Case for Quality Open Forum
May 10, 2016

WebEx and live studio participation at the Graduate Center of St. Cloud State University (SCSU)
1. Introductions and the Momentum for the Case for Quality  
(Dwight Abouhalkah via Webinar and Jackie Torfin on the Campus of SCSU)  
9:00-9:10am

2. CfQ conversation with a healthcare provider (Dr. Michael Ruhlen)  
9:10-9:45am

3. Case for Quality: Question for the audience (Dwight/Jackie)  
9:45-9:50am

4. The Four Case for Quality Working Groups  
9:50-11:00am

   • Jodie Bastian, the Maturity Model, Marla Phillips, Metrics,  
   Mike Schiller, Advanced Analytics, and Pat Baird, Competency  
   →The WG purpose, current status, where we are going – pilots, future plans and timelines

5. Call to action – Forum attendees to dialogue with the Working Groups  
11:00-11:20am

“If the working groups could accomplish one thing for me or my stakeholder group, it would be…”

6. Case for Quality at the FDA (Bill MacFarland)  
11:20-11:50am

7. Closing Remarks (Dwight)
Why FDA Launched Case for Quality

• FDA found:
  − Repetitive quality issues among device manufacturers
  − Stagnant data regarding the quality issues

• The Movement Begins:
  − FDA engaged McKinsey to analyze device quality issues. Findings published in the 2011 “Understanding Barriers to Quality” white paper
  − FDA Developed Case for Quality Forums
  − September 2014 FDA awarded contract to MDIC for CfQ project
  − MDIC: the first public-private partnership created with the sole objective of advancing medical device regulatory science.
  − Since 2014 MDIC has driven creation of models, methods and metrics to enable a new culture of quality across medical device ecosystem.
The Case for Quality

• The FDA and medical technology companies, healthcare providers, payers and patients should collaborate to inspire adoption of quality practices that, when present in device design and production, enhance patient safety and access to high quality medical devices.

• Elevate and shift the device sector focus from regulatory compliance to a state of sustained product quality.

• Create continuous engagement with a broad set of stakeholders to advance device product quality.
The Case for Quality Stakeholders

- Consumers/Patients
- Healthcare Payers
- Healthcare Providers
- FDA and Medical Device Industry
Four Working Groups: Focusing the Movement

Device Quality Metrics

Maturity Model

Competency

Advanced Analytics
Case for Quality Open Forum

A Conversation about Healthcare Teamwork and Quality

Michael Ruhlen, MD, MHCM, FAAP, FACHE

May 10, 2016
Quality Leadership
Healthcare is Now a Team Sport
YOUR Teams

Cardiorespiratory monitors
IV smart pumps
Central lines
Left ventricular assist devices
Anesthesia equipment
Respiratory therapy devices / tubing
Surgical instruments
Cardiac rehabilitation equipment

Implantable pacemakers
BP monitors
Cardioversion equipment
Foley catheters
IV devices
Pulse oximeters
Fluoroscopy lab equipment
Medical laboratory diagnostic equipment
YOUR Teams
YOUR Teams
Dear CVICU team,
You may not remember us.....
Dear CVICU team,
You may not remember us, but my dad was a guest of yours in September-October of 2014........
Dear CVICU team,
You may not remember us, but my dad was a guest of yours in September-October of 2014........
Dear CVICU team,
You may not remember us, but my dad was a guest of yours in September-October of 2014........
He had emergency quadruple bypass surgery and was sedated in CVICU for almost a month. We know now that he didn’t have good odds of making it through at all.
He had emergency quadruple bypass surgery and was sedated in CVICU for almost a month. We know now that he didn’t have good odds of making it through at all.
He had emergency quadruple bypass surgery and was sedated in CVICU for almost a month. We know now that he didn’t have good odds of making it through at all.
But, because of you and the amazing care you gave to him (and to us!), he beat the odds and is still with us today.
But, because of you and the amazing care you gave to him (and to us!), he beat the odds and is still with us today.
But, because of you and the amazing care you gave to him (and to us!), he beat the odds and is still with us today.
He was able to walk me down the aisle on April 10, 2016 and I will never be able to thank you enough for that. You gave him back to us and you will always have a special place in our hearts.
We are forever grateful........
Medical Device Innovation Consortium (MDIC) *proposed* Case for Quality Framework

**The Questions We are all Asking**

- I don't know exactly what product quality even means*
- OK, thanks for telling me what it means... how do I recognize it, measure it, know if I have it?*
- Daunting! How do I figure out the practical 'know how' to implement this well in my company?*
- How can we help the business people appreciate the value of quality so they will support our efforts?*
- Is FDA going to support this approach?*

**Case for Quality Framework**

Initiated from FDA's 2012 Whitepaper: "Understanding the Barriers to Device Quality"

**产品质量定义**

- 如何测量
- 如何实施

**如何推导价值**

- 如何从合规转变为质量文化

**您的输入是需要的**

As you listen and interact today...

