

Analysis of difficulties in the application of FMEA in industries of the industrial pole of Manaus, Brazil

Análise das dificuldades na aplicação do FMEA em indústrias do pólo industrial de Manaus, Brasil

Análisis de dificultades en la aplicación de FMEA en industrias del polo industrial de Manaus, Brasil

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Abstract

Organizations of all types and sizes have focused almost entirely on meeting their customers' needs through quality products. Tools capable of detecting and resolving failures are increasingly used to guide production processes. In this sense, this study aimed to analyze the difficulties of operationalization of FMEA in four industries that operate in the industrial pole of Manaus. The method consisted of collecting data through semi-structured interviews with professionals responsible for executing these organizations' tools, organized and analyzed with semantic and content analysis techniques. The results showed that the tool is operationalized in five major stages. The difficulties encountered are due to human nature, such as difficulty working as a team and its members' commitment, and methodological, such as handling control and analysis forms periodic updating of data and information. The conclusion presented is that the tool's complexity can be reduced if digital and electronic mechanisms are used in its operation.

Keywords: FMEA; Difficulties in the application; Industrial pole of Manaus; Failure analysis; Quality tool.

Resumo

Organizações de todos os tipos e tamanhos têm se concentrado quase inteiramente em atender às necessidades de seus clientes por meio de produtos de qualidade. Ferramentas capazes de detectar e resolver falhas são cada vez mais utilizadas para orientar e orientar os processos de produção. Nesse sentido, este estudo teve como objetivo analisar as dificuldades de operacionalização do FMEA em quatro indústrias que atuam no polo industrial de Manaus. O método consistiu na coleta de dados por meio de entrevistas semiestruturadas com os profissionais responsáveis pela execução das ferramentas dessas organizações, organizadas e analisadas com técnicas de análise semântica e de conteúdo. Os resultados mostraram que a ferramenta é operacionalizada em cinco grandes etapas. As dificuldades encontradas são decorrentes da natureza humana, como dificuldade de trabalho em equipe e comprometimento de seus integrantes, e metodológicas, como manuseio de formulários de controle e análise, atualização periódica de dados e informações. A conclusão apresentada é que a complexidade da ferramenta pode ser reduzida se forem utilizados mecanismos digitais e eletrônicos em seu funcionamento.

Palavras-chave: FMEA; Dificuldades na aplicação; Polo industrial de Manaus; Análise de falhas; Ferramenta da qualidade.

Resumen

Las organizaciones de todos los tipos y tamaños se han centrado casi por completo en satisfacer las necesidades de sus clientes a través de productos de calidad. Las herramientas capaces de detectar y resolver fallos se utilizan cada vez más para orientar los procesos productivos. En este sentido, este estudio tuvo como objetivo analizar las dificultades de operacionalización de FMEA en cuatro industrias que operan en el polo industrial de Manaus. El método consistió en la recolección de datos a través de entrevistas semiestruturadas con los profesionales encargados de ejecutar las herramientas de estas organizaciones, organizadas y analizadas con técnicas semánticas y de análisis de contenido. Los resultados mostraron que la herramienta está operativa en cinco etapas principales. Las dificultades encontradas se deben a la naturaleza humana, como la dificultad para trabajar en equipo y el compromiso de sus miembros, y metodológicas, como el manejo de formularios de control y análisis, actualización periódica de datos e información.

La conclusión presentada es que la complejidad de la herramienta se puede reducir si se utilizan mecanismos digitales y electrónicos en su funcionamiento.

Palabras clave: FMEA; Dificultades en la aplicación; Polo industrial de Manaus; Análisis de fallas; Herramienta de calidad.

1. Introduction

Organizations are constantly looking to improve their products and operations processes (Wlazlak, Säfsten & Hilletoft, 2019; Amrina & Lubis, 2017; Olalere et al., 2016). Both the growing demands of customers and the challenges of continuous improvement of their internal processes lead organizations to propose these efforts, resulting in practical productivity gains. Through these procedures, new production procedures and instruments are developed, with particular attention to those that make it possible to identify product flaws before they are directed to their distribution chains.

Organizations of all types create and perfect their procedures and tools suitable for their specific purposes to pursue continuous improvement. These tools are linked to the acquisition of quality. Quality is conformity between what customers want and what is effectively delivered to them. In this particular aspect, the Failure Mode and Effect Analysis (FMEA) emerges as a robust tool capable of providing high-quality results. However, given the complexity of the tool and its operation, few studies focus on understanding these difficulties of putting it into practice.

This study aimed to analyze the difficulties of operationalization of FMEA in the industries of the industrial pole of Manaus. The intention was to identify these difficulties and create a possible classification of them based on semantic fields. Therefore, the survey method was made operational with a research protocol that had its data collection instrument in the semi-structured interview. Semantic and content analyzes helped to generate the results presented here.

2. FMEA: Conceptual and Processual Aspects

The literature review showed that FMEA is a quality tool (Fattahi & Khalilzadeth, 2018; He et al., 2020; Guinon et al., 2020; Maisano, Franceschini & Antonelli, 2020; Menezes, 2020). This perception is a type of instrument that can be used on a particular object to provoke a previously defined result. Therefore, as a tool, FMEA aims to detect flaws and non-conformities in products and services with the primary objective that these products and services are within previous quality standards. The understanding is that with the use of FMEA, possible flaws, errors, and non-conformities can be detected in time to be appropriately rectified, repaired, and conformed to the attributes related to them.

