Case for Quality Collaborative Community

A Collaborative Community Convened by the Medical Device Innovation Consortium (MDIC)

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Background

After an in-depth review of device-quality data and feedback from the medical device ecosystem, the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) found widespread manufacturing risks that affected product quality. The review also showed that manufacturers focusing on and managing those risks often become more productive, receiving fewer complaints, opening fewer corrective and preventive actions, and having lower quality-related product costs. Recognizing that an investment in quality has long-term payoffs for all medical device stakeholders, CDRH launched its Case for Quality (CfQ) program in 2011.

Focusing on quality can also promote a smoother submission-review process and, therefore, faster access to high-quality devices. Better product quality also helps hospitals, payers, healthcare providers, and patients to be confident that the devices they rely on will perform as intended. Predicting and managing the right risks can also enable device manufacturers to reduce costs and increase profits by focusing on quality during medical device design and production. Simply put, an investment in quality has long-term payoffs.

The Medical Device Innovation Consortium

In late 2012, the Medical Device Innovation Consortium (MDIC) was formed to advance regulatory science at the medical device industry level. MDIC is the first-ever public-private partnership created to promote medical device regulatory science for patient benefit. CDRH entered into a public-private partnership (PPP) with MDIC in 2012 to advance the use of regulatory science in the total product life cycle of medical devices. MDIC’s work is unique and complementary to trade associations such as AdvaMed and the Medical Device Manufacturers Association (MDMA).

This unique PPP joined patients, regulators, industry, and nonprofits together to improve medical technology. This is accomplished through four core initiatives that focus on clinical science, health economics and patient value, data science and technology, and the National Evaluation System for health Technology Coordinating Center (NESTcc).

Within the Data Science and Technology initiative, FDA and MDIC are working to enhance medical device quality and patient safety through CfQ. The FDA-MDIC collaboration launched in 2014 to expand FDA efforts to elevate the focus of device stakeholders beyond regulatory compliance to advancing device quality and safety. Reflecting the CfQ guiding principles of trust, transparency, and collaboration in 2020, MDIC transitioned CfQ into a collaborative community (CfQcc) under the oversight of the CfQcc Steering Committee, with MDIC serving as the Convener.

CfQcc focuses the medical device ecosystem—FDA, manufacturers, healthcare providers, and others—on product quality, a focus that boosts patient safety and outcomes and adds value to all stakeholders. Through initiatives and working groups, FDA and stakeholders develop practices, tools, and metrics to promote product quality, from product design and manufacturing to product performance. CfQcc likewise supports regulatory practices that promote these goals. CfQcc helps FDA identify device makers that consistently produce high-quality products. This allows FDA to support these companies’ operations while focusing resources on manufacturers less able to meet regulatory requirements.

CfQcc efforts include the Voluntary Improvement Program (VIP), Medical Device Information Analysis & Sharing (MDIAS), Corrective and Preventive Action (CAPA) Process Improvement Pilot Study, Accelerate Sustainable Capability Pilot, Culture of Quality Initiative, and CfQcc Forums.
Voluntary Improvement Program (VIP)

CfQcc identified the need for a different approach to evaluate quality in the manufacturing of medical devices. By emphasizing consistent quality manufacturing alongside compliance, stakeholders can advance device quality and safety, potentially improving patient outcomes. After a thorough assessment of methods to accomplish this, FDA and MDIC determined that a complimentary two-pronged approach could have the most impact: (1) quality appraisals using the Capability Maturity Model Integration (CMMI) V2.0 and (2) changes to FDA regulatory activities to increase emphasis on quality during medical device manufacturing. The VIP pilot was launched in 2018 to implement this methodology, enrolling device manufacturing sites already in good standing with FDA. Participating sites underwent an appraisal by the CMMI Institute to assess their capability to manufacture high-quality medical devices. FDA and pilot participants committed to solution-focused interactions with early engagement and transparency.

The VIP pilot is now transitioning into a fully operational program. It leverages the Medical Device Discovery Appraisal Program (MDDAP), which is a version of the CMMI framework of proven best practices and appraisal methodology that has been tailored for the medical device industry. MDDAP provides a model by which device makers can measure their capability to produce high-quality devices and increase patient safety. CfQcc and FDA expect to complete the VIP transition to a fully operational program in fiscal year 2021.

In the VIP, an experienced appraisal team will evaluate an organization’s capabilities through a conversational approach. The results are then summarized so that the organization can quickly identify areas of strength and opportunities for improvement.

