Use of Lean Sigma Methodology for Quality System Improvements

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Webinar Version

Agenda

Topics:

- Introduction
- Regulatory Environment
- Project Strategy
- Project Flow & Review
- Define Phase
- Remediation Phase and its importance
- Measure Phase

Introduction

- In the last decade, thousands of patients have been impacted by product recalls from different Medical Device Manufacturers.
  - Recalls have been either a voluntary decision of the manufacturer or a compulsory mandate from the Food & Drug Administration (FDA). Recalls are mostly driven by a potential safety hazard that the product poses on human life or by serious compliance deviations.
- As a result, Manufacturers face increased scrutiny from FDA.
  - The agency has increased their workforce and frequency of inspections.
  - Inspectors have raised the bar in terms of the rigor, thoroughness and questioning used during their audits.
  - Inspections are focused on:
    - Proactive identification of compliance risks
    - Determining if the manufacturers are correcting issues promptly.

Regulatory Environment

- Increase on warning letters.

	January – May 2008	January – May 2010	Increment
Warning Letters	**188**	**228**	**21.3% ↑**
Warning Letters to Medical Device	**60**	**64**	**6.7% ↑**

Regulatory Environment in Puerto Rico

- FDA continues to issue observations for local manufacturing sites as well as to overarching Business Units.
- FDA visited multi-site companies and detected differences in approaches of the Quality System.
  - Observations seen in one facility were also found in other facilities of the same manufacturer. This is perceived by the agency as repeated findings.
- The Agency Expects the manufacturers to take a systemic approach to solve noted deficiencies

The Journey!

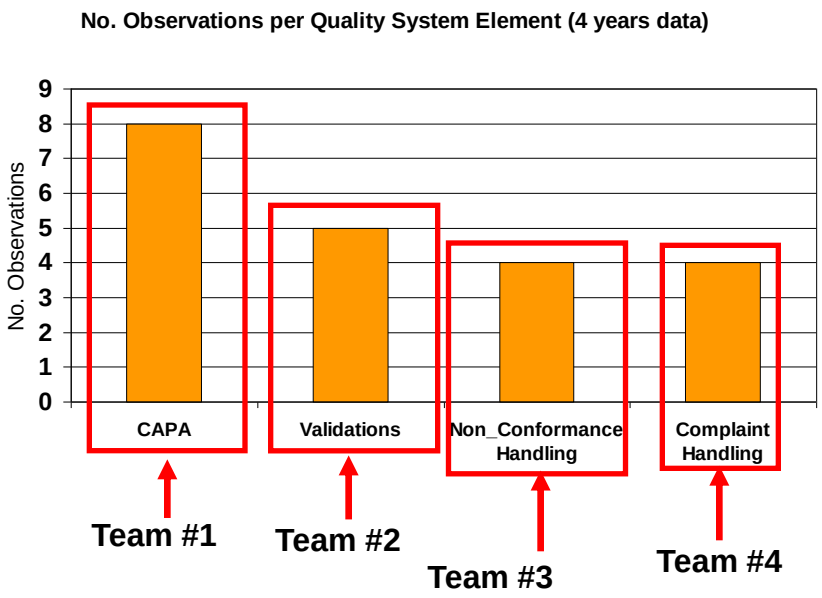
- A thorough approach is needed to show the regulatory bodies that we as Medical Devices Manufacturers are striving to find the true root causes of the issues and to permanently correct them.

- The approach is DMAIC!
  - The methodology has been historically proved to reduce defects.
    - Defect in this case = regulatory observations or findings
  - Also helps to reduce variability
    - E.g. Different procedures across facilities of the same manufacturer for the same Quality System Element.
  - Proven methodology on finding true root causes
  - Systemic Improvements (no bandages)

- The journey consists of using DMAIC not only to solve regulatory issues but to implement a culture of continuous improvement across the organization.

