Using Lean Six Sigma Tools to Improve the Laboratory Process Flow in an Analytical Laboratory Located in the Puerto Rico West Region to Increase Quality and Customer Service Satisfaction

Siarel Mercado Porrata
Master of Manufacturing Competitiveness
Edgar Torres, Ph.D
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— During the past years and up to this day, many Manufacturing Companies in Puerto Rico are challenged through tough economic instability and uncertain environment. In an effort to maintain their operational facilities on-going, such companies are focusing on cost-reduction and process optimization in their manufacturing areas. Some companies consolidate their efforts in one plant or facility obtaining efficient results. In some cases, those approaches are not enough to reach companies goals. Several activities such as outsourcing laboratory testing are an alternative that manufacturing companies can look further to reduce costs. Outsourcing is less expensive when compared to on-site laboratories. A laboratory company located in the west region has been growing over the past years due in part to an increase in outsourcing demand from companies all over the island. In order to sustain the increase amount of workload demand, the company will need to incorporate lean six-sigma philosophy and technological elements into their process flow to meet customer's needs. The company is challenged every day to deliver a high quality service throughout a wide source of materials (excipients and active ingredient) and different pharmacopeia specifications. This laboratory company is committed to achieve their vision through a cultural adoption of continuous improvements. This article presents the process improvement of the firm using the DMAIC approach.*

Key Terms *— Deliver on Time, Inventory System Design, Layout Improvement, Lean Six Sigma in Laboratory Operations, Waste Reduction.*

PROFILE

The company presented in this article is a full-service contract analytical laboratory providing chemistry and microbiology testing services to the pharmaceutical, medical device, and drug-device combination product industries. Their services include a full service microbiology laboratory, method development/validation, medical device chemistry, raw material testing, stability testing and storage, and product release testing. It is FDA registered, DEA Licensed and ISO/IES 17025 Accredited. The firm has two (2) analytical laboratories. The chemistry laboratories facilities (LS) are located in Oakdale, Minnesota and San Germán, Puerto Rico. Environmental laboratories facilities (LO) are located in mainland, see figure 1.

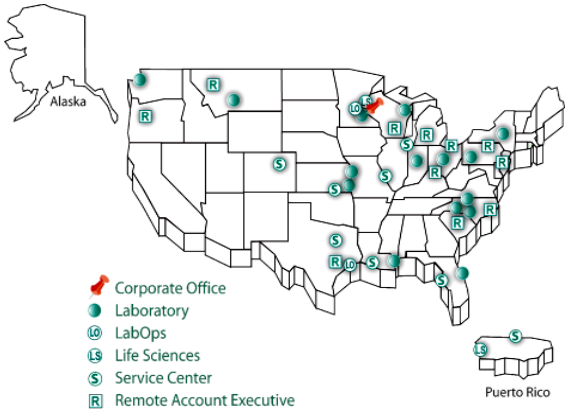


Figure 1
Laboratories Locations

INTRODUCTION

The analytical laboratory provides new alternatives that would benefit the manufacturing industry in Puerto Rico and allowed them accomplished their goals and business need by high

quality analytical services offerings. [1] Raw Materials, In-process and Finish Products can be tested off-site maintaining the same standard quality but reducing their operational costs.

Due to increase in the demand for materials testing the laboratory started to measure their quality service. For 2011 the delivery on time was 82%. This percent on time was not acceptable for the company and management establish a goal to accomplish to demonstrate their business competitiveness to the clients. The proposed goal was set to 90% of delivery on time. In order to reduce delays that affect the service, the company must identify which is the major offender factor for the reason late. A pareto analysis will be used to identify the major offender and evaluate using lean six-sigma tools to reduce or eliminate waste and variability in the laboratories process flow.

OBJECTIVE

The main objective of this project design is to maximize the laboratory area by layout improvements to promote better work flow, the creation of a workstation and increasing work space for equipment's, chemical materials and standards. [2] Develop a new on-line platform to maintain a healthy inventory thus helping reduce a late delivery respond time to clients associated to material shortage. Support the site to maintain our quality control standards to fulfill the demands for the future growth of the company.

CONTRIBUTIONS

This project design supports the company's goal to provide a continuous high quality service by optimizing our laboratory facility layouts and process flow. It will be also a tool to identify areas of opportunities to work with and prevent possible issues that will cause downtime and interrupt the ability to deliver a high quality service. Through this research analysis it is estimated to avoid 54% of sublet, increase 11% of percent on time, and reduce delivering late of a the major offender of the metric (50%).

