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Change Adoption Plan

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Agenda

- What is the Change Adoption Plan?

- Desired Outcomes of CfQ Adoption

- Desired Future State Benefits of CfQ Adoption

- Culture of Quality

- Quality System Model Benefits

- Challenges to Adoption

- Recommendations

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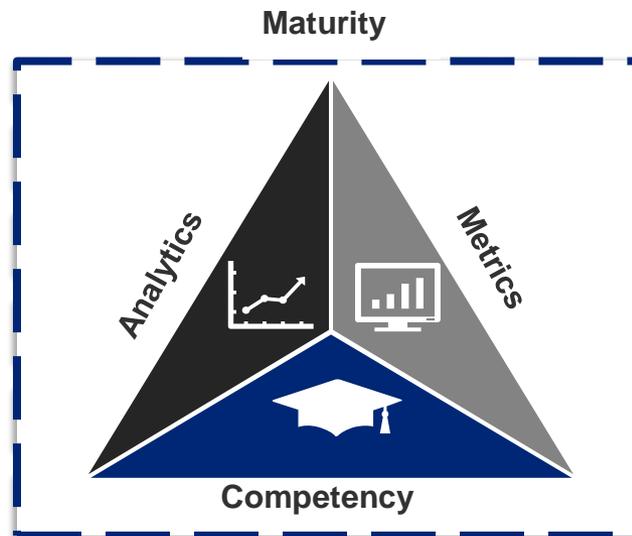MEDICAL DEVICE INNOVATION CONSORTIUM

What is the Change Adoption Plan?

The purpose of this Change Action (Adoption) Plan (CAP) is to provide a view of the current state of implementation of CfQ elements, specifically the quality system maturity model, along with other key initiatives, and to set the vision for tomorrow.

CAP Goals

- Creating a guiding coalition

- Developing a change vision

- Empowering broad-based action

- Generating short-term wins

- Incorporating changes into the culture

CAP Guiding Principles

- Create a sense of urgency

- Persevere

- Develop a sustainable vision

- Engage stakeholders across MDIC, industry, the FDA, Healthcare Providers, Patients, and Payers

Desired Outcomes of CfQ Adoption

While the set outcomes of improving product quality and patient safety at lower total quality cost were key to respondents desire to implement the CfQ, other goals and key themes were expressed by stakeholders.

Desired Future State Benefits of CfQ Adoption

The Case for Quality enables the FDA and industry the opportunity to work with customers, including patients, providers, and payers to define the quality attributes and increase the visibility and transparency of those attributes for customers.

Product Quality Improvement

Improved oversight of quality and ability to shift focus from compliance-driven activities to enable more focus on improvement of product quality and patient safety

Alternative Approaches to Regulatory Oversight

Shift away from traditional enforcement activities for those companies who demonstrate CfQ adoption through advanced Maturity Model scores and consistent compliance (e.g., fewer inspections, more collaboration instead of immediate enforcement on recalls/compliance findings, etc.)

Improved Ecosystem / Industry Partnership

Facilitate direct interactions with the FDA in a non-inspection setting and foster communications between the FDA and Industry to collaboratively solve issues including expanding interaction between Industry Leaders (CEOs, COOs) and FDA Leadership

Patient Safety / Product Quality

Allocation of Resources

Resources at both the FDA and within Industry can be better allocated; in the FDA inspectors can be deployed to the companies who need the most assistance, not just based on schedules or volume, and within industry, resources can reduce focus on pure compliance for the sake of compliance and turn toward improving quality and advancing innovation

Culture of Quality

Moving toward a focus on the patient, not a focus on compliance requirements, working together to solve issues without strain of enforcement

Quality Drives Business

Shift toward quality as a competitive advantage, providing transparency and communications about the state of quality and creating informed patients and healthcare providers, including producing an improved ROI, the investment in the level of product quality and patient safety is a strong bet where improvements in quality come at a fair price for both the government and more importantly the medical device companies

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Culture of Quality – Quality Function

A Culture of Quality focuses on product quality and services beyond just satisfying compliance requirements throughout the organization. To foster a Culture of Quality, the Quality function transitions from a Guardian into new roles within the organization.

