



Improve Compliance in Medical Device Manufacturing

The MDIC Accelerate Sustainable Capability (ASC) Pilot Study

The ASC Pilot Study helps medical device manufacturers that are struggling to achieve or sustain regulatory compliance.

Benefits



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

Participants

Medical device manufacturers that:

- 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



Study Details



About 18 months



No cost for study activities

Study Activities

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



Collaborators



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