Quality System Improvement

Adlin Maldonado Santiago
Master of Engineering in Manufacturing Engineering
Advisor: Carlos González, PhD.
Industrial and Systems Engineering Department
Polytechnic University of Puerto Rico

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 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. This project seeks the improvement of the quality system by looking the performance of the subsystems. This will provide a better standing of the company within the regulatory requirements and will simplify processes. The DMAIC methodology will be used to conduct the analysis and define opportunities to improve. DMAIC were selected as the appropriate method to use since is a data-driven quality strategy used to improve processes.*

Key Terms *— Continuous Improvement, Quality System, Regulations, Subsystems, System Monitoring.*

INTRODUCTION

The sector dedicated to the care of human health is one very challenged due to the complexity of the products being manufactured and controls that must be taken in place. Therefore, must be sustained by a solid quality system in where all the areas should be monitored for compliance.

Industries are seeking for continuous improvement projects in where the processes can be simplified to improve the quality of the products and comply with regulations and standards.

The quality system is defined in the company by subsystems which are the following: Material Control, Equipment & Facility Controls, Production & Process Controls, Corrective & Preventive Actions, Manual Commitments, Document and Record Management, Change Control, Supplier Quality, Training, Customer Surveillance, Quality Audits, among others. Each one of the subsystems are monitored to ensure that the quality system requirements are effectively stablished and effectively maintained.

This research project will be focused in an improvement of the quality system from the standpoint of the evaluation of the subsystems for compliance of the timeframe stablished for completion of activities.

Problem Statement

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.

Research Description

This project will seek for opportunities to improve during the individual processes in where activities were not completed during the timeframe stablished. As part of the research a deep understanding of the individual processes is necessary to identify what is preventing or prevented the completion of the activities in specified timeframe. In conjunction with the evaluation of the

extension requests process and monitoring system used.

Research Objectives

This project is about improving the quality system by evaluating subsystems to comply with requirements stablished. This project aims to achieve a 100% of completion of activities on the required period or extended as needed or applicable.

Research Contributions

This project seeks to maintain the health of the quality system by looking at the overall process. This is done through eliminating the waste which can occur when the processes are maintained without the view of inefficiencies. The purpose is to drive efficiencies towards fewer errors by facilitating and have better processes integration, continuous improvement culture, engagement of employees, better internal communications, among others. All of those characteristics lead to improve quality and cost savings, which is the main purpose of the project.

To comply with regulations and standards, it is necessary to maintain and monitor our quality systems. In order to reduce the impact of the problem and increase the impact of recovery, a continuous improvement culture is necessary. Based on that, this project may contribute to other resources which are looking on how to improve the quality system and may serve as an example.

LITERATURE REVIEW

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) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A 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 quality management systems, is the most prominent approach to quality management systems [2].

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 your process is behaving as planned is the first step in being able to improve the process, which is the goal of having a QMS. For each process, comparing the results to the expected results that were planned per the objectives, and correcting the process when results don't meet expectations, is crucial. For instance, if you are monitoring your process for corrective actions, which is planned to have no repeat problems after a corrective action is determined to be effective, but your company continues to have problems repeat, the process needs to have the root cause of this problem identified and addressed to achieve effectiveness, refer to Figure 1 [3].

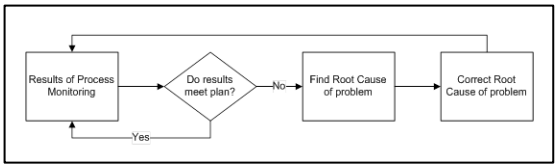

Figure 1
Process Monitoring

Regulatory Requirements

The purpose of the regulations are to ensure we make a safe product and patients are protected. An effective QMS in not just about documents, it is about how is managed to implement requirements across all the quality system.

Industries which are regulated by the FDA "Food and Drug Administration", the Quality System (QS) Regulation (21 CFR 820.5) indicates that each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part. There are

explained 7 major subsystems approach for the Quality System which are shown in Figure [4].

