Case for Quality Forum
Arlington, VA
November 28, 2018
Welcome to the MDIC Case for Quality Forum
Arlington, VA

• Overview of MDIC Case for Quality activities
• Goals for the day
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<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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| 8:30 – 9:00 a.m. | MDIC Case for Quality  
• Welcome  
• Overview of MDIC Case for Quality activities  
• Goals for the day | Pamela Goldberg, MDIC  
Beth Staub, Stryker |
| 9:00 – 10:00 a.m. | Keynote  
Building Digital Analytics Foundation for Autonomous Factories at Western Digital | Attila Lengyel, Western Digital |
| 10:00 – 10:15 a.m. | Break |                                                |
| 10:15 – 11:00 a.m. | Results from the CDRH Voluntary Medical Device Manufacturing pilot | Cisco Vicenty, CDRH  
Kim Kaplan, CMMI  
George Zack, Two Harbors Consulting |
| 11:00 – 11:30 a.m. | What we learned about running the pilot | Kim Kaplan, CMMI |
| 11:30 a.m. – 12:30 p.m. | Program Oversight Panel – how have other industry-regulatory program managed governance | Panel:  
Rachel Rath, MDIC NESTcc  
Ann Sheldon, Medtronic (for MedAccred)  
Eric Chang, MITRE (for ASIAS)  
Moderator: Steve Silverman, AdvaMed |
| 12:30 – 1:15 p.m. | Lunch |                                                |
| 1:15 – 1:30 p.m. | Results from the CDRH Voluntary Medical Device Manufacturing Program Survey | George Serafin, Grant Thornton |
| 1:30 – 2:15 p.m. | Small group discussion: Scaling the pilot | Discussion leaders:  
• Cisco Vicenty  
• George Serafin  
• Kim Kaplan  
• George Zack  
• Lisa Griffin Vincent |
| 2:15 – 3:30 p.m. | Group discussion and Q&A | Moderator: Stephanie Christopher |
| 3:30 – 4:00 p.m. | What’s next and closing remarks | Cisco Vicenty |
MDIC AND THE CASE FOR QUALITY
What is MDIC?

Public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.

**HIGHLIGHTS**

- 65 participating member organizations
- Leading resource on issues important to the Medtech innovation ecosystem
- Initiated six projects
- Congressional testimony on modernizing clinical trials
- $35M + funding from grants and contracts for Program initiatives
MDIC Case for Quality

Vision

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.
MDIC Case for Quality

Goals

Develop new tools, methods and metrics for innovators, manufacturers, regulators, and providers that improve product quality and patient experience
A brief history of Case for Quality: Collaboration across the industry

2011 – CDRH launches the Case for Quality

2014 – MDIC awarded BAA

2017 – Putting the pieces together

2014-16 – MDIC Case for Quality project initiatives

2018 – Expanding our reach across the medical device quality ecosystem
## Executive Summary

- **Key Strategic Priorities** identified include: Quality Maturity Model Roll-out, Cross-Industry Sector Collaboration, Talent Development and Increased Industry Representation

- Significant support to include **Software as a Medical Device (SAMD)** in 2020 Strategic Planning

- **Top Processes having the most impact to MDIC’s Charter are** Risk Management, Supplier Quality Management, CAPA, and Design Controls

- **Top Talent Development Aspects having the most impact to MDIC’s Charter are** Communications with Business Executives, Education & Training, and Quality Leadership

- **Top Cultural Aspects having the most impact to MDIC’s Charter are** Individual Accountability, positioning the Quality Function as Business Partner, and Continuous Improvement

### Survey Results

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

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Launched CFQ working groups in 2018

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<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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<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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Product quality outcomes analytics

Develop a standardized method for calculating, analyzing and presenting the Seven Dimensions of Quality

- Consistency allows for a fair comparison of devices
- Standard calculation for each Quality Dimension
- Supports Evidence Based decision making
- Level the playing field for device comparison

In 2019, working group will continue test cases with Dell and NEST
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
• 2018 Working group
• Product Quality Outcomes Analytics – Submitting a NEST test case
• CDRH priorities
• MDIC Forums in 2019
Coming up on December 6

MDICx Series

Thursday, December 6, 2018 at 1 p.m. ET

Q4 UPDATE: CDRH Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program

Representatives from CDRH and CMMI will provide updates on pilot progress, lessons learned from manufacturers, CDRH and CMMI, and changes made to the program through this quarterly MDICx webinar series.

Register at http://mdic.org/mdicx
Learn more about the Case for Quality

• Interested in the pilot? Learn more at: http://mdic.org/cfq/enroll/

• Engage in upcoming Forums: http://mdic.org/cfq/register/

• Quarterly webinars, including past webinars, available at: http://mdic.org/mdicx