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Implementation of Lean Manufacturing Tools to Increase Efficiency and Validate Equipment in the Production of Extrusion Hoses

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Abstract

Process validation and operational efficiency are two key elements in the medical industry. This article presents the case of the validation of three pieces of equipment used in the extrusion hose production process at a medical device manufacturer. The company faces operational and equipment validation challenges, which have led to inefficiency values up to 50.20% and a quality level below the 90% standard. One of the main problems is Poor Weld MASK defects, with 47 cases; failed EOL test, with 40 cases; and Broken Wire HUM, with 32 cases. The objective of this project is to increase operational efficiency and validate the equipment. To this end, the following four-phase method was implemented: Phase 1: Initial diagnosis; Phase 2: Application of Lean Manufacturing tools; Phase 3: Formal validation of equipment; and Phase 4: Monitoring and continuous improvement system. Lean Manufacturing tools such as 5S, Value Stream Mapping, Kaizen, and SMED were applied in each phase. As a result, the equipment was validated with CPk values of 1.45, 1.05, and a rejection rate of less than 10%. In addition, operational inefficiency was reduced, reaching values of 16.70% to 18.10%. The percentage of defects was reduced from 14.47% to 3.79%, EOL was reduced by 71.72%, and USW by 63.16%, improving the quality indicator from 70% to 82.7%. Cycle times were reduced in all areas. This leads to the conclusion that lean manufacturing tools are an efficient instrument for validating equipment and increasing the operational efficiency of a production process.

Keywords

Process validation, medical devices, lean manufacturing, Installation qualification, and Operational qualification.

1. Introduction

The medical device industry is one of the most regulated sectors in the world. Medical device manufacturers must ensure the safety and efficacy of their products and provide evidence of the safety, efficacy, and quality of their devices (Kramer et al., 2014). One of the requirements for demonstrating the quality of a medical device is the validation of

the equipment used in the manufacturing processes. Operational efficiency in production processes is critical to the success of medical device manufacturers (Roy & Srivastava, 2024), as it helps them ensure the sustainability, safety, efficacy, and profitability of medical devices (Lee et al., 2013). For companies to increase their profits, they must increase the efficiency of their manufacturing processes. In turn, to ensure that processes operate continuously within specified parameters and that equipment is fit for its intended use and can operate continuously, companies must validate them (Xu et al., 2018). Validation, therefore, ensures that manufacturing companies operate their processes continuously, efficiently, and sustainably.

This article presents a case study of a manufacturing company located in the city of Tijuana, Mexico. This company has begun producing specialized hoses for the treatment of sleep apnea. The manufacturing process for these hoses consists of the following operations: 1) Stripping (removal of excess material or tube scraps), 2) Assembly (joining of final product components), 3) USW (ultrasonic welding process), 4) Cutting (cutting the tubes to the required size), 5) VIM (visual inspection of the molding process), and 6) EOL (End of Line) (final phase before packaging and product shipment).

The company faces operational and equipment validation challenges. This compromises the efficiency of the production process and the ability to guarantee a quality standard above 90%. One of the problems is the reduction in product quality. Figure 1 shows the different types of defects and their frequency. The three most frequent types of defects are Poor Weld MASK, Fail EOL test, and Broken Wire HUM. These defects account for about 77.27% of the total. If they are eliminated, product quality will be significantly improved.

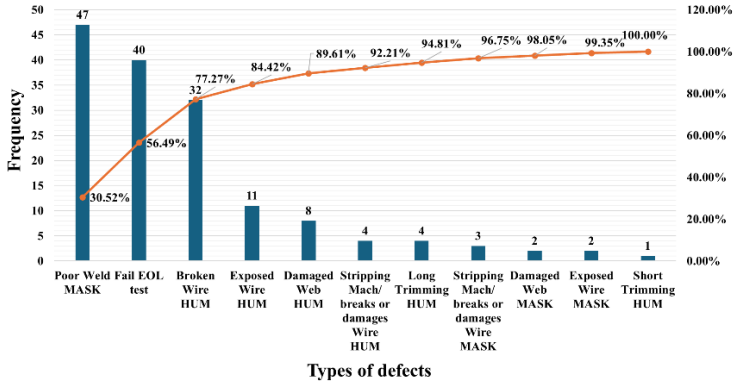

Figure 1. Pareto diagram of hose defects

At the same time, the company needs to validate new equipment. Failure to do so could lead to multiple risks, such as patient safety issues; regulatory non-compliance resulting in penalties, product recalls, and loss of customer and user confidence; high costs; and damage to reputation. Table 1 shows the percentage of operational inefficiency at different stages of the plastic hose production process during November 2024, focusing on the percentage of NG (Non-Good), i.e., the number of defective or wasted products on each day of the month.

