reasonable. Moreover, investigation of microfluidic literature and web/brochure offerings of microfluidic companies indicated the type of responses which can be expected regarding particular issues. Therefore, looking for common wording was used instead of any formal method of coding. This simplification was performed manually due to the restricted set of data obtained. For analysis of a large amount of data, the author recommends usage of specialised software (e.g. NVivo) or any automation method to speed up the process.

Looking for common wording strongly depended on the question. Example of this type of analysis is given below. The question for which answers are used as an example of the analysis is *B6* from the second part of the questionnaire, *B – Design Methodology*. The question selected is **B6. How did you obtain the specifications?**

Table 3-2 Respondents' answers on question B6 –common words

934051	customer tests
934447	knowledge of field
936131	Discussions with clients for needs, discussions with fabrication foundries for capabilities of technology, in house expertise for design and implementation support
975655	Derived from conversation with our customers
1003630	from the customer
1013415	Hmmm This is matter of hard discussion with the customer. Takes a long time and never ends. It's a bottleneck in the design process.
1024526	Contact by industrial partners
1082354	Cooperative research with customer
1084568	self engineering
1126066	from client
1685292	customers or by particle size
1742522	market research

Common words identified in the text in Table 3-2 are identified using various underlines. In this example, words are: clients, research and design which appear

twice, discussion which appears three times (however, once it is repeated by the same respondent, this causes it to be counted only once), and customer which appear six times. Therefore, analysis starts with the customer, which is the most common word, and issues connected to it.

These individual words, however, should not be taken out of context. Therefore, each repetition was investigated in terms of meaning. Hence, for customer, the following expressions were identified: customer tests, derived from conversation with customers, from the customer, matter of hard discussion with the customer and cooperative research with customer. All of them have the same meaning. Therefore, 6 out of 12 respondents obtained specifications from the customers. This work was repeated for other common words identified. Short connectors, such as and, of, but, for, etc., were not included as repeatability.

Looking for Similarities in Meaning

The next step involved looking for similarities in meaning, which involved searching for usage of synonyms. This step is presented in Table 3-3. Therefore, synonyms for two words were identified: for the word customer – the word client, and for the word discussion – conversation. Also, here data should not be taken out of context; therefore, whole expressions were analysed.

Table 3-3Respondents' answers on question B6 –similar meaning

934051	customer tests
934447	knowledge of field
936131	Discussions with clients for needs, discussions with fabrication foundries for capabilities of technology, in house expertise for design and implementation support
975655	Derived from conversation with our customers
1003630	from the customer
1013415	Hmmm This is matter of hard discussion with the customer. Takes a long time and never ends. It's a bottleneck in the design process.
1024526	Contact by industrial partners
1082354	Cooperative research with customer
1084568	self engineering
1126066	from client
1685292	customers or by particle size
1742522	market research

As previously, answers connected to customer are presented. Therefore, the following expressions were listed: customer tests, discussion with clients for needs, derived from conversation with customers, from the customer, matter of hard discussion with the customer, from clients and cooperative research with customer. All of these statements showed that specifications were obtained from customers. This corrects previous findings, changing 6 out of 12 to 8 out of 12 respondents who gather input data for the design process from customers. It also showed that more than one form of input was used: test, discussion and cooperative research.

Looking for Differences

The last step involved looking for differences in the answers. These differences were also analysed at two levels – differences in wording and in meaning. The first step is visible in Table 3-4 where words which were not repeated were underlined. It can be observed that only issues which were not discussed before are underlined - if a phrase in which a particular word is placed was analysed in one of the previous steps, it is not analysed here.

Table 3-4Respondents' answers on question B6 –differences between responses

934051	customer tests
934447	knowledge of field
936131	Discussions with clients for needs, discussions with fabrication foundries for capabilities of technology, in house expertise for design and implementation support
975655	Derived from conversation with our customers
1003630	from the customer
1013415	Hmmm This is matter of hard discussion with the customer. Takes a long time and never ends. It's a bottleneck in the design process.
1024526	Contact by industrial partners
1082354	Cooperative research with customer
1084568	self engineering
1126066	from client
1685292	customers or by particle size
1742522	market research

It can be observed that all of these phrases are unique in terms of wordings. However, two of them are connected in terms of meaning: knowledge about the field and self engineering.

The following discussion can be undertaken as a connection between phrases based on previously gathered knowledge from the literature and initial investigation of companies' offerings. *In the highly technology driven area, with many factors influencing design, self engineering requires a high volume of knowledge about the field.* Discussion of data and conclusions were held till all the data from the questionnaire could be analysed.

Another fact which was observed is that sentence - *Takes a long time and never ends. It's a bottleneck in the design process - w*ithout additional information it does not have any meaning. In these cases, phrases, which were used before in analysis were recalled to provide context; in this way, the whole answer from the respondent was analysed.

Hmmm This is matter of hard discussion with the customer. Takes a long time and never ends. It's a bottleneck in the design process. This statement showed, along with previously extracted information about obtaining specification through discussion with the customer, that working with customers can have negative implications.

All identified differences were analysed in this manner. It allowed analysis of the whole text without omitting any additional information. This method was, however, time consuming, and can be automated using word analysis software. Shortcoming of using the software is the possibility to omit the nuances which require knowledge about the area characteristics. For this reason, a step by step analysis was performed by the researcher without professional analytical software support.

When the core issue was addressed, any remaining information was extracted based on the strength of the connection to the core issue. Any additional information provided by a respondent was analysed in the same way as a core issue based on used wordings. Information extracted as unique for a particular issue – mentioned only by one respondent – was noted and, using any contradicting information identified, compared with the respondent's work experience (not only number of years, but also type) and education type.

After analysis of the whole questionnaire was accomplished, a comparison of obtained information with previous findings was undertaken. This comparison started with literature and was followed-up in a similar manner with web/brochure investigation findings. This comparison was performed with a bottom-up approach. It started by comparing details question by question, and followed up issue by issue to the highest level of overall view. This type of analysis was selected because it allows a structured detailed view to understand small details of the problems before judgements can be made.

To present findings, as well as some raw results of the survey analysis clearly, a PowerPoint file was prepared. This PowerPoint file consisted of bullet points regarding methodology used to collect data for this stage, survey results and results of its analysis. The selected form allowed highlighting of some repetitions of information, which resulted as overlapping of some areas of interest in all core issues (e.g. people knowledge, area immaturity). This output was decided to be the first structure draft of the previously mentioned desensitised report which has been sent to participants of the survey as thanks and part of the validation process.

Analysis of the survey allowed identification of gaps in the obtained information. To fill these gaps and to clarify some additional issues, a series of follow-up interviews were performed as an appropriate data collection method. To allow this next stage of data collection, additional analysis of the survey results was required. Preparation of the semi-structured questionnaires, specific for each interviewee but general enough to allow for data analysis and comparison, required another point of view on the data. Therefore, analysis of the data from the survey was performed not only in common context, but followed by analysis of individual answers from particular respondents in the context of the previous analysis results. This analysis was approached following the questionnaire structure. It was focused on what is missing and where explanation or elaboration is recommended. The level of details provided by a particular respondent in each question of the survey was compared with other respondents. Also, clarity of answers was confirmed and, where necessary, follow-up questions and clarification issues listed for the interview.

This analysis allowed the preparation of a semi-structured questionnaire for each of the interviewees. To remove time waste during the interview and minimise time taken from the respondents, data obtained from the survey were considered as a base for the questionnaire and their collection not repeated. This also aimed to focus responses on particular issues and investigate them more deeply, consequently, enhancing the quality of the research.

Summary of the analyses:

- Analyse basic statistics from the survey provided by website holders – automatic generation of the general report on answers.
- Filtering responses – deleting empty records.
- Following structure of the questionnaire as a base for analysis.
- Putting all answers together – respondents' identification numbers have been kept to allow for information source identification.
- Selecting answer on the core information which a question was addressing:
    - Looking for common wording.
    - Looking for similarities in meaning.
    - Looking for differences.
- Identifying information (related to the main questions) which were provided by respondents:
    - Looking for common wording.
    - Looking for similarities in meaning.
    - Looking for differences.
- Analysis of remaining data
    - Looking for common wording.
    - Looking for similarities in meaning.
    - Looking for differences.
- Comparison of unique/contradicting information with respondents' statistics to get a view on relevance of responses.
- Comparison of obtained information with literature findings.

- Comparison of obtained information with web/brochure investigation findings.
- Analysis targeting semi-structured questionnaire preparation for interview.

3.2.3.4. Analysis of the Interviews

Any problems faced by the respondents during the survey such as misunderstanding the context of the question, were addressed when preparing for the interviews. The methodology selected for data analysis from the interviews was similar to the survey data analysis. Data from the interviews were analysed in a systematic manner, see Figure 3-9. After each interview was accomplished, the set of data from a particular interviewee was analysed. The analysis started by reading and descriptive coding of the notes from the interview.

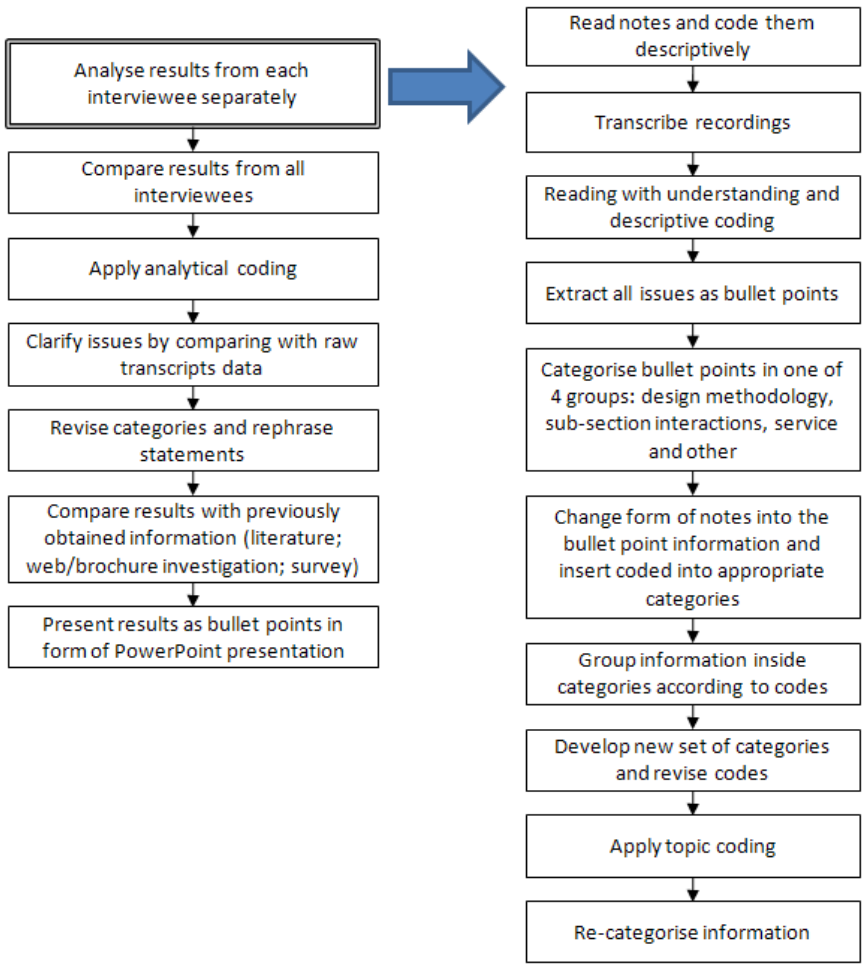


Figure 3-9 Interview analysis methodology

Difference in the approaches for analysis includes coding. In the survey, categories were imposed by the questionnaire structure, which shortened the analysis and implied using coding as repetitive work. In the interviews, coding was considered useful. Although semi-structured questionnaires were developed based on survey results and on previous investigations, during the interview, a free flow of ideas from the interviewees was encouraged during the interviews. Therefore, new issues were discussed during the interviews.

Consequently, interviews after transcribing were read with understanding and coded using descriptive codes. Coded data were overlapping between the three core issues: design methodologies, services and sub-section interactions. Therefore, after coding the transcript, all the issues raised were extracted as bullet points. These bullet points were then categorised according to the three main issues addressed. Information which was considered important and was not directly connected to any of these categories was placed in category other.

Inside each of the categories, bullet points (from notes and transcripts) were grouped according to descriptive codes, e.g. CUST for customer and DP for design process. Coding has been done, as for the literature, in an informal manner without generation of the code list. Grouping coded data resulted in the development of a set of categories and necessity to revise codes in a topic-code way. This change resulted in the development of an arrangement similar to the survey questionnaire structure based on issues extended by number of categories. This categorisation allowed systematised information and minimised number of repetitions.

After all of the interviews were performed, all data were put together. This collection of information in the form of bullet points was analysed following a prepared structure based on commonalities, then similarities, and finally differences in used language. This comparative analysis presented obsolescence of some of the categories and requested change for the analytical codes to extract proper meaning of data. This effected in moving back to the transcript of interviews for clarification of information obtained. Consequently, categories were revised and statements rephrased.

Results from this analysis were compared with results obtained from the previous analysis. Comparative analysis of data obtained from all sources allowed the development of a guideline for the design of microfluidic devices which can deal with sub-section interactions. The guideline, with methodology used to develop it, is presented in Chapter 5.

The results from interviews were attached to the PowerPoint file, with survey results and analysis. The tentative conclusions on both sections were extracted separately, and conclusions regarding the overall view of findings extracted at the end. The results section of the presentation was separated and restructured. In this way, five PowerPoint files were prepared as thanks for contribution to data collection.

3.3. Strengths and Weaknesses of the Methodological Approach Used

The developed methodological approach possesses a number of strengths and weaknesses. Both advantages and disadvantages are mainly a result of the formal research approach selected as a base for the research methodology. Characteristics of the developed methodology with the highest importance are presented below.

Strengths:

- Is area and project specific, therefore allowing more accurate results to be obtained – selection of the techniques to be used in the project realisation was based on the investigation results. All methods to be used emerged from data and reflected the most suitable approach regarding the state of the area and available resources. This allowed for effective exploitation of possessed capabilities and an optimal data gathering.
- Can be reproduced – implemented methodology has been detailed in a manner allowing for its reproduction. All steps undertaken were noted and detailed to allow readers to apply it in their work.

- Time-efficient – developed methodology incorporates many simultaneous tasks that allow time to be saved during project realisation. Incorporation of concurrent data collection and analysis stages allowed not only for selection of more appropriate methods to be used in further stages, but also maximised the exploitation of time designated for the research.
- Combination of best features –methodology applied has not been invented by the author, but possesses solid ground in existing formal approaches. However, due to limitations of this original base, it has been developed as a combination of the features and principles of the formal methodology and logical actions considered as appropriate regarding area characteristics.

Weaknesses:

- Strong dependence on the investigator's skills – the developed methodology is based on grounded theory and, therefore, possesses some of its limitations. Strong dependence on investigator was minimised by incorporation of a systematic approach to research. However, development of the concepts from data depends on the personal skills of the researcher. Moreover, usage of the interviews as one of the data collection methods increased this risk due to dependence of this technique on the interviewer's abilities.
- Lack of external validation of the methodology before research commencement- the methodology is research specific and novel. It has been developed by the author based on grounded theory approach and, therefore, has not been applied anywhere else before this research. Evaluation of the methodology used has been approached as a retrospective discussion of the methodological approach.
- Time-consuming work incorporated – some of the tasks incorporated in the research – transcribing interviews, manual text analysis - have been time consuming. These tasks could be omitted by other researchers by usage of computer software particular for the task.

3.4. Summary

To assure quality of the research, a methodological support has been sought. On the path to develop a suitable methodological approach, a number of approaches have been investigated, broadening the scope outside the microfluidic domain.

Many considerations led to the concept of 'methodological fit', the investigation of which, when applying microfluidic domain characteristics, allowed for identification of exploratory type of research for the area. Therefore, a qualitative methodology has been identified as adequate, with incorporation of limited quantifications.

Review of existing qualitative research methodologies allowed identification of grounded theory as the optimal choice based on area characteristics and specifics. However, this methodology showed significant limitations and, therefore, has been only partially applied.

The necessary adjustments have been incorporated to develop a sufficient methodological approach for the research. Basic principles of grounded theory have been kept, such as concurrent data collection and analysis, while minimising the formality of the approach – no memoing. This approach has been explicitly presented in this chapter.

The main idea of the methodology used is lack of pre-selection of all methods to be used for data collection and analysis upfront, but developing a suitable approach based on emerging data. Applying this to the research domain resulted in usage of the following methods, listed in chronological order: literature review, web/brochure investigation, survey and interviews. Each method combines data collection and analysis that allowed a suitable successive technique to be used.

Detailed approaches for data collection and analysis have been presented, together with the rationale behind their selection and implications of their use. This mix of literature and field investigations allowed the author to obtain academic and industrial views on the domain. Both phases have been approached in a systematic

manner, mainly using the Microsoft Office package (Word, Excel) for data storing, breaking-down, categorisation, etc.

The developed approach for the research has a number of limitations, as well as strong points. It presents a novel methodology. It strongly depends on the researcher's skills and creativity and incorporates a number of time consuming manual tasks which could be automated. It emerged directly from information about the domain and has been built up based on the research data – hence, it is considered as most suitable. Moreover, it is time efficient due to concurrent actions undertaken and detailed, allowing for reproduction by others. The results, which have been obtained by execution of this methodological approach, are presented in other parts of this thesis.

Chapter 4
Microfluidic Design Practice

This chapter presents the current state of microfluidic design from a practitioner's perspective. Presentation of the AS-IS state of microfluidic domain is scoped around three topics: design methodologies, service and sub-section interactions. It summarises practitioners' work in academia and industry, and underlines gaps in existing approaches.

Firstly, design methodologies and methods currently applied for microfluidic development are briefed. This starts by giving an overview of design practice in the domain. It continues with an introduction of how microfluidic designers are undertaking device design and development, and what processes they follow. It is summed-up by providing characteristics of microfluidic design.

Next, practitioners' work regarding service considerations in microfluidics is presented. This presentation constitutes two parts: an investigation of service type offerings in the microfluidic domain and an identification of how services and issues connected to them are incorporated in microfluidic device design.

Thirdly and finally, the issue of sub-section interactions is investigated. This includes aspects of this issue such as: how it is viewed in the area – its importance and how it is addressed by practitioners when designing the device.

The presented aspects of microfluidic design practice help to scope the demand of microfluidic design. This clarifies the nature of the guideline, the development of which has been identified as the research aim.

4.1. Methodology for Capturing Microfluidic Design in Practice

Capturing microfluidic design in practice has been approached by multiple data collection methods. Data obtained through them were systematically analysed and output of this analysis is presented in this chapter. Methodological approach used for data collection and analysis with description of techniques used is presented in Section 3.2 with indication of its strengths and weaknesses in Section 3.3.

Participants of the study were from diversified organisations in terms of size and types of microfluidics under development. Organisations have been located worldwide and not only companies but also research institutes were included (with dominating number of responses from industry). Countries which have given input to the study include: Germany, UK, Canada, USA, Switzerland, Sweden, France, Republic of Singapore and Australia.

Although majority of information characterising microfluidic design have been obtained directly by analysis of collected data – experts' answers – models for design of microfluidics were extracted by the author rather than presented by participants. As one question in the survey, which was repeated during the interviews, participants were asked to describe step by step how they undertake microfluidic design. A number of other questions scoped characteristics of their work.

Variation among style in answers has been observed. In the survey mostly participants listed numbered steps which they follow without any elaboration. These steps have been transferred into graphical representation, flow-charts, which are presented in Section 4.2.2.1. Extraction of the models in the interviews has been more analytical. Although this same question has been stated, the author had chance to ask about process's details. Some of the respondents freely elaborated on the type of work they undertake – from this elaboration step by step processes in which devices are developed have been extracted by following path of their work. Additional questions were asked during given description as well as at the end to fill gaps in the processes and assure obtaining complete flow. Therefore, processes

obtained from the interviews are more descriptive and give deeper insight into process followed for microfluidic design (see Section 4.2.2.2).

Characteristics of the design as well as service-orientation and sub-section interactions issues have been covered in relevant sections of the survey as well as during interviews. In addition, service-orientation benefits were captured from information provided by organisations on their websites and in brochures. Performed analysis allowed to scope the information directly how it is presented in Sections 4.2.3, 4.3 and 4.4. Microfluidic design characteristics identified crucial have been distinguished as separate section (Section 4.2.2.1 - Customer input/involvement, Section 4.2.2.2 - Requirements from Designers, Section 4.2.2.3 - People's involvement, Section 4.2.2.4 - Design support and IP (Intellectual Property) rights).

4.2. Design Methodologies and Models

An investigation of the practitioners' work in microfluidic design has been performed in two parts. The first part of the investigation has been executed using survey to gather a broad view on how devices are designed in the domain. The second part has been undertaken using interviews to clarify issues arising from the survey and to allow the author to obtain a deeper knowledge about microfluidic design.

The survey showed, and interviews confirmed, that people working on microfluidic device design are not familiar with any formal methodology for design and development of these devices. They do not recognise a general methodology for the domain which would be widely applied. Rather, their work involves using their own in-house developed method on a project basis. This investigation confirmed literature indications that design of microfluidic devices is case dependent (confirmed by 77% - 10 out of 13 respondents). This case dependence is visible in a number of factors which characterise microfluidic design and in the implicit processes used for it.

Due to the lack of developed design processes and methodologies for design of microfluidics, the models have been extracted from practitioners' responses. These models are presented below. Different amounts of information can be derived from the models based on their source, survey or interviews; therefore, models have been split into these two categories for reader convenience.

After the microfluidic design model presentation, the characteristics of design in this domain are discussed. This order has been selected for reader's convenience allowing a clearer view of how a particular characteristic is used in the presented processes. This visualisation underlines the importance of particular features of microfluidic design which will influence the shape of the solution to address the domain issues (see Chapter 5).

4.2.1. Design Models

4.2.1.1. Models Identified via Survey

The survey allowed for extraction of three design processes from respondents' answers. The amount of information in these models is limited. Design processes in the survey were not elaborated by respondents, but only indicated or briefed. Extracted models are presented according to the time order in which they were obtained.

Model 1

The first model (see Figure 4-1) presents the end-to-end design process. It does not include afterlife of the product which, in the case of the majority of microfluidic devices, is omitted due to their disposability[13]. This process includes the method and the source of the input data, as well as the form of the output. It presents the logical transfer between the stages when an input for one phase is an output from the previous one. Moreover, it represents crucial fabrication considerations at early stage of design. This model shows customer involvement in the decision making process and simulation. Evaluation of the design itself is based here on the simulation results

[13] Majority of microfluidic devices are designed as disposable due to contamination issue

using FEA (Finite Element Analysis) and CFD (Computational Fluid Dynamics) tools. The output of the process is the design sent for the fabrication in the organisation of the respondent or, as in many cases as mentioned by literature, in microfluidic foundry. This model seems straight forward, however, it incorporates iteration inside the steps whenever obtained results do not meet the objectives.

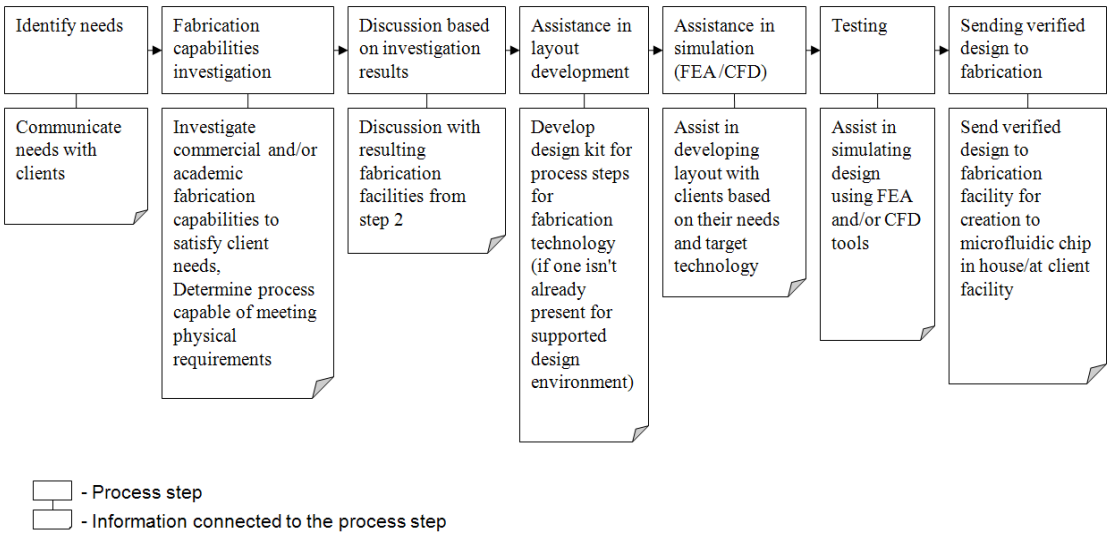


Figure 4-1 Microfluidic design models extracted from the survey - Model 1

Model 2

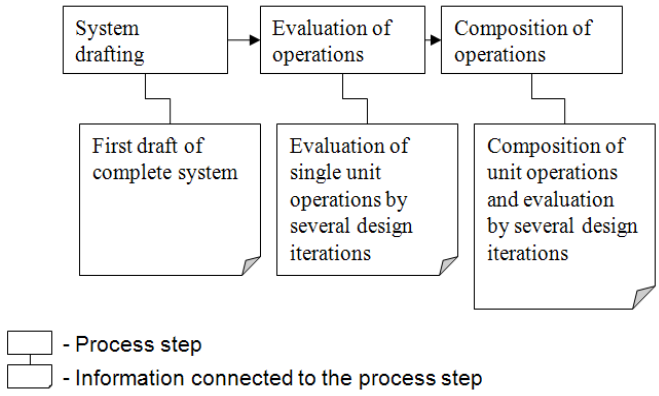


Figure 4-2 Microfluidic design models extracted from the survey - Model 2

Model 2 (see Figure 4-2) is the most condensed of all those extracted - it appears as just a part of the design process. Input and output are not specified here. There was no method mentioned using which information necessary in steps is obtained. Iteration is incorporated inside stages, however, there is no indication of decision

making instances. This process does not present any specifics of microfluidics. Not only it is without technological focus, but it does not even indicate fabrication consideration needs. This is not a design process, but rather a set of general tasks which are done in every design and which can fit every product.

Model 3

The last model extracted from the survey responses (see Figure 4-3) presents five stage iterative design. Model 3 does not present the end-to-end design process. Although it indicates input to the process, it does not specify how to obtain it. Phases are phrased as outputs or what is accomplished in particular milestones. An exception is the last stage which involves not only the action type description, but also the iterative loop to the beginning of the process, relating output of the process to its beginning. This process indicated that, design is selected based on the CFD simulation results. This model does not explicitly highlight technology considerations in any design stage. Also, it is rather generic and does not present a flow between phases.

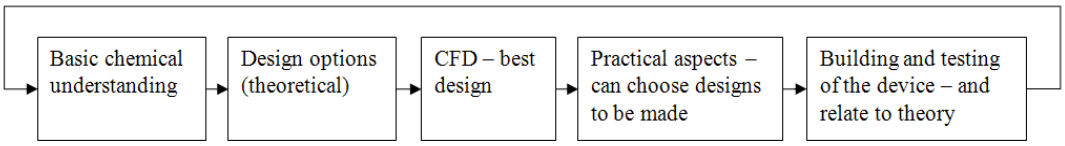


Figure 4-3 Microfluidic design models extracted from the survey - Model 3

The visualised models present approaches for microfluidic design in various levels of details and in various scopes. Only one of them is constructed in a fluent manner, allowing understanding of how different phases of work are interconnected to develop a device. Variation of the models underlines case dependence of microfluidic design, as mentioned in literature. From the obtained answers regarding design of microfluidics, only three models were extracted and limited information visualised using them. To deepen the knowledge on this topic and get a clearer view on it, interviews were conducted, the results of which, concerning microfluidic design processes, are presented below.

4.2.1.2. Models Identified via Interviews

Investigation of the microfluidic design using interviews allowed the author to obtain more descriptive information regarding issues raised. Interview techniques – face to face and phone interviews using semi-structured questionnaires – permitted clarification during information acquisition, and by this, increased accuracy and reliability. Each conducted interview resulted in a design process which is followed by the participant when designing microfluidic devices. Since none of the participants had their process draft prepared in advance, the presented processes are a result of the interview analysis.

The reader will not be taken through the presented processes step by step, but the main characteristics will be underlined. In this manner, the reader will be able to analyse processes by him/herself, which are in the majority self explanatory, and confront them with the microfluidic characteristic issues pointed out by the author.

Model 1 – Interview

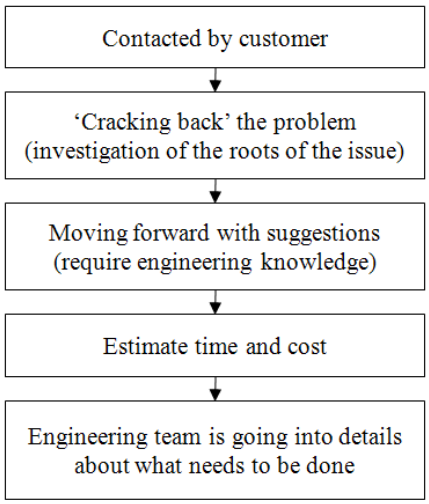


Figure 4-4 Microfluidic design models extracted from the interviews - Model 1 pre-design

Organisations have various methods to approach the design. One of the factors influencing design approach is the sponsorship of the project. The participant of the first interview underlined that in many cases, an additional pre-design stage is necessary before a decision on accepting the project can be undertaken. Moreover,

microfluidics should be only developed when they are the answer for a particular issue. This pre-design process is presented in Figure 4-4. It can be observed that this part of the process also requires knowledge and domain understanding to make decisions regarding suitability of the approach, and whether the organisation possesses sufficient resources for project realisation. Even before a project is agreed on, the engineering team is involved in the decision making process in a broad context.

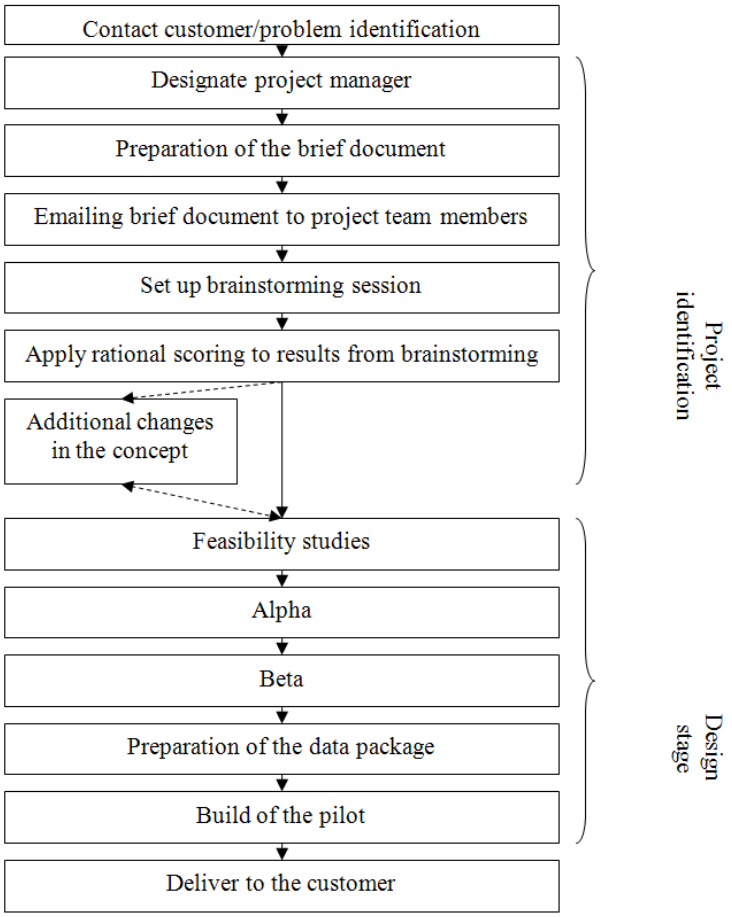


Figure 4-5 Microfluidic design models extracted from the interviews - Model 1

The design process model is presented in Figure 4-5. The process is divided into two stages: project identification and design stage. The first part is considered crucial due to the fact that all decisions made in this stage will be executed in the next one, and any iteration incorporated is recommended to take place here. There are a number of requirements regarding people involved in the design process – their knowledge, competence, background and, most of all, experience. Use of concepts at the early

stage of design is automated by usage of a standard method – rational scoring[14] - and creative thinking is encouraged by using brainstorming sessions. However, additional changes of the concepts are allowed, based on their examination using feasibility studies and incorporation of fabrication consideration at the early stage of design (sometimes before the project is undertaken).

The presented model is an end-to-end design process. Input and output are specified in terms of the data ownership and their form. Phases described as 'Alpha' and 'Beta', are detailed design stages in which calculations and modelling are taking place. Both of them are case dependent, which makes it difficult to describe them if the organisation is developing various types of microfluidic devices. This process does not underline the necessity of simulation as a decision making stage, but instead puts focus on prototyping. Involvement of the customer in this process is not visible throughout, but only at the first and the last step.

Model 2 – Interview

The second model also presents an end-to-end design approach (see Figure 4-6). It specifies type and source of input data, as well as output. It underlines that microfluidics is not an answer for every design problem and should not be forced as one. This process involves the customer in design, at least in milestones, which are established by the designer rather than by the client.

The presented model appears straight forward. It does not underline the importance of iteration, which is aimed to be minimised due to costs, however, it is still present inside the stages. Also visible is the lack of focus on simulation, which is replaced by prototyping as the evaluation method for the device. The interviewee is using model based design as the detailed design stage, which is not described in detail due to its case dependence.

[14] assigning weights to criteria and evaluating concepts based on obtained score – the higher score the more optimal is the concept.

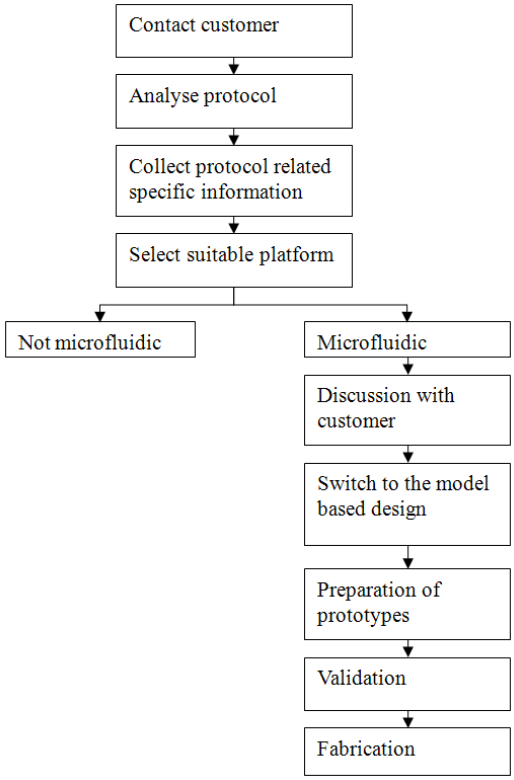


Figure 4-6 Microfluidic design models extracted from the interviews - Model 2

This model also incorporates a requirement for knowledge and a deep understanding of the area regarding collection of the protocol related information, selection of the platform for the development of the device and the design itself.

Model 3 – Interview

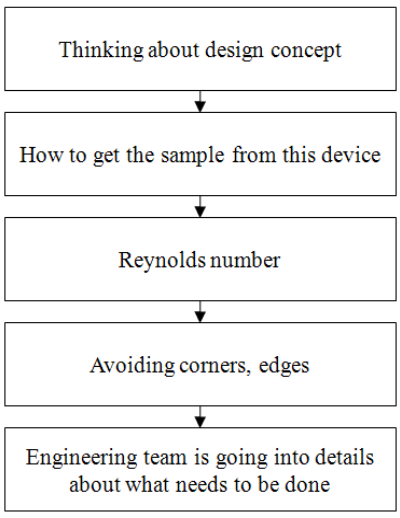


Figure 4-7 Microfluidic design models extracted from the interviews - Model 3

The third model (see Figure 4-7) acquired is the shortest obtained during interviews. It presents a five-stage approach for designing microfluidics. This process is not developed as an action specific set of stages. It consists of steps and data considered by the participant as crucial for the microfluidic development. It is not an end-to-end design process. It does not incorporate specified input and it is not clarified how and from where data are obtained. Also, output is not clear. There is no specification of the output form and details of how the product will be validated.

This model underlines the importance of technology consideration in microfluidic design. It confirms the fabrication driven approach to design, claimed by literature. Manufacturing details such as necessity to avoid sharp edges, corners, consider surface quality for possible blockage of the fluid, change in its behaviour, etc., drive this process. The main difference between the macro- and microfluidics, which is highlighted by the Reynolds number, is analysed here to understand basic fluid behaviour that is expected from the device under consideration. This model also underlines the requirement for deep domain understanding and knowledge about fluid behaviour in micro scale, which has to be supported by experience due to limited understanding of the area.

Model 4 – Interview

The fourth model presented consists of two variants. The variant A (see Figure 4-8) presents the design process which is usually taking place when the participant is designing to prove a principle. This means that the device is novel, does not exist in the market, and therefore, its performance is unknown. Even in these cases, existing products and functionalities previously developed are investigated to avoid reinventing the wheel.

The variant A model presents the end-to-end (no product afterlife phases) design approach. It specifies input and output in terms of its form. Also in this model, simulation is replaced by experiments and prototyping, due to the inability to accurately model behaviour of fluid in micro-scale, especially when principles are

under investigation. The presented development process is focused on the functionality of the device under development.

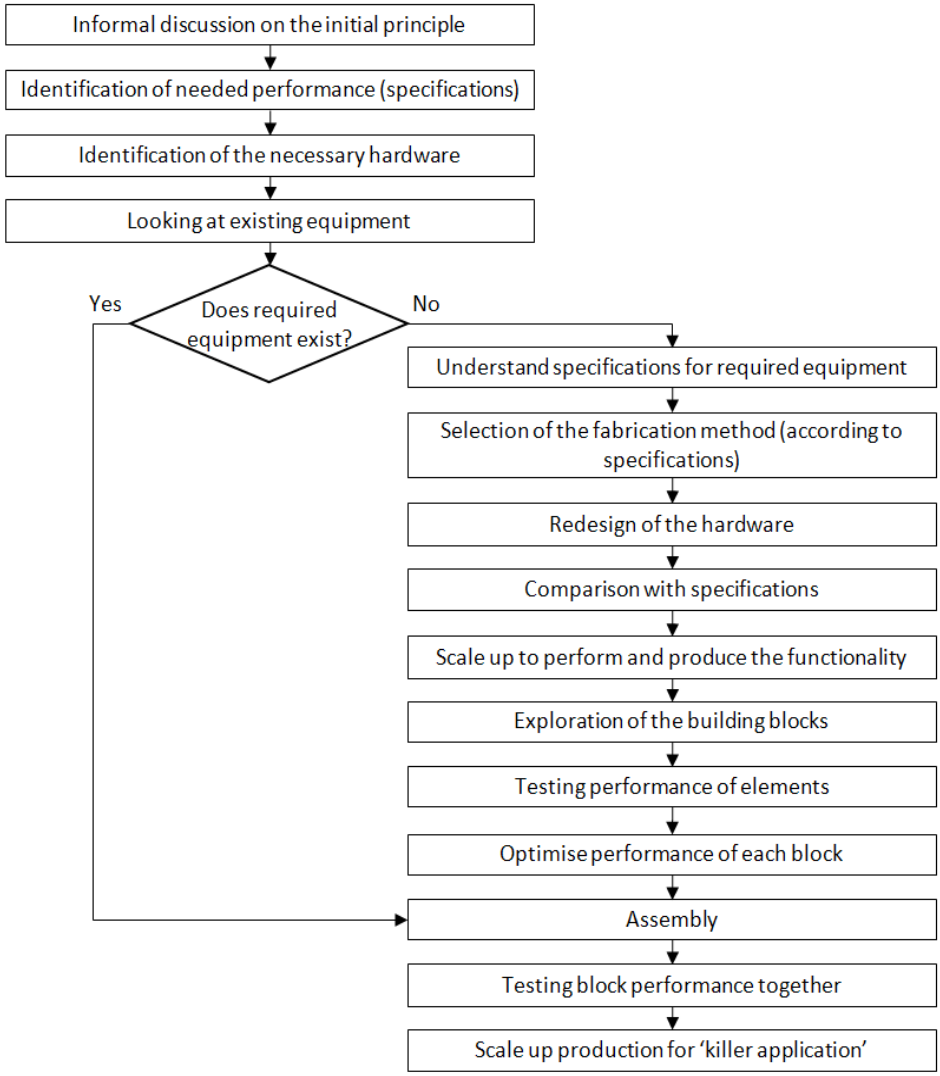


Figure 4-8 Microfluidic design models extracted from the interviews - Model 4A

Although technological consideration in terms of the fabrication process does not appear explicitly, every time hardware is mentioned, manufacturing comes into account. Therefore, this process is considered as technology driven. It puts focus on testing elements. It starts as a top-down approach and uses a bottom-up approach for validation meet specifications.

The variant B (see Figure 4-9) presents an approach in which the device is developed on customer order. These types of devices usually do not require proving principle

investigations; therefore, they take less time and the investigation process is less expensive. However, some of them can incorporate elements which are novel, require novel functionality or solutions. Then, the cost of an investigation increases, and the path followed in variant A takes place. When the device is just a combination of functionalities developed previously, the design process is simplified.

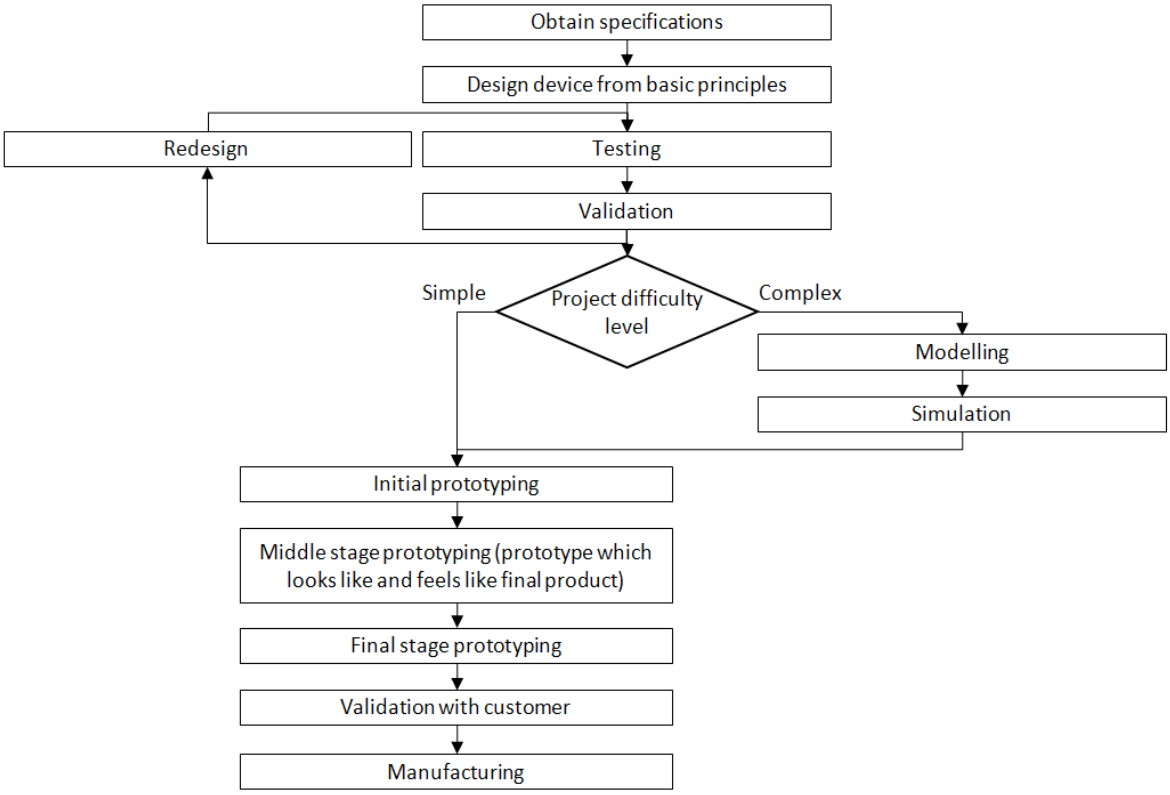


Figure 4-9 Microfluidic design models extracted from the interviews - Model 4B

The variant B underlines projects for which simulation is considered as justified. Due to cost of simulation and often mismatch with experimental results obtained, this step is omitted by the interviewee when design is considered simple. More complex devices (combination of various functionalities etc.) are often simulated to minimise cost of variations in prototype developments such as manufacturing cost for complicated moulds.

Both variants underline the importance of prototyping and, especially for variant B, iteration is incorporated in the process. Experimentation is considered crucial, as

well as knowledge and experience of the designer working on the microfluidic development that has been highlighted by the participant.

Model 5 – Interview

The last model extracted from the interviews is presented in Figure 4-10. This process is microfluidics specific. It also presents the end-to end (no product afterlife phases) design process. Methods of obtaining specifications were clarified, as well as an input and an output form. This process is focused on generalisation and automation - these targets are aimed to be achieved by using unit operations providing basic functionalities and assembling them. In this manner, modularity is helping in speeding up future designs.

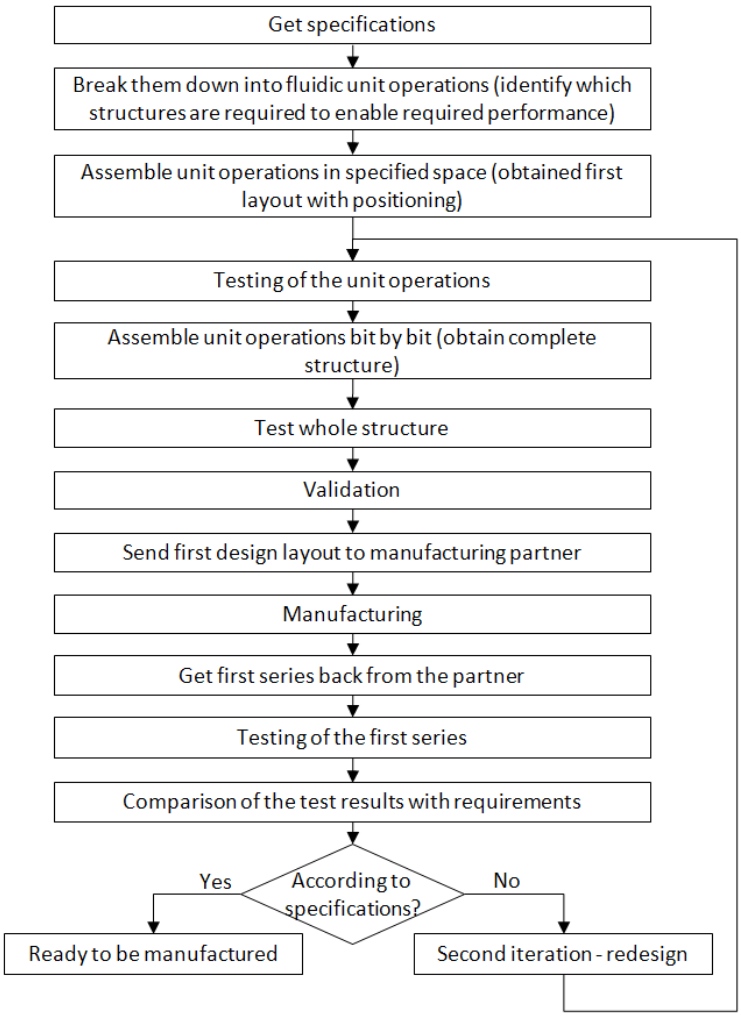


Figure 4-10 Microfluidic design models extracted from the interviews - Model 5

As in previous models, the importance of prototyping and testing is underlined. These experiments are used as a validation method for comparison with specifications. In contrast to other processes in Model 5, testing appears also after manufacturing due to usage of foundry for manufacturing, which creates demand for confirmation that devices are of good quality and no faults are incorporated when scaling up production.

Model 5 presents a bottom-up approach to design and development of the product from detail to architecture level. This approach, although considered as beneficial for evaluation in literature, has been underlined as harmful for design of micro-scale devices, due to the fact that the whole device often did not perform according to the standard or did not provide the required functionality.

4.2.2. Microfluidic Design Characteristics

Organisations approach design of microfluidics in various ways. As presented in Figure 4-1 – Figure 4-10, methods used can be classified as decision making processes and presented using a flowchart.

People's approach to design varies in details; however, in the majority, it is structured and intensive. Particular methods which organisations use in designing microfluidic devices were developed over a number of years. This is what assures that projects will be delivered on time and deal with number of issues and uncertainties. The first step in the design is not common across organisations - although all of them use similar steps, their order is different. Some organisations start from the problem identification and 'crack back' the issue to understand real requirements, whereas others go straight to selection of the manufacturing method as a highly technology driven approach, or even select a microfluidic platform for fabrication and restrict design to one highly specialised type of microfluidic devices.

Approach to design varies depending on the project sponsorship from public or private sector. Government and research council projects are approached as more structured since they require almost all of the work to be done upfront. This means that before the contract is signed off by officials, a majority of details regarding

methodologies, manufacturing methods and milestones of the project have to be established upfront. This almost never happens with commercial projects. In these, milestones are mostly established by designers as a deadline or point of consultation of obtained results with the customer. Level of formality in government/council sponsored projects is also higher - these are a lot less supportive in terms of changes of project specifications and methods used. Every deviation, even in terms of operation methods, has to be recorded and documented. However, even this type of microfluidic projects can be viewed as challenging in terms of the application documents for funding. Work done upfront is analogous to customer demanded microfluidic design project's realisation. Although the device is not physically developed, the method for it has to be specified. Moreover, even if the process for realisation of these formal projects is established, the one upfront is not; therefore, it cannot be used for general design of microfluidics.

During design, more than one idea can be selected at the conceptual design stage. However, the level of details required and number of issues under consideration, time and cost of the design allow for selection of a limited amount of concepts. Before any modelling is performed, the design is narrowed to one concept to cut costs. Consideration of a high number of factors and uncertainties in every concept investigation increases the cost of design with selection of any additional concept to proceed with. However, it also increases the probability of meeting requirements due to low feasibility of success with first design. This practice is common in design of many types of devices. It does not present any special aspect of microfluidics, rather similarity to conventional design.

Specifications for microfluidic devices are technical, which confirms previous findings. Organisations seek detailed information required for development of microfluidic devices, however, it is rarely obtained in 'one go'. Obtaining specifications is considered as a 'bottleneck in the design process' due to customer involvement and limited possibility to influence it. Specifications are required to be 'very precise for the application'. One of the organisations uses various methods to obtain specifications, depending on the type of project undertaken: a fundamental

work proving principle requires only a vague idea at the beginning; when they design sensors where microfluidics are one of the elements – specifications are more a matter of modelling and understanding the contribution of microfluidics to the performance of the device; where microfluidic element is the core, clear specifications are required. This indicates that various levels of details are required upfront in projects. The product requirement document[15] (where applicable) is very extensive and includes details such as perform to address regulations (e.g. electrical standards), conditions of work, level of input from operator and safety standards to be followed, especially for working environment. Organisations however usually end up modifying and changing specifications to obtain the required function. This is due to the novelty of the area, customer lack of deep domain understanding and, consequently, problems in receiving suggestions and detailed requirements from their side.

Design of microfluidic devices is time consuming. However, time used for design varies depending on the organisation and project. Development of microfluidics from scratch takes on average 3-6 years. These very long development cycles are due to device novelty, immaturity of the area, number of issues which need to be investigated during the design, and lack of suitable design methodologies. These factors can be viewed as typical in an area which recently started developing and knowledge about which is limited.

Interviewees were not familiar with any particular design methodologies for microfluidics. Their own design processes varied in terms of number of steps, output type, specification capturing, etc. An output can be in the form of a prototype, which will be handed to someone else for manufacturing, design files (e.g. computer files) or manufactured devices. They use various methods of design evaluation, such as measurement setup for rotating disks, theoretical models and experimentation, customer validation, and validation based on network dependencies. Variation between these processes is similar to when comparing design processes from

[15] document listing specifications for the design of the device

different domains. There are commonalities with broad design approach for novel and highly technological products.

Organisations, in the majority, develop disposable microfluidic devices, which allows them to avoid dealing with afterlife of products. Also, disposing the devices is left to the customer/user. Since various types of fluids require various disposal methods, organisations prefer to delegate this responsibility further.

There are many factors influencing microfluidic design. Some of the organisations included these factors explicitly in the process steps, and others combine them inside one step. They are at a high level - e.g. technology, various liquid behaviour and surface, and at a detail level such as Reynolds number, avoiding corners and no sharp edges. Even domain immaturity itself imposes additional difficulties in this area by increasing problems with setting up models, validating them with experiments, etc.

Practitioners confirmed literature's indication about an iteration requirement in the microfluidic design. According to them, this necessity is dictated by fabrication, in particular, and by decisions made which cause impossibility of manufacturing some structures. Iterations are minimised to save money and time and, when possible, should be transferred to the early stage of design due to their increasing cost when moving down the design process.

Not all organisations develop products which end-up in the market. Therefore, their considerations of the customer in the process vary. Some of them recently started commercially visible products, when, in previous projects, they limited market considerations to competitiveness of production processes and user interaction requirements. This influenced their consideration of market success, which they view as faster, cheaper, more convenient and/or solving problems never solved before and demanding microfluidic devices. Organisations also evaluate their performance on the market (38% - 5 out of 13) against expectations and past data in terms of money. This has been expected as for conventional organisations operating in a competitive market. Microfluidic organisations do not make any additional

and/or specific effort for their area to measure competitiveness and market performance of their products.

Factors which determine the market success of microfluidic devices, according to respondents are: reliability, user-friendliness and optimal performance of the device. However, not all organisations include even this amount of end-user considerations inside their design process, restricting themselves from investigating non-profit factors. This evaluation scheme can explain the commercial success rate of 45% (5 out of 11 respondents), which has been identified by respondents for market performance of their devices.

Design processes adopted from other micro-domains failed for microfluidics. There has been a view that in comparison to the highly tuned and perfected semiconductor industry, the microfluidic domain is different. Application of methods used for microelectronics has not met expectations due to their high level of specialisation and problems caused with the transfer of the approaches to other domains.

It can be observed that processes extracted from interviewees' responses present various levels of maturity. There is almost proportional dependence between maturity of the process and how generic it is in the organisational context. Processes which present similar level of details across the steps allow for task separation to the degree which will permit splitting of responsibilities. Others can cause confusion of actions, and are characterised by both very detailed and very high level concepts incorporated into steps in the flow. Detailed processes allow decisions on customer interaction and to clearly present the form of an input and an output of the process.

Due to the broad and multidisciplinary knowledge required for microfluidic design, its automation creates demand for support tools. Organisations underlined that commercially available tools are not sufficient for their needs - e.g. cannot properly simulate CFD for 2 phase flow. For them, it is often less costly to develop in-house software than buy a market tool, train people and discover that demanded functionality is not included. Therefore, the majority of organisations develop their own in-house tools. These tools are in various stages of development and maturity,

however, all of them are in-use. They also have different forms of the software, through database to wiki-type tools.

Development of these tools is work in progress which started recently. As a feed into them, models developed in new projects are used. Also, simulation data, when possible, are stored.

Development of new models is also undergoing work. Development of some models leads to the discovery of missing and necessary elements, for example, connectors. These tools allow for reuse of models in new projects, which speeds-up work.

Support tools used for design vary from traditional pen and paper through CAD (Computer Aided Design) and CFD tools to in-house developed. These tools are used for knowledge capture and reuse, and aim to automate the design process. However, CFD simulation is more costly in the UK compared to Asian countries. Therefore, this work is often delegated, if not omitted, when possible. Rules incorporated in design support tools are extracted from experience, and many of them are still not written down. Some of these rules are still waiting to be extracted from operation units.

The standard element of design, which was not identified for microfluidics during literature review and survey, has been identified by some interviewees as a liquid valve and set of elements such as pumps, mixers, and droplet generation function. This classification allowed organisations to develop design support tools required. However, some interviewees confirmed the view that although they consider the existence of standard elements of design for microfluidics in industry, all standard elements are not recognised.

4.2.2.1. Customer Input/Involvement

Customer involvement in design of microfluidics varies. Over 54% of respondents (7 out of 13) involve customers in the design process, although not all of them have the same number of projects generated by a customer. The customer does not always

originate contact with microfluidic companies. Microfluidic organisations actively search for potential customers and co-workers.

Some organisations have up to 90% of their business generated by the customers. The rest of the projects are undertaken: on the internal demand, to prove a principle, or to obtain a new cutting edge technology. Differences, in terms of the customer's involvement when projects are originated by them, vary from only obtaining specifications and validation of the concept (3 out of 13 – 23%), through milestones (2 out of 13 -15%) to throughout the process (2 out of 13 - 15%).

Organisations have different views on how important is the customer's presence in the design. Some people claim that work with customers to obtain specifications is a bottleneck in their process and can take up to 2 months. These organisations are trying to minimise this involvement. Others claim that the customer is a driving force of the process, and satisfying his/her needs can be achieved only by close cooperation. They claim that customers are important, i.e. make decisions about the design (e.g. readiness for manufacturing, concept selection, etc.), however, working with them is time expensive. This group is trying to optimise work with the customer to achieve the best possible output without overruns. They involve the customer only when it can be justified.

People working on the design of microfluidic devices are required to have a deep knowledge and experience about the area. With the customer, this situation does not have a place - customers are not specialised in microfluidics (neither in design nor in manufacturing). They are expected to be specialised in their own area and know what problem they are facing. Usually, they are lacking experience in microfluidics, which causes them to make wrong assumptions about fluid behaviour on a micro-scale and what is possible to be achieved.

Customers understand what their product needs to do, but not the complexity of the device itself. In many cases, they are not able to specify all the necessary parameters for correct implementation of microfluidic systems, or even how to measure or obtain these parameters. Organisations help them to clarify needs, but it requires

investment of resources. In some cases, customers decide to be secretive about the type of work they are trying to do - they only provide organisations with limited information about what they will develop. In these cases, the risk of missing the target increases. Although, organisations can develop a device which will meet the functionality requirement, it might not meet the overall purpose and solve the true issue faced.

Obtaining specifications from customers is used by 69% (9 out of 13) of respondents, however, they do not use the customer as single source of information every time. Microfluidic organisations also use other sources, such as: self engineering 15% (2 out of 13), knowledge about the field 23% (3 out of 13) and market research 15% (2 out of 13).

All customer relationships identified in the microfluidic domain are B2B (Business to Business). Microfluidics are supplied to R&D (Research and Development) departments, laboratories, companies which integrate them in big multi-analysers, etc. Organisations do not offer devices to individual customers in this domain. Individual customers are not even considered as profitable, due to the necessity for high production demand to make manufacturing profitable. These small, individual demands will need to occur in a 'tremendous amount' to make business feasible. This type of sale creates additional administration costs and, by this, increases the final device price. At the same time, however, a B2C (Business to Customer) relation type creates a new, unexploited multimillion dollar market and, by this, a future for microfluidics.

4.2.2.2. Requirements from Designers

Due to vagueness of the area, its immaturity and high technicality, a number of requirements are stated for the designers to be able to successfully develop microfluidics.

Designers in the microfluidic domain have to have a deep knowledge about the area and implications of the physics phenomena that occur in it. "Microfluidic design

requires an enormous amount of engineering knowledge to make logical suggestions on what is possible to be achieved" (Interviewee A). Underlined by literature, a requirement for a deep knowledge of fluid behaviour in micro-scale is confirmed by interviewees. To understand the field and the way that devices operate, a strong fluidic background is necessary.

Moreover, experience in microfluidic design and development is stated as a necessity. Skills in micro device design and manufacturing are not obtained purely by education - understanding customer problems and finding a way to address them requires experience. All interviewees respond based on their previous work. One of them claimed that "experience, knowledge and a small amount of calculations allow them to get fast and accurate rough design, evaluate its performance and make new designs based on it" (Interviewee A). In the immature area of microfluidics, relying on historical work and IP rights is a common practice. As a minimal experience, which is sufficient to make sensible suggestions for successful microfluidic design, one of the interviewees pointed out at least 0.5 year of hands on practice in the field, and a small amount of knowledge about influencing factors.

Deep knowledge and experience required made people specialise in their own areas. However, microfluidic design, depending on the targeted application, requires a combination of knowledge from various areas. Therefore, a multidisciplinary team is required, which was underlined as crucial by respondents and confirmed by previous findings.

Knowledge and experience of people working in microfluidics from other domains can be as beneficial as harmful. Historical work of some organisations proved that experience in manufacturing of micro-devices from silicon restricted the view of people in what is possible to be manufactured in their own production line. They were not able to think outside of the known patterns when people from microfluidics approached them.

4.2.2.3. People's Involvement

As well as the type of knowledge which is demanded from designers of microfluidic devices, the number of people working on projects varies. Although all of the interviewees stated that microfluidic devices cannot be designed by a single person, one of them claimed designing them alone. This statement is supported by years of experience of this particular interviewee, and type of devices under development. These devices are an example of very simple microfluidics – in majority, limited to two surfaces and one or few uncomplicated channels. Due to possessed experience, this interviewee is able to develop them alone in terms of design - prototyping and manufacturing is done by other people. However, for more complicated and/or novel devices, this interviewee works in cooperation with other people in order to develop them. Other respondents claimed that "It is not possible to design microfluidic devices alone (by one person)" (Interviewee E). An average number of people working on the design varies from 2 to even 150 or more; this number depends on the project size, budget and duration. Specialisations of people involved in the design process vary according to the knowledge required for the development of a particular type of device.

Also, involvement of the people throughout the projects varies. They are involved when their tasks occur, with the exception of the group leader or people responsible for the project - this allows minimisation of cost.

People are involved in different ways in microfluidic design. They are involved individually, as part of the group under leadership, or as a group with a moderator.

4.2.2.4. Design Support and IP rights

The majority of the microfluidic design organisations use design support tools. 79% (11 out of 14) of respondents claimed usage of these tools, mentioning CAD and CFD as the most common type of support sought. In their work, they use one of the above mentioned or a combination of them. However, only 31% (4 out of 13) of

respondents use component libraries, out of which 75% clearly stated (and the rest implied) that these libraries have been developed in-house.

Respondents underlined lack of comprehensiveness of commercially available microfluidic design support tools. They highlighted their significant limitations and demand to develop their own design aids. Development of these design aids, according to them, in many cases is less expensive than investment in a commercially available tool in which the required capability is missing or is restricted.

Lack of commercially available comprehensive component libraries is connected to IP rights in the microfluidic domain, which are considered very important. Organisations do not always possess IP rights for the products which they are developing, and therefore, they are not allowed to reuse all models developed. Technology is the main driving force in microfluidics, hence focus of organisations is on keeping IP rights and protecting data. However, it constrains the possibility of knowledge storing and reuse, and by this, restricting the process automation within organisations designing on orders where the customer is keeping the ownership of the models and their components, and not only of the final products.

As can be observed, microfluidic design requires a number of factors to be accounted for. They are necessary to successfully design and manufacture the device. Practitioners' work in the domain presents how domain characteristics identified in literature are accounted for by designers in real life. All mentioned factors and characteristics of microfluidic design practice have given a new view on area maturity. It showed that the area is more mature than literature is indicating, but, at the same time, showed a number of gaps to be filled and allowed the discovery of problems faced by the practitioners. To address these problems in a suitable manner, investigation of practitioner work in the service-orientation aspects of microfluidics has been undertaken, the results of which are presented in the section below.

4.3. Service

A view on microfluidic organisations practice in terms of services has been obtained using two approaches. Firstly, an initial view has been grasped using web/brochures investigation. Secondly, a section considering this issue has been incorporated into the survey and by follow-up interviews. Discussed results of both the investigations are presented in this section.

4.3.1. Services Identified in the Domain

Investigation of the categorisation of microfluidic devices (see Appendix 6) has been undertaken to show whether service thinking is incorporated in these products. The most relevant from a service point of view were categorisations according to functionality and application. However, both of them were more focused on operating principles of the devices than on the needs that the device will fulfil. Hence, investigation of the offerings of 38 companies has been undertaken. This investigation showed that services offered in the industry seem broader and more mature than lack of literature in this area for microfluidics suggests.

79% of the companies were identified to incorporate services in their offerings. This indicates that the majority of them scope their operations for providing not only microfluidics as technical solutions, but also as a 'whole package' – product plus additional service. This indication is supported by the fact that 77% of services identified were directly connected to microfluidic devices. Moreover, not all of the identified microfluidic companies offered products. 71% of the investigated organisations scoped their core operation around developed devices. However, the other 29% of organisations based their offerings purely on services. This raises questions about the differences between the industry and academic view of the maturity of microfluidics area.

Although services identified vary in terms of type (see Figure 4-11), they are mainly scoped around design consultancy and production capabilities. Services range from the feasibility studies, through design and maintenance to manufacturing of the

device. However, these services are not exhaustively described with indication of adaptability to individual needs. Services related to a product, when described, are identified as technical and cover, in the majority of cases, maintenance, repair and user training.

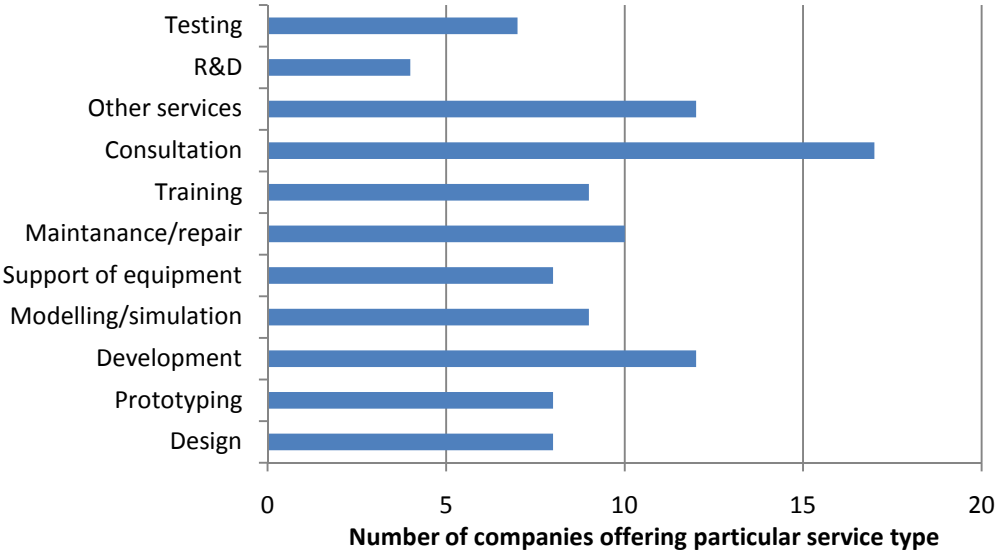


Figure 4-11 Types of services offered by microfluidic companies

Based on the indications from literature, the majority of the services identified in the industry were expected to be manufacturing based. To make their own production economical, due to the high cost of the production equipment for micro-manufacturing, some companies diversified service offerings around the manufacturing process – design, simulation, etc. Therefore, they use other companies' manufacturing facilities. Hence, studies were expected to indicate that the only service identified will be the establishment of the organisations as foundries and providing manufacturing capabilities. Surprisingly, the results obtained showed that 80% of the companies offering services do not include manufacturing on demand. It was unexpected to note that other services are dominant.