Business Partner assisting the organization with becoming risk intelligent and operationally efficient – not just the auditor or enforcer of compliance.
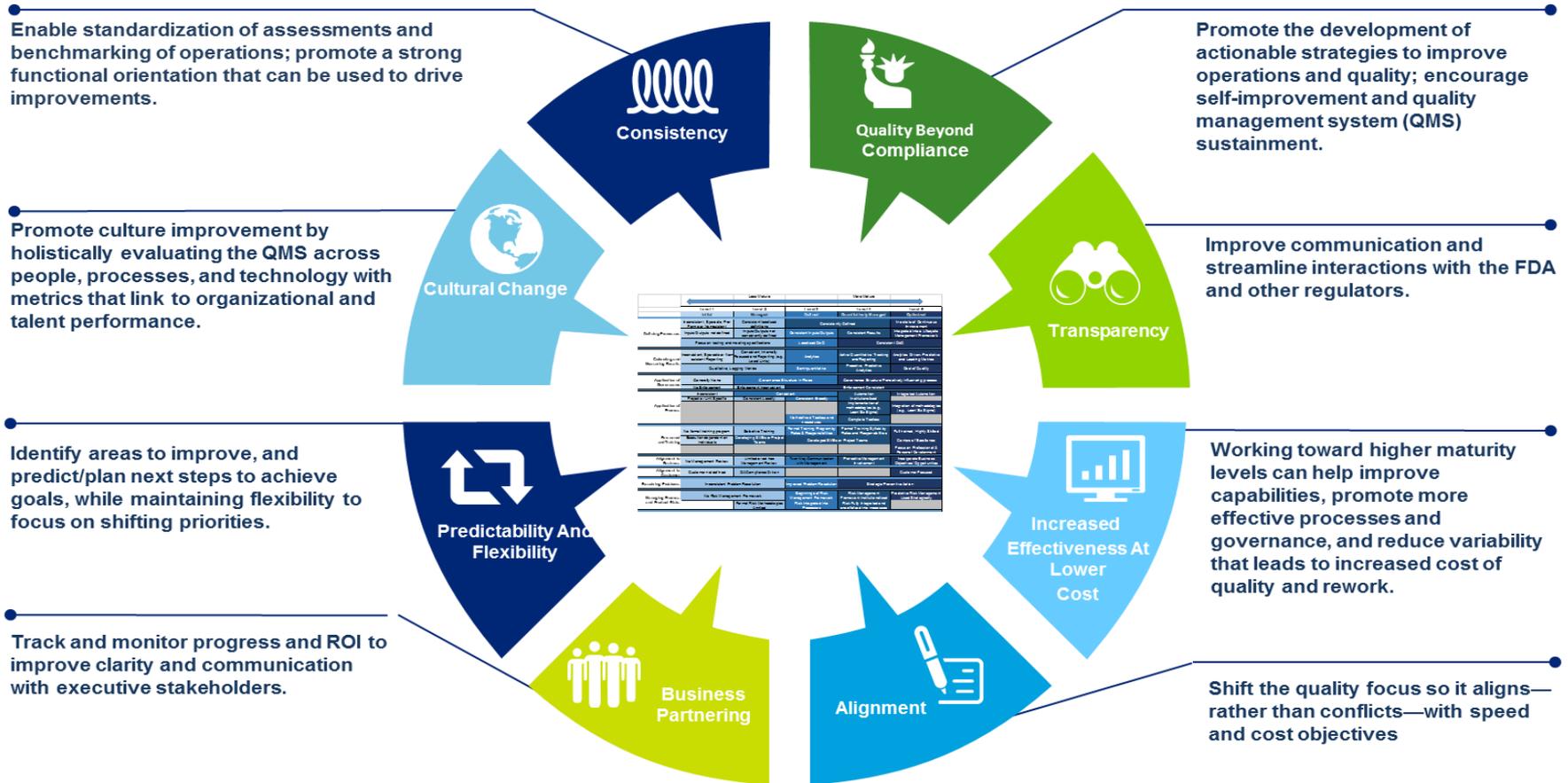
Enabler of the business assisting them with achieving their strategic objectives not only through value preservation (e.g. cost of compliance, value of quality as evidenced by lower scrap cost, fewer design and process changes, less product field actions, etc.) but also value realization (**Value of Quality**) as evidenced by increased market competitiveness, accelerated time to market, improved merger and acquisition integration.

Facilitator of collaborative interactions with ecosystem partners, including Consumer/Patient, Healthcare Providers, Payers, the Medical Device Industry, and the FDA, to enable bringing new, innovative products to market faster, advancing regulatory science, and regulatory pathways that can keep up with the speed of innovation.

Quality System Model Benefits

Implementing a standard, recognized maturity model across the medical device industry, could produce a wide range of benefits.

Enable standardization of assessments and benchmarking of operations; promote a strong functional orientation that can be used to drive improvements.

Promote culture improvement by holistically evaluating the QMS across people, processes, and technology with metrics that link to organizational and talent performance.

Identify areas to improve, and predict/plan next steps to achieve goals, while maintaining flexibility to focus on shifting priorities.

Track and monitor progress and ROI to improve clarity and communication with executive stakeholders.

Promote the development of actionable strategies to improve operations and quality; encourage self-improvement and quality management system (QMS) sustainment.

Improve communication and streamline interactions with the FDA and other regulators.

Working toward higher maturity levels can help improve capabilities, promote more effective processes and governance, and reduce variability that leads to increased cost of quality and rework.

Shift the quality focus so it aligns—rather than conflicts—with speed and cost objectives

Consistency

Quality Beyond Compliance

Cultural Change

Transparency

Predictability And Flexibility

Increased Effectiveness At Lower Cost

Business Partnering

Alignment

Challenges to Adoption

Clear Vision & Plan: The goal of exploring the maturity model as a quality framework is well understood, but in the current state it is not clear what it would take to actually implement or what timeline or effort level is required of industry.

Momentum & Resources: Concerns were raised by interviewees about the resources planned for the development, implementation, and sustained operations of CfQ elements. It is imperative that momentum continue or the enormous amount of work already put in will be at risk.

Implementation Effort & Demonstrated ROI: As the efforts progress and implementation becomes more imminent, there is a need for an understanding of the amount of effort that this will entail and the return on investment that can be expected.

The FDA/Industry Relationship: There is still work to be done to improve the FDA/Industry relationship. Additional training is needed to familiarize with CfQ initiatives, in order to better engage and recognize industry efforts to focus on quality and achieve more than the compliance baseline.

Healthcare Provider, Patient, and Payer Acceptance: There has been limited engagement with end-user stakeholders such as HCPs, patients and payers and therefore insufficient data to suggest that they would use these models and information as anticipated.

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Recommendations

Recommendations

Regulatory Incentive Definition & Commitment

Change Management & Communication

Dedicated Project Resources

Measure & Monitor ROI

Business Operations

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Join the Movement

- Join CfQ and MDIC
- Participate in Working Groups and help us drive implementation

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Questions?

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