Table 1. Monthly values of Non-Good

Date	Stripping	Ensamble	USW	Cutter	VIM	EOL	%NG
4-Nov	1.13%	6.77%	4.09%	5.71%	19.65%	5.68%	29.97%
5-Nov	5.07%	6.45%	6.52%	23.00%	19.20%	9.76%	27.38%
6-Nov	2.53%	4.14%	10.22%	13.89%	15.57%	3.39%	38.15%
7-Nov	3.96%	9.55%	5.30%	8.00%	20.85%	11.82%	28.60%
11-Nov	2.05%	4.61%	5.34%	8.14%	8.52%	7.03%	26.49%
12-Nov	0.82%	4.39%	3.19%	10.48%	12.76%	13.61%	21.81%
13-Nov	1.60%	3.58%	9.17%	5.06%	3.83%	9.41%	28.20%

14-Nov	1.67%	3.48%	7.43%	4.37%	9.14%	11.43%	33.14%
15-Nov	3.79%	10.42%	4.02%	1.41%	18.13%	9.68%	34.07%
19-Nov	1.52%	5.09%	3.07%	4.56%	8.96%	9.22%	50.20%
20-Nov	0.83%	0.63%	7.89%	5.05%	10.75%	16.56%	26.22%
21-Nov	5.79%	6.45%	8.51%	1.57%	18.88%	15.87%	49.87%
25-Nov	1.79%	3.06%	11.06%	8.49%	5.23%	6.24%	41.00%
26-Nov	2.98%	1.62%	4.62%	5.47%	9.53%	7.53%	30.90%
27-Nov	0.46%	2.86%	3.15%	6.40%	14.74%	9.58%	31.98%
28-Nov	0.28%	1.69%	6.78%	13.95%	16.76%	14.24%	28.29%
29-Nov	1.07%	3.92%	9.30%	12.00%	19.84%	18.63%	32.96%

The values in the %NG column represent the overall level of inefficiency in the production line. This percentage should be less than 10%. However, it can be seen that on all dates in November, it exceeds this threshold. Problems are identified at multiple stages of the process. For example, Cutter and VIM have high peaks in defects, indicating problems in tube cutting and product validation. EOL also shows high values, suggesting that most defects are not detected until the end of the process, increasing waste. The variability in the values indicates a lack of stability in production, possibly due to machinery failures, lack of standardization, or human error. This translates into material loss and high costs, operational inefficiency, regulatory non-compliance and risks in the medical industry, and a poor image for the company.

On the other hand, Table 2 identifies problems related to time studies and operator allocation. It can be seen that some operations use almost 100% of the cycle time (e.g., Trimming Hum and Hum Overmold). Other operations have very low processing times (such as Remove gate, with only 3.8 seconds per part), which generates idle time (22.25 seconds per part). This difference causes uneven use of the target cycle time (26 s), revealing an imbalance in the distribution of the workload along the production line. In addition, operator allocation is inconsistent. While at some stations each activity has one operator, at others a single worker handles multiple parts. This creates bottlenecks and inefficient use of installed capacity, as well as production delays and, ultimately, a decrease in overall productivity, i.e., process efficiency.

