



Medical Device Discovery Appraisal Program

CDRH Case for Quality Pilot Program

Cisco Vicenty Francisco.Vicenty@fda.hhs.gov

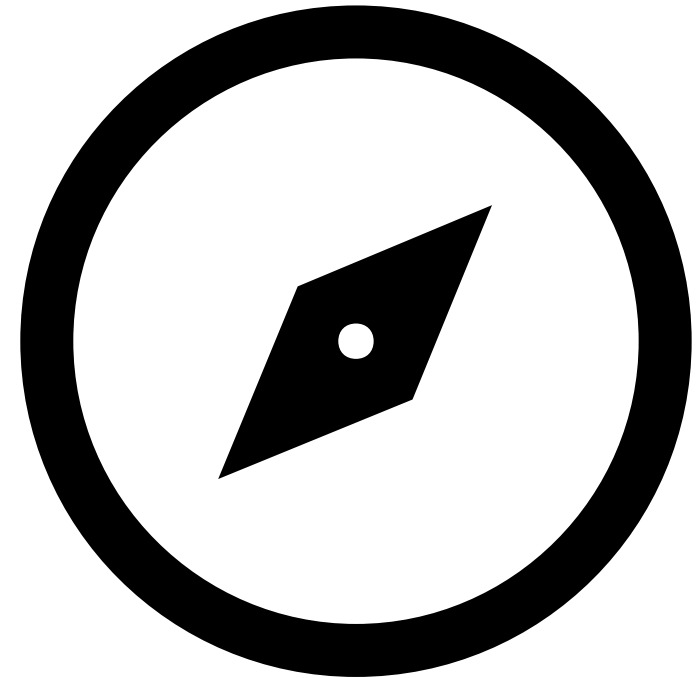
Kimberly Kaplan kkaplan@cmmiinstitute.com

George Zack george.zack@twohc.com

June 28, 2018

Today we will cover:

- What has been done with the Medical Device Discovery Appraisal Program thus far?
- Where is the program expected to go in the remainder of the year and into 2019?



What has been done?

- 14 appraisals performed (28 enrolled across 16 organizations)
- Appraisals performed across 11 CMMI v.2 practice areas to level 2 capabilities
- Appraisal teams are 2-6 staff members depending on appraisal scope
- Incremental improvements to program execution operationalized
 - Mentor Program
 - Updates to tools and templates used by appraisal teams
 - Rollout of FDA benefits (e.g. 30DCN, updates to inspection benefit)
 - Refined governance model of program (e.g. participants calls, regular MDICx sessions)

What has been done?

Appraisal activities are considered value add:

“The maturity assessment provided us with an evaluation of the health of our operations, engaging individuals most familiar with our day-to-day work. The assessment helped us identify strengths and weaknesses and opportunities for further consideration. As important, the assessment helped us develop operational excellence metrics that will measure the continuous execution and quality oversight of our processes. Now, a cross-functional team is exploring how we can capitalize on what we learned to further advance our processes and our ability to provide world-class products and services to our customers.”

– *Kathie Bardwell, Senior Vice President & Chief Compliance Officer, STERIS Corporation*

What Participants Think of the Appraisal Program

The CMMI Institute surveyed early adopters of the Medical Device Discovery Appraisal Program to understand their experience.



believed the appraisal identified improvement areas to increase overall product quality.



had a positive experience with the appraisal approach and execution.



would recommend this program to other organizations.

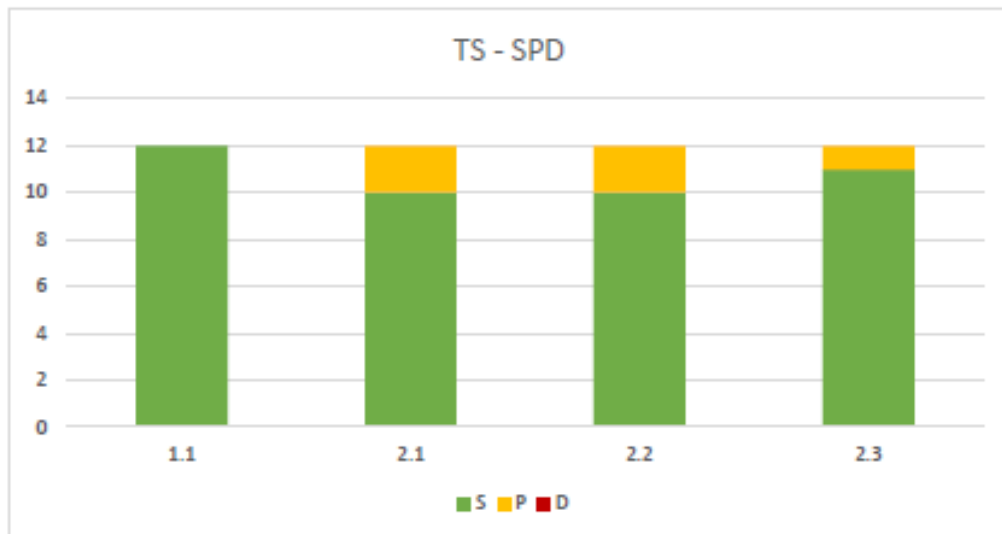
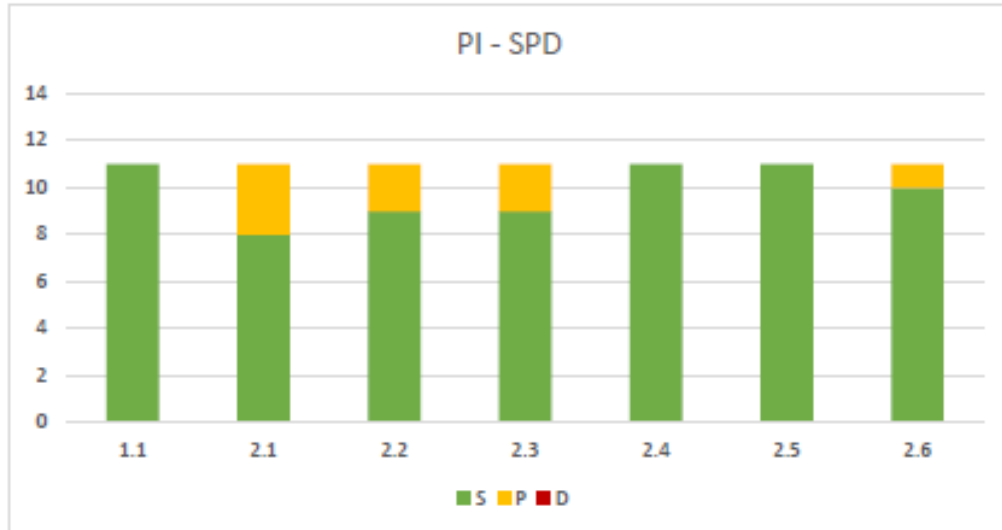
What has been done?

