MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

CULTURE OF QUALITY

An Initiative of the Case for Quality Collaborative Community (CfQcc)

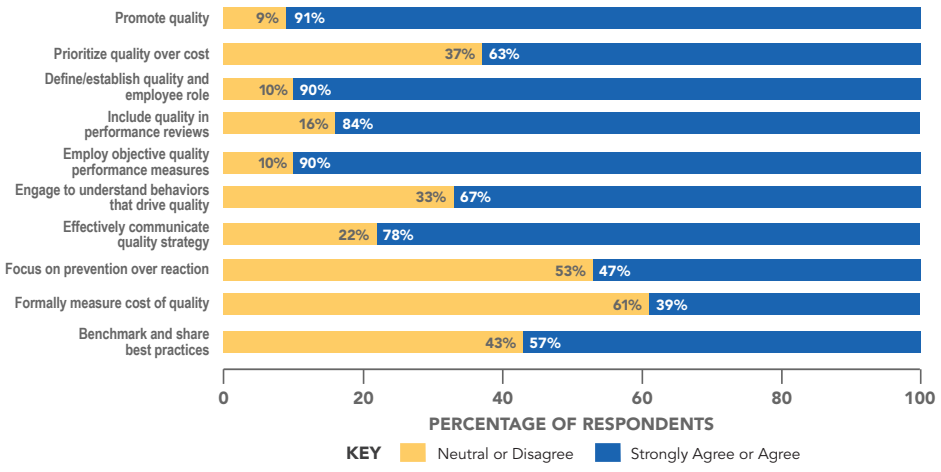
A culture of quality in medical device organizations transcends compliance and serves as a clear competitive differentiator. In an industry facing increasing competition, regulations, and customer demands, and a mandate for innovation, today's medical device leaders are committed to cultivating a culture of quality. But what that culture looks like and how it manifests in an organization will vary with the leader and the organization. An opportunity exists to develop resources that provide concrete goals and actions to help medical device leadership move from a reactive to a proactive approach to quality.

CfQcc Culture of Quality Initiative

The Culture of Quality Initiative was inspired by the results of an MDIC quality survey of medical device industry employees in which 90% of respondents reported that their leaders actively promote quality across activities and functions. Nearly two-thirds (63%) prioritized high-quality performance over costs and competing priorities. Most organizations proactively encouraged understanding of how quality applies to jobs and performance reviews.

MDIC saw an opportunity to further facilitate a culture of quality by creating a Quality Leadership Engagement Playbook for medical device leadership. The playbook describes 10 best practices for moving from a culture of compliance to a culture of quality and offers guidance for piloting the best practices within an organization.

Survey Results: Moving Beyond Compliance Toward Quality



RESOURCES

Leadership Engagement Playbook
https://mdic.org/resource/case-for-quality-leadership-playbook/

Case for Quality Survey
https://live-mdic.pantheonsite.io/wp-content/uploads/2019/06/Leadership-Engagement-Update.pdf

HOW TO GET INVOLVED

Learn more.

Get to know the Culture of Quality! For more information, contact Alan Baumel, CfQcc Program Director, at abaumel@mdic.org

Pilot the Leadership Engagement Playbook.

We are looking for executive leaders willing to engage in pilot studies to demonstrate the benefits of the Leadership Engagement Playbook.

Share your ideas.

If you have an idea for this project, we want to hear from you. Please reach out to Alan Baumel, CfQcc Program Director, at abaumel@mdic.org

CASE FOR QUALITY COLLABORATIVE COMMUNITY (CfQcc)

This Culture of Quality Initiative is an effort of the Case for Quality Collaborative Community (CfQcc). CfQcc offers a unique forum for medical device stakeholders to move beyond baseline regulatory compliance activities and collaboratively develop sustained predictive practices that advance medical device quality and safety to achieve better patient outcomes.

Collaborative Communities provide a forum for public and private sector members to proactively work together to achieve common objectives and outcomes. FDA does not lead Collaborative Communities, and their work does not replace established regulatory mechanisms. However, FDA may choose to participate in a Collaborative Community and support, leverage, and/or adopt solutions that emerge.