FMEA is also seen as a method (Rizkya et al., 2019; Nouredine et al., 2007; Peeters, Basten & Tinga, 2018; Mikulak, Mcdermott & Beauregard, 2017). It is designated as the set of steps used to reach a final result. As a method, the FMEA is a means of ordering the analysis action to understand and analyze all possible chances of failure in a process and, as a consequence, to obtain undesirable effects. From this analysis, it is possible to identify possible failure modes, thus promoting solutions that minimize the potential cause.

Methodology pointed out in Santos, and Carneiro Neto's (2018) studies and Baynal, Sari, and Akpinar's (2018) is semantically intrinsic to the method. Here, the definition of methodology is the study of methods. The methodology aims to capture and analyze the various methods' characteristics, evaluate their capabilities, potential, limitations, and criticize their use implications. Based on the methodology concept, we have the FMEA to analyze and discuss all methods to identify indicators to control the process better.

The FMEA perspective as an approach is understood and handled (Maggiull et al., 2020). More abruptly, the approach refers to the form of contact with specific content. It is possible, for example, to take a systemic, global approach, seeking to understand the whole so that, from then on, know its parts, or conversely, contacting the parts to, in reverse, know the whole. The different FMEA approaches vary following the intended objectives.

The procedure, found in the study by Latinovic et al. (2020)) and technical, in the research by Liu et al. (2019), were the equivalence terms that had fewer references but that are linked to the ideas of tools and method. This connection means that the different perceptions are part of the same semantic field. For example, methodology, procedure, and technique are related to how something is done, commonly called a method. The approach is a term that designates a specific way of dealing and dealing with something closely related, therefore, both to the method's idea and a tool. Determination and integration are part of the methodological art by requiring knowledge and skills from the subject to integrate seemingly irreconcilable aspects of reality based on appropriate procedures and techniques.

For this study, when discussing FMEA, the central idea intended to be transmitted is the method. This term is equivalent to the idea that a series of activities are to be developed using certain procedures, techniques, and specific tools, all integrated into each step of the process. Method, therefore, is the path taken by FMEA to analyze the risks and the reliability of the production process. This choice was because most of the literature covers this semantic field (method, methodology, procedure, technique, and approach).

2.1 FMEA attributes

The literature shows that the most frequent attribute of FMEA is risk analysis (Latinovic et al., 2020; Santos & Carneiro Neto, 2018; He et al., 2020; Peeters et al., 2018; Mikulak et al., 2017; Fattahi & Khalilzadeh, 2018). Risk analysis is a technical study that aims to identify and understand the possible non-conformities that may happen, taking into account some parameters, such as objectives, internal controls, and operational processes. For FMEA, the risk analysis attribute is a process whose mapping can be carried out based on five steps to identify, define, measure, control, and improve the variables' performance, according to the risks previously analyzed. This procedure allows you to fill in the FMEA matrix.

One of the purposes of FMEA is to reduce failures (Menezes, 2020; Guinon, 2020; Santos & Carneiro Neto, 2018; Noureddine et al., 2007). It is essential to understand that failure and defect are related but distinct concepts. The failure occurs when a system fails to perform its function, while the defect occurs when a component does not meet a defined, measurable technical specification. Through the FMEA, it is possible to carry out previous simulations that identify the probabilities of one and the other. Based on these probabilities, production analysts can run specific tests to confirm or not the possibilities. If confirmed, actions can be directed to reduce or even eliminate them.

The reliability analysis was pointed out by Rizkya et al. (2019), Liu et al. (2019), Maisano et al. (2020), and Guinon (2020) as one of the attributes of the FMEA. The objective of reliability is to determine the probability of failure, considering the variables of the problem. For example, with the FMEA form application, it is possible to have more multidisciplinary knowledge about the process, giving greater visibility to the failure modes and the impact of the failure. This procedure makes it possible to create an analysis reducing the likelihood of errors, adding more excellent reliability to the process. With prior knowledge of what may not work or not work correctly, production analysts can act, leading you to all stages of the production process to generate quality components and products.

2.2 Operational aspects of FMEA

Process evaluation consists of seeking knowledge of the functioning of each stage of the process, from entry, transformation, and exit (Baynal et al., 2018). Through this procedure, opportunities for improvement can be identified, making the process more efficient and reliable. For this reason, when starting to fill in the FMEA form, one of the prerequisites is the process mapping, followed by the identification, detection, and calculation of the risk priority number (NPR), the junction of these steps configures an assessment of the process. Table 1 summarizes these findings.

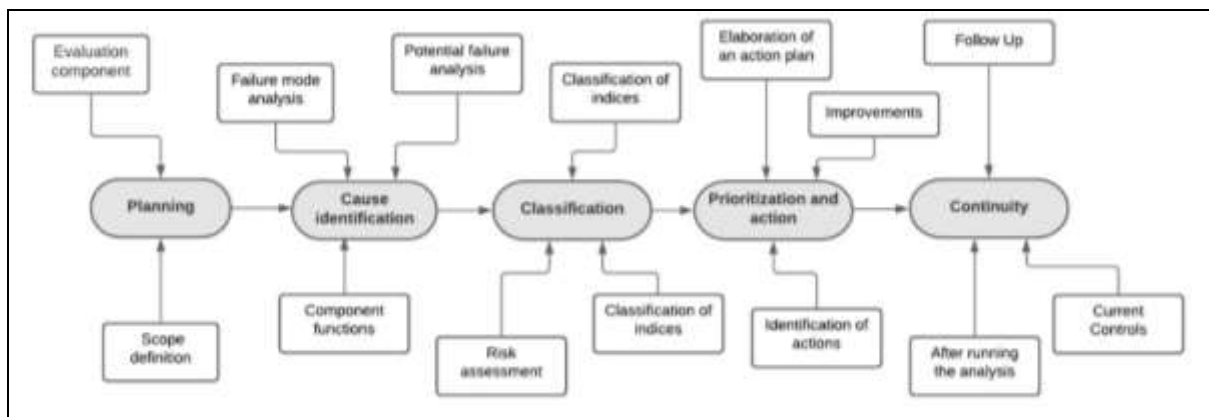
Table 1. Summary of FMEA attributes.

