Proceedings of the International Conference on Industrial Engineering and Operations Management

Publisher: IEOM Society International, USA DOI: 10.46254/BA08.20250397
Published: December 20, 2025

Application of Poka Yoke and Kaizen Tools to Improve the Capacity of the Packaging Manufacturing Process in the Pharmaceutical Sector

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Abstract

The pharmaceutical industry is dedicated to the development, production and marketing of medicines for the treatment and prevention of diseases. For this reason, there is a growing need to improve the quality of its production processes in order to obtain a product that meets all quality standards and fully satisfies the customer. To achieve this satisfaction, the sector must use lean manufacturing tools to improve processes and control production. The objective of this study is to analyze and understand the importance and impact of implementing lean manufacturing tools, using the systematic literature review research method. By implementing this philosophy, a significant improvement in the manufacturing company is expected.

Keywords
Industrial Pharmaceuticals, Production Flow, Manufacturing Systems, Pharmaceutical Products, Lean Manufacturing

1. Introduction
The pharmaceutical packaging manufacturing sector is a fundamental pillar in the supply chain for medicines and healthcare products. These packages not only serve to contain and protect products, but also guarantee their quality, safety, and traceability throughout their shelf life. However, the industry faces growing challenges due to market demands, strict regulatory requirements, and pressure to adopt sustainable practices. In addition, the COVID-19 pandemic highlighted the need to redesign operational processes in all health-related industries. As a result, all companies in the sector, including VHOPlast S.A.C., had to implement strategies to ensure stricter standards of quality and efficiency, while facing disruptions in the global supply chain and peaks in demand.

Pharmaceutical packaging plays a critical role in the effectiveness of medicines and healthcare products. According to NTS No. 182-MINSA/DIGEMID-2022 of the Peruvian Ministry of Health, they must meet strict technical requirements, such as withstanding temperatures of up to 30°C ± 2°C and relative humidity levels of 65% ± 5%, in order to preserve the quality of the contents. Any failure to comply with these specifications can compromise patient safety and the manufacturer's reputation. Likewise, they must guarantee product protection, and packaging must comply with international environmental regulations. For example, the NTP-ISO 18604:2020 standard, approved in

Peru by INACAL, establishes the requirements for packaging to be recyclable and meet recovery criteria, encouraging the use of more sustainable materials and processes.

The main objective of this research is to respond to the challenges faced by VHOPlast S.A.C. since 2019 in terms of improving quality, reducing defects, and optimizing productivity. To this end, improvements will be made through the implementation of Lean tools such as Poka Yoke and Kaizen. This methodology will not only solve internal problems, but also strengthen the company's position in a competitive and regulated market, benefiting both the company and its customers.

1.1 Objectives

The research seeks to demonstrate that the implementation of Poka Yoke and Kaizen will increase the production efficiency of plastic droppers for the pharmaceutical sector in the company under study. First, the bottleneck will be identified to understand the main constraints affecting the current process. Second, Poka Yoke mechanisms will be applied to ensure early detection of errors in machines and operational activities, thus preventing the generation of defective products. Finally, the Kaizen methodology will be used to train and engage employees in a cultural change aimed at continuous improvement, encouraging their active participation in the optimization of the production process.

2. Literature Review

2.1 Lean Manufacturing in the pharmaceutical industry

The Lean Manufacturing philosophy has established itself as a key approach to improving efficiency, reducing waste, and increasing competitiveness in the pharmaceutical sector, demonstrating that its tools optimize processes, ensure quality, and reduce cycle times. Nenni, Giustiniano, and Pirolo (2014) show that, in a company with 100 million containers per year, Lean improves continuous flow and reduces downtime through standardization. Likewise, Chowdary and George (2012) argue that its systematic application reduces costs and increases production yield by eliminating bottlenecks and controlling waste. Finally, Sieckmann et al. (2018) show that, even in small and medium-sized companies, practices such as 5S and visual control help to overcome structural limitations and increase productivity and quality.

