Voluntary Pilot Meeting Preview: How will CDRH apply assessments in the voluntary program?

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CDRH Voluntary Program Pilot Workshop

Target Date: October 10, 2017*
Location: Great Room
Bldg. 31
FDA
Silver Spring, MD

* Final details of the workshop are pending clearance

Workshop Overview

Background – Case For Quality and CMMI

Voluntary Quality Program Pilot Framework and Implementation Plan

Modifications to FDA Activities

Benefits and Value Discussion

Risks and Mitigations

Voluntary Program Update

- Process for participant removal from workplan
- Established FDAs expectations for high manufacturing capability
- Established submission requirements and modifications (30-Day, Site Changes, PMA Manufacturing Module)
- Developed program risk tracker
- Developed implementation plan outline and draft
- Public meeting schedule

- Federal Register Clearance
- Develop process routing for submissions throughout pilot
- Establish instructions and templates for pilot submissions
- Develop feedback and interaction framework
- Formalize “Rules of engagement” for pilot
- Implementation plan draft

- Development of Imports (Trusted Trader) program to facilitate incoming product for manufacturers
- Modifications to corrections and removal requirements and classification
- Established 510(k) submission team to find opportunities in the 510(k) submission space

FDA Assurance Expectations

Identify key behaviors FDA would need to see demonstrated in order to provide assurance of high-manufacturing quality and responsiveness.

Manufacturing Behaviors	
Manufacturer can demonstrate traceability throughout their production processes, suppliers, and distributed products	Manufacturer can demonstrate a focus on establishing, sustaining, and improving control over their production, supply chain, and product quality
Manufacturer can demonstrate a effective use of metrics and advanced analytics capability	Manufacturer demonstrates visibility in their data and metrics. The relevant metrics are available through all levels of management and staff.
Manufacturer can demonstrate a high patient-safety focus and responsiveness to issues and speed in identification, containment, and action	Manufacturer can demonstrate a strong focus on proactive prevention and continuous improvement

Focus Areas	High-Capability Characteristics	
Supplier Oversight	• *Robust selection* • *Two-way communication and data flow* • *Manufacturer and supplier integrated into each others development*	• *Supplier incentive programs* • *Supplier quality culture review*
Traceability	• *Tracking is automated or semi-automated* • *Prevents errors from human input or interaction*	• *Full forward and backward traceability within one day from serialized identifier*
Proactive prevention and error-proofing	• *Proactive line design for continuous flow* • *Maximize automation, automated inspections, or applied technology* • *Established continuous improvement programs*	• *Poke-yoke where appropriate* • *Design for Manufacturing and Design Transfer focus* • *Error-proofing to control for 5Ms (Man, Materials, Methods, Measurements, Machines*
Risk-Mitigation	• *Linked and dynamic control plans with consistent feedback using real data and analytics to drive re-evaluation of risk* • *Early clinical engagement and patient safety considerations*	• *Error-proofing and mitigation driven by risk management* • *Risk drives control measures* • *Responsiveness to issues tracked and in performance objectives*
Critical Outputs	• *Clear flow from patient to personnel, and process* • *Comprehensive use of internal and external data sources*	• *Linked to control plans* • *Captured in systems for easy retrieval*
Data Collection and Analysis	• *Robust data collection design, characterization, and utilization* • *How, when, why and who captured electronically* • *Automated and provides timely feedback.* • *Correlation of product quality outcome data with internal quality system metrics*	• *Pushed vs pulled, Data triggers trend and assessment analysis* • *Integrated sources (internal, external, supply)* • *Data is easily available to staff and informs business decisions*
Strategic Quality Planning	• *High-level strategic quality plan driving shared objectives and goals.* • *Long term roadmap*	• *Patient and product quality focus* • *Drives organizational alignment and patient focused culture* • *NPS, Market Share, business results tied to quality objectives/performance*
Training and Development	• *Training to competency with built in verification → validation of effectiveness of training* • *Automated and active enforcement of training*	• *Patient and product quality focus and impact integrated into training* • *Formal engagement programs*

How will CDRH apply assessments in the Voluntary Program?

What it is not!

How will CDRH apply assessments in the Voluntary Program?

- Assessment appraises where organization is journey from Initial Heroic Efforts to an Organizational Excellence and Continuous Improvement Culture
- How capable is your system to learn and progress?

How will CDRH apply assessments in the Voluntary Program?

- Understand if there are gaps that need to be addressed
- Understand if the maturity appraisal can be applied on an industry wide scale
- Increase confidence in a manufacturers quality system
- Understand what the right behaviors to focus on are

How will CDRH apply assessments in the Voluntary Program?

What data is shared? Appraised organization:

Full scorecard +
specific results against model

From appraisal team
to appraised and to PMO

	SP1.1	SP1.2	SP1.3	SP1.4	SP1.5	SP1.6	SP1.7	SP2.1	SP2.2	SP2.3	SP2.4	SP2.5	SP2.6	SP2.7	SP3.1	SP3.2	SP3.3	SP3.4	SP3.5	Establish a Policy	Plan the Process	Provide Resources	Assign Responsibility	Provide Training	Control Artifacts (CM)	Involve Stakeholders	Monitor & Control	Process Adherence	Provide Status to HLM	Practic	Score
REQM	S	P	P	S	S															P	P	P	S	S	P	S	P	P	S	15	70.95%
PP	S	S	P	S				S	P	P	P	S	S	S	P	P	S			D	S	P	S	S	S	S	S	P	S	24	76.0%
PMC	S	S	P	S	S	S	P	S	S	S										D	S	P	S	S	S	S	S	P	S	20	81.2%
SAM	S	S	P					P	S	S										S	P	P	S	S	S	P	S	P	S	16	78.1%
MA	P	P	P	P				S	S	P	S									D	S	S	P	S	S	S	S	P	S	18	72.2%
PPQA	P	P						P	P											P	P	S	P	S	S	P	P	D	P	14	56.1%
CM	P	S	S					S	S						S	P				P	P	S	P	S	S	P	S	P	S	17	76.4%
																												Overall		124	73.7%

