Using Six Sigma Methodology and Technology to Improve Quality Audit Process Cycle Time

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Abstract

At the “Pharmaceutical Company Y”, the cycle for launching a product can take an average of 46.7 days. The proposal for this study seeks to reduce this cycle time to 30 days. This project illustrates the improvements that can be achieved when a company understands and applies Six Sigma tools and methodologies to reduce the cycle time between product manufacturing and product approval for shipment. The company must have quality control that ensures that the final product meets the acceptance parameters, but at the same time that the release time is reduced so that the product is shipped in less time. The application of the Six Sigma concepts, the DMAIC methodology and the development of an electronic checklist optimizes the quality audit process and the final approval, provided that the audits are carried out with the manufacturing process in parallel.

Introduction

Currently, it can take between 45 and 49 days to ship the products, with an average of 46.7 days. This paper will explain the importance of implementing improvements in the cycle time in a quality audit in the pharmaceutical manufacturing. Applying the principles of the Six Sigma methodology in the reduction of the cycle time to speed up the release management of a product for shipment.

Background

The quality audit of batch production will be improved through the application of DMAIC principles, process mapping, and the development of an electronic checklist. This type of study and improvement could be extended to other operations within manufacturing. When proposing to use the methodology called Six Sigma, it must be understood that it is a set of techniques and tools used for process improvement. Using the project of White, García, Hernández, and Meza [1] as an example.

The DMAIC is a flowchart that illustrates all the inputs and outputs of an event, process, or activity in a systematic, easy-to-read format. The company will be able to identify problem areas that affect the general expectation of quality of a service and/or product from the customer's point of view. Process mapping is a technique used in the Six Sigma project to visualize the steps involved in a certain activity or process. This will result in the identification of areas that need improvement and a better understanding of the batch release report. Explaining that "Each of the tools used to record and visualize the system. Even with different functions, the main objective is the same which is to identify the main problems to be addressed". Shahar and Mohd [2]

Problem

Shorter cycle time will mean higher efficiency, lower cost, and higher product availability. Productivity increases as cycle time decreases, and customer satisfaction will be high as products are delivered ahead of their expected delivery time. Using the principles of Six Sigma, it will be possible to reduce the cycle time of a quality audit from 46.7 days to 30 days in a period of 3 months of implementation. “The selection of right projects in a Six Sigma program is a major concern for early success and long-term acceptance within any organization.” Ray and Das [3].

Methodology

The Six Sigma technique was used for both observational and experimental parts in this design project; entirely dependent on the execution procedure and application of the methodology. Based on the five major phases of DMAIC, the research consists of implementing tools to minimize time in the last step of shipments approval.

Define- This project was inspired by the manufacturing line of parenteral products of a pharmaceutical business in Puerto Rico. Weighing, formulation, filling, lyophilization, sealing, inspection, and packaging are the areas that consume the most audit time by quality personnel (QA), resulting in these manufacturing areas as internal clients of the operations and the service of the quality audits that decide with their functions the shipment approval. Table 1 compiles the final timings utilized for ten commercial batches, where the current cycle time could be observed reflected during the batch audit before being certified for shipping. Using this reference data, a set of questions were generated to guide the proposed study. Refer to Table 2.

Table 1
Original study date

Quality Audit before implementation of improvements			
Batch	Starting Date	Ending Date	Total time (days)
1	03/10/22	04/25	46
2	03/13/22	04/29	47
3	03/16/22	04/30	47
4	03/19/22	05/06	48
5	03/22/22	05/10	49
6	03/26/22	05/10	45
7	04/01/22	05/17	46
8	04/03/22	05/21	48
9	04/08/22	05/23	45
10	04/10/22	05/26	46
		Average	46.7

Table 2
Voice of the Customer (VOC)

Questions that seek to define the objectivity of the current process.	
Answer on a scale of 1 to 5, with 1 being completely disagree, 2 disagree, 3 neutral, 4 agree, and 5 completely agree.	
Do you think the current batch approval cycle time for shipment represents the effort of streamlining processes in manufacturing?	
With the current market demand, does the current wait time for shipment meet the customer's needs?	
Do you think that the waiting time for product shipment approval is a reason that affects the quality of life of our customers?	
Do you think that incorporating the final quality audit together with manufacturing can speed up and reduce the time in which a batch is approved?	

The approval time cycle of 10 batches were recorded from March 10 to May 26, 2022, with 100% exceeding the indicated goal, resulting in a delay for the product to reach the hands of patients.

Measure- As part of the planned data collecting strategy, a process map was created to understand the distribution of work time according to the stages of real manufacturing, as illustrated in Figure 1. This serves in determining the appropriate method for measuring the process in order to efficiently use resources to achieve concurrent work of manufacturing activities alongside audits.

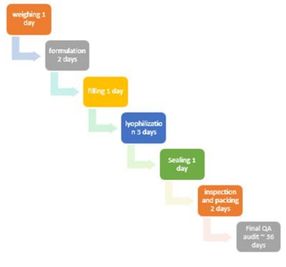

Figure 1 Process Map

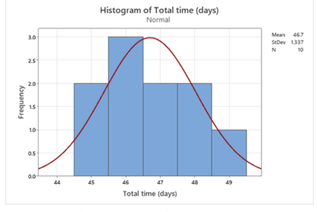

Figure 2 Histogram of Total time(days)

The objective of this project is to reduce the time cycle for the approval of a lot for shipment. The data obtained shows that the distribution of the data does not fit in the expected between the values is intended for the process to be. It is evident that most of the batches have a frequency of being released when reaching 46 days of process audit, as shown on the histogram graph.

