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Production Capacity Increase in Medical Device Manufacturing Assembly Lines

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Abstract

This paper addresses the reduction of downtime in key operations. It also addresses the continuous improvement in the process without modifying the process flow, applying the DMAIC (Define, Measure, Analyze, Improve and Control) methodology. In which the information of this work will be focused, explaining the activities to be developed to improve the cycle time in the production line and at the same time to be able to cover the new customer demand. It includes in a general way the necessary validation process of the product, objectives delimited by the norms and regulations for the manufacture of medical products are raised. Engineering studies are presented in detail to determine parameters, validations to ensure equipment installations, a protocol with its respective report where statistical studies of capacity and stability of critical processes are shown. As part of the objectives, capacity was increased by 60% in the production line, reducing the cycle time of operations and eliminating bottlenecks through the implementation of new equipment and ergonomic improvements.

Keywords

Bottlenecks, downtime, continuous improvement, DMAIC (Define, Measure, Analyze, Improve, and, Control.

1. Introduction

Over the past two years, the world in general has witnessed a shift in consumer priorities. Despite the difficulties in continuing global manufacturing production due to the worldwide pandemic of COVID-19, not only did companies manufacturing essential products continue to work, but demand volumes increased. Now more than ever, the utilization of raw materials and installed production capacity has become more important and waste generation less tolerable. The Baja California medical device manufacturing cluster has been part of this reality, in which projects have been aimed at reducing downtime, increasing linear flow, reducing waste in general and validating each of the changes proposed during the improvement process.

This case study was developed in a company that provides assembly services for medical products, the objective was to reduce and/or eliminate bottlenecks and unnecessary operations, in order to generate an increase in production

capacity in the line and as a final result meet the new customer demand. The times of each operation were analyzed, as well as the bottlenecks within the production line, which helped to detect possible improvements that could be modified. The company previously had two suppliers for the production of the "Hand Controller", which is a fundamental part of one of its most demanded products for sale. One of those two suppliers is the company NPA de México (Jabil Healthcare Baja). For reasons of better service and higher quality, the ACIST Customer decided to move all its production demand to Jabil Baja. As a result of the decision made by the customer, a SIPOC (Supplier-Inputs-Process-Outputs-Customer) was performed to know which part of the entire supply chain was affected by this increase in demand, which was reviewed with planning the management of the new acquired demand. Some of the points that were reviewed were: the capacity of the sterilizer, the capacity of the suppliers with purchases, the increase of shifts, which leads to the involvement of Human Resources with the hiring and training of direct personnel, among others. Ergonomic analyses were also performed at all stations, and it was decided to make some ergonomic improvements for the well-being of the operator. For example, the change of chairs, bringing the material closer to the operator, avoiding unnecessary movements, etc., because at the time of increasing the pace, the aim was to avoid safety and health problems for the operators.

The problem to be solved by implementing Six Sigma tools is to eliminate all bottlenecks and operations that do not add value to the line, in order to increase the capacity of the production line to 60% of its current capacity. The initial demand for this product was 29,400 boxes per month (50 boxes per hour) and the new demand required by the customer was 37,440 boxes per month (80 boxes per hour), so this project was carried out. The ATP Hand Controller production line has one sub-assembly and 12 operations. It runs in parallel, meaning that each operation is double (mirror mode) and the flow is from right to left. Specific project objectives include:

- Increase production capacity from 50 cases to 80 cases per hour, for which would be 60% more capacity.
- Reduce production shifts from 4 to 3 per day.
- Decrease labor cost by $35,000 per month.

Hand Controller line demand increased due to ACIST requirement from 16,000 cases to 32,000 cases per month. Due to this increase in demand, Jabil Healthcare Baja made the decision to open a third and fourth production shift (Friday through Sunday morning/afternoon) to cover this increase and run the line 24/7 (see table 1 and figure 1).

