Updates on Quality Management Maturity

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IPA's 9th Global Pharmaceutical Quality Summit
Agenda

- Introduction to Office of Quality Surveillance (OQS)
- Drug Shortages and Supply Chain Vulnerabilities
- Introduction to Quality Management Maturity (QMM)
- Update on QMM Program Development
15 Years of Service to Global Public Health

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INTRODUCTION TO OFFICE OF QUALITY SURVEILLANCE (OQS)
Office of Quality Surveillance (OQS)

VISION

• To be the global benchmark for pharmaceutical quality surveillance.

MISSION

• OQS turns intelligence into insights and actions to promote the availability of quality medicines for the American public.
Sleuths for Drug Quality!

OQS leverages pharmaceutical intelligence on manufacturers and the products they make, knowledge of CGMP regulations/guidance, and analytics to help the Office of Pharmaceutical Quality (OPQ) assure drug quality and availability:

- Surveil quality throughout the product lifecycle
- Understand and model pharmaceutical supply chains
- Advance the science of quality surveillance
- Promote industry adoption of mature quality management practices
SHORTAGES AND SUPPLY CHAIN VULNERABILITIES
Reasons for New Shortages

Percentage of Drugs Newly in Shortage by Reason, Calendar Years 2013-2017

- Quality Issues: 62%
- Unknown: 18%
- Increase in Demand: 12%
- Natural Disaster: 5%
- Production Discontinuation: 3%

Most drugs in shortage were experiencing supply disruptions, specifically quality issues.

Source: Internal FDA Data

Percentage of Drugs Newly in Shortage by Reason, Calendar Years 2022-2023

- Quality Issues / Manufacturing Delays: 40%
- Increase in Demand: 40%
- Availability of API: 11%
- Natural disaster/PHE: 5%
- Product Discontinuation: 5%

Note: Percentages do not equal 100% due to rounding.

Source: Internal FDA Data
Drug Shortages – One potential solution

• Root Cause: *The market does not recognize and reward manufacturers for “mature quality systems” that focus on continuous improvement and early detection of supply chain issues*

• Enduring Solution: *Incentivize drug manufacturers to invest in QMM*
INTRODUCTION TO QUALITY MANAGEMENT MATURITY (QMM)
Drug manufacturers achieve higher levels of quality management maturity (QMM) when they successfully integrate business and manufacturing operations with quality practices and technological advancements to optimize product quality, enhance supply chain reliability, and drive continual improvement.
Benefits of Quality Are Nothing New

• “Quality always costs less” – W. Edwards Deming
  o Achieving quality outcomes requires investment
  o Good quality does not imply higher costs
  o Organizations whose quality practices are the most sophisticated are not necessarily the ones that spend the most

• Cost of poor quality – Loss of production, rework, scrap, loss of business, recalls

• Cost of quality – Inspection and prevention costs
  o Labor costs for audits, preventive/predictive maintenance, training, design improvement, implementation of advanced control mechanisms (e.g., SPC)

• High levels of QMM will lead to:
  o Greater customer satisfaction
  o Operational efficiencies – increase in productivity
  o Higher revenues
QMM Program Goals

1. Foster a strong quality culture mindset

2. Recognize establishments that have advanced quality management practices and acknowledge establishments that strive to continually improve quality management practices

3. Identify areas where quality management practices can be enhanced and provide suggestions for growth opportunities

4. Minimize risk to product availability to assure reliable market supply
Addressing misconceptions... the truth is...

QMM assessments are not used to evaluate compliance with CGMP

QMM assesses manufacturing establishments, not product quality

Maturity is independent of establishment size or age, and types or numbers of products produced

QMM assessments are distinct from the collection of quality metrics

QMM is NOT an additional burden or requirement
UPDATE ON QMM PROGRAM DEVELOPMENT
Recent Milestones and Publications

Two QMM Pilots
completed between 2020-2022

CDER White Paper #1
April 2022

Small Business and Industry Assistance (SBIA) Workshop
May 24-25, 2022

Article on benchmarking quality practices with D&B
October 2022

FDA Advisory Committee
November 2, 2022

Article on lessons from pilot programs
January 2023

CDER White Paper #2
August 2023

FRN announcing docket of public/stakeholder feedback
September 2023

FRN soliciting volunteers for the program
January 2024

Volunteers selected for the 2024 program
April 2024
Stakeholder Engagement Efforts

On **November 2nd, 2022**, the Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted unanimously (9-0) in support of the development of CDER’s QMM Program.

CDER committed to engaging with stakeholders and soliciting public input to develop the QMM Program.

Following the advisory committee, CDER engaged with multiple internal and external stakeholders.
QMM Pilot Programs (2020-2022)

Pilot 1
Domestic FDF Manufacturers
7 establishments

Pilot 2
Overseas API manufacturers
8 establishments

Lessons Learned
- Assessment process
- Scoring approach
- Assessor behaviors
- Perceptions of the assessment questions
- Reports
- Ratings
Discusses Practice Areas, Assessment Protocol and Rubric to evaluate how effectively establishments monitor and manage quality and quality management systems.

Discusses selection of up to 9 volunteer establishments.

Federal Register Notice closed March 25, 2024.

CDER will use learnings to refine assessment tools, output, and business processes.

FRN soliciting volunteers for the program

January 2024
QMM Practice Areas

- Management Commitment to Quality
- Business Continuity
- Advanced Pharm. Quality System
- Technical Excellence
- Employee Engagement
QMM Practice Areas

Management Commitment to Quality
• All levels of management need to make a commitment to quality.
• Management is responsible for setting the tone and modeling a culture of quality and ensuring quality objectives are aligned with their business objectives and strategic plan.
• Management is responsible for allocating resources to support quality objectives and continual improvement activities.
• Management plays a central role in creating clear and open communication channels.

Business Continuity
• Ensure business operations are sustained during expected or unexpected disruptions.
• Effectively identify hazards, analyze and mitigate risks, implement good governance, and establish robust monitoring programs.

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QMM Practice Areas

**Advanced Pharmaceutical Quality System**
- Implementation of optimized practices and procedures to enhance the PQS.

**Technical Excellence**
- Development and implementation of advanced technologies, processes, methods, and practices that are fit for purpose.
- Use of novel solutions.

**Employee Engagement and Empowerment**
- Empower employees to take ownership of their work and become committed partners in achieving the establishment’s quality and business objectives.
QMM is Valuable to All

- Patients and Consumers.
- Manufacturers
- Purchasers and Payers
- Healthcare Professionals
- Pharmacies
- FDA

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Reference

• Drug Shortages: Root Causes and Potential Solutions

• CDER’s Office of Pharmaceutical Quality White Paper on Quality Management Maturity (April 7, 2022)

• Vision of CDER’s QMM Program

• QMM Pilots: CDER’s Lessons Learned

• Lessons from CDER’s Quality Management Maturity Pilot (AAPS Journal, January 2023)

• CDER’s Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development (August 2023)
Questions?

Contact us at CDER-QMM@fda.hhs.gov