System Performance Laboratory Optimization

Christian Caraballo Vázquez
Master of Engineering in Manufacturing Engineering
Advisor: Carlos González, Ph.D.
Industrial and Systems Engineering Department
Polytechnic University of Puerto Rico

Abstract *— This project seeks to optimize the efficiency of a medical device laboratory process applying tools of the Lean Six Sigma methodology and eliminating non-value activities to complete transfer of a new product avoiding convert the current process in a bottleneck. The main objective is increasing the efficiency and throughput rate from 1.7 to 2.2 lots per shift while focusing on reducing the variability in the lots lead time. The Lean Six Sigma strategy involves the use of statistical tools within a structured methodology for gaining the knowledge needed and achieve faster and less expensive quality improvements. The strategic goal is to continually improve processes that have a real impact on business metrics to become a world class company. In this case, the throughput rate was increased from 1.7 to 2.9 lots per shift due to increase technician's efficiency by 29%, while reducing the number of resources and the variability in the lots lead time from 1.26 to 0.81. The total project saving was $31,687 between reducing headcount and scrap cost saving.*

Key Terms *— Bottleneck, DMAIC, Lean Six Sigma, Quality Improvement, Statistical Variation.*

INTRODUCTION

In the medical device manufacturing world there are operations where must be modifying constantly through innovation and continuous improvement to increase quality level and production rate. The manufacturer is the agent responsible that guarantee cost reduction and the efficiency of the process to deliver the product on time and achieve the customer satisfaction. The company manufacture test strips used for diabetes patients to monitors the glucose in blood. As part of this manufacturing process, there is a System Performance Laboratory were the strip product functionality is tested after a manufacturing process called Conversion process. The two tests perform are: Homogeneity (HA) and Black Current (BC). This product testing is the process more critical in the operations where the tests are carried out to validate the quality and functionality of the strips.

The company is focus in optimize the efficiency of the process to complete the transfer of a new product and a code assignment testing verification from Indiana to Puerto Rico. Due to the lead time variability and complexity of this testing process, the aim of the project is to improve the system performance process to increase the output per day of this laboratory to consistently achieve the established goals. The current output goal is approximately 1.7 lots per day in one shift. Based in this current scenario will be necessary increase the output per day to prevent a bottleneck in this manufacturing step once the new product is integrated.

PROBLEM STATEMENT

The company are undergoing a new product transfer that is directly related to the current System Performance testing laboratory output. New product estimated output rate is 2.2 lots per shift. This project aims to design a more efficient, balanced and capable process, since current throughput rate of product is 1.7 lots per shift. Due to that the new product estimated output is higher than the current throughput is necessary solve this problem because the process could become a bottleneck for the operation. The company's approach is to prepare and improve the efficiency of the current laboratory applying tools of the Lean Six Sigma methodology like DMAIC improvement strategy for when the new product arrives.

RESEARCH DESCRIPTION

The intent of this research is to improve the system performance process to increase the output of this laboratory and reduce variability in the lot lead time to consistently achieve the established goals. In this way, it seeks to optimize the overall laboratory efficiency eliminating non-value activities to complete the transfer of a code assignment testing verification and the new product transfer successfully.

RESEARCH OBJECTIVES

The company wants to undertake this project in order to prepare the current laboratory output for when the new product arrives. This project aims to optimize the laboratory process to increase efficiency and current output from 1.7 lots per shift to 2.2 lots per shift while focusing on reducing the variability in the lead time per lot of the testing laboratory output. The principal action is achieving the goals established and make all improvements necessary using Lean Six Sigma methodology (DMAIC tools) to avoid that the current process become a bottleneck to the operation. The proactive and reactive actions plan will be carried out considering the packaging department capacity to maintain a work balance.

RESEARCH CONTRIBUTIONS

Through the execution of this project, it is expected provide an improvement design to enable System Performance laboratory to increase the current throughput per shift for AVIVA product. Also, this project seeks analyze the testing operator's practices and non-value activity in the shifts to increase efficiency, reduce the testing release time and improve the customer satisfaction with the delivery on time of the lots. The project scope is strictly limited to the AVIVA product and the System Performance Testing Laboratory, considering the Conversion and Documentation release process, since they are inputs and outputs of the testing laboratory.