Also, contradictory to literature is the offering of the maintenance and repair for some of the microfluidic devices. While literature sees them mostly as low cost and disposable devices which do not need to be maintained, industry presents even enhancement services for microfluidic products. However, these services are offered only for devices designed and developed 'in house'. Maintenance and/or repair

utilities were identified as offered by 26% of the investigated companies. This shows that there is a market for microfluidic devices which can be used frequently, not as a one time cheap product. This perspective, in connection to promising customisation forecasts for microfluidic devices, creates an opportunity for service based offerings to be exploited more in this area.

Creation of services around products, such as maintenance and repair, in organisations which manufacture others' designs, requires high flexibility. Manufacturing processes for microfluidics require consideration and planning for every type of device. Therefore, manufacturing facilities have to be adjusted to satisfy client requirements. Since even the process of production is discussed with the customer, providing services for products, which are not standardised, would increase the risk in organisations' operations. Development of general processes for utilities based on other companies' products will not only be insufficient, but also not economically feasible. High risk incorporates lack of property rights for the device and high flexibility required to make it. Therefore, organisations provide a broad range of utilities for 'in house' developed devices and services at the front end of the manufacturing process. These include help to obtain specifications, clarify them, confirm feasibilities of concepts, modelling, simulation, prototyping, testing and fabrication.

Offerings provided by microfluidic companies do not show any pattern (see Figure 4-12) - they vary across the area. Some of the organisations offer only products, others only services, while the majority combine both. Companies focus their work on a particular phase of the product life cycle, focusing their operations at the front, middle or back end of the process (disposal and/or reuse phases were not identified). However, not all of the companies that offer design capability also offer modelling, simulation and prototyping. There are no commonalities between these selling prospects. This could be due to the infancy of the area, which was indicated by literature, where everything is mainly developed 'in house', and offerings were established because of the existing demand rather than planned as a whole.

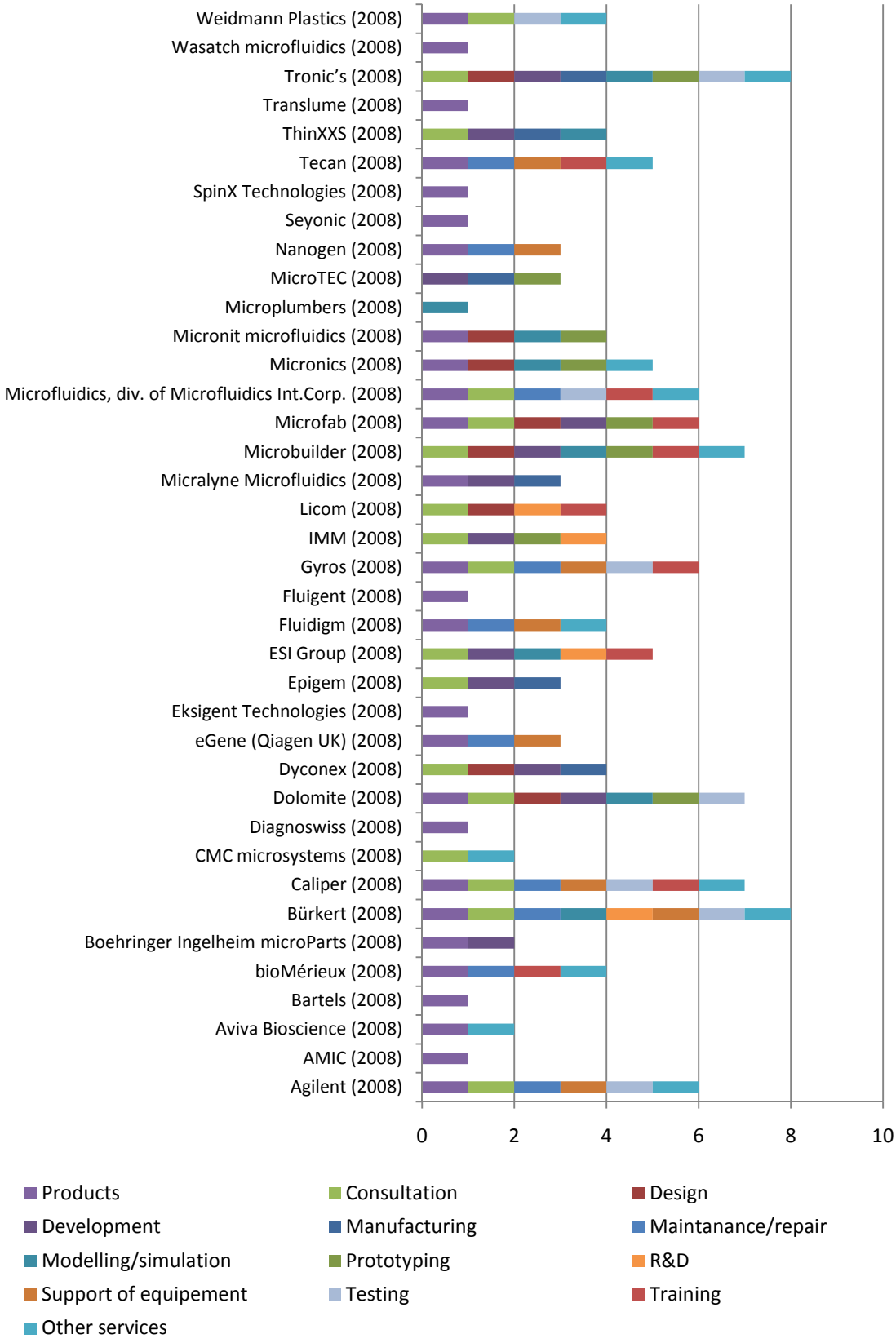


Figure 4-12 Offerings of the microfluidic companies

Offers of devices as services were not identified. Offerings were product focused and devices, even by name, indicated more operating principle than usability. Also, classification of products was according to areas in which they can be applied or operating purpose - e.g. DNA analysis, not usage such as cancer detection. Review of literature suggested that industry is not ready for incorporation of service thinking into the design process. However, investigation of offerings contradicts this claim. This area, in terms of services, is more mature than what literature suggests. Therefore, a practical investigation of services and issues connected in microfluidic device design has been undertaken and is presented below.

4.3.2. Services and Issues Related in Microfluidic Design

Since the websites indicate a higher maturity than literature of the microfluidic domain, in terms of services and orientation of the design process towards them an industrial/academic survey with follow-up interviews has been conducted, incorporating questions regarding services and related issues.

Results of this investigation contradicted literature in which the issue of services was hardly mentioned. However, this contradiction has been restricted due to the fact that only limited consideration is paid to services by microfluidic practitioners.

Although the importance of services in microfluidics' future has been underlined by all respondents, and 53% of them stated that their products are designed as a set of functions with focus on performance, 65% claimed to consider utilities in the design process and 70% to incorporate service thinking in the design; a confirmation of these claims could not be obtained. This lack of service presence can be observed in the microfluidic design models and characteristics identified in the previous section.

59% of respondents' organisations offer utilities for microfluidic products, which confirms the initial investigation's finding regarding higher maturity of the area in terms of services. But types of service consideration in terms of offerings for microfluidics were identified as restricted to support more complicated equipment

with software, maintenance and repair for platforms (not disposables) and design services for microfluidics.

Due to the fact that the majority of microfluidic devices are designed as disposable, and a high percentage of their application is in the medical domain where contamination is a sensitive and important issue, consideration of the product life after sale is minimal. It is restricted to providing software (updates, upgrades). However, a majority of organisations do not support design with software, leaving it up to their industrial partners. Regulations discourage the majority of organisations from taking any responsibility for collecting and disposing used devices as a service. Therefore, users are solely responsible for this, and the service opportunity is not taken advantage of.

The design services offered are identified by providers as very flexible and customisable. They are developed based on a business plan in the majority of organisations. Not all organisations view flexibility in the same way. In few cases, flexibility and customisability means selection from a catalogue, i.e. choice from provided options such as dimensions, production, and flow.

Organisations do not provide any other service type offerings. Leasing of microfluidics, in their opinion, is too risky (contamination), and scientific contracts (research for someone else) are considered as beneficial only by a small number of respondents. Organisations are restricted by views on what is currently happening. Failures that happened previously in the area discouraged them to try out new types of offerings, and the area immaturity increased the difficulty to develop them. Therefore, potential is, not only, unexploited but opportunities are also not investigated. Instead, organisations are focusing on current work and cutting edge research in terms of technology.

70% of respondents claimed to incorporate service thinking in the design, but the majority of them tend not to consider potential add-ons for their products, which can create service opportunities. According to a majority of respondents, any work beyond providing basic functionality to the device is not considered. Only a limited

number of organisations incorporate add-on considerations as actions in their design process, and when doing so, they focus on interfaces: within the product and with the environment, on both micro- and macro- scale.

Given the described characteristics, the presence of services and service-thinking has been recognised in the area - although, the full potential is not exploited.

4.4. Sub-section Interactions

There has been no formal method identified for simplification of microfluidic devices, although organisations identify this issue as important and try to deal with it in various manners. They are trying to decrease complexity of devices by minimising number of parts, convincing customers to simplify demands (minimise number of required functions, shape of the device, etc.), minimising number of cycles in the design, fixing specifications, simplifying procedures and standardising them, understanding unit operations and their network dependencies, solving one issue at a time, and simplifying the production process. From all of these methods, only minimising number of parts refers directly to the device structure - the rest of them influence it indirectly through the design process. Moreover, many of the mentioned methods have trade-offs.

Another method by which organisations are simplifying their work and design is the minimisation of end-user input required in device operation. They use self-operating, self-controlled operation units where actors and manual processes are not needed. This aims to minimise the risk of contamination. These types of systems are also less expensive in use – no manual work needed – and more precise and reliable than having manual input on this (micro) scale.

The mentioned standardisation also has various forms – usage of same software across product range, development of a generic platform with generic software, use of operation units manufactured and tested for wide range of parameters, etc. These methods are work in progress. People have been thinking about standardisation of microfluidics for over 10 years (Interviewee C), and this issue is still not fully

addressed. As a result of conflict between generalisation and integration requirements, a split can be identified between modular and monolithic approaches. Integration, underlined as crucial (Interviewee D), mostly requires mass production of inexpensive devices. Moreover, it is demanded by leakage proof channelling and constant fluid behaviour requirements, which are the base for microfluidics. In other words, continuous integration leads to monolithic design.

Both monolithic and modular approaches have their own pros and cons. Interviewees confirmed previously indicated issues that decide on their suitability. They agree that in some cases, modularity is not suitable, which increases costs but also increases flexibility, helps in dealing with customers' issues, etc., but cost of modification of monolithic devices is significantly higher. Some of them see modular devices as a way for standardisation which allows for exchange of operation units with creation of new functionality. They agree that choice between approaches depends on application. However, not all of the interviewees have a common view of which approach is better. Although the monolithic approach presents benefits for the 'killer applications', it does not allow for automation. Therefore, a modular approach seems to address more issues raised by this research.

An issue which is of high importance in microfluidics is disposability. A majority of microfluidics are designed as disposables, due to the risk of contamination faced in many applications. Few respondents claimed disposability as being a barrier for performing modular design. They view modularity as an unjustified development cost for one-time use devices.

Issues connected to both monolithic and modular approaches, and identified as critical for microfluidics, are sub-section interactions and, more precisely, interfaces. Although people underline the importance of this issue, they fail to address it properly. Although 70% (7 out of 10) of respondents work in organisations which influence sub-section interactions, only 22% (2 out of 9) confirm familiarity with methods to deal with it. Organisations lack established methods to assess interfaces. Some of them are trying to standardise interfaces of products and operation units inside them, to provide a base for fast reconfiguration and add-ons. However, this

situation is rare. More often, organisations limit themselves to minimise number of interfaces leading to integration. One of the methods to deal with this issue is usage of connectors. These elements evolved from simple need for leakage proof fluid channelling and cause organisations to develop common interfaces which allow interchange ability.

Not all organisations integrate microfluidics as part of other micro- or macro-devices, and when it happens, people often underestimate the role of connectors and issues related to implementation. Therefore, some of the microfluidic devices need to be able to operate with other micro or macro products. Development of common interfaces, although creating cost and difficulties upfront, significantly simplifies future work.

4.5. Summary

The investigation of microfluidic practitioners' work has been performed using various methods (e.g. survey, interviews) and data sources (e.g. experts, web/brochures). This allowed the author to obtain a broader perspective of the issues under investigation. It confirmed and contradicted literature findings across explored topics, which have been presented above.

The investigation has been scoped around three topics: design methodologies, services and sub-section interactions. In all mentioned subjects, a confirmation of and a contradiction with the literature findings were performed.

Exploration of the current practice of microfluidic design showed lack of use of formal design methodologies, and confirmed literature findings on case-dependent and application-dependent design. Structured design models have been identified as limited but required at the same time. A general design process to be applied across the domain has not been identified; although the requirements for standardisation and automation demanding it were clearly stated. Design models, when extracted, vary in details. However, all models identified were driven by technology and, more precisely, fabrication.

A number of factors influencing design – such as limited knowledge about particular aspects of microfluidics (e.g. behaviour of certain liquids) multidisciplinary team, hands-on experience - have been identified as necessary to be included but missing in some of the existing approaches. These provided a base for what is missing and required in the microfluidic design from a practitioner's, product's and operation's view.

Results of an investigation of service practice in the microfluidic domain contradicted the limited volume of literature regarding this topic. Service offerings for microfluidics have been identified as existing and going beyond 'manufacturing for others' and 'designing for others'. Although presence of a limited number of services has been noted and no pattern across them discovered, their existence provides an indication that practitioners are making steps outside of purely technological development, and that the first step towards an 'experience economy' in this area has been taken. Nevertheless, no service-orientation has been identified in the design processes in the domain. The importance of services and service connected considerations has been acknowledged by practitioners, but this could not be confirmed in the description of their work. Moreover, a negative attitude towards offerings outside traditional scope has been recognised in many cases.

Similarly, the topic of sub-section interactions has been identified as crucial by practitioners. However, the ways in which they try to tackle it have been inadequate given the importance of the issue. A limited number of informal methods have been identified, but none of the practitioners was able to indicate any formal method used by his/her organisation to deal with aspects of sub-section interactions. Move towards standardisation has been identified as a common practice in the domain; however, organisations are attempting to standardise to various degrees using a variety of methods. One of the important aspects of sub-section interactions, according to practitioners, are interfaces - between components/modules and with the environment. Moreover, this issue can provide a method to address sub-section interactions' impact by moving towards standardisation.

In summary, the microfluidic domain has been identified as more mature than the limited volume of literature on it. An overlap of service-orientation, sub-section interactions and design methodologies has not been identified explicitly and/or implicitly. However, importance of all three subjects has been underlined by practitioners. Due to a high customisation potential of microfluidics and promising forecasts of this area's profitability (Appendix 1), with an indications that the movement towards an 'experience economy' has already started in this domain, the research aim has been considered as valid and a scope for the guideline, is identified. Moreover, based on additional characteristics identified and information obtained concerning issues necessary to be addressed, the context of the guideline has been identified. The proposed guideline and methodology leading to its development are presented in the following chapter – Chapter 5.

Chapter 5
The Guideline and Design Enablers

This chapter is presenting the main contribution of this research – the developed solution to address microfluidic design issues. The solution consists of the guideline for service-oriented design of microfluidic devices that can deal with sub-section interactions and the design enablers. First, the methodology used to obtain the solution is presented. Then, the developed solution is explained. Explanation starts by presentation of the guideline overview and the design enablers. Last part of the solution's explanation is a presentation of the stages incorporated in the guideline with recommendations of actions to be undertaken in their realisation.

5.1. The Solution's Development Methodology

To ensure the comprehensive use of data, the suitability of the developed framework and its comprehensiveness, a methodology has been established. This methodology aims to help in the systematic development of the guideline and guarantee that relevant issues will be addressed.

Methodology has been developed to address the research aim and, although, it was scoped on development of the guideline, as a result of its execution the solution has been developed going beyond expected guideline. Despite the fact that the solution consists of the guideline and design enablers, one development methodology has been used for both. Variation in approach to development appears on the later step of the methodology and will be clearly indicated – till then methodology is presented as execution of the research aim.

Based on the exploratory character of the conducted research and based on the area characteristics (relative immaturity, lack of design methodology, etc.) to obtain

'methodological fit' (Edmondson & McManus, 2007) many qualitative research methodologies have been reviewed (see Section 3.1.2). As a result of this investigation, the grounded theory (Glaser & Strauss, 1967) has been selected (see Section 3.1.1 for evaluation criteria and Section 3.1.3 for optimisation) as the fundamental approach. However, considering the shortcomings of this methodological framework (time consuming, needs theoretical sensitivity to transfer from data to theory and back (Glaser, 1978), necessity of a structured approach to theoretical sampling, and saturation of data and theory, which are required before theory development can be claimed (Goulding, 2005), etc.), it has been used only partially in the solution development (see Section 3.1.4 for the grounded theory methodology presentation and 3.1.5 for its applicability for the research).

The grounded theory was proposed by Glaser & Strauss (1967) for social studies. This approach uses comparative methods to derive a theory from qualitative data. It is based on systematic gathering and analysis of data which allows substantive or formal theory to be obtained. A substantive theory is context specific in terms of area of enquiry and is readily modifiable when formal theory is conceptual and requires further development (Backman & Kyngäs, 1999). The grounded theory has been used in the data collection, analysis and in the guideline validation. Its characteristics and usage will be pointed out where appropriate.

The solution has been developed incrementally. The author following Glaser's (1978) approach regarding coding decided to withdraw from any attempts to create a 'start list' (Miles & Huberman, 1984) of codes or a long list of precodes before data are collected. In this way, codes emerge from data, hence, data are better represented by codes, and analysis is more open-minded and context-sensitive. As a starting point, three themes of investigation (i.e. not yet codes) have been established: design of microfluidics, services and complexity. These themes have been used as a first step in the literature research.

The main approach of the grounded theory, regarding simultaneous data collection and analysis, has been applied in the research. Data have been collected from four sources: literature, web/brochures investigation, survey and follow-up interviews.

Identification of the gaps in literature allowed the author to scope web/brochure investigation, the results of which allowed the preparation of the survey. After the survey results were obtained, they were used for the preparation of the semi-structured questionnaires to be used in the interviews.

Theoretical sampling has been applied as the grounded theory recommends. It started by being as broad as possible and later data determined the samples (objects of investigations – groups, participants). However, deviation occurred in the order of investigation. While the grounded theory starts with the field investigation followed by a literature study, the development of the solution started with the literature review which scoped the next step of work and provided an indication of the group targeted for the field investigation as a sample. Based on the initial literature results in the investigation of design methodologies for microfluidics, complexity and service-orientation, further investigation was required on narrower topics. The literature investigation was approached using a number of keywords which led to new sets of issues that needed to be explored. Analysis of the literature started with the first paper being read using coding. At first, information connected to the three main categories was identified: design methodology for microfluidic devices, services and complexity were coded descriptively (Miles & Huberman, 1984). Codes were not noted anywhere formally as a list but used only for the researcher's convenience as an abbreviation. Other techniques used in the initial analysis – before data were stored on the computer – include annotations and ideas storing.

Coded information has been categorised using Excel spreadsheets. While collecting data and analysing the re-categorisation and change of codes has been identified as a necessity, analysis for each categorisation has been approached by starting from common aspects, followed by similar meanings and finishing with differences. Each of these aspects has been approached for investigating the reasoning behind issues raised and how it can influence the design process in the microfluidic domain. The results of this analysis preceded the selection of the web/brochure investigation as the next step of data collection, followed by the survey.

The next source of data was preselected based on the literature. As a result, offerings of 38 organisations (chosen based on reports regarding microfluidics market) were reviewed in terms of products, services and services connected to products. This investigation aimed at capturing service thoughts in the microfluidic domain, as indicated by the nature of offering. Data have been analysed using an Excel spreadsheet and classified according to pattern discovered and observed commonalities. This nature allowed the extraction of types of services offered and categorised them according to observed dependencies. Obtained data have been compared with literature studies. This scoped the framework for the survey.

The survey was placed online for three months as a structured questionnaire. As a group sample to be investigated, microfluidic practitioners were selected from both industry and academia. Contact methods used include: email and contact via websites. After one month, the survey was analysed for its clarity and user-friendliness. An updated version was uploaded on the portal and organisations which had not filled in the survey were contacted in the same way as before and by using the LinkedIn network. Analysis of the survey results have been approached in both a qualitative and quantitative manner. Quantitative analysis has been used to underline aspects of the investigations which were more established and to analyse distribution (interest of people in the domain, number of organisations using particular methodologies in their work, etc.). In survey data analysis, the use of grounded theory is limited. Analysis has been approached in a logical manner rather than by applying formal coding. Data have been analysed by the identification of common wording, followed by similarities (synonyms and close meanings) and finishing with differences. Data have been approached starting from single words and putting them into context where the analysis was done manually (i.e. no specific software was involved). When the core issue was addressed, any remaining information was extracted based on the strength of its connection to the core issue. Any additional information provided by a particular respondent was analysed in an analogical approach to the core issues – based on the wording used. Results from the analysis have been compared with the literature and web/brochure investigation findings. This comparison affected the scoping of the interviews.

The interviews were determined by survey participation. The grounded theory approach, in which one part of an investigation allows the selection of a sample group for the following one, has been applied. The interviews were approached in a face-to-face manner and by phone (because of cost and distance). Five in total interviews were conducted and data from them analysed in a systematic manner. Each interview was recorded for confirmation purposes, and analysed based on transcripts and notes. This step has been undertaken, following grounded theory, in a formal manner. However, micro-analysis coding introduced for grounded theory by Strauss and Corbin (1998) is considered as time consuming, leading to confusion (Allan, 2003) and producing 'over-conceptualisation' (Glaser, 1992), and has therefore been identified as not sufficient. To overcome these issues, key point coding has been used. The data analysed have been coded using three levels of codes: descriptive (initially), topic (as a result of categorisation) and analytical (underlying meaning of data). A list of codes, however, has not been generated and only hand-written codes have been used by the researcher before transferring data into suitable files. Categorisations mentioned have been approached using commonalities, similarities and differences, identified previously as being useful in the survey.

According to grounded theory, any additional data should be collected until all categories are saturated. This approach has not been followed strictly in view of the time frames imposed by the project. Saturation has been obtained regarding identified categories based on the literature studies. However, collection of the data from the field investigation was stopped when the obtained data (in terms of their novelty and importance) could not be justified (any new units of data were not sufficient for resources invested in their collection).

Comparison of the interviews' results with information obtained from other sources permitted the first draft guideline. At this stage, the guideline form had not been selected but was left to emerge from the contextual analysis of information. This was intended to obtain the most suitable manner in which microfluidic design could be enhanced by addressing service-orientation and sub-section interactions.

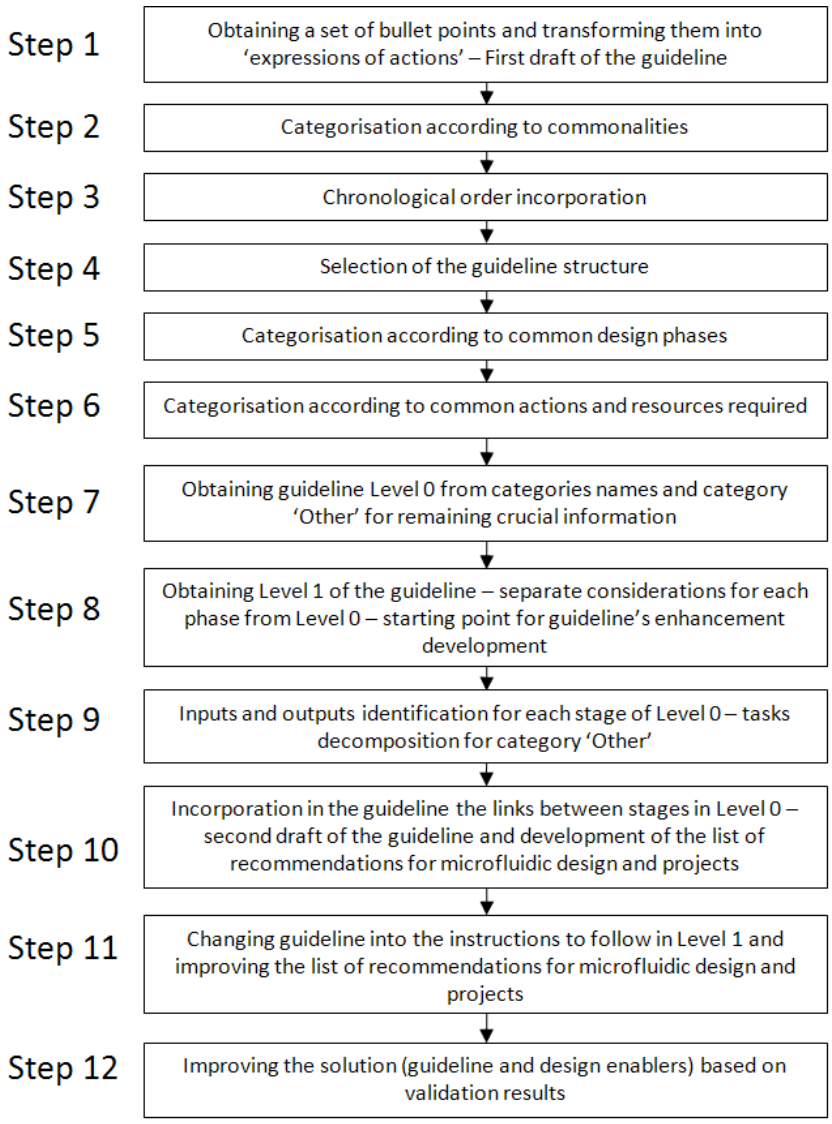


Figure 5-1 The Guideline development- categorisation steps

The first draft of the guideline was prepared as a set of concepts in the form of bullet points (step 1 Figure 5-1). These concepts evolved from comparative analysis undertaken inside (comparison of respondents' answers in the survey, comparisons between researchers' views in literature, etc.) and between (comparison of survey responses with literature indications, comparison of interviews with web/brochure results) the data sources. These bullet points were not categorised upfront, their order was determined as they were obtained. The form of the bullet points varied, from general principles of models identified e.g. fabrication driven, to actions to be performed by designers e.g. store models for future reuse. This variation connected

with differences in the level of detail among bullet points required the incorporation of significant changes. As an initial change, bullet points were transformed into 'expressions of actions'. This allowed them to be phrased as recommendations which incorporate best-practice and address identified gaps.

A new set of recommendations was categorised using commonalities as a method which emerged from the information (step 2 Figure 5-1). As a result, 13 categories were identified: Microfluidics characteristics, Requirements from designers, People involvement, Client/customer involvement, Design process, Design support, Prototyping, Manufacturing, Add-ons, Device success/failure – market acceptance, Modularity/simplification, Services and Other. As can be observed, these categories overlap on many issues. This categorisation identified a requirement for further development.

During extraction of the concepts as bullet points, it was noticed that many of them were characterised by dependence from other actions (i.e. have to be performed before, during or after). Therefore, chronology has been used as a driving force for the next step (step 3 Figure 5-1). For 'expressions of actions' which were not possible to be assigned to a particular space in the chronological frame obtained, three labels were allocated: early, middle and late, to identify where in the development life cycle of the microfluidic device they are applicable. In cases when 'expressions' were not possible to be assigned to just one label they were assigned to multiple or marked as 'difficult to place'. Performing time-ordering showed a high variation in the level of detail among 'expressions of actions' and re-shaped previously developed categories.

Incorporation of the chronological order in the 'expressions of actions' showed that it was necessary to decide on the overall shape and representation form of the guideline (step 4 Figure 5-1). Hence, best-practices from literature and microfluidics practitioners' work have been reviewed, which identified design processes as the most desirable. In considering the characteristics of recognised models, literature indications regarding the benefits of a structured approach to design, and lack of a general model in this domain, the grounded theory approach (allowing a process

type output to be obtained) was confirmed as an appropriate choice. To allow the developed guideline, as a design process, it was characterised by four main characteristics of substantive theory: fit, understanding, generality and control, so, adjustments to recent guideline form were necessary. Therefore, to increase fit, characteristics of the best-practice in the models were summarised regarding their influence on the shape representation; for understanding, control and generality aspects, familiar approaches for microfluidic designers were looked at while keeping in mind the flexibility to be applied for the development of various types of microfluidic devices. The main shape of the guideline has been sought among existing design models identified in literature and in practitioners work. Regarding that literature models seemed ambiguous and the practitioners were mostly not familiar with them, a representation familiar for them and easy to understand and adopt has been search for. Although, the design models for practitioners work have been extracted by the author, the overall shape of them - flow-chart - has been indicated during face-to-face interviews by quick sketches made by interviewees and in the survey by listening design steps with numbering. As a result, the flow-chart has been selected as being familiar for the majority of designers and used by them on daily basis as a main guideline representation. This framework allowed the scoping of further categorisation which was required to prepare a second draft of the guideline.

A new theme of categorisation has been decided on by restructuring according to the common design phases identified in the 'expressions of actions' (step 5 Figure 5-1). This categorisation allowed the usage of some categories from the first categorisation (step 2 Figure 5-1) such as prototyping and manufacturing (as a phase) and demanded the splitting of some 'expressions of actions' into more detailed tasks to be incorporated into the newly obtained categories. The result of this categorisation has been a set of small categories. This form of the guideline has been identified as not acceptable regarding 'understanding' and 'control' characteristics of the substantive theory (see Section 3.1.2.3). An overwhelming number of steps to be implemented in the first view of the prepared framework – result of incorporation of obtained small categories, and identification of variation in the level of detail among

them – have been identified as discouraging from potential usage of the guideline. Presentation of the high number of issues under consideration in the first view can discourage readers from using the guideline by viewing is as complicated, time-consuming to execute and confusing regarding interdependencies.

Consequently, a new and final categorisation (step 6 Figure 5-1) has been applied. It has been based on merging categories together based on common actions and time, with considerations of the resources needed at particular stages. As a result, Level 0 steps of the guideline have been obtained by transforming categories into 11 steps (step 7 Figure 5-1). However, additional effect of this categorisation allowed to identify a category of information considered essential and not assigned to any particular step - this category has been labelled 'Other'. Usage of these additional category achieved saturation regarding categorisation. As can be observed category with this name occurred at second step of categorisation, however, its content changes with every categorisation step. Final content obtained at this step has been used as an input to develop an addition to the guideline. From this step onward development of the guideline has been proceed with development of its enhancement.

Analysis of the information contained inside guideline's stages and consideration of the design approach led the author to the selection of a decision making process representation where possible (step 8 Figure 5-1). The preparation of bullet points in the first instance in the form of actions to follow, i.e. to identify, to develop etc., allowed a faster development of processes. Information was analysed from the point of view of its importance and clarity of representation of required actions, as well as what needed to be obtained. This judgement, based on the research findings, identified that some of the stages are circumstantial – they should not always appear in the design process. It also allowed to see which actions are possible to be merged or should be divided further. Information prepared in this manner shaped Level 1 of the guideline.

At the same time category 'Other' has been examined regarding potential of incorporation of contained information inside the guideline. This examination led to

conclusion that identified issues spread across stages and cannot be assigned to any particular. Moreover, levels of details across incorporated information vary and not all of them are interlinked or even close to each other regarding their presence in the design process. Furthermore, many issues inside the category when assigned a chronological label they possessed a number of them or were marked as 'difficult to place'. Therefore, temporary placement in the category 'other' has been viewed as the starting point for development of the enhancement for the guideline

In the mean time Level 1 of the guideline has been used as feedback to Level 0. It allowed the identification of input and output at every stage in terms of information necessary to start work and provide results (step 9 Figure 5-1). This identification imposed order on the stages and allowed the incorporation of links and iteration loops inside the guideline (step 10 Figure 5-1). Also, information regarding project dropouts was verified by showing what information is generated at a particular stage and what can go wrong.

A second draft of the guideline has been reviewed in terms of the four characteristics of the grounded theory (Glaser & Strauss, 1967). The guideline approach has been identified as: fitting into the microfluidic domain, understandable by designers of these devices, general enough to allow for the development of a variety of microfluidics and flexibility in the projects, and requiring improvements in terms of designer's control on the project.

Improvement in terms of control has been obtained by changing the guideline language at Level 1 in the instruction (step 11 Figure 5-1). This imposed changes on the decision making process representations to make them more explicit. Validation of the guideline, based on the four characteristics mentioned earlier, gave satisfactory results.

Following the guideline's development path information contained in the category 'Other' tried to be brought to similar level of details by decomposition of tasks (step 9 Figure 5-1). This decomposition led to conclusion of lack of comparability between certain topics covered and identification of the issues included as a set of additional

recommendations. Regarding the function of the information contained inside the category and scope which was covered by it - it has been renamed as a 'list of recommendations for microfluidic design and projects' (step 10 Figure 5-1).

Change of the language used in the guideline at Level 1 in the instruction has been also applied for 'list of recommendations for microfluidic design and projects' (step 11 Figure 5-1). In this manner the solution used for the validation has been developed.

Based on the validation (Chapter 6) – for which separate methodology has been developed (Section 6.1) – a number of improvements have been incorporated into the solution. Incorporation of these potential improvements has been accounted for when developing the methodological approach for the research aim execution – however, lack of information regarding its results did not allowed to plan it in details. Details regarding enhanced aspects of the solution have been identified while discussing feedback from validation (Section 6.4) and the final version of the solution is presented below.

5.2. The Solution

In this section developed solution is presented. The solution consists of the guideline and a set of design enablers. Regarding the multilevel composition of the core element of the solution – the guideline – presentation of the solution is undertaken by showing an overview on the guideline and explaining design enablers before details regarding elements of the core are given. Hence first, an overview on the guideline providing an explanation regarding its functions and the meaning of its graphical representation is given. It is followed by the design enablers consisting of recommendations to be applied when using the guideline and undertaking microfluidic projects. The design enablers are presented as a set of bullet point actions to be followed. Finally, step by step instructions for the guideline usage is given.

5.2.1. The Guideline - an Overview

The developed guideline, on the high level – Level 0 – consists of ten fundamental steps and one additional one, depending on how well understood is the functionality

required from the device to be designed and the complexity of the project. On the high level the guideline looks as presented in Figure 5-2.

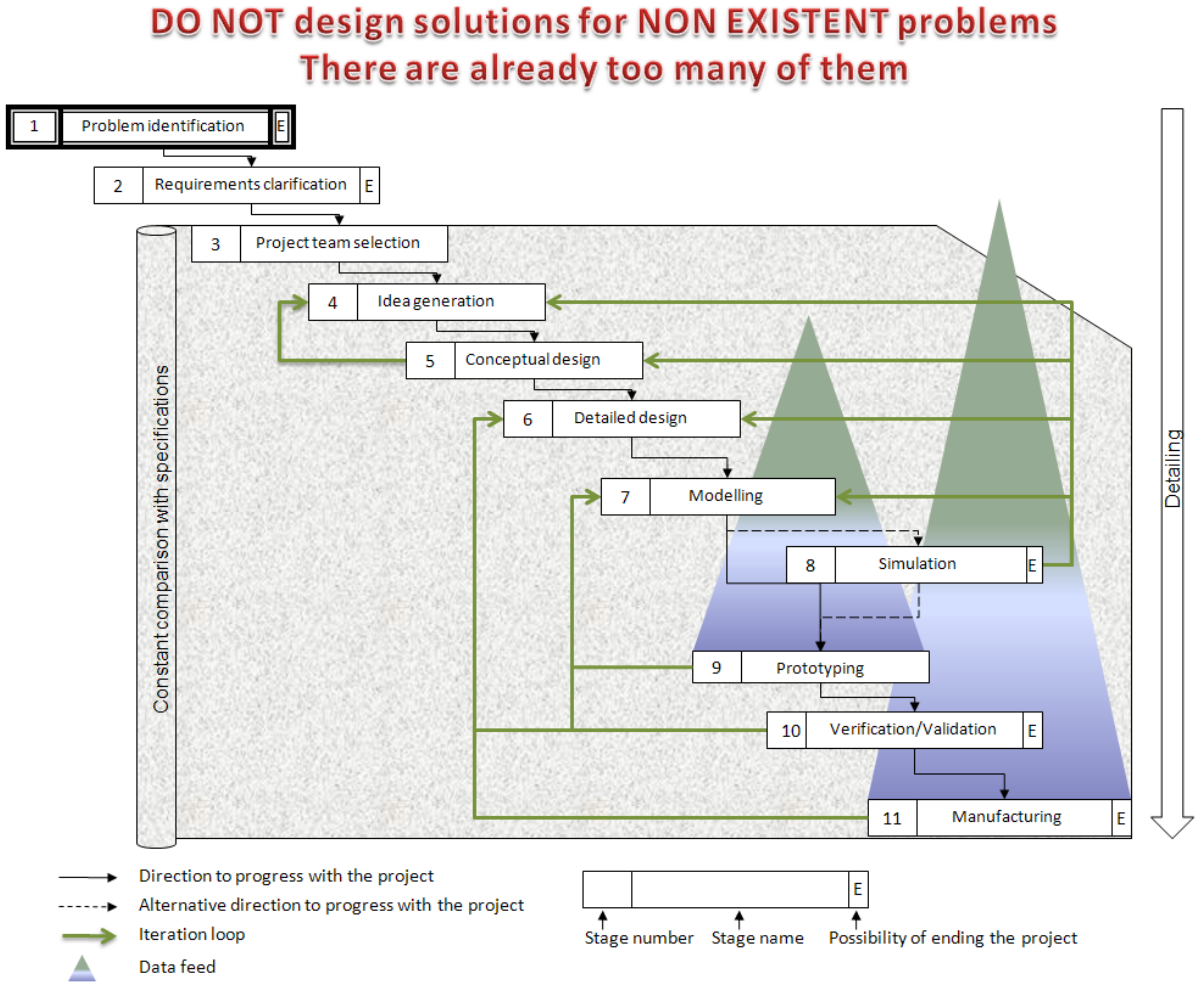


Figure 5-2 Guideline for service-oriented design of microfluidic devices which can deal with sub-section interactions

The guideline starts with the theme which summarises its purpose and restrictions. The theme '*DO NOT design solutions for NON EXISTENT problems. There are already too many of them*' presents how the projects should be approached and provides the rationale for the work to be undertaken.

Stages 1-7 and 9-11 are obligatory but stage 8 requires justification to be incorporated into the design process. Black solid line arrows between the guideline's stages show the path for the designers to follow. The dashed style arrows show alternative routes when an additional step is required. The double line a round the frame of stage 1–

Problem identification – is used to emphasise the importance of this step. Details regarding particular stages will be presented in Section 5.2.3 and discussed accordingly in Section 7.2.3.

Iteration loops which can occur during the guideline implementation between stages are visualised using green arrows (see Figure 5-2). As can be observed, they are not present between all steps of the model in any correctly performed design. Designed devices can require changes (independent of the project team performance) which are originated or identified in one of five steps: in conceptual design (stage 5), simulation (stage 8), prototyping (stage 9), validation/verification (stage 10) and manufacturing (stage 11). In the conceptual design, when the application of detailed requirements in ideas from the idea generation stage shows any problems (i.e. do not address all of the issues) then additional concepts are required. At the simulation stage, a number of problems can occur:

- Simulation results show adjustments required in the models regarding shape, fluid behaviour models etc. – loop to the modelling stage (stage 7).
- Simulation results show changes required on the detailed design stage (stage 6): change of material (i.e. same class but different type for other properties), increase or minimise thickness of elements, minimise roughness of surfaces, etc.
- Simulation results show major changes required in the conceptual model (stage 5).
- Simulation results show requirement for major changes where developed concept is not able to address the issue – loop to idea generation stage (stage 4).

The first two mentioned loops from the simulation occur often as a result of incremental improvement in the design, but the first obtained results are usually not perfect regarding novelty of domain. The other two loops are aimed to be eliminated in view of their high cost and time-consuming changes required.

At the prototyping stage, loops can occur during the proof of the working principle or when the fluid behaviour is not fully understood. These loops are due to the novelty of the area and the trial and error approach of the applied investigation. As a result, changes in models are required to achieve the necessary performance. As the domain matures, these loops should be eliminated.

Similarly, the validation/verification stage provides feedback into modelling. This loop can occur due to the test results from the prototyping and/or change of the market/client demand in long-term projects. Loops from the verification stage to the modelling and detailed design stages can occur for these same reasons as loops (to these stages) from the simulation stage. This is a natural way to make improvements; however, it should be minimised at this point. The later in the process changes are incorporated, the more expensive they are in terms of money and time. In manufacturing, the loop to the detailed design stage is caused by the need to adjust fabrication equipment and the additional calculations required.

The arrow on the right hand side of the guideline (see Figure 5-2) represents the increasing amount of detail in the design. It also shows a top-down approach to design implemented in the guideline. It represents the transition from architectural structure to detailed design.

Possible outputs from the project realised using the guideline are indicated in Figure 5-2 by the letter E – 'end of design'. In the first two stages, this end is due to the project dropout. Project dropouts are not the same as failure, they are a conscious decision that the project is not beneficial to be continued inside the organisation. The end of the project at the stage of simulation, verification/validation or manufacturing is equivalent to delivering a client requested form of the output: a simulation verified design, verified and working prototype, or a verified and working device.

The guideline requires comparison of the outcome at every stage with the specifications. Comparison should start at stage 2 when the project team is selected and continue throughout the project until delivery of the output to the client. This

comparison should be done on a daily basis by keeping track of changes and requirements.

The funnels leading to the prototyping (stage 9) and manufacturing (stage 11) represent data fed into these stages. As can be observed, the amount of data increases as the process progresses. For prototyping, information starts to be collected at the idea generation stage when development of an idea is agreed. Similarly, in a systematic manner, information regarding manufacturing is collected. The difference is in the starting point of collection. Although, in the problem identification stage, some knowledge about manufacturing methods for microfluidics is required to be fed into the final manufacturing stage, this actually starts during the requirements clarification. During this stage, the manufacturing process can even be agreed upon; however, it is built up in terms of details throughout the process of product development.

5.2.2. Design Enablers

During the identification of the method to address the specifics of microfluidic design, a number of issues have been identified. Development of the guideline has addressed the majority of them. A significant amount of work, which could not be included in any particular stage of the guideline or that required different levels of details to those presented (in Level 0 or Level 1), needed to be incorporated in a different manner for addressing the project's realisation. Some of the issues raised could not be assigned to one project but required repetitive work with multiple types of devices. These issues have been addressed in the form of a recommendations list which is presented below. Regarding the function which is played by them in the microfluidic design they have been named 'design enablers' – since they enable future design of microfluidics.

A prepared guideline, for the service-oriented design of microfluidic devices that can deal with sub-section interactions, consists not only of the presented process and steps incorporated within it but also a set of design enablers. The set comprises:

- Involve the client in milestones (and critical decision points) and during validation/verification, i.e. do not involve him/her at all the steps between the milestones unless project's specifics or organisation's operation requires it,
- Establish core elements in the set of microfluidic devices (standard element or elements of design),
- Develop models of already validated and produced products,
- Slowly develop an in-house database of modules/components (component library),
- Establish a group of general modules providing basic functions (e.g. mixing, channelling etc.),
- Validate created models for a variety of fluids,
- Encourage informal communication inside the project team but do not eliminate a formal one.

5.2.3. The Guideline - Stages

The differences between conventional design models, existing models and the guideline developed are more visible inside the stages. A description of the steps required and recommended in these stages is provided below.

Presentation of the stages has been approached using decision making process diagrams and graphical visualisation. A decision making process diagram incorporates two types of blocks: actions – represented by rounded rectangular text boxes, and decisions – represented by diamond text boxes. A double line frame around a box representing action indicates further decomposition of this process step is required. Usage of the parallelogram shape indicates data split inside the issue considered – viewing it from different aspects which are indicated textually. Rectangular boxes (sharp corners) have been used for considerations and suggestions for the guideline user inside the process which can be implemented during the action. For a summary of the decision making processes diagrams' representations, see Figure 5-3.

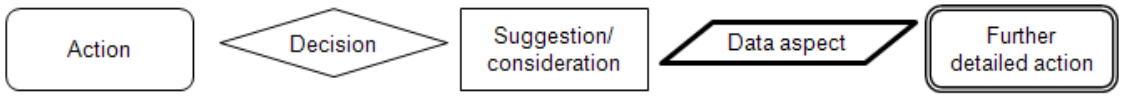


Figure 5-3 Legend for the decision making processes diagrams

These diagrams usually start by identification of the preceding stage in a grey font separated by a dash and finish by identifying in the same manner successive stage(s) – exceptions obviously being the first and last stages.

The graphical visualisation of considerations has been approached using rectangular text boxes. The majority of the considerations were interconnected in a multiple manner (represented by arrows in Figure 5-7). This high interdependence of issues and a fact that some of them are case specific (not all issues are applicable for every type of microfluidic device) did not allow them to be put in time order. Possible connections were presented only on the first consideration's visualisation and omitted in the following for clarification purposes.

A number of considerations, as well as steps in the decision making processes, have been elaborated on in the discussion section. To allow the reader to make a quick association of the issues, they have been marked on the pictures according to their appearance in the particular stage and then referenced in brackets when discussed. Marking uses the first letters of the stage name, e.g. PI1 – Problem Identification stage first issue, and where necessary one of the letters from the word for distinction has been incorporated (e.g. modelling = MD and manufacturing = MF).

PLEASE NOTE:

INFORMATION PROVIDED ON DECISION MAKING PROCESSES IS NOT ELABORATED ON IN THE TEXT

5.2.3.1. Problem Identification

This stage is presented in graphical form in Figure 5-4. This figure presents the second level of the model decomposition and provides a deeper understanding of

what is required. The basic rule to follow in project identification is – "Do not design solutions for non existent problems. There are already too many of them".

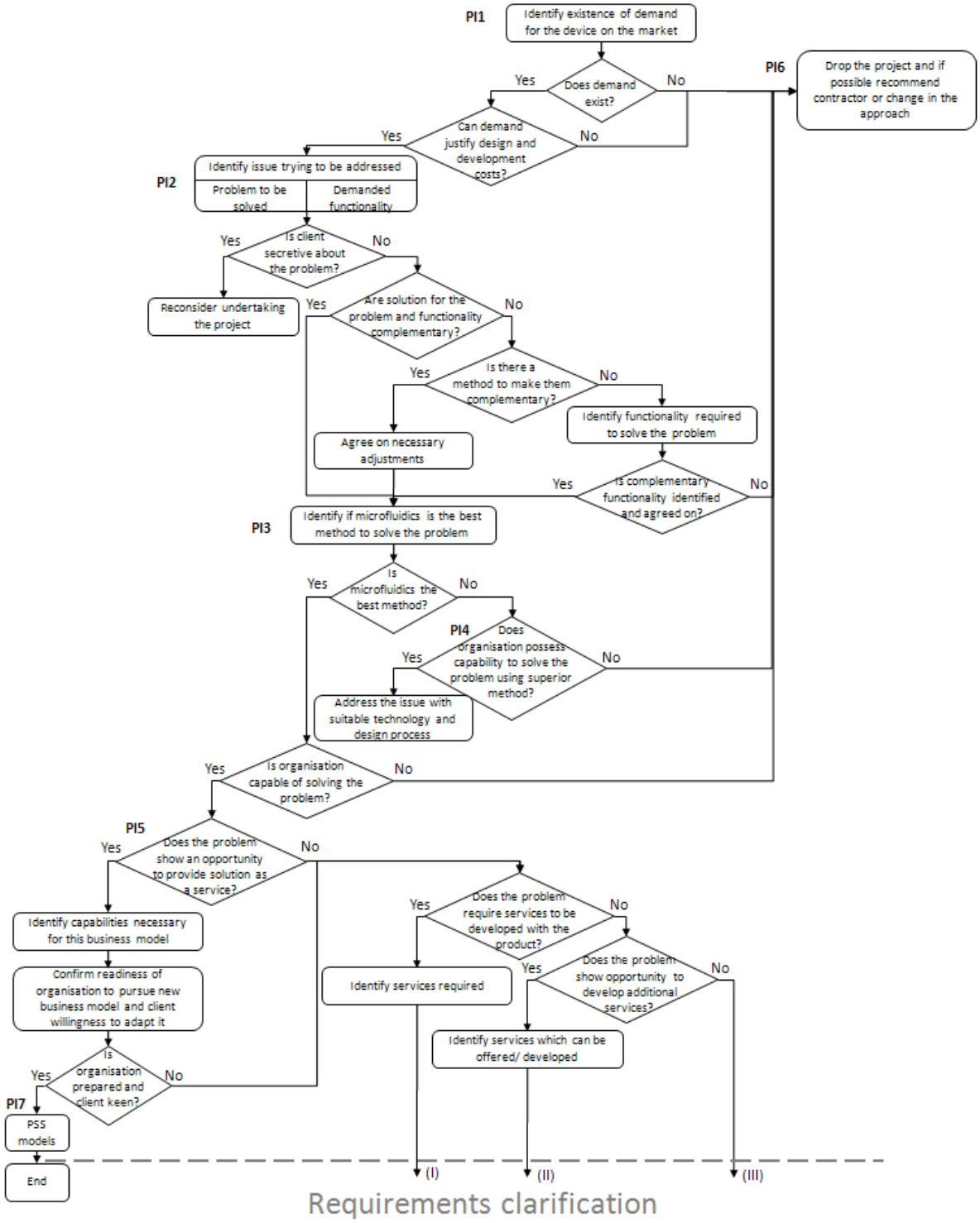


Figure 5-4 Problem identification stage (PI1-7 are discussed in Section 7.4.3.1)

The origination of a project can be internal or external (client demand). The majority of projects originate from customer demand and this process incorporates more issues to be considered. Presentation of the problem identification stage is undertaken as a result of client demand. The process presented is aimed to be followed during decisions made on project realisation but within a broad scope. Additional considerations inside these steps are left for the organisation, i.e. the person undertaking the project, to decide upon. Factors such as the cost/profit equation are left for the later stages. However, if according to the broad identification of the problem, the organisation is not able to deliver on time and within cost, then the project should not be undertaken.

This stage results in five points for dropping realisation of the project: one is recommendation of the project reconsideration, two are recommendations for usage of another design approach and the remaining three outputs lead to the next stage of the guideline requirements clarification. An identification of the market demand is still a necessity for projects originated internally and the lack of market demand removes the project from realisation.

5.2.3.2. Requirements Clarification

When demand for the device on the market is identified, steps to proceed depend on how the project was originated. Figure 5-5 presents clarification of requirements in a project originating from a client order, whereas Figure 5-6 presents project which was originated by the organisation for various reasons, e.g. recognising a new opportunity in the market, the new technology, etc. Both demands have to find confirmation within the market before they will be undertaken.

As mentioned in Figures 5-5 and 5-6, a project brief is recommended to be developed as a standard document in the organisation which will allow clients to specify their needs more clearly. Some of the organisations already possess this type of document (naming can vary) also several customers possess a project brief and provide it when starting the project. Even when project has not originated from client demand completion of a project brief is advised.

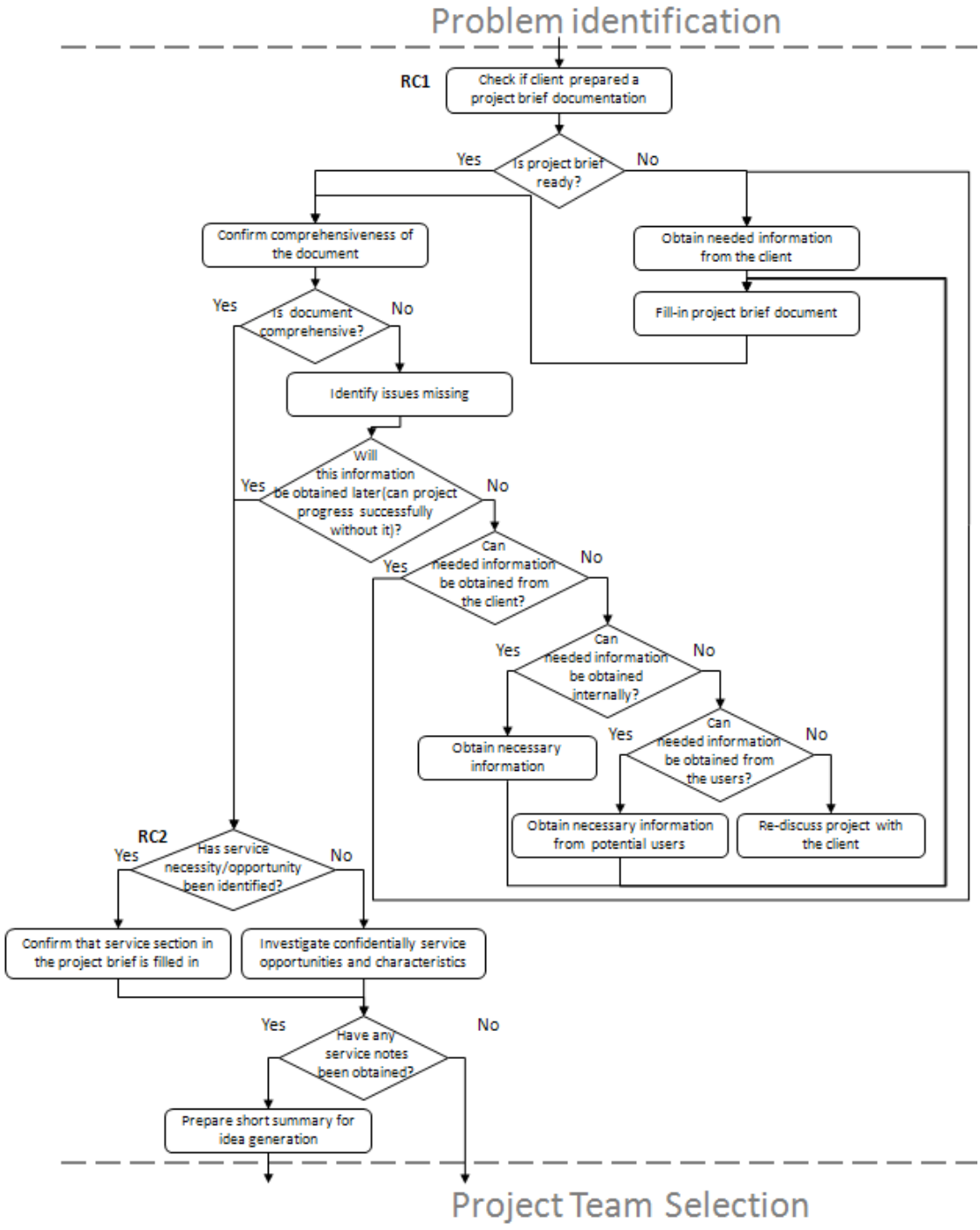


Figure 5-5 Requirements clarification stage – project originated by the customer (RC1-2 are discussed in Section 7.4.3.2).

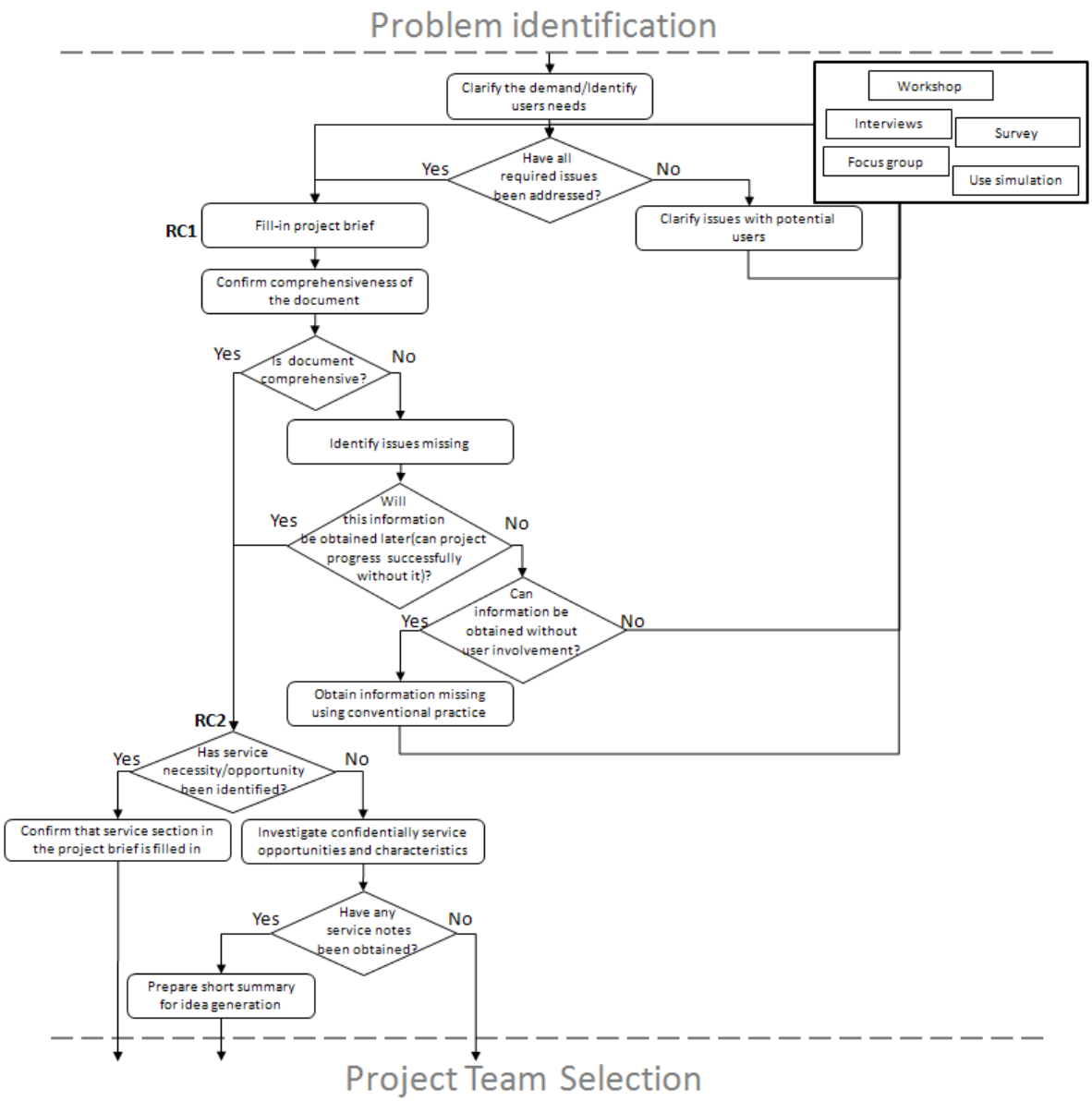


Figure 5-6 Requirements clarification stage – project originated by organisation (RC1-2 are discussed in Section 7.4.3.2)

Recommendations for the project brief are as follows:

- Flexible structure document – identifying crucial characteristics for a variety of devices.
- Be restricted to the capabilities possessed by the organisation – what can be offered, e.g. if the organisation can manufacture only in one type of material, if dimensions to be offered are restricted, or if the organisation can outsource

part of the development work due to a lack of in-house equipment then it should be explicitly stated.

- Functionality of the device should be explicitly described.
- Identify restriction from the client side i.e. materials, manufacturing methods to be applied, etc.
- Problem to be solved should be expressed.
- Brief to be kept confidential to assure client's truthfulness.
- Identify the IP rights to the device under development and if possible components/modules of it.
- Prepare service section.
- Identify conditions of use.
- Identify implementation method and conditions.
- Identify risk management appropriate for the project e.g. involving higher number of developers, development of more than one type of architecture (parallel solutions) – include in the brief only when justified.

The service section should allow for addressing issues raised by the problem identification. In the case of outputs I and II (see Figure 5-4), it needs to allow for identification of demanded services and provide characteristics to allow for scoping them. This section must be structured in a manner which will allow it to be omitted when an opportunity for service type offerings is not identified and/or when the client is not interested in them. However, the project leader is requested to note identification of the service opportunities coming up, to allow their development in the organisation and to have a better identification of clients' demands. This identification is advised to be undertaken in a subtle manner, preferably without client awareness.

Capturing characteristics can be done from various aspects of requirements clarification. Identification of conditions of use, implementation methods and conditions provide the highest opportunity to extract service features. Captured characteristics and prepared notes should be transferred into a short summary and used as an input into the ideas generation session.

Information at this stage will not be collected in a sequential manner. Figure 5-7 presents main issues which are necessary to be considered during requirements clarification (please note that presented issues are just an indication – depending on developed device new characteristics will appear and some of indicated will not be applicable). These issues are interdependent (illustrated using arrows) which does not permit them to be put in time order.

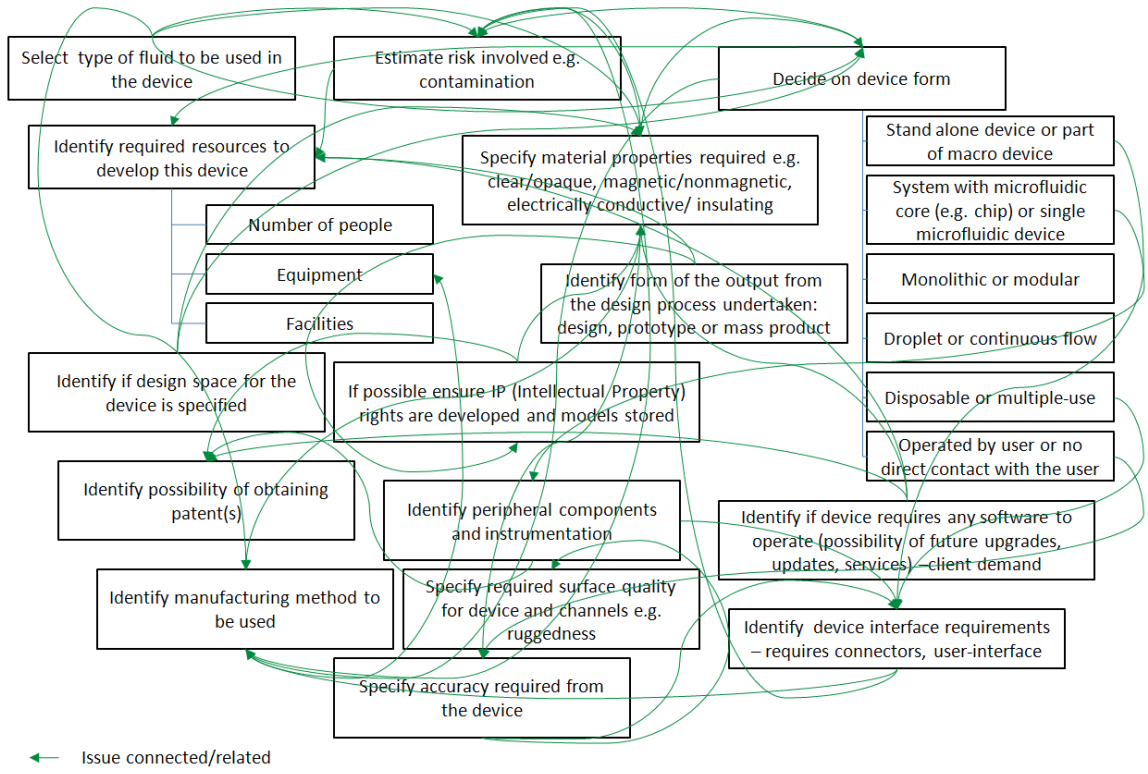


Figure 5-7 Issues which need to be considered at Requirements Clarification stage

Each decision implies additional constraints and has to possess the proper rationale e.g. selection between a modular and monolithic approach should be based on several rules such as: do not select the monolithic approach if the device does not have 'killer application' – mass production without any variety between devices. The selection of a modular or monolithic approach to design, a type of fluid flow in the device or establishment, if this device is a stand alone or part of a bigger system, are fundamental to ensure the generation of suitable ideas and are recommended to be specified upfront.

Requirements clarified for the device development should be compared with requirements from project realisation perspectives such as: cost and duration of the project, resources necessary from administration side, risk management. Both types of requirements are indicated to be incorporated in the project brief document and should be clarified before approaching next design stage.

5.2.3.3. Project Team Selection

After all requirements have been clarified, team members for the project need to be selected. It is essential to be done by a person or people with knowledge of the field and experience in microfluidic design. The team has to be multidisciplinary and involve at least 1 person with experience (i.e. more than 6 months hands on practice) in product breakdown and project realisation for microfluidics. At this stage, decisions about how many (and from which areas) people need to be involved has to be made. This number should represent the size of the project, its interdisciplinarity and will be dependent on the allocated and available resources. Involvement of at least one person representing service aspect of the organisation is recommended. This person's involvement should depend on the level of service-orientation which will be incorporated in the device when it will reach the last stage of design. If organisation develops device on client's demand and the client is not interested in any services an involvement is recommended only at the idea generation stage to provide a 'fresh perspective' and to provide possibility of enabling services in the device to be developed. If client is interested in the services which can be offered with the device or device is developed to address market or internal demand involvement throughout the process can enable if not a service offering with the device at the end of the process then enable services in the future. An organisation cannot allow for 'double booking' of resources. Ensuring that incorporation of the resource management system within the organisation has been accomplished, is advisable.

The inclusion of people previously responsible for gathering information from the client (client demand project)/originating the idea (internal project) in the team should be encouraged. If these people's knowledge is considered to be insufficient for

the whole process, their involvement at the ideas generation stage should be reviewed. If specifications do not evolve through the process, an involvement at comparison with specification steps is recommended.

5.2.3.4. Idea Generation

This stage can be approached as in a conventional design, but with the incorporation of creative design methods. A recommended set of idea generation methods include variations of: brainstorming, six thinking hats, lateral thinking, delphi, etc. The organisation is advised to select a method with which it is familiar.

