

## An Improved Method of Failure Mode Analysis for Design Changes

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### Abstract

Customers and market changes behaviour are a large part of the product creation and modification. Though, design changes introduce new potential failures into the products. In this paper, it is presented an integrated method which turns attention to the analysis of design changes. The method is based on FMEA and DRBFM methods, and on remarks from four focused interviews. The interviews showed the necessity of a structured process of managing engineering changes, multidisciplinary work, empowerment of responsibilities, committed personnel and understanding of the modifications. Yet, further work must be undertaken to assess and validate the novel method.

### Keywords:

Failure Analysis, Design Changes, FMEA, DRBFM

## 1 INTRODUCTION

In the global market, product development has shown to be one of the most important business processes for companies in the achievement of competitive advantage [1]. Over the last decade, new products have been appearing at an ever increasing pace. Also, product modifications have increased significantly to meet existing needs, emerging wants, and latent expectations of consumers [2]. Most new products in engineering are designed by modification from existing products, namely, product development involves the steady evolution of an initial design [3] [4].

However, changes always create an increased potential failure in the design [5] [6]. The failures can affect the reliability and availability of a product and can cause profit loss to both manufacturer and user. This is particularly true in the automobile industry. Many researches have shown that besides financial harm, disclosure of product defects (such as recalls) can result in negative abnormal results on the automakers reputation [7] [8], with consequent losses in stock market valuation [8] [9] and product sales [8] [10]. In a typical month, several recall campaigns of motor vehicles are carried out by automobile manufacturer to correct defective vehicles [9] and its incidence are increasing over the time [8]. Likewise, the same evidences of profit losses were found for non-automotive recalls [11].

In this the scenario, companies have the challenge to proactively prevent failures during the early stages of the new product development (NPD) process, since the later a failure is detected into the product life cycle, the bigger becomes its financial consequences [12]. Several methods of design failure analysis currently exist and are used in industry, but by far the most widely used is the Failure Mode and Effect Analysis (FMEA) method [13].

The FMEA helps designers to understand and know the potential modes of a failure, to assess the risk of each known potential failure mode, and to identify countermeasures to avoid the failure to occur [14]. It has been intensively applied over the years in the NPD

process. Nevertheless, as previously discussed, many defects are being discovered by the final consumer. Moreover, the FMEA method has several shortcomings, for instance, it does not take into account potential failures due to changes.

Therefore, the goal of this paper is to advance an integrated method to proactively find potential failures introduced by design changes. The method was named Failure Mode and Effect Analysis of Modifications (FMEAM). In this paper, it is adopted that the terms change and modification have exactly the same meaning. Also, the review emphasis is placed on failure analysis just for product design; not for manufacturing process.

A combination of literature review, regarding the methods FMEA and Design Review Based on Failure Mode (DRBFM), and findings from four focused interviews were the sources of evidence to define the proposed method.

The interviews not only helped to understand practical analyses to avoid failures when a product is modified, but also they provided substantial ideas of how the FMEAM could be integrated into the NPD process.

Design changes can be problematic because designers are not always aware of the connectivity between the different parts of a product and can inadvertently ignore the incidental effects of change [3]. Inspected failures due to change can be avoided through high redundancy in the product or, more economically, through an intelligent anticipation of later failures due to the change [15]. Thus, the FMEAM should bring superior results to the NPD process.

The rest of this paper is organized as follows: section 2 describes the research methodology; in section 3 a brief literature review is given, encompassing the methods FMEA and DRBFM; in section 4 the interviews are described; section 5, which constitutes the major part of this paper, is where the FMEAM is presented and the procedure of carrying it out is explained; and section 6 concludes the paper by discussing the approach taken by FMEAM and pointing out further work.

## 2 METHODOLOGY

Research approaches can be divided into the categories: quantitative, qualitative and mixed [16]. Also, they can be classified as exploration, descriptive, predictive, and explanatory research [17] [18] [19]. Exploration research involves [17] an attempt to determine whether or not a phenomenon exists; i.e. Does X happen? Descriptive research involves [17] examining a phenomenon to more fully define it or to differentiate it from other phenomenon; i.e. What is it? How is it different? Predictive research involves [17] identifying relationships that enable us to speculate about one thing by knowing about some other thing; i.e. What is it related to? Explanatory research involves [17] examining a cause-effect relationship between two or more phenomena; i.e. What causes it?