- What are your reactions?
  - Framework
  - Projects
  - Approach to working together
- What could be added, adjusted, re-prioritized?
- Any other suggestions?
- Any way you want to be more involved?
The Questions We are all Asking

“I don’t know exactly what product quality even means”

“OK, thanks for telling me what it means…how do I recognize it, measure it, know if I have it?”

“Daunting! How do I figure out the practical ‘know how’ to implement this well in my company?”

“How can we help the business people appreciate the value of quality so they will support our efforts?”

“Is FDA going to support this approach?”
Case for Quality Framework

- How to Measure
  - MDIC/Xavier Metrics
  - MDIC Maturity Model

- How to Implement
  - Advamed Library of Successful Quality Practices
  - MDIC Competency Training

- Product Quality Definition
  - Advamed/FDA Definition

- How to Derive the Value
  - MDIC Advanced Analytics: Customer Based Scorecard
  - FDA Data Transparency

- How Evolve Culture from Compliance to Quality
  - FDA Library of Practices
  - FDA CTQ Battery Pilot
  - FDA Inspectional CTQ Handbooks
Response to “Compliance”
Response to “Collaboration”
Questions for Dr. Ruhlen…?
Audience to think about…

“If the working groups could accomplish one thing for me or my stakeholder group, it would be…”
Case for Quality Open Forum
May 10, 2016

The Four Working Groups

Jodie Bastian, Marla Phillips, Mike Schiller, Pat Baird
MDIC Open Forum
Quality System Maturity Model Update

May 10, 2016
Background / Objective: Quality System Maturity Model

Background

In May 2015, MDIC presented research on current Maturity Models established across various industries and provided recommendations regarding how specific options can be adopted by MDIC stakeholders including, but not limited to, industry members and the Food & Drug Administration. As a result of this research, a quality system maturity model work stream was formed to develop and conduct a Quality System Maturity Model Proof of Concept (POC) for the medical device industry that is focused on promoting product quality and patient safety.

Objective

The objective of this proof of concept is to evaluate the feasibility of a Quality System Maturity Model that can be applied across small, medium, and large medical device organizations, product types and classifications. This effort will also help gain an understanding of the effort required to develop the overall model and serve as an input into the Change Adoption Plan.
MDIC Maturity Model Proof Of Concept (POC) Program

What the POC is:

A proof-of-concept to understand at a high-level if the applicability of the CMMI model consistently across an industry is feasible, identify any issues with assessors/industry/FDA, and develop a plan for the full scale deployment.

Focused on Manufacturing Quality (and may be further limited to a sub-process) to develop a working model of CMMI for Medical Devices for the POC

Structured to provide training and planning for the POC companies - plans are to provide sufficient training on CMMI to POC companies related to the POC area, provide time for the POC companies to collect requested information, and host the “assessment” at an off-site location with CMMI, MDIC, FDA, and POC company

What the POC is not:

A complete CMMI assessment of all areas at the assessed company, business, product, or plant. This will not be an official assessment as this is structured as a limited proof-of-concept.

A formal FDA “audit” or “assessment”; engagement guidelines are being drafted to facilitate open communication between the companies and the FDA while limiting the scope of how the FDA can use the discoverable information.
Industry Benefits

The MDIC Quality System Maturity Model is structured to advance the overall Case for Quality (CfQ) program, including quantifying success and strengthening relationships within the business and with regulators.

**Partnership with Business**

The maturity model will provide for better partnership with the business. As the maturity model is tested, the elements related to the business will be explored and methods to progress the relationship developed.

**Leadership Involvement**

Participation in Maturity Model development will provide a platform for participants to interact with their leadership to develop a clear narrative around the benefit of quality and the way to progress product quality and safety.

**Behavioral Shift**

Behavior shift, evidenced by companies and regulators progressing through the maturity model for the right reasons and allowing more transparency with regulators.

**Improved Business Operations**

Improved business operations, evidenced by improved internal metrics, proven ROI, and ability to proactively invest in improving quality.

**Patient Safety / Product Quality**

Improved oversight of quality and ability to shift focus from compliance-driven activities to enable more focus on improvement of product quality and patient safety.

**FDA Interaction**

Facilitate direct interactions with the FDA in a non-inspection setting:

- Influence over the “next generation” of how the FDA interacts with industry in a more collaborative manner
- Provide inputs into the potential regulatory benefits of high maturity. Potentially including reduced pre-market approvals, fewer routine inspections, etc.