Table 1. Activities and times for the line

No.	Description	Cycle time (Seg)
1	RewindTwin Tubing y attach fastener	5.10
2	Cut Twin Tubing	4.90
3	Separate Twin tubing and assembly of female luer	6.40
4	Assembly of Male Luer	5.60
5	Assembly of Bladder Saline	5.50
6	Assembly of Bladder Contrast	5.20
7	pre-assembly and pressing of Top y Botton housing	6.00
8	Leakage and occlusion test	7.20
9	Inspection of HC and place inside the pouch	9.20
10	Introduction of the high pressure pipe and stopcock	4.30
11	Inspection and sealing of pouch	7.00
12	Sealing and final inspection	4.80
13	Place in cart	5.10
A	Uretano Sub Assy	4.80
B	Paste labels	3.90

As part of a Continuous Improvement and Cost Reduction Project, a joint initiative was taken between Jabil Healthcare Baja and ACIST to increase production capacity to meet ACIST's new demand for only three production shift changes (A, B and C). To seek the reduction of these shifts and the increase in capacity, the takt time will need to be reduced to 4.5 seconds. This will be achieved by improving the current stations, replicating and integrating equipment on the line in order to have a better flow and meet demand. The capacity of the current line and the projection are shown in table 2:

Table 2. Current capacity and projection

Linea Hand Controller	Takt Time	Boxes per hour	Capacity per month (boxes)	Number of shifts
Current line	7.2	50	29,400	4
Proposed line	4.5	80	37,440	3

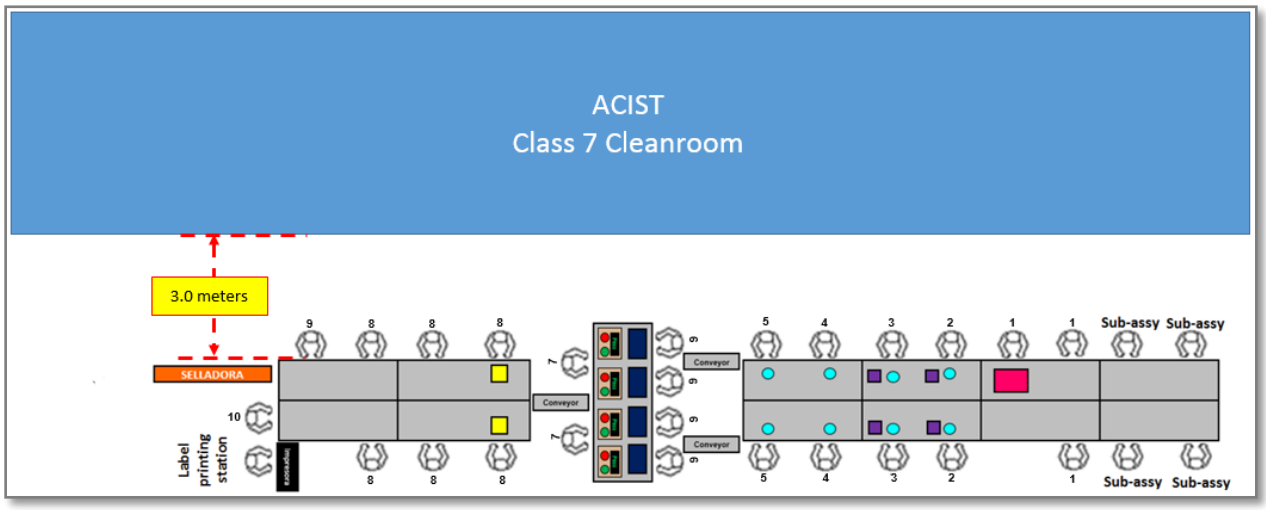

Figure 1. Current lay out

The rest of the document is structured as follows: Section 2 presents a literature review on continues improvement and applications for medical devices manufacturing. Section 3 presents the methodology applied to decrease bottlenecks, downtime through the DMAIC methodology. Section 4 shows the results obtained by applying the methodology. Finally, Section 5 shows the conclusions and a discussion of the results obtained in this research.

2. Literature Review

2.1 Tools for improve production capacity

The reduction of process costs is a requirement for maquiladora companies in Tijuana; companies use different tools, methodologies and techniques to achieve this, such as continuous improvement, also called kaizen (Arredondo-Soto et al. 2021), lean manufacturing, six sigma, Deming Cycle (Arredondo-Soto et al. 2018 and Realyvásquez-Vargas et al. 2018), 8D for 8 disciplines (Realyvásquez-Vargas, Arredondo-Soto, García-Alcaraz, et al. 2020) and, work standardization (Realyvásquez-Vargas, Arredondo-Soto, Blanco-Fernandez, et al. 2020). Production capacity is affected by waste, and depending on the type of waste, the appropriate tool is chosen. For companies with quality problems and with resources to invest in training, Six Sigma is recommended; in case of not having resources, Kaizen can be applied. On the other hand, if the problem is related to downtime and linear flow, Lean Manufacturing tools are the best. The reality is that it is becoming more and more common to see companies mixing these tools to obtain better results. The goal is always to provide value-added products at the lowest cost and in the shortest possible time. Other variables of interest that add intangible value, if not to the product then to the brand, have now also been considered, and here sustainability strategies are included. The reality is that waste reduces the production and response capacity of companies and is the main obstacle to be dealt with in order to increase the competitiveness and permanence of companies.