The research approach and its source of data collection have to be chosen according to the purpose of the research. In this work, the research the approach taken was qualitative and it can be classified as a descriptive research.

Descriptive research requires that the investigator begin with a descriptive theory. Accordingly, a review of literature about the methods FMEA and DRBFM was undertaken. Then, four focused interviews were conducted with product design stakeholders from different companies. Focused interview is used in a situation where the respondent is interviewed for a short period of time, usually answering set questions [18].

The Interviews were carried out aiming at understanding the practical analyses performed to avoid failures when a product is modified. In all interviews the first quarter was conversational to comprehend the scenario of the company which the interviewee works for. Specific questions dealt with how the analyses are done, their objectives, whether they are formal or informal, which are the employees involved, and whether the lessons learnt are registered and further reused. Contextual questions probed which are the benefits and difficulties of analyses, the resources and efforts necessary to accomplish the analyses.

## 3 LITERATURE RESEARCH

It is appropriate to present a brief of the literature review about the methods FMEA and DRBFM.

### 3.1 FMEA, shortcomings and adaptations

Failure Mode and Effect Analysis (FMEA) is a quality method that identifies, prioritizes, and mitigates potential problems in a given product. FMEA begins with identification of functions or requirements of a system, subsystem or component, ways that they can fail and its potential causes of failure. A small, but representative, group with members of the design team and other disciplines familiar with the product life cycle performs the analysis in one or more meetings. For each failure mode and cause, the team identifies the probability that they can occur and scores them on a scale from 0 to 10. After identifying the effects, the analysis scores the severity of each end effect on a similar scale. The team documents which actions have already been taken, and which actions have still to be performed in order to avoid or to detect the failure mode. Finally, the detection rating scored refers to the likeliness of catching the failure modes before they happen. The product of these terms is the risk priority number (RPN) which gives a relative magnitude for each failure mode.

If an FMEA is done properly, the resulting documents contain a lot of knowledge about the product design. Thus, it is a valuable source of know-how for the

company. Furthermore, since it supports the early detection of weaknesses in a design, a reduction of development costs and fewer changes during series production are expected [20].

However, there are numerous shortcomings within the failure analysis of FMEA, its implementation and utility. Some of these shortcomings include a lack of well-defined terms [21], problems with the terminology [22], problems with identifying key failures [23] and it is treated as a stand-alone technique [20], which is neither integrated with the design process, nor with other methods of quality management. Other common complaints of the FMEA method is that it is tedious and time consuming [13] [24] [25], its analyses are subjective (based on the user's experience) [26], it is considered by the engineers to be "laborious" [20], the analysis is often done to check rather than to predict [22].

When concerned with product design, it is important that failure analysis is carried out early in the design process in order to reduce the necessary amount of redesigns. It is important to perform failure analysis in conceptual design, but it has been reported that FMEA is commonly performed too late in the NPD cycle and has very little effect on the overall product design [27].

To overcome the FMEA shortcomings, many adaptations and improvements have been made to its process, application and target. Previous papers [25] [26] have described concepts for automated FMEA employing qualitative simulators and reasoning process to produce a report that is more timely, complete and consistent in the design cycle. Other authors [28] take automated FMEA a step further, developing a concept for analysis of the effects of significant multiple failures as well as single failures. A software that uses quantitative simulator has been developed [29], to produce results that are not only more accurate for designers, but are also more useful to test and diagnostics engineers. Bayes belief networks has been employed [21] to provide a language for design teams to articulate, with greater precision and consistency and less ambiguity, a physical system failure cause-effect relationship, and the uncertainty about their impact on customers. It has been shown [30] that "function to structure mapping" can be used in the early stages of design to assess diagnosability; i.e., a measure of the ease of isolating the cause of a malfunction.

### 3.2 DRBFM

DRBFM is a method of discovering problems and developing countermeasures by taking notice of and discussing intentional changes (design modifications) and incidental changes (changes in part environment) [31]. It is carried out, throughout the NPD process, to guide the design engineer during the engineering change process, to integrate design, production, quality and supplier personnel into this process, and to achieve a robust design [32].

DRBFM was developed by Tatsuhiro Yoshimura, who has worked at Toyota Motor Corporation for 32 years. In the Japanese automobile manufacturer, Yoshimura was one of the responsible engineers to assure the quality and the reliability of the products, dedicating his professional life to avoid problems before they occur. However, the other employees acting as "troubleshooters", namely, solving problems just when they appeared, were apparently the heroes of the company [33]. It has been reported [33] that the summary for Yoshimura of this experience is similar than the findings of the study conducted by MIT: "Nobody Ever Gets Credit for Fixing Problems that Never Happened" [34].

