Updates on Quality Management Maturity

Dr Jacquin Jones
U.S. FDA India Office – International Relations Specialist

27-28 June 2024
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

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!

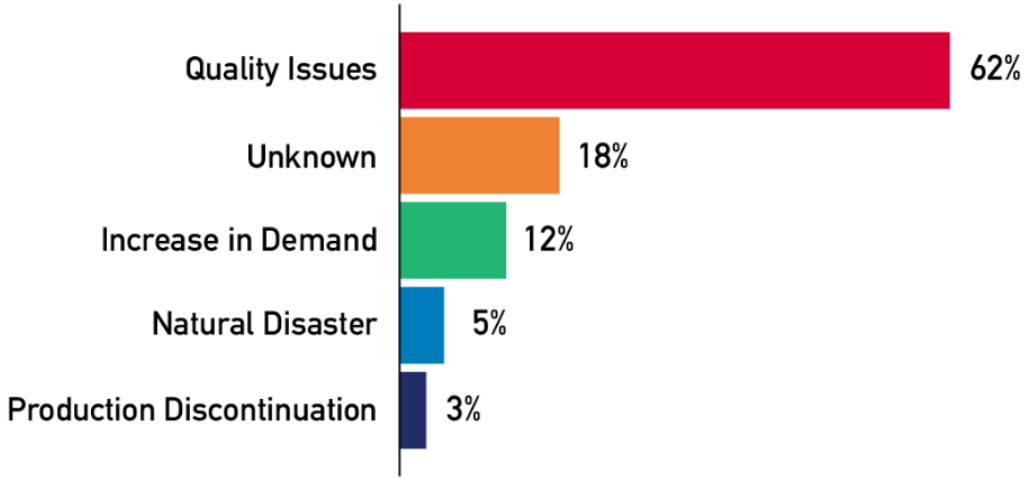
OQS leverages pharmaceutical intelligence on manufacturers and the products they make, knowledge of CGMP regulations/guidance, and analytics to help the Office of Pharmaceutical Quality (OPQ) assure drug quality and availability:

- 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

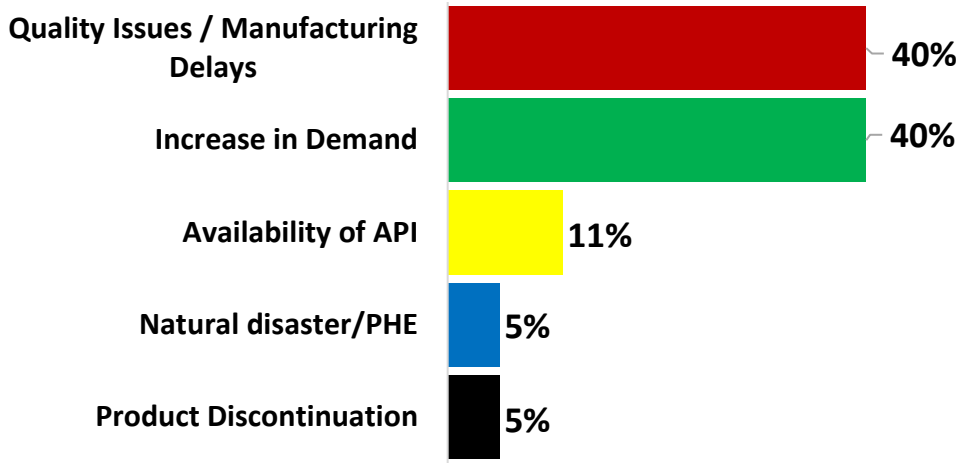
Percentage of Drugs Newly in Shortage by Reason, Calendar Years 2013-2017



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



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

Source: Internal FDA Data

Drug Shortages – One potential solution

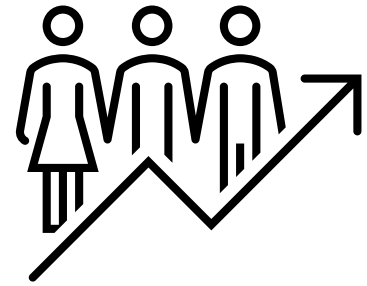
- Root Cause: *The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues*

