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RISK MANAGEMENT APPLYING FMECA IN PHARMACEUTICAL PACKAGING PRODUCTION: IMPLEMENTATION OF ISO 15378:2017 – CASE STUDY

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The quality of primary pharmaceutical packaging materials is crucial to ensure product safety and regulatory compliance. This study aims to apply the FMECA (Failure Mode, Effects and Criticality Analysis) method to manage risks and improve the production process of pharmaceutical packaging at CENTRA MED, a company in Algeria specialised in the manufacturing of primary packaging for the pharmaceutical and medical industries. The study is part of a project to achieve certification to the ISO 15378:2017 standard. In this case, we adopted a qualitative method based on a research-action approach. We collaborated with internal stakeholders within the company to support them in designing and implementing appropriate tools. Data were collected through observation, document analysis, and interviews. As a result, based on collected data, a FMECA matrix was developed to identify and assess production risks. This enabled the implementation of corrective and preventive actions, evaluation of their effectiveness, and improved control over risks. The approach helped eliminate unacceptable risks, reduce undesirable ones, and strengthen the management of acceptable risks.In the end, the results confirmed the effectiveness of FMECA in optimizing processes and meeting quality requirements. The originality of our study lies in the fact that it fills a gap in the literature, addressing the lack of previous research on the application of FMECA in the implementation of the ISO 15378 standard. Its added value lies in the fact that it led to CENTRA MED achieving ISO 15378:2017 certification.

Keywords: **Quality; Risk Management; FMECA; ISO 15378: 2017; Pharmaceutical Packaging; CENTRA MED**

JEL Classification: **L15, L65, M11**

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1. Introduction

The growing demand for quality health products, driven by evolving scientific knowledge, requires pharmaceutical companies to implement quality management systems that incorporate risk management and full traceability of operations. The primary objective is to ensure that customers receive quality products that meet their requirements, as well as the safety standards necessary for their use. In this context, pharmaceutical industries are required to establish a structured quality system responsible for defining and implementing a quality policy within the organization. Risk management is a fundamental component of this policy, enabling the assessment and control of risks associated with various activities and requiring a systematic process for risk identification and analysis (Corine, 2017). The objective is to ensure product quality and patient safety, as well as to comply with regulations and economic constraints. Risk management methods include Failure Modes, Effects, and Criticality Analysis FMECA, a systematic analysis approach that identifies potential risks and failures in a process and implements preventive actions to minimize these risks.

This study is conducted within the framework of a certification project for CENTRA MED, an Algerian company specializing in the manufacturing of primary packaging for the pharmaceutical and medical industries, in accordance with ISO 15378:2017. This international standard outlines the specific quality management system criteria for producers of primary packaging materials for pharmaceuticals. ISO 15387:2017, which was created in accordance with ISO 9001:2015 and incorporates Good Manufacturing Practices (GMP), covers every aspect of the packaging materials' lifecycle, including design, production, control, and distribution, to ensure that they meet the stringent safety, quality, and regulatory requirements of the pharmaceutical sector. It offers an organized and risk-based framework that aids businesses in managing contamination risks, locating crucial control points, and guaranteeing traceability and uniformity in production procedures. By making sure that packaging materials do not adversely affect the quality, efficacy, or safety of pharmaceutical items, the objective is to preserve patient safety and product integrity.

The objective of this study is to conduct a FMECA method on CENTRA MED's pharmaceutical packaging production process to manage risks, thereby ensuring compliance with ISO 15378:2017 requirements. Because the FMECA approach is a flexible and broadly applicable risk management technique, we choose to employ it. This analytical method is very helpful when trying to methodically discover, assess, and reduce possible risks because it can be tailored to a variety of situations and procedures. Additionally, the host company made it clear that this method had to be used in order to meet the requirements of the applicable standard. FMECA was a reasonable and strategic choice for our research because of the connection between the organization's expectations and the advantages it provides.

The research question was formulated as follows: "How can the FMECA method be applied to manage production risks at CENTRA MED?" To address this research question, an Action research (AR) was conducted using qualitative data collection methods. This approach was deemed particularly suitable for achieving the research objectives.

This paper is structured into five distinct sections: following a review of the literature and relevant prior studies, the project scope is defined, the research methodology is outlined, and the results are presented and then discussed.