METHODOLOGY

During a walkthrough within the company's analytical laboratories, a model plan was developed in order to create a unique database including all areas of opportunities gathered which had a direct impact on the quality of their services. [1] This information was presented to management for evaluation. A pareto chart for 2012 was presented including all the major offenders. An action plan was taken to meet the established goal. A step-by-step methodology approach was selected for project completion; See figure 2 for the road map and tools to eliminated waste in the laboratories environment. This approach was documented as followed:

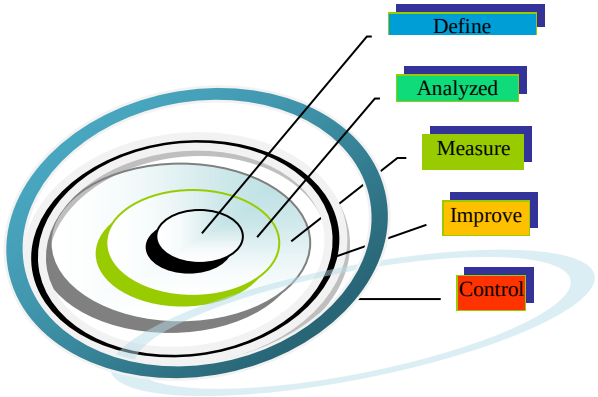


Figure 2
DMAIC Methodology

Define Phase

The following team members shown on Figure 3 develop a project charter to evaluate the problem statement and the positive impact on customer's benefits to meet company goals.

Project Name: Optimization Process Flow of the Analytical Laboratory Area			
Location: San German	**Organization Group:** QA Laboratory	**Project Leader:** Siarel Mercado	**Improvement Methodology:** Lean Six-Sigma
Problem Description: The analytical laboratory company since 2011 received an increase in demand which affected the organization flow process and subsequently the service causing an unacceptable response to customer's needs.			
Scope: Implementation of Lean Six Sigma tools in the Analytical and Microbiological Laboratories at Oakdale and San German Laboratories**.**			

Customer Benefits: This project design supports the company's goal of operational goal to continuous offering a good quality of service by optimizing our laboratories facility layout and analyst process flow.			
Core Project Team Members	Name: Nilsa Martínez Role: General Manager	Name: Juan Colón Role: QA Supervisor	Name: Admilkar Perez Role: IT Specialist
	Name: Julio Ramírez Role: QA Director	Name: Rosamerie Valle Role: Scientist II	Name: Marcos Perez Role: Equipment Coordinator

Figure 3
Project Charter

Measure Phase

The analysis execution step was the area identified with opportunity to improve. Each area in the process flow has established their individual cycle time in order to maintain the expected company goal of 10 days delivery. Figure 4 shows a high level process flow. The analysis execution (laboratory operations) step was mostly completed in more than 4 calendar days. A lean six-sigma plan was established to cover this issue. [3]

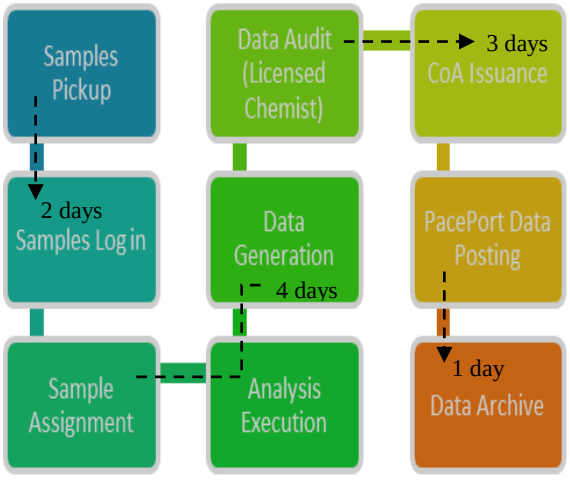


Figure 4
High Level Process Flow
Company Goals: Total Cycle Time for each Department
Average TAT <10 working days

Multiple tasks must be followed on a daily basis within the laboratory to complete the analysis execution. In some cases, these activities can cause stress and fatigue leading to errors and/or delays in the tests performed. The percent on time overall for 2011 was 82% indicating an unsatisfactory laboratory performance, see figure 5. In 2012 the company started to incorporate lean culture. An improvement was made based on the 92% of time overall, see Figure 6.

