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Innovating Better Medical Devices Faster at Lower Costs

Medical device manufacturers with a strong compliance profile can sign up to be industry leaders in a pilot program that aims to offer better patient safety outcomes through performance improvements against a set of proven best practices. Results may pay for themselves through a competitive advantage of increased quality, lower costs, and saved time.

What is the Medical Device Discovery Appraisal Program (MDDAP)?

The MDDAP partnership brings together the FDA, the Medical Device Innovation Consortium, and the medical device industry...

FDA INDUSTRY MDIC

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...to leverage the ISACA CMMI framework and appraisal method so that device makers can measure their capability to produce quality products through an independent assessment of their organization.

Over 70 Companies are Enrolled, with Room for More—Why Participate?

In recognition of a participant's commitment to pursue quality beyond compliance, and leveraging performance information obtained from the appraisal, **FDA is able to simplify regulatory requirements to reduce the burden and disruption from compliance activities.**

INSPECTIONS
- Facility is removed from routine inspection
- Facility is removed from risk-based work plan

→ Potential cost savings of $20K-$140

30-DAY CHANGE NOTICES
- Streamlined submission
- Bundle multiple products & changes
- Accelerated approval - 5 days

→ More submissions, improved employee morale, faster time to market for device improvements, and re-deployment of FTE resources, potentially saving $10k-$500k.

PRODUCT TRANSFER
- Streamlined submission
- Accelerated approval - 3 weeks

→ Easier and faster transfer of products for reduced distribution costs.

PMA MANUFACTURING SECTION
- Streamlined submission
- Waive pre-approval inspection

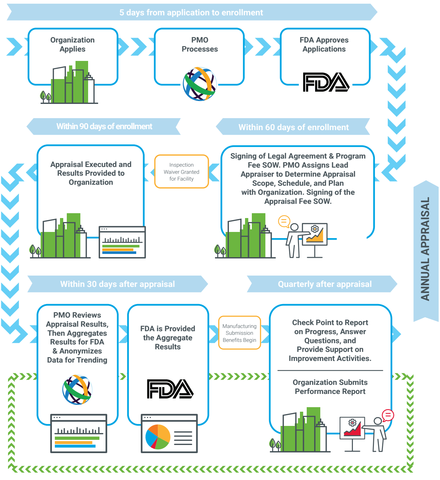
→ Products can reach market faster, to respond to patient needs.

A Culture of Quality— Across the Healthcare Ecosystem

The CMMI framework and appraisal method **helps organizations identify opportunities to improve business performance:**

How Does MDDAP Work?

This is not an invitation to heightened regulatory scrutiny by the FDA—there is no downside to participating in the pilot. **This voluntary "conversational" engagement is focused on understanding how to improve quality and outcomes;** it is not focused on "checking the box" for regulatory compliance.



RESULTS FROM EARLY ADOPTERS OF THE MDDAP PILOT PROGRAM SAY:

91% Believed the appraisal identified improvement areas to increase overall product quality.

93% Had positive experience with the appraisal approach and execution.

100% Would recommend this program to other organizations.

HOW IS THIS DIFFERENT THAN AN FDA INSPECTION?

WHAT MDDAP IS	WHAT MDDAP IS NOT
• Focus on capabilities and activities that add value to the organization	• Does not check for compliance to CFR as that is a requirement to enroll in the program
• Collect information from staff in a conversational manner to understand how work is actually performed	• Does not review SOPs with those who typically manage audits in a "front room"/"back room" manner
• Drive discussions for how to improve performance in a focused way that makes sense to the business	• Does not expect all identified opportunities to be addressed like a corrective action list

Program Cost vs. Return on Investment (ROI)

A standard $5,000 annual Program Fee is required to support each enrolled facility in the program. A separate Appraisal Fee will be determined based on the scope of work required to complete the appraisal and varies based on company size, location, and complexity. Note, reduced fees are available for organizations registered as a "small business" with an FDA SBD number. All enrolled organizations stand to benefit from a cost, time, and resource perspective.

One organization realized annual savings of nearly $300k

Another organization increased production capacity by 11%, resulting in an additional $15M in sales

"The maturity assessment provided us with an evaluation of the health of our operations, engaging individuals most familiar with our day-to-day work. **The assessment helped us identify strengths and weaknesses and opportunities for further consideration.** As important, the assessment helped us develop operational excellence metrics that will measure the continuous execution and quality oversight of our processes. **Now, a cross-functional team is exploring how we can capitalize on what we learned to further advance our processes and our ability to provide world-class products and services to our customers.**"

Kathie Bardwell
Senior Vice President & Chief Compliance Officer
STERIS Corporation

"Innovize has had a great experience going through the MDDAP assessment with experienced and well-trained assessors. **The types of concerns found by the assessors provide a great roadmap to help Innovize improve our costs, efficiencies and achieve a higher maturity level.**"

Mark Rutkiewicz
VP Quality
INNOVIZE

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For more information on the Medical Device Discovery Appraisal Program, go to https://cmmiinstitute.com/medicaldevice