MDIC Maturity Model

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October 26, 2016
Quality System Model Benefits

Implementing a standard, recognized maturity model across the medical device industry, could produce a wide range of benefits.

- Enable standardization of assessments and benchmarking of operations; promote a strong functional orientation that can be used to drive improvements.
- Promote culture improvement by holistically evaluating the QMS across people, processes, and technology with metrics that link to organizational and talent performance.
- Identify areas to improve, and predict/plan next steps to achieve goals, while maintaining flexibility to focus on shifting priorities.
- Track and monitor progress and ROI to improve clarity and communication with executive stakeholders.
- Promote the development of actionable strategies to improve operations and quality; encourage self-improvement and quality management system (QMS) sustainment.
- Improve communication and streamline interactions with the FDA and other regulators.
- Working toward higher maturity levels can help improve capabilities, promote more effective processes and governance, and reduce variability that leads to increased cost of quality and rework.
- Shift the quality focus so it aligns—rather than conflicts—with speed and cost objectives.

Increased Effectiveness At Lower Cost

Consistency

Quality Beyond Compliance

Cultural Change

Transparency

Predictability And Flexibility

Alignment

Business Partnering
What is the Capability Maturity Model Integration (CMMI®)?

- An internationally recognized framework
- Flexible and agnostic to the project, product, or services lifecycle
- A representation of mature capabilities
- A measurement mechanism:
  - baselining tool (gap analysis)
  - benchmarking tool (ratings potential)
- Describes an improvement path
Continuous Improvement

Data-driven Decision making

Useful Process Infrastructure

Plan your work; Work your plan

Work happens

Maturity Levels

Initial

Managed

Defined

Quantitatively Managed

Optimizing
Use of the Standard CMMI® Appraisal Methodology for Process Improvement (SCAMPI®SM) to demonstrate the CMMI® framework to the MDIC and FDA Stakeholders
CMMI® SCAMPI Classes

Provides full flexibility: DISCOVER
- Appraisal process
- Model scope
- Organizational scope

Provides less flexibility: AFFIRM
- Appraisal process
- Model scope
- Organizational scope
- Gather evidence for all practices

Least flexible: PROVE
- Appraisal process
- Model scope – required elements for rating
- Organizational scope – sampling rules
- Evidence gathered and considered with affirmations

Breadth of tailoring

Depth of investigation

Maturity level rating only possible for SCAMPI A
Generic Goal 2: Institutionalization

Protects the organization’s work practices in times of stress

GG 2 Practices “Institutionalization”

- Set Policy
- Plan the Process
- Provide Resources
- Assign Responsibility
- Train People
- Control Work Products
- Identify and Involve Relevant Stakeholders
- Monitor and Control the Process
- Review Status with Higher Level Management
- Objectively Evaluate Adherence
How is CMMI® Different from other quality system models?
CMMI® relationship to QSR and others

Compare the components

CMMI® ↔ QSR ↔ Others

• “What are the differences?”

Compare the implementation

CMMI® begins with a broad question & uses Appraisals to evaluate

• “Who are your clients internal and external, and what are their requirements”

QSR begins with the specific question & uses Audits to evaluate

• “What medical device products do you make, and how do you manage the process”

Other standards based begin with a prescriptive approach & use Audits to evaluate

• “What medical devices and components do you make, and how do you execute the specific measures and activities to ensure within thresholds?”
CMMI and Regulatory

CMMI (Certified Coach)

Regulatory & Notified Bodies
(Rules of Engagement/Enforcement)
CMMI - Six Sigma - ISO

CMMI (What)

Six Sigma (How)

ISO (Prescriptive tolerance)
We want to see it work!!!