2.2 Six Sigma

The Six Sigma methodology has a growing application not only in the industry but in almost any field. This methodology, which in turn is an administrative philosophy, started in Motorola and due to its effectiveness has transcended throughout the world by different companies and industries (Caulcutt 2001). This methodology goes hand in hand with continuous improvement and lean manufacturing, since, although they proceed in different ways, they have the same purpose. To carry out Six Sigma, it is necessary to follow certain steps which form the DMAIC cycle (acronym in English) that consists of 5 phases: Definition, Measurement, Analysis, Improvement and Control, which will be detailed later. A crucial point for Six Sigma is the variation, as Deming (1994) said "The enemy of every

process is the variation". Taking care of variation is the key to success for any industry, because if the variability of a process is reduced, the production and operation costs are also reduced, the quality of the product is also improved and as a consequence of all this, customer satisfaction can be achieved.

Six Sigma is a statistical quality term that refers to the number of 3.4 defects per million opportunities, it is also a metric and a goal. Most companies operate under a much lower level of quality, usually between 2 and 3 sigmas which means between 66,000 and 300,000 defects per million, so it is important for any company to raise these levels to achieve an advantage in the market and for this the Six Sigma methodology can be used (Chowdhury 2001). Six Sigma is a methodology based on projects and work teams, that is, the team of people in charge acts on a project using the DMAIC on a specific performance problem. In order to solve these problems the team must be based on certain techniques and tools characteristic of Six Sigma that will help in each phase of the cycle and as a whole to develop the project. These tools will be enunciated and explained below. For this project these tools will be directed to processes and number of defects since this is what we are trying to improve. Now the phases of Six Sigma.

3. Methods

The method applied in this research was DMAIC (Define, Measure, Analyze, Improve and Control) from Six Sigma.

Stage 1 DEFINE

At this stage the proyect charter and SIPOC (Supplier, Inputs, Process, Output, Consumer) are developed as is shown in tables 3 and 4. The project team consists of: the Sr. quality engineer, the production supervisor, the maintenance technician, the project manager, and the Sr. manufacturing engineer support (Table 3, table 4 and table 5)

Table 3. Project charter

Title		"Increase of Productive Capacity in the Hand Controller production line".
Problem statement		In the production line Hand Controller ATP, we are looking to reduce and/or eliminate bottlenecks and unnecessary operations in the operators, in order to generate an increase of productive capacity in the line of approximately 60%, to meet the new customer demand.
Goal		Propose, together with an interdisciplinary team of the company, methodologies and/or procedures that allow the reduction of bottlenecks in the "Hand Controller" production line of the Jabil plant; using DMAIC methodologies, to meet the demand.
Specific target		Increase the production capacity from 50 boxes to 80 boxes per hour, which would be 60% more capacity. Decrease labor costs by $35,000 per month.
Scope		The bottlenecks generated at the workstations will be addressed, until strategies are proposed to help mitigate the causes of these bottlenecks.
Focus	**Area**	Manufacture
	Process	Generation
	Product	Hand Controller
Projected savings		$35,000 dlls monthly

Table 4. SIPOC

Supplier	Input	Process	Output	Customer
Materials department	Twing tubing and pin	Rewind of twing tubing and pin	Twing tubing rewined with pin	Operation 2
Previous operation	Twing tubing	Cut of twing tubing	Twing tubing cut	Operation 3
Materials department and previous operation	Twing tubing and female luer	Separation of twing tubing and assembly of female luer in saline tub	Female luer assembly	Operation 4
Materials department and previous operation	Twing tubing and male luer	Assembly of male luer in contrast tub	Male luer assembly	Operation 5
Materials department and previous operation	Air blabber and saline tub	Assembly of air bladder and saline tub with using of alignment fixture	Air bladder assembled in saline tube	Operation 6