Attributes	Authors
Risk analysis	Latinovic et al. (2020); Santos & Carneiro Neto (2018); He et al (2020); Peeters, Basten & Tinga (2018); Mikulak et al. (2017); Fattahi & Khalilzadeh (2018).
Failure Reduction	Menezes (2020); Guinon (2020); Santos & Carneiro Neto (2018); Noureddine et al. (2007); Maggiuli et al. (2020)
Reliability analysis	Rizkya et al. (2019); Liu et al. (2019); Maisano et al. (2020); Guinon (2020).
Process Evaluation	Baynal et al. (2018).

Source: Authors.

These four attributes of FMEA pointed out by the literature present a logical scheme. It all starts with risk analysis, a procedure that aims to identify the possibilities of something not going as expected at each stage of the production process. Then, the possibility of each stage presenting risks is calculated by measuring the reliability (which is the degree to which each stage will be able to present the same performances continuously) of each one of them. Based on the reliability matrix, those steps with the highest probability of occurrences are chosen to analyze the risks further and take action, improving it. These three procedures represent a way of evaluating the production process. Figure 1 shows all the FMEA application steps.

Figure 1. FMEA application steps.



Source: Authors.

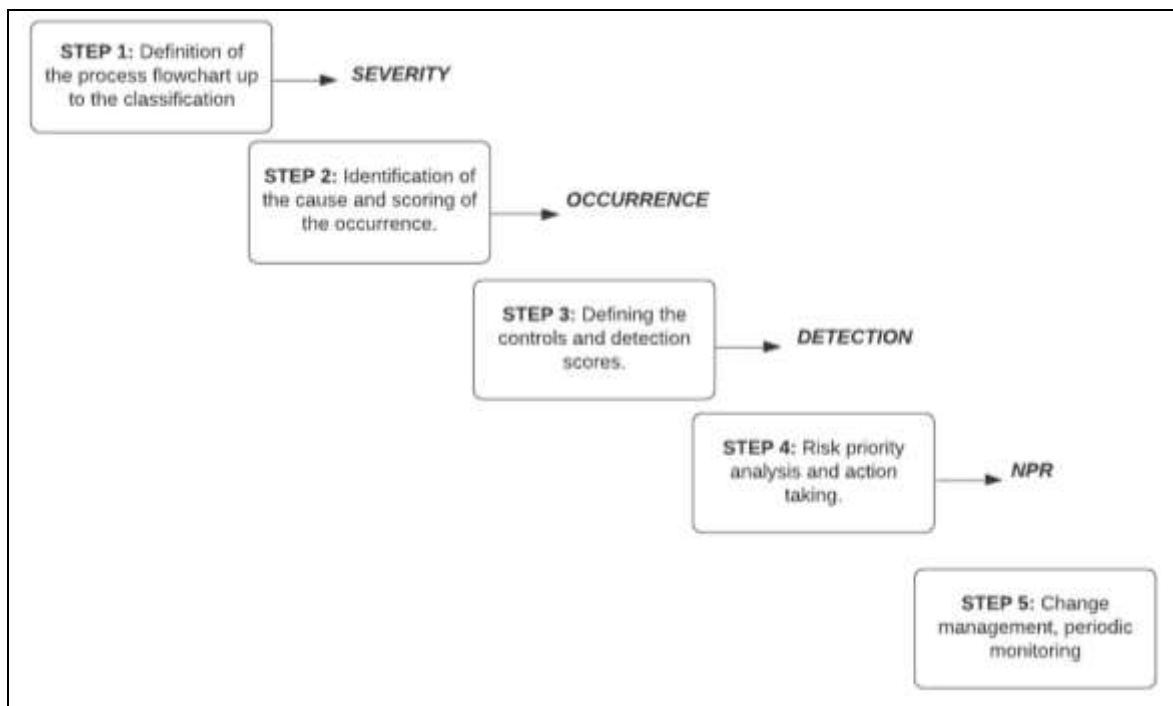
The attributes of FMEA found in the literature are risk analysis and reliability analysis to reduce failures in the production process. When identifying risks, FMEA allows attention to be directed to those who are more likely to occur, leading analysts to act to make the production process more reliable. It happens when all steps are reliable, which is the occurrence of risks within a certain acceptable standard. Since every production process contains risks, the reliability analysis allows us to point out the extent to which each of them can be considered acceptable. There are several terminologies as to the vocabulary of each stage, but they have the same functionalities. The bibliographic survey mapped the objective of each stage with the linking of its variant nomenclatures.

The first stage of operationalization is planning (Malheiro et al., 2019; Pereira, 2019). According to the literature, there are variant vocabularies, but we will use the term planning to refer to a more comprehensive context in this work. It is necessary to make a complete evaluation of the process in question, identifying and evaluating all the process's functions and requirements to start the planning s. Process mapping is a powerful tool for the strategic and more efficient planning of a

factory's operations. They can be represented in the form of flowcharts, maps, reports, or tables, visually representing many of each stage's functions, facilitating the analysis of the integration of all elements. It is important to emphasize that the mapping must represent value and activities without added value directly in the process. Those that do not modify the product are also part of the process.