The VIP pilot is not heightened FDA scrutiny. It focuses on understanding how to improve quality and outcomes versus a “check-the-box” approach. The engagement:

- Collects information to understand how work is actually performed
- Highlights capabilities and activities that add value
- Drives focused and sensible performance-improvement discussions

The engagement does not:

- Review standard operating procedures (SOPs) with staff that typically manages audits in a “front room/back room” model
- Check for Code of Federal Regulations (CFR) compliance (this is a requirement to participate)
- Expect all identified opportunities to be addressed like a corrective action list

Recognizing participants’ commitment to quality and leveraging performance appraisal information, FDA can simplify regulatory requirements, reducing associated burden for medical device manufacturers. For example, FDA can:

- Forego routine and risk-based inspections
- Streamline and accelerate the review and approval for manufacturing process changes and transfers
- Direct resources to innovation and improvement
More than 80% of the program participants report that the appraisal benefited product quality, and more than 90% report a positive experience. Participants have seen hundreds of thousands of dollars in operational improvements as well as millions of dollars in revenue opportunities.

**Guiding Principles**

The VIP is a continuous improvement tool, not a new compliance requirement, and is complementary to other process and business improvement plans:

1. It is more important to establish a baseline and show progress than have a perfect measure or solution.
2. Participants need not achieve a specific maturity level to continue or qualify for FDA modifications. Participants have a compliant quality system, and the appraisal will improve that system.
3. FDA modifications reflect a commitment to improvement, transparency, and engagement.
4. The appraisal engages primarily with staff doing the work and considers the effectiveness of processes and systems. Minimal preparation is required and disruption should be limited.
5. The focus of the appraisal is the people and their work, the processes, and the outcomes, not compliance or number of documents.

Under the oversight of the CfQcc Steering Committee, the VIP Governing Committee directs the strategic vision of the VIP to promote patient benefit and advanced healthcare outcomes.
Medical Device Information Analysis & Sharing (MDIAS)

FDA and CfQcc are working with the MITRE corporation to develop the capability to analyze medical device data to improve healthcare outcomes. This new CfQcc program, which began in earnest in early 2020, is referred to as Medical Device Information Analysis and Sharing (MDIAS), a data-sharing collaboration that recognizes that widely sourced data can provide powerful insights.

The MDIAS project is modeled on other successful public-private partnerships that advanced safety in various industries and applications.

Information Analysis

MDIAS will fuse various healthcare data sources to identify quality and safety trends and assess the impact of changes in the operating environment. Data will be safeguarded by an independent trusted third party (TTP) to foster broad participation and engagement.

Data sources will include both public and non-public data. Public sources include data on OpenFDA, medical device reports, and device recalls. MDIAS is expected to be operational in 2021. Governed by a broad set of agreements with FDA and industry partners, MDIAS will have the ability to query and analyze millions of narrative and digital device records.
Information Sharing

MDIAS will enable the exchange of data and analytical capabilities among its partners. The MDIAS vision is to facilitate data sharing from device manufacturers, healthcare providers, patients, payers, trade associations, universities, and government. All partners will receive aggregate analysis results, enabling each partner to make the quality and safety improvements those analyses suggest. Ultimately, the entire industry—and the patients it serves—will benefit.

Under the oversight of the CfQcc Steering Committee, an MDIAS Governing Committee will direct MDIAS to conduct analyses to characterize the root causes for known risks and to mine data to discover emerging vulnerabilities. Aggregate deidentified results of these analyses will be shared with MDIAS partners to advance healthcare outcomes. MDIAS will also establish benchmarks so that partners may assess their own performance against the industry.

Proof of Concept

In 2020, stakeholders representing FDA, device manufacturers, and healthcare providers began work with the TTP to conduct an MDIAS proof of concept (PoC). This PoC demonstration is slated to finish in 2021.
CAPA Process Improvement Pilot Study

CfQcc has made a significant impact on medical device manufacturing. For example, the VIP has been embraced by many medical device companies and looks to improve product quality and patient outcomes. To that end, CfQcc facilitated industry and FDA collaboration to bring together best practices to recast the corrective and preventive action (CAPA) process as a risk-based continuous-improvement process.

Today's CAPA process has become highly focused on compliance. Moreover, manufacturers struggle to determine which issues require a more structured CAPA process and which issues may be solved in alternative ways. While the concept of a risk-based approach is not new, many medical device companies still apply a “one-size-fits-all” methodology; subjecting most issues to a rigid and heavily documented CAPA process then becomes overburdensome, inefficient, and less effective.

