Welcome to the MDIC Case for Quality Forum
Philadelphia, PA

• Agenda
• MDIC and the Case for Quality
• Goals for today
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

2014-16 – MDIC Case for Quality project initiatives

2017 – Putting the pieces together

2018 – Expanding our reach across the medical device quality ecosystem
MDIC 2020 Strategic Planning Workshop (April 2018) Executive Summary

Survey Results

- **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

Proposed 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
Executive Summary:

Survey Question #1
- Please rank what you believe should be the strategic priorities of the MDIC CfQ 2020 Strategic Plan
  1. Quality Maturity Model Rollout
  2. Cross-Industry Sector Collaboration
  3. Talent Development tied with Increased Industry Representation

Survey Question #2
- MDIC CfQ should include software as a medical device as a focus area in its 2020 Strategic Plan
  1. 10% Strongly Disagree
  2. 20% Neutral
  3. 30% Agree
  4. 40% Strongly Agree

Survey Question #3
- Rank what processes you think MDIC CfQ could have the most positive impact aligned with its charter
  1. Risk Management
  2. Supplier Quality Management
  3. CAPA

Survey Question #4
- Rank what aspect of talent development you think MDIC CfQ could have the most positive impact aligned with its charter
  1. Communications with Business Executives
  2. Education & Training
  3. Quality Leadership

Survey Question #5
- Rank what cultural aspects you think MDIC CfQ could have the most positive impact aligned with its charter
  1. Individual Accountability
  2. The Quality Function as Business Partner
  3. Continuous Improvement
## New 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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<tbody>
<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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Single request for today

**Engagement**

- Today’s engagement will drive performance and keep our momentum
- We will continue to shape and influence across the medical device quality ecosystem
- In April, we determined the “what” we wanted to take on to support our mission and vision
- Today, we have an opportunity to refine and focus on the how
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
Medical Device CEOs Engagement

INFLUENCE CEOs AND KEY LEADERSHIP OF MEDICAL DEVICE COMPANIES TO LEAD / CHAMPION IN QUALITY INITIATIVES
April 2018 Results Snapshot: Cultural Aspects
(Question #5)

Survey Question

- Rank what cultural aspects you think MDIC CfQ could have the most positive impact aligned with its charter

Top 3 Responses

1. Individual Accountability
2. The Quality Function as Business Partner
3. Continuous Improvement
### New CFQ working groups

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
<th>Project leader(s)</th>
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<td>Redesign CAPA</td>
<td>Leverage cross-industry best practices and collaboration to fundamentally recast CAPA as a continuous improvement (CI) framework</td>
<td>Luann Pendy, Medtronic</td>
</tr>
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<td>Engage the C-Suite</td>
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<td>Joe Sapiente, Hologic</td>
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<td>Quality as a Career Option</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>Jackie Kunzler, Baxter and Carol Montandon, J&amp;J</td>
</tr>
<tr>
<td>Create an industry Safe Space</td>
<td>Create a non-competitive, collaborative, and sanction-free environment enabling open discussions on a variety of critical improvement initiatives.</td>
<td>Conor Dolan, Boston Scientific</td>
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### Problem Statement

“Quality” has become synonymous with “Compliance” because of work across the industry over the last decade to address and remediate compliance issues. “Quality” is viewed more as the quality function’s responsibility rather than the overall company’s responsibility. The business case for quality is hard to quantify.

Starting with the "tone at the top" there is a need to engage CEOs in product quality initiatives and create recognition across the industry to facilitate change for organizations to adopt "Big Q" principles and the value of Quality as a strategic priority.

### Approach

- How do we engage & measure engagement of leadership?
- Start with MDIC membership?
- How do we identify parameters of successful engagement?
- How do we align with mid-managers who may have conflicting objectives (through-put vs. quality)?
- Do we need a benchmark CEO – what does good look like?

