Case for Quality: FDA & Industry 2014 Update

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October 6, 2014

2013 Case for Quality Activities

Sub-Initiative   **Activities**

Focus on Quality

Develop, implement, and assess a pilot that changes engagement during an inspection
Assess internal/external incentives and measures
Benchmark with other quality performance models

Data Transparency

Provide relevant device quality data
Gather and assess stakeholder data needs
Develop a framework for delivering releasable information

Stakeholder Engagement

Engage industry and other stakeholders in national venues
Engage industry and FDA districts in local venues
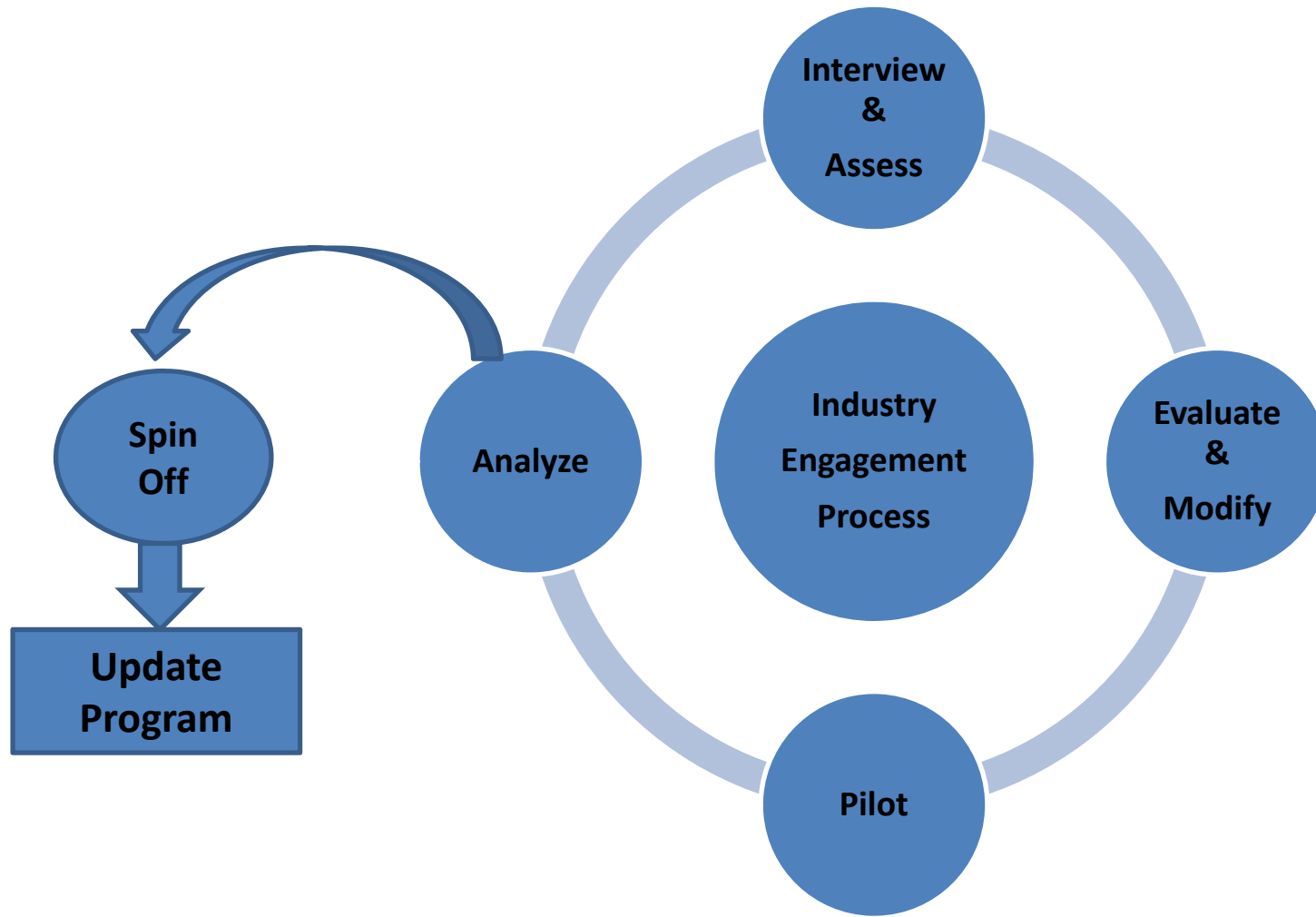**Partner with stakeholders to develop collaborative forums and trustful engagements**

Case for Quality: Battery Pilot

- **Implantable battery-containing devices**
- **Inspections focused on critical-to-quality (CtQ) factors**
- **Prioritized Form FDA-483s**
- **Does the pilot improve focus on quality and resource allocation?**

Case for Quality: Battery Pilot

- **Four of six inspections completed and another started; two more during 2015 surveillance inspections**

- **Two sets of investigator and firm interviews completed**

- **Lessons learned so far:**
  - **Communication**
  - **Engagement**
  - **Resources**
  - **Modifications**

Successful Pilots Can Be Expanded

More Critical-to-Quality Work

	PMA-CtQ	Public Input-CtQ	RBWP-CtQ
ASD Branch	❶❷❸④		❺
CD Branch		❶❷	
POND Branch		❶	❷
REGO Branch		❶❷	
Total # Inspectional Guidances by 12/31/2014:	FDA Pilot: 1 CDRH Stage 1: 1 CDRH Stage 2: 11 Total: 13		

CtQ-PMA Inspectional Approach (in process)

- **Current program:**
  - Focus on whether PMA sites are inspection ready
  - Most firms hit the mark
- **Reward firms that get it right. Perhaps:**
  - Sponsor describes how it defines CtQs
  - Sponsor's primary site gets a CtQ-directed inspection
  - Push CAPA+PPC+MDR to post-approval inspection

Case for Quality: Maturity Model

Crosby Maturity Grid – *Sample Assessment Model*

Measurement Categories	Stage 1: *Uncertainty*	Stage 2: *Awakening*	Stage 3: *Enlightenment*	Stage 4: *Wisdom*	Stage 5: *Certainty*
Management understanding and attitude	No comprehension of quality as a management tool. Tend to blame quality dept. for "quality problems"	Recognizing that quality management may be of value but not willing to provide money or time to make it happen	While going through quality improvement program learn more about quality management; becoming supportive and helpful	Participating . Understand absolutes of quality management. Recognize their role in continuing emphasis	Consider quality management as an essential part of company system
Quality Organization status	Quality is hidden in manufacturing or engineering departments. Inspection probably not part of organization. Emphasis on appraisal and sorting	A stronger quality leader is appointed but main emphasis is still on appraisal and moving the product. Still part of manufacturing or other.	Quality department reports to top management, all appraisal is incorporated and manager has role in management of company	Quality manager is an officer of company; effective status reporting and preventive action. Involved with customer affairs and special assignments	Quality manager on board of directors. Prevention is main concern. Quality is a thought leader.
Problem handling	Problems are fought as they occur, no resolution, inadequate definition; yelling and accusations	Teams are set up to attack major problems. Long-range solutions are not solicited	Corrective action communication established. Problems are faced openly and resolved in an orderly way	Problems are identified early in their development. All functions are open to suggestion and improvement	Except in the most unusual cases, problems are prevented.
Quality improvement actions	No organized activities. No understanding of such activities.	Trying obvious "motivational" short-range efforts.	Implementation of a multi-step program. With a thorough understanding and establishment of each step.	Continuing the multi-step program and starting other pro-active/preventative product quality initiatives.	Quality improvement is a normal and continued activity
Company quality posture	"We don't know why we have quality problems"	"Is it absolutely necessary to always have problems with quality?"	"Through management commitment and quality improvement we are identifying and resolving our problems"	"Defect prevention is a routine part of our operation"	"We know why we do not have problems with quality"
Cost of quality as % of sales	Reported: Unknown Actual: 20%	Reported: 3% Actual: 18%	Reported: 8% Actual: 12%	Reported: 6.5% Actual: 8%	Reported: 2.5% Actual: 2.5%

Medical Device Quality Measures Working Group

- **Goal: predictive internal measures of device quality across the product lifecycle (pre-production, production, and post-production)**

- **Deliverable: a recommendation for FDA-stakeholder discussion:**
  - A set of critical measures;
  - That yield aggregated metrics; and
  - That are indicators of product quality

Medical Device Recalls: 2003-2012
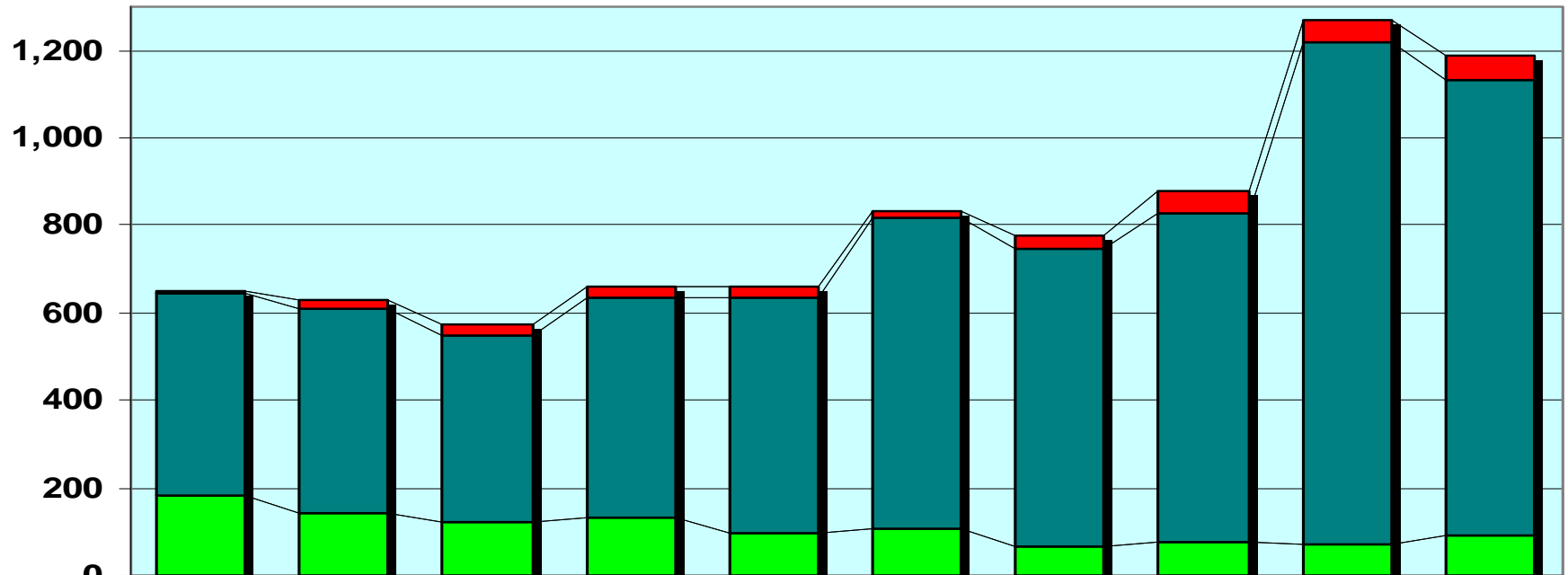
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
■ Class I	7	24	26	22	26	14	32	49	50	57
■ Class II	460	466	422	505	540	710	677	753	1152	1043
■ Class III	183	141	124	132	96	108	67	74	69	90
Totals	650	631	572	659	662	832	776	876	1,271	1,190

Reasons for Recall Growth

- **Industry Growth:**
  - **FY 2008: 19,153 registered establishments/117,618 device listings**
  - **FY 2012: 24,133 registered establishments/157,441 device listings**
- **High-risk/problematic devices: AEDs, ventilators, infusion pumps, radiation safety**
- **Impact of 806 citations**

Adjusted Counts: FY 2003-FY 2012
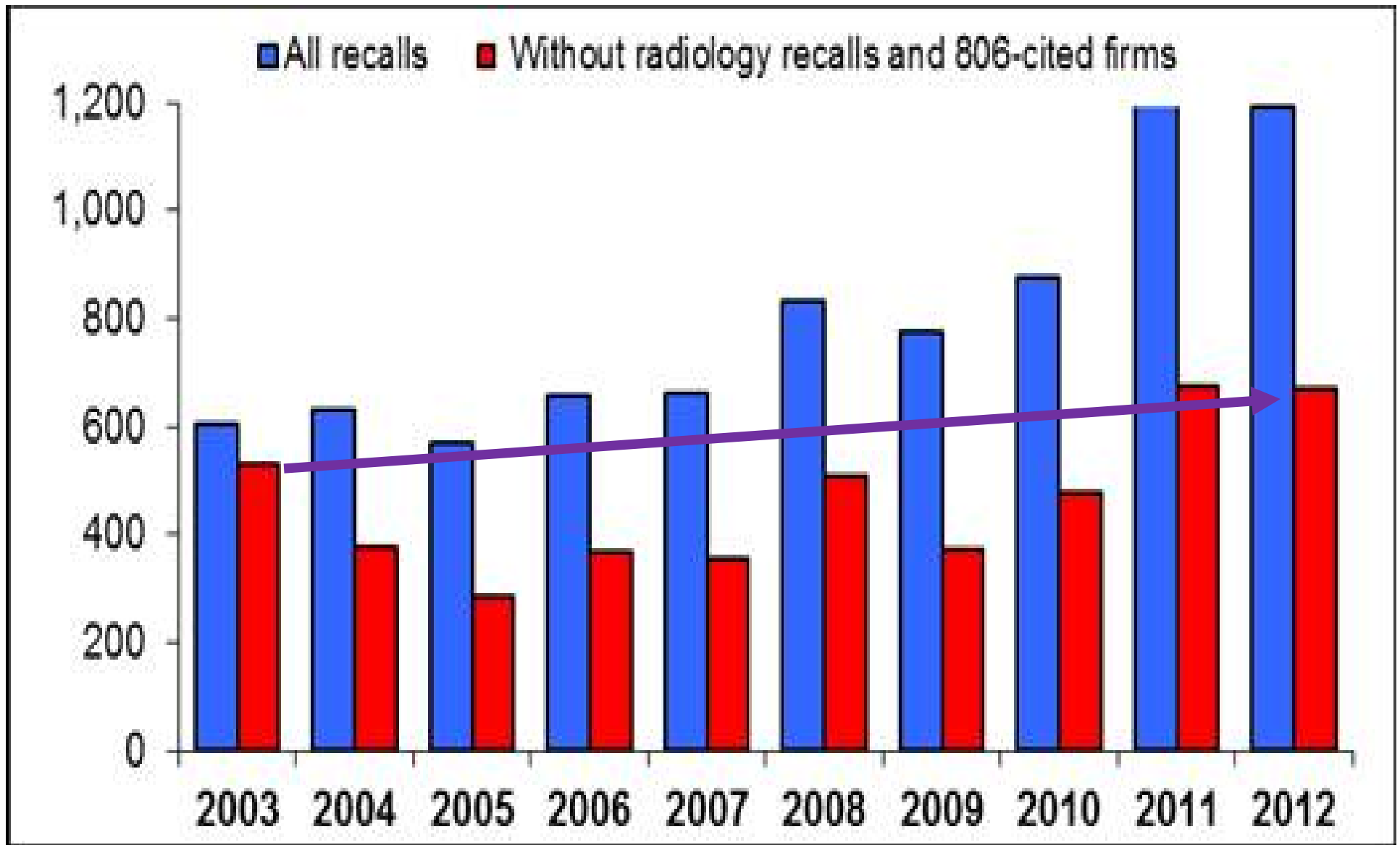
Stakeholder Forum

- **Prior strategy:**
  - **Engage stakeholders at national and local meetings**
  - **Good for awareness and buy-in, less good for continuity and issue development**
- **Current strategy:**
  - **Continue national and local engagement**
  - **Create a standing CfQ stakeholder forum:**
    - **Regular and predictable meetings**
    - **Selected topics**
    - **Participant continuity**