- Enduring Solution: *Incentivize drug manufacturers to invest in QMM*

INTRODUCTION TO QUALITY MANAGEMENT MATURITY (QMM)

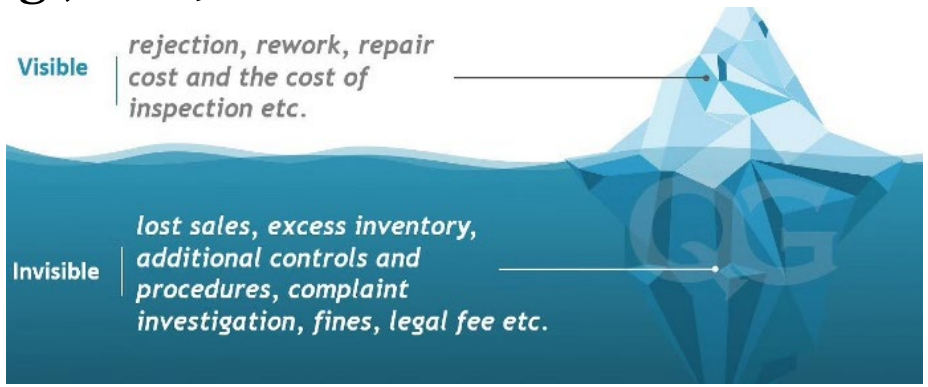
Understanding QMM

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
  - Achieving quality outcomes requires investment
  - Good quality does not imply higher costs
  - 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
  - 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:
  - Greater customer satisfaction
  - Operational efficiencies – increase in productivity
  - 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

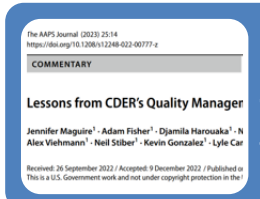
QMM is NOT an additional burden or requirement

UPDATE ON QMM PROGRAM DEVELOPMENT

Recent Milestones and Publications

Two QMM Pilots

completed between 2020-2022



Article on lessons from pilot programs

January 2023

CDER White Paper #1

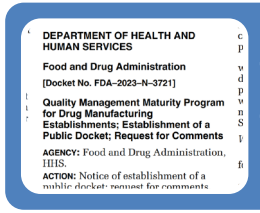
April 2022

CDER White Paper #2

August 2023

Small Business and Industry Assistance (SBIA) Workshop

May 24-25, 2022



FRN announcing docket of public/stakeholder feedback

September 2023

Article on benchmarking quality practices with D&B

October 2022

FRN soliciting volunteers for the program

January 2024

FDA Advisory Committee

November 2, 2022

Volunteers selected for the 2024 program

April 2024

FDA Advisory Committee

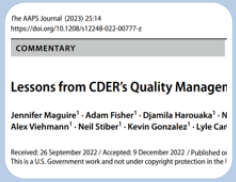
November 2, 2022

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.


The AAPS Journal (2023) 25:14
https://doi.org/10.1208/s12248-022-00777-z
COMMENTARY
Lessons from CDER's Quality Manager
Jennifer Maguire[1] · Adam Fisher[2] · Djamila Harouaka[3] · N
Alex Viehmann[3] · Neil Stiber[2] · Kevin Gonzalez[1] · Lyle Car
Received: 26 September 2022 / Accepted: 9 December 2022 / Published or
This is a U.S. Government work and not under copyright protection in the

[Article on lessons from pilot programs](#)
January 2023

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

FRN soliciting volunteers for the program

January 2024

2024 QMM Prototype Assessment Protocol Evaluation Program – Federal Register Notice

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

QMM Practice Areas

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.

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

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


FDA
U.S. FOOD & DRUG
