



CASE FOR QUALITY

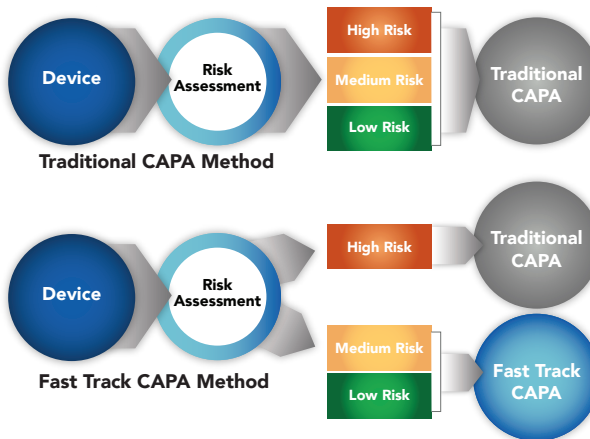
#MakeCAPACool

Study of Organizations Implementing Framework Strategies, Case for Quality Collaborative Community (CfQcc)

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

Medical Device Innovation Consortium (MDIC) recently completed a pilot study focusing on the risk-based improvement framework to move beyond baseline regulatory compliance activities and collaboratively develop sustained practices that advance quality. The experiences from the framework pilot study will be shared through a collaborative white paper to be published by MDIC.



Resources

Available at www.mdic.org

- CAPA Process Improvement White Paper
- CAPA Process Improvement Auditor Training
- CAPA Process Improvement Pilot Study Overview

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 #MakeCAPACool 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.

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.

LEARN MORE ABOUT MAKING CAPA COOL

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

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