Update on FDA Medical Device Quality Initiatives

MedCon 2014

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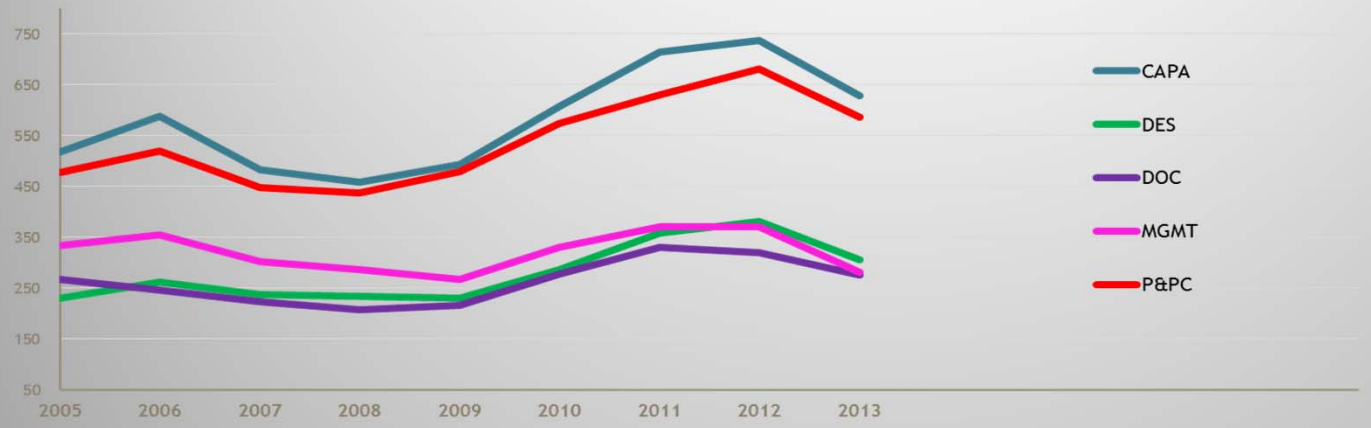
Agenda

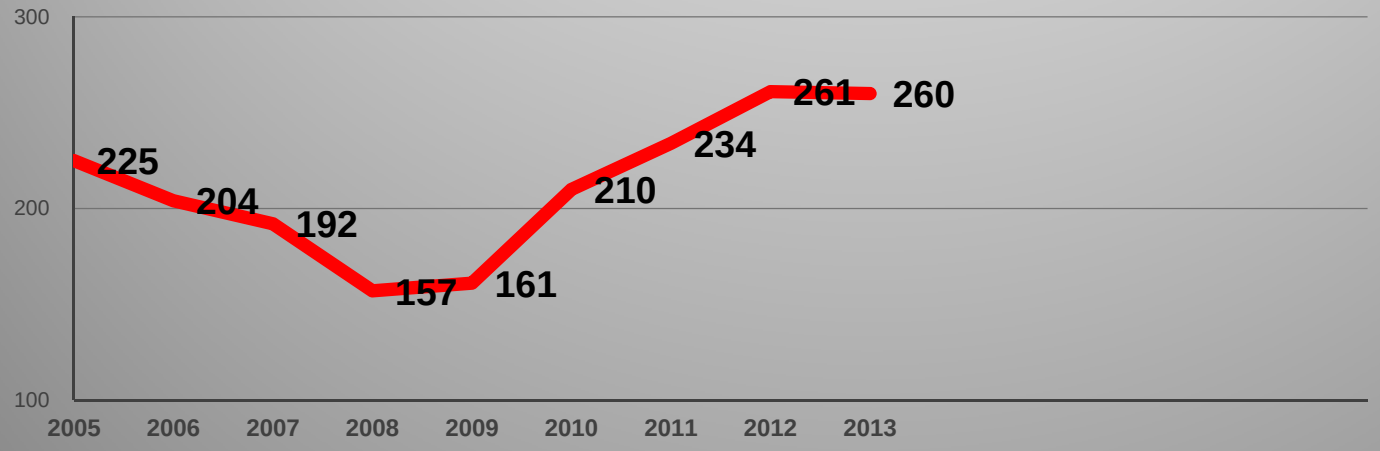
- **Why a quality strategy?**
- **How does quality differ from compliance?**
- **FDA Quality Initiatives:**
  - **The Case for Quality (CfQ)**
  - **The Voluntary Compliance Improvement Pilot (VCIP)**
- **The Office of Compliance Reorganization**

Why a Quality Strategy?