2. Literature Review

Pharmaceutical industries implement a quality management system to ensure that their products meet the required standards of quality and safety for consumer use. Risk management is an essential component of this system (Khomsi, El Marnissi, El Harti, & Allou, 2019). Among the systematic tools and techniques for preventing potential issues, the FMECA method is widely used.

FMECA method highlights the critical points of a system to either eliminate them or implement preventive measures (Chapeaucou, 2000; Mougin, 2003). It is an inductive approach used to analyze system reliability (Trehel, 2015). It starts with identifying failures to then study the root causes and effects on the system (Severac, 2022).

FMECA method identifies failure modes, prioritizes them based on a Criticality Index (CI) calculated by multiplying their frequency, severity, and detectability scores, and assesses the impact of potential safety measures as well as the effect of improvements on CI reduction (Kaestli, 2014). This method has been applied in various domains, including high-risk industries such as aviation and the nuclear sector, and has also been used for pharmaceutical risk analysis. Indeed, FMECA method is considered a total quality tool adaptable to any sector (Recht, 1996). For (Thellier, 2019), FMECA is founded on fundamental principles. These include the simplification of analysis through the decomposition of a process into distinct stages, the anticipation and mitigation of adverse events, risk evaluation based on the causal relationship between failure mode causes and their effects, and the quantitative assessment of risk to establish prioritization and ensure its reduction to an acceptable threshold.

(Hurtrel, Beretz, Renard, & Hutt, 2012) consider FMECA to be an effective and relatively simple method to implement. Its application requires multiple brainstorming sessions, as it relies on a multidisciplinary approach and the active participation of individuals directly involved in the system. This collaborative process fosters knowledge sharing and collective awareness of operational realities. (El Marnissi & al., 2020) emphasize that the effectiveness of FMECA largely depends on the pooling of information and the establishment of a multidisciplinary and multifunctional working group, which may require training and methodological support. The

authors highlight that the application of this method in the pharmaceutical sector necessitates periodic execution, given the frequent changes affecting the industry.

Despite its advantages, the FMECA method may be regarded as inherently subjective, as it relies on the evaluation of specific criteria derived from expert judgment and group discussions rather than objective data from empirical feedback (Hurtrel, Beretz, Renard, & Hutt, 2012; Trehel, 2015). (Ledoux, 2014) further identified limitations associated with this approach, notably the potential incompleteness in the identification of failure modes. Consequently, FMECA does not provide a comprehensive, cross-sectional analysis of potential failures and their repercussions. This limitation necessitates the implementation of complementary methodologies, such as fault tree analysis or reliability diagrams.

Scientific research on the application of ISO 15378:2017 are limited due to its specialization in the field of primary packaging materials for the pharmaceutical industry, which limits its scope and academic appeal. Furthermore, data sharing and the advancement of research are impeded by the technical and operational nature of the standard as well as the confidentiality inherent in this industry. Additionally, there's a genuine research gap because ISO 15378:2017 elicits minimal scholarly interest, in contrast to more universal standards like ISO 9001, ISO 14001 and others. The absence of case studies, comparative analyses, and integration models, particularly in Algeria, highlights this gap and offers a useful chance to investigate its use, impact, and compatibility with other quality management frameworks. It is within this context that our study intervenes, offering a novel contribution both from a practical and academic perspective.

This study is the first in Algeria to examine the application of FMECA in ensuring the compliance of with the ISO 15378:2017 requirements. Drawing on the experience of CENTRA MED, the second company in Algeria to obtain this certification, it demonstrates the effectiveness of this approach in identifying and controlling risks throughout the production process. The findings highlight the impact of FMECA on optimizing industrial processes, reducing nonconformities, and fostering continuous quality improvement. Furthermore, the study underscores the critical role of standardization, training, and collaboration in maintaining sustainable compliance with international requirements. Beyond serving as a model for other companies in the sector, this research opens avenues for integrating additional quality tools to strengthen risk management and enhance industrial performance.

3. Research Background and Scope

This study was conducted at CENTRAMED, a company founded in 2020 in Sétif, a wilaya in eastern Algeria. CENTRAMED specializes in the manufacture of plastic primary packaging materials, primarily for the pharmaceutical and medical industries. The company offers a diverse range of standard products, including pharmaceutical bottles, caps, pods, and spoons. In addition to its standard offerings, it provides customized solutions, producing plastic packaging tailored to specific customer

needs and shaping medical devices made of plastic. Among its flagship products are blood glucose test strip containers, pharmaceutical pill containers, pods, and spoons.

