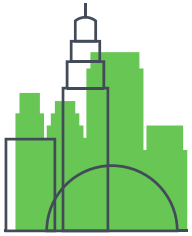



Medical Device Discovery Appraisal Program

Status Update - February 2019

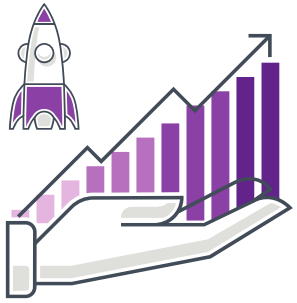
Kim Kaplan, CMMI Institute
Francisco Vicenty, FDA CDRH
George Zack, Two Harbors Consulting

Quick review - What is this program?

This program leverages the CMMI framework as the standard maturity model by which medical device organizations may measure their capability to produce high quality devices and increase patient safety. FDA will adjust their engagement activities and submission requirements as a recognition of this independent assessment of quality maturity. The CDRH Voluntary Medical Device Manufacturing and Product Quality pilot was announced in the Federal Register on December 28, 2017.

Reduced defects / rework

Reduced costs



Accelerated time to market

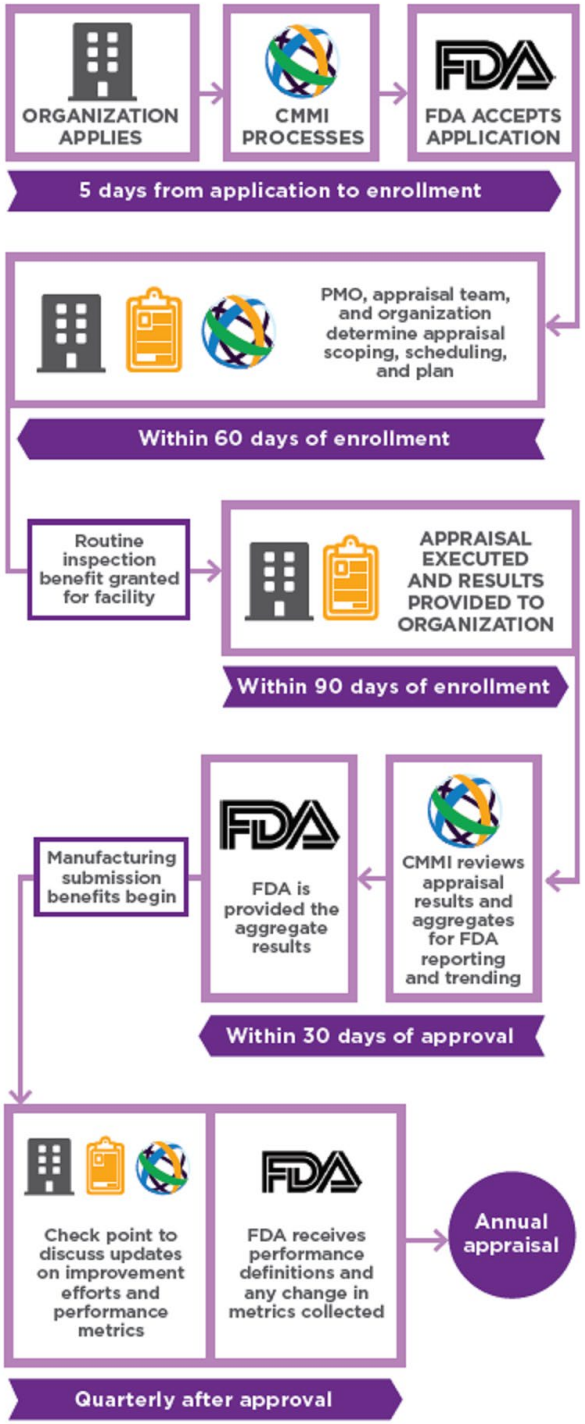
Increased Customer Satisfaction

A culture of quality - across the organization.

What is the **Medical Device Discovery Appraisal Program** (MDDAP)?

