Analysis of Equipments' Maintenance in a Production Line: Corrective and Preventive Approach: A Case Study in a Pharmaceuthical Industry

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This study aims to underscore the importance of effective maintenance management within the pharmaceutical industry. This is achieved by meticulously analyzing available data from a production filling line and leveraging real-world data from a public pharmaceutical facility. The research provides cogent recommendations to catalyze substantive improvements in maintenance management practices. The case study draws upon data from the service order management software employed in a specific filling line, employing the Failure Mode and Effect Analysis (FMEA) methodology to delineate critical components within the production process. Among the principal findings, it becomes evident that the prevailing preventive maintenance practice exhibits inadequacies in mitigating the incidence of corrective maintenance interventions. In light of these findings, the study advocates for adopting maintenance management protocols aligned with the ethos of Industry 4.0. By embracing contemporary practices inherent within Industry 4.0 frameworks, such as predictive maintenance and data-driven decision-making, pharmaceutical enterprises stand poised to optimize operational efficiencies and enhance overall maintenance efficacy.
Keywords: Pharmaceutical Industry. Corrective Maintenance. Preventive Maintenance. Predictive Maintenance. Maintenance Techniques.

Since the advent of the Industry 4.0 paradigm, companies have leveraged technological advancements to bolster competitiveness, enhance quality, and minimize waste in production processes, ultimately bolstering net profits. The pharmaceutical sector has embraced these strategies, evolving its quality policies, adhering to good manufacturing practices, and enhancing regulatory compliance under the oversight of bodies such as the World Health Organization (WHO) and the National Health Surveillance Agency (ANVISA). This evolution aims to boost productivity while upholding product quality standards.

Maintenance is a crucial strategic function for achieving organizational objectives, as it plays a pivotal role in supporting management and addressing production challenges. According to statistics from the Brazilian Association of Maintenance and Asset Management (ABRAMAN), Brazil incurs a maintenance cost equivalent to 4.3% of its Gross Domestic Product (GDP), slightly higher than the global average of 4.1%. This translates to significant expenses, emphasizing the imperative for organizations to continuously improve their maintenance management practices by assimilating innovative knowledge and adopting best practices from leading industrial nations. Moreover, contemporary production and maintenance management models incorporate Cyber-Physical Systems, which advocate for integrated production and maintenance workflows utilizing AI programming. These systems leverage machine learning and data collected directly from equipment to facilitate predictive and prescriptive maintenance techniques.

Another pivotal aspect in contemporary production and maintenance management models is the integration of Cyber-Physical Systems [6]. These systems advocate for a cohesive approach to production and maintenance management, leveraging AI programming [7] rooted in machine learning and data collected directly from devices

Received on 22 September 2023; revised 20 December 2023.
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J Bioeng. Tech. Health 2024;7(2):232-237

and equipment within the production environment. This framework develops predictive [8] and prescriptive [9] maintenance techniques, enabling proactive problem-solving and optimization of maintenance activities.

This research endeavors to underscore the significance of effective maintenance management by analyzing available data to identify consistent indicators that can facilitate the adoption of a more efficient model within the pharmaceutical industry. Specifically, the study uses quantitative and qualitative methodologies to scrutinize machine stoppage data, critical process alarms, and data on corrective and preventive maintenance activities over a defined period. By evaluating the performance of current maintenance practices, this research sheds light on the absence of a systemic approach to assessing the effectiveness of maintenance management within the pharmaceutical sector.