Table 2. Hose production process cycle times

Process areas	Parts	Number of operators	Cycle time (seconds)	Idle time by part (seconds)	Idle time	Total idle time by operator
Trimming Hum	2	2	52	26	0	0
Trimming Mask	2	2	36	18	8	32
Strippinng	2	2	33	16.5	9.5	38
Assembly Hum	4	4	32	8	18	288
Assembly Mask	4	4	32	8	18	288
USW	4	4	51	12.8	13.25	212
Cutter	4	1	79	19.8	6.25	25
Hum Overmold	4	1	94	23.5	2.5	10
Mask Overmold	4	1	79	19.8	6.25	25
Remove core	4	1	44	11	15	60
Remove gate	4	1	15	3.8	22.25	89
EOL Tester	2	2	36	18	8	32
Packaging	1	1	10	10	16	16
		Maximum cycle time/parts		26		

1.1 Objectives

The overall objective of this project is to implement Lean Manufacturing tools in the medical extrusion hose production line to increase operational efficiency and validate equipment. On the other hand, the specific objectives are: 1) to reduce the production cycle time by 20%; 2) to reduce the percentage of defective products (%NG) to less than 10%; and 3) to validate the three main pieces of equipment: Stripping, USW, and EOL.

2. Literature Review

2.1 Lean Manufacturing

Lean manufacturing is one of the most popular approaches to improving operational efficiency, as it focuses on minimizing waste and maximizing product value (Mostaghimi & Behnamian, 2023). This approach has been widely adopted in the automotive, aerospace, and healthcare industries. Lean manufacturing is based on five principles, which are: 1) value, i.e., the customer's willingness to pay for a given product or service; 2) value stream, which refers to the

complete set of activities necessary to deliver a product or service to customers, including both value-adding and non-value-adding activities; 3) flow, which refers to the continuous movement of products and services through the value stream; 4) pull, which is a production principle that focuses on producing only what is needed when it is needed; and 5) perfection, which is the ultimate goal of lean manufacturing and refers to the continuous pursuit of waste elimination and value creation (Khayrullina et al., 2015). These principles guide organizations in their pursuit of operational excellence.

The application of lean manufacturing offers companies the following benefits (Lewis, 2000): it helps reduce costs, improves quality, increases flexibility, increases employee engagement, and provides organizations with a competitive advantage.

2.2 5S

The 5S methodology is a structured approach to workplace organization and standardization that is widely used in various organizational contexts, such as healthcare, education, and office environments. It focuses on five principles: Sort, Set in Order, Shine, Standardize, and Sustain. The Sort principle focuses on the systematic removal of unnecessary items from the workplace. Its application involves three steps: identify, sort, and discard (Do et al., 2023). The Set in Order principle focuses on ensuring that essential items are stored in designated locations. Its application involves two steps: organizing and labeling. The principle of Cleanliness focuses on ensuring that employees work in clean and well-maintained environments. The steps to apply it are cleaning and inspecting. The principle of Standardization focuses on establishing standardized work procedures. Its application involves the steps of documenting and communicating. Finally, the principle of Discipline focuses on cultivating a sense of ownership and responsibility among employees. Its application involves two steps: training and rewarding (Kang et al., 2022). These principles enable organizations to create and maintain clean, organized, and efficient workplaces.

Implementing the 5S brings the following benefits to organizations: it improves efficiency and fosters a culture of continuous improvement, improves workplace safety, improves employee productivity, reduces operating costs, improves employee morale, and improves product quality (Bayo-Moriones et al., 2010).

2.3 Value Stream Mapping

Value Stream Mapping (VSM) is a tool that provides a visual representation of the flow of materials and information in a process, allowing organizations to identify and eliminate activities that do not add value (called waste) from a holistic perspective, improving the efficiency and effectiveness of processes (Kumar et al., 2018). A value stream is the set of activities, both value-adding and non-value-adding, necessary to deliver a product or service to the customer. VSM focuses on a specific product or service and maps the activities of the entire value stream, allowing organizations to analyze and improve their end-to-end processes.

A VSM consists of four components: process steps, information flow, material flow, and lead time. Process steps are represented as rectangles and indicate the activities in the value stream. Information flow is represented as arrows and indicates the direction of information transfer. Material flow is represented as a dashed line and indicates the movement of materials in the process. Lead time is represented as a clock symbol and indicates the time required to

complete each process step (Binder, 2007). By analyzing these components, organizations identify bottlenecks, delays, and activities that do not add value to their processes and implement specific improvements (Zhao et al., 2015).

