Innovating Better Medical Devices Faster at Lower Costs

Medical device manufacturers with a strong compliance program may report a computer that allows for a better patient safety oversight, through performance improvements across a set of revenue and product development levels while avoiding the cost and time associated with traditional approaches.

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

The MDDAP partnership brings together the FDA, the Medical Device Innovation Consortium, and ISACA, an independent third-party assessor, to simplify regulatory requirements to reduce the burden and disruption from traditional inspections.

How Does MDDAP Work?

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- Waive pre-approval inspection
- Streamlined submission
- Accelerated approval - 5 days
- Bundle multiple products & changes
- Facility is removed from routine inspection
- Easier and faster transfer of products for OEMs
- Reduced defect rates
- Reduced rework
- Faster time to market for device improvements,

How is this different than an FDA inspection?

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WHAT PROGRAM PARTICIPANTS SAY ABOUT MDDAP:

- One organization realized annual savings of nearly $300k
- Another organization increased production capacity by 40% to help Innovize improve our costs, efficiencies and achieve a higher product quality
- One organization moved from a reactive approach and execution.

Program Cost vs. Return on Investment (ROI)

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