MDICx – Update on the Case for Quality Voluntary Improvement Program (CFQ VIP)

Kim Kaplan, CMMI Institute
Mark Rutkiewicz, Innovize
Francisco Vicenty, US FDA Center for Devices and Radiological Health
George Zack, Two Harbors Consulting

May 15, 2019
MEDICAL DEVICE
DISCOVERY APPRAISAL PROGRAM

15 May MDICx Webinar
Case for Quality Voluntary Improvement Program
Kim Kaplan kkaplan@cmmiinstitute.com
George Zack george.zack@twohc.com
WHAT IS THE MEDICAL DEVICE DISCOVERY APPRAISAL PROGRAM (MDDAP)?

This program leverages the CMMI framework as the standard maturity model by which medical device organizations may measure their capability to manufacture high quality devices and ultimately increase patient safety. FDA will adjust their engagement activities and submission requirements as a recognition of this independent assessment of quality maturity. The pilot launched on January 2, 2018.
COMPLIANCE IS IMPORTANT, BUT IT’S NOT ENOUGH. HOW DO WE BUILD A CULTURE OF QUALITY?

- 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
- To reduce disruption and burden to innovative changes:
  - Forgo surveillance, post-approval, and risk-based inspections
COMPLIANCE IS IMPORTANT, BUT IT’S NOT ENOUGH. HOW DO WE BUILD A CULTURE OF QUALITY?

- Quarterly check points with appraiser
- Quarterly submission of metrics
- To reduce disruption and burden to innovative changes:
  - Manufacturing change notice submissions, streamlined & accelerated, 5 business days vs. 30 days
  - Manufacturing site changes, streamlined & accelerated, 10 business days
  - Original PMA manufacturing, streamlined, waiver of preapproval inspection
<table>
<thead>
<tr>
<th>Organization</th>
<th>High Level Roles for Pilot</th>
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<tbody>
<tr>
<td>Pilot Steering Committee</td>
<td>Provides direction, guidance, and pilot process input</td>
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<td>FDA</td>
<td>Provides regulatory modifications; verifies participants; reviews aggregated results, performance report, and overall industry data trends; provides pilot process input</td>
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<td>MDIC</td>
<td>Coordinates working groups, quarterly webinar updates, and periodic public forums; provides pilot process input</td>
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<tr>
<td>Appraisers</td>
<td>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</td>
</tr>
<tr>
<td>Participating Medical Device Manufacturers</td>
<td>Receives appraisals; drives continuous improvements within organization; participates in check points to report progress and receive guidance; provides pilot process input</td>
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<tr>
<td>CMMI Institute Program Management Office</td>
<td>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 appropriate stakeholders; manages appraisal issues; adjust approach based on feedback from all stakeholders</td>
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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.
**WHAT DOES SUCCESS IN THIS PILOT LOOK LIKE?**

**Success Components**

- **Value to Participants**
  What value are stakeholders getting from program?  
  “Program Effectiveness”

- **Consistency & Scalability**
  Is the program sustainable?  
  “Program Adoption”

- **Elevating Industry**
  The long term “next steps”...

**Success Identification**

- **What**: Appraisal identifies opportunities for improvement, reduced regulatory burden, increased innovation, faster time to market
  **How**: Survey results, participant feedback, appraiser feedback, FDA feedback, lessons learned incorporated into program

- **What**: Program operations are performed consistently for growing # new participants
  **How**: Number of appraisals, wait time to appraisal, number of appraisers trained in the program, lessons learned incorporated into program

- **What**: Industry baseline for organizations to benchmark improvement journey
  **How**: trend participant results & quality performance metrics over time
Facilities Enrolled
45 actively enrolled over 22 Companies

Appraisals Executed
45 all time
5 YTD

Time from Enrollment to Appraisal
116 days

Appraisers in Program
18 current, 20+ pending

Trained
Embedded ATMs
37 participants
9 FDA
PROGRAM EFFECTIVENESS
(207 survey respondents)

Experience with appraisal
- 91.3% positive
- 8.7% neutral

Value to product quality
- yes: 86.4%

Conflict with compliance
- no: 97.9%

Appraisal has value add
- yes: 93.7%

Recommend pilot
- NPS +46
  (n = 54)
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://cmmiinstitute.com/MedicalDevice
The FDA’s Case for Quality: Voluntary Pilot Program Update
May 15, 2019

Cisco Vicenty
Program Manager, Case for Quality
Strategic Initiatives Staff
Office of Product Evaluation and Quality, CDRH
Effectiveness
### CDRH Pilot metrics to date

