Raw Material Sampling Process Optimization using Lean Six Sigma Methodology

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Abstract *— Pharmaceutical Industry needs reduce the costs without impact the quality of the product. The principal objective of this project is the reduction of the cycle time of a raw material sampling process from 8 days to 2 days. This project demonstrates the application of Lean Six Sigma and DMAIC to the efficiency of a process. The tools using during the project: Voice of the Customer, SIPOC, High Level Process Map, Measure System Analysis, Process Capability, Pareto, Control Charts, Cause & Effect Matrix and Control Plan. As result of this project a cycle time reduction from 8 days to 3 days.*

Key Terms *– Cycle Time, Lean Six Sigma, Raw Material, Six Sigma.*

INTRODUCTION

All pharmaceutical industry operates in a competitive environment of with limited resources. The most successful are those that maximize the resources and optimize the process. To be competitive in the market the industries developed improvements plans to reduce cost, defects, time and increase customer satisfaction. The improvement plan is focused in maintaining the quality of the product, the security, the performance and improvement process of the cycle time.

Research Description

The focus of this project is on the pharmaceutical industries is to reduced the cycle time, reduce the costs and the inventory. The release cycle time to the raw material sampling process of pharmaceutical products increased from 2 days to 8 days so, is exceeding its expected lead time affecting the production plans and increasing the inventory levels for raw materials. The importance of this project is use tools to develop the tasks made in the sampling process to reduce the cycle time. The methodology that is going to be used for this project is DMAIC, define, measures, analysis, improve and control.

Research Objectives

The principal objective of this project is to implement efficiencies in the raw materials sampling process to improve compliance and reduce cycle time. The actual sampling cycle time for raw materials is 8 days exceeding the expected cycle time of 2 days and affecting the release total cycle time.

Research Contributions

This project contributes to the company approximately $109,728 which is equivalent to 1 week of production in savings on the production of the manufacturing area with this contribution we help the company to be more competitive.

LITERATURE REVIEW

In this chapter we will discuss relevant background information for our project definitions and investigations of the applications and tools of the methodology of Lean Six Sigma. The principal objective of this project is to reduce cycle time in the sampling process fist we need to understand the meaning of the cycle time. The required period to complete one cycle of an operation from start to finish is known as the cycle time process [1]. Other concepts we researched in this section are Lean manufacturing, Six Sigma, and Lean Six Sigma.

Lean Definition

Lean philosophy is the identification and elimination of waste [2]. Lean eliminates all the wastes from the process and basically there are 7

types transportation, inventory, movement, waiting time, overproduction, over processing and defects [2].

Definition of Six Sigma

The Six Sigma is a methodology for a continuous process improvement and indicates no more than 3.4 defects per million opportunities (DPMO) [3].

Definition of Lean Six Sigma

Lean Six Sigma is the combination of a lean philosophy and six sigma methodology [4]. Lean Six Sigma can be applied to, elimination of wastes, optimization of the resources, reduce costs, reduce inventory, reduction of variability, and customers satisfaction [4].

METHODOLOGY

Based on the objectives established we will be describing the methodology using through the development of the Project Design. To reduce cycle time in the sampling process with tools of Lean Six Sigma applying the methodology DMAIC this are the five phases to the improvement: Define, Measure, Analyze, Improve and Control.

Define Phase

In this phase we will describe the Project Charter that includes the description of the problem, business cases, goals and scope. As part of define phase we will make a Voice of the Customer, Critical to Quality, Stake Holder Diagram, High level Process Map and SIPOC. The first step after define the Chapter Project is validate the problem statement, the business case, the goal and the scope of the process and determine if our project has a financial impact. Using statistical tools we will be determinate the expectations of the clients goal and relevance of the project.

A project is started because a customer needs some problem solved. To establish the customers specification a tool to be used is the Voice of the Customer we will use the interviews. To define specifications and requirements clearly of our client we will use qualitative descriptions.

The SIPOC diagram is a tool that means: Supplier, Input, Process, Output, and Customer help us clearly understand the purpose and the scope of a process [5]. The first step to construct the diagram is visit to the area to understand the process, determine the customers the suppliers that provide inputs to the process and define the sequences of activities to produce outputs.

The High Level Process Map is flow diagram of the process. The purpose of this tool is to visually represent the process from the beginning until the end.