Project Strategy

- Opportunities (Example):



- One team assigned per Quality System Element.
- Team composition is as follows:
  - Team leader
  - Dedicated team members with representation from all sites
    - ✓ Members should have a thorough knowledge on the topic (CAPA, Validation, etc.
  - Sponsor or Champion assigned from top management
  - Black Belt or Master Black Belt
  - Subject Matter Experts
  - External Compliance Experts available for team consulting (optional, but helpful in some cases)

Project Flow and Review

Remediation Goal

Define

Problem Statement

Goal Statement

Remediation

Gap Analysis

SME Review of proposed remediation

Implementation of Remediation Action Plan

The phase review must:

- Be performed as indicated in the diagram to ensure that the team is going in the right direction.
- Phase Review presented to steering committee (representatives of management).
  - Committee needs to grant phase closure approval in order for the team to be promoted to the next phase.

System Redesign Goal

Measure

In depth understanding of current processes and inputs

Assessment of current process capability (risk)

Identify likely inputs

Analyze

Determine Key Inputs for system redesign

Improve

Evaluate options for countermeasures and optimize

Predict impact on risk

Implement

Control

Support new process – Check and Adjust

Determine final process capability (risk)

Ensure sustainability

Phase Review

Define Phase

Define Phase

- The purpose of this phase is to:
  - Define the problem and its consequences in the organization
  - Establish the project goal, team, timeline and project scope

Define Phase: Questions to Answer

- Define Phase
  - What requirements or regulations need to be met?
  - What problem needs to be solved?
  - What process output reflects that problem (risk score)?
  - What would success look like (goal statement)?
  - What stakeholders will be impacted by this project?
- Required Tools
  - Project Charter

Define Phase: Background and Current State

–Where can we improve?

- Quality System Element (QSE) Status Across Multiple Sites
  - **FDA Findings**
    - list
  - **Internal Audits**
    - list
- QSE Status Across the enterprise

Define Phase: Background and Current State

–What requirements or regulations needs to be met?

- Refer to ISO, CFR and/or Corporate/Sector requirements and regulations?

Define Phase: Problem Statement

–What issue needs to be addressed?

Problem Statement:

Findings Summary:

Define Phase: Process Output to be Improved

- How does the output perform now?

Baseline Capability

Failure Mode or Defect Type	Severity	Frequency or Probability of Occurrence	Baseline Risk Evaluation Score
Findings: Untimely completion of records	9	4	36
Inadequate CAPA Investigations	9	3	27
Incomplete procedures	9	5	45
	Overall Risk Evaluation		**108**

Example of Severity Definition

Product Safety & Effectiveness Impact	Product Quality Impact	Regulatory Compliance/Quality System Impact
Critical • A Nonconformance that is likely to result in hazardous or unsafe conditions for individuals using or coming into contact with the product. • A Nonconformance that is likely to prevent performance of a vital product function. **Major** • A Nonconformance that has the potential to result in hazardous or unsafe conditions for individuals using or coming into contact with the product or has the potential to prevent performance of a vital product function. • The situation is likely to prevent performance of a product function. **Minor** • Not Applicable	**Critical** • A Nonconformance that is likely to result in release of product not suitable for use, or shipment of nonconforming product. **Major** • May result in the release of product not suitable for use or not meeting customer requirements but would not likely result in a hazardous or unsafe condition. • The absence or breakdown of an element of the management system that materially reduces its ability to assure controlled processes and products. **Minor** • A Nonconformance that is not likely to materially reduce the usability of the product for its intended purpose. • Does not result in the release of product not suitable for use or not meeting customer requirements	**Critical** • A number of major Nonconformances in a system element. • Repeat occurrences, failure to correct or inadequate correction of major Nonconformances from previous Audits/inspections. • Systemic failure of the Quality System or one of its sub-systems. • Failure of two or more related subsystems. **Major** • A number of minor Nonconformances in a given activity or against a given element. • Repeat occurrences, failure to correct, or inadequate correction of minor Nonconformance from previous Audits/inspections. • Failure of one of the sub-systems of the Quality System that is not systemic. **Minor** • An isolated lapse in implementing or following any requirement which does not indicate a systemic problem with the Quality System.

Severity Scoring	Frequency Scoring	Risk Evaluation
Critical = 9	Far Too Often >20% = 5	Effect * Frequency
	High Probability 10-20% = 4	
Major = 3	Moderate Prob 5-10% = 3	
	Very low Probability3-5% = 2	
Minor = 1	Low Probability 1-3% = 1	
No Risk = 0	3.4 ppm or better = 0	

Define Phase: Goal Statement

–What would success look like (goal statement)?

