MDICx – Q4 Quarterly update on the CDRH Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program

Francisco Vicenty, CDRH
Kim Kaplan, CMMI
George Zack, Two Harbors Consulting
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December 6, 2018
What is this program?

Pilot program

- 3rd-party maturity appraisal that leverages the Capability Maturity Model Integration (CMMI) framework to assess a medical device organization’s capability to produce high-quality devices and increase patient safety
  - Quarterly progress check with lead appraiser
  - Quarterly metrics/KPI submission to FDA
- Pilot was announced on December 28, 2017 and will run from January 2, 2018 and continue through December 28, 2018

FDA adjustments

- 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 section
  - Streamlined submission
  - Forgo preapproval inspection
<table>
<thead>
<tr>
<th>Organization</th>
<th>High Level Roles for Pilot</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pilot Steering Committee</strong></td>
<td>Provides leadership, direction, guidance, and pilot process input</td>
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<tr>
<td><strong>FDA</strong></td>
<td>Provides regulatory modifications; verifies participants; reviews aggregated results, performance report, and overall industry data trends; provides pilot process input</td>
</tr>
<tr>
<td><strong>MDIC</strong></td>
<td>Coordinates working groups and quarterly webinar updates; provides pilot process input</td>
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<tr>
<td><strong>Appraisers</strong></td>
<td>Executes appraisals; provides results and improvement opportunities to participants; executes check points; submits appraisal plan and results for QA; provides pilot process input</td>
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<tr>
<td><strong>Participating Device Manufacturers</strong></td>
<td>Receives appraisals; drives continuous improvements within organization; participates in check points to report progress; provides pilot process input</td>
</tr>
<tr>
<td><strong>CMMI® Institute Program Management Office</strong></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 participants / steering committee; manages appraisal issues; adjust approach based on feedback from steering committee and stakeholders</td>
</tr>
</tbody>
</table>
**Current Governance 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 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.
Current Governance 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.
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
Program Adoption Metrics to Date

- **# of Enrollees**
  - 18 Organizations | 36 Facilities

- **# of Appraisals**
  - 24 Complete | 5 Scheduled

- **Time from enrollment to appraisal execution (days)**
  - Year 1 = 113 | Year 2 = 91
Did the appraisal identify areas or processes that could improve how work is performed to increase product quality?
86% YES | 14% NO

Did the appraisal practice areas conflict with any regulatory compliance assessment areas?
98% NO | 2% YES

Did you find the appraisal to be of value?
94% YES | 6% NO

Would you recommend this program?
99% YES | 1% NO
Lessons Learned

**What**: Broaden Scope of Baseline Appraisal  
**Why**: Improve Value-Add to Participant

**What**: Embedded Appraisal Team Member Training and Certification  
**Why**: Internal Participant Resource, Reduce Cost, Increase Capacity

**What**: Multi-Site Appraisals  
**Why**: Capture TPLC, Reduce Cost, Increase Value to Participant

**What**: Reappraisals defined with Core, Electives, Scope Range  
**Why**: Balance Tailorability with Consistency, Minimize Cost

**What**: Performance Report in Check Points and Reappraisals  
**Why**: Balance Ease with Consistency, Align with Analytics Team
Next Steps

• 2019 Considerations
  • Scaling, Expanding, Adjusting, Exploring

• Mitigate Identified Risks
  • Operational, Adoption, Unplanned

• Leverage Working Groups
  • Additional Regulatory Benefits, Program Features, Multi-Site Appraisals, Reappraisals, Performance Measures, Medical Device Context

• Provide Additional Information
  • Ex: Model At-A-Glance, Program Overview, and FAQs
  • Resources listed on next slide
General Information:
http://cmmiinstitute.com/MedicalDevice
http://mdic.org/cfq/enroll/

Resources:
2017 Oct 10: FDA Public Meeting Presentation
2017 Nov 15: MDIC 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
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
Case for Quality Program Pilot

Cisco Vicenty
Program Manager, Case for Quality
Office of Compliance, CDRH
December 6, 2018
For Discussion

