Innovating Better Medical Devices Faster at Lower Costs

Medical device manufacturers turn to a strong compliance partner to improve their overall business operations in a focused, integrated manner. The Medical Device Discovery Appraisal Program (MDDAP) helps organizations identify opportunities to improve business performance:

- Waive pre-approval inspection
- Streamlined submission
- Accelerated approval – 3 weeks
- Streamlined submission
- Accelerated approval – 5 days
- Bundle multiple products & changes
- Streamlined submission
- Facility is removed from routine inspection

How Does MDDAP Work?

This voluntary “conversational” engagement is focused on understanding how to improve quality and compliance activities.

- One-on-one conversations with those who typically manage audits
- Does not review SOPs with CFR as that is a requirement to enroll in the program
- Brought together a variety of individual perspectives and stakeholders
- Collect information from staff to identify areas to increase overall product quality.
- Identifies improvement areas leading to better patient safety outcomes

*With the appraisal approach helps organizations identify opportunities to improve business performance:

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Program Cost vs. Return on Investment (ROI)

One organization realized annual savings of nearly $300k.

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

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Innovate with the appraisal approach to simplify regulatory requirements to reduce the burden and disruption from FDA inspections.

This is not an invitation to heightened regulatory scrutiny by the FDA—there is no downside to participating in the pilot.

In the pilot, we helped them develop operational excellence metrics that will measure the continuous execution and weaknesses and opportunities for further improvement.

The maturity assessment provided us with an understanding of how work is actually performed in a conversational manner to help simplify regulatory requirements to reduce the burden and disruption from FDA inspections.

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

In recognition of a participant’s commitment to process quality or regulatory compliance, the Medical Device Discovery Appraisal Program (MDDAP) is an opportunity to receive feedback on your processes and our ability to provide world-class products and services to our customers. “We believe the appraisal program is critical to the success of our business.

This is the opportunity to leverage the ISACA CMMI framework and appraisal method so that organizations can identify opportunities to improve quality and compliance activities.

A Culture of Quality—Across the Medical Device Industry

For more information on the Medical Device Discovery Appraisal Program, go to meddev.isaca.org/appraisal.