Update from the Office of Compliance: Case for Quality

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2016-17 Office of Compliance Top Priorities

- Promoting a Culture of Quality
  - Quality in the Office
  - Case for Quality
Promoting a Culture of Quality
Goals:

• Develop systems and procedures to support the Center goal to be eligible for ISO 9001 certification

• Develop tools and structures to support decision making that assesses safety and compliance across a product’s life cycle.
  – Better collaboration between pre and post market staff
  – Increase in the number of staff members who can work in roles across the product lifecycle: pre-market, post-market, and compliance
The Case for Quality

• Reinforces compliance with regulatory requirements
• Still have repetitive quality system issues among major device manufacturers, unrelated to product quality

Our Future Approach

• Need to emphasize patient safety and product quality across the product lifecycle
• Shared goals among stakeholders
Compliance ≠ Quality

“...one device manufacturer can meet FDA requirements and still make a poor quality device whereas a second manufacturer may not comply with all FDA requirements and yet make a high-quality device”

Jeff Shuren, M.D., J.D.,
Director CDRH

***NOTE: Compliance to regulations is still important, as it is required – a high quality product is not a substitute for a compliant product under our current statutory situation
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm
Case for Quality Goals

- Identify new metrics and measures to see how device quality is measured, monitored and controlled
- Collaborate to see what performance and organizational expectations result in higher quality
- Explore how we should change our policies and practices to foster a culture of quality
- Advance solutions for increasingly complex and dynamic ecosystems
- Address needs of the public by ensuring availability of high quality medical devices
FDA Regulatory Paradigm Shift

What does a focus on quality mean for FDA?

- Increased manufacturing and product confidence
- Faster time to markets, better information to drive regulatory decisions, improved resource allocation
- What is most important to patients

Program changes beyond inspections:

- Remove participants from the agency work plan for routine inspections
- Waive pre-approval inspections where appropriate
- Engagement and meetings on issue resolution
- Reduced submission requirements and faster FDA response
- Accelerated approval path
- Competitive market around product excellence
Where is CfQ Going?

2017
- FDA announces a voluntary, quality focused program ready to pilot

2018
- Voluntary program pilot
- Management of results using quality tools
- Begin collecting and monitoring outcome metrics

2019
- Focus on improvement and enhancement of the program
- Share outcome indicators publicly
- Expand resources for new innovators and firms struggling with compliance

2020
- Expand program options and tools
- Improve premarket/post market decisions
- Leverage real world data for regulatory decisions

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Voluntary Program Update

- Process for participant removal from workplan
- Established FDAs expectations for high manufacturing capability
- Established submission requirements and modifications (30-Day, Site Changes, PMA Manufacturing Module)
- Developed program risk tracker
- Developed implementation plan outline and draft
- Public meeting schedule

- Federal Register Clearance
- Develop process routing for submissions throughout pilot
- Establish instructions and templates for pilot submissions
- Develop feedback and interaction framework
- Formalize “Rules of engagement” for pilot
- Implementation plan draft

- Development of Imports (Trusted Trader) program to facilitate incoming product for manufacturers
- Modifications to corrections and removal requirements and classification
- Established 510(k) submission team to find opportunities in the 510(k) submission space
Why does this matter to FDA?

It is all about the patient

Creating a learning regulatory system.

People and resources

Flexibility and responsiveness.
Enabling Smart Regulation Principles

Globally Harmonized

Promote Innovation

Promote Patient Engagement

Protect Patient Safety

Adaptive and Responsive

Outcome Focused

Risk Based

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Bringing it all together

- Patient preference
- Increased innovation
- Accelerated approval
- Customer focus
- Patient safety

- Quality maturity
- Continuous improvement
- Learning organization
- Trust and assurance

- Outcome Analytics
- Product experience transparency
- NEST
- Real World Evidence

- Adaptive, data driven oversight
- Lower regulatory burden
- Learning regulatory framework

Patient Focus
Organizational Excellence
Product Quality
Smart Regulation

FDA
Why is CfQ important to you?
Thank You!