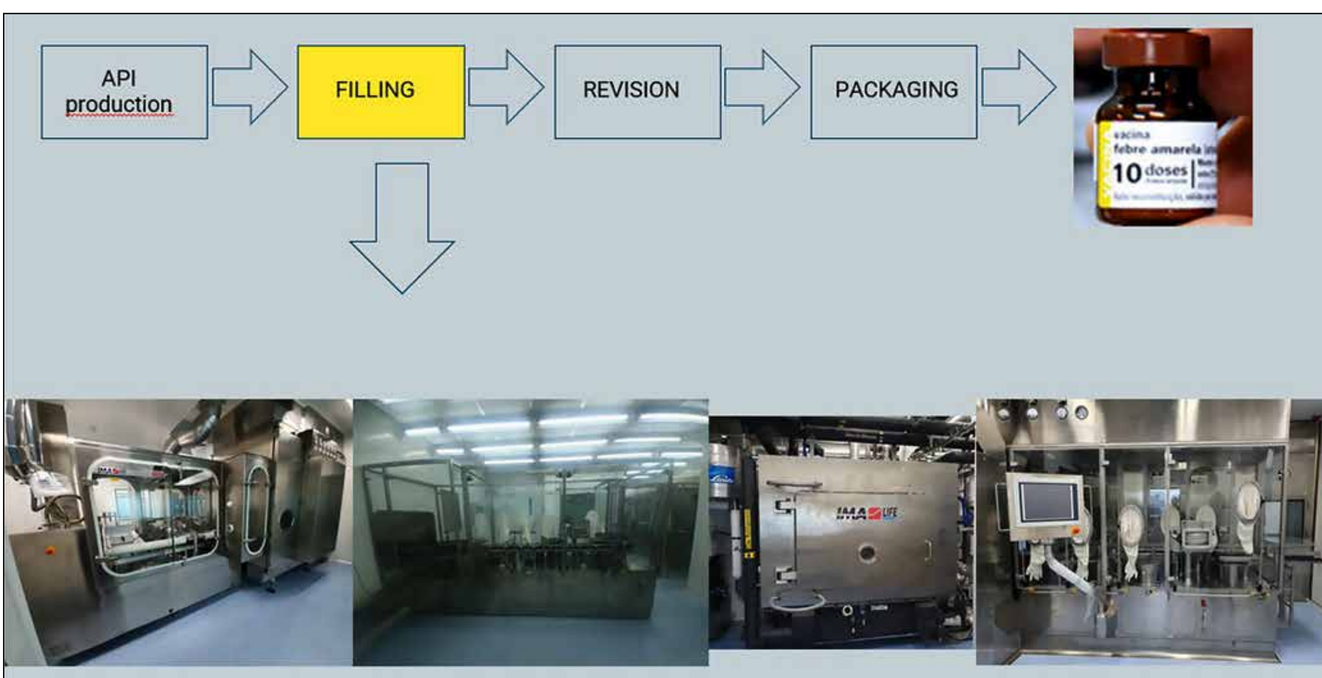
Materials and Methods

This case study was carried out in a Fiocruz pharmaceutical laboratory (Oswaldo Cruz Foundation), founded in 1976, which currently has a total of 41,722 m² of built area. As this laboratory has an extensive portfolio in manufacturing vaccines, biopharmaceuticals, and reagents, the study will focus on a vaccine production line, specifically on the bottling process of a lyophilized product. The bottled product undergoes dehydration, is frozen under a vacuum, and then sublimated. This process is carried out to ensure a longer shelf life of the product. Figure 1 shows the vaccine production macro process and pictures of the filling line, composed of a bottle washer, deproteinization tunnel, filling machine, lyophilizer, and capping machine.

The factory maintenance manager software, customized for the pharmaceutical industry under the name ENGEMAN, was utilized for this study. This software facilitated the extraction, processing, and cataloging of fault messages and alarms from the equipment itself, with the primary objective of identifying and addressing the leading causes of downtime within the lyophilized filling line from 2015 to 2020.

To analyze failures in both corrective and preventive maintenance activities associated with the lyophilized filling line, the Failure Mode and Effect Analysis (FMEA) methodology will be

Figure 1. Macro process of a freeze-dried filling line.



employed. FMEA is a systematic tool designed to identify and scrutinize the modes and root causes of failures occurring on the factory floor. By studying the consequences of these failures, FMEA aids in formulating and adopting appropriate maintenance measures. Through FMEA, it becomes feasible to pinpoint actions that could eliminate or mitigate the likelihood of future failures.

Furthermore, this study seeks to juxtapose the current maintenance techniques practiced within the factory with alternative approaches, such as predictive maintenance. Predictive maintenance involves real-time data acquisition from the factory floor, enabling proactive identification of potential issues before they escalate into critical failures. This comparative analysis aims to discern the efficacy and potential benefits of implementing predictive maintenance techniques within the pharmaceutical manufacturing environment.

Results and Discussion

The ENGEMAN factory maintenance manager software, tailored specifically for pharmaceutical industry applications, served as the primary tool for this study. It facilitated handling fault and alarm messages originating directly from equipment, aiming to export, process, and catalog the primary causes of stoppages within the production line spanning from 2015 to 2020. For the analysis of failures in both corrective and preventive maintenance activities associated with the lyophilized filling line, the Failure Mode and Effect Analysis (FMEA) methodology will be employed. FMEA is a systematic tool designed to identify and scrutinize the modes and root causes of failures occurring on the factory floor. By evaluating the consequences of these failures, FMEA assists in formulating and adopting appropriate maintenance measures. Through FMEA, it becomes feasible to pinpoint actions that could eliminate or mitigate the likelihood of future failures. Furthermore, this study intends to compare the current maintenance techniques practiced within the factory with alternative approaches, such as predictive maintenance. Predictive maintenance involves real-time data acquisition from the factory floor, enabling proactive identification of potential issues before they escalate into critical failures. This comparative analysis aims to discern the efficacy and potential benefits of implementing predictive maintenance techniques within the pharmaceutical manufacturing environment. Preventive maintenance, as described in [12], primarily aims to reduce the likelihood of failures that may disrupt the production process, thereby minimizing the need for unscheduled corrective maintenance actions. Analyzing available data for the lyophilized filling line will evaluate and propose acceptable and reliable preventive maintenance activities performed [13], ensuring optimal operational efficiency and reliability. In possession of the reports issued by ENGEMAN of the records of the maintenance orders carried out on the filling line, it is necessary to filter the raw data since the field for the description of the fault that occurred is only sometimes easy to understand. Quantitative data refinement work was carried out (Figure 2):

