An Introduction to CDER’s Emerging Technology Team

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LCDR Tara Gooen Bizjak
Senior Science Policy Advisor
Office of Policy for Pharmaceutical Quality
Division of Guidance, Regulations & Standards
CDER, FDA
tara.gooen@fda.hhs.gov
Brief History:
Early 2000s: FDA’s Pharmaceutical Quality for 21st Century Initiative

• Succeeded at many levels:
  – ‘Enabling’ of modern technology (e.g., PAT)
  – Updates to GMP regs; revised GMP guidance
  – Multiple ICH documents:
    • Pharmaceutical Development and QbD
    • Quality Risk Management
    • Quality Systems
  – Question-based review
  – Formation of Pharmaceutical Inspectorate
  – Risk-based selection of facilities for inspection
Brief History (cont.)
Early 2000s: FDA’s Pharmaceutical Quality for 21st Century Initiative

Vision

“A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight.”
Current Challenges

• Generic application review backlog and large number of manufacturing supplements
  – Time required for regulatory approval potentially holds back or blocks facilities improvements, e.g., site changes, major upgrades
  – Manufacturers with robust quality systems should be able to manage such changes without regulatory oversight

• Need for ongoing innovation in manufacturing
  – Regulatory oversight one factor in lack of industry adoption of modern manufacturing technology

• State of drug quality?
  – Lack useful quality indicators across-industry
  – Can we prevent quality problems?
Drug Shortages – State of Quality?

Figure 1. Number of New and Prevented Shortages by Dosage Form, 2005-2012

Source: Data from FDA’s internal drug and biologics shortages databases.

Figure 2. Drug Shortages by Primary Reason for Disruption in Supply in 2012

Risk to product quality

Benefit of availability
Mission
The Office of Pharmaceutical Quality assures that quality medicines are available to the American public.

Vision
The Office of Pharmaceutical Quality will be a global benchmark for regulation of pharmaceutical quality.

One Quality Voice
OPQ: One Quality Voice
Value Statements

• Put patients first by balancing risk and availability
• Have one quality voice by integrating review and inspection across product lifecycle
• Safeguard clinical performance by establishing scientifically sound quality standards
• Maximize focus and efficiency by applying risk-based approaches
• Strengthen the effectiveness of lifecycle quality evaluations by using team based processes
OPQ: One Quality Voice

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OPQ: One Quality Voice
Value Statements

• Enhance quality regulation by developing and utilizing staff expertise
• Encourage innovation by advancing new technology and manufacturing science
• Provide effective leadership by emphasizing cross-disciplinary interaction, shared accountability, and joint problem solving
• Build collaborative relationships by communicating openly, honestly, and directly
OPQ: Organizing Principles of Change

• Same quality standards for all drugs; lifecycle approach
  – Clinically relevant specifications
• Unified policy and standards development/analysis
• Establish clear standards for review and inspection
  – Clear enforcement policies
  – Surveillance including quantitative metrics
• Specialization and team review: integration of review and inspection for a quality assessment
• Accountability: Overall QMS and evaluation system
Defining Theme: **One Quality Voice**

- **One Quality Voice for Drugs**
  - *OPQ will centralize quality drug review—creating one quality voice by integrating quality review, quality evaluation, and inspection across the product lifecycle.*

- **One Quality Voice for Patients**
  - *OPQ will assure that quality medicines are available for the American public.*

- **One Quality Voice for Industry**
  - *OPQ will establish consistent quality standards and clear expectations for industry.*

- **One Quality Voice for Healthcare Professionals**
  - *OPQ will anticipate quality problems before they develop and help prevent shortages.*

- **One Quality Voice for Healthcare Purchasers**
  - *OPQ will emphasize quality metrics.*
What is the Emerging Technology Team (ETT)?

• A small cross functional team with representation from all relevant CDER review and inspection programs
• Vision: Encourage and support the adoption of innovative technology to modernize pharmaceutical development and manufacturing where the Agency has limited review or inspection experience. Includes:
  – Innovative or novel product, manufacturing process, or analytical technology subject to CMC review
  – Existing or planned submission(s)
The ETT Charter

• Provides a forum for knowledge sharing and scientific discussion
• Provides consistency, continuity and predictability
  – Facilitates establishment of review and inspection standards and policy
• Supports GMP manufacture of quality product over the lifecycle
• Long term goals:
  – Engage international regulatory agencies to share learnings and approaches
  – Modernizing pharmaceutical development and manufacturing
Role of ETT

• Provides perspective on quality review and inspections
  – ETT members serve to lead/co-lead cross-functional team during review process
  – Participates or supports relevant inspection(s) and/or pre-operational visits
  – Identify and capture decisions that may inform future FDA approaches and decisions
• Serve as advocates for innovative technology while balancing risk vs. benefit
• Identify and evaluate roadblocks relating to existing guidance, policy, or practice
• Early applicant engagement with the ETT is recommended
• Contact us: CDER-ETT@fda.hhs.gov
Summary

- FDA has made some progress in improving its overall approach to regulating pharmaceutical quality, but major challenges remain.
- Re-organization and re-alignment to achieve a “One Quality Voice” approach.
- We are planning to make coordinated organizational, process, and policy changes that will move us more towards our articulated vision.