Case for Quality Forum
San Diego, CA
February 25, 2019
# MDIC Case for Quality Forum Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>8:30 – 8:40</td>
<td>Welcome from ASQ</td>
<td>Michelle Vargas, ASQ</td>
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<td>8:40 – 8:50</td>
<td>Welcome from Illumina</td>
<td>Gary Workman, Illumina</td>
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<td>8:50 - 9:10</td>
<td>Welcome and introduction to MDIC</td>
<td>Pamela Goldberg, MDIC</td>
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<td>9:10 – 9:40</td>
<td>MDIC Case for Quality</td>
<td>Joe Sapiente, Hologic</td>
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<td></td>
<td>Status update on all the working group activities</td>
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<td></td>
<td>Goals for the day</td>
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<tr>
<td>9:40 – 10:25</td>
<td>Advancing quality and regulatory science</td>
<td>Tim Stenzel, MD, PhD</td>
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<td>in the CDRH Office of In Vitro Diagnostics and Radiological Health</td>
<td>Director, Office of In Vitro Diagnostics and Radiological Health, FDA Center for Devices and Radiological Health</td>
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<td>10:25 – 10:40</td>
<td>Break</td>
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<tr>
<td>10:40 - 10:50</td>
<td>CDRH and the Case for Quality</td>
<td>Francisco Vicenty, CDRH</td>
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<td>10:50- 11:30</td>
<td>Overview of the Case for Quality Voluntary Improvement Program</td>
<td>Francisco Vicenty, CDRH</td>
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<td>Kim Kaplan, CMMI</td>
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<td>George Zack, Two Harbors Consulting</td>
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<td>11:30 – 12:00</td>
<td>Illumina experience in the CFQ VIP Pilot</td>
<td>Ravi Nabar, Illumina</td>
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<td>12:00 – 12:45</td>
<td>Lunch</td>
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<td>12:45 – 1:30</td>
<td>Modifications to CFQ VIP in 2019: Design quality practices and modifying submission review</td>
<td>Francisco Vicenty, CDRH</td>
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<td>Jeff Slutsky, NSigma Solutions Inc</td>
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<td>1:30 – 2:15</td>
<td>Advancing the Case for Quality by Transforming CAPA</td>
<td>Kathryn Merrill, Medtronic</td>
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<td>2:15 – 3:15</td>
<td>Small group discussions:</td>
<td>Discussion leaders:</td>
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<td>- CAPA</td>
<td>- Kathryn Merrill</td>
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<td>- Modified (streamlined) review submissions</td>
<td>- Cisco Vicenty</td>
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<td>- Design Practices (measurement &amp; monitoring)</td>
<td>- George Zack</td>
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<td>- Demonstrating controls</td>
<td>- George Serafin</td>
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<td>- CFQ VIP Program Features</td>
<td>- Erin Keith</td>
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<td>- Payal Patel</td>
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<td>- Kim Kaplan</td>
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<td>3:15 – 3:30</td>
<td>Break</td>
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<td>3:30 – 4:00</td>
<td>Q&amp;A – large group discussion</td>
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<td>4:00 – 4:30</td>
<td>What’s next and closing remarks</td>
<td>Cisco Vicenty</td>
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<td>- What to expect at the next Forum</td>
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Welcome to the MDIC Case for Quality Forum
San Diego, CA

WORKING GROUP ACTIVITIES UPDATE
Results from MDIC 2020 Strategic Planning Workshop

April 2018 Key Themes

1. **Cross-industry Collaboration** focused on:
   a. Risk Management
   b. Supplier Quality Management
   c. CAPA
   d. Design Controls

2. **Talent** developed through:
   a. Communications with Business Executives
   b. Education & Training
   c. Quality Leadership

3. **People & Culture** promoted through:
   a. Individual Accountability
   b. Quality Function as Business Partner
   c. Continuous Improvement

2018-2019 Working Groups

1. **CAPA**: Fundamentally recast CAPA as a continuous improvement (CI) framework