The second stage identifies the causes, where a survey is made of all possible failures that a component may cause and the history of failures that have already occurred, relating to the failure's cause. Identifying the causes may seem easy, but companies may not know if their production process has failed. They end up losing the opportunity to correct errors for the customer and learn from this error. The identification must be described as an estimate in terms of something controlled or corrected, with technical grounds, before the product leaves the manufacturing zone. Moore (1997) explains the mechanisms for finding faults: checks in the process, investigation of accidents, diagnostics of machines, analysis of complaints and complaint forms, interviews and questionnaires, and use of specific methods for fault analysis.

Figure 2. Steps for executing the method.



Source: Authors.

The third step is the classification. The evaluation of the detection level stands out, where the analyst must look for ways to define controls and accurate data collection in real-time of the process. It presents the detection of the production process for the implementation of the detection control definitions. An attempt is made to estimate the current controls' ability to detect potential failure modes in consideration before the product leaves the manufacturing zone. Analytical Instrumentation is geared towards excellence in quality. It refers to relatively sophisticated equipment with the automatic and independent operation, which has the purpose of measuring one or more characteristics of a sample of the process that flows through it continuously. With the consolidation of the process control data, a detection score is assigned to define the current controls' effectiveness. The control is classified according to its power to detect the failure. The higher the score value, the lower the score. Figure 2 shows the FMEA operational steps.

The fourth step is prioritization and action. Here, the Risk Priority Number (NPR) attribution is applied, which is calculated to prioritize correction and improvement actions. The risk is calculated based on the multiplication between

severity, occurrence, and detection. Risk is defined as the variable of a hazard associated with an undesirable event's probability and the severity of its consequences. The Attribution of NPR values is estimated on a scale of 1 to 1000. The scale is evaluated. The more significant risks point to the recommendation of improvement actions. Actions are recommended to improve process controls. They must reduce severity, occurrence, or non-detection. The person responsible for the recommended action is indicated, as well as the deadline for implementation. These actions must be described in the scope effectively implemented.

The fifth and final step is continuity. After applying all the previous steps, the revision of the FMEA form is indicated. The FMEA must be revised whenever there is a change in the specific product or process. Even if there are no changes, the form must be periodically reviewed to check for potential flaws to incorporate unforeseen flaws during the form's first application, with a reassessment. Figure 2 represents the literature review's theoretical scheme to guide and guide this study's empirical surveys.

3. Research Methodology

The present study aims to analyze the main flaws in the application of FMEA in four industries that operate in the industrial pole of Manaus, in the Brazilian Amazon. It tried to answer three guiding research questions: 1) What are the demographic characteristics of FMEA operators in the factories surveyed? 2) What were the main difficulties in applying the FMEA found by the operators? 3) How did these failures happen? What are the causes of these failures?

The methodology used was qualitative, with an individual unit of analysis and departmental analysis to ensure greater depth in understanding the responses. It means that the respondents collected the data individually to explain the phenomenon's occurrence in their production department. The analysis perspective was synchronous since the study's purpose was to explain a given reality in its static sense. It was a photograph of the explained reality.

3.1 Study design

The general outline of the study can be summarized in six major stages. The first was planning, where the problem, the scope of the study, the general objective, and guiding questions were defined. The second stage focused on the literature review to recompose state of the art on FMEA, highlighting the understanding of its conceptual scope and how it is put into practice, identifying the analytical dimensions and their respective analysis categories. The third stage was performed based on the dimensions and analytical categories, whose product was the study protocol used in the research, following Silva et al. (2020). The fourth stage consisted of operationalizing the data collection strategy and transcribing the collected data to an electronic spreadsheet, called data mass, according to Nascimento-e-Silva (2012; 2020a; 2020b; 2021). The fifth step was data analysis, using semantic techniques and content analysis. The semantic technique consisted of identifying words and phrases with the same semantic meaning. The content analysis sought to understand the meaning of different phrases and words used by respondents in the context of FMEA. The interpretation of the results was the sixth and final stage, resulting from the comparison of the results obtained with the empirical data analysis with the theoretical framework of reference constructed with the literature review's aid.

3.2 Population and sample

This research population consisted of all industries operating in the industrial pole of Manaus that use FMEA in their production process. Among the 12 identified, only four consisted of participating in the study by providing data and information about their experiences and practices using this quality tool. Thus, the sampling was restricted to those organizations that agreed to participate in the study. It was impossible to investigate the phenomenon in all organizations that

use the tool, which would help in the inference effort. It was gained an opportunity to deepen knowledge since small samples allow, through semi-structured interviews, to learn about intricacies that are not possible in extensive sample studies. Thus, ten professionals from the four organizations were interviewed.

3.3 Data collection instrument and strategy

The construction of the data collection instrument followed the guidelines of Silva et al. (2020). First, a research protocol was elaborated, with all the rules and guidelines to be followed during the field research stage. A script of interviews was then elaborated containing data about the respondents, the experiences with the FMEA, and the main difficulties of implantation and continuous operation of this tool. The script was prepared based on the theoretical framework of reference, according to the recommendations of Nascimento-e-Silva (2012; 2020a; 2020b; 2021).