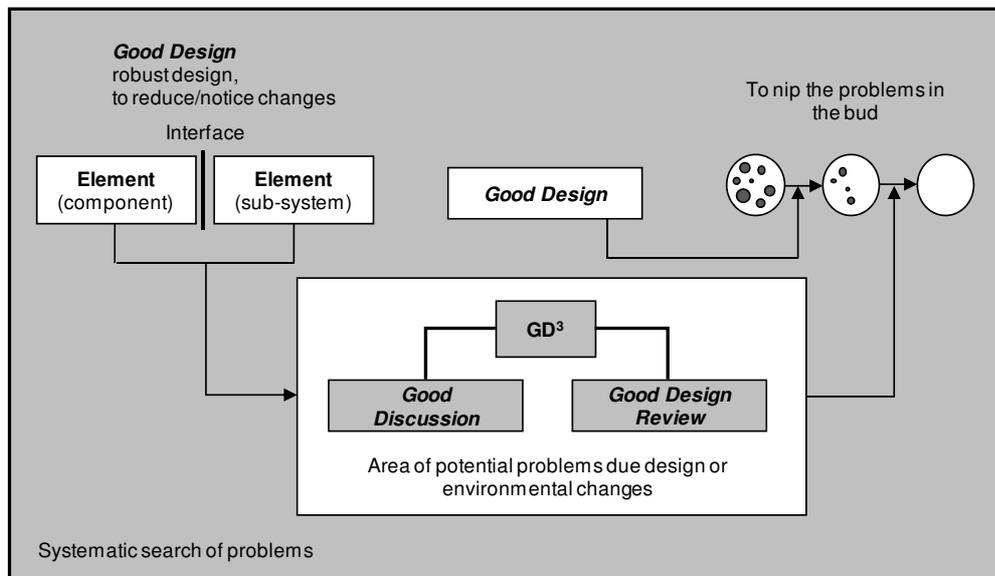


Figure 1: GD<sup>3</sup> philosophy.

Despite that, Toyota has successfully implemented the DRBFM method. Nonetheless, the method has not yet deeply investigated by the academic researchers nor broadly disseminated throughout other companies.

A recent study [8] showed that Toyota has the highest product variety of all other car manufacturers and has low volume of recalled vehicles as a percentage of registrations. This suggests an ability on Toyota's part to simultaneously offer relatively high variety whilst retaining tight control of product development and manufacturing processes [8].

Toyota has a philosophy called GD<sup>3</sup> or *Mizen Boushi* (roughly translated as "countermeasures"). GD<sup>3</sup> stands for Good Design, Good Discussion and Good Design Review [35]. The principles of Good Design are to use, as much as possible, robust components and avoid design changes to reduce the complexity of the error prevention. Besides, this principle tries to nip the problems in the bud. Good Discussion and Good Design Review are the processes of thoroughly discussing design plans to discover previously undetected problems and they are used to formulate the best countermeasures to these problems [31] [5]. The GD<sup>3</sup> philosophy is represented in figure 1. In Toyota, the DRBFM method is applied in this context.

#### 4 THE INTERVIEWS

Results from the interviews and respective description of companies are summarised in the following subsections

##### 4.1 First interview

The first interview was performed with the design engineering manager from a medium firm, which manufactures machines and equipments for plastic transformation. They manufacture two segments of machines: for bag making - automatic machines for small and large plastic bags, T-shirt bags, rounded-bottom bags, sleeve labels pre-perforated or not; and for thermoforming and vacuum forming - machines for one-way packaging, i.e., pots, lids and trays.

When a family of machine is required to be modified, a design engineering group first creates a virtual model and performs virtual tests. Then, a complementary analysis of failure is done based upon knowledge of the group; therefore, there is the need of competent employees. The analyses are done to verify the novel design and to prevent failures from happening in field.

However, the company's major difficulty is the short time to test the new machine before sending it to the client. For this reason, sometimes, after a couple of months, when they have already sold a few machines of the new model, a design error can be found and they need to make a recall. It was said by the interviewee that this is a better situation than not sending the machine to the client and losing the sale.

Lessons learnt are registered in a validation report for further sharing, but this has not shown to be efficient. So, most of the lessons learnt are verbally shared.