**Current Pilot Statistics**
- 51 Accepted sites
  - 46 Active Sites/22 Companies
  - 5 Multi-site appraisals
  - 14% are FDA recognized small businesses
  - Class I Only Sites: 2
  - Class II Only Sites: 7
  - 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: 16
  - All Class Products at Site: 12

**CDRH Metrics**
- 45+ Modified change notices reviewed
- 88% Reviewed in 5 days or less
  - Average review time (2.8 days)
- 1 Reviewed in 10 days with 7 changes in one submission
- 3 required the 30-days to complete
  - 1 had drug-component change that required CDER consult
  - 1 site was not yet approved for the modifications
  - 1 Required additional subject matter consults

**Site transfer**
Streamlined site transfer submission developed by CDRH reviewers
- First site change received
  - Target: 180 days → 10 business day review
  - Currently at **35 days** → Resource Issue

**Inspection Metrics**
- Routine Inspections Waived: 45
- Pre-Approval Inspections Waived: 4
- For causes that occurred: 3
  - No observations
- Foreign sites: 16
Pilot experience results

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)

Comments:

• The objectives were clearly defined and the meetings and line of questions were well-organized.
• CMMI Consultants were knowledgeable and great to work with.
• Every effort was made to put me at ease and help me understand the process.
• I felt 90% of the appraisal results resonated with me and what I know about our organization. That's a pretty good success rate for such a short time with us.
• The majority of weaknesses identified during the process highlight legitimate areas for improvement.
• A huge leap forward in identifying the issues that hold back a compliant, high-performing company.
• The overall approach, if supported, genuinely will be more effective than the reactionary approach to traditional inspections.

Experience:

“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
Pilot impact metrics

Value analysis was based on data provided based on comparison to traditional compliance audits and an average manufacturing change implementation improvement of 21 days for pilot sites as compared to non-pilot sites.

**Patients/Providers**
- 37% of manufacturing changes were to improve product quality and were implemented 21 days faster
- Increase in manufacturer improvement submissions, including changes to reduce manufacturing defects
- 882 High-risk patients received treatment due the 21 day difference → Greater than $10 Million dollar savings in annual healthcare costs
- Increase implementation of manufacturing automation to improve traceability and error-proofing (18%) of changes
- Defect reductions (99 PPM → 19 ppm)

**FDA**
- Increase in submissions to improve product quality
- Increased engagement on process improvement
- Improved submission decision consistency
- Increased sponsor engagement
- Increased resource visibility and allocation for inspections and reviews
- Improved impact traceability
- Improved data-analytics on changes, products, and sites
- Best practice sharing among manufacturers
- 11 – 46% Improvement in performance over 1 year

**Manufacturers**
- Assessment costs
  - FDA/ MDSAP: $140-350K – Site operations disrupted
  - Pilot appraisal: Less than $80K – No operation disruptions
- Reported change notice value examples
  - $286 K Annual savings
  - 10 Dedicated inspection employees reallocated to higher value operations due to improvement
  - 11% Production capacity increase → Greater than $15 million in product sales
- Strategic/systemic improvement implementation vs compliance resolution
Next Steps
Ongoing work

Finalizing pilot summary and assessment report

CDRH has received budget authority to support effort

Developing operationalization proposal and strategy for 2020

Continuing current pilot efforts and improvements and engagements as long as capacity allows
Information, Engagement, and Collaboration

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- For additional information, enrollment, or feedback
  - [http://mdic.org/cfq/](http://mdic.org/cfq/)
  - [http://mdic.org/cfq/enroll/](http://mdic.org/cfq/enroll/)
  - caseforquality@fda.hhs.gov

- Program Updates
  - [http://mdic.org/mdicx/](http://mdic.org/mdicx/)

- Public Workshop
  - [https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm568069.htm](https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm568069.htm)

- Pilot FR Notice

- For any issues or concerns contact
  - Francisco.vicenty@fda.hhs.gov or Jennifer.Kelly@fda.hhs.gov
Thank you
AGENDA

• Innovize Background
• Our Continuous Improvement Path and Culture
• Innovize’s 3 Year Results
INNOVIZE

• Medical device contract manufacturer in St Paul MN, USA
  • Family owned with 160 employees

• Primary products are converted products and components
  • Innovize does not own any product designs

• Over 200 medical device customers
  • Build over 2000 different products and components

• FDA registered with 35 finished medical devices
INNOVIZE’S QUALITY SYSTEM UPGRADE