Materials department and previous operation	Air blabber and contrast tub	Assembly of air bladder and contrast tub with using of alignment fixture	Air bladder assembled in contrast tube	Operation 7
Materials department and previous operation	Bottom and top housing	Assembly of bottom housing and top housing	Bottom housing and top housing asembly	Operation 8
Previous operation	Previous assembly	Leakage and occlusion test	Leak and occlusion test performed	Operation 9
Previous operation	Previous assembly	Check for defects, set winding and verify joints	Assembly inspected and fitted	Operation 10
Materials department and previous operation	Assembly, pouch and kit	Insert controller and kit to pouch Insert PV and stopcock into pouch	Assembly and kit inserted into pouch	Operation 11
Materials department and previous operation	Previous pouch, PV and stopcock	Inspection of seal, points to be inspected	PV and stopcock inserted into pouch	Operation 12
Previous operation	Pouch	Pouch sealing	Pouch sealed	Operation 13
Previous operation	Pouch		Pouch inspected	Operation 14
Previous operation	Finished good	Transport to packaging	Final product in pouch	Operation 15
Materials department and previous operation	Box and finish good	Packing of ATP product	Packaging ready for strapping	Operation 16
Materials department and previous operation	Pallet and strapping	Palletizing of packaging	Load ready and complete	Client

Stage 2 MEASURE

In this stage, the data collection for the value stream map (VSM, see figure 2) and the line balancing are performed.

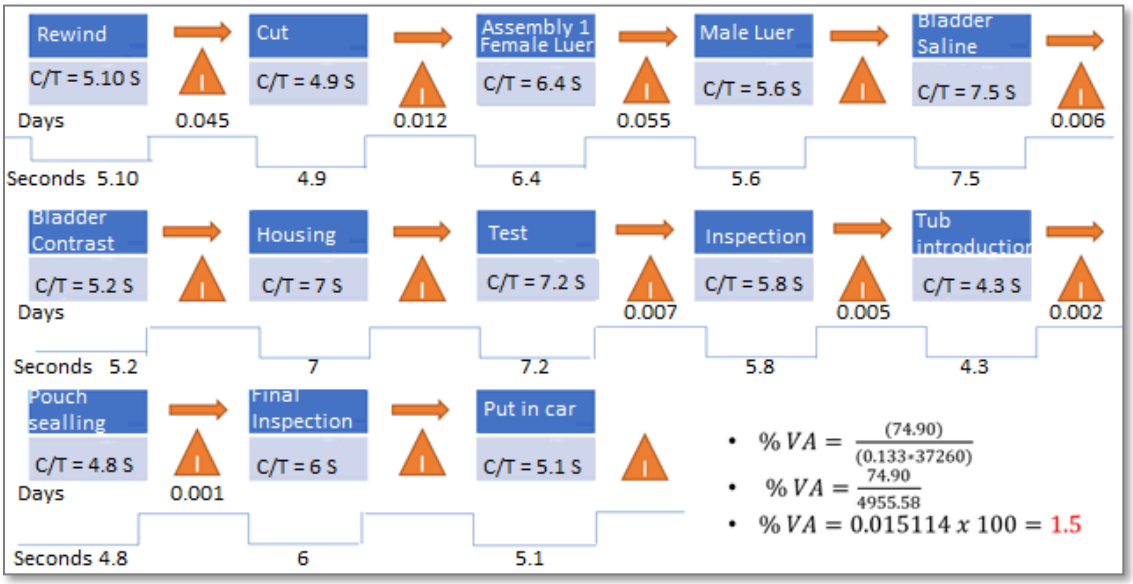

Figure 2. Value stram map

The workday is 12 hours per shift, with one hour as break. Then, there are10.35 effective hours, or 621 minutes or 37,260 seconds. The desired production is 80 cartons per hour or 800 pieces per hour (3,600 seconds), with an efficiency of 90%.

$$Cycle\ Time = \left(\frac{Time}{Production}\right) * Efficiency = \left(\frac{3{,}600\ seconds}{800\ pieces}\right) * 0.90 = 4.05\ seconds/piece \quad \text{Equation (1)}$$

$$Tack\ Time = \frac{Time}{Production} = \frac{3{,}600\ seconds}{800\ pieces} = 4.5\ seconds\ per\ piece \quad \text{Equation (2)}$$

$$Production\ Rate = \frac{Demand}{Time} = \frac{800\ pieces}{3{,}600\ seconds} = 0.222\ piece\ per\ second \quad \text{Equation (3)}$$

$$No.of\ workers = \frac{(Production)(Standard\ Time)}{(Time)(Efficiency)} = \frac{(800*81.10)}{(3{,}600*0.90)} = 21.20 \quad \text{Equation (4)}$$