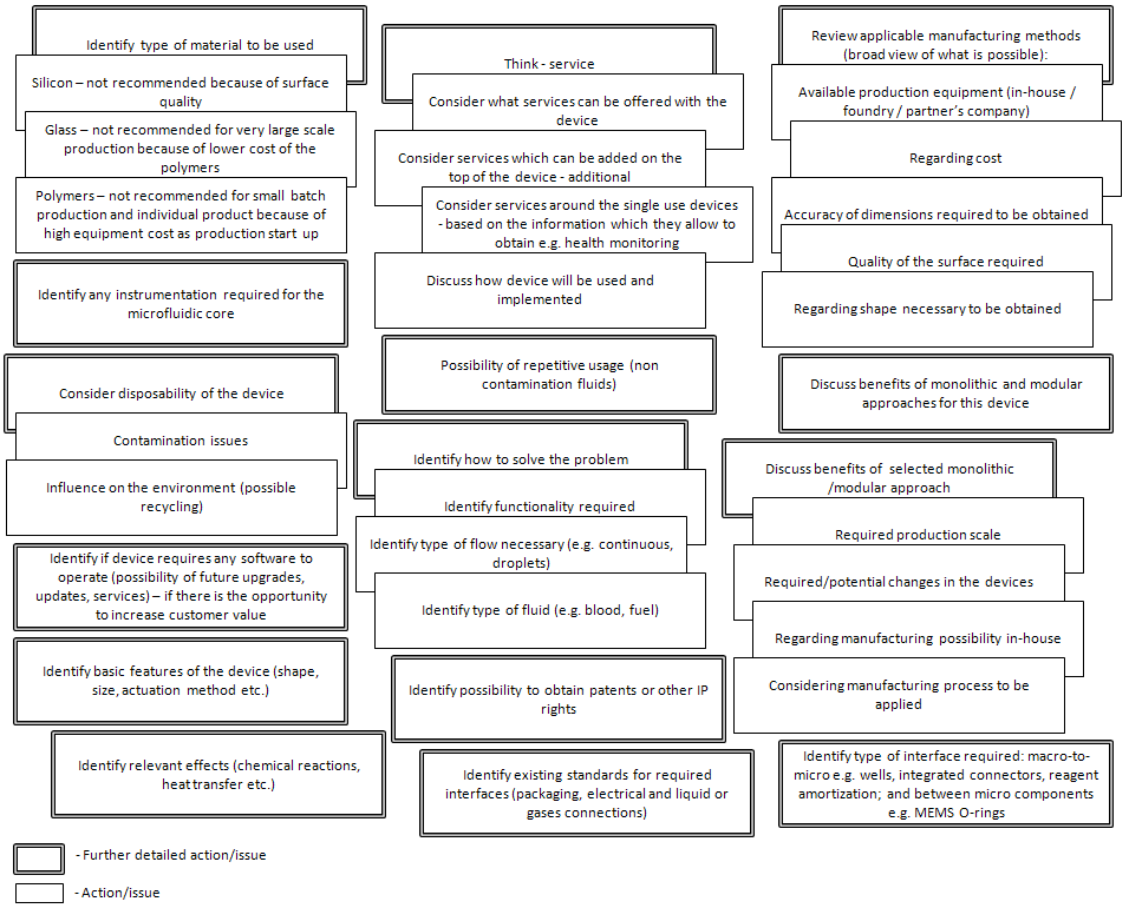


Figure 5-8 Issues to be included in the idea generation stage

The main issues to be discussed in the session (applying the creative design method) are presented in Figure 5-8. The issues mentioned are general ones for every

microfluidic device. Additional issues are expected to be incorporated with regard to specific projects.

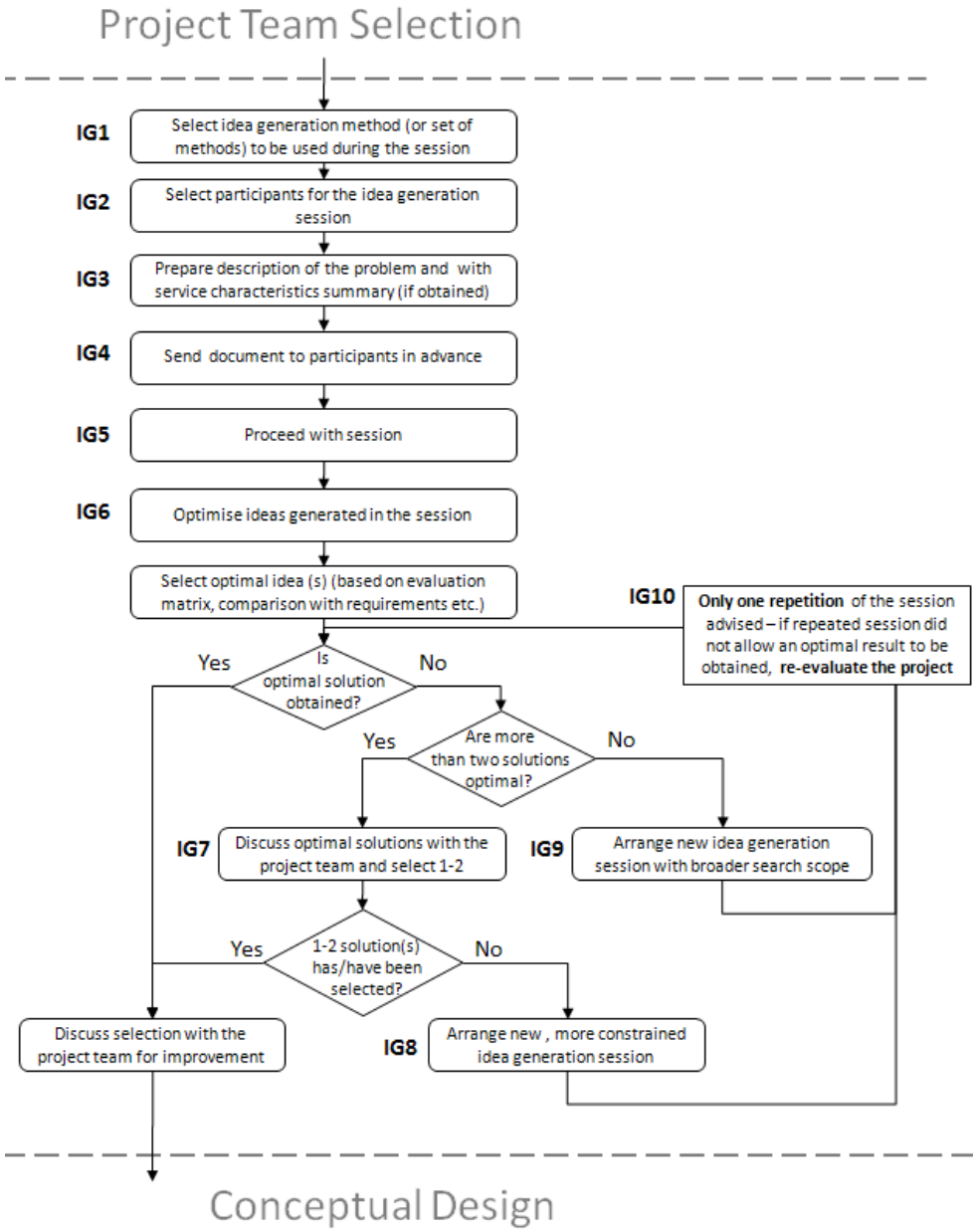


Figure 5-9 Idea generation stage (IG1-10 are discussed in Section 7.4.3.4)

It is imperative that participants of the idea generation session will not only be the project team (required) but also, if possible, other people from the organisation working in the field (engineers, chemists, software specialists, service, etc.) who can have valuable suggestions. This selection has to be made with regard to specifications to address all required competencies and broaden the scope for a 'fresh

view'. Involvement of the person originating the idea (in internal projects) or clarifying recommendations with clients (projects on client's demand) is advisable. Results from the session should be optimised before they are used as inputs to the next conceptual design phase. Figure 5-9 shows a high level view of how it is proposed to approach this stage.

The session needs to be chaired by one person. It is proposed that this position be given to the team leader or the person with the highest experience in the domain. The chair should act as moderator for the session and not impose any decisions but only allow people to express their opinions. The chair's opinion, as the person with the highest competence, has to be left until the end so as not to influence others if ideas are expressed verbally.

It is advisable for the session to be scoped with constraints. Before the session, the moderator is encouraged to prepare a short summary of the discussion topic (background to the project and characteristics required) and what is required from the participants. This document should incorporate a service characteristics summary if obtained from the previous phase and include data from the project brief. Prepared in this manner, documentation is expected to be sent to the participants in advance, giving them sufficient time to familiarise themselves with any problems. No more than a week and not less than two days is recommended.

Following list is just a suggestion what types of services can be considered for microfluidics (please note this list is not comprehensive and not suitable for every organisation and type of device):

- Maintenance and repair,
- Research type contracts – doing microfluidic research for other organisations – performing theirs experiments,
- Software update and upgrade,
- Offering own capabilities:
    - Design,
    - Modelling,

    - Simulation,
    - Prototyping,
    - Manufacturing.
- Disposing devices – collection and recycling – 'getting rid of' used microfluidic devices,
- Training,
- Implementation,
- Development of connectors/interface instrumentation between microfluidic device offered and other customer's equipment,
- Services base on data obtained from the microfluidic device, e.g.:
    - Monitoring of phenomena,
    - Database development,
    - Analysis and diagnostics.

All the ideas generated must be evaluated after the session – not during it. When the session is finished, the criteria based selection method is recommended to be used. Criteria can be established based on specifications for the project as well as on basic factors such as cost, time and performance. Each criterion should have weight depending on the importance of the criterion in the particular project. Selected in this manner, one or two optimal solutions are expected to be used as input(s) to the next phase. Proceeding with more than two solutions is discouraged. In case many solutions are considered as optimal and/or solutions have not been achieved, then a follow-up session should be arranged with a broader scope if the issues were not targeted initially – to find a solution(s), or in a more focused context if many solutions were considered to be optimal. It is suggested that the session should not be repeated more than once; if this situation occurs, then realisation of the project should be re-evaluated.

5.2.3.5. Conceptual Design

In the conceptual design stage (see Figure 5-10), the concept selected as the optimal from the idea generation stage has to be developed. Development is recommended to

start by assigning tasks to the project team and establishing time frames. These tasks are intended to develop the concept.

Consideration and planning of the service delivery is advised to be approached in the same manner as every other design step. Details regarding tasks to follow are presented in Figure 5-11. Services should be considered with regard to the necessary infrastructure, resources, delivery methods, profitability and demands. During development of the product at an architectural level, as at the components/modules levels, team members are asked to account for the services for which this element will be delivered and give the value for the customer that it will help to deliver.

When/if consideration of services is performed by the assigned team members, development of the optimal idea into the concept at the architectural level needs to be performed by others. After the design of the architectural level is agreed on in a broad scope, the product breakdown, which was initiated by the idea in the generation session, has to be performed. This breakdown means the separation of the structures which can be developed simultaneously with regard to interactions between them. In this way, existing modules/components and those still to be developed are identified.

In the case when all required modules/components exist (i.e. were developed previously in the organisation or acquired from other sources), investigation and evaluation of their interconnections is advised. Modules/components which do not yet exist are recommended to be developed by setting up concrete requirements (quantitative and qualitative) and identifying the methods required to fulfil them.

Issues to be included in the development of components/modules and concepts are presented on Figure 5-12. The majority of these issues are interdependent and they cannot be put into time order.

The outcomes of this phase must be revised regarding changes imposed on the planned process, their cost of implementation and manufacturability of the structure. Manufacturability has to be considered not only in terms of one single device but also in the scope of quantity required as a process outcome.

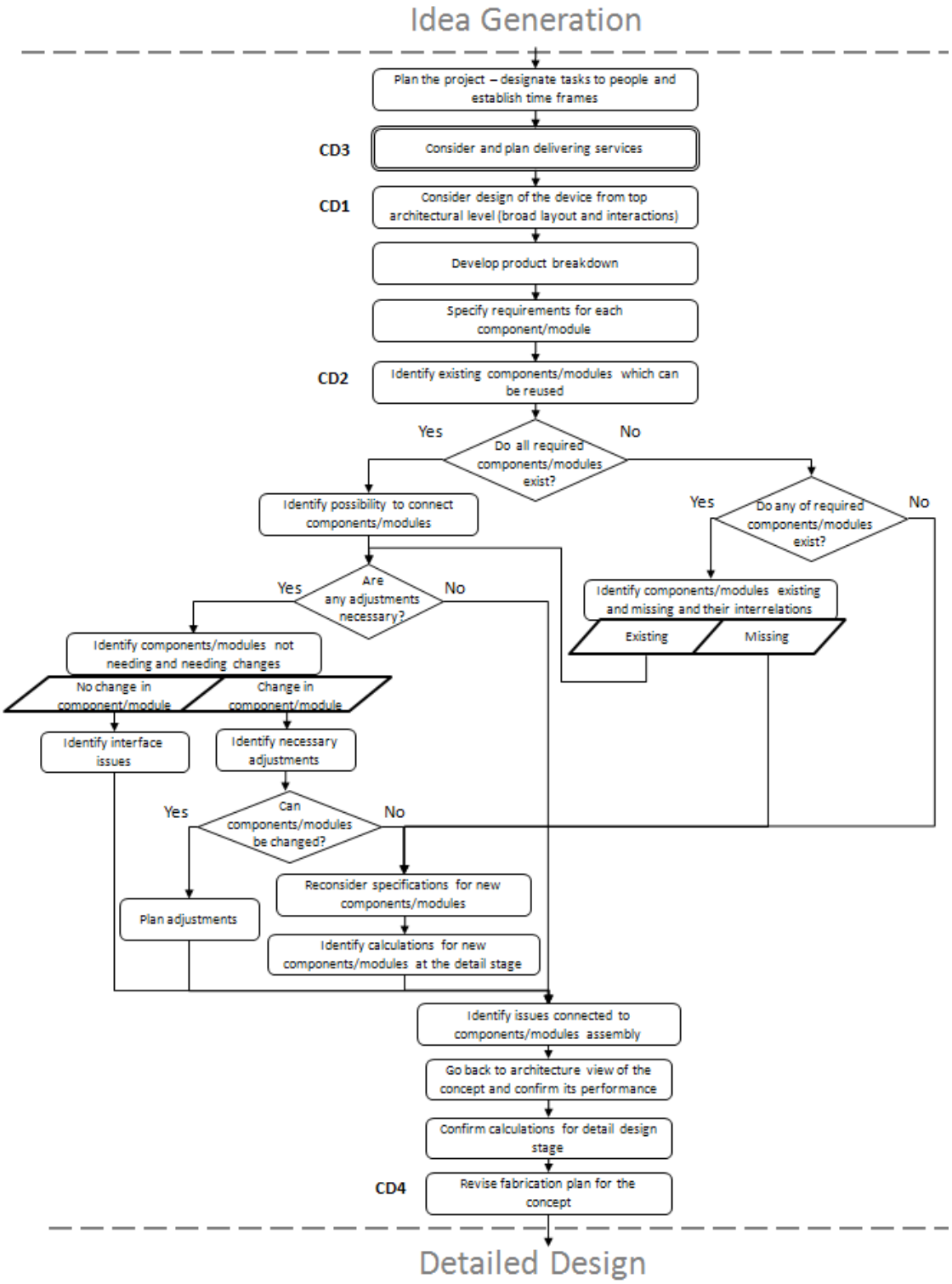


Figure 5-10 Conceptual design stage (CD1-4 are discussed in Section 7.4.3.5)

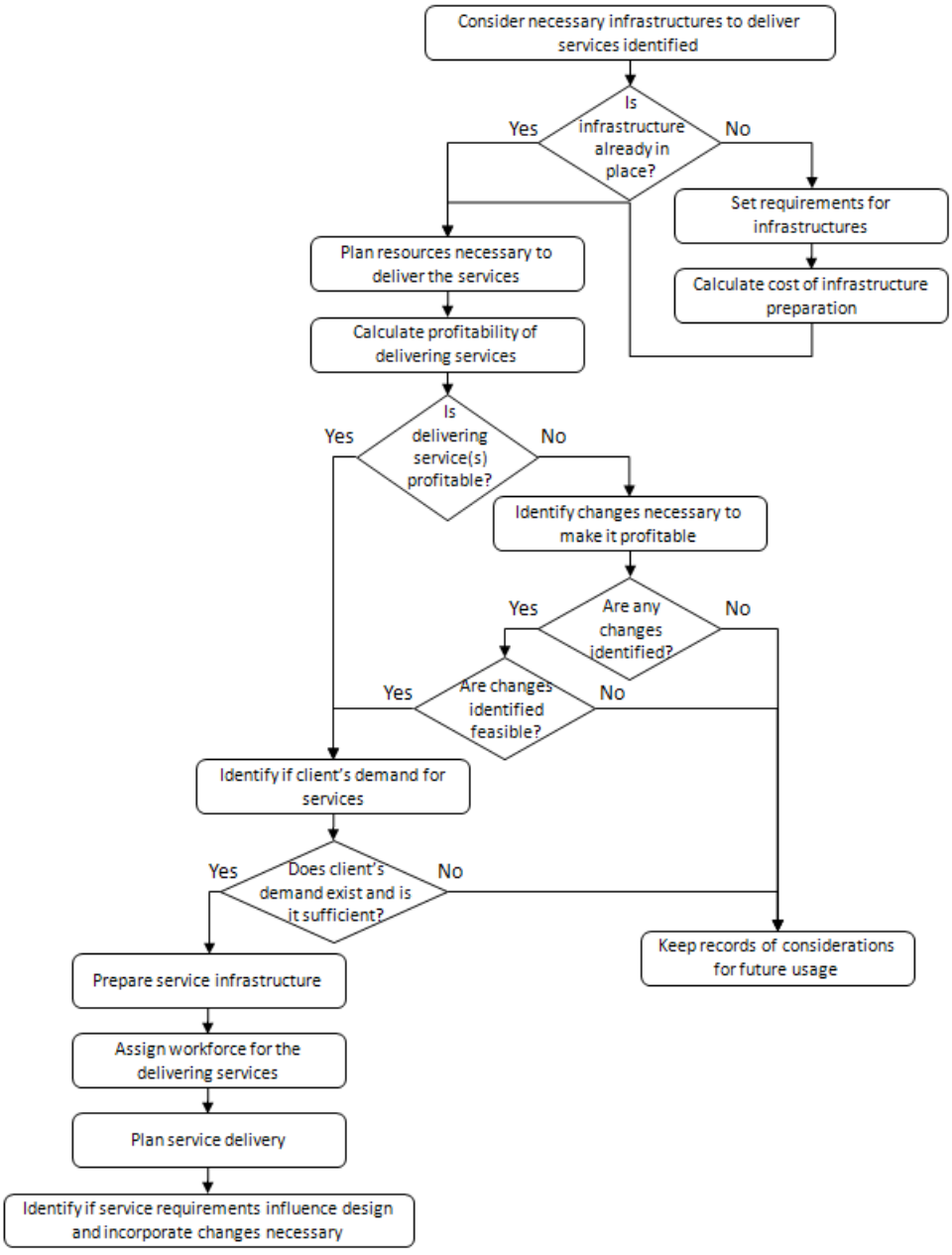


Figure 5-11 Consider and plan delivering service step

Therefore, the step 'revise fabrication plan for the concept' in Figure 5-10 should include:

- Adjustment for the process in comparison to previous stage output,
- Identification of manufacturing method for each component/module,
- Identification of the production scale-up issues,
- Identification of manufacturing facilities able to deliver the products (internal and/or external),

- Identification of manufacturing equipment necessary,
- Identification of materials to be manufactured from,
- Rough identification of process parameters.

If, for any of the components/modules or concepts, manufacturing information is not able to be specified and there is no indication how and from where this data can be obtained, this element is expected to be reconsidered or replaced.

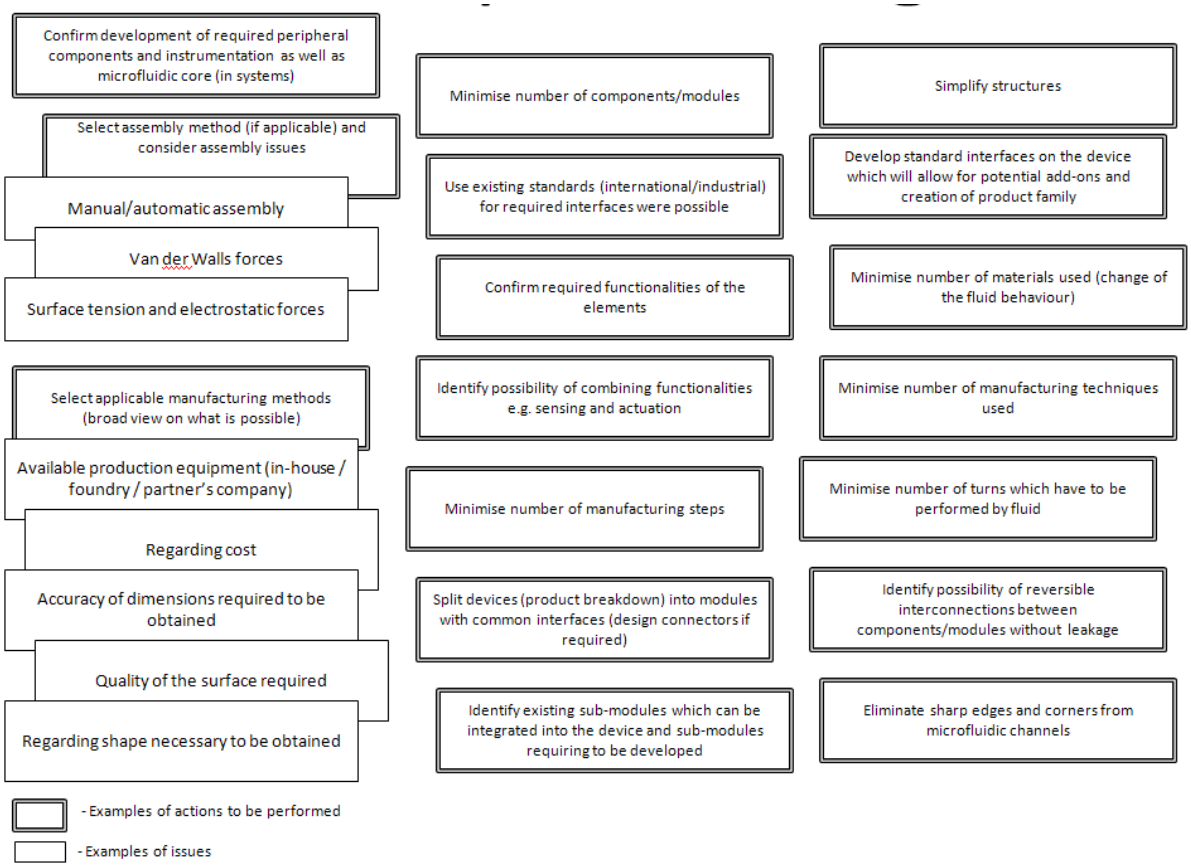


Figure 5-12 Issues to be included in the conceptual stage

In case when in the previous stage – idea generation – two concepts were decided to be progressed with in this stage, they should be approached in an identical manner and upon the outcome, the optimal solution selected using a set of criteria. It is essential that one of the criteria will be manufacturability and also, if applicable, assembly of structures. The remaining criteria are to be decided by the organisation.

5.2.3.6. Detailed Design

The detailed design stage is recommended to be based on a comprehensive calculation of the flows, materials, manufacturing processes and assembly (if applicable). In this step, all data required as the inputs for the modelling, simulation, prototyping and manufacturing (depending on desired outcome) have to be prepared. Figure 5-13 presents the process to be followed in this stage. Methods used for calculations are left to be decided by the organisation as well as the software used. However, the quality of this stage output has to allow for usage of the CAD and CFD systems for modelling of structures and fluid behaviour and, in some cases, simulation. Specific steps depend strongly on the device type and differ based on the functions required from the device. Therefore, they are not described here.

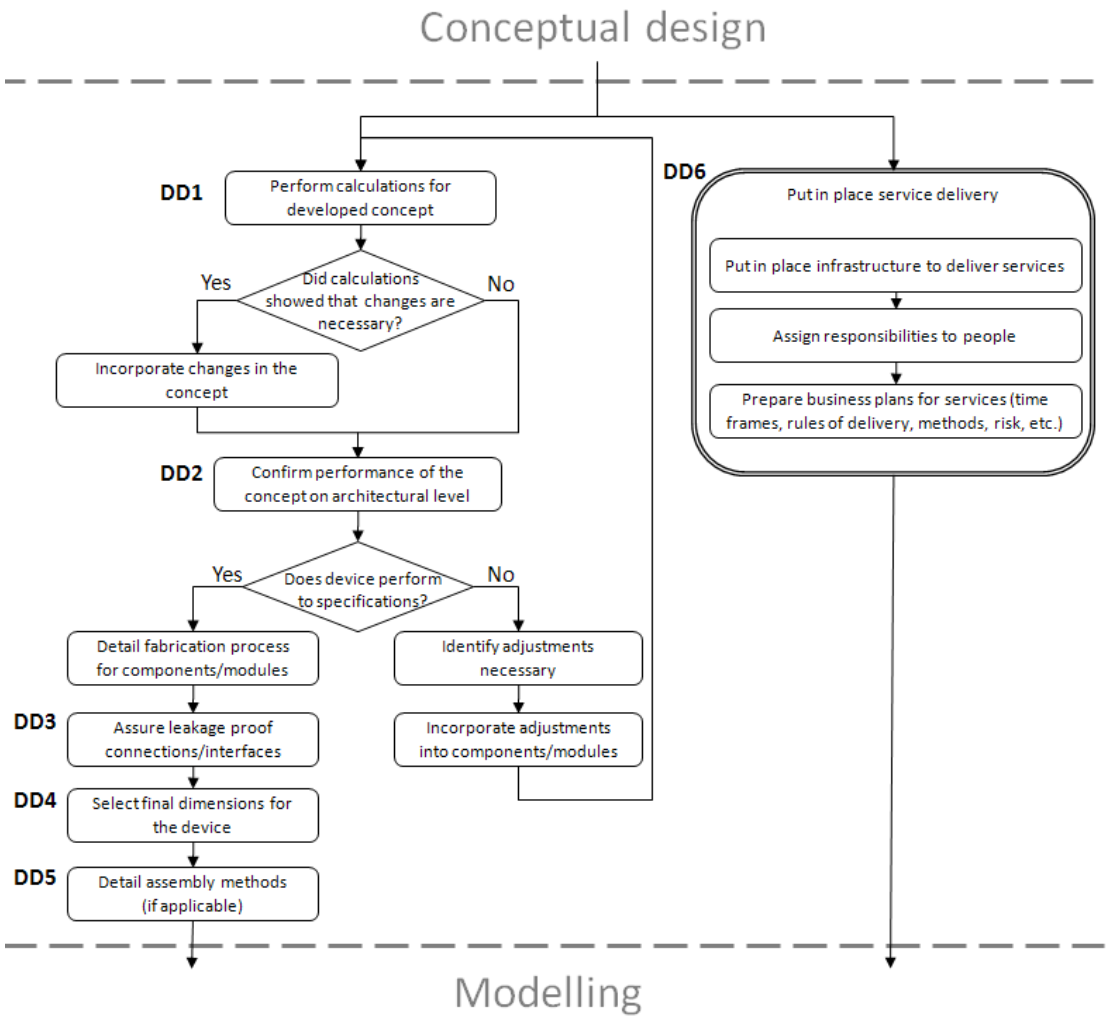


Figure 5-13 Detailed design stages (DD1-6 are discussed in Section 7.4.3.6)

In this stage, no approximation is allowed; all of the requirements have to be met. Also, the fabrication process has to include all the corrections obtained from the calculations performed.

Those members of the project team designated to service considerations are asked to work in close cooperation with the rest of the team and discuss any changes which the services and data obtained can have on the product structure and creation of customer value.

5.2.3.7. Modelling

In this stage, models of the device and the fluid behaviour within it need to be developed. Software used among organisations, and requirements which are imposed by usage of a particular software, vary. Therefore, no unique method for creating models was recommended. Selection of the particular software has, therefore, been left to the organisation to decide upon. In a situation when none of the commercially available software is considered suitable, the development of in-house tools is encouraged. Process to follow for this stage is presented in Figure 5-14.

The following recommendations are made to be incorporated at this stage:

- Model separate components/modules independently.
- Store CAD models and fluid behaviour models in a form which will allow for future reuse.
- Link CAD models with fluid behaviour models to increase dependability of structures.
- Test models as components/modules as well as a whole device model.

The modelling performed can result in a set of actions: simulation or prototyping. Progressing to any of the stages below depends on the complexity of the device designed and the level of knowledge about its basic principle of work. This decision should be made during modelling or before, e.g. when the project is planned, decided by the client. This step is advised to be approached as follows - identify if basic principle of device is fully understood:

- If the device appears simple and its principle of work is understood, the step of simulation of flow behaviour can be omitted and the physical prototyping can be approached.
- If the device and/or project appears complex or is not fully understood, proceed with computational simulation until results are satisfactory for prototype fabrication.

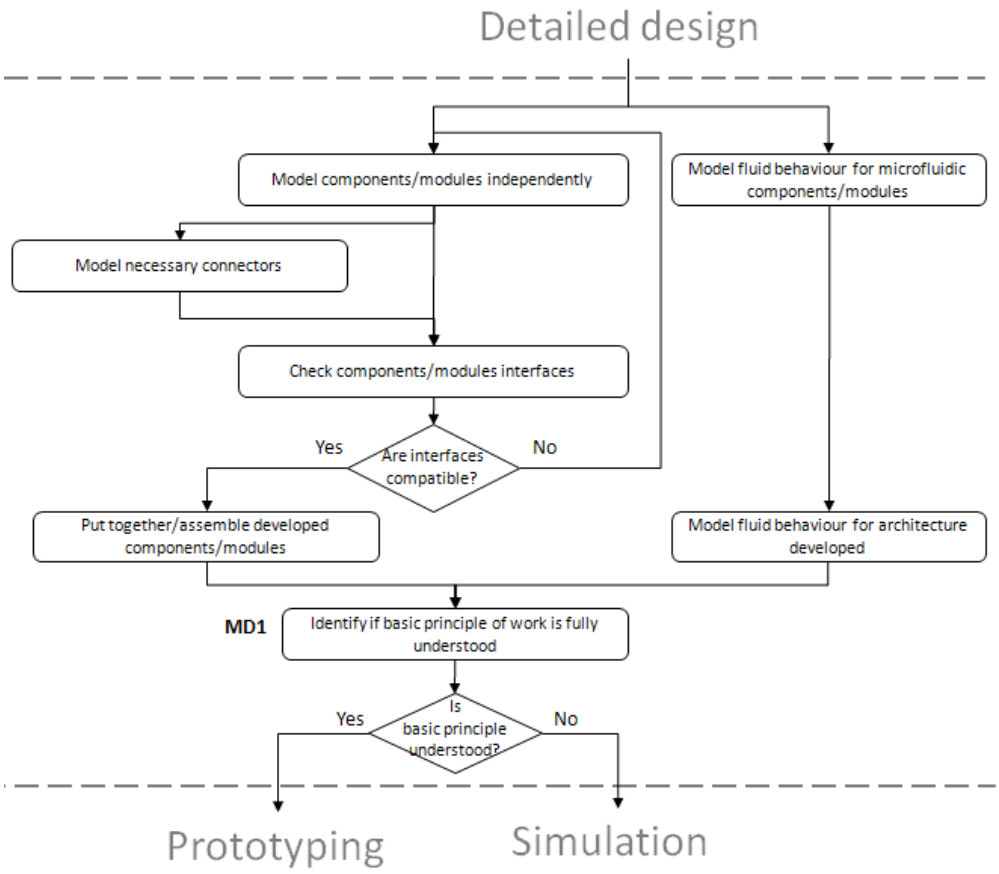


Figure 5-14 Modelling stage (MD1 is discussed in Section 7.4.3.7)

If organisations possess microfluidic modelling capabilities they can offer it as a service increasing their portfolio. Other recommendations regarding service type considerations are narrowed to continuation of actions started at detailed design stage for putting in place service delivery and if organisation develop device which they will commercialised a preparation of the marketing campaign (or execution of it depending on risk incorporated and time till commercialisation).

5.2.3.8. Simulation

Simulation, as modelling, strongly depends on the software used by the organisation. The software selection, as previously, is left for the organisation to decide upon. The type of simulation and whether results obtained are satisfactory in order to proceed with prototyping will depend on the project leader's decision. The only recommendations in this phase are to store simulation models for future reuse and as for modelling in terms of services: to offer possessed capabilities (if any) as a service, continue with putting in place service delivery and/or marketing campaign.

5.2.3.9. Prototyping

An input to the prototyping stage can consist of models with or without simulation results. Information to be used for preparation of the prototype should be systematically collected from the beginning of the concept development. It is suggested that the output from the modelling stage (and simulation results when appropriate) be used to complete the necessary data. Organisations are advised to select the prototyping method and materials to be used based on the capabilities they possess. This necessary stage should be approached in phases. Phases can also include going from basic general prototypes and detailing them during the building process.

Prototypes developed have to be validated and, if they are not meeting requirements, a new prototype should be prepared. Every prototype needs to be validated, with emphasis on the validation of the device as a whole. In some cases the equipment used at the prototyping stage is recommended to be reused in the production process (e.g. wafer of the final prototype) with a view to the production being scaled-up.

Prototyping for other organisations is recommended only when cost of setting-up the equipment is justified (including reconfiguration of the production line to required for own purposes after assign job is finished). Other recommendations regarding service aspects include continuation of tasks undertaken on previous steps

(service delivery, etc.) to be prepared for verification of the device from service point of view.

5.2.3.10. Validation/Verification

Validation and verification (see Figure 5-15) are expected to be performed with regard to specifications and, if development of the device takes a long time, with consideration to the present situation in the market. Confirmation here is sought regarding the existence of a market demand, as previously identified for the device, and details which could change from the moment when project was agreed on till this stage has been reached.

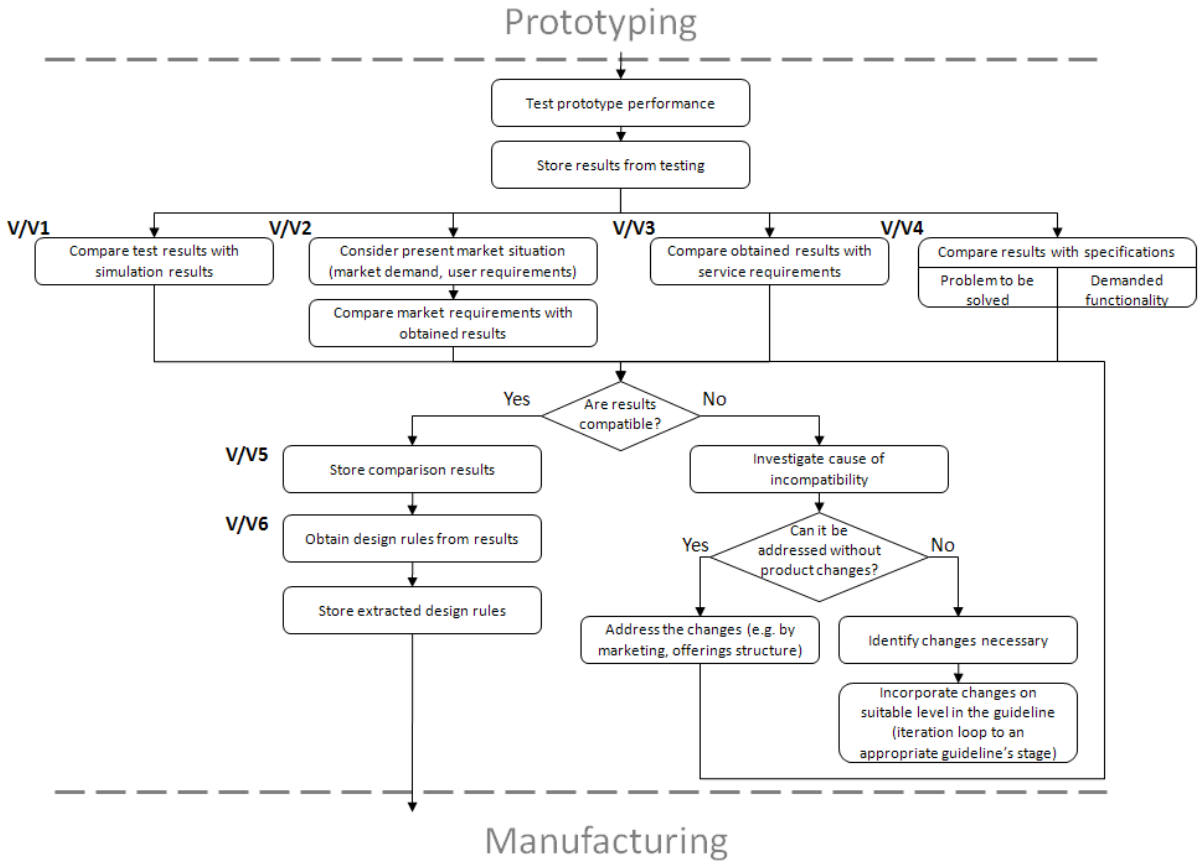


Figure 5-15 Validation/Verification stage (V/V1-6 are discussed in Section 7.4.3.10)

It is imperative for the validation to be based on the prototype prepared in the previous phase. If the simulation stage is performed, the results should be compared with the prototype test results and any differences investigated. Results from testing

are recommended to be stored in a form allowing them to be reused in the database with comments for their interpretation (i.e. putting them in the right context). Also, from the obtained results, design rules should be extracted to be used in the future designs. Design of the product is advised to be verified with a bottom-up approach going from the detail level to the architectural level regarding calculations, mathematical models etc. If the output of design (device) is solving the targeted problem, it is validated successively.

5.2.3.11. Manufacturing

It is necessary to plan the whole manufacturing process in advance and put equipment in place before this stage begins. Where possible, equipment used in prototyping is recommended to be used in manufacturing (see Figure 5-16). In this stage, fabrication should be performed according to the plan and scaling-up production issues resolved – if not resolved previously. They need to be taken into consideration in advance. In the case of devices being manufactured using foundries or partners' facilities, the batch produced should be tested against the required performance and any problems solved.

Unsuccessful results from tests can be obtained for various reasons and all of them need to be properly addressed, e.g. if manufacturing equipment was faulty recommended action to be undertaken could be the change of the equipment or usage of the foundry. The successful output of the guideline usage is considered as delivery (or collection, depending on the agreement) of the manufactured and tested products to the client.

If organisations possess microfluidic manufacturing capabilities they can offer it as a service increasing their portfolio. This service type offering, however, should not collide with fabrication for own purposes and as other offerings be carefully calculated in terms of profitability and risk. Delivery of after sale services to the client is not incorporated in the guideline. It should be done according to the process established in the organisation for particular type of service and in respect to the sign-off contract.

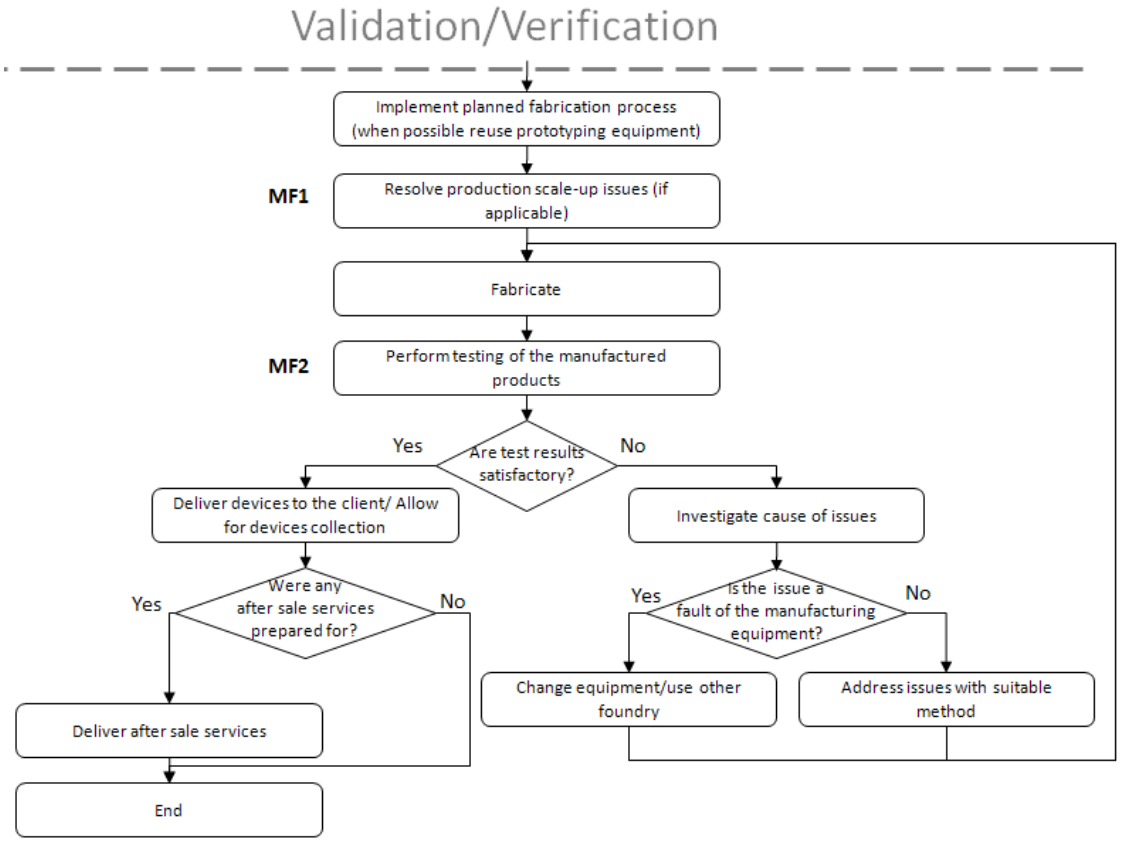


Figure 5-16 Manufacturing stage (MF1-2 are discussed in Section 7.4.3.11)

5.3. Summary

To address issues which microfluidic domain is currently facing and will face in the near future a solution has been developed. This solution consists of two elements: the guideline and design enablers. The guideline for service-oriented (Section 7.4.2) design of microfluidic devices that can deal with sub-section interactions (Section 7.4.3) is the core element and direct result of realisation of the research aim when the set of design enablers is being a result of partial adoption of the grounded theory in methodological approach.

To assure comprehensive exploration of the domain and development of a suitable approach for it, a methodology has been established. Partially based on the grounded theory, the developed methodological approach aims to systematise work and select the best method for data collection and analysis based on the concepts emerging from data.

The core element of the solution – the guideline has been developed at two levels: Level 0 – which presents the overview on the guideline and Level 1 which details the stages. The Level 0 guideline incorporates 10 obligatory and one additional stages. It presents a top-down approach to design with bottom-up verification incorporated inside one of the stages. It underlines the importance of manufacturing as driving force in the process and of constant comparison with specifications to meet the objectives. The guideline incorporates the theme 'DO NOT design solutions for NON EXISTENT problems. There are already too many of them' underlying the main DO/DO NOT in microfluidic design. It also presents iteration loops.

Regarding the number of issues necessary to be included in microfluidic design and issues faced by designers, the guideline has been extended by a set of design enablers. This set is proposing a list of recommendations to be followed across the microfluidics projects' realisation to improve organisations' performance.

The issues connected to the design enablers can be observed inside the stages of the guideline. Each stage is presented from the point of view of considerations which need to be incorporated and tasks which have to be undertaken. Visualisation has been approached using decision making process diagrams and graphical aids. Each stage as well as the overview of the guideline has been concisely developed, considering application difficulties which can be faced by potential users.

Chapter 6
Validation

Having developed the solution to address issues faced by microfluidic design, the next step is to evaluate its appropriateness for the area and representation of crucial aspects. A multiple validation approach for testing of the solution presented in Chapter 5 and discussed in Chapter 7 is described in this chapter.

This chapter presents (see Figure 6-1) the approach to validation, followed by the results of applied testing and their discussion. The validation has been approached in two stages: validation of the investigation findings (results from the data collection and analysis) and validation of the proposed solution (the guideline and design enablers). Validation by experts has been used as a basis for both stages, as well as structured questionnaires as a feedback source. Moreover, the validation of the solution has been undertaken in multiple ways. In addition to the mentioned feedback source and technique, it incorporated validation sessions and comparative analysis for the core element of the proposed solution – the guideline for service oriented design of microfluidic devices that can deal with sub-section interactions. This analysis has been based on comparison with existing models from literature and practitioners' work.

The results of these validation attempts are presented and discussed here. Furthermore, the discussion incorporates, where identified, necessary adjustments of the solution based on obtained feedback. These adjustments are elaborated for their suitability and benefits, and have been incorporated in the solution presented in Chapter 5.

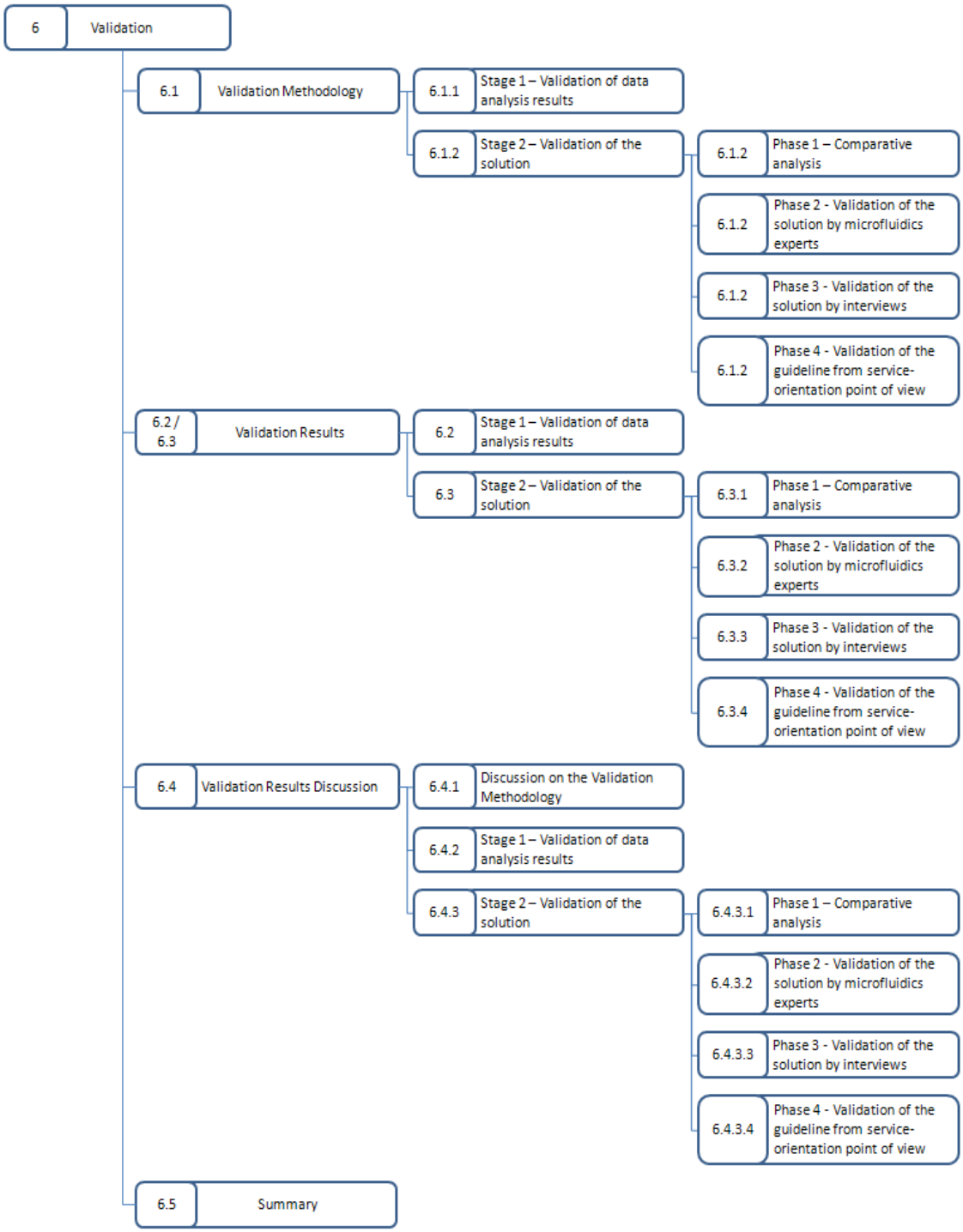


Figure 6-1 Validation Chapter structure

6.1. Validation Methodology

Validation of the research has been carried out in two stages: validation of the findings obtained from literature and practitioners' work analysis, and validation of

the developed solution. The first validation stage, Stage 1, aspired to assure quality of the information used to develop a solution for the domain's issues, while the second, Stage 2, to validate this solution. For the usage of the grounded theory as a partial methodological approach and hence, emergence of the solution directly from the 'data', the quality of solution has been considered crucial.

This section presents both validation attempts as prepared and performed. It highlights details regarding the arrangements and participants involved, giving the rationale behind the steps. Discussion of the validation approach presented and its limitations is given in section 6.4.1.

6.1.1. Stage 1 - Validation of Data Analysis Results

The first stage of the validation approach is a validation of data analysis results by participants of the study. This validation aspired to confirm findings regarding microfluidic design with practitioners, to assure the quality of the solution.

Pure results (without discussion etc.) were sent to participants of the study to obtain feedback regarding any irregularities. Results were sent on Tuesday 02/03/2010 via email to 12 participants. They were prepared as a set of PowerPoint presentations. The set consisted of 5 parts:

- 1 – Design processes
- 2 – Problem identification and requirements clarification
- 3 – Developing the concept
- 4 – From models to products in the market
- 5 – Domain characteristics in terms of design and its future

One month was given to the participants to give the feedback regarding the presented findings. The feedback obtained did not show any irregularities in the study. However, some points considered important were noted.

Only three participants replied back to the author with the feedback regarding the analysis results. The feedback obtained is presented in section 2 of this chapter. Lack of contact from other respondents has been interpreted as a confirmation that no

major mistakes were identified in the sent documents, and that the work on guideline development could be undertaken fully.

6.1.2. Stage 2 - Validation of the Solution

The second stage of the validation approach, Stage 2, is the validation of the proposed solution. Considering resources available for the project performing the 'ideal validation' has been viewed not feasible. This validation has been estimated as taking more than 3 years which were available for the project. It has been identified as implementation of the solution on a new device design process, starting from problem identification and finishing with product's end-of-life, if not disposal (for the guideline). This implementation should be performed in organisation commercialising microfluidics not only on the theoretical basis. Moreover, it should not only follow one single device, but a number of them, incorporating number of application to a specific type of microfluidic device, as well as various types (for the guideline and design enablers) to allow for identification of the market acceptance of developed products, and design process automation and standardisation achieved in the organisation. Based on the lack of perspective to perform described validation, other methods have been applied, which incorporate multiple validation sources.

The validation of the solution was performed in 4 phases:

1. Validation of the guideline by comparative analysis
2. Validation of the solution by microfluidic experts via feedback forms
3. Validation of the solution by microfluidic experts via interviews
4. Validation of the guideline from service point of view

Please note that the respondents, during the evaluation process for phases 2 and 3, were asked to evaluate 'the guideline', which consists of the guideline with design enablers. Therefore, their statements about 'the guideline' have been used as evaluation of the solution. This terminology has been clarified and adjustments made in the thesis. Therefore, every time the guideline is mentioned in the main body of the thesis, the author is referring to the core part of the developed solution - not including design enablers.

To allow the reader to obtain a real view on how the research has been approached, the authentic versions of the document, presenting the solution for validation (Appendix 7.1) and the feedback forms (Appendix 7.2) with motivation behind used questions (Appendix 7.3), are attached.

The design enablers have been eliminated from two validation attempts - phases 1 and 4. Restriction of the validation only to the core element of the solution – the guideline - has been deliberated. Elimination of the design enablers from a comparative approach has been based on the lack of equivalents indentified in the area. Elements directly corresponding to the design enablers (in the same way as models correspond to the guideline) were not recognised. Elimination from the validation regarding the service-orientation aspect has been a result of prioritisation used, considering restricted time available for validation sessions. Priority has been given to the guideline as a process to follow, and even the guideline itself has been reduced to highlighting only service-aspects incorporated. Details of used approaches for all phases for the validation of the solution and its elements are given in appropriate parts of this section.

Phase 1 - Validation of the Guideline by Comparative Analysis

The first step of the solution's validation has been performed by the author. It has been based on comparative analysis of the guideline with existing models identified as applicable for microfluidics and used by microfluidic practitioners. This comparison has been divided into three parts. The first part consisted of comparing it with literature models, then with models obtained from the survey results and, finally, with models obtained from the interviews. Comparative analysis has been approached by underlying differences and commonalities among the solution and the models. To increase clarity of the comparison, each model has been compared to the guideline separately. Although no other person was involved at this stage, the results have been consulted with supervisors. Results of this assessment are presented in section 2 of this chapter.

Phase 2 - Validation of the Solution by Microfluidic Experts via Feedback Forms

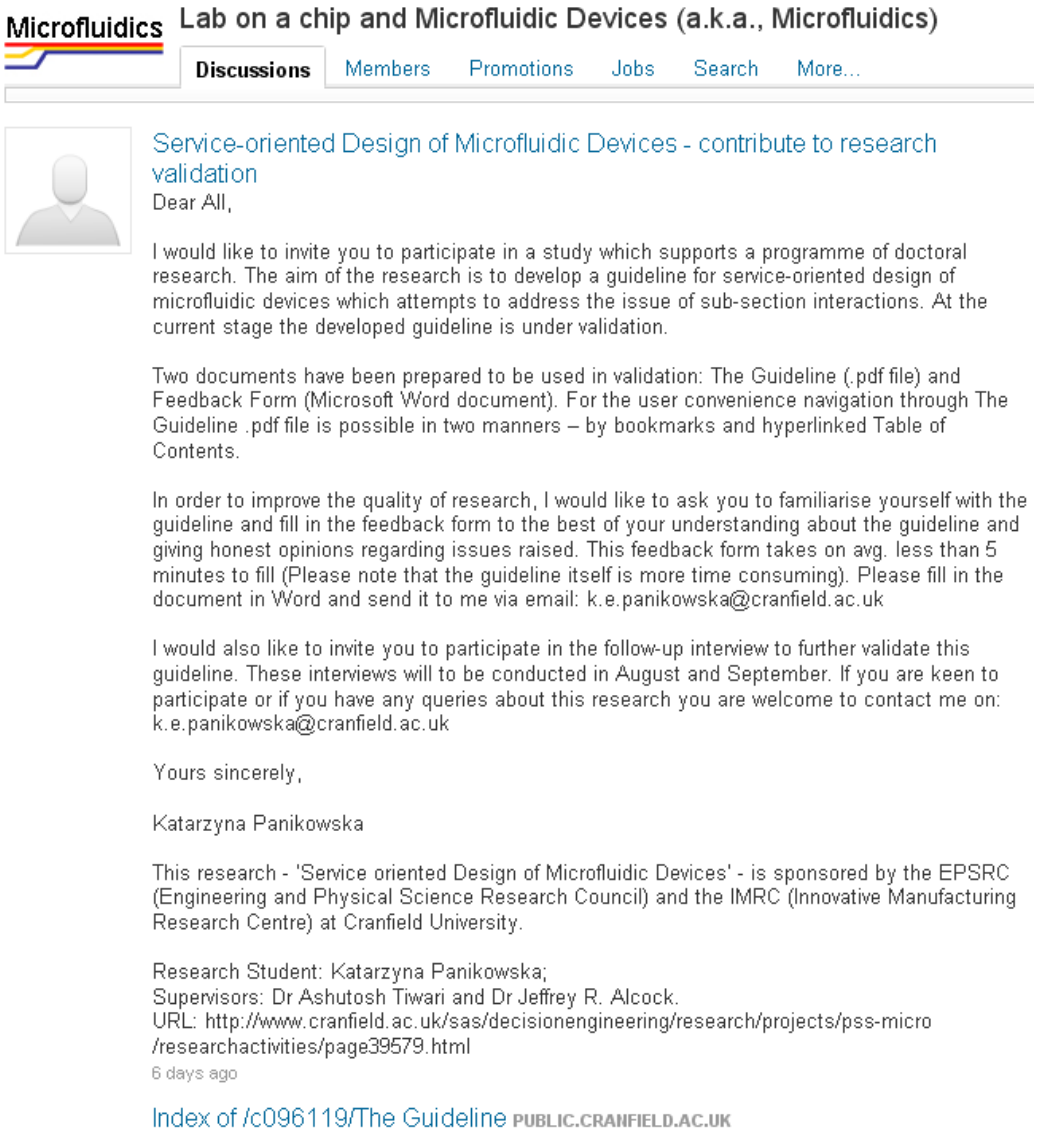
The prepared solution was sent as a .pdf file to the microfluidic practitioners for validation. The file was sent via email to seven respondents, five of whom were the interview participants; it was sent on 30th July 2010. In addition to the solution, a feedback form document was attached. This document, prepared using Microsoft Word, contained two feedback forms – The Solution's Feedback Form and The Solution's Validation Form (see Attachment 7.1). The Solution's Feedback Form consisted of open questions requiring experts' opinion on the solution's context, while The Solution's Validation Form consisted of closed questions aiming to evaluate the solution in a quantitative manner.

The feedback forms were prepared considering the following main issues:

- Minimise time for respondents to fill the form.
- Capture main issues raised by the work presented.
- Maximise the output to be captured – quality of responses and its influence on the work presented.

The first validation attempt (seven potential respondents) has been based on presentation of the solution and attached feedback form. Following a recommendation from one of the participants, the author used the website of the European Technology Platform for Micro- and NanoManufacturing (MINAM) for further guideline popularisation. At that time the author did not possess the MINAM membership; therefore, the mentioned participant placed prepared documents with a short message in the MINAM newsletter. In this manner, the solution was sent to over 600 members of the micro- and nano- community on 23rd August 2010.

Due to limited feedback obtained from respondents, the solution has been dissemination for validation also by LinkedIn microfluidic group. Figure 6-2 presents the message prepared and placed in the portal on 25th August 2010. This message incorporated links to the solution and the feedback form documents placed on the university server.


Microfluidics Lab on a chip and Microfluidic Devices (a.k.a., Microfluidics)

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Service-oriented Design of Microfluidic Devices - contribute to research validation

Dear All,

I would like to invite you to participate in a study which supports a programme of doctoral research. The aim of the research is to develop a guideline for service-oriented design of microfluidic devices which attempts to address the issue of sub-section interactions. At the current stage the developed guideline is under validation.

Two documents have been prepared to be used in validation: The Guideline (.pdf file) and Feedback Form (Microsoft Word document). For the user convenience navigation through The Guideline .pdf file is possible in two manners – by bookmarks and hyperlinked Table of Contents.

In order to improve the quality of research, I would like to ask you to familiarise yourself with the guideline and fill in the feedback form to the best of your understanding about the guideline and giving honest opinions regarding issues raised. This feedback form takes on avg. less than 5 minutes to fill (Please note that the guideline itself is more time consuming). Please fill in the document in Word and send it to me via email: k.e.panikowska@cranfield.ac.uk

I would also like to invite you to participate in the follow-up interview to further validate this guideline. These interviews will to be conducted in August and September. If you are keen to participate or if you have any queries about this research you are welcome to contact me on: k.e.panikowska@cranfield.ac.uk

Yours sincerely,

Katarzyna Panikowska

This research - 'Service oriented Design of Microfluidic Devices' - is sponsored by the EPSRC (Engineering and Physical Science Research Council) and the IMRC (Innovative Manufacturing Research Centre) at Cranfield University.

Research Student: Katarzyna Panikowska;
Supervisors: Dr Ashutosh Tiwari and Dr Jeffrey R. Alcock.
URL: http://www.cranfield.ac.uk/sas/decisionengineering/research/projects/pss-micro/researchactivities/page39579.html

6 days ago

Index of /c096119/The Guideline PUBLIC.CRANFIELD.AC.UK

Figure 6-2 Dissemination of the guideline for validation via LinkedIn

The analysis of obtained feedback from this validation phase has been undertaken by preparation of an excel file. The file has been prepared in the form of three Excel spreadsheets: for results from Feedback Forms, for results from Evaluation Form and for additional questions. The headers incorporated in the particular spreadsheets, and used as a base for analysis, are presented in Tables 6-1 – 6-3.

Table 6-1 Feedback Forms' analysis spreadsheet

No.	Date	Name	Name of organisation	Type of organisation	Questions

Table 6-2 Evaluation Forms' analysis spreadsheet

No.	Name	Name of organisation	Type of organisation	Questions

Table 6-3 Additional questions' analysis spreadsheet

No.	Name	Question - Date	Question	Answer - Date	Answer

Additional feedback was obtained via email from respondents, trying to clarify issues incorporated in the solution to obtain a better understanding. It was decided to document the specifics of some of the questions and their relevance for the solution's quality. The author kept records of all questions and provided answers to minimise bias - e.g. by selection of only positive statements regarding the solution. All records have been dated to allow for tracking back the issues. A record of the answers on raised issues has been kept to speed-up the work of incorporating improvements in the solution after its evaluation, by providing clarification/changes if/when necessary. This minimised the amount of work to be performed at a later stage by elimination of duplication, and provided an approach similar to memoing[16] in tabular form.

In addition, answers regarding topics covered in the feedback forms have been incorporated from the interviews, which have been conducted as Phase 3 of the validation. This allowed the author to obtain, in total, eight feedbacks from microfluidic design experts on the proposed solution. Results of this validation attempt are presented in point 3.2 and discussed in Section 6.4.2.

Phase 3 - Validation of the Solution by Microfluidic Experts via Interviews

An additional validation by microfluidic designers has been sought to obtain their view on the solution. Selection of this approach has been based on a number of factors:

- Assure the solution's evaluation by microfluidic practitioners – uncertainty of obtaining feedback forms on time.

[16] is a process of writing a short description of the ideas about codes and their relationships which appear when coding and analysing (Glaser & Strauss, 1967)(see Section 3.1.4)

- Assure validation from academic and industrial perspective – possibility to compare both views on the developed solution.
- Opportunity to investigate issues in detail while answering validation feedback forms question set.

To ensure multiple validation approaches used for the research, one participant from each area (academia and industry) was viewed as a sufficient number for the interviews. Both interviews were conducted via phone to minimise invested resources (cost and time, e.g. transport) – interviews were conducted on 26th and 28th October 2010. Equipment used included: speakerphone (loudspeaker function), digital recorder and notepad. Recording has been used only for confirmation purposes. A list of questions from the feedback form has been expanded by the list attached in Appendix 7.4, which also provides rationale for each question.

An analysis of the interviews has been approached in a systematic manner. After each interview, the recordings have been transcribed to Word document and compared with notes taken manually. Results from interviews have been compared, and data covering validation feedback forms have been incorporated into the dataset for Phase 2 of validation. Responses given for the additional questions have been analysed separately by identification of common aspects, similarities and differences as in the analysis of the survey and interviews results from the research data collection stages (see Sections: 3.3.3.3 and 3.3.3.4). Results obtained in this manner are presented in Section 6.3.3.

Phase 4 - Validation of the Guideline from Service Point of View

The last phase of the solution's validation has also been focused on the core part of the solution – the guideline. The design enablers have been omitted in this phase due to limited time available for presentation and as a result of prioritisation of the aspects considered as core for the solution.

The service-orientation has been selected as the aspect to be validated due to the availability of experts in the service domain to participate in the study and the lack of expertise in this domain possessed by microfluidic designers. However, one

expert from the microfluidic domain was invited to participate in one of the sessions. This allowed the author to see if the amount of service-orientation incorporated in the solution can be considered as acceptable based on the area's characteristics.

The validation was approached in two identical one hour sessions. The first session took place on 27th August 2010 at 14:00 with seven participants, and the second on 2nd September 2010 at 15:00 which involved three attendees. The following agenda was prepared for both sessions:

1. Presentation (30-45 min.):

- Introduction to research:
    - Microfluidics – what it is
    - Microfluidic characteristics in design
    - Service-orientation
    - Think services – current practice in microfluidics
- The guideline
- Questions and Answers

2. Feedback (5-10 min.):

- Service-orientation of the Guideline Evaluation Form

The following topics were selected for presentation:

- Introduction to research – Due to the limited knowledge of the participants about the microfluidic domain, the context of the research and the developed approach was incorporated into the presentation by providing background information. To minimise time spent on the introduction and maximise the guideline presentation, four main topics were presented:
    - Definition of microfluidics – majority of participants were not specialised in microfluidics

    - Microfluidic characteristics in design – majority of participants lacked experience in design of microfluidic devices
    - Service-orientation – provide the context for the guideline – represent what service-orientation means in the research conducted
    - Current state of services and service-considerations in microfluidic domain – presentation of the current state of the domain aimed to place the guideline in context of what issues need to be addressed
- The guideline – Due to the limited time available and limited knowledge about microfluidics within the session participants, the guideline was presented only from a service point of view. This minimised time used for the session and provided focus for the experts on aspects which they were competent to validate.
- Questions and Answers – this time was allocated to explain any issues which required clarification, in case of participants not asking questions during the presentation. Many aspects of the guideline showed potential to catch participants' attention.
- Feedback – Regarding the specifics of validation – from a service point of view – a new feedback form suitable for it was prepared. This aimed to capture expertise of the participants regarding the service-orientation of the guideline and any additional improvement to be incorporated.

The above mentioned feedback form can be found in Appendix 7.5 with rationale behind the questions used in it. Time to fill it in was estimated at approximately 5-10 minutes due to its length and the nature (difficulty level) of the questions incorporated.

An analysis of the data obtained from the guideline validation, from a service point of view, was undertaken using an excel file. The headings from the spreadsheet used for data input are presented in Table 6-4. Data have been input systematically after each session.

Table 6-4 Service-orientation of the Guideline Feedback Forms analysis spreadsheet

No.	Name	Organisation	Professional Activity	Service expertise	Questions

Since the majority of the questions in validation were qualitative, the analysis started from quantitative data. In this manner, an overall score of the guideline has been obtained for which other responses provided rationale. Qualitative analysis has been approached on a question by question basis, without identification of respondents. This type of analysis attempted to increase validation accuracy by elimination of the influence of the positive or negative attitude of the respondent towards presented guideline. In this manner, the core issues raised have been separated and all issues identified have been listed. If any issues were repeated, they were marked as of high importance and moved towards top of the list. This allowed identification of aspects of the guideline which could be improved and could mature the framework. When all questions were analysed, the analysis was repeated on a respondents' basis, based on their background and attitude towards the guideline. This analysis provided explanation of the probable rationale behind particular statements (positive and negative) about the presented approach. Results from this validation phase are presented in Section 6.3.4.

6.2. Stage 1 Results – Validation of Data Analysis Results

Obtained feedback regarding the result of the data analysis consisted of three responses. Two respondents viewed the presented information as interesting and confirming their views. One respondent contradicted the obtained results as overly complicated, giving an example of his/her organisation's work when designing microfluidics.

Summary of obtained feedback includes:

- Condensed information is needed ("to be understood by people and influence their decisions about what they do") – the most important issues need to be highlighted in the solution to be developed.

- Design of microfluidics is presented in a more difficult way than in reality – contradiction with organisation's own process to develop polymer microfluidics or MEMS, considered as fast and pragmatic since 1996, consisting of:
    - Option 1 – customer orders - "I would like to have", brainstorming (e.g. short text via email), development of microfluidic system, sending the drawing for approval and sending parts the customer needs.
    - Option 2 – an online order via organisation's website, "my quote", sending in sketch or detailed 3D CAD (or even combination between electronic layout eCAD or CAD and 3D CAD is possible for fluidics with integrated "intelligence").
- The study clearly points out the high potential of microfluidics - but also the main challenges in lab-on-a-chip (LOC) development and commercialisation.
- The study confirms - in general, respondent's own argumentation, while providing extensive background information.

Views on how these results have been used are presented, together with their discussion, in Section 6.4.2.

6.3. Stage 2 Results – Validation of the Solution

6.3.1. Phase 1 - The Guideline vs. Microfluidic Design Models

Lack of formal methodologies identified for development of microfluidic devices, and limitations of models existing in the micro-domain generate the requirement to enhance design in this area. To address the issue, a solution has been proposed, which has been presented in Chapter 5. The proposed solution consists of two elements: the guideline and design enablers. The solution is trying to address the issues which are considered crucial for microfluidics, and are missing in existing approaches. The guideline, as the core element of the solution, presents a design process which is proposed as an alternative for insufficient models existing in the

area. To underline the advantages of the guideline in comparison to existing approaches, a discussion is presented below.