LITERATURE REVIEW

Forrest W. Breyfogle III emphasizes that the competition day by day continues to get tougher, there is much pressure on product development, manufacturing, and service organizations to become more productive and efficient. The companies need to create innovative products in less time improving quality and productivity, decreasing costs and increasing production volumes with fewer resources. McCracken and Kaynak (1996) affirmed that as quality increases, productivity increases, since when quality is improved by identifying and eliminating the causes of errors and rework, more usable output is available for the same amount of labor input. In manufacturing sector, the cycle time to complete the activities required for customers is now a key parameter. Thus, when a quality improvement effort reduces rework, redundant operations, and other deficiencies, a simultaneous reduction in cycle time occurs [1], [2].

Improvement is an activity in which every organization carries out tasks to make incremental improvements, day after day. Douglas C. Montgomery mentioned that the quality improvement methods can be applied to any area within a company or organization, including manufacturing, process development, engineering design, finance, distribution and logistics, customer service, and field service of products. Quality improvement is the reduction of variability in processes and products. Therefore, the quality improvement is the reduction of waste. Effective quality improvement can be instrumental in increasing productivity and reducing cost. Joseph A. Defeo has proven that Lean Six Sigma methodology to be a very effective framework for implementing quality improvement and reduce the variability in the processes [3], [4].

Frank M. Gryna introduced that the statistical variation can only be described in statistical terms and play a central role in quality improvement efforts. Statistics helps to analyze data properly and draw conclusions, considering the existence of

variation. Variability is a fact of nature and a fact of industrial life. In any production process, a certain amount of inherent or natural variability will always exist. Jack Welch (GE CEO) has observed that the variability has significant customer impact [2], [3].

Lean and Six Sigma are essential combination to implement process improvements that will put the organizations in the best competitive position. Joseph A. Defeo shows that lean is a systematic methodology for the continuous improvement that identifies and eliminates the process activities that do not add value "waste" to make it a faster and efficient one. The lean approach is eliminating non-value-added activities like producing late services, defectives products, excess finish goods inventory, excess internal transportation of products, excessive inspection and idle time of workers due to lack of work balance. There are several tools to solve the problem of waste or non-value-added activities such as: 6s, kaizen and poka-yoke [5]. On another hand, Six Sigma is a systematic methodology that uses data analysis in order to measure and to improve the business performance through variability reduction in the processes at low cost. Frank M. Gryna too supports that Six Sigma approach is a collection of managerial and statistical concepts and techniques that focus on reducing variation in processes. In addition, this methodology helps identify, optimize, and prevent defects and inefficiencies in the manufacturing processes to meet with the quality of the product and to exceed the customers' satisfaction [1], [2].

Lean Six Sigma methodology has an improvement strategy that consists of five main phases: Define (D), Measure (M), Analyze (A), Improve (I), Control (C), better known as DMAIC, where each phase has deliverables and different tools that are of great help to complete each phase successfully. The phases of DMAIC are a guides or sequences that explains the steps in the approach along with the specific tools and that is used usually for high complexity level projects. [3], [4].

- **Define (D):** This first phase is the most important, since the problem (customers, CTQ, business case) is defined in this phase and important characteristics are identified for the client as well as the project team at the operational level. The purpose is to create a general image of the process to achieve management commitment and reach an agreement between the client, the team and the sponsor about the definition of the problem, the scope, the project plan and the performance goals regarding to the metrics of the organization. Some of the tools used to achieve these objectives are: Project Charter, SIPOC, Process Mapping and CTQ Tree.
- **Measure (M):** The main objective of this phase is to understand the status of the process and gather reliable data on quality, cost and delivery to evaluate the state of the current process "baseline". Moreover, in this step the measurement and data collection system are evaluated, the appropriate data collection strategy is established through Gage R&R or Attribute Agreement, the required level of improvement for the CTQs is identified through Control Chart and Capability Analysis, a detailed imagen of the process is created by means of Value Stream Mapping and the validation of the Project Charter is carried out. This phase is interrelated with the first phase, since they are phases that can be re-evaluated at any time during the execution of the project.
- **Analyze (A):** Once the data is collected correctly, it is analyzed to identify differences between the current performance and the goals, identify potential sources of variability and identify the X's factors of the process that significantly affect the Y's. These factors can be improved by documenting the potential causes, prioritizing the improvement opportunities and the evidence of the analysis that shows the relationship between the critical X's and the CTQ. Hypothesis tests, regressions, DOE, control charts and multi-variables are some of the tools that help us to identify and analyze the root causes of the CTQs.

