FASTER SAMPLE DELIVERY TO THE MICROBIOLOGY LABORATORY USING LEAN SIX SIGMA

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ABSTRACT

This article presents the Lean Six Sigma tools used to identify the factors that impact the timely arrival of environmental water samples to a Microbiology Laboratory in a biotechnology industry .The inherent variations which cause an inefficiency in a process can be identified using the DMAIC (Define, Measure, Analyze, Improve, Control) Methodology, which are the different stages of the Six Sigma tool. The Microbiology Laboratory needs to improve the service it provides by, it would be determine the inherent variations which cause waste or inefficiency in the process. Among the objections of the Microbiology Laboratory, one was to reducing the time delay for the delivery of the samples from 2.7 to 2.1 hours. In addition, the lab needs to decrease or eliminate the non value added which affects the process.

INTRODUCTION

The research was completed to assess the effectiveness of the lean Six Sigma program. The benefits of the, Lean Six Sigma includes increased productivity, safety, quality, use of floor space and increased employee control. In addition, it improves organization and input on decisions impacting the work.

Six Sigma got its start in 1979 in the Motorola Corporation. It focuses on preventing problems by:

- Reducing variation in every process
- Eliminating errors in every process
- Improving methods and processes
- Basing decision on data and facts

Six Sigma, is a high impact process that uses techniques to reduce process variance, and confines errors to 3.4 defects per million opportunities. It implements control mechanisms that ties in quality, cost, process, people, and accountability. Six Sigma begins with an understanding of customer requirements and values (referred to as voice of customer identification factor) [6]. Six Sigma's process enables the identification of factors critical to customer satisfaction. It can increase productivity, reduce costs, shorten lead times, and enhance customer partnerships provided management plays a high visible role in the process. As defined, it does more with less human effort. It provides customer satisfaction in less time, since waste and inefficiency can creep into virtually any process, the concept of "Muda" in Lean terminology and variation in the Six Sigma vernacular are equally applicable to pharmaceuticals systems and services. This does not imply, however, that a certain amount of translation and adaptation are unnecessary [4].

The Six Sigma methodology that reduces defects and improves processes in the biotechnology laboratory has been met with both skepticism and enthusiasm on behalf of microbiologists. While Six Sigma can result in significant improvement in laboratory processes, it is not a methodology that can be adopted without a significant outlay of time, expense and energy [5].

The results obtained by using Six Sigma to reduce the time for the delivery of the water samples to the microbiology laboratory will be discussed as follows:

- The different phases of Six Sigma

- Results obtained in each one of the phases
- Recommendations and suggestions
- A brief description of the Six Sigma technique.

Defining and Measuring Processes

During the define phase, a process map was developed where the process flow was observed visually and it helped us facilitate the understanding of the process (See Figure 1).

The time frame covered in the project is from the time the sample is taken until the technician picks it up and delivers it to the laboratory. The objective of the project was to reduce the laboratory's waiting time for the water samples.

Also in this phase the SIPOC was developed to identify the scope of the project. The scope of the project identified the factors or circumstances that are affecting the collection and delivery of the samples to the microbiology laboratory.

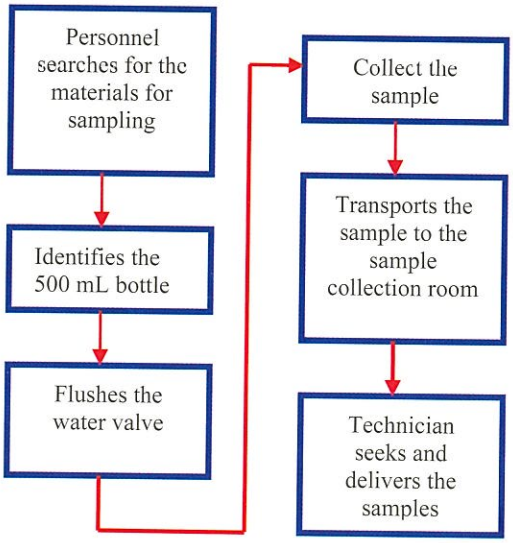

Figure 1: *Process Map*

To determine the client needs a CTQ's Tree was developed. In a "CTQ's Tree" the clients' needs are identified and the facilitating activity to determine the "Critical to Quality" (see Figure 2).

In the measuring phase, a measurement system analysis was identified. The laboratory team knew that any variation would affect the process but did not have a measurement system. In this phase different tools were used to measure the process. The aim was to set a baseline through the development of a clear and meaningful measurement system. The most important objective of this phase was to identify the desired level of improvement evaluating the measurement system and the data collection. In addition, a more focused problem statement needed to be developed.