Technical Solution and Product Integration practices are typically satisfied

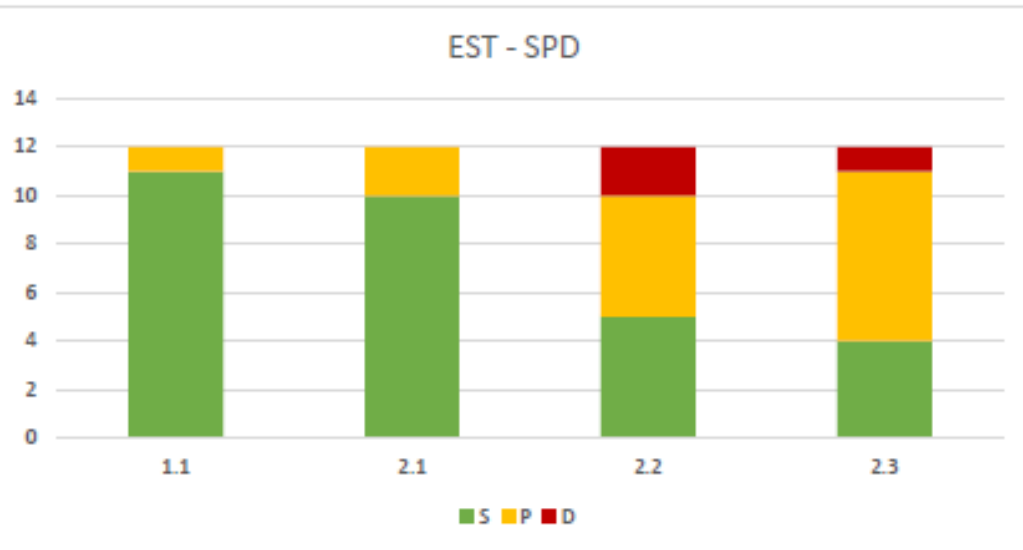
TS: Design and build solutions that meet customer requirements.

PI: Integrate and deliver the solution that addresses functionality and quality requirements.

Hypothesis: TS/PI are typically satisfied as these are areas that align well with existing regulation.



What has been done?



Estimation practices related to sizing of work, and subsequently effort, cost, and duration are less likely to be satisfied.

Estimation: Estimate the size, effort, duration, and cost of the work and resources needed to develop, acquire, or deliver the solution.

EST 2.2 Develop and keep updated estimates for the size of the solution.

EST 2.3 Based on size estimates, develop and record effort, duration, and cost estimates and their rationale for the solution.

Hypothesis: EST practices while of value to the business in their ability to assure delivery and availability of product and services are less likely to be satisfied as they are not current a focus within regulation.

Where is the program going?

- Execute program to a target of 30 appraisals in 2018
- Assess practice areas at higher levels of capability, review results and shift as necessary
 - TS/PI being reviewed to level 3 capability
- Provide information how practice areas impact product / service quality
 - Collaboration with CfQ Analytics effort
 - Performance Report
- Define 2nd appraisal process by end of Q3
 - Set up core practice areas / capabilities and electives to drive greatest value to the business (DEV, SVC, OB areas)
- Craft 2018 lessons learned and 2019 proposed approach document (Q4)

Additional Information

General Information: <http://cmmiinstitute.com/MedicalDevice>

Webinars:

- June 5th MDICx Webinar: <http://mdic.org/wp-content/uploads/2018/06/MDICx-20160605-combined.pdf>
- February 27th MDICx Webinar: <http://mdic.org/wp-content/uploads/2018/03/20180227-MDICx-MDDP-slides.pdf>
- November 15th MDIC Meeting Presentation: <http://mdic.org/cfq/case-for-quality-public-forum-presentations/>
- October 10th FDA Public Meeting Presentation: <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm568069.htm>

Recent MedTech Insight Article(s):

<https://medtech.pharmaintelligence.informa.com/MT122693/Device-Week-May-18-2018--Medtechs-Next-Top-Maturity-Model-Part-1>

CMMI CFQ VS MDSAP...THE SAVINGS ARE CLEAR

