Optimization of the Registration Process of Products on the Pharmaceutical Industry of Puerto Rico

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Abstract

Registration Process for Pharmaceutical products in Puerto Rico has unique requirements for the marketing, sale, and distribution. The Organizations must be approved before they can market, sell or distribute the product. The estimated products without registration on the organization are 4,800 products; these products belong to inventory from 2016, 2017 and 2018 years. Under this scenario, the organization decides to implement a standardized process using the tools of Lean and Six Sigma Methodologies. The cycle time reduction after the implementation process is 95.9%. After the implementation of the improvements 55 products can be registered in 405 minutes. The organization can register 1,100 products for month with one resource. The reduction of the cycle time by 95.9% allows increasing quality, customer satisfaction and reduction of the inventory of unregistered products.

Problem Statement

The registration of prescription drugs and non-prescription drugs are not a continuous process. The poor registration process increases inventory and holds the release of the products. The registration of a drug requires a series of steps and attached documentation that are not structured. The optimization of the registration process is essential to reduce the cycle time of the product on the drugstore. The cycle time can be defined as the time we spent manufacturing an order. The time starts counting since the system place the order request; the system instantly assigns a date that the request must be released. This research enables structuring the registration process using the Methodologies of Lean Manufacturing and Six Sigma. Also gives the opportunity to create a continuous process free of wastes, improving quality and performance. The optimization allows to deliver a high-quality product and reduce costs. The organization must be competitive in the market and increase customer satisfaction.

Objectives

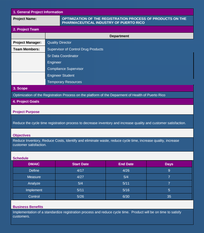
The research objectives are the following:

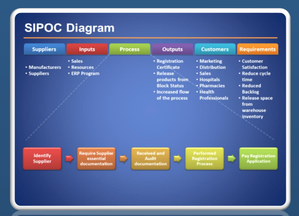
- Reduce the cycle time of registration process of prescription drugs and non-prescription drugs by 10%
- Create a structured and continuous process.
- Identify and eliminate wastes.
- Identify possible improvement opportunities
- Evaluate and prioritize the alternatives identified.
- Increase quality and customer satisfaction.
- Implement identified improvement opportunities.

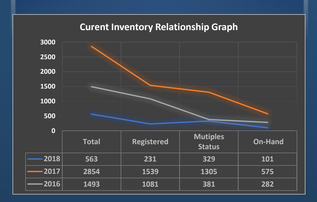
Methodology

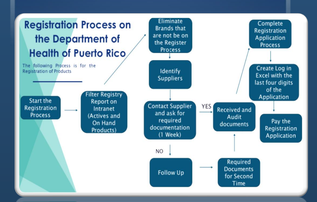
The objectives submit to this research project will improve the registration process for products by using methodologies and tools. Six Sigma Methodology and Lean Manufacturing principles are the tools that will be used for the research project. Six Sigma DMAIC (Define, Measure, Analyze, Implement, Control. Lean Tools (Project Charter, SIPOC, VOC, Process Maps, Measure Sheets, 5's). The Registration Process use DMAIC as a guideline for improvements. DMAIC and Lean tools used will be illustrated as follows:

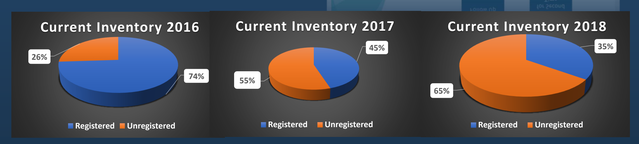
Methodology (Continued)

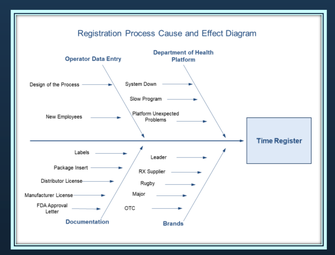


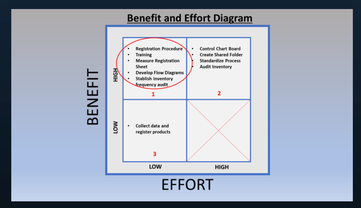












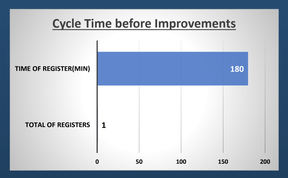
After improvement phase, the registration process reduced cycle time significantly. The registration process was measured without the standardization and improvements established, showing the results are a waste of time. After the implementation of the standard operating procedures, process maps to guide the Sr. Data Coordinator, the cycle time of the registration process reduces.