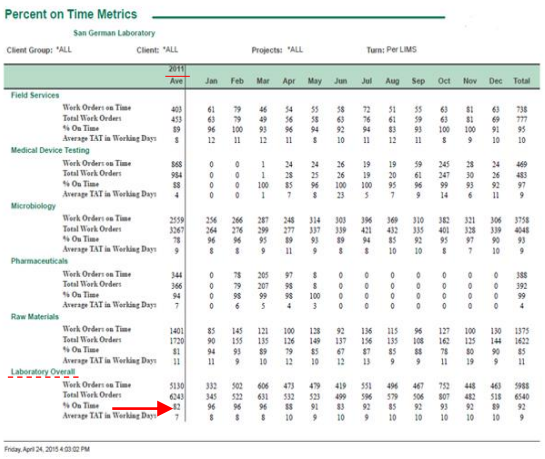


Figure 5
Percent on Time Metrics 2011

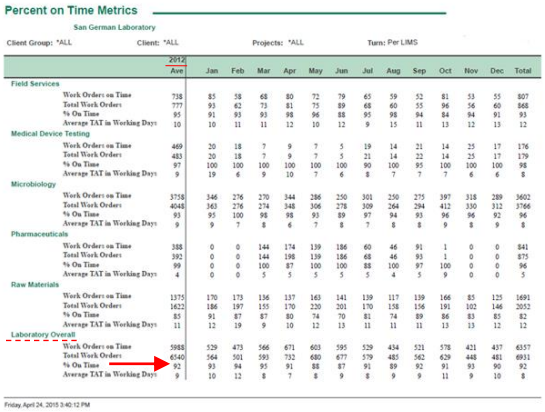


Figure 6
Percent on Time Metrics 2012

Figures 7 and 8 are pareto charts showing the major problems affecting directly the process flow of the laboratory operations. A pareto chart is a tool that helps identify and categorize the source of problems or common causes. These categories are described as:

- Re-work: Analysis that has to be repeated due to unsatisfactory elements in the testing performed.
- Workload: Not enough space with the laboratory to perform multiple testing's at the same time. Poor layout causes analyst to spend too much time searching for glassware and reagents. Not enough space to commit with the laboratory workload capacity.
- Missing Materials: An inefficient inventory increasing non-value added activities and waste of time.

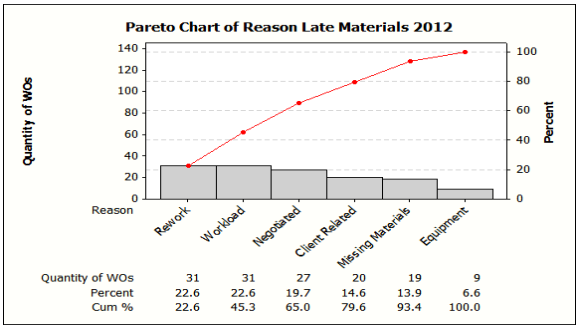


Figure 7
Pareto Chart of Reason Late 2012

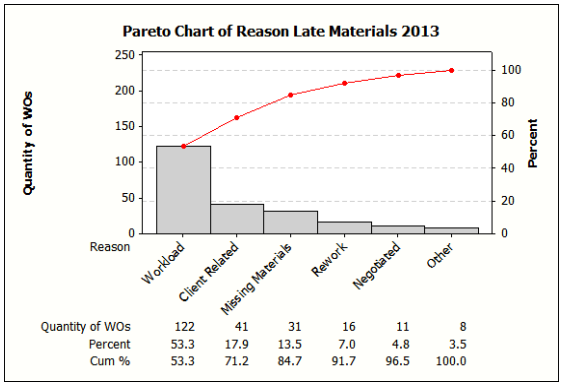


Figure 8
Pareto Chart of Reason Late 2013

Analyzed Phase

The major offenders were individually classified and a cause and effect diagram (fishbone) was developed to identify this causes, see figure 9. A cause and effect diagram is an efficient tool to consider all possible causes of the problem rather than the obvious one. [4]

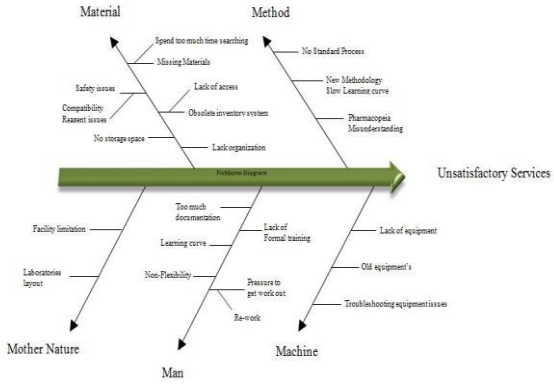


Figure 9
Cause and Effect Diagram

Re-work:

- The expertise of the chemistry analysts was increasing in parallel with the amount of workload. All personnel, including supervisors, had to learn on-the-go, as new testing's arriving at the site would require the use of different pharmacopeia including but not limited to US, Europe, Japan and the ACS. [5] At the same time, a client deadline must be met. There was no standardized process of the data being generated and the amount of documentation needed to complete the tests was a non-value activity.
- Management was committed to improvement activities and recognizes the learning curve is a process that must take place to elevate the analyst performance.

