ARTICLE

Transitioning to a Culture of Quality

The U.S. Food and Drug Administration (FDA) and the Center of Devices and Radiological Health (CDRH)

The Food and Drug Administration regulates about 25 cents of every dollar spent by American consumers.[1] The FDA is responsible for ensuring the safety, efficacy and security of human and veterinary pharmaceuticals, biological products, medical devices and diagnostics, cosmetics, tobacco, and the safety of the U.S. food supply.[2] The FDA's Center of Devices and Radiological Health *regulates approximately 200,000 unique medical devices sold in the U.S. market, manufactured by 18,000 companies in over 21,000 facilities worldwide.*[3]

FDA's Case for Quality Program

Core to the FDA's mission is the focus on high-quality products that will better protect and promote public health. In 2011, the FDA launched its Case for Quality program[4] with several objectives:

- Create a collaborative platform between industry, healthcare providers, patients, payers and investors to focus on promoting higher-quality and safer medical devices;
- Identify device manufacturers and their manufacturing practices that consistently manufacture high-quality devices that are also consistent with FDA laws and regulations;
- Leverage these manufacturing practices to share with other companies to improve the quality of their devices

[1] https://www.fda.gov/science-research/advancing-regulatory-science/executive-summary-strategic-plan-regulatory-science#:~:text=In%20the%20U.S.%2C%20FDA%2Dregulated,of%20every%20American%20every%20day

[2] https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate

[3] MDIC Case for Quality Presentation, Annual Meeting, September 2018

[4] https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality

The Medical Device Innovation Consortium (MDIC), a first of its kind, public-private partnership between the FDA and the medical device industry

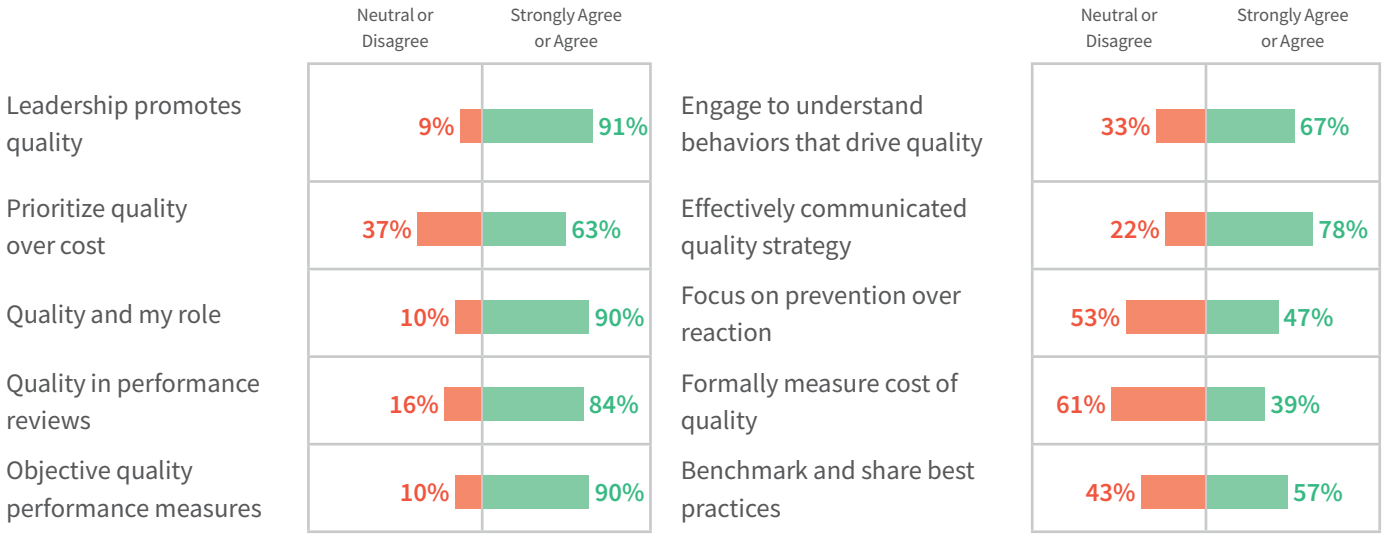
The Case for Quality program led to the creation of the Medical Device Innovation Consortium in late 2012, a first of its kind, public-private partnership with the sole objective of advancing regulatory science to benefit patients.[5] This organization brings together representatives from the FDA, the National Institutes of Health (NIH), the Centers for Medicare & Medicaid Services (CMS), the medical device industry and patient organizations to collaborate and improve the development, manufacturing and commercialization of higher-quality and safer medical devices and also foster the innovation of new medical technologies. Over the years, there have been successful initiatives across clinical science, manufacturing, and data science and technology, each positively impacting large and small medical device manufacturers to the benefit of patients.

