CMMI® Institute

IMPROVING PATIENT SAFETY THROUGH CONTINUOUS IMPROVEMENT

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TITLE: New Business and Market Development

ORGANIZATION: CMMI Institute

CMMI® Institute

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.

Reduced defects / rework

Reduced costs

Accelerated time to market

Increased Customer Satisfaction

A culture of quality - across the organization.

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

B. Braun
Baxter
Booz Allen Hamilton
Boston Scientific
Carver Global Health Group
CMMI Institute
CVRx
Deloitte
FDA, Health and Human Services
Two Harbors Consulting
Grant Thornton
Innovize
Johnson & Johnson
Medical Device Innovation Consortium
Medtronic
Siemens
Stryker

Aug '16

Proof of Concept

FDA observed virtually, a native CMMI® SCAMPI C appraisal for a medical device contract manufacturer

Sep - Nov '16

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

innovize
let's make it better

CVRx
Medicine ReEnvisioned™

Johnson & Johnson

Oct '16

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

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MEDICAL DEVICE EVALUATION

Aug '16

Sep - Nov '16

Oct '16

3 Pilots

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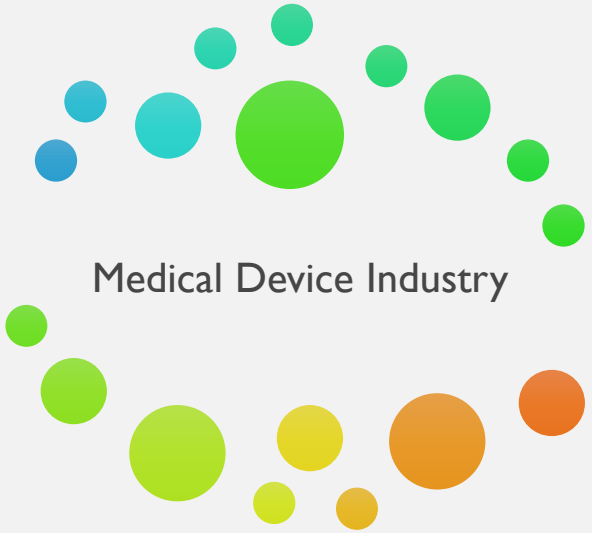
POSITIVE FEEDBACK

- 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)

QUALITY MATURITY MODEL PROGRAM…



Participant Status
- Status definitions: good standing, increased oversight, regulatory follow-up,
- Implications of status
- Conflict resolution
- Voluntary/involuntary exit

Enrollment
- Definition and selection of participants
- FDA recognition/ support for participants
- Expectations of participants
- ROI –success stories
- Investment

Appraisal
- Training of LA's and ATMs
- Costs identification
- Specialized LA's
- SCAMPI C appraisal with MedDev guidance
- Check-in appraisal

Metrics
- Appraisal results –for FDA
- Appraisal results de-identified
- Performance metrics de-identified
- Data repository

Communication
- FDA communication plan (performance and status)
- Industry best practices
- Industry performance tracking

Continuous Improvement
- Program
- Model tailoring (guidance, profiles, etc)
- Training (program and industry)

Oversight Framework

FDA

- Drives submission requirements: full manufacturing
- 30-Day Notices, Site Changes, and Original PMA Manufacturing Reviews
- FR Program Announcements
- Confirms progress and impact on objectives
  - Manufacturing focused project
  - Development focused project
  - Quality Program Implementation Success

Steering Committee (SC)

