Implementation of the Maturity Model

MDIC Case for Quality Forum
Voluntary Medical Device Manufacturing and Product Quality Program

November 15, 2017
Speakers

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Overview

• Overview of the CMMI assessment process
• Enrollment to date
• How the MDIC maturity model working group will incorporate feedback from the pilot into the model
• Q&A
<table>
<thead>
<tr>
<th>Organization</th>
<th>High Level Roles for Pilot</th>
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<tbody>
<tr>
<td><strong>Pilot Steering Committee</strong></td>
<td>Provides leadership, direction and pilot process input</td>
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<tr>
<td><strong>FDA</strong></td>
<td>Provides regulatory modifications, verifies participants, reviews detailed findings and improvement, provides pilot process input</td>
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<tr>
<td><strong>MDIC</strong></td>
<td>Coordinates working groups of enrollment, appraisal, metrics, communications and program oversight; provides pilot process input</td>
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<td><strong>Appraisers</strong></td>
<td>Execute appraisals, provide findings to participants, executes checkpoints, provides full datasets to coordinating center, provides pilot process input</td>
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<tr>
<td><strong>Participating Device Manufacturers</strong></td>
<td>Receives appraisals, drives improvements within business, participates in checkpoints to report progress, provides pilot process input</td>
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<tr>
<td><strong>CMMI PMO</strong></td>
<td>Provides model, manages enrollment/de-enrollment, provides playbook for appraisers, provides appraiser training, connects appraisers to participants, adjusts appraisal scope as necessary, assures appropriate appraisal and appraiser consistency, collects appraisal data, trends data, provides deidentified data to participants/steering committee, manages appraisal issues, adjusts approach based on feedback from steering committee and stakeholders</td>
</tr>
</tbody>
</table>
Organization enrolls
PMO starts enrollment processing
FDA approves enrollee
FDA, PMO, Appraisal Team, Organization determine scoping / scheduling / plan
Regular feedback to all stakeholders inspect & adapt
Appraisal performed, specific and full results provided to organization, baseline performance measures collected
PMO review and collects appraisal data for reporting, trending for participants
Participants can expand appraisal scope for their needs
Check point follow up performance measurements reviewed, additional CMMI review as appropriate
Manufacturing submission benefits begin
Within 90 days of enrollment:
Within 30 days of enrollment:
Within 5 days from enrollment to approval:
Within 90 to 180 days post appraisal:
FDA is provided aggregate scores and performance measures
Available to any device manufacturer distributing into the US

High Level MDDA Program Flow
What is a high level description of appraisal activities?

**Planning**
- Detailed scoping with executive sponsor/sampling determinations
- Scheduling with site coordinator and appropriate logistics planning
- Appraisal plan creation and submission
- Collection of performance measures (metrics collection form)
- Pricing

**On-site**
- Discovery appraisal including interviews
- Document review as able
- Crafting of findings
- Verification of findings
- Presentation of readout
- Heat map

**Post Activity**
- Report finalization
- Submission of data to appropriate groups
- Improvement planning
- Checkpoint follow ups

**Checkpoints**
- Performed on regular intervals to determine progress
- Update performance measures
What data is shared? Appraised organization:

From appraisal team to appraised organization and to CMMI Institute PMO:
Full “heat map” + specific results against model:

<table>
<thead>
<tr>
<th>Category</th>
<th>1.1</th>
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- S: Satisfied
- P: Partial
- D: Deficient

Total: 66%
What data is shared? FDA:

From CMMI Institute PMO to FDA:
Practice area results & overall result for an organization:

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<th>Practice Area</th>
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Legend:
- S: Satisfied
- P: Partial
- D: Deficient
What is collected in the metrics collection form?

- High level view into organization’s risks and issues
- Aggregate of all products at facility and not for individual products (instructions provided)
- Specific to organization depending on how they manage that data, tools, and function of the organization
- Allows organization to demonstrate their specific progress over time and tie that to their continuous improvement path
What is the check point process?

- The goals of the check point process are to (1) encourage continuous process improvement and (2) encourage engagement in the program.

- Allows for trending of demonstrated progress and regular identification of areas of concern.

- Check points with the CMMI Lead Appraiser occur at least every six months but can occur quarterly if the organization chooses to do so.

- The appraisal data tool and “heat map” is updated at these check points as appropriate.

- Check point occurs on the phone/digitally over the course of 1-2 hours.
How is this different than an FDA inspection?

**MDDA**

- Focus is on actual capabilities and activities of value add of the organization
- Interviews/data collection from people who perform work which provides an atmosphere for actual inspection to improve from
- Drives a conversation of how to actually improve in a way that makes sense to the business

**The Difference**

- Looks beyond the CFR, and not just strict compliance
- Interviews/data collection are not from just those in the “front room” or those who manage audits
- Does not focus on just a corrective action list to “get into compliance”
How are appraisals assured to be performed consistently?

- Lead appraisers undergo a rigorous certification process (application, training, examination, observation, on-going review) to assure process and quality expectations are met.

- The CMMI appraisal method definition document (MDD) explicitly defines expectations, behaviors and requirements of appraisals.