2.2 Application of Kaizen in industrial settings

The Kaizen philosophy, based on continuous improvement through small, sustained changes, has proven particularly useful in industries where quality and precision are critical, such as pharmaceutical packaging manufacturing. Rojas-Benites et al. (2021) point out that its implementation in small and medium-sized Peruvian companies made it possible to reduce waste through 5S, standardization, and collaborative work, improving productivity and the organizational climate. Bevilacqua et al. (2015) show that Kaizen tools, such as root cause analysis and standardization, reduce changeover times (SMED) and optimize processes in pharmaceutical plants, improving overall equipment efficiency. Likewise, Karam et al. (2018) highlight that the integration of Kaizen with other Lean tools reduces setup times and strengthens staff participation, which is key to sustaining long-term improvements.

2.3 Use of Poka Yoke in critical manufacturing processes

Poka Yoke, which aims to prevent human error through fail-safe controls, is essential in industries where quality defines consumer safety, such as the pharmaceutical sector. Khlat, Harb, and Kassem (2014) point out that the application of Lean tools—including Poka Yoke—reduces process variability and increases product reliability. Its relevance is critical in stages such as injection, blowing, and assembly, where minimal failures compromise the integrity of the container. Aguilar et al. (2023) show that Poka Yoke devices can reduce rework by 30% and waste by 20%, in addition to improving product uniformity. Likewise, Bucko et al. (2022) show that this tool drastically reduces non-conforming parts—from 23% to 0% for certain defects—and reduces cycle times, demonstrating its direct impact on industrial efficiency.

2.4 Relevance of Lean tools for the manufacture of pharmaceutical packaging

The manufacture of pharmaceutical packaging requires high standards of precision, traceability, and quality, as any defect can compromise the stability of the medicine (Sierra et al., 2010). Uriarte and Navajas (2014) point out that optimizing design and production through systematic methodologies, such as those derived from Lean thinking, ensures quality, reduces variability, and complies with health regulations. The integration of Lean, Kaizen, and Poka Yoke is thus positioned as a key strategy for complying with certifications such as ISO 9001, improving productivity, and ensuring the safety of the final product. In Peru and the region, studies by the Ministry of Production (2022) and CIES (2016) indicate that competitiveness depends on the ability of companies to optimize processes, reduce defects, and sustain continuous improvement practices.

3. Methods

This article is a case study, which was conducted in a company belonging to the pharmaceutical and manufacturing sector, which allowed an analysis of the operation of companies in this industry.

An improvement model based on the Lean Manufacturing tools previously mentioned was proposed with the purpose of increasing efficiency in the production of plastic droppers. This approach covers elements such as optimizing production times and reducing quality errors in order to achieve a more agile, accurate, and efficient process within the sector. The model proposed contains an input, which is the low production capacity efficiency index, and what is sought is that the output can increase the value of the indicator so that it is above the industry average. For this purpose, the model has three development phases: initial diagnosis, identification of problems, and implementation of solutions. These phases can be seen in Figure 1.

First, a diagnosis of the problem to be addressed was made by analyzing the current situation of the company and its production processes involved, with the following steps: an analysis of the main measurement indicators that allow the company's performance to be evaluated, a value stream map (VSM) to identify the main process failures, an Ishikawa diagram to determine the factors causing the problem, and finally, a problem tree that evidences the problem to be addressed and its economic impact, in addition to its reasons and fundamental factors. This identified the main causes of low productivity as inadequate infrastructure, where we identified a lack of modern and efficient facilities; equipment maintenance and repair problems, where the response time to equipment failures generated unplanned downtime; and, finally, a large amount of waste due to inadequate quality control.

Once the problems and their causes had been identified, a research was conducted to find tools that could provide engineering solutions and improve efficiency, with the aim of improving the productivity indicator. For this, the proposed model considers the appropriate integration of the Lean Manufacturing tools used, which are Kaizen and Poka-Yoke. Finally, the level of productivity improvement is measured once the simulation has been carried out, and the current situation is compared with the situation proposed by the model. Taking the above into account, Figure 1 shows the proposed model and its development.

