Product Flexibility and Machine Throughput Optimization

Pedro J. Oliver Márquez
Master in Manufacturing Competitiveness
Dr. Rafael Nieves Castro
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— For almost five years, a pharmaceutical manufacturing company has been operating an automated manufacturing line with only two full-time (8-hour) shifts, four validated codes/products and left with 28% availability of run-time daily. The main goal of this project was to manage and validate more products within this automated manufacturing line that could improve the equipment's material throughput and running time. It brought forth ideas such as product flexibility, process automation, and product family standardization, which resulted in an increase in material logistics and material and production scheduling. Based on Lean manufacturing practices and SIPOC methodology tools, the project had rigorous results. The tested idea brought a 29% increase in material throughput and 11% in the machine's running time, ensuring a future manufacturing capacity within other manufacturing lines that could be used as an example for other internal sister sites and/or regular manufacturing entities. These results provided numerous future follow-up ideas that could help improve the idea of production optimization within the manufacturing scenarios.*

Key Terms *— material throughput, medical devices, product flexibility, SIPOC.*

PROBLEM STATEMENT

A Medical Devices manufacturing company has five production lines, with a stable and positive outcome. There is one line that is only active during two shifts: Shift A and Shift B. Shift C is downtime, without production. The reason is that there are only two products that are validated to be manufactured in that respective production line. One way to solve this is by validating more products to run so that it will open more capacity in the other production lines and will generate more productive time, avoiding that downtime.

Research Description

This research will be based on Process Optimization. It will require developing a "perfect state" to know the limits of the machine, will require a more robust understanding of the relationship between the machine's computer and the machine's capabilities. All the specific details and characteristics regarding the production line are important for this research, since they will direct to a possible shorter and applicable solution that will increase the machine's productivity.

Research Objectives

As narrow as can be, the objective of this project on pre-research will be to increase Line #5 output production by 30%. There is a high possibility that this goal could be achieved by introducing new products within Line #5, an automated process that will require an additional shift to fulfill the new output numbers. By achieving that main objective, production will be increased at Line #5 and the quality turnbacks caused by its regular process will be reduced. This could also open a production line capacity gap, making possible the achievement of some other goals that will be supported along the way.

Research Contributions

Results from this research will contribute in many ways. The main objective will directly affect the organization by optimizing and standardizing an effective and productive line of work. The contribution when Line #5 increases its production is to avoid scrap material and quality turn-backs. We believe that providing an organized and variable mindset will align a good set of personnel that will commit as a team and will execute not only at planning, but also with continuous state-of-the-art improvements. The main goal will be to achieve this one goal on production optimization, but this also means a positive change in capacity assessment within other production lines that will raise flags for new opportunity c d defies and fewer quality events.

LITERATURE REVIEW

To follow up with the research background, we will evaluate the main areas or topics: Throughput Improvement, where subtopics like demand and capacity will require a more defined character; Lean Manufacturing principles, with product family classification, waste identification, and the importance of maintenance within a production line; and the role Automation will play in production improvement.

Throughput Improvement

Process optimization is a trade-off between maximizing the time performances and the process by considering the process dynamics. [1] It will depend on capacity and demand, even though throughput will consist of the goods or services from a process. Based on the finished goods, we evaluate whether to standardize the production in Line #5 by optimizing the flexibility among the other manufacturing lines. It is expected that some constraints will affect the results. Some of these constraints are the "Demand-Constrained" (which usually happens when the demand is smaller than the effective capacity, therefore the throughput is held by the demand) and the "Capacity-Constrained processes" (which regularly happens when the capacity from the machine, equipment, or process—i. e. design/manufacturing standard—is less or smaller than what the customer requires, the demand. This is where knowing the process is of utmost importance. When process variables are known, it is easier to identify the underlying reason or reasons behind the throughput losses. [2] One management principle described in many places is the impact of process control policies to the throughput: process control policies that limit inventory in the process by not authorizing resources to process more flow units, or by not allowing flow units to enter the process, which results in throughput loss [2]. Roughly stated, how many times manufacturing companies are tied to legal regulation adjusted to their products and how these affect the effectiveness of their manufacturing environment. This is when often engineers enter the equation to force or enable a fluent process based on the regulations and increase the throughput under the stated parameters.

