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.

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.

5 days from application to enrollment
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Organization Applies
PMO Processes
FDA Approves Applications

Within 90 days of enrollment
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Appraisal Executed and Results Provided to Organization
Signing of Legal Agreement & Program Fee SOW. PMO Assigns Lead Appraiser to Determine Appraisal Scope, Schedule, and Plan with Organization. Signing of the Appraisal Fee SOW.

Within 60 days of enrollment
- Inspectors Waiver Granted for Facility

Within 30 days after appraisal
- PMO Reviews Appraisal Results, Then Aggregates Results for FDA & Anonymizes Data for Trending
FDA is Provided the Aggregate Results

Quarterly after appraisal
- Check Point to Report on Progress, Answer Questions, and Provide Support on Improvement Activities.
Organization Submits Performance Report

ANNUAL APPRAISAL

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

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