The VSM process consists of five key steps. In the first step, companies select a product or service that is strategically important and has significant potential for improvement. In the second step, a VSM is created to map the current state of the value stream for the selected product or service (Forno et al., 2014). Data on process steps, information flow, material flow, and lead time are collected to create the current state VSM. In the third step, the current state VSM is analyzed, identifying bottlenecks, delays, and activities that do not add value. In the fourth step, a future state VSM is created that represents the optimized value stream. Improvements are identified and implemented to eliminate bottlenecks, delays, and activities that do not add value. In the final step, the improvements identified in the future state VSM design are implemented (Andreadis et al., 2017).

VSM offers the following benefits: it provides a holistic view of the process, is easy to understand and communicate, focuses on waste elimination, and is a structured approach that can be applied consistently and effectively. However, VSM has the following disadvantages: it requires data collection and analysis; it focuses on process efficiency, which can have a negative impact on process effectiveness; it is a static tool, so the current state of VSM can quickly become obsolete (Dadashnejad & Valmohammadi, 2019).

2.4 Kaizen

Kaizen is one of the most effective strategies for making incremental improvements to processes, products, and services that translate into performance improvements (Chung, 2018). The four fundamental principles of the Kaizen philosophy are “standardization”, “waste elimination”, “continuous improvement”, and “employee participation”. Standardization refers to establishing the best-known methods for performing tasks, which serve as a baseline for future improvements. Waste elimination involves identifying and eliminating any activity that does not add value to the customer. Continuous improvement is the essence of the Kaizen philosophy and encourages organizations to constantly seek better ways of doing things. Finally, employee involvement is crucial to the successful implementation of Kaizen practices (Staniškienė et al., 2018).

Successful implementation of Kaizen practices comprises four steps: 1) identifying the area requiring improvement, 2) planning improvement actions, 3) implementing the actions, and 4) evaluating the effectiveness of the actions. The implementation of Kaizen brings the following benefits: it improves organizational performance, facilitates knowledge sharing and collaboration among employees, improves employee motivation and satisfaction, promotes a culture of continuous improvement, and improves the flexibility and responsiveness of the company (Wolniak & Grebski, 2023).

2.5 SMED

The Single Minute Exchange of Die (SMED) is a methodology that focuses on changeover processes (downtime processes), and its objective is to significantly reduce the time required for these processes, thereby increasing the efficiency of machinery and resources (Moreira & Pais, 2011). The implementation of SMED consists of four steps. The first step is to select a machine or production line suitable for SMED implementation. The second step is to measure the current changeover time for the selected resource. The third step is to analyze the current changeover process using SMED principles. The final step is to apply the identified improvements and measure the new changeover time. The difference between the new and old times provides a measure of the effectiveness of SMED implementation (Singh et al., 2018).

The implementation of SMED offers the following benefits: reduced changeover times, increased production flexibility, reduced inventory levels, improved product quality, smaller batch production, increased production flexibility, increased production volumes, product variety, and improved quality (Singh et al., 2018).

3. Methods

The following materials are required to carry out this project: colored labels, posters, paper value stream maps, SAP® software, Kanban boards, tape measures, stopwatches, containers, shelves, thermocouples, thermometers, thermostats, heaters, coolers, pressure gauges, micrometers, digital calipers, thickness and roughness gauges, speed sensors, Minitab® software, AutoCAD®, polymers, lubricating oils, parts cleaners, adjustment tools, extrusion machine,

biocompatible plastics, high-resolution cameras, tensile testing equipment (tensile machines), validation forms, manufacturer's manuals, calibration certificates, qualification and risk assessment study forms, certificates of conformity, compression and flexing machines, optical measurement systems, standard operating procedure (SOP) forms, and internal audit report forms, deviation record forms, and training report forms.

The method is divided into four phases: 1) Initial diagnosis to understand the current state of the process, 2) Application of Lean tools focused on optimizing time, quality, and organization, 3) Formal validation of critical equipment used in production, and 4) Monitoring and continuous improvement system to sustain the progress achieved. The activities carried out in each of the phases are described below.