• In 2013, Innovize had a typical Quality System certification:
  • ISO 9001 and ISO 13485
  • Built to met the FDA Quality System Regulation (QSR) 21 CFR 820
• Procedures written to meet ISO and FDA QSR requirements
  • But the ISO standards state to define your process interactions
• In 2014, started conversion to a process architecture with 20 business processes using the Consiliso approach per my books
  • Medical Device Company in a Box, The Case for Consiliso, A Blueprint for Quality Systems. Published October 2017
  • Consiliso, The Blueprint for Integrating Business Processes in Medical Device Companies. Published April 2018
Quality - Continuous Improvement

Delusional Improvement

Wasteful Compliance

Level 1: Warning Letter
Level 2: 483s/NC
Level 3: Compliant
Level 4: Bulletproof
Level 5: World Class

Quality - Compliance to Requirements

*Found in Consiliso books
www.Consiliso.com
Mark Rutkiewicz
INNOVIZE PROOF OF CONCEPT ASSESSMENT JUNE 2016

• In Jan 2016, FDA QSIT inspection of Innovize – no findings
• Innovize involved in Proof of Concept assessment in June 2016
• FDA watching assessment over video conference
  • Conversation on how you do your work, not an audit
• CMMI V1.3, Maturity Level 2 covering:
  • Configuration Management (CM)
  • Requirements Management (RM)
# Proof of Concept Assessment Results June 2016

## Table Legend
- **D**: The intent of the practice is absent or poorly addressed. Goal achievement is unlikely.
- **P**: The intent of the practice is partially addressed. Goal achievement is threatened.
- **S**: The intent of the practice is adequately addressed. Goal achievement is supported.
- **NY**: The practice has not yet been deployed.
- **NA**: Not Applicable

## Score Legend
- ≥ 95%: Blue
- 80% - 95%: Green
- 50% - 80%: Yellow
- 25% - 50%: Orange
- < 25%: Red
- NA: Grey

## Maturity Level 2 Process Areas

| Process Areas | Score | Practic | Req
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<td><strong>CM</strong></td>
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**Overall**: 12 53.3%
INNOVIZE PILOT ASSESSMENT OCTOBER 2016

• Innovize launched new ERP system 8/1/2016
• Innovize involved in Pilot assessment in October 2016
• CMMI V1.3 Maturity Level 2 covering:
  • Configuration Management (CM)
  • Requirements Management (RM)
  • Project Planning (PP)
  • Project Monitoring and Control (PMC)
  • Supplier Agreement Management (SAM)
  • Measurement and Analysis (MA)
  • Process and Product Quality Assurance (PPQA)
PILOT ASSESSMENT RESULTS OCTOBER 2016

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<tr>
<th>Maturity Level 2 Process Area</th>
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Score: **Overall 124**

Score: **83.3%**
FDA AND THE MDDAP ASSESSMENT

• In July 2017, FDA launched CDRH Voluntary Medical Device Manufacturing and Product Quality Pilot Program
• No goal to achieve a level, must stay on the journey
• Innovize first to signup and assessed in Dec 2017
INNOVIZE MDDAP INITIAL ASSESSMENT

- Innovize continued to improve our business processes with the new ERP system
- Certified to the new versions of ISO 9001 and 13485
- Changed to CMMI V2.0, Maturity Level 2 with 11 Practice areas
# INNOVIZE MDDAP ASSESSMENT RESULTS DECEMBER 2017

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<tr>
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- **S**: Satisfied
- **P**: Partial
- **D**: Deficient
INNOVIZE MDDAP SECOND ASSESSMENT

• Innovize continued to improve our business processes
• Using CMMI V2.0, moved to Maturity Level 3 with 12 Practice areas, added Incident Resolution
INNOVIZE MDDAP ASSESSMENT RESULTS DECEMBER 2018

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INNOVIZE NEXT STEPS

• Direction for next assessment
  • Continue with Level 3 reassessment
  • Include others throughout the company
  • Add documentation review of some foundation practice areas, like CM and TS
Q&A

Please use the chat box feature on Zoom to ask your question
Connect with MDIC

• Next Case for Quality Forum is June 20 in Arlington, VA. Details at: https://mdic.org/project/case-for-quality-forums/

• Interested in the CFQ VIP initiative? Learn more at: https://mdic.org/project/cdrh-quality-pilot/

• Next MDICx: Tools for Advancing Patient-Centered Medical Device Clinical Trials, June 18 at 12 p.m. Eastern. Details at: https://mdic.org/event/tools-for-advancing-patient-centered-medical-device-clinical-trials/