Maturity Model Workstream
–July 2017 Update

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MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
Align › Achieve › Accelerate
Develop a program which leverages CMMI as the standard maturity model by which medical device organizations may measure their capability to produce high quality devices and improve patient safety. FDA will adjust their engagement activities and submission requirements as a recognition of this independent assessment of quality maturity.

Goal Statement

- Completed POC to prove out the mechanics & value of the modified CMMI model. Discovery style was determined to be enough to open the discussion of FDA incentives.
- Completed Pilots to demonstrate industry could use it and find value in it. Scalable to size and type of organizations (Innovize, CVRx & J&J). Determined need for 90d checkpoint in order for FDA to feel comfortable with any incentives.
- Held Panel between Industry and FDA to hear companies experienced in the CMMI model. It's about the right metrics and culture, not the score. Appraisals are experiences, not scored audits.

2017 Objectives

- Conclude FDA will support the program and who within FDA is empowered to make this decision
- Determine if 3 Pilots are sufficient to conclude the execution and sustainment of the program
- Conclude how the program will be made scalable for ~17 participants in 2018
- Establish a 3rd Party to Audit CMMI as a compliant, sustainable organization
- Collect, interpret and publish results for industry and FDA to view
- May be others that we determine as we develop the program
- Lock in incentives from FDA

Reduced defects / rework  Reduced costs  Accelerated time to market  Increased Customer Satisfaction

A culture of quality - across the organization.
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.

Sample of Companies That Are Appraised Against the CMMI Framework

<table>
<thead>
<tr>
<th>Information Technology</th>
<th>Healthcare</th>
<th>Electrical &amp; Automotive</th>
<th>Gov/Defense/Space</th>
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</thead>
<tbody>
<tr>
<td>Accenture</td>
<td>McKesson</td>
<td>Samsung</td>
<td>NASA</td>
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<tr>
<td>Intel</td>
<td>Booz, Allen, Hamilton</td>
<td>GM</td>
<td>U.S. Air Force</td>
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<tr>
<td>HP</td>
<td>Ericsson</td>
<td>Honeywell</td>
<td>Boeing</td>
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<tr>
<td>Wipro</td>
<td>Infosys</td>
<td>Motorola</td>
<td>General Dynamics</td>
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<tr>
<td>IBM</td>
<td>Siemens</td>
<td>Hitachi</td>
<td>U.S. Navy</td>
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<tr>
<td>Ericsson</td>
<td>Argyll &amp; Sutherland</td>
<td>BMW</td>
<td>Raytheon</td>
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<tr>
<td>Infosys</td>
<td>CGI</td>
<td>Siemens</td>
<td>Northrop Grumman</td>
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<td>Nokia</td>
<td>AETNA</td>
<td>NEC</td>
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<td>NEC</td>
<td>Booz, Allen, Hamilton</td>
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A Diverse Team

The Maturity Model Working Group 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.

<table>
<thead>
<tr>
<th>B. Braun</th>
<th>Deloitte</th>
<th>Medical Device Innovation Consortium</th>
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<tbody>
<tr>
<td>Baxter</td>
<td>Double Play Process Diagnostics</td>
<td>Medtronic</td>
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<tr>
<td>Booz Allen Hamilton</td>
<td>Edwards Life Sciences</td>
<td>Regulatory &amp; Quality Solutions LLC</td>
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<tr>
<td>Boston Scientific</td>
<td>FDA, Health and Human Services</td>
<td>Siemens</td>
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<tr>
<td>C.R. Bard</td>
<td>GE Healthcare</td>
<td>Spectranetics</td>
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<tr>
<td>Carver Global Health Group</td>
<td>Grant Thornton</td>
<td>St. Jude Medical</td>
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<td>CMMI Institute</td>
<td>Innovize</td>
<td>Stryker</td>
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<td>CVRx</td>
<td>Johnson &amp; Johnson</td>
<td>Two Harbors Consulting</td>
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<td>Veeva Systems</td>
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Proof of Concept
FDA observed virtually, a native CMMI® SCAMPI C appraisal for a medical device contract manufacturer