2. **CEO Engagement**: Promote Quality as a "strategic priority" for all parts of an organization

3. **Quality as a career**: Make Quality a foundational start to a successful career within the MedTech industry

4. **Safe Space**: A non-competitive, collaborative, and sanction-free environment enabling open discussions on a variety of critical improvement initiatives
## 2018 CFQ working groups

<table>
<thead>
<tr>
<th>Redesign CAPA</th>
<th>Engage the C-Suite</th>
<th>Quality as a Career Option</th>
<th>Create an industry Safe Space</th>
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<tr>
<td>Leverage cross-industry best practices and collaboration to fundamentally recast CAPA as a continuous improvement (CI) framework</td>
<td>Influence CEOs and senior leaders of medical device companies to participate in quality initiatives in a meaningful way to effect change in their organizations and the industry. Promote Quality as a &quot;strategic priority&quot; for all parts of an organization through strong leadership, strategic alignment, and tone at the top.</td>
<td>Establish a Quality discipline at the college/university level and educate students on the benefits of making Quality a foundational start to a successful career within the MedTech industry</td>
<td>Create a non-competitive, collaborative, and sanction-free environment enabling open discussions on a variety of critical improvement initiatives.</td>
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Updated Project Charter: Redesign the CAPA Process as a Continuous Improvement Framework  
[#makeCAPAcool Case for Quality Workstream]

### Problem Statement
CAPA is currently a compliance-centric process rather than a continuous improvement cycle. CAPA is very costly and effort-intensive, with the perception of limited value. Other industries leverage their CAPA processes as a continuous improvement vehicle that implements cost-effective changes in a much shorter time frame driving higher product quality. The opportunity is to leverage cultural & procedural best practices across various industries to design a compliant medical device CAPA process that drives continuous improvement, higher product quality, improved patient safety.

### Outcomes
- Outline of a CAPA process framework, based on cultural & procedural best practices, which is effective and easy to understand/use.
- Outline a less burdensome process to execute CAPA actions
- Communication plan for the benefits of the CAPA process as a continuous improvement mechanism.

### Benefits
- Improved product quality and patient safety
- Significant reduction in the cost of poor quality
- Resets culture to the original premise of corrective and preventive action to achieve continuous improvement rather than transactional compliance
- Significant reduction in the overall time to investigate and implement CAPAs
- Inversion of the current proportion of corrective vs. preventive actions.
- Decreases the amount of time required to fix problems.
- Leans out the quality management system (QMS)

### High Level Implementation Plan
- Identify dedicated support team members for Working Group and hatch Cross-Industry participation (with FDA attending)
- Develop report-out plan between #makeCAPAcool team & the Steering Committee.
- Define CAPA, outline detailed current state of CAPA process, benchmark within non-Medical Device industries, and understand the strengths/opportunities & pain points of the current process to identify critical improvement areas.
- Leverage analysis outputs to define and develop a framework and operating model for continuous improvement with understanding of how this will impact regulations (including ISO, MDSAP).
- Test the CI Framework with the Working Group and deliver a future state CAPA process by Q2 2019
- Draft a white paper (produced 18-24 months after), to capture team recommendation

The team is now piloting a proposed CAPA framework!
Leadership Engagement - Status

The workstream is on-track, with our leadership survey set to launch in early March.

Past

- Meet bi-weekly to advance project
- Moved from 'C-suite' to 'Leadership' target
- Completed cover letter and survey
- Survey will define a baseline upon which to build

Future

- Set to launch survey in March
- Results will be factored into Playbook
- Playbook Pilot will run 6 months to identify leading practices
- Successes will be communicated at end of Pilot (December 2019)
- Pilot will continue with final report Sep '20
Make Quality an attractive first step in your career

**High Level Implementation Plan**
- Assess the inventory of Quality programs
- Develop partnerships with University engineering programs and the FDA
- Create framework for Quality curriculum
- Create a pilot program for Quality Day and Undergraduate recruiting programs