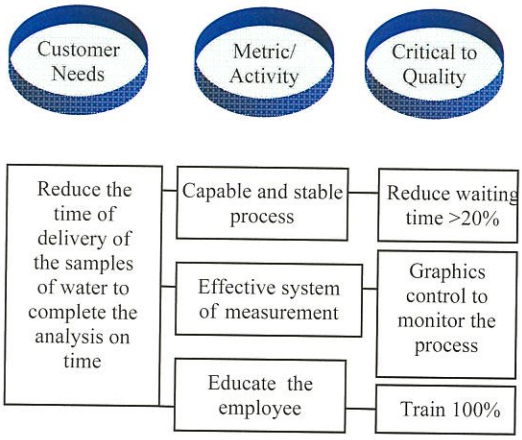

Figure 2: *CTQ'S Tree*

With the data collection performed, various graphs were created, such as the Individual Value Plot in which the following was observed:

- The majority of the rooms in which the sample collection took place.
- The sampling time was over 150 minutes.
- There were only two areas in which the sampling times were below 100 minutes.

To visualize in detail the behavior of a process, an I-MR Chart was created. This graph shows that the difference in the average waiting time from one event to another was 9 minutes (see Figure 3).

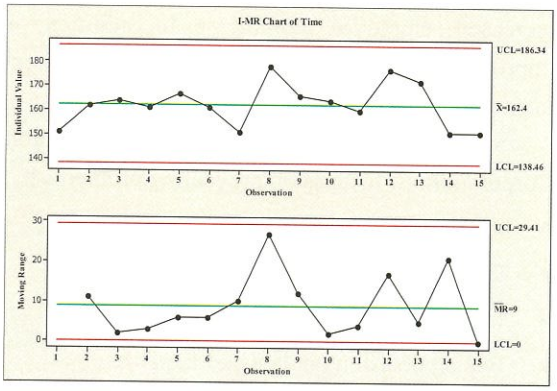

Figure 3: *I-MR Chart*

According to the data obtained, the baseline for the time it takes for the sample to arrive to the laboratory was 162.4 minutes, which equals 2.7 hours. The goal was to reduce the arrival time of the sample by 20%. This is equal to 129 minutes, which is about 2.2 hours.

ANALYZING AND IMPROVING PROCEDURES

The analysis phase aims to identify the critical factors of a "good" product or service, and the root cause of defects. Changes were implemented in the adjustment of the process (x's) to improve the results (y's). The process was redesigned to reduce defects, and that the changes made were effective.

In this phase the tool of the 5 Why's was utilized to investigate a specific failure and to find a root cause for the problem. The most important 5 Why's were:

- Why does the employee have to degown to take the sample in the warehouse room?
- Why isn't the laboratory technician notified when the sample was placed in the refrigerator in warehouse room?
- Why doesn't the sampler have access to LIMS (Laboratory Information Management System) to receive the samples in a computerized system?
- Why is there no computerized system to collect the sample in the area where sampling is performed?
- Why hasn't the sampler been trained on the importance of delivering the sample to the receiving or warehouse room as soon as possible?

The Fishbone Diagram was utilized to visualize root causes. Input variables were assigned values in terms of what effect they would have on the Key Process Output Variable (KPOV). In the Fishbone Diagram the different factors that could affect the process were evaluated.

In this phase, several steps were taken to have a positive impact on the process. The following steps were implemented:

- Computer systems were placed computer near the sampling area.
- The samplers were trained to use the computer system (LIMS) utilized by the company for the sample collection.
- The importance of delivering the samples as early as possible was emphasized to the employee.
- The laboratory technician was trained to verify which samples were collected in the computer system to avoid making unnecessary trips to the sample collection room.
- A method of communication was established with laboratory personnel when problems with the samples collection were encountered.

In the improvement phase, the best solutions with controlled risks were selected and implemented. The effects of the solutions were then measured with the KPI's (Key Performance Indicators) developed during the measuring phase.

Among the results obtained in this phase was to reduce the sample's delivery time to 124.7 minutes, which was equivalent to 2.2 hours. This reduction in time was observed after implementing some of the recommendations made in the analyzing phase. Plotted on the I-MR chart, the reduction of time was demonstrated and the process was maintained consistent. This indicated that the process was more stable since the difference between the average time of one event to another was 3.6 minutes. This showed that the recommendations provided, had a positive impact on the process. After carrying out various significant changes, adjustments can be seen as there was a decrease in the variability and the time of delivery of the sample diminished significantly. The average is currently 3.64 minutes between events compared to a previous average of 9 minutes between samples (see Figure 4). A significant change is observed once making some adjustments.

It can be observed how a decrease in variability diminished the sample delivery time significantly.