Lean Manufacturing

From the broad scenarios of this methodology, the research focuses specifically on product families. Optimization of such processes must take a broad view and control both process parameters and design variables to minimize the raw material utilization and the time of machining operations. [1] Seeing and analyzing a process by product family could impact a business's capacity and demand. Capacity and demand must balance to ensure proper flow. With too little capacity, you have unhappy customers; with too much capacity, you have waste. [3] Let's not forget that this methodology will work in a perfect environment; that is why the theoretical and actual values are required to be calculated. How functions, departments, and organizations work needs to be redefined to make a positive contribution to the value stream. [3] This is considered a vivid value, could be seen as average but will never be the same, and requires a careful study to compare past data daily. As for our project purpose, it will be aimed specifically to how to produce and manufacture the same product family in the same manufacturing line. As a result, flexibility will be achieved within the automated and non-automated production lines. Also, it will allow for more capacity for new products under development that will require more care and observation to be manufactured on semi-automated processes and the standardization on a scheduled basis, which could be seen as a positive result across the manufacturing floor. Still under the Lean Manufacturing strategies, equipment maintenance used to be carried out by the operator. After work was organized and more specialized, maintenance was turned over to specialists. [3] This comes from the Total Preventive Maintenance (TPM) practices, which help identify the source of losses and eliminate them. It also provides accountability to the employees who work directly in the production line. They are the ones the truly know "what's wrong" and the possible technical root causes. Some will say that maintenance is only to clean up or check some gauges, but it means a lot more than what it seems. Accurate and achievable equipment maintenance done to the letter will result in a reduction of machine breakdowns and possible quality rejections. To complement this, a planning method is needed, a way to prioritize resources and actions. This is called reliability-centered maintenance (RCM). [3] This RCM will be divided into three types: reactive, which will have the lowest importance; preventive, which is the common maintenance provided to the equipment; and predictive maintenance, which has the highest importance of all. This predictive maintenance will be required to be done inside the "equipment's designed standards." Predictive maintenance requires to be calculated before it can take place. By taking into consideration timely maintenance, the process and equipment can be manipulated to perform to its total productive parameters taking into consideration the safety productive environments.

Automation

The allocation and distribution of tasks between human operators and technical sub-systems. [4] The use of automation has increased in the past years, some seeing it as a technology take-over, others as a positive way to increase production without depending on nor exploiting human resources. It is sometimes also seen as a way to achieve desirable goals up to a high positive level with the use of a shortlist of personnel. Automation not always requires headcount reduction within manufacturing environments, since even up-to-date equipment will require to be managed by fewer people. There are a lot of variables through which automation will affect a manufacturing entity, and in our case study or project it will be production and throughput increase. The downtime of manufacturing processes is reduced extensively using condition monitoring techniques and the expertise of human workers could be used in much more useful ways. [5] By bringing new technologies and more robust processes, manufacturing will lead to more accurate results. This could lead to channeling the real areas of focus where optimization needs support.

All these three major key inputs (Throughput, Lean Manufacturing, and Optimization) are a good way to channel our problem statement and bring us an accurate result. Therefore, we could transfer products between lines of production without affecting the regulated parameters nor the productive capacity/demand from other areas. This will achieve positive results that could be then challenged on other processes in future have a standard process divided within value streams and good quality outcomes.

METHODOLOGY

Based on the problem statement, this research will be based on Process Optimization in a manufacturing facility where medical devices are produced, the market is increasing with new products, and one out of five manufacturing lines is 90% automated. This brought forward this research for possible ways to increase and/or mix production materials at manufacturing Line #5 to optimize the company's production under the already established regulations and quality parameters. It was decided that we would focus on production flexibility to achieve the goal of process optimization. The research was based on the methodology of mixed concept, in which we will first evaluate the required parameters or boundaries to increase manufacturing in the automated line (Line #5) by ±30%. Some of this are the machine's effectiveness, production targets against process cycle time, material specs, number of inputs, electrical components, and their controls. For this, practices such as SIPOC (Supplier, Inputs, Process, Output, and Customer), Total Preventive Maintenance (TPM), and Benchmarking were used as part of the research in terms of capacity analysis, total outcome, production rates and practices, quality percentage, and throughput improvements. Since two similar but different processes (a manual process and an automated process) are being compared, production data from the past 12 months (2021) was used as a theoretical value so that we could compare the results from a perfect scenario panorama.

