

# 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.



### 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.



### Change Notices

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



## 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

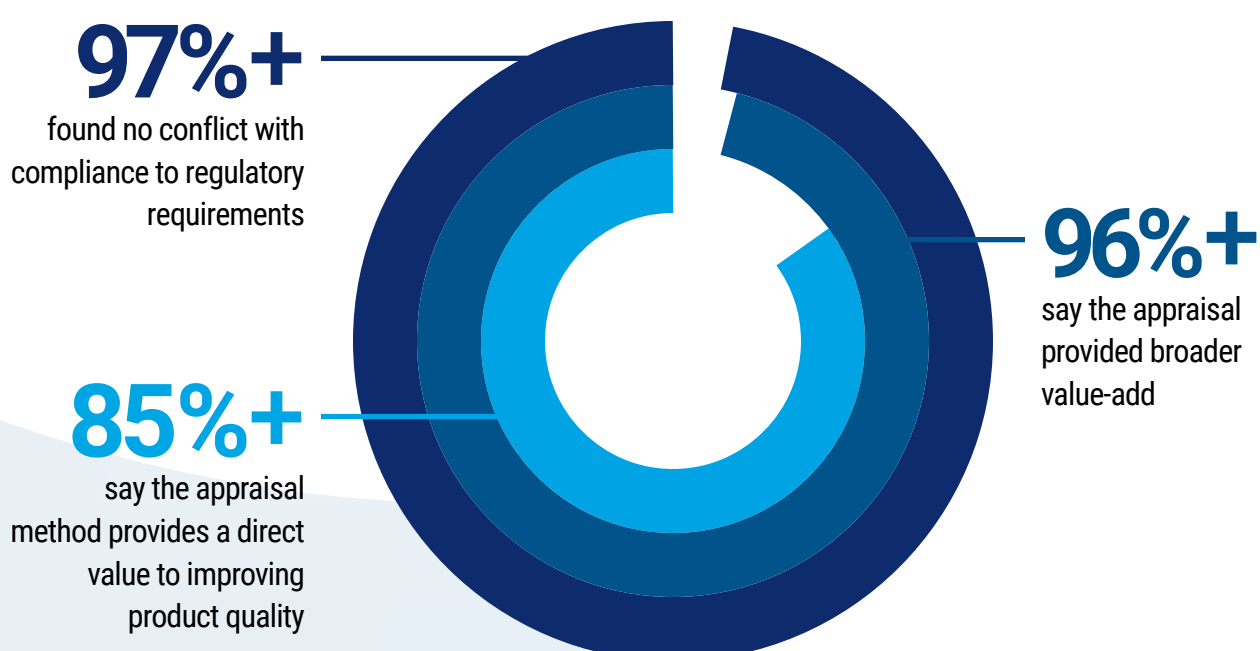
because of the easier and faster transfer of products

to an **MDDAP**

Participant site.

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

## What Participants Are Saying\*



\*Based on responses from surveyed CMMI/VIP participants.

“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

## Change Notices: Before and After VIP



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.