The research protocol foresaw that the professionals responsible for the operationalization of FMEA in their organizations would be interviewed. This rule was previously provided to organizations so that they could select the professionals to be interviewed. The organization itself scheduled the interview. The interview took place on the scheduled day and time. The interviewer asked the question and each interviewee individually provided the answers, recorded as they were answered, including errors in Portuguese. For each item in the interview script, several questions were asked so that the answer was perfectly understood.

3.4 Data organization and analysis strategy

After each interview was completed, the data obtained were organized with the help of electronic spreadsheets. Following the directions of Silva et al. (2020) and Nascimento-e-Silva (2012; 2020a; 2020b; 2021) again, a spreadsheet called the mass of data was built. The first column on the right identified the respondents, and, from it, on the left, data related to each variable and item in the interview script were placed. This procedure allowed the data on the time of experience using the tool, for example, to be placed in the same column, facilitating its handling.

After the data were organized in the data mass, they were reorganized to generate the sought answers, variable by variable, item by item. Quantitative data were organized using descriptive statistics and displayed in graphs and tables; qualitative data were subjected to semantic and content analysis, seeking to identify the similarities and differences in responses to understand their explicit and latent meanings.

3.5 Interpretation strategy and results generation

The quantitative results were interpreted around statistical representativeness. It used modal values to determine why a specific behavior was the case with the most frequent failures and differences when no behavior prevailed over the others. Knowing what is common allows us to know what is consensual, whose modal frequencies are higher. Simultaneously, what is unusual is perceived through the significant variation detected by the low fashion values. Thus, significant, moderate, or low variation detected empirically was compared with the theoretical framework predicted, and, based on this comparison, each partial result was generated.

The results based on qualitative data took similar paths but with the application of different techniques. It was possible, for example, to know what were the main flaws in the application of FMEA with the use of descriptive statistics. However, to know why these failures, the reason why they occurred, it was necessary to apply content analysis. For example, the discovery of methodological reasons as causes of failures was only necessary because the theory says that there are procedures to prepare FMEA forms. It is necessary to know each step of applying the tool. New products and processes need more methodological attention from the instrument so that the complexity of the tool needs to be reduced. When these aspects

are problematic, it appears that there are methodological problems in the application of the tool. This procedure was followed for the generation of all results structured in qualitative data.

3.6 Study limitations

Despite the methodological rigor employed, this study has at least two limitations. The first limitation concerns the small sample size. The number of respondents in each organization was increased to detect various intricacies of the phenomenon. The ideal would be that all organizations had been investigated. The second was that it took into account only one source of evidence, the semi-structured interview. If the organizations analyzed had authorized the analysis of internal documents, data and results from the two sources of evidence could be compared and further deepen the explanations about the phenomenon in these companies' reality. Anyway, as the intention was to understand the various difficulties in operationalizing the FMEA, these limitations do not compromise the results presented here.

4. Results and Discussion

To analyze the data collected, the results obtained from the field research carried out through a questionnaire with professionals in the field are presented, the answers were organized and shown graphically. In this way, it is possible to interpret the most frequent answers to have a more robust answer. Besides, it is possible to draw comparisons in the relationship of responses, according to the correspondent's profile, to raise trends to conclude.

4.1 Demographic aspects of respondents

Regarding working time with FMEA, four respondents said they had a lot of experience, and five said they had less time to use the tool. Suppose we draw a line from the age of 6 years of experience. In that case, the necessary experience is perceived in the set of respondents to provide sufficient explanations to understand this tool's application in the organizations of which they are part. It is possible to verify that when professionals are introduced to the theoretical knowledge of the FMEA tool, they tend to apply it practically in the daily life of their process. In graph 1, it can be seen that the trajectory of the Confmea line is almost entirely superimposed on the graph's path with the ApliFmea line. The FMEA is a step-based tool based on the knowledge acquired from the process and potential failures. After carrying out the study, it is necessary to apply the tool to understand its steps better, and with each realization of the FMEA matrix, new factors are raised. It is also possible to have a panoramic view of the failure mode and effect analysis.

The FMEA was defined to be answered by collaborators with knowledge and experience (Laurenti et al., 2012), thus enabling variability of product/process factors that can lead to failure mode, thus increasing the accuracy of detection and types of actions for possible failures. Based on the professional's experience, the accuracy of the failure modes and effects is more outstanding, based on the experience gained over time in that process. The follow-up that the professional acts, over time, mistakes and successes makes the professional a specialist in what he routinely experiences, thus having greater predictability of the variables work. Collaborators who have more academic knowledge also add to the robustness of the FMEA with the application and incorporation of methods and techniques found in the literature, proving them in practice.

A more significant number of male respondents showed that the engineering area's professional choice is mainly made up of men. In the engineering area, the male gender in the industry still prevails, but the number of women has been increasing. Women represented half of the professionals. As it is a quality tool, the feminine gender seems to have a more critical detailed look concerning men, making the detection of non-conformities more critically praised.

The expression "professional choice" used here means a complex and often painful process in which young men and women face an uncertain future and under intense social pressure. Often, the so-called "professional guidance" is the context in

which the discussion is located, and also, very often, the subject is approached from a psychoanalytic perspective (Lombardi, 2006). Young people experience pre-mature social pressure to choose their professional future. A survey investigated how people and organizations in the "transition" are dealing with the impact of technology, 63% of people have already changed careers, and 48% intend to change careers in the next 12 months. Of these people, 70% say they want a career more aligned with their interests and life purpose. The family factor influences the process of choosing the profession. Within it, the mothers' invisible in the students' speech, especially the engineering, stands out. When reporting the influence of family members in their choices, they are, in most cases, male (Lombardi, 2006).

