Investigation Process Improvement in a Pharmaceutical Company

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Abstract

Manufacturing companies are subject to product incidents. These are managed by investigators to identify root causes, solutions and avoid reoccurrence. Investigation completion within time ensures that product will reach the customer. Pfizer Pharmaceuticals LLC had an increment in investigations that exceeded the established due date. Using the Define, Measure, Analyze, Improve and Control (DMAIC) methodology, causal factors were identified and addressed by standardizing investigation planification and execution. Furthermore, controls were placed to ensure process monitoring by placing strategic meetings to discuss investigation using the improved standardize process and monthly monitoring.

Introduction

Pfizer Pharmaceuticals LLC is a pharmaceutical company that manufactures and packages solid dosage drug products. In this company there is an Investigation Department. The purpose of this department is to perform an evaluation of the incidents related to product lots to identify potential root causes and applicable actions to avoid reoccurrence. Based on the current procedures, the investigation department has 30 days to complete investigations based on the incident discovery date. The investigation department was facing an area of opportunity regarding the completion of investigations within the established due date. The increment in exceeded investigations has impacted the release of product to patients.

Background

In order to stay competitive, organizations need to continuously improve their processes [1]. Process improvement is nothing but the understanding of an existing process and introducing process changes to improve quality of product, reduce costs, improve overall efficiency of process or accelerate productivity [2]. Companies are measured based upon their product delivery, price and quality. By reducing or eliminating issues that arise such as but not limited to delays in product delivery the companies can have a competitive advantage. One of the methods to perform process improvement is by performing process standardization. Standardization reduces the variations of the process and improves the quality of products and processes [3].

Problem

There was an increment of investigations that exceeded the established 30-days due date. Lots that are implicated in the investigations are placed in global batch hold; this prevents that the lot to go further into the manufacturing or packaging process until investigation resolution and applicable actions are completed. This causes unplanned delays regarding drug delivery to the customer (patient).

The objective of this project was to improve and standardize the investigation process. Based on this objective, it is expected that more investigations are completed within the established due date.

Methodology

The methodology used to execute the project was DMAIC. This methodology is widely used to improve and optimize different processes. This methodology includes five stages to perform the improvements, these stages are defined as the acronyms for the methodology.

Define: In this stage, the problem was identified. As previously indicated it was identified that there was an increment in investigations that exceeded the established due date. An objective was defined as well, to improve and standardize the investigation process.

Measure: Data was collected to have a better understanding of the current status. Multiple interviews were performed to investigators and quality personnel to obtain inputs and outputs of the investigation process. Furthermore, a total of 30 investigations were evaluated to obtain the following data: open date, actual start date, completion date, type of investigation, additional actions, and information regarding whether the investigation was closed on time or not.

Analyze: The 30 investigations were analyzed and it was identified that a total of 17 investigations were completed within the established due date, while 13 investigations exceeded the established deadline. Figure 1 shows the comparison.

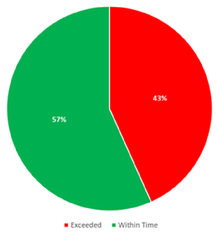

Figure 1. Exceeded vs Completed in Time

Further evaluation was performed to have a better understanding when the investigations were actually started and compare this information with the date that they were completed. From the evaluation it was identified that there was no correlation between these elapsed times. Figure 2 shows a comparison of the elapsed times.

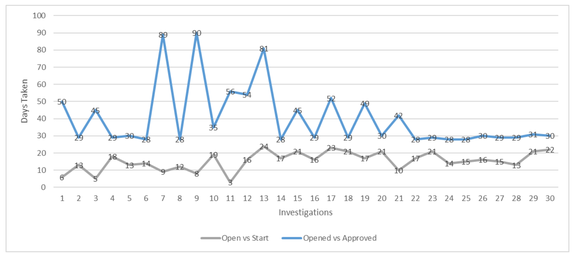

Figure 2. Comparison of Elapsed Times

A further evaluation was performed to identify causal factors that could have been related to the exceeded investigations. Refer to Figure 3 for fishbone diagram.

