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Improving Equipment Availability on a Pharmaceutical Production Line by Analyzing Reliability and Maintainability

Yuniel Mendez Pupo[1*]; Jesús Cabrera Gómez[2]

[*1]Pharmaceutical Laboratory Genfarma, Hanoi, Vietnam
[2]José Antonio Echevarría Technological University of Havana, Center for Studies in Maintenance Engineering. Havana, Cuba
*Corresponding Author

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***Abstract*—** *This research addresses the low availability of critical equipment in a physiological serum production line, characterized by frequent unscheduled shutdowns. The objective was to propose a plan to improve the availability of critical equipment, specifically in the serum filling machine, identified through a criticality and complexity analysis based on mathematical models and expert criteria. Key performance indicators such as reliability, maintainability and availability were evaluated. Initial results showed limited reliability, a high mean time to repair (10.02 h), and an availability of 89.4%, lower than the desired standard (>95%). 60% of the failures were mechanical in nature, which oriented the analysis towards the identification of causes using tools such as the Ishikawa diagram. Based on the opportunities detected, a comprehensive plan of corrective actions was designed, which included the improvement of maintenance procedures, staff training, optimization of spare parts management, implementation of condition monitoring and technological updating. The partial application of the plan showed positive results: reduction of the average repair time to 5.56 h and increase in availability to 93.59%, as well as significant improvements in the mechanical reliability of the equipment. It is concluded that the systematic implementation of the proposed plan contributes to improving the operational performance of critical equipment, increasing production efficiency and reducing economic losses in the physiological serum production line.*

Keywords*— *Availability Improvement, Reliability and Maintainability Analysis, Critical Equipment Management, Industrial Maintenance, Failure Analysis.

I. INTRODUCTION

In the industrial field, the availability of critical equipment is a determining factor in ensuring the operational efficiency and profitability of production plants [1]. In the case of the pharmaceutical industry, where quality standards and production times are demanding, any unplanned interruption can have significant repercussions on productivity and economic income. This paper presents the results of research focused on improving the availability of physiological serum production lines, specifically in a plant where unscheduled shutdowns have generated considerable economic losses and affected the fulfillment of production plans. The study focused on a serum filling machine, identified as the most critical equipment through a hierarchy analysis based on mathematical models and expert criteria. Through detailed analysis, key indicators such as maintainability, reliability, and availability were evaluated, using tools to model fault behavior and repair times [2]. The proposals for improvement presented included aspects such as the rationalization of maintenance procedures, staff training, technological modernization and inventory management. These actions seek not only to increase the availability of equipment, but also to enhance its reliability and reduce downtime, positively impacting the company's productivity and competitiveness. This work constitutes an important contribution to maintenance in the pharmaceutical industry, by combining theoretical foundations with practical solutions, supported by real data and the experience of a group of experts [3-5]. It is estimated that the implementation of its results will allow the plant to achieve higher levels of efficiency and meet national and international demands, ensuring the quality of its products and the sustainability of its operations.

II. MATERIAL AND METHODS

2.1 Methodology Overview

The methods of analysis and synthesis were used, and a theoretical study of the existing systems and assets was also carried out for the hierarchization of technological systems [6,7]. Empirical methods based on expert criteria were also used, with experienced specialists and technical personnel being selected and consulted, through the application of surveys [8]. The surveys were used to determine the degree of validity and acceptance of the models used. This methodology had already been validated in another biopharmaceutical company, so it was adopted for this study [9].

The model used for the analysis of the starting situation of the selected asset was the exponential model, which is a probabilistic model widely used in engineering analysis and calculations, as it is a simple model capable of adapting to different experimental scenarios. It is widely used in the analysis and determination of maintenance indicators such as reliability and maintainability. Together with the Weibull model, it allows the identification and simulation of the operational stage in which the equipment or mechanical components are found [10-13].

2.2 Data Source

The data used for the investigation were taken from the maintenance management software used by the company, corresponding to the period from June 2020 to June 2025, taking information from the 43 equipment and systems that make up the entity. Failure frequency data and other previously validated variables [9] were collected, obtaining the values for the analysis of all equipment from the interpolation of the failure criteria given by the manufacturers and the actual one after analyzing the historical records of each equipment. This is a widely used source to perform tasks related to the Engineering and Maintenance department, which provides a varied and reliable database.