Transitioning from a "Culture of Compliance" to a "Culture of Quality"

Company culture is one element recognized by both the FDA and industry as vital to the success of any organization and central to a quality management program. The life sciences industry, consisting of pharmaceuticals, biotechnology, and medical devices and diagnostics, is highly regulated by a complex and evolving global framework of laws, regulations and standards, and subject to enforcement by the FDA and other international health authorities. Within most life sciences organizations, this has fostered a "culture of compliance" that focuses on the laws and regulations themselves – even though these laws and regulations are intended to define minimum requirements. This has created a "check-the-box" mentality and an emphasis on **"doing things right rather than doing the right things"** which ultimately impacts patients and providers. In contrast, a "culture of quality" embodies the principles of "customer" (provider and patient) requirements driving the product development life cycle, enabled by an effective and efficient process of continuous improvement—with sustained regulatory compliance an expected outcome rather than as a primary objective.

Culture of Quality Baseline

88 complete responses, baseline average is 71% agree or strongly agree



Source: Presentation Medical Device Innovation Consortium, April 28, 2021

[5] https://mdic.org/about/mission-purpose/

The Leadership Engagement Playbook

The MDIC Case for Quality Executive Committee periodically identifies critical topics to put in front of the industry for collaborative solutions. During a more recent strategy session, the committee identified the importance of strong leadership engagement in fostering a culture of quality.

Pat Shafer, a managing director in FTI's Health Solutions practice, led a collaborative effort, bringing together FDA, medical device executives and subject matter experts to develop and publish a Leadership Engagement Playbook.[6] The playbook is a detailed guide to assist medical device CEOs and other executives in "setting the tone at the top" and developing plans to lead their organizations' transformations to a culture of quality.

The team started with a survey to capture a baseline understanding of how industry leaders viewed their current performance (see figure). The feedback highlighted opportunities to prioritize quality over cost, formally measure the cost of quality, focus on prevention over reaction, and benchmark and share best practices.

Team members collected best practices from across the medical device industry and identified ten that enable executive leadership to successfully plan and execute this transformation, with specific considerations regarding change management and adoption and properly measuring the value of quality across the organization.

Developing real-time, continuous visibility of design and manufacturing quality measures such as "right the first time" and effectively implementing ideas for improvement, coupled with people/culture measures (such as pulse survey scores and tracking the number of quality issues identified in-house vs. from complaints) empower organizations with a "finger on the pulse" and the ability to respond and change faster.

The survey also highlighted the importance of executive leadership, role definition, behaviors and communications. A culture of quality starts at the top of an organization and is driven by clear and consistent communications. In addition, quality planning activities, value statements and regular training activities are essential to role definition and drive desired behaviors and outcomes.

The playbook is valuable to medical device manufacturers of all classes of products (Classes I-III, each product class with higher levels of risk and commensurate regulatory controls and requirements), geographic focus and footprint, and size. Moreover, the quality principles and leading practices embodied within the playbook are equally applicable for other industries, from automotive and heavy machinery to high-tech and consumables.

[6] MDIC Leadership Engagement Playbook: A Report of the Case for Quality Collaborative Community (CfQcc); January 14, 2021.

PAT SHAFER
Managing Director
+1.646.379.8307
Pat.Shafer@fticonsulting.com

GEORGE SERAFIN
Senior Managing Director
+1.212.841.9352
George.Serafin@fticonsulting.com

DAVID GRUBER, MD
Managing Director
+1.917.214.8318
david.gruber2@fticonsulting.com