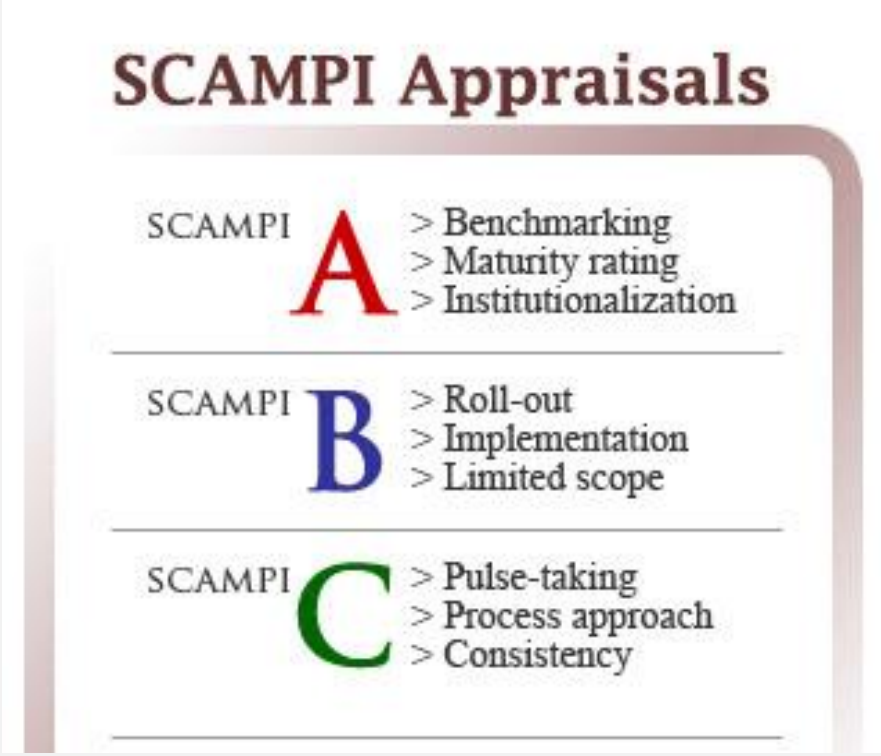
- Concur on Program Priorities and Objectives
- Monitors metrics, risks, issues against objectives
- Decision making
- Pilot criteria, selections and reviews
- Membership: Permanent: FDA, MDIC Teams, PMO Ad hoc: Assessors and Pilot organizations as needed

PMO –CMMI Institute

- Manages the overall project plan and schedule
  - Continuous improvement and learning focus
- Manages cross-program metrics and progress towards objectives, reports to Steering Committee
- Develops, implements & Manage 3rd Party Maturity Assessments & Framework
- Manages Assessments Activities
  - (SMEs/assessors, training, planning and coordination)
- Manages communications, outreach and action follow-up on behalf of SC

SCAMPI LEVEL & FDA INCENTIVES

- Pilots demonstrated to FDA that the model can work:
  - Agreement that this is moving in a positive direction
  - The appraisals yield granular, beneficial discussions
  - Starting with SCAMPI C is acceptable to FDA
  - Establish integration with other MDIC Work streams
  - FDA wants to enable the Program to utilize evidentiary levels (SCAMPI A)



FDA REGULATORY MODIFICATIONS

Regulatory Activity Modifications

- Pilot Phase
  - Inspections
    - Remove from routine surveillance
    - Waive pre-approval inspections where appropriate
  - Issues
    - Engagement – Rapid resolution
  - Manufacturing submissions
    - Reduce submission for 30-Day Notices, Site Changes, and PMA Originals
- Program Expansion
  - Development submissions
    - 510(k) and PMA Original
    - Accelerate approval path
  - Comparative metrics and data
    - Faster, more indicative way of assessing performance

Benefits

- Industry
  - Tangible value
  - Faster time to market
  - Improve resource deployment
- FDA
  - Redeployed resources
    - Estimated 15 – 22 Average FTEs Redeployed
  - Faster and more effective data
  - Focused reviews
    - Where does FDA add value
- Patients
  - Increased responsiveness to issues
  - Proactive improvements
  - Faster access to products and improvements

Approach	Deliverables	Comments
• The FDA, MDIC and CMMI Institute Are Collaborating on the Program • Incentives for Industry will be developed for Program Participants	• Finalize the Program • Prepare for Launch in 2018	• <We should insert the time and resource commitment for each company that participates>

Q1 activities	Q2 activities	Q3 activities	Q4 activities

• Steering Team Presentation
  • February
• Present proposal to MDIC Forum & Obtain Feedback
  • March
	• Manufacturing Focused Project
	  • Identify internal program modifications, key metrics needed to monitor progress, communication needs, data reporting expectations
	  • March to June
		• FR Public Meeting Announcement
		  • Coordinate meeting, expectations, participants, and objectives for announcing the program proposal
		  • August
		• Final Pilot
		  • September
			• Development Focused Project
			  • July to October
			• Finalize Quality Program Implementation & Deliver Public Announcement
			  • Define Rules
			  • November

WHAT'S NEXT?

- Create a program which leverages the CMMI framework to drive continuous improvement
- Determine how we collect, analyze, and share the assessment results
- Determine how do we evaluate the effectiveness of the program
- Define milestones for how quickly we need to scale
- Establish how the FDA program shifts bring value to participants as increasing maturity levels are achieved

QUESTIONS?