- **Improve (I):** The focus during this phase is to make the necessary or proposed changes in the X variables in order to achieve and improve the objectives of the CTQs. As part of a good practice in this fourth phase, potential solutions must be documented and prioritized through a Pugh Matrix, perform a risk analysis (FMEA) of the selected solution and evaluate if the solution is effective through a pilot study. Therefore, the control charts, the flowchart of the new process and the solution implementation plan must be used to ensure that the process is stable, predictable over time and meets customer requirements.
- **Control (C):** In this last phase is where you must identify the strategy to avoid recurrence of the problem, since the goal is to implement a mechanism or process to prevent the recurrence of problems and sustain improvements to prevent unexpected changes occur. To achieve the objectives, it is important to update the documents and procedures, evidence the training, develop, document and implement a control plan to monitor the process, and create mechanisms Poka-Yoke to avoid errors.

METHODOLOGY

Due to the improvements opportunities and innovation that have all the companies is the very importance know different strategies or methodology that help to solve the common operations issues like the variability and bottleneck in the processes. Through the execution of this project, it is expecting analyze current laboratory process and operator's practices identifying quality improvements to reduce the variability in the lot lead time and increase efficiency and current output from 1.7 lots per shift to 2.2 lots per shift for AVIVA product. The purpose of this project is achieving the goals and make all improvements necessary using Lean Six Sigma methodology. Joseph A. Defeo defined Lean like the process of optimizing system to reduce costs and improve efficiency by eliminating product and process waste vs. Six Sigma that is associated with the reduction of variability, defects and quality improvements. Lean is an important complement of Six Sigma that fits perfectly in the DMAIC [3].

Douglas C. Montgomery recommended use DMAIC for attack easily and efficiently issues of variability and throughput improvement, since it is a very general procedure or guide and it focuses on the effective use of a small set of tools. DMAIC is a structured five-phase problem solving procedure typically used in quality improvement that establish best practices to ensure that the solutions are permanent and can be replicated in other business operations [4]. Figure 1 presents the DMAC Roadmap with the deliverables in each phase. The DMAIC procedure used in this project are divided in the following phases:

- Define the problem clearly.
- Measure the current level of performance.
- Analyze collected data to determine the causes of the problem.
- Improve the process through quality improvement tools to solve the problem.
- Control to eliminate the recurrences of the problems and hold the improvements.

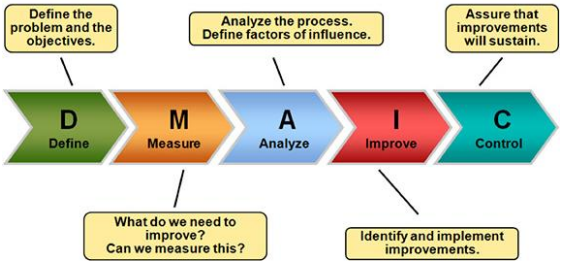


Figure 1
DMAIC Roadmap

The proposed methodology to undertake this project is focused on the improvement and design of a more efficient Testing Laboratory for Aviva product, mainly using:

- Apply Statistical Quality Control & Lean Six Sigma to analyze current process performance, determine process capability, verify the effectiveness of the solutions implemented and sustain said improvements using DMAIC

methodology and the different quality tools corresponding to each step like Project Charter, SIPOC and Process Map. Value Stream Mapping to breakdown the process and Capability Analysis. Other tools like FMEA and SMED will be considered.

- Perform Motion and Time Studies in order to improve current performance and reduce possible bottlenecks or inefficiencies in the system using the MOST Technique or sampling by chronometer and Spaghetti Diagram. Furthermore, if necessary we can use some tools and concepts of Production Planning and Control such as Input/Out and Capacity Analysis.
- Apply Economics and Managerial Cost Accounting to determine cost saving opportunities and other key information like fixed and variable costs. Also, to quantify the impact of proposed improvements while considering feasibility.

RESULTS AND DISCUSSION

All projects must be focus with the corporate business objectives and demonstrate the future success of an improvement effort like is the case of this project where seek optimize the laboratory process with the arrival of the new product through Lean Six Sigma Methodology. This operating and customer-focused methodology reduce the process variability, drives out waste in the processes, raises levels of quality, and improves the performance of the processes. Through of the DMAIC strategy, will discuss the results obtained.

Define

In this phase, the objective is to identify the project opportunity and to reach an agreement with the customer, the team and the sponsor on the problem statement, critical to quality characteristics (CTQ), project scope, project plan team and performances goals. Some deliverables use in this phase are: Project Charter, SIPOC and Process Map.

First, the Project Charter was completed to define the business case, project objective and project scope. The project objectives are focused in the corporate goals and the future benefits to the customer and organization. Figure 2 shows a Project Charter for the optimization of the System Performance Laboratory.