The design enablers were not compared with existing input from the models due to limited presence of any information available. Information present in the literature and practitioners work has been used to develop the enablers, as well as identify gaps and methods used to fulfil them. Therefore, no comparison in this matter will be beneficial for the reader, since the discussion of the design enablers is available in Section 7.2.2.

The presented comparison is divided into three parts: with literature models, with models obtained via survey and with models obtained via interviews. In all three cases, similarities and differences are highlighted to provide better understanding of the guideline contribution. Each model is compared to the guideline individually, to provide better clarity.

6.3.1.1. Guideline as Compared to Literature Models

Literature models considered most suitable for microfluidics based on domain characteristics (Section 2.1.5) are: the sickle model (Section 2.1.2), the V model (Section 2.1.2) and 'top-down' methodology (Section 2.1.3). All three models influenced shape of the guideline. Moreover, information contained in the models and their basic principles were also applied for its development. Results of the models compared to the guideline are given in Table 6-5 and discussed in Section 6.4.3.1.

Table 6-5 Comparative analysis of the guideline with literature models

Characteristics/Model	Sickle model	V-model	'top down' methodology	The guideline
Designing and detailing	Indicated by sickle shape	Indicated in V-shape	Clear split on levels	Indicated by arrow on right hand side of the Level 0
User-friendliness	Theoretical approach, not ready for application	Theoretical approach, clear	Pragmatic, not clear in some details	Easily understood and possible to be applied
Approach (Top-down, Bottom-up, unstructured, structured)	Top-down + Bottom-up, roughly structured	Top-down, structured	Top-down, highly structured	Top-down design with bottom-up verification recommended; structured
Level of methodology (amount of details)	General	General	Relatively detailed and structured	Multi-level, general as well as relatively detailed and structured
Service-orientation in design	-	-	-	Incorporated
Principle of work	Sickle transition from conceptual stage, through basic design to concrete detailed design, with incorporation of abstraction levels	Iterative development of design object contains multi-domain elements, between the concept and detailed stages	Incorporation of detail information about elements of the device, starts from protocols and by incorporation of architectural and geometrical synthesis leads to manufacturing of the object	Follows design steps on high level (Level 0) and decision making processes with indicated considerations on each stage of detail level (Level 1)
Levels of abstraction	Replace by combination of hierarchical levels with detailing and design phases	-	-	Overall indication of transferring from architecture to detailed level by arrow on right hand side of the Level 0 diagram
Iteration	Yes	Yes	Loop incorporated into the process	Loops incorporated into the process
Input	System of Objectives (no	Requirements (no indication	Protocols defined by device	Customer input, market

	indication how to obtain it)	how to obtain them)	users	demand, Project brief
Output	Design ready for fabrication	Reengineering after product recycling	Design ready for fabrication	Vary from design, through simulation results, prototype to manufactured products and possible services
Number of steps	N/A	Not indicated	14 plus iterations	10 obligatory + 1 circumstantial
Direction of the design flow	Sickle	Straight forward with iteration on the design stage	Flow-chart	Flow-chart with graphical aids (arrows, funnels, loops)
Type of methodology (part of the PLC - Product Life Cycle- represented)	Design stage	PLC, end-to-end	End-to-end without product afterlife	End-to-end without product afterlife stages but with add-on considerations and services to be offered after commercialisation
Consideration of technology	Through process preparation	Explicit, late	-	Explicit, early
Validation	Outside circle reached through all levels of the product architecture	Cause of iteration, centre of the process, lack of verification after assembly	Divided into stages: Built-in Self-test (BIST) and physical verification	Stage of the guideline, certain information is validated at every stage by constant comparison with specifications
Prototyping	Outside circle reached through all levels of the product architecture	-	As physical verification stage	Stage of the guideline with data/information feeding in from the idea generation
Design support tools	-	-	Identified	Recommended
Dependence on the software	-	-	High	Low-high (recommended development of aids)

6.3.1.2. The Guideline as Compared with Practitioners Work

For practitioner work, as for literature, no general design models have been identified as existing in the domain (Section 4.1). Therefore, the models have been extracted from practitioners' responses in the survey and based on the answers from interviews. Due to different levels of detail incorporated in the models, comparison with the guideline has been divided accordingly between models obtained from the survey and from interviews. Results of comparisons are presented in Table 6-6 for the survey and Table 6-7 for the interviews, and discussed consequently in Section 4.3.1 subsection B.

Table 6-6 The guideline as compared with practitioners work – models obtained via survey

Characteristics/Model	The guideline	Model 1	Model 2	Model 3
Type of methodology (part of the PLC represented)	End-to-end without product afterlife stages, but with add-on considerations and services to be offered after commercialisation	End-to-end without product afterlife stages	Design steps missing	Design steps missing
Level of details across the model	Constant	Irregular	Very high level	Irregular
Testing	Based on prototyping, simulation when justified	FEA/CFD tools	By design iterations	Last step based on build
Iteration	Yes	-	Yes	Yes
Input	Customer input, market demand, Project brief	Client's needs	-	Basic chemical understanding
Output	Vary from design, through simulation results, prototype to manufactured products and possible services	Verified design sent to fabrication or fabricated	-	Built and tested device
Approach to design	Recommended modular; however, monolithic also enabled	-	Modular	-

Table 6-7 The guideline as compared with practitioners work – models obtained via interviews

Characteristics/Model	The guideline	Model 1	Model 2	Model 3	Model 4	Model 5
Problem identification	Crucial	Crucial	First step	First step	First step	First step
Searching for true demand	Identification of problem and functionality demanded	Identification of problem and functionality demanded	-	-	Functionality	-
Customer requirements capturing document	Project brief	Brief document	Protocols	-	-	-
Techniques to be used	Indicated and recommended	Pointed out	-	-	-	-
Evaluation of the design	Mainly based on prototype testing, comparison with specifications, simulation when justified and market	Prototype	Prototype	-	Testing the performance of elements, followed by building blocks and whole device; prototyping and	Testing unit operations, network dependencies, testing of the first series

	demand				simulation when required ; evaluation by customer	
Microfluidics not to be forced	Explicitly stated	Implicitly incorporated	Explicitly stated	-	-	-
Process generality	General	General	Case specific	General	General	General
Approach to design	Recommended modular; monolithic also enabled	Modular / monolithic	Modular	-	Modular	Modular
Number of prototypes	Single/Multiple	-	Multiple	-	-	-
Customer involvement	Case dependent	Only at the beginning	On two stages	-	Two stages	-
Level of technicality	Low to medium	Low	Low to medium	High	Low	Low
Informality in discussions	Recommended	-	-	-	Incorporated	-
Knowledge reuse	Yes	-	-	-	Yes	Yes
Fabrication considerations	Early stages	Early stage	Early/medium stage	Half way through the process	Half way through the process	Half way through the process
Production scaling-up	Yes	-	-	-	Yes	Yes
Constant comparison with specifications	Yes	-	-	-	-	Yes

6.3.2. Phase 2 - Validation of the Solution by Microfluidic Experts

Results from the solution's validation by microfluidic experts, through feedback form, are provided below. They have been obtained in a quantitative and qualitative manner. First, the quantitative results are given (Section 6.3.2.1) as an overall evaluation of the solution proposed, and its presentation and structure. Next, the qualitative feedback regarding the solution's context and its suitability (Section 6.3.2.2) are presented following the structure of the feedback forms.

6.3.2.1. Quantitative Validation Results

Respondents validated the solution in a quantitative manner using the nine-statement feedback form. Results of this validation are presented below. Usage of the five-step scoring allowed the author to provide a range of degrees to which respondents agree with statements and, at the same time, an opportunity for them to be neutral (score 3). Based on the given scoring, from one as strong agreement to five as strong disagreement, average results have been obtained. These results have been categorised in two groups, according to the topic to which statements relate: structure and an overview.

Table 6-8 Quantitative results of validation of the solution by microfluidic experts through feedback forms

Regarding	Statement/Score	Average	Lowest	Highest
The structure of the solution	The solution is presented clearly	1.6	3	1
	The solution is easy to follow	1.75	3	1
	The length (number of stages) of the solution is appropriate	2.38	5	1
The solution as a whole (structure plus context)	The content of the solution met my expectations / needs	2.88	4	2
	The solution is incorporating novelty in microfluidic design	3	4	2
	The solution is enhancing microfluidic design	2.25	3	1
	I am keen to apply the solution or its aspects in my future work	2.38	5	1
	The solution needs significant improvements	2.88	4	2
	The solution is...	B - good	C	A

One of the questions, which evaluates the solution as a whole as excellent / good / fair / poor, incorporated this four point rating scale. This scale was used to prevent the respondent from being neutral.

Results obtained from the analysis of the evaluation forms are given in Table 6-8 and discussed in Section 6.4.3.2.

6.3.2.2. Qualitative Validation Results - Validation of the Solution's Context

The results that form the qualitative analysis will be presented in a manner based on the core issue addressed. Hence, presentation of the results will follow the structure of the feedback form used in the validation.

Seven core topics were identified in the validation results:

1. The novelty incorporated in the solution
2. The strongest point of the solution
3. The weakest point of the solution
4. Aspects of microfluidic design not addressed by the solution
5. Aspects of microfluidic design overly addressed by the solution
6. Place for improvement
7. The solution's suitability to respondent's organisation's needs

Each topic is presented separately, regarding input given by experts on this matter.

<u>The Novelty Incorporated in the Solution</u>

Half of the respondents have not observed any novelty in the proposed solution. The remaining respondents indicated the following novelties in the presented solution:

- A complete description of the entire microfluidic product design process.
- A systematic compilation of and the derivation of development rules and decision trees from the collected information (existing facts in the domain) – the solution is identified as possessing valuable information for efficient management of microfluidic development projects by LOC designers, and for the collaboration between customers and LOC service providers during the development process.
- Service-orientation of the solution.
- Possibility to omit simulation stage as a recommendation.

The Strongest Point of the Solution

All respondents were able to identify the strongest point of the solution. However, their view on what it is varied. The majority of experts identified the structured and systematic approach of the solution as its strongest point; the following justification has been given for this claim:

- An opportunity to structure the ideas for beginners in 2D (Two Dimensional) fluidics (e.g. wafer processing and similar approaches).
- An opportunity to follow the solution in a systematic manner, one point after another, in such a way that you cannot 'fail'. In the sense that if you follow it, you should be able to, quickly identify where the problem is and go back.
- Selected chart format is clear and easy to follow, even for non specialists.
- Increase of success probability, or at least understanding of the project realisation timeframes, by structuring work.
- The solution prompts the designer to focus on microfluidic requirements in a logical and ordered manner.

Others highlighted comprehensiveness of the solution and amount of details incorporated as the strongest point, giving the following rationale:

- Detailed design flow, well integrated with sensible business decision making.
- Very detailed and comprehensive flow charts and questionnaires for the development stages. These elements give an outline for scheduling of the tasks, for moderation of the task related project meetings, and for preparation of task related reports and documents.
- Efficiency and predictability of the development process is improved, collaboration is enhanced and the total effort for the development can be decreased. It is a substantial step towards a "Microfluidic Design Automation Process" as a counterpart to the Electronic Design Automation.

One of the experts identified the strongest point as determining the process steps through requirements clarification, whereas the other highlighted the issue of

consideration of 'whether microfluidics is the best method to solve a problem', which, in his opinion, is probably not considered enough by microfluidic researchers.

The Weakest Point of the Solution

Experts were not single-minded in identification of the weakest point of the proposed solution. Some of the experts identified missing elements, as the biggest weakness of the solution, where others pointed out existing characteristics and elements.

The weakest aspect of the solution, in the opinion of the experts, is as follow:

- Late presentation of the awareness of manufacturing possibility in the solution - awareness of manufacturing possibility is in the mind of industrial developers before design, simulation, development and prototyping even starts – while the solution presents it at a later point,
- Incorporation of the amount of project management consideration to a point in which the solution resembles a short course in project management,
- Written in an abstract perspective – considered as a necessity; the expert also indicated interest in testing the solution by using it to obtain services from a microfluidic manufacturer,
- Generality,
- Lack of incorporation of system development aspects – chip component and required instrumentation,
- Missing issues of pricing and cost minimisation - how to design to minimise cost in terms of materials, dimensions, processing steps, etc. (included in many design software packages),
- Missing feedback from idea generation to requirement clarification stage in the guideline – necessity to adapt the requirements to the chosen solution as a result of very broadly worded requirements,
- Treating microfluidics as ASIC (A*pplication-specific Integrated Circuit*) design – viewing physicochemical compatibilities, chemical and biochemical

kinetics (interactions etc.) as complications not being 'straightforward' enough to put into the type of solution which is presented in this research.

Aspects of Microfluidic Design Not Addressed by the Solution

Experts were asked directly to indicate what is missing in the proposed solution. Their opinion, as for the weakest point, varied, showing the following number of issues not addressed:

- Aspects of 3D multifunctional systems (all systems together) as produced,
- Difficulty to find critical information due to the overflow of given considerations – in particular, information regarding choice of material and production method for a certain sample/liquid in the solution proposed, which is critical for microfluidics due to the characteristics of liquid behaviour,
- Lack of basic quantities and specific properties of materials (e.g. clear/opaque, electrically conductive / insulating or magnetic / nonmagnetic) mentioned (e.g. pressure, flow rate, volume or temperature), explicitly in critical points of the solution,
- Strategies and decision trees for risk management,
- Cost and patenting aspects of microfluidics,
- Issues of molecular biology and drug discovery applications (life science and chemistry),
- Some aspects regarding the technical properties of the product (specifications important for the function).

One of the experts claimed that "it is quite general at the moment nothing is missed out but if you will make it more specific then..." narrowing down the scope of design upfront will be the 'must'.

Aspects of Microfluidic Design Overly Addressed by the Solution

Only two experts suggested aspects of the solution which, in their opinion, have been overly addressed. Some of the experts were expecting an emphasis on one

particular stage of the solution, e.g. modelling or simulation, which was not identified by them. These overly addressed aspects are project management consideration and focus of the solution on conventional aspects. The expert highlighting management considerations, recommended omitting them by incorporation of suitable references, while focusing on conventional aspects has been considered due to insufficient development of novel areas of microfluidics.

Place for Improvement

Experts viewed the possibility of the solution's improvement in many aspects. They recommended:

- Shortening it.
- Making it open for different questions (surface energy, conductivity, details of the fluids itself – all this counts in microfluidics).
- Elimination of project management issues such as idea generation, iteration cycles, etc.
- Include a representative list of companies for which this solution is intended.
- Add risk management strategies.
- Include system platform development.
- Differentiate between LOC development (minimised risk, straight implementation of a custom protocol using reusable microfluidic components) and basic microfluidic research projects (development and evaluation of new microfluidic concepts and operation units).
- More specific/less general.
- Deciding to carry out CFD vs. simple excel models or taking an experimental approach.
- Using academic papers to help design devices.
- Include comparison of different materials, e.g. costs, performance, scale up.
- Include comparisons of different CAD software for designing chips.
- Include file formats used with different software and masking processes.

- Issues specific for microfluidics should be more explicit – clarification of the solution .
- More specific details about materials selection and manufacturing processes as they relate to microfluidic device design.
- Narrow the scope - focus only on the areas which are sufficiently advanced and understood.
- Put more weight on requirements clarification.

Future steps suggested transferring the solution into the form of a software tool, such as knowledge based software.

The Solution's Suitability to Respondents' Organisations' Needs

Opinions regarding suitability of the solution for experts' organisations were divided. Half of the respondents claimed its appropriateness, whereas the other half indicated issues which need to be resolved from their point of view.

Reasons given by the experts, who supported the suitability of the solution, include its compact form, ease to read, and comprehensiveness in terms of management of microfluidic research projects and industrial projects. They identified a number of tasks which can benefit from using the solution:

- Planning of the project
- Offer creation
- Design development and validation
- Selection of development partners
- Creation of reports
- Scheduling of project meetings.

Moreover, they highlighted increasing knowledge of the customer by cooperation during the solution utilisation, and therefore, qualifying him/her to give more valuable suggestions. Hence, it benefits commercialisation.

One of the experts mentioned partial suitability, indicating necessity for adjustments by minimisation of project management aspect. The partial suitability has been claimed based on the client/supplier decision phase which has been highlighted as important. Another expert indicated the proposed solution as widening the current practice of his/her organisation.

Lack of suitability has been identified by three experts: one of them supported this statement due to the maturity of the organisation's processes in place, the second due to the immaturity of the solution and indicated the possibility of the proposed solution's suitability after further development, and the third claimed that in his/her organisation, microfluidics are designed differently.

Presented evaluation by the respondents has been discussed in Section 6.4.3.2. Both quantitative and qualitative results are elaborated on regarding their suitability, implications and how they influenced final version of the solution presented in Chapter 5.

Regarding the uncertainty of obtaining the presented feedback and to increase the reliability of the research, interviews with microfluidic design experts were conducted, the partial results of which have been incorporated in the presented information set. The remaining results of this evaluation are presented below.

6.3.3. Phase 3 - Validation of the Solution by Interviews

Results of the solution's validation via interviews expanded the feedback obtained through feedback forms. They provided additional information, showing what can influence the potential users' willingness in the solution's adoption and more. These findings are presented below and elaborated on in Section 6.4.3.3.

To increase the possibility of the solution's adoption, one of the interviewees requires it to be proved in terms of cost and time minimisation efficiency, underlying it as a factor slowing down microfluidic technology. A case study based on an industrial prototype application of the solution, whose results can be compared to a conventional design method, is considered here as a sufficient proof. The second

interviewee suggested a target audience for the solution as organisations with an unstructured, or insufficiently structured, approach to design. This identification has been based on careful consideration of his/her design practice and its comparison with the proposed solution.

Factors which are currently discouraging interviewees from adoption of the solution are:

- Generality of the document - requirement to be more specific in terms of microfluidics.
- Broad spectrum of issues under consideration – need to narrow down the solution for particular needs/applications/types of devices.
- Length of the document – length of five pages is recommended as a maximum for this type of the document to be used by practitioners.

One of the propositions in which the solution, and therefore considerations inside it, can be narrowed down is the upfront decision tree. This decision tree is recommended to incorporate characteristics of materials to be used, fluid to be used (gas or liquid), flow characteristics, physical characteristics of device to be developed (e.g. pressure, temperature), etc. Based on this tree, the issues to be considered are narrowed down in terms of technological considerations. Therefore, the design process incorporates less data and starts to be less complicated.

Interviewees agree that an organisation can benefit from using the proposed solution by incorporation of rigorous steps in their design routine (if they posses it). Many microfluidic organisations are 'university spinouts' operating in an ad-hoc manner, which, in the majority, brings them failure. Incorporation of this systematic approach, including service considerations, will organise their approach and, therefore, increase probability of success.

Both interviewees see application of the solution in design department/development team/R&D and at designers' level in an organisation. In addition, depending on the size of the company, senior people responsible for manufacturing can be interested

in it for influencing manufacturing stages based on device design and vice-versa. However, according to them, the solution should not be sought to be applied by a marketing and sales department or above this level in big organisations.

6.3.4. Phase 4 - Validation of the Guideline from Service-orientation Point of View

Validation of the guideline from a service point of view involved nine experts in the service area and one expert in the microfluidic domain. Results obtained, as presented below, are further discussed in Section 6.4.3.4.

Using the four point scale, participants were asked to evaluate the guideline from a service-orientation point of view. As an effect, the guideline has been viewed as GOOD on average.

Nine participants identified novelty in the presented approach, from which eight acknowledged new information in comparison to previously possessed knowledge. One participant stated against it, claiming similarity of the guideline appearance to the conventional design process in the macro domain. Reasons stated for novelty included:

- Everything beside structure of general design process.
- Microfluidics.
- Consideration of services in design process.
- Integration of top-down and bottom-up approaches.

Participants identified a variety of elements as the strongest point of the guideline in terms of services. The three main categories under which these statements were classified are:

- Structured, step by step and detailed approach to design incorporating services, e.g. use of flowchart for representation, and detailed guidance with decision making within each step,

- Incorporating services into design process, e.g. taking services into account, reflecting both inside and outside perspective in the conceptual design, 'deliver service step' within conceptual design,
- Considerations in upfront stages, e.g. in depth analysis of each stage of the guideline, with special emphasis on upfront stages.

Additional factors mentioned include aspects such as help to avoid design mistakes, and help to overcome interface problems.

As the weakest point of the guideline, 50% of the respondents mentioned its generality. Other issues pointed out include:

- Not highlighted what services can be offered for a specific organisation.
- Types of services possible to be offered only mentioned partially.
- No comparison of services.
- Combining designing and realisation issues.
- Lack of explicit service consideration for team selection, modelling, simulation and prototyping stages.
- Impossible to identify the compromise in terms of microfluidic type devices which enable more services – compromise on disposability, on flow type, etc.

Based on characteristics of the microfluidic domain presented during the validation session and aspects of the guideline oriented towards services, 50% considered the guideline as sufficiently addressing service-orientation. Rationale provided includes:

- Possibility of the guideline utilisation to a selected extent by the designers.
- Challenges experienced in the domain.
- Consideration of all stages, from problem identification to manufacturing.
- Relative comprehensiveness.

Other participants provided a variety of views on the developed approach. One participant mentioned requirement for improvement in terms of service assessment and measurement, one saw it as providing opportunity/awareness for micro-device

manufacturers, whereas the other 30% considered lack of adequate data (more details regarding the guideline required).

Participants suggested the following methods to improve the guideline:

- Categorisation of services during use phase.
- Categorisation of the companies.
- Explicit example on guideline use.
- Provide a tutorial session for the guideline.
- More thinking about services to design better product for satisfying customer needs.
- Incorporate end-of-life considerations into the guideline.
- Focus on microfluidics should be more explicit.

Experts were asked one hypothetical question. The situation given to them has been as follows – assuming that their organisation is designing microfluidics (based on domain characteristics presented to them) do they consider the guideline as addressing its needs when designing microfluidics. 40% of the respondents consider the question as not applicable, due to the fact that they work in other domains, and withdraw from hypothesising. Another 20% stated pro lack of sufficient knowledge to answer this question, even in a hypothetical manner. The remaining 40% of respondents answer in a hypothetical manner, that the guideline is sufficient and beneficial.

Presented results are discussed in Section 6.4.3.4, with highlights of which aspects of the guideline have been enhanced based on the validation findings.

6.4. Discussion

6.4.1. Discussion on the Validation Methodology

Regarding the lack of possibility to perform the 'ideal validation' (see Section 6.1.2), a multiple validation approach has been selected. Other reasons behind selection of multiple methods to perform validation include:

- Uncertainty of experts' participation – involving people in the research is always a difficult aspect. Participation of practitioners is always 'under the question mark' in research.
- Multidisciplinarity causes difficulty in finding experts able to evaluate all aspects of the solution – this research lies at the overlap of three areas - microfluidic design, services and sub-section interactions. Finding experts qualified in all the areas at the same time is considered as improbable, due to lack of literature on the topic.
- Economic climate – research started just before the recession. Even in the situation at present when the economy is recovering (IMF, 2010), people are not very keen to spend time out of their working hours on additional activities. This influences research in a negative manner, decreasing the number of potential respondents for the data collection stage.
- Increase of the research quality – validation has been viewed as an important stage in the research for its quality assurance. Multiple sources of validation decrease possible bias from being incorporated and increase the probability of future adoption of the output.

Validation has been approached in two stages: validation of data analysis results and validation of the solution. The first stage assured good quality information for the framework to be developed from, by:

- Identification of any major mistakes in the data set before they are incorporated into the framework.
- Verification of the information obtained from various sources.
- Identification of analysis comprehensiveness.

The second stage of validation has been approached in multiple ways, which are presented in Section 6.1. The approach used possesses the following main limitations:

- Comparative analysis not performed by experts in all the areas included in the research (microfluidic design, service and sub-section interactions).

Validation of the solution by separate groups of experts from the domain has been undertaken in a non comparative manner.

- Limited feedback obtained.
- Ideal validation approach not possible (see Section 6.1.2).
- Experts in a particular area showed lack of knowledge in other areas (microfluidics vs. service).
- Limited duration of workshops required narrowing down the aspects of solution to be presented.

6.4.2. Stage 1 – Discussion of Findings from Validation of Data Analysis Results

Limited feedback has been obtained on the analysis. Only 25% of contacted experts provided feedback on the sent dataset. Because the participants were asked to identify mistakes and gaps in the presented information, lack of feedback has been considered as confirmation of presented results.

Positive feedback regarding the results will not be discussed. Aspects of the results which respondents point out as questionable have been interpreted in the following manner:

- Condensed information is needed – this is a recommendation for generation of the solution. The solution developed aims to address issues crucial for microfluidic design. The author acknowledges the importance of highlighting in the framework the main issues which the designer will have to focus on, regarding the number of factors which need to be taken into account in the design.
- Design of microfluidics is presented in a more difficult way than in reality – the claim of overcomplicating the microfluidic design process has been seen as relevant from an organisation's point of view, however, not applicable for the whole microfluidic area. One respondent claimed that his/her organisation has provided fast and pragmatic development of microfluidic devices since 1996 - this means over 14 years of experience in design in the

domain. Also, the organisation provides development of polymer microfluidics and MEMS - not all types and variations of microfluidics. Moreover, the organisation's portfolio has been reviewed, and indications of high automation in their approach identified. The organisation is highly specialised in narrow types of microfluidics that allowed them to automate the process and to present the selection of the device to be developed for the customer in a similar manner to 'choosing from the catalogue'. Therefore, the organisation presents only one point of view on the design process for microfluidics.

Obtained feedback did not show inconsistency in results of the analysis or any major mistakes and gaps. Therefore, the results have been used as an input for the solution's development.

6.4.3. Stage 2 – Discussion of the Solution's Validation

The discussion section for the solution's validation is scoped according to the results section. Therefore, firstly results of the comparative analysis of the guideline with existing microfluidic devices' design models are elaborated. Next, evaluation of the solution by microfluidic designers via feedback forms is discussed, followed by their input via interviews. Finally, the evaluation findings from a service-orientation point of view of the guideline are discussed. Mentioned discussions include identification and where appropriate improvements in the solution based on the evaluation.

6.4.3.1. Phase 1 - Comparison with Microfluidic Design Models

Results of the comparison of the guideline with design models existing in the microfluidic domain are presented in Section 6.3.1. This comparison consists of two elements: comparison with literature models and comparison with practitioner work. Findings summarised in the results sections, are elaborated below.

A. The Guideline as Compared with Literature Models

A summary of the results from comparison of the literature models, showing potential to be applicable for design of microfluidics with the guideline (as the main part of the proposed solution), is given in Table 6-5 in Section 6.3.1.1. These results are elaborated to highlight elements used in the development of the guideline and their importance for microfluidics.

The Sickle Model

The sickle model's (see Section 2.1.2, Figure 2-5) strong points have been applied in the guideline. However, its overall shape has not been used. The shape of the model, which is implied by its name, indicates smooth transition between designing and detailing. However, this model presents a more theoretical approach than the possibility to be easily understood and applied. Therefore, an approach more familiar for designers has been selected.

The sickle-model presents design in a 'top-down' approach, which has been considered as beneficial for microfluidics and transferred into the guideline. Also, consideration of technology regarding process preparation has been incorporated – however, in a more explicit manner. In the guideline, this process planning is approached from the very early stages of design in a broad manner, and detailed with progressing work.

The validation and prototyping are presented in the sickle model as the outside circle that reaches through all levels of the product architecture (structural, component and system). In the guideline, prototyping is left as one of the last phases, though information feeding in is collected systematically from the moment a concept starts to be developed, and final validation is performed afterwards. However, validation of certain parts of the information obtained, as well as models developed, is undertaken inside every phase before output from it reaches another stage. This validation has a similar aim - to assure successful preparation of the prototype and minimise iterations.

The V-model

The guideline, as the V-model (see Section 2.1.2, Figure 2-6), presents the end-to-end design process; however, without steps for the product afterlife, due to the fact that the majority of microfluidic devices are developed as disposables. Therefore, afterlife phases are mostly not considered, or considered only for big multi-analyser type devices. Considerations of adds-on for the product and services, which can be scoped in these phases, are encouraged in the guideline.

The V-model presents an iterative process of work which the guideline tries to minimise to decrease the cost of design. However, because iteration should not be eliminated from the design, it was encouraged inside the phases and up-front of the design process rather than in later stages.

Consideration of technology takes place in the V-model after the system concept is agreed on, while for the guideline, this work is simultaneous and, in some cases, technology even comes first. This early incorporation allows targeting the manufacturing process more accurately and avoiding costly iterations. Regarding focus of the guideline on microfluidics, and not on micro-scale devices in general (that incorporates well established domains such as microelectronics), the technology puts pressure on what is possible to be made.

Verification, which is the main cause of iteration in the V-model, has been addressed in the guideline inside the stages as an intermediate solution and, after the prototyping phase, as product evaluation. The V-model does not incorporate verification after assembly is performed, which, in terms of microfluidics, could cause failure of the device performance.

The 'Top-down' Methodology

Connection of the 'top-down' methodology (see Section 2.1.2, Figure 2-7) to the guideline is the most visible from the three models identified in literature. Its overall shape is similar regarding the usage of flow-chart as the method of process presentation. The guideline depends less on the software - many sources underlined

the lack of sufficient commercially available tools for microfluidic design - however, encourages their usage. Especially, usage of the libraries and their development is supported by the guideline for present and future use.

Another similarity between the model and the guideline is the 'top-down' approach incorporated in the design. It is considered as more suitable for microfluidics, assuring their functionality as a whole device after elements (components) are connected.

In contrast to the 'top-down' methodology, the guideline is more general to allow designers to work on various types of microfluidic devices. It does not include steps which will force usage of a particular manufacturing technology or eliminate the possibility of adding new functionality. Moreover, it incorporates decision making points and considerations of going beyond traditional scope and specifications to explore new potential benefits for the organisation. At the same time, inside the stages, it includes underlying issues particular for microfluidic domain.

The 'top-down' methodology has been unclear about obtaining some information and steps which has been avoided in the guideline development. Therefore, each information/action which is incorporated into the main guideline, as well as inside stages, considers input/output data and their sources to simplify its implementation by potential users.

B. The Guideline as Compared with Practitioners Work

Results of the comparison between the guideline and practitioners work are presented in Section 6.3.2.2. Various details of models extracted from the area, based on the data source, are used to scope the results and have also been kept for discussion. Therefore, this comparison is divided into two parts: comparison with survey models and comparison with models obtained from interviews. Discussion is scoped for the comparison of individual models with the guideline.

B1. The Guideline vs. Models Identified in the Survey

Models extracted from the survey were less detailed regarding limited information used as an input. Therefore, their input in the guideline is restricted to what can be observed in Table 6-6 (see Section 6.3.1.2) and the discussion given below.

Model 1

The guideline, as the model 1 extracted from the survey, presents an end-to-end approach to design. All stages presented in the model are incorporated into the guideline. This incorporation, however, was not a direct transfer as phases, but as tasks incorporated inside the main stages. This action aimed to keep information on similar levels of detail across the guideline, and fill gaps between stages identified in the model from other sources.

Testing was performed in the model, based on assistance using FEA/CFD tools. In the guideline, these tools were recommended to be used only when justified, and testing was encouraged based on a prototyping approach.

Model 2

Information, which model 2 consists of, has been transferred into the guideline. Preparation of the system draft, evaluation of the unit operations and their compositions were incorporated as possible tasks to follow inside the guideline stages. However, the main contribution of this model is incorporation of a modular approach to design, as recommended in the guideline for the majority of devices. This aims to allow future customisation and speeds-up the design of microfluidics.

Model 3

The model 3 is missing a lot of information required for microfluidic design. All steps incorporated in this model have been included, as in previous models, inside the guideline as tasks and considerations. Building and testing of the device and then links to theory have been underlined as one of the main steps in this process. This step is incorporated in the guideline as prototyping and validation stages. However,

the main similarity of the guideline with model 3 is iteration inside stages, which minimises costly iteration between them.

As can be observed, the presented models have a limited influence on the shape of the guideline - although, other information obtained in the survey regarding people working on microfluidic designs, factors influencing it, working with the customer, modularity/integration issues, etc., helped in forming it. Interviews had similar influence in terms of the guideline context; however, processes of design obtained from them allowed to decide on the guideline final structure.

B2. The Guideline vs. Models Extracted using Interviews

The large amount of information fed the guideline directly from models identified during interviews. This input is highlighted in Table 6-7 (see Section 6.3.1.2) and elaborated below.

Model 1

The model 1, extracted from interviews (see Section 4.1.2.2, Figure 4-5), and the guideline have many common aspects. All of the stages included in the model have been transferred into the guideline as stages, as tasks or as issues to be considered during particular phases of design.

Identification of the problem and finding true demand for the developed device is the first step of the model. Since the guideline is focused on addressing not only present, but also possible future demands of microfluidics, commercialisation of these devices has to be included upfront. Therefore, project identification is considered as the most important stage in the process, and any dropout of the project at this stage is not considered as a failure, but as a strategic decision of an organisation.

Part of this identification is 'cracking back' the problem to identify what customers really want and confronting it with given specifications. Understanding of an action

which a device will be performing, in terms of the 'problem' which will be solved by it, allows designers to work more accurately. Therefore, true understanding of the issue which is undertaken in model 1, has been directly transferred into the guideline.

The standard document identified in this model has also been pointed out in other approaches and in survey responses. It has been included in the guideline as a recommendation to create a standard document for the microfluidic devices development if the organisation does not possess one. It will allow for fast identification of information necessary to start a project and, consequently, improve project planning accuracy.

The model 1 is pointing out usage of particular techniques when, in the guideline, techniques are recommended more broadly. This allows the user to select a tool preferred by him/her based on given examples and/or principle which is aimed to be achieved.

Similar to the model, the guideline is putting focus on evaluation of design using prototyping. This building of the pilot can be developed in stages, due to novelty of some devices requiring a trial and error approach.

Model 2

The model 2 (see Section 4.1.2.2, Figure 4-6) is similar to the model 1 in some key aspects. It recommends usage of protocols for data input, and it highlights that microfluidics should not be a forced solution. Both of these aspects have been transferred, as mentioned for the previous model, into the guideline.

This model points out the presence of one stage, 'select suitable platform', which states that the process for design of microfluidics should be case specific. The guideline is addressing this issue by showing the opportunity for variations inside the stages. Although case dependence of microfluidic design seems to be omitted in the high level of the guideline, this is done on purpose. By development of the general model, all types of microfluidic devices can be designed, also types which are

not even currently considered possible. This can include devices not requiring a 'platform'. This aspect also allows the minimisation of possible reluctance of using the model by designers, which could appear when identifying particular equipment or functions not used in their design.

As in the previous case, validation using prototypes has been identified as beneficial for the domain and is present in both processes. Model 2 indicates development of multiple number of prototypes, which is recommended due to the possibility of not 'making-it-right-first-time' when it comes to the area with limited knowledge about physical mechanisms.

Customer input, which in the model 2 is visible in two stages, has been incorporated into the guideline in a flexible manner. The guideline suggests involving the customer not on a strict basis, but depending on the projects. This involvement can be identified at milestones – to make sure that the customer is getting what he/she demanded, only upfront and at the end – if this is preferred by him/her or throughout when justified.

Model 3

The model 3 (see Section 4.1.2.2, Figure 4-7) varies from the other models extracted from the interviews. It is focused on the main issues to be considered, rather than actions. Issues identified in this process are fed into the guideline: as requirements to be addressed – Reynolds number, as constraints imposed on every design – avoiding corners, edges; as task to be undertaken inside design stages – thinking about the design concept; as an option of what a device is aiming to perform and identification of the issues interconnected with this function – getting a sample out of the device, and underlying project management and decision making points in dividing the work and delegating.

Model 4

The model 4 is presented in two variants, A (see Section 4.1.2.2, Figure 4-8) and B (see Section 4.1.2.2, Figure 4-9). As in the previous cases, all steps from both models

have been considered and fed into the guideline. However, a number of key issues, also raised by this model, have influenced the guideline's shape.

The first of the aspects of the model is informality of some discussions, which can lead to novel concepts. Whereas a formal meeting encourages imposing constraints and known facts, an informal discussion gives confidence to think 'out of the box'; therefore, it allows innovation. This aspect has been included in the guideline at its beginning, and is recommended throughout the process inside the team as cooperation support.

The other issue is examination of existing equipment regarding providing required functionality to avoid reinventing the wheel, and usage of it as a source of ideas to develop new solutions. Both model 4 and the guideline incorporate these investigations as time saving in the long term view, and a possible creativity trigger.

The model 4 underlines the need to understand specifications for required equipment. This aspect has been discussed as incorporated in the guideline under problem identification broadly, and later in detail when the concept matures. Moreover, designers need to understand what has to be done to achieve these specifications and be able to plan their realisation path. These considerations, which go beyond model 4, are also included in the guideline.

Model 4 includes fabrication consideration almost half way through the design process. This consideration is recommended to take place earlier, at least in the broad scope, and has been addressed in the guideline. This small variation aims to minimise iterations and increase accuracy of the first design draft.

Other key aspects, which are highlighted by the model 4 and used in the guideline, are: an importance to understand that scaling-up production changes the device and can cause problems with manufacturing, and that simulation considered essential in literature is replaced by prototyping – with more accurate results. Although it seems that production of a single device and batch/mass production should have these same principles, and therefore, these same results should be obtained, but the reality is different. Hence, a consideration of the production scaling-up, mostly to mass

production, needs to be addressed by designers. The guideline points out this issue as one of the subjects to be discussed and planned during the design. The importance to justify simulation has been underlined many times when discussing previous models, and is addressed in the guideline.

Commonality between both processes includes importance of evaluation - not only components, but also the device as a whole, and iteration in prototyping to obtain better results. This iteration is recommended not on a loop basis, but as the various stages of prototypes that limit the number of costly changes in the created mould for example.

Model 4 highlights the customer as validating the product. The guideline recommends a validation approach which depends on the form of the output selected and the project. An organisation, on an individual case basis, should decide how the design output will be validated. Although the customer is underlined as making the final decision about the device's suitability, it can be only one of many evaluation factors - though, it will be a dominant factor.

Model 5

Compared to the guideline, model 5 (see Section 4.1.2.2, Figure 4-10) presents a reverse approach to design. The model 5 presents a bottom-up approach when the guideline is prepared as a top down design. The bottom-up approach is incorporated in the guideline as a way of verification regarding its benefits.

One of the constraints usually imposed on microfluidics is design space. This factor, indicated in the model 5, has been incorporated as a requirement to be confronted by designers upfront in the design process due to its importance for the whole design.

Other aspects of the model which have been incorporated in the guideline are modular approach to design (development of the fluidic unit operations) and production scaling-up. Although the guideline allows for selection of a monolithic approach and points out when this type of architecture is beneficial for the majority

of applications, modularity is encouraged. This model takes production scaling-up further than other models. It underlines that using a foundry production facility can incorporate additional factors and therefore, changes in the device performance. Hence, the first serial produced should be tested before the product is delivered to the customer. This recommendation has been seen as important and, consequently, included in the guideline.

Model 5 also reminds that obtained results should always be confronted with specifications. The guideline follows this approach in every verification point and during validation and manufacturing stages.

It can be observed that the developed guideline is close to the models representing practitioners' daily routine. This aims to increase the ability of designers to incorporate small incremental changes which will move their design into the future and overcome change resistance. Moreover, it is a result of incorporating best practice from the domain, which was confirmed to be successful and should be formalised. However, the guideline goes beyond what has been extracted from the models – it addresses gaps not only inside them, but also between, to assess the future needs of microfluidic design. This contribution is discussed in Chapter 7 and summarised in Chapter 8.

6.4.3.2. Phase 2 – Discussion of the Solution's Validation Results by Microfluidic Experts via Feedback Forms

Validation of the solution using experts' feedback has been considered as a sufficient method to assure quality of the research output. Results of the validation, which have been presented in Section 6.3.2 regarding evaluation via feedback forms, are discussed below. Discussion is scoped around evaluating the rationale of the obtained feedback, its implications and impact on the final form of the solution presented in Chapter 5.

Discussion of validation results via feedback forms have been divided into two parts: (A) discussion of quantitative results and (B) discussion of qualitative results. This

split aims to provide the reader with an overview for the validation results before detailed feedback is presented.

A. Quantitative Validation Results

Quantitative validation results can be viewed in two parts with regards to the issues which they concern: the structure and the overall evaluation. The structure of the solution is evaluated in terms of its clarity, ease of following the approach and its length (number of stages). The overall evaluation concerns: meeting expectations of experts, incorporation of novelty, willingness of experts to use the solution in their work, necessity of improvements and the overall score. The applied scoring pattern has been indicated in Section 6.3.2 (for details, see Appendix 7.3), and the interpretation of obtained results (see Section 6.3.2.1, Table 6-5) is given below.

The average score obtained for the structure of the solution is 1.92, which indicates the solution is seen in a positive manner. The solution is viewed as clear and easy to follow; however, its length is questionable. Only one of the respondents strongly challenged the solution length. This negative score was caused by the number of pages on which the whole solution is presented, not by the number of stages incorporated in the guideline as the core part of the proposed solution. This same indication of requirement to shorten the solution can be observed in one of the improvements recommendations given. The author acknowledges the extensive length of the document which has been used for evaluation. Reasoning against shortening the document at this stage incorporates a number of factors, including available time and necessity of familiarisation of experts with the whole solution, not only a brief experience of it. By developing a shortened version of the solution, incorporating attachments and references, the author risks lack of validation of certain aspects of the work. By omitting part of the solution, the organisations could miss the service-oriented considerations or other valuable suggestions - which constitute the contribution of the solution to knowledge in the domain and can help them in the future.

All scores obtained for the overall solution's evaluation are positive. The proposed solution has not met the expectations/needs of two experts, according to two, it does not incorporate novelty, needs significant improvements according to one expert, and one person identified is as not applicable to his/her work. However, the majority of experts were keen to apply the solution or its aspects in their work.

Mismatch between presented solution and practitioners expectations/needs can be caused by the type of solutions they are looking for in their work. The solution proposed presents the general guideline for design of microfluidics supported by the design enablers, and hence, it is characterised by generality and high level considerations, with only indications of tasks to be undertaken, and it requires adjustments for particular organisations' needs. However, the practitioners may be seeking plug and play solutions. They want to have a tool which will indicate exact steps to follow and, regarding current practice in the domain, specify all technological details for their particular type of device.

The experts viewed the solution as enhancing microfluidic design, generally were contented with the level of novelty incorporated and, most of all, keen to apply the presented solution or its aspects in their future work. They evaluated the solution as GOOD - which summarises the evaluation as successful.

B. Qualitative Validation Results

Qualitative responses from the experts allowed clarification of the level of suitability of particular elements incorporated in the proposed solution to their work. Experts viewed the solution based on seven topics around which the results section for the qualitative validation via feedback forms has been scoped (see Section 6.3.2.2). The discussion below has been scoped accordingly.

Regarding variation incorporated in the background, work experience and current work responsibilities of experts, as well as types of organisations they are working for and types of devices under development, opinions of experts have been expected to vary as well. Therefore, in some cases, it can be observed that features viewed by one person as positive are questioned by someone else. Below, the author tries to

address all issues raised, both positive and negative, to establish true evaluation output.

1. The Novelty Incorporated in the Solution

Disagreement between experts can be observed in the first topic covered – solution's novelty. Half of the respondents have not identified anything new for themselves in the presented solution, while others indicated novelty in the solution's aspects. Respondents had various backgrounds and work experience what influenced their view in terms of novelty. Where novelty has been identified by one respondent other claimed against e.g. identification of the completeness of the solution for representation of microfluidic design process has been contradicted by statement of recalling in the memory similar guidelines developed in microchip design and related areas by other expert. Based on this indication, of similar guidelines existing, the author tried to identify them and if they address issues mentioned; however, these approaches, were identified, were technology driven and neither incorporated service-orientation nor dealing with sub-section interactions.

Novelty in terms of service-orientation has been identified by one of the experts. This identification confirms technology driven approach to design in microfluidics. In addition, this technicality is supported by novelty identified as possibility to omit simulation stage which by one expert has been recognised as necessary. Presentation of the simulation stage as circumstantial is explained in Section 7.2.3.8. Performance of simulation requires justification in terms of resources invested. While in some organisations, which focus their work on this aspect of microfluidics, it will be considered necessary, other companies designing devices from scratch and manufacturing them can find it hard to justify required resources. Therefore, consideration of the simulation as a fixed element of the microfluidic design process has been rejected by the author until simulation tools are able to provide more accurate results in an affordable manner.

Lack of novelty has been claimed by viewing the solution as compilation of logical steps to tackle engineering problem and 'an impression' that the domain is facing similar challenges to other domain when applying project management. Both claims

seem to be a result of generality of the solution. Accustomed to technology driven design processes microfluidic designers with experience in product development can view presented approach as common sense, especially if they are working in mature organisations.

2. The Strongest Point of the Solution

Highlighted by the participant as being a structured, detailed and systematic approach to design, the solution met the main points missing in presented models existing in the domain. Moreover, experts see potential benefits from implementation of the solution based on the strongest points mentioned by them. Reflecting on the solution as having potential to increase success probability, allowing for better project planning and speeding up mistake identification, supported the view as suitable for domain requirements.

Mentioned contradictions between experts' opinions can be seen in identification of the strongest points of the solution. One aspect mentioned by some experts, is comprehensiveness of the presented solution, which was contradicted by others who claim of missing issues. Another aspect is presentation of the solution as detailed when, in the following part of the evaluation, some experts highlight the generality of the solution and missing details as the weakest point of it.

Opinions which differentiate themselves from the majority were: identification of requirements clarification as determining following steps in design process and pointing out 'sense' of microfluidics selection. The author acknowledges both issues as important, putting focus on identification of 'whether microfluidics is the best method to solve a problem' as crucial for the domain. Development of microfluidics should be performed only when it is the best method to solve the problem and market demand has been identified (Section 7.2.1) - and what has been confirmed by the expert is not happening enough in the domain.

3. The Weakest Point of the Solution

Experts were less single-minded with identification of the weakest point of the solution. Their views were influenced by the type of devices they are developing, their complexity and characteristics, and methods of work currently employed.

The author acknowledges some of the aspects mentioned as weaknesses which were aimed to be minimised and can be claimed as incorporated into the solution. However, some of the aspects are viewed as a misunderstanding of the solution presented. The following weaknesses identified by experts, fall into this second category:

- *Late presentation of the awareness of manufacturing possibility in the solution* – the awareness of manufacturing possibilities (technology selected, materials etc.) has been indicated from the first stages of the guideline. In the first stage – Problem identification – the organisation is asked not to undertake a project, if it cannot deliver on time and within cost. This identification can be based on lack of possessed manufacturing capabilities. Regarding the fact that many factors can influence this decision, this step can be argued against. However, in the second step of the guideline, in an explicit manner (see Section 5.1.3.2), identification of the manufacturing methods is suggested to be incorporated in the 'project brief' – a standard document which scopes the project under realisation. Manufacturing is also indicated as a driving force in the Level 0 of the guideline, by incorporation of the 'data funnel', leading to this stage and starting at the requirements clarification stage. Hence, this claimed weakness is considered as not justified.
- *Treating microfluidics as ASIC design* – the author is the first to point out that microfluidics does not resemble microelectronics, and design in both domains requires incorporation of an area's specifics. In Section 2.1.2, the author highlights the unsuitability of the most popular design model for microelectronics – VLSI- for microfluidics' needs, due to the clear separation of manufacturing and design stages which cannot occur in the relatively immature microfluidic domain. Moreover, the author is the first to admit

that the solution needs to be adjusted to a particular organisation's needs and characteristics. The author acknowledges that the presented solution is general in nature and does not indicate considerations for each possible type of microfluidic devices to be developed and for every application, but highlights what types of considerations should be undertaken. It has been recognised that the knowledge in this area is mainly implicit. Hence, design highly depends on designers' creativity. However, the presented solution does not disregard any subgroup of microfluidic devices based on its type or application market. Complexity and simplicity of microfluidic devices, depending on type of products developed by organisations, is one of the reasons for the generality of the solution. The author did not attempt to explain how to perform CFD analysis and which technical properties have priority for which application, and therefore, are considered more crucial from a chemical or physical perspective. The aim was to take microfluidics closer to service future and minimise sub-section interactions impact. Hence, the claim of this weakness is considered as not justified in terms of comparison to ASIC, and reasonable in consideration of necessary adjustment for the life-science applications purposes.

- *Missing issues of pricing and cost minimisation* – pricing aspects are not missing from the solution – they, as many other aspects, are just indicated so as not to overload a potential user with information. The price minimisation was one of the drivers for the selected form of the solution, where simulation is performed only on a justified basis (Section 7.2.1). The costing aspects are mentioned explicitly across the core solution's part – the guideline – starting from problem identification – by delivering on time and within cost, through requirements clarification (see Section 5.2.3.2 Figure 5-6), idea generation (see Section 5.2.3.2 Figure 5-7) and more. The author acknowledges that more aspects of cost minimisation could be incorporated if the solution was focused on cost minimisation as the core issue. However, regarding the fact that this factor is considered as important and incorporated explicitly among other equally crucial aspects, the claim of the pricing and cost as missing issues is considered invalid.

- *Missing feedback from idea generation to requirement clarification stage in the guideline* – interactions between the requirements and output from the idea generation stage happen by comparison, which is clearly indicated in the Level 0 of the guideline. Although, the author encourages changing the design under development according to the requirements, if requirements need to be changed, it should be communicated to the client - to agree on. Moreover, a confirmation of the market demand on the adjusted output is required. The loops, aim to be eliminated as they lead to costly design iterations. Hence, the weakness, although recognised as rational, is viewed as not being valid for this solution.

Remaining weaknesses of the solution have been acknowledged by the author as reasonable and partially addressed as limitations of the solution developed. Especially generality of the solution, which has been pointed out by one of the experts, has been discussed from various points of view in the thesis (see Sections: 7.2.1- generality as confirmation of theory development; 7.4.1 – generalisation of the guideline; 7.4.4 – generality of design enablers; 7.5.2 – solution capability's limitations). It is viewed as a limitation and opportunity at the same time, and it is incorporated on purpose, recognising necessary trade-offs.

Similar implications to generality are incorporated into the statement about the solution as being written in an abstract perspective. Even the expert who claimed it recognised the necessity of this form. Moreover, it has been extended by showing interest in testing the solution by using it to obtain services from a microfluidics manufacturer.

The remaining weakest aspects of the solution identified by the experts are acknowledged by the author as valid. These characteristics relate to:

- *Incorporation of project management considerations to a point at which the solution resembles a short course of project management -* incorporation of general steps to follow and recommendations has been a necessity to provide a context to other specific tasks which allow development of a device, incorporation of

service-thinking in the process, and dealing with sub-section interactions. Elaboration on how to perform some steps has been incorporated, based on practitioners and literature design process models which possess significant gaps in this matter. Referencing suitable books regarding project management tasks is recognised as showing potential for shortening the solution's presentation. However, it incorporates the risk of omitting some tasks by future users. Regarding the fact that only one expert identified project management aspects as overly addressed, no change in this matter will be incorporated in the solution at this point, and only a possibility of shortening presentations of core aspects of the solution incorporated in future work (see Section 8.3.2).

- *Lack of incorporation of system development aspects* – the solution has been focused on development of all microfluidic devices. For the devices which are more complicated, the solution does not restrict itself only to the part of the device which incorporates microfluidic function, but is trying to address development of the device as a whole. The author acknowledges that the solution presented for validation did not incorporate explicit suggestions regarding system development - although, application of a top-down methodology has been used to assure performance of these types of devices by starting development from the architectural level – which means performance as a system. Consequently, the incorporation of limited changes making the considerations of system development more explicit was performed based on this feedback.

4. Aspects of Microfluidic Design Not Addressed by the Solution

For identification of aspects missing in the solution, as for identification of the weakest aspect of it, experts' opinions varied. Some of the weaknesses were based on inability of experts to identify a particular aspect as covered in the solution, which can be identified above. As previously, the author identified some of the aspects claimed as missing as present in the solution developed. This category includes:

- *The cost and patenting aspects of microfluidics* – the costing aspect is present in the solution - e.g. Section 5.2.1, Section 5.2.3.2 Figure 5-6 and Figure 5-7 - although, patenting has not been incorporated per se, but by highlighting the IP rights' importance in Section 5.2.3.2 and Figure 5-6.
- *Lack of basic quantities and specific properties of materials mentioned explicitly in critical points of the solution* – the basic quantities have been incorporated in the guideline in the form of an indication. Regarding the high number of technical aspects needed to be incorporated for each type of microfluidics, not all of them were listed. These quantities, such as heat transfer, chemical reactions, fluid type, material selection, can be found, for example, in Section 5.2.3.2 Figure 5-7. Although the examples given by the expert were not covered per se, their equivalents, mentioned above, were used as indicators.

Another group of aspects identified, which the author acknowledges as not incorporated and has justification for omitting them in the solution's development, is as follows:

- *Aspects of 3D multifunctional systems (all systems together) as produced.*
- *Issues of molecular biology and drug discovery applications (life science and chemistry).*
- *Some aspects regarding the technical properties of the product (specifications important for the function).*
- *Strategies and decision trees for risk management.*

Another option is to create a type of expert system incorporating all possible options. However, this will require resources not possessed in this research. Risk management, as well as many other aspects of project management, were not incorporated into the solution to minimise information overflow distracting from the microfluidics specific focus. Aspects of all types of microfluidics were impossible to cover. Therefore, characteristics were only indicated in terms of technical considerations, which makes many crucial parameters for various device types as 'missing'.

These claims are in contradiction with one made by another expert '*the difficulty to find critical information due to the overflow of given considerations*'. To make it possible to develop a general solution for the microfluidic domain, prioritisation rules have to be applied and tradeoffs need to be made. Therefore, not all parameters for microfluidics are explicitly mentioned, but their types in terms of considerations are indicated.

Another expert pointed out that the solution *"is quite general at the moment nothing is missed out but if you will make it more specific then..." narrowing down the scope of design upfront will be the 'must'.* The author of the solution agrees that it needs adjustment for a particular organisation's needs and incorporation of characteristics of the type of microfluidics that they are working on. This adoption itself will narrow the solution's scope and provide a manageable amount of information to work with.

5. Aspects of Microfluidic Design Overly Addressed by the Solution

The majority of respondents did not identify any issues overly addressed in the solution. Some of the experts were expecting emphasis on one particular stage of the solution, e.g. modelling or simulation. However, they did not consider it as negative in any way. Only two experts suggested the following aspects as needing to be minimised: amount of project management considerations and focus of the solution on conventional aspects. Both mentioned issues can be summarised as tasks allowing for any project realisation. Issues covering these topics have been discussed above, when identified by experts as the weakest aspects of the solution. Moreover, the overall view of the majority did not identify these issues as overloading the process, but rather providing a structure and context of work.

6. Place for Improvement

Diversification among the experts influenced captured views on covering which issues can benefit the solution. Their recommendations vary mostly according to the characteristics of the particular type of microfluidics they are working with, or the organisation's operations.

Some of the issues have been discussed when mentioned as weaknesses: *add risk management strategies, open for different questions (surface energy, conductivity, details of the fluids itself – all this counts in microfluidics), elimination of project management issues such as idea generation, iteration cycles etc., more specific/less general, more specific details about materials selection and manufacturing processes as they relate to microfluidic device design and include system platform development*. Other issues were covered from a different angle and require additional elaboration. These issues are:

- *Put more weight on requirements clarification* – requirements clarification is considered as one of the crucial stages since it defines specifications for the design outcome. However, this stage is considered as elaborated in sufficient manner, and indicated as important to an adequate extent so as not to cause underestimation of other aspects of the design.
- *Narrow the scope - focus only on the areas which are sufficiently advanced and understood* - the solution is recommended to be adjusted to the organisation's needs and type of device to be developed. Narrowing the proposed solution to only advanced types of microfluidic devices will minimise benefits which it can bring to new organisations working in the area. Also, it will eliminate its potential to be applied as a general process in the domain. Moreover, there are many views of which areas of microfluidics can be considered as sufficiently advanced and understood, since knowledge in the domain is considered limited and industry mostly do not publish.

  A similar issue is faced by the recommendation to *differentiate between LOC development and basic microfluidic research projects.* It implies narrowing the scope of the solution and makes it not applicable across microfluidic domain. However, addressing it by development of alternative paths for designers to follow is considered beneficial and included in recommendations for future work (Section 8.3.2).
- *Microfluidics and focus on issues specific for this domain* should be more explicit – *clarification of the solution* – the author acknowledges that some indications of technical aspects of microfluidics have been considered as not sufficiently underlined in the solution. Practitioners from this area are used to the high

technicality and the technology and fabrication driven design. Therefore, as presented in Chapter 5, the guideline incorporates more explicitly mentioned technology aspects than the solution which was presented for validation (see Appendix 7.1). However, as underlined above, only the main indications are included to minimise information overload.

Remaining improvements varied from general to specific. Specific recommendations were mostly given in terms of automation of the solution and transforming it into a tool – a design aid in the form of a database or similar – which can be used to shorten design time. In the discussion of quantitative validation results, a mismatch between the presented solution and practitioners' expectations is elaborated on. The experts' expectations, as microfluidic practitioners, regarding the solution are clearly visible in the following recommendations:

- *Deciding to carry out CFD vs. simple excel models or taking an experimental approach.*
- *Using academic papers to help design devices.*
- *Comparison of different materials, e.g. costs, performance, scale up.*
- *Comparisons of different CAD software for designing chips.*
- *File formats used with different software and masking processes.*
- *Transfer the solution into a form of software tool such as knowledge based software.*

Some of these recommendations have been incorporated as considerations into the solution presented in Chapter 5, while others have been transferred into recommendations for future work (Section 8.3). The suggestion considered general is to *shorten the solution* - which has been incorporated as a recommendation for future work to increase its potential for adoption by practitioners.

The final recommendation was to include a *representative list of companies for which this solution is intended*. The solution targets all microfluidic practitioners as potential users. Identification of potential users of the solution inside organisations, as well as its intended manner of use, is presented in Section 7.3.

7. The Solution's Suitability to Respondent's Organisation's Needs

Results of the validation of the solution via feedback forms by microfluidic experts regarding its suitability to respondents' organisations' needs, highlighted the benefits seen by them from potential adoption. These benefits are listed in the results section (see Section 6.3.2.2) and will not be discussed further. Half of the experts did not see application of the solution in their organisations in complete form, or even partially. Focusing the discussion on negative points aspires to improve the quality of the proposed solution.

Partial suitability of the solution has been identified in two cases:

- Suitability of the *client/supplier decision phase*, which has been *highlighted as important* with the claim of *overly addressed project management issues* – this issue has been discussed under weaknesses and missing aspects of the solution indicated by experts,
- *Widening current practice of the organisation* – the solution does not need to be applied in its entirety to bring benefits to the organisation (Section 7.3). The author is recommending usage of the solution with the current practice of the organisation, to minimise change resistance of the employees and increase adoption of a 'good practice'.

Unsuitability of the solution for a particular organisation's practice has been claimed based on:

- *The maturity of organisation's processes in place* - the expert highlighted the suitability of the solution for less mature organisations, and indicated an improvement applied for processes being in place in his/her organisation. The proposed solution is developed as general for the microfluidic domain, where the majority of organisations show a lack of sufficient design processes in place. For mature organisations with a highly structured operation, it offers benefits of service-orientation and particular considerations which can be missing in their current practice.

- *The immaturity of the solution* and *possibility of its suitability after further development* – the proposed solution is the first attempt to develop a general design process for microfluidics. A similar process has not been identified as existing in the domain. Moreover, it is trying to address issues of service-orientation and sub-section interactions. Furthermore, the solution, although validated by multiple methods, has not been validated by practical adoption – development of microfluidic device with commercialisation. Regarding these aspects, the author acknowledges the immaturity of the solution and the reluctance of the experts to implement it in the current form.
- *Microfluidics are designed differently* – If an organisation's practice is considered as optimal and none of the aspects presented in the solution seem to be profitable, its adoption is not necessary. However, this particular expert is mostly working solely on device development on what is considered 'simple' microfluidics, and his/hers pattern of work varies from the trend observed in the area; this is considered as influencing the response.

Discussion of both quantitative and qualitative results from the validation of the solution by microfluidic experts, via feedback forms, allowed the author to see a piece of additional work on the solution which should be undertaken. Mentioned adjustments, where appropriate, have been incorporated into the solution (Chapter 5), maturing it in comparison to the one presented for validation (Appendix 7.1). This evaluation has been just one of the methods used to validate the solution. To increase reliability of the research, the interviews with microfluidic design experts were conducted. Partial results of these have been incorporated in the presented information set, while the remaining results are presented in Section 6.3.3 and discussed below.

6.4.3.3. Phase 3 – Discussion of Results from the Solution's Validation by Microfluidic Experts via Interviews

Evaluation of the solution via interviews allowed the author to view it from an academic and an industrial perspective. Contradictions between the academic and

industrial views in the area have not been observed. Both interviewees underlined similar aspects of the solution in questioned issues, which are elaborated below.

The evaluation is considered as successful regarding positive feedback obtained on the developed solution from the feedback forms and from interviewees. The discussion of the validation results via interviews will be approached in a similar manner to the previous results section. Answers on questions which were incorporated in the feedback form were analysed and discussed in the feedback form section (Section 6.4.3.2) and will not be repeated. Only additional information will be elaborated.

As a factor which will increase the adoption of the solution, one expert underlined its validation in terms of being industrially proven. This statement comes from the academic side. An evaluation through a case study is common practice for design processes; however, academic validation seems to be considered valid for the academic environment. Application of the solution for development of a prototype was considered as a validation approach in this research. However, it was rejected for a number of reasons – project time-frames, required resources, etc.

The recommendation given by the second interviewee, regarding a designation of the solution for organisations possessing an insufficiently structured design approach, has been incorporated when developing the solution by addressing it to the new designers. This recommendation indicates limited possibility of the solution being viewed as helpful by mature and highly structured organisations. For these organisations, the solution will need significant changes since, at the moment, it seems to offer them service-orientation indications on a high level, and suggestions on how to deal with sub-section interactions which some of them already possess. This limitation is due to the generality of the solution, which causes the necessity for adjustments for individual needs, as well as immaturity of the area, which has been stated by the majority of organisations in the domain.

Three main factors discouraging potential users from the solution's adoption have been identified. The main one being generality which is required to fulfil one of the

purposes of its development – provide a 'one' general methodology for the domain. This limitation can be minimised by a further solution's development for multiple application variants. However, this is considered out of the scope of the project and consuming resources which are not possessed by the researcher (time and cost).

The second issue is connected to the first one – the broad spectrum of issues under consideration. This issue can be resolved by pointing out particular – demanded - application for microfluidics – therefore - adjusting the solution for one set of needs.

The third issue is length of the document. The solution has been presented for evaluation as a 30-page document (see Appendix 7.1), including a number of diagrams which are a significant part of it and are not elaborated on in the text to shorten the manuscript. This length has been viewed as too long by industry. A length of five pages has been suggested as sufficient for a future version of the guideline, with appendices and references provided if/where necessary. This form has been considered by the author as reasonable for industrial application in a well structured organisation, and insufficient for the purpose of validation where a full picture of the solution has to be 'grasped' by the experts before they are able to evaluate it. Shortening the solution is recommended for the organisations if/when they adjust it for their own purposes, since this will allow them to prioritise tasks and considerations according to their own offering patterns and capabilities.

A possibility of incorporation of the upfront decision tree is just one of the methods to decide upon the type of microfluidic device and its characteristics. This part of the process has been incorporated by filling in the 'project brief document', and where not identified (due to lack of data) in idea generation session. Incorporation of the decision tree upfront of the guideline will allow development of various versions of the solution as a result narrowing the issues under consideration. However, to make this approach comprehensive, all possibilities (variants) should be presented (design process for each type of microfluidics). This is excluded due to resources available in the project. Therefore, the decision on the method to be used to decrease the considerations in design (decision tree, expert system, experience, etc.) is left to the organisation adopting the solution.

Interviewees underlined benefits which organisations can obtain from using the solution. In their opinion, the most beneficial will be incorporation of a structured design approach which, in many cases, is missing in the microfluidic organisations. This, in cooperation with orientation towards services, will help them to organise their work and increase probability of success.

Usage of the solution, in the opinion of the interviewees, covers, in the majority, the author's indication of who should apply it and how. The difference is that the author sees the possibility of solution utilisation more broadly in microfluidic organisations (see Section 7.3).

Interviewees helped to clarify validation of the proposed solution for the microfluidic area. This evaluation, considered as successful, allowed receipt of mainly positive feedback regarding the developed approach, and indications of how this work can be further enhanced. The next section discusses the validation from the service point of view, which allows for viewing the presented work in a less technology-oriented manner.

6.4.3.4. Phase 4 - Validation from Service Point of View

Evaluation of the guideline from a service point of view can be considered as successful. The guideline has been viewed by the validation sessions' participants as, on average, good and sufficient for the domain. Participants recognised novelty in the presented approach for the domain. Many of them did not have contact with microfluidics before; therefore, they based their statements on the characteristics of the domain presented by the author. This can incorporate certain limitations in the results obtained; hence, a participant with a microfluidic background was involved.

Overall, there were no significant differences between views of service experts and microfluidic expert in terms of the guideline evaluation from a service point of view. Difference occurred in terms of details in comments on what is present and required in the guideline. The microfluidic expert provided a more detailed view on the needs of the area regarding its characteristics that allowed seeing clearly how service experts' evaluation can be applied to the guideline to enhance it.

The strongest component of the guideline comes from providing a structured guidance for microfluidic devices which incorporates service considerations. The most crucial part of the guideline, in terms of services, has been identified as its front end. This confirms focus placed by the author on detailing the front end of the process to minimise iteration at later stages and to assure better quality of the output.

A contradictory view on the lack of novelty in the approach, based on resemblance of the guideline to the conventional design process, is argued by the author in the discussion of the guideline in view of its generalisation potential (see Section 7.4.1). The author acknowledges commonality of the processes at a high level, and points out variations when approaching the design, i.e. fabrication driven process.

A participant confirmed one of the limitations of the guideline (see Section 7.5.2) – its generality. Making the guideline more specific will contradict one of the targets stated for the research – its contribution by development of the general methodology which the area lacks. Therefore, this limitation will not be mitigated. However, other aspects mentioned by the respondents provide the opportunity in terms of their potential to enhance the guideline.

Main weaknesses of the guideline and their applicability are as follows:

- Not highlighted what services can be offered for a specific organisation, types of services possible to be offer were only mentioned partially, and no comparison of services has been made – incorporation of services classification is considered as beneficial for the area. However, this expands beyond the scope of this research. Services should be identified depending on the products which an organisation is putting on the market, based on the market/customer demand. To make the scope manageable, two options for research are recommended: investigation of the services from a customer perspective – identification of the true demand - and narrowing the types of microfluidic devices under investigation to clarify the type of services which are suitable for them (contradict the development of a general approach).

Moreover, this aspect has been included as one of the recommendations for future research. Therefore, comprehensive classification will not be provided in the guideline.

