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

<table>
<thead>
<tr>
<th>Practice</th>
<th>Percentage of Respondents</th>
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<tbody>
<tr>
<td>Promote quality</td>
<td>9% 91%</td>
</tr>
<tr>
<td>Prioritize quality over cost</td>
<td>63%</td>
</tr>
<tr>
<td>Define/establish quality and employee role</td>
<td>10% 90%</td>
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<tr>
<td>Include quality in performance reviews</td>
<td>84%</td>
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<tr>
<td>Employ objective quality performance measures</td>
<td>10% 90%</td>
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<tr>
<td>Engage to understand behaviors that drive quality</td>
<td>33% 67%</td>
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<tr>
<td>Effectively communicate quality strategy</td>
<td>22% 78%</td>
</tr>
<tr>
<td>Focus on prevention over reaction</td>
<td>53% 47%</td>
</tr>
<tr>
<td>Formally measure cost of quality</td>
<td>61% 39%</td>
</tr>
<tr>
<td>Benchmark and share best practices</td>
<td>43% 57%</td>
</tr>
</tbody>
</table>

Survey Results: Moving Beyond Compliance Toward Quality

KEY
- Neutral or Disagree
- Strongly Agree or Agree
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.

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.