Quality System Improvement

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Abstract

This research project is focused on the improvement of the quality system in a healthcare/medical industry. Quality system is defined as the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. Based on the Food and Drug Administration (FDA) regulation, each manufacturer shall stablish and maintain a quality system that is appropriate for the specific for the medical device designed and/or manufactured. Basically, is important to ensure that the quality systems requirements are effectively stablished and maintained in accordance with the regulations.
A set of activities belonging to different sub-systems are monitored consistently with the purpose to define the health of the quality system and understand what is needed to be improved. The DMAIC methodology was used to conduct the analysis and define opportunities to improve. The quality system is in good standing due the completion of all the activities and sustainability, in where DMAIC tools were applied.

Introduction

This project seeks the improvement of the quality system by looking the performance of the subsystems for compliance of the timeframe stablished for completion of activities. This will provide a better standing of the company within the regulatory requirements and will simplify processes. DMAIC were selected as the appropriate method to use since is a data-driven quality strategy used to improve processes.
The quality system is defined in the company by subsystems which are the following:

Material Control	Manual Commitments
Production & Process Controls	Document and Record Management
Equipment & Facility Controls	Change Control
Corrective & Preventive Actions	Supplier Quality
Training	Customer Surveillance

Table 1
Quality Subsystems

Background

A system is defined as a series of actions, activities, elements, components, departments, or processes that work together to define a purpose. System effectiveness is a measure of the degree to which a system can be expected to achieve a set of specific (mission) requirements. Subsystems are major divisions of a system that are still large enough to consist of more than one process [1].
A Quality Management System (QMS) helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. ISO 9001:2015, the international standard specifying requirements for QMS, is the most prominent approach to quality management systems [2].

> *FDA Guidance "Quality Systems Approach to Pharmaceutical CGMP Regulations*", a well-built quality system should reduce the number of (or prevent) recalls, returned or salvaged products, and defective products entering the marketplace [3].

Background Cont.

The processes of the quality management system need to be monitored, and measured if possible, to ensure that they are performing as designed. Ensuring that the process is behaving as planned is the first step in being able to improve the process, which is the goal of having a QMS. Refer to Figure 1 [4].

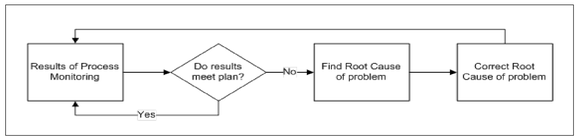

Figure 1
Process Monitoring

Problem

As part of the monitoring activities performed to the quality system was identified that timeframe stablished for completion of activities for some subsystems was not meet. Activities were required additional time for completion but were not extended.

Methodology

In order to deliver quantifiable and sustainable results, DMAIC methodology was used. In this case, the quality system consist on multiple factors that has to be considered in order to have a sustained improvement.
The project has to be conducted in different phases as different processes are measured within the quality system. Each one of them has to be evaluated individually to understand what is causing the problem within the system.

The following tools will be used for the resolution of the problem:

Define	• Project Charter (Problem Description, Goal, Scope, Team Distribution) • Preliminary Evaluation
Measure	• Data gathering for each subsystem. • Conduct Focus Groups, Brainstorming Sections • Process Mapping
Analyze	• 5 why's and cause/effect tools will be used for analysis.

Table 2
Tools to be Used DMAIC

Results and Discussion

The results obtained through the five phases of the DMAIC methodology were as follows:

Define – As part of the define phase a Project Charter was used. The team members were also identified, subject matter experts were selected. The scope was defined in terms on which subsystems will be part of the evaluation.
A preliminary evaluation was performed to breakdown the scope and simplify the review process. During this evaluation were identified that from the eleven (11) subsystems, three (3) were not meeting:

1. Equipment & Facility Controls – Extraordinary Maintenance
2. Manual Commitments
3. Training Evaluations

Results and Discussion Cont.