**Accelerate with Pathway**
- Elements in place:
  - Key Focus Areas
  - Rigor of Program
  - Curriculum
  - Success Factors

**Program Pilot**
- Xavier will pilot course fall 2019
- Internships with industry
- Industry SMEs as faculty
- Evaluate success factors for university, industry, and students

**Achieve**
- Establish a Quality discipline at the College/University level
- Educate students to the benefits of making Quality a foundational start to a successful career
Cardiovascular ImpLantable Electrode CompArative Reliability (CLEAR)

Data Collaborator:  **STAR Clinical Research Network** (formerly Mid-South CRN)
Facilities:  **Wake Forest Baptist Health (WFBH)**
            **Vanderbilt University Medical Center (VUMC)**

Purpose:

The primary objective of this project is to examine the feasibility of establishing a sustainable, efficient process for generating information to compare the reliability of medical devices, using different data sources, including electronic health records data, CMS claims data, device manufacturer databases, and the FDA’s Medical Device Adverse Event Reports (MAUDE) database.

Agreement from one MFG to participate (MDT), preliminary contact with others

Final study proposal submitted to NESTcc on Feb 7th

Anticipating response early March.
Case for Quality Voluntary Improvement Program (CFQ VIP)

• Continuation of the MDIC CFQ Maturity Model workstream and the CDRH Voluntary Medical Device Manufacturing and Product Quality Program
• Working group launch in February
• Working on a charter and governance framework for the expanded, full program
• To be launched at the Q4 CFQ Forum
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GOALS FOR THE DAY
Brief History of Case for Quality (CfQ)

Why

Risk to patients from quality issues and hampered innovation in manufacturing and product development practices

- High industry focus on meeting regulatory requirements versus adopting best quality practices
- Low investment in automation and digital technologies
- No competitive market around medical device quality

What

Collaborative effort that focuses on organizational excellence and product quality

- New ways to assess organizational performance, focusing on quality, shifting from inspection
- Adapt regulatory oversight to increase agility, responsiveness, simplification, error-proofing, and enable continuous rapid improvement
- Drive connections within systems, increase visibility into product quality to enable market drivers

2011
FDA launched Case for Quality*

*Understanding Barriers to Medical Device Quality (FDA October 31, 2011)

Patients in the U.S. have access to high-quality, safe, effective medical devices, of public health importance, first in the world.

Elevate the focus of all medical device stakeholders from baseline regulatory compliance to sustained, predictive practices that advance medical device quality and safety to achieve better patient outcomes.
What does it take?

- Focusing on quality
- Collaboration and engagement from all stakeholders
- Faster Innovation
- Focus continuous improvement
- An adaptive and responsive regulatory framework

It is all about the patients!
FDA Case for Quality – How can this be leveraged?

- Providing products of highest quality and reliability
- Proactive patient and customer-centric quality culture
- Complying with applicable regulations efficiently
- Shape and influence regulatory policies
- Breakthrough strategy to accelerate regulatory science and shape and influence regulatory policy
Goals for today

“Engagement”

- Drives performance and momentum
- Supports our mission and vision
- Supports CHDRH priorities
- Continue to shape and influence across the medical device quality ecosystem
- Today, we have an opportunity to
  - Influence the scaling of the program beyond the pilot
  - Shape the foundation of program governance and
  - Learn from others that have managed governance
What to expect in 2019

- CDRH Voluntary Medical Device Manufacturing pilot
- Governance CfQ VIP
- 2018 Working group
- Product Quality Outcomes Analytics
- CDRH priorities
- MDIC Forums in 2019
Learn more about the Case for Quality

- Interested in the pilot? Learn more at: [https://mdic.org/project/cdrh-quality-pilot/](https://mdic.org/project/cdrh-quality-pilot/)
- Engage in upcoming Forums: [https://mdic.org/project/case-for-quality-forums/](https://mdic.org/project/case-for-quality-forums/)
- Quarterly webinars, including past webinars, available at: [https://mdic.org/mdicx-series/webinar-archive/](https://mdic.org/mdicx-series/webinar-archive/)