III. RESULTS AND DISCUSSION

3.1 Prioritization of Equipment

The application of the proposed technology, composed of the two mathematical models [9,14] to determine the criticality and complexity for a company in the biopharmaceutical industry, allowed us to obtain a hierarchical list of the technological systems belonging to a physiological serum production plant. Out of a total of 43 pieces of equipment and systems, 15 remained the most critical and complex.

As a result of the analysis carried out, it was determined that the most critical and complex asset is the "Serum Filling Machine 1" [15].

3.2 Reliability, Maintainability and Availability of the Serum Filling Machine 1

Reliability values are determined by equations (1), (2), and (3). Based on the mean time between failures (Equation 1), the failure rate was estimated according to Equation (2) and reliability, applying the exponential model given in Equation (3).

$$MTBF = \frac{hours\ worked}{number\ of\ failures} \tag{1}$$

$$\lambda = \frac{1}{MTBF} \tag{2}$$

$$R(t) = e^{-\lambda t} \tag{3}$$

In the period analyzed, the hours worked by the machine totaled 10,160 and the number of failures amounted to 120. Therefore, the MTBF results in 84.67 hours and the failure rate is 0.01181 failures/hour.

When applying Equation (3), it was obtained as a result that in a time of 24 hours the reliability is 75.32%.

For the analysis of the behavior of the maintainability indicator, the data obtained by the company were taken into account where, between these years, the unavailability time of the selected serum filler was 1,202.4 hours for the 120 failures recorded. With the data obtained, the mean time to repair a component when a failure occurs (MTTR) was calculated, according to Equation (4).

$$\text{MTTR} = \frac{\text{Total hours of inactivity}}{\text{Number of stops}} \tag{4}$$

The mean time to repair is approximately 10.02 hours.

With the determination of the MTTR, the repair rate (μ) was determined, a parameter that allows evaluating the probability of a component to be repaired in a certain time and was calculated according to Equation (5).

$$\mu = \frac{1}{MTTR} \tag{5}$$

Once the repair rate was determined, it was possible to find the value of the maintainability indicator for a period of 2 hours that is the desired one in the entity for any machine failure. The maintainability indicator was determined by applying Equation (6).

$$M(t) = 1 - e^{-(\mu t)} \tag{6}$$

As a result, it was obtained that there is approximately a 16.5% probability that repairing this machine will be completed in 2 hours. Given that the indicator must reach 90% for that period to be considered acceptable, the result obtained can be considered very low.

Once the values of the reliability and maintainability indicators for serum filler 1 have been determined, its availability is determined, expressed by Equation (7).

$$Availability(A) = \left(\frac{MTBF}{MTBF+MTTR}\right) \tag{7}$$

An availability for the serum filling machine 1 of 89.4% was obtained, a value considered low with respect to international standards where the indicator is expected to be higher than 95% [16].

3.3 Failure Analysis

The failures recorded during the period studied were analyzed, and it was advisable to classify them by category according to their mechanical, electrical or automatic nature [17]. The result of this classification is shown in Figure 1.

