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

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

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

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

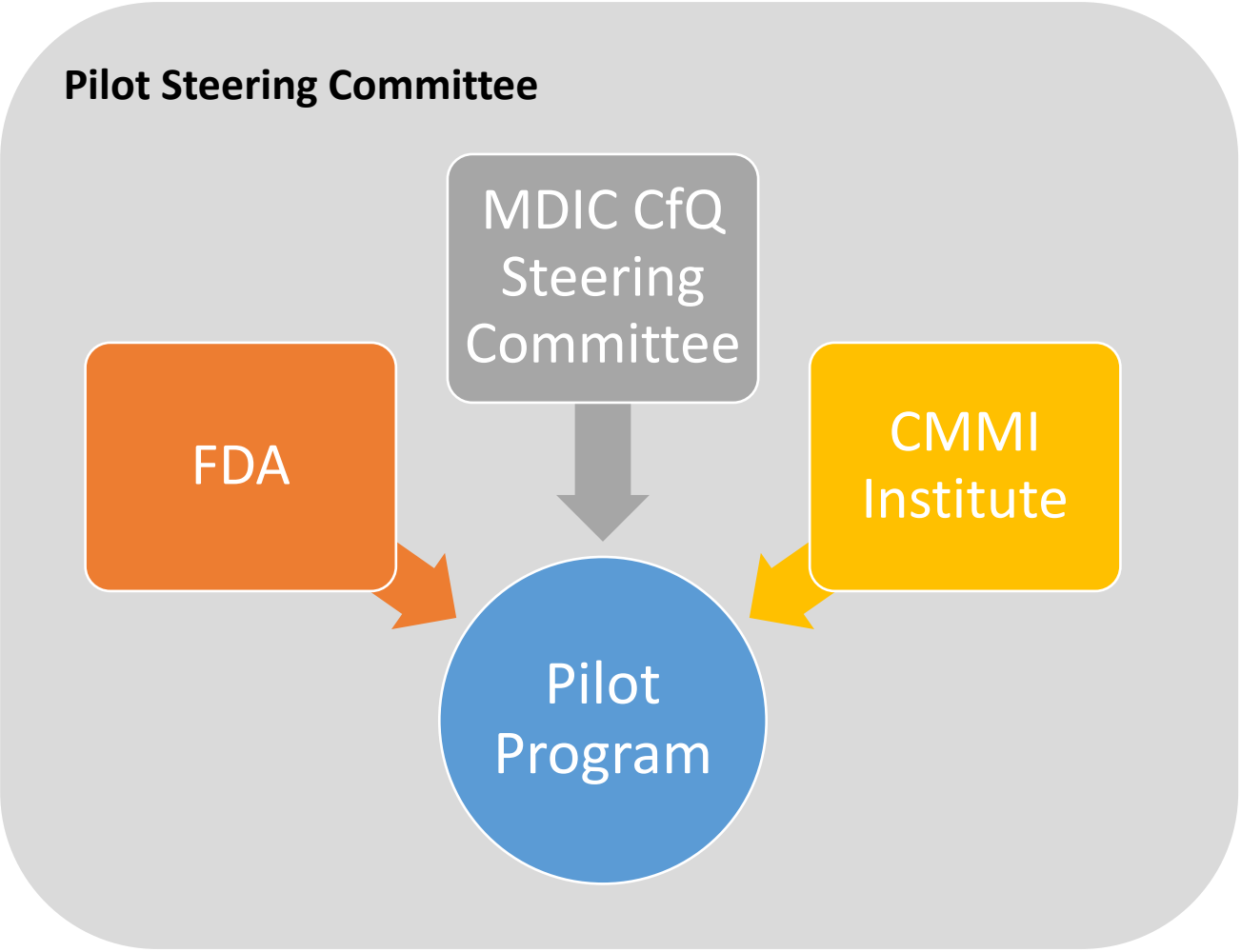
Pilot Modifications – Structured data example

Field	Description	Purpose	Example
Change Order Number	Firms internal tracking number for change and supporting data	Provides a link to the data normally submitted that can be referenced	ECO-123456
Affected Submissions	PMA Number and Supplement number for the change	Provides link to FDA records	PMA999999/S130
Type of Change	Drop down of change category	Allows for trending on common data categories	Inspection Method, Inspection Type, Automation, Process, Supplier, Documentation, Material, Tooling, Equipment
FEIs	FEI Numbers of locations impacted by the change	Links to FDA Site records	30000000000
Devices Affected by Change	Device Identifier or UDI of the product affected by the change	Provides structured link to product data including, models, specialties, etc…	79643169056053
Description of Change	Brief description of change	Allows for FDA to determine if change needs another submission type.	Remove redundant inspection step after wash.
Reason for Change	Drop down of change categories	Allows for trending of change drivers	Cost Improvement, Process Efficiency/Improvement, Error-Proofing, Complaint

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?

U.S. FOOD & DRUG ADMINISTRATION

Thank You!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