##### 4.2 Second interview

The second interviewee is a project manager from a medium-sized manufacturer of medical-ophthalmic equipments. There, the "engineering change management" process is systematically structured and controlled. All the analyses of design changes are coordinated by an improvement group. First, they document who requested the change, the type of change (structural, material, treatment, etc.), the reason (cost reduction, upgrade, improvement of technology, etc.), product documents (drawings, procedures, lists, etc.) that may need to be modified, and the "in charge" of the modification. Then, the group judges the risk of the change. If there is a risk, a change process is started; otherwise, no analysis is needed. The improvement group empowers a multidisciplinary team (mechanical and electrical specialists) to assess the potential failures introduced by the modification. For that, the team uses the methods FMEA and FMECA (Failure Mode, Effects and Criticality Analysis) complemented with CAD (Computer Aided Design) and FEM (Finite Element Method) analyses, followed by several tests executed in functional prototypes and discussions within the members of the multidisciplinary team. After the tests, the new design is approved or declined by the project manager (technical responsible).

It was said that recalls do not occur due to modifications, but rather to upgrades and technology improvements. Also, it was stated that before implementation of the design changes management process, requests for modifications were constants and they diminished just after the implementation. Nonetheless, it was added that the beginning was difficult for the employees to aware themselves that it was necessary to work in group.

### 4.3 Third interview

A third interview was done with the research and development manager from a medium-sized company. The enterprise develops equipments for automation to a broad range of segments, such as, ethanol, pulp and paper, chemical, metallurgical and agricultural.

They have a structured and formal process for engineering change. The process can be initiated by claims from costumers or when internal personnel or the field technical support give suggestions of improvements. Subsequently, the manager and the head of the research and development department carry out a critical analysis identifying impacts (in the company) of the modifications, risks involved, necessary resources and time, and level of difficulty for implementing it. Then, if the modification is approved, a plan is developed which includes necessary personnel, schedule of alterations, and needed tests.

Tests are performed by groups of software and hardware specialists in different modules. The groups can consult a database of previous problems. After the tests, the engineering development manager gathers the tests results and approves the modification or not.

It was said that the analysis is carried out to clearly identify what is needed to be done, and to become known the possible failures in the functionality of the equipment due to the change. The benefits related were: higher quality and reliability of products, more efficient work (focus on necessary work), superior customer satisfaction and decline of reworks.

A good and fast product development depends on the company's labour force. Therefore, the interviewee pointed out that the main difficulty is to have skilled labour to correctly perform the analyses.

Besides, the interviewee affirmed that a product modification causes higher probability of failure, and added that their recalls are associated with a design modification. Although a pressure to quickly launch the novel product into the market exists, it is better to have a robust product, rather than a weak product with a client. Owing that, they have spent larger time with the tests.

### 4.4 Fourth interview

The fourth interview was carried out in a local site of a large global manufacturer of hermetic compressors for air conditioning and refrigeration products and centrifugal pumps. They produce hermetic compressors for domestic and commercial refrigeration and air conditioners.

An interview was conducted with the manager of product engineering group. When asked how failure analyses of "new" and "variant" products were done there, it was answered straight away "through the FMEA method". He added saying "a design error discovered by the client can cause us large financial harm", consequently he recognizes the necessity of applying FMEA.

In the company, the FMEA is used to check the design using nonfunctional prototypes to help visualization. This is done during a meeting promoted by the product designer (leader), who summons leaders from the quality departments, manufacturing process, supply chain (if supplier is involved) and research and development (if it is a new product). However, it is common for the leaders not to attend the meeting and also to lack knowledge about what was modified in the product. Thus, as the meetings are inefficient, many of them are needed to accomplish the necessary work.

In the end, it was answered that the lessons learnt are documented, yet are not retrieved in further analyses. The interviewee concluded saying that their recalls are not frequents, mainly occurring due to failures from the

manufacturing process and less due to design modifications.

### 4.5 Findings

Results from the interviews not only confirm that design modifications introduce potential failures into the product, but also suggest the necessity of the following:

- Multidisciplinary work;
- Structured process of managing engineering changes;
- Empowerment of responsibilities;
- Committed personnel;
- Understanding of the modifications.

## 5 DESIGN FAILURE MODE AND EFFECT ANALYSIS OF MODIFICATIONS (FMEAM) PROPOSAL

FMEAM was developed based on literature about FMEA and DRBFM methods, and remarks from the focused interviews. FMEAM attempts to find any potential failures introduced into the product due to modifications.