Closed FDA Panel Conversation
At the FDA’s request, assembled a panel of Medical Device Executives to discuss benefits of CMMI appraisals to improving product quality

3 Pilots
Conducted three CMMI® SCAMPI C appraisals tailored for the medical device industry. Pilots represented: contract manufacturer, large product developer and early-stage in clinical testing

- How valuable was the appraisal?
  - Low (0%), Medium (66%, 17), High (34%, 9)
- Were there any appraisal assessment areas that conflicted with regulatory requirements?
  - 100% No (26/26)
- Did the appraisal identify areas or processes that could improve how work is performed to improve product quality?
  - 98% Yes (25/26)
- Did the appraisal accurately identify the culture of the leadership’s value of quality and resourcing to monitor, assure and improve product quality?
  - 100% Yes (26/26)
FDA Regulatory Modifications

Regulatory Activity Modifications
- Inspections – Process established
  - Move from audit to appraisal and remove participant from routine surveillance
  - Waive pre-approval inspections where appropriate
- Proactive engagement on quality issues – Expectation established, process and communication path in development
- Manufacturing submissions
  - Reduce submission requirements and accelerated approval for 30-Day Notices, Site Changes, and PMA Originals – Submission modifications established, routing and tracking process in development
  - Expanded efforts
    - Easing product importation – Process in development
    - Corrections, Removals, and Enhancements – Process in development
    - 510(k) Submission Review Modifications – FDA Team kicked-off. Initial meeting with industry participants.

Benefits
- Industry
  - Tangible value – Cost savings in inspections and disruptions, increased value from optimization activities, decrease cost of inventory hold,
  - Accelerate quality improvements – Allows for faster and more continues improvement opportunities
  - Improve resource deployment and utilization
- FDA
  - Redeployed resources - Estimated 15 – 22 Average FTEs
  - Faster and more effective assurance
  - Focused activities – Leverage value of FDA engagement
- Patients
  - Increased responsiveness
  - Faster access to improved products
  - Increased patient focus
**Open Forum**

Collected input on:
- Program goals
- Potential Issues
- Planned incentives
- Considerations for working group sub teams

**Next Steps**

- Complete internal routing development
- Work with Maturity Communications/Governance team on establishing feedback process and engagement rules
- Develop reduced submission instructions and templates
- Engage 510(k) manufacturers on value proposition
- Communication with field on activities and engagement
- Complete implementation plan
- FDA Public Meeting
- Issue Pilot Participation FR

**Open Forum**

Q3 / Q4 ‘17

Mar ‘17

Jul ‘17

Mar ‘17

Jul ‘17

Q3 / Q4 ‘17
March Open Forum Input

**FDA Clarification**
What are the implications for other FDA programs and what will be stated publicly?

**Operationalization**
We need a detailed/precise understanding of the scope, frequency and implications of participating.

**Safe Environment**
How do we insure a learning environment in which mistake are tolerated/expected?
March Open Forum Input (Continued)

Value Proposition
How to simply demonstrate value to my organization?

Role of CMMI and Oversight
How will CMMI Institute, MDIC and FDA ensure the consistency, fairness and control of the program?