Table 5. Line Balancing

No.	Operación	Standard Time (Seconds)	No. of workers	Line flow
1	To rewind Twin Tubing and adjust pin	9.3	1.753549	5.13245
2	To cut Twin Tubing	5.5	0.803368	6.2238
3	To separate Twin tubing and assembly of female luer	8.0	1.133169	7.05985
4	To assembly Male Luer	7.4	1.054796	7.015575
5	To assembly Bladder Saline	11.4	1.534486	7.168525
6	To assembly Bladder Contrast	10.4	1.514526	6.602725
7	Pre-assembly and press of top and botton housing	9.2	1.719321	5.35095
8	Leakage tests and occlusion	23.8	5.080225	4.7242
9	Inspection of the HC and placing into the pouch	20	2.576871	7.76135
10	Insertion of high pressure tube and stopcock	5.4	1.535792	3.25565
11	Inspection and sealing of the pouch	4.0	0.790514	5.06
12	Pouch weighing	5.1	0.949929	5.26355
13	Place on trolley	6.3	1.017829	5.8949
	Total		21.46	

$$Pieces\ per\ hour = \frac{(Number\ of\ workers\ with\ slower\ flow*Time)}{(Standard\ Time\ operation)} = \frac{(2.5*3{,}600)}{(20)} = 450\ \text{pieces} \quad \text{Equation (5)}$$

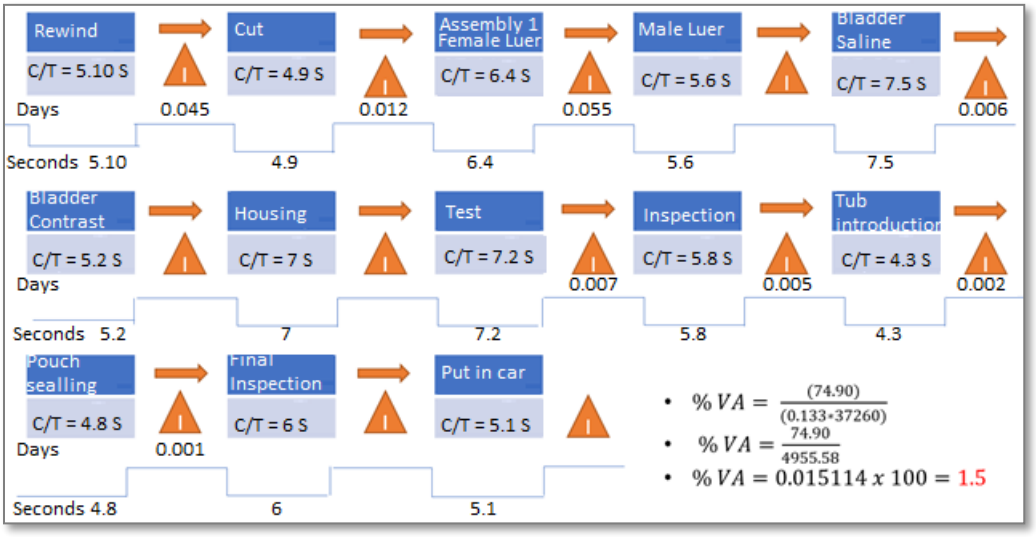

Figure 3. Value stram map

Stage 3 ANALYZE

Ishikawa Diagram, Pareto Chart, and Root-Cause analysis are used to determine (figures 3 to 6) analyze in a more complete way what happens in the production line.