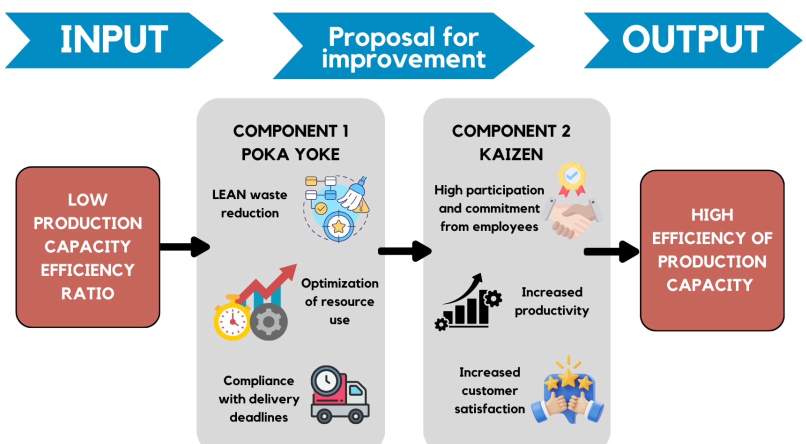

Figure 1. Proposal for improvement

4. Data Collection

In order to collect data for the research, it was necessary to extract information from diverse sources, such as scientific articles and research books on the tools used. In addition, questionnaires were conducted to survey managers and operators on how the improvements would impact their daily work. Feedback was also obtained on the activities carried out, and quantitative data on production before and after the implementation of the sensors was recorded, measuring the defect rate and cycle times. With the information obtained from the workers, we used process sheets to analyze how the process is structured and identify the flow. We also used production records, which guided us on purchase orders and their control. Finally, we used technical data sheets to review the product specifications. During the analysis of the production process at VHOPlast S.A.C., we identified that there are 4.2% defective drippers in the process, which indicates that the quality level is less than 96%. Once the problem and the reason for the delays in the process had been identified, a problem tree was drawn up to explain the causes, which could result in losses in waiting times and excess waste generation. With the information obtained and the current state of the process, it was verified that the use of Lean Manufacturing tools would help us solve the productivity problem. Figure 2 shows the flow of entities within the system.

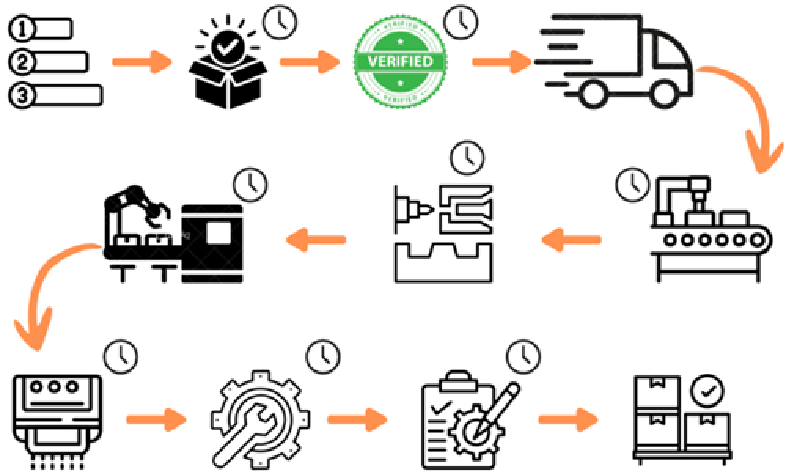

Figure 2. Entity flow within the system

4.1 Implementation of Kaizen and Poka-Yoke

In this phase, Lean Manufacturing tools are put into practice through experimentation and pilot tests within the company. To this end, the correct implementation of two Poka-Yoke sensors in the injection processes to detect waste was validated, as well as the application of Kaizen principles at the three quality control points in order to inspect more efficiently and correct errors more quickly and with greater teamwork.

- For the Poka-Yoke tool, the company executives were informed about the implementation after determining the current state of the company. To do this, the activities where the improvements were to be implemented were chosen in order to make proposals for possible solutions. Then, prototypes of the solutions were developed, and pilot tests were carried out to verify their correct functioning. The solutions were then integrated into the activities and staff were trained to report on their operation. Once this was in place, performance monitoring and measurement began to evaluate and make the necessary adjustments to continue with the improvement. Finally, the new production process was documented, standardizing the implementations and adopting the official improvements.

- For the Kaizen tool, managers were first informed about the tool and its benefits. Then, training began for all workers on the basis of Kaizen. To this end, monthly meetings were scheduled with staff and activities were carried out to facilitate understanding. After the general training, specialized training was conducted by area to explain how the methodology works. Then, small short-term improvements were initially implemented and measured using indicators to see the results. Finally, they were implemented on a larger scale and monitored to measure performance and promote a culture of continuous improvement.