Goal Statement:

Scope:

In Scope:

Out of Scope:

Project Charter Template

Problem Statement

Replace this note with text describing the problem and the consequences of the problem.

Project Goal - Improvement

Replace this note with text describing the goal in the format of e.g. “Reduce the (quality system element) risk from the baseline evaluation of ___ to ___ by (date).
Long Term: Zero Critical or Major observations from external parties

Resources

Project Team
- (Sponsor)
- (Team Leader)
-

SME’s:

-

Stakeholders:
-
-

DMAIC Timeline

Phases	Planned	Actual
Define		
Remediation		
Measure		
Analyze		
Improve		
Control		

Audit & Gap Analysis Findings (Source & Quantity)

Replace this text with a the source of any findings, and the quantity

Failure Modes (findings) addressed by this project

Failure Modes:

1)

2)

3)

4)

5)

6)

Scope

Scope includes:
-
-

Scope excludes:
-
-

Remediation Phase

Remediation Phase

- The purpose of this phase is to:
  - Perform a gap assessment to determine how are the company procedures aligned to the regulations.
  - Generate an action plan with dates to address the identified gaps.
    - Gaps which poses a high risk should be addressed urgently with mitigating actions.

Remediation Phase: Questions to Answer

- Remediation
  - How were Gaps identified?
  - What Gaps were found?
  - How is the team proposing to correct deficiencies?
  - What are the interim controls?
    - How were SMEs involved in development?
    - What good practices were leveraged?
  - To what degree is this process ready for audit? How was that confidence developed?

Measure Phase

Measure Phase

- The purpose of this phase is to:
  - Understand the process
  - Measure the size of the problem. How big is it?
    - Calculate the baseline capability for your process output.
  - Identify inputs that are likely to affect the output

Measure Phase: Questions to Answer

- Measure
  - What does the process look like today?
  - How do inputs flow into that process?
  - How does the output perform now?
  - What inputs are likely to effect the output?
  - Are the problem statement and goal still accurate?
- Required Tools
  - Process (Genba) Observation
  - Baseline Capability
  - Process Map
  - Cause & Effect Matrix

Measure Phase: Baseline Capability (Risk)

- How does the output perform now?

Key Takeaway:
Identify the baseline risk with data

Baseline Capability

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Measure Phase: Process Map

- What does the process look like today?
- How do inputs flow into that process?

Key Takeaway:

Identify process outputs and their corresponding inputs.

CAPA

Inputs to Process Step	Process Step	Outputs from Process Step
Availability of procedure Level of procedure completeness Training Level / knowledge of personnel Connection between applicable procedures and work instructions Availability of Work Aids / Guidelines Ease of access to work instruction / procedures / standardized work / guidelines / work aids	**Initiate CAPA**	Timely Generation of the record Adequate / Complete Record generated
Availability of procedure Level of procedure completeness Training Level / knowledge of personnel in the system Availability of Work Aids / Guidelines Ease of access to work instruction / procedures / standardized work / guidelines / work aids	**Manage CAPA System**	Timely Updated and Completed Record Adequate / Complete Record maintained in the system

Measure Phase: Cause & Effect M

- What inputs are likely to effect the output?

Key Takeaways:

- **Correlate the inputs identified in the process map against the findings.**
- **Move the inputs with the highest correlation scores to Analyze Phase (Pareto)**

		Outputs or Findings needing to be resolved			
		Findings Severity Ranking			
No.	Inputs from Process Map *(Rank Correlation of Input to Finding)*	9 Untimely completion of records	9 Inadequate CAPA Investigations	9 Incomplete procedures	Correlation Score
1	Availability of procedure	3	9	0	108
2	Level of procedure completeness	1	9	9	171
3	Training Level / knowledge of personnel	9	9	9	243
4	Connection between applicable procedures and work instructions	0	1	1	18
5	Availability of Work Aids / Guidelines	9	9	1	171
6	Ease of access to work instruction / procedures / standardized work / guidelines / work aids	3	3	0	54

Input (cause) - Output (effect) ranking scale
0 = No Correlation
1 = Slight Correlation
3 = Moderate Correlation
9 = Strong & Direct Correlation

Severity ranking
Critical = 9
Major = 3
Minor = 1
No Risk = 0

End of Webinar

Questions?