Carnauba Dispenser to Improve Coated Tablets Elegance

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Abstract

This study describes the implementation of Six Sigma for improvement of the addition process of carnauba wax on coated tablets in a pharmaceutical industry. Due to the frequent complaints received from customers for covered engraving on tablets with carnauba wax, the company carried out a Six Sigma project. The Six Sigma methodology provides an organized structure for problem analysis and problem solving. Using DMAIC phases the problem was defined; the variables influencing the process were measured; the causes for the tablet elegance defect were analyzed; improvements were scheduled and made until level of customer satisfaction were reached. A new tool was implemented for the addition of carnauba wax during coating drying step. The project implementation achieved to increase productivity and allowed process standardization, improving customer service and quality.

Introduction

Covered engraving is a frequent complaint from patients taking coated tablets. This is commonly associated with the use of carnauba wax on the final stage of the tablet coating process. As a pharmaceutical industry, the expectation is to improve carnauba application so it does not affect the elegance of the tablet. To achieve this, a new tool needs to be created for the carnauba addition step during tablet coating process, and subsequently implementation and control of the proposed improvement plan.

Background

Tablet coating consists of applying an edible paint on the surface of a pharmaceutical dosage form to achieve specific benefits. The addition of carnauba wax helps patients swallow the tablets. A very small amount is added onto a batch of tablets after they have been sprayed and dried. These are mixed together in the rotating pan for a few minutes before unloading from the tablet coating machine. The amount of carnauba established per SOP is added manually from a bag directly to the coated pan. This procedure may cause extra carnauba to adhere onto some tablets, covering the tablet logo.

Problem

A defect that makes it through to your final product leads to poor customer satisfaction eventually affecting the reputation of the company. The development of this research consists in a design proposal of a tool with the appearance of a saltshaker. This tool, called carnauba dispenser, will be introduced to distribute the product more evenly to the tablets. This work will help to meet customer's requirements and answer their needs while delivering the best quality of our products. The main objective of this work is to decrease by 20% the customers complaints related to coated tablet appearance and to standardize an operating method towards reduction or elimination of the identified waste.

Methodology

The methodology in this research can be described as interactive problem-solving process. Six Sigma methods were integrated to reduce a specific defect on coated tablets. "This is a well-structured methodology that can help a company achieve expected goal through a continuous improvement methodology. [1]"

DEFINE: The problem faced by the organization was that the operational method of adding carnauba wax was covering tablets engraving (see Figure 1). This was resulting in reportable defects and extra efforts for support and resolution of customer complaints.

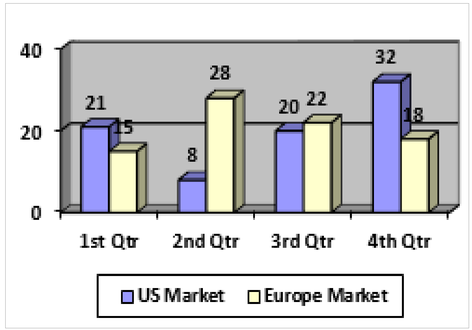

Figure 1: Customer Complaints (2019)

MEASURE: Five closed-ended questions narrowly focused for the respondent to answer accurately. The results of the surveys are processed based on a scale where each question is assigned a numerical value so it can be analyzed to show the incidence of each of the variables. This quantitative survey will provide numerical data to analyze and evaluate corrective action. Once the carnauba dispenser is implemented and batches go to market, the plan is to ask customers to complete a post-purchase survey

Supplier (S)	Input (I)	Process (P)	Output (O)	Customer (C)
Customer	Complaint – Call, letter, mail	Resolution of complaints	Closed complaints	Patients
Customer Care	Discussion with customer, Action plan		Customer feedback	
Raw Material Supplier	Repair, Carnauba wax			
Quality Assurance	Compilation & Follow up meeting			

Figure 2: Process SIPOC Diagram

Results and Discussion

ANALYSIS: A brainstorming session was conducted by a cross functional team to identify the root causes of the problem and find a corrective action. Also, an Ishikawa diagram was created to find the possible root causes: Carelessness, distribution of the excipient, lack of appropriate tool and others.

Five QA associate responses used after inspecting lots where the tool was implemented to conduct hypothesis test. The proposed null hypothesis is H_0: $\mu = 3.2$ and alternative hypothesis H_A: $\mu \neq 3.2$ where $\alpha = 0.05$.

One-Sample T: Quality

Test of μ = 3.2 vs ≠ 3.2

Variable	N	Mean	StDev	SE Mean	95% CI	T	P
Quality	5	3.200	2.049	0.917	(0.655, 5.745)	0.00	1.000

Figure 3: Minitab T-Test

Hypothesis test p value > 0.05 so null hypothesis is accepted. There is no difference between QA associates answers and standard responses, so the survey was validated and supplied to a sample greater than 30.

IMPROVE AND CONTROL: The tool was added to SOPs for coating process. Also, process guides were discussed in the production area to emphasize its importance in order to mitigate human error due to lack of information on the manufacturing process. Company emphasized the responsibility at every level to identify problems and suggest ideas, creating positive attitudes towards the improvement process.

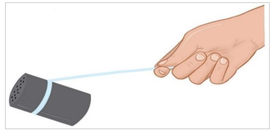

Figure 4: Carnauba Dispenser Prototype

The new tool consists of a stainless steel container with small holes that is manipulated by holding the Teflon handle. The required amount of carnauba will be transferred to the carnauba dispenser by the operator. Then, performing multiple agitations, the carnauba will be randomly distributed.

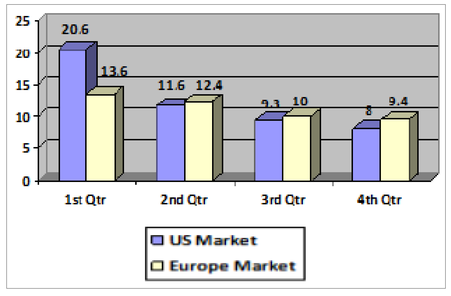

Figure 5: Customer Complaints (2020)

The implemented tool helped towards overall method improvement for taking action for the particular complaint significantly reducing more than 20% customer complaints for the specific coated tablet defect.

Conclusions

It is important to monitor the quality of delivery of a product or service in order to make customers more loyal. This approach keeps the providers with their eyes open to identify the changes that occur in the industry and to have the information in time to adapt and grow. Lean Six Sigma methodology tools were used not only to reduce the production waste, but also to standardize the required methods for continuous improvement of the process so that it continues to operate efficiently and effectively. This study demonstrates an overview to conduct real improvements and how Six-Sigma is embraced to improve the customer complaint resolution process of an organization, improve customer-supplier relation, and finally increase customer satisfaction.

Future Work

Appropriate feedback analysis can help to discover more improvement opportunities for timely and efficient delivery of the product or service. This approach helps to improve any process which eventually can enhance profitability and customer satisfaction.

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References

[1] C. Wei, G. Sheen, C. Tai, and K. Lee. "Using Six Sigma to improve replenishment process in a direct selling company." *Supply Chain Management*, vol. 15, no. 1, pp. 3-9, 2010. doi: 10.1108/13598541011018076 .