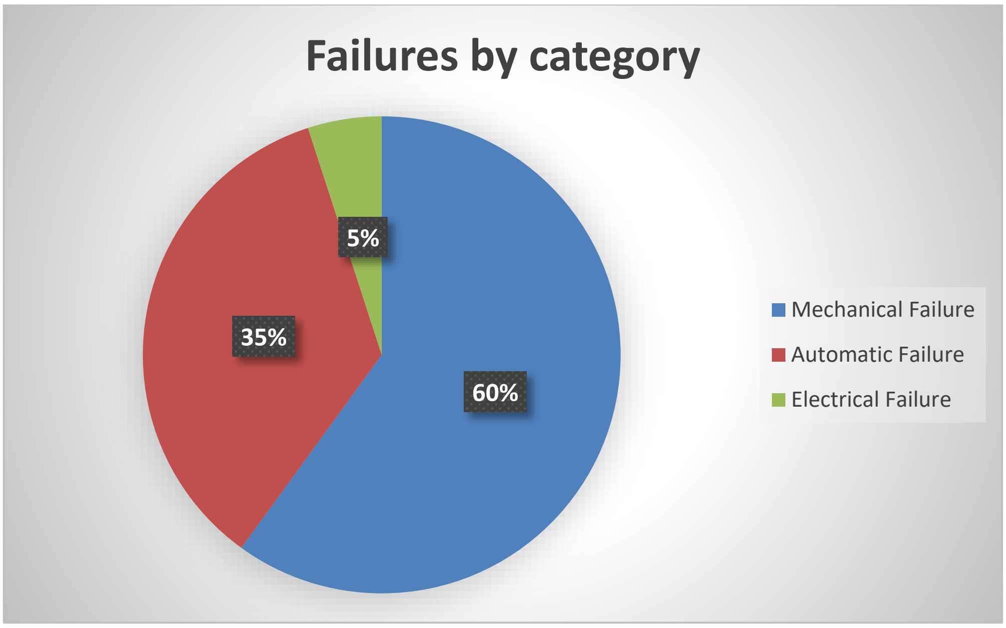

FIGURE 1: Failures by Categories

The failure analysis showed that 60% correspond to mechanical failures, highlighting problems associated with component wear, maintenance deficiencies and human error. 27 types of mechanical failures were detected, 18 of which occurred on more than one occasion.

For the mechanical failures detected, an analysis of possible causes was carried out that contributed to the low reliability, maintainability and availability identified. Based on a brainstorming session carried out by the group of experts, 21 potential causal factors were detected. With which a cause-effect diagram (Ishikawa or fishbone) was elaborated where the problem to be solved is located in the head and its potential causes are the bones [18]. It was possible to identify bottlenecks and opportunities for improvement, as can be seen in Figure 2.

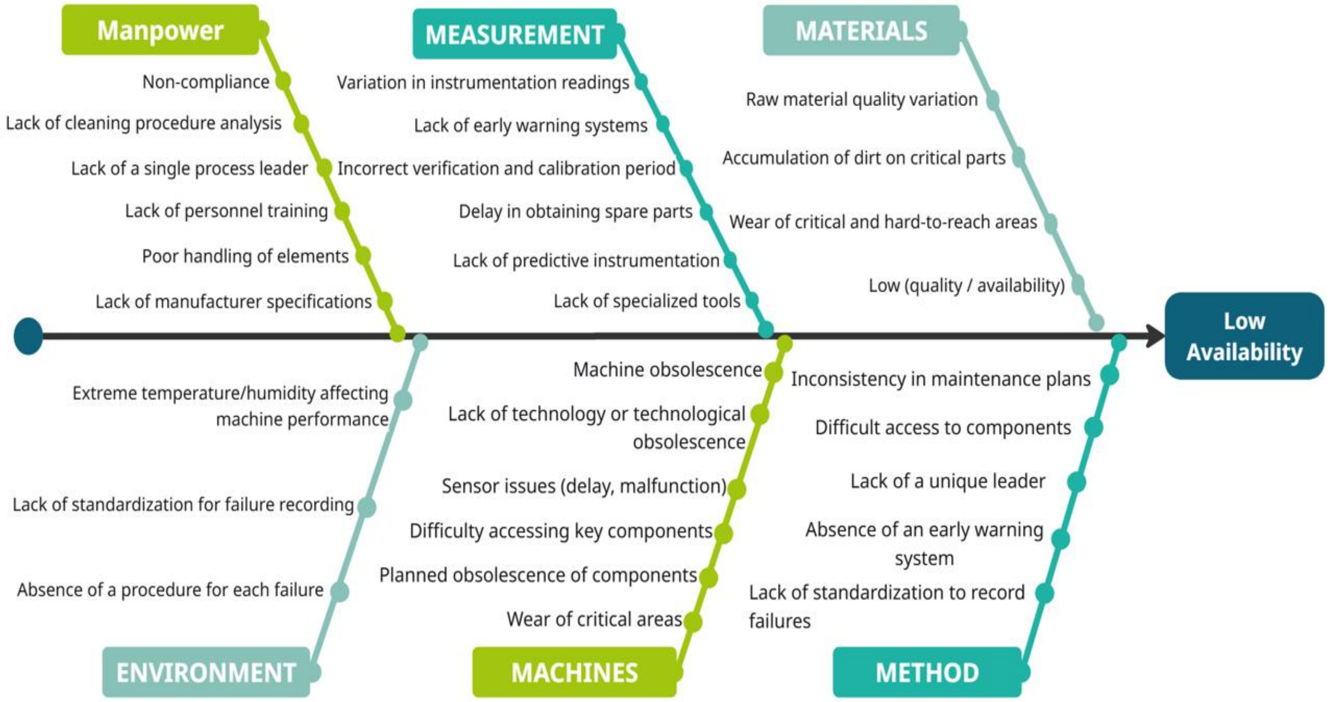

FIGURE 2: Cause and Effect Diagram of the Serum Filler 1

Based on these results, an improvement plan aimed at increasing MTBF and reducing MTTR was partially implemented.