CENTRAMED is committed to obtaining ISO 15378:2017 certification, a standard that defines specific quality requirements for manufacturers of pharmaceutical primary packaging. This strategic initiative aims to reinforce its commitment to quality, product safety, and regulatory compliance. To achieve this, the company has enlisted the expertise of a consultant specialized in management systems to support the project team and the certification process, providing guidance and technical assistance throughout the project.

To define the scope of the study and establish the objectives of the analysis, WH-questions were used. This approach enables a comprehensive identification of a given event by addressing the following key questions: What? Who? Where? When? How? How many? Why?

Table 1. Project scope

Question	Response
What	The Implementation of the FMECA Method as Part of the ISO 15378:2017 Standard Implementation
Who	Ourselves (Intern) QHSE Manager (Quality, Health, Safety, and Environment) Management Systems Consultant Production Manager Quality Control Manager Quality Assurance Manager
Where	CENTRAMED Pharmaceutical Primary Packaging Company Primary Packaging Manufacturing (Production) Process
When	Internship period (January-May 2023)
How	Action Research (AR)
Why	Manage risks and meet ISO 15378:2017 requirements

Source: Own

4. Research Methodology

4.1 Type of search

The research conducted in this study is Action Research (AR), which is qualitative in nature (Catroux, 2002). It is defined as “a participatory process that integrates theory and practice to develop solutions relevant to human and organizational challenges” (Reason, 2008)

Action Research (AR) is an approach aimed at driving organizational change and improvement through collaboration with internal stakeholders. The researcher plays a crucial role in assisting

these actors in understanding and resolving concrete operational challenges (Belimane, 2022). It is important to highlight that, as an intern at CENTRAMED, we were actively involved in this project, not merely as observers, but as stakeholders contributing directly to the implementation of the ISO 15378 standard, particularly by integrating the FMECA tool into the production process. We collaborated closely with both the host company and the consulting firm supporting them in the deployment of the ISO 15378 standard; under the supervision of the QHSE Manager and the Management Systems Consultant, we conducted an analysis of production milestones, identified potential risks, and proposed corrective actions to mitigate failures. Additionally, our role involved assessing risk criticality to ensure compliance and uphold the quality of pharmaceutical products.

Thus, action research was chosen as it was deemed appropriate for the implementation of the ISO 15378:2017 standard. The literature review revealed that qualitative methods are widely used in similar research. Additionally, action research was found to be particularly relevant for improving practices and performance within organizations. This approach enabled an understanding of and active participation in an improvement process. Collaboration was established with internal business stakeholders to support them in the design and implementation of appropriate tools.

4.2 Data collection methods

Document analysis, participant observation, and semi-structured interviews were employed as data collection methods. The table below provides a definition of each method and explains its implementation.

Table 2. Data Collection Methods

Methods	Description	Process
Document analysis	A systematic review of written materials. It requires the analysis and interpretation of data in order to derive meaning, gain understanding, and acquire empirical knowledge (Bowen, 2009)	The internal company documents were reviewed, including: Production history (batch records/ sheets); Nonconformities (discrepancy sheets); Customer complaints; Quality control reports.
Observation	Observational data collection involves the direct observation of processes or behaviors within an organization over a limited period. This method provides factual data, which is less subject to interpretation than verbal data (Thietart & al., 2017)	During the factory observation, the production steps were carefully analyzed, and risks and critical points in the manufacturing process of pharmaceutical primary packaging were identified.

Methods	Description	Process
Semi-structured interviews	The interview process is used to collect verbal information for further analysis (...). The semi-structured interview combines open-ended questions, which encourage open discussion, and closed-ended questions, which elicit specific information, thereby balancing precision with the exploration of relevant topics (Thietart & al., 2017);	Five (5) semi-structured interviews were conducted, each lasting between 2 and 6 hours, focusing on specific questions related to the different steps of the manufacturing process. The interviewed population included: Management Systems Consultant QHSE Manager Production Manager Quality Control Manager Quality Assurance Manager The objective of these interviews was to gather sufficient data on the production process in order to effectively carry out the different stages of risk management: identification, prioritization, treatment, and monitoring. This information was also essential for the completion of the FMECA Matrix.

