Update on FDA Medical Device Quality Initiatives

MedCon 2014

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Agenda

• Why a quality strategy?
• How does quality differ from compliance?
• FDA Quality Initiatives:
  – The Case for Quality (CfQ)
  – The Voluntary Compliance Improvement Pilot (VCIP)
• The Office of Compliance Reorganization
Why a Quality Strategy?

2005-2013 FDA Form 483 Observations

• We are consistently seeing a high volume of the same issues year after year
• We must ask whether we are using the right methods to improve device quality

2005-2013 Inspections with OAI Outcomes
Why a Quality Strategy?

**Percent of firms inspected**

**Domestic; Annual**
- Inspected: 26%
- Not inspected: 74%

**Foreign; Annual**
- Inspected: 3%
- Not inspected: 97%

122 Warning Letters were issued in the 2012 calendar year – 3.8% of total investigations resulted in a Warning Letter.
Quality Versus Compliance: Current State

- Business Objectives
- Quality Objectives
- Compliance
Quality Versus Compliance: Future State

Business Objectives

Quality Objectives

Compliance
FDA Quality Initiatives

CDRH

ORA

CfQ & VCIP

Stakeholders
The Case for Quality

• Support and ownership of quality go beyond quality/compliance units

• A culture of quality yields benefits.

• Recent trends highlight the importance of quality.

• “Understanding Barriers to Medical Device Quality”

• October 31, 2011 webcast:
  http://fda.yorkcast.com/webcast/Viewer/?peid=7134123bd5c94d909fdae41fce3469411d
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The Case for Quality Implementation Plan

Initiative 1:  Focus on Quality

Initiative 2:  Enhanced Transparency

Initiative 3:  Stakeholder Engagement
What have we heard?

Stakeholders

1. Safe communications
2. Collaboration
3. Inspection engagement
4. Critical to quality
5. Clear expectations
6. Incentives

Internally

1. Communications
2. Collaboration
3. Inspection engagement
4. Critical to quality
5. Clear expectations
6. Incentives
2014 Case for Quality Activities

**Sub-Initiative** | **Activities**
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**Focus on Quality** | 1. Develop, implement, and assess a pilot that changes engagement during an inspection  
2. Assess internal/external incentives and measures  
3. Benchmark with other quality performance models

**Data Transparency** | 1. Provide relevant device quality data  
2. Gather and assess stakeholder data needs  
3. Develop a framework for delivering releasable information

**Stakeholder Engagement** | 1. Engage industry and other stakeholders in national venues  
2. Engage industry and FDA districts in local venues  
3. Partner with industry and other stakeholders to develop collaborative forums and trustful engagements
Case for Quality: Battery Pilot

- Implantable Battery-Containing Devices
- Up to 5 Manufacturers
- Inspections focused on factors that affect device quality
- Prioritized Form FDA-483s
- Does the pilot improve quality and resource allocation?
Successful pilots can be expanded.
The Voluntary Compliance Improvement Pilot

• CDRH Strategy 4.2. Establish a Voluntary Compliance Improvement Pilot Program
  – Goal 4.2.1. By September 30, 2013, CDRH will take steps to move certain manufacturers at risk of compliance action . . . to a state of improved performance by allowing these manufacturers to enter into a remediation agreement with the agency . . . .
  – By September 30, 2013, launch the Voluntary Compliance Improvement Pilot Program.
Voluntary Compliance Improvement Pilot

- Up to 5 manufacturers
- Alternative to surveillance inspections
- Expert consultants certify that participants have defined problems, analyzed root causes, and taken effective corrective action.
- Manufacturers self-identify and correct deficiencies; FDA redirects resources to firms unable to take these steps.
The Office of Compliance is reorganizing:

From:

- Division of Risk Management Operations
- Division of Enforcement A
- Division of Enforcement B
- Division of Bioresearch Monitoring
The Office of Compliance is reorganizing:

To:

Office of Compliance

- Division of Analysis and Program Operations
- Division of Manufacturing and Quality
- Division of Premarket and Labeling Compliance
- Division of International Compliance Operations
- Division of Bioresearch Monitoring