5. Results and Discussion

Following the initial diagnosis of the injection process and the quality control area, high variability in production and a considerable number of non-compliant parts were identified, mainly associated with human error and a lack of standardization in certain stages of the process. Based on this, Kaizen and Poka Yoke interventions were implemented, focused on eliminating the root causes of defects and strengthening process control. To this end, presence sensors were installed as a Poka Yoke mechanism in the injection stage to prevent failures due to material shortages or incorrect movements, and Kaizen practices were incorporated into the inspection area to unify criteria, reduce rework, and ensure greater uniformity in the verification of parts. These actions made it possible to establish a more stable and controlled environment, reducing error events and facilitating early detection of deviations (Figure 3).

Figure 3. Map of the process before the intervention

As a result of the joint application of these tools, significant improvements were observed in product quality and operational efficiency. The implementation of the Poka Yoke device reduced the frequency of defective parts associated with operating errors, contributing to a more reliable process. At the same time, Kaizen practices applied to quality control made it possible to reduce rework, better organize activities, and establish a more stable flow. In addition, staff showed greater commitment to process control, reflected in a reduction in downtime and more rigorous compliance with defined inspection standards.

To evaluate the impact of the proposed improvements, a "To Be" model was built in the simulation software, incorporating the changes defined during the diagnostic phase. The main tools applied were Poka-Yoke sensors installed on the injection machines, the reinforcement of Kaizen practices in quality control, and the standardization of operational activities.

The inclusion of the Poka-Yoke system made it possible to immediately detect the absence of material or faults in the placement of components before the mold was closed. This improved visual control of the process and significantly reduced errors that, in the initial scenario, generated defective parts. As a result, the proportion of products requiring quality control review decreased from a higher initial percentage (before the pilot) to a lower level during the simulation of the improved model, due to greater confidence in correct production. Likewise, the percentage of parts approved in the inspection increased, reflecting a trend toward more stable and less variable processes. On the other hand, activities related to the preparation and order of the area were optimized using Kaizen principles. This included identifying critical cleaning points, standardizing repetitive tasks, and reducing unproductive time associated with corrective inspections.

The proposed Figure 4 represents the complete path of the product within the injection line: from material feeding, mold closing, automatic detection using Poka-Yoke sensors, quality inspection, and final output to the packaging area. This diagram clearly shows the critical activities and the points where improvements were made.

Figure 4. Graphical representation of the improved model

5.1 Numerical Results

The indicators obtained after the simulation are presented below. These results consider the performance of the production process under the improved scenario.

- Efficiency level (%): 91.69 / 86.15 x 100% = 106.42%
- Productivity level (%): 117.83 / 100 x 100% = 117.83%
- Defective products level (%): 3.64 / 5.77 x 100% = 63.09%

Complementary metrics such as MTBF, MTTR, OEE and Effectiveness were also evaluated to strengthen the analysis. These indicators provide broader insight into equipment reliability, operational availability, and workforce performance. Their inclusion supports a more comprehensive understanding of the system's overall improvement.

5.2 Graphical Results

Based on the pilot run and the simulation developed in the proposed model, the following graphical results were generated, allowing the performance of the process under the implemented improvements to be visualized (Figure 5 and Figure 6):