**Product Quality Improvement**

Improved oversight of quality and ability to shift focus from compliance-driven activities to enable more focus on improvement of product quality and patient safety.
CMMI model is being built out for selected POC areas

Communications for potential POC participants are developed and are being rolled out to finalize participation

Rules of Engagement between Industry and the FDA are drafted and in the process of official sign-off

Potential benefits of model use are drafted
Alignment within Case for Quality framework

Library of Successful Practices

Maturity Model

Device Quality Metrics

Competency

Advanced Analytics

Improve Device Quality
How we measure success

Near term success will be measured by our ability to complete two series of proof-of-concept assessments in 2016 with meaningful sets of participants and receive feedback that will both promote continued interest and enthusiasm within the industry and FDA and serve as an input into the development of the longer term roadmap to complete the maturity model.

- Development of open communication pathways with regulators, evidenced by more proactive discussions between industry and regulators and fewer formal regulatory actions
- Improved quality of products, evidenced by fewer regulatory actions, fewer recalls/field actions, fewer device failures or issues
- Industry-wide acceptance, evidenced by multiple firms participating in the maturity model program
- Behavior shift, evidenced by companies and regulators progressing through the maturity model for the right reasons and allowing more transparency with regulators
- Improved business operations, evidenced by improved internal metrics, proven ROI, and ability to proactively invest in improving quality
Questions for Jodie…?
FDA/Xavier University

Medical Device

Quality Metrics Initiative

May 10, 2016
Presentation Objectives

1. Purpose and Outcome
2. Process
3. Timelines
4. Deliverables
Purpose:
To provide a system of metrics across the Total Product Lifecycle that enables companies to assess and improve the robustness of their critical-to-quality practices, and therefore, risk to product quality.

Outcome:
Identification of quality system metrics that will inform decisions and trigger action in a way that shifts the Right-First-Time mentality closer to the initial days of development. Final report on-target for June 2016.

How?
Lead a diverse team of industry professionals and FDA officials through a rigorous methodical process with outcomes linked to patient safety, design robustness, process reliability, quality system robustness, and failure costs.
Rigorous TPLC Approach

Enterprise-Wide Continual Improvement

- Pre-Production
- Production
- Post-Production

- Transfer

- R&D Continual Improvement & Risk Mgmt.
- Production Continual Improvement & Risk Mgmt.

- 35+ team members
- 2 years of work continuity
- 97 Gold/Silver Activities
- 208 Survey Respondents
- C&E Matrix of 125 ideas
- 17 measures identified
## Timeline and Process