Workload:

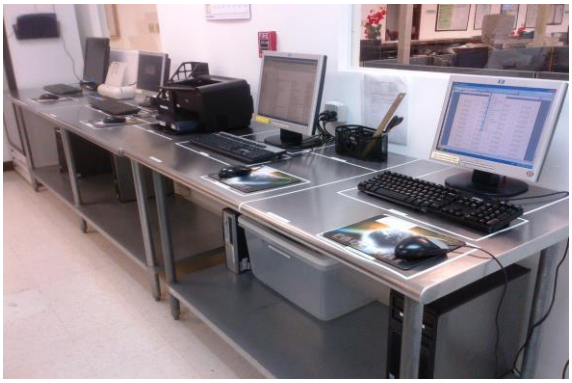
- Further evaluation of the layout facilities demonstrates a renovation has to be made in the laboratory areas by adding more per square feet. At the same time, new projects required additional laboratory space and the purchase of new equipment's to satisfy business needs. Creating a workstation for testing and allow new equipment installations in the area. Reducing sublet to increase business goals and reorganize laboratory layout in order to increase capacity.

Missing Material:

- An obsolete inventory system in place is the most common waste that directly affected the analyst performance in the laboratory. This will cause a delay on the analysis execution. To many non-value activities performed such has lack of material organization, not having material in the point of use and establish the maximum and minimum of the supplies is on example of this problems. A new inventory must be developing.

Improvements Phase

Kaizen activities were performed through the laboratory areas but not limited in office area and organizational staff members. 6S Philosophy was implemented through all laboratories, see picture 1. [6] The culture of Lean and Six Sigma allow the organization to continuous improvements.



Workstation Area

Organized Materials in the Point of Use

Picture 1
6S Tools

An individually Control Sheet analysis for data entry (CS) was created to reduce the documentation activities and able to standardize the documentation practice. Follow the GMP's regulations and training the personnel. Those activities was available to reduce analyst re-work allowed the employs get a better performance. A re-work reduction was noticed within one year of improvement, the 2013 re-work average was 15, see figure 10.

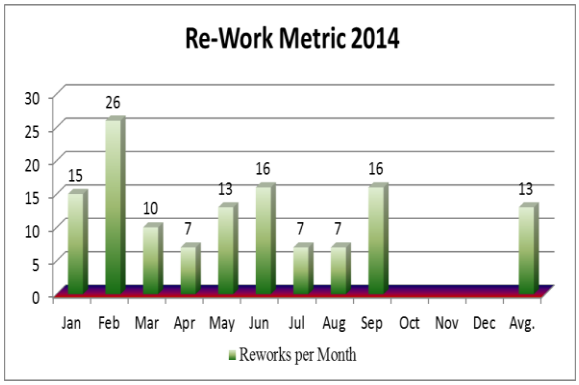


Figure 10
Re-Work Metric for 2014

The reason late are now mostly related to client issues rather than company issues, see figure 11 for Pareto chart of reason late 2014

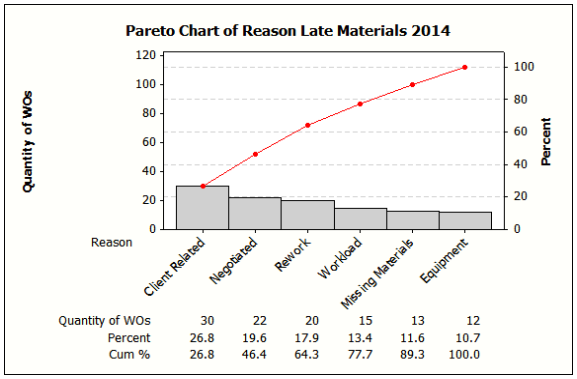
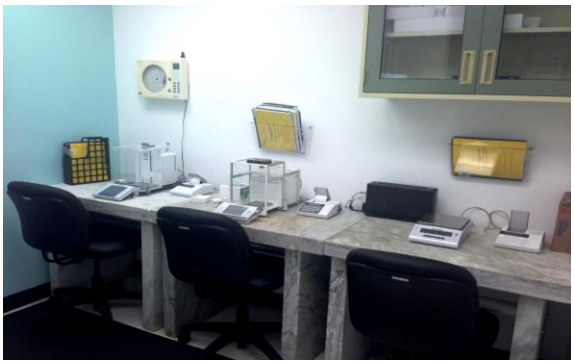