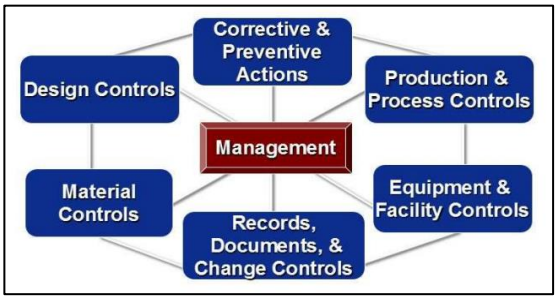

Figure 2
7 Subsystems of a Quality System

FDA Guidance "Quality Systems Approach to Pharmaceutical CGMP Regulations" [5]:

- This guidance is intended to help manufacturers implementing modern quality systems and risk management approaches to meet the requirements of the Agency's current good manufacturing practice (CGMP) regulations (2l CFR parts 210 and 211).
- A quality system addresses the public and private sectors' mutual goal of providing a high-quality drug product to patients and prescribers. A well-built quality system should reduce the number of (or prevent) recalls, returned or salvaged products, and defective products entering the marketplace.

General Aspects of Continuous Improvement

Continuous improvement is an ongoing effort to improve products, services or processes. These efforts can seek "incremental" improvement over time or "breakthrough" improvement all at once. Among the most widely used tools for continuous improvement is a four-step quality model—the plan-do-check-act (PDCA) cycle. Others commonly used such as Six Sigma and Lean, emphasize employee involvement and teamwork; measuring and systematizing processes; and reducing variation, defects and cycle times [6].

Six Sigma is a method that provides organizations tools to improve the capability of their business processes. The emphasis is on the DMAIC approach to problem solving: Define, Measure, Analyze, Improve, and Control. DMAIC refers to a data- driven improvement cycle used for improving, optimizing and stabilizing business processes.

In general, can be implemented as a standalone quality improvement procedure or as part of other process improvement initiatives such as lean [7].

- Define: Select the appropriate responses to be improved.
- Measure: Data must be gathered to measure the response variable.
- Analyze: Identify the root causes of defects, defectives, or significant deviations whether in or out of specifications.
- Improve: Reduce variability or eliminate the cause.
- Control: With the desired improvements in place, monitor the process to sustain the improvements [1].

PROJECT METHODOLOGY

In order to deliver quantifiable and sustainable results, DMAIC methodology will be used. It is a structured approach and will allow to effectively manage the process to minimize the gaps. 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 (Refer to Table 1):

Table 1
Tools to be Used DMAIC

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.

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, refer to Table 2 to review a summary.

Table 2
Project Charter

Project Charter	
Problem Statement	
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.	
Goal Statement	
This project is about improving the quality system by evaluating subsystems to comply with requirements stablished. This project aims to achieve a 100% of completion of activities on the required period or extended as needed or applicable.	
Scope	
In Scope	A total of eleven (11) subsystems are being monitored as part of the quality system: Material Control, Equipment & Facility Controls, Production & Process Controls, Corrective & Preventive Actions, Manual Commitments, Document and Record Management, Change Control, Supplier Quality, Training, Customer Surveillance and Quality Audits.
Our Scope	Other subpsystems or subprocesses.

A preliminary evaluation was performed to breakdown the scope and identify which are the subsystems that were not meeting the established timeframe for completion and extensions were not requested. This was performed to simplify the review process. During this evaluation were identified that from the eleven (11) subsystems, three (3) were not meeting (Training, Equipment & Facility Controls, Manual Commitments). Situations for the other subsystems were not reported, the whole scenario was evaluated to revise that there were no gaps among other subsystems. In addition, during the preliminary evaluation were identified that subsystems in where information is evaluated and frequently overlooked, as example: CAPAs, Complaints, SCARs are not contributors of this defect.

Measure – Data gathering was performed about the subsystems, were confirmed the following quantity from each subsystem not complying with the corresponding date for closure. An excel spreadsheet was used for the data gathering which included the record number, record due date, extension request number (if any) and YES/NO field for disposition (Complies/Do not Complies). Each of them were evaluated individually for a period of 7 (January to July) months. Refer to Table 3 to review findings summary:

Table 3
Data Summary for Subsystems

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

Focus Group sections were arranged per each system considered as contributor by a random selection, starting with Extraordinary Maintenance as from the total of past due records which is sixty-eight (68), fifty-two (52) corresponds to this system, refer to Figure 3. Individual analysis will be conducted as processes are different from each system.