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kick-off</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11 Critical Systems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>97 Gold/Silver Activities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>C&amp;E Matrix of 125 Ideas</strong></td>
<td></td>
<td>Finalization of 17 Measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Selection of Top 3 Measures</strong></td>
<td></td>
<td></td>
<td></td>
<td>Pareto Analysis and Team Voting</td>
</tr>
<tr>
<td><strong>Conversion of Top 3 Measures into Metrics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>“Best Practices” Documents</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MDIC Adoption</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First</td>
<td>Last</td>
<td>Title</td>
<td>Company</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>----------------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Paul</td>
<td>Andreassi</td>
<td>Vice President of Quality &amp; Regulatory</td>
<td>Fisher &amp; Paykel Healthcare</td>
<td></td>
</tr>
<tr>
<td>Pat</td>
<td>Baird</td>
<td>Director, Engineering</td>
<td>Baxter Healthcare</td>
<td></td>
</tr>
<tr>
<td>Anupam</td>
<td>Bedi</td>
<td>Director of Quality</td>
<td>AtriCure</td>
<td></td>
</tr>
<tr>
<td>Pankit</td>
<td>Bhalodia</td>
<td>Director, Health Industries Advisory PLS</td>
<td>PwC</td>
<td></td>
</tr>
<tr>
<td>Kankshit</td>
<td>Bheda</td>
<td>Manager, Health Industries Advisory PLS</td>
<td>PwC</td>
<td></td>
</tr>
<tr>
<td>Steve</td>
<td>Binion</td>
<td>Director Regulatory Affairs/Corporate Clinical Development</td>
<td>BD</td>
<td></td>
</tr>
<tr>
<td>Robin</td>
<td>Blankenbaker</td>
<td>Divisional Quality Operations Leader</td>
<td>W.L. Gore &amp; Associates</td>
<td></td>
</tr>
<tr>
<td>Gina</td>
<td>Brackett</td>
<td>Compliance Officer</td>
<td>FDA</td>
<td></td>
</tr>
<tr>
<td>Patrick</td>
<td>Caines</td>
<td>Dir, Quality &amp; Global post market surveillance</td>
<td>Baxter Healthcare</td>
<td></td>
</tr>
<tr>
<td>Tony</td>
<td>Carr</td>
<td>Vice President, Global Quality Systems</td>
<td>Boston Scientific</td>
<td></td>
</tr>
<tr>
<td>Kara</td>
<td>Carter</td>
<td>Senior Director, QA Operations</td>
<td>Abbott Vascular Division</td>
<td></td>
</tr>
<tr>
<td>Vizma</td>
<td>Carver</td>
<td>Founder and CEO</td>
<td>Carver Global Health</td>
<td></td>
</tr>
<tr>
<td>Ryan</td>
<td>Eavey</td>
<td>Senior Manager, Quality Systems</td>
<td>Stryker</td>
<td></td>
</tr>
<tr>
<td>Joanna</td>
<td>Engelke</td>
<td>Senior Vice President Global Quality</td>
<td>Boston Scientific</td>
<td></td>
</tr>
<tr>
<td>Chris</td>
<td>Hoag</td>
<td>Director of Global CAPA and Quality eSystems</td>
<td>Stryker</td>
<td></td>
</tr>
<tr>
<td>Frank</td>
<td>Johnston</td>
<td>Corporate Director, Regulatory Compliance</td>
<td>BD</td>
<td></td>
</tr>
<tr>
<td>Jonathan</td>
<td>Lee</td>
<td>Senior Associate, Health Industries Advisory PLS</td>
<td>PwC</td>
<td></td>
</tr>
<tr>
<td>First</td>
<td>Last</td>
<td>Title</td>
<td>Company</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>--------------------------------------------------------------</td>
<td>----------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Bill</td>
<td>MacFarland</td>
<td>Director, Division of Manufacturing Quality</td>
<td>FDA</td>
<td></td>
</tr>
<tr>
<td>Kristin</td>
<td>McNamara</td>
<td>Senior Advisor</td>
<td>FDA</td>
<td></td>
</tr>
<tr>
<td>Rhonda</td>
<td>Mecl</td>
<td>Supervisory CSO</td>
<td>FDA</td>
<td></td>
</tr>
<tr>
<td>Brian</td>
<td>Motter</td>
<td>VP Quality and Compliance, Diabetes</td>
<td>J&amp;J MD&amp;D</td>
<td></td>
</tr>
<tr>
<td>Ravi</td>
<td>Nabar</td>
<td>Sr. Director Supplier Quality Management</td>
<td>Philips</td>
<td></td>
</tr>
<tr>
<td>Steven</td>
<td>Niedelman</td>
<td>Lead Quality Systems and Compliance Consultant</td>
<td>King &amp; Spalding LLP</td>
<td></td>
</tr>
<tr>
<td>Pete</td>
<td>Palermo</td>
<td>VP Quality Assurance</td>
<td>CR Bard</td>
<td></td>
</tr>
<tr>
<td>Marla</td>
<td>Phillips</td>
<td>Director</td>
<td>Xavier University</td>
<td></td>
</tr>
<tr>
<td>Greg</td>
<td>Pierce</td>
<td>President and Founder</td>
<td>Engisystems</td>
<td></td>
</tr>
<tr>
<td>Susan</td>
<td>Rolih</td>
<td>Executive Vice President, Regulatory &amp; Quality Systems</td>
<td>Meridian Bioscience, Inc.</td>
<td></td>
</tr>
<tr>
<td>Joe</td>
<td>Sapiente</td>
<td>VP Global Quality Operations</td>
<td>Medtronic</td>
<td></td>
</tr>
<tr>
<td>Benjamin</td>
<td>Smith</td>
<td>Vice President, Global Quality System &amp; Compliance</td>
<td>Biomerieux</td>
<td></td>
</tr>
<tr>
<td>Isabel</td>
<td>Tejero</td>
<td>Quality System Workgroup Lead CSO</td>
<td>FDA</td>
<td></td>
</tr>
<tr>
<td>Shelley</td>
<td>Turcotte</td>
<td>WW Director Quality Information Systems</td>
<td>DePuy Synthes</td>
<td></td>
</tr>
<tr>
<td>Sam</td>
<td>Venugopal</td>
<td>Partner, Health Industries Advisory PLS</td>
<td>PwC</td>
<td></td>
</tr>
<tr>
<td>Marta</td>
<td>Villarraga</td>
<td>Principal Biomedical Engineering</td>
<td>Exponent</td>
<td></td>
</tr>
<tr>
<td>Monica</td>
<td>Wilkins</td>
<td>Divisional Vice President of Quality &amp; Business Support</td>
<td>Abbott</td>
<td></td>
</tr>
</tbody>
</table>
## Top 3 Metrics

<table>
<thead>
<tr>
<th>Phase/Metric Name</th>
<th>Metric Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre- Production:</strong> Design Robustness Indicator</td>
<td></td>
</tr>
</tbody>
</table>
Assess the number of product changes that are related to product or process inadequacies or failures  

\[
\text{total # of product changes} \div \text{total # of products with initial sales in the period}
\]
| **Production:** Right First Time Rate |  
Assess the number of production failures related to product and process inadequacies or failures  

\[
\text{# of units mfg. without non-conformances} \div \text{# of units started}
\]
| **Post- Production:** Post-Market Index |  
Assess an aggregate of post-market indicators with root causes of product or process inadequacies or failures  

\[
\text{Index:}
\text{Complaints} \times 0.20 + \text{Service Records} \times 0.10 + \text{Installation Failures} \times 0.20 + \text{MDRs} \times 0.20 + \text{Recalls (units)} \times 0.20 + \text{Recalls (total)} \times 0.10
\]
**Purpose:** To help organizations understand how best to use the output from the metrics to inform decisions and trigger actions