Communication
How to increase industries basic understanding of program and its value?
March Input - Addressed

**Enrollment**  
Led by Macil Krieser

1. Qualifications and requirements to join program are defined
2. Online enrollment form has been drafted

**Appraisal**  
Led by Ron Lear

1. Definition of appraisal playbook underway to tailor for device appraisals including scoping, appraiser qualifications, possible appraisal questions, sharing of results

**Metrics**  
Led by Patterson Shaffer

1. Program metrics have been drafted to cover:
   - Program adoption, execution, and effectiveness
   - Value to Industry and to the FDA
2. Specific engineering and quality metrics are being considered for future implementation

**Communication & Prog Integration**  
Led by Becky Fitzgerald

An FAQ was created to address:

1. Why CMMI was chosen
2. Expectations of Companies Participating & Not Participating
3. Information Sharing (IP, Result) Rules
4. Cost, Benefits & Use Cases for small and large companies

CMMI PMO being defined to assure quality and scaling of program
March Input – Pending Resolution

1. Further define activities from enrollment to execution of appraisal (scheduling, scoping)

- 1. What is the frequency of follow ups to the appraisal?
- 2. What scoping parameters are leveraged for what “size” of benefit?
- 3. How are appraisal issues resolved?

2. What is the ongoing communication / marketing / education strategy for this program?

- 1. How will the metrics evolve as the program evolves?
- 2. What is reported and to whom?
- 3. Guidance on how metrics are defined, captured, and reported

- 1. What other regulatory benefits can be provided by the FDA?
- 2. What is the length of pilot and quantity of companies
Next Steps

Q3

Complete definition of operations

Complete initial definition of enrollment, appraisal, operational, measurement expectations for initial service offering

Open enrollment for early adopters for initial appraisals starting in September

Q4

FR announcement by FDA

Execute program for early adopters, inspect and adapt and refine as necessary

Open Forum

Collected input on:

- Program goals
- Potential Issues
- Planned incentives
- Considerations for working group sub teams
How do I enroll my organization?

• [http://mdic.org/cfq/enroll/](http://mdic.org/cfq/enroll/)
Questions?
Appendix
**Goal Statement**

Develop a program which leverages CMMI as the standard maturity model by which medical device organizations may measure their capability to produce high quality devices. FDA will adjust their engagement activities and submission requirements as a recognition of this independent assessment of quality maturity.
Before Industry will Embrace the Program, the FDA Recognized Several Hurdles

1. Industry, FDA and MDIC Teams need to commit to developing the elements of this voluntary quality-focused program

2. To date, we have participants agreeing on benefits, but there is still too much ambiguity on the “how” to drive momentum or program deliverables

3. Everyone is waiting for the FDA to demonstrate commitment to the program (i.e. regulator relief for participants)
SCAMPI Level & FDA Incentives

• Starting the Program
  − FDA is ready to define and commit to significant review and engagement modifications
  − Scoped to companies that have had successful audits with FDA already
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<thead>
<tr>
<th>Approach</th>
<th>Deliverables</th>
<th>Comments</th>
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<tr>
<td>• The FDA, MDIC and CMMI Institute Are Collaborating on the Program</td>
<td>• Finalize the Program</td>
<td>• &lt;We should insert the time and resource commitment for each company that participates&gt;</td>
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<td>• Incentives for Industry will be developed for Program Participants</td>
<td>• Prepare for Launch in 2018</td>
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<table>
<thead>
<tr>
<th>Q1 activities</th>
<th>Q2 activities</th>
<th>Q3 activities</th>
<th>Q4 activities</th>
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<tr>
<td>• Steering Team Presentation</td>
<td>• Manufacturing Focused Project</td>
<td>• FR Public Meeting Announcement</td>
<td>• Development Focused Project</td>
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<tr>
<td>− February</td>
<td>− Identify internal program modifications, key metrics needed to monitor progress, communication needs, data reporting expectations</td>
<td>− Coordinate meeting, expectations, participants, and objectives for announcing the program proposal</td>
<td>− July to October</td>
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<td>• Present proposal to MDIC Forum &amp; Obtain Feedback</td>
<td>− March to June</td>
<td>− August</td>
<td>• Finalize Quality Program</td>
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<tr>
<td>− March</td>
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<td>• Final Pilot</td>
<td>Implementation &amp; Deliver Public Announcement</td>
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<td>− September</td>
<td>− Define Rules</td>
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<td>− November</td>
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