FMEAM aims to encourage creative discussion of even more issues than FMEA does, by stimulating each other's brains to make one another notice things, thus preventing problems. FMEAM links design and evaluation in order to promote an integrated prevention of failures.

It should be seen as a live document integrated with the NPD process, rather than just a task to be done after the design is completed. Namely, its documentation shall be constantly updated with data from the results of evaluation and field.

### 5.1 Conducting FMEAM in a integrated manner

Most current FMEA procedures are a one-time task done in the phase of Testing and Validation, which may serve as an important design check, but otherwise, it contributes little to the design. The proposal here is a series of activities to be done throughout the NPD process.

During the Conceptual Design phase, data, such as field reports, checklists and other guidelines based on lessons learned, technology advances, and the history or analysis of similar designs, which has proven to be successful, should be collected and block diagrams developed - to illustrate the physical and functional relationships between items and interfaces within the system.

In the Detailed Design phase a FMEAM meeting shall be conducted just prior of the release of final drawings. The following tolls, regarding the concerned system of the analysis, must be provided beforehand of the FMEAM meeting:

- Block diagram: to show interdependencies of functional entities and interfaces.
- Fault tree analysis (FTA): to show logical relationship between a failure and its causes, and to provide a logical framework for expressing combinations of component failures that can lead to system failure.
- Change point list: a list of what has been changed or intended to be changed in the components of the system. This list aims to clearly identify and organize the changes. Examples of change point could be change in structure, material, surface, thermal treatment, manufacturing process and stress/load.
- Relational matrix between functions and components: a matrix which correlates the components and its functions. It intends to clarify failure modes by identifying which function is affected.
- Previous drawings and prototypes (if available): to help visualization.

- History of field failures: to prevent a known problem from occurring again.

The tools should be used throughout the FMEAM meeting. They are meant to identify the intentional changes made and also the changes resulting from them. In addition, they should help to visualize the system structures and the functions of components during the FMEAM meeting.

Results from the discussion of the FMEAM meeting shall be reflected in the Testing and Validation phase. In addition, redesigns may occur in the NPD process. Therefore, those results should be also reflected in redesigns in a timely manner.

Finally, during the Product Use and Support phase, FMEAM should be used as a guide to collect field data for assessing analysis accuracy, and for developing maintenance troubleshooting procedures.

Conducting the FMEAM in this manner it shall enforce a disciplined review of the baseline design and may allow timely feedback to the design process.

### 5.2 Adaptations made in the traditional FMEA worksheet

The headings of the FMEA table were modified. The scores for severity, occurrence, detection, and the risk priority number (RPN) were replaced by "Adverse effects on customer" with a scale of three levels: A, B, C (A being the most important). The "customer", as referred to for the purpose of FMEAM, includes not only the "end users" but also the design staff and teams of the subsequent processes and the engineers operating in such fields as the production, assembly, service, etc.

The most relevant section inserted was "Discussion Results", since the value added by FMEAM activity depends on the extent that new and specific items are identified and entered into this section. The section encompasses "Items to reflect in design work" and "Items to reflect in evaluation work", each of them followed by a column "Responsibility and deadline", where the person responsible to follow-up the action and the deadline for its implementation is entered.

Table 1 shows the FMEAM headings.

### 5.3 Performing FMEAM

FMEAM has to be performed in a meeting by a multidisciplinary team to take advantage of sharing their specific knowledge. The design engineer responsible for the system (part), which will be analysed, should lead the meeting.

Engineers from design, evaluation, production engineering and manufacturing, inspection and material departments shall be selected for the meeting. Yet, experienced engineers with the intention of getting actively involved in the discussion by putting themselves in the place of the design leader should be selected.

In the FMEAM meeting, initially, the design engineer (leader) should explain the mechanism and the functions of the concerned part, a general idea of its design, and any specific factors that have been given special consideration. The participants then should ask questions and/or make remarks about any matter of concern in relation to the given explanation, and discuss with the design engineer based on the raised questions and indications. It is a way of ensuring thorough mutual understanding among FMEAM team in relation to the concerned part.

Afterwards, the discussion is conducted by filling out the FMEAM worksheet sections. The following elucidates all the headings of the worksheet.

