Unidirectional Flow Gasket application to buffer tanks

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Abstract

In order to reduce the number of deviations that occur annually in the plant, through a design it is expected to reduce this problem taking into consideration the cost factor, lead time and especially the quality of the products made. Using lean six sigma, applying the DMADV methodology as a guide to define the problem, measure the parameters of the scope of work, analyze the current problem, design the part that will improve the process to be achieved and finally validate that in effect it meets the objective of the research, to reduce the number of deviations. During our research, we were able to observe a reduction of 54% having a profit of $218,750, decreasing the original value of deviations occurred. It is worth mentioning that through this research we saw improvements in the lead time process, cost and even process quality. The application of the unidirectional flow gasket to the current systems of buffer prep in the plant to improve the quality of the products that are carried out on an annual basis could be seen as a great contribution to maintain a reliable process that meets the requirements of manufacturing and industry.

Key Terms *— DMADV, Lean Six Sigma, Buffer Tank, Improve, Quality, Lead time*

Project Description

Currently, as in any pharmaceutical organization that focuses on service and quality systems, a series of important factors are taken into consideration that are key to offer an excellent operational service in the market. It is for this reason that the focus throughout the manufacturing process is the quality of the different procedures that are executed daily, emphasizing on improving services to meet customer needs. To meet the focus is important to draw a line of goals and approaches that allow to perform the work in an efficient way in which always have as a priority to make improvements to a system to optimize it, exceeding the expectations to be achieved along the product that is being carried out to meet the needs of both the customer and the desired product.

Objectives

- Reduce deviation of buffer tanks procedure to %50 or more, to see an impact in cost and quality.

Methodology

In order to carry out the following research entitled "Unidirectional Flow Gasket" related to the possible deviations that can be found, we will work using the methodology of DMADV (Define, Measure, Analyze, Design and Validate) due to its focus in the area of analysis and validations, two factors of great importance that will be worked on during the course of the research being carried out, on the other hand, the implementation of lean six sigma will be vital to identify losses with a focus on customer needs, in order to optimize a quality process.

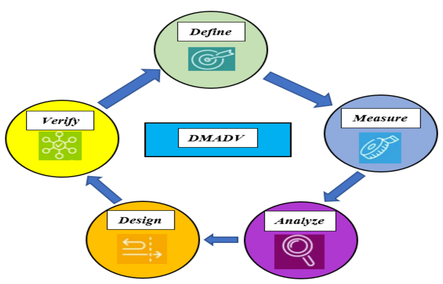

Illustration # 1: DMADV diagram

Results and Discussion

A series of calculations that will help both the reader and the researcher to measure costs: The following calculations demonstrate and measure the amount of losses that are generated on an annual basis when a deviation occurs during a buffering process where it can be seen from the operator costs, training per employee, cost per operator hour when there is a deviation, total cost of batches on an annual basis and finally the costs lost due to deviations on an annual basis.

Results and Discussion, cont.

$$\textit{Cost of annual deviation loss} = 13\ \frac{\textit{desviation}}{\textit{annual}}\left(\frac{31{,}250\ \textit{dollars}}{1\ \textit{desviation}}\right) = \$406{,}250\ \frac{\textit{dollars}}{\textit{annual}}$$

$$\textit{Total cost of annual lots} = 1{,}400\ \textit{tanks}\left(\frac{75{,}000}{1\ \textit{tank}}\right) = \$105{,}000{,}000\ \textit{dollars}$$

$$\textit{Cost per operator hour when there is a diversion} = 12\ \textit{operator}\left(\frac{\$19.80\ \textit{dollars/hour}}{1\ \textit{operator}}\right)\left(\frac{5\ \textit{hour}}{1\ \textit{desviation}}\right) = \$1{,}188\ \frac{\textit{dollars}}{\textit{desviation}}$$

$$\textit{Cost of training per employee} = \left(\frac{\$238\ \textit{dollars}}{12\ \textit{hours}}\right)\left(\frac{1440\ \textit{hours}}{9\ \textit{month}}\right) = \$3.173\ \frac{\textit{dollars}}{\textit{month}}$$

$$\textit{Annual cost per operator} = \$3.173\left(\frac{\textit{dollars}}{\textit{month}}\right)(12\ \textit{month}) = \$38.076\ \textit{dollars}$$

Illustration #1: DMADV diagram

In order to develop a better understanding to demonstrate a complete process and how it is impacted, a system was developed via a diagram known as SIPOC (Supply, Input, Processes, Outputs and Customers) as represented in the illustration #6, where you can see a series of five steps that define the importance of it, where in the first step we have the supply part, is that which is responsible for supplying such as customers, contractors and other factors that provide some entity, then we have the inputs that are orders, products, money.

Suppliers	*Inputs*	*Processes*	*Outputs*	*Customers*
Client or customer	Orders of clients	Buffer Prep	Orders are entered	Customers
Retail Customers	Orders from suppliers	Media Prep	Money received	Managers Department
Same company in other states	Product demand	Purification Prep	Data entry	Product Quality
Other buildings	Amount of money	Assembly team	FDA metrics	Safety
Contractors		Up stream		

Illustration # 2: SIPOC diagram

Define Phase

Currently the leader of manufacturing companies in Puerto Rico has been affected by a series of deviations, a term used to identify processes that have been affected or compromised when talking about the quality of a product, this throughout history has represented monetary losses. This process is a very distinctive within the organization, since it is the process where a process is conditioned to be able to cultivate a cellular process used to develop medicines for the home, in order to improve the quality of life of patients. Now this process has been identified as a process of continuous improvement to improve a quality system by increasing many factors that are affected within the manufacturing process, which want to be improved in order to avoid losses and reduction of quality of the products that are made to patients. As a result, a project charter was developed to demonstrate the origin of the problem and how it will be worked throughout this research in order to minimize the losses that are seen daily in the workplace.

