MEDICAL DEVICE INNOVATION CONSORTIUM

MDIC Case for Quality 2020 Strategic Plan Work streams

June 27, 2018

Background & Timeline

- ***February, 2018***
  - MDIC receives proposals for assistance with the Case for Quality 2020 Strategic Plan Development
- ***March, 2018***
  - Grant Thornton selected to provide assistance with Case for Quality 2020 Strategic Plan Development
  - Approach includes surveying the Steering Committee to identify key themes and topics for strategic plan development
  - Survey sent to Steering Committee
- ***April, 2018***
  - Survey results compiled and three key theme areas identified to explore at the in person Strategic Planning session

Background & Timeline

- ***April, 2018***
  - April 12, 2018 – All Day Strategic Planning Working Session Conducted with the Steering Committee members
  - Three topics selected to explore during the working session:
    - Industry Cross-Collaboration
    - Talent
    - People & Culture
  - Working Session Agenda
    - Three teams focused on Goal Setting for each area
    - Teams selected 2-3 goals for each topic & further defined the impact/benefits, key activities, dependencies, duration and estimated timeline to achieve the goal
    - Report out by each team to the group (approx. 10 Goals presented)
    - Steering Committee members voted on their top 3 Goals

Background & Timeline

- ***April, 2018***
    - Four Goals were selected to become initiatives in the CfQ 2020 Strategic Plan & Steering Committee members have committed to lead and support each initiative:
        - Redesign the CAPA Process as a Continuous Improvement Framework
        - Create a Cross-Industry “Safe Space”, and Pilot a Predictive Quality Analytics Model
        - By 2020, 85% of Medical Device CEOs Engaged in Quality Initiatives
        - Make Quality an Attractive First Step in your Career
- ***May 10, 2018***
    - Detailed CfQ 2020 Strategic **Work streams** were reviewed by the Steering Committee and finalized
- ***June 27, 2018***
    - TODAY – Team working sessions this afternoon

Redesign the CAPA Process as a Continuous Improvement Framework

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Description

Leverage cross-industry best practices and collaboration to fundamentally recast CAPA as a continuous improvement (CI) framework

Estimated Timeline and Duration

Start	Finish	Duration
Q3 2018	Q2 2019	9 Months

MDIC CfQ Steering Committee Lead

- Luann Pendy
- Joe Sapiente (Support)

Problem Statement

CAPA is currently a compliance-centric process rather than a continuous improvement cycle that is very costly and effort-intensive, with 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 identify and leverage best practices across various industries and design a medical device industry-standard CAPA process and best practices that drives continuous improvement, higher product quality, improved patient safety and sustained compliance.

Interim Milestones and Completion Dates

Group Review: Q4 2018

Framework Deliverable: Q2 2019

Key Dependencies

- Identification and commitment of industry SMEs willing to collaborate

Outcomes

- Improved product quality and patient safety
- Inversion of the current proportion of corrective vs. preventive actions
- Significant reduction in the overall time to investigate and implement CAPAs
- Significant reduction in the cost of poor quality

Benefits

- Resets the original premise of corrective and preventive action to achieve continuous improvement rather than transactional compliance
- Leans out the quality management system (QMS)
- Decreases the amount of time required to fix problems

High Level Implementation Plan

- Identify dedicated support team members for Working Group and hatch Cross-Industry participation (with FDA attending) on quality benchmarking
- Deconstruct the CAPA process, and perform a SWOT analysis to identify critical improvement areas, then leverage the outputs to define and develop a framework and operating model for continuous improvement
- Test the CI Framework with the Working Group and deliver a recast template of the CAPA process by Q2 2019
- Draft a guidance document (produced 18-24 months after), and a white paper to guide the regulation
- Develop selective rewards and recognition program for improving CI processes (i.e., developing the “Baldrige Award” for CI / CAPA Improvement)

Create a Cross-Industry "Safe Space", and Pilot a Predictive Quality Analytics Model

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Description

Create a non-competitive, collaborative, and sanction-free environment enabling open discussions on a variety of critical improvement initiatives. Pilot the safe space with an improvement effort in developing a Quality-centric predictive analytics model in the MedTech industry

Problem Statement

Collaboration efforts between industry and regulators that can drive industry-wide change with respect to product quality and patient safety are limited by concerns of regulatory retaliation when company problems are shared in the spirit of problem-solving and to gain a common understanding of systemic industry issues. The opportunity exists to leverage highly successful efforts in other industries such as A&D where industry and regulators have come together and successfully implemented positive changes concerning commercial aviation fatality risk.

