Office of Pharmaceutical Quality

Robert Iser
Associate Director for Policy Development (acting), OPS

Member OPQ Transition Team & OPF Transition Sub-Team

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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.”

- Dr. Janet Woodcock
FDA’s Pharmaceutical Quality for 21st Century Initiative

• Successes:
  ▪ ‘Enabling’ of modern technology (e.g., PAT)
  ▪ Updates to GMP regulations; revised GMP guidance
  ▪ Multiple ICH documents:
    ▪ Pharmaceutical Development and Quality by Design
    ▪ Quality Risk Management;
    ▪ Quality Systems
  ▪ Question-based review
  ▪ Formation of Pharmaceutical Inspectorate
  ▪ Risk-based selection of facilities for inspection
Current Challenges
(Not All-Inclusive or In Order of Priority)

- Drug Shortages
- State of Quality?
- GDUFA Backlog
- Internal Process Improvements Needed
- Multiple Systems / Databases
- Risk Based Quality Assessment Not Fully Realized
- Knowledge & Lifecycle Management
- Communication / Silos
- Innovation is Not Increasing
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
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

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
One Quality Voice for Drugs:

Centralize quality drug review—creating one quality voice by integrating quality review, quality evaluation, and inspection across the product lifecycle.

Consistent quality standards and risk-based approaches.
One Quality Voice for Patients:

OPQ will assure that quality medicines are available for the American public.

OPQ will assure patients of quality drugs by balancing potential quality risks with the risk of a patient not getting a drug.
One Quality Voice for Industry:

OPQ will establish consistent quality standards and clear expectations for industry.

Product standards should be captured in clinical quality attributes and clinically-relevant specifications.

Identifying quality problems, requiring corrective actions where standards are not met, and making enforcement decisions will require close interaction between OC, OPQ, and ORA.
One Quality Voice for Health Care Professionals:

OPQ will anticipate quality problems before they develop and help prevent drug shortages.

With better knowledge of product and facility quality, we can help assure better quality drugs that are consistently available.
OPQ Structure

OPQ Immediate Office

- Office of Programs & Regulatory Operations
- Office of Policy
- Office of New Drug Products
- Office of Lifecycle Drug Products
- Office of Process and Facilities
- Office of Surveillance
- Office of Testing & Research
- Office of Biotechnology Products
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 using quantitative metrics
- Specialization and team review: **integration of review and inspection** for quality assessment
- Accountability: Overall **QMS** and evaluation system
Lifecycle Approach

• Propose to organize review by dosage form
  – same team to review generics to ensure efficiency and consistency
• Integrated team for review of facility and manufacturing process
  – also will assess need for inspection
• Surveillance activity for all facilities manufacturing marketed drugs or API
Policy and Standards

• Proposed Office of Policy
• Much greater emphasis on developing and maintaining standards
• Develop standards and assess whether standards achieved the quality impact intended
• Support FDA Council on Pharmaceutical Quality
  – Stakeholder Centers
Surveillance

• Develop clear, written standards and inspectional procedures
  – Reinforcing industry QMS as the primary driver of quality
• Use of metrics in assessing facilities operating at risk or are operating in control based on a strong QMS
• To evolve new approaches towards manufacturing supplement requirements
Pharmaceutical Quality Platform

Risk-based Inspection and Review

1. Plan,
2. Execute, & Track

3. Analyze & Decide

- Field Alerts
- Recalls
- Drug Quality Reports

Pharmaceutical Quality Surveillance & Risk Evaluation

- Pre-market inspections
- Post-market inspections

Master Data Repositories

External Risk Factors: Foreign Regulatory Agencies etc.

Facility/Site Selection

Pharmaceutical Quality Platform
Centralized Operations (OPRO)

• Propose CMC review with centralized project management
• Address questions early and communicate frequently
• Aim for more targeted and efficient process with fewer repetitive reviews
• Review Practices to be further refined
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Thank you for your attention!