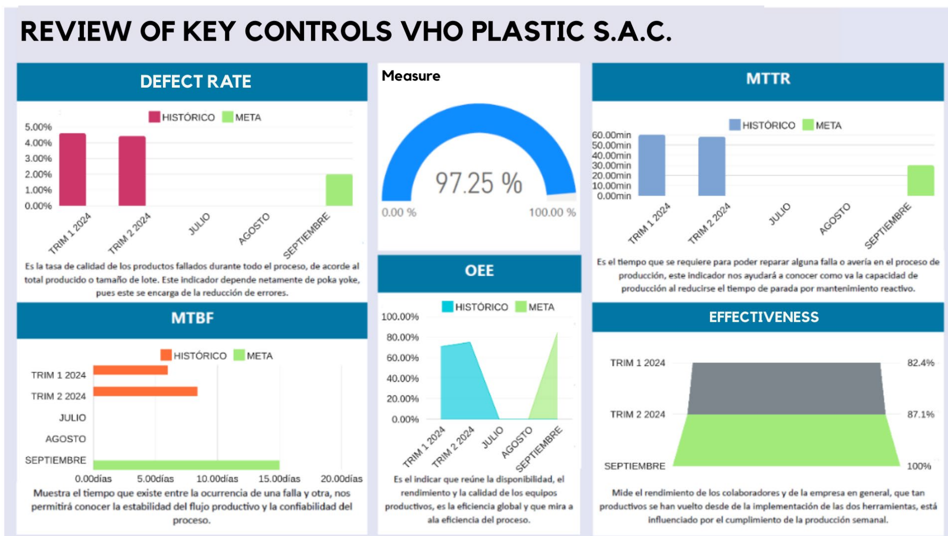

Figure 5. Monitoring of key controls

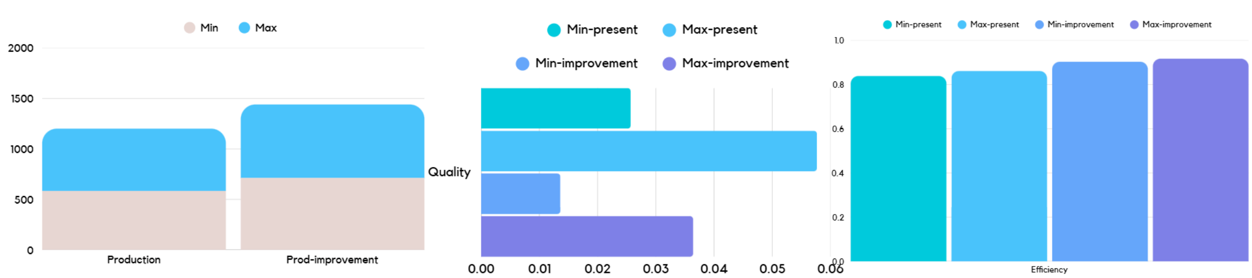

Figure 6. Indicators As Is and To Be

5.3 Validation

The proposed model was validated based on a period of direct implementation of Kaizen and Poka Yoke tools in the injection process and in the quality control area. During this period, data was collected before and after the intervention, allowing for a comparison of both scenarios and an evaluation of the effectiveness of the improvements applied. With the information obtained, key indicators were recalculated, including the percentage of defects, times associated with reprocessing, and productivity levels (Table 1).

Table 1. Comparison of indicators results between scenarios

Indicators	Initial Situation	Final Situation
Productivity Level (%)	100%	117.83%
Defective Products (%)	5.77%	3.64%
Efficiency (%)	86.15%	91.69%

The comparison of results shows significant reductions in the production of non-compliant parts, as well as an increase in inspection efficiency and process stability. This variation confirms that the main objective of the study was achieved, given that all indicators show improvements over the initial situation, validating the usefulness of the tools implemented. However, it is recognized that, as this is an initial intervention, the company could obtain even greater results through successive cycles of continuous improvement, consolidating the system implemented and extending it to other areas of the process.

6. Conclusion

The joint implementation of Kaizen and Poka Yoke methodologies at VHOPlast S.A.C. led to significant improvements in the organization's production performance and operational management. The results obtained confirm that the standardization of activities, the reduction of errors, and the active participation of staff generated sustained increases in efficiency, consistently validating the objectives set at the beginning of the study. The cost-benefit analysis shows that the benefits derived from the intervention, including the reduction of non-compliant products, increased productivity, and increased customer satisfaction, far outweigh the costs associated with implementation, supporting its technical and economic viability.

Intangible improvements were also identified, related to strengthening staff commitment and consolidating a more orderly and collaborative work environment, factors that contribute positively to organizational performance. The findings show that the application of Kaizen and Poka Yoke not only optimizes pharmaceutical packaging manufacturing processes but also establishes a solid foundation for the development of a culture of continuous improvement, an essential condition for maintaining competitiveness in a sector characterized by high standards of precision and quality.

This study also provides support for future investments in Lean methodologies within VHOPlast S.A.C. and opens opportunities for its application in other operational areas, establishing a frame of reference for further research and for the sustainability of the company in a highly demanding industrial environment.

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