The intent of the CAPA process improvement pilot study is to design a more effective, efficient, and user-friendly process that would drive higher product quality while still meeting the intent of the regulations. A white paper details these efforts, summarizing initial findings and recommendations, including a proposal for a risk-based improvement framework. The initial phase of the CAPA process improvement pilot study has been well received by industry and looks to make a significant impact on the continuous improvement of medical device manufacturing. Currently CfQcc is seeking additional firms to participate in the pilot study.
High-Level Pilot Process Summary

Enrollment

1. **ENROLLMENT REQUIREMENTS**
   - No Official Action Indicated
   - Good standing with regulatory bodies
   - CIQ VIP site

2. **TEAM APPROVAL**
   - Gain approval for site enrollment
   - Identify team sponsor

3. **SITE LEADERSHIP APPROVAL**
   - Ensure top-level leadership at site is aligned with site participation

Prework & Pilot Activation

1. **BASELINE DATA COLLECTION**
   - Collect baseline metrics for comparison purposes (2 months)

2. **UPDATE INTERNAL PROCESS**
   - Implement framework into site strategy, Quality Plan, and applicable Quality Management System

3. **PILOT ACTIVATION**
   - Initiate “Active Pilot Work”
   - Initiate Pilot Data Collection

3-Month Progress Check

1. **EXECUTE 3-MONTH PROGRESS CHECK**
   - Complete 3-month progress check with FDA team members

2. **WEEKLY PILOT SITE MEETING**
   - Site Pilot Leader holds weekly status meetings

3. **BIWEEKLY TEAM MEETING**
   - Escalate Pilot Data Collection Issues & Lessons Learned
   - Problem solve

4. **QUARTERLY SURVEY**
   - Complete quarterly survey
   - Escalate issues, Lessons Learned
   - Problem solve

5. **EVENT LEVEL DATA COLLECTION**
   - Collect event data
   - Escalate issues, Lessons Learned
   - Problem solve

Active Pilot Work

Transition
Accelerate Sustainable Capability (ASC) Pilot Study

Building on the success of VIP, MDIC is facilitating a pilot study between the medical device industry and FDA to reconsider how sites under an administrative action can reach faster and more sustainable compliance. The goal is to test a systemic improvement method that allows compliance actions to be closed sooner and more sustainably while maintaining metrics and risk assessments connected to FDA oversight. MDIC is currently seeking firms interested in participating in the pilot study.

Apply at https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/
Culture of Quality Initiative

CfQcc recognizes that medical device industry leaders are committed to a culture of quality that transcends compliance and serves as a competitive differentiator. Accordingly, the device industry is taking a proactive approach that requires a commitment to measuring quality investments. More device companies are being measured and paid based upon the quality of their products and services.

Beyond the commitment to patients, a culture of quality is critical for four reasons. First, organizations are trying to stop hemorrhaging value due to poor quality. Second, FDA is advancing its expectations for an organizational commitment to quality. A third and increasingly compelling reason is customer demand; the patient’s call for quality and the power of patient advocacy groups are key quality drivers. Lastly, the availability of real-world data provides opportunities to measure quality. Thus, organizations are now focused on quality because they know that it can produce top-line and bottom-line results. Device makers increasingly recognize the need for a strong culture of quality. An MDIC quality survey of medical device industry employees revealed that 90% of organizations report that their leadership actively promotes quality across activities and functions. Nearly two-thirds (63%) prioritize high-quality performance over costs and competing priorities, while most organizations encourage staff understanding of how quality applies to jobs and performance reviews.

Survey Results: Moving Beyond Compliance Toward Quality

<table>
<thead>
<tr>
<th>Promote quality</th>
<th>9%</th>
<th>91%</th>
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<tbody>
<tr>
<td>Prioritize quality over cost</td>
<td>10%</td>
<td>90%</td>
</tr>
<tr>
<td>Define/establish quality and employee role</td>
<td>16%</td>
<td>84%</td>
</tr>
<tr>
<td>Include quality in performance reviews</td>
<td>10%</td>
<td>90%</td>
</tr>
<tr>
<td>Employ objective quality performance measures</td>
<td>22%</td>
<td>78%</td>
</tr>
<tr>
<td>Engage to understand behaviors that drive quality</td>
<td>33%</td>
<td>67%</td>
</tr>
<tr>
<td>Effectively communicate quality strategy</td>
<td>43%</td>
<td>57%</td>
</tr>
<tr>
<td>Focus on prevention over reaction</td>
<td>53%</td>
<td>47%</td>
</tr>
<tr>
<td>Formally measure cost of quality</td>
<td>61%</td>
<td>39%</td>
</tr>
<tr>
<td>Benchmark and share best practices</td>
<td>43%</td>
<td>57%</td>
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Leadership Engagement Playbook

MDIC saw an opportunity to further facilitate a culture of quality by creating a Leadership Engagement Playbook for medical device leadership. The playbook highlights leaders’ roles in influencing product quality, 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. To expand this work, the Culture of Quality working group will collaborate with industry leaders to develop and pilot practices within their organizations and publish case studies for broader industry use and benefit.

Download the playbook at https://mdic.org/resource/case-for-quality-leadership-playbook/

Case for Quality Forums

The Case for Quality Forum series provides an ongoing venue for discussing areas of quality improvement, opportunities for improving device quality, and steps all stakeholders can take to accelerate adoption of best practices. Since the series began in 2016, more than 785 people representing 340 different organizations including medical device firms, government agencies, academic institutions, and consultancies have participated.

Learn more at https://mdic.org/project/case-for-quality-forums/
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