Problem Statement and Research variables were real time (the time that the machine or production line is actually producing), a shift length of 8 hours (480 mins), the number of available "inputs" (in these scenarios the nozzles were a value-added variable), and the GOAL, or interpreted the output from this equation. These nozzle variables and GOAL (output) were variable when measured and evaluated. It was shown that the number of nozzles is standard for the MPF (L5), since it consists of an automated sequential process. These nozzles work all under the same Program Logic Controller (PLC), and will all be working or will all be down or out of production. On the other hand, in manufacturing Line #2, the inputs at the filling process nozzles are evaluated individually, since it is a process that depends on human labor. This variable raised flags as a good direction to take in the research, since it focused on the impact of the problem statement to increase the production throughput of Line #5. Although Line #5 does need personnel, the percentage of availability to produce is higher than that of Line #2.

Recurrent Gemba walks (to gather information through observation in the actual process floor and generally interacting with production employees) were performed to compare and analyze the provided data and clear any process questions. Technical support was requested from the Automation department to acquire a different point of view and search for new ideas on how new machinery or controllers could help improve Line #5 production in terms of reducing headcount or increasing the throughput in the machine run time.

Another angle that was triggered in this research was the capacity between the production lines. At first, the list of solutions that could be produced between production lines to perform a capacity analysis and verify the regulation, if any, to solve between the lines. For this the upcoming demand for Volume C was requested to study the future state of this product and how much or little it could affect its manufacturing between the two production lines. Visiting a sister company with a similar process and identifying some positive key points were positive actions. These key points could be transferred to our process and help us narrow down to a more productive process, also providing good results on our problem statement.

This said, this research aimed for three Key Variables or similar directions, which affects the increase in production, whether in a flexible production between lines, optimizing Line #5 into a more technologically-advanced process and increasing production manufacturing to its real-time production standard. Also, some gaps were generated that could lead to further research, which were open capacity space in Line #2 for new products under development, cost-saving on headcount reduction, and maximizing the human dependable production line throughput. Another topic worth researching in future was the standardization of raw material between solutions, which could lead to logistics standardization and scheduling.

RESULTS AND DISCUSSION

This section presents the research data and substantial results obtained from 2021 production outcomes (table 1) that affected positively the problem statement of this project due to increased production time and throughput at manufacturing Line #5. The variables taken into consideration between manufacturing lines to evaluate the results of the project (theoretically) were the number of nozzles to be used, the production capacity of the machine, quality percentage compared to production rate, the demand in the upcoming months in 2022, and their Takt-Time, or how long would it take between lines to achieve the customer's demand.

Table 1
Volumes A, B, and C - Manufacturing process comparison and its variables

	Volume A & B		Volumen C	
	L5 - MPF (Max)	**(AVG) L5 - MPF**	**L2 - MAX**	**(AVG) L2**
(Jan/21 - Dec/21)				
Real time (Hr)	8	7.2	7.5	7.0
# Nozzles	10	10	8	8
GOAL units (variable)	86,500	70,014	70,000	57,500
Completed units	74,149	74,747	67,578	45,404
Scrapunits	7,266	3,690	528	254
Good Units	72,000	71,078	67,060	45,882

This showed how the production of Volume C could affect if it were manufactured on automated Line #5. The results shown further on were obtained taking into consideration the overall demand between the family of products on each line and the required headcount (per manufacturing line) (table 2) to produce the required demand per shift.