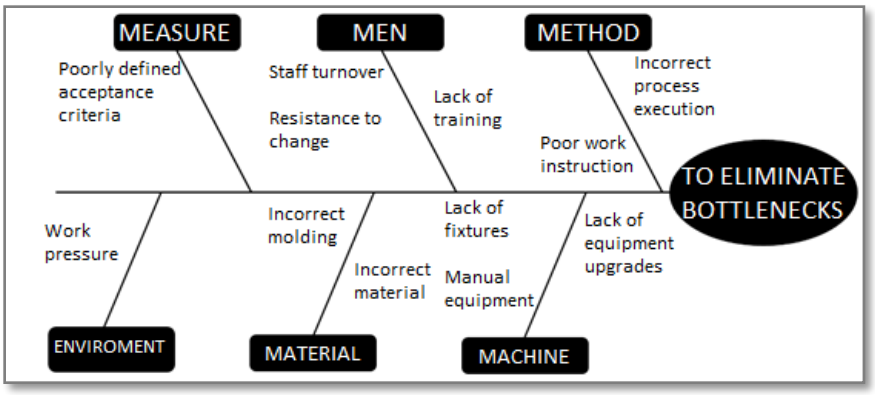

Figure 4. Ishikawa Diagram

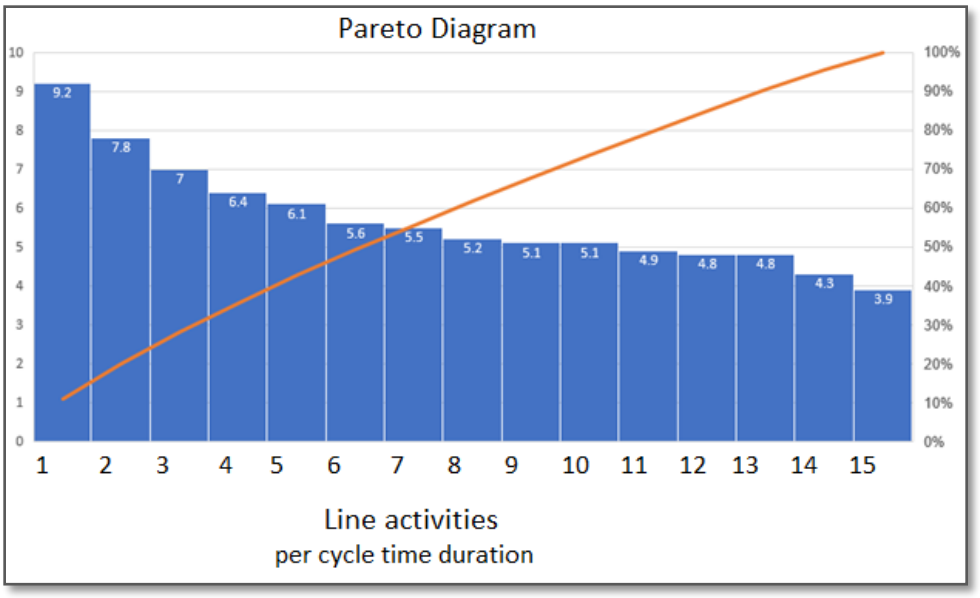

Figure 5. Pareto Chart

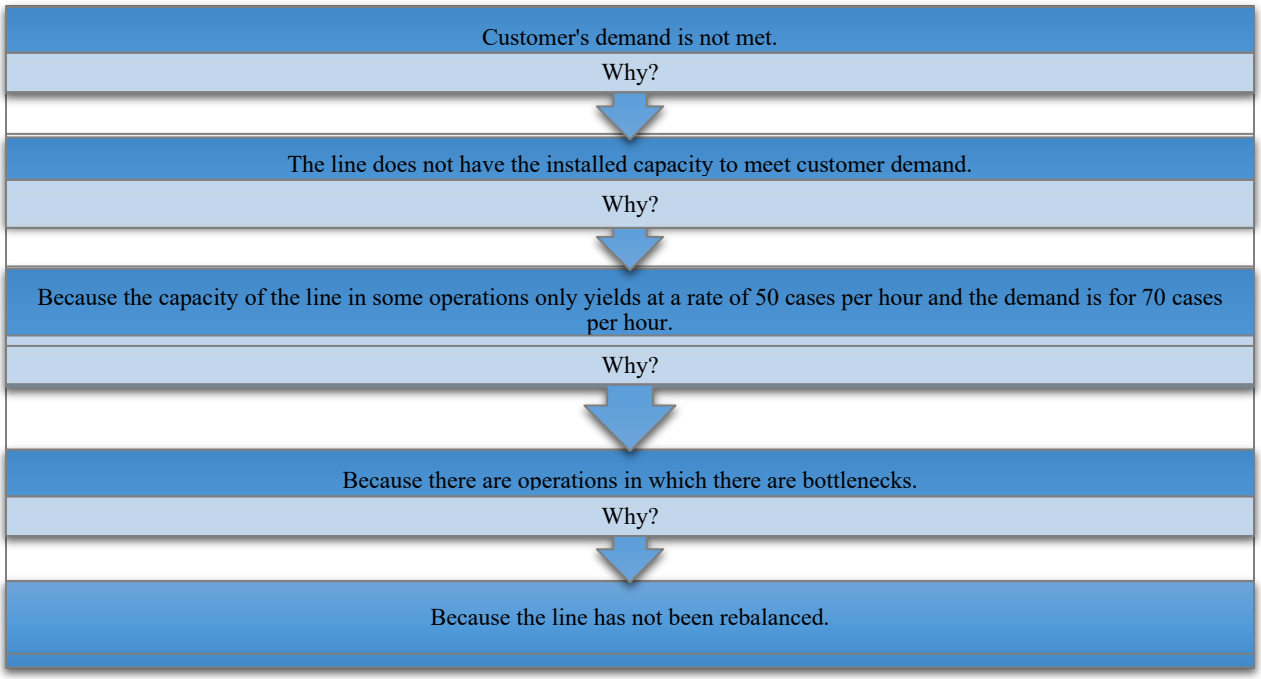

Figure 6. Root Cause Analysis

Stage 4 IMPROVE

At this point we will discuss the proposals that will be made for the reduction of bottlenecks in the process. Each of the proposals will be described in general terms, the advantages and benefits that can be obtained with its implementation will be established, as well as the necessary changes. In order to analyze the possible improvements that will allow the reduction of bottlenecks in the process, the types of causes were taken from the Pareto diagram. The improvement proposals for the process that emerged as a result of the analyses previously carried out by the engineering group, the improvements to be considered in the "Hand Controller" line are in table 6.

The design of the proposed manufacturing line is shown in figure 7. In implementing these improvement changes, it was necessary to carry out an Installation Qualification, an Operation Qualification and a Process Qualification, the validation of which was performed; as required by standard 13485 for industries manufacturing medical devices.

Table 6. Selected improves

Operation	Improve	Team
