Update on CDER's Quality Management Maturity Program

Jennifer A. Maguire, PhD
Director, Office of Quality Surveillance
Office of Pharmaceutical Quality
CDER | US FDA

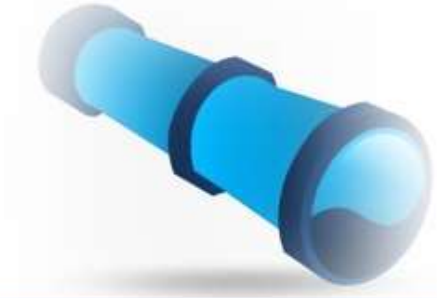
[Pharmaceutical Quality Symposium] – October 2021

Learning Objectives

- Understand the role of the Office of Quality Surveillance
- Learn about CDER's Quality Management Maturity Program and the ongoing pilots

Learning Objective One:

The Office of Quality Surveillance (OQS)



2018-2022
OQS Strategic Plan

VISION

The Office of Surveillance continuously monitors and provides the state of quality for all regulated sites and products.

OQS has a 5-year Strategic Plan that supports OPQ's priorities while advancing the OQS vision and mission

MISSION

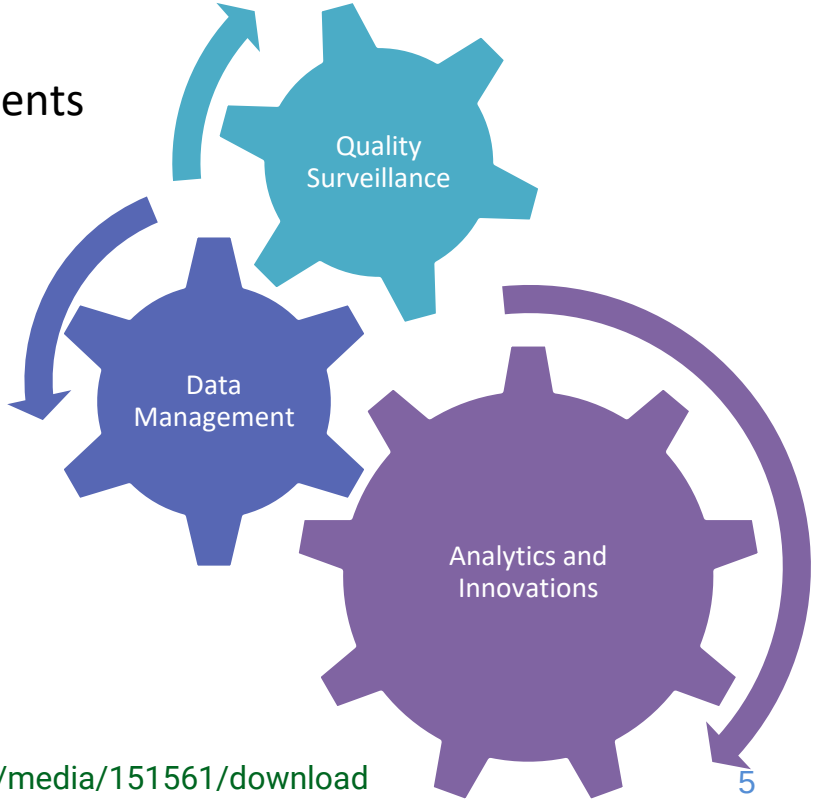
The Office of Surveillance assures that quality medicines are available through signal detection, data analysis, review of the state of quality, and proactive stakeholder engagement.

STRATEGIC PRIORITIES

PRIORITY 1: EMPOWER	PRIORITY 2: CULTIVATE	PRIORITY 3: SURVEIL
Strengthen our organizational foundation to achieve comprehensive surveillance of sites and products.	Build strategic partnerships to promote pharmaceutical quality.	Advance a consumer-centric approach to quality surveillance through risk-reduction, prevention, and effective response.

Office of Quality Surveillance

- Monitor quality and manage information about CDER-regulated sites and products
- Use intelligence collected and analytics to make data-driven decisions that can reduce risk to patients
  - Prioritization of sites for CGMP inspections
  - Human drug surveillance sampling programs
  - Site engagement
  - Characterize the state of quality*
- Proactively identify potential quality signals and trends before serious quality problems occur
- Continuously improve surveillance strategies by applying new methods or techniques

