Regulatory Opportunities of the Voluntary Improvement Program

The Case for Quality Voluntary Improvement Program (CfQ VIP), leverages the Medical Device Discovery Appraisal Program (MDDAP) as the framework by which medical device companies can measure their capabilities against best practices.

Participants in VIP may benefit from several opportunities to help accelerate improvements to device quality and manufacturing.

Opportunities

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

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

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

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

What Participants Are Saying*

**Change Notices: Before and After VIP**

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*Based on responses from surveyed CMMI/VIP participants.

Program Results

More submissions have increased innovation and time to market for device improvements, and re-deployment of resources saving

**US$ 10–50k**

Distribution costs WERE REDUCED because of the easier and faster transfer of products to an MDDAP Participant site.

Products can reach market FASTER and respond better to PATIENT NEEDS.

Interested in learning more about MDDAP and applying for the Case for Quality Voluntary Improvement Program? Visit [www.isaca.org/mddap](http://www.isaca.org/mddap) today.