- For the pilot/early adopter program, all MDDAP appraisal team members will be vetted by CMMI PMO to assure alignment with pilot program considerations and that they are trained on the details of the MDDAP program.

- An MDDAP team will be comprised of at least two members – a lead appraiser and an appraisal team member, whose combined knowledge will include significant medical device experience.

- Standard expectations and tools (e.g. appraisal data tool and “heat map”, appraisal plan templates, method definition document, practice areas in scope) are set for all MDDAP appraisals.

- All appraisal results are reviewed for process and product quality assurance by the CMMI PMO, including conflict resolution.
Program Adoption Metrics to Date

- **# of Enrollees**
  - 7 Organizations || 9 Facilities

- **# of Appraisals**
  - 1 Complete || 1 Current || 4 Scheduled

- **Time from enrollment to appraisal execution**
  - Range = 52 - 136 || Mean = 89 || Target = 90

- **Future: Program Effectiveness Metrics**
Learning from and modifying the program

HOW IS FEEDBACK COLLECTED?

• Post-appraisal survey for appraised organization participants to determine appraisal effectiveness

• “Lessons learned” performed post-appraisal with appraisal team

• Open feedback sessions with MDIC Core Working Group

• General feedback collected from all other channels
Learning from and modifying the program

**HOW IS FEEDBACK PROCESSED**

- Surveys & lessons learned datasets managed by CMMI PMO for regularly input into MDIC Core Working Group
- Working Group mini-teams formed as appropriate to make or approve changes to the program, metrics, benefits, appraisal processes, etc.
- Artifacts (playbooks, trainings, FAQs, communication materials, etc.) modified as necessary

Regular feedback from all stakeholders inspect & adapt
### What does pilot program success potentially look like?

<table>
<thead>
<tr>
<th><strong>Scope</strong></th>
<th><strong>Success consideration</strong></th>
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<tbody>
<tr>
<td>Program execution – is the program sustainable?</td>
<td>Number of appraisals, wait time to appraisal, number of appraisers trained in the program, lessons learned incorporated into program</td>
</tr>
<tr>
<td>Program execution – are stakeholders getting value from program?</td>
<td>Appraised organization survey results, appraiser feedback, FDA feedback, other stakeholder feedback, lessons learned incorporated into program</td>
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<tr>
<td>The long term “next steps”…</td>
<td>Consideration of trending metrics of industry participants, understanding of organizational improvement made to address quality based on engagements</td>
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Coming together

Maturity Model
- Program Creation
- Industry Assessment

Product Quality Dashboard
- Dashboard Creation
- Value Analysis Team Assessment

Device Quality
Improved Patient Outcomes
Looking toward Correlation between Maturity Model Heat Map, Firm Internal Metrics and Product Quality Dashboard
Learning already in progress...

- Increasing appraisal bench
- Discerning requirements for medical device experience
- Consideration of PAs in scope
- Multi-site appraisals with appropriate scope
- Lessons learned
Additional informational material

- Expanded FAQs
- High-level model details
- Detailed overview of program flow
- Expectations for appraisal activities, including pre/post
Current Timeline

2017 Q3

- Complete definition of operations
- FR announcement by FDA
- Initial scoping / scheduling conversations to drive Q4 appraisal activities for early adopters

2017 Q4 - 2018

Execute early adopters appraisals, inspect and adapt and refine as necessary

ENROLL NOW!

http://cmmiinstitute.com/MedicalDevice
QUESTIONS?
APPENDIX
What is CMMI®?

• The Capability Maturity Model Integration (CMMI®) is a capability improvement model that can be adapted to solve any performance issue at any level of the organization in any industry.

• The Model provides guidelines and recommendations for helping your organization diagnose problems and improve performance.

• Used by over 10,000 organizations from more than 100 countries all over the world, CMMI helps you identify and achieve measurable business goals.
Many other industries and companies have successfully leveraged CMMI to achieve their quality goals. We are building upon this success and modifying it for the Medical Device Industry.
Who has been involved?

The Maturity Model Working Group within MDIC is comprised of a blend of small, medium, and large-sized companies as well as professional services firms that will enable the development of a viable program available to a broad spectrum of organizations within the Medical Device Industry.

- B. Braun
- Baxter
- C.R. Bard, Inc.
- Booz Allen Hamilton
- Boston Scientific
- Carver Global Health Group
- CMMI Institute
- CVRx
- Deloitte
- Double Play Process Diagnostics
- Edwards
- FDA, Health and Human Services
- General Electric
- Grant Thornton
- Innovize
- Johnson & Johnson
- Medical Device Innovation Consortium
- Medtronic
- Regulatory and Quality Solutions LLC
- Siemens
- Spectranetics
- St. Jude Medical
- Stryker
- Two Harbors Consulting
- Veeva Systems
What does the CMMI® Institute PMO Do?