- Output can be used to understand root causes
- Output can be combined with the output of other metrics to understand a more holistic picture, analyze trends, etc.
- Goal is to provide a feedback loop to improve systems that allowed the failure to occur originally
- Work to improve the systems from the earliest point possible

**Timeline:**
- **October:** Kick-off and Champions identified
- **November:** Team members begin drafting and soliciting input.
- **December:** Gathering input - Includes feedback from firm SMEs
- **January:** Champions present key input received
- **March:** Champions present drafted processes to team members
- **June:** Recommended process finalized - Includes Pilot Lessons Learned
PwC Pilot Study

Pilot Study Goal: to demonstrate that the metrics are sensitive enough to differentiate between varying levels of product quality within a single company

- 8 companies are enrolled
- Each company is conducting a 2 year retrospective pilot for all 3 metrics
- PwC is assessing the effort level involved in data collection
- PwC has generated and is testing a number of hypotheses to understand correlations between metric results and product quality
- Only in-company comparisons can be made, since company-to-company comparisons involve variables that could lead to false conclusions
1. List of 97 Gold and Silver activities that are above compliance across 11 critical systems and 3 phases of production

2. Identification of 17 measures linked to impact to patient safety, design robustness, process reliability, quality system robustness, and failure costs

3. Conversion of 3 measures into defined metrics

4. 2 year Retrospective Pilot Study completion and analysis

5. “Best Practices” for how to implement Metric Output
Questions for Marla…?
Case for Product Quality Outcomes Analytics

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Align › Achieve › Accelerate

May 10, 2016
Our multidisciplinary team
Stakeholders can benefit from access to medical device quality information…

…yet there is no formal feedback loop to reward the market for quality
Our analytics pilot seeks to…

Determine if cross-manufacturer comparative analysis of quality for knee and defibrillator implants is feasible and effective for value analysis team purchase decisions.
Our definition of medical device quality consists of seven domains

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

5. **Compatibility**: Device is compatible with related devices or drugs, the use environment or relevant standards.

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

7. **Effectiveness**: Device produces the effect intended by the manufacturer relative to the medical condition(s).
Ways to improve data robustness

Operating model to scale and sustain access to this information in the future

1. Gather data from multiple sources
   1. Publically available (e.g., FDA MDRs, PubMed, Healthcare User Forums, Clinicaltrials.gov)
   2. Registries
   3. Hospitals

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

Our journey
## Our (anticipated) timeline

<table>
<thead>
<tr>
<th>Activities</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plan</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Finalize pilot plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Onboard analytics vendor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Develop participant guide, data sharing agreements and feedback survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Confirm pilot participants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Analyze and publish dashboards</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Analyze <strong>FDA MDR and Recall</strong> data and publish results</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Collect feedback on MDR and Recall analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Analyze <strong>publicly available data</strong> and publish Comparative Quality Report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Analyze <strong>registry and hospital data</strong> and update Comparative Quality Report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Summarize and recommend</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Collect <strong>feedback</strong> on the Comparative Quality Report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Summarize pilot results and <strong>recommendations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Analysis of MDR and Recall data shared with VACs
- Comparative Quality Report shared with VACs
- Feasibility and Effectiveness Report

TBD
The art of the possible for medical device quality analytics

A comparative quality summary report would allow users to quickly compare products along multiple quality categories.

Survival analysis as a measure of product reliability.

Cluster text to identify common themes related to product safety and effectiveness.

Sentiment analysis of text (e.g. from healthcare user forums) to gain insights into patient satisfaction and device effectiveness.

For illustrative purposes only – pilot dashboards may vary.
Questions for Mike...?
Competency-Development Project
What is the Competency-Development Project?

**Purpose:** The purpose of this project is to improve medical device Quality by improving overall competency, awareness, and understanding across key stakeholders that have the most influence on device Quality.

**Problem Description:** Inconsistent understanding of what comprises device Quality, and a lack of clarity of other stakeholder’s perspectives, needs, and constraints, is a contributing factor to inefficiencies and risks across the medical device industry.