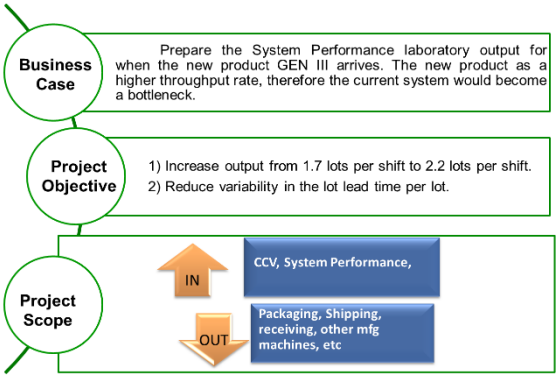


Figure 2
Project Charter

Also, the SIPOC diagram was elaborated to understand who the main customers of the laboratory process are including their needs, requirements & constraints. This tool gives simple overview of a process where the acronym means Supplier, Input, Process, Output and Customer. Figure 3 is a SIPOC diagram developed for identify, visualize and improve the basic elements in the laboratory process.

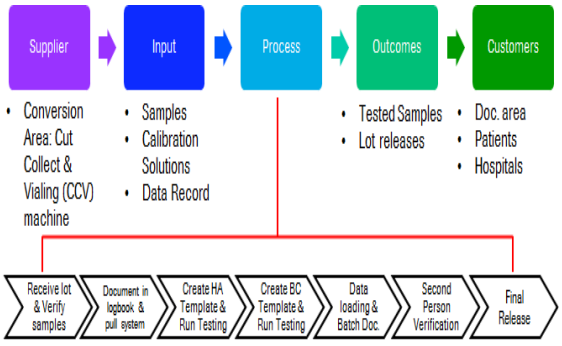


Figure 3
SIPOC Diagram

Another tool that was constructed is the process map that provide much visual detail and facilitate understanding about what needs to be

changed in the process. The processes are illustrated graphically in figure 4.

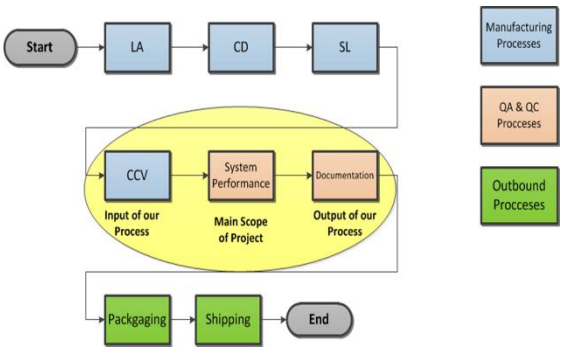


Figure 4
AVIVA Process Map

This graphic aid shows the AVIVA process complete, but the main scope of the project is System Performance considering the input and output process.

Measure

The aim of this phase is to understand the current state of the process and to collect reliable data on throughput, lot lead time, delivery, quality and cost. In order to evaluate the current process performance and has a detailed view of the process was developed the lab technician process flowchart in figure 5. The technician tasks represent a 60% of the activities (value added and non-value added) affecting the throughput rate per shift.

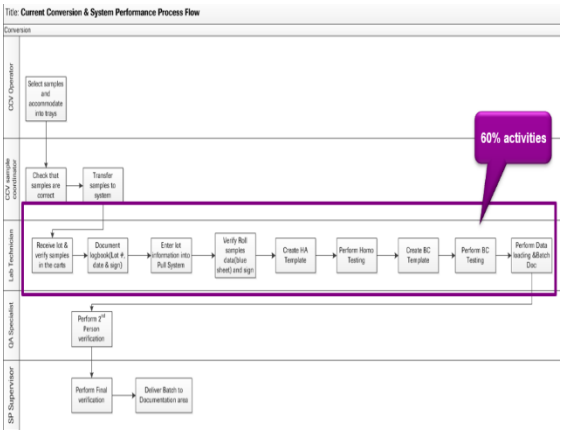


Figure 5
Lab Technician's Current Process Flowchart

The technician activities were evaluated to make sure that their time is spend mostly on value added activity (testing). After evaluating the process, it was found that the technicians had many non-value added tasks. For this reason, the goal is to reduce or externalize unavoidable non-value activities, however, the activities will be transferred to other resources with lower utilization. The time study was performed to set a baseline performance of the process that would lead to a proper capacity analysis. Figure 6 presents the initial metrics (baseline).