Measure Phase

The Measure phase is to collect data and document to set a clear view of the current state this serves as a baseline to evaluate potential solutions. The actions in this phase are Detailed Process Map, Data Collection Plan, and Measurement System Analysis and we are going to include graphics to determine the current performance of the process.

The Detailed Process Map is the tool that represents the process in a sequence of task. For the development of this map we will visit the area of the process obtaining detailed observations. This observation will be help to identify all the task performed during the entire sampling process and determine if are value add activities or not value activities and identify opportunities to improve the process.

Analyze Phase

In Analyze, the data collected in measure is examined to identify the potential causes of process variation. Statistical tools are used in this phase for data analysis includes graphs, also we can use visual representation such as Causes and Effect Diagram, help to find potential root causes. The diagram we will be making it with the operator of the process to establish the causes of the cycle time is high.

Improve

Process improvement solutions are implemented in the Improve phase after analyze the root causes.

Control Phase

The objective of the final phase of the DMAIC is ensure that the gains obtained during improve are maintained long after the project has ended. In this section we will create a Control Plan to monitoring the all improvement of the sampling process.

RESULTS

The principal purpose or the project is reduce cycle time for the raw material sampling process using the methodology Lean Six Sigma. As part of the discussion of the result we will be including detailed the five phases define, measure, analyze, improve, control.

Define Phase

The project chapter was made in this phase that include define the problem, goals, scope.

- Business Case - The release cycle time for raw materials is exceeding its expected lead time affecting the production plans and increasing the inventory levels for raw materials. The financial impact is $109,728 which is equivalent to 1 week of production.
- Problem Statement - Implement efficiencies in the raw materials sampling process to improve compliance and reduce cycle time. The actual sampling cycle time for raw materials is 7.9 days with a standard deviation of 9.4 days exceeding the expected cycle time of 2 days and affecting the release total cycle time.
- Goal Statement - Reduce the raw materials sampling cycle time from 7.9 days to 2 days.
- Scope – Start: Raw Material deliver by warehouse to QO for sampling. Stop: Raw Materials lot sample received in the laboratory.
- Out of scope- Packaging components, finished goods, and In-process samples.

To establish the customer specification we used the voice of the customer, as part of this tool we made 4 individual interviews to QC Manger, Warehouse Supervisor, QO Technician, Documentation Technician and we obtained the following information:

Table 1
Voice of the Customers

Critical of Satisfaction	Driver	Prioritization	Metric
Reduce documentation	Delivery	9	Quantity of Paper
Reduce non-value added activities	Cost	7	Quick Wins
No impact to raw materials quality	Quality	9	Compliance; SOP
Reduce error associate to the sample labels	Quality	5	Compliance
Reduce cycle time	Delivery	9	Reduce to 2 days
No impact to production plan	Delivery	3	Compliance

The high level process map was made with observation in the sampling are from the beginning until the end.

Table 2
SIPOC

Supplier	Input	Process	Output	Customers
Warehouse QO Technician Documentation Technician	Documents	Sampling Labeling	Sample	QO Technician Documentation Technician Lab Analyst

SIPOC diagrams help a team and the sponsor agree on project boundaries, scope and verify the process inputs and input [5].

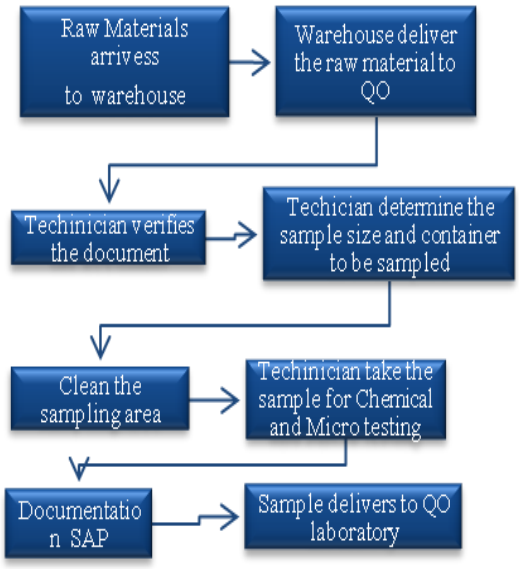

Figure 1
High Level Process Map

Measure Phase

In this phase we were collecting data to determine statistical the actual process and so far are our goal. To compile the data we made a Data Collection Plan, to establish from where we will be collecting the data and the information necessary for our project.