### Interim Milestones and Completion Dates

**Framework Deliverable:** Feb 2019 – outline for how companies can get traction – leverage existing programs, etc. – integration with AdvaMed - what the future deliverables look like

**Playbook** – including how to measure

**Results report** – presenting how the industry has progressed

### Outcomes

- Improved patient outcomes through higher quality medical devices
- Higher performing “Quality” organization (entire company; not quality function)
- Behaviors that demonstrate a strategic focus on "Doing the Right Things" and a Quality Mindset – “I own quality” and “Quality begins with me”
- Transparency and collaboration between regulators and industry
- Quality isn’t an initiative – it’s part of the DNA of the company

### Benefits

- Transition from a culture of compliance to a culture of quality
- Elevate awareness and visibility of Quality as a strategic priority
- Demonstrated behaviors supporting a Quality mindset that are recognized and rewarded
- Cost improvements – revenue improvements

### High Level Implementation Plan

- Identify and define quality initiatives
- Clarify scope to determine which population of CEOs is being targeted
- Target by different sectors (e.g. cardio, neuro)
- Ensure diversity in company size
- Publish list of CEOs engaged in quality initiatives
- Recognize both CEO and the quality initiatives
- Identify which companies are participating in quality initiatives
- Create business case/value proposition as it relates to Quality to inspire the CEO

### Estimated Timeline and Duration

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<thead>
<tr>
<th>Description</th>
<th>Start</th>
<th>Finish</th>
<th>Duration</th>
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<td>Influencing CEOs and key leaders of medical device companies to lead / champion quality initiatives in a meaningful way that will effect change in their organizations and the industry. Promote Quality as a &quot;strategic priority&quot; being integral to all parts of an organization through strong leadership, strategic alignment, and tone at the top.</td>
<td>Q4 2018</td>
<td>Q4 2020</td>
<td>2 Years</td>
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### Key Dependencies

- Creating a sufficient number of quality initiatives to be meaningful
- Company and CEO / key leadership participation
- Quality behaviors modeled and recognized
- Communications / recognition – quality kept front-of-mind
- Achieve early wins or capture other success stories – communicate success (case studies)
- Look at other industries for models

### Objective: By 2020, 85% of Medical Device CEOs Engaged in Quality Initiatives

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<th>MDIC CfQ Steering Committee Lead</th>
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<tr>
<td>Joe Sapiente</td>
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<td>Jackie Kunzler (Support)</td>
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Case Study 1

Quality Begins with me: Medtronic’s approach to bring mission to life

- Quality Begins with Me: - Promotes a quality culture that nurtures Patient Centric Mindset
  - Become a Trusted Partner to our stakeholders
  - Connect to Hearts & Minds of the employees

- An effort to infuse a culture of quality and ingrain quality behaviors:
  - Courageous, Accountable, Preventive & Patient Focused

- Operationalizing quality behaviors through five work-streams:
  - Product Awareness, Visual Management, Continuous Quality Improvement, Recognition & Communication

- Deployed across the Enterprise Value Chain:
  - Suppliers, All Medtronic Employees & Customers

- Effectiveness & Improvement Opportunities evaluated through Culture Assessments
  - Quality Culture Index

- Monitoring impact on Results through COPE and recognitions for Quality Behaviors

- Shared with FDA & AdvaMed, adjudged as Industry Best Practice by CEB
Case Study 2: Quality First Culture
Medha Trivedi: Stryker

1. **Quality First initiative**: A massive transformational journey led and championed by Group President for GQO (Global Quality and Operations)
   - Going from a highly decentralized organization to a unified centralized quality-oriented organization delivering on the mission of making healthcare better through keen focus on improving quality.
   - Successful top-down leadership through change management enabling organization to understand the “why” behind the change to transform successfully with employees fully committed and owning it.

2. **Quality Day**: Dedicated day for various activities intended to drive Quality Culture
   - Leadership brings in Patients who will interact with all functions and all levels and tell their story - how high quality product saved/improved their life. Huge engagement in driving case for quality with employees!
   - Leadership brings in Surgeons to share their experiences and reiterate how important it is for them to have devices that work at first try! Very impactful for engineers, product assemblers, inspectors to gain customer connection and hear importance of quality.
   - Showcase projects and recognize individuals/teams that embody the Quality First culture.
Learn more about AdvaMed’s Quality Culture Workstream

October 17th Quality Culture Playbook webinar
Q&A