Source: Own

4.3 Data Analysis and Processing

The data collected through the three research methods enabled the development of the FMECA matrix in a structured table format to identify and assess potential risks in the production process. This table includes process steps, their functions, failure modes, effects, causes, frequencies, and detection controls, as well as the risk assessment (S*F*D). Additionally, it proposes corrective actions, with designated timelines and responsibilities, to mitigate or eliminate these risks.

Table 3. Matrix Structure

Operation / Activities	Position	Failure Mode	Potential Effects	Severity	Probable Causes of Defects	Frequency	Detection Control	Detection	S*F*D	Action Plan	Timing	Responsible	Severity	Frequency	Detection	S*F*D

Source: CENTRA MED Internal Document

For the evaluation of practices, the following indicators and scales were used:

- Frequency (F): The occurrence rate of the failure mode;
- Detectability (D): The probability that the failure will not be detected;
- Severity (S): The impact of the failure on the customer or end user.

Scoring grids for each evaluation criterion were initially proposed by the management systems consultant and subsequently discussed with the other managers to ensure a consistent and objective numerical assessment. This approach aimed to facilitate a more accurate estimation of failure criticality. The final scoring grids adopted for each criterion are presented below:

Table 4. Severity assessment score

Score	Assessment	Detail
200	Catastrophic	Nonconforming packaging integrity and presence of contaminants that may affect the quality of the pharmaceutical product
100	Critical	Deviation from specifications affecting packaging integrity Compromised product cleanliness
50	Serious	Deficiency compared to CQA specifications without affecting packaging integrity
25	Minor	Cosmetic defect that is noticeable and bothersome to the end consumer
5	Negligible	Cosmetic defect (not visible to the end consumer)

Source: CENTRA MED Internal Document

Table 5. Frequency assessment score

Score	Assessment	Detail
5	Very common	Occurs daily under normal conditions of use
4	Common	Occurs monthly under normal conditions of use
3	Likely	Occurs once or twice a year under normal conditions of use
2	Rare	Occurs once a year under normal conditions of use
1	Very rare	Occurrence has never been observed, except under certain special conditions

Source: CENTRA MED Internal Document

Table 6. Detection assessment score

Score	Assessment	Detail
5	Undetectable	Impossible to predict when it will occur
4	Difficult to detect	Difficult to anticipate its occurrence
3	Detectable	Detectable only after an action is taken
2	Easily detectable	Easily detectable once actions are implemented
1	Obvious	Detectable without any measurement

Source: CENTRA MED Internal Document

It is important to precise that the risk criteria evaluation was conducted in close collaboration with the company's management team. The decision to use a severity rating scale up to 200 was made internally, with the aim of achieving a more detailed and nuanced assessment of risk severity.

This approach allowed for a more precise analysis, tailored to the specific context and criticality levels of the company's production processes.

The scoring of the estimation criteria enabled the calculation of the Risk Priority Number (RPN), also referred to as the Criticality Index (CI), using the following formula: **CI=S×F×D**

The CI is the product of the scores assigned to the Severity (S), Frequency (F), and Detectability (D) of a given failure. It helps determine the priority level of the identified failure modes, answering the question: Which issues require the most urgent attention?

Table 7. Priority scale

Risk Level Assessed	Definition of Risk	Acceptability
≤150	Negligible risk	Acceptable without any action
>150 and ≤450	Acceptable risk	Acceptable with actions taken
>450 and ≤1200	Adverse risk	Not acceptable – Risk control measures to be taken in the medium term
>1200	Unacceptable risk	Not acceptable – Emergency risk control measures

Source: CENTRA MED Internal Document

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5. Implementation process & Results

The findings from the interviews, observations, and document analysis were instrumental in developing a comprehensive and structured FMECA matrix.

In this section, we present the steps followed in carrying out the project, as well as the main results obtained.

5.1. Steps of the Implementation Process

To develop the FMECA matrix, we adopted a seven-step approach:

Step 1: Establishing the Work Team

The analysis team was composed of the following members: Ourselves, Management Systems Consultant, QHSE Manager, Production Manager, Quality Assurance Manager, Quality Control Manager. The objective to be achieved was to analyze production process risks and develop an FMECA matrix.

Stage 2: Conducting a Functional Analysis

After carefully observing the production processes during our visits, a functional analysis was performed (Table 8). In addition, the production procedure was reviewed in detail to better understand the process flow. This approach provided a deep understanding of each process step and its role in achieving production goals.