3.1 Phase 1: Initial diagnosis of the process

The objective of this phase is to understand the current state of the production line and identify the main problems. To do this, data is collected on cycle times, the percentage of NG, and process efficiency. At each workstation, a time study is carried out using stopwatches, active and idle times are recorded, and the number of operators per station is noted. Next, the net time and idle time per operator are calculated, and tasks that can be merged, divided, or moved are identified. In addition, a VSM is applied to identify waste, bottlenecks, and stations with unbalanced times, critical points are visually identified, and the current VSM is documented.

Subsequently, a motion study is performed. A critical or representative station in the process is chosen, and the activity performed and the conditions under which it is performed are specified. Next, the operator's movements during a complete cycle are recorded. The movements are divided into steps: prepare, pick up tool, position part, weld, inspect, among others. These movements are classified into three categories: 1) adds value, 2) does not add value but is necessary, and 3) does not add value. The times and movements are recorded on an analysis sheet. Once this is done, pauses, delays, and idle times, or delays are detected, and the average time and standard time for the operation are calculated. Next, waste (overproduction, inventory, defects, overprocessing, delays, transportation, or movements) is identified.

3.2 Phase 2: Application of Lean Manufacturing tools

This phase is carried out with the intention of reducing waste, improving organization, and increasing operational efficiency. First, the future VSM is designed. To do this, a product with stable flow that is representative of the area is chosen, and data from the current process is recorded. Cycle times are measured with a stopwatch, intermediate inventories are recorded, and waiting points and unnecessary movements that generate defects are identified. Operators are also recorded by station, as well as their activities. Next, the VSM drawing is made. In addition, overproduction, waiting, transportation, reprocessing, and excess inventory events are identified, and Lean Manufacturing tools are selected to eliminate them. The new flow drawing contains the proposed changes: lower inventory, shorter times, better flow conditions, and visual communication. The current state is compared with the previous one, measuring total time, takt time, productivity, inventory level, and scrap percentage. The entire process must be validated and documented for continuous improvement and feedback purposes.

Next, the 5S method is applied in the production area. Everything necessary is classified, identified, and separated from the unnecessary, removing tools, materials, or documents that are no longer useful. Then, the necessary items are organized, and a fixed place for each tool or material is assigned and labeled. Next, machines, tools, and work areas are cleaned, establishing a daily routine to maintain optimal conditions and identifying sources of dirt. To standardize, visual and written procedures are created to maintain order and cleanliness, and posters, labels, and signs are placed that remind people of the rules, responsibilities, and frequencies for these tasks. Finally, discipline is encouraged to comply with the 5S daily, and audits are conducted to ensure sustainability and promote continuous improvement.

To implement SMED, all activities involved are identified, separating external activities from internal activities. Then, as many internal activities as possible are converted into external activities to reduce changeover time. Next, the necessary steps are standardized. Finally, staff are trained to follow the established procedures, and periodic measurements are taken to verify the reduction in changeover times and improve the effectiveness of the process.

To implement Kanban, replenishment points and maximum and minimum inventory levels are defined for each material or component. This allows you to visualize when it is necessary to place an order or move stock to avoid shortages or excesses. Next, physical signs or Kanban cards are designed and placed in strategic locations to facilitate visual communication between processes and ensure a constant flow. These cards are placed on each hose, each color corresponding to the line (A, B, C, and D) on which the material has been worked. Each line has a different list of operators and machines. To generate traceability in the process, each line will be identified by a color: Line A: GREEN, Line B: BLUE, Line C: YELLOW, Line D: ORANGE. This helps to detect and eliminate defects in each of the hoses. Finally, the performance of the system is monitored, and inventory levels and order points are adjusted according to actual demand in order to maintain an efficient flow and avoid interruptions in production.

Lastly, staff are given brochures and information on process symbologies and are trained with training documentation and quality alerts, raising awareness of each of the colors used in the process.

3.3 Phase 3: Validation of critical equipment

The objective of this phase is to verify that key process equipment operates safely, efficiently, and in compliance with medical regulations. To this end, equipment is selected for formal validation based on an assessment of its impact on product quality, user safety, and process stability. The following technical criteria are established for the assessment: direct impact on critical product specifications, relationship to regulatory compliance (ISO 13485/FDA), operational complexity and sensitivity to errors, failure history and associated %NG, and interconnection with other key processes. Each criterion is evaluated on a scale of 1 (low impact) to 5 (critical), and partial scores are assigned to all equipment involved. Equipment that exceeds 17 points is selected as critical equipment for validation, as it presents high combined criticality.