In this case study, two classic types of maintenance models are employed: i) reactive or corrective maintenance, commonly referred to as "run to failure", wherein maintenance is performed only after equipment failure occurs without prior analysis, and ii) preventive maintenance, which involves scheduled interruptions of the operating system to address necessary corrections and replace parts according to predetermined expiration dates set by the manufacturer, irrespective of whether the machine exhibits faults [14]. Figure 2 depicts a quantitative analysis of the utilization of these two classic maintenance models. Surprisingly, implementing preventive maintenance did not decrease the number of corrective services; instead, it resulted in an increase (Figures 3 and 4).

From the results depicted in Figure 3, it becomes evident that the filling line encounters more issues related to the electrical part than the mechanical part. This observation can be attributed to this line's numerous parameters and electronic components

Figure 2. Number of filling line failures per year.

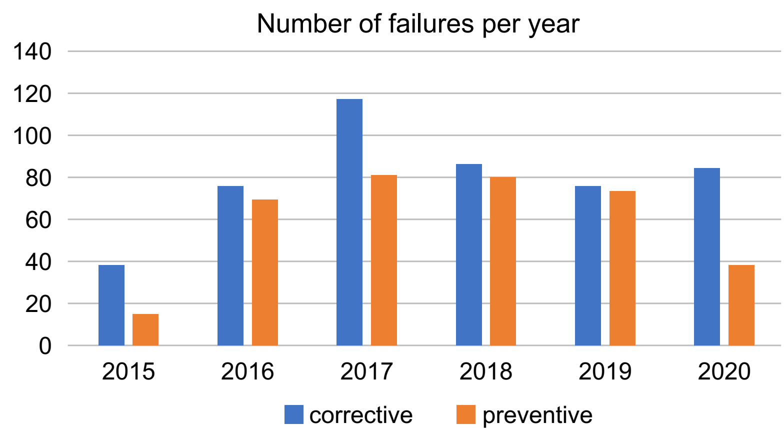


Figure 3. Number of mechanical *vs* electrical failures.

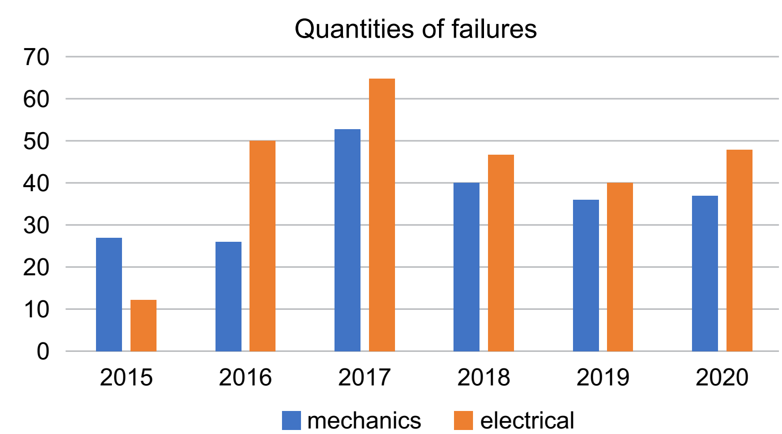
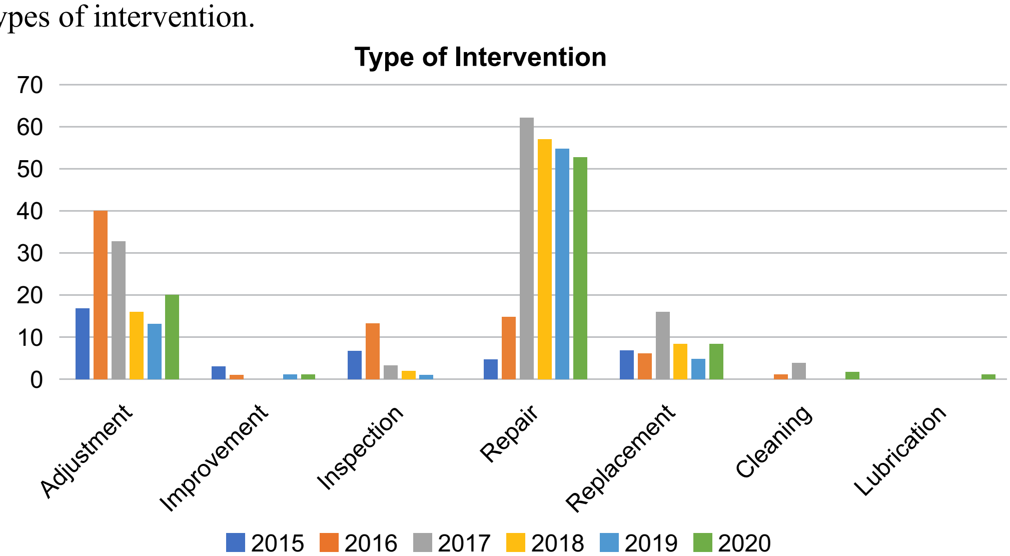


