ASQ 509 Biomed SIG presentation:

FDA and the Case for Quality – 2016 Update

December 15, 2016

William MacFarland
FDA/CDRH/OC/Division of Manufacturing and Quality
Agenda

• Case for Quality
  – Where did we come from?
  – Where are we today?
  – Where are we going?

• A few focused questions for you:
  – Metrics best practices?
  – Now put your regulator hat on...
  – Now put your ecosystem hat on...
Center for Devices and Radiological Health

• One of 5 product-focused FDA review centers
  – Medical Devices
  – Radiological Health (includes Electronic Products)
• Premarket Review
• Postmarket Surveillance
• Compliance & Enforcement
• Science and Standards
CfQ: Where did we come from?

• 2009: Our Center Director, Jeffrey Shuren Ph.D., MD, reviews three class I recalls all from the same firm.

• 2011: Barriers to quality whitepaper
  – The relationship between quality and compliance – historically more focus on compliance than quality
  – Historically underutilized comparative quality information
  – Increasing complexity of devices and use environments with static quality practices

Note¹
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm277272.htm
CfQ: Where did we come from?

- 2012: Regardless of data source, seeing the same issue

We are consistently seeing a high volume of the same issues.

Are we using the right methods to improve device quality?
CfQ: Where did we come from?

• 2012: Good quality practices, not just compliance. Identified several focus areas:
  • Focus on good company practices that lead to quality outcomes
  • Regulatory emphasis on preventive quality practices
  • Encouraging companies to view compliance as one part of achieving quality, not the ultimate goal
  • Focus on identifying and addressing causes of quality failures
CfQ: Where did we come from?

- **2013:** FDA communicating it’s vision for device quality

<table>
<thead>
<tr>
<th>Current state</th>
<th>Future state</th>
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<tr>
<td>- FDA assesses firms’ quality practice against the Quality System Regulation (QSReg)</td>
<td>- FDA continues to assess firms’ compliance with the QSReg</td>
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<td>- FDA’s interaction with firms is mainly focused on compliance</td>
<td>- FDA and industry emphasize that good quality practices drive better products and protect public health</td>
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<td>- Some firms focus on FDA observations rather than focus on underlying causes</td>
<td>- FDA focuses with firms on root cause analysis, designing quality into the product, and optimizing corrective actions</td>
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CfQ: Where did we come from?

• 2014: Recognizing the need for collaboration
  As part of the Case for Quality, collaborate with the AdvaMed, the American Society for Quality (ASQ), Medical Device Innovation Consortium (MDIC) and other members of the ecosystem to identify, develop, and pilot metrics, successful practices, standards, and evaluation tools that will be specific to the medical device industry and focus on assuring product and manufacturing quality.
2015: Alignment within Case for Quality Framework

Library of Successful Practices

Maturity Model

Device Quality Metrics

Competency

Advanced Analytics

Improve Device Quality

FDA
CfQ: Where Are We Today?

- 2016: Case for Quality - A Priority for CDRH

**Goal:** Strengthen product and manufacturing quality within the medical device ecosystem

- By September 30, 2016, develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements.
- By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools.
- By December 31, 2017, propose a voluntary program to recognize independent evaluation of product and manufacturing quality.

To accomplish these goals, CDRH will take several steps including the following:

- Resources permitting, continue to implement the CDRH Quality Management Framework.
- Develop education and training for CDRH staff to facilitate adoption of practices characteristic of a culture of quality and organizational excellence.
CfQ: Where Are We Today?

• 2016 Goal: Strengthen Product and Manufacturing Quality within The Medical Device Ecosystem
  • By September 30, 2016, develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements
  • By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools
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CfQ: Where Are We Today?

Shift the medical device ecosystem to focus beyond regulatory compliance to sustained device quality for improved patient outcomes.
CfQ: Where Are We Today?

- 2016: MDIC Piloted the Maturity Model (CMMI®)
CfQ: Where Are We Today?

• About those CMMI assessments (SCAMPI)

Provides full flexibility: DISCOVER

• Appraisal process
• Model scope
• Organizational scope

Provides less flexibility: AFFIRM

• Appraisal process
• Model scope
• Organizational scope
• Gather evidence for all practices

Least flexible: PROVE

• Appraisal process
• Model scope – required elements for rating
• Organizational scope – sampling rules
• Evidence gathered and considered with affirmations

Maturity level rating only possible for SCAMPI A
CfQ: Where Are We Today?

• 2016: Analytics/Quality Outcomes

1. Gather data from multiple sources
   - Interviews with Value Analysis teams to understand current state
   - Publicly available (e.g., FDA MDRs, PubMed, Healthcare User Forums, Clinicaltrials.gov)
   - Registries

2. Extract information across seven quality domains
   - Safety
   - Effectiveness
   - Reliability
   - Usability
   - Compatibility
   - Patient Experience
   - Availability

3. Generate and share dashboards
   - Hospital Value Analysis Committees
   - Manufacturers

4. Gather Voice of Customer feedback
   - Surveys
   - Focus group sessions

5. Report out observations and recommendations
   - Ways to improve data robustness
   - Operating model to scale and sustain access to this information in the future
CfQ: Where Are We Today?