**Mission Statement:** Improve device Quality and patient safety by promoting programs where regulators, payers, providers, and industry professionals learn together in a collaborative environment. Move beyond cost-containment and compliance to a more holistic realization of Quality aligned with stakeholder’s needs.
The Plan

1. Determine Competency gaps
2. Prioritize gaps
3. Choose pilot subjects
4. Collect information about subjects
5. Develop whitepaper, job aides, training materials, etc
6. Publish & promote
Step 1. Determine Gaps - Competency Heat Map

We outlined 24 competencies and their importance in 44 roles covering Manufacturers, Regulators, Patients, Payers, and Providers

We assessed the ideal & current state for these competencies (1056 pairs)

Greatest opportunity is with Manufacturers & Providers, to improve Execution and understand the Value of Quality.
Step 2: Prioritize Gaps

<table>
<thead>
<tr>
<th>Committee Ranking of Gaps</th>
<th>Gap Size</th>
<th>Votes</th>
<th>Forum Survey of Relevance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding the difference between compliance and Quality</td>
<td>-1.1</td>
<td>18</td>
<td>Understanding Value: Understand Cost of Poor Quality</td>
</tr>
<tr>
<td>Proactive approach to Quality (vs. reactive)</td>
<td>-1.1</td>
<td>12</td>
<td>Execution: Proactive approach to Quality (vs. reactive)</td>
</tr>
<tr>
<td>Understand cost of non-compliance?</td>
<td>-1.0</td>
<td>10</td>
<td>Execution: Knowing what Quality looks like</td>
</tr>
<tr>
<td>What makes a good management review? (focus on causes not symptoms) (look at updated 13485)</td>
<td>-1.0</td>
<td>9</td>
<td>Regulatory Awareness: Understanding the major technologies</td>
</tr>
<tr>
<td>Knowing what Quality looks like</td>
<td>-1.0</td>
<td>8</td>
<td>Regulatory Awareness: Understanding of applicable regulations and how to comply</td>
</tr>
<tr>
<td>Dealing with information overload - how do you communicate the important things upwards</td>
<td>-0.9</td>
<td>8</td>
<td>Soft Skills: Communication skills</td>
</tr>
<tr>
<td>Understanding Cost vs. Value proposition (targeted cost reduction efforts can eventually lead to higher cost over long term.)</td>
<td>-0.9</td>
<td>7</td>
<td>Execution: Understanding the difference between compliance and Quality</td>
</tr>
<tr>
<td>Understand appropriate implementation of Quality Systems</td>
<td>-0.9</td>
<td>6</td>
<td>Regulatory Awareness: What makes a good management review?</td>
</tr>
<tr>
<td>Understand Cost of Poor Quality (direct costs, marketshare, cost of CAPA, cost of FCA)</td>
<td>-0.9</td>
<td>5</td>
<td>Regulatory Awareness: Understand appropriate implementation of Quality Systems</td>
</tr>
</tbody>
</table>

We compared top gaps from our internal survey to results from the Oct 8th meeting, and found a good correlation.
Step 3: Choose Pilots

We are moving forward on the topics of Management Review and Understanding the Cost of Poor Quality.

We like these topics because Management Review is an area that is very tactical – we could immediately start seeing improvements, and CoPQ is very strategic – very impactful but might take awhile to see improvements.

2016 Deliverables:

- Management Review:
  - Draft MR guidance, w/examples and job aides
  - Webinar training based on guidance
  - “TedTalk” (focus on the sell)

- Awareness of Cost of Poor Quality:
  - Draft CoPQ guidance, w/examples and job aides
  - Webinar training based on guidance
  - Panel discussion @ AdvaMed
  - Executive Forum (video)
### Step 4. Collect Information about Subjects

#### Step 4.1 Identify Categories and Cost drivers

<table>
<thead>
<tr>
<th>Category</th>
<th>Cost or cost driver</th>
<th>Feasibility</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recalls</td>
<td>Non-plant Recall Costs</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Recalls</td>
<td>Plant Recall Costs (Plant mfg. related Recalls)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Remediation</td>
<td>Consulting costs - temps, etc</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Rework</td>
<td>Retraining time and expense</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Recalls</td>
<td>Customer service Recall Costs (Labor)</td>
<td>1.3</td>
<td>1.0</td>
</tr>
<tr>
<td>Recalls</td>
<td>Field-related recall costs</td>
<td>1.3</td>
<td>1.0</td>
</tr>
<tr>
<td>Recalls</td>
<td>Reimbursement for extra procedures for implanted devices</td>
<td>3.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Distribution</td>
<td>Inventory expired / sent to scrap</td>
<td>1.0</td>
<td>1.3</td>
</tr>
<tr>
<td>Rework</td>
<td>Scrap of expired materials</td>
<td>1.0</td>
<td>1.3</td>
</tr>
<tr>
<td>Rework</td>
<td>Scrap of obsolete materials</td>
<td>1.0</td>
<td>1.3</td>
</tr>
<tr>
<td>Complaints</td>
<td>Cost to investigate complaints</td>
<td>1.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Holds</td>
<td>QA Holds at the DC’s (Labor and Freight)</td>
<td>1.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Opportunity Costs</td>
<td>Company brand perception</td>
<td>3.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Opportunity Costs</td>
<td>Cost of regaining lost customers (measureable campaigns)</td>
<td>3.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Opportunity Costs</td>
<td>Loss of income (general)</td>
<td>3.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Opportunity Costs</td>
<td>Lost sales</td>
<td>3.0</td>
<td>1.5</td>
</tr>
</tbody>
</table>

#### Step 4.2 Rank them for the Feasibility of collecting data and the potential impact of a change.
Step 5. Develop Whitepaper…

The target audience includes the C-Suite, to get buy-in, and the action-taker, who needs to improve quality and/or reduce costs. The intended outcome is a broad understanding of the importance that Quality has to every stakeholder group, understand how to quantify and communicate the hidden CoPQ, and to be able to communicate a vision regarding the benefits of good quality.