Table 2
Headcount in manufacturing lines

PROCESS/AREA	Line 2	Line 5
Printing	6	2
Filling	9	0
Inspection	4	5
Racking	12	3
Material Handler	1	1
Group Leader	1	1
TOTAL (Head Count)	33	12

Some other things that were observed and assessed were key points such as the machine's effectiveness, production targets against process cycle time, material specs, number of inputs, electrical components, and their controls.

For this, practices such as SIPOC, TPM, and Benchmarking were used as part of the research in terms of capacity analysis, total outcome, production rates and practices, quality percentage, and throughput improvements.

In this research, SIPOC (figure 1) stands for:

- **Supplier:** Contacting raw material suppliers was required to get their inputs or point of view on increasing our demand.
- **Inputs:** To consider manufacturing Volume C in Line #5, run-time will need to be increased, which at the same time will increase its efficiency.
- **Process:** The complete manufacturing and assembly process of the product (printing, filling, inspection, racking).
- **Output:** For this we will take our final product fully assembled and ready to be packed and shipped after being sterilized and pouched.
- **Customer:** In this case it will be considered the next manufacturing process, which is sterilization or making it free from bacteria or any other unwanted particle.

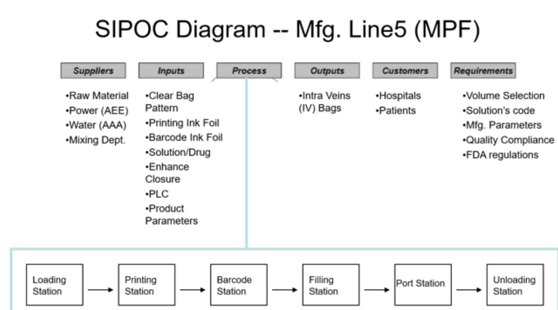

Figure 1
Key process identifiers for SIPOC methodology at Line #5 (MPF)

The only aleatory event in when the same product could be manufactured on different shifts, as shown on table 3, only happens in manufacturing Line #5, which is 90% automated and only requires a total headcount of 12 people from beginning to start, while in the regular production, Line #2 requires 33 operators to run, resulting in higher availability of Line #5 (table 2), since it will require 63% less personnel to be able to run and manufacture.

Table 3
Solution/products validated at manufacturing lines

Product	Code	Volume (mL)	Filling Line	
			2	5
A	#1	Volume B	V	
	#2	Volume E	V	
B	#3	Volume E	V	
	#4	Volume B	V	
	#5	Volume E	V	
	#6	Volume B	V	
	#7	Volume E	V	
	#8	Volume B	V	
C	#9	Volume A	V	
	#10	Volume B	V	
	#11	Volume C	V	PEN
	#12	Volume A	V	
	#13	Volume B	V	
	#14	Volume A	V	
	#15	Volume B	V	
	#16	Volume D	V	V
	#17	Volume B	V	V
D	#18	Volume C	V	PEN
	#19	Volume A	V	
	#20	Volume B	V	
	#21	Volume D	V	
	#22	Volume B	V	
	#23	Volume A	V	V
	#24	Volume B	V	V
	#25	Volume A	V	
	#26	Volume B	V	

Blue	Volume A
Red	Volume B
Yellow	Volume C
Dark grey	Volume D
Purple	Volume E

The validated products of each line and their respective codes were assessed to clearly understand the capacity and availability between the manufacturing lines. Table 3 shows that in Line #2 26 different codes are validated to run and be processed, while there are only four codes in automated Line #5.

This is where manufacturing Line #5 (MPF) showed to have an opportunity to increase its production time and material throughput by integrating production demand Volume C. The major constraint was personnel availability (mechanics, technicians and personnel) for a new "Shift C."