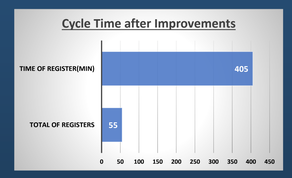
Results

After evaluation of the data the average to perform the registration process on the platform is eight minutes (7.8 minutes). The registration process measured to determine that 55 registrations can be performed over 6.5 hours of work per day. Always taking in consideration other causes that can influence on the working hours. The calculations performed shows that 95.9% was the cycle time reduction for this process.

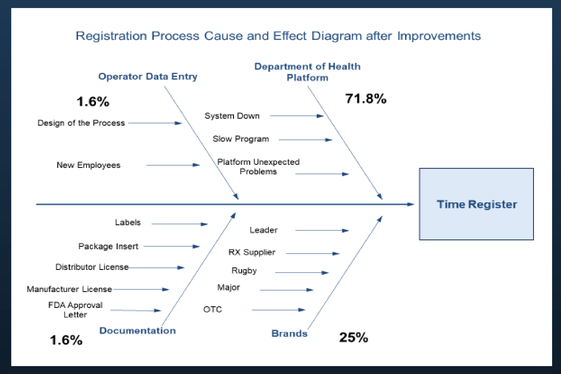
Cycle Time Reduction

	Total of Registers	Time of Register(min)
Cycle Time Before	1	180
	Every 180 Minutes	
After Improvement	55	405
Cycle Time After	Every 7.4 minutes	
Improvement	Reduction of Cycle Time was of 173 minutes, which is 95.9% of reduction	





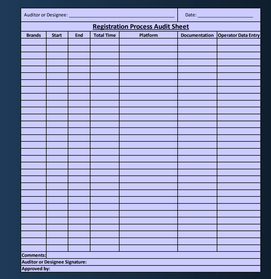
The results show that a total of 1,100 registers can be completed for month with one resource. After the training of personnel the accumulation of the inventory can be reduced in a minimum period. It is essential that the data require the products to be registered be available in the shared folder created.



The registration process was affected most by the platform, brands and documentation. The creation of a shared folder increases the number of registers performed per day. This improvement reduces the time Sr Data Coordinators spent searching for the data and performed registration process. The process mapped guide and established the time required to follow up documents to maintain the continuous flow of the process. Cause and effect diagram shows the results of which are the leading causes that affect the registration process. The Department of Health Platform is 71.8% the primary cause that affects the registration process. Some recommendations will be suggested to the organization to work with the situation.

Results (Continued)

The control of the process is essential to maintain the continuous flow and don't allow the accumulation of inventory. Some tools were developed during the design project. They are Process Maps and Registration Audit Sheet. The control of the process after the implementation of the improvements are Standard Operation Procedure, VOC, Visual Control Board, Registration Measure Audit Sheet, 5's tool and Process Maps.


Auditor or Designee: _____ Date: _____

Registration Process Audit Sheet

Brands	Start	End	Total Time	Platform	Documentation	Operator Data Entry

Comments:
Auditor or Designee Signature:
Approved by:

The Voice of Customer tool will still on the registration process to audit if customer demands and requirements are satisfied. Visual Control Boards will be created to helps the organization to know how the registration process is running. The control board will allow making the adjustments and improvements necessary for the success and the maintenance of the continuous flow of the registration process. All successful implementation must include constant training, revision, and audits frequently.

Conclusion

The Lean and Six Sigma Methodologies were crucial for the design and improvement of the project. The cycle time reduction objective was 10%, but the improvement of the process after the design project is 95.9%. The goal was achieved making a structured process, identifying, and eliminating waste, identifying possible improvement opportunities, evaluating, prioritizing and assigning responsibilities and finally implementing improvement opportunities in the process. The tools used increase customer satisfaction and reduce inventory allowing the release of products.

Some contributions of the design project are the reduction of cycle time to register the products, cost reduction, increase the efficiency of the process. Also, guarantee quality and performance of the registration process, have product on time in the market, eliminate waste, establish Lean and Six Sigma methodologies, eliminate non-value-added activities, increase customer satisfaction and complies with the regulatory requirements.

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