Optimization in the Account Registration Process in Automated Equipment.

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Abstract

Over the years technology has increased in the manufacturing areas. Companies have moved to obtain automated equipment for the manufacture of their products. In the pharmaceutical industry, this equipment's has been implemented in order to increase production. The equipment is managed by operators and each operator must have access to them. The pharmaceutical industry in the US is governed by the FDA and it has guidelines to ensure the proper use of this equipment and those who use it (21 CFR part 11). During this project, improvements were made to the process of creating accounts for automated teams, where positive results were obtained for the company. Thus, creating a standardized system with quality controls. In addition, the time it took a staff to create an account was reduced from 82 minutes to 51 minutes in this process. For the development of this project, the Six Sigma methodology and its DMAIC tool were used to determine the defects of the process and thus achieve the main objective.

Introduction

Optimizing a program or a process drastically helps grow a company. During this project, you will find information on how a process is optimized, what tools were used, and how to integrate these tools into the optimization. This research aims to develop a standardized system in the account creation process for automated equipment company employees to comply with FDA regulations. This project was made to minimize the time of creating an account. The methodology used was Six Sigma with Dmaic. This could be applied to our project since it is necessary to measure the current process to define the real problem to improve the process. On the other hand, reference articles on optimization projects were used to apply it in ours.

Problem

The pharmaceutical industry is a highly regulated industry in which each of the activities carried out must follow an SOP procedure, "Standard Operating Practices," where states how to carry out a particular job or task. The IT area, "Information Technology" of a pharmaceutical company, oversees managing and supplying all access to the equipment used in the facilities. Before providing these accesses, specific steps must be followed, such as the personnel requesting access being trained on that equipment, and their supervisor authorizing it. With all this, a form is filled out and delivered to the IT personnel. During the past months, the department has gone through several events with the control of documentation with the forms used to create accounts. In recent audits, sheets have been found that have been received for several months and have not been processed. This, incurring in deviations to GDP "Good Documentation Practice" due to lack of realization now and not being contemporary data, means that it was not documented at the moment. The regulatory agency "Food and Drug Administration," known by its acronym FDA is an agency of the US Department of Health. It seeks to safeguard the quality and protection of biological products and medicines used by human beings. The FDA maintains quality and safety through its guidelines known by its acronym CFR "Code of Federal Regulations." One of the federal regulations is 21 CFR part 11, which establishes the integrity of the data using a registry and electronic signatures so that the data obtained in a process is not eliminated or manipulated.

Methodology

The methodology used in this project consists of the following stages:

- **Define**: in this stage, the affected areas will be identified, the problem will be defined, the scope of the project using SIPOC and the areas for improvement will be defined.
- **Measure**: in this phase, the variables that caused the defects were identified and measured. In this project, a time study was carried out in the creation of automated equipment accounts.
- **Analyze**: the objective of this phase is to understand why the defects are generated. Data obtained in a time study was used to analyze the variations and work performance.
- **Improvement**: in this phase, the solutions to eliminate the defects were implemented.
- **Control**: in the last phase, a monitoring system for the new process is implemented. It is based on a control system through a record book in order to guarantee the integrity and continuity of the process.

Figure 1
Dmaic

Results and Discussion

Define

The objectives were met during the project's development and an impact was created in the IT department. The project's purpose was to implement a standardized system where the time to develop equipment accounts is reduced. Using the Six Sigma Dmaic tool, it was possible to define the problem to optimize the process of creating accounts in automated equipment. The SIPOC tool was used to establish the areas that are impacted. Using the SIPOC tool, the process of creating an account for teams was identified. By making the diagram they can identify the areas related to creating an account.

Suppliers	Inputs	Processes	Outputs	Customers
QA Area	Training Report	Account Creation	Operator with Access to Equipment	Manufacturing Area
Manufacturing Area	Supervisor Approve			Packaging Area
Packaging Area	Manager Approve			

Table 1
SIPOC

Measure

To identify the defects in creating an account for equipment, the IT department was asked for the sheets made three months before and after the optimization of the process.

Month	Sheets created before optimization	Sheets created after optimization
1	25	40
2	20	35
3	23	35

Table 2
Sheets created Before and After Optimization

Data was obtained from the time of the creation of accounts of 30 sheets. The time of the orders before the optimization of the process was carried out by means of a time study. The time data after the optimization of the process was obtained from the new accounts created.

