FDA Updates
Opening Plenary

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Topics

• CDRH Reorganization
• Food & Drug Administration Reauthorization Act (FDARA)
• Benefit-Risk
• Case for Quality
FDA TPLC Benefits

- Organic connections within the organization
- Fuller picture of device, firm, industry
- Streamlined decisions and processes
- Shared priorities
- Professional growth
Other TPLC Benefits

- Better understanding of firm operations
- Improved knowledge of technology
- Deeper bench strength
- Better customer service
- A “one stop shop” for industry
Flexibility to inspect medical device facilities based on risk

Greater predictability and transparency to the inspection process
Ability to recognize international auditing organizations for inspection purposes
A risk-based approach for site selection and targeted inspections

- Novel devices
- Rapidly evolving technology
- Compliance history
- Adverse event trends
- Experience from reviews and interactions
Key Messages

- Risk-based approach to inspections with added predictability and transparency
- Expanding use of regulatory audits
- Application of benefit-risk and least burdensome principles
- Increasing focus on device and manufacturing quality, and not compliance alone
Post-Inspection Follow-up

Be responsive to findings

Develop a plan with clear timelines and deliverables

Conduct systemic review and corrective actions

Provide clear, well-organized responses

Provide reasonable and timely updates on progress
Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 27, 2016.
The draft of this document was issued on June 16, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Compliance at 301-796-5900.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
### Assessing Benefit-Risk

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<thead>
<tr>
<th>Benefit</th>
<th>Risk</th>
<th>Other Factors</th>
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<tbody>
<tr>
<td>• Type of Benefit</td>
<td>• Risk Severity</td>
<td>• Uncertainty</td>
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<td>• Magnitude of benefit(s)</td>
<td>• Nonconforming product risks</td>
<td>• Mitigations</td>
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<tr>
<td>• Likelihood patients experience one or more</td>
<td>• Duration of exposure to population</td>
<td>• Detectability</td>
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<tr>
<td>benefits</td>
<td>• False positive or false negative results</td>
<td>• Failure mode</td>
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<td>• Duration of effects</td>
<td>• Patience tolerance of risk</td>
<td>• Scope of the device issue</td>
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<td>• Patient preference on benefit</td>
<td>• Risk factors for healthcare professionals</td>
<td>• Patient impact</td>
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<tr>
<td>• Benefits for healthcare professionals or</td>
<td>or caregivers</td>
<td>• Preference for availability</td>
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<tr>
<td>caregivers</td>
<td></td>
<td>• Nature of violations/</td>
</tr>
<tr>
<td>• Medical necessity</td>
<td></td>
<td>• Nonconforming product</td>
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<td>• Firm compliance history</td>
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**Goals:** arrive at the same risk determination, weigh options while minimizing disruption of care and protecting public health
Impact on Decision Making

Assessment indicates **high benefits** to patients with **little risk**

FDA works with manufacturer interactively or without formal enforcement action

Assessment indicates **low benefits** to patients with **high risk**

FDA takes compliance or enforcement action to address problem
Case for Quality

Why

Risk to patients from quality issues and hampered innovation in manufacturing and product development practices

What

Collaborative effort that focuses on organizational excellence and product quality

High industry focus on meeting regulatory requirements versus adopting best quality practices

Low investment in automation and digital technologies

No competitive market around medical device quality

New ways of assessing organizational performance and focusing on quality

Adapting regulatory oversight to increase agility, responsiveness, and enable continuous improvement

Increasing visibility into product quality to enable market drivers
Case for Quality Goals

- Collaborate in developing performance and organizational expectations and an appraisal process that result in increased manufacturing and product quality.

- Identify objective metrics and measures that focus on how organizational performance and product quality are measured, monitored, and controlled by manufacturers.

- Adapt FDA policies and practices to simplify regulatory engagement, increase visibility, improve responsiveness, foster a culture of quality within industry and FDA, and accelerate access to high-quality medical products.

- Advance solutions for increasingly complex and dynamic ecosystems.

- Develop a competitive marketplace around product quality that will accelerate and ensure the availability of high-quality medical devices.
Direct Value Across Stakeholders

**FDA**
- 30-Day Notices consumed 15-22 FTEs
- Site Changes consumed 5 FTEs

**Manufacturers**
- $30M/month top line.
- $1.2M/year savings 1 facility based on optimized processes and resource allocation (69 30-Day Notices)
- FDA audit cost (10 Days) - $140K
- Limited submissions and improvements due to regulatory resources

**Patients/Providers**
- 11 product quality improvements at one facility to patients 60-days sooner
- Increase product improvements
- Faster implementation of corrections to safety issues
CDRH Pilot Programs

• Premarket Approval Critical to Quality
• Voluntary Medical Device Manufacture and Product Quality
• Digital Health Pre-Certification Program
• Medical Device Single Audit Program
PMA CtQ Pilot

What is the pilot?
- Early interaction with FDA through pre-submission process on device characteristics that are critical to quality and how they are controlled

What Does FDA get?
- Earlier engagement on manufacturing reviews
- Improved understanding of essential device features and manufacturing processes

What changes?
- Waive preapproval inspection prior to PMA decision
- Conduct a focused inspection after PMA approval decision

FR for the PMA CtQ Pilot
# Voluntary Program Pilot

## What is the pilot?
- The pilot involves voluntary participation in a third-party maturity appraisal performed by CMMI.
- A baseline set of effectiveness metrics is collected.
- There will be pulse checks of those metrics at 90 – 180 day intervals.

## What Does FDA get?
- Progress report from CMMI of how the quality system is performing at the appraisal.
- Objective metrics as a baseline to monitor progression and benchmark.
- Engagement and feedback on quality objectives.

## What changes?
- Forgo surveillance inspections and appropriate post-approval or risk-based inspections.
- Manufacturing change notice submissions.
- Streamlined submission.
- Accelerated acceptance 48 hours vs 30 days.
- Manufacturing site changes.
- Streamlined submission.
- Accelerated approval – 1 week Target.
- Original PMA Manufacturing Section.
- Streamlined submission.
- Forgo pre-approval inspection.

FR for the December 28, 2017 Pilot Announcement:
Medical Device Single Audit Program

Regulatory Authorities (RA)

Enforcement

Threshold For RA Action

Manufacturers

Audit

Audit Report

Assessment

Auditing Organizations (AO)
Vision: Expansion of MDSAP

• Deploy an information system to facilitate the information sharing
• Broader use of MDSAP audit reports by participating Regulatory Authorities
• Inclusion of additional Regulatory Authorities
• Use of MDSAP audits by other regulators requiring compliance to ISO 13485
• Increased harmonization among regulators
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<th>MDSAP</th>
<th>PMA CtQ</th>
<th>Voluntary Program</th>
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<tr>
<td>• Compliance audit meeting multiple international jurisdictions</td>
<td>• Engagement with FDA on key device characteristics, manufacturing controls</td>
<td>• Maturity appraisal identifying value provided to customers and business</td>
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<td>• Replaces routine FDA surveillance inspection</td>
<td>• Faster PMA decision, targeted inspection following approval</td>
<td>• Replaces routine surveillance inspection, streamlines PMA 30 day notice and site change reviews, fosters interactive approach with FDA</td>
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FR for the PMA CtQ Pilot
Key Messages

FDA employs a risk-based inspectional approach and is taking steps to increase predictability and transparency of the process.

We’re looking to expand use of audit information collected by external and international partners.

We’re applying benefit-risk and least burdensome principles in postmarket decisions.

We’re working with industry to promote a focus on quality over compliance using novel methods.
THANKS!

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