2005-2013 FDA Form 483 Observations



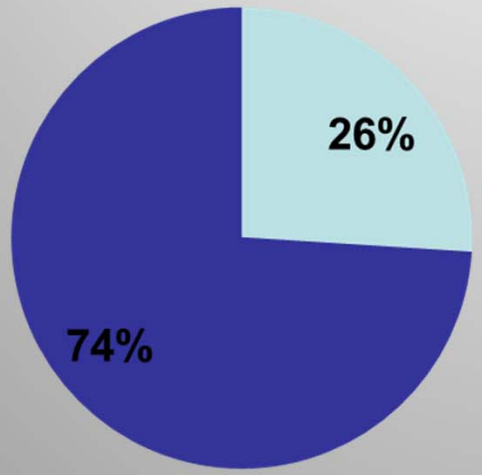
2005-2013 Inspections with OAI Outcomes



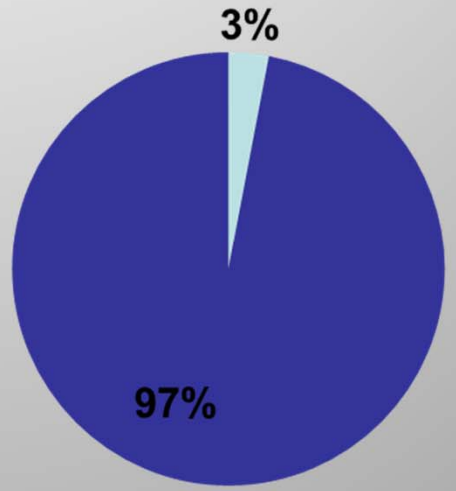
- We are consistently seeing a high volume of the same issues year after year
- We must ask whether we are using the right methods to improve device quality

Why a Quality Strategy?