Table 3
Data Collection Plan

Question	Data Source
a) What is the delivery time of raw material from receiving to QO specialist for sampling?	Manual gathering using excel form
b) What is the delivery time of sample from receiving to QO specialist for sampling? Receiving date in SAP.	SAP
c) Sampling process touch time? Sampling process cycle time (documentation & others)?	SAP
d) What is the delivery time of sample from sampling area to QO lab?	SAP
e) What is the cycle time to log in samples in SAP?	Observations – get data from operators in form

The purpose the Measure System Analysis is assuring that our system of measure is accuracy.

Table 4
Measure System Analysis

Measure System Analysis	
Step	Sampling Process
Measurement System Accuracy	Forms Record
	As per SOP and GMP, activity document on-time when completed and is subject to audit

The baseline summary present as is process has a non-normal distribution with the P-value 0.005. The mean is 7.8 days, and the median is 9.4 days. The standard deviation 9.5, at a 95 percent confidential level, the average days has increased between 5.6 and 10.0.

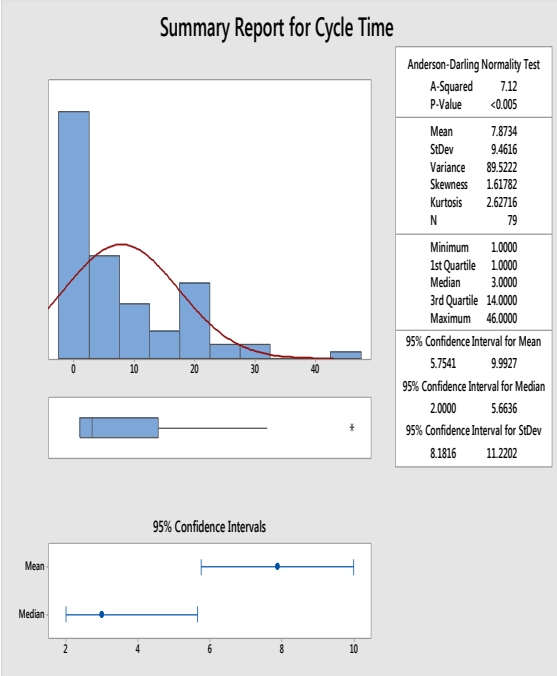

Figure 2
Summary report for Cycle Time

To determinate if the process is inside the control limits of our customer we made a graphic of control chat of the individual data. The graphic show the data is outside the limits of control and the variation of the process. The sample size is 79 each point represent one raw materials and the days that the raw materials arise to the receiving area until is delivery to the laboratory.

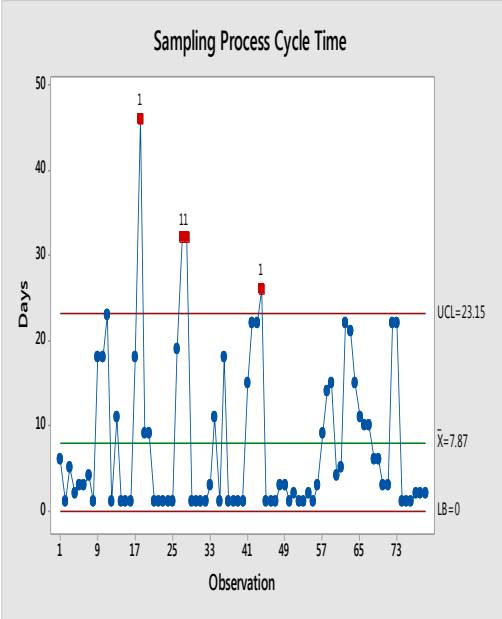

Figure 3
Sampling Process Cycle Time

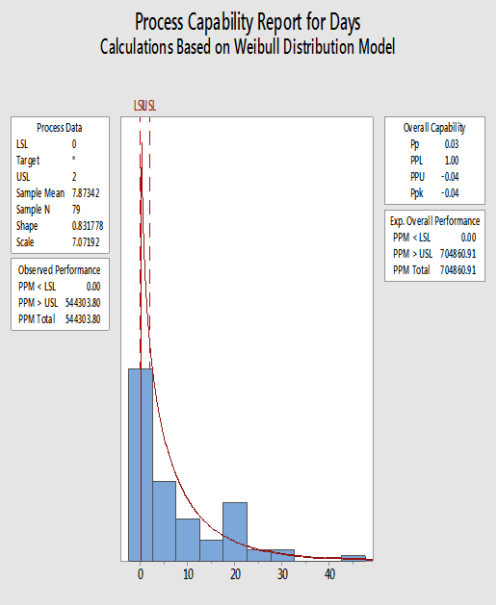

Figure 4
Process Capability

To determinate the disperse of the data and how far is our process from the specifications of the customer we made a graphic of Process Capability. The graphic of capability process show us that the process is not in control.