7	Increase the number of operators from 2 to 4 for leak testing operations.	The number of equipment will remain the same.
8	Add two more operators for visual inspection.	Magnifying lamps required for this operation.
Sub Assembly	Relocate the polyurethane subassembly.	No additional equipment or accessories are required for this relocation.
9	Remove the coil, to pass it off as a subassembly.	No additional equipment or accessories required for this relocation.
10	Replicate the bag sealing operation.	Add new band sealer equipment.
11	Relocate and replicate the weighing operation	Add new scale equipment.
Label workstation	Relocate the printing operation.	No additional equipment or accessories are required for this relocation.

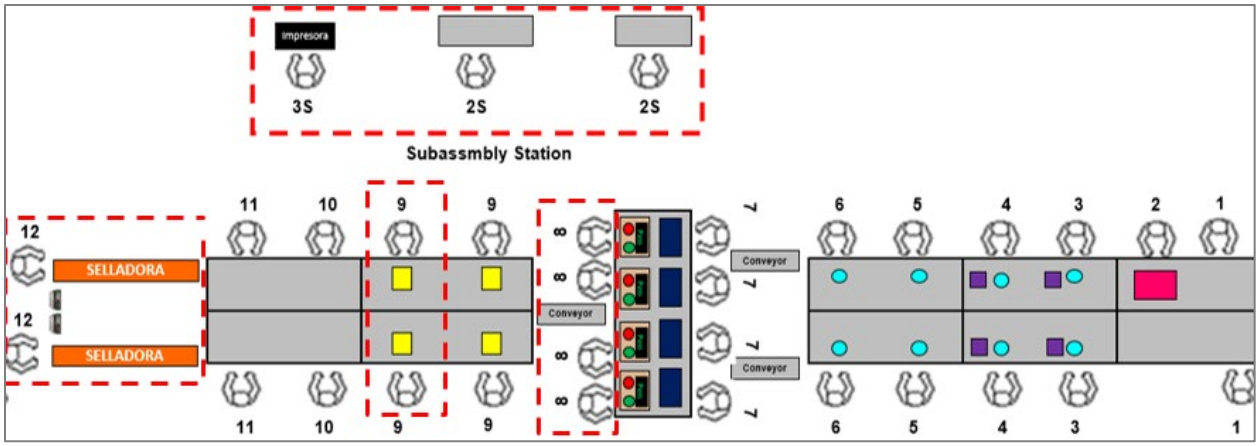

Figure 7. Proposed lay out

Stage 5 CONTROL

At this stage we have to ensure that once the process has been analyzed, corrected and stabilized, the conditions of this process are monitored through statistical techniques for its control. One of the tools commonly applied in companies is the hour by hour format for production control and monitoring. At the company, all the lines on the production floor have their hour-by-hour board, which can be used to observe the state of production and whether the day's goal was met at the end of the shift.