Pilot program

- Medical Device Manufacturers that market devices in the US and have no Official Actions Indicated in the last 5 years are eligible to apply for the program
- Manufacturer undergoes a 3rd-party appraisal that leverages the Capability Maturity Model Integration (CMMI) framework to assess the facility's capability to manufacture high-quality devices
  - Quarterly check point with appraiser
  - Quarterly submission of metrics
- As part of the larger Case for Quality initiative (2011), the pilot began on January 2, 2018
  - FDA has announced their intention to transition the pilot into a full program during the 2019 year



Compliance is important, but it's not enough. How do we build a culture of quality?

FDA adjustments

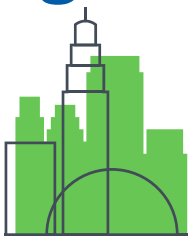
To reduce disruption and burden to innovative changes:

- Forgo surveillance, post-approval, and risk-based inspections
- Manufacturing change notice submissions
  - Streamlined submission
  - Accelerated acceptance
    - 5 business days vs. 30 days
- Manufacturing site changes
  - Streamlined submission
  - Accelerated approval
    - 10 business days
- Original PMA manufacturing
  - Streamlined submission
  - Forgo preapproval inspection
- Additional modifications being considered via working group
  - Industry, FDA, MDIC, Institute, and Appraiser stakeholders

Who is involved in the Program?

Organization	High Level Roles for Pilot
 Pilot Steering Committee	Provides leadership, direction, guidance, and pilot process input
FDA	Provides regulatory modifications; verifies participants; reviews aggregated results, performance report, and overall industry data trends; provides pilot process input
MDIC	Coordinates working groups, quarterly webinar updates, and periodic public forums; provides pilot process input
 Appraisers	Plans and executes appraisals; provides results and improvement opportunities to participants; executes check points; submits appraisal plan and results for QA; provides pilot process input
 Participating Device Manufacturers	Receives appraisals; drives continuous improvements within organization; participates in check points to report progress and receive guidance; provides pilot process input
 CMMI® Institute Program Management Office	Provides model; manages enrollment/de-enrollment; provides detailed documentation guidelines for appraisers; provides appraiser training; connects appraisers with required team experience to participants; adjusts appraisal scope as necessary; assures appropriate appraisal and appraiser consistency; collects, trends, and provides deidentified appraisal data to participants / steering committee / FDA; manages appraisal issues; adjust approach based on feedback from steering committee and stakeholders

Standing Program Meetings and Structure



Bi-Monthly Alignment Meeting with MDIC, FDA, and the CMMI Institute PMO to:

- Review the current state of the program, relevant metrics, and results;
- Discuss connection points with industry;
- Make decisions; and
- Address lessons learned and next steps in program;

Bi-Monthly Appraiser Meetings with the Institute to discuss:

- Scheduling and coordinating of upcoming appraisals;
- Review evolving program activities and expectations; and
- Discuss lessons learned to improve appraisal best practices for MDDAP.

Monthly Participant Meetings with all participants in the program (representatives), the Institute (PMO), MDIC, and FDA (CDRH). These meetings are focused on:

- Reviewing the program, relevant metrics, and results;
- Discussing connection points between FDA and industry (e.g. benefits); and
- Addressing next steps in program.

As necessary, working groups are created from this larger group to address any specific concern, issue, or topic requiring attention.

Standing Program Meetings and Structure

Quarterly MDICx webinars with the public to provide a broad update from:

- MDIC;
- FDA;
- Institute PMO; and
- Industry participants regarding their experiences.

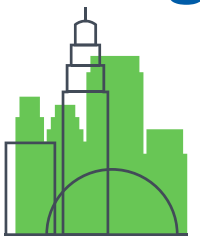
Case for Quality Forums (quarterly or as needed) with the public to:

- Gather input and feedback; and
- Share the latest updates, lessons learned, and next steps.

Steering Committee Meeting (quarterly or as needed) to:

- Receive guidance from the committee; and
- provide or discuss the latest updates, lessons learned, and next steps.

Program Working Groups and Structure



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.