Figure 11
Pareto Chart of Reason Late 2014

Renovation and restructure the layout of the laboratory were followed of the lean elements to reduce waste. Productivities and efficiency was delivering in the Analytical laboratory. New areas were created in order to increase equipment capacity. Sublet practices were eliminated and the profit company increase. The input of created workstation areas make the firm hiring more

analysts for the laboratory and get a flexibilities process. Reducing the workload and late delivering. 6S were establish to set in order the materials and supplies necessary to complete the work. [6] Picture 2, 3 and 4 shows some of the layout improvements. An increase in equipment capacity was observed thanks to these layouts improvements, see picture 5.

Before Improvement
Unstable balances due to inadequate supporting bench



After Improvement
Balances successfully located on marble top benches.

Picture 2
Before and After Balance Room

Before Improvement
Workstation area (approximately 7'x 4' square feet).

After Improvement
New workstation area (approximately 8'x 6' square feet) with conduit and wiring for electrical power to support equipment use.

Picture 3
Before and After Wet Chemistry Area

Before Improvement
HPLC equipment's on wooden tables limit the space area.

After Improvement
Top benches installed to maximize HPLC capacity and providing space for storage and waste disposal.

Picture 4
Before and After HPLC Room Area

Agilent HPLC

Maldi-Toff equipment

Picture 5
New Equipment Acquisition

The overall percent of time for 2014 was 95%, see Figure 11. The elimination of non-value added activities helped the company process to increase performance and reducing the major offender.

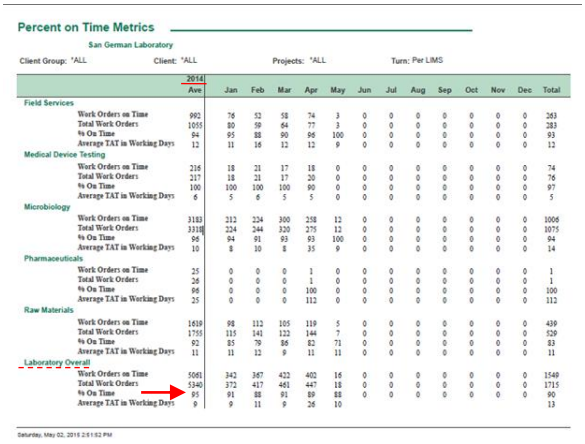


Figure 11
Percent on Time Metrics 2014

Design and develop a new electronic inventory system that are visible in the network for all the analytical personnel and able to short, storage and classify on a compatibility material, see figure 12, 13 and picture 6. [7] Also stablished the maximum and minimum material to reduce cost and time of searching materials. Inventory System called a best practice by EPA Inspectors.

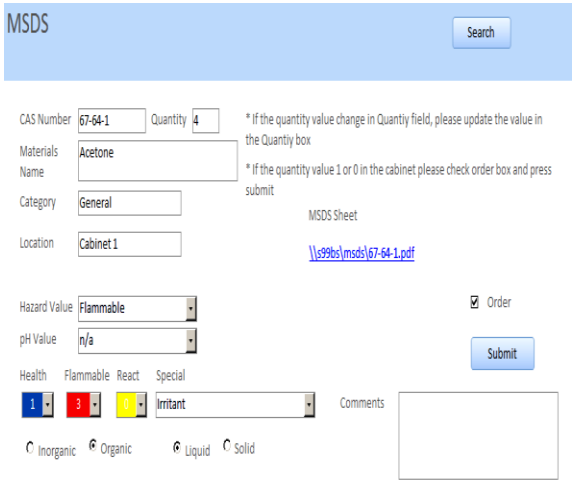


Figure 12
Picture of a New Electronic Access Inventory System Platform
The Structure Query Language (SQL) Microsoft Access was used to create the electronic inventory platform.

