Voluntary Medical Device Manufacturing and Product Quality Program

FDA Modifications to Decrease Regulatory Burden

Public Workshop
October 10, 2017
Overview

• Pilot modifications

• Why the regulatory modifications?

• What does it mean?

• What happens after the pilot?
Pilot Modifications

• Inspections

• PMA Original Manufacturing Section

• Site Changes

• 30-Day Change Notices
Pilot Modifications - Inspections

What?

- Site is removed from routine inspection
- Site is removed from risk-based workplan
- Appraisal and check-ins are used

When?

Starts once site is accepted into the enrollment

Why?

Site has already demonstrated a compliant quality system.

Focus is to drive improvement in system

Inspection can disrupt process and shift focus

Receive more robust and objective data
Pilot Modifications – PMA Manufacturing Section

What?

- Streamlined submission
- Include notice of participation in pilot
- Product specific records – Design plan
- Sampling of supporting documents for critical processes
- Waive pre-approval inspection

When?

Available once appraisal has completed and FDA has summary and benchmark data

Why?

- Move away from product specific to system focus
- Increased transparency and confidence
- Accelerates approval
- Reduces artifact generation and review
Pilot Modifications – Site Changes

What?

- Streamlined submission
- Include notice of participation in pilot
- Structured data elements
- Sampling of supporting documents for critical processes
- Accelerated approval of change – 1 week

When?
Available once appraisal has completed and FDA has summary and benchmark data

Why?
- Appraisal assures system capability
- Increased transparency and confidence
- Accelerates move to capable manufacturing sites
- Reduces artifact generation and review
Pilot Modifications – 30-Day Change Notices

What?

- Streamlined submission
- Include notice of participation in pilot
- Structured data elements
- Bundle multiple products and changes in one submission
- Acceptance of change and distribution within 24 hours
# Pilot Modifications – Structured data example

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
<th>Purpose</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Order Number</td>
<td>Firms internal tracking number for change and supporting data</td>
<td>Provides a link to the data normally submitted that can be referenced</td>
<td>ECO-123456</td>
</tr>
<tr>
<td>Affected Submissions</td>
<td>PMA Number and Supplement number for the change</td>
<td>Provides link to FDA records</td>
<td>PMA9999999/S130</td>
</tr>
<tr>
<td>Type of Change</td>
<td>Drop down of change category</td>
<td>Allows for trending on common data categories</td>
<td>Inspection Method, Inspection Type, Automation, Process, Supplier, Documentation, Material, Tooling, Equipment</td>
</tr>
<tr>
<td>FEIs</td>
<td>FEI Numbers of locations impacted by the change</td>
<td>Links to FDA Site records</td>
<td>300000000000</td>
</tr>
<tr>
<td>Devices Affected by Change</td>
<td>Device Identifier or UDI of the product affected by the change</td>
<td>Provides structured link to product data including, models, specialties, etc...</td>
<td>79643169056053</td>
</tr>
<tr>
<td>Description of Change</td>
<td>Brief description of change</td>
<td>Allows for FDA to determine if change needs another submission type.</td>
<td>Remove redundant inspection step after wash.</td>
</tr>
<tr>
<td>Reason for Change</td>
<td>Drop down of change categories</td>
<td>Allows for trending of change drivers</td>
<td>Cost Improvement, Process Efficiency/ Improvement, Error-Proofing, Complaint</td>
</tr>
</tbody>
</table>
Why the regulatory modifications?

- Increased confidence and trust

- Improve focus on value from the submission

- Reduce focus on artifact generation and review

- Develop new understanding of performance and data driven decisions

- Increase capacity for improvement
Pilot Governance

- Leadership
- Evaluates pilot progress
- Reviews and approves significant changes in direction or scope
- Serves to address appeals in cases of program de-enrollment
- Identify operational governance requirements
# Pilot Steering Committee Roles and Responsibilities

## FDA

- **Role**
  - Regulatory expertise and pilot oversight
- **Responsibilities**
  - Verify participant standing
  - Regulatory program modifications
  - Review and monitor appraisal summary results
  - Receive baseline effectiveness metrics
  - Receive and review effectiveness metric check-ins
  - Engage on public health and safety issues
  - Collect pilot feedback, Provide updates to the MDIC Steering Committee, and report trends or learning through pilot

## MDIC CfQ Steering Committee

- **Role**
  - Industry and stakeholder collaboration, pilot leadership and oversight
- **Responsibilities**
  - Review of pilot progress and data trends
  - Leadership and direction to resolve pilot issues
  - Identify sustainable governance requirements
  - Coordinate stakeholder communication

## CMMI

- **Role**
  - Maturity and appraisal program management and maturity model subject matter expertise
- **Responsibilities**
  - Manages maturity model, playbook, training, and appraiser certification
  - Manages pilot enrollment activities
  - Manages appraisal or appraiser specific issues
  - Oversight and scoping of appraisal
  - Collection of appraisal data, trending, and data summary for steering committee
  - Implements changes to pilot or appraisal based on feedback
  - Provide SME to participants and FDA
Why maturity?

• Identifying organizational capabilities and improvement opportunities

• Provide guidance of how to drive and prioritize improvements that deliver value on business objectives

• Enhance confidence, trust, and transparency

Trusted Collegues!
Pilot goals

• **Appraisal**
  • Understand the scalability of the CMMI model and appraisal
  • Evaluate pilot program
  • Evaluate if pilot increases improvement efforts

• **Identify objective performance metrics**
  • Outcome and product quality focused

• **FDA**
  • Improve inspection resources
  • Improve review resources
  • Improve visibility into industry trends
  • Identify high performing firms and practices

• **Industry**
  • Improve resource utilization
  • Increase speed and capability to make improvements
  • Improve quality culture
  • Reduce disruption
Learning mindset

• Approach this with an open mind

• Learn what works well, what needs to improve, what is not delivering value

• Focus on adapting

• Feedback and communication
Questions?
Thank You!