Once the equipment has been selected, installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) are performed to ensure that it is installed and operating correctly, stably, and in a controlled and repeatable manner. To conclude that the validation was satisfactory, at least 95% of the units processed must meet the established quality requirements. Any deviation is documented and evaluated based on internal control and continuous improvement procedures. This phase confirms that the production system is under statistical control and capable of maintaining the quality and performance required by the customer. At this stage, all evidence generated during the execution of the IQ, OQ, and PQ validations is consolidated, ensuring that the results obtained are correctly recorded, signed, and controlled in accordance with internal procedures and applicable standards.

3.4 Phase 4: Monitoring and continuous improvement system

This phase aims to ensure the sustainability of the improvements implemented and promote a culture of continuous improvement. To monitor process performance and ensure stability, key performance indicators (KPIs) are established to evaluate efficiency, quality, and production times objectively. These KPIs are overall equipment effectiveness (OEE), %NG, cycle time, and changeover time. If the OEE is less than 85%, %NG is greater than 2%, or cycle time or changeover time is considered high, the causes are investigated and improvements are implemented. Subsequently, internal audits are conducted periodically to maintain discipline, order, and continuous improvement by detecting deviations, correcting them, and ensuring that Lean practices are sustainable.

Finally, a continuous training plan is developed and implemented to develop and reinforce the skills of operational, technical, and supervisory personnel in Lean tools. This ensures continuous improvement and the sustainability of the good practices implemented.

4. Results and Discussion

Table 3 shows a comparison of the percentage of defects (%NG) before and after the implementation of Lean Manufacturing tools. There was a significant decrease in defects at all stages analyzed. For example, at VIM, the percentage of defects fell from 14.47% to 3.79%, at EOL it fell by 71.72%, and at USW by 63.16%. On average, the percentage of non-conforming products fell from 31.23% to 17.42%, which is equivalent to an improvement of 43.71%. These results reflect a significant improvement in operational efficiency.

Table 3. Comparison of %NG Before vs. After

Stage	Average Before (%)	Average After (%)	Difference (%)	Improvement (%)
Stripping	2.17	0.93	1.24	57.14
Assembly	4.83	3.05	1.78	36.85
USW	5.7	2.1	3.6	63.16
Cutter	8.72	5	3.72	42.66
VIM	14.47	3.79	10.68	73.81
EOL	9.76	2.76	7	71.72
%NG	31.23	17.42	13.65	43.71

In terms of cycle time, Table 4 shows that it decreased in all areas, with the largest reduction in Hum Overmold, at 18.8 seconds, and the smallest in Packaging, at 2 seconds.

Table 4. Original vs. final cycle time

Process area	Original cycle time (s)	Optimized cycle time (s)	Reduction (%)
Trimming Hum	52	41.6	20
USW	51	40.8	20
Cutter	79	63.2	20
Hum Overmold	94	75.2	20
Packaging	10	8	20

With a uniform 20% reduction in cycle times, a more balanced production line was achieved, improving workload distribution between stations, promoting continuous and stable flow, and more efficient use of installed capacity.

4.1 Increase in OEE

After applying Lean Manufacturing tools, various KPI values improved significantly. For example, the percentage of non-conforming product (%NG) decreased by an average of 19.88%, while the quality indicator improved from 70% to 82.7%. Similarly, OEE improved by an average of 15.36%.

4.2 Reduction of times (SMED)

Following the implementation of the SMED system at key stations, the average changeover time at USW was reduced from 32 to 14 minutes (an improvement of 56%). At Mask Overmold, changeover time decreased from 29 to 13 minutes (an improvement of 55%). It was also possible to reduce the total downtime due to changeovers by more than 10 hours per month, which allowed for the production of approximately 480 additional units per month, under the target cycle time parameters (approximately 26 seconds per part). In addition, equipment availability improved by 7%, contributing to the overall increase in line efficiency.

The implementation of SMED was one of the most effective Lean strategies within the project. Its impact was not only reflected in the direct reduction of changeover times, but also in greater responsiveness to production variations, less inventory accumulation between batches, and a substantial improvement in organization.