Program Adoption

Facilities Enrolled:
37 actively enrolled over 20 Companies

Appraisals Executed:
36 all time, 1 YTD

- Appraisals Scheduled: 2
- Appraisals being scoped: 5

Time from Enrollment to Appraisal:
114 days

Appraisers in program:
14 current, 13 pending

Trained Embedded ATMs:
27 participants, 9 FDA

Program Effectiveness

Post-Appraisal Survey Results:

(194 respondents)

Experience with appraisal

positive: 91.2%

neutral: 8.8%

negative: 0%

Value to product quality

yes: 86.3%

Conflict with compliance

no: 97.9%

Appraisal has value add

yes: 93.7%

Would recommend pilot

NPS +49 **(n=41)**

"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

SVP & Chief Compliance Officer

STERIS Corporation

Program Metrics

Current Pilot Statistics

- 42 Enrolled sites
  - 37 Active Sites/20 Companies
  - 5 Multi-site appraisals
  - 14% are FDA recognized small businesses
  - Class I Only Sites: 1
  - Class II Only Sites: 6
  - Class III Only Sites: 3
  - Class I and Class II Sites: 6
  - Class I and Class III Sites: 0
  - Class II and Class III Sites: 14
  - All Class Products at Site: 7

Inspection Metrics

- Routine Inspections Waived: 40
- Pre-Approval Inspections Waived: 4
- For causes that occurred: 3
  - No observations
- Foreign sites: 9

CDRH Metrics

- 45+ Modified change notices reviewed
- 94% Reviewed in 5 days or less
  - Average review time (2.8 days)
  - **One reviewed in 13hr**
  - **Another completed in less than 16hr**
- 1 Reviewed in 10 days with 7 changes in one submission
- 2 Converted to traditional 30-Day
  - 1 had drug-component change that required CDER consult
  - 1 site was not yet approved for the modifications
- Working with data and participant to find other trends to drive improvement