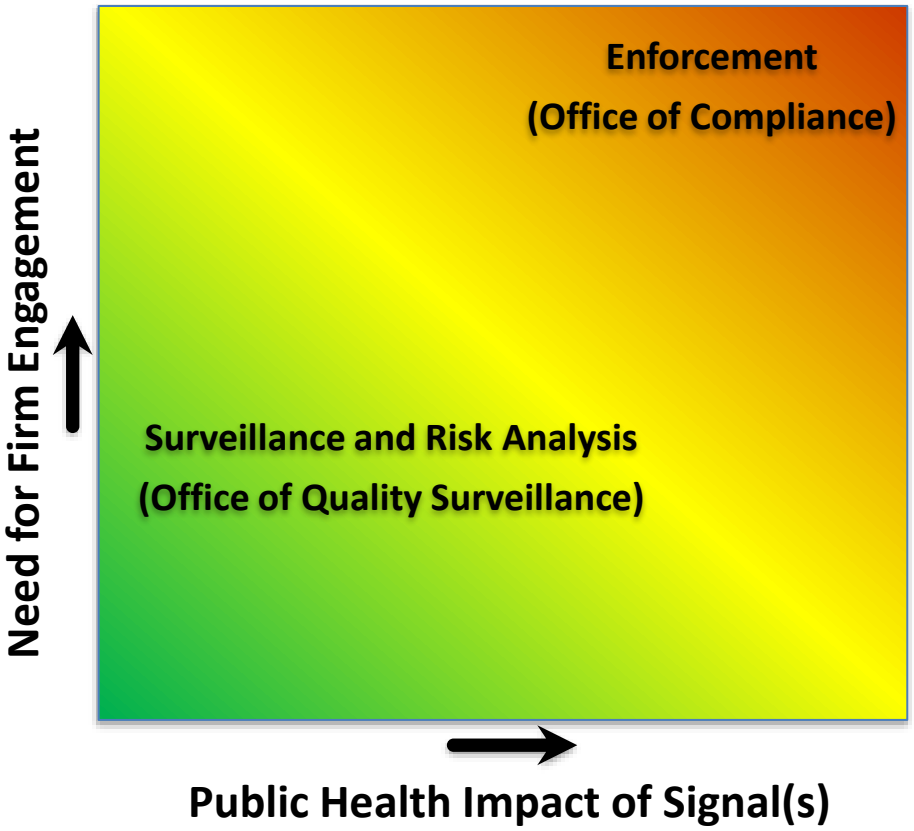


RSPQ published AUG 2021 at https://www.fda.gov/media/151561/download

Sources of Intelligence

- **Facility and Inspection Data**
  - Registration and Listing
  - Inspection findings
  - Profile Class Codes, Imports, Business operations, etc.
- **Quality Defect Reports**
  - Field Alert Reports (FARs)
  - Biological Product Deviation Reports (BPDRs)
  - MedWatch Reports
  - Recalls (Type I, II, III)
  - Consumer Complaints
  - Informants
- **Drug Quality Sampling and Testing Results**
- **Application data**
  - Original and Supplements
  - Annual Reports
- **Quality Metrics (future)**
- **Quality Management Maturity (future)**
- **External data**
  - 704(a)(4) requests
  - Foreign regulatory authority information
  - Public information – social media, consumer reviews (e.g., drugs.com), blogs, news outlets, etc.

Surveillance Throughout the Lifecycle



Challenge Question #1

Which of the following statements is NOT a function of the Office of Quality Surveillance?

A. Monitor quality and manage information about CDER-regulated sites and products.

B. Use intelligence collected and analytics to make data-driven decisions that reduce risk to patients.

C. Proactively identify potential quality signals and trends before serious quality problems occur.

D. Develop and implement compliance and enforcement policies and actions to protect patients from products that are produced under conditions that may pose a risk to public health.

Learning Objective Two:

Quality Management Maturity

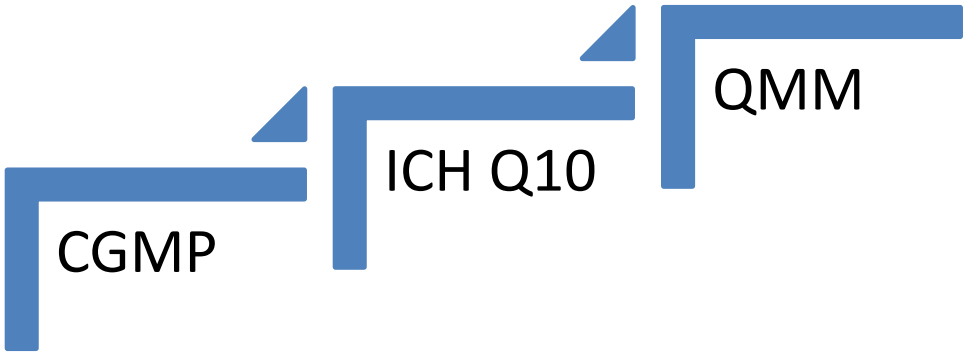
Important Context

- Drug Shortages: Root Causes and Potential Solutions, published in October 2019, examines the underlying factors responsible for drug shortages
  - ***The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues***