GET INVOLVED WITH CULTURE OF QUALITY TODAY!

Contact Alan Baumel, Program Director for CfQcc, at abaumel@mdic.org.

About MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, industry, nonprofits, and patient organizations to improve the processes for development, assessment, and review of new medical technologies. We are working toward faster, safer, and more cost-effective innovation for patient benefit.

MDIC has been formed to add value at the intersecting needs of the medical device industry, the FDA, and the related organizations that are together responsible for a vibrant medical device industry that serves the public health needs of the United States.

Vision

MDIC, through its public-private partnership, aims to advance regulatory science in the medical device industry. MDIC will coordinate the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.

Initiatives and Programs

MDIC's initiatives focus on four areas, each of which has one or more programs to meet a specific need:

1. Clinical Science – Addresses the biggest barriers to collecting adequate clinical evidence in the support of new medical technology by creating blueprints for innovative clinical trials techniques, developing standards and metrics for effective clinical trial designs, and encouraging the collection of adequate and appropriate clinical and patient preference data

- Clinical Diagnostics
- Early Feasibility Studies
- Science of Patient Input

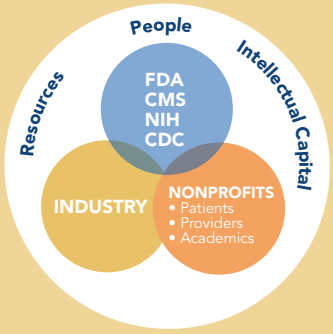
2. Data Science & Technology – Fulfills the promise of advances in data analysis by creating tools and methods to use advanced data analysis techniques and new technology to accelerate the collection of clinical data, remove barriers to patient access, and monitor product safety, quality, and effectiveness

- Case for Quality Collaborative Community
- Computational Modeling and Simulation
- Cybersecurity
- External Evidence Methods
- Systemic Harmonization and Interoperability Enhancement for Lab Data (SHIELD)
- 5G-Enabled Health Technologies

3. Health Economics & Patient Value – Creates predictability and transparency of evidentiary requirements for coverage and improves pathways for coverage, coding, and payment to speed patient access and amplify the patient voice in selection of treatment options

4. National Evaluation System for Health Technology Coordinating Center (NESTcc) – Works with stakeholders across the medical device ecosystem to catalyze the timely, reliable, and cost-effective development of Real-World Evidence to enhance regulatory and clinical decision-making.

MDIC COLLABORATORS



LEARN MORE ABOUT MDIC

Learn more about MDIC by visiting www.mdic.org, sending a message to info@mdic.org, or calling (202) 828-1600.

MDICx Series

WEBINARS BY MDIC

MDIC's informative series of online workshops, the MDICx series, features emerging trends in medical technology, regulatory science, MDIC projects, and subject matter experts sharing perspectives, progress, and opportunities. Visit mdic.org/mdicx-series to view upcoming webinars or submit a proposal.

MDIC ANNUAL PUBLIC FORUM

Every year, MDIC's Annual Public Forum (APF) brings together MDIC members and the broader medical device and diagnostics community to share insights on current trends in regulatory science and the progress MDIC has made in advancing the field. Learn more at https://apf.mdic.org/agenda/

Past panel topics have included:

- Developing a patient-centered regulatory strategy
- Assessing the Use, Impact, and Role of RWE in the U.S. and EU
- Mitigating cybersecurity risks to ensure device security and patient safety

Past guest speakers have included:

- FDA Commissioners Hahn, Gottlieb, and Califf; Acting Commissioner Sharpless
- Tamara Syrek Jensen, Director of the Coverage and Analysis Group, CMS
- Danelle Miller, Vice President, Global Regulatory Policy & Intelligence - Roche Diagnostics

MEMBERSHIP

MDIC members are leaders in the medical technology industry. MDIC focuses on providing patients access to innovative medical technologies, so many of our members are companies that can help us serve this mission. Member organizations are substantially involved in medical and/or medical device research, development, treatment, or education; the promotion of public health; or expertise in regulatory science.