Survey respondents are in the range of 27 to 52 years. It is a wide range of age differences. It was also noted that more than half of the interviewees are in their 30s. The most active industrial sector professionals working directly in engineering are in the age range between 30 and 40 years. According to the study by Laurenti, Rozenfeld and Franieck (2012), time of experience in the process/product is essential for better use of the FMEA tool. The experience time can be validated with the knowledge acquired over the years or the experience of using the FMEA tool.

Regarding the positions held in the companies in which the respondents are working during the interviews, it is possible to notice that half of the interviewees occupy the engineer position. The second-largest occupy the position of analysts. It can be seen that for the four positions mentioned, training in the engineering area can be a fundamental element. The professional who graduates as an engineer has a wide range of positions at different hierarchical levels. To stand out in the sector, it is not enough to have academic training in engineering but to implement the tools learned in a more optimized way with results, considering that each segment has its particularities. However, it needs to be correctly interpreted to suit the process in question, which varies based on the professional's profile.

It is important to emphasize that the position does not isolate the interviewee from his profession. Currently, many engineers occupy the position of analysts, as well as a consultant and the specialist. In the analyst's group, there are also professionals trained in specialized courses, but in the same area as engineers' relevance. Many companies use the versatility and multifunctional knowledge of engineering professionals to qualify for jobs with a lower salary range. Companies are increasingly looking for excellence and knowledge in all hierarchies; the increase in the number of engineering professionals trained in the last ten years has caused companies to replace technicians and analysts with trained engineers at a higher cost. Low with the professional and higher level of training of the professional.

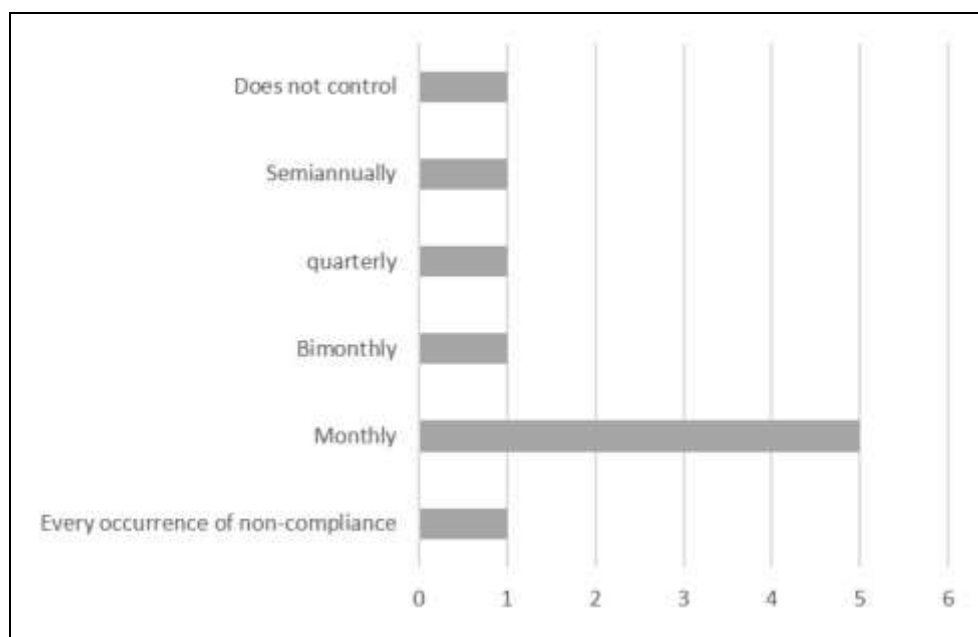
The respondents' degree of academic training can be divided into three groups: 2 with specialized training, five bachelor's degrees, and three postgraduates. The number of postgraduate professionals to obtain this training is also counted as bachelor and technology graduates based on the graph. It is possible to increase the level of professionals to specialists in quality based on the interested parties' incentives. Considering that the training as a base is already completed and the postgraduate courses have a shorter duration than an undergraduate course, obtain more qualified labor to obtain results and profit.

Most of the FMEA applicators' training is linked to a bachelor's degree in engineering and postgraduates also in the area of engineering. Quality can be defined as the set of attributes that make a good or service entirely suitable for the use for which it was designed, meeting several criteria, such as operability, safety, fault tolerance, comfort, durability, ease of maintenance, and others (Lins, 2000). Quality has become an area of complementation, with standardized tools and execution processes applied in any process regardless of direct engineering training. There is currently no baccalaureate course in quality. Still, professionals from any area can introduce themselves in quality because each form of the application is differently linked to the professional's basic training.

4.2 Difficulties in operationalizing the FMEA

Graph 1 shows the FMEA control frequency, that is, the periodicity in which the evaluation process is consulted and reapplied. Respondents pointed out the following frequencies: quarterly, half-yearly, uncontrolled, monthly, and for each occurrence of non-compliance. As shown in Graph 1, 90% of the interviewees claim to use an established frequency to control the applied FMEA. The FMEA surveys the modes and effects of possible failures. It is necessary to consult all the data collected to determine if none of the problems raised has occurred over time to prove if the actions and measures adopted are meeting the process effectively. With the consultation to the FMEA applied, it is also possible to add more information and failure modes that, perhaps, the last time it was applied was not raised, or new potential causes added to the changes inherent to the process over time.

Graph 1. Degree of frequency of FMEA control.



Source: Authors.