Table 8. Functional Analysis of the Production Process

Steps	Description
1. Raw Material Receipt	Receive raw materials necessary for the production of various types of packaging; Verify raw material conformity to specifications;
2. Preparation of Rooms and Machines	Room Cleaning & Disinfection: Before starting production, production rooms must be cleaned and disinfected to remove contaminants;
	Preparation of Machines: Cleaning, disinfection, and configuration of machines prior to the commencement of production;
3. Raw Material Preparation	Prepare raw materials needed for production according to specifications which involves weighing, mixing ingredients, and other preparation processes;
4. Start of Production	Manufacture of pill box vials, blood collection tubes, and stoppers: Injection of plastic for producing vials, blood tubes, and stoppers in the injection room;
	Conduct quality control of manufactured vials, tubes, and caps;
5. Filling the Stoppers with Desiccant	Add desiccant to stoppers in the filling room. This step applies specifically to stoppers for products requiring desiccant to preserve their quality; Perform quality control of the filled caps;
6. Product Packaging	Conduct quality control of packaged products to ensure compliance with standards and specifications; Store products under appropriate conditions to preserve their quality.

Source: Own

Step 3: Qualitative Investigation of Failures (Data Collection)

First, interviews were conducted with the managers involved in the production process. These interviews provided valuable insights into potential failures and associated risks. Next, a direct observation of the production process was performed, which allowed for the detection of potential failures that may not have been identified during the interviews. The observation also facilitated a deeper understanding of the process and an analysis of its critical points. Finally, internal documents were analyzed to identify past failures and recurring issues.

Through this combined approach, satisfactory results were achieved for the qualitative failure investigation. Detailed information on potential failures, probable causes, and associated effects or consequences was collected. These results served as a basis for taking preventive actions and implementing corrective measures to improve the quality and reliability of the production process.

Step 4: Quantitative Investigation of Failures

After identifying failures, their Criticality Index (CI) was evaluated based on their Frequency (F), Detectability (D), and Severity (S) (Tables 4, 5 & 6).

Step 5: Prioritization

Once the CI of each failure mode was determined, we classified them to identify those requiring priority corrective or preventive actions (Table 7).

Step 6: Investigation of Preventive/Corrective Actions

At this stage, the team was committed to managing the identified risks and reducing the CI by implementing targeted measures. The objective was to decrease both the probability of failure occurrence and failure detection.

In accordance with risk management principles, corrective and preventive actions were proposed based on the estimated risk level for each identified failure. These proposals were then submitted for approval by the QHSE Manager.

It is important to note that the corrective actions were suggested by the project team through interviews conducted. Team members actively contributed to identifying necessary measures to correct failures and prevent recurrence, leveraging their expertise and diverse perspectives in the decision-making process.

The proposed actions were specifically designed to address the root causes of identified failures. These included: Process improvements; Enhanced quality controls; Staff training; Implementation of follow-up procedures, etc. Once approved by the QHSE manager, these preventive and corrective actions were implemented. They played a critical role in risk reduction and the overall improvement of the production process. Additionally, the effectiveness of these actions was continuously monitored to ensure their relevance and efficiency in failure prevention.

Step 7: Follow-up on Actions and Re-evaluation of Criticality

For each identified failure mode, a new CI was calculated using the same methodology as before but incorporating the effects of the implemented corrective and preventive actions. The objective

of this re-evaluation was to assess the impact of these actions on risk reduction and overall process improvement.

5.2. Results Achieved

Through the various data collection methods used, we identified the following:

- 26 failure modes, each with adverse effects;
- 63 potential causes that can impact these failure modes;
- 25 control techniques to detect these failures.

After calculating and evaluating the CI for each failure mode, we obtained the following results (Table 9):

Table 9. Ranking of Risks according to their CI

Risk Level Assessed	Number of Risk
≤150	1 Negligible risk
>150 and ≤450	7 Acceptable risk
>450 and ≤1200	8 Adverse risk
>1200	11 Unacceptable risk

Source: Own

Once the criticality of these failure modes was calculated, an action plan was immediately implemented by assigning responsibilities to ensure its timely execution. A total of 78 recommendations for preventive and corrective actions were formulated, considering that certain actions could be commonly applied to different steps of the production process. These recommendations were proposed on 10/03/2023 with primary objective to reduce criticality and effectively control risks within the production process.