CDRH Metrics to Date

Change notice data

Next steps
## CDRH Program Metrics

<table>
<thead>
<tr>
<th>Current Pilot Statistics</th>
<th>CDRH Metrics</th>
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<tbody>
<tr>
<td>• 40 Enrolled sites</td>
<td>• 38 Modified change notices reviewed</td>
</tr>
<tr>
<td>• 36 Active Sites/18 Companies</td>
<td>• 35 Reviewed in 5 days or less</td>
</tr>
<tr>
<td>• 4 Multi-site appraisals (Appraisal where the whole value stream is evaluated, not just the specific site performance)</td>
<td>• Average review time (2.8 days)</td>
</tr>
<tr>
<td>• 14% are FDA recognized small businesses</td>
<td>• <strong>One reviewed in 13hr</strong></td>
</tr>
<tr>
<td>• Class I Only Sites: 1</td>
<td>• 1 Reviewed in 10 days with 7 changes in one submission</td>
</tr>
<tr>
<td>• Class II Only Sites: 6</td>
<td>• 2 Converted to traditional 30-Day</td>
</tr>
<tr>
<td>• Class III Only Sites: 3</td>
<td>• 1 had drug-component change that required CDER consult</td>
</tr>
<tr>
<td>• Class I and Class II Sites: 6</td>
<td>• 1 site was not yet approved for the modifications</td>
</tr>
<tr>
<td>• Class I and Class III Sites: 0</td>
<td></td>
</tr>
<tr>
<td>• Class II and Class III Sites: 13</td>
<td></td>
</tr>
<tr>
<td>• All Class Products at Site: 7</td>
<td></td>
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</tbody>
</table>

## Inspection Metrics

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

## Site transfer

Streamlined template developed by ODE reviewers. 2 participants ready to test
Manufacturing 30-Day Change Notices

Change Notice Modifications Break Down

- 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

Improvements on product quality implemented 21 days sooner
Next steps

• Work with participants to capture and quantify impact of changes and pilot
• Develop pilot summary and assessment report
• Extend pilot to 2019
• Extend assessment to design practices and develop appropriate modifications to accelerate design related reviews
• Define operational program beyond 2019
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](mailto: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.
Questions?
Thank you
Why participate in the MDDA pilot?

- FDA & Edwards Lifesciences Mission
  - Patients should have access to safe, effective, high quality medical devices

- Benefits Support Mission
  - Improved Compliance
  - Higher Quality
  - Positive Economics
MDDA Experience

Completed at Edwards Lifesciences Draper Facility 2017 & 2018
MDDA Preparation

**Intake**
- Three one-hour meetings
- Defined Scope – Practice Areas
- Defined Duration – 1 Week
- Identified Interviewees