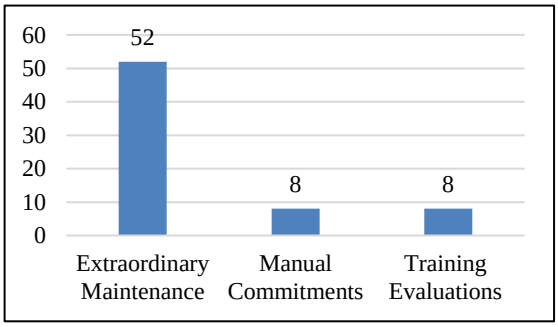

Figure 3
Top Offender, Extraordinary Maintenance

Analyze – During the Focus Groups sections that were organized the following was obtained:

- Background information were collected from different teams to identify causes in the processes. Tool used was a process flow diagram for areas that were useful.
- Through the brainstorming process, inputs were received from the key players of the process.

Extraordinary Maintenance

Process – The estimated due date to complete and close a maintenance is 30 days, if the maintenance cannot be completed within the due date established the owner of the maintenance must use a form for extension request. To evaluate the process of the maintenance timeliness, three focus groups sections were conducted.

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. As require a nonconformance investigation and results from laboratory. During the process is not possible to anticipate an out of action limit leading to generate time extensions.
- 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. This triggers a record to be past due when the situation was planned and in real time was extended using the form over the estimated due date. Refer to Figure 4 Process Map – Extraordinary Maintenance.

Data regarding open maintenances for tracking purposes was not presented with necessary information as status of the maintenance and extensions requests which makes difficult to understand which the state of the record.

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. It was identified that does not specify the timeliness for out of limits reported during monitoring tests. This situation was identified the common source for maintenances taking over 30 days.

Training – Electronic system were used to review the training history. The personnel responsible for execution of the maintenances were trained and personnel involved during the process in applicable procedures.

People – The accountability of the actions were not clear as exposed during the focus group, as the activities depending of the type of maintenance involves different areas. Procedure has the details that a plan must be completed when extension will be requested for actions in risk for completion. Specifies that the owner, personnel who creates the maintenance, must request the extensions as needed and must monitor for completeness.

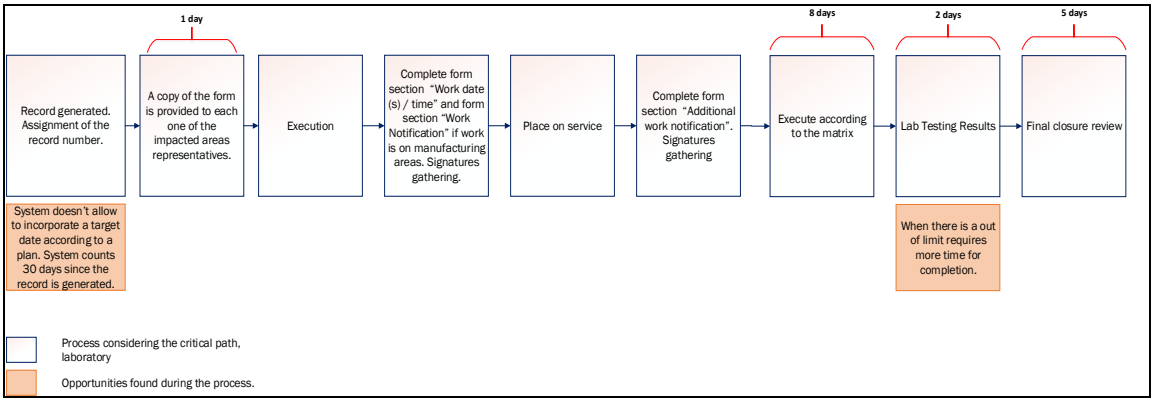

Figure 4
Process Map – Extraordinary Maintenance

Manual Commitments

During the Focus Group section performed, a review of the procedures and processes was performed. A 5 why tool was used, the discussion was oriented on why the process for time extensions was not followed.