Methodology (Cont.)

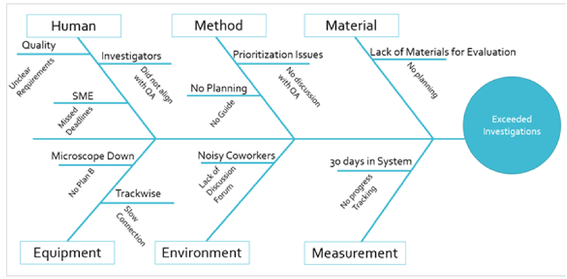

Figure 3. Fishbone Diagram

After the analysis performed it was identified that the root cause of the exceeded investigation was related to planification issues since there was no guide to aid in the investigation process. Furthermore, there was no discussion forum to address roadblocks in the investigation process. These unclear requirements and lack of forum caused different delays in the investigation process and rework near the closure of the investigations.

Improve: To reduce the delays related to lack of planification regarding investigators not aligning to QA requirements a checklist was provided to the investigators. This checklist included two sections. The first section included a list of information required to be reviewed by the investigator prior to conduct the investigation plan. This included: incident report, relevant procedures, photos, initial interviews, logbooks, samples, training evidence and supporting documentation. The second section included questions that will guide the discussion of the investigator and quality approver of the investigation execution an effective manner to ensure that the investigation will be complete and priorities are addressed.

As a guide for the investigator to perform the investigation process in an efficient standardized way, a role card was created using the platform Microsoft Teams and information gathered in the measurement stage. Refer to Figure 4 for standardized role card in Teams.

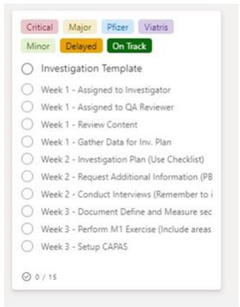

Figure 4. Standardized Role Card

Control: For the Investigation Plan Checklist, the control placed was an update to the relevant procedure with the checklist. Therefore, it is a requirement to perform the investigation plan as established. In the case of the Investigation Team Standardize Role Card, a bi-weekly meeting is being held with the investigators, quality approvers, managers, and area representatives (ad hock). In this meeting the role cards are shared and the investigations are discussed.

Methodology (Cont.)

Furthermore, a monthly meeting will be held to present quantity of investigations were closed in time and compare with previous months for trend analysis. This forum will be also used to present concerns regarding the investigation process and identify areas of opportunity for continuous improvement of the department.

Results and Discussion

The DMAIC methodology was used to execute the project. A fishbone diagram was used to identify causal factors. Based on the causal factors identified two implementations were performed.

To reduce the delays related to lack of planification regarding investigators not aligning to quality approver requirements a checklist was provided to the investigators that included a pre-work to perform prior the discussion, and a checklist to guide the investigator and quality approver in the investigation plan. Furthermore, to guide the investigator into performing the investigation process in an efficient standardized way a role card was created using the platform Microsoft Teams. Finally, controls were placed to ensure that the standardize process created is maintained. Based on this standardized investigation process it is expected that more investigations are completed within the established due date.

Conclusions

A checklist was provided to guide investigation effective planification and a role card was also provided to reduce process variation. The implementation of process standardization in the investigation process is an effective way to reduce process variation. Based on the fact a standardized process was created and controls were placed to ensure that the implementations are maintained it is expected that the amount of exceeded investigations is reduced.

Future Work

Continuous improvement is an important factor in maintaining a competitive advantage. Future projects should include reducing the 30-days due date. This could aid to accelerate the disposition of products placed in Global Batch Hold and patients could receive their products without major delays.

References

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[3] Mlvka, M., Prajova, V., YakimoviCh, B., Korshunov, A., & Tyurin, I. (2016 C.E.). Standardization – One of the Tools of Continuous Improvement. Science Direct, 149, 329–332.