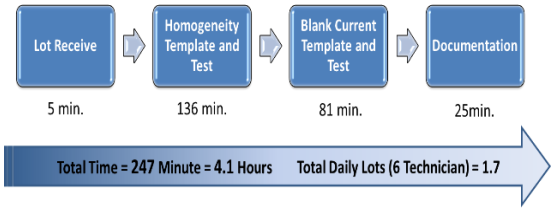


Figure 6
Time Study – Technicians' Initial State

The total time of the testing for one lot between 6 technicians is approximately of 4.1 hours. Through of the time study, was determined that the throughput rate in the laboratory process is 1.7 lots per shift. This time study contains TDN (Temporary Deviation Notice) that altered the data due to the additional samples. Also, was considered the lunch time, allowances, unavoidable interruptions, test run time, data loading and all other activities include.

Analyze

The objective in this phase is to use the process data to identify the sources of variability and determine the causes of the defects, cycle time and throughput problems, waste and inefficiency in the process. This phase explores and understand relationships between and among process variables and develop insight about quality improvements [4]. The different tools that were used in this phase are: Cause and Effect Diagram, Input/Output Analysis and FMEA (Failure Modes Effects Analysis). After evaluating the current state, the following opportunities where found regarding the laboratory throughput in figure 7.

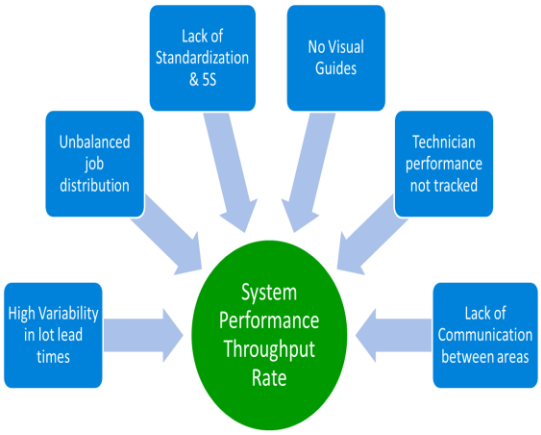


Figure 7
Summary of Opportunities – Throughput Rate

The cause and effect diagram in figure 8 were used to identify the drivers that were causing inefficiencies or variability. The highlighted observations were the critical components that were addressed in this project like standard work, scrap, missing samples, work distribution, among others.

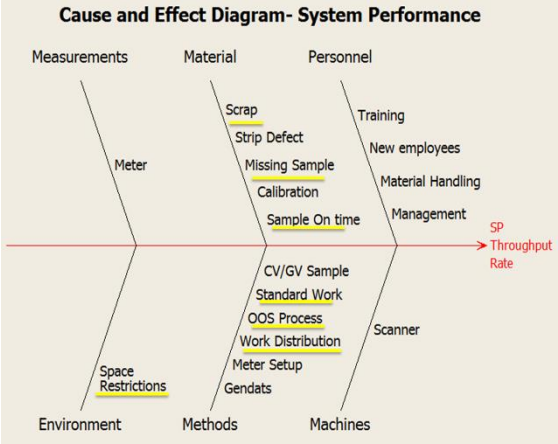


Figure 8
Cause & Effect Diagram – Throughput Rate

An Input/Output Analysis was developed to capture variations in the receipt rate of the lots in the laboratory (process input) and the release rate of the lots (process output) to documentation area. Ideally, the target is to receive and release 2.2 lots/day which is equivalent to 11 lots/week, but the current throughput in many times is 1.7 lots/day or less. Figure 9 and 10 shows the charts of the input/output analysis regarding to the amount of lot received per day. These charts demonstrated that the process have a high variability due to lack of standardization and uncertainty in samples arrival time. This process variability causes unpredictable process, increase in lot lead time, decrease the efficiency of the technicians, and uncertainty in weekly target completion.

