



ACCELERATE SUSTAINABLE CAPABILITY (ASC) PILOT STUDY

A study to help medical device manufacturers with compliance issues improve performance and compliance

Medical device manufacturers that participate in the ASC Pilot Study are testing a systemic improvement methodology that can help them:

- Improve product quality and safety
- Reach compliance quickly
- Structure systems for continuous improvement
- Identify metrics to monitor product safety throughout the pilot

MDIC is accepting applications for the ASC Pilot Study.

About the ASC Pilot Study

The Medical Device Innovation Consortium (MDIC) is managing the ASC Pilot Study under a grant from FDA’s CDRH. The medical device industry and the Information Systems Audit and Control Association are also collaborating on this study.

MDIC will pay for all activities during the study, which will last about 18 months. Activities include:

- Initial Capability Maturity Model Integration (CMMI) appraisal
- Action plan reviewed by the FDA
- Quarterly checkpoints
- Performance metrics
- Residual risk assessment facilitated by Mgmt-Ctrl

The FDA generally will not conduct planned routine inspections during the study. Participants may request a Certificate for Foreign Governments, if needed.

APPLY NOW



WHO CAN APPLY?

Medical device manufacturers can apply to participate in the ASC Pilot Study if they:

- Market medical devices in the U.S.
- Have an established Quality Management System (QMS) (see 21 CFR Part 820)
- Have 2 or more major deficiencies as:
 - Self-reported voluntarily
 - Cited in an FDA Form 483 during a recent inspection
 - Cited in an Advisory Action or Request for a Regulatory Meeting (open Warning Letter, Untitled Letter, or Regulatory Meeting)

APPLY NOW

LEARN MORE

- FDA Announcement of the MDIC ASC Pilot Study
- Frequently Asked Questions
- ASC Pilot Study Playbook
- ASC Pilot Study Information Session Recording

ASK QUESTIONS

MDIC CfQ Associate VP [Joe Sapiente](#)
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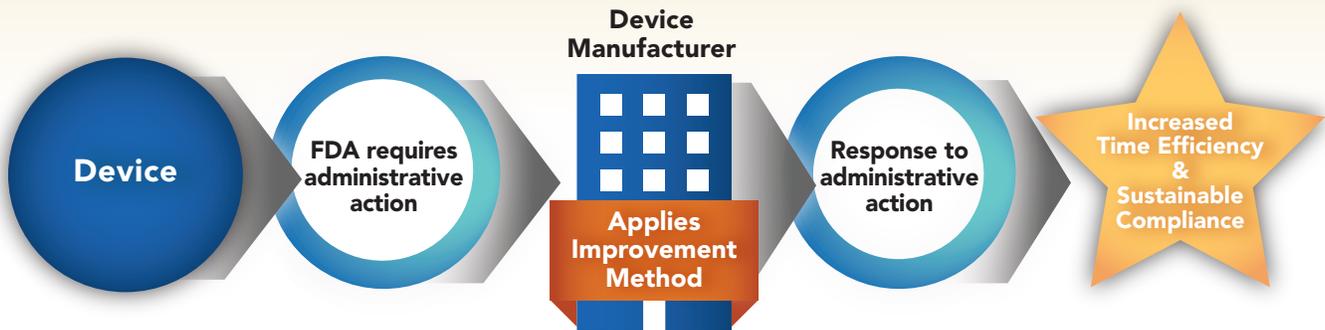


Supporting Quality in Medical Device Manufacturing

The ASC pilot study is part of MDIC's Case for Quality Collaborative Community (CfQcc), which brings together the FDA and other medical device stakeholders to enhance device quality and patient safety. The Case for Quality Collaborative Community recognizes and supports best practices for consistent quality manufacturing. This program allows the FDA to identify high-quality device manufacturers and allocate its resources to assist other device manufacturers in increasing their quality.

The Case for Quality Collaborative Community is part of MDIC's Data Science & Technology initiative, which creates tools and methods to use advanced data analysis techniques and new technology to:

- Accelerate the collection of clinical data
- Remove barriers to patient access
- Monitor product safety, quality, and effectiveness



About MDIC

MDIC is the first-ever public-private partnership created to advance medical device regulatory science for patient benefit. MDIC brings together representatives of the FDA, NIH, CMS, industry, non-profit organizations, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies. Data Science & Technology is one of four MDIC initiatives. The other initiatives are:



Clinical Science



Health Economics and Patient Value



National Evaluation System for Health Technology Coordinating Center (NESTcc)

Our work is unique and complementary to trade associations such as AdvaMed and MDMA.

LEARN MORE ABOUT MDIC

Visit our [website](#).

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