Case for Quality

Forum

September 27th, 2018
JOE SAPIENTE

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

1st, 2nd and 3rd Responses Summed

1st, 2nd and 3rd Responses Based on Scoring Multiplier

- Individual accountability ("quality begins with me")
- Quality function as a business partner
- Continuous improvement
- Innovation
- Leadership action and communication
- Global vs. regional (local) quality system

Number of Responses

Values Based on Score Multiplier

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<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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Project leader: Luann Pendy, Medtronic  
Project leader: Joe Sapiente, Hologic  
Project leader: Jackie Kunzler, Baxter and Adrienne Brott, J&J  
Project leader: Conor Dolan, Boston Scientific
Objective: By 2020, 85% of Medical Device CEOs Engaged in Quality Initiatives

Description
Influence 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 "strategic priority" being integral to all parts of an organization through strong leadership, strategic alignment, and tone at the top.

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
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

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

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

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

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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<tr>
<th>Start</th>
<th>Finish</th>
<th>Duration</th>
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<tr>
<td>Q4 2018</td>
<td>Q4 2020</td>
<td>2 Years</td>
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MDIC CfQ Steering Committee Lead
• Joe Sapiente
• Jackie Kunzler (Support)
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