The major sections of the whitepaper will cover:

“The hook”
Problem Statement
Vision for Industry
Value Proposition
Process Steps
Getting Started
Impact to Patient Safety
Parting Thoughts
The whitepaper will provide examples to illustrate our approach to CoPQ. To make the examples consistent, and to help jump-start their own projects, we have developed an example dashboard in the form of a multi-tab spreadsheet. We realize that some people will skip reading the whitepaper and will immediately jump into the dashboard, so we are trying to make it a standalone tool.
Cost of Quality Management
Strategic Path to Business Excellence

Cost of Quality Indicator - 77%
Baseline: 80%  Target: 30%

Cost as a % of Sales Indicator – 20%

Total Cost ($/time period) Indicator - $100K

This section of the dashboard represents a single indicator of CoQ monitored by the Management on periodic basis. The cost targets will be calculated using a weighted method and based on each cost category level represented in the speedometer charts below. By clicking on the hyperlink (arrow in the diagram), the user may access the cost information (scorecard, charts, raw data) to determine next steps.

The CoQ indicators will provide a user-friendly visual to determine if further actions are needed. Based on the analysis, actions that had been taken to reduce costs. Each cost category will be based on the process capability, quality issues, design robustness, and marketing KPIs.

Estimated Savings ($)
Reactive vs Proactive State
Cost Categories Overtime
Customer Lost Sales Model
Customized / Various CoQ KPIs

These charts represent the current state for company quality management. Based on the outcome, the company should take actions according to the recommendations provided. Potential actions will be listed under the chart.

Cost of Poor Quality
Cost of Good Quality

Controversial Costs
Internal Failure Costs
External Failure Costs

Appraisal Costs
Prevention Costs
Step 5. ..and Develop Job Aid

Conclusion: The prevention costs are low compared to Internal and External Failure costs. This is an indication that the company is loosing money due to multiple product issues and follows reactive state of control rather than proactive.
Management Review

With regards to **Management Review**, we expect to be able to leverage some of the existing work from the Metrics team, particularly around what to measure and possible confounding aspects of the measures (e.g. how can you get a false sense of confidence?)

Management Review will follow a similar process to develop a whitepaper and job aides.

Additionally, ISO 13485:2016 has an updated section regarding Management Review, and this will be supplemented by a guidebook that is expected to be published in early 2017.
## Key Deliverables / Milestones

<table>
<thead>
<tr>
<th>Milestones / Deliverable</th>
<th>Due Date</th>
<th>Percent Complete</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop high-level suggestions</td>
<td>3 Dec 15</td>
<td>100 %</td>
<td>C</td>
</tr>
<tr>
<td>Elaborate suggestions for low-hanging fruit</td>
<td>17 Dec 15</td>
<td>100 %</td>
<td>C</td>
</tr>
<tr>
<td>Plan Phase 2</td>
<td>7 Jan 16</td>
<td>100 %</td>
<td>C</td>
</tr>
<tr>
<td>CoPQ: Develop complete list of costs of poor quality</td>
<td>8 Mar 16</td>
<td>100 %</td>
<td>C</td>
</tr>
<tr>
<td>CoPQ: Define CoPQ Dashboard</td>
<td>31 Jul 16</td>
<td>60%</td>
<td>G</td>
</tr>
<tr>
<td>MR: Develop Guidance document</td>
<td>31 Jul 16</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>AdvaMed presentation</td>
<td>17 Oct 16</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

## Results / Accomplishments

- Have narrowed focus to 1 tactical (Management Review) and 1 strategic (Cost of Poor Quality) topic. Identified & ranked potential interventions to address these issues.
- For Management Review, developed a draft list of deliverables and outlined a project plan regarding the content and develop activities around those deliverables.
- For Cost of Poor Quality, developed an initial list of cost drivers for device manufacturers, health authorities (FDA) and provider groups.
- Developed a draft abstract for AdvaMed 2016 – a Cost of Poor Quality panel discussion.