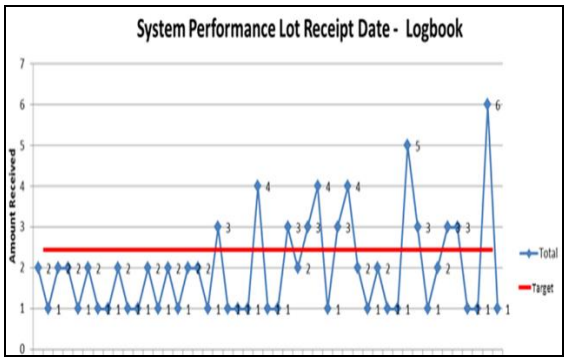


Figure 9
Input Analysis

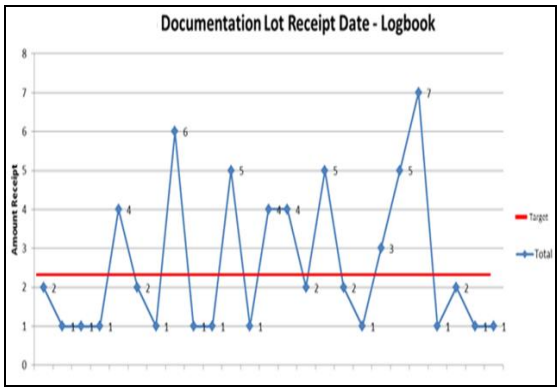


Figure 10
Output Analysis

In order to identify and reduce wastes due to excess movements a Spaghetti Diagram was designed in figure 11. The root cause of the high movement of the technicians in this diagram is due to the location of the office tools, trays, raw material, SOP and forms in the laboratory. Moreover, was used a FMEA in the table 1 to prioritize the different roots causes like potential sources of variability, failures or defects in a process and to evaluate the risk analysis. Through this tool was identified that the potential failure mode were the missing samples and samples out of order due to potential causes of lack of standardization, operator error and excess material movements respectively.

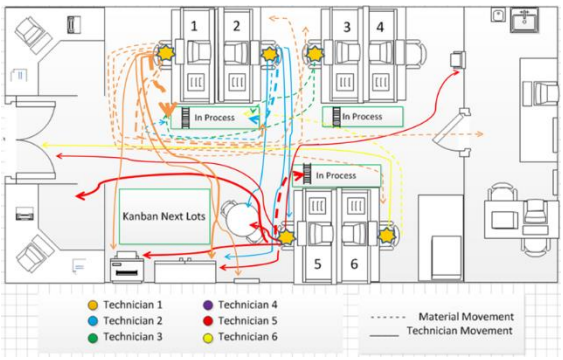


Figure 11

Spaghetti Diagram – System Performance Layout

Table 1

Failure Modes Effects Analysis

FMEA – System Performance

Process Input	Potencial Failure Mode	Potencial Failure Effect	SEV	Potencial Causes	OCC	Current Controls	DET	RPN	Action Recommended
Sample	Late delivery	Increases Lot Lead Time	8	Operator busy on other tasks	6	Defined Job Distribution	3	144	QA Specialist Coordination with mfg
				Lot has event	5	MRB	2	80	1. Do not prepare cart 2. Give high priority
	Missing Sample	Re sampling required at Warehouse	7	Lack of Standard Work	8	None	8	448	Standard Work
				Operator error	8	None	8	448	Standard Work
	Out of Order	Decreases Technician Testing Time	5	Excess Material Movement	6	None	7	210	Standard Work
				Operator error	7	None	7	245	Standard Work
Material Handling	Late Disposal of Cart	Increases Lot Lead Time	7	Technician fails to perform disposal	9	Finished Lot Documents	2	126	Asign Accountability
	Late cart Retrieval to AVIVA	Increases lot delivery time	5	No defined resource for activity	5	Temporary Resource	2	50	Communication System & New Layout

Improve

This phase is using to make specific change in the process in order to improve the outputs, document potential solutions, make evident of the solutions effectiveness, and implement a plan for the solution for achieve the desired impact on process performance. Foremost, a re-layout and 5S was performed in the figure 12 to reduce wastes due to excessive movement and unnecessary material transportation. This re-layout helps to minimize the technician's and material movements achieve increase the efficiency of the technicians due to that the locations with major frequency were re-located to eliminate the non-value added activity. When comparing the figure 11 and 12, the technician excessive movement and unnecessary material transportation decreased considerably.

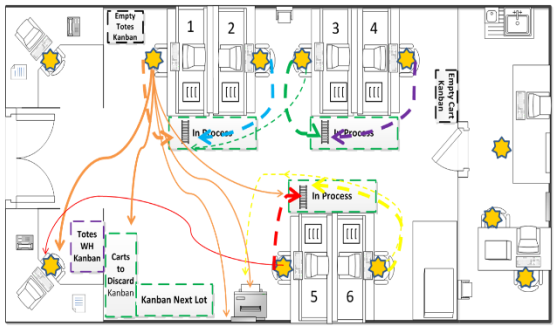


Figure 12

Spaghetti Diagram with the New Layout

After evaluating the technician's process and identifying some non-value tasks, it was performed a job distribution to reduce or externalize non-value activities for the technician. Some technician responsibilities were assigned to QA Specialist since this role has a lower percentage utilization. The changes in figure 13 show a benefit of 20% in activities' reduction for the technicians, meaning an increase in weekly testing time of 55 minutes.