The Pareto chart is shown in descending order to identify the greatest opportunities for improvement.

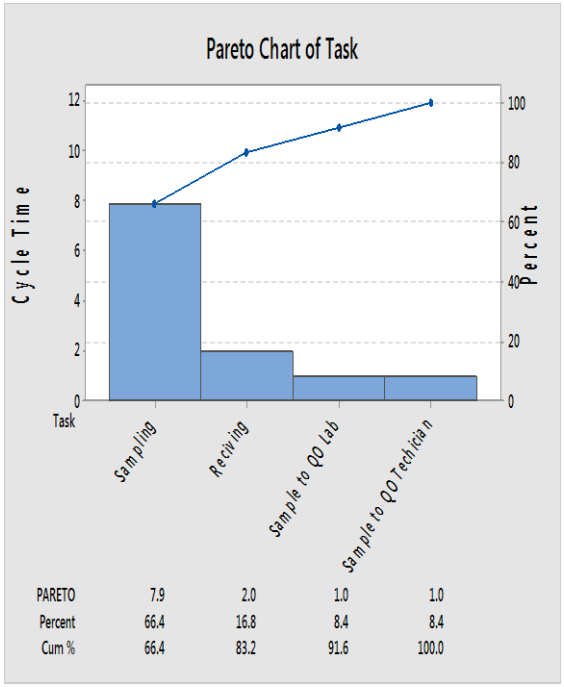

Figure 5
Pareto Chart

Analyze

To determinate the root cause was realized a cause and effect diagram. A brainstorm was made with the QO technicians all the ideas were classified in 4 categories Measurements, Material, Personnel, Methods and Equipment the result was the following:

Table 5
Cause & Effect Matrix

Cause & Effect Matrix				
Rating of Importance to Customer	10	5	10	

Process Inputs		Reduce the cycle time	Reduce the documentation	No impact the quality	Total
x1	Change of sampling priorities	10	10	10	**300**
x2	Need to weight bottles	10	10	10	**300**
x3	Need to document in SAP the quantity of sample	10	10	10	**300**
x4	F2 use the sampling room	10	1	1	**115**
x5	Problem with the vendor list	5	1	1	**65**
x6	Problem with certificate of analysis	10	1	1	**115**
x7	Waiting for the raw materials	5	1	1	**65**
x8	Make labels out of SAP	10	10	1	**210**
x9	Write the labels	10	10	1	**210**
x10	Waiting the instructions of reduction program	5	1	1	**65**
x11	Waiting for the supervisor write and sign the document	1	5	1	**65**
x12	Waiting for special instruction	5	1	1	**65**

Improve Phase

In this phase we are discuss the implementation in the sampling area. The fist improvement was change to receiving area in 24 hours process. New form for "Inspeccion al recibir el material" was developed. The change triggered a reduction in errors associated to vendor list, COA and others that reduce total cycle time.

Each raw material was handled through a special service request which specifies the sampling quantity per bottle. Review with laboratory quantity required per raw material to perform testing for release. The second implementation was establishing a standardization of raw materials quantity, to reduce the variation of samples quantity. Following table:

Table 6
Standardization of Raw Materials Quantity

Description	Retention	Chemist	Micro
Dextrose Monohydrate	200g	400g	
Dextrose Monohydrate	200g	400g	
Lean Beef		90g	
Lean Beef		5000g	90g
Lean Beef		5000g	90g
Sodium Chloride	100g	200g	
Sodium Chloride	100g	200g	
Soy Protein	100g	200g	
Soy Protein	100g	200g	
Tallow Edible JP	100g	200g	
Tallow Edible	100g	200g	
Tallow Edible	100g	200g	
Tallow Edible JPN	100g	200g	

Before standardize weight the QO Technician need to refer to an especial instruction give the weight for each the raw material and goes to SAP and subtract the quantity. This process takes 10 min in the computer and 20 steps waking to the office. Quality technicians printed off line sampling labels due to errors with SAP Sampling instructions. Sampling instruction in SAP were corrected allowing labels to be printed automatically when t-code was executed. Before the QO Technician need 5 minutes for small quantities of lot and 25 minute for large quantity of lot.