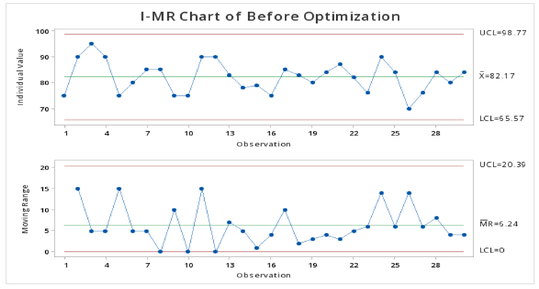

Figure 2
Time Variation Before Optimization

Results and Discussion

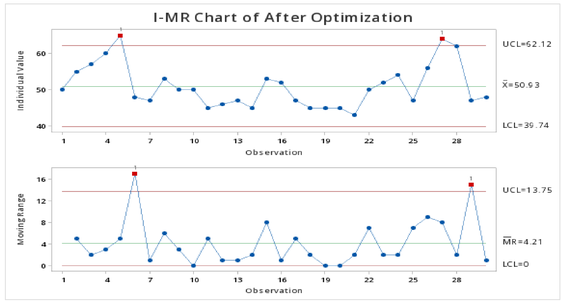

Figure 3
Time Variation After Optimization

Based on the time variation before standardization, the average was 82 minutes. Based on the time variance after standardization, the average review time was 51 minutes.

Analyze

During the measurement phase, it was observed that the system accounts were not created on time due to different interruptions. They were analyzed, and a new method of working with them was established. One of the changes implemented was that when the account sheet was delivered, it had the training certification taken. Thus, the technician can check in the system if the requested personnel have or do not have the training to complete the sheet. With the segregation of areas, an increase has been observed in the number of sheets made in the months that the standardization of the process was carried out . There is an increase in 3 months of a total of 42 sheets completed. This shows that the root cause of the delay in the accounts is the need for more information on the sheets and the need to have the areas assigned to the technicians. On the other hand, the time to create an account decreased after the process standardization.

Improve

For the continuous improvement phase, the optimized account creation process was reorganized. A monthly inventory verification system is also being established to determine how the equipment accounts are working and how many are being made per month. This work will be carried out by the supervisor of the technicians, or a person designated by the supervisor to have control outside of the technicians who work on these sheets. With this system, the efficiency of each employee will be measured when creating the accounts.

Control

The purpose of the control phase was to ensure that the implemented improvements continue to be met and that the process continues effectively. This project implemented changes in the way accounts are executed and payrolls are worked on. A control logbook was implemented to provide a number attached to the sheet. This logbook can be filled out by any technician who receives the sheet. This technician will be in charge of delivering the sheet to the corresponding place. This will help keep track of the forms coming into the department, who receives them, and who completes them. Employees assigned to account creation must use the "First In, First Out" policy to avoid accumulating forms; They will be made later as they are received

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Form Tracking Log				
Control #	Area	Receive Performing by/date	Complete Perfomed by/ date	Comment
1				
2				
3				
4				
5				
6				

Table 3
For Tracking Log

Conclusions

Through this project, it was possible to meet the main objectives: to optimize the process of creating accounts in the IT department to comply with the federal statute 21 CFR part 11. This was carried out using the Six Sigma methodology and its Dmaic tool. The causes of the loss of time when creating an account were identified, and a system was implemented to mitigate these causes. This way, the account creation process was standardized in automated equipment reducing time and increasing the efficiency of the process. In addition, the number of forms that are processed has increased significantly. A new system was implemented where the forms are received by a technician when they arrive at the department and are segregated by areas to be more efficient when working on them. By making this change, it was possible to distribute the workload to the employees equitably, and their performance was increased. This project showed that optimizing a process would be reflected not only in the area that is worked on but also in all departments. The benefits of optimizing a process are minimizing human errors, eliminating waste of time, and getting the most productivity out of the impacted area. This project demonstrated that the loss of time in a process or an area would affect the final product in a chained way.

Future Work

During this project, a series of ideas were presented that can help in future research, that would help develop a more robust account creation system. One of the ideas is to use a virtual system in which sheets of paper are eliminated, and tickets are created with the information of the requesting employees. Thus, reducing the use of paper and using technology in our favor. Also, create a union with the training system with system to create an account to speed up the process; when the staff takes the training, a ticket or work request is generated to create your account at the moment, reducing the time to develop a sheet and deliver it personally.

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