- Quality Outcomes – plans for dashboards

**Overview**
Intended to orient user and explains the quality domains, the data sources, KPIs, and gold, silver, bronze rankings. Also describes and explains how rankings are portrayed visually.

**Dashboard 1**

**Dashboard 2**

**Dashboard 3**

**Dashboard 4**

**Rankings by Data Source**
Displays a table of KPI rankings by company and at individual data source level. Each source is identified whether quality of data is high, medium, low.

**Rankings by Manufacturer**
Collapses the individual data sources and displays a table of KPI rankings by company. Individual data sources are aggregated using weighted average.

**Rankings by Product**
Displays a table of KPI rankings by company and product, similar to third dashboard.
CfQ: Where Are We Today?

• 2016: Proposed a Pilot
CfQ: Where Are We Today?

- Pilot on hold – how do we know these are the right metrics?

### Metric Subcategory

<table>
<thead>
<tr>
<th>Metric Category</th>
<th>A. Approach to Control</th>
<th>B. Trending</th>
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<tbody>
<tr>
<td>I. MDIC QS</td>
<td>-</td>
<td>Table 1</td>
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<tr>
<td>• Preproduction</td>
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<td>• Production</td>
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<td>• Postproduction</td>
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<td>II. Device Specific</td>
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<td>• Characteristic A</td>
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<td>• Characteristic D</td>
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Draft metrics language:
CfQ: Where Are We Today?

Are device companies Maturity Capability continuously improving, maintaining, decreasing?
Are the device companies working to meet device S&E, Reliability, Availability of products for coordinating entities?
Case for Quality (CfQ)

Maturity Model
- CMMI® - SCAMPI C, SCAMPI A

Metrics
- Pre-Production – Total # changes / Total # of projects
- Production - Total # units mfg RFT / Total # units started
- Post Production – Index

Advances Analytics - VAC
- Safety
- Effectiveness
- Reliability
- Patient Satisfaction
- Usability
- Availability
- Compatibility

Competencies
- Project Management
Focused Discussion: Metrics

• What are the best practices for defining quality metrics that have utility:
  – on “the shop floor”;
  – in business management reviews; and,
  – at the corporate level?
Focused Discussion: Metrics

• Put your FDA hat on. At what point do you need to have ownership over:
  – Defining quality metrics;
  – Reviewing quality metrics;
  – Having access to the quality metrics?

• Do you care about:
  – Business focused metrics that have some relevance to quality (e.g. cost of rework)?
Focused Discussion: Metrics

• Put your device ecosystem hat on. To what extent are you interested in:
  – Leading indicators of quality, not just lagging indicators.
  – Quality metrics that are specific to a specific device (e.g. XYZ model of wheelchair)
    • Vs. metrics that are generalized across a device type (e.g. powered wheelchairs)
    • Vs. metrics that are generalized across all types of devices
Contact Information

Bill MacFarland
Division of Manufacturing and Quality
Tel: 301-796-5547
Email: william.macfarland@fda.hhs.gov,

FDA, Center for Devices and Radiological Health
Office of Compliance
Division of Manufacturing and Quality
Building WHITE OAK #66
10903 New Hampshire Avenue
Silver Spring, MD 20993

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BACKUP SLIDES
CfQ: Where Are We Today?

• Value Analysis Teams: “What is quality?”

**Effectiveness:** Device produces the effect intended by the manufacturer relative to the medical condition(s).

**Patient Satisfaction:** Device was perceived to meet or exceed patient expectations of usability and outcome.

**Availability:** Device is available to fill first request orders.

1. **Safety:** Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.

2. **Reliability:** Device system or component is able to function under stated conditions for a specified period of time.

3. **Usability:** Device minimizes the risk of user errors by patients or clinicians.

4. **Compatibility:** Device is compatible with related devices or drugs, the use environment or relevant standards.
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<th>Phase/Metric Name</th>
<th>Metric Calculation</th>
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| **Pre-Production:** Design Robustness Indicator | total # of product changes  
  total # of products with initial sales in the period |
| Assess the number of product changes that are related to product or process inadequacies or failures |
| **Production:** Right First Time Rate | # of units mfg. without non-conformances  
  # of units started |
| Assess the number of production failures related to product and process inadequacies or failures |
| **Post-Production:** Post-Market Index | Index:  
  Complaints * (0.20) + Service Records * (0.10) +  
  Installation Failures * (0.20) + MDRs * (0.20) +  
  Recalls (units) * (0.20) + Recalls (total) * (0.10) |
Concept for Score Levels – for Pilot

Top level: No inspection

Quality Floor:
Level 1 Inspection

Everyone Else:
Level 2 Inspection
CDRH Device Metrics – the origins

Baldrige Results Scoring Methodology

HACCP CCP Concept

2 Scoring Subcategories
- Approach to Control
- Trending