Figure 4. Types of intervention.



requiring adjustments. Additionally, it is imperative to assess the history of utilities within the building housing the filling line. Fluctuations in electrical power may necessitate using uninterruptible power supplies (UPS) or power generators to ensure the integrity of data recorded during the filling process. Interventions were categorized into broad groups to establish a standardized nomenclature for interpreting maintenance data, including adjustment, improvement, inspection, repair, exchange, cleaning, and lubrication. Figure 4 illustrates the significant adjustments and repairs carried out during interventions on this filling line. By examining the types of interventions, it becomes evident that enhanced training and collaboration between production and maintenance teams could effectively mitigate production downtime. Utilizing the Failure Mode and Effect Analysis (FMEA) tool to categorize critical points of the filling line qualitatively, it becomes feasible to identify components that have historically undergone exchange, adjustment, or repair, thereby enabling the proposition of alternative maintenance approaches.

Table 1 summarizes the significant components exhibiting this filling line's highest Risk Priority Number (RPN). The RPN is calculated as the product of severity, occurrence, and detection weights associated with component failure.

According to Table 1, the compressor and vacuum pump are the most critical components of the filling line and require special attention in maintenance because they are rotating machines, and wear occurs with greater incidence. Through this type of analysis, a more effective methodology can be proposed to maintain the critical components of the equipment through the proposed actions.

Conclusion

This case report article data about corrective and preventive maintenance activities spanning 5 years were meticulously analyzed within a filling line of the pharmaceutical industry. These data were sourced from the factory maintenance management software known as ENGEMAN. The outcomes of maintenance orders generated within this software were methodically cataloged, sorted, and identified using an Excel spreadsheet. Subsequently, the Failure Mode and Effect Analysis (FMEA) tool was employed to analyze and identify the primary critical components of the filling line. The application of preventive maintenance was then evaluated quantitatively and qualitatively compared to corrective measures. Based on the findings, the following conclusions can be drawn:

i) There is a need to review and refine preventive maintenance procedures based on historical failure data to establish a more reliable preventive maintenance regime.

Table 1. FMEA analysis identifying critical components.

Nº	Component	Failure Causes	Severity	Occurrence	Detection	RPN	Action
1	Compressor	Mechanical Wear	5	8	8	320	Implementation of predictive maintenance mode
2	Pump vacuum	Low Oil Level	6	10	5	300	Review the maintenance procedure and staff training
3	Condenser	Pipe Obstruction	7	5	8	280	Improve the quality of the equipment supply water
4	Piping	Crack in the Pipe	6	4	9	216	Piping repair
5	Pump vacuum	Contamination with Oil Moisture	5	8	5	200	Review the operation procedure and staff training

ii) Investing in operational and maintenance training initiatives to better mitigate identified failures and enhance overall maintenance efficacy is imperative.

iii) It is necessary to enhance the collection and filtering of maintenance data and integrate this database using advanced artificial intelligence (AI) techniques such as machine learning. This integration can facilitate more informed and assertive decision-making in maintenance management.

iv) Implementing predictive maintenance modalities should be prioritized to minimize downtime in the production process and ensure heightened reliability and quality in maintenance processes within the pharmaceutical industry.

By addressing these key conclusions, pharmaceutical companies can optimize maintenance practices, enhance operational efficiency, and bolster product quality and reliability.

Acknowledgments

The authors declare no conflicts of interest.

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