Use of Lean Sigma Methodology for Quality System Improvements

By: Roberto Murillo
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Webinar Version
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.**

<table>
<thead>
<tr>
<th></th>
<th>January – May 2008</th>
<th>January – May 2010</th>
<th>Increment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Warning Letters</strong></td>
<td>188</td>
<td>228</td>
<td>21.3% ↑</td>
</tr>
<tr>
<td><strong>Warning Letters to Medical Device</strong></td>
<td>60</td>
<td>64</td>
<td>6.7% ↑</td>
</tr>
</tbody>
</table>
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.
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)
**Remediation Goal**

Define

- Problem Statement
- Goal Statement

Remediation

- Gap Analysis
- SME Review of proposed remediation
- Implementation of Remediation Action Plan

**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

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.
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 need 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?

## Findings

<table>
<thead>
<tr>
<th>Failure Mode or Defect Type</th>
<th>Severity</th>
<th>Frequency or Probability of Occurrence</th>
<th>Baseline Risk Evaluation Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Untimely completion of records</td>
<td>9</td>
<td>4</td>
<td>36</td>
</tr>
<tr>
<td>Inadequate CAPA Investigations</td>
<td>9</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>Incomplete procedures</td>
<td>9</td>
<td>5</td>
<td>45</td>
</tr>
<tr>
<td><strong>Overall Risk Evaluation</strong></td>
<td><strong>108</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Severity Scoring

- **Critical** = 9
- **Major** = 3
- **Minor** = 1
- **No Risk** = 0

### Frequency Scoring

- **Far Too Often >20%** = 5
- **High Probability 10-20%** = 4
- **Moderate Prob 5-10%** = 3
- **Very low Probability 3-5%** = 2
- **Low Probability 1-3%** = 1
- **3.4 ppm or better** = 0

### Example of Severity Definition

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<tr>
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Define Phase: Goal Statement

What would success look like (goal statement)?

Goal Statement:

Scope:
In Scope:

Out of Scope:
## 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

### SME's:
- 

### Stakeholders:
- 

<table>
<thead>
<tr>
<th><strong>Project Team</strong></th>
<th><strong>Phases</strong></th>
<th><strong>Planned</strong></th>
<th><strong>Actual</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Sponsor)</td>
<td>Define</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Team Leader)</td>
<td>Remediation</td>
<td></td>
<td></td>
</tr>
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### DMAIC Timeline

<table>
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<tr>
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<tbody>
<tr>
<td>Define</td>
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<tr>
<td>Remediation</td>
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<td></td>
</tr>
<tr>
<td>Measure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analyze</td>
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</tr>
<tr>
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<td></td>
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<tr>
<td>Control</td>
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## 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
The purpose of this phase is to:

- Perform a gap assessment to determine how 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
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?

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**Overall Risk Evaluation**

108

**Key Takeaway:**
Identify the baseline risk with data

### Example of Severity Definition

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<tr>
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<th>Frequency Scoring</th>
<th>Risk Evaluation</th>
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<tbody>
<tr>
<td>Critical</td>
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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.

<table>
<thead>
<tr>
<th>Inputs to Process Step</th>
<th>CAPA Process Step</th>
<th>Outputs from Process Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability of procedure</td>
<td></td>
<td>Timely Generation of the record</td>
</tr>
<tr>
<td>Level of procedure completeness</td>
<td></td>
<td>Adequate / Complete Record generated</td>
</tr>
<tr>
<td>Training Level / knowledge of personnel</td>
<td>Initiate CAPA</td>
<td>Timely Updated and Completed Record</td>
</tr>
<tr>
<td>Connection between applicable procedures and work instructions</td>
<td></td>
<td>Adequate / Complete Record maintained in the system</td>
</tr>
<tr>
<td>Availability of Work Aids / Guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ease of access to work instruction / procedures / standardized work / guidelines / work aids</td>
<td>Manage CAPA System</td>
<td></td>
</tr>
</tbody>
</table>
### Measure Phase: Cause & Effect Matrix

- 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

<table>
<thead>
<tr>
<th>No.</th>
<th>Inputs from Process Map (Rank Correlation of Input to Finding)</th>
<th>Findings Severity Ranking</th>
<th>Correlation Score</th>
</tr>
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<tr>
<td></td>
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</tbody>
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#### 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
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- **No Risk** = 0
End of Webinar

Questions?