In addition, a plan revision date was scheduled for 05/05/2023. This review allowed for an assessment of the effectiveness of the measures implemented and the identification of any necessary modifications or adjustments. During the review, we obtained the following results:

- A total of 65 actions have been implemented, some of which apply to multiple steps in the production process;
- 4 actions had already been in place before being recommended;
- 9 actions had not yet been carried out at the time of the review.

These results provide insight into the progress made in implementing the recommended preventive and corrective actions while highlighting the additional efforts needed to achieve the set objectives.

After reviewing and monitoring the action plan recommendations, the criticality of failure modes was re-evaluated. This reassessment was conducted in consultation with the project team members responsible for implementation. As a result, we have reorganized the failure modes based on their CI as follows:

Table 10. Ranking of Risks according to new CI

Risk Level Assessed	Number of Risk
≤150	9 Negligible risk
>150 and ≤450	17 Acceptable risk
>450 and ≤1200	2 Adverse risk
>1200	0 Unacceptable risk

Source: Own

This re-evaluation provided an updated view of the criticality of failure modes, enabling better prioritization and the implementation of appropriate actions for effective risk control.

The table below (table 11) compares the risk classification based on their criticality before and after the implementation of the action plan.

Table 11. Comparing Risks Classification (Before/After)

Risk Level Assessed	Before Action Plan	After Action Plan
≤150	1 risk	9 risk
>150 and ≤450	7 risks	17 risks
>450 and ≤1200	8 risks	2 risks
>1200	11 risks	0 risk

Source: Own

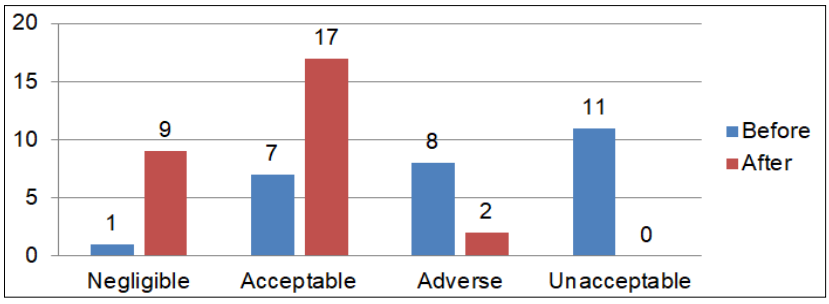

Figure 1. Comparing Risks Classification

Source: Own

Table 12 represents a part of the FMEA analysis we conducted. It clearly demonstrates that the implementation of risk-reduction actions led to a significant decrease in risk levels, bringing them down to thresholds considered acceptable by the organization.

Table 12. A part of the FMECA Matrix

Operation / Activities	Position	Failure Mode	Potential Effects	Severity	Probable Causes of Defects	Frequency	Detection Control	Detection	S*F*D	Action Plan	Timing	Responsible	Severity	Frequency	Detection	S*F*D
Prepare rooms and machines	Temperature and/ or HR measurement	Unstable/ Incorrect measurements	Errors in final product quality, additional costs.	50	Low battery	3	Quality control, observations from production personnel.	4	600	System status test every month	04/02/2023	Logistics Manager / Quality Control Manager	50	1	2	100
		Problems logging data	Errors in final product quality, additional costs.	50	Connection issues	3	Quality control, observations, data review.	4	600				50	1	1	50
		Wrong Data	Errors in final product quality, additional costs.	50	Calibration issues	3	Quality Control	4	600	Adhere to calibration schedule			50	1	1	50
		Error/ Missing measurement	Errors in final product quality, additional costs, production delays.	50	T/HR are outside the sensor specifications	3	Quality control, observation	3	450	Never use sensors outside their measuring ranges			50	1	2	100

Source: Own

6. Discussion

According to ISO 15378, risk control is a fundamental requirement to ensure the quality and safety of products intended for customers. (Khomsi, El Marnissi, El Harti, & Allou, 2019) emphasized that the pharmaceutical industry implements a quality management system to

ensure the required product quality and safety, with risk management and its tools playing an essential role.

In this study, FMECA was employed to assess risks, and the results confirmed its effectiveness. Qualitative and quantitative analyses were conducted to reduce the probability of failure occurrence and improve failure detection in the manufacturing process. FMECA not only identified the critical stages of the production process but also recorded a significant number of failure modes.