1. Why time extensions process was not followed?

   Personnel was not aware that an action was assigned to them.

2. Why the personnel were not aware of the action?

   The mechanism used doesn't require an acknowledgment to begin the process.

3. Why the mechanism used doesn't required an acknowledgment?

   Form used to assign actions doesn't contain an acknowledgement field signature.

4. Why form doesn't contain an acknowledgment field?

   Procedure does not require an acknowledgment if the owner is different to the person who assigned.

In addition, it was observed that data regarding open documents for tracking purposes has not been presented consistently which represents that there is a low visibility of the actions for completion on time.

Training Evaluations

Process – During the Focus Group section, a review of the process for Training Evaluations was performed. Training Evaluations are assigned to the supervisor when a training is not performed on the specified timeframe. It is used to document if there is impact or not to the product or 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 which shouldn't be assigned to them.
- 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.

Method – The procedure establishes that the evaluation must be completed in a period of 20 working days and if can't be completed during the timeframe established an extension must be generated following instructions on procedure. No gaps were identified during the review of the procedure.

People – Personnel was aware about the requirement of training and timing for completion of Training Evaluations but lose the tracking of the activity, date passed without noticing. An opportunity was also found as some of them were aware that training did not corresponded but were not aware about the process for training removal.

Training – Personnel trainings were revised on procedure which request the timeliness for completion of the Training Evaluations. Each one of them were trained per procedure.

Additional Evaluation - Quality System Tracking

- Data is collected from different sources manually to present the overall performance and reports are not standardized, not allowing to automate the process.
- Reports are not consistently updated by system owners which makes difficult the visibility to upper management for actions completion. This contributed to the failure on detection on time.

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. Form was updated to include the column to request the signature of the action owner.

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.

Additional Evaluation - Quality System Tracking

- Standardization of the process for data collection in order to centralize the information for visibility.
- Discussion held with the system owners for tool deployment and responsibilities discussion.

As general, a retraining was provided emphasizing the requirements based on the evaluation performed and gaps found. This also covered requirements of other subsystems as preventive action. In addition, the focus groups sections helped to learn deeper about different systems and understand the needs. Created conscience and procedures were fully discussed to clarify doubts.

All records were closed and completed during the review period as mitigation. Monitoring of the quality system is being performed more frequently and reported to the management. It is presented in this review what is due in the next two weeks for preparation, advice and escalation as necessary. In addition, each subsystem is monitored individually by system owners for follow up and completion of activities.

Control – To understand if the actions were effective, the criterion that were stablished after actions implemented was to monitor for fourteen (14) days the system as overall. The fourteen days period were selected as in a daily basis across all subsystems, commitments has to be completed. Not only for Training Evaluations, Maintenances or Manual Commitments. During the period from 09/24/18 to 10/08/18, after the last action implementation on 09/23/18, records were reviewed among the quality system. Records in were the due date was between the review period were evaluated to revise if were closed on/before due date or if an extension was generated for them. Based on the evaluation performed, records were closed during the corresponding period or an extension was requested to complete the activity.

CONCLUSION

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.

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

[3] M. Hammar. (2014, April 15). *ISO 9001 Monitoring and Measurement: The basis for evidence-based decisions*

[Online]. Available: https://advisera.com/9001academy/blog/2014/04/15/monitoring-measurement-basis-evidence-based-decisions/.

[4] US. Food and Drug Administration (FDA). (2018, April 1). *CFR - Code of Federal Regulations Title 21* [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1.

[5] US. Food and Drug Administration (FDA). (2006, September). *Quality Systems Approach to Pharmaceutical CGMP Regulations* [Online]. Available: https://www.fda.gov/downloads/Drugs/Guidances/UCM070337.pdf.

[6] ASQ: The Global Voice of Quality. (2018). *Continuous Improvement Model - Learning Resources| ASQ*. [Online] Available: http://asq.org/learn-about-quality/continuous-improvement/overview/overview.html.

[7] ASQ: The Global Voice of Quality. (2018). *Define, Measure, Analyze, Improve, Control (DMAIC Approach) | ASQ* [Online]. Available: http://asq.org/learn-about-quality/six-sigma/overview/dmaic.html.