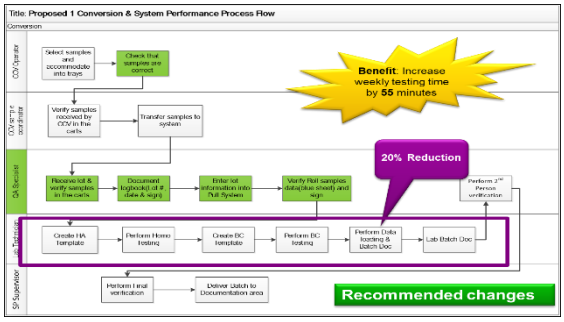


Figure 13

Proposed System Performance Process Flow

In addition, a standard work was designed to the samples process in the CCV machine with the aim of ensuring that the samples received at the laboratory are organized, complete, correct and arriving on time. This would lower input variation since was identified that the laboratory had high scrap due to excess samples arriving at laboratory for testing. Through quality improvements the revisions to CCV sampling plan were made and the problem was solved by implementing a new sampling plan that minimized human interaction and reducing scrap with a cost saving of approximately $15K.

After implementing some of the recommendations, the time studies were performed to develop a capacity analysis and to propose a job distribution reducing lot lead time, minimize interruptions & increased amount of time spent in testing process. The capacity analysis in the table 2 shows like was achieve improve the output rate through of quality improvement from 1.7 to 2.9 lots per shift with 5 technicians. The lots release daily reached overcome the target established of 2.2 lots per shift. One technician less than the initial state. The new job distribution was designed for a headcount of 7 resources where four technicians are dedicating to testing fulltime, with at least two lots processed at the same time, one technician called runner perform other activities like batch review, discard of carts and hold for disposition creation, and two technicians dedicated to the validations of the testing of the new product fulltime.

Table 2

Capacity Analysis – New Scenario

Improved Scenario	*Time (per Cart)*	*Resources*
Template Scanner HA	13	2
HA Dosing	***170***	***2***
Total Time HA	***183***	***2***
Template Scanner BC	13	2
BC Dosing	***50***	***2***
Total Time BC	***63***	***2***
Data Export	6	1
Data Loader	42	1
SCAD3S Report	12	1
Testing Summary Results Lot Release (Analytic y INDY test)	37	1
Verification/Code Release	9	1
Other (Setup)	15	1
Total Minutes	***367***	
Total Hours	***6.1***	
Total Daily Lots	***1.1***	
Total Daily Lots (5 Technician)	***2.9***	

In addition to the job distribution recommendations, this capacity was reached with the following recommendations: the lots receipt activity should be performed by the QA Specialist, workstation must have the materials required to perform your job to reduce movement waste time, and the technicians will rotate throughout the different job responsibilities. When comparing the initial metrics with the results, the throughput rate of the testing laboratory increased while reducing the number of resources.

Finally, in the figure 14 and 15 was illustrated the process capability for the daily lots completion after implementing the quality improvements. The process capability is an effective tool in reducing variability as much as possible. Some reduction in variability from 1.26 to 0.81 could be observed although there are more areas of opportunities regarding lot lead time variation. The recommendations given must be performed daily. However, there is a lack of on-time cart delivery from manufacturing area affects the laboratory output.

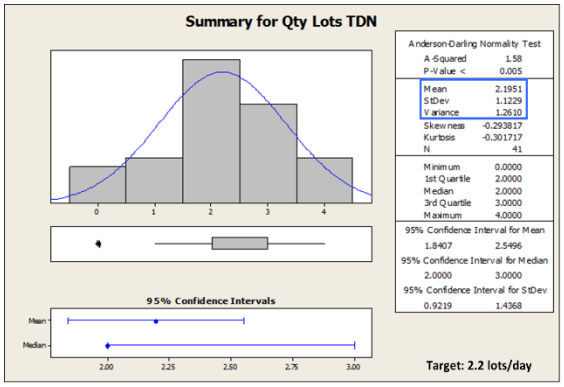


Figure 14

Minitab Capability Analysis – Qty Lots (Before)

