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.

<table>
<thead>
<tr>
<th>Manufacturing Behaviors</th>
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<tr>
<td>Manufacturer can demonstrate traceability throughout their production processes, suppliers, and distributed products</td>
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<td>Manufacturer can demonstrate a focus on establishing, sustaining, and improving control over their production, supply chain, and product quality</td>
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<td>Manufacturer can demonstrate a high patient-safety focus and responsiveness to issues and speed in identification, containment, and action</td>
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<td>Focus Areas</td>
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<td><strong>Supplier Oversight</strong></td>
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<td><strong>Traceability</strong></td>
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<td><strong>Proactive prevention and error-proofing</strong></td>
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<td><strong>Risk-Mitigation</strong></td>
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<td><strong>Critical Outputs</strong></td>
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<td><strong>Data Collection and Analysis</strong></td>
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<td><strong>Strategic Quality Planning</strong></td>
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<td><strong>Training and Development</strong></td>
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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

<table>
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<tr>
<th>Practice</th>
<th>Score</th>
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<td>REQM</td>
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<td>PP</td>
<td>24</td>
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<tr>
<td>PMC</td>
<td>20</td>
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<tr>
<td>SAM</td>
<td>16</td>
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<td>MA</td>
<td>18</td>
</tr>
<tr>
<td>PPQA</td>
<td>14</td>
</tr>
<tr>
<td>CM</td>
<td>17</td>
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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.
- **N/A**: 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

The intent of the practice is absent or poorly addressed. Goal achievement is unlikely.
The intent of the practice is partially addressed. Goal achievement is threatened.
The intent of the practice is adequately addressed. Goal achievement is supported.
The practice has not yet been deployed.
Not Applicable
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
Thank You!