Quality Alerts Notifications Evaluation and Response Solution for Sites to Communicate Computer Systems Potential Issues in an Alignment Form and Integrated Process

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Abstract

The Quality Alert Process is used to communicate IT or computer system related situations that have the potential to adversely impact regulatory requirements (e.g., product quality, patient safety, record integrity and privacy) as well as potentially impacted sites/areas. In addition, the pharmaceutical industry is a highly and strictly regulated environment. Therefore, the data generated in this process are important in order to demonstrate compliance at all time. A commercial off-the-shelf (COTS) software was identified to standardizing a global practice also will be help us to communicate all the sites at the same time, with the same information and method. For develop a global solution Lean Six Sigma methodology were used to implement the requirements to this process.

Introduction

The current manufacturing process are working more fast and faster than in the past years. In addition, the information is taken a most important position in order to take final decisions. Also, the information thru the Quality systems is handled by computer systems in order to have the complete information and data integrity (e.g. batch records, process performance, stability samples). Therefore, the information technology (IT) and departments as Quality are working closely and more integrated to each other.

Background

Quality Alerts Process under the Quality Management is a wide-ranging concept, which covers all matters, which individually or collectively influence the quality of a product. It is the sum total of the organized arrangements made with the objective of ensuring that products are of the quality required for their intended use.

To ensure product quality, safety, and efficacy for our customers, it was designed a quality system that meets or exceeds the regulatory requirements of the countries in which our products are distributed. This quality system with the help of IT group is a framework for achieving the stated quality requirements through the management of resources, processes, and data. Identifying, understanding, and managing interrelated processes as a system strengthens with the ability to meet its objectives and to effect continual improvement in operations. This quality system represents a scientific based philosophy that ensures drug products, process, systems, and devices consistently meet or exceed customer needs. In addition, we need to remember that the Pharmaceutical Industry is one of the most regulated workplaces across different manufacturing industries. Therefore, attend any situation quickly will be avoid situation with drug products as well as patient safety.

Problem

This research pursues simplify the Quality Alert process with the reduction of at least a 30% in the cycle time to evaluate and document the alert impact. In addition, this research has the north to standardize the Quality Alert process and covert it in sustainable as well as no people dependent.

Methodology

DMAIC methodology will be used for this project in order to achieve the project goals. In addition, Lean Thinking will be pursuing for all the projects steps. Therefore, each one of all project steps will be defined from the quality management as well as IT standpoint when applicable.

- Define: In this phase it is expected to define a clear scope of the project. Therefore, a project charter will be developed in order to state: Project Goal, Project Participants, Stakeholders, Requirements, Constraints, Milestones, Communication methods and Deliverables. In this phase the Voice of the Customer (VOC) as well as Voice of the Business (VOB) will be evaluated to understand the real customer/business requirements.

- Measure: The Measure phase will include a Value Stream Mapping (VSM) of the Current Process with the objective of identifying real output (Process Time Estimate) from the customer as well as requirements. With this information obtained and gathered from the customer a Critical to Quality (CTQ) tree or analysis will be conducted. In addition, business requirements will be defined. In this project the customer represents one of the plants or sites where the solution will be implemented. This will include a team of Quality Personal, Information Technology (IT) and Quality Management.

- Analyze: as part of this phase, the data and information obtained from the Measure phase will be evaluated, in order to establish the necessary approach for implementation. Also, in this phase will help how to concentrate the efforts to accomplish deliverables of the project. In addition, weekly meetings were arranged, including representatives from the site as well as the core team members of the global solution.

- Improve: in this part of the project phase, an implementation of the project will be taking place of the process improvement as well as the tool to be used in all the company sites. Therefore, deployment plan needs to be approved by global as well as the SME's impacted as per process improvement and modifications with the require trainings.

- Control: This project was pursuing since quality management require a better tool to follow-up and track the quality alerts into the sites. However, the group of Information Technology (IT) will be providing support in this step, they will be accountable for the support of the process after project implementation. For this phase, the site or plant should expect: Unified transition, IT support and Reports.

Results and Discussion

This research pursues simplify the Quality Alert process with the reduction of at least a 30% in the cycle time to evaluate and document the alert impact. In addition, this research has the north to standardize the Quality Alert process and covert it in sustainable as well as no people dependent.

Results and Discussion

Define – A project charter was prepared in order to identify requirements, require personnel and stakeholders. As part of the Define step was take into consideration the Voice of the Customers (VOC) as well as the Voice of the Business (VOB). For VOC/VOB Refer to Figure 1. In addition, in this step a SIPOC (Supplier, Input, Process, Output and Customer) was used. For SIPOC Refer to Figure 2.

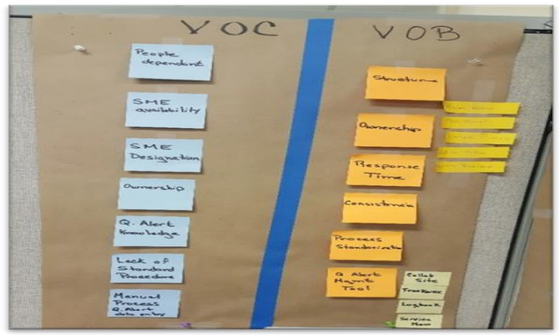

Figure 1

Figure 2

Measure – A Value Stream Mapping (VSM) was created to assess all the current process to evaluate and document the impact (if any) of the Quality Alert Notifications into the Site. With this tool we obtain an overview of information flow to complete the Quality Alert Evaluation. In addition, with this tool we focus on the customer requirements and help to understand where the sites depart one from each other.

Analyze – For the analyze phase a Cause-and-Effect Diagram was prepared. After understanding the value steps in the Quality Alerts Notification Process obtained in the VSM in the Measure Phase understand how the current controls from sites are to notify, evaluate and respond the Quality Alerts impact, that are important to assure that the process improvement will be achieve. In this diagram we capture the require resources as personnel (SME's), procedures, documentation tools (computer systems). In addition, a Benchmark was issue to obtain and evaluate the tools that the global sites used to perform the Quality Alert evaluation as well as the ownership that in charge of this action.

Improve – In this Phase a Flow Chart was created with the new Quality Alert Management Process (refer to Figure 6 & Figure 7). With the proposal of the new management process to evaluate and document the Quality Alerts notifications, we request and cycle time improvement from 20 days to 8 days.

Control – To assure process sustainability a global procedure was put effective, required personnel trained (e.g. SME's, Coordinators, Owners, QA representative) and the new mechanism defined to document the evaluation and final resolution of the notification. In this phase IT group support all the sites coordinators and SME's in order to assure the proper use of the computer tool and assist in any doubt that arise during the Quality Alert notification and documentation.

Conclusions

The Quality Alerts Evaluation and response was improved in local plants (Puerto Rico) as well as Global Sites. We establish a standardize mechanism that allow us to evaluate the Quality Alerts notifications in the same way using the same tools and the evaluation performed by the corresponding Subject Matter Experts (SME's) by the area(s) impacted.

The objectives pursing in this project were successfully fulfilled. Therefore, the customer requirements and business reequipments were achieve with the help of the correct project staffing. Since, the project strategy, process evaluation and process modifications were defined using the knowledge from the SME's.

Future Work

As a future work and pursue sustainability, the SME's from all company sites will be meet each quarter to evaluate and calibrate lessons learned from the process and the where is the current pain. This is important to identify future row blocks and can be use as a continues improvement tool.

Acknowledgements

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