4.3 Line balancing and waste reduction

Table 5 presents the most relevant results in the operational structure after the implementation of Lean Manufacturing tools, specifically in line balancing. There is evidence of a significant reduction in the number of operators at stations with idle time, without compromising the overall cycle time. For example, Trimming Hum and Mask were consolidated, reducing duplication of functions.

Table 5. Line balancing after implementing Lean Manufacturing

Process	Operators before	Operators after	Adjusted cycle time (s)	Observation
Trimming Hum	2	1	45	Redistribution with Trimming Mask
Trimming Mask	2	1	40	
Stripping	2	1	35	Load better distributed
Assembly (H+M)	8 (2x4)	5	42	Combined into a single cell
USW	4	3	48	Remains as a minor neck
Cutter	1	2	40	Reinforced to reduce neck
Overmold (H+M)	2 (1+1)	2	42	Load balanced between both
Remove (core+gate)	2 (1+1)	1	38	Sequential grouped operation
EOL Tester	2	2	36	No changes
Packaging	1	1	18	Compatible with the final speed

At critical stations such as USW and Cutter, resources were maintained or reinforced, allowing bottlenecks to be cleared. Other stations, such as the Remove gate, were sequentially integrated, increasing flow efficiency without the need for additional personnel. This new scheme allowed cycle times between stations to be much closer to each other, aligning the speed of operations and significantly reducing waste due to waiting, overprocessing, and work-in-progress (WIP).

The redistribution of workloads also favored an environment prepared for future implementations of pull systems (Kanban). As a result, accumulated idle time was reduced by more than 40%, eliminating long waits between stations, which led to a more synchronized flow, less WIP accumulation, and a decrease in defects due to handling and waiting times.

4.4 Equipment validation (IQ, OQ, PQ)

The validation of critical process equipment (Stripping, USW, and EOL) was carried out in accordance with established protocols, following the IQ (Installation), OQ (Operation), and PQ (Performance) qualification stages.

- Stripping showed stable performance with a validated cycle time of 35 seconds and a dimensional average of 10.02 mm (tolerance: 9.5–10.5 mm), obtaining a Cpk = 1.45, which indicates that the process has high capacity and very low variability ($\sigma = 0.11$ mm).
- In USW, parameters such as welding energy, pressure, and time were validated, with a cycle time of 47 seconds and an average energy of 75.1 J (tolerance: 70–80 J), achieving a Cpk = 1.05, indicating that the process is acceptable and capable, although it is closer to the lower acceptable limit (1.00). The process shows slightly more variability ($\sigma = 1.55$ J), but still meets specifications (70 to 80 J).
- In the case of EOL, as it is a "good/bad" functional inspection station, no Cp or Cpk capability analysis was applied. Instead, its ability to detect non-conforming parts was evaluated, recording a rejection rate of 5%, which is within the acceptable limit of 10%.

During the PQ stage, all three pieces of equipment maintained their performance within the defined parameters, demonstrating repeatability, stability, and compliance with quality criteria.

5. Conclusion

The case presented in this project clearly shows that the correct application of Lean Manufacturing tools, specifically 5S, Value Stream Mapping, Kaizen, and SMED, represents a reliable strategy for reducing defective parts, decreasing production times, validating equipment, and increasing efficiency in a production process.

The results obtained in this project are similar to those of Pinto et al. (2018), who implemented 5S in one production line and, once it was validated, implemented it in other lines. For their part, Rahardjo et al. (2023) present a case study on the manufacture of vacuum degassing equipment. In this study, these authors use Lena Manufacturing tools such as VSM and SMED. As a result, they managed to increase the Cpk index from 1.278 to 2, created a safer working environment, and increased production yield to 100%. In another case study, Habib et al.(2023) applied 5S, SMED, and VSM in a labeling and packaging plant, reducing lead time and improving OEE. Finally, Jiménez-Delgado et al. (2023) implemented 5S and VSM in a textile industry company, improving product quality and reducing lead time.
The results of this project, together with those shown in previous studies, confirm that the application of Lean Manufacturing tools has a positive impact on the efficiency of manufacturing processes..

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