VOLUNTARY IMPROVEMENT PROGRAM
Delivered by ISACA

Innovating Better Medical Devices Faster at Lower Costs

Medical device manufacturers with a strong compliance profile can participate in a 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 Voluntary Improvement Program

This collaborative program brings together the FDA, the Medical Device Innovation Consortium, and the medical device industry 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.

Be rewarded for your dedication to continuous improvement!

FDA simplifies regulatory requirements to reduce the burden and disruption from compliance activities.

INSPECTIONS

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

Potential cost savings of **$20K-$140**

30-DAY CHANGE NOTICES

Program data enables use of a modified submission format with reduced timeframes (resource permitting) for PMA and HDE 30-Day Change Notices

More submissions, improved employee morale,faster time to market for device improvements,and re-deployment of FTE resources, potentially saving **$10k-$500k**.Many have accelerated approval within 5 days.

PRODUCT TRANSFER

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

Easier and faster transfer of products for **reduced distribution costs.** Many have accelerated approval within 3 weeks.

PMA MANUFACTURING SECTION

Program data enables use of a modified submission format for Premarket Approval Application (PMA) or Humanitarian Device Exemption (HDE) Manufacturing Modules.

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

Read the details of these Regulatory Opportunities in the FDA Final Guidance ***Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program***

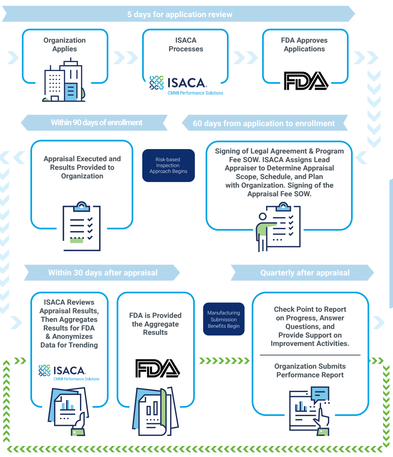
A culture of quality— across the healthcare ecosystem

The Voluntary Improvement Program **helps organizations identify opportunities to improve business performance:**

- **Reduced Defects & Rework**
- **Reduced Costs**
- **Accelerated Time to Market**
- **Increased Customer Satisfaction**

How does the program work?

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



WHAT PROGRAM PARTICIPANTS SAY ABOUT VIP:

85%+ IDENTIFIED IMPROVEMENT AREAS TO INCREASE QUALITY

27% DECREASE IN TIME TO CLOSE COMPLAINTS

65% INCREASE IN DAILY PRODUCTION

HOW IS THIS DIFFERENT THAN AN FDA INSPECTION?

WHAT THE APPRAISAL IS	WHAT THE APPRAISAL 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 $8,000 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

"VIP has demonstrated that focusing on quality and continuous improvement has impactful results for patients and drives significant value for participating manufacturers. With the release of the final guidance for VIP, CDRH has published policy leveraging the third-party maturity appraisal in its day-to-day operations. This milestone establishes our commitment to VIP, enables the program to grow, and provides CDRH a foundation to implement additional improvements in our goals to improve the quality and safety of medical devices. There is a very exciting opportunity ahead for us."

Fancisco Vicenty
Case for Quality Program Manager
FDA CDRH

"The results from our VIP 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