Measure Phase

A value stream map which represents the process that needs to be carried out to make the different products that are made daily for patients, you can see how it is carried from the batch order process, where about 70 batches are produced annually, which represents an amount of 1,500 tanks per year. In the illustration you can see the amount of lead time of each of the processes using as a reference the connotation of minutes to have a homogeneous pattern in the process to obtain our results obtained as the total amount of lead time with a value of 11,185 minutes of process and change over with a total of 1,710 minutes, these two results show the amount of duration of the processes from its origin to be delivered to the consumer or customer.

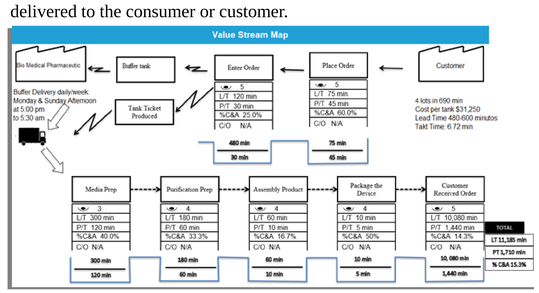

Illustration # 3: Value Stream Map

Analyze Phase

In this next phase we will be explaining in more detail the different reasons why the deviations during the different processes affect so much the quality and integrity of the products that are carried out during the processes of this one. Currently there are about 13 (thirteen) deviations per year causing a loss of $406,250 dollars, where within that margin of error it has been found that within that number of deviations between 7 (seven) or 8 (eight) are caused by human error. Some of the main causes that affect this process are due to unwanted components that can be introduced by mistake into the product being manufactured such as plastics, glass, tools, PPE, gaskets, among other factors that affect the integrity of our products. With the following research it is expected to be able to reduce this percentage of losses by 54% of the costs.

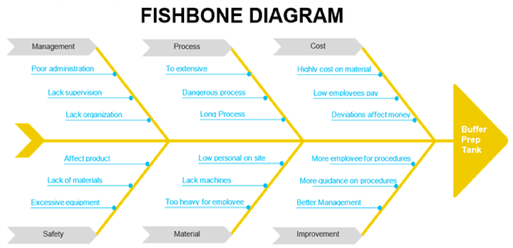

Illustration # 4: Fishbone diagram

Design Phase

The material selected to be able to develop the piece was Alloy 316, since it is sought to implement a piece that will withstand the different chemicals such as acetic acid, being a resistant metal alloy this problem of decomposition of the piece will not be one that has to be contemplated with so much frequency. The purpose of this design is as follows:

- Prevent PPE equipment from entering the tank
- Plastics
- Tools (pliers, torque wrenches, among others)
- Glass (larger than 2x2 inches in size)
- Straps
- Gloves

Illustration # 5: Design made in SolidWorks

It should be noted that the following design chosen to improve the process of creating buffer tanks, has as its main objective to prevent unwanted objects from damaging the quality of the product being worked on. Some of the characteristics that are sought to prevent during this process are the following:

- Plastics
- Tools or PPE (Personal Protection Equipment)
- Glass
- Cable Ties
- Garters
- Gaskets

Validate Phase

For the validation process of our research related to the improvement of a tank system known as buffer, we implemented a system known as 5S, which is composed of 5 (five) phases, which are composed of ***SORT, SET IN ORDER, SHINE, STANDARDIZE and SUSTAIN***. In the illustrated image on the back, we can see how this technique was implemented to develop a system that is able to function autonomously and with a system that allows continuous improvement.

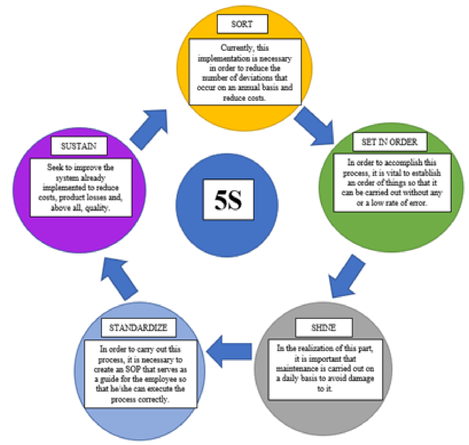

Illustration # 6: 5S diagram

Conclusions

The "Unidirectional Flow Gasket" which has been identified as a tool for continuous improvement during the buffer creation process, according to the different studies carried out. This system using the DMADV methodology (design, measure, analyze, design, and validate) using as reference the Lean Six Sigma practices and its different practices we could see a result in improvements of up to 54% of decrease in the deviations caused by human errors, now the other 46% is due to problems occurred using the OIT system of which the implementation to be carried out is not directly correlated. Now when talking about cost we could see a significant savings of $218,750, seeing a savings of $15,444 in cost per operator on an annual basis, having a decrease in lead time of 65 hours. With this information we can say that the reduction of deviations has decreased to the amount of 6 deviations annually at a cost of $187,500 considering the original value factor of $406,250. During the process of this investigation there were some setbacks that directly affected the investigation as many of the permits requested from the entity or company were denied in order to perform data collection among other things. According to dialogue with plant engineers it is understood that the following implementation in the buffer tank systems would be an excellent one for the different benefits that this brings at the time of realizing the same ones. With the information provided within the investigation it can be determined that it was a successful one and meets the requested parameters as had been stipulated from the beginning the scope of our work.

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