4. Results and Discussion

In this section we can compile the different results in each of the improvement actions carried out throughout this project based on the order in which the objectives were established. As shown in the figure 8, the quantities produced per day in the production line "ATP Hand Controller", it is progressively observed that the line has a constant behavior, where at the beginning it is a little off target, but finally it reached the production plan to meet customer demand. It can be said that the changes implemented in the line were successful, because the project objectives were achieved. However, monitoring should be done on a daily basis to keep track and identify if at any time the goal is not being met and to take corrective actions. The installed capacity is greater than the demand and if we seek continuous improvement we will be able to achieve better efficiencies and therefore the opportunity to have much more work will grow.

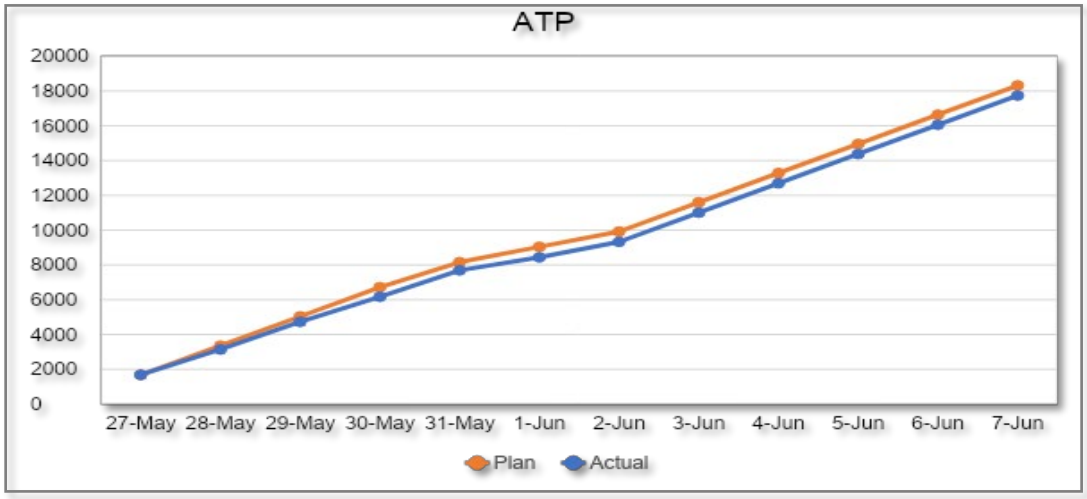

Figure 8. ATP Production Balance

5. Conclusions

As part of the multidisciplinary team of the engineering area it is important to take responsibility for the actions that are being carried out and perform them in the most appropriate way, as a manufacturing engineer it is necessary to follow the DMAIC methodology so that the process and the product to be manufactured comply with the requirements established by ISO-13485. Once the results of the different improvements made in the production area have been analyzed, we can conclude by mentioning the importance of seeking continuous improvement in the processes. The development of this project demonstrates that with the use of DMAIC tools aided by experts in the process and with the help of tools such as SIPOC and Line Balancing, to mention a few, we can direct the efforts of a work team towards the fulfillment of continuous improvement. There are different methodologies and tools to solve problems and acquire knowledge, so we must always take into account all solution options, keeping in mind the technical and economic feasibility. This also forces us to make the necessary considerations about which techniques to apply depending on the complexity of the problem.

During the evaluation process in the ACIST area, which had an insufficient production capacity to cover the new demand of the Customer, it was decided to make an improvement proposal supported by the DMAIC methodology in order to increase the production capacity of the "ATP Hand Controller" line. A line balance was performed to detect which were the workstations with bottlenecks and focus on them to reduce cycle times of operations, also applied tools such as the 5 whys and Pareto diagram to find the root cause and based on these results, implement improvements. Documentation and organization were key to the completion of this project, the organization to perform the tasks in a timely manner if any activity was delayed efforts or resources were added if it was in the critical path, for the part of documentation everything must be recorded for future audits. In all projects there will be pressure to release them in the established time or reduce the execution time of certain faces, as well as trying to reduce costs, however it is important to remember that it is not convenient to deliver a project on time and with lower cost if it does not work or if the final patient runs any risk, quality is everyone's responsibility and this responsibility is in the organization and in the staff that executes the validation. Next we will see the objectives of the before and after project:

- Increase production capacity from 50 boxes to 80 boxes per hour, by which would be 60% more capacity.
- Increased 60% of production capacity from 50 boxes to 80 boxes per hour.
- Reduced production shifts from 4 to 3 per day.
- Reduced production shifts from 4 to 3 per day.
- Decrease $35,000 dlls labor cost per month.

Final project savings was approximately $32,000 per month.

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Biographies

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