Medical Device Discovery Appraisal Program (MDDAP):

The Case for Quality Voluntary Improvement Program (VIP) Explained

- BUILD SUSTAINABLE CAPABILITIES.
- DELIVER HIGH-QUALITY PRODUCTS.
- EXCEED BUSINESS OBJECTIVES.

Problem

Compliance requirements provide industry with the framework to establish a baseline level of quality and safety. However, treating compliance as an end goal, rather than a starting point, can result in cultural behaviors that may limit an organization's capability to continuously improve. When compliance is the end goal, companies may be less likely to consider more innovative, systemic, holistic or long-term solutions to improve outcomes, quality and safety.

Solution

The Case for Quality Voluntary Improvement Program (VIP) was developed in collaboration with the medical device industry, U.S. FDA, the Medical Device Innovation Consortium (MDIC) and ISACA.

VIP leverages ISACA's Medical Device Discovery Appraisal Program (MDDAP), a tailored version of the CMMI framework and appraisal methodology to help medical device manufacturers better understand, measure and improve their capabilities to deliver high quality products. It is the first Case for Quality program recognized by the FDA that offers participants regulatory opportunities to help **accelerate improvements to device quality and manufacturing.**

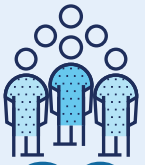
> "The medical device ecosystem is increasingly complex requiring new tools and approaches to providing the superior products with improved safety expected by patients, health care providers, and regulators. Results from participants in VIP have been impactful and support the concepts and approach developed for the program"
>
> —Cisco Vicenty, Case for Quality Program Manager, FDA CDRH

Outcomes

Participants surveyed about VIP said they experienced:

27%

decrease in time taken to close complaints

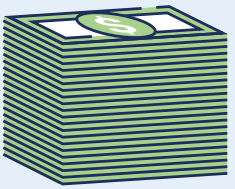


880+

additional high-risk patients received life-saving treatment

$15M+

in product sales reported from operational improvements in streamlined change notice process



4x

increase in manufacturing capacity, resulting in increased revenue

How it works

Trained and experienced appraisers first seek to understand how an organization functions by talking to those who do the work. This evidence is then evaluated against a proven set of best practices to identify opportunities for improvement. Leaders are empowered to prioritize the opportunities that most align to their business objectives. Quarterly check points enable the organization to track progress and receive guidance on improvement projects.

PARTICIPANTS SAY*

90%+

had a positive experience with the appraisal activities

> "The results from our MDDAP appraisal were actionable and were clearly defined in a way that we understand them. The appraisal and the process highlighted things that we would not have gotten from a compliance audit because the CMMI methodology identified process improvements against a proven set of best practices. That input for us was valuable because these were things we were not focused on before. We really value that."

—Rob Becker, Senior Director, Quality, Edwards Lifesciences

Regulatory Opportunities

Manufacturers who demonstrate a commitment to continuous improvement in the program may benefit from the following VIP-specific regulatory opportunities:

Inspections: Program engagement informs a risk-based approach to FDA inspection planning and resource allocation for routine surveillance, pre-approval and post-market inspections.

Change Notices: Program data enables use of a modified submission format with reduced timeframes (resources permitting) for Premarket Approval Application (PMA) and Humanitarian Device Exemption (HDE) 30-Day Change Notices.

Site Changes: Program data enables use of a modified submission format with reduced timeframes (resources permitting) for PMA and HDE Manufacturing Site Change Supplements.

Manufacturing Modules: Program data enables use of a modified submission format for PMA or HDE Manufacturing Modules.

Why you should participate

VIP promotes a culture of quality throughout an organization to support goals:

- REDUCED DEFECTS AND REWORK
- LOWERED COSTS OF QUALITY
- ACCELERATED TIME TO MARKET
- INCREASED PATIENT SATISFACTION

Eligibility information

- Be part of the lifecycle for medical devices distributed in the U.S. (Class I, II, III).
- Companies should have prior compliance history or compliance profile (i.e. U.S. FDA inspection or MDSAP audit), as well as site registration and device listing wi th U.S. FDA.
- Facilities must not be under Official Action Indicated (OAI) status or subject to a judicial action Voluntary Action Indicated (VAI) is acceptable.

Read the full eligibility requirements on our website or contact us for details.

PARTICIPANTS SAY*

96%+

reported the appraisal provided broader value-add to the organization

> The MDDAP program has enabled BSC to establish new relationships with peer companies for sharing of best practices, while also strengthening our relationship with FDA. And significantly, it has given our participating sites access to the impactful regulatory benefits that this program offers—which in turn benefits our patients and customers around the world."

Conor Dolan, VP Global Quality Systems & Supplier Quality, Boston Scientific

PARTICIPANTS SAY*

85%+

believed the appraisal identified opportunities to improve product quality

Join a growing community that learns from each other

VIP provides many ways for participants to engage with each other and shape the directon of the program, including working groups, mentorship opportunities, monthly participant calls and more.

Apply today!

Learn how your organization can improve its capabilities to deliver high quality products at **isaca.org/mddap**

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*Based on responses from surveyed CMMI/VIP participants.

ISACA

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