Measure – Data gathering was performed about the subsystems, were confirmed the following quantity from each subsystem not complying with the corresponding date for closure.

Subsystem	Total of Records	Total of Records Past Due	% of non-compliance per area
Extraordinary Maintenance	175	52	29.71%
Training Evaluations	60	8	13.33%
Manual Commitments	34	8	23.52%
Total	269	68	

Table 3
Data Summary for Subsystems

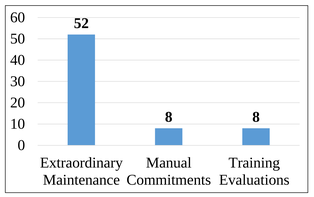

Figure 2
Top Offender, Extraordinary Maintenance

Analyze – Focus Group sections were arranged per each system considered as contributor by a random selection.

Extraordinary Maintenance:

Process - During the evaluation were identified opportunities in the design of the process based on the following:

- No realistic timeliness for maintenance closure (30 days) when there is an out of action limit on certain monitoring tests.
- Electronic Logbook for maintenances doesn't allow to incorporate a target date per a plan since automatically counts 30 days since the record is generated.

Method – Procedure requires 30 days for completion of the maintenance, there is no explanation how to address situations that can affect the completion process and as consequence extensions mechanisms must be used more frequent.

Manual Commitments:

A 5 why tool was used, the discussion was oriented on why the process for time extensions was not followed. During the reviewed of the process was identified that the Form used to assign actions doesn't contain an acknowledgement field signature and procedure does not require an acknowledgment if the owner is different to the person who assigned.

Training Evaluations:

Process - Each one of the cases were evaluated and were identified the following:

- In some cases, trainings assigned were not related to their current role or curriculum.
- System was not sending automated notifications as common, as a remedy an alternate system (email notification) was used to notify requirements of training.
- No tracking was provided to Training Evaluations as there were transition of personnel, no system owner immediately assigned to monitor for the completion of this task.

Results and Discussion Cont.

Improve – The following actions were taken to improve the quality system:

Extraordinary Maintenance:

- The procedure for Extraordinary Maintenance was revised in order to include exceptions when out of limits are reported. A timeliness guidance was provided depending on the type of exceptions that can occur during the process.
- The Electronic Logbook was updated to include a column when exception occurs to document the completion date when more than 30 days are needed, is not based in an automatically calculated field.

Manual Commitments: The procedure for Manual Commitments was revised in order to instruct that the owner must be notified and sign at the moment of the record creation.

Training Evaluations:

- Training system upgraded to send automated emails, was tested for functionality and was working as expected.
- New strategy of training was implemented in order to assign training based on specific curriculum.
- Personnel were trained to provide the follow up of the activities. In addition, a backup resource was assigned and trained. An automated system is being evaluated as preventive to avoid human dependency.

Conclusions

The quality system is in good standing due the completion of all the activities and sustainability, in where DMAIC tools were applied. During the evaluation, records were closed during the corresponding period or an extension was requested to complete the activity as per applicable procedures. Which means that the project objective of 100% adherence to the process was achieved. This will provide a better standing of the company within the regulatory requirements and will simplify processes.

Acknowledgements

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References

[1] B. Wortman, "Enterprise-Wide Deployment," in *The Certified Six Sigma Black Belt Primer,* Indiana, Quality Council of Indiana, 2014, pp. 1-42.

[2] Asq.org. (2018). *What Is a Quality Management System? | ASQ* [Online]. Available: http://asq.org/learn-about-quality/quality-management-system/

[3] Accessdata.fda.gov. (2018). *CFR - Code of Federal Regulations Title 21* [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

[4] Hammar, M. (2018). *ISO 9001 Monitoring and Measurement: For evidence-based decisions* [Online]. Available: https://advisera.com/9001academy/blog/2014/04/15/monitoring-measurement-basis-evidence-based-decisions/