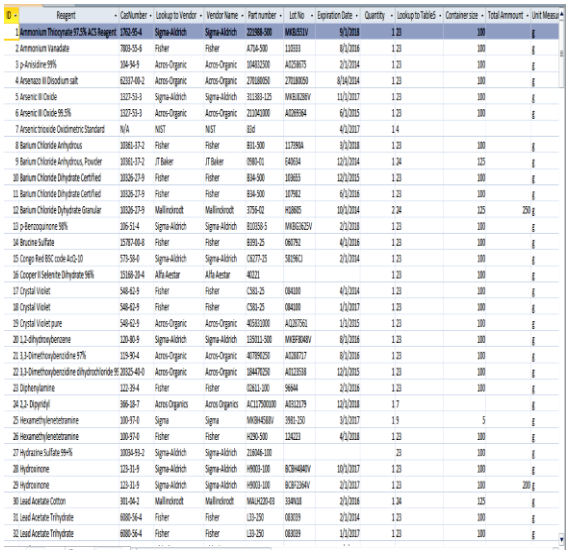


Figure 13
Picture of a Searching Electronic Inventory System

Picture 6
Reagents Strategically Located as Part of the Area Standardization to Reduce Searching Cycle Time

Table 1 shows the overall improvement and accomplishment of the company.

Table 1
Analytical Laboratory Improvement

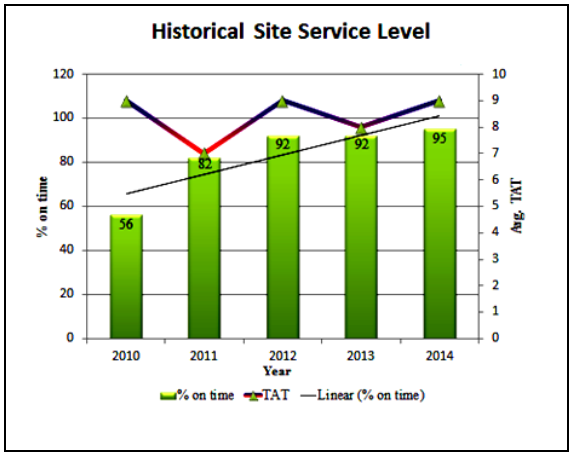
Improvement	Accomplishment
Percent on Time	Percent on time for the Raw Materials Department from 82% (2013) to 92% (2014) Increased 11%
Delivering late a materials for not having a reagent for the task completed	Representative a reduction of more than 50% No EPA finding on audit of 24 Jul 2014 avoiding federal and local fines of $500K. Inventory System called a best practice by EPA Inspectors
Sublet Practice	Sublet Reduction of 54% from 2013 to 2014 $258,911 less than in 2013
Workload (layout renovation)	Increase of 14% of test reported Revenue per square feet of $558K (Benchmark $400K)

An increase of percent on time when compared the overall percent on time from 2013 and 2014 was observed, see Table 2.

Table 2
Overall Percent on Time by each Department

Company Departments	2013	2014
Field Service	93%	92%
Medical device	98%	100%
Microbiology	96%	96%
Pharmaceuticals	96%	96%
Raw Materials	82%	92%
Overall Plan	92%	95%

Figure 14 shows that a significant overall percent improvement was made from 82% on 2012 and 95% on 2014.



Company Goals: Average TAT <10 (working days), and Percent on Time > 90%

Figure 14
Historical Site Service Level

Control

The Laboratory Company monitors all monthly metrics to get a current status to look for areas of opportunities and also to evaluate the performance of the quality service. Management Gemba walk are in place to monitored all actions taken to ensure that the process are fully implemented and standardize by all personnel. The firm stablishes the followed ideas to keep company improvement.

- Share best practices between San German and Oakdale
- Employees Relations Committee role out in San German
- [(1)] Award and Recognition (Program Ideas)
- Kaizen workshops
- Voice of the customer (Internal & External)
- Site quarterly communications
- Client survey

[(1)] Chairman Award $1,000 prize per Laboratory for the best productivity improvement idea. All local award winners posted in company platforms for a chance of a trip to Hawaii (Grand Chairman's Award) selected from local winners.

CONCLUSION

The laboratory company corporation has successfully implemented Lean Six Sigma tools. Their results exceed company expectation accomplishment on cost avoidance, increase workspace flow and optimization their laboratories process flow. Avoid 54% of sublet, increase 11% of percent on time, and reduce delivering late of a major offender more than 50%. In overall percent on time improvement moved from 92% to 95%.

The firm has a potential to continuous growing and keep offering and expanded their quality service to the customer given them as opportunity to be competitive in a market on the business needs.

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