This gave a total of 1.12M units in 2022 (table 4) and the manufacturing standard from Line #5 (MPF) of 180 UPM (units per minute). The implemented analysis and production flexibility of manufacturing for Volume C in production Line #5 achieved a projected outcome that aligns to the main goal of increasing its production throughput while in compliance with on-time delivery to customer. April's demand numbers for 2022 for Volume C were achieved under the new project design at automated Line #5 (MPF) in fewer shifts compared with production Line #2. The total demand of 160,000 units (80,000 units from each code) (table 4) was achieved in four special part-time shifts (table 5) and produced 41,176 units of Good Units over April's required demand, which provided good direction to increase the product's demand output. At the same time, it provided production time relief to Line #2 which produces and has already 26 different codes validated and now has a whole 480-minute (8-hour) shift for any high-priority codes. This Line #2 will have more positive downtime to assess the production of new upcoming products without affecting the quality and delivery of the product.

Implementing Volume C at manufacturing Line #5 (MPF) showed a good trend and significant effect. This production flexibility directly affected the project's main goal, which was to reduce

Table 4

Volume C demand for year 2022

Code (Vol C)	Sum of Jan-22	Sum of Feb-22	Sum of Mar-22	Sum of Apr-22	Sum of May-22	Sum of Jun-22
#11	-	60,000	-	80,000	-	-
#18	77,000	173,000	80,000	80,000	80,000	80,000
Grand Total	**77,000**	**233,000**	**80,000**	**160,000**	**80,000**	**80,000**

Code (Vol C)	Sum of Jul-22	Sum of Aug-22	Sum of Sep-22	Sum of Oct-22	Sum of Nov-22	Sum of Dec-22
#11	80,000	-	-	-	80,000	-
#18	80,000	160,000	80,000	80,000	80,000	80,000
Grand Total	**160,000**	**160,000**	**80,000**	**80,000**	**160,000**	**80,000**

Table 5

Volume C at Manufacturing Line5 (MPF) on 3.7-hr run time

Created Date	Batch	Area	Line	Shift	Machine	Prod Qty	Scrap	Good Units	Code
4/4/2022	P4285xx	MPF	Line5	EXP	Fill-5 All Nozzles Prod	33,904	1,695	32,209	#11
4/52022	P4262xx					35,228	2,818	32,410	#18
4/6/2022	P4268xx					35,800	1,832	33,968	#18
4/7/2022	P4276xx					39,144	2,740	36,404	#11
4/12/2022	P4280xx					35,213	2,183	33,030	#11
4/18/2022	P42820xx					35,271	2,116	33,155	#18
					Total (Qty)	214,560	13,384	201,176	

machine downtime (off-time) while increasing material throughput in manufacturing Line #5 (MPF) by 30%. These special part-time shifts are complete 240-minute (4-hour) shifts, and with good communication with the logistics team they could be scheduled in future to when manufacturing the same codes within Volumes A or B. This way, a “changeover,” or a change of code affecting the machine production’s downtime, would not be required. When MPF run-time was measured based on the new special part-time shifts, it improved slightly from 60% to 77% in a 24-hour day (figures 2, 3, and 4). At the same time, the material throughput (units produced under the new special shift) was measured against the output of Volume C, compared with the month of April 2021 output data only with Volumes A and B (1,897,940 units and a scrap rate of 8.7%), and it showed that the MPF output increased by a 29.2%, with an average 7% of scrapped units, or units that did not pass the quality inspection, although water was used during the experimental runs and the production for the last week of April 2022 was measured using a real-time average weekly production of 755,00 units. The main target to increase production throughput by 30% at the MPF was not achieved, although it helped Engineering and Management raise flags for some areas of opportunity with the MPF, Set-Up, Planned Downtime, Quality Detractors, and SCRAP.

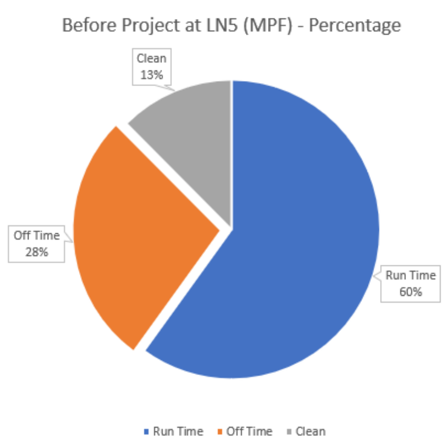

Figure 2
Time distribution in a 24-hour timeframe for manufacturing in Line #5 (MPF)