Proof of Concept
Native CMMI®
Proof of Concept Results

Take notice REQM SP1.1

Take away:
Open dialogue = higher level of trust  
Impact  
transparency into issues
Trust

Core ingredient implementing CMMI® and desired outcome for quality devices

"Without trust we don’t truly collaborate; we merely coordinate or, at best, cooperate. It is trust that transforms a group of people into a team."

www.twicial.com

Cirque du Soleil

www.tnlp.valuecenter.com
How would it work?
Case for Quality (CfQ)

Maturity Model

- CMMI® - SCAMPI C
- SCAMPI A

Metrics

- Pre-Production – Total # changes / Total # of projects
- Production - Total # units mfg RFT / Total # units started
- Post Production – Index

Advances Analytics - VAC

- Safety
- Effectiveness
- Reliability
- Patient Satisfaction
- Usability
- Availability
- Compatibility

Competencies

- Project Management
Case for Quality (CfQ)

Maturity Model
- CMMI® - SCAMPI C

Metrics
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Advances Analytics - VAC
- Safety
- Effectiveness
- Reliability
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Competencies
- Project Management
MDIC trusted
Medical Device Ecosystem
Promoting Quality

Case for Quality (CfQ)

Metrics
Competency
Analytics

Best Practices

Industry Trends
to Identify
Areas for Improvement

MedDev Appraisals

Appraisal Results

Medical Device Capability tracking
Has anyone done this before?
Is there proof that there is value?
Panel of CMMI® experts
“\textit{I believe the potential of this initiative to change our industry is huge.}”

\textbf{Take-a-Ways}

- Bottom up, \textbf{not} Top Down
- The \textbf{right} data metrics, \textbf{not more} data metrics!
- It’s a journey of continuous process improvement, not driven to attain a certification or rating
- Listen and learn - NOT Audits or tests

\textbf{ROI}

- 108\% to less than 12\% post-release support costs (\textbf{dev cost: post-release})
- Predictive staffing levels to support launch
- 510k clearance from 6 months to 2 months
- Employee staff morale improve as their issues were heard and addressed
Need more info?  
How would medical device data be included?
# Proof of Concept and Pilots

## De-Identified

### Maturity Level 2 Process Areas

<table>
<thead>
<tr>
<th>Process Area</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1.1 to P1.6</td>
<td></td>
</tr>
<tr>
<td>P1.7 to P1.9</td>
<td></td>
</tr>
<tr>
<td>P1.10 to P1.15</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>75.7%</td>
</tr>
</tbody>
</table>

- **Score Calculation:**
  - Each process area is scored based on a predefined scale.
  - The overall score is calculated by averaging the scores of all process areas.

- **Process Areas:**
  - P1.1 to P1.9
  - P1.10 to P1.15
  - P1.16 to P1.20

- **Score Example:**
  - Process Area P1.1: Score 58.96%
  - Process Area P1.2: Score 88.91%
  - Overall Score: 75.7%
Native CMMI® POC vs MedDev CMMI® Pilot #1

### Maturity Level 2 Process Areas

<table>
<thead>
<tr>
<th>Process Areas</th>
<th>Score</th>
<th>Overall</th>
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<tbody>
<tr>
<td>REQM</td>
<td>5</td>
<td>58.98%</td>
</tr>
<tr>
<td>PP</td>
<td>0</td>
<td>49.3%</td>
</tr>
<tr>
<td>PMC</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>SAM</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>MA</td>
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<td>0%</td>
</tr>
<tr>
<td>PPQA</td>
<td>7</td>
<td>53.3%</td>
</tr>
</tbody>
</table>

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<tbody>
<tr>
<td>REQM</td>
<td>15</td>
<td>88.91%</td>
</tr>
<tr>
<td>PP</td>
<td>24</td>
<td>83.7%</td>
</tr>
<tr>
<td>PMC</td>
<td>20</td>
<td>90.4%</td>
</tr>
<tr>
<td>SAM</td>
<td>16</td>
<td>80.9%</td>
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<tr>
<td>MA</td>
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<td>77.4%</td>
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<tr>
<td>PPQA</td>
<td>14</td>
<td>82.1%</td>
</tr>
<tr>
<td>CM</td>
<td>17</td>
<td>79.1%</td>
</tr>
</tbody>
</table>

Overall 124 83.3%
Survey results

Pilot #1 & #2 - 90% interviewees responded

Did the appraisal interviews identify areas or processes that could improve how work is performed to increase product quality?