Percent of firms inspected
Domestic; Annual



Percent of firms inspected
Foreign; Annual

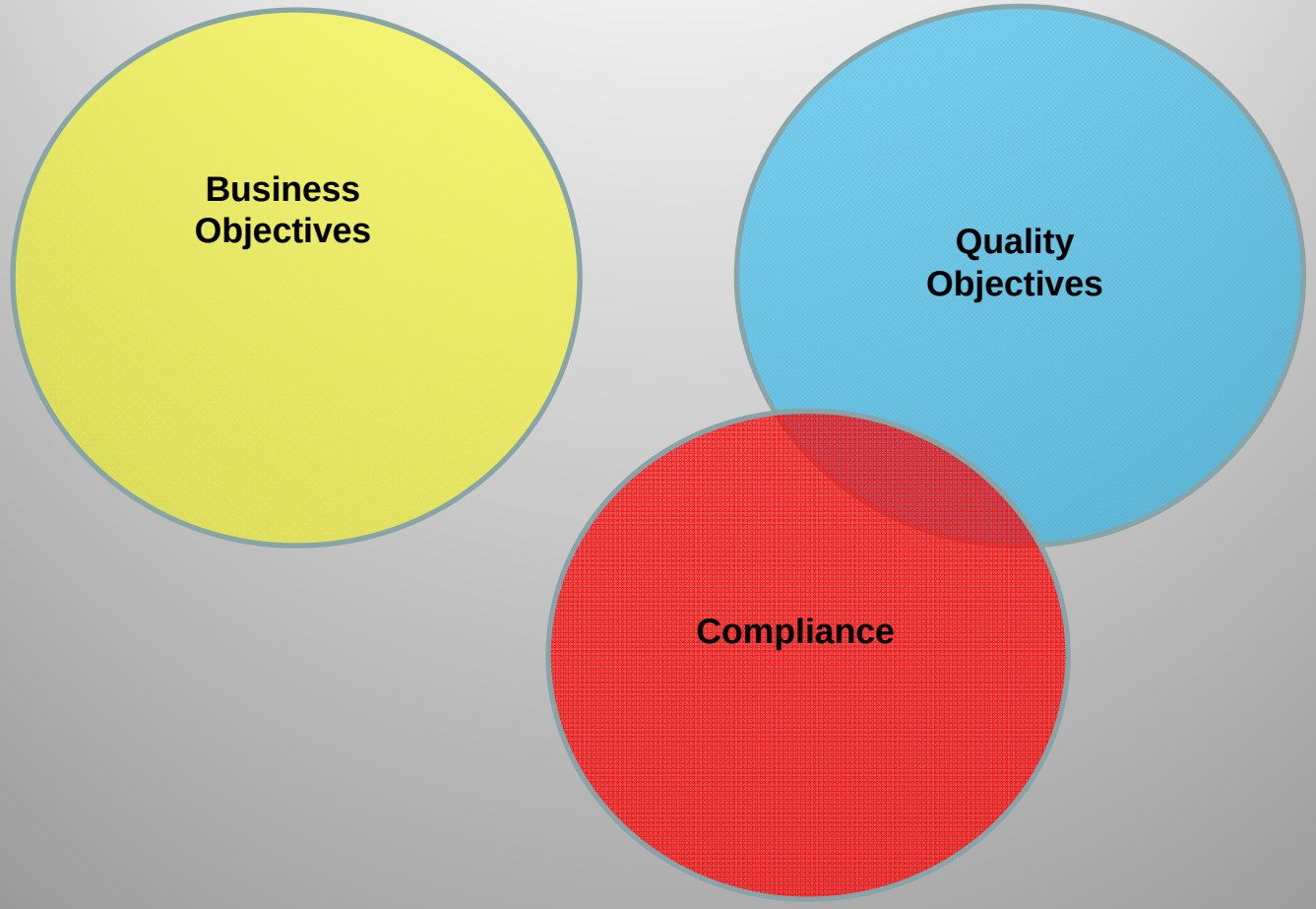