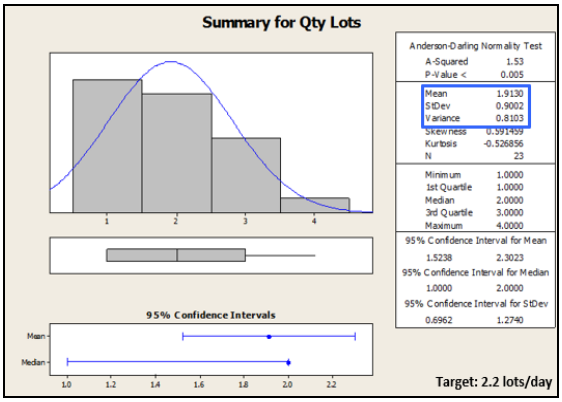


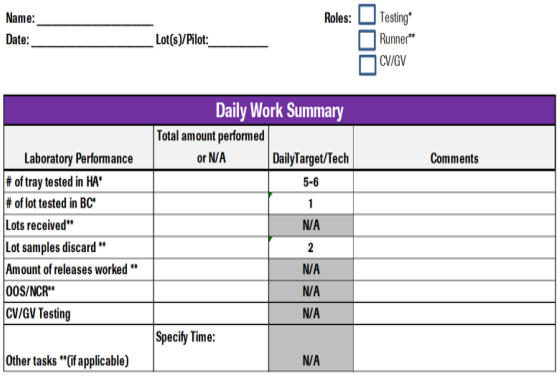
Figure 15

Minitab Capability Analysis – Qty Lots (After)

Control

In the last phase was installed mechanisms or processes that prevent the problem recurrences and to sustain the gains or recommendations. An efficiency tool was developed in the figure 16 to track performance of technicians in order to measure the progress. Support was provided to

management to develop this tool and measure the testing performance, since was not tracked before.



Name: _____ Roles: ☐ Testing*
Date: _____ Lot(s)/Pilot: _____ ☐ Runner**
☐ CV/GV

Daily Work Summary			
Laboratory Performance	Total amount performed or N/A	DailyTarget/Tech	Comments
# of tray tested in HA*		5-6	
# of lot tested in BC*		1	
Lots received**		N/A	
Lot samples discard **		2	
Amount of releases worked **		N/A	
OOS/NCR**		N/A	
CV/GV Testing		N/A	
Other tasks **(if applicable)	Specify Time:	N/A	

Figure 16
Efficiency Tool

Moreover, a standard work was developed to minimize errors by stating clear and concise instructions regarding the handling of the samples in the CCV machines. The goal is that samples arrives complete, organized, correct and on time. Due to the communication inefficiencies between the laboratory and manufacturing department, visual boards were designed to improve and minimize non-value added activities and interruptions. Also, a spreadsheet was designed to keep track of lots between areas and improve communication between processes.

CONCLUSION

The company strategic goal is to continually improve processes that have a key impact on business metrics to become a world class through of the implementation of Lean Six Sigma projects and quality improvements. This project was focused in improving the problems and opportunities in the laboratory process that could affect the manufacturing flow with the arrival of the new product. The project objectives were reached with the integration of the different Lean Six Sigma tools since was increased output from 1.7 lots per shift to 2.9 lots per shift, reduced the variability in the lot lead time per lot from 1.26 to 0.81 and increased the technician's efficiency by 29%. Immediately, the total project saving was $31,687 between reducing headcount and scrap cost saving.

To maintain the objectives achieves is necessary assure conversion area delivers 2.2 lots per day continuously to System Performance. This is an issue because currently their throughput remains with variation and is not consistent with the target of 2.2 lots per day. Also, continuous tracking of lot flow, CCV standard work and job distribution must be held to validate lot lead time reduction. In the future, the company should consider a new layout where the conversion and laboratory areas closer, facilitating communication to improves the inefficiencies. Also, continuous improvement of the tools developed in this project like the efficiency tool and standard work should be considered based on feedback.

REFERENCES

[1] F. W. Breyfogle III, *Implementing Six Sigma: Smarter Solutions Using Statistical Methods*. New York, NY: John Wiley & Sons, Inc., 1999.

[2] F. M. Gryna, et al. *Juran's Quality Planning & Analysis for Enterprise Quality*, 5th Ed., New York, NY: McGraw Hill, 2007, pp. 18, pp. 67-107, pp. 545-546, pp. 702.

[3] J. A. Defeo, *Juran's Quality Handbook: The Complete Guide to Performance Excellence*, 7th Ed., New York, NY: McGraw Hill, 2017, pp.157-162, pp. 387-398, pp. 429-458.

[4] D. C. Montgomery, *Introduction to Statistical Quality Control*, 7th Ed., John Wiley & Sons, Inc., 2013, pp. 1-70, pp. 355-387.

[5] J. P. Womack, et al., *Lean Thinking: Banish Waste and Create Wealth in your Corporation*, New York, NY: Free Press, 2003, pp. 15-28.