- Combining design and realisation issues – identified by one of the participants as the weakness has been a result of terminology differences. To avoid this confusion in the future, clarifications on the aspects pointed out by the respondents were incorporated. This involved a change in Section 5.2.3.2 in Figure 5-7 regarding issues which need to be considered at the Requirements Clarification stage. This change involves separation of the project management specifics from product/service design realisation. Vocabulary previously used could lead to misunderstanding and focusing on the management tasks instead of the design tasks.
- Lack of explicit service consideration for team selection, modelling, simulation and prototyping stages – the author acknowledges limited input of service-orientation in the mentioned phases. Although not explicitly phrased, services are present in the mentioned stages; the continuation of work from the previous stages regarding service development is expected. To avoid confusion for the reader, elaboration of service actions to be undertaken is incorporated in the mentioned stages.
- Not possible to identify a compromise in terms of types of microfluidic devices which enable more services – a compromise on disposability, on flow type, etc. – this was pointed out to address trade-off in the solution's development. The author acknowledges the potential of contribution of the research in terms of '*which tradeoffs enable services in microfluidics*'. Some tradeoffs have been identified during the research. However, they were not listed and/or elaborated. This weakness will be added to the future research recommendations to enhance knowledge in the area.

The majority of participants considered the guideline as sufficient and providing an opportunity to microfluidic designers, some required additional information to be confident in judging this aspect, and one person stated a requirement for improvement. This requirement has been supported by the need for service

assessment and measures for it to be identified. The author does not consider these aspects as a necessity at the current state of design practice identified in the domain (see Chapter 4). However, as mentioned previously, service classification leading to this assessment is considered as useful and recommended.

Suggested by participants, the methods to enhance the guideline have been viewed in the following manner:

- Categorisation of services during use phase – considered beneficial and incorporated in the Future Research recommendations.
- Categorisation of the companies – Categorisation of the companies from a services point of view can help to develop the service base offering by identification of common characteristics for the group. This issue provides the opportunity for new research and/or continuation of the current research from a different point of view.
- Explicit example on the guideline usage – considered as beneficial by visualisation of how the guideline can be applied in practice. The author does not feel competent to prepare an example without cooperation of a microfluidic designer who will provide specific knowledge required in the device development. Also, as mentioned a number of times, microfluidics development requires a multidisciplinary team, and the author does not posses the expertise required in the domains such as chemistry and software development, which is considered crucial in many device types. Therefore, this work has been left for microfluidic designers as experts.
- Provide a tutorial session for the guideline – development of the guideline tutorial requires narrowing it to a particular type of microfluidic device which the adopting organisation will be interested in. Regarding the fact that the guideline aspires to be a general design process in the microfluidic domain, a number of tutorials needs to be prepared to provide details on implementation of the guideline. An alternative is preparation of one tutorial for a general guideline which an organisation will be able to adjust, and this approach seems most preferable.

- More thinking about services to design a better product for satisfying customer needs – the guideline has been prepared to answer the demand for service-orientation of people already possessing service based offerings and is not focused purely on products. Incorporation of additional service considerations at front end stages can discourage people, who do not posses service capabilities at the moment, from using the guideline by shifting their attention away from the microfluidic device, and therefore, develop a solution not addressing the technical problem sufficiently.
- Incorporate end-of-life considerations into the guideline – regarding the fact that the majority of microfluidics are disposable, end-of-life phases have been eliminated from the guideline considerations. The author acknowledges, however, the potential of services in the product afterlife. Therefore, a short list of potential services is intended to be added at the end of the guideline to address this issue.
- Focus on microfluidics should be more explicit – the guideline is addressing issues particular for microfluidics, and characteristics of their design scoped it. The guideline has been reviewed from the perspective of being microfluidics explicit, again with consideration of other aspects mentioned by microfluidic designers in their feedback questionnaires (Sections 6.4.3.2 and 6.4.3.3). This resulted in changes incorporated in the solution, of which the final version is presented in Chapter 5.

The answers regarding sufficiency of the guideline for addressing needs of organisations developing microfluidics have been identified as positive. Summarising, the participants viewed the guideline as novel and beneficial for the area.

6.5. Summary

This chapter presents and discusses the validation of the solution developed to address the needs of the microfluidics area in terms of design. First, it presents the approach to validation, giving its rationale and implications. Next, it shows results

of the validation. Finally, the interpretation of the results is given, incorporating the influence of the feedback on the final structure of the solution.

The validation has been prepared as multiple approaches due to the impossibility of performing an 'ideal validation' within the research constraints. The 'ideal validation' has been considered as adoption of the solution by an organisation for product development, from the beginning of the process through to successful commercialisation. Because of the infeasibility of this approach, multiple approaches have been used.

Validation has been scoped in two stages: validation of the findings obtained from literature and practitioners work analysis, and validation of developed solution. The first validation stage, Stage 1, has been performed to assure quality of the information used to develop a solution for the domain's issues; the second, Stage 2, to validate this solution. Due to the usage of grounded theory as a partial methodological approach, and therefore, emergence of the solution directly from the 'data', the quality of data has been considered crucial.

Stage 1 validation has been considered successful and has confirmed the accuracy of findings. The Stage 2 validation has been approached in multiple ways to increase reliability of the results and aspects to be covered. This stage included two validations of the solution as a whole, and two validations of the guideline as the core part of the solution.

As mentioned, Stage 2 consisted of four phases: (1) the validation of the guideline by comparative analysis, (2) the validation of the solution by microfluidic experts via feedback forms, (3) the validation of the solution by microfluidic experts via interviews and (4) the validation of the guideline from a service point of view. The design enablers have been eliminated from two validation attempts, due to the following factors: lack of equivalents indentified for comparative analysis, and restricted time available for the validation session.

Validation has been performed (covering a number of perspectives on the solution) by internal and external experts, by academic and industrial practitioners, by

microfluidic designers and service specialists. Moreover, a variety of techniques have been applied: questionnaires, interviews, workshops and comparative analysis. Therefore, the validation approach is considered sufficient.

The solution presented in Chapter 5 has been validated in a systematic manner based on the prepared validation approach. Results of all validation attempts evaluated the solution and its core element as GOOD. The evaluation is considered as successful based on, in the majority, the positive feedback obtained. Although a number of improvements have been recommended by experts, not all of them have been considered as valid and incorporated in the final version of the solution (see Chapter 5). A number of recommendations have been identified as out of scope for this research. However, regarding their potential to enhance microfluidic design and to bring benefits to the domain, they have been used as an additional input for the future research (Section 8.3.1) and for maturing the solution (Section 8.3.2). Conclusions for the validation, as well as for the research as a whole, are presented in Chapter 8, with identification as to what extent the research aim has been achieved by development of the validated solution.

Chapter 7
Discussion

The proposed solution has been developed based on literature models, indications from literature regarding microfluidic design and characteristics, and practitioners' work in the domain. Each element of the solution possesses its own rationale. To underline the importance of considerations and steps incorporated into the solution, the rationale has been omitted from the solution's presentation; this has been discussed in this chapter. The discussion in this chapter is divided into five parts: (1) methodology for the solution's development (2) the solution's structure and rationale (3) the solution's application (4) its main attributes and (5) limitations.

Firstly, the strengths and weaknesses of the methodological approach for the solution's development are presented in Section 7.1. They are described based on rationale behind them, their implications and attempts of their minimisation.

Secondly, the structure and rationale behind the developed solution are given in Section 7.2. The solution has been discussed at two levels: high - which includes the guideline overview (Section 7.2.1) and design enablers (Section 7.2.2) and detailed – presenting the guideline's stages (Section 7.2.3).

Thirdly, the solution's application method is presented in Section 7.3. It discusses who is intended to apply the proposed framework (Section 7.3.1) and how (Section 7.3.2), giving the motivation behind recommended responsibilities.

Fourthly, the main attributes of the solution are highlighted in Section 7.4 regarding the opportunity to generalise it (Sections 7.4.1 and 7.4.4), its service-orientation (Sections 7.4.2 and 7.4.4) and how sub-section interactions (Sections 7.4.3 and 7.4.4) were addressed in it. Discussion has been separated into these three issues as they are considered to be of high importance, and they have been structured based on the

advantages and disadvantages of their implications. Furthermore, the discussion has been divided into the presentation of the guideline in Sections 7.4.1 – 7.4.3 and design enablers as 7.4.4.

Finally, the solution's limitations are presented in Section 7.5 based on their rationale and implications. The limitations are divided into two groups: being a direct result of the used methodological approach (Section 7.5.1) and capabilities which the developed solution possesses (Section 7.5.2).

7.1. The Solution's Development Methodology

As part of the project's methodological approach, a methodology for the proposed solution development was established (see Section 5.1). This methodology allowed for systematic and comprehensive building of a suitable solution to address the microfluidic domain design issues.

The methodological approach for the research possessed a number of strengths: being area and project specific, therefore allowing more accurate results to be obtained, reproducibility, time-efficiency and providing a combination of best features; and weaknesses: a strong dependence on investigator's skills and creativity, lack of external validation of the methodology and incorporation of time-consuming work. These strengths and weaknesses (for details see Section 3.3) are also valid for the proposed solution development methodology. However, additional aspects of the methodology created a new set of characteristics, and advantages and disadvantages for the developed approach.

Strengths previously not listed and valid for the proposed solution development methodology include:

- Iterative solution development – achieved by a number of categorisation steps. Iterative development of the proposed solution allowed the maturing of the approach during its development. Progressing from the first draft of the framework towards its final shape, in a systematic manner, allowed for filling the gaps identified and design enhancement.

- Assurance that the output is strongly connected to data and the area – basing the approach on grounded theory allowed for development of the solution as emerging from data. Therefore, the whole project has been approached as specific for the microfluidic domain. However, the methodology for the proposed solution development took it further by incorporation of the elements already existing in the area in the new framework - e.g. shape of the guideline. This reliance on the existing aspects, with incorporation of the domain needs, allowed the author to capture best practice in the domain.
- Consideration of solution acceptance during development and incorporation of suitable enablers – the methodology incorporates considerations of the designers' daily work and what they are used to. These considerations occurred not only during the shape selection for the developed framework, but also throughout it, starting with data collection and investigation of the current practice in the domain. Reliance on familiar approaches aims at increasing the proposed solution's adoption and decreasing change rejection, which is natural for human beings.

Additional weaknesses of the methodological approach are as follows:

- Possible disconnection of the approach with what industrial practitioners in the area would prefer - sporadic contacts with practitioners and their limited involvement in the proposed solution's development could lead to issues for the approach adoption. This limitation could be avoided by the involvement of practitioners during the development as consultants of the work and not only as experts for validation. This limitation shows potential for more accurate validation due to the fact that people are less keen to criticise their own work. Therefore, if practitioners were used at the development stage of the solution, they would be seeking their own feedback in the work instead of evaluating the framework from the utilisation point of view. Moreover, practitioners in the microfluidic area, as in any other domain, are seeking tools to use rather than methodologies which are, in many cases, too general and require adjustment to be implemented. The presented methodology

allowed bridging of the gap in academia and development of a general methodology for the domain, not the tool itself; therefore, people's willingness towards its implementation is more questionable.

- Possible bias incorporated on the basis of author's prior knowledge in the design domain – the author possesses a degree in engineering design which is not connected to the microfluidic domain. Therefore, her familiarity with existing design methodologies for macro domains can be viewed as potential bias. The author attempted to mitigate this bias by consultation on the approach during its development with supervisors, and by providing rationale for every step on the way (to avoid influences). Systematic development of the solution allowed minimisation of potential bias and use of previous knowledge for the benefit of the research as an additional set of data, increasing the comprehensiveness of the investigation.

In the process of minimisation of limitations of the methodological approach used, the disadvantages have been viewed as opportunities and used to enhance the developed solution. Therefore, the advantages outnumbered disadvantages, presenting the used approach as suitable for the domain and sufficient for the realisation of the research aim.

The solution itself possesses limitations and advantages as an effect of the methodology and data used. Discussion of the framework developed in this manner is presented below.

7.2. The Solution's Structure and Rationale

This section discusses the proposed solution to address microfluidic design's needs regarding its structure and rationale. It is scoped in three parts: the guideline overview discussion, discussion of design enablers and detailed discussion of the guideline steps. Due to the fact that the proposed solution consists of two elements, both the guideline and a set of design enablers are elaborated upfront in order to provide a complete view of the solution. Various levels of details and amounts of information incorporated in both parts of the solution placed a requirement for

further explanation of the guideline to clarify its content. Therefore, the third element of discussion from the structure and rationale point of view has been incorporated as discussion of the guideline in a detailed manner – discussion of the guideline's stages.

Firstly, an overview of the guideline has been discussed regarding its main shape and elements. The rationale behind the guideline's appearance has been given. Moreover, strong and weak points of the guideline are emphasised, as well as the advantages and disadvantages of usage in particular aspects.

Secondly, a discussion of design enablers for microfluidics has been provided. This discussion is framed in a different way. It has been approached in a structured manner, listing as bullet points for enablers: rationale behind, strengths and weaknesses. This alternative manner has been selected to explain the recommendations, when a discussion of some of their elements can be found inside the guideline's stages, where appropriate.

Thirdly, to simplify the comparison of the guideline with the rationale behind its development the discussion has been framed following the guideline's steps (as presentation of the solution in Chapter 5). The reader will be taken, step by step, through the guideline stages and given justification for the actions undertaken at each stage. This discussion is linked directly to the issues inside the guideline including incorporation of the decision making process diagrams' alphanumerical codes and referring to them where appropriate. These codes (see Section 5.2.3) have been assigned in the order of the discussion. Issues mentioned are discussed regarding their rationale, strengths and weaknesses for microfluidic designers.

7.2.1. The Guideline Overview (Level 0) Discussion

The guideline is intended to enhance the design process and acceptance of microfluidic devices in the market. It aims, in the short term, to simplify and standardise methods used for the design of microfluidic devices. It intends to enable the establishment of one general design process for microfluidics in the organisation, which can be flexibly used with minimal changes in all microfluidic projects. In the

long term, it aspires to automate the design process and make it easier to follow for less experienced designers. Moreover, it should be self improving based on captured knowledge throughout the process usage and adjustments incorporated by the organisation to match designers' particular demands. It aims to prepare companies for a service-oriented future of the domain by slowly increasing their engagement in this intangible area and improve customer value delivered.

The contribution of the guideline lies in suggestions of considerations at particular steps and in the arrangement of tasks. The guideline summarises issues which should be considered during the design of microfluidic devices. It fills the gaps in general processes for microfluidic design and inside existing models applied within this domain.

As can be observed, the guideline is more similar to conventional design processes (see Section 5.2.1, Figure 5-2) than models identified in the literature as being micro-design specific. Also, it presents more commonalities with the 'top-down' methodology developed by Chakrabarty and Su (2005) than with 'sickle model' or 'V-model'. However, it incorporates features of all of them e.g. an iterative approach to design, increasing amount of information feeding into the stages, consideration of fabrication at the early stage of design, and many more. This shape similarity is caused by the selection of a flowchart for guideline representation and characteristics pointed out by microfluidic practitioners - e.g. minimising iteration due to costs. A flowchart has been selected as an approach used by designers on a daily basis, which aspires to increase the probability of the guideline's adoption and makes it easier to follow.

Selection of the top-down approach has been based on many indications regarding superiority of this approach for the micro-domain (Chakrabarty & Su, 2005; McCorquodale et al., 2003; Melin & Quake, 2007; Liu et al., 2007; Mukherjee, 2003). It has been identified as allowing for simplification, automation and optimisation at the lowest level of the hierarchy, for which a bottom-up approach can be a barrier. A bottom-up approach has, however, been incorporated in the validation/verification stage due to its benefits in reviewing design. The top-down approach is represented

in the main model by the arrow on the right-hand side, and both approaches are visible inside Level 1 of the guideline. Lack of visibility of the bottom-up approach for the verification on the high level (Level 0) of the guideline has been selected for view clarification i.e. not to overwhelm the guideline user with high amounts of information and confuse him/her when approaching design. This can be considered as a limitation of the guideline. The rationale behind this is to increase adoption and simplify the steps by providing an easy-to-understand portion of information in a straightforward manner.

Iteration is incorporated in every design process, although its minimisation decreases the cost of design. During the presentation of the guideline, it is mentioned that iteration can occur independently of the designers' work, even if everything has been considered and approached correctly, due to the domain immaturity and lack of knowledge about some mechanisms connected to microfluidics. This iteration has been identified between five stages: conceptual design, simulation, prototyping, validation/verification and manufacturing. Iteration between other stages, e.g. modelling and detail design, indicates that something has been missed or neglected in a previous phase. All the iteration loops are indicated as possible to occur; however, they are discouraged and should be avoided or transferred to earlier stages if possible. The later changes are incorporated in the process the higher cost they generate.

The recommended constant comparisons of the design outputs with specifications is time consuming, considering the overall amount of effort used, and is tedious work due to its repetitiveness. However, this step is necessary to deliver customer satisfaction and allow for 'keeping an eye' on the project target. It assures fast reaction to any changes crucial in microfluidics where modifications are expensive, especially in manufacturing.

As presented in the guideline, possible project dropouts are not equal to failure and should not be regarded as such. They should be considered as conscious and strategic decisions for the organisation. Points at which projects can 'end' have been indicated on the guideline as crucial for the main theme of the guideline – 'Do not design

solutions for non existent problems. There are already too many of them'. This self-explanatory statement is supported in terms of recommending what can be done if the project is not suitable for microfluidics by showing organisations alternative options.

The funnels of data presented in the model for prototyping and manufacturing stages indicate that input is not obtained here on a stage-gate basis. The fabrication considerations are incorporated in the guideline at an early stage of design, which is necessary for microfluidics and drives the process. Technology limitations force significant constraints on how these devices can be designed. To minimise the cost of design, manufacturing has to be planned as soon as possible, and all the changes in the data which influence this process kept up-to-date. The guideline presents this approach, which is considered to be one of its strongest points. A significant limitation is lack of enhancement allowing for inexperienced designers to select from various manufacturing methods, considering the constraints of production processes. Development of a tool allowing this is part of the recommendations for further research; however, due to the number of factors which have to be taken into consideration when developing various types of microfluidics, this tool will need to be restricted to a particular type or application.

The guideline has been developed, using partially the grounded theory approach, by extracting theory from data. It also has been validated using four factors regarding its relevance as a theory (Glaser & Strauss, 1967): fit, understanding, generality and control. Therefore, the guideline has been scoped to fit the microfluidic domain, be understandable by designers of these devices, be general enough to allow for development of a variety of microfluidics and flexibility in the projects, and give control to the designer on the project. This evaluation allows the author to state that the guideline emerged from data in this domain and, therefore, it is peculiar to microfluidic issues.

7.2.2. Design Enablers Discussion

To enhance usage of the guideline by incorporation of additional considerations (not included in the guideline but considered important and necessary), the design enablers have been listed. The set of design enablers has been a result of the guideline development process. During categorisation of data a significant amount of data showed different levels of generality to those incorporated inside the guideline stages (Level 1) and high level model (Level 0). These same sets of data showed difficulty in being assigned to any particular stage or a couple of stages. To incorporate this information in the project's realisation, enablers have been listed separately to be applied across projects. Each of the design enablers has its own purpose, as well as strengths and weaknesses, and these are presented below.

Involve the client in milestones (and critical decision points) and during validation/verification, i.e. do not involve him/her at all the steps between the milestones unless the project's specifics or organisation's operation requires it,

- Rationale: assures that project is going according to their needs – to minimise time and costs.
- Strengths: client specifies what he/she wants, up-to-date changes in requirements.
- Weaknesses: consumes resources, not always relevant feedback because of client's lack of sufficient knowledge.

Establish core elements in the set of microfluidic devices (standard element or elements of design)

- Rationale: design process automation allowance.
- Strengths: development of component library, reuse of modules/components across products, increased efficiency of components search in similar types of projects, saving time and money.
- Weaknesses: problem with element selection of one core element in multidisciplinary products development, IP rights to modules/component.

Develop models of already validated and produced products

- Rationale: allow for their reuse in future projects, minimise cost of development.
- Strengths: no reinventing the wheel, no experiments necessary, modules' performance is known.
- Weaknesses: IP rights to modules/components.

Slowly develop in-house database of modules/components (component library)

- Rationale: design process automation allowance, reuse of modules/components in future projects.
- Strengths: decreases time consumed in device development, efficient search of components/modules by specifications.
- Weaknesses: time consuming, IP rights to modules/components.

Establish group of general modules providing basic functions (e.g. mixing, channelling, etc.)

- Rationale: design process automation allowance.
- Strengths: development of component library, reuse of modules/components across products, saving time and money in the long term.
- Weaknesses: IP rights to modules/components, time consuming.

Validate created models for a variety of fluids

- Rationale: design process automation allowance, reuse of modules/components in future projects.
- Strengths: development of diversified component library.
- Weaknesses: cost of validation, time consuming.

Encourage informal communication inside the project team but do not eliminate a formal one

- Rationale: improves customer value.
- Strengths: helps to resolve issues arising during the project, stimulation of creativity and thinking process of team members, people will feel more comfortable addressing problems and admitting to lack of knowledge about particular areas, as well as shortcomings of certain solutions, when during formal meetings they can show reluctance towards this.
- Weaknesses: team members avoid formal routes of communication, this can decrease control over the project for team leader in large groups.

7.2.3. Detailed Guideline (Level 1) Discussion

The amount of details incorporated in the guideline placed a requirement for elaboration on the rationale behind particular tasks incorporated in its structure. This reasoning is given below. To allow the reader a fast comparison between the guideline elements and rationale behind them, the discussion follows the guideline's stages according to their presentation in Chapter 5. Each stage has been elaborated on separately, regarding the reasoning behind considerations and tasks suggested, and its limitations.

Many steps incorporated inside the guideline's stages are a common design practice and are self-explanatory; therefore, their discussion is omitted. Moreover, the discussion is linked directly to issues inside the guideline by incorporation of the alphanumerical codes in process diagrams. These codes (see Section 5.2.3) have been assigned in the order of the discussion for the elements of the guideline considered critical.

7.2.3.1. Problem Identification

Many microfluidic devices are developed to prove a principle or establish new cutting edge technology. These types of devices are struggling to find an application in the market - too many of them are 'waiting on the shelves' in organisations

looking for a 'killer application' which will make their manufacturing profitable. To avoid this issue, this step is recommended to be added at the front, as a priority in the design. Moreover, the basic principle is stated to underline the importance of the market demand (PI1). This step is additional to the work currently done by organisations and requires the investment of resources – both money and time. Therefore, many organisations can be reluctant to implement it. However, it is considered crucial to provide commercially successful offerings.

Identification of the issue which is addressed by client (PI2) is advised to be undertaken from two aspects: functionality and problem. Sometimes, what the client is trying to achieve is not what he/she is considering as requirements in terms of functionalities. Required functionality often can not help in solving the issue or can be easily misunderstood and, although a developed device will perform according to specifications, it will not help to solve the issue. To avoid this, a step is required which will clarify the client's problem. Being secretive about the issue only increases the possibility of being misled in design. Undertaking the project should be reconsidered by the organisation in the case of a customer being secretive about a problem which he/she is trying to solve. This situation does not take place in projects originated internally.

Microfluidics is a relatively new field which offers significant benefits, however, in a very restricted domain. It is not the universal solution for everything (PI3). In many cases, there are easier and better methods to solve particular issues. Microfluidics must not be forced to maximise the number of devices in the field, but only used to address problems which require the unique capabilities offered by them.

When microfluidics is not the best method to address a particular issue and the organisation undertaking the project is diversified (PI4), the latter can offer capabilities from other domains which will better help to solve the problem. Finishing a long and potentially expensive project which is not 'the best possible method to address the problem' can only assure a 'one time income' not a long term relationship.

Identification of the issue which the client is trying to address also provides an opportunity for service-orientation (PI5). However, steps leading towards services were left to the end of problem identification stage to ensure a logical sequence of steps. Link between demanded functionality and problem solving ability captures real need and, therefore, delivers customer value instead of just ensuring that a device is working.

The problem identification stage showed five possibilities for project dropout (PI6). Each of them suggests looking at recommendations of other organisations to help solve the client issue. This can ensure that when a potential client has an issue in the future, which can and should be addressed by microfluidics, s/he will contact the organisation again.

The microfluidic domain has been identified as not ready for PSS. Offering functionality instead of a device is one of the PSS offering types (PI7). This type of offering requires a good basis of services and a business model implemented to support the device for the duration of the contract. An organisation which identifies a customer demand for this type of contract, however, can assure itself a long lasting relationship and, therefore, a loyal client and stable income over a long period of time. Due to the lack of the PSS type business models identified in the domain and immaturity of the area, this suggestion is left for the organisation as a step to be taken in the future.

As mentioned in the guideline, service-orientation is starting to be incorporated at this stage. The possibility of a functionality offering instead of a device is only one aspect of this. Other points are based on more approachable service type offerings and considerations. Identification of a broad scope of services which can be offered with the device, and for the device, will not only increase the organisation's income, but also deliver a higher value to the customer, and hence provide advantage over competitors. Depending on the organisation's readiness, the device type under development, customer decisions and service opportunities, the next step of the guideline incorporates various service thoughts.

7.2.3.2. Requirement Clarification

Clarification of requirements is necessary in every case to assure that the organisation is able not only to deliver, but also to do so on time and within the cost specified, as well as assure the quality of the deliverable. The guideline underlines this necessity and its dependence on the project origin. Client demanded projects require different sets of skills (applied during requirement clarification) from internally started projects. Managing the relationship with the client can be difficult and delicate work. Therefore, there is a requirement for the organisation's contact person, who will obtain this data, to possess a particular set of skills. A combination of selling skills with deep engineering and microfluidic knowledge is necessary for the domain. These skills will allow the contact person to discuss with the customer what characteristics and data are needed, and to negotiate on technological aspects, which in many cases is required.

The guideline puts focus on the development of a project brief document (RC1). This document is intended to automate the process and simplify the work of less experienced designers by providing a checkpoint of what the organisation requires and has to offer. Regarding the broad range of microfluidic devices which can be developed, only high level suggestions are given in terms of the document scope. The organisation has to adapt the project brief to their capabilities and offerings. This document is aimed to be filed independently of project origination. If the organisation is developing a product on its own demand, this document will clarify the needs and help keep track of work progression. It will be used in the later stages for comparison between specifications and the results of the design.

The guideline is oriented towards services that are underlined in this stage by incorporation of the service-section in the project brief, and consideration of the service characteristics in the decision making process (RC2). These characteristics are aimed to be investigated, even if the client is only targeting the development of the device and is not interested in the service opportunities. Hence, it can be viewed as time-consuming and not value adding in the short term. In the long term view, it attempts to collect characteristics to develop service-based offerings. Hence, it

creates for the organisation the opportunity for diversification of profit sources and the acquisition of new markets.

The requested lack of client awareness in the case of output III (see Section 5.2.3.1, Figure 5-4), during identification of the service opportunities, is a strategic decision. The majority of clients have a negative attitude about contractors spending time on work outside the contract scope, even if it will improve the value in the future. To avoid misunderstandings and in order not to confuse the client with an offering which is not prepared or only scoped briefly, it is recommended to capture demands and characteristics confidentially.

Some of the issues specified (see Section 5.2.3.2, Figure 5-7) are common for every design process, such as identification of required resources to develop the device. Few issues are common across particular types of domains such as intellectual property (IP) issues, which for new and/or immature domains where component libraries are not commonly available and many models simply do not exist, is more sensitive and crucial. The issue of novelty allows for competitive advantage and discourages knowledge sharing across the field. Therefore, it slows down the development of the design support tools. Re-use of models, which these issues are concerned with, will in the future speed up the design of devices; however, this requires a systematic work. Other issues are domain specific, such as the type of flow in the device.

7.2.3.3. Project Team Selection

Project team selection is one of the stages not illustrated by the decision making process. This has been considered as not required, due to the common presence of this step in design. It incorporates a set of suggestions concerning the team for the project and people's knowledge. The structure of the team strongly depends on the organisation and project under consideration – its size, number of people available, and experts in the field, etc.

The person/people who clarify requirements with the client should be involved with the team. In this manner, a better insight into the specifications will be given by

incorporation of their insight into the client's attitude and reactions when clarifying demands. In the case of internally originated projects, the person who came up with the original idea should be involved. This involvement is connected to personal motivation due to 'own ideas' development. This allows employees to feel appreciation of their ideas within the company and increase their commitment. A shortcoming of this can be lack of sufficient knowledge in the microfluidics particular to the project or a lack of experience. These factors slow down development work and tie up resources which can be used for other work. Therefore, when a lack of sufficient knowledge is identified, the person is encouraged to be involved in the idea generation stage to provide an insight and in other stages while comparing the outputs with specifications, if specifications are not evolving in the project.

This stage is common in every design process. The guideline does not differ from any conventional design process in this manner, but highlights the need for multi-discipline involvement, deep knowledge of the design area and experience within the team.

7.2.3.4. Idea Generation

The idea generation stage is now a common design practice. Many organisations are using creative methods to enhance design, solve difficult issues and find 'out of the box' ideas. There is no 'one' creative design method which is suitable for every organisation. The organisation is asked to select a method (IG1) based on the familiarity of the project team with particular techniques. This selection will ensure the speeding up of work by minimising training costs and focusing on the problem instead of focusing on the need to learn new techniques. The majority of people are averse to changes, and minimising them improves the adoption of the process. This point has, however, a weakness because of the possibility of avoiding the usage of other, more suitable methods for a particular project.

The selection of participants (IG2) for the idea generation session should be undertaken for project specifications. People with the competence needed for project

realisation (as in the project team) are expected to be involved, as well as additional participants who can provide input from connected areas, thus broadening the idea generation space. To involve a person from the requirement clarification stage, as explained in the previous step, is considered beneficial in this step. Providing insight about a client's behaviour during clarifications can save time. Incorporation of the idea originator within the team is, however, more controversial. Passion for and appreciation of the acknowledgement of their work can be counteracted with potential sensitivity and rejection of any ideas that vary from their original one. Hence, the project leader has to decide if the person who originated the project will or will not be present in the idea generation stage, depending on the personality of the participant and their ability to be part of the team.

Variation from conventional approaches is among the issues to be considered and also the manner of undertaking the session. Within creative methods constraints are eliminated or encouraged to be minimised. These methods encourage borrowing problem solving methods from other domains and being as broad as possible. In microfluidics, the scope of this session needs to be more constrained – a certain amount of focus is necessary on the number of issues which need to be considered during design . Constraining the idea generation session, in terms of scope for microfluidics, is mainly due to the amount of knowledge about the area which is necessary to make sensible suggestions. Therefore, the organisation is asked to prepare documentation (IG3) and send it to participants (IG4) before the session, including what is expected from them. Time suggested is between two days and one week. No more than a week is recommended to allow for a fresh view on the project, and not less than two days to allow for reading it with understanding and rethinking.

Given the limited experience of microfluidic designers in service development and identification of the microfluidic domain as technology driven, a list of services which can be offered were included in this stage. This list is not comprehensive and has been placed just as a suggestion – this has been clearly stated. This list aims to trigger the reader into seeing what type of services can be offered with the currently

developed device or that are enabled to be incorporated later, and broaden his/her perspectives during an idea generation session.

The session (IG5) is recommended to be moderated to encourage opinion sharing. The opinion of the moderator needs to be expressed at the end, as the person with the highest competence, so as not to influence others. In situations when a senior person in the organisation will be participating, for this same reason, his/her opinion should be expressed at the end.

A summary of the service characteristics is advised to be incorporated in the document briefing for the session. These characteristics can be used not only to develop the service type offerings, but also to help in thinking about the 'out of the box' ideas since service is not usually considered. As in previous phases, some organisations may consider this to be a waste of time and exclude this from the session.

In the case when, after the ideas session optimisation (IG 6), the result constitutes multiple choices, the selection of a maximum of two ideas to progress with is preferred. Proceeding with more than two solutions is not recommended (IG 7) due to the design cost. A number of considerations which have to be taken into account and uncertainties in the design caused by immaturity of the area means that the high cost of any additional ideas to progress with are not justified in the long term. However, when two ideas are equally good, their development for a limited amount of time is considered beneficial to avoid selection of an inappropriate one. This step increases the cost, but at the same time, increases the probability of success with the design.

When more than two solutions seem optimal, or when none of them appears to address all the issues in the specifications, then a new session should be performed. A more focused session (IG 8) will allow the group to focus their view on what is necessary and achievable. If discussion after the first session was found to be insufficient, then a broader session scope can allow for novel solutions. In a broader session (IG9), borrowing ideas from other domains and the minimisation of

constraints can allow for 'fresh' ideas'; however, at the same time, it is more time consuming and increases the risk of losing focus on what has to be achieved.

Repetition of the session (IG 10) is encouraged using the same method. Usage of various approaches (e.g. brainstorming and six thinking hats) during the same project can refresh the ideas; however, it can be risky due to the possible confusion of participants. To minimise the risk of a participant losing focus (and instead of working on the solution to the problem by trying to understand the steps to be followed in the new approach) a usage of one approach is encouraged.

7.2.3.5. Conceptual Design

Based on the literature findings, a top-down approach has been selected (CD1) as suitable for microfluidics. The conceptual design stage is the part of the guideline where this approach is highlighted, although practice investigation (survey, interviews) has shown that currently a bottom-up approach is used. Development of the concept starts with the architectural level and goes into detail using product breakdown. Working with the top-down approach ensures that all of the elements developed will fit together, which is critical in both modular and monolithic approaches. By using this manner of development, focus is placed on the performance of the device as a whole and interactions between elements. It highlights the importance of interfaces between the device sections.

Complexity of work at this stage depends on the amount of information from previous projects which can be reused by an organisation (CD2). With every new model developed and stored, the organisation will build up its capabilities, speed up the design process in the future, and simplify the conceptual and detailed design stages. Even in cases when all the necessary components/modules exist, the idea of putting them together to fit into the concept can be problematic. Therefore, development of common interfaces and suitable connectors is advised. Moreover, the top-down approach, using which the first high level concept is developed before the details of sections are considered, ensures that the device will operate as required. At the same time, it imposes on identified existing modules changes that will fit into

the developed architecture rather than the opposite. This leads to demand driven design rather then technology. These considerations have led to both the need for verification of the concept as a whole before elements of it are sent for detailed calculations in the next design stage and conformance of concept comprehensiveness at the architectural level before detailed calculations can be assigned to the project team. Project team tasks should be planned up front of this phase to allow for concept development.

As can be observed (see Section 5.2.3.5, Figure 5-10), the conceptual design stage is more concerned with the usage of existing modules, and interface issues, and hence, deals with sub-section interactions. The consideration of services (CD3) is not neglected either (see Section 5.2.3.5, Figures 5-10, 5-11), although in many organisations, these will be omitted, at least at the beginning of guideline acceptance, because of the different mind sets being applied. There is a general recommendation, while developing the concept, to keep in mind the services it can help obtain and the value which it delivers as a whole, and similarly, for every component/module later. Moreover, the infrastructures necessary to deliver services need to be considered and prepared at this stage with a workforce assigned to the task and methods planned to deliver those services.

Revision of the fabrication process is considered here as crucial. Information obtained until now and in this phase should allow planning of the manufacturing process. Due to the technology driven design of microfluidics, if decisions on fabrication are not undertaken at this point, costly iterations or failure of the project are likely. Therefore, the fabrication process is expected to consider that 'what is possible to be manufactured is not an issue in prototyping but in final production' however decisions cannot wait till then. Moreover, preparation of the equipment needed and setting up parameters for the process need restrictions due to the area immaturity and the simulation results' lack of dependability which create a strong reliance on the trial and error approach.

7.2.3.6. Detailed Design

The detailed design stage is based on detailed calculation (DD1) of the flows, materials, manufacturing processes and assembly (if applicable). It assures that quality of the surfaces will be met, and that they will be the same across the device to assure stable flow, etc. The presented approach for the detailed design stage is similar to the conventional design process, not only for micro but also for macro-scale devices. The specificity of microfluidics is captured at the conclusion of manufacturing planning which, at the end of this stage, should be agreed on in a final state (details agreed on), whereas in a conventional design, it is happening during and after the prototyping stage. Any changes which are incorporated later, due to the area immaturity and the number of iterations, tends to be minimised over time with increased knowledge about the domain.

The detailed design stage continues with a top-down design approach and confirmation of the device performance at the architectural level (DD2). It is focused on the calculations and their value for customer satisfaction. Separation of the steps for a leak-proof device (DD3), assembly methods planning (DD4) and decisions on final dimensions (DD5) aim to underline the importance of these tasks - they are crucial for microfluidics and cause the main issues in this domain. Selection of a modular approach to design, which in the guideline is encouraged for the majority of devices, has been identified as increasing the risk of leakage, and the assembly issues which arise then have to be resolved. This weakness of the process, however, has the advantages of standardisation and reuse which, in monolithic approaches, are minimal.

Service delivery (DD6) is a set of tasks which should be incorporated when service opportunities were identified at a previous stage. Formalisation of service planning, its preparation as a business plan, arrangement of the necessary infrastructure and implementation of resources are important for the creation of successful service offerings, but also time consuming. This process is not identified as taking place extensively in the microfluidic area, and initial steps suggest the need to guide organisations in the initiation of this type of work. Recommendations here are

limited and are encouraged to be taken further by organisations, by adapting the guideline to their needs and specifics. The guideline is limited by its generality for all microfluidic types need, and therefore, does not present all the steps which should be incorporated for a particular form of device. Also, the high technicality of this step does not allow for going into great detail without the usage of specific software, which is not included here.

7.2.3.7. Modelling

The modelling stage is approached as in conventional design. Specific modelling software for microfluidics is not recommended here, but left to organisations to decide upon. Organisations are advised to invest in the development of in-house tools, as the particular issues of an organisation may not be fully addressed by commercially available software. This can also decrease both the cost of training and implementation of aids which are not suitable for the task.

Recommendations made at the modelling stage, which are to be incorporated in the process, have their own rationale regarding usage of particular parts of the device in future projects without interfering with: part integrity, automation of the process by development of the in-house component/modules library, increase in dependability of structures, and assurance of device performance to deliver customer value.

The decision to perform simulation (MD1), if not made before, has to be decided at the modelling stage. Due to the high cost and the questionable dependability of the simulation results, undertaking simulation has to be justified by a clear client requirement or project specifics, e.g. complexity and lack of sufficient understanding of working principle. These factors mean that simulation results will be an output from the design process or that information obtained from the previous phases is not sufficient to start prototyping.

Organisations possessing microfluidic modelling capabilities can consider offering it as a service. This will provide an additional profit source and increase diversification of offerings. However, it should not intervene with realisation of key projects. An assurance of resources availability for the work and profitability are necessities.

Realisation of the service delivery process, indicated in the previous design phase, is considered as a simultaneous work undertaken during the modelling stage. Due to limited identification of well established service offerings in the area, development of these aspects of the process can take longer, because of restricted familiarity of organisations with service development.

7.2.3.8. Simulation

All aspects discussed for modelling also apply to simulation. Considerations of the low accuracy and dependability (even if simulation is performed correctly, input data and the model created can be questioned due to limited knowledge in the area) of simulation results, in comparison to prototyping, do not allow the use of this stage every time in the process. Even development of the component library, for some elements, can be insufficient to perform simulation in a time constrained project. Therefore, in some cases, if the organisation possesses an in-house capability, they can perform simulation afterwards (when the project is finished and they possess IP rights) if cost of that simulation is feasible.

Performing simulation after the project is accomplished can help in increasing the accuracy of possessed simulation tools by providing 'real life' models and results (based on device performance) which can be used for comparison and therefore help in extracting behavioural rules. Results from these simulations can be linked to developed models to expand existing component libraries and speed-up future designs.

Suggestion regarding service type offering at this stage is as in modelling – decision on utilisation of own resources for other organisations projects is left to the organisation, and development of service delivery, if started, is encouraged to continue.

The guideline is very limited in terms of suggestions at this stage. The rationale for the minimal suggestions given includes the high technicality and dependence of the stage on the project under realisation and the software used.

7.2.3.9. Prototyping

Consideration of prototyping as a crucial stage is due to the area immaturity and lack of sufficient understanding of physical failure mechanisms. To overcome these issues, a trial and error approach is undertaken as the fastest way to obtain real data regarding fluid behaviour and allowing for evaluation of the device's design.

A number of prototyping stages are considered to be useful, especially when a new principle is proved, and much functionality is novel and, therefore, has to be evaluated separately before testing of the device as a whole. Therefore, prototyping is recommended to be approached in phases. Using phases is considered to be more beneficial due to detailing of the prototypes and the possibility of their preparation as components/modules before putting them together. In this manner, the cost of the development of detailed manufacturing routines, which later may need changes, is minimised. A disadvantage is the limited predictability of the prototyping output and this, therefore, influences the results.

The guideline view on the prototyping stage is limited due to the lack of tangible contact with many types of prototypes when using the methodology for this stage. Contact with a restricted number of cases, given mainly by verbal description rather than first hand experience, constrains suggestions which can be given to the microfluidic designers at this stage.

Prototyping on demand can be considered as a service type offering by the organisation possessing this capability. However, in comparison to modelling and simulation, providing a prototyping service is viewed as improbable if not connected with manufacturing or design process. Prototyping service, as any other, needs to be beneficial for both sides (organisation and customer) and a number of factors need to be included in the decision making process (available resources, reconfiguration time and cost, setting up, etc.). Other service type consideration incorporated in this stage is constrained to finalising the work concerning service delivery due to its comparative verification role in the next stage.

7.2.3.10. Validation/Verification

Validation is very important since it allows for deciding whether or not the device is ready to reach the market. Comparison of the test results from the prototyping stage has to be made with results obtained from simulation (if applicable) (V/V1), market (V/V2), service (V/V3), investigation and requirements (V/V4), as specified beforehand by the client. Due to the length of time for the realisation of some of the microfluidic projects, evolution of the market demand is considered to be probable. Therefore, confirmation of the existence of the market demand previously identified for the device and nuances which could change from the moment when the project was first agreed on up to when this stage has been reached are recommended.

Since the results obtained from the prototype testing are considered to be more dependable than those from the simulation, they are stated as the basis for comparison. However, any incompatibility needs to be investigated in terms of its cause(s). This aims to ensure functionality of the device, its performance as being up to standard, delivery of customer satisfaction and success in the market place.

The comparison results obtained should be stored with comments for future reuse (V/V5). Comments help to put results into the right context and explain any nuances which can be misleading in the data for someone else to use. Extraction of the rules (V/V6), from both the comparison results and the design, increases performance over a period of time and allows for the development of better organisation and device type specific design processes. In this way, it also helps in automation.

Validation and verification are not seen here as the same. Verification is a confirmation that a device is working and it is performed throughout the design at every stage by comparison with the specification. It is also accomplished by testing prototypes – modularly and as a whole. Verification is encouraged to be performed with a bottom-up approach, going from the detail level to the architectural level. This ensures comprehensiveness of the structure and identification of the smallest incompatibilities within it. The bottom-up approach is an analytical approach,

highly recommended for this type of work (Fedder, 1999). Validation is partially accomplished by comparison of the device performance with the specifications; however, it is more about solving the issues raised at the beginning. The device is validated when it delivers customer value.

7.2.3.11. Manufacturing

Manufacturing is the last stage of the guideline. The guideline assumes that only scaling-up issues (MF1), if not resolved previously, should be dealt with at this stage, with fabrication performance and testing of the first products and/or batches.

Usage of the equipment from prototyping is recommended to cut the cost of the processes and limit the environmental footprint, which may be large due to both the disposability of the majority of microfluidic devices and their contaminant features. This has a significant impact on cost of machining and other fabrication expenses.

The mentioned testing (MF2) is a necessity, because mass production raises a number of problems, such as external factors and the environment, which, within prototyping, can be easily controlled. The whole manufacturing process has been planned in advance during the product design; therefore, it should be effective and efficient in order to allow the device to reach the market at the right moment. This step, which appears simple in its nature, has been undertaken partially throughout other design stages, and is driving microfluidics and, therefore, also the guideline.

Manufacturing capability possessed by an organisation can be considered for development of the service type offering. This consideration is not connected to the device developed, but to the enhancement in the organisation's offerings by incorporation of profit source diversifications. Designating part of the organisation's resources to provide a foundry type service involves a number of issues to be dealt with (risk, cost, requirement, etc.) and is considered outside scope of the guideline.

7.3. Solution's Implementation – Who and How

The solution is composed of two elements: the guideline and design enablers list. The proposed solution is addressed to various people in the organisation designing microfluidics. The usage of the guideline varies depending on the users' work specifics and the level of engagement in the microfluidic design process. This section presents who the author sees as the user of the solution, and how this utilisation is proposed to be performed.

7.3.1. Who is the Target User of the Solution?

The prepared solution is designated for organisations designing microfluidic devices. It does not matter if designing microfluidics is the only or core work of the organisation, or one of many ways to make a profit. The solution aims to help to make commercialisation of these devices easier and successful in the future.

Various users of the solution can be identified based on their work specifics and the level of their engagement in the microfluidic design process. The following groups of users can be specified:

- Microfluidic designers/project team member – end-users of the guideline and design enablers. They will be executing tasks and applying suggested considerations in their daily work.
- Team/project leader – primary users of the solution. Responsible for solution adoption on a project basis.
- Project manager – if different from team leader, responsible for suitability of the solution for organisation's needs.
- Senior management –overview of the design approach. Responsible for aligning the solution with organisational strategy.

7.3.2. How to Adopt Proposed Solution?

The solution is intended to be used in various ways by different groups of users. Three groups of potential users, which are indicated above (Section 7.3.1), will be

involved in adoption of the solution to different extents. The author's suggestions on how they should be involved in this process are given in Section 7.3.2.1, followed by a description of the propositions for the solution's usage in 7.3.2.2.

7.3.2.1. Utilisation of the Solution from Users Perspective

Microfluidic designer/project team member

Microfluidic designers are the end-users of the solution. Their work with it consists of executing tasks assigned by the team leader and cooperation with other project team members to develop the microfluidic device. They are responsible for applying considerations suggested in the guideline and following prepared processes, building on them with their own knowledge and experience and developing a new, more comprehensive set of considerations to be used in the current and future projects.

Team leader

The team leader is the primary user of the solution. S/he is responsible for management and implementation of the guideline in the microfluidic design project, as well as certain design enablers (see Section 7.3.2.2). Utilisation of the solution includes identification of task executors for the project, designation of responsibilities and making sure that people deliver on time, within a scope and up to quality.

Project manager

The project manager, if different from team leader, is responsible for assurance of suitability of the solution to fulfil the organisation's needs. This function is required for adoption of the solution by incorporation of specifics particular for the organisation, such as level of service-orientation, identification of end-customers, type of microfluidic devices developed, etc. S/he has to obtain necessary information from superiors on the organisational strategy and identify sources of knowledge which will help to adjust the solution, e.g. sales and marketing department for the offering strategy. This person should adjust the solution to the organisation's needs to make it fit the purpose – development of microfluidic devices with services in mind.

Senior management

The solution is intended to be used by the design team and team leader in task execution in a microfluidic design project. However, application of the guideline is viewed also from a strategic point of view. The organisation should adjust the guideline according to its offerings strategy. This means that it should decide upon, for example, type of devices which will be developed, customer who will be targeted, type of customer relation (B2B/B2C) and level of service-orientation in the process, depending on the structure of its offerings that also includes sales and marketing strategy.

The senior management indicates here involvement of a higher level of managers in the organisation who have authority on decisions regarding strategy of the organisation. The name and level of hierarchy in the organisation structure depends here on the organisation size – in the multinational organisation with diversified operations and offerings, this function for microfluidic division can be assigned to the middle management.

The senior management involvement aims to assure incorporation of organisational strategy and suitable decision on service-orientation in the solution. They are responsible for assigning a person in charge of the design and, therefore, in charge of preparation of the solution's adjustments for organisational needs. They should assign representatives from relevant areas (departments) of the organisation and leave selection of people to be involved in adjusting the solution to the delegated employee. They should, however, communicate the need to adjust the solution and their involvement in the process to employees. This will help to increase willingness of the solution utilisation and decrease rejection of changes.

7.3.2.2. Utilisation of the Solution from Composition's Perspective

The proposed solution is composed of the guideline and a set of design enablers. They are to be applied together. They complement each other to enhance an organisation's performance in commercialisation of the device. However, there is an option to use just one part of proposed solution or particular elements of it. Partial

utilisation of the solution, by extraction of its elements and incorporation in the organisation's design process, is left to be decided upon by the organisation, while a description of how the solution is intended to be utilised as a whole is given below.

Before the solution is applied, however, it needs to be adjusted for the organisation's needs, which narrows its scope and makes it more specific for both the guideline and design enablers. This work is suggested to be done by one person – project manager. This position should be appointed by senior management, based on their strategic plan and organisational policy. Once agreed on, it can be used in the organisation's design processes.

To show how both elements of the proposed solution present a different scope of the design, a description of the usage is given separately for both of them. Afterwards, the overlap between both sections is highlighted for clarification.

The guideline

The guideline is directly connected to a project. It is to be applied on a project realisation basis, while many of the design enablers are to be applied across projects to bring benefits. The guideline is to be used every time a microfluidic device is designed.

One application of the guideline = single project realisation

The guideline is to be applied by the team leader as a primary user who will designate particular tasks and processes to the end-users (designers/project team members). The considerations given in the guideline are limited and given as examples of types of deliberations that should be included. Therefore, they will expand when applied in practice. The team leader has to manage the project according to the solution adopted, and make sure that work is done to the organisation's standard (quality, time, cost, etc.). After every usage, the solution should be updated by incorporation of any adjustments necessary. This practice assures continuous improvements and leads to operational standardisation and process automation.

Design enablers

Although all design enablers are to be applied every time a project is undertaken, their impact is based on cross-analysis of information gathered from many projects. The following pattern is to be applied when using the enablers:

- Involve the client in milestones (and critical decision points) and during validation/verification, i.e. do not involve him/her at all the steps between the milestones unless the project's specifics or organisation's operation requires it

This enabler is to be used in every project execution. It is suggested as a general recommendation based on area characteristics, level of maturity and indication of how knowledgeable an average client in the domain is. However, depending on the project specifics and organisation's policy, the client can be more involved. This enabler should be decided on when adjusting the solution to the organisation's needs and executed by the team leader.

- Establish core elements in the set of microfluidic devices (standard element or elements of design)

This enabler is to be executed once and kept as a constant for all microfluidic projects undertaken by the organisation. Decision on it should be based on the organisation's offerings.

- Develop models of already validated and produced products

As for the previous enabler, development of models of already validated and produced products is a one time work. However, it involves more working hours and investigation of the IP rights to the previous products. This task is based on previous work done by the organisation and it will benefit in future projects' realisation. It requires allocation of resources (designers for models development, database to store the models, etc.), which are a one time decision to be undertaken. It is highlighted as additional work for the organisation on top of the current projects, and therefore, its realisation can be spread over time to minimise resources 'freeze' (designers develop models, therefore they are not able to work on current projects).

- Slowly develop an in-house database of modules/components (component library)

  Development of the in-house database is recommended to be spread over time similar to building models based on previous products. This work should be undertaken with time urgency to allow for storage of the current models and omit 'piling up' work to be done in the future.

- Establish a group of general modules providing basic functions (e.g. mixing, channelling, etc.)

  This enabler is to be executed every time a new type of microfluidic device is introduced for products drastically varying from standard offerings of the organisation and as a one time work for existing production. Decision on the elements included in the group should be based on products offered by the organisation.

- Validate created models for a variety of fluids

  Validation should be undertaken on a project basis and the team leader should assign a person to be responsible for it. However, in time pressured projects, it can be performed after the project ends under condition of possession of the IP rights to the modules. This validation is also to be performed on previous product models (when developed) in the manner suggested for model development (spread over time).

- Encourage informal communication inside the project team but do not eliminate a formal one

  This enabler is to be executed on a project basis. The team leader should be responsible for its execution and control if informality does not eliminate formal meetings. This enabler is to be applied across the guideline execution and during application of other enablers to maximise cooperation in the organisation.

It can be observed that the guideline is connected to the current work of the organisation when the scope of design enablers is more broad, ranging from the past to preparation for the future. Hence, their execution has also been assigned in various ways. Complementarities of both elements of the solution lead to automation of the organisation's design processes and standardisation of their work.

When used together, the guideline and design enabler speed-up work realisation and structure the existing knowledge of the organisation to be used in future projects.

7.4. The Main Attributes of the Solution

As a result of filling the gaps identified in the microfluidic design domain, the proposed solution can be characterised as possessing three main attributes: generality, service-orientation and sub-section interactions. Although the solution consists of two parts - the guideline and design enablers - it can be observed that the structures of both parts vary. To underline the presence of the mentioned attributes more clearly, they are elaborated in terms of both solution's parts separately: first for the guideline (Sections 7.4.1 – 7.4.3) and then for design enablers (Section 7.4.4). All attributes are discussed regarding their limitations and advantages, as well as benefits which they can bring for microfluidic organisations.

The first attribute is a direct result of bridging the main gap identified in the area – lack of a general design methodology suitable for the domain. This generality has been pointed out as a limitation and necessity, and elaborated throughout the thesis. However, what is the potential to generalise the solution? What needs to be changed to apply it to other micro domains? What changes are required to make it universally applicable (macro-domains)? Answers to these questions are given in Section 7.4.1 for the guideline and 7.4.4 for design enablers.

Next, service-orientation of the solution is summarised. This summary has been considered necessary due to the importance of this attribute in the solution and the potential it gives to the domain profitability. In this section, an indication is given of where in the proposed solution service-orientation can be found and how it is incorporated in the context (in Section 7.4.2 for the guideline and 7.4.4 for design enablers).

Thirdly, the last attribute is presented. As with service-orientation, the methods to deal with sub-section interactions are spread throughout the solution and incorporated in its various stages in different levels of detail. Therefore, in Section

7.4.3, a summary of the guideline's sub-section issues is given, and Section 7.4.4 indicates how design enablers support this work.

7.4.1. Generalisation of the Guideline

The guideline has been developed partially based on the grounded theory approach. As emerged from the data about microfluidic design, it is specific for this domain. This particularity is visible across all the stages. However, the effort required to make this guideline general for the whole micro-domain, or other design domains, will be indicated below.

The guideline incorporates high technology orientation; therefore, it is suitable for fabrication driven domains. This characteristic is common across micro-domains and new immature domains, where limited production methods are dictating what is achievable. This focus constrains the application of the guideline for more mature domains in which the separation of design stages and manufacturing proves to be profitable, and allows for the automation and simplification of the process.

To make it useful for other domain(s), the characteristics of microfluidics have to be replaced with the characteristics of other domain(s). Moreover, all considerations in the guideline were scoped for microfluidics, and they will have to be generalised and/or replaced, e.g. a structured approach to the idea generation, which is recommended, as the more mature domains face lack of creativity and repetitiveness in ideas. The problem identification stage, underlined for microfluidics as crucial, is not as important for domains with different levels of maturity. For more novel domains which have just been discovered, identifying cutting edge technology is beneficial in itself, and commercial application is not an issue while for more mature domains, the market is driving both the design and development processes.

The design of microfluidics in general requires mass market application and considerations of scaling-up production which are valid for all the domains. However, levels of importance vary depending on the profitability of manufacturing a certain number of units which, for microfluidics, have to reach, on average, millions of parts.

The guideline recommends constant comparison with specifications. This feature is not justified in better established domains because of the repetitiveness of work and ease of following targets. For long term projects, comparison is still valid at the milestones, even in well established domains; however, its frequency can be minimised.

The simulation, underlined as an additional step in other micro-domains, is considered crucial, and the prototyping, underlined here as vital, has proved to be just an additional confirmation of simulation. The generalisation of the guideline needs to take into account these characteristics by incorporating flexibility in shifting the basis of comparison from one set of results to another, depending on the domain for which the devices are developed.

The guideline is limited in terms of product afterlife. As the majority of microfluidics are disposable (contamination issues), consideration of the design process has been limited until the products reach the market. Hence, a number of services have been eliminated from the considerations. Other types of devices which incorporate issues such as collection of products and recycling in their PLC (Product Life-Cycle) require the incorporation of suitable considerations in the design. Moreover, service opportunities created by this afterlife should be incorporated at the appropriate stages.

Targeted by the guideline, the sub-section interaction issue is important in every design domain, especially for cross-domain products. This aspect of the guideline, as well as its service-orientation due to movement of the industry towards 'experience economy', has been considered as useful and appropriate. The service-orientation, however, will require major enhancement to address the issues of more mature domains' readiness, in which potential to offer functionality instead of the product is greater and potential of this approach to be suitable is higher.

7.4.2. Service-orientation in the Guideline

Part of the guideline contribution shows potential for an expansion of the existing offerings by services, and encouraging slow but consistent changes in the mindset

leading towards service-orientation. The guideline itself does not suggest completely changing the offering style for the services (offering functionality instead of device), because the domain is not mature enough to consider it beneficial. However, it aims to simplify this transition in future by including some service characteristics in the design scheme.

An indication of the guideline service-orientation can be found at Level 0 in the theme 'Do not design solutions for non existent problems. There are already too many of them'. This statement is addressing the intangibility of services as the development of solutions, not products, and incorporates the approach of service-thinking to change the mindset of developers. More explicitly, service-orientation can be identified in the guideline at Level 1, where its presence is highlighted across the stages. The service-thinking is initiated at the problem identification stage by transforming product design (in terms of functionality) into solving a customer problem. This intangible aspect of the project, which can be measured by customer satisfaction, starts a shift in the mindset necessary to create service-type offerings.

During the requirement clarification in the project brief – a recommended documentation for every project under realisation – the service section has been advised to be incorporated in order to address the level of services identified in a particular project. In the case of any negative attitude of clients towards going beyond traditional offerings, the informal collection of service characteristics is recommended. These characteristics can be used to enhance the organisation offering by helping in other projects or in the preparation of business plans for services.

In a similar manner, service-thinking is incorporated in the other stages of the guideline and has been presented in diagrams visualising the decision making processes. Regarding identifying the current state of the service offerings and service-thinking in the microfluidic domain, considerations incorporated in the guideline are not extensive. They provide insight into the service opportunity and suggest data collection methods for their development. However, co-creation of services with clients is not even considered at this early stage of service

introduction. Therefore, with maturation of the area, a more advanced introduction of services can be approached if considered beneficial. Currently, the client can be discouraged by the introduction of service co-creation due to his/her investment of resources in this approach with questionable revenues. This uncertainty is caused by lack of the established base of services in the microfluidic domain.

Due to technology driven design of microfluidics and immaturity of the area in terms of services, a short list of potential service type offerings has been included in the idea generation stage. Moreover, capabilities possessed by an organisation in terms of modelling, simulation, prototyping and manufacturing have been indicated inside the guideline stages as showing opportunity to be included in an organisation's portfolio as services.

The majority of services are developed for products during the use phase (on the clients' side), or end of it, such as collection, recycling, or reusability. In microfluidics, the latter phases are, in the majority, eliminated due to the disposability of the devices. Therefore, the focus in the guideline has been on the design phase and its surrounding opportunities. For large multi-analysers, consideration of product disposal should take place only when the organisation providing the microfluidic element is the provider of the total equipment. Otherwise, responsibility is shifted on to the final equipment manufacturer and, therefore, they will deliver services for the device.

The guideline introduces the service-oriented design of microfluidic devices which enhance the current state of the microfluidic domain in this aspect; however, it does not exploit the full potential of service-orientation which can occur in a more mature domain. It is not transferring products into services or allowing the sale of a product as a service. This type of service transformation will require implementation/transformation of the business model, an established range of service offerings and a suitable infrastructure. However, the guideline provides a step in this direction.

7.4.3. Sub-section Interactions in the Guideline

While service-orientation is clearly presented in the guideline at Level 1 and can be identified in the decision making processes, the sub-section interaction issue has been addressed more implicitly. The sub-section interaction is addressed mainly through two issues: interfaces and modularity.

The interfaces have been identified as vital for both types of microfluidic devices: modular and monolithic. The guideline is encouraging designers to standardise their designs and, therefore, also the interfaces and connectors. Development of standard connectors and interfaces permits not only the simplification of future work by allowing 'plug and play' modules but also additional adds-on for the devices and the creation of new profit opportunities. This standardisation is leading towards a modular approach to design, which allows for customisation of the devices by rearranging modules or redesigning one or a few modules instead of redesigning the whole device.

Moreover, designers are asked to minimise the number of interfaces and simplify their designs to avoid complicated structures where they are not necessary. By doing this, the number of sub-sections is decreased and interactions between them are less complicated.

This initial work on sub-section interaction is leading towards simplification and automation of the whole design process by the development of component libraries and the reuse of design data in future projects. The guideline is encouraging the development of standard element(s) of design and component/module libraries for designed structures and simulation models linked to prototype test results. These links increase the reliability of structures and hence accuracy of design. The presented automation will feed back to the sub-section interaction simplification by optimising the development of modules and allowing designers to focus on connectors and interfaces inside the device, as well as within the surrounding environment.

7.4.4. Three Main Attributes in Design Enablers

As well as in the guideline, the set of design enablers incorporates three main attributes: generalisation, service-orientation and sub-section interactions. Their presence, however, manifests in a different, more self-explanatory manner. Only two enablers are microfluidic specific – establishment of core elements in the set of microfluidic devices and validation of created models for a variety of fluids. To generalise them to be used for other micro domains, the replacement of technology features needs to be done by suitable characteristics, e.g. for microelectronics, validate models for a variety of current densities. This same action needs to be undertaken when generalising enablers further to be used in macro domains.

The design enabler discussing customer involvement only at the milestones and at critical points of the project emerged from the domain characteristics. Although this enabler will be valid for many other micro-domains, and even some macro domains, customer knowledge in the area, validity of his/her suggestions, and inputs and issues needed to be considered during the design process will need to be taken into account. For some areas, this enabler will be invalid.

Remaining design enablers, although valid for the microfluidic domain, are also valid for the majority of micro and macro domains. They do not need to be generalised to be adopted. However, their suitability for the domain has to be confirmed before applying them.

The service-orientation is implicitly incorporated in design enablers. The direct presence can be observed in customer involvement, which provides the opportunity to gather service knowledge and expectations as well as address opportunities. This attribute is incorporated when suggesting steps leading to modularisation and standardisation which will allow customisation and, in longer term, the potential for service development by minimisation of technological problems faced by the area.

The last attribute – sub-section interactions - is also incorporated in an implicit manner. Every time a suggestion is given which leads to modular design, the sub-

section interactions are standardised. This means that five out of seven enablers are indirectly targeting this attribute and supporting the guideline in dealing with it.

As can be observed, design enablers are more general than the guideline. They also incorporate main attributes at the higher level, while the guideline incorporates particular considerations to tackle the domain problems. Hence, they are considered as supporting the guideline in service-orientation enabling and dealing with sub-section interactions while (through the generality incorporated) leading towards standardisation and automation of processes.

7.5. Solution's Limitations

As presented in Chapter 5 and discussed above, the proposed solution for addressing microfluidic design's needs incorporates limitations. Due to the fact that the core part of the proposed solution is the guideline for service-oriented design of microfluidic devices which can deal with sub-section interactions, all of the recognised limitations deal with this. Each limitation has been investigated based on its source(s) and attempted to be minimised, as presented below.

7.5.1. Limitations Imposed by the Method

- Bias from the author – the author is not specialised in the microfluidic domain, although, she possesses knowledge of the design domain itself and connected areas. This imposed a limitation on the established solution and, at the same time, provided an opportunity. Lack of knowledge about what can and cannot be done in the microfluidic domain did not constrain the view on incorporating services in the developed approach. This limitation was viewed as an opportunity for a fresh view on what can be achieved and how, and was attempted to be bridged by an area investigation and constant learning about microfluidics.
- Limited set of data used for development of the solution –limited number of responses on the survey and interview data presents only a sample of what is currently happening in the microfluidic practice. This gap was attempted to

be bridged by maximising the number of respondents and sources for data collection. Moreover, during the solution's validation, which is presented in Chapter 6, a broader spectrum of experts was approached, expanding from microfluidic design to the service-orientation aspect by involvement of experts from the service domain.

- Limited time for development of solution and its validation – due to restriction in the project duration, adjustments needed to be made to the solution development and validation approaches – for example, the 'ideal validation' (see Section 6.1.2) of the developed solution in practice would take a couple of years. It would include implementation of a new design starting from problem identification and finishing with product's end-of-life. This implementation should not only follow one single device, but a number of them, incorporating repetitions in the device type, as well as various microfluidic device types to allow for identification of the market acceptance of developed products, design process automation and standardisation achieved in the organisation. Given the time limitations, other validation methods have been applied, which incorporate multiple validation sources.
- Adoption of proposed solution by practitioners – an attempt to change the current methods is expected to cause resistance and reluctance. Every change in an organisation and the methods using which people are doing their jobs incorporates risk of attitude - people naturally resist change. However, since the majority of microfluidic organisations did not present any structured approach to design, at least not well established, designers should be, to some extent, keen to tryout new methods which can simplify their work.

7.5.2. Solution's Capability Limitations

The major limitation incorporated in the capabilities of the proposed solution is its generality. The solution has been developed as specific for the microfluidic domain, but at the same time, general to allow for development of all types of devices identified in the domain. This generality increases the number of adjustments necessary to be made when implementing the solution for any organisation. Hence,

it increases potential difficulties with the solution's adoption by practitioners and a probability of its rejection by potential users.

At the same time, this generality bridges the gap in identification of the general design process for the area. Moreover, it allows for diversification in the type of microfluidic devices which can be developed based on the proposed solution and allows for various sizes of organisations with various levels of maturity, service capabilities and resources to implement it.

This limitation was only attempted to be minimised by making the design microfluidics specific. This minimisation has been approached through the solution's development methodology as directly emerging from domain data based on its characteristics and, furthermore, by additional highlights of microfluidics specific considerations to make the importance of technological driving force explicit as a result of experts' validation.

Another limitation is the restricted applicability of the solution for mature organisations in the microfluidic domain. Factors characterising the domain point towards the formal general design process, however, the organisations already possessing structured and well optimised processes for design can interpret the solution as not applicable for them.

Although, for a mature organisation, the structured approach presented by the solution can be viewed as existing, they can find aspects of service-orientation and sub-section interactions as beneficial when combined with their daily design routine. This limitation of the solution will be minimised with increase maturity of the area and, hence, maturity of the proposed process.

7.6. Summary

To develop a suitable solution for addressing the microfluidic domain's design needs, a methodology has been established, based partially on the grounded theory. This methodology, identified as possessing a number of strengths and weaknesses, has been developed based on the area's characteristics, its level of maturity and available resources for the research. Review of the strengths and weaknesses of the developed methodological approach allowed viewing it as an opportunity to address the domain's needs.

The developed solution, consisting of the guideline and the set of design enablers, has been developed based on academic and industrial microfluidic designers' best-practice. Composition of the solution as a two part design enhancement has been a result of the development of a methodological approach and a direct effect of the gathered data analysis. In addition, factors considered as increasing the adoption of the solution by potential users have been incorporated, e.g. flow-chart representation, which effected Level 0 appearance of the guideline.

Resemblance of the guideline to a conventional design process can be observed in the design flow presented at Level 0. At the same time, additional features of the model (data funnels for prototyping and manufacturing stages, top-down design approach, constant comparison with specifications) lead the guideline user towards micro-specific design, which turns into microfluidics when achieving detailed level of the guideline (Level 1) and following particular decision making processes and considerations.