Inspected

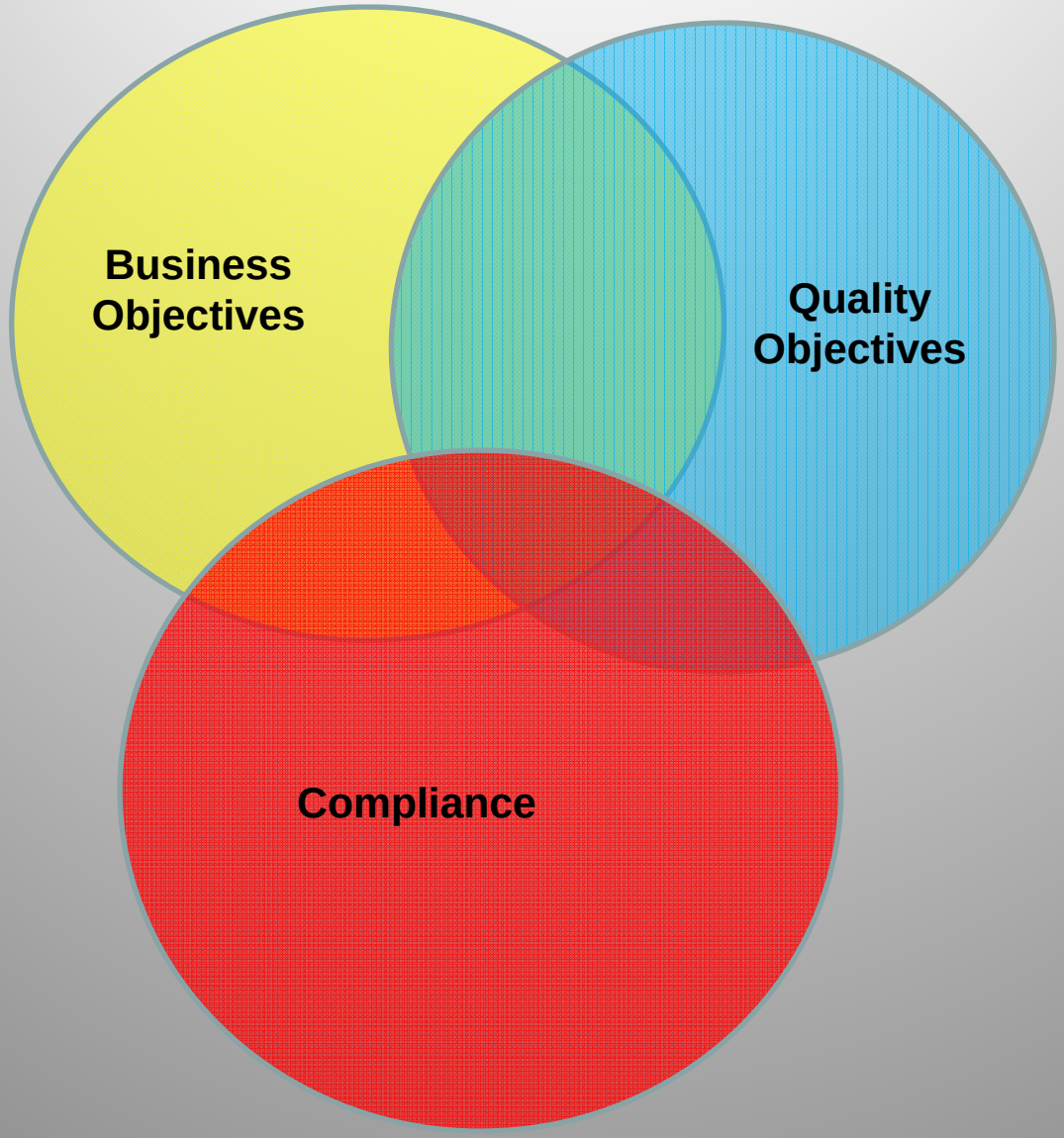
Not inspected

122 Warning Letters were issued in the 2012 calendar year – 3.8% of