**Logistics**
- Two Appraisal Teams
- Two conferences rooms
- Internet and Projection
- On-site Lunch

**Resources**
- 36 Participants
- 3 Hours over 2 Days
- Normal Business Hours

**Support**
- No Backroom
- No Procedures
- No Records
## MDDA Week

<table>
<thead>
<tr>
<th>GMT-07</th>
<th>Mon 11/6</th>
<th>Tue 11/7</th>
<th>Wed 11/8</th>
<th>Thu 11/9</th>
<th>Fri 11/10</th>
</tr>
</thead>
<tbody>
<tr>
<td>8am</td>
<td>MDDA Appraisal Team 12050 Lone Peak Plaza</td>
<td>MDDA Appraisal Team Edwards Lifesciences</td>
<td>MDDA Appraisal Team Edwards Lifesciences</td>
<td>MDDA Appraisal Team Edwards Lifesciences</td>
<td>MDDA Appraisal Team Edwards Lifesciences</td>
</tr>
<tr>
<td>9am</td>
<td>MDDA Kick Off SLC East Assembly Room</td>
<td>MDDA Appraisal - Planning (PLAN); Monitoring &amp; Control (MC); Estimating (EST) SLC Golden Spike</td>
<td>MDDA Appraisal - Validation SLC Golden Spike</td>
<td>Follow Up Interviews Conference Room &lt;private&gt;</td>
<td>Follow-up - Validation of SLC Golden Spike</td>
</tr>
<tr>
<td>10am</td>
<td>12:30-1:30p MDDA App Configuration Managers SLC Capital R</td>
<td>12:30p – 2p Governance (GOV) Ken and Wett SLC Golden Spike</td>
<td>1p – 2p Follow-up - Validation SLC Golden Spike</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12pm</td>
<td>3p – 5p MDDA Appraisal - Managing Performance and Measurement (MPM) SLC Golden Spike</td>
<td>3p – 4p Validation for RDM/PQA Interviews</td>
<td>3p – 5p MDDA Appraisal Results Read out SLC East Assembly Room</td>
<td></td>
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</tr>
<tr>
<td>6pm</td>
<td>6p MDDA Appraisal Team Daily Wrap</td>
<td>6p MDDA Appraisal Team Daily Wrap</td>
<td>6p MDDA Appraisal Team Daily Wrap</td>
<td>6p MDDA Appraisal Team Daily Wrap</td>
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- Site wide sessions in green
- Interview sessions in blue
- Validation sessions in red
## MDDA scope

### Appraisal Practice Areas – Level 2

| Requirements Development and Maintenance (RDM) |
| Planning (PLAN) |
| Monitor & Control (MC) |
| Managing Performance and Measurement (MPM) |
| Configuration Management (CM) |
| Process Quality Assurance (PQA) |
| **Technical Solution (TS) ** |
| **Product Integration (PI) ** |
| Estimating (EST) |
| Governance (GOV) |
| Implementation Infrastructure (II) |

### Out of Scope

| Supplier Agreement Management (SAM) |
| Risk Management (RSKM) |
| Decision Analysis and Resolution (DAR) |
| Causal Analysis & Resolution (CAR) |
| Process Management (PM) |
| Process Asset Development (PAD) |
| Verification and Validation (VV) |
| **Organizational Training (OT) ** |
| Peer Reviews (PR) |

* Expanded to Level 3 for 2nd Appraisal
** Added to scope for 2nd Appraisal
## MDDA vs. Compliance Audit

<table>
<thead>
<tr>
<th></th>
<th>MDDA</th>
<th>Compliance Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dedicated Resources</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Duration</td>
<td>1 week</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Personnel</td>
<td>~ 240 person hours</td>
<td>~ 1500 person hours</td>
</tr>
<tr>
<td>Total Cost</td>
<td>$74,000</td>
<td>$140,000</td>
</tr>
</tbody>
</table>

- Defined Duration
- Pre-planned Events
- Minimal Business Interruption
- Organized
- Less Expensive
Initial MDDA Impressions

**Positives**
- Structured & Organized
- 2 Appraisers per Practice Area
- Scheduled Work Time
- Sensitive to Reporting Structures
- Validation – Feedback and Learning
- Active Communication
- Open Engaging Environment
- Employee Feedback

**Improvements**
- CMMI Services Agreement *
- Terminology
- Practice Area Purpose and Roles Unclear *
- Facility Tour First *
- System Expertise not Product Knowledge *
- 4-6 Interviewees per Practice Area *
- Inclusion of Front Line Professionals*

**MDDA Structure**
- MDDA Scope Flexible Over Annual Cycles
- Device Classification Alignment with MDDA Practice Areas
- Use of Embedded Appraisers *

* Improvements Demonstrated During 2\textsuperscript{nd} Appraisal
Essential Elements of Product Quality

Primary Assessments
- Product and Process – Management & Operations Reviews
- Quality System – MDSAP & Internal Audit
- Site Execution – Management & Operations Reviews & MDDA
- People – Employee Surveys & MDDA
MDDA Next Steps for Edwards Lifesciences

MDDA Allows Long Term Structural Thinking 
Results Built Over Time
Q&A

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

• We’re taking the Case for Quality Forum to the West Coast in 2019
  – February 2019 in San Diego
  – More details soon

• Interested in the pilot? Learn more at: http://mdic.org/cfq/enroll/