- And recommends enduring solutions
  - ***Developing a rating system to incentivize drug manufacturers to invest in QMM for their facilities***
- Program aimed at recognizing and rewarding manufacturers for "mature quality systems" that achieve sustainable compliance and focus on continuous improvement, business continuity plans, and early detection of supply chain issues


Quality Management Maturity
Quality Metrics
Business Continuity
Leadership Commitment to Quality
Communication and Collaboration
Sustainable Compliance
Quality Culture
Enhanced Pharmaceutical Quality System (PQS)
Customer Experience
Manufacturing Strategy and Operations
Employee Ownership and Engagement
Knowledge Management
Advanced Analytics
Productivity Optimization (5S)
Risk Management
Continual Improvement

Steps to Quality Management Maturity

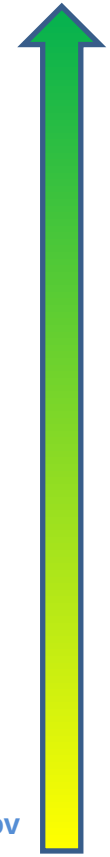


- Current Good Manufacturing Practice (CGMP) establishes a minimum standard
- Fully realizing the 21st century pharmaceutical quality vision requires a transparent method of evaluating and communicating QMM
- *QMM is a measure of the consistency, reliability, and robustness of business processes established and maintained to achieve quality policies and objectives, including a focus on continual process and system improvement*

Building a QMM Program

- Learn from efforts to date
  - PDA Quality Culture Initiative
  - ISPE Advancing Pharmaceutical Quality Program
  - University of St. Gallen Research
  - FDA/CDRH Case for Quality Pilot Program
  - Dun & Bradstreet Quality Benchmarking Study
- Conduct outreach to purchasing organizations, pharmacy chains and other federal agencies
- Execute 2 pilot programs announced 10/2020 through FRN using QMM framework developed in coordination with 3rd party appraisers
  - QMM FDF Pilot Program – includes domestic manufacturers of drug products marketed in the U.S.; Contract awarded to Pacific Force Consulting Group, LLC
  - QMM API Pilot Program – includes foreign manufacturers of API used in drug products marketed in the U.S.; Contract awarded to Shabas Solutions, LLC
- Seek and incorporate stakeholder input

Rating Quality Management Maturity



"Above the Bar" Behaviors

- **Maturity Level 5: Optimized** ← Best in Class
- **Maturity Level 4: Managed**
- **Maturity Level 3: Defined** ← Enhanced PQS
- **Maturity Level 2: Developmental** ← Enhanced PQS
- **Maturity Level 1: Initial** ← Minimally Compliant

Two Assessment Frameworks

Domestic FDF Pilot (Pacific Force)

- Self-Assessment Protocol
- Follow-up Conversation and Evidence Collection
- Covers 6 “Program Areas”
  - Leadership and Governance
  - Operations
  - Continual Improvement
  - Stakeholder Engagement and Satisfaction
  - Knowledge Management
  - Workforce Engagement

Foreign API Pilot (Shabas)

- Facilitated Virtual Assessment with Evidence Collection
- Covers 4 “Pillars”
  - Sustainability
  - Risk Management
  - Compliance
  - Quality Culture

QMM and QM

- Quality metrics are a key aspect of a mature PQS
  - Using data-driven approaches to reduce quality issues and drive continual improvement
- Any assessment conducted to assess a site's QMM would be an evaluation at a point in time
- Quality metrics data would be important to provide information about the quality of the site and manufacturing process performance on an ongoing basis and in between on-site assessments

Challenge Question #2

Which major root cause of drug shortages identified in the report to Congress is the impetus for a Quality Management Maturity Program?

A. Lack of incentives to produce less profitable drugs

B. Market does not recognize and reward manufacturers for mature Quality Management Systems

C. Logistical and regulatory challenges make it difficult for the market to recover after a disruption

Summary of Key Take Aways

- Current research indicates that quality metrics and quality culture programs are good business practices and important elements of modern pharmaceutical manufacturing
- Both strong quality metrics and quality culture programs are part of quality management maturity
- OQS continues to engage stakeholders and support related academic research
- Our goal is to keep all sites in compliance and all products available for the patient
- **OQS monitors the state of quality for sites and products to assure every dose is safe and effective, free of contamination and defects and patients can be confident in their next dose**

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Jennifer A. Maguire, PhD
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No one can do this alone…
Let’s work together to improve global pharmaceutical quality to improve the lives of patients


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