total investigations resulted in a Warning Letter

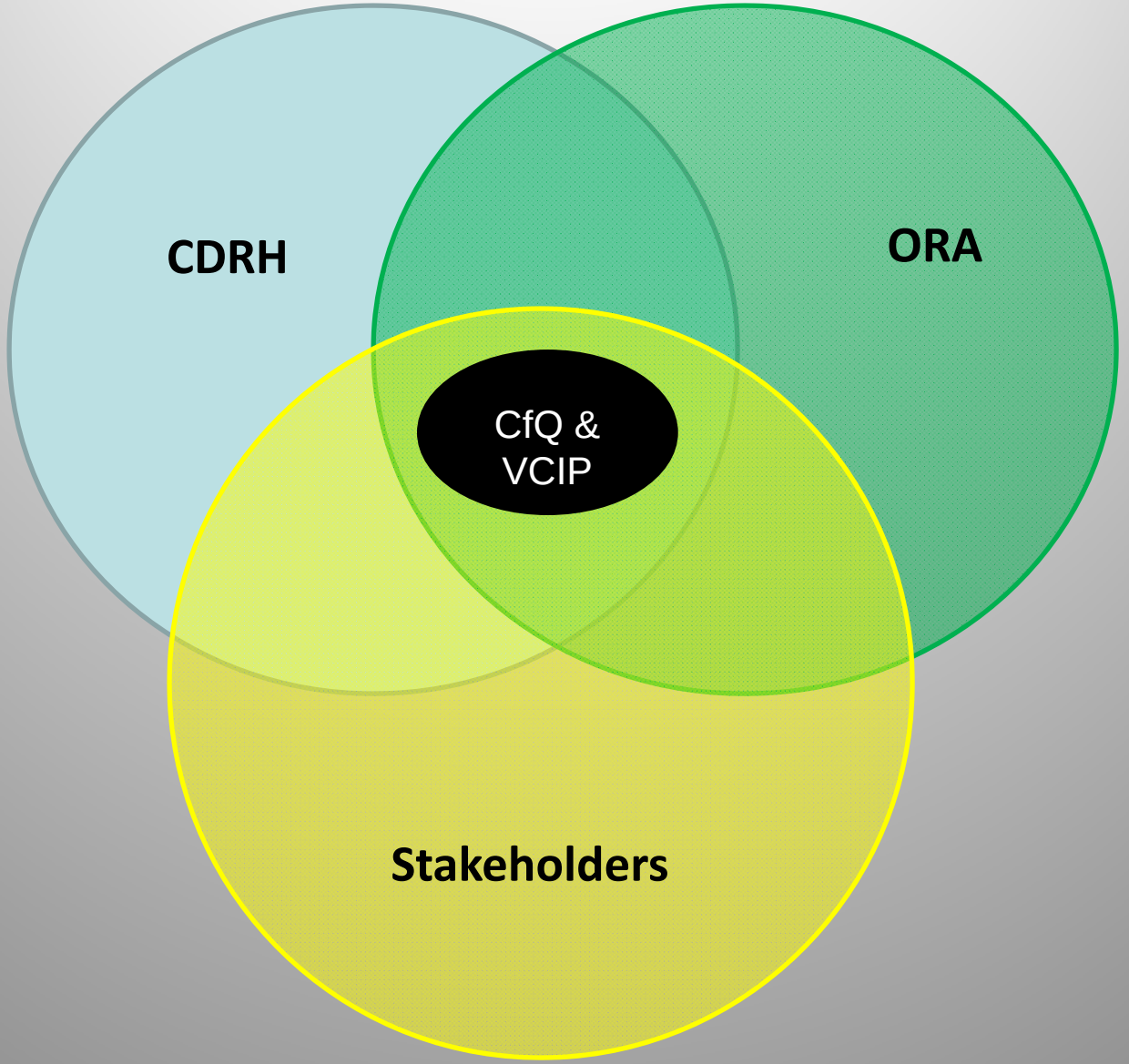
Quality Versus Compliance: Current State