The diagram shown in Figure 2 classifies the possible causes into six categories, applying the so-called 6M: Machine, Method, Materials, Labor, Environment and Measurement, used to obtain a broader vision in the analysis of opportunities for improvement and the corresponding establishment of corrective actions [19].

3.4 Implementation of the Improvement Plan

Improving the availability of serum filler 1 could be done in three ways:

1) Improving reliability, based on an increase in MTBF [20,21].
2) Improve maintainability, based on a reduction in MTTR [22,23].
3) Simultaneously achieve an increase in MTBF and a decrease in MTTR [24].

Due to the impact of the possible causes, which could cause interruptions of the serum filling machine 1, a group of measures were proposed and implemented to improve availability by adopting the third of the variants mentioned above. For this purpose, brainstorming was developed and the criteria of the experts were once again used.

Table 1 shows the opportunities for improvement identified, as well as the corresponding corrective actions to be implemented.

TABLE 1
OPPORTUNITIES FOR IMPROVEMENTS AND CORRECTIVE ACTIONS

Opportunity for improvement identified	Corrective Action
Poorly prepared work orders	Maintenance staff training. Service Order Audits.
Measurement errors	Modification of calibration procedures. Determination of new operating times and calibration of instruments.
Workmanship errors	Modification of the machine's cleaning procedure. Creation of a continuous training program for operators and maintainers.
Obsolete machine technology	Updating the components of the equipment. Preparation of a stock of specialized tools, exclusive use in the equipment.
Manufacturing Raw Material	Work with suppliers of higher quality raw materials. Return to the original dimensions of the jar lids.
Wear and tear due to operating time	Assignment of a person responsible for maintenance tasks. Creation of an inventory of parts with a high wear rate. Installation of condition-based monitoring systems. Establishment of a lubrication plan. Recalculate the times between interventions to the team.
Incorrect working methods	Implementation of a checklist of maintenance tasks. Increase the frequency of cleaning the area. Compliance with the provisions for cleaning, failure registration, shutdowns and start-ups.

The 18 corrective actions were set out in an implementation timeline spread over a 2-year period. Not all the proposed actions needed extra economic resources for their implementation, as some were part of or included in the work contents of different areas and jobs. The actions that were implemented immediately were those that required the least economic resources and then, depending on the availability of money, time and resources required, the rest of the actions. It was estimated that the total cost of the implementation of all the actions was around 1.4 million dollars.

3.5 Technical-Economic Results

The partial implementation of the proposed actions led to variations in the technical indicators of the equipment, in particular the Mean Time Between Failures (MTBF), the Mean Time To Repair (MTTR), Maintainability (M), Reliability (R) and Availability (A).

The company, in the course of 2024, 2025 and the first quarter of 2026, implemented a group of actions, some fully and others partially. Of the actions included in the proposed plan, the following have already been partially or fully implemented:

- Staff training.
- Creation of a continuous training program for operators and maintainers.
- Creation of a stock of specialized tools, exclusive use in the equipment.
- Implementation of a checklist of maintenance tasks.
- Carrying out audits of service orders.
- Modification of the machine's cleaning procedure.
- Designation of a person responsible for maintenance tasks.
- Creation of an inventory of parts with a high wear rate.
- Establishment of a lubrication plan.
- Increased frequency of cleaning of the area.
- Compliance with the provisions for cleaning, failure registration, shutdowns and start-ups.
- Audits of service orders.
- Recalculate the times between interventions to the team.

To analyze the behavior of the indicators, the data recorded during the 17 months between January 2024 and May 2025 were considered for the "after" analysis, compared with the baseline period of June 2020 to December 2023 (which excludes the implementation period to avoid overlap). For the after period, the hours worked by the equipment were 4,635, the number of hours of inactivity was 317 and the number of failures was 57. The MTBF calculated for this new period was 81.31 hours, a figure slightly lower than the previous baseline value of 84.67 hours recorded between 2020 and 2023. The MTTR calculated for this new period was 5.56 hours, which is lower than the previous baseline value of 10.02 hours.