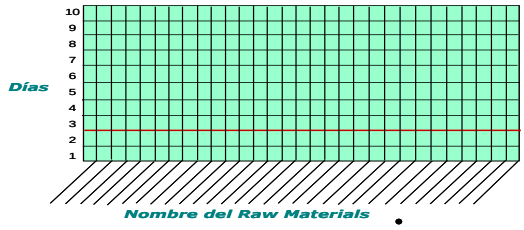

Figure 6
Tiempo de Ciclo de Muestreo

Visual tool was provided for documented sampling activities (pending or completed).

The summary grafic show the data after the improvement the average of the process decreased from 8 days to 3 days and the standard deviation 9.5 from to 2 .2.

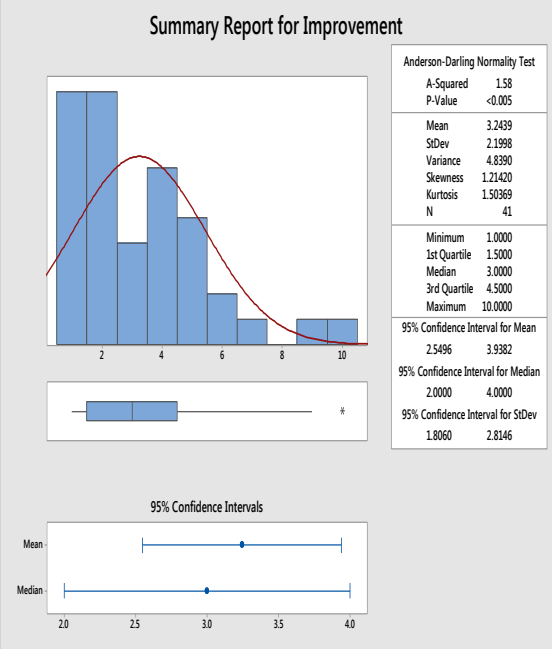

Figure 7
Summary of Improvement

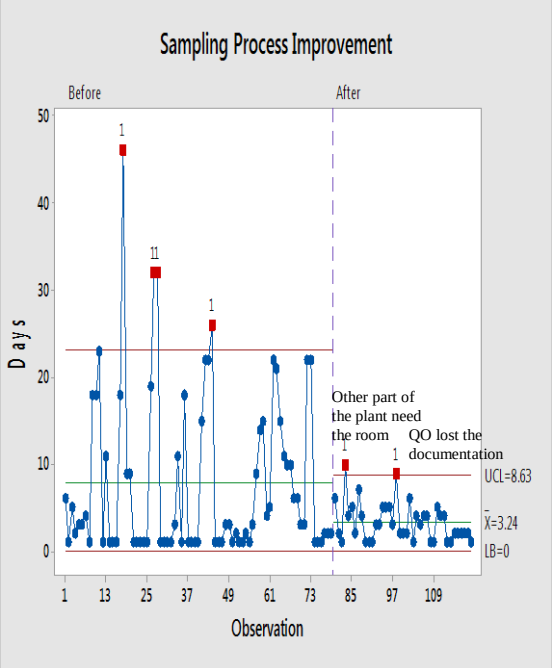

Figure 8
Control Chart Improvement

The Control Chart the improvement in the sampling process area. Only two points are out of the limit because special causes.

Control Phase

Once a solution is implemented the next step is control to assure the improvements are maintained. As part of the control plan the QO technician documented every day in the visual chart and the supervisor performed a meeting weekly to discuss the chart.

CONCLUSION

As part of this project we were able to apply various tools of Lean Six Sigma to reduce cycle time in the sampling area in a pharmaceutical. Some tools used SIPOC, High Level Process Map, Stakeholder Diagram, Cause & Effect Diagram, Control Chart, Pie Chart, Pareto Chart and Measure System Analysis. Following the DMAIC process approach provides a number of benefits, we made a standardization of the bottles, implement the use of t-code, change to receiving area in 24 hours, optimization the process, reduce number of documentation paper and the labels, no impact to raw materials quality and create a visual chat. The objective was to reduce the cycle time in 2 days with the implementation in the raw materials sampling process we reduce the cycle time to 3 days and the inventory levels decrease.

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