A set of design enablers, which complements the guideline in enhancing microfluidic design, has been presented based on its rationale, strengths and weaknesses. This set is considered as value-adding for the organisation in the realisation of microfluidic projects by allowing for process automation and standardisation of operations in an organisation. Moreover, it provides the opportunity to decrease resources in future projects and enables/encourages knowledge reuse.

Further elaboration of the guideline structure allowed presentation of the rationale behind particular tasks and recommendations. It also uncovered strengths and limitations of the developed guideline at a detailed level. This elaboration gives the reader deeper insights into the guideline.

The proposed solution is designated for organisations designing microfluidics, regardless of whether this is their only, core or additional source of profit/revenue. The solution can be adopted as a complete set (the guideline with the set of design enablers), partially (the guideline or the set of design enablers) or in a customised

manner (particular elements incorporated in the existing organisation's design approach). Various parts of the solution have different utilisation patterns and hence required investment of suitable resources.

The proposed solution is addressed not only to the microfluidic project team but also as possessing a broader impact on the organisation. Potential users are identified in the design team as well as in senior management positions giving a strategic insight into adjustment of the solution for an organisation's specific needs. Therefore, the utilisation recommendation for particular user groups has been given.

The proposed solution can be identified as possessing three main attributes: generality, service-orientation and sub-section interactions. The presence of all attributes can be identified in the guideline and design enablers. The first attribute is a direct result of the attempt to fill the gap requiring 'one' general design process which the domain lacks. This generality creates as many limitations as it brings benefits to the domain from the solution capabilities' perspective. Potential for the solution's further generalisation is explored by identification of changes necessary to make it suitable for all types of micro devices and, even further, for macro domains. The remaining two attributes are the results of execution of the research aim, orienting the guideline towards services and trying to deal with sub-section interactions. The service-orientation incorporated in the solution allows potential users the utilisation of the service thinking in their design process in various manners, according to their willingness and possessed service capabilities. The dealing with sub-section interactions is incorporated less explicitly - it has been spread in the form of considerations throughout the proposed solution. The prepared solution indicates various methods to minimise sub-section interactions, with the focus on interfaces as an issue which concerns microfluidic designers the most.

The developed solution has a number of limitations which the author has attempted to eliminate or minimise. These limitations have two primary sources: development methodology used to obtain the solution and solution's capabilities. The methodological driven limitations consist of combination of people's expectations, author's previous experience and knowledge, resources available for the project and

used dataset, while major limitations from the capability side are its generality and limited applicability to the needs of mature organisations in the domain. Generality is highlighted as the main benefit and the main limitation of the proposed solution, and the view of the reader on this characteristic depends on individual preferences and the organisation's needs, while applicability for mature organisations' needs underlines potential benefits which arouse for them from two out of the three main attributes of the solution: service-orientation and sub-section interactions.

Chapter 8
Conclusions and Future Research

This Chapter consists of four parts: Contribution to Knowledge, Research realisation, Recommendations for Future Research and Conclusions. First, the contribution of the research to knowledge is presented. Second, a comparison of the research aim and objectives with research achievements is highlighted. Thirdly, future research areas are indicated, with topics to be investigated and options maturing the proposed solution underlined. Finally, general conclusions from the research are drawn.

8.1. Contribution to Knowledge

The research contribution has been identified in two areas: through realisation of the research and through the research output. Realisation of the research allowed the author to prepare a compare the microfluidic design domain with other design domains. This comparison resulted in identification of microfluidics as a unique design domain. Since a similar summary of the domain characteristics and a comparative analysis of micro design domains have not been identified for microfluidics, a contribution to knowledge has been indicated.

The contribution to knowledge obtained through the research output, is as follows:

- Development of a general design process, which is lacking in the area.
- Providing an insight for microfluidic designers into service opportunities.
- Attempt to minimise sub-section interactions impact on the design outcome.

The proposed solution aims to enhance the design process and acceptance of the device in the market. It aims, in a short term view, to simplify and standardise methods used for design of microfluidic devices, and to automate the process to make it easier to follow for less experienced designers. In a long term view, it should

be self improving, based on captured knowledge throughout the process usage and adjustments required in the organisation, to match with designers' particular demands. It should allow establishment of one general process in an organisation for microfluidic design, which can be flexibly used with changes in all projects under realisation. It aims to prepare companies for a service-oriented future of the domain, by slowly increasing their engagement in this domain and improving customer value delivered.

The contribution of the solution is in suggestions of considerations in particular steps and arrangements of the tasks. The solution is summarising issues which should be considered during the design of microfluidic devices. It fills the gap in the general process for microfluidic design and gaps inside existing models applied in this domain.

It is contributing by showing potential for expansion of the existing offering, and encouraging slow but consistent changes of the mindset, leading towards service-orientation. The solution itself does not suggest changing the offering style to pure service or offering functionality instead of the device, due to the fact that the domain is not mature enough to consider it beneficial. However, it aims to simplify this transition in the future by including some service characteristics in the design scheme.

The proposed solution also tries to address the issue of sub-section interactions by putting focus on the interfaces and development of standard elements. The recommendations, which show what needs to be considered, lead the designer towards standardisation. Therefore, usage of the solution may allow decreasing the time of design and the development of a 'pick and play' type of database with microfluidic modules.

8.2. Research Aim and Objectives Compared with the Research Achievements

The research has been undertaken by identification of the aim and objectives which attempted to help in its realisation. The research aim, "**to develop a guideline for service-oriented design of microfluidic devices that can deal with sub-section interactions**", was attempted to be addressed using five objectives. A summary of the realisation of these objectives and the research aim is presented in this section.

8.2.1. Research Objectives as Compared with Research Achievements

Objective 1:

To understand the state-of-the-art in the service-oriented design of microfluidic devices

Investigation of the state-of-the-art in the service-orientated design of microfluidic devices was based on literature and practitioners' work. This research was scoped around two issues: design methodologies for micro-devices, especially, for microfluidics and service-orientation of microfluidics. Results from this investigation are presented as literature findings in Section 2.1 (Microfluidic Design) and 2.2 (Service-orientation) and as practitioners' work in Section 4.2 (Microfluidic Design) and 4.3 (Service-orientation).

The following main conclusions have been extracted from the objective realisation:

- Relative immaturity of microfluidic domain.
- Lack of 'one' general process for design of all microfluidic devices.
- Identified design processes in the area considered not sufficient.
- Identification of microfluidics as a unique design domain.
- Commercially available support tools for design of microfluidics considered insufficient.
- Structured approach to design required.
- Service-orientation not identified in the domain's design processes.

- Limited information available regarding service-oriented design.

Objective 2:

To identify the influence of sub-section interactions on design of microfluidic devices

The second objective has been achieved partially, similar to the first one, based on literature studies. Results of these studies are elaborated in Section 2.3. The second part of realisation of objective 2 was based on investigation of methods using which practitioners in the area are dealing with sub-section interactions and how this issue influences microfluidics and their work. These issues were incorporated in the survey as a short section. Findings regarding this investigation are presented in Section 4.4.

The following conclusions could be drawn regarding the influence of sub-section interactions on the design of microfluidics:

- Micro-devices are increasingly getting complex, which has a negative impact on design.
- Sub-section interactions identified as crucial.
- Limited methods to deal with sub-section interactions identified in literature and in practitioners work.
- Lack of formal method to address sub-section interactions applied in the domain.
- Interfaces as aspect of sub-section interactions raising high concern.

Objective 3:

To identify how service requirements are defined for microfluidic devices

Identification of how service requirements are defined for microfluidic devices has been undertaken directly and indirectly. Indirect realisation of the objective 3 has been undertaken by identification if service requirements are present in the manner in which devices are classified. This review of categorisation can be found in

Appendix 6 to show its indirect relevance for the research outcome. It allowed the author to identify that there is no categorisation of microfluidic devices according to the service requirements, and the closest identified is classification according to the application. Direct investigation of the service requirements has been undertaken through the literature (Section 2.2) and investigation of practitioners' work (see Section 4.3 and Appendix 4) by web/brochure investigation, survey and interviews.

The following conclusions have been drawn from realisation of objective 3:

- Lack of service-orientation in categorisation schemes of microfluidic devices.
- Limited services present in the domain.
- Higher maturity of the microfluidic domain in service area than what literature suggests.
- Minimal consideration of services in offerings.
- Lack of consideration of services in design.
- Reluctance to move away from conventional product offering.

Objective 4:

To develop a guideline for service-oriented design of microfluidic devices that can deal with sub-section interactions

The realisation of objective 4 started through the development of a suitable methodology for addressing the domain's problems. The methodology has been partially based on the grounded theory that allowed selection of appropriate methods for data collection and analysis based on the domain characteristics. Systematic data collection and analysis stages allowed minimisation of invested resources in obtaining results for the solution's development. Results obtained have been validated (see Section 6.1.1) by respondents, who confirmed their correctness (see Section 6.2 and 6.4.1). Details regarding the methodological approach used are incorporated in Section 5.1 for development methodology, Section 7.1 for its discussion, and Chapter 3 for the overall methodology for the research and details regarding data collection and analysis approaches.

The developed solution consists of two elements: the guideline (for service-oriented design of microfluidic devices that can deal with sub-section interactions) and the design enablers. As can be observed, the core part of the solution is the realisation of objective 4 as stated. A set of design enablers which aspires to automate and standardise the design process in microfluidic organisations has been developed as an additional enhancement of the guideline. The solution has been developed based on literature models, best practice from microfluidic designers from industry and academia, and identification of elements currently missing and considered crucial. The developed solution has been presented in Sections 5.2 and 5.3 and discussed in Sections 6.2 and 6.3.

Discussion of the main attributes of the proposed solution, presented in Section 6.4, shows how generality, service-orientation and sub-section interactions characterise the guideline and design enablers. The solution has been developed as specific for microfluidic domain but also as characterised by generality to allow for development of various types of these devices. Service-orientation has been incorporated in the guideline explicitly through tasks, processes and even suggestions of services which can be offered by an organisation. Task to perform and processes leading to service development or service-enabling have been incorporated broadly to allow organisations with various level of interest in services and different level of maturity to implement it. Examples of the tasks include: confirm that service section in the project brief is filled in (Section 5.2.3.2, Figure 5-6) or put in place infrastructure to deliver services (Section 5.2.3.6, Figure 5-13). An issue of sub-section interactions has been tackled through persuasion of modularity, standardisation and automation. It has been addressed by number of considerations across the guideline, e.g. identify sub-modules which can be integrated into the device and sub-modules required to be developed (Section 5.2.3.5, Figure 5-12), and in the design enablers, e.g. establish core element in the set of microfluidic devices (Section 5.2.2). Therefore, this confirms that the proposed solution incorporates characteristics required by objective 4.

The following conclusions have been drawn from the realisation of objective 4:

- Selected methodology considered suitable to address identified gaps in the domain.
- General design process considered suitable for microfluidics has been proposed.
- Service-orientation has been incorporated into the design process for microfluidics.
- Sub-section interactions have been addressed in proposed solution.

Objective 5:

To validate the proposed guideline using multiple methods

Since, the realisation of objective 4 allowed the development of the solution which consists of the guideline and design enablers, objective 5 focuses on validation. Realisation of the last objective has been accomplished through questionnaires, interviews and workshops. It included validation by academic and industrial microfluidic practitioners, service experts and by performing comparative analysis. Details of this approach have been presented in Chapter 6. Validation has been considered as successful, and the following conclusions have been drawn:

- Proposed solution evaluation considered successful.
- Feedback obtained regarding the solution is mostly positive.
- Solution identified as:
    - Structured.
    - Compact.
    - Detailed.
    - Service-oriented.
    - Addressing a number of issues faced by microfluidic domain.
    - And requiring some improvements.
- Validation considered sufficient.

8.2.2. Research Aim Compared with Research Achievements

Based on the realisation of all stated objectives, the research aim is concluded to have been achieved. The guideline for service-oriented design of microfluidic devices that can deal with sub-sections interactions has been developed. Moreover, the developed guideline has been enhanced by a set of design enablers. Composed of these two elements, the solution has been successfully validated and, although it does not address all problems that the microfluidic domain is facing, it presents a step in the 'right direction'.

8.3. Future Research and Research Limitations

8.3.1. Future Research

Realisation of the research has underlined a number of gaps in the domain. Some of the identified gaps have been addressed in this research. However, due to the limited resources available and, consequently, the necessity to narrow the scope of the research, a number of gaps still remain.

The following topics are considered as beneficial to be investigated for microfluidic organisations:

- *Microfluidics as a service* – exploration of the microfluidic domain from customers' point of view – where there can be a place for future microfluidic devices as viewed by their current and potential users. Investigation should include categorisation of services demanded and type of offering which will attract customers.
- *Service enablers in microfluidics* – identification of the tradeoffs necessary to be made to provide services in the domain. Answering questions such as: does disposability enable or limit services? Is it worth designing multiple-use devices (dealing with contamination issues in many cases) using potential services which can be built on the product afterlife phase? Is service potential connected to the type of fluid flow or any other physical parameter of the device? The main question to be answered is - what enables services in the

microfluidic domain? This research can help to develop service offerings in microfluidic organisations and allow them if/when profitable transition into offering a service instead of a product.

- *Offering of microfluidics on a B2C basis in the medical domain* – investigation of what needs to be done for microfluidic devices, e.g. point-of-care, to be sold to individuals. What risk is connected with the possible misuse of the devices, and what implications would this have for users, as well as for the producers and their partners? This research is recommended as part of the future action for providing microfluidics as a service to users. Focus on POC (Point-of-Care) devices will help to narrow the research and provide an easy to understand form of service offering on a long term basis.
- *Manufacturing of microfluidics* –the area can benefit from a set of rules for the selection of the most suitable manufacturing method for particular types of microfluidics. This set of rules can be developed in terms of the tool, new guideline, checklist, etc. Further research will show the limitations and advantages of using particular methods, as well as the technical implications of using particular materials in the processes. This research will allow further enhancement of the design process by the automation of the manufacturing method selection and process planning for fabrication, as well as, for less experienced designers, selection of the material and its constraints.
- *Services in microfluidics afterlife* – the majority of microfluidic devices have been developed as disposable. Research with focus on a particular type of microfluidic devices (which will present what is happening with particular types of devices on the customer side after they are used) can bring benefits for manufacturing organisations by providing them with knowledge to undertake a service. Alternatively, it can present which elements of devices show potential to be updated and upgraded. In this way, the potential of service delivery in product afterlife can be exposed.
- *Design support tools for microfluidics* – due to the fact that organisations identified commercially available tools for design of microfluidics as insufficient, identification of requirements which are not met will help in design process enhancement in this area. Organisations are developing in-

house solutions to help in daily work. What aspects of this work are not addressed? Which mechanisms are missing? Which functions are insufficient? Where is the gap? To answer these questions, two approaches are recommended. First, an investigation of existing support tools for design of microfluidics by comparative analysis between commercially available tools. Second, a research conducted among organisations using commercially available and in-house developed support tools. Research is recommended to have a benchmarking character.

8.3.2. Research Limitations

Research limitations have been pointed out in various parts of the thesis. They have been included in difficult chapters of the thesis, which refer to the part of work they are concerned with directly. Therefore, limitations can be found in the following parts: Section 3.3 - Strengths and weaknesses of used methodological approach for the research, Section 7.1 - The solution's development methodology, and Section 7.5 – The solution's limitations. All limitations of the research have been included in the mentioned sections, and restating them here is considered as a repetition.

Future work, recommended to be done for directly addressing the limitations of the presented solution and enhancing microfluidic design, is as follows:

- *Shorten presented solution* – there is a requirement to shorten the presented solution by providing a couple of page document with references, or presenting the developed framework in the form of a computer software. This presentation will increase the willingness of the practitioners to familiarise themselves with the proposed solution, and therefore, its adoption. This work has not been incorporated in the presented thesis due to the time frame available.
- *Provide variants of the solution for narrower types of microfluidics* – this diversification will minimise the adjustments needed to be incorporated by microfluidic organisations; hence, it will increase the potential of the

solution's adoption. In addition, it will narrow the amount of consideration to be incorporated in the solution from a technology perspective.

- *Incorporate "manufacturing of microfluidics" research findings* –the possible tool developed based on the proposed solution will allow less experienced or new designers to make more accurate decisions and more experienced to develop products faster. This could lead to automation and standardisation of the microfluidic design.
- *Incorporate "microfluidics as a service" research findings* – incorporation of results from the identification of microfluidics service requirements (from a customer perspective) will allow to better address customer needs in design and in offering development. It will clarify demands for microfluidic devices.
- *Proving the solution in practice* – adjusting the developed solution for a particular organisation's needs. This validation should be performed by an organisation which aims to deliver a device to the market.

The above mentioned potential research topics and methods to mature proposed solution are the main recommendations made by the author as a result of the research conducted. During development of the solution, and even before, in investigation of the three domains (microfluidic design, service and sub-section interactions) on the borders of which the research lies, many more gaps have been identified. Some of them present the potential to be conducted as research with contribution to knowledge, and others appear as consultancy work. However, all, if addressed, will help microfluidic organisations in the design and commercialisation of their products and in the future work. The topics which have been recommended above are considered as most beneficial based on the current state of industry and existing trends in academic research.

8.4. Conclusions

As presented in Section 8.2, the realisation of the research aim and objectives allowed the author to draw a number of conclusions from every phase. To summarise the research, three main conclusions from it can be drawn:

Development of 'one' design process for microfluidics is possible – however, it is compromised by its generality

During the research, a solution has been developed to address microfluidic design issues. Some of the problems identified in the area were the application specific design methods used and lack of formal design methods used. These issues caused lack of 'one' methodology suitable for design of all types of microfluidics. The proposed solution overcomes this issue, however, it is characterised by generality, which has certain implications. Most of all, it needs adjustments for a particular organisation's needs.

Service-orientation can be addressed in microfluidic domain in a flexible manner

The microfluidics area has been classified as immature in terms of service-orientation. There is no service-orientation identified in the categorisation scheme for microfluidics, services identified at present in the area are limited, and practitioners are not keen to go beyond traditional offerings. However, some services are present and, therefore, the 'natural' transition towards an 'experience economy' is considered as started. Service-orientation can be addressed in microfluidics by incorporation of service considerations into the design process. However, this incorporation needs to be done in a flexible manner, taking into account the reluctance of potential users to go 'out of their comfort zone' (new type of offerings) and various levels of organisations' maturity in terms of services and the service foundation possessed by them (service type offerings, delivery systems in place, service planning processes, etc.).

Sub-section interactions are crucial but not addressed properly in the domain they can be tackled by standardisation attempts

Although sub-section interactions have been identified as crucial for microfluidics, formal methods to address them were not identified in the domain, and informal approaches were identified as limited. The solution developed tries to tackle this issue by explicit steps and implicitly across the process by persuasion of modularity in design and tasks leading towards standardisation and automation. Development

of standard connectors and interfaces minimise the types of interactions which can occur and, hence, simplifies the design.

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Appendices

Appendix 1 Market Drivers for Microfluidics

This appendix provides background knowledge about microfluidic market. It shows area profitability and supports research rationale.

1. Market Drivers for the Design of Micro-Systems and Micro-Technologies

In the past ten years research into, and the use of, small-size devices has rapidly increased, highlighting micro-technology as a very strong economic driver in the 21st century. Prognoses of "a large volume of product in micro-systems technology (MST) within the next decade" (Tietje & Ratchev, 2007) have been supported by facts of the strong growth in new process technologies, new device concepts and applications, and new markets in the field of MST/MEMS (Senturia, 1998). Market research shows not only rapid annual growth in this sector but also trend predictions of its further development. According to the NEXUS report (2005) which represents the state of the industry, for 2004, with predictions up to the year 2009, the commercialised micro-devices with direct customer applications showed the highest potential in terms of market growth (see Figure 1) and market share (see Figure 2).

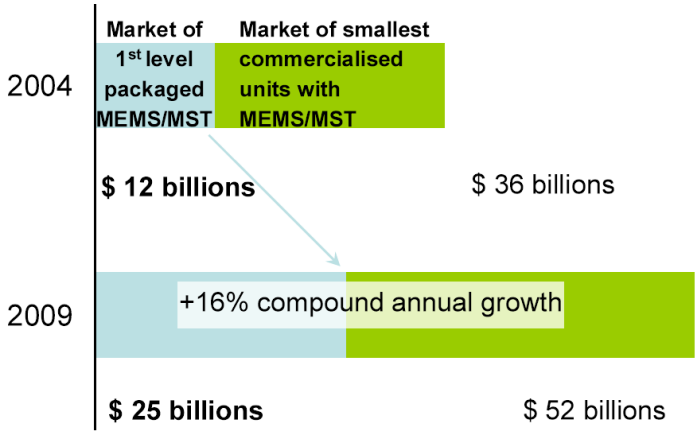

Figure 1 Total market for MEMS/MST in 2004 and 2009 (NEXUS, 2005)

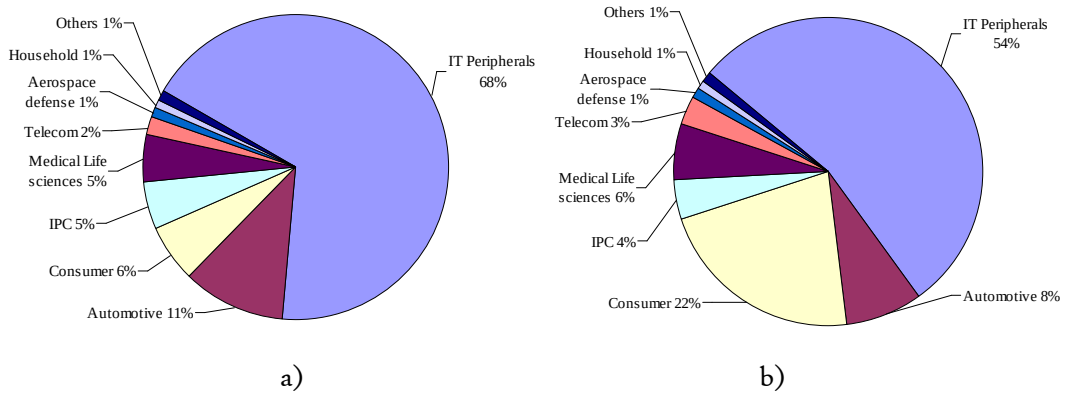

Figure 2 MST/MEMS market by application, a) 2004, b) 2009 (NEXUS, 2005)

NEXUS's prognosis regarding market-share by application of MST/MEMS for 2009 indicates that although the IT peripherals domain will continue to be the largest sector for microsystems, its market share will decrease because of the expansion of usage of these devices by individual customers.

The report underlines, however, that the increase in market share is not equal to the increase in terms of revenue. This situation is mainly due to a pressure on development of low cost devices. This demand for bringing MEMS to market at very low cost has so far only been satisfied in markets requiring extremely large quantities of parts, on the order of tens of millions or higher (Fedder, 1999). However, demand of low cost micro-scale devices is one of the drivers that elongate time-to-market of for these products.

Due to the high non-recoverable costs of design, which occur as a result of the multidisciplinarity and highly specialised knowledge required to accomplish the design process, the smaller markets for MEMS sensors and actuators that need custom design are often ignored. Therefore, MEMS continues to be dominated by high-volume markets (Mukherjee, 2003).

Current design of micro devices is driven by technology and fabrication methods. However, a clear focus on the manufacturability of products, without consideration of their application, may lead companies to stage when, after many years of device development, they can find no, or very limited commercial use for the device, which in some cases can lead to bankruptcy (Mukherjee & Fedder, 1998).

Table 1 presents time-to-market for existing micro-scale devices. It can be observed that the implementation of the lessons learned in the earlier commercialisation of devices, such as pressure sensors, has not yet led to significantly decreases in time-to-commercialisation of newer devices. This fact is presented by irregularity in products development time from discovery to commercialisation and in the cost reduction stage itself.

Table 1 Time-to-market for MEMS/MST (Grace, 2004)

Product	Discovery	Product evolution	Cost reduction	Full commercialisation
Pressure sensors	1954-1960	1960-1975	1975-1990	1990
Nozzles	1972-1984	1984-1990	1990-1996	1996
Accelerometers	1974-1985	1985-1990	1990-1998	1998
Valves	1980-1988	1988-1996	1996-2002	2002
Gas Sensors	1986-1994	1994-1998	1998-2005	2005
Photonics/display	1980-1986	1986-1998	1998-2005	2005
Rate sensors	1982-1990	1990-1996	1996-2006	2006
Radio frequency (RF)	1994-1998	1998-2001	2001-2008	2008
Micro relays	1977-1982	1993-1998	1998-2008	2008
Oscillators	1965-1980	1980-1995	1995-2009	2009
Bio/chemical sensors	1980-1994	1994-2000	2000-2010	2010

Grace (2006) has presented 14 major barriers for commercialisation of MST/MEMS. Those barriers can be classified into groups according to the factors which appear to rely on them:

- Economic barriers:
    - R&D – where regarding that significant part of funding was shifted to Nanotechnology still was observe grew of efforts from $884.8 billion US in 1998 to $925.5 billion US in 2006,
    - Market Research – currently provided by number of organisations,
    - Profitability – small number of successful MEMS/MST companies,
- Technological barriers:
    - Established Infrastructure – where significant improvement can be observe from year 1998 where majority of equipment was adopted from semiconductors industry to current state where a selection of over 60 worldwide sources of MEMS/MST foundries in business exist,
    - Design for manufacturing – technologically-oriented design focus on fabrication methods available.

- Management barriers:
    - Industry Association - in 1998, no association existed to promote the MEMS industry when in 2006 number of organisations growing not-for –profits could be identified e.g. MEMS Industry Group (MIG),
    - Industry Roadmap – where 2 roadmaps were identified, NEXUS and MANCEF, and are viewed as out of date, not adequately providing necessary information or even not recognisable by respondents identified by Grace,
    - Creation of Wealth - small number of killer applications, and lack of product differentiation and adequate marketing,
    - Venture Capital Attraction – interested in high volume production and companies with fats grow rate,
    - Technology Cluster Development - no less than 35 MEMS/MST/NANO clusters have been formed since the first one in Dortmund Germany in 1986, they are adding value to local and federal economy,
    - Management expertise – acquired from semiconductor industry,
    - Employment – depended on the industry growth.
- Customer and service requirements barriers:
    - Standards – necessity to create and adopt many process, packaging and testing standards for MEMS/MST in aim to decrease cost of devices and their time-to-market.
    - Marketing – where technologically oriented people do not put enough pressure on customers' need assuming that if they will build the device customer will come by him-/herself.

This presentation of barriers from point of view of considered factors' evolution over last couple years showed increased interest in micro-domain. It also highlights that although customer requirements are incorporated in design of these devices they were considered as important for their future development.

Fedder (1999) listed items which are required for commercialisation of application specific MEMS, however his list is technology driven and automation focused. It

derived from the methodology developed by him and aim to speed up work and even make it entirely technology dependent. His list consist of: inexpensive access to microstructural processes, preferably integrated with the domain; CAD tools for partitioning design; materials and process characterization encoded in design and technology files; improved testing methods and equipment; improved packaging methods and equipment. Cost and time minimisation approach is clear in this list, however majority of this factors are needed for every design process and restricted access to them or lack of these resources have harmful impact on design.

2. Market Drivers for the Design of Microfluidic Devices

Part of the MST market is Microfluidics. The term 'microfluidics,' refers to the "science and technology of systems that manipulate small amounts of fluids, generally on the nanoliter scale and below" (Melin & Quake, 2007:213). These devices have been an area of significant interest during the last decade. Many of them have been based on MEMS architectures (Ocola et al, 2005).

Although, microfluidics have many applications, and further possibilities of their utilisation are still being investigated, many researchers agree as to where the highest demand for them exists: in two distinctive applications: point-of-care (POC) diagnostics and life science research. Malleo, Haas and Kraft (2005) and Hardt (2005), for example, see the most promising future for these devices in analytical chemistry and biomedical assays.

The forecasts presented above for MST/MEMS market included microfluidic devices. However, separate market researches for this sector can also be identified. A recent EMMA report (Yole Développement, 2009), noted that the market for microfluidic devices will exceed $3b in 2014. BCC Research (2006) have claimed that size of the global market for microfluidic technologies was an estimated $2.9 billion in 2005, and estimate potential growth to $3.2 billion in 2006 and $6.2 billion by 2011. Their report predicted an average annual growth rate (AAGR) of 14.1% from 2006 till 2011.

However promising the forecasts of microfluidics' market presented above, it should be noted actual growth to date has fallen short of are and major market

penetration has been observed in only a few applications of these devices (Hardt, 2005). Particular barriers for design and commercialisation of microfluidic devices were not identified as listed by any researchers, however due to similarities of domains problems which MEMS and microelectronics have to faced appear to be applicable.

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Appendix 2 Service-oriented Design of Products

This appendix is a supplement to Chapter 2 as it provides information about service connected literature. It reviews the most popular approaches in service design.

Investigation of the literature regarding design methodologies for microfluidics showed gaps in terms of capturing of customer and service requirements into this process. Market researches allow for identification of benefits, which can bring customisation of the micro-devices. To make this next step into the future possible customer and service focus is recommended. But what is the purpose of going into service-orientation and what this orientation really means?

1. Movement Towards Services

According to some researchers transformation in offerings from products to services is nothing more or less then natural. Society is shifting to an 'experience economy' (Tukker, 2004). This transformation could be observed in the 90's when USA manufacturers start to go downstream in aim to be competitive (Wise & Baumgartner, 1999). This movement toward customer was started by identification of potential benefits in change from traditional approach of only producing and selling goods to providing services required for operation and maintenance of products. Researchers identified "that in many manufacturing sectors, revenues from downstream activities represents ten to 30 times the annual volume of the underlying product sales" (Wise & Baumgartner, 1999). This movement was motivated not to acquire the highest possible market share in particular area by increasing number of customers but to create strong relationships with them and attain their loyalty. Since the longer customer is retained, the higher is the profit impact (Voss, 1992). Acquiring insight into customers' needs not only allows to refine offerings to make them more suitable for users but also to satisfied their needs faster.

Since movement downstream is not beneficial in case of every company it has to be justified. Indicators such as: ratio of installed units to annual new-unit sales, the

customer's usage cost over PLC (Product Life Cycle) relative to the price, etc. have to be taken into account. A big investment in supplying services to the customer has to have opportunity of revenue in the future. In the best positions are companies that already have strong relationships with their clients and going downstream will not cause conflicts for them with their other channels (e.g. previously used distributors).

Companies on their way to incorporate services into their offerings followed variation of approaches. Some of them required reorganisation of whole enterprise (Horwitz & Neville, 1996), e.g. PSS (Product-Service System), SOA, other change in culture and people mindsets. Degree to which manufacturing concentrate on services depends on selected approach from which most popular service-oriented approaches are: DFS (Design for Service), PSS and SOD. Also use of nomenclature strongly depends on application area what can be observe by particular usage of the term 'service-oriented design'. To show potential of these and/or similar approaches in the future of microfluidics most popular of towards service-orientation are briefly described.

2. Design for Service (DFS)

On the way to incorporate services in the offerings manufacturers started to consider them as a part of design process. However, their focus was only on services which are provided for the product itself – on maintenance. In aim to create customer-centric products, for which service and maintenance need to be consider at the earliest stage of the design concept (Teresco, 1994), they developed DFS approach.

This approach was created as type of Design for X (e.g. Design for Manufacturing - DFM, Design for Assembly – DFA). It supplies a method of designing a product for efficient maintenance and repair. It considers assembly issues in aim to speed up replacement processes. Later on its principles were incorporated in many software tools, such as DFMA (Design for Manufacturing & Assembly) software tool (Raplee, 1999), to improve product at the design stage e.g. by helping in estimation of assembly and reassembly time.

DFS clear focus on maintenance and repair as services which are incorporated into the design process limits other aspects which can and have to be considered in this process. Similarly focus of other DFX on the one aspect – X - pushes on the further plan other needs e.g. manufacturing methods, achieving of proper performance and/or other types of customer requirements. Since these aspects such as high technology dependence are critical for microfluidics DFX approaches won't be further investigated as not leading to fulfilment of customers' and manufacturers' demands.

3. Product-Service Systems (PSS)

Other recently popular approach is a PSS. A PSS is a special case of servitization (Baines et al, 2007). It is defined as "a marketable set of products and services capable jointly fulfilling a user's need" (Morrelli, 2002) without necessarily transferring the ownership of the product to him/her. In all of the cases integrated combination of tangible products as intangible services is designed to enhance competitiveness and foster sustainability simultaneously (Tukker, 2004; Tukker & Tischner, 2006). Researchers identified few different types of PSS (Tukker, 2004; Tukker & Tschner, 2005). Most widely spread approach identifies three types of PSS: product-oriented, use-oriented and results-oriented. Differentiation between these types is based on the product ownership and payment agreements with a customer.

This harmonious design of products and services leads to optimisation of ownership cost and require a cultural shift in organisation applying it. Movement toward PSS is visible e.g. in aerospace industry (Harrison, 2006; Wong et al, 2007) but successful stories about its implementation can be found in many other domains (Manzini & Vezzoli, 2001, 2002). However, as movement downstream, this approach also is not suitable for every organisation. Regarding long – four years in case of Boeing (Harrison, 2006) - and costly transition to PSS from traditional method of operation it is not always profitable. Sometimes risk of applying a PSS and methods which it represents is not profitable in comparison to present performance of a company.

In transition from products to services researchers have not pay great attention to which extend services should be integrated, how this integration should be carried out and what challenges have to be faced in the product offering. It is also not clear what factors decide about considered product-service mix (Oliva & Kallenberg, 2003). They also, in adaption of PSS, in majority rely on the product development process viewing service development as an extension of it which they frequently left out (Tukker & Tischner, 2005).

Discussing development of a PSS approach researchers focus on organisation changes, mainly in terms of culture, and sustainability issues (Manzini & Vezzoli, 2002; Mont, 2002). Describing scope of transition required and principles which underlying a PSS approach researchers rarely discussed methodological implications of it in design discipline (Morrelli, 2002) as well as design and development of PSS aspects itself (Tan & McAloone, 2006). One of the issues raised in this area is lack of sufficient knowledge of designers of products about services what can be bridged by creation of multidisciplinary teams. To fill this gap Morrelli (2002, 2002a) studied designer's role in creation of a PSS. Although, his work was focus on whole PSS design in terms of organisation change not on the design process itself, he pointed out that logical location of the design activities introduce new challenges. This location is in:

- Management methodologies - interaction with user regarding his/her needs have to be accurately planned, to address them properly,
- Better understanding of cultural, social and technological frames – users, designers and service providers shape the service together,
- Control and address of the event sequence in diachronic services – needs for introduction of new tools;

and these aspects are also valid to design of any product with services in mind.

Due to the facts that a PSS is focused rather on organisational changes than on design flow, and on existing services - mainly maintenance - rather then new one, at least on the first stages, investigation of this issue was abandoned. A PSS is considered as not suitable step for microfluidics on the current stage of their

development when design process itself for products is not fully understood and therefore it can bring more harm then benefits.

4. Service-oriented Design (SOD)

Meaning of the term 'service-orientation' strongly depends on area of application and can be misunderstood by many people. In majority it is used in IT context (Artus, 2006). This not new idea evolved from traditional service providing, such as a blacksmith or a doctor, started as an IT experiment in mid-90's to enable servers to communicate with each other by leveraging infrastructure (Dubray, 2006). It is defined as a "paradigm characterized by the explicit identification and description of the externally observable behaviour, or service, required by an application" (Liu & He, 2006).

SOD originated from the area of component based design, which is focused on breaking design into set of components and relations between them and distinguishing between externally observable behaviour and internal realisation of that behaviour. SOD is "a software development paradigm that utilizes services as fundamental elements for developing applications/ solutions" (Liu & He, 2006). It is a process of designing application support for business processes (Quartel, Dijkman & van Sinderen, 2004), a method in which existing services in organisations are supported by development of suitable software for them.

According to Erl who wrote series of articles about service-orientation (Erl, 2007) and its principles (Erl, 2006a-f) this paradigm represents evolution of IT, and its roots can be found in areas such as BMP (Business Process Management), Object Orientation, Web Services etc. and among others 'separation of concerns'. This theory states that breaking down problem into smaller individual concerns helps to solve it. Erl highlight eight principles of SOD, according to him services: share a formal contract, abstract underlying logic, are loosely coupled, composable, reusable, autonomous, stateless and discoverable. He introduced these principles in aim to presents SOD as a first step to create SOA (Service-Oriented Architecture).

SOA approach creates integrated system which supports all of the services in organisation. It is "a set of guidelines, principles and techniques by which business processes, information and enterprise assets can be effectively (re)organised and (re)deployed to support and enable strategic plans and productivity levels that are required by competitive business environments" (Papazoglou & van den Heuvel, 2006). Sorofan (2008) stated that service-orientation can be observed in all the areas not only in IT by viewing fundamentals of SOA such as: use of standards, design for reuse, composition vs. creation, in almost all the disciplines from finance to products' manufacturing.

Although service-orientation approach presented above is viewed as beneficial for organisation its potential applicability for microfluidics in current situation is very vague. Basic principles mentioned such as use of standards, composition vs. creation are already prove to be useful, however point of view of IT applications creation of all the services in the manufacturing organisation is out of considered scope. Due to this fact further investigation of issues connected to services orientation of microfluidics and services design is recommended.

5. Design of Services

Presented approaches to incorporate services were mainly focused on change in the offerings which incorporates change management and even change of organisational structure. Only process which considered design flow was constrained to maintenance and repair and omitted other significant issues. Due to this fact investigation of design process for service itself in brief was considered necessary.

A process for design of a service differs from designing of a product. This human centred approach requiring outside-in perspective is concerned with systematic application of design methodology and principles to integrate the possibilities in aim to perform a service (Holmid, 2007). Some researchers worked on development of design methodologies to create product-based services businesses (Uchihira et al, 2007). During this process they identified difficulties which designers of a products facing when they are trying to design a services. These

obstacles are that skills, mental models, design processes, and organisations in which designers were working were focused on optimizing a product design what is claimed to required different mindset. Due to these facts and difficulties of manufacturing companies with: designing a feasible service scheme, manage service businesses, bridging a gap between outright selling and interactive value creation and continuous service operations, which were listed as most important issues separate process for service design has been developed.

Traditionally new services were developed using trial and error approach. In aim to design a service that "delivers" Shostack (1984) proposed to design a service blueprint. This blueprint allows for exploration of all of the issues incorporated in creating and managing the service. Development of a blueprint includes: identification of processes which constitute the service, isolation of critical fail points (bottlenecks, errors etc), establishment of time frames, analysis of profitability with tolerances (how delayed process can be before it will decrease benefits significantly) and highlight of the tangible evidence. The tangible evidence is maintaining credibility of service in the clients' eyes. It is a physical proof of the service which can be represented by people who provide the service or circumstantial evidence e.g. ticket to the cinema. This tangible evidence provides user with verification of the service's effectiveness, reminds that service took place, what makes it easier for provider to acquire customer loyalty.

A blueprint helps cut down the development time and inefficiency of random service development and gives a broad view on service management prerogatives (Shostack, 1984). It allows to account customer behaviour towards the service change and modify service for maximum efficiency, can materially improve the marketers' ability to design and manage services, encourages creativity, pre-emptive problem solving and simplify implementation. Service blueprint provides visual and quantitative description of all the elements constitute the service, which can be easily mock-up into prototype and test. This evaluation of total entity is a base for permanent benchmark against which execution can be measured, modifications analysed, competitors compared, prices established and plans for promotion developed (Shostack , 2001). Other method for design of services which

was identified by Shostack (2001) was molecular modelling approach. However, this approach is addressed as marketing tool for service development.

Following this work Tukker and Tischner (2005) during their research on PSS development issues investigated service design. They established that every service design consists of three phases: analysis, creation and realisation. They highlight blueprinting as one of the tools which help in realisation of these phases adding gap analysis and QFD (Quality Function Deployment) as other relevant however mostly from managerial point of view. Blueprinting according to them is realised in 8-9 following steps:

- Identification of the service.
- Mapping the service process from customer's point of view.
- Drawing the line of interaction.
- Drawing the line of visibility.
- Mapping contact employee actions, both onstage and backstage.
- Drawing the line of internal interaction.
- Mapping internal support activities.
- Adding evidence of service at each customer action step.

Adding non-physical evidence of service at each customer action step – step added by Reijnhoudt recommended for product-oriented companies approaching service market.

Tukker and Tischner identified also other methods for service development: a systematic innovation management system, which consists of 5 steps: idea generation, concretion, assessment, decision and realisation; a service engineering development – 3 stages: service creation, service development and service management and an integrated reference model for service engineering – 4 steps: analysis, definition of new processes, pilot application with feedback and the roll-out. Steps identified in these methods can be recognized as part of service development process presented by Brezet et al. in 2001 (see Figure 1). This general process has been confronted with product development process to underline differences.

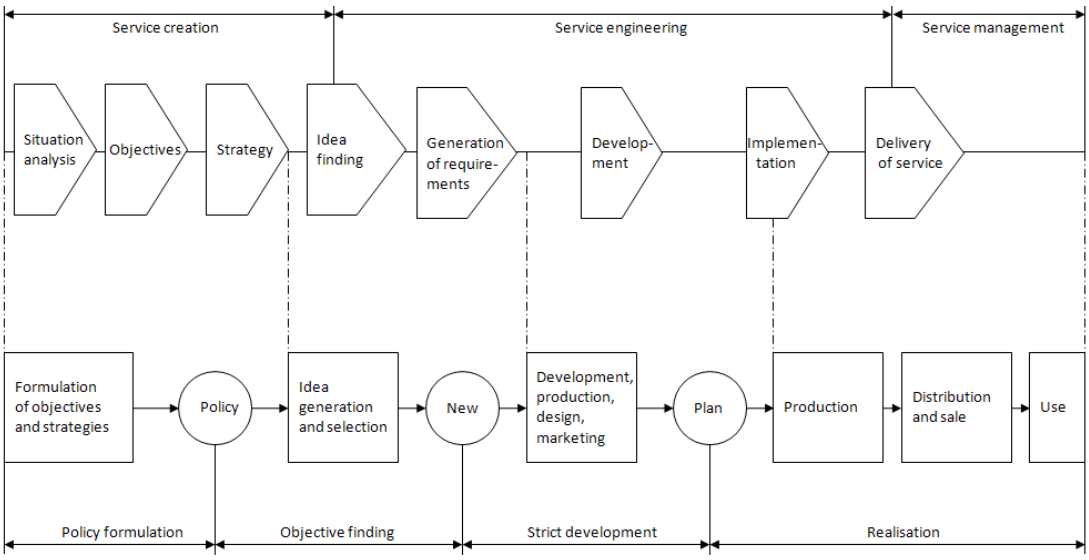

Figure 1 The product development process compared with the service development process (Tukker & Tischner, 2005)

On Figure 1 which compares design processes for product and service can be observed that service design is more oriented towards customer and marketing issues when product design is more mature. These processes vary in terms of lead time, executors, flexibility, variables and level of experience integrating environmental aspects into the flow (Tukker & Tischner, 2005). Holmlid (2007) underlines similarities between product and service design during examination of service design against interaction design based on Buchanan's framework. According to him service's and product's design are similar in terms of: processes (highly explorative and somewhat analytical), production (highly physical), materials (highly tangible), aesthetics (highly visual and somewhat experiential) and customer focus (mass market). He also claims that service design pay more attention to symbolic, enactive and depictive representations, have more ongoing production, is more virtual, spatial temporal, social, active, customizable, dynamic, focused on use and performance, and need more organisational support and taking into account customer's customer. All of these features are due to intangibility and close contact with clients which are characteristics of services.

6. Designing Products with Services in Mind

Regarding highly technology driven design flows of microfluidics and lack of their market orientation, not fully understood forces working on these devices as well as

their other specifics creation of systems such as PSS is not profitable in short term view and/or in current situation. However, movement toward similar approaches can bring benefits and simplified any transition in future. Due to this fact investigation of design with services in mind is recommended.

Designing with service in mind is in simple terms designing thinking about market requirements for functionality and what customer want to achieve by using the product rather then designing just physical products itself. This approach was used for many years in macro-scale production by incorporation of market requirements into design specifications and creation of methods such as UCD (User-Centered Design).

UCD is both a broad philosophy and variety of methods (Abras, Maloney-Krichmar & Preece, 2004). It is based on involvement of users in design and evaluation process to acquire clear understanding of their tasks and requirements. It is considered as "the key to product usefulness and usability" (Mao et al., 2001). Investigation of usability of UCD methods in industry undertaken by Mao et al. (2001), showed that after more than decade of the existence their exploitation was not very common due to organisational and technical reasons. They highlighted as most often used methods: informal usability testing, user analysis/profiling, evaluating existing systems, low-fidelity prototyping, heuristic evaluation, task identification, navigation design and scenario-based design. As most commonly used measure for these UCD methods by almost all the respondents Mao et al. identified customer satisfaction. However, this measure was underlined as not sufficient and lack of proper measurement method has been pointed out. This variety of methods however was created to make devices more usable and easier to adapt for a customer. These methods make products more suitable for customers by their involvement in the design process and capturing their requirements, however they do not solve issue of providing functionality instead of a product.

Literature regarding strictly designing with services in mind was not identified, however regarding huge amount of documentation discussing variety of product/service designs' aspects as well as issues concerning services themselves partial discussion of this issue was identified. Some of the issues were identified in

PSS literature when researchers were talking about providing functionality instead of products and selling them, however there is lack of work concerning product/service design flow in PSS itself. Other issues were identified in design for services by consideration of what will happen with product after commercialisation - researchers started to change their point of view on the products and customer relations. In design of services discussion of product and service designs dissimilarities allowed view aspects which have to be taken into account when service instead of product will be provided. And most importantly satisfying customer instead of selling him/her a product allow to think out of the established patterns what foster creativity, which is underlined as so important nowadays, and by it innovation.

7. Summary

Movement from products to services is considered as natural in today's world. Many industries continue it from 90's when recognition of its profitability started to be visible in industry. Level of services and type of orientation of companies however vary depending on approaches undertaken by them.

Focusing on the design flow DFS methodology was recognised as one of the first attempts to incorporate services into the design process. However, limitations which this method represents by focusing only on maintenance and repair aspects of products highlight lack of its suitability for microfluidics area.

Methodologies such as PSS and SOD which represents movements towards services itself were identified as business focused rather then design flow oriented. A PSS itself although provided possibility of selling functionality instead of product itself what will create different mindset was considered as useful. However, lack of literature directly connected to the design flow was identified and due to this fact investigation of this area was abandon. Similarly SOD, showing basic principles which are already incorporated in design of microfluidics such as use of standards, presented high focus on the IT aspects and operational services provided by companies rather then scoped around products. Especially these issues were underlined when SOD was transferred to SOA approach.

Comparison of design processes for product and service showed amount of customer orientation which is required when designing a service and vagueness of the issues which have to be taken into consideration. This issue discussed as support regarding lack of suitable literature from previous approaches was followed by investigation of design with services in mind. Similarly in this area, although allowed for reference to macro-scale design methodologies and viewing their similar considerations, direct literature was not identified. Due to this fact aspects regarding designing with services in mind were identified in literature regarding discussed previously approaches regarding services.

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Appendix 3 Complexity in Engineering Design and Micro-devices: A Review of Literature

This Appendix presents the second part of the literature review work. This part reviews the existing literature regarding complexity in the area of engineering design and micro-devices. The outcome is a conference paper that has been presented at The 6th International Conference on Manufacturing Research (ICMR08) Brunel University, UK, 9-11th September 2008.

Complexity in Engineering Design and Micro-devices: A Review of Literature

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Abstract

THIS PAPER SUMMARIZES THE MAIN FINDINGS OF A SURVEY OF COMPLEXITY LITERATURE FOR ENGINEERING DESIGN AND REVIEWS THE USE OF THIS WORD IN MICRO-DEVICES LITERATURE. THE GENERAL VIEW ON THE DEFINITION OF THE WORD COMPLEXITY IS CAPTURED AND COMPLEXITY TYPES ARE IDENTIFIED. THE PAPER UNDERLINES THE SUBJECTIVITY AND CONTEXT-DEPENDENCE OF MEANING OF COMPLEXITY, AS IT IS CURRENTLY USED. THE PAPER PROVIDES IDENTIFICATION OF THE COMMON CHARACTERISTICS OF COMPLEXITY DEFINITIONS AND THE REASONS WHY PEOPLE ATTEMPT TO DEVELOP OR INFLUENCE DEFINITIONS OF COMPLEXITY. THE PAPER CONCLUDES THAT A SUFFICIENT DEFINITION OF COMPLEXITY FOR MICRO-DEVICES HAS NOT BEEN PROVIDED AND HIGHLIGHTS HOW THIS ISSUE IS CURRENTLY VIEWED IN LITERATURE.

Keywords: complexity definition, type, micro-devices.

1.0 INTRODUCTION

Miniaturization has absorbed the attention of researchers from many decades. Increasing demand for new and smaller solutions with incorporation of multi-functionality has lead to the increasing “complexity” of these devices. The word “complexity” has been used to describe the large number of designed and manufactured micro- and nano- devices, the multidisciplinarity of the designs, the high technology equipment used for their production and assembly, as well as the lack of knowledge about micro-scale physics, chemistry and biology and hence of device function. Owing to this issue, the complexity literature has been investigated with the aim of identifying a sufficient definition of this word for the micro-devices domain. To fully understand how complexity is viewed five main topics were investigated: 1) universal definitions of complexity, 2) types of complexity, 3) reasons to define complexity, 4) sources of complexity and factors influencing it, and 5) complexity in micro-devices. All of them are presented in following sections of the paper.

2.0 COMPLEXITY DEFINITION

Complexity is established as important field of study [1]. However, the word “complexity” is not only hard to define [2], [3] but in many areas, a precise definition is still not available. Factors that influence this difficulty are the context-dependence and subjectivity of complexity [4]-[6]. Researchers have made attempts to generate a universal definition of complexity, which have resulted in several journal publications, conferences, books and

doctoral dissertations. Resulting from this body of work, "Complexity Theory" has been established as a separate domain of study with diverse applications. Despite this effort, the definition of complexity provided by researchers still varies in different fields (and sometimes even across the same field) showing a discrepancy in terms of meaning, usage and quantification.

In an attempt to define complexity, many researchers have started by identifying what it does not mean. They have indicated differences between complexity and complicatedness [6], [7], randomness [8] and other issues which influence complexity and can be confused with it, such as size, lack of knowledge, variety, and order/disorder [4]. Other authors have tried to establish its meaning by highlighting common characteristics, such as those given by Corning [5] who describes complex phenomenon as those that consist of many parts, with have high number of relationships/interactions, and in which the parts produce combined effects that are not easily predicted and may often be novel. Other features are pointed out by Simon [9] who stated that: complexity critically depends on system description, which can be simplified by correct representation, that a complex system is characterized by redundancy and that its hierarchy can be often described in economical terms (aggregation of redundant components and consideration of them as integrated units).

Complexity has been defined in many areas of study such as chaos theory, fuzzy logic, networks, philosophy, psychology, and statistics. [9]. Amongst these definitions are: algorithmic information context (AIC)[17] or "Kolmogorov's Complexity", length of the message, or "Crude Complexity", introduced by Gell-Mann, logical depth of a string in programming, created by Bennet, average amount of information stored at any time in order to make an optimal forecast, "Forecasting Complexity", established by Grassberger and many more. Each of these definitions is context specific. The majority of them suffer from a defect in construction, as they contain within the explanatory definition the word "complex". A trend is observable in the literature for the presentation of such circular definitions of complexity. These are then followed by the core part of the work, which is a focus on the measurement of this phenomenon and, having gained this quantitative tool, on methodologies to decrease complexity.

The area which provides more suitable definition for products, systems and any other materialistic creations is engineering design. Although, definitions particular to engineering design are focused mainly on the information which the system, device, and product contain, several diverse definitions are available. El-Haik & Yang [10] present complexity as "a quality of an object with many interwoven elements, aspects, details, or attributes that makes the whole object difficult to understand in a collective sense". Although, this definition is valid for every object it is not specific enough to allow for quantification as well as not present the whole meaning of complexity. Another, frequently cited, definition of complexity was introduced by Suh in connection with axiomatic design. He defined complexity very broadly with the aim of providing an absolute measure for it, this quantitative approach being visible in first words of definition. According to Suh, complexity

[17] simultaneously discovered by three independent scientists: Kolmogorov, Chaitin and Solomonoff

is 'a measure of uncertainty in understanding what it is we want to know or in achieving a functional requirement (FR)' [6]. Both these definitions are focused around understanding a design from the points of view of difficulty and uncertainty. Hence, these definitions may cause problems where the design is "fully understood" or could be represented in simple manner, but would still be considered as "complex" by an observer. In the case of full understanding of design, the complexity would be measured as zero, which would indicate that there is no complexity in the device, despite the clear appearance of complexity to the observer.

Is it possible to design a device which is characterized by a complete lack of complexity? Some researchers claims that the answer to this question is 'no.' El-Haik & Yang [10] presented the idea of "irreducible complexity" which they considered a universal quality in all objects. However, they underlined that this level of complexity may significantly vary. This view was supported by Colwell [11] who based his opinion of the minimum amount of complexity required on systems performance – the impossibility of separate parts of the system performing the functions required from the device, or performing them inadequately, if they are not connected. He supported his view by citing Einstein's statement of the simplicity limitations in order to achieve required performance of a design outcome.

3.0 SUB-TYPES OF COMPLEXITY

The inconsistency in definitions of complexity causes differences in identification of their sub-types in the literature. Suh [6] identified four time-related sub-types of complexity: time-independent real complexity – 'a measure of uncertainty when the probability of achieving functional requirements is less then 1.0 because the system range is not identical to the design range', time-independent imaginary complexity – caused by lack of knowledge, time-dependent combinatorial complexity – caused by unpredictability of future events and time-dependent periodic complexity – existing in finite time period with predictable number of combinations of events. Adami [3] divided complexity into physical and structural. His domain of study was biological organisms; however he adapted the AIC definition of complexity, which was created for programming. Zamenopoulos and Alexiou [12] recognized sub-types of complexity as: functional and behavioural, whereas Tomiyama et al [13] noted both complexity by design and intrinsic complexity of multi-disciplinarity.

These sub-types of complexity were created based on particular characteristics identified by researchers and each author has provided their own sub-types referring to particular domain of research. However, some overlap of these sub-types of complexity, in terms of their meaning, can be identified. This overlap is tabulated in Table 1. Since the development of a universal measure of complexity is "hard to imagine" [3], the creation of complexity subdivisions makes it possible, in the majority of cases, to group features which can be measured in order to provide a quantitative indication of complexity level.

Table 1 Sub-Types of Complexity

Type of Complexity Indicated / Researcher(s) / Literature Source	Heylighen [2]	Adami [3]	Edmonds [4]	Thomson et al. [5]	Earl, Eckert & Clarkson [7]	McGuire [8]	Colwell [11]	Zamenopoulos & Alexiou [12]	Tomiyama et al. [13]	Funes [14]	Suh [15]	Kim [16]	Bose, Albonesi & Marculescu [17]	Gell-Mann [18]
Own definition	x		x	x				x			x			
Irreducible complexity							x							
Information complexity					x									
Kolmogorov		x	x			x		x		x				x
System complexity			x											
Observer complexity			x											
Löfgren's Interpretation and Descriptive Complexity			x											
Kauffman's number of conflicting constraints			x											
Physical		x												
Structural	x	x						x						
Functional	x							x						
Structural hierarchical	x													
Functional hierarchical	x													
Behavioural								x						
Crude complexity										x				
Logical depth			x							x				
Forecasting complexity										x				
Computational Complexity			x							x				x
Gell-Mann's Effective Complexity										x				
Complexity by design									x					
Intrinsic complexity of multi-disciplinarity									x					
Suh complexity											x	x		
Time-independent real											x	x		
Time-independent imaginative											x			
Time-dependent combinatorial											x			
Time-dependent periodic											x			

4.0 WHY A DEFINITION OF COMPLEXITY IS REQUIRED

Many authors have put considerable effort into defining complexity, but what was their purpose? What actions did they undertake once their definition of complexity was established? A number of authors have stated that the reason for their work is that complexity is harmful. However, others have pointed out that only specific types of complexity are damaging, whereas other types are useful and even required.

Suh [6] claimed that a 'vast sum of human and financial resources are wasted due to our inability to deal with engineering complexities.' Thomson et al. [5] pointed out that higher complexity than originally anticipated for the project, participates in cost and schedule overruns. Both authors accepted the unavoidability of complexity but blamed incorrect or inadequate management of complexity for badly influencing design. They criticized the general lack of knowledge about complexity, which lead to its misunderstanding. Their views have some commonality with the idea of "irreducible complexity", however they do not provide information about what level of complexity is acceptable.

As a reason to properly define complexity in a specific context, Suh [6] provided a view of the opportunity of its reduction and an increase in the system's reliability and robustness. In his complexity theory there are 3 harmful types of complexity: time-independent real and imaginary complexity, cause over-runs of projects in terms of time and cost, and time-dependent combinatorial complexity, leads system to a chaotic state and results in a system's failure. Suh underlined firstly, the necessity of reducing time-independent imaginary complexity, which could be achieved by writing down the design equation (showing relationship between the functional requirements and design parameters for particular product)[15], and, secondly, the need to change time-dependent combinatorial complexity to periodic complexity, what can provide long-term stability of the system.

Colwell [11] highlighted that the reduction of complexity is compromised by minimization of functionality and/or other tradeoffs. This value-adding complexity view is, in his opinion, only reasonable to a certain extent, beyond which the cost of increasing complexity is not necessary. He stated that each attempt to create complexity in design should be justified, and when this justification cannot reasonably be provided complexity should be reduced. Negative impacts of this additional amount of complexity, in his opinion, included: longer development schedules; design errata, follow-on design issues and cost and time overruns.

5.0 SOURCES OF COMPLEXITY

Since, complexity is such an important aspect in any design, sources of it should be characterized. Identification of the reasons for a particular level of complexity, as well as those features which influence it, can help with its measurement and then, potentially, changes in its level, if required. Rodríguez-Toro, Jared and Swift [9] claimed that proper management of complexity sources can help in the reduction of 'design effort' which results in a shortening of development time and in cutting project costs.

According to Suh [6], complexity is caused by poor design, which can be result of, for example, a non-systematic approach to design, or a lack of knowledge (understanding) about the system under consideration. Earl, Eckert & Clarkson [7] stated that complexity has its origins in a combination of order and uncertainty, where the ordered background of existing designs, processes and requirements is combined with an uncertain change process and unpredictable outcome. However, both of these approaches are very broad, and hence can be very freely interpreted.

Thomson et al. [5] introduced more detailed identification of the factors which influence complexity in design, which can be considered as sources of complexity. They established, the concept of a "Design Complexity Map", which represents those attributes of a design affecting complexity. They identified six groups of factors: knowledge and sources, artefacts, design activity, external and internal aspects (e.g. technology, life phase systems), decision making and actors. Each of these groups contains at least two subgroups and each subgroup has number of positions underneath. Although, this map has been designated to represent complexity of the team environment during the design process, it is also valid for the design outcome itself. When applying this framework to a product, issues presented have to be divided into those that have direct impact on the complexity of design outcome, such as part artefacts, and show potential to be measured, and those with indirect impact such as actors participating in the design process. This framework shows potential to influence the complexity of the design outcome in the conceptual phase by both indicating which elements have to be taken into account and by providing an opportunity to measure complexity.

6.0 COMPLEXITY IN MICRO DEVICES

With regard to the high number of definitions provided for complexity and their sub-types, the assumption of the possibility of a special meaning of "complexity" for micro-scaled devices seems reasonable. Several attempts to define the complexity of micro-devices are available in the literature. However, it is notable that within the domain of micro-devices, devices are often stated to be either simple or complex without a definition of "complexity" or an explanation of where is the border between simple and "complex" lies.

Within this domain, there are three main methods by which definition of complexity is derived: by creation of a definition by the researcher, by adaptation of someone else's approach or by the identification of characteristics.

Zhou [19] represents an example of the first method. He defines complex micro-devices as 'devices composed of parts made from different materials fabricated by various technologies,' and claims that this complexity is continuously increasing due to new demands on the market. This definition, created for micro-assembly, is very broad and does not provide sufficient meaning of the word "complexity" for whole micro-devices domain.

The second approach, to adapt approach to complexity and its measurement from the macro scale, was undertaken by Kim [16], [20]. He applied the "axiomatic" approach to multi-scale systems design with a focus on micro and nano-scale. His work showed the possibility of a reduction its quantification. However, this is one of few attempts identified were a definition created for macro-scale was adapted in micro-scale domain. Kim states that usage of "functional periodicity" will allow the decrease of overall complexity by transformation of a system with time-dependent combinatorial complexity to a system with time-dependent periodic complexity, which was identified as less harmful. He also claims that by consideration of uncertainty associated with functions axiomatic design approach can help in understanding complexity in micro- and nano-assembly. Although he noted that

'information content well-characterizes the real complexity of tiny product manufacturing,' Kim neither states that the definition of complexity provided by Suh [6] is suitable for micro-devices nor created his own definition for this domain.

Finally, Albers and Marz [21] are an example of last method. They noted that every micro device is a multi-technology product. They stated that the design of these small devices, if they are aimed to be optimal and innovative, has to be realized as an integration of technology, process and product development, material sciences and simulation, embracing all these disciplines. They described the process of micro-technology design and manufacturing as very complex due to the unavailability of proper tools and the high degree of uncertainty of the functionality of products after manufacturing processes. This uncertainty, according to certain definitions of complexity confirms the high complexity of these devices, however it does not quantify its level nor solve the problem of identifying the sources of complexity.

Although, these attempts at definition of complexity for the micro-scale have been identified, the amount of available literature regarding this topic is small. However, several authors have described the necessity to decrease the level of complexity in micro-devices, especially regarding the negative influence of complexity on micro-architecture in terms of testability and manufacturing cost [17]. At the macro-scale, this harmful impact of complexity, beyond "irreducible complexity", as well as the concept that complexity increases rapidly as the system scale order grows [16], have convinced many researchers to attempt to measure and influence it. However, any impact, if achieved, has been measured relatively to the prior state, and new methods created have not been applied universally owing to the subjectivity of the judgments incorporated in their definition.

7.0 CONCLUSIONS

The literature presented above shows the increasing interest of scientists in "complexity." However, it also underlines the inconsistency in definitions of this word, its context dependence and subjectivity across different domains as well as inside an area of research. A large number of definitions have been outlined, most of them created *ad hoc* to undertake projects, and characterized by a focus on quantification of a particular issue. The development of complexity definitions, however vague and/or narrow, in the majority is aimed at decreasing the level of complexity owing to the consideration of complexity by majority of researchers as having a destructive effect.

The literature shows that some investigation of complexity has been undertaken in micro-devices domain. However, there is no sufficient definition of complexity identified particular to this domain. This leads to the suggestion that further studies should be undertaken to define and influence complexity for micro-devices.

ACKNOWLEDGEMENTS

The authors would like to thank the Innovative Manufacturing Research Centre (IMRC) at Cranfield for their funding and support.

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Appendix 4 Services Provided for Microfluidic Devices

This appendix supplements Chapter 4 by detailing service offerings of microfluidic organisations.