Analyzing the efficiency of the data obtained versus the desired data in the objective, having an efficiency of:
Efficiency= (New cycle time / average cycle time actual) * 100%
E= (30 days/46.7 days) * 100%
E=64%
Low efficiency's outcome makes it easier to see where this process needs to be improved. This will speed up the product's release to the market and ensure that patients receive it.

Results and Discussion

Analysis- In the development of the analysis, the Pareto Chart (Figure 3) was used to find out which was the time that had the greatest incidence of being repeated to use it as an improvement item. This indicates that the current audit cycle time norm is about 46 days, and any batch surpassing that amount may indicate issues with production and documentation.

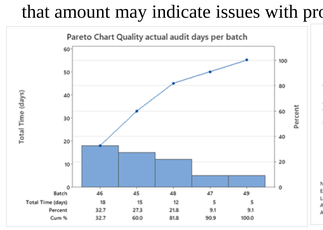

Figure 3 Pareto Chart

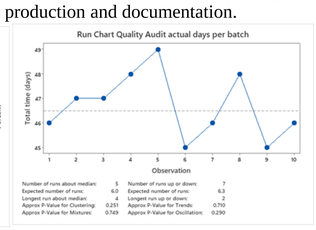

Figure 4 Run Chart

A run chart (Figure 4) was made to study the impact of the current time cycles, where 5 points out of the 10 samples used in this study are above the current cycle average. When analyzing the data from the run graph, the following values are obtained: Clustering has a P-value of 0.251, Mixtures has a P-value of 0.749, Trends has a P-value of 0.710, and Oscillation has a P-value of 0.290. The same when compared against the value $\alpha = 0.05$, it cannot be concluded that they have a greater tendency for any behavior. Analyzing Figures 5 and 6, shows the process of bringing a product to market is not under control. Both figures show how the data is outside the expected ranges, according to the proposal of this 30-day project.

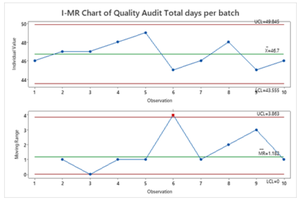

Figure 5 I-MR Chart of Quality Audit days

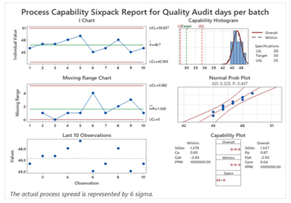

Figure 6 Process Capability Sixpack

Cpk used to assess the potential capability of a process based on the value and its location determined the process needs improvement. The value obtained in this analysis is lower, which is an indication that the process needs improvements.

Improve- Improvement- As part of the improvement design in this project, the nature of the business was taken into consideration. One of the ideas for improving cycle time in the final audit of a product is parallel execution. This means that within the stage of a process, for it to be completed, it must be audited in detail as part of the regular process. Part of the improvements promoted in this project is the development of a checklist that could be filled in while working in parallel with the process, as can be seen in Figure 7.

Figure 7
Process Map of Manufacture Activities with QA Audit in Parallel

Table 3 Quality Check

Checklist: Quality Assurance Audit Process		
1. - Identification of the audit		
Area:	Start time and date:	
Audit type: ☐ Process ☐ Final	Time and date of completion:	
Product:		
2. - Auditor		
Name:	Tel.: Email:	
3. - Checklist		
	Yes	No
1) Does the process meet quality standards?		
2) Were any discrepancies observed in the process?		
3) The production time is within the acceptable range?		
4) Is the documentation complete?		
5) Are there pending corrections?		
6) Did any quality or safety event occur?		
7) Are the equipment and tools used in its calibrations?		
8) The materials used in the batch were within the use date?		
9) Does the lot meet the expected appearance?		
10) Was there any delay?		
11) Were the documents and procedures effective?		
Comments:		
Complete by:		
Approved by:		

Control- To ensure that the new conditions in which the process has been placed are within the established parameters, the electronic checklist must be included as part of the official documentation. Quality personnel will need to be trained in the use of this new tool and procedures will need to be developed that explain its use and approach. The new flow work implies concentrating 14 days during the different stages of the process to audit it exhaustively, allowing an additional 16 days for any type of review and correction that must be carried out.

Conclusions

The use of the Six Sigma technique in the quality auditing process results in the construction of a standardized work tool and the removal of diverse tasks that do not bring value to the process. Knowing the workflow aids in identifying actions that provide little value and cause the batch release to be delayed.

When QAs are directed to operate in parallel with production, it takes fewer days to approve a lot for shipment. Process optimization is responsible for the removal of this lost time and parallel execution. The application of DMAIC concepts, process mapping, and the creation of an electronic checklist can help to align the project's objectives. With the use of cycle time as mentioned by Taifa and Vhora [4], " is one of the viable parameters which needs to be optimized as much as possible whenever the manufacturing industry is trying to improve efficiency, cost base and customer responsiveness.”

Future Work

To cut waiting times and increase output, this kind of research and development may be applied to different industrial processes as management, supply chain and warehouse. This study takes a method that minimizes time waste and sets up the process as a series of simultaneous jobs. In the end, this results in a decrease in time and an increase in capital for the business, allowing for the introduction of more items onto the market and improved customer satisfaction as a result of increased access to their product.

Acknowledgements

Dr. Maria Garcia Sandoval was one of the persons that had the most influence during this study. Her first contribution came while I was enrolled in her MMP6250 Audit Program Management class, her class influenced the topic selection for this project and she agreed to be my mentor. Dr. Denisse M. Cobian was another individual who was quite significant, since her review influenced the improvement of attention to little things. The greatest resource for my literary search was the university's database.

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