Estimated Timeline and Duration

Start	Finish	Duration
Q3 2018 (Safe Space)	Q4 2019	18 Months
Q1 2019 (Analytics)	Q4 2019	12 Months

Interim Milestones and Completion Dates

Identify cross-industry experts: Q3 2018

Invite industry POCs and Kickoff for Predictive Analytics: Q1 2019

MDIC CfQ Steering Committee Lead

- Conor Dolan
- Luann Pendy (Support)

Key Dependencies

- Safe Space: Quality of established models should be assessed
- Predictive Analytics: dependent on maturity of safe space environment

Outcomes

- Enables a significantly improved environment for identifying root causes for the most challenging improvement initiatives
- Delivers an enhanced, standardized approach for assessing and implementing predictive analytics technologies in the MedTech industry

Benefits

- Permits the most open dialogue concerning sensitive improvement subjects in a non-punitive environment
- Leverages well-established models for the environment (i.e., emulating Federal Aviation Administration (FAA) / Department of Defense (DoD) Quality "Safe Space")
- Gain a broader view of quality performance improvement from leading industries, their trusted traders, suppliers and contractors

High Level Implementation Plan

- Introduce safe space and the predictive analytics pilot concepts as new project proposals during the June 2018 steering committee forum
- Identify an integrated (i.e., safe space and predictive analytics) plenary working group to address these goals
- Recognize a network of SMEs to address quality issues, Med Device and other industry representatives, other regulatory agencies – (e.g., International Medical Device Regulators Forum [IMDRF])
- Understand and assess FAA (Commercial Aviation Safety Team CAST) and DoD safe space models and use these outputs as a basis to build framework to socialize with key leadership
- Leverage the SME network to develop and "road test" the pilot predictive analytics concept, within the safe space environment, once established (~6-9 months)
- Identify data for pilot and build the predictive analytics model for Quality

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

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Description

Influence CEOs of medical device companies to participate in 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.

Estimated Timeline and Duration

Start	Finish	Duration
Q4 2018	Q4 2020	2 Years

MDIC CfQ Steering Committee Lead

- Joe Sapiente
- Jackie Kunzler (Support)

Problem Statement

"Quality" is viewed more as the quality function's responsibility rather than the overall company as "Quality" has become synonymous with "Compliance" consequent to the significant level of effort across the industry over the last decade to address and remediate compliance issues. 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

Interim Milestones and Completion Dates

Framework Deliverable: Q1 2019

Key Dependencies

- Creating a sufficient number of quality initiatives to be meaningful
- Company and CEO participation

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
- Transparency and collaboration between regulators and industry

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

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

Make Quality an Attractive First Step in your Career

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Description

Establish a Quality discipline at the College/University level and educate students to the benefits of making Quality a foundational start to a successful career within the MedTech industry

Estimated Timeline and Duration

Start	Finish	Duration
Q3 2018	Q4 2019	18 Months

MDIC CfQ Steering Committee Lead

- Adrienne Brott
- Jackie Kunzler (Support)

Problem Statement

A job in quality is not viewed as a positive first step for undergraduates and young professionals to start their career. Other positions within R&D, supply chain and manufacturing, or sales and marketing are currently identified as areas where young professionals can build a successful career in the MedTech industry. Quality theory and principles are not taught as part of undergraduate curricula and only available in select graduate programs or professional certifications that require years of experience to qualify. Undergraduates are currently unaware of the role and value of Quality within an organization or attribute it to be more of a compliance, documentation-intensive, non-technical position

Interim Milestones and Completion Dates

Engagement Framework Deliverable: Q1 2019

Key Dependencies

- University interest
- FDA engagement

Outcomes

- Expand Quality theory and principles into the undergraduate curricula
- Increase awareness of the opportunity and value of starting a career in Quality

Benefits

- Create a quality-centric mindset and framework through innovative means
- Implement early exposure to a Quality curriculum to promote the significance of the Case for Quality (CfQ), which will lead to improved product quality and patient outcomes
- Recruit high potential candidates that also possess academic credentials with respect to quality theory

High Level Implementation Plan

- Assess the inventory of Quality programs and leverage cross-industry (automotive and methods of education
- Develop partnerships with University engineering programs and the FDA to develop a framework for the CfQ Quality curriculum
- Create the framework by leveraging the FDA within a 6 month time window
- Create a pilot program for:
    - Quality Day – which would include a forum and speaker (possibly from the FDA)
    - Undergraduate recruiting programs