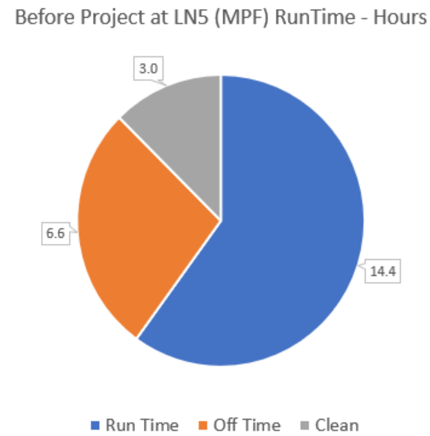

Figure 3
Manufacturing Line #5 (MPF) 24-hour distribution

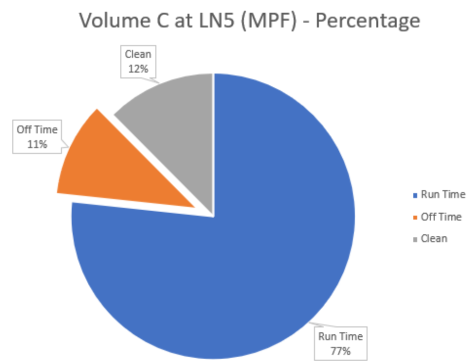

Figure 4
Percentage of time distribution at the MPF when "Part-time" shift is included

CONCLUSIONS

This design project aimed to find a solution to increase the run-time of manufacturing Line #5 by implementing product flexibility between manufacturing lines using various types of mindsets and practices, providing more efficient and positive production process standards. These are methodologies such as Lean Manufacturing strategical thinking to reduce waste and bring more ideas for continuous change and future research. Manufacturing Line #5 (MPF) still showed to have areas of opportunity, which, once accounted for, will increase mechanics’ downtimes and will improve product quality. Just this “product flexibility” gave a lot to talk about, since it did affect manufacturing operations across multiple departments that will continue to face new challenges and opportunities.

The results indicated that, by adding a new "special shift" to the MPF, available time was increased by 11%, and its effectiveness (and at the same time, its production throughput) by 29%. Further findings show numerous details on how to improve logistics for scheduling across manufacturing areas and activated the Automation department for new technologies to sharpen the process. While executing the design project, causes out of our control such as the pandemic affected the acquisition of personnel and availability for machine set-up and raw material preparation, as this "overtime" personnel was required as part of the experimental project, but we look forward to acquiring more headcount for this new "shift."

We conclude that this production scenario is being taken into consideration for medical products and real-time output. The reason for it not being an ongoing project is the length of time required to generate, validate, and run this scenario in a federally-regulated medical device manufacturing company.

REFERENCES

[1] D. Marini and J. R. Corney, "Concurrent optimization of process parameters and product design variables for near net shape manufacturing processes," *J Intell Manuf*, vol. 32, pp. 611-631, Feb. 2021 [Online]. Available: https://doi.org/10.1007/s10845-020-01593-y

[2] S. M. R. Iravani, "Chapter 6: Chapter Preliminaries," in *Operations Engineering and Management: Concepts, Analytics and Principles for Improvement*, 1st ed. New York: McGraw-Hill, 2020.

[3] K. Caldwell, R. Edgeman, and K. Snyder, "Lean Value Stream Management," in *Juran's Quality Handbook: The Complete Guide to Performance Excellence*, 7th ed., J. A. Defeo, Ed. New York: McGraw-Hill, 2016.

[4] J. Frohm, V. Lindström, M. Winroth, and J. Stahre, "Levels of Automation in Manufaturing," *Ergonomia - International Journal of Ergonomics and Human Factors*, vol. 30, no. 3. pp. 181-207, Jan. 2008 [Online]. Available: https://www.researchgate.net/publication/255793362_Levels_of_Automation_in_Manufacturing

[5] H. S. M. Beigi, "Automation in Manufacturing," in *1st Annual Conference on Technological Advancements in Developing Countries*, Columbia University, NY, 1993.