Table 1 Services provided for microfluidics

Company name	Products	Services	Services for products
Agilent (2008)	• 2100 Bioanalyzer • RNA Solutions • DNA Solutions • Protein Solutions • Cell solutions • 1200 HPLC-Chip System	• Instrument Lifecycle Planning (Instrument Warranty, Services with Instrument Purchase, Agilent Instrument Lifecycle Program, Asset Maximization Program, After Warranty Services) • Compliance Services (Qualification Overview, Classic Edition Qualification Services , Enterprise Edition Qualification Services, Software Edition Qualification Services , Network Edition Qualification Services) • Agilent Service and Support Plans (Agilent Advantage Gold Plan, Agilent Advantage Silver Plan, Agilent Advantage Bronze Plan, Repair Service Plan, Intelligent Repair, Services Bundles, Instrument Exchange, Preventive Maintenance Service, Ion Source Cleaning Service, Multi-Vendor Service, Lab	• Instrument Lifecycle Planning (Instrument Warranty, Services with Instrument Purchase, Agilent Instrument Lifecycle Program, Asset Maximization Program, After Warranty Services) • Compliance Services (Qualification Overview, Classic Edition Qualification Services , Enterprise Edition Qualification Services, Software Edition Qualification Services , Network Edition Qualification Services)

		Resource Management) • Relocation services • Software services & update and software Revision Tables	
AMIC (2008)	• 4castchip – cardiac POC	• OEM services	No indication of services identified
Aviva Bioscience (2008)	• Sealchip • hERG Electrophysiology Assay and Cell Lines	• Electrophysiology on Demand (EPOD) • Cardiac Safety: Ion Channel Screening Services : - HERGEXPRESS - provide clients with reliable high quality data that can provide clear guidance to their medicinal chemistry departments. - GLP – for customers who presents the data to regulatory agencies • Cardiac sodium channel - allows clients to establish if their compounds is a blocker of this important cardiac channel	No indication of services for products
Bartels (2008)	• Alchemist® - dosing robot • Micropumps • Microvalves • CE Chips • Nano Well Plates	-	-
bioMérieux (2008)	• Diagnostic solutions.	• Training for bioMérieux products. • Preventive and corrective maintenance of the systems. • Technical library access	• Training for bioMérieux products. • Preventive and corrective maintenance of the systems. • Technical library access.
Boehringer Ingelheim microParts (2008)	• MicroDegasser - Microfluidic degasser module for analytical instrumentation • X-Check Disc -	• Production of microfluidic systems, e.g. for in vitro diagnostics, medical technology and drug discovery	-

	Centrifugally driven microfluidics for quality assurance • Lilliput® Chip - Diagnostic chip for clinical microbiology (identification of microorganisms, antibiotics susceptibility tests).	• Development and production of microfluidic components for analytical instrumentation	
Bürkert (2008)	• Solenoid valves and micro pumps for preferred use in analytical, medical or biotechnical applications	• R&D • Consulting (e.g. product optimisation) • Engineering (clean production facilities and in-house tool-shop, 3D CAD design and simulation, material research, analysis etc.) • on-site assembly and commissioning • installation • Testing • After sales services	• Involvement in the specifications and requirements obtaining, design process, manufacturing and maintenance
Caliper (2008)	• LabChip® systems, LabChip® instrument and experiment-specific reagents and software	• Service & Support • The Technical Support Hotline for assistance with: • Instrument troubleshooting - Software troubleshooting - Replacement part information - Repair instructions • Installation Services/First to Science • Maintenance & Service Contracts • Instrument Validation Services • Training and Certification	• Service & Support • The Technical Support Hotline for assistance with: • Instrument troubleshooting - Software troubleshooting - Replacement part information - Repair instructions • Installation Services/First to Science • Maintenance & Service Contracts • Instrument Validation Services • Training and Certification
CMC Microsystems (2008)	• Environment and equipments – not products by themselves	• Design environments: CAD tools for design and fluidic analysis with finite element analysis techniques • Prototype manufacturing	• Access to environments and equipments with support

		services: Dual plane in-channel electrode metallization (tantalum-gold electrodes) technology; Fabrication of networks of closed microchannels in glass substrate • Technology files and user guides for manufacturing processes • Engineering support	
Diagnoswiss (2008)	• GRAVI™- Chips (is a polymer cartridge with an array of 8 micro-channels, designed for running magnetic bead based ELISA protocols with standard immunology reagents), GRAVI™- Lab (a fully automated platform, for unattended running of bead-protocol ELISA tests with standard immunology reagents), GRAVI™- Cell (open immunoassay instrument for running bead-based protocols with standard immunology reagents, in record times), GRAVI™- Soft, accessories and reagents	-	No maintenance necessary due to gravitation principle of work
Dolomite (2008)	• Microfluidic pumps. • Connectors. • Microfluidic chips. • Membrane devices.	• Custom design project (including inspection and fluidic testing and the development of fluidic and electrical interconnects, modelling of the microfluidic device	Design of products, rapid prototyping of microfluidic devices along with the ability to ramp up to volume manufacture. Indication of services provided for created products after sell not provided

		performance including, fluid and heat flow, diffusion effects and reaction kinetics). • New system or instrument development project (feasibility study, 3D product concepts, system schematics and cost estimates, design approval, development of all the software, control and mechanical systems and devices required for the end product, complete manufacturing data pack ready for production).	
Dyconex (2008)	Manufacturing custom products	• Design support	No indication of services after sell
eGene (Qiagen UK) (2008)	• Products for DNA & RNS analysis	• Technical service	• Technical service – no other indication – no description of this service provided
Eksigent Technologies (2008)	• Express LC – pharmaceuticals • The ExpressRT™-100 – reaction monitoring • Eksigent's flexible NanoFlow Metering platform • EKPump	-	-
Epigem (2008)	Foundry and consultancy, with manufacturing offer of: LOC microfluidics devices, microlens arrays, ultra high resolution flexible circuit boards, polymer waveguides, other micro-optical products	• Product Development • Contract Manufacture for polymer microsystems, pilot/speciality coating and UV embossed structures	• Consultancy and manufacturing for clients from polymer
ESI Group (2008)	• Software tools for: biochips, clinical diagnostics, inkjets, fluid dynamic bearings, mixing analysis and surface binding & chemical reaction analysis	• Collaborative R&D (Methodology development, Process automation) • Training and technical support • Consultation and	• Simulation of interacting physics in micro-devices (CFD) – by product, and for their product (software) training and technical

		product development services for the design and optimisation of products	support
Fluidigm (2008)	• BioMark™ - real-time PCR assays • TOPAZ® - protein crystallization	• Installation (prepare customer site, subsequently, installs instrumentation, and conducts on-site training) • Service (one-year warranty on replacement parts, labour, and travel) • User Documentation • Applications Support (system operation and scientific applications). • Service Agreements/Support Plans	• Installation (prepare customer site, subsequently, installs instrumentation, and conducts on-site training) • Service (one-year warranty on replacement parts, labour, and travel) • User Documentation • Applications Support (system operation and scientific applications) • Service Agreements/Support Plans
Fluigent (2008)	• Flow control tools - MFCS microfluidics flow control systems and accessories, • Genetic testing - Enhanced Mismatch Mutation Analysis (EMMA™) - for the detection and discovery of unknown mutations, Emmalys (software)	-	-
Gyros (2008)	• Gyrolab Workstation - bioanalytical system that addresses critical needs within the development of therapeutic proteins, from early screening of drug candidates to the completion of clinical trials • Gyrolab CD Laboratories	• GxP Validation Support: Installation Qualification (IQ) supporting validation of Gyrolab in customer's working environment, Operational Qualification (OQ) ensuring proper operating procedures are in place following installation,	• GxP Validation Support: Installation Qualification (IQ) supporting validation of Gyrolab in customer's working environment, Operational Qualification (OQ) ensuring proper operating procedures are in place following installation,

	• Gyrolab software (control, evaluator, viewer) • Consumables & Accessories	IQ/OQ services performed • Application Support: Identification of the most suitable binding pair for customer application, Optimization and verification of immunoassays, Basic and advanced user training courses, User seminars and networking, sharing knowledge and experiences • Instrument Service: Ensures instrument continues to work at 'best performance', Preventive maintenance, instrument care, Choice of service levels to match customer needs	IQ/OQ services performed • Application Support: Identification of the most suitable binding pair for customer application, Optimization and verification of immunoassays, Basic and advanced user training courses, User seminars and networking, sharing knowledge and experiences • Instrument Service: Ensures instrument continues to work at 'best performance', Preventive maintenance, instrument care, Choice of service levels to match customer needs
IMM (2008)	-	• R&D • Development of prototypes for complete microfluidic package solutions in the fields of bio(medical) and industrial analytics • Industrial analytics of fluids or fluid films	-
Licom (2008)	-	• R&D services • Design services • Manufacturing services (from prototyping to high volume production) • Feasibility Studies and Concept Evaluation • Workshops' organisation	• Realisation of products - assistance from material characterisation and proving the concept trough
Micralyne Microfluidics (2008)	• Foundry • standard and Protolyne® Microfluidic Chips manufactured on	• Product development • Manufacturing	No additional after sales services identified

	demand		
microbuilder (2008)	-	• services for the development and manufacturing of prototypes and products: • Feasibility studies • Design and simulation services • Product development • Multi-project wafer services • Prototype manufacturing • Series production • CoventorWare modules • Training and education	• Realisation of products -services allowing to design and manufacture (by contract with thinXXS), However, they do not produce or sell product by themselves
Microfab (2008)	• Complete Systems • Printhead Assemblies • Drive Electronics • Dispensing Devices • Pressure & Temperature Control Subsystems • Optics Subsystems	• Manufacturing Micro-optics Products & Technology • Solder Bumping Services & Technology, which can be used for process development, prototyping, and small to medium lot manufacturing. • Application Development Services: assist in defining the requirements of the application; assist in generating a plan to develop the materials, processes, and designs required for the application; rapidly demonstrate the feasibility of the application in our laboratories, providing early data to a risk assessment; design and fabricate the equipment required to implement the application, using MicroFab's currently available	Design and manufacturing of customer products. No indication of services for offered products

		commercial equipment where possible, customizing it when necessary. • Ink-Jet Seminar	
Microfluidics, division of Microfluidics International Corporation (2008)	• Microfluidizer® processor - fluid processors for deagglomeration and dispersion of uniform submicron particles and creation of stable emulsions and dispersions	• Address your formulation challenge Process consulting • Off side demonstrations • Regional seminars • Purchase opinions • Customized in-house seminars and training • Testing • Starts-up • Training and maintenance • Preventive maintenance contracts	All services scoped around offered products
Micronics (2008)	• microFlow™ System - a low-pulse pump system that enables real time assessment of fluids in flow • Active™ Lab Cards - for use with the microFlow™ System • Access™ Cards - manually activated cards for exploration of the principles of microfluidics in H-Filter® and T-Sensor® formats.	• Micronics' full service lab card development capabilities include • Fluidic modelling as a core component of card design • On-card sample preparation, mixing/separation and analysis • Reagent printing and waste storage on card • Surface chemistries and materials analysis and selection for optimum card performance • Integration of filters, arrays, slides, electrodes and other components on card • Disposable Microfluidics Lab Card Development • Passively driven microfluidic structures - making fluids flow with gravity, absorption, and capillary action	• Design and prototyping of elements. No indication of services for products

		without additional driving mechanisms • Microfluidic polymeric structures – 3D circuits, sample/reagent input, cell lysing, mixing, on-card valving, cell and particle focusing, and hybrid circuit structures (polymers, glass, metals, silicon, etc.) • Rapid prototyping - complex fluidic modelling, efficient polymer laminate prototyping, designing for high volume production	
Micronit microfluidics (2008)	• Fluidic Connect - Microfluidic connection platform enabling user-friendly interconnections between the Fluidic Chips and peripheral equipment (like a pump or detector) • Fluidic Chips - Glass microfluidic chips for various applications (microreactors, micromixers, cross channel chips) compatible with the Fluidic Connect platform. • Capillary Electrophoresis - LOC products for on-chip capillary electrophoresis. Also available with a CE setup tool kit.	• Design, simulation, prototyping and high volume manufacturing	• Design, simulation, prototyping and high volume manufacturing, no services for offered products have been identified
Microplumbers (2008)	Service offerings	• Diffusion, Flow, and Chemical Reaction Modelling	• Diffusion, flow, and chemical reaction modelling for customers products
MicroTEC (2008)	Manufacturing custom products	• Development and contract manufacturing of	No after sell services indicated

		components, microsystems and microstructures, • Prototyping • Batch production	
Nanogen (2008)	• NanoChip® 400 System – which is not available for sale from 2007, other products are for instrumentation (readers), reagents, test kits and CE kits	• Support for sold equipment	• Support for the sold equipment
Seyonic (2008)	• Pipetting Systems • Miniature High Speed Flow Sensor Module	-	-
SpinX Technologies (2008)	• The SpinX solution consists of: • Microfluidic gCards™, which are organized into a gStack™ • Spinx Lab, a bench-top instrument; • SpinXplorer™ and AssayStudio™ control and assay setup software. • gCards and gStacks	-	-
Tecan (2008)	• Platforms for Biopharma/Research and Clinical Diagnostics: • The Freedom EVO series – systems for automate genomic, proteomic, drug discovery, and other life science applications. • Freedom EVO 75 – systems for DNA extraction, PCR set-up and ELISA • Freedom EVO MultiChannel Pipetting - solutions for 96- or 384-channel sample transfers. • Freedom EVO / REMP SSS Factory - storage, retrieval and reformatting of compounds and	• Installation • Preventive maintenance • Repair • Upgrades • Training	• Installation • Preventive maintenance • Repair • Upgrades • Training • Service contracts (complete, maintenance, repair)

	DNA samples • Freedom EVOlyzer® - ELISA analyzer offers fully automated microplate processing and includes state-of-the art reader, washer and incubation units • Freedom EVO Clinical* - pipetting platform for clinical diagnostic applications • Genesis FE 500™ - pre-analytical system • Tecan Integration Group (TIG) – customised solutions		
ThinXXS (2008)	Foundry – do not offer products by themselves	• Manufacturing services for microfluidic systems include: - Realize a wide range of channel architectures. - Choose the material according to application requirements. - Modify surface properties as needed. - Insert nickel, gold, or platinum electrodes. - Integrate functionalities such as micropumps, micro mixers or biochemical sensors. - Ensure the compatibility of the microfluidics with common macro equipment. - Develop highly complex LOC systems as disposables. - Produce small to large scale	• Development, production and distribution of micro-structured components and systems made of plastics

		volumes.	
Translume (2008)	• Microfluidic chip, • Fluid monitoring system	-	-
Tronic's (2008)	Foundry – manufacturing on demand – custom products – no off the shelf components	• Product Development and Contract Manufacturing: Translate and transition ideas and product concepts to manufacturing • Transfer concepts and technologies from third parties • Customize product platforms for customer specifications/applications • Custom Packaging and Assembly • Specialized Test and Characterization Protocols • End-to-end services: - Modelling, simulation and design for manufacturing - Process development and qualification - MEMS electronic interface development management - Development, industrialization and optimization of specialized packaging - Product testing, characterization and reliability - Supply chain development and management for custom MEMS components - Manufacturing and delivery of qualified products - Product FMEA, SPC, QPC and continuous quality	No after sell services identified

		improvement • Co-design	
Wasatch microfluidics (2008)	• The Continuous Flow Microspotter™ (CFM), uses flow to deposit arrays of biomaterials on surfaces • The CFM is comprised of an array printing instrument and a microfluidic print head	-	-
Weidmann Plastics (2008)	• Cassette for Blood Gas Analyzer • Cartridge for Coagulation Monitoring • LabCD TM	• Manufacturing using micromoulding • Development of the production processes and mass production of a replicated microfluidic system for drug discovery applications • Technical Evaluation Service	No after sell services indicated

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Appendix 5 Survey Appendices

This Appendix provides the details of the survey. It provides rationale behind questions used (Appendix 5.1), report from the questionnaire piloting session (Appendix 5.2) with used questionnaire (Appendix 5.3) and evaluation form (Appendix 5.4) and improved version of the questionnaire placed as an online survey (Appendix 5.5).

Appendix 5.1 Rationale for Survey Questions

Question (Q): Have you ever taken part in designing microfluidics device?

Question indicates if person have relevant experience and the knowledge to answers question about design methodologies for microfluidic devices. It is followed by request for clarification of the role in design and its description.

Q: Do your company design microfluidic devices?

Question indicates if the respondent is presently working on microfluidic devices design and if his answers are reliable.

Design Methodology section

Q: Are you familiar with any particular methodology for the design of microfluidic devices?

Answer will provide information if the person is familiar with any design methodology for microfluidic devices. This methodology can be formal in which case name of it will be sufficient for identification or can be created 'in house' or as a result of modification of existing literature approaches in which case description of the method will be necessary.

Q: Did you follow any particular methodology when designing microfluidic device(s)?

Question reveals experience of the respondent in usage of particular methodologies in design of microfluidic devices. It is followed by request of elaboration o the

topic and description of the methodology used and situation in which it was followed.

Q: Do you develop more than one type of microfluidic devices?

Selection of this question is based on possibility of offering by the organisation more than one type of microfluidic devices. To avoid any misunderstanding indication to select most well established design is stated.

Q: What was the reason for the selection of this particular device for development?

Question indicates how the design started and what the input in the design process was. It shows where the idea was originated from.

Q: How did you obtain the specifications?

Regarding lack of information in investigated literature about methods of obtaining specification for design of microfluidic devices this question was consider as necessity. Answer on it will provide insight of how industry establishes their target in design of microfluidic devices.

Q: Who were the target customers (B2B, B2C, particular group of people)?

Only customer input identified for design of microfluidic devices was specifications in terms of performance, size and cost. There was no indication for who devices were designed and if this influenced the process. This question will provide answer on this issue.

Q: Were the customers involved in the design process?

There is no indication about customer role in design of microfluidic devices. This question will provide answer on the involvement of the customer and request additional information such as: which stages, what type of involvement and what an input was given by the customer.

Q: Did you use any methods to capture customer needs, expectations from the product?

Answer will provide and insight in the methods used to capture customer needs and expectation. It will show if the design practice is more oriented towards customer or technology as indicated by literature.

Q: Did you, for the development of this particular device, followed any design methodology (if A1 is answered No follow to next question)?

Hence the questions are scoped around on design process and participants could indicate more than one design methodology as familiar, clarification is required of the method followed.

Q: Please describe the design process for this device step by step

Each design process is unique in some aspects. Regarding various factors which designers can and cannot influence description of the followed design path for particular microfluidic device is requested.

Q: Did you use any design support tools?

Literature indicated technology driven design of microfluidic devices. This question will allow to compare one of the aspects of technology orientation with industrial practice.

Q: Did you use any components libraries during the design?

Literature indicated clear requirement for development of components libraries for microfluidic devices and lack of the proper databases and standard element in this area. This question will confront these issues with an industrial practice.

Q: How did you evaluate the design (if it meets the specifications and/or will be economically justified)?

There is no indication on when to stop the design process and when the device is decide to be ready to manufacture. Regarding lack of suitable tool for verification of microfluidic devices and knowledge about failure mechanisms in this area

decision on when its evaluation need to be answered. This question is aiming to provide this answer.

Q: When did you decide that the device is ready to be manufacture?

When previous question discuss evaluation of the device this one point at which stage design is accomplished. However, reasoning behind the question is similar.

Q: How long did it take to design the device?

Answer on this question will provide time frames for the design of microfluidic devices and allow to compare it with literature indications.

Q: How long it did it take to launch it on the market?

Since commercialisation of microfluidic devices according to literature in time consuming comparison with industrial practice is necessary to provide view, how they deal with this issue in raising competition on the market.

Service-orientation of products section

Q: Does your company offer any services with microfluidic products?

Regarding lack of information about services in literature and contradicting indication given by microfluidic companies' brochures and websites this question is stated as introduction to the section.

Q: Does your company offer functionality instead of the device?

Answer of this question will indicate maturity of service thinking in the microfluidic industry.

Q: Did you consider services when designing the product?

Consideration of services during the design process is predicted to be scoped around utilities, however since in literature even this indication was not find answer will provide better insight into the area.

Q: Did you incorporate service (service thinking) into design process?

Service thinking in the design differs from thinking about services as utilities. Answer on this question will provide information if the company thought about offering the device as functionality and transition of the design to the next stage – design of services.

Q: How important in your opinion services are in today's microfluidic market and how important will they be in the future?

This question is aiming in capturing companies view on services in the microfluidic domain in terms of utility and movement toward functionality offerings. Answer will show if the area is more mature in the industry than in academia or services are still not considered even as the future.

Sub-sections interactions section

Q: Does your company offer/design modular or monolithic microfluidic devices?

Question identifies the respondent have the first hand experience of dealing with modular designs. Hence, if he/she is able to answer the questions in this section and what he/she can be ask on the possible follow-up interview.

Q: Have you offered/designed modular microfluidic design in the past?

Question identifies the respondent have the first hand experience of dealing with modular designs. Hence, if he/she is able to answer the questions in this section and what he/she can be ask on the possible follow-up interview.

Q: How important in your opinion (and/or in vision of the company) are the interactions between sub-sections in the modular device (for microfluidic and for any other devices)?

Question identifies view of the respondent on modularity and sub-section interactions.

Q: Did your company influence sub-section interactions in any way?

Answer provides information about industrial practice in the companies of dealing with sub-section interactions, regarding restricted amount of methods identified in the literature.

Q: Are you familiar with any other (than mentioned in question C4) method to deal with sub-section interactions?

Answer provides information about industrial practice of dealing with sub-section interactions based on previous experience of designers, regarding restricted amount of methods identified in the literature.

Appendix 5.2 Piloting Questionnaire Report

Report

Piloting session for the questionnaire

MSc Eng. Katarzyna Panikowska

1. Introduction

The purpose of the session was to evaluate questionnaire prepared as a part of a PhD research 'Service-oriented Design of Microfluidic Devices'. Prepared questionnaire will be use in the industrial survey aiming in gathering information regarding design methodologies for microfluidic devices, their service-orientation and methods used to deal with sub-section interactions.

1.1 Background

High investments and promising future of micro-scale technologies is causing increasing interest in this area. Designers are trying to develop methodologies which will fulfil all of the requirements that nowadays world can think about, however created by them methodologies are still not sufficient for multi-domain specific area which is microfluidic.

Investigation of design methodologies which exist in this area showed that four major approaches to design are currently applied: unstructured, which is slowly replaced by structured, top-down and bottom-up. These approaches are mixed in aim to develop universal design flow for all micro-scale devices. However, this is still work in progress since all of the identified methodologies are application specific and show necessity for improvement. Some of the methodologies also incorporate significant bias by lack of wide verification and validation – they are verified only by their authors or description of the verification method is not provided.

Factors which are working in micro-scale differ not only from macro-scale in terms of forces but also between domains. Microfluidics is relatively new area in comparison to microelectronics or even more recent MEMS and due to this fact it is not so mature. This immaturity is visible in lack of understanding of the area and therefore possibility to model it properly. Hence, tools which aid design of microfluidic devices are still under development.

Customer and service demands are not clearly identified and discussed by researchers for microfluidics. Literature regarding design methodologies for micro-

devices is very technical and mathematically and computer application driven. There is a common focus on the development of specific techniques inside the design process in aim to automate it and speed up the tasks. Many researchers support development of library catalogues, which will allow for selection of most commonly used parts, as well as development of new software tools for modelling and simulation by presenting a view that current one although useful are not sufficient. Due to this technology driven approach other requirements then size, performance and in some cases price are not taken into consideration.

A design process for custom devices has to be elastic and allow for incorporation of different modules depending on customer demands. Therefore, interactions between sub-sections as one of complexity factors are on high importance. Increasing interest of scientists in "complexity" with the inconsistency in definitions of this word, its context dependence and subjectivity across different domains as well as inside an area of research led to a large number of its definitions. The literature regarding complexity in micro-devices domain shows that some investigation has been undertaken. However, there is no sufficient definition of complexity identified particular to this domain. Also although, issue of sub-section is considered as important for micro-scale devices, no sufficient literature has been identified in this area. Some researchers approached design of modular microfluidic devices, what can be considered as beginning of addressing this issue.

Literature also presents lack of service-orientation of microfluidic area and gaps in terms of discussing issues of services in this domain. Regarding identified benefits from customisation of these devices movement towards services, indicated as 'natural' in any domain, should be perform.

Followed this literature study an identification of the offerings presented by 38 microfluidic companies showed mismatch between literature and industrial practice. Services offered in the industry seams more broad and mature than lack of literature in this area for microfluidics would suggest. However, services were mainly scoped around design consultancy and production capabilities. Services for offered products were only mentioned, not exhaustively described with indication of adaptability to

individual needs. Services connected to product where identified were technical and cover in majority maintenance, repair and user training. However, offers of devices as services were not identified. Offering were product focused and devices even by name indicated more operating principle than usability purpose. Also classifications of products were according to areas in which they can be applied or operating purpose e.g. DNA analysis not single usage purpose itself such as cancer detection what in B2C relations is viewed profitable.

These led to selection of the industry/academic survey in microfluidic area as a method to compare literature findings with practice and to obtain a true view on the area and its maturity.

Survey was selected base on several factors:

- It will allow to capture current practice of the industry/academia without influencing their view with results obtained from literature,
- It will allow to target higher number of respondents and obtained more realistic results,
- It will be cost effective regarding selection of email as source of survey popularisation (savings in terms of transport),
- It will allow to establish initial contacts with microfluidic industry and academic institutes working in domain,
- It will allow for selection of follow-up participants for detail investigation base on gathered information.

Survey will be perform using questionnaire which evaluation was a subject of the session. The evaluation session was aiming in identification: if the questionnaire is prepared to be used in the industry and any necessary improvements to be incorporated. Based on the questionnaire developed for the industry and academic one will be build up with minimisation of changes to allow for comparison of survey outputs.

1.2 Questionnaire

Questionnaire (see Appendix 4.3) has been developed based on:

- literature investigation of included areas,
- identified gaps from microfluidic companies brochures and websites,
- a interview with an area expert - one of the people responsible for design of a microfluidic device to measure sugar level in blood,
- previous experience of the authors in development of questionnaires and interviews.

It is aim to target designers working on development of microfluidic devices in industry.

Structure

Questionnaire has been built in the following manner:

1. Short introduction of the questionnaire, its purpose, usage of gathered information, contact in case of queries, type of questions used and method of answering the.
2. Personal details of the respondents – gathered for statistical purposes and assurance that information is real and can be trusted – confidential, not for public view.
3. Questions identifying which section of the questionnaire respondent will be qualified to fill in – base on posses knowledge.
4. Three sections (for motivation for separate questions from the questionnaire see Appendix 4.1) :
    a. Design Methodology – questions regarding design methodologies for microfluidic devices, targeting people working directly in the area with experience in the field – companies designing microfluidic, who not necessarily deal with their manufacturing and/or sell.

   b. Service-orientation - questions targeting people who design microfluidic devices, commercialise them and/or offer them on the market ,
   c. Sub-sections interactions - questions regarding sub-section interactions in microfluidic devices, targeting people working directly in the area with experience in the field – companies designing microfluidic, who not necessarily deal with their manufacturing and/or sell as well as people with experience in modular products design.
5. Question regarding any missing information – incorporated in case if respondent want to elaborate on any topic which in his/her opinion is relevant for the presented questionnaire and was not included in.
6. Thank you note with request for the email in case if agreement for further participation will be given by respondent.
7. Witten by respondent date and place where questionnaire was filled – for statistical purposes, to establish rate of answers and confirm geographical impact of research.
8. Two additional pages for the notes in case if the space provided for the open questions was not sufficient.

Type of questions in the questionnaire was mixed between close Yes/No answers and open, which were follow up for the selected close option e.g. if an answer is Yes please describe methods used.

Questionnaire was estimated to take from 15 to 25 minutes based on number of questions which respondent will be qualified for e.g. in case if section A – Design Methodology will be omitted time of the questionnaire was estimated as bottom of the time frames.

1.3 Evaluation Form

To provide better view on the session evaluation form has been developed base on the form used by companies and academia to evaluate courses, workshops ad

questionnaires filling and other types of sessions. Standard set of questions was prepared and is presented in Appendix 4.4.

Questions used in this form required rating of the session and the questionnaire used from 1 till 5 where 1 mean that respondent strongly agree with given statement and 5 that he/she strongly disagree, and A-D where *A. excellent / B. good / C. fair / D. poor*.

Evaluation form also included section for additional comments and personal data of the respondent to allow for comparison with set of answers given on the questionnaire.

2. Piloting Session

Session has been established for duration of approximately 1 hour. Time was estimated to allow for realisation of the session plan. Due to restricted availability location of the session which is visible on the forms (see Attachment) was changed to cost studio. This change did not influence session as undertaken before session started. Session had been recorded taking notes by facilitator and using digital recorder for confirmation purposes.

Session details:

- **Date:** 17 February 2009
- **Scheduled time:** 11:00 - 12:00
- **Place:** Cranfield University, Building 50, Cost studio
- **Facilitator:** Katarzyna Panikowska
- **Participants:** Dr Ashutosh Tiwari,
  Dr Jeffrey R. Alcock
- **Session plan:**

1. Short introduction (5 minutes)
2. Filling questionnaire (15-25 minutes)
3. Filling evaluation form (5 minutes)
4. Discussion (25 minutes).

Plan for the session has been followed. In advance before participants arrived facilitator prepared the room by providing printed version of the questionnaire in 3 copies, printed version of the evaluation form in three copies (see Appendix 4.4), stationary (to fill in questionnaires and for taking notes), notebook and a digital recorder.

Session started on time. Participants took their seat and after short introduction about the session they start to fill-in questionnaires. Communication between them was restricted. However, they were instructed that in case of any queries facilitator will help them. No queries have been raised during filling-in part of session.

Questionnaire was filled below and in estimated time:

- First respondent accomplished questionnaire below estimated time – in 12 minutes - omitting section A – Design Methodology.
- Second respondent filled-in all the sections in the questionnaire and accomplished the task in 16.5 minutes.

After accomplishment of the questionnaire by the first person both participants were instructed to followed directly to fill-in evaluation form after the questionnaire.

After the evaluation form were filled in participants were allowed to make direct notes about suggested improvements for the questionnaire on the margins of the forms in particular places (where the improvement should be incorporated) and discuss them afterwards.

As a result of the filling the questionnaire only one question from the questionnaire required clarification in terms of the level to which answer should be detailed. All other questions were understandable and presented logical flow of thoughts and actions. Discussion and the notes lead to the list of suggested improvements presented below.

Key suggested improvements:

- Include questions regarding background of respondents – to assure proper analysis of gathered information – in respect to the expertise level of respondents,
- Rephrase some questions to make them more explicit e.g. in question A3 replace word 'common' with popular/profitable/well established in regards to offerings,
- More descriptive introduction and short information for each of the sections in the questionnaire
- Offer participants access to the analysed results of the survey in form of a copy of the conference/journal paper produce as an output.

As a follow up of the discussion on the questionnaire online method of the survey has been selected. This selection allows to target broader audience as well as to present separate short introduction for each section of the questionnaire what will increase its clarity. Online questionnaire will help to get rid of issue of note pages and allow respondent to express themselves without words limits as well as to tract their progresses and minimise time of filling by excluding text formatting, what will be required when using word document form.

Session was concluded by participants as successful. Evaluation form showed positive feedback from the questionnaire as well as from the facilitator performance. Regarding relatively small amount of changes required and their nature (questions are substantially correct and clear as well as structure of the questionnaire) follow up session for the new version of the questionnaire was considered as redundant.

3. Conclusions Remarks

Piloting session for the questionnaire was concluded as successful. Questionnaire was identified as well structured and arrange in logical order. Questions were identified as clear and explanatory. However, minimal improvements were identified to increase rate of answers and details of information capture. Next piloting session was considered and concluded as not necessary regarding small amount of changes required.

Appendix 5.3 Questionnaire Used During the Session

Questionnaire

This questionnaire aims at gathering information for PhD research 'Service-oriented Design of Microfluidic Devices' sponsored by EPSRC and IMRC at Cranfield University. By answering these questions you will be helping us to provide insight in the industrial practice in design of microfluidic devices and methods to deal with sub-section interactions in modular devices.

All answers are confidential and you will not be able to be identified from the information you provide. In case of any questions and/or queries please contact Katarzyna Panikowska on k.e.panikowska@cranfield.ac.uk.

Please mark the appropriate box with a tick or a cross. Some questions will require written answer, if your answer is longer than space provided please answer on additional pages provided.

Name:……Company:……...

Position:……

1. Have you ever taken part in designing microfluidics device?

□ No

□ Yes (please describe what was it and what was your role)

……..

2. Do your company design microfluidic devices?

□ No (go to section B)

□ Yes

A. Design Methodology

A1. Are you familiar with any particular methodology for the design of microfluidic devices?

□ No

□ Yes (describe it/them)

……
……

A2. Did you follow any particular methodology when designing microfluidic device(s)?

□ No

□ Yes (describe it/them)

……
……

A3. Do you develop more than one type of microfluidic devices?

□ No

□ Yes (please focus in this section on one particular example which represents your most common offering)

A4. What was the reason for the selection of this particular device for development?

……
……

A5. How did you obtain the specifications?

……
……

A6. Who were the target customers (B2B, B2C, particular group of people)?

……
……

A7. Were the customers involve in the design process?

□ No

□ Yes (describe on which stages, what type of involvement and input given by the customer)

……
……

A8. Did you use any methods to capture customer needs, expectations from the product?

□ No

□ Yes (describe it/them)

……
……

A9. Did you, for the development of this particular device, followed any design methodology (if A1 is answered No follow to next question)?

□ No

□ Yes (please describe it)

……
……

A10. Please describe the design process for this device step by step

……
……

A11. Did you use any design support tools?

□ No (follow to question A13)

□ Yes (please describe it/them)

……
……

A12. Did you use any components libraries during the design?

□ No

□ Yes (describe it/them)

……
……

A13. How did you evaluate the design (if it meets the specifications and/or will be economically justified)?
……
……

A14. When did you decide that the device is ready to be manufacture?
……
……

A15. How long did it take to design the device?
……

A16. How long it did it take to launch it on the market?
……

B. Service-orientation of products

B1. Does your company offer any services with microfluidic products?
□ No

□ Yes (please describe it/them)

……
……

B2. Does your company offer functionality instead of the device?
□ No

□ Yes (please elaborate)

……
……

B3. Did you consider services when designing the product?
□ No

□ Yes (what was the type of consideration)

……
……

B4. Did you incorporate service (service thinking) into design process?
□ No

□ Yes (please elaborate how)

……
……

B5. How important in your opinion services are in today's microfluidic market and how important will they be in the future?
……
……

C. Sub-sections interactions

C1. Does your company offer/design modular or monolithic microfluidic devices?
□ modular (go to question C3)

□ monolithic

C2. Have you offered/designed modular microfluidic design in the past?
□ No (please follow to the end of questionnaire)

□ Yes (describe it/them)

……
……

C3. How important in your opinion (and/or in vision of the company) are the interactions between sub-sections in the modular device (for microfluidic and for any other devices)?
……
……

C4. Did your company influence sub-section interactions in any way?
□ No

□ Yes (please describe what methods they used to deal with it)

……
……

C5. Are you familiar with any other (than mentioned in question C4) method to deal with sub-section interactions?
□ No

□ Yes (please describe it/them)

……
……

3. Please provide any additional information which your consider relevant:
……
……
……

Thank you for your participation in the research. If you consider taking part in the interview to help further in this research (if requested) please provide your email address

E-mail:……..

Date:……. Place:……

Notes:

Appendix 5.4 Questionnaire Piloting Session Evaluation

Questionnaire piloting session

Cranfield University, Building 50, Dr Ashutosh Tiwari's office, 17/02/2009

EVALUATION FORM

THEME:

Questionnaire pilloting as part of a PhD research ‚Service-oriented Design of Microfluidic Devices'

Date: Tuesday, 11:00

Rating scale: (1) - strongly agree (2) - agree (3)- nor agree neither disagree (4) - disagree (5) – strongly disagree please circle

1. The content of the *questionnaire* met my expectations / needs

   (1) (2) (3) (4) (5)

2. The questions were clearly stated

   (1) (2) (3) (4) (5)

3. The length of this *questionnaire* was appropriate

   (1) (2) (3) (4) (5)

4. Enough space for discussion and queries was provided

   (1) (2) (3) (4) (5)

5. The time frame of the *questionnaire* was kept

   (1) (2) (3) (4) (5)

6. Instructions were clear:

   (1) (2) (3) (4) (5)

7. Pilloting session instructor was:

Rating scale: A. excellent / B. good / C. fair / D. poor Please circle:

(A) (B) (C) (D)

Comments:

.....

.....

.....

.....

.....

Name, Address (optional):

.....

.....

.....

Professional activity:

☐ Clinical Practice ☐ Academic Practice & Research ☐ Other _____

We thank you for filling in the evaluation sheet and returning it after the session. If you do not return this form immediately after the questionnaire *pilotting session*, please deposit your completed form at the meeting secretariat by *Wednesday, 18/02/2009, 17:30.*

Appendix 5.5 Survey Questionnaire

Questionnaire

Microfluidics – design, services and modularity

This questionnaire aims at gathering information for PhD research 'Service-oriented Design of Microfluidic Devices' sponsored by EPSRC and IMRC at Cranfield University. The research aims to develop a service-oriented methodology for design of microfluidic devices that can deal with sub-section interactions. On the current stage it is focus around comparison between literature findings and industrial practice regarding related areas. By answering these questions you will be helping us to provide insight in the industrial practice in design of microfluidic devices and methods to deal with sub-section interactions in modular devices.

To thank you for the contribution in our research we will provide you with a copy of the report from the survey findings in form of a journal/conference paper. Please mark the appropriate box with a tick or a cross. Notice that some questions will require written answer. Please answer all the questions to your best knowledge. In case of any questions and/or queries please contact Katarzyna Panikowska on k.e.panikowska@cranfield.ac.uk.

A. Background

In this section you will be asked to answer some questions regarding your background and current position as well as to provide personal details. All the information provided in this section is confidential and gathered for statistical purposes and to guarantee correctness and quality of gathered information. You will not be able to be identified from the information you provide in the analysed version which will be accessible by other parties.

A1. What is your name?

A2. What is your age?

A3. What is highest education degree you obtained and what is your specialisation if obtained?

A4. What is the name of the organisation you are working for?

A5. In which country your organisation is placed?

A6. How this organisation is connected to microfluidic domain?

A7. What is the position you currently held in the organisation? Please describe your responsibilities.

A8. How long you are working on this position?

A9. Please describe your previous work positions

Now you will be asked to answer couple general questions which will indicate which section of the questionnaire is most appropriate for you.

A10. Have you ever taken part in designing microfluidics device?

□ No

□ Yes (please describe what was it and what was your role)

A11. Does your organisation design microfluidic devices?

□ No (go to section B)

□ Yes

B. Design Methodology

In this section you will be asked to provide information regarding methods used by you and/or your organisation in design of the microfluidic devices. If currently you are not working on design of microfluidic devices but you were working on them in the past please answer questions based on one of your past projects.

B1. Are you familiar with any particular methodology for the design of microfluidic devices?

□ No

□ Yes (please if standardised – name it/them, if modified or in house methods - describe it/them)

B2. Do you follow any particular methodology when designing microfluidic device(s)?

□ No

□ Yes (describe it/them)

B3. Do you develop more than one type of microfluidic devices?

□ No

□ Yes (please focus in this section on one particular example, which represents your most established microfluidic offering)

B4. What were the reasons for the selection of this particular device for development?

B5. How did you obtain the specifications?

B6. Who were the target customers (B2B, B2C, particular group of people)?

B7. Were the customers involved in the design process?

□ No

□ Yes (describe in which stages, what type of involvement and input given by the customer)

B8. Did you use any methods to capture customer needs, expectations from the product?

□ No

□ Yes (describe it/them)

B9. Did you, for the development of this particular device, followed any design methodology?

□ No

□ Yes (please describe it)

B10. Please describe the design process for this device step by step

B11. Did you use any design support tools?

□ No (follow to question B13)

□ Yes (please describe it/them)

B12. Did you use any components library during the design?

□ No

□ Yes (describe it/them)

B13. How did you evaluate the design (if it meets the specifications and/or will it be economically justified)?

B14. When did you decide that the device is ready to be manufactured?

B15. How many people were involved in development of this device (please indicate their job titles and roles)?

B16. How long did it take to design the device (please indicate weeks/months/years)?

B17. How long did it take to launch it onto the market?

B18. Have this device been successful on the market?

□ No (please follow to question B20)

□ Yes (please describe in what term)

B19. Did you evaluate success of the device?

□ No

□ Yes (please describe how)

B20. What did you do with it, did you change it to make successful or take it off from the market?

B21. What would you change to make it successful?

□ No

□ Yes (please describe how)

C. Service-orientation of products

In this section of the questionnaire you are asked to answer question regarding service-orientation of the design processes for microfluidic devices and utilities provided for your offerings. Answers will help to asses maturity of service thinking in the area.

C1. Does your organisation offer any services with microfluidic products?

□ No

□ Yes (please describe it/them)

C2. Does your organisation offer functionality instead of the device?

□ No

□ Yes (please elaborate)

C3. Do you consider services when designing the product?

□ No

□ Yes (what was the type of consideration)

C4. Do you incorporate service (service thinking) into design process?

□ No

□ Yes (please elaborate how)

C5. How important in your opinion are services in today's microfluidic market and how important will they be in the future?

D. Sub-sections interactions

In this part of the questionnaire you will be asked to discuss issues connected to interactions between sub-sections in modular products and microfluidics in particular. By term sub-section interactions is understood relation between modules of the device and their interoperability.

D1. Does your organisation offer/design modular or monolithic microfluidic devices?

□ modular (go to question C3)

□ monolithic

D2. Have you offered/designed modular microfluidic design in the past?

□ No (please follow to the end of questionnaire)

□ Yes (describe it/them)

D3. How important in your opinion (and/or in vision of the organisation) are the interactions between sub-sections in the modular device (for microfluidic and for any other devices)?

D4. Did your organisation influence sub-section interactions in any way?

□ No

□ Yes (please describe what methods they used to deal with it)

D5. Are you familiar with any other (than mentioned in question D4) method to deal with sub-section interactions?

□ No

□ Yes (please describe it/them)

Please provide any additional information which your consider relevant and which was not incorporated in any part of the questionnaire:

E. Questionnaire evaluation

Thank you for filling in previous sections of the questionnaire. If you consider taking part in the interview to help further in this research (if requested) please provide your email address

E-mail:…….

Could you please now spend couple minutes to evaluate this questionnaire. This will help us to improve our survey. Please circle appropriate rate.

Rating scale:

- *(1) - strongly agree*
- *(2) - agree*
- *(3) - nor agree neither disagree*
- *(4) - disagree*
- *(5) - strongly disagree*

E1. Instructions were clear

(1) (2) (3) (4) (5)

E2. The questions were clearly stated

(1) (2) (3) (4) (5)

E3. The length of this questionnaire was appropriate

(1) (2) (3) (4) (5)

E4. Enough space for discussion and queries was provided

(1) (2) (3) (4) (5)

E5. The time frame of the questionnaire was sufficient

(1) (2) (3) (4) (5)

E6. I enjoyed filling in the questionnaire

(1) (2) (3) (4) (5)

E7. I would recommend filling in this questionnaire to my colleagues

(1) (2) (3) (4) (5)

E8. If any of the questions make was not clear for you or in your opinion require changes please put its number in the box below and sugest improvements or indicate the issue

Thank you

Thank you for your help in our research. We very much appreciate your cooperation and hope that you enjoyed participating in this survey. We also hope for your future collaboration.

MSc Eng. Katarzyna Panikowska,

PhD Student at Cranfield University

Appendix 6 Classification of Microfluidics According to Functionality

This appendix presents a classification of microfluidic devices. This investigation of classification attempts has been undertaken to identify if service-thinking is incorporated in this scheme.

1. Classification of Microfluidics According to Functionality

Microfluidics is a relatively new area. Although, its beginnings are stated for 1980's when a micro gas chromatographic air analyser was made in Stanford and an ink jet printing nozzle array was made in IBM (Tay, 2003), mature knowledge about this domain is still not obtained.

"Microfluidics covers the science of fluid behaviours on the micro-/nano-scales and the design engineering, simulation, and fabrication of fluidic devices for the transport, delivery, and handling of fluids on the order of microliters or smaller volumes" (Bhushan, 2007:523). Although, manipulation of the fluid in microfluidic devices takes place in micro-scale their dimensions and volume scale differ in broad range what is presented on Figure 1.

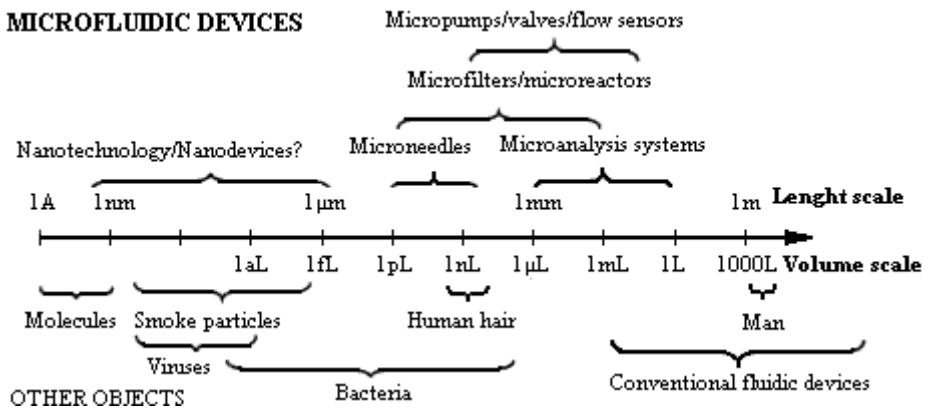

Figure 1 Size characteristics of microfluidic devices (Nguyen & Wereley, 2006)

There is no 'one' method to categorise microfluidic devices. From the service point of view most desirable would be classification base on function performed by the product in term of its utilisation. However, in majority researchers pointing out

most popular types of microfluidic devices, such as micropump, micro-valve etc., to indicate variety of products possible to manufacture in these area, and rarely structured categorisation of products in this domain is provided.

Majority of splits among identified is based on forces used to operate the device. Jackson (2007) stated that there are two basic types of microfluidics: active and passive. Passive microfluidics is "a control topology in which the physical configuration of microfabricated system determines the functional characteristics of the system with and without an external power source" (Jackson, 2007). These types of devices use physical properties such as shape to perform particular functions. Passive devices are considered as easy to fabricate, but offering lower degree of diversity in terms of application in comparison to active microfluidics. Also, active microfluidics are usually more expensive due to their desired functional and fabrication 'complexity' (Bhushan, 2007). Passive devices are further categorised according to: fluid medium (gas or liquid), application (biological, chemical and other), substrate material (silicon, glass, polysilicon, polymer, others) and function (microvalves, micromixers, filters, reactors, etc.).

Microfluidic devices can be also categorized according to the materials from which they are manufactured (silicon, glass, polymer) as well as main force used by the device as base of work. Figure 2 presents this classification with indication of companies which offer products in particular area. Usage of main force operating in the device was used also by Kulrattanarak et al. (2008) as point of segregation (see Figure 3). They pointed out four types of forces operating in microfluidics: Brownian Ratches – periodic arrays of asymmetric obstacles placed in micro-channels, imposing collide of moving particles with asymmetric obstacles; flow line sieving devices – based on interactions between the driving flow field and the steric interactions of particles, with confining walls or solid objects placed in the flow field, to fractionate particles; external force field for lateral displacement – based on the physical properties of the particles e.g. gravity, centrifugal, electric force; and trapping force field – where using externally applied inhomogeneous force field particles can be trapped or deflected.

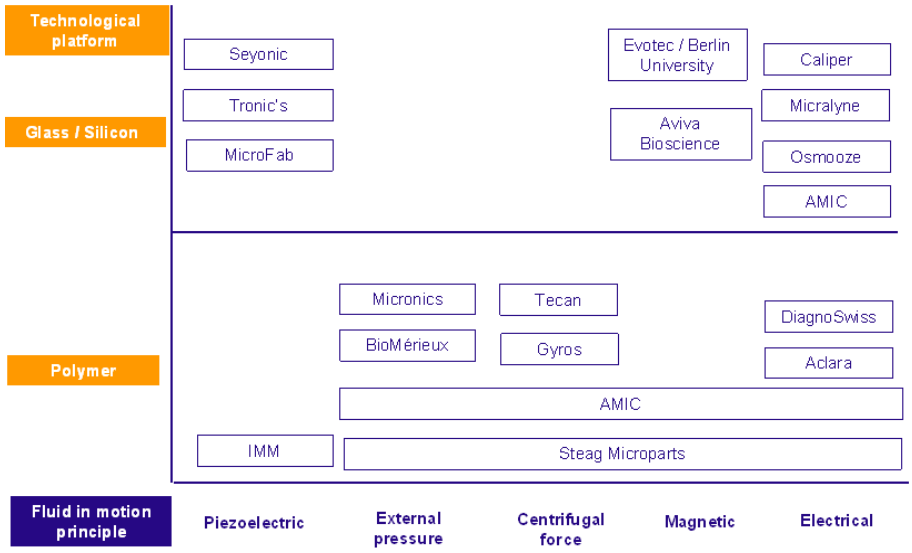

Figure 2 Microfluidic manufacturing technologies (Mounier & Provence, 2003)

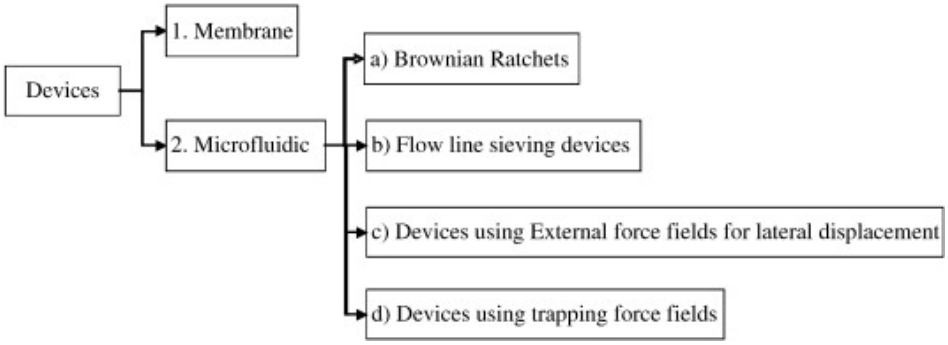

Figure 3 Classification tree of devices (Kulrattanarak et al., 2008)

Other classification is based on the fluids used in devices (Liu & Grodzinski, 2002). It distinguishes between: Newtonian (e.g. air, most aqueous solutions) and non-Newtonian (e.g. blood, liquid metals), where in microfluidic for approximation purposes most of applications are treated as Newtonian.

Another split is presented by Berthier (2008) who have distinguished these devices according to the liquid flow incorporated in the structure. This split can be seen as presented on Figure 4. It is more suitable for considered, service-driven approach, then forces base categorisations. It incorporates also volume of fluid which is viewed as suitable per particular category of devices. Extracted most common classification of the devices according to the flow type is presented on Figure 5. However, this

categorisation presents step closer to the services it still do not incorporates functionality of the devices and by it their applications.

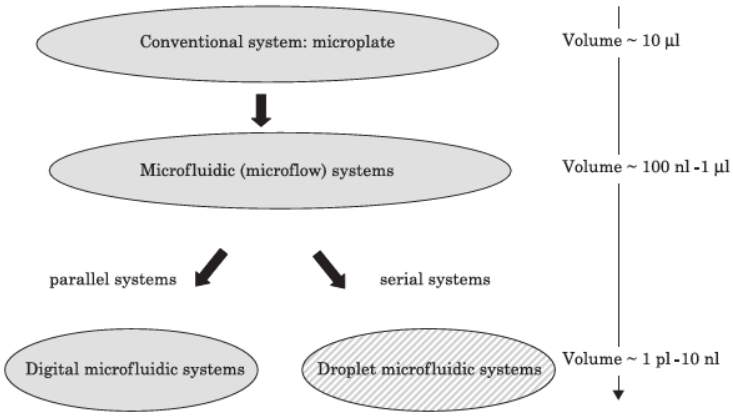

Figure 4 Scheme of the different scales of fluidic systems (Berthier , 2008)

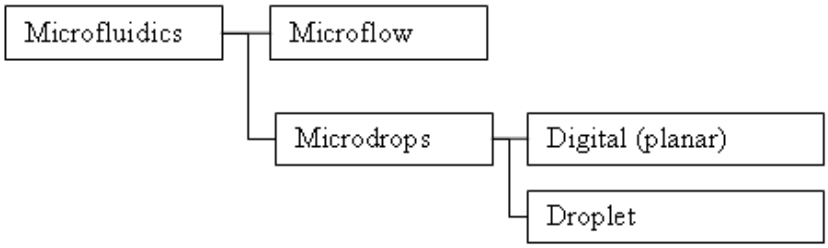

Figure 5 Classification of microfluidics based on fluid channelled

Mounier & Provence (2003) in report for Yole Dévelopment classified microfluidic components of the devices according to their applications (see Figure 6). Although, this categorisation is suitable for service-oriented introduced by them approach need to be completed. Categorisation presented by them is restricted to the medical application area disobeying other fields such as fuel cells.

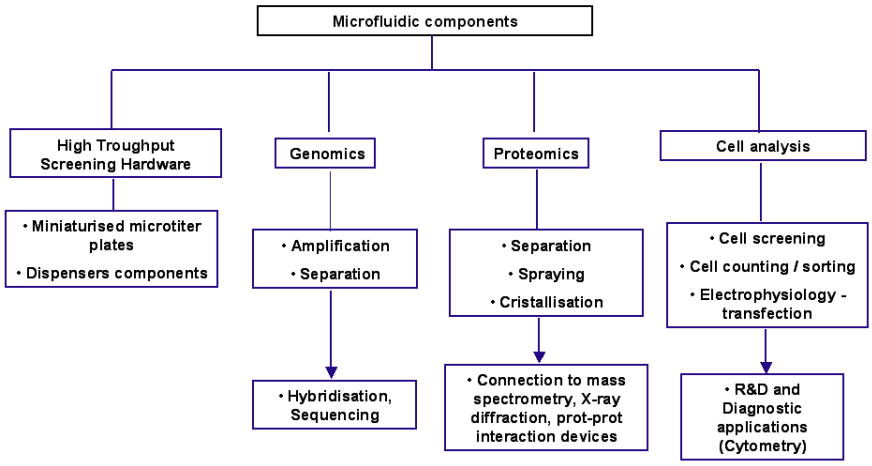

Figure 6 Microfluidics applications (Mounier & Provence, 2003)

Erickson & Li (2004) presented 'integrated microfluidic devices' developed after year 2000. They classified these devices into following manner:

- For DNA analysis:
  - Polymerase chain reaction (PCR).
  - Integrated PCR and separation based detection.
  - Integrated DNA hybridization.
  - Other devices of interest.
- Devices for separation based detection:
  - General capillary electrophoresis.
  - Integrated detectors for laser induced fluorescence.
  - Other detection or separation mechanisms.
- Devices for cell handling, sorting and general analysis:
  - Cell handling and cytometry.
  - Dielectrophoretic cellular manipulation and sorting.
  - General cellular analysis.
- Devices for protein based applications:
  - Protein digestion, identification and synthesis.
  - Coupling of microfluidic devices with protein arrays and mass spectrometry.
  - Other devices of interest.

- Integrated microfluidic devices for immunoassay.
- Integrated devices for chemical analysis, detection and processing:
    - Integrated microreactors.
    - Chemical detection and monitoring devices.
    - Fuel processing devices and microfuel-cells.
- Other devices of interest:
    - Integrated optical sensing elements.
    - Electronics cooling.
    - Integrated devices for fundamental analysis.

As can be observe in this categorisation it presents only devices developed in years 2000 – 2003 so it is restricted in terms of time frames as well as categories of microfluidics known as lab-on-a-chip (LOC). This classification also is partially based on the operation principles instead of functionality and application itself, although in some cases basic operation principle is equal to the utilisation purpose. Erickson & Li presented by listing these devices showed broad application field which microfluidics gain in last decade. By creation of this list they make clearer that each user will exploit microfluidic device in specific way – one area of application can mean variety of utilisation methods e.g. devices for DNA analysis can be used for identification purposes as well as to detect presence of genes claimed to be responsible for particular behaviour and/or genetic diseases. This broad utilisation of one type of device show that regarding number of microfluidic devices and their wide area of application, especially in medical analysis and diagnostic, should be investigated from industry offerings point of view, and how companies are selling their products currently to narrow the research scope.

References:

Berthier, J. (2008), "Microdrops and Digital Microfluidics", William Andrew, Inc., available at: http://www.knovel.com/web/portal/browse/display?_EXT_KNOVEL_DISPLAY_bookid=2076 (accessed 26th September 2008).

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Appendix 7 Validation Documents

This Appendix is a supplement to Chapter 6 Validation as it provides documents used during the validation and rationale behind their development (for questionnaires). It presents original documents used in the validation before experts feedback has been incorporated (Appendix 7.1). Moreover it includes forms used for its evaluation by microfluidic experts (Appendix 7.2) with rationale behind questions used (Appendix 7.3), list of additional questions used during evaluation via interviews with motivation for each questions (Appendix 7.4) and feedback form used during validation by service experts (Appendix 7.5).

Appendix 7.1 The Solution as Used for Validation

Service-oriented design of microfluidic devices

The Guideline

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Date: 11/08/2010

Summary

The main contribution of the research "Service-oriented Design of Microfluidic Devices" is the guideline addressed to microfluidic designers and organisations developing this type of devices. The guideline aims to enhance current state of design practice in microfluidic domain. It is trying to introduce service-orientation devices and simultaneously to deal with sub-section interactions. It intends to provide what is currently lacking in the domain - a general design methodology- and to automate and simplify microfluidic design by presentation of considerations which have to be undertaken during the design and by providing an indication of the steps to be followed by designers within this process.

The guideline for service-oriented design of microfluidic devices consists of general design methodology – the guideline itself – and a list of recommendations for microfluidic organisations and designers to follow when designing and undertaking microfluidic projects. The guideline consist of two levels – Level 0 – the high level model of how design should be undertaken – and Level 1 – the detail stages from the Level 0 when step by step instruction of actions to be undertaken and issues to be consider is given.

This document presents an overview on the guideline, a list of recommendations extending it and also how to follow the guideline. The overview provides an explanation of the guideline regarding its functions and the meaning of its graphical representation. It is followed by a list of recommendations to be applied when using the guideline and undertaking microfluidic projects. The list of recommendations has been given as bullet point actions to be followed. Finally, step by step instructions for the guideline usage is given.

1.1. Overview

The developed guideline, on the high level – Level 0 – consists of ten fundamental steps and one additional one, depending on how well understood is the functionality required from the device to be designed and the complexity of the project. On the high level the guideline looks as presented in Fig. 1.

The guideline starts with the theme which summarises its purpose and restrictions. The theme *'DO NOT design solutions for NON EXISTENT problems. There are already too many of them'* presents how the projects should be approached and provides the rationale for the work to be undertaken.

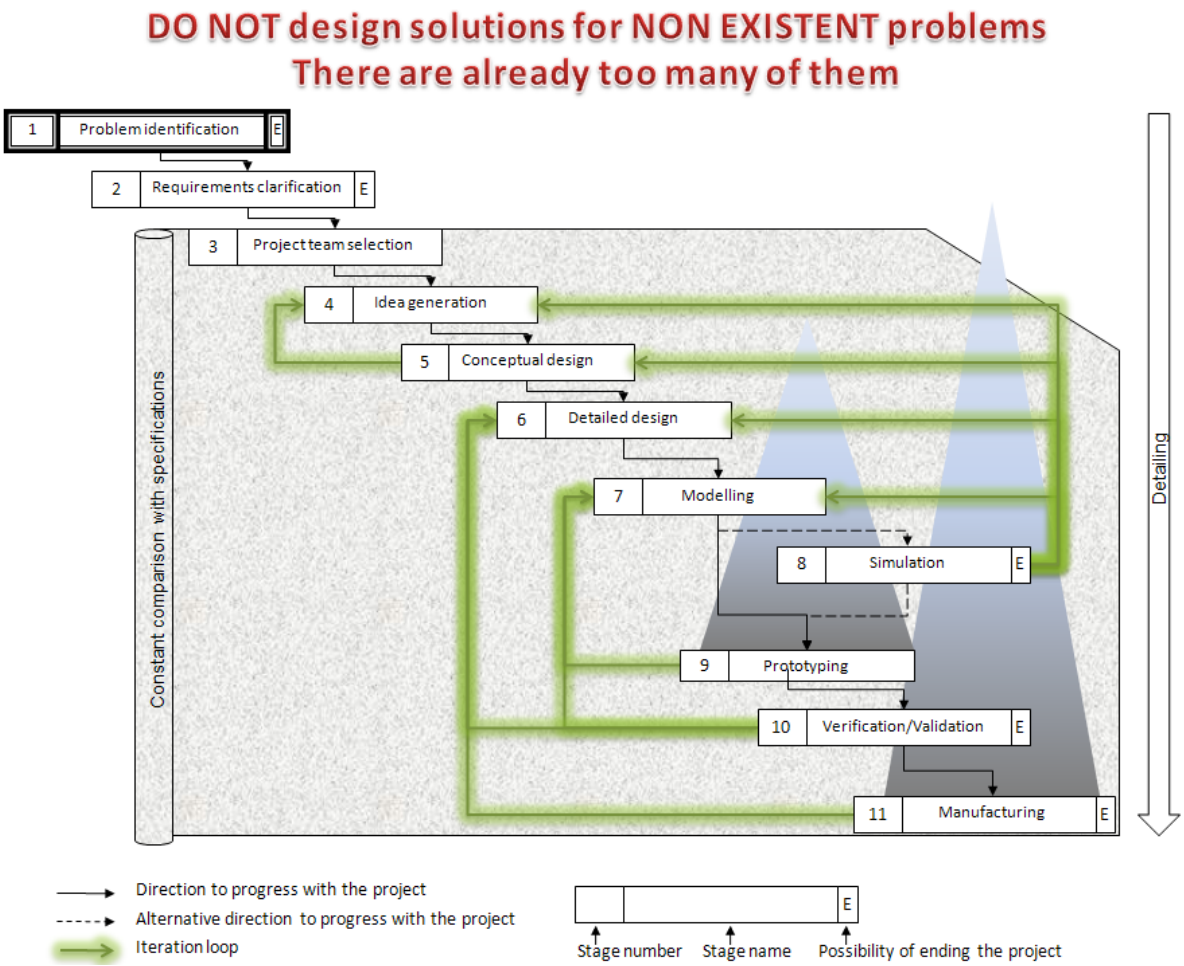

Figure 1 Guideline for service-oriented design of microfluidic devices which can deal with sub-section interactions

Stages 1-7 and 9-11 are required when stage 8 requires justification to be incorporated into the design process. Black solid line arrows between the guideline's stages show the path for the designers to follow. The dash style arrows show alternative routes when an additional step is required. The double line round the frame of stage 1 of the guideline – Problem identification – is used to emphasise the importance of this step. Details regarding particular stages will be presented in section 3.1 and discussed in section 3.2 (discussion provided on request).

Iteration loops which can occur during the guideline implementation between stages are visualised using green arrows (see Fig.1). As can be observed, they are not present between all steps of the model in any correctly performed design. Designed devices can require changes independent of the project team performance which are originated or identified in one of five steps: in conceptual design (stage 5), simulation (stage 8), prototyping (stage 9), validation/verification (stage 10) and manufacturing (stage 11). In the conceptual design, when the application of detailed requirements in ideas from the idea generation stage shows any problems (i.e. do not address all of the issues) then additional concepts are required. At the simulation stage a number of problems can occur:

- Simulation results showed adjustments required in the models regarding shape, fluid behaviour models etc. – loop to the modelling stage (stage 7)
- Simulation results showed changes required on the detailed design stage (stage 6): change of material (i.e. same class but different type for other properties), increase or minimise thickness of elements, minimise roughness of surfaces etc.
- Simulation results showed major changes required in the conceptual model
- Simulation results showed requirement for major changes where developed concept is not able to address the issue – loop to idea generation stage (stage 4).

The first two mentioned loops from the simulation occur often as a result of incremental improvement in the design, when the first obtained results are usually not perfect regarding novelty of domain. The other two loops are aimed to be eliminated in view of their high cost and time-consuming changes required.

At the prototyping stage, loops can occur during proving the principle work or when the fluid behaviour is not fully understood. These loops are due to the novelty of the area, and the trial and error approach of the applied investigation. As a result, changes in models are required to achieve the necessary performance. As the domain matures, these loops should be eliminated.

Similarly the validation/verification stage provides feedback into the modelling. This loop can occur due to the test results from the prototyping and/or change of the market/client demand in long-term projects. Loops from the verification stage to the modelling and detailed design stages can occur for these same reasons as loops (to these stages) from the simulation stage. This is a natural way to make improvements; however, it should be minimised at this point. The later in the process changes are incorporated the more expensive they are in terms of money and time. In manufacturing, the loop to the detailed design stage is caused by the need to adjust fabrication equipment and the additional calculations then required.

The arrow on the right hand side of the guideline (see Fig.2) represents the increasing amount of detail in the design. It also shows a top-down approach to design implemented in the guideline. It represents the transition from architectural structure to detailed design.

Possible outputs from the project realised using the guideline are indicated in Figure 1 by the letter E – ‘end of design’. In the first two stages this end is due to the project dropout. Project dropouts are not equal to failure, they are a conscious decision that the project is not beneficial to be continued inside the organisation. The end of the project at the stage of simulation, verification/validation or manufacturing is equal to

delivering a client requested form of the output: a simulation verified design, verified and working prototype, or a verified and working device.

The guideline requires comparison of the outcome at every stage with the specifications. Comparison should start at stage 2 when the project team is selected and continue throughout the project until delivery of the output to the client. This comparison should be done on a daily basis by keeping track of changes and requirements in mind.

The funnels leading to the prototyping (stage 9) and manufacturing (stage 11) represent data fed into these stages. As can be observed, the amount of data increases as the process progresses. For prototyping, information starts to be collected at the idea generation stage when development of an idea is decided. Similarly, in a systematic manner, information regarding manufacturing is collected. The difference is in the starting point of the collection. Although, in the problem identification stage, some knowledge about manufacturing methods for microfluidics is required to be fed into the final manufacturing stage, this actually starts during the requirements clarification. During this stage, the manufacturing process can even be agreed on; however, it is built up in terms of details throughout the process by product development.

1.2. General recommendations for the project and design

During identification of the method to address the specifics of microfluidic design, a number of issues have also been identified. Development of the guideline has addressed the majority of them. A significant amount of work, which could not be included in any particular stage of the guideline or that required different levels of details to those presented (in Level 0 or Level 1), needed to be incorporated in a different manner regarding the project's realisation. Some of the issues raised could not be assigned to one project but required repetitive work with multiple types of devices. These issues have been addressed in the form of a recommendations list which is presented below.

A prepared guideline for the service-oriented design of microfluidic devices that can deal with sub-section interactions, consists not only of the presented process and steps incorporated within it but also a short list of recommendations regarding the process. The list comprises:

- Involve the client in the milestones (and critical decision points), i.e. do not involve him/her at all the steps inside the milestones,
- Establish core elements in the set of microfluidic devices (standard element or elements of design),
- Develop models of already validated and produced products,
- Slowly develop an in-house database of modules/components (component library),
- Establish a group of general modules providing basic functions (e.g. mixing, channelling etc.),
- Validate created models for a variety of fluids,
- Encourage informal communication inside the project team but do not eliminate a formal one.

1.3. Stages

The differences between conventional design models, existing models and the guideline developed are more visible inside the stages. A description of the steps required and recommended in these stages is provided below.

Presentation of the stages has been approached using decision making processes diagrams and graphical visualisation. A decision making processes diagram incorporate two types of blocks: actions – represented by rounded rectangles text boxes, and decisions – represented by diamond text boxes. A double line frame around a box representing action indicates further decomposition of this process step is required. Usage of the parallelogram shape indicates data split inside the issue considered – viewing it from different aspects which are indicated textually. Rectangular boxes (sharp corners) have been used for considerations and suggestions for the guideline

user inside the process which can be implemented during the action. For a summary of the decision making processes diagrams' representations, see Fig. 2.

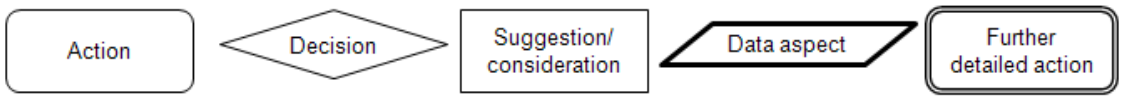

Figure 2 Legend for the decision making processes diagrams

These diagrams usually start by identification of the preceding stage in a grey font separated by a dash and finish by identifying in this same manner successive stage(s) – exceptions obviously being the first and last stages.

The graphical visualisation of considerations has been approached using rectangular text boxes. The majority of the considerations were interconnected in a multiple manner (represented by arrows in Figure 6). This high interdependence of issues with the cooperation of their dependence on the project (not all issues are applicable for every type of microfluidic device) did not allow them to be put in time order. Possible connections were presented only on the first consideration's visualisation and omitted in the following for clarification purposes.

A number of considerations, as well as steps in the decision making processes, have been elaborated on in the discussion section. To allow the reader to make a quick association of the issues, they have been marked on the pictures according to their appearance in the particular stage and then referenced in brackets when discussed. Marking uses the first letters of the stage name, e.g. PI1 – Problem Identification stage first issue to be discussed, and where necessary one of the letters from the word for distinction has been incorporated (e.g. modelling = MD and manufacturing = MF).

1.3.1. Problem identification

The stage discussed is presented in graphic form in Figure 3. This figure presents the second level of the model decomposition and provides a deeper understanding of

what is required. The basic rule to follow in project identification is – "Do not design solutions for non existent problems. There are already too many of them".