## Issues/Risks / Actions

<table>
<thead>
<tr>
<th>Activity</th>
<th>Target Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management Review: Develop initial list of data and cultural metrics</td>
<td>19 May 16</td>
</tr>
<tr>
<td>CoPQ: Develop whitepaper</td>
<td>4 Jun 16</td>
</tr>
</tbody>
</table>

N/A = N/A
<table>
<thead>
<tr>
<th>First</th>
<th>Last</th>
<th>Title</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joe</td>
<td>Sapiente</td>
<td>VP Global Quality Operations</td>
<td>Medtronic</td>
</tr>
<tr>
<td>Pat</td>
<td>Baird</td>
<td>Director, Engineering</td>
<td>Baxter Healthcare</td>
</tr>
<tr>
<td>Jim</td>
<td>Hadley</td>
<td>Director, Quality Operations</td>
<td>Medtronic</td>
</tr>
<tr>
<td>Kim</td>
<td>Lewandowski-Walker</td>
<td>National Expert</td>
<td>FDA</td>
</tr>
<tr>
<td>Patterson</td>
<td>Shafer</td>
<td>Specialist Leader - Life Sciences R&amp;D Practice</td>
<td>Deloitte</td>
</tr>
<tr>
<td>Mark</td>
<td>Swanson</td>
<td>Director, Medical Technology Quality Graduate Program</td>
<td>St. Cloud State University</td>
</tr>
<tr>
<td>Gin</td>
<td>Schulz</td>
<td>VP Quality Assurance</td>
<td>CR Bard</td>
</tr>
<tr>
<td>Mutahar</td>
<td>Shamsi</td>
<td>Specialist Leader – Regulatory Risk &amp; Compliance</td>
<td>Deloitte</td>
</tr>
<tr>
<td>Joanna</td>
<td>Gallant</td>
<td>Owner/President</td>
<td>Joanna Gallant Training Associates, LLC</td>
</tr>
<tr>
<td>Kristin</td>
<td>McNamara</td>
<td>Senior Advisor</td>
<td>FDA</td>
</tr>
<tr>
<td>Dorota</td>
<td>Wulpiuk</td>
<td>Manager, Quality Initiatives</td>
<td>Baxter Healthcare</td>
</tr>
<tr>
<td>Kiesha</td>
<td>Thomas</td>
<td>OC lead / Program Alignment Training</td>
<td>FDA</td>
</tr>
<tr>
<td>Audrey</td>
<td>Beckman</td>
<td>SVP, Strategic Quality Initiatives</td>
<td>Zimmer Biomet</td>
</tr>
<tr>
<td>Sharon</td>
<td>Segal</td>
<td>Vice President</td>
<td>AdvaMed</td>
</tr>
<tr>
<td>Deborah</td>
<td>Reuter</td>
<td>Senior Vice President of Education</td>
<td>AAMI</td>
</tr>
<tr>
<td>Barbara</td>
<td>Ruf</td>
<td>Quality Director</td>
<td>Zimmer Biomet 83</td>
</tr>
<tr>
<td>Kevin</td>
<td>Slatkavitz</td>
<td>President and Founder</td>
<td>ThinkQuality LLC</td>
</tr>
</tbody>
</table>
Questions for Pat…?
Case for Quality Open Forum
May 10, 2016

The Case for Quality at the FDA

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Align › Achieve › Accelerate

William MacFarland
MDIC Case for Quality Open Forum
Case for Quality at the FDA
May 10, 2015

William MacFarland
FDA/CDRH Of Compliance
Outline

• (10 minutes) Update on FDA projects
• (10 minutes) Interviews with FDA CfQ Participants
• (10 minutes) Q&A with forum attendees
UPDATE ON FDA PROJECTS
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.
Updates on FDA Projects

- Maturity Model
- Analytics
- Quality Metrics
- Library of Quality Practices
- PMA CtQ
- CtQ Guidance Documents
INTERVIEWS WITH FDA PARTICIPANTS
Robin Newman

• How have your expectations for CfQ changed since coming to FDA?
Steve Solomon

- Has the progress on quality been what you anticipated?
Jan Welch

- How is Case for Quality different from previous quality efforts?
Kristin McNamara

• How does this device quality effort compare to other FDA regulated products?
• How unique is this cross-agency approach to other agency efforts?
Ann Ferriter

• What do you anticipate as the next challenges for CfQ?
Cisco Vicenty

• How unique to the device industry is the challenge of promoting device quality?
Contact Information

Bill MacFarland
Director, 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
2016 Key Deliverables

• **August**: Working groups will have completed pilots/POC and analyzed resulting data from their teams.

• **September**: Change Adoption Plan
  - The plan, created with input from the FDA, will propose a set of actions to help facilitate improved device quality as well as what would need to change to effectively implement a Quality System Maturity Model.
  - Plan components include ways to: continue engaging key leaders across all stakeholders, develop the business case for quality, communicate the movement to all stakeholder groups, pilot potential product quality solutions, and assess the quality culture through organizational behaviors.
Closing Remarks

• Survey Monkey

• Fall 2016 OPEN Forum: Watch for more news as to location and timing. This OPEN forum is the culmination of our work so far as detailed in the Change Adoption Plan.