Given that the overall reliability index of the equipment showed a slight decrease, the evolution of mechanical failures was detailed, comparing their frequency before and after applying the proposed actions. Table 2 shows the monthly variation in the failure rate (λ), where a reduction indicates improvement. Seventeen of the mechanical failures that occurred before the measures were implemented did not occur again; another ten persist, and new failures also occurred, highlighted in blue in Table 2.

TABLE 2
COMPARISON OF MECHANICAL FAILURE RATES BEFORE AND AFTER ACTIONS

Nature of the Fault	Before the Actions λ (Failures/month)	After the Actions λ (Failures/month)
Technical malfunction	0.58	0.12
Air leak problems	0.38	0.35
Machine Oil Pump Problems	0.25	0.06
Extruder Problems	0.21	0.12
Blade Problem	0.17	0.12
Bearing Issues	0.17	0.06
Problems with conveyor mats	0.17	0.18
Problem with machine cleanliness	0.13	0.06
Problems with the machine's valves	0.08	0.12
HMI Problem	0.04	0.06
Problems in the desuperheater	0	0.06
Bottle gripper failures	0	0.12
Blade misalignment	0	0.12
Defective heating element	0	0.06
Problems with the filler shaft	0	0.06
Problems in the die-cutter	0	0.12

The implementation of the actions managed to reduce seven of the ten repeated failures in both periods and although new failures occurred and others increased their frequency, these variations were not significant. Overall, the machine's mechanical failure rate decreased from 2.17 to 1.76 per month. Overall reliability showed slight variations, a significant improvement in the mechanical reliability of the system was observed. This showed that the actions applied had a positive impact, although there are still opportunities for improvement in the electrical and automatic subsystems.

As a result, it was obtained that there is approximately a 30.20% probability that repairing this machine will be completed in 2 hours. Although the result obtained is still considered very low, it increased by approximately 13.7% as is shown in Table 3.

In the case of the MTTR, it decreased by almost 5 hours, which reflected an improvement in this indicator. MTBF increased by 3 and a half hours, which also reflected an improvement in this indicator. Availability increased to 93.59%, being slightly higher than the period prior to the implementation of the improvement actions (see Table 3).

TABLE 3
TECHNICAL INDICATORS

Technical indicators	UM	After (Jan 2024-May 2025)	Before (Jun 2020-Dec 2023)	Δ
Mean time between failures (MTBF)	h	81.31	84.67	-3.36
Mean time to repair (MTTR)	h	5.56	10.02	-4.45
Maintainability (2 h)	%	30.2	16.5	13.7
Reliability (24 h)	%	74.44	75.32	-0.88
Availability	%	93.59	89.4	4.19

IV. CONCLUSION

In summary, this study investigated a proposed plan for improving the availability of the equipment identified as the most critical in a production line of the physiological serum plant. Based on the analyses carried out and the results obtained, an action plan was proposed, the implementation of which contributed to the improvement of the availability of the critical equipment identified, which was the serum filling machine 1. Some of the actions included in the plan are being successfully implemented or are in the process of being implemented and the first results are already being observed.

1) Serum Filling Machine 1 is regarded as the most critical and complex equipment of the serum plant.
2) The starting values for the reliability, maintainability and availability indicators are low and can be improved. Before the proposed improvement plan was implemented, it was estimated that these values were, respectively, 75.32% for 24 hours of continuous work, 16.5% for a repair time of 2 hours and 89.4%.
3) For the Serum Filling Machine 1, 60% of the failures recorded are mechanical in nature and the focus was on them for the identification of opportunities for improvement in availability and the allocation of corresponding corrective actions.
4) The proposed improvement plan for Serum Filling Machine 1 sufficiently takes advantage of the identified improvement opportunities and is based on the corrective actions associated with those opportunities.
5) The proposed availability improvement plan is in the process of being implemented and is beginning to show its first results, highlighting the increase in availability from 89.4% to 93.59%, approaching the value expected by the entity, which is 95%.

Prospects for further development of the work in the future:

1) Complete the implementation of the proposed availability improvement plan and ensure its systematic follow-up.
2) Carry out a new analysis of the reliability, maintainability and availability indicators, once some time has elapsed after having completed the total implementation of the improvement plan.
3) Gradually extend the analysis carried out to the remaining critical equipment identified.
4) Investigate the emergence of new failure modes (desuperheater, bottle gripper, blade misalignment, heating element, filler shaft, die-cutter) and develop targeted corrective actions to address these newly identified failure mechanisms.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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