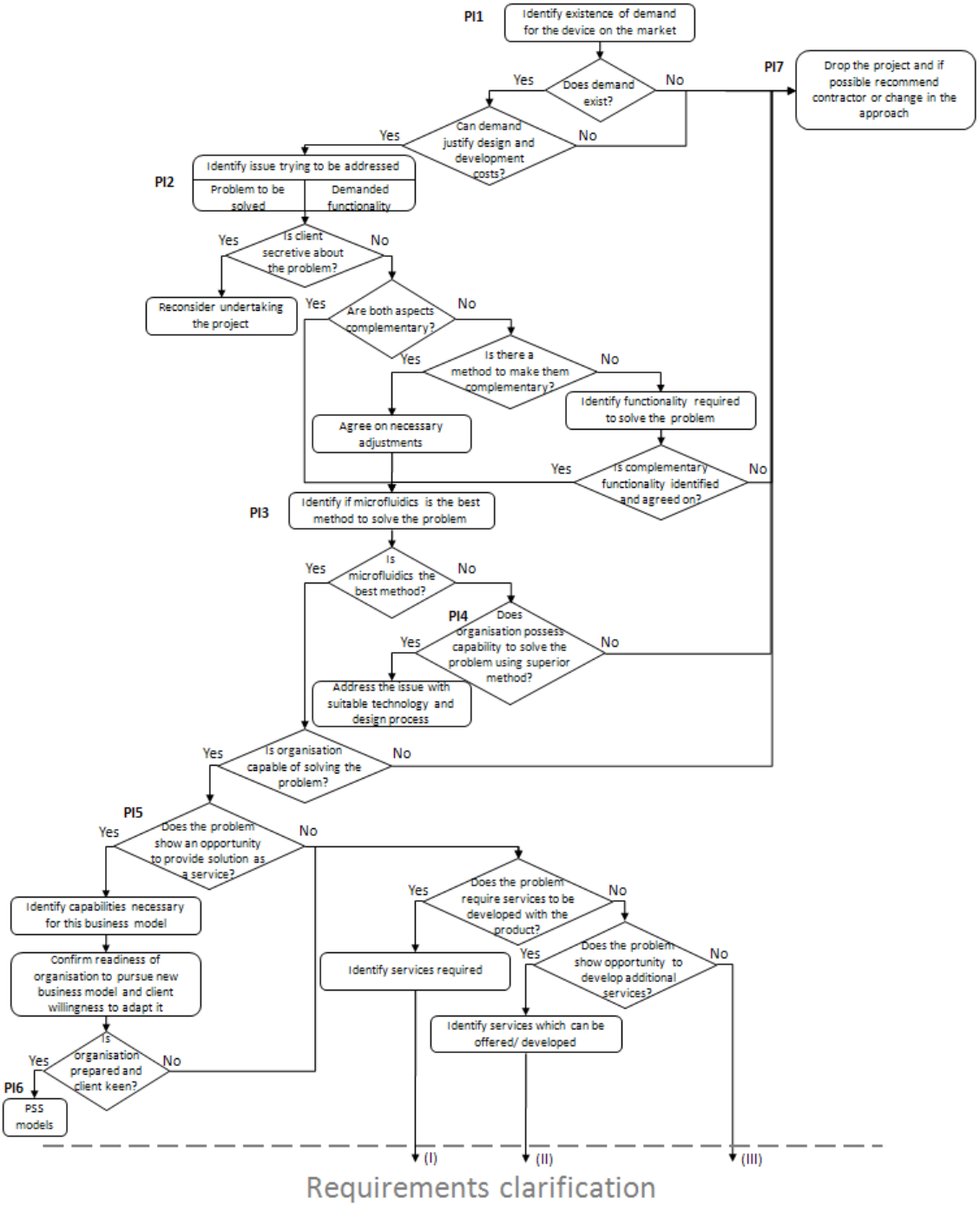

Figure 3Problem identification stage (PI1-7 are discussed in section 4.3.1)

The origination of a project can be internal or external (client demand). The majority of projects originate from customer demand and this process incorporates more issues to

be considered. Presentation of the problem identification stage is undertaken as project realisation as a result of client demand. The process presented is aimed to be followed during decisions made on project realisation but within a broad scope. Additional considerations inside these steps are left for the organisation, i.e. the person undertaking the project, to decide upon. Factors such as the cost/profit equation are left for the later stages. However, if according to the broad identification of the problem, the organisation is not able to deliver on time and within cost, then the project should not be undertaken.

This stage results in five points for dropping realisation of the project: one is recommendation of the project reconsideration, two are recommendations for usage of another design approach and the remaining three outputs lead to the next stage of the guideline requirements clarification. An identification of the market demand is still a necessity for projects originated internally and the lack of market demand eliminates the project from realisation.

1.3.2. Requirements clarification

When demand for the device on the market is identified, steps to proceed depend on how the project was originated. Figure 4 presents clarification of requirements in a project originating from a client order, where the Figure 5 presents project which was originated by the organisation for various reasons, e.g. recognising a new opportunity on the market, the new technology. Both demands have to find confirmation within the market before they will be undertaken.

As mentioned in Figures 4 and 5, a project brief is recommended to be developed as a standard document in the organisation which will allow clients to specify their needs more clearly. Some of the organisations already possess this type of document (naming can vary) also several customers possess a project brief and provide it when starting the project. Even when project has not originated from client demand completion of a project brief is advised.

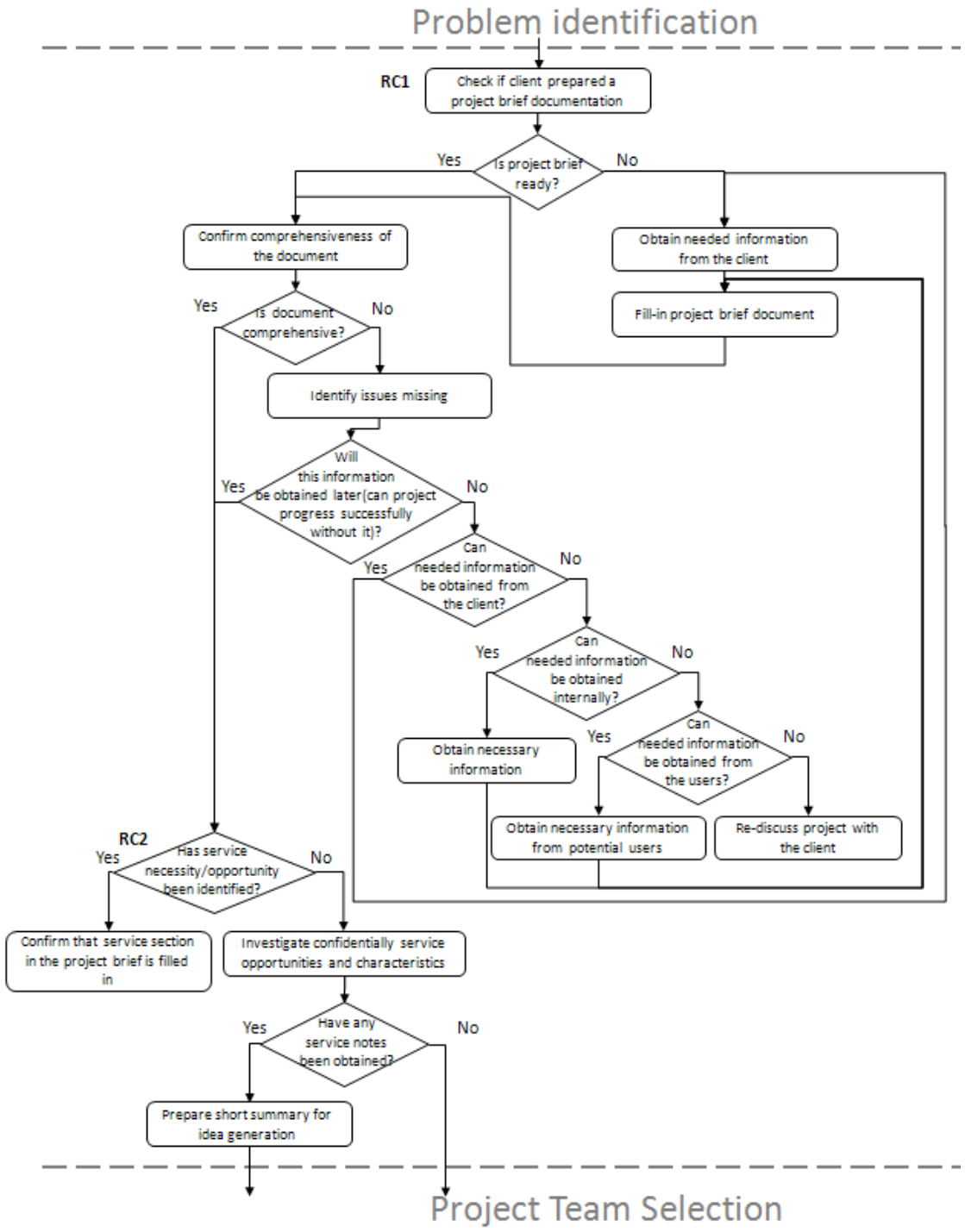

Figure 4 Requirements clarification stage – project originated by the customer (RC1-2 are discussed in section 4.3.2)

Recommendations for the project brief are as follows:

- flexible structure document – identifying crucial characteristics for a variety of devices;

- be restricted to the capabilities possessed by the organisation – what can be offered, e.g. if the organisation can manufacture only in one type of material, if dimensions to be offered are restricted, or if the organisation can outsource part of the development work due to a lack of in-house equipment then it should be explicitly stated,
- functionality of the device should be explicitly described,
- identify restriction from the client side i.e. materials, manufacturing methods to be applied etc.,
- problem to be solved should be expressed,
- brief to be kept confidential to assure client's truthfulness,
- identify the IP rights to the device under development and if possible components/modules of it,
- prepare service section,
- identify conditions of use,
- identify implementation method and conditions.

The service section should allow for addressing issues raised by the problem identification. In the case of outputs I and II (see Fig.3) it needs to allow for identification of demanded services and provide characteristics to allow for scoping them. This section must be structured in a manner which will allow it to be omitted when an opportunity for service type offerings is not identified and/or when the client is not interested in them. However, the project leader is requested to note identification of the service opportunities coming up, to allow their development in the organisation and to have a better identification of clients' demands. This identification is advised to be undertaken in a subtle manner, preferably without client awareness.

Capturing characteristics can be done from various aspects of requirements clarification. Identification of conditions of use, implementation methods and conditions provide the highest opportunity to extract service features. Captured characteristics and prepared notes should be transferred into a short summary and used as an input into the ideas generation session.

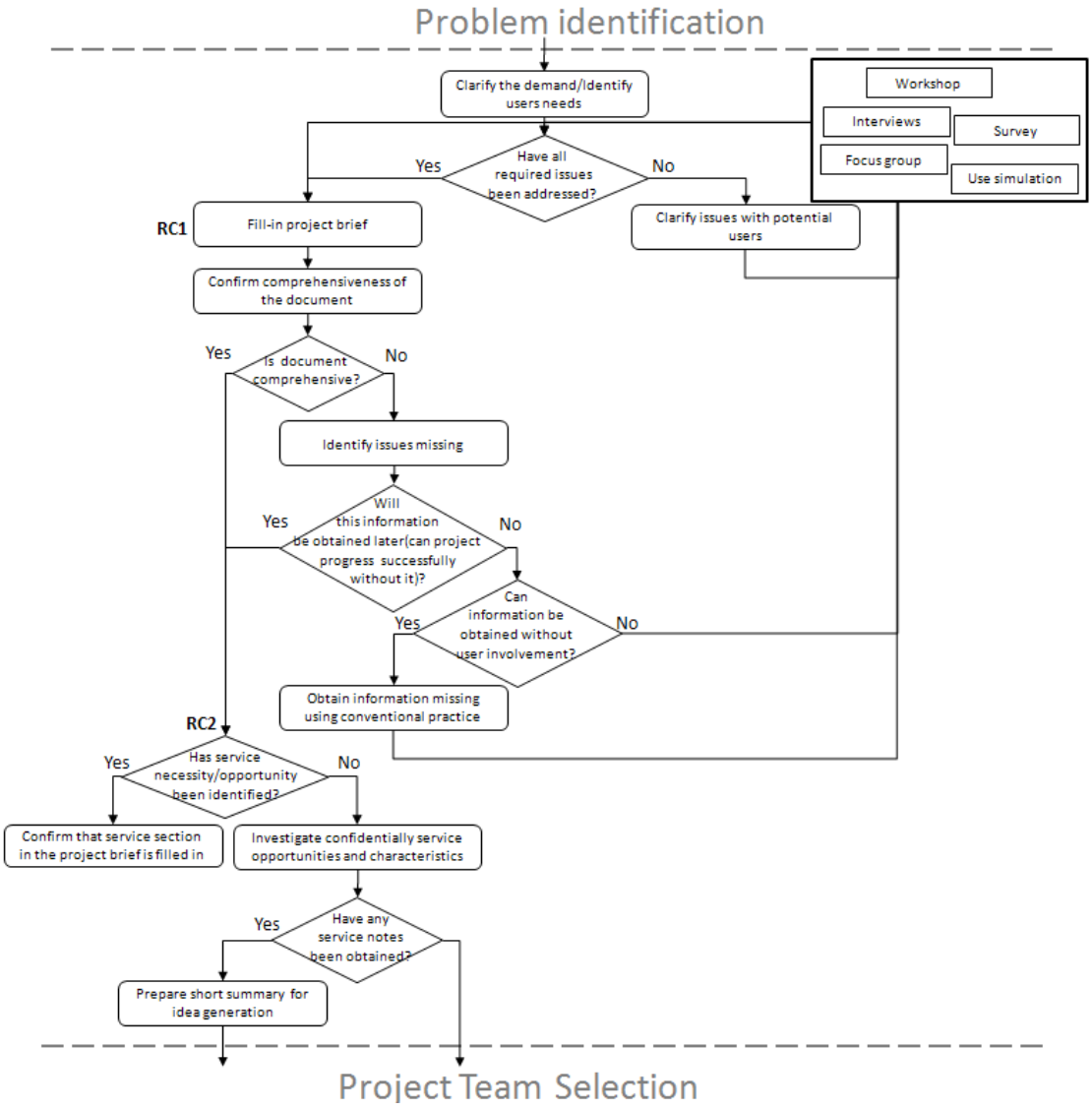

Figure 5 Requirements clarification stage – project originated by organisation (RC1-2 are discussed in section 4.3.2)

Information on this stage will not be collected in a sequential manner. Figure 6 presents issues which are necessary to be considered during requirements clarification. These issues are interdependent (illustrated using arrows) which does not permit them to be put in time order.

Each decision implies additional constraints and has to possess the proper rationale e.g. selection between a modular and monolithic approach should be based on several rules such as: do not select the monolithic approach if the device does not have 'killer application' – mass production without any variety between devices. The selection of a

modular or monolithic approach to design, a type of fluid flow in the device or establishment, if this device is a stand alone or part of a bigger system, are fundamental to ensure the generation of suitable ideas and are recommended to be specified upfront.

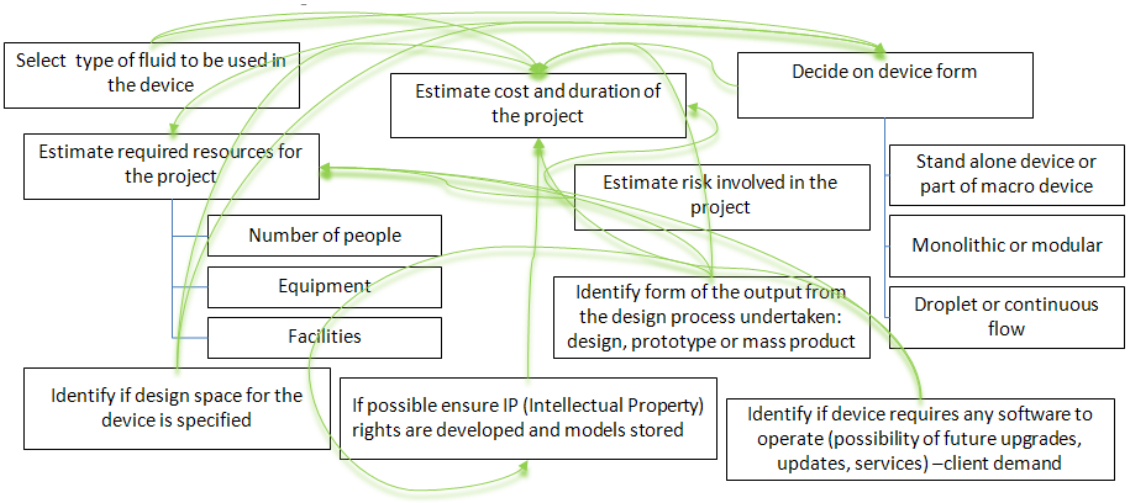

Figure 6 Issues which need to be considered at Requirements Clarification stage

1.3.3. Project Team Selection

After all requirements have been clarified, team members for the project need to be selected. It is essential to be done by a person or people with knowledge of the field and experience in microfluidic design. The team has to be multidisciplinary and involve at least 1 person with experience (i.e. more than 6 months hands on practice) in product breakdown and project realisation for microfluidics. At this stage decisions about how many, and from which areas, people need to be involved has to be made. This number should represent the size of the project, its interdisciplinarity and will be dependent on the allocated and available resources. An organisation cannot allow for 'double booking' of resources. Ensuring that incorporation of the resource management system within the organisation has been accomplished, is advisable.

The inclusion of people previously responsible for gathering information from the client (client demand project)/originating the idea (internal project) in the team should be encouraged. If these people's knowledge is considered to be insufficient for the

whole process their involvement at the ideas generation stage and, if specifications will not evolve through the process, a comparison with specification steps is recommended.

1.3.4. Idea generation

This stage can be approached as in a conventional design, but with the incorporation of creative design methods. A recommended set of idea generation methods include variations of: brainstorming, six thinking hats, lateral thinking, delphi etc. The organisation is advised to select a method with which it is familiar.

The main issues to be discussed in the session (applying the creative design method) are presented in Figure 7. The issues mentioned are general ones for every microfluidic device. Additional issues are expected to be incorporated with regard to specific projects.

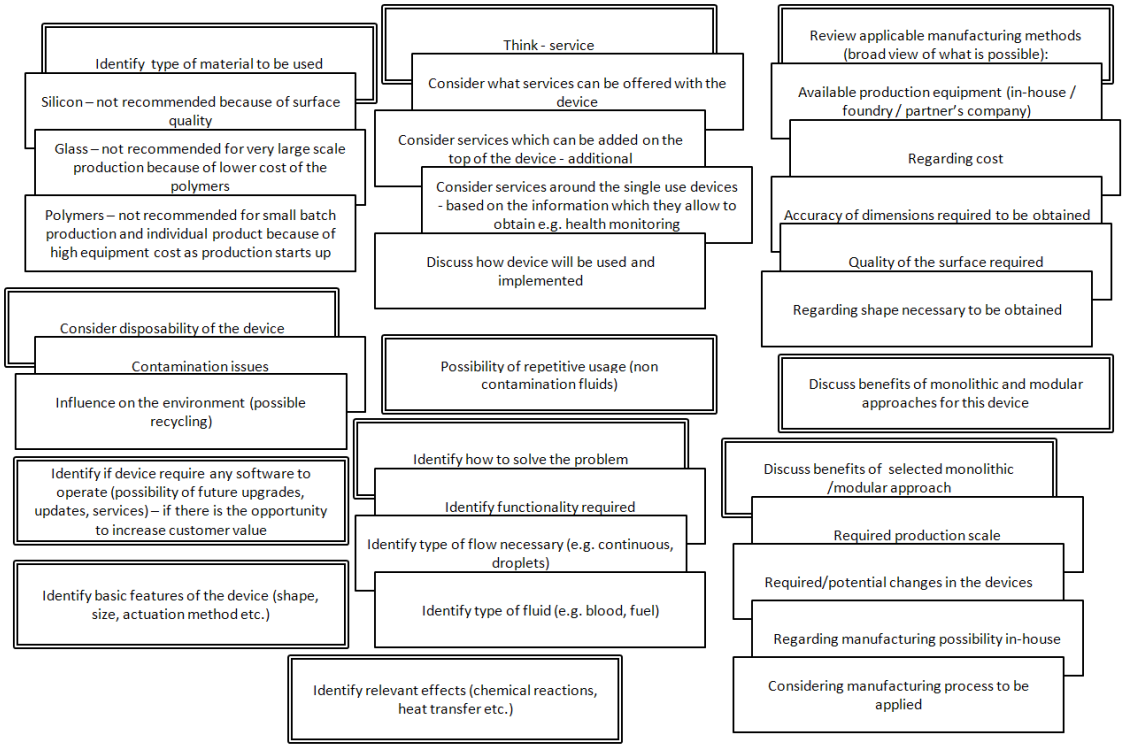

Figure 7 Issues to be included in the idea generation stage

It is imperative that participants of the idea generation session will not only be the project team (required) but also, if possible, other people from the organisation working in the field (engineers, chemists, software specialists etc.) who can have valuable suggestions. This selection has to be made with regard to specifications to address all required competences and broaden the scope for a 'fresh view'. Involvement of the person originating the idea (in internal projects) or clarifying recommendations with clients (projects on client's demand) is advisable. Results from the session should be optimised before they are used as inputs to the next conceptual design phase. Figure 8 shows a high level view of how it is proposed to approach this stage.

The session needs to be chaired by one person. It is proposed that this position be given to the team leader or the person with the highest experience in the domain. The chair should act as moderator for the session and not impose any decisions but only allow people to express their opinions. The chair's opinion, as the person with the highest competence, has to be left until the end so as not to influence others if ideas are expressed verbally.

It is advisable for the session to be scoped with constraints. Before the session, the moderator is encouraged to prepare a short summary of the discussion topic (background to the project and characteristics required) and what is required from the participants. This document should incorporate a service characteristics summary if obtained from the previous phase and include data from the project brief. Prepared in this manner, documentation is expected to be sent to the participants in advance, giving them sufficient time to familiarise themselves with any problems. No more than a week and not less than two days is recommended.

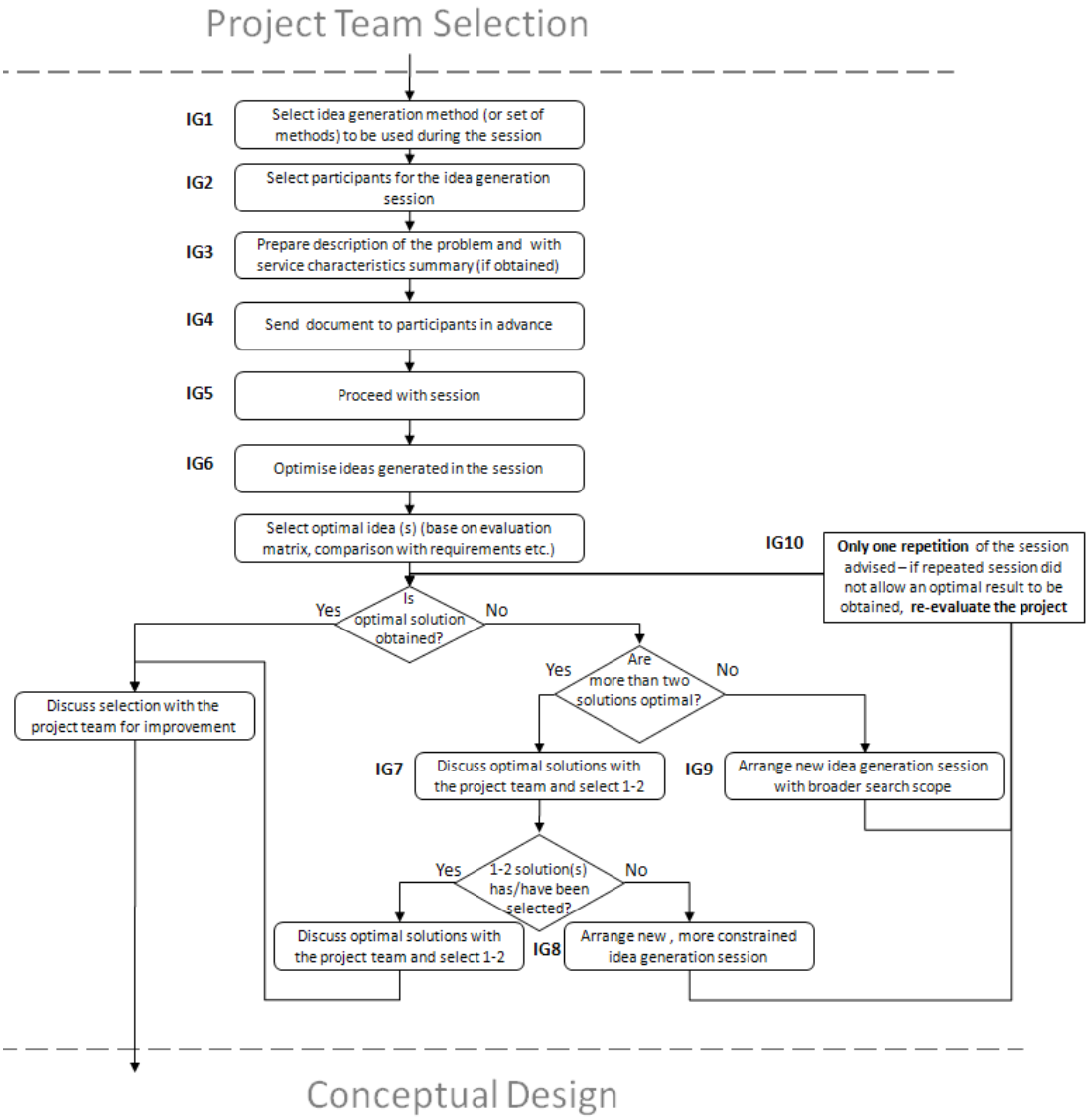

Figure 8 Idea generation stage (IG1-10 are discussed in section 4.3.4 - discussion to be provided on request)

All the ideas generated must be evaluated after the session – not during it. When the session is finished, the criteria based selection method is recommended to be used. Criteria can be established based on specifications for the project as well as on basic factors such as cost, time and performance. Each criterion should have weight depending on the importance of the criterion in the particular project. Selected in this manner, one or two optimal solutions are expected to be used as input(s) to the next phase. Proceeding with more than two solutions is discouraged. In case many solutions are considered as optimal and/or solutions have not been achieved, then a follow-up

session should be arranged with a broader scope if the issues were not targeted initially – to find a solution(s), or in a more focused context if many solutions were considered to be optimal. It is suggested that the session should not be repeated more than once; if this situation occurs, then realisation of the project should be re-evaluated.

1.3.5. Conceptual design

In the conceptual design stage (see Fig.9), the concept selected as the optimal from the idea generation stage has to be developed. Development is recommended to start by assigning tasks to the project team and establishing time frames. These tasks are intended to develop the concept.

Consideration and planning of the service delivery is advised to be approached in the same manner as every other design step. Details regarding tasks to follow are presented in Fig.10. Services should be considered with regard to the necessary infrastructure, resources, delivery methods, profitability and demands. During development of the product at an architectural level, as on the components/modules levels, team members are asked to account for the services to which this element will be delivered and give the value for the customer that it will help to deliver.

When/if consideration of services is performed by the assigned team members. development of the optimal idea into the concept at the architectural level needs to be performed by others. After the design of the architectural level is agreed on in a broad scope, the product breakdown, which was initiated by the idea in the generation session, has to be performed. This breakdown means the separation of the structures which can be developed simultaneously with regard to interactions between them. In this way, existing modules/components and those still to be developed are identified.

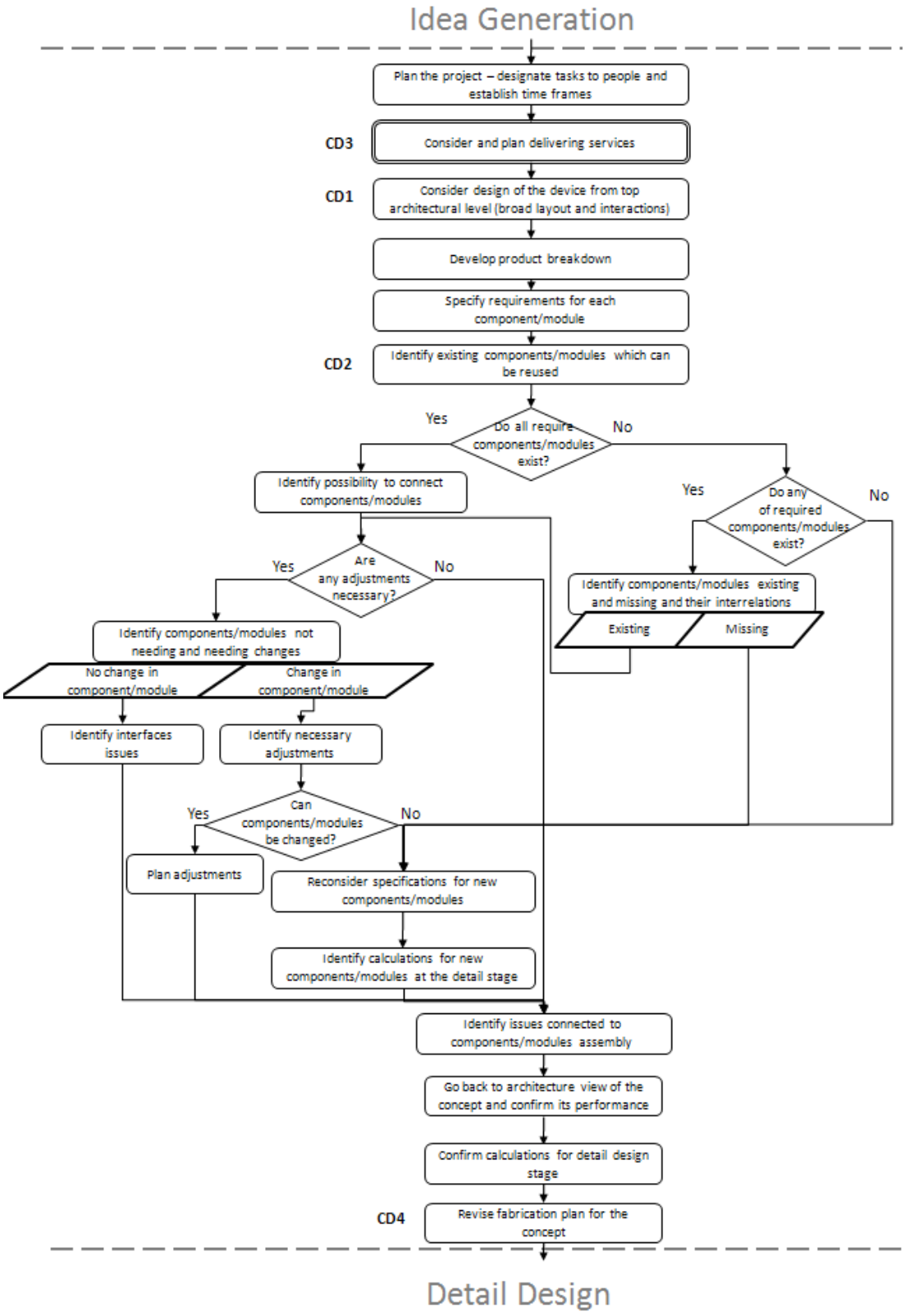

Figure 9 Conceptual design stage (CD1-4 are discussed in section 4.3.5 - discussion to be provided on request)

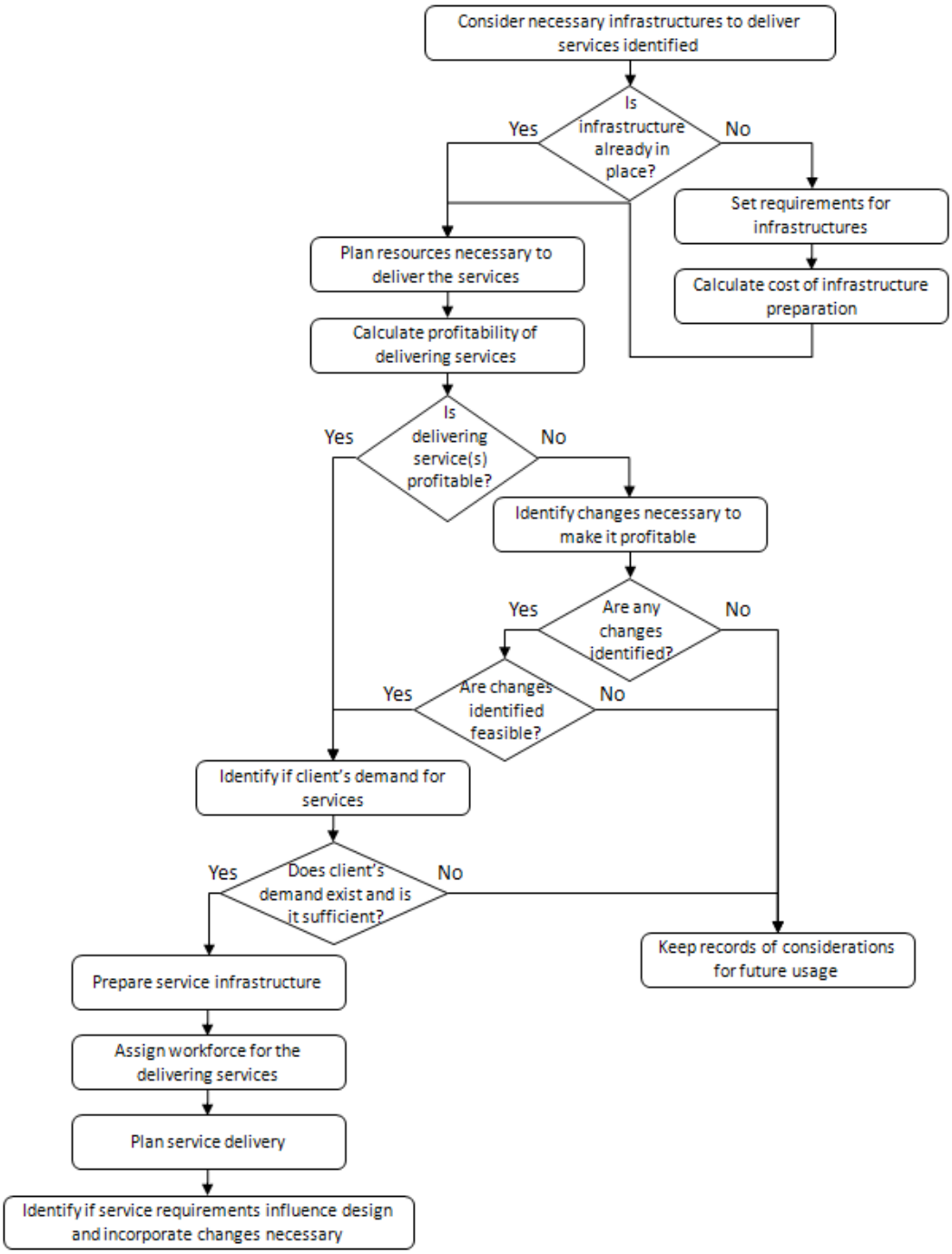

Figure 10 Consider and plan delivering service step

In the case when all required modules/components exist (i.e. were developed previously in the organisation or acquired from other sources) investigation and evaluation of their interconnections is advised. Modules/components which do not yet exist are recommended to be developed by setting up concrete requirements (quantitative and qualitative) and identifying the methods required to obtain them.

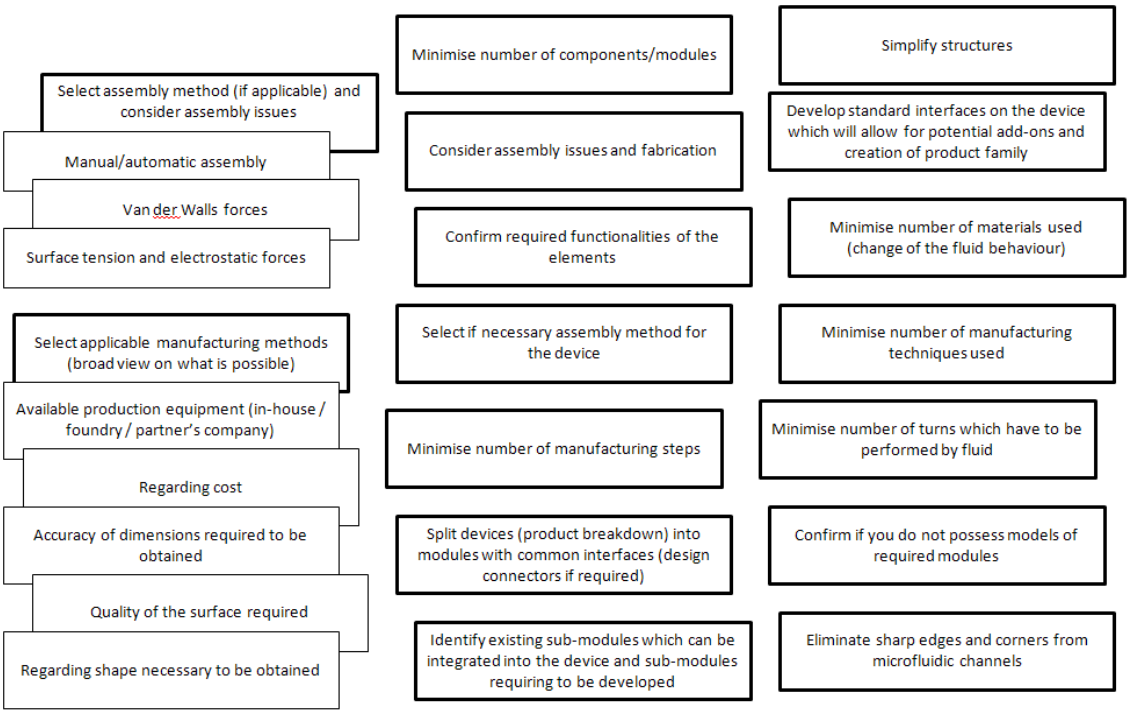

Figure 11 Issues to be included in the conceptual stage

Issues to be included in the development of components/modules and concepts are presented on Figure 11. The majority of these issues are interdependent and they cannot be put into time order.

The outcomes of this phase must be revised regarding changes imposed on the planned process, their cost of implementation and manufacturability of the structure. Manufacturability has to be considered not only in terms of one single device but in the scope of quantity required as a process outcome.

Therefore the step 'revise fabrication plan for the concept' in Fig.10 should include:

- Adjustment for the process in comparison to previous stage output,
- Identification of manufacturing method for each component/module,
- Identification of the production scale-up issues,
- Identification of manufacturing facilities able to deliver the products (internal and/or external),
- Identification of manufacturing equipment necessary,
- Identification of materials to be manufactured from,

- Rough identification of process parameters.

If, for any of the components/modules or concepts, manufacturing information is not able to be specified and there is no indication how and from where this data can be obtained, this element is expected to be reconsidered or replaced.

In case when in the previous stage – idea generation – two concepts were decided to be progressed with this stage, they should be approached in an identical manner and upon the outcome, the optimal solution selected using a set of criteria. It is essential that one of the criteria will be manufacturability and also, if applicable, assembly of structures. The remaining criteria are to be decided by the organisation.

1.3.6. Detailed design

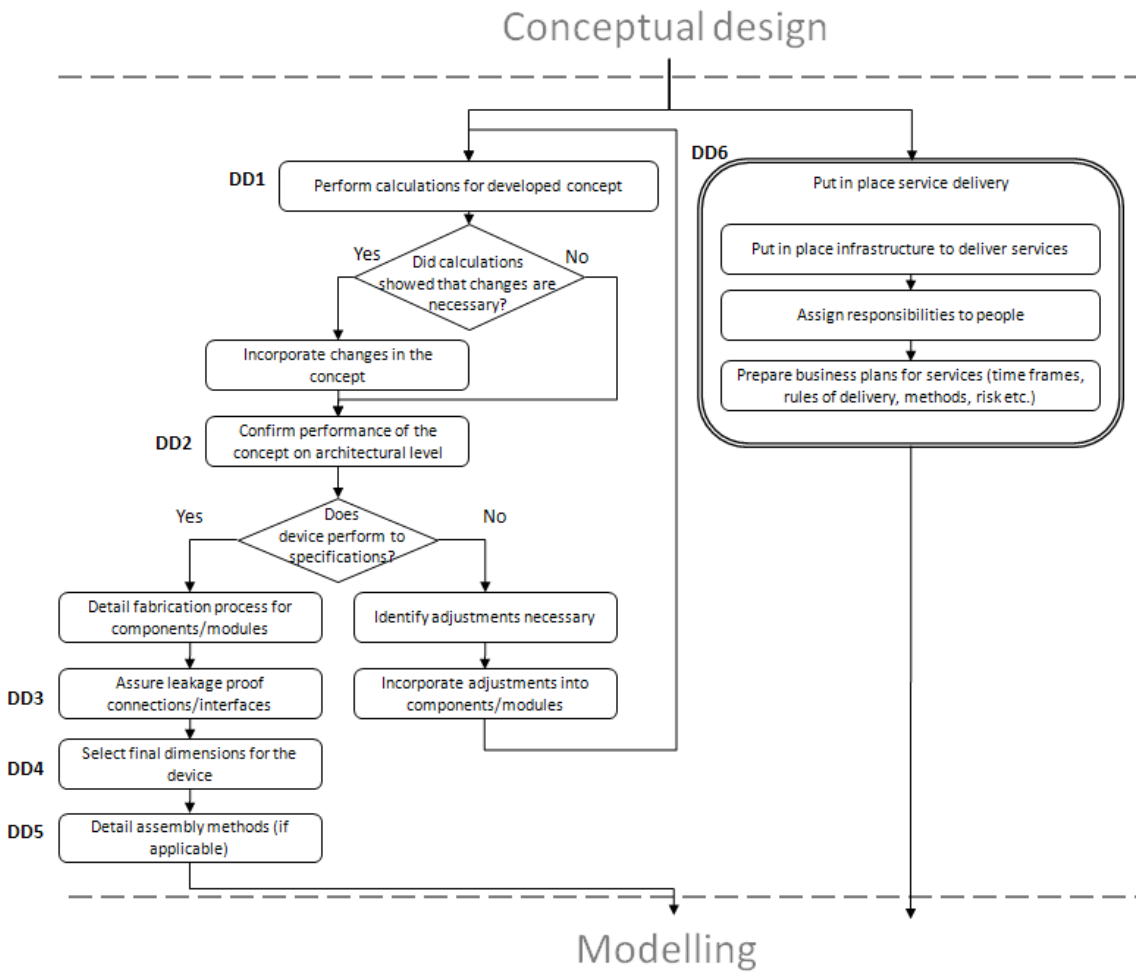

Figure 12 Detailed design stages (DD1-6 are discussed in section 4.3.6- discussion to be provided on request)

The detailed design stage is recommended to be based on a comprehensive calculation of the flows, materials, manufacturing processes and assembly (if applicable). In this step, all data required as the inputs for the modelling, simulation, prototyping and manufacturing (depending on desired outcome) have to be prepared. Figure 12 presents the process to be followed in this stage. Methods used for calculations are left to be decided by the organisation as well as the software used. However, the quality of this stage output has to allow for usage of the CAD and CFD systems for modelling of structures and fluid behaviour and, in some cases, simulation. Specific steps depend strongly on the device type and differ for every function required from the device. Therefore, they are not described here.

In this stage no approximation is allowed; all of the requirements have to be 100% met. Also, the fabrication process has to include all the corrections obtained from the calculations performed.

Those members of the project team designated to service considerations are asked to work in close cooperation with the rest of the team and discuss any changes which the services and data obtained can have on the product structure and creation of customer value.

1.3.7. Modelling

In this stage, models of the device and the fluid behaviour within it need to be developed. Software used among organisations, and requirements which are imposed by usage of a particular software, vary. Therefore, no unique method for how to create models was recommended. Selection of the particular software has, therefore, been left to the organisation to decide upon. In a situation when none of the commercially available software is considered suitable, the development of in-house tools is encouraged. Process to follow for this stage realisation is presented in Figure 13.

The following recommendations are made at this stage to be incorporated in the process:

- Model separate components/modules independently
- Store CAD models and fluid behaviour models in a form which will allow for future reuse
- Link CAD models with fluid behaviour models to increase dependability of structures
- Test models as components/modules as well as a whole device model

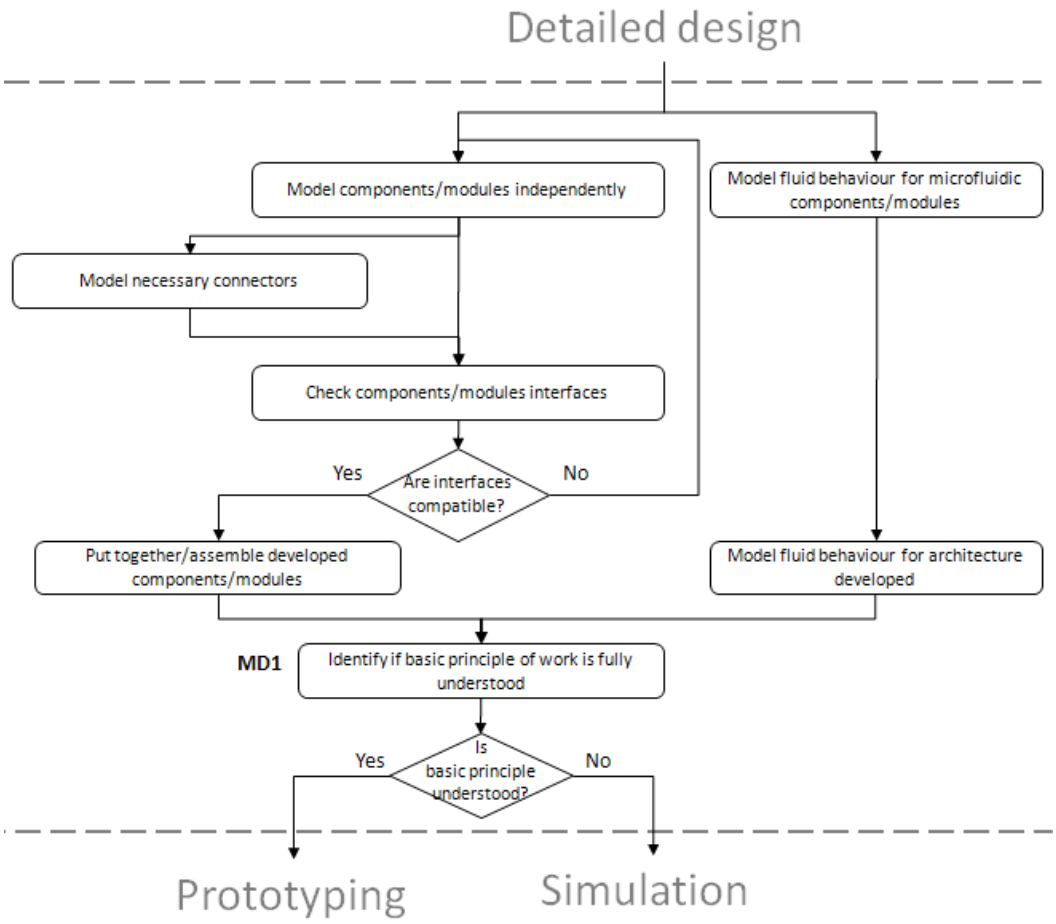

Figure 13 Modelling stage (MD1 is discussed in section 4.3.7 - discussion to be provided on request)

The modelling performed can result in a set of actions: simulation or prototyping. Progressing to any of the stages depends on the complexity of the device designed and the level of knowledge about its basic principle of work. This decision should be made during modelling or before, e.g. when the project is planned, decided by the client. This step is advised to be approached as follows - identify if basic principle of device is fully understood:

- If the device appears simple and its principle of work is understood, the step of simulation of flow behaviour can be omitted and the physical prototyping can be approached
- If the device and/or project appears complex or is not fully understood, proceed with computational simulation until results are satisfactory for prototype fabrication

1.3.8. Simulation

Simulation, similarly to modelling, strongly depends on the software used by the organisation. The software selection, as previously, is left for the organisation to decide upon. The type of simulation and when results obtained are satisfactory in order to proceed with prototyping will depend on the project leader's decision. The only recommendation in this phase is to store simulation models and the results for future reuse.

1.3.9. Prototyping

An input to the prototyping stage can consist of models with or without simulation results. Information to be used for preparation of the prototype should be systematically collected from the beginning of the concept development. It is suggested that the input from the modelling stage (and simulation results when appropriate) be used to complete the necessary data, not to start their collection. Organisations are advised to select the prototyping method and materials to be used based on the capabilities they possess. This necessary stage should be approached in phases rather than using iteration. Phases can also include going from basic general prototypes and detailing them during the building process.

Prototypes developed have to be validated and, if they are not meeting requirements, a new prototype should be prepared. Every prototype needs to be validated, with emphasis on the validation of the device as a whole. In some cases the equipment

used at the prototyping stage is recommended to be reused in the production process (e.g. wafer of the final prototype) with a view to the production being scaled-up.

1.3.10. Validation/Verification

Validation/Verification (see Fig.14) are expected to be performed with regard to specifications and, if development of the device takes a long time, with consideration of the present situation in the market. Confirmation here is sought regarding the existence of a market demand, as previously identified for the device, and details which could change from the moment when project was agreed on till this stage has been reached.

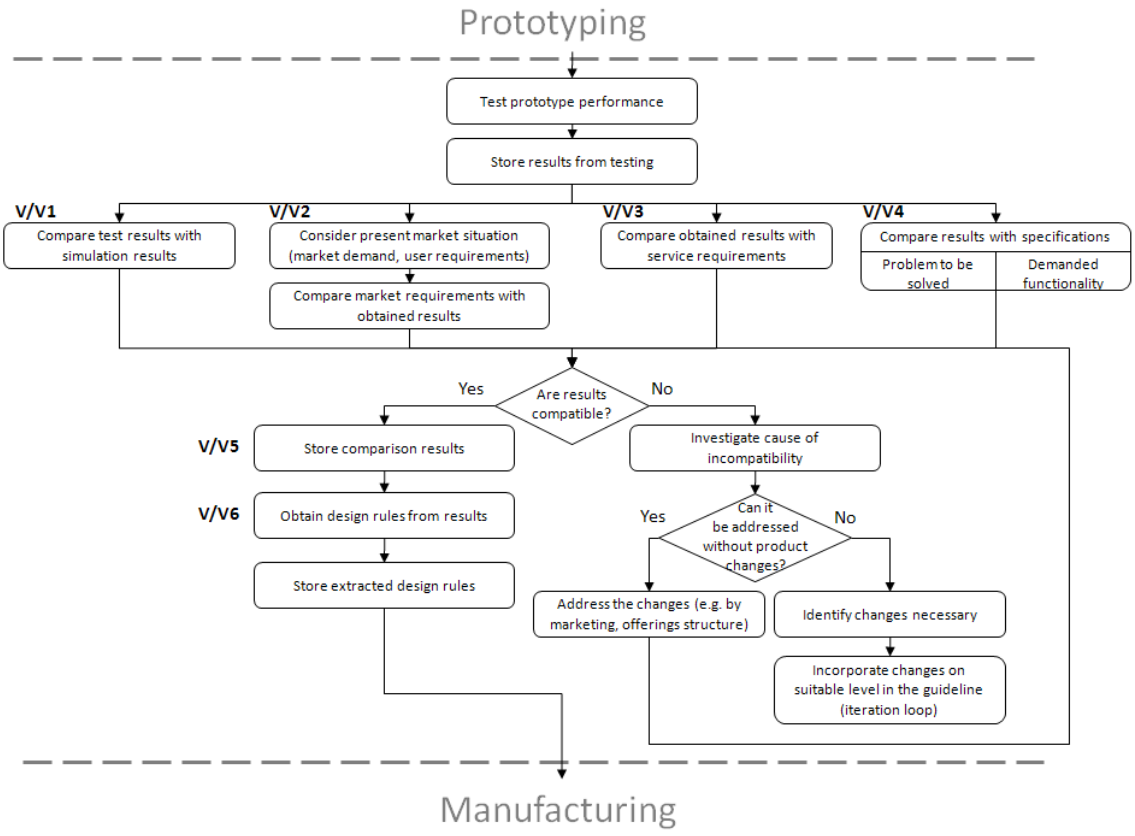

Figure 14 Validation/Verification stage (V/V1-6 are discussed in section 4.3.10 - discussion to be provided on request)

It is imperative for the validation to be based on the prototype prepared in the previous phase. If the simulation stage is performed, the results should be compared with the prototype test results and any differences investigated. Results from testing

are recommended to be stored in a form allowing them to be reused in the database with comments for their interpretation (i.e. putting them in the right context). Also, from the obtained results, design rules should be extracted to be used in the future designs. Design of the product is advised to be verified with a bottom-up approach going from the detail level to the architectural level regarding calculations, mathematical models etc. If the output of design (device) is solving the problem it is validated successively.

1.3.11. Manufacturing

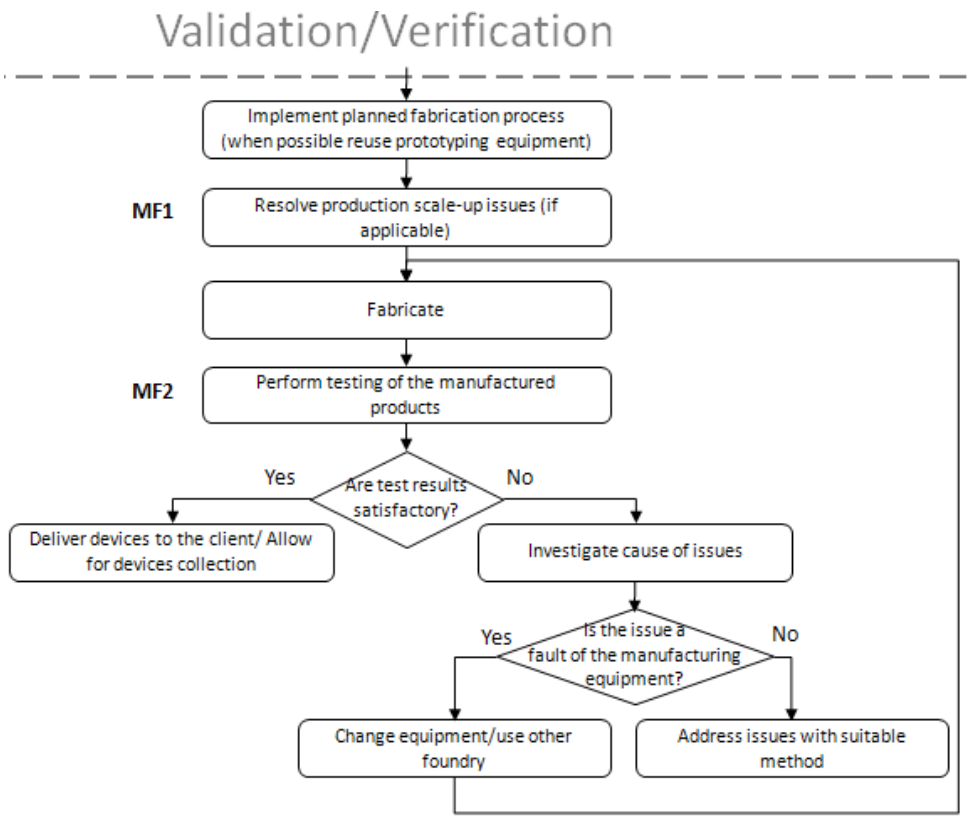

Figure 15 Manufacturing stage (MF1-2 are discussed in section 4.3.11 – discussion to be provided on request)

It is necessary to plan the whole manufacturing process in advance and put equipment in place before this stage begins. Where possible, equipment used in prototyping is recommended to be used in manufacturing (see Fig.15). At this stage fabrication should be performed according to the plan and scaling-up production issues resolved –

if not resolved previously. They need to be taken into consideration in advance. In the case of devices being manufactured using foundries or partners' facilities, the batch produced should be tested against the required performance and any problems solved.

Unsuccessful results from tests can be obtained for various reasons and all of them need to be properly addressed, e.g. if manufacturing equipment was faulty recommended action to be undertaken is the change of the equipment or usage of the foundry. The successful output of the guideline usage is considered as delivery (or collection, depending on the agreement) of the manufactured and tested products to the client.

Appendix 7.2 Solution Validation Feedback Forms

The Guideline Validation
FEEDBACK FORM

THEME:
The guideline feedback form – part of the service-oriented guideline for microfluidic devices design which can deal with sub-section interaction validation process. It is aiming to validate suitability of the guideline and provides practitioners' insight on it.

Please fill-in this document in Word and save changes - When answering please elaborate

1. Is anything in the guideline was new for you?

2. What do you consider as the strongest point of the guideline and why?

3. What do you consider as the weakest point of the guideline and why?

4. Are there any aspects of microfluidics design not addressed by the guideline?

5. Are there any aspects of microfluidics design overly addressed by the guideline?

6. How in your opinion the guideline can improve?

7. Do you think that the guideline is addressing needs of your organisation when designing microfluidics?

Comments:

.....

.....

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.....

.....

Name, Organisation (optional):

.....

Professional activity:

☐ Industrial company ☐ Academic Practice & Research ☐ Other

_____

We would like to thank you for filling in the evaluation sheet and returning to the sender/facilitator. Your participation is a valuable input in the 'Service-oriented design of microfluidic devices' PhD research.

The Guideline Validation
EVALUATION FORM

THEME:

The guideline evaluation form – part of the service-oriented guideline for microfluidic devices design which can deal with sub-section interaction validation process.

Rating scale: ***(1)*** *- strongly disagree* ***(2)*** *- disagree* ***(3)****- nor agree neither disagree* ***(4)*** *- agree* ***(5)*** *– strongly agree*

Please underline appropriate answer for following statements

(function available in the toolbar 'Font' in the menu 'Home' – icon representing  *).*

1. The content of the *guideline* met my expectations / needs
   (1) (2) (3) (4) (5)

2. The guideline is presented clearly
   (1) (2) (3) (4) (5)

3. The guideline are easy to follow
   (1) (2) (3) (4) (5)

4. The length (number of stages) of the guideline is appropriate
   (1) (2) (3) (4) (5)

5. The guideline is incorporating novelty in microfluidics design
   (1) (2) (3) (4) (5)

6. The guideline is enhancing microfluidics design
   (1) (2) (3) (4) (5)

7. I am keen to apply the guideline or its aspects in my future work
   (1) (2) (3) (4) (5)

8. The guideline needs significant improvements
   (1) (2) (3) (4) (5)

9. The guideline is:

Rating scale: A. excellent / B. good / C. fair / D. poor ***Please underline***

(A) (B) (C) (D)

Comments:

.....

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.....

Name, Organisation (optional):

.....

Professional activity:

☐ Industrial company ☐ Academic Practice & Research ☐ Other

_____

We would like to thank you for filling in the evaluation sheet and returning to the sender/facilitator. Your participation is a valuable input in the 'Service-oriented design of microfluidic devices' PhD research.

Appendix 7.3 The Guideline Validation Feedback Forms Rationale

The feedback forms have been developed in standard form as possessing following parts:

- An introduction- This section is introducing the aim of the form to the respondents and explaining what is expected of them. It presents in the brief how they should answer the questions given in the main body.

  Two types of the rating scale used 1-5 and A-D. Two rating scales have been used to clearly separated section in the form which evaluates the form of the guideline from its context. In the first attempt the feedback form used rating scale 1-5 where 1 indicated strong agreement and 5 strong disagreement with given statement. Regarding that many people considered 5 as a maximum score in terms of positivity and were confused in the first attempt to answer this scale has been reversed when popularised the guideline via webportal and discussion groups.

  Selection of the five points scale allowed to diversified the opinions and provided choice for respondents instead of yes/no answer. It has been selected to provide the user with opportunity to select being pro or against particular opinion or staying neutral. Five points scale has been considered as sufficient to diversified opinions and capture respondents views.

  Scale A to D has been selected as four steps to force recipient to select positive or negative opinion regarding the developed guideline. This scale eliminated neutral view on the framework and has been chosen to underline different type of the question in the form.
- Main body of the feedback forms – This section has been prepared for both forms as short lists of questions. All the questions try to evaluate the guideline in term of its structure and presentation manner as well as the guideline's quality and the context incorporated.
- Comments section – This section has been left for the respondents to fill in feely. Possibility to omit any issues which respondents can see as valuable has been a rationale to prepare these sections.

- Name, organisation(optional) – This section has been marked as optional. It has been prepared purely for the classification purposes and not to be disclosed.
- Personal activity: three categories: industrial company, academic practice & research and other – This section has been placed for classification purposes. Differentiation between academic and industrial point of view in terms of microfluidic design justifies separation of the validation views for this two areas. View of the obtained feedback in the light of the area from which it has been obtained can provide a better insight and understanding of particular issues.

Rationale behind questions in the main body of validation forms:

A. **The Guideline Validation - FEEDBACK FORM**

1. Is anything in the guideline was new for you?

This question aims to indicate level of novelty incorporated in developed framework.

2. What do you consider as the strongest point of the guideline and why?

This question is trying to identify which aspect of the guideline is the most valuable for the potential users. This information will help in possible enhancement of the framework after evaluation.

3. What do you consider as the weakest point of the guideline and why?

Answer on this question will highlight place for improvement in the guideline. It will help to improve quality of work by addressing problem faced by the users.

4. Are there any aspects of microfluidics design not addressed by the guideline?

This question tries to identify what aspects relevant for the area and potential users were omitted in the guideline development. Answer on it will help to improve quality of the developed framework by incorporating any missed issues for considerations.

5. Are there any aspects of microfluidics design overly addressed by the guideline?

This question tries to identify aspects which are considered by the respondents as over extensively described in the guideline. An answer for it will help to minimise time which user spends applying guideline by shortening time designated for particular tasks.

6. How in your opinion the guideline can improve?

Author stays with the opinion that there is always place for improvement and capturing others points of view helps to acquire more ideas. By answering this questions respondents will give their own view what will simplify usage and/or application of the guideline in their daily work and therefore improve it.

7. Do you think that the guideline is addressing needs of your organisation when designing microfluidics?

Organisations needs vary. The flexibility incorporated in the guideline is trying to tackle issues imposed in design of all types of microfluidic devices in universal manner. By answering this question respondents will give an insight how applicable is developed framework for their organisation.

B. The Guideline Validation - Evaluation Form

1. The content of the guideline met my expectations / needs

This statement tries to capture what potential guideline user was expecting from the guideline description in comparison to its final form. Answer will help to establish if the guideline is meeting its aim.

2. The guideline is presented clearly

This statement shows if the guideline is presented in clear, understandable manner.

3. The guideline are easy to follow

This statement shows difficulties in applying the guideline and its potential to be use.

4. The length (number of stages) of the guideline is appropriate

The length of the guideline can be considered as a barrier for it to be used. This statement is capturing view of respondents regarding this issue – it presents if it does not discourage potential users.

5. The guideline is incorporating novelty in microfluidics design

Current state of the design maturity varies across microfluidic organisations. Also, the issue of novelty is crucial in the PhD research. This statement shows how novel the guideline is for the respondents in their daily work- does it meet its aim in addressing novelty in the current design practice.

6. The guideline is enhancing microfluidics design

Enhancement of the microfluidic design is the main benefits seek during the guideline development. This statement helps to clarify if this aim has been achieved.

7. I am keen to apply the guideline or its aspects in my future work

Any tool cannot be considered as useful if not used. This statement shows the potential of the guideline to help in the area by identification of people's willingness to implement it or any of its aspects.

8. The guideline needs significant improvements

This statement shows if the guideline is viewed by respondents as mature enough to be useful in their work. It helps to identified if issues identified were addressed properly for microfluidics.

9. The guideline is: A. excellent / B. good / C. fair / D. poor

Rating the guideline in the four points scale helps to validate it quantitatively. It indicates overall attitude of the respondents to the context which has been presented in the guideline as well as its form.

Appendix 7.4 Additional Questions for the Interviews and Their Motivation

Question (Q): What would **convince** you to **use** the guideline?

This question tried to identify external factors and adjustments in the solution which will help to improve its acceptance.

Q: What is convincing you currently to use the guideline?

It is another way of asking about the strongest point of the solution from utilisation perspective. If respondent is not convinced to use the solution he/she instead of indication the positives will answer the next question.

Q: What is **discouraging** you currently from **using** the guideline?

This question attempts to identify factors negatively influencing adoption of the solution.

Q: What would discourage you from using the guideline?

This question has a hypothetical form. It attempt for the interviewee to place him/herself in the situation of the solution adoption in case if he/she consider the solution as not applicable. Therefore, it will still provide indication of necessary improvements.

Q: How in your opinion microfluidic organisations can **benefit** from the guideline **usage**?

Answer on this question can help in convincing people to use the solution. It provides view of potential users in terms of what is important for them and which aspects should be highlighted in the solution.

Q: How in your opinion microfluidic organisations could benefit more from the guideline?

This form of question is more general. It attempted for the interviewee to have a broader view on the solution – beyond their organisation scope. In this way they can identify factors which also for them can be beneficial.

Q: In your opinion is the guideline specific enough for microfluidics?

This question has been based on indications from few respondents regarding necessity of highlighting microfluidic technology more explicitly in the solution.

Q: On what level if organisation, if any, do you see application of the guideline?

This question aims to confirm view of the author how and by whom the solution should be utilised. It is also providing view on who is really involved in the microfluidic design process in interviewees' organisations.

Appendix 7.5 Validation of the Guideline from Service Point of View - Agenda and Feedback Forms

1. Agenda

The Validation Session
Service-orientation of the Guideline Validation Session

Participants:

Workshop is targeting people dealing with change of the offerings from products to service types, service design and services. It is not designated to microfluidics designers.

Aim:

Workshop aims to evaluate service-orientation of the guideline from external point of view.

Objectives:

Identify if the guideline is sufficient in terms of services.
Identify places for possible improvements.
Obtain external for the area point of view on the guideline.

Agenda:

1. Presentation:
    a. Introduction to research:
        i. Microfluidics – what it is
        ii. Microfluidics characteristics in design
        iii. Service-orientation
        iv. Services identified for microfluidics
    b. The guideline
2. Filling in forms:
    a. Service-orientation of the Guideline Evaluation Form
    b. The Guideline Evaluation Form
    c. The Workshop Feedback Form

2. Feedback Form

Service-orientation of the guideline

Evaluation Form

Please answer questions truthfully to your knowledge

1. Was anything in the guideline new for you (if yes what)?

2. What do you consider as the strongest point of the guideline in terms of services and why?

3. What do you consider as the weakest point of the guideline in terms of services and why?

4. Is guideline addressing service-orientation issues sufficiently? Please explain your answer

5. In terms of services - how in your opinion the guideline can improve?

6. Do you think that the guideline is addressing yours organisation needs when designing microfluidics? *If lacking knowledge about the domain please indicate it and gave your personal opinion since your understanding of presented characteristics of the domain*

7. In terms of service-orientation the guideline is:
   Rating scale: *A. excellent / B. good / C. fair / D. poor* *Please underline*

   (A) (B) (C) (D)

Comments:

.....

.....

.....

.....

.....

Name, Organisation (optional):

.....

Service expertise (How your current or previous work was/is connected to services)/Other sufficient expertise e.g. in microfluidics:

.....

Professional activity:

☐ Industrial company ☐ Academic Practice & Research ☐ Other

_____

We thank you for filling in the evaluation sheet and returning to the facilitator. Your participation is a valuable input in the 'Service-oriented design of microfluidic devices' PhD research.

3. Motivation for Used Questions

As can be observed questions used in the feedback form for the validation from service point of view as similar to used in the solution validation feedback form (see Appendix 6.2). Therefore, the motivation behind the questions is analogous. Difference is orientation of the questions on service aspects of the solution instead of on the solution as a general microfluidic design aid.

Due to the fact that possibility of service experts to be qualified in microfluidics is considered as low, question six which was not modified on the form during the session has been indicated to participants as hypothetical.

Original Q6: Do you think that the guideline is addressing yours organisation needs when designing microfluidics? *If lacking knowledge about the domain please indicate it and gave your personal opinion since your understanding of presented characteristics of the domain*

Participant were asked to based on given during the presentation characteristics of the area imagine that they are working in organisation designing microfluidic devices and then answer the question. Motivation for this question, in comparison to general feedback on the solution, aims in potential to identify how the solution will be viewed by higher management, which in larger organisations is often disconnected from hands on design practice.