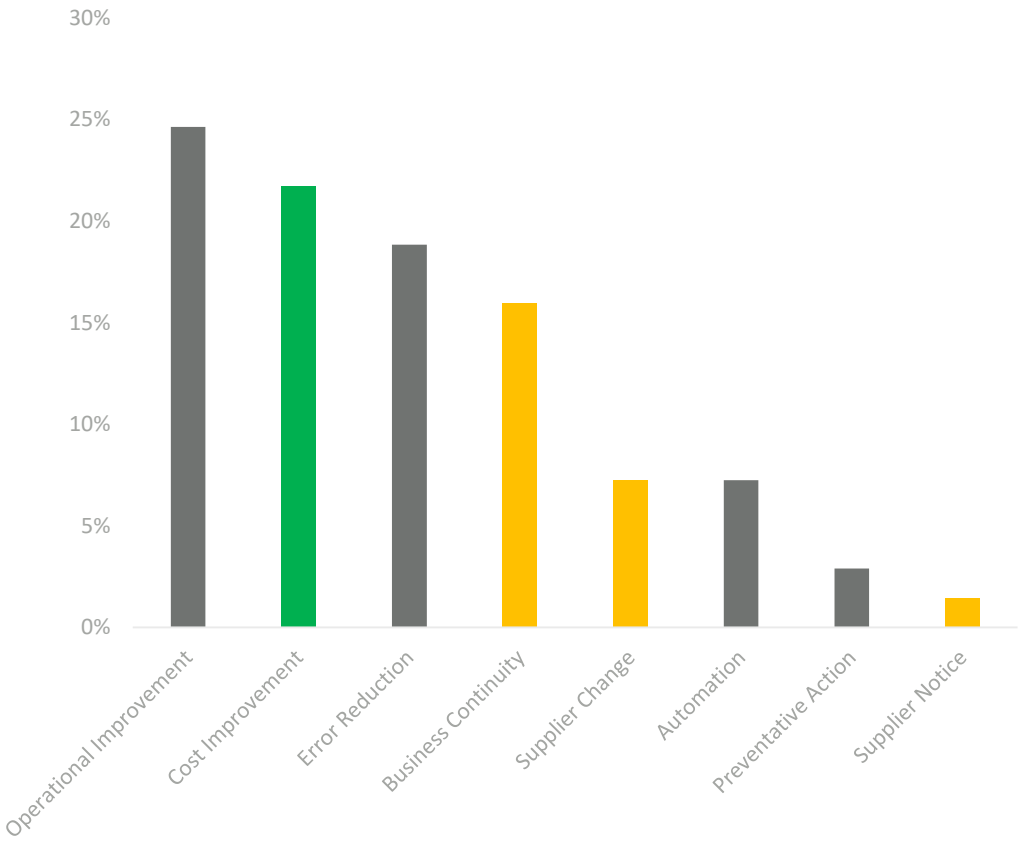
Site transfer

Streamlined site transfer submission developed by ODE reviewers

- 3 participants to testing in Q1 of 2019
- Target 10 business day review

Change notice metrics and impact

Change Notice Modifications Break Down



Improvements implemented 21 days sooner

Average pilot acceptance time – 3 Days

Average non-pilot acceptance time – 24 Days

30% of changes were direct quality improvements that reduce or prevent defects

Impact of streamline reported by participants

- One change resulted in $286,000 additional cost savings
- Another improvement change removed occurrence of manufacturing error that required visual inspection and allowed 10 FTE to be reallocated to higher value operations
- One change increased production capacity at organization by 11%. The 21 extra production days resulted in 882 additional high-risk patients receiving products and treatment.

The 21 day difference in one change resulted in more than $15 Million dollars in extra sales

2nd Appraisals – some initial outcomes

Practice Area		# of practices appraised	% "score"
Estimating (EST)	1st appraisal	5	80%
	2nd appraisal	6	82%
Governance (GOV)	1st appraisal	5	90%
	2nd appraisal	7	76%
Implementation Infrastructure (II)	1st appraisal	3	57%
	2nd appraisal	6	48%
Monitor and Control (MC)	1st appraisal	6	90%
	2nd appraisal	10	75%
Managing Performance and Measurement (MPM)	1st appraisal	9	79%
	2nd appraisal	14	66%
Product Integration (PI)	1st appraisal	7	83%
	2nd appraisal	10	85%
Planning (PLAN)	1st appraisal	10	90%
	2nd appraisal	14	76%
Requirements Development and Mgmt (RDM)	1st appraisal	7	83%
	2nd appraisal	14	73%
Technical Solution (TS)	1st appraisal	4	90%
	2nd appraisal	10	85%
Configuration Management	1st appraisal	7	90%
	2nd appraisal	7	76%
Process Quality Assurance	1st appraisal	5	90%
	2nd appraisal	6	73%
Incident Resolution and Prevention (IRP)	1st appraisal	not appraised	
	2nd appraisal	11	63%
Aggregate Score	1st appraisal	68	83%
	2nd appraisal	115	73%

Practice Area		# of practices appraised	% "score"
Estimating (EST)	1st appraisal	5	60%
	2nd appraisal	4	65%
Governance (GOV)	1st appraisal	5	70%
	2nd appraisal	5	60%
Implementation Infrastructure (II)	1st appraisal	3	40%
	2nd appraisal	3	57%
Monitor and Control (MC)	1st appraisal	6	65%
	2nd appraisal	6	65%
Managing Performance and Measurement (MPM)	1st appraisal	9	73%
	2nd appraisal	8	59%
Product Integration (PI)	1st appraisal	7	76%
	2nd appraisal	10	90%
Planning (PLAN)	1st appraisal	10	75%
	2nd appraisal	10	70%
Requirements Development and Mgmt (RDM)	1st appraisal	7	61%
	2nd appraisal	7	76%
Technical Solution (TS)	1st appraisal	4	78%
	2nd appraisal	10	80%
Configuration Management	1st appraisal	7	69%
	2nd appraisal	7	83%
Process Quality Assurance	1st appraisal	5	60%
	2nd appraisal	5	50%
Organizational Training	1st appraisal	not appraised	
	2nd appraisal	3	57%
Aggregate Score	1st appraisal	68	66%
	2nd appraisal	78	66%

