The Competency Workstream Update

MDIC Case for Quality

26 October 2016
Case for Quality Competency Working Group
Establish an industry Competency Model and identify and address key areas for improvement

**Approach:**
- Identify stakeholders and competencies
- Prioritize needs
- Select two starting points as pilots

**Output:**
- Heat map 24 x 44 = 1056 data pairs
- Isolated pockets vs. rich opportunities
- Top-down & bottom-up!
Whitepapers have been developed for Management Review and Understanding the Cost of Poor Quality.

We like these topics because either one alone can help to improve Quality, and they can start at opposite ends of an organization.

Management Review allows C-Suite to better understand what is going on inside of their organization, and in fact, the recent update to ISO13485 has additional emphasis on Management Review.

Understanding the Value of Quality (VoQ) can help front-line managers understand where their costs truly are, and can highlight areas for Quality investments.

Because there is so much existing literature about VoQ, much of our focus has been on that topic.
The Value of Quality

**Objective:** To provide industry with a common, comprehensive playbook for measuring and monitoring quality costs and investments to provide a foundation for quality improvement.

**Audience:**

The target audience includes the C-Suite, to get buy-in and drive a strategic view of quality, and the action-taker, who needs to improve quality and/or reduce costs.

**Intended outcome:**

- Broad understanding of the importance that Quality has to every stakeholder group, inside and outside the company
- Ability to quantify and communicate the hidden CoPQ
- Ability to communicate a vision regarding the benefits of good Quality

**Content:**

The paper includes

- Purpose and principles of measuring cost of poor quality and value of quality
- Recommended metrics and dashboard
- Approaches for implementing a Cost of Poor Quality / Value of Quality program
Cost of Poor Quality Metrics

The initial work was to define the Costs of Poor Quality for manufacturers and for other stakeholders impacted by manufacturing quality issues.

**Approach:**

- Representatives from manufacturers, providers and the FDA identified cost drivers.
- Costs were prioritized to identify the metrics for inclusion in the MDIC CoPQ dashboard.
- Benefits of Good Quality metrics were identified however it was determined that challenges related to data collection precluded reliable reporting.
- Investment in Good Quality metrics were identified and included separately in the dashboard.

<table>
<thead>
<tr>
<th>Category</th>
<th>Cost or cost driver</th>
<th>Feasibility</th>
<th>Impact</th>
<th>Description</th>
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<td>Recalls</td>
<td>Plant Recall Costs (Plant recall related Recalls)</td>
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<td>1.0</td>
<td>The costs of Plant Investigation and changes made attributable to preventive compliance solutions.</td>
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<td>Non-plant Recall Costs</td>
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<td>The costs of both recall action (plant related to a Plant) and changes made attributable to preventive compliance solutions.</td>
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<td>Customer service recall labor costs associated with customers receiving incorrect or defective devices.</td>
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<td>Field-related recall costs</td>
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Manufacturers

Providers

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<th>Frequency</th>
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<td>Costs related to inspection findings.</td>
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<td>Hours related to compliance follow-ups may be borne by device manufacturer.</td>
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FDA
The Value of Quality Dashboard

The VoQ Dashboard provides select views for leadership and quality professionals: CoPQ informs leadership of failure costs to inform improvement efforts - investment in quality measures help quality professionals optimize quality spend.
Management Review
The second topic selected as part of the competency initiative was Management Review. The primary deliverable is a Management Review Guidance document.

**Objective:** To provide industry with a template and guidance for conducting effective Management Review.

**Approach:**
The team collected samples of management review charters, reports and SOPs. The samples were analyzed and leading practice gleaned to form the basis of the guidance document.

**Content:**
The guidance document provides
- Background on Management Review
- An outline for the Management Review process
- Examples of Management Review tools
- Advice for getting started
Future Thoughts

The VoQ White Paper, the VoQ Dashboard and the Management Review Guidance document are in draft form. They have been written or developed and are ready for review beyond the original Competency Team. Our request is that group agree to undertake this review and provide comments.

A strong theme in many of our discussions has been making these concepts as clear and adoptable as possible.

The VoQ dashboard is quite comprehensive and has a number of nifty features – this also means that some people may be intimidated by the complexity of it all.

One suggestion is to make a Powerpoint plus an instructional video showing how to use the VoQ dashboard tool.