Table Legend

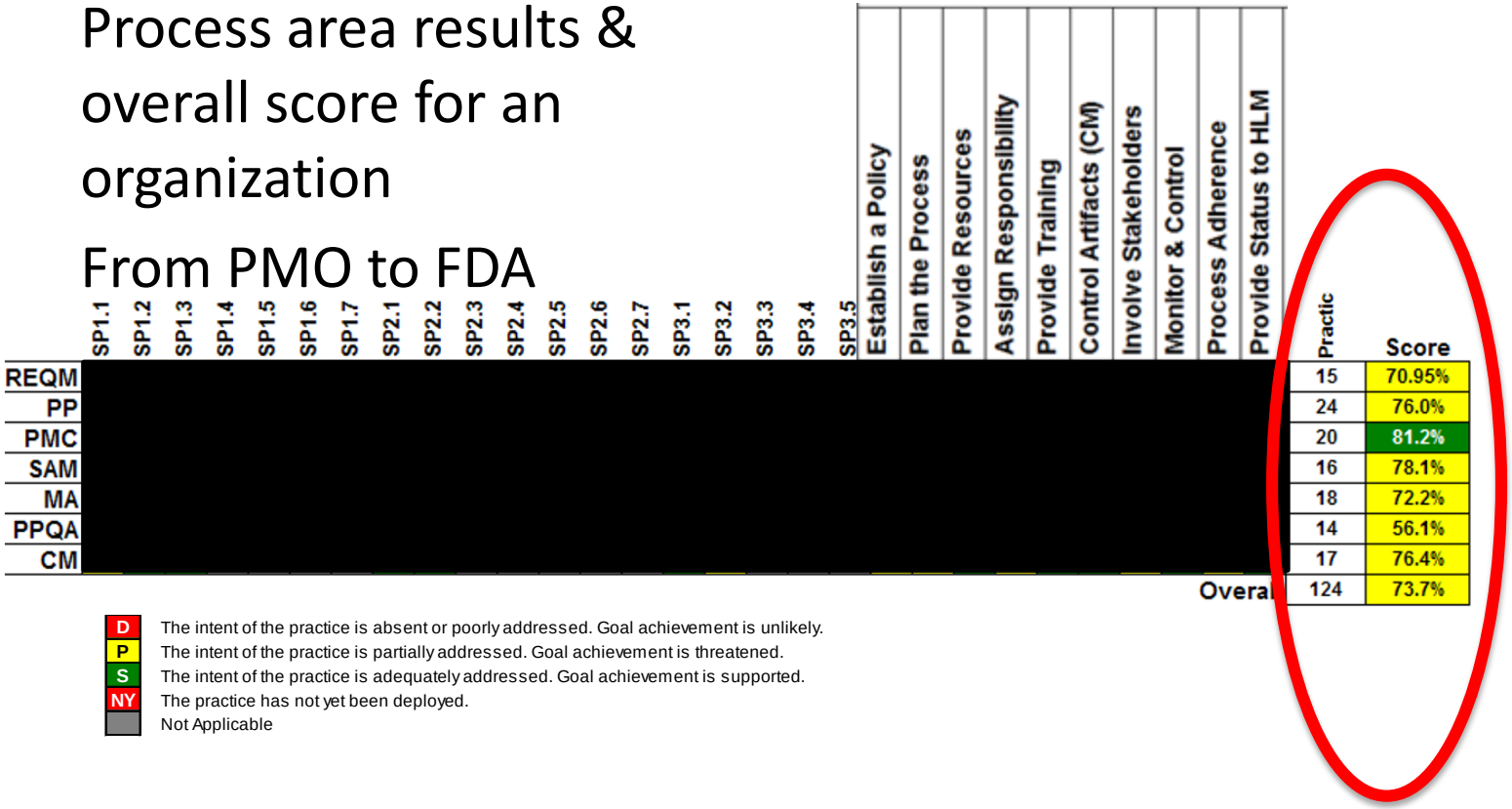
D	The intent of the practice is absent or poorly addressed. Goal achievement is unlikely.
P	The intent of the practice is partially addressed. Goal achievement is threatened.
S	The intent of the practice is adequately addressed. Goal achievement is supported.
NY	The practice has not yet been deployed.
	Not Applicable

How will CDRH apply assessments in the Voluntary Program?

What data is shared? FDA:

Process area results & overall score for an organization

From PMO to FDA



How will CDRH apply assessments in the Voluntary Program?

- Leverage initial scores to establish baseline appraisal
- Trend scores in process areas across manufacturers, industries, sites
- Monitor changes or improvements at the manufacturer over the course of the pilot
- Use score, trend, action plans, and metrics identified to monitor effectiveness and sustain regulatory changes

Closing Thoughts

- Participants are already compliant this is about moving beyond that discussion
- We are all learning. It is OK to not have all the answers
- Metrics and data may change as we learn
- Active engagement and open feedback are critical

Questions

FDA U.S. FOOD & DRUG ADMINISTRATION

Thank You!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