According to the literature, it is possible to notice no standard time interval for monitoring the FMEA form after it is applied. The periodicity can be defined according to the process that will be evaluated by the multidisciplinary group, according to the group's availability for proper application. The team and the need for the evaluated process in question need to obtain the best reliability of the process/product. Half of the interviewees present a monthly control of the FMEA applied. This periodicity contributes to the process having a more remarkable periodicity, better control, and reliability.

According to Lafraia (2001), an item's reliability is the probability that it will perform the required function, for an established time, under defined conditions of use. Reliability is generally linked to failures during the product's life and is, therefore, an aspect of engineering uncertainty. The higher the reliability, the less likely it is that a failure will occur. Since the FMEA is a tool with the proposal to reduce and minimize failures before they occur, the longer the periodicity of the control's application, the more robust the data will be in the form and makes the application increasingly efficient and effective.

As shown in Figure 3, all the difficulties presented by the respondents are implicit in two aspects. The first is the human factor: team engagement, bringing the team together, commitment, and time availability. The second is the methodological aspect: elaboration of the form, lack of knowledge of a new product and process, complexity of the tool, and periodic updating. Taking actions to reduce the difficulty of applying these two factors, the FMEA is applied more and more

efficiently by its operators. For the human factor, it is necessary to provide the necessary resources for the commitment and commitment of employees, such as infrastructure, to set aside time to focus exclusively on the preparation of the FMEA to keep the team motivated others. For methodological factors, there are several ways to approach the application steps adapted to the process's reality in question.

Figure 3. Mind map of the main difficulties in applying the FMEA.



Source: Authors.

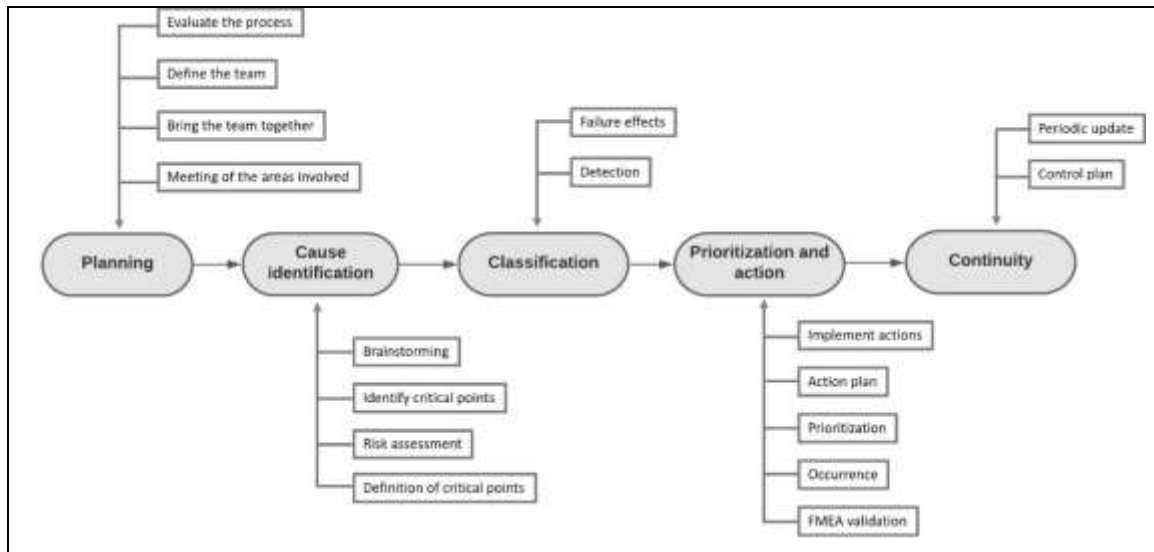
In the mental map presented in Figure 3, we can see more clearly the difficulties presented by the FMEA applicators. A series of difficulties we can point out that it is the methodology of the tool and who is applying it, which often is not raised as an important requirement in several cases. It is the human factor. According to Guerreiro (2003), the role of the human factor in organizations has been raised. It begins to be perceived as a significant differential between success and failure in achieving qualitative and quantitative results.

Some aspects related to the human factor are raised to obtain high performance from the FMEA operators. They are 1) the importance of developing managerial actions capable of providing the clarity of the objectives of the improvement of processes, 2) seek people's commitment to them, 3) provide the necessary conditions to carry out the work through teams, 4) stimulate the formation of a systemic view of reality, and 5) create a continuous flow of communication at all organizational levels, among others.

4.3 FMEA operational steps

Figure 4 shows a schematic based on the semantics of each stage applied by each interviewee. All the steps and sequences described in five steps are obtained: Planning, Identifying the cause, classification, prioritization, and action, and finally, continuity. As seen, there are several methodologies in the literature for applying the FMEA. Each of the applications serves different processes, hierarchical organization, and intervening methods so that the stages can vary. Some cases presented in which the application was limited to just three stages; in other cases, up to 6 stages were presented.

Figure 4. The flow of the FMEA steps.



Source: Authors.

Some variations were observed in several steps and types of steps. However, it was possible to verify some similarities between the majority. In graph 8, a proposal of steps of the FMEA is presented to be followed, based on what was studied in the literature and respondents' responses based on their experiences in the labor market. It was possible to reorganize the applied steps and incorporate them into one that covers the objectives of those presented in the graph above with the nomenclature assigned to them. The evaluation of the question process, such as the team's definition and the definition of the members, falls into the planning stage. The definition of critical points, the possible risks, and brainstorming are attributed to identifying the cause. The forms of detection and the effects that failures can propagate are included in the classification. After the previous steps, it is necessary to develop an action plan, prioritizing the occurrences and taking actions is applied as prioritization and action. Ensuring that the FMEA applied is controlled with the updated process variables is classified as the tool's continuity.

4.4 Discussion of results

One of the alternatives to reduce the difficulties in operationalizing the tool would be to maintain control frequency with less frequency than the one currently used. It could guarantee better accuracy both in the collection and in the analysis of the data. The greater the consistency of revisiting the form, the greater the tendency be to predict possible new occurrences of non-conformities. The revisiting of the form implies a frequent update of the possible variability in the process. It makes it possible to predict new modes and effects of failure. The consistency of the control application impacts the more excellent reliability of the results obtained. It is also worth mentioning that reliability is linked to possible failures during the execution of the process, configuring an aspect of uncertainty. The lower the probability of a failure occurring, the greater the reliability, making the application more effective.

In Mesquita's understanding (2014), FMEA is a manual method. For this reason, it depends on people for elaboration, application, and bureaucratic control. As it is an always alive tool, it is recommended that your planned actions be constantly revisited to anticipate some risks and possible failure. As the purpose of applying the tool is to increase the quality of the final product. The greater the revisiting of the form and constant monitoring of the decisions taken, the less likely it is that unforeseen failures will occur. This procedure helps to keep the control up-to-date from the incorporation of possible variables

that may arise during the production process. This constant update of the tool reduces possible doubts during the application and maintenance phases.

It was found that there are several different formats and steps for the application of FMEA in the organizations surveyed. As much as the final objective is reached, the route to reach it is presented in different formats. This variability in application modes can lead to biased results, according to the multifunctional team's interpretation that is applying the tool. These two factors are directly linked. To the knowledge of the tool, it is necessary to understand how to apply it in the production process and by whom. Those responsible for its application must constantly maintain the importance of clarity of objectives in improving the process so that all team members' commitment is obtained.

Andrade (2000) presents nine steps for the application of FMEA in systems and environmental management. Silva's model (2019) is applied in four stages in civil construction, whereas Neves et al. (2007) contain ten stages used in the hospital system. As can be seen, the number of stages has tremendous variability in the literature, depending on the application area. It leads to the realization that the number of steps must be following the methodology chosen for the application by the team that uses the tool. In this study, all the variants found in the surveyed companies' practice could be summarized in five steps: Planning, identification of the cause, classification, worsening and action, and continuity.

There is no restriction of position or hierarchy to operate the FMEA. According to the findings in Graph 4, the organizations surveyed do not distinguish between positions or academic backgrounds to compose the tool's operators. The essential requirement is that the individual is wholly and directly involved in the application process. The more diverse the multifunctional team's composition is, the greater the collection of data and information tends to be. And this is influenced by the experiences and histories of failures and errors detected and monitored. Selecting people from different hierarchical positions enriches brainstorming, group discussion, which makes use of the spontaneous contribution of ideas by all participants. It is obtained and used in the analysis of the same process. The greater the diversity, the greater the possibility of considering many possible failure modes and effects. It improves the tool's operationalization process.

Risks come in many forms and different activities. It is essential, then, that the analysis be made from the multidisciplinary debate with professionals from different areas of knowledge. It is worth remembering that there were countless problems raised. Specific technical knowledge was often necessary to understand them, as found in Ferreira and Andery's (1998) study. The greater the range of areas of activity of the FMEA application team members, the greater the types of possible failure modes and effects raised for the completion of the form. Again, this makes it possible to survey more stock options to forecast each item before impacting the process. In summary, the more diverse the team's formation, without distinction of position or hierarchy, the better the results presented tend to be because this expands the perspectives and the points of view for the understanding of the process.

5. Conclusion

This study showed that the main difficulties for applying FMEA are of human and methodological nature. To apply the tool, it is necessary for all members of the team who will apply it to understand the tool. In addition to understanding, there must also be the individual commitment of people and all aggregate areas to make the application practical. The greater the diversity, the greater the likelihood of operational difficulties occurring.

The difficulties encountered in this study occur in the following stages: a) when the team elaborates, b) makes, and c) fills out the form. The causes of these difficulties are 1) lack of knowledge of the new product or process during the introduction of new models, 2) lack of training in how to perform the correct application of the tool, 3) difficulty in maneuvering the control of the applied FMEA's and 4) periodicity inadequate to review each applied form. The human factor is, therefore, the central issue in the difficulty of application. Due to the lack of team engagement, difficulty in gathering all the

members, as they are from different hierarchies and sectors, there is no individual and collective commitment, nor the availability of professionals to dedicate themselves to the application.

It also contributes to accentuate the difficulties and misinterpretations of the stages, especially when adapting the tool to the process for which it will be used. Interpretation is nothing more than determining the precise meaning of the text. In many cases, the intermediation of those who have an easier understanding to disseminate in more transparent and more precise language understands the other members. The incorrect application occurs when sequences of established steps are not followed. There is no consolidation of each element's substeps to obtain the correct degree of importance for each item.

It is recommended that at least three studies be carried out to deepen the studies on the difficulties of applying the FMEA. The first is a case study using the proposed FMEA sequencing model in the industry using at least three evidence sources: interview, observation, and document analysis. The second proposal is to carry out a study to integrate the process capability represented in statistical measures indicating the variation rate in the process about the specifications established in the FMEA. The third is an analysis of different experiences of improvements in the elaboration of control and reliability for the FMEA.

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