Today’s corrective and preventive action (CAPA) process is highly focused on compliance. Many manufacturers struggle to determine which issues require a more structured CAPA process and which issues can be solved in alternative ways. As a result, manufacturers typically apply a resource draining one-size-fits-all CAPA approach. Implementing a risk-based CAPA approach can lead to a more effective, efficient, and user-friendly process that remains compliant.

**CAPA Process Improvement Pilot Study**

The CAPA Process Improvement Pilot Study focuses on developing a risk-based improvement framework for CAPA and a pilot process for implementing the framework.

- **Device**
- **Risk Assessment**
- **Traditional CAPA Method**
  - High Risk
  - Medium Risk
  - Low Risk
  - Traditional CAPA

- **Device**
- **Risk Assessment**
- **Fast Track CAPA Method**
  - High Risk
  - Medium Risk
  - Low Risk
  - Fast Track CAPA

**CASE FOR QUALITY COLLABORATIVE COMMUNITY (CfQcc)**

The CAPA Process Improvement Pilot Study 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.

**HOW TO GET INVOLVED**

**Join the Pilot Study.**

We are actively recruiting participants in the Pilot Study. To participate, please contact Alan Baumel, Program Director for CfQcc, at abaumel@mdic.org.

**Share your ideas.**

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

**RESOURCES**


**LEARN MORE ABOUT THE CAPA PROCESS IMPROVEMENT PILOT STUDY TODAY!**

For more information or to join the Pilot Study, 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.

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.