**Program assures / provides:**
- Enrollment Management
- Appraisal Scheduling / Scoping Management
- Appraiser Pool Management (selection, training)
- Appraisal / Appraiser Quality Review
- Result collection and distribution / updates to Steering Committee
- Updates program (following SC approval)
- Data management and anonymized trending for review to FDA and industry (quarterly for participants)
- Facilitate interactions between stakeholders as necessary

**Defined to assure program quality and scale:**
- MDDAP Appraisal Method Document
- MDDAP Appraisal Playbook
- MDDAP Appraisal Materials
- MDDAP Appraisal Data Tool and “Heat Map”
- PMO Operations Playbook
- Enrollment form
- Training materials
- Onboarding materials
- FAQs
What Does the MDDA Program Cost?

Costs associated with the program are intended to cover:

• the appraisal
• multiple check points to encourage and drive continuous improvement
• program management

The actual amounts will vary depending on:

• number of product lines / different processes
• number of appraisal team members
What practice areas are in scope for an appraisal?

- Estimating
- Planning
- Monitor and Control
- Configuration Management
- Process Quality Assurance
- Governance
- Managing Performance and Measurement
- Requirements Development and Management
- Technical Solution
- Product Integration
- Implementation Infrastructure

Plus any other additional practice areas the sponsor/appraisal team scope into the appraisal.
What data is shared: Trends with industry

From PMO - trending data
No company specifically identified
Is this another FDA Audit or Inspection?


• The CMMI maturity appraisal process is not intended to serve as an FDA inspection nor is it intended to be a new regulatory requirement. Conducting independent assessments using a maturity model is intended to be a driver of continuous process and product improvement and business value to voluntary participants in the pilot program.
Who is the CMMI® Institute?

- The global leader in the advancement of best practices in people, process, and technology.

- Provides tools and support for organizations to benchmark their capabilities and build maturity by comparing their operations to best practices and identifying performance gaps.

- For over 25 years, thousands of high-performing organizations in a variety of industries, including aerospace, finance, healthcare, software, defense, transportation, and telecommunications, have earned a CMMI maturity level rating and proven they are capable business partners and suppliers.
What is this program?

This pilot 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 July 25, 2017.

A culture of quality - across the organization.
## Why this program v. others FDA offers?

<table>
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<tr>
<th>Program</th>
<th>Description/Objectives</th>
<th>Assessment</th>
<th>Modifications</th>
<th>Status</th>
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<tbody>
<tr>
<td>VCIP (Voluntary Compliance Improvement Program) Pilot</td>
<td>Pilot allows a manufacturer to self-identify compliance issues and correct the issues before FDA inspection is performed.</td>
<td>FDA Compliance Audit</td>
<td>FDA would allow one year to implement corrections before inspection.</td>
<td>Not Active</td>
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| MDSAP (Medical Device Single Audit Program) | The program allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program. (USA, Canada, Brazil, Japan, and Australia.) | MDSAP recognized third party compliance audit  
Performed annually  
Manufacturer is responsible for costs of the audit.  
Audit report and findings available to all participating countries | FDA accepts results for routine surveillance inspections.  
Allows manufacturer to leverage one audit to fulfill requirements for multiple regulatory organizations  
Benefit: Reduces the burden and disruption of audits required by multiple regulatory body.  
Auditor provides more detail and guidance on findings. | Active Program |
| PMA Critical-to-Quality Pilot       | The pilot allows a PMA manufacturer meeting the participation criteria to engage on new PMAs early in the review process and identify their critical to quality requirements, the relevant controls, and supporting data. The pilot objectives are to provide a focus and engagement on quality attributes earlier in the review | FDA Compliance Audit                | Pre-approval inspection is waived for manufacturer who demonstrates a focus on identifying critical to quality attributes and effective controls  
Benefit: Early engagement with the manufacturing review team and accelerates the premarket approval by waiving premarket inspection and performing a post-market inspection after 6 months. | Pilot      |
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<tr>
<td>Case For Quality Voluntary Medical Device Manufacturing and Product Quality Pilot (MDDAP)</td>
<td>The pilot focuses on using a maturity appraisal to drive continuous improvement and organizational excellence at a medical device manufacturer. The enrolled manufacturer will participate in a maturity appraisal conducted by the CMMI Institute and commit to early engagement with CDRH and submission of objective pulse metrics established during the appraisal to monitor improvement and progress.</td>
<td>Third-Party Quality System Maturity Appraisal performed by certified team Performed annually during pilot Manufacturer is responsible for costs of appraisal which varies on size and scope of appraisal activity Requires submission of baseline performance metrics during appraisal and resubmission of the metrics as progress monitor at established intervals through the pilot year. Requires commitment for feedback into appraisal process and pilot</td>
<td>Manufacturer is removed from surveillance work plan. Additional data allows FDA to streamline manufacturing submission reviews. Site changes, PMA Manufacturing Sections, and 30-Day Notices. Can be applied to US or Foreign Sites but only fulfills FDA Regulatory requirements Benefit: Reduces the burden and disruption of audits and focuses on shifting resources to innovation and improvement Allows streamlined submissions and accelerated review and approval Waives pre-approval inspection for PMA Originals Appraisal team provides feedback on what is succeeding, what has opportunity for improvement, what is or is not driving value for you customers or business based on your business objectives.</td>
<td>Pilot</td>
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