2nd Appraisals – some initial outcomes

Practice Area		# of practices appraised	% "score"
Estimating (EST)	1st appraisal	5	62%
	2nd appraisal	4	65%
Governance (GOV)	1st appraisal	5	80%
	2nd appraisal	7	83%
Implementation Infrastructure (II)	1st appraisal	3	57%
	2nd appraisal	3	90%
Monitor and Control (MC)	1st appraisal	6	73%
	2nd appraisal	6	82%
Managing Performance and Measurement (MPM)	1st appraisal	9	79%
	2nd appraisal	14	69%
Product Integration (PI)	1st appraisal	7	83%
	2nd appraisal	10	90%
Planning (PLAN)	1st appraisal	10	80%
	2nd appraisal	10	80%
Requirements Development and Mgmt (RDM)	1st appraisal	7	90%
	2nd appraisal	14	90%
Technical Solution (TS)	1st appraisal	4	90%
	2nd appraisal	10	90%
Configuration Management	1st appraisal	7	83%
	2nd appraisal	not appraised	
Supplier Agreement Management (SAM)	1st appraisal	not appraised	
	2nd appraisal	7	90%
Process Quality Assurance	1st appraisal	5	80%
	2nd appraisal	not appraised	
Aggregate Score	1st appraisal	68	76%
	2nd appraisal	85	83%

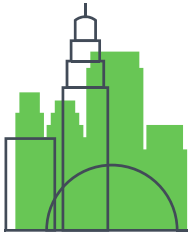
Performance Measures

Reduce reappraisal scope and/or increase the length of time to reappraisal via data transparency.

- Identify additional information needs and outcomes
- Consider improvement opportunities to the methodology
- Discuss potential synergies for continuous monitoring

Performance Measurements and Objectives

#	Quality domain	Quality domain definition	Quality objective	Business objective	Measurement	Level of Measure	How measurement is calculated	Indication of good performance	Limitations or blind spots	Capture frequency	Report frequency	Target	Actual (Q2 FY19)	Actual (FY19 YTD)
1	Safety*	Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.	To provide a safe work environment for our employees	No lost employee hours; sustain the site as a safe place to work	Employee Safety	Facility and aggregate across the division	Number of recordable cases x 200,000 divided by number of employee labor hours worked	The value decreases	Potential for high fluctuation due to the small number of employees	Monthly	Quarterly	≤ 2.0	0.32	0.31
2	Reliability*	Device system or component is able to function under stated conditions for a specified period of time.	Customer product is serviced right, the first time; without dosimeter re-reads	Process product in order to consistently meet Customer and business expectations	First Pass Yield	Facility and aggregate across the division	Percentage of irradiation runs moving through production without any dosimeter re-reads	The value increases	None identified	Monthly	Quarterly	≥ 99.0%	99.1%	99.3%
3	Availability*	Device is available to fill first request orders.	Customer product is handled and processed without causing physical damage to the material	Reduce financial loss and business impact to our Customers	Damages	Facility and aggregate across the division	Total dollar amount of damaged product	The value decreases	None identified	Quarterly	Annually	< $500,000 globally	LN Actual $0	LN Actual $10,000
4	Effectiveness*	Device produces the effect intended by the manufacturer relative to the medical condition(s).	Reduce recurrence of high risk events	Optimize the time of our resources	CAPA Management	Facility and aggregate across the division	Percentage of events (complaints and nonconformances) that result in a CAPA	The value decreases	Potential for high fluctuation due to the small number of events	Monthly	Quarterly	≤ 25%	16%	12%
5	Effectiveness*	Device produces the effect intended by the manufacturer relative to the medical condition(s).	Do everything we say we are going to do	Reduce costs or time spent to rework nonconforming runs: process runs on time and to specification	Operational Effectiveness	Facility and aggregate across the division	Nonconformances, complaints, re-reads and damages as a % of production runs	The value increases	None identified	Monthly	Quarterly	≥ 98.0%	97.6%	98.2%



Additional Information

General Information:

http://cmmiinstitute.com/MedicalDevice

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