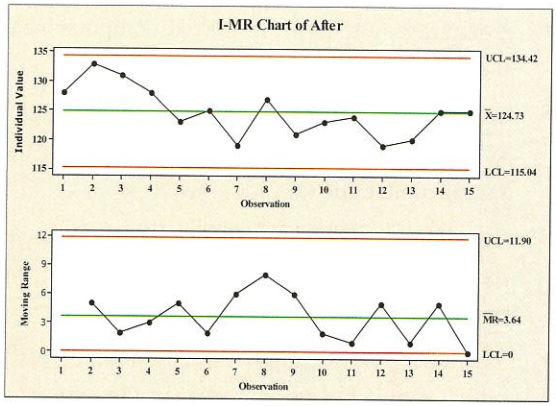

Figure 4: *I-MR Chart of Time*

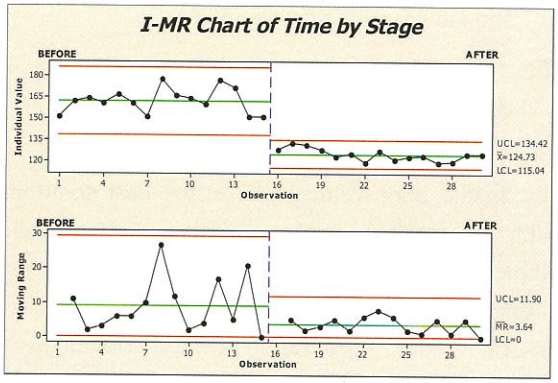

Figure 5: *I-MR Chart of Time by Stage*

CONTROLLING RESULTS

In the Control phase, a plan was implemented to utilize graphs to visualize the process constantly. It was necessary to detect the time when the process needed adjustments in order to rapidly execute a plan of action and avoid losing control of the process. The graphs mostly utilized would be the individuals to visualize and evaluate each area independently and the moving range of the charts. A report was developed in the sample collection system, which compiles data, by "point" to facilitate the creation of the graphs. For this purpose, laboratory personnel were trained to draw a plan for the collection of data.

Another measure that evaluated, was to facilitate the employee who uses gowning, the delivery of samples to the assigned room; since he/she had to degown , therefore, the samples were not delivered early because to go back in they have to dress again. One of the most important measures was to educate the employee to understand and visualize the importance of monitoring and improving the process, because at a long term, it is beneficial for all of us.

The Six Sigma methodology has many advantages. It is a vigorous process that engages front line employees in process redesign. It utilizes data and the voice of customers to determine the factors that are most critical to quality controls. Accountability is put in place to ensure that the process remains efficient. This approach provides manufacturing and laboratory personnel with the tools to take a good process and make it better.

CONCLUSIONS

Positive results were obtained in this project through the use of, techniques, such as Lean Six Sigma, positive results were obtained; many changes and benefits were observed since the process had changes. In addition, with the availability and cooperation willingness of the personnel involved, solutions were obtained by interchanging ideas. This process generated a positive energy flow, resulting in creative ideas to change the present processes to reduce waste.

Lean and Six Sigma were utilized in conjunction to offer better benefits. This relationship has been expressed as follows:

- Strengthen the process applying Lean techniques.
- Ensure the maintenance of the improved status of a process can be maintained using Six Sigma techniques.

The combined effect of Lean Manufacturing and Six Sigma has led to improvements in product quality and turnaround time. These improvements have resulted not only in cost reduction, but also the possibility of presenting these improvement stories to the customers [3].

In the pharmaceuticals industry, the factors that determine the quality and efficiency are usually the

flow of information and interaction between people. Six Sigma helps in streamlining the flow of information and achieving strategic business results by initiating cultural shifts all throughout the organization. Six Sigma focuses on improving processes rather than just concentrating on the task, which helps in increasing the scope of improvements. It provides the necessary tools and methodologies that help in analyzing and transforming human performance, necessary for achieving significant long-term improvements [2].

Six Sigma helps in defining a vision for the future, identifying specific goals, and establishing quantitative measures for turning that vision into reality. It helps in formulating goal plans and setting timelines to move from current performance levels to Six Sigma performance levels. The plans are defined after documenting their effects on the organization's work processes that may include flow of information and procedures.

Positive results were obtained by implementing minor adjustments in a short period of time.

In order to prevent the process from relapsing, it is very important to continue educating and training the employee, so that they are willing to maintain and continue improving the process.

Last, but not least, to sustain the continuous improvement movement, the quality control area observed that by using Lean Six Sigma techniques, the process improved significantly [1]. It is very important to continue monitoring and watching the process. One of the many benefits obtained in the process was that the technician could perform additional tasks, without the need to use additional personnel, and the quality of the analysis improved significantly.

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Lumarie García se graduó del programa de Maestría en Manufactura Competitiva, en la colación de grados de 2009. La señora García posee dos grados de bachillerato en Química y otro en Contabilidad. Sus intereses en investigación van alineados al área de Gerencia de Calidad.