The FDA’s Case for Quality: Voluntary Manufacturing and Product Quality Pilot and a Virtuous Cycle of Improvement for the Medical Device Industry

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I appreciated the nonchalant nature of the interviews. I felt that we actually got to discuss how we perform to our processes and this drove discussion on improvements.

What’s happening now?

<table>
<thead>
<tr>
<th>Applications</th>
<th>Appraisals</th>
<th>Diverse product classification mix</th>
<th>Participant results</th>
</tr>
</thead>
<tbody>
<tr>
<td>32 Qualified</td>
<td>14 Completed</td>
<td>Class I 1</td>
<td>• Improved clinical trial enrollment</td>
</tr>
<tr>
<td>2 Withdrawn</td>
<td>8 Scheduled</td>
<td>Class II 7</td>
<td>• Improved capability performance</td>
</tr>
<tr>
<td>23 US</td>
<td>9 In scoping</td>
<td>Class III 3</td>
<td>• Improved employee engagement</td>
</tr>
<tr>
<td>9 OUS</td>
<td>3 Multi-site</td>
<td>Class I and Class II 5</td>
<td>• Quantifiable value and process improvements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Class II and Class III 12</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>All classes 2</td>
<td></td>
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</tbody>
</table>

- Improved clinical trial enrollment
- Improved capability performance
- Improved employee engagement
- Quantifiable value and process improvements

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### Participant results

<table>
<thead>
<tr>
<th>CVRx</th>
<th>1.1</th>
<th>1.2</th>
<th>2.1</th>
<th>2.2</th>
<th>2.3</th>
<th>2.4</th>
<th>2.5</th>
<th>2.6</th>
<th>2.7</th>
<th>2.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimating (EST)</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>60%</td>
<td></td>
</tr>
<tr>
<td>Planning (PLAN)</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>S</td>
<td>P</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>P</td>
<td>70%</td>
</tr>
<tr>
<td>Monitor and Control (MC)</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>S</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>82%</td>
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<tr>
<td>Configuration Management (CM)</td>
<td>S</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
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<tr>
<td>Managing Performance and Measurement (MPM)</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>S</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>S</td>
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<td>Requirements Development and Maintenance (RDM)</td>
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<td>P</td>
<td>S</td>
<td>P</td>
<td>S</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>61%</td>
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<td>Process Quality Assurance (PQA)</td>
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<td>S</td>
<td>P</td>
<td>S</td>
<td>P</td>
<td>S</td>
<td>P</td>
<td>70%</td>
<td></td>
<td></td>
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<tr>
<td>Governance (GOV)</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>S</td>
<td>S</td>
<td>60%</td>
<td></td>
<td></td>
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<tr>
<td>Implementation Infrastructure (II)</td>
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<td>D</td>
<td>P</td>
<td>D</td>
<td>27%</td>
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<tr>
<td>Product Integration (PI)</td>
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<td>P</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>83%</td>
<td></td>
</tr>
<tr>
<td>Technical Solution (TS)</td>
<td>S</td>
<td>P</td>
<td>S</td>
<td>S</td>
<td>P</td>
<td>65%</td>
<td></td>
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</tbody>
</table>
What is FDA learning from the data?

Improving the system

- New collaborative projects
  - Simplify CAPA System
  - “Safe-space” – solve problems, learn, improve
- Improving measurement and responsiveness
Changing the status quo

DEFENSE

Compliance Audit

Maturity Appraisal

VALUE

Lesson

Least burdensome

7 Changes
10 Days

1 Change
28 Days

2 Changes
1 Day

1 Change
30 Days

Hesitancy → Engagement

Problem solving mindset

New opportunities, collaborative learning, and ideas

Assumptions and reactivity → Understanding and insight
Compliance indicators vs. Quality indicators

Early participant indicators

• NCR
  – NCR trends
  – NCR resolution timelines
• CAPAs
  – Counts open vs. closed vs. overdue
• Field actions open per site
• ECO#/turn time
• Scrap rate trends (positive vs. negative trend events)
• Projects exceeding planned timeline
• Yield trends (positive vs. negative trend events)

Recent performance indicators submitted

<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Details Submitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Pass Yield</td>
<td>• Details of what is monitored</td>
</tr>
<tr>
<td>Financial Damages</td>
<td>• Three year trends</td>
</tr>
<tr>
<td>CAPA Management Operational Effectiveness</td>
<td>• Annual quality target</td>
</tr>
<tr>
<td></td>
<td>• Quarterly trend</td>
</tr>
</tbody>
</table>

Quality Domains

Safety
• Device and procedure related adverse events in commercial and clinical compared to literature search meta-analysis for similar products and procedures
• Quarterly comparison rates

Effectiveness
• Clinical and registry data compared to hypotheses identified in study plans
• Procedure related adverse events compared to literature search meta-analysis for similar products and procedures for training and IFU effectiveness
• At least annually

Reliability
• Accelerated voltage life test
• Run down testing on devices returned with remaining battery life
• Device adverse events benchmarked against similar product

Availability
• Inventory and sales volume by geography
• Quarterly with management review
On the horizon

Establish full FDA program
Expand appraisal focus to include design, supplier management, and servicing
Expand streamlined review strategy to design reviews
  Enable faster responsiveness and product quality (continuous product quality improvement in 510(k) products)

Year two and beyond
Streamline with operational and product quality performance metrics
Expand practice areas and capability levels
Integrate with Product Quality Outcome Analytics
Thank You