MDIC CfQ Forum

20 June 2019
Program Adoption

**Facilities Enrolled**
45 actively enrolled over 22 Companies

**Appraisals Executed**
44 all time
9 YTD

**Appraisers in Program**
20 current, 20 pending

**Time from Enrollment to Appraisal**
116 days (Y2 – 369 days)

**Trained Embedded ATMs**
37 participants
9 FDA
Program Effectiveness – Baseline Appraisals
(199 survey respondents)

- Experience with appraisal:
  - 91% positive
  - 9% neutral

- Value to product quality:
  - yes: 85.4%

- Conflict with compliance:
  - no: 98%

- Appraisal has value add:
  - yes: 94%

- Recommend pilot:
  - NPS +54
  - (n = 46)
Program Effectiveness - Reappraisals
(37 survey respondents)

Experience with appraisal
96% positive
4% neutral

Impact to product quality
- Better knowledge of what product quality is and how to produce it
- Common language across teams, improved communication
- Better process improvement, different perspective = new ideas
- Pathway towards risk mitigation of nonconforming products
- Increased customer satisfaction, reduction in waste (time/product)
- Increased rigor and predictability in new product development
- Greater focus and understanding of measurement systems

Recommend pilot
NPS +70
(n = 37)
Program Working Groups

Additional Regulatory Benefits
**Objective:** To identify, develop, test, and finalize any additional regulatory benefits in consideration for participants of the Program.

Performance Measures
**Objective:** To reduce reappraisal scope and/or increase the length of time to reappraisal via data transparency, by identifying additional information needs and outcomes, considering improvement opportunities to the methodology, and discussing potential synergies for continuous monitoring.

Reappraisals
**Objective:** To define and develop the standards and exceptions for conducting reappraisals.

Multi-Site Appraisals
**Objective:** To define and develop the standards and exceptions for conducting multi-site appraisals.

Program Features
**Objective:** To identify, develop, test, and finalize new desired features of the Program, as well as identify, analyze, and resolve any undesirable features of the Program.

Medical Device Context
**Objective:** To define, build, and formally develop the additional CMMI model context to support the intended tailoring for the medical device industry.
Participant Workshop Outcomes

Additional Regulatory Benefits
Discussed potential areas to reduce repetitive information submitted. Further explore streamlining original PMA manufacturing module.

Performance Measures
Reviewed commonly submitted measures and variance in definitions, WG would like additional context to drive to quality measurements over “compliance” measurements, and determine how to drive more proactive vs. reactive measures.

Reappraisals
Agreement to leverage objective evidence at some point in continuous improvement journey – no sooner than year 3, need to define how to operationalize.

Multi-Site Appraisals
Reviewed 5 performed multi-sites performed to date, determining common approaches and possibly policy definition
On the Horizon

Greater flexibility in tailoring reappraisals and ongoing data submission to meet the needs of participating medical device manufacturer’s while simultaneously providing greater transparency to FDA, allowing for the provision of greater or more expansive regulatory modifications.

**Transparency by way of:**

- Appraisal Outputs
- Frequency of Info
- Rigor of Appraisals
- Visibility of Data
- Practice Areas / Practices
- Additional Areas of FDA Interest
On the Horizon

As we formalize the program, in what ways can we expand?

- OUS Markets
- Total Product Lifecycle (upstream/downstream)

Other Branches of FDA
Additional Information

Resources:
2017 Nov 15: [MDIC Meeting Presentation](#)
2017 Oct 10: [FDA Public Meeting Presentation](#)
2018 Feb 27: [Q1 MDICx Webinar](#) and [Slides](#)
2018 May 7: [Medtech's Next Top Maturity Model: Part 1](#)
2018 May 8: [Medtech's Next Top Maturity Model: Part 2](#)
2018 June 5: [Q2 MDICx Webinar](#) and [Slides](#)
2018 June 25: [Medtech's Next Top Maturity Model: Part 3](#)
2018 June 27: [MDIC Case for Quality Open Forum](#)
2018 July 11: [Greenlight Guru Case for Quality Webinar with Cisco: Part 1](#)
2018 Aug 16: [Greenlight Guru Case for Quality Webinar with Cisco: Part 2](#)
2018 Sept 5: [MDIC Annual Public Forum](#)
2018 Sept 12: [Q3 MDICx Webinar](#) and [Slides](#)
2018 Sept 20: [Medtech’s Next Top Maturity Model: Part 4](#)
2018 Sept 20: [Greenlight Guru Case for Quality Webinar with Cisco: Part 3](#)
2018 Dec 6: [Q4 MDICx Webinar](#) and [Slides](#)
2019 Jan 9: [Global Medical Device Podcast re: CfQ with George Zack](#)

General Information:
[http://cmiinstitute.com/MedicalDevice](http://cmiinstitute.com/MedicalDevice)