MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

VOLUNTARY IMPROVEMENT PROGRAM (VIP) OF THE CASE FOR QUALITY COLLABORATIVE COMMUNITY (CfQcc)

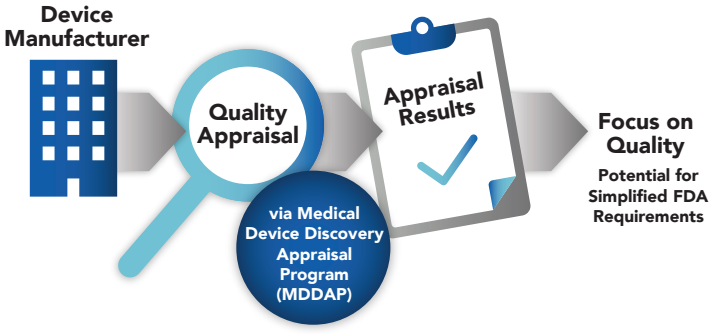
A culture of quality cultivated by leaders and executives, serves as not only as a clear competitive differentiator but instills confidence for regulators and users. Moving from a culture of compliance to one of quality takes commitment from the entire organization.

The VIP at MDIC charts a path to how a device manufacturer can consistently demonstrate and evaluate quality and how the FDA could potentially recognize and reward quality within an organization.

Defining a path for manufacturers to improve quality and demonstrating how doing so may reduce regulatory burdens, could advance the shift to a culture of quality.

CfQcc Voluntary Improvement Program

The cornerstone of the Voluntary Improvement Program (VIP) is emphasizing consistent quality manufacturing alongside compliance to advance device quality and safety. Device manufacturers who are committed to quality undergo a third party quality appraisal. The appraisal seeks to measure the capability to manufacture high quality devices. Participants of MDIC's VIP have benefited from improved product quality, significant savings from operational improvements, enhanced revenue opportunities, and decreased regulatory burdens.



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.

ABOUT MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, NIST, and other agencies, industry, non-profits, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies.

MDIC coordinates 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.

We are driving faster, safer, and more cost-effective innovation for patient benefit.

CASE FOR QUALITY COLLABORATIVE COMMUNITY (CFQCC)

The Voluntary Improvement Program is an effort of the Case for Quality Collaborative Community and offers a unique forum for medical device stakeholders to move beyond baseline regulatory compliance activities and collaboratively develop sustained predictive practices. These predictive practices could 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.

CONTACT

For further information contact the MDIC Case for Quality Team at CfQcc@mdic.org.