Answered: 17   Skipped: 0

Did the appraisal interviews identify areas or processes that could improve how work is performed to increase product quality?

Answered: 17   Skipped: 0

Do FDA audits identify areas or processes that could improve how work is performed to increase product quality?

Answered: 17   Skipped: 0
Survey results

Were there any appraisal interview areas that conflicted with regulatory compliance assessment areas?

Answered: 17  Skipped: 0

- Yes
- No

Did the appraisal accurately identify the culture of the organization's leadership's value of quality and resourcing to monitor, assure, and improve product quality?

Answered: 17  Skipped: 0

- Yes
- No
Survey results

How many hours did you put into the Appraisal process?

Answered: 17  Skipped: 0

Range of hours: 1-25

How valuable was the appraisal?

Answered: 17  Skipped: 0

- low
- medium
- high

Range of hours: 1-25
Interpreting maturity & culture of an organization

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.
- **Not Applicable**

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**Table**

<table>
<thead>
<tr>
<th>Practice</th>
<th>Score</th>
<th>15</th>
<th>20</th>
<th>24</th>
<th>16</th>
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</table>
Tool to drive Best Practice development
## Company / Parent Organization

<table>
<thead>
<tr>
<th>Size</th>
<th>(Note: single selection)</th>
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<tbody>
<tr>
<td>X-Small (1-40 people, 0-$4M in sales)</td>
<td></td>
</tr>
<tr>
<td>Small (30-100 people, $5M-$49M in sales)</td>
<td></td>
</tr>
<tr>
<td>Medium (80-300 people, $50M-$499M in sales)</td>
<td></td>
</tr>
<tr>
<td>Large (300-3000 people, $500M-$5B in sales)</td>
<td></td>
</tr>
<tr>
<td>X-Large</td>
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</tr>
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</table>

## Organizational Unit

<table>
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<th>Size</th>
<th>(Note: single selection)</th>
<th>Instantiations/ projects (note: multi-select for each instantiation)</th>
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</thead>
<tbody>
<tr>
<td>X-Small (1-40 people, 0-$4M in sales)</td>
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<td>Research</td>
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<td>Small (30-100 people, $5M-$49M in sales)</td>
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<td>Manufacturing - HW</td>
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<tr>
<td>Medium (80-300 people, $50M-$499M in sales)</td>
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<td>Manufacturing - SW</td>
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<tr>
<td>Large (300-3000 people, $500M-$5B in sales)</td>
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<td>Product Design-HW</td>
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<tr>
<td>Division(s) within Corporation</td>
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<td>Product Design-SW</td>
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<tr>
<td></td>
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<td>Test - bench - mechanical</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Other: write in field</td>
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What does it take?
Pilot LOE

Our hours:
150 cum hrs Appraisal Team
each Class C style
MedDev Appraisal
Excluding travel, pre-appraisal prep

Average per participant: 8.25
Range of hours 1-25
8-12 participants
Total cumulative 80 hours
What was the workgroup’s experience?
What’s next?
Proposed Implementation Program Development

• Data for Dec 2017:
  • Appraisal Collector and repository
  • CMMI® - for official record
  • MDIC - for Ecosystem ‘Opt-In’ and ‘De-identified’ workgroup planning
  • 30 encounters: Appraisals and Check Points
  • On-going feedback from participants

• Training
  • Industry on the Best Practices
  • Specialized MedDev Lead Appraisal and Appraisal Team Member (CMMI®)

• Memorandum Of Understanding
  • Criteria & triggers: more support, regulatory action, volu exit
  • Communication Plan
  • FDA Recognition of Ecosystem participation
  • Process Quality: conflict resolution