1. Component name / change: enter the name of the component subject to analysis. Enter the modification made or planned to be made in it and the details of the modification. In the case of a newly adopted part, it is preferred to have a comparable part on hand, if possible, for the purpose of comparative evaluation.
2. Function: enter the function intended for the subject of analysis by as concisely as possible. If there are more than two intended functions, enter all such functions separately.
3. Potential failure mode due to change: enter as how the component will fail as a result of the modification. If there are more than two intended functions, make separate entries for each of the functions. Also make entries regarding the factors that cause the loss of commercial value, such as abnormal noise and poor appearance quality, in a concrete expression phrased from the customer's point of view.
4. Root cause / dominant cause: the causes of the failure of function and commercial value are, in a sense, the weak-points of the current design. Indicate, therefore, the root causes of the failure and loss of commercial value as concretely as possible to facilitate the future implementation of the measures formulated from design perspective and to allow participants to clearly visualize the concern.

Active discussion about the design changes						
Component name / change	Function	Potential failure mode due to change	Root cause / dominant cause	Adverse effects on customer (System)	Importance	Current design to avoid concern point (incl. design rule, design standard & check items)
Discussion Results					Action Results	
Items to reflect in design work	Resp. & Dead Line	Items to be reflected in evaluation work	Resp. & Dead Line			

Table 1: FMEAM headings.

5. Adverse effects on customers: customers, as explained in the previous section, can be assumed to exist in various levels. In this column, indicate the phenomena, which customers will presumably experience, using expressions phrased from customer's point of view. So, the type of adverse effects can be clearly understood. Classify the adverse effects into three ranks - A, B or C - according to the severity of impacts and enter the rank in the "Importance" column.
6. Current design to avoid concern point: enter the considerations made in the design to prevent the failure and loss of commercial value. Entries shall be made in such a manner so that the information in this column can be readily associated with the relevant information in the "Root cause / dominant cause" column.
7. Items decided in FMEAM to reflect in design work and to reflect in evaluation work: the participants are to make attempts to identify potential problems through discussion, and then summarize the decisions made into these columns using concise expressions. Enter those items that should be considered in the design work into the "Items to reflect in design work" column and those items to be considered during the test and evaluation work, such as in relation to the conditions and items of evaluation, into the "Items to reflect in evaluation work" column. Be sure to provide clear and readily understandable instructions on what needs to be done. Enter the name of responsible employee and the deadline of implementation into the "Responsibility and deadline" column, for each of the Items decided.
8. Action results: For each items listed in the previous columns (7.), enter the information regarding the date of implementation of the measures, details of measures implemented, and the consequences of the implementation.

Finally, a FMEAM report shall be written to summarize the results, reports the decisions and recommended actions to be taken for elimination or reduction of failure. Also, it should include the problems which could not be corrected by design. Since FMEAM is intended to be a living document, this report shall be integrated in the NPD process as a deliverable to the design and evaluation work.

## 6 FINAL REMARKS

Failure Mode and Effect Analysis (FMEA) has been intensely used to ensure the quality and reliability of products. Additionally, over the years, several adaptations and improvements have been made in the method FMEA. Besides the use of the FMEA and the several attempts to mitigate its shortcomings, many incidents in the field are still occurring, which is costly to companies.

This paper has presented a method to analyzing the effects of changes made in the design. The method was conceived from the knowledge that changes carry a higher potential failure. It is based on the methods FMEA and DRBFM and on findings from focused interviews. The novel method was called Failure Mode and Effect Analysis of Modifications (FMEAM) and it aims to assure the product quality after design changes.

The interviews indicated that when carrying out analyses of engineering changes, it should be a structured process. Additionally, it was accentuated that there is a need of multidisciplinary work group, empowerment of responsibilities and personnel committed with the work and aware of the modifications.

Neither isolated nor just for design checking the FMEAM should be applied. Furthermore, its practice should comprise a continuum application within and between NPD processes in order to constantly be detected potential failures and to create a historic of potential failures due to changes.

FMEAM should promote identification of potential problems through active discussion of modifications and the causes of such problems. Consequently, it is vital that all participants of the discussion have a good understanding of the substance of the modifications.

Although FMEAM method was based on stabilised methods, certainly, it is necessary to take further action research approaches, in order to establish the feasibility, usability and utility of the new method.

In Summary, the intention of the proposed method is to meet the current necessity of companies, which are to launch novel products into the market in shorter cycles and to effectively assure the quality of its new products.

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