Quality Versus Compliance: Future State



FDA Quality Initiatives



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”** http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM277323.pdf
- **October 31, 2011 webcast:**
  http://fda.yorkcast.com/webcast/Viewer/?peid=7134123bd5c94d909fdae41fce3469411d
- **http://fda.yorkcast.com/webcast/Viewer/?peid=7134123bd5c94d909fdae41fce3469411d**

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

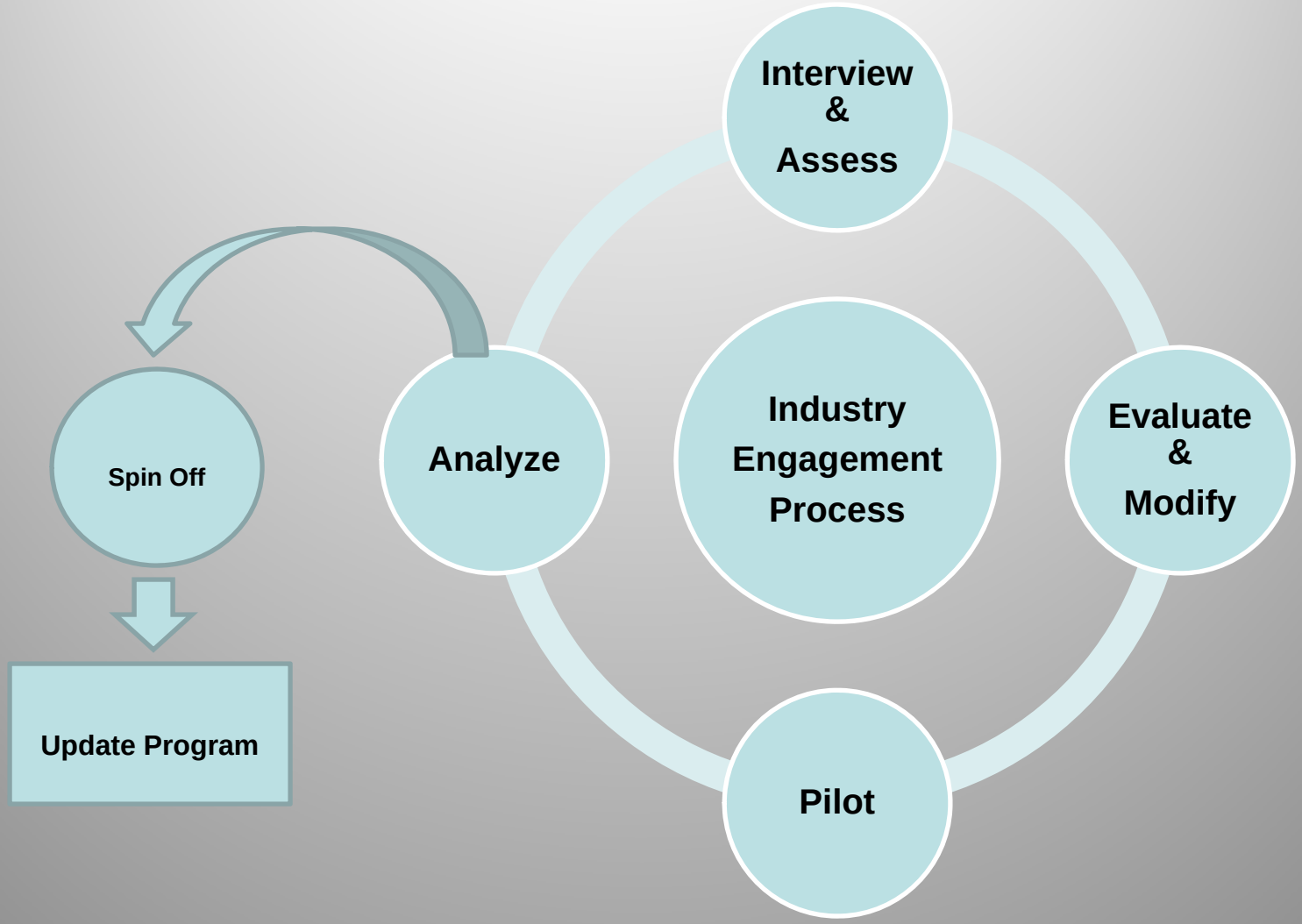
2014 Case for Quality Activities

Sub-Initiative	Activities
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

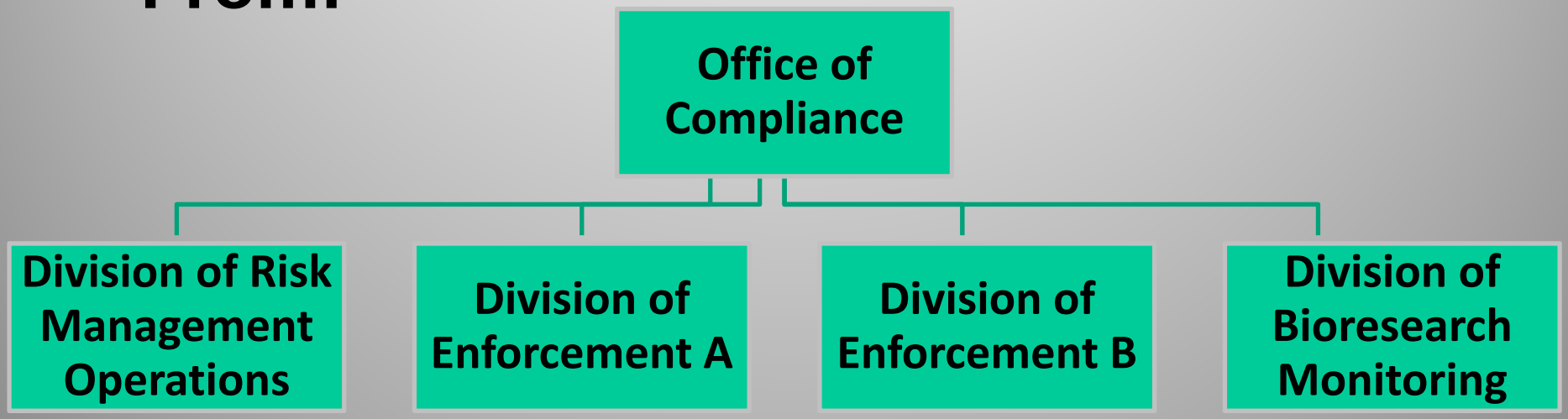
- **CDRH Strategy 4.2. Establish a Voluntary Compliance Improvement Pilot Program**
  - **Goal 4.2.1. By September 30, 2013, CDRH will take steps to move certain manufacturers at risk of compliance action . . . to a state of improved performance by allowing these manufacturers to enter into a remediation 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:



The Office of Compliance is reorganizing:

To: