Case for Quality: FDA & Industry 2014 Update

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CDRH Office of Compliance

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### 2013 Case for Quality Activities

<table>
<thead>
<tr>
<th>Sub-Initiative</th>
<th>Activities</th>
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| **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

Spin Off

Update Program

Interview & Assess

Industry Engagement Process

Evaluate & Modify

Pilot

Analyze

Update Program
## More Critical-to-Quality Work

<table>
<thead>
<tr>
<th></th>
<th>PMA-CtQ</th>
<th>Public Input-CtQ</th>
<th>RBWP-CtQ</th>
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</thead>
<tbody>
<tr>
<td>ASD Branch</td>
<td>1 2 3 4</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>CD Branch</td>
<td></td>
<td>1 2</td>
<td></td>
</tr>
<tr>
<td>POND Branch</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>REGO Branch</td>
<td></td>
<td>1 2</td>
<td></td>
</tr>
<tr>
<td><strong>Total # Inspection</strong></td>
<td></td>
<td><strong>FDA Pilot:</strong> 1</td>
<td><strong>Total:</strong> 13</td>
</tr>
<tr>
<td><strong>Guidances by 12/31/2014:</strong></td>
<td></td>
<td><strong>CDRH Stage 1:</strong> 1</td>
<td><strong>CDRH Stage 2:</strong> 11</td>
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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

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

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

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