SERIALIZED PRODUCTS IN PHARMACEUTICAL INDUSTRIES: UPDATE STRATEGIES THROUGH SIX SIGMA TO DECREASE THE COUNTERFEIT.

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Abstract

This article discusses the serialization method established in the packaging lines on a manufacturing department of a pharmaceutical plant. It was developed an Installation, Operational and Performance Qualification to standardize and ensure the new requirements stablished by Food and Drug Administration (FDA). This process was design with the Six Sigma approach, using DMAIC. This process will allow the pharmaceutical to enhance the security of their products and comply with the Drug Supply Chain Security Act (DSCSA).

Introduction

The global pharmaceuticals industry faces problems of counterfeiting, which it implies a malfunction of the supply chain, specifically the tracking system. The pharmaceutical companies and governments of countries worldwide are convinced that counterfeiting by organized crime can be avoided significantly by implementing product serialization. Analyzing the current state, a DMAIC project is developed in order to stablish the new parameters of FDA. This research crate a complete plan in order to develop the advantages using serialization in the packing of medical devices.

Problem Statement

The pharmaceutical companies and governments of countries worldwide are convinced that counterfeiting by organized crime can be avoided significantly by implementing product serialization. The products should be identified by a unique serial number, batch number and expiration date day. This allow that the lifecycle of the product can be traced from production, through the distribution and in the end to dispensation to patients at the hospital. [2]

Research Description

This research will create a complete plan to establish to develop the advantages of using the serialization of the medical devices. This will allow the pharmaceuticals industry to improve competitiveness, a reliable product, and a secure supply chain. At the end, it will decrease the counterfeiting, the organized crime, and the loss of medical devices.

Objectives

- Develop a strategy to standardize the supply chain distribution of medical devices.
- Guarantees broad knowledge about the importance of serialization in the pharmaceutical industry.
- Increases the leveraging of global best practices by the implementation of serialization.
- Reduce counterfeiting and organized crime.
- Provide a better tracking system of the medical devices.

Methodology

Figure 1: DMAIC

Define Phase

In the process identification, will be realized, in this case, perform the label with the serial number, the lot number, the expiration date and the 2D- Barcode. A Project Charter is going to be executed, it which is defined the scope of the project, the objectives and it will be determined the people that will be part of this project. In this case the scope of the project is to identified all the products that go through a packaging line and perform the serialization of the product. The members of the team will be the Senior Technician and the operators that have the training to perform the changes in the Label System. The team will be in charge for validate the protocol performing a SIPOC Diagram.

Figure 2: Example of a Project Charter

Measure Phase

In the measure phase, the sample will include ten (10) case labels of each product in which can be verified that the label commit with the proposed parameters. The challenge of the phase measure is that the label includes the serialization number, the expiration date, the lot number and the 2D-Barcode. Also, a software backup will be performed. A 200% case label verification will be performed. The people in charge of this activity will going to be the Senior Technician and one of the operators. It is important to document all these parameters following the Good Manufacturing Practices. In this phase a flowchart will going to be performed to better comprehended of the process.

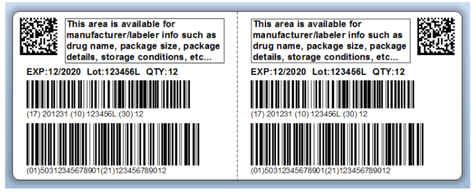

Figure 3: Final Product Identification Label Homogeneous Case, Serialized Corner Wrap. [4]

Methodology

Analyze Phase

In the phase of analyze the labels collected are going to be analyzed with the objective of identify the labels that have the acceptance criteria and to recognize is there is a fail on the Labelling System. This phase is crucial to commit with the objective of the project, because this is the result that the team are going to present to the pharmaceutical and to the FDA. In this phase the past label is going to be compared with the actual label. If the analyze phase has the approval of the pharmaceutical managers the process will going to be standardize.

Improvement Phase

In the Improvement Phase a process of implementation will going to be performed. The process will be validated and the changes in the label will be permanent to commit with the laws of FDA and to avoid the counterfeiting. Also, the benefits of this implementation will be going to be evaluated.

Control Phase

In the control phase, there will be performed the Standard Operation Procedures (SOP's), and the procedure of the new changes must be provided to the people of the Manufacturing Plant to notify the changes and to commit with the federal laws. After the implementation of the procedure and trimestral report must be completed to confirm that the process does not have changes and if an improvement can be made.

Results and Discussion

Due to the accomplishment with the approval of the pharmaceutical managers the procedure was executed and the results expected were the actual results. The project charter was effective and the SIPOC diagram. The procedure was evaluated to determine actual status of the criteria acceptance for the Serialized products and that the label complete with the serial number, the format of the expiration date, the lot number and the 2D-Barcode. The process was performed for Packaging Line one (1), two (2) and three (3).

All the parameters were accepted and the respective training were performed to the employees. The data collected from the labels were validated from the supervisors from Packaging Line one (1), two (2) and three (3). Now, the products commit with the Drug Supply Chain Security Act (DSCSA). The SOP'S were developed and training for the procedure was given to the personnel to belongs to the manufacturing area. The Manufacturing personnel are waiting to perform the trimestral report to confirm that the process did not suffer any change and if an improvement can be made.

Conclusions

Serialization promotes a secure way to protect the products in the Pharmaceutical Industry. This project ensures the new requirements stablished by Food and Drug Administration (FDA). Examples of serialization were proposed in this project. New methodologies like Six Sigma and DMAIC were used as performance tools in order to create an strategic plan to develop the procedures and techniques of quality. Realizing this project the pharmaceutical to enhance the security of their products and comply with the Drug Supply Chain Security Act (DSCSA).

A decrease in the counterfeiting and the organized crime is expected because now the product can be traced trough the supply chain. The pharmaceutical plant validate the process and now the products are serialized. By the developing of the SOP the personnel of the Manufacturing Department were trained.

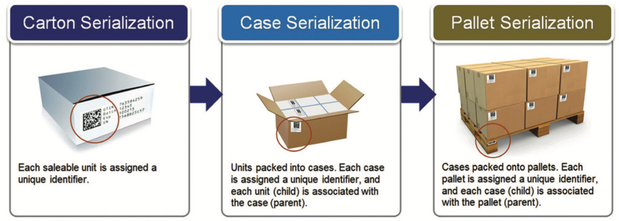

Figure 4: Types of serialized product codes.

Future Work

This research project has the objective of introduce de change in expiration date day and the serialized case labels. The future work will be to change and the addition of the serialized codes in the medical device product.

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