The development of the FMECA matrix for the manufacturing process followed the steps recommended by (Kaestli, 2014). These steps enabled the calculation of the Criticality Index (CI) by multiplying the severity, occurrence, and detection ratings. This rigorous approach yielded reliable and expected results.

The conclusions of (El Marnissi & al., 2020), consistent with those of (Hurtrel, Beretz, Renard, & Hutt, 2012), indicate that FMECA's effectiveness largely depends on information sharing and the formation of a multidisciplinary and multifunctional working group, sometimes requiring training and methodological support. This approach was adopted in the initial phase of FMECA implementation in this study, with the formation of a working group and awareness-raising about the project's significance.

Calculating the CI facilitated the identification of the most critical failures and high-risk areas in the manufacturing process, providing a solid basis for prioritizing corrective and preventive actions to mitigate risks and improve process reliability.

Applying FMECA identified various failure modes in the production process, and the obtained results were relevant due to effective communication among the concerned stakeholders. However, contrary to the conclusions of (Ledoux, 2014), who suggested that this tool does not provide a transversal view of potential failures and their consequences, the present study did not necessitate the use of complementary tools such as fault trees or reliability diagrams, although their inclusion could enrich the analysis.

Finally, these findings align with the recommendations of (Thellier, 2019) regarding the application of FMECA. The adopted approach enabled the identification, evaluation, and management of risks by decomposing the process into different stages, anticipating adverse events, and assessing the causes and effects of failure modes. This methodology facilitated risk prioritization and the implementation of appropriate preventive and corrective measures. The fundamental principles of this approach were fully integrated into the identification, evaluation, and management of manufacturing process risks, thereby contributing to the continuous improvement of product quality and safety.

As highlighted in the literature review, there is a notable gap in the existing literature concerning the use of FMECA as a risk management tool, specifically within the context of certification to the

ISO 15378 standard. On the one hand, this gave originality to our study and, on the other, made it difficult to discuss our results in comparison with previous studies. Although there is an abundance of literature on FMECA in general, the highly specific and critical nature of pharmaceutical production, an area directly tied to human health, led us to consider that comparing our results with those obtained in other less sensitive sectors seemed inappropriate.

7. Conclusion

The risk analysis conducted as part of our study aligns with the implementation of the ISO 15378:2017 standard at the CENTRA MED pharmaceutical site. This methodology can be applied to various activity processes within the pharmaceutical industry. Although it requires significant time and effort to gather the necessary information, it offers long-term benefits in terms of time savings and financial efficiency for the company.

The results obtained in this study are relevant and clearly demonstrate the contribution of the FMECA methodology to risk management at CENTRAMED. Indeed, following the implementation of the action plan, the risk classification was modified, with the elimination of risks exceeding 1,200 and a reduction in the number of risks with criticality between 450 and 1,200 from 8 to 2. These managed risks were in fact reclassified, which explains the observed increase in the number of risks with criticality between 150 and 450, as well as in those with criticality below or equal to 150.

We are delighted to share that CENTRA MED successfully achieved ISO 15378:2017 certification (Appendix) with no non conformities identified. Our significant contribution to this project was the implementation of FMECA in the company's production process, which is also recognized as a strong point. The implementation of FMECA played a key role in CENTRA MED's ISO 15378 certification process. This proactive approach resulted in enhanced control of production risks and compliance with the standard requirements.

Although our study had limitations due to time constraints, it nonetheless contributed to a better understanding of the risks in the production process. It is recommended to continue this work and allocate more time for a more comprehensive risk assessment to ensure effective and continuous management of product safety and quality within the company.

Finally, our study will serve as a reference for pharmaceutical industries, providing them with a detailed approach to better manage their risks. It can also be useful for other companies from different sectors, provided that necessary adaptations are made to their specific contexts.

Data Availability Statement

The study was conducted as part of an agreement between the National Higher School of Management and Centra Med, a company specializing in pharmaceutical packaging, for the preparation of a master's thesis in the field of "Quality Management." This thesis was improved and transformed, after its defense, into a scientific article. It is worth noting that the work led to

Centra Med obtaining ISO 15378 certification, with the AMDEC analysis (which can be obtained by request) being one of the positive aspects of this certification. The data are available in the library of the National Higher School of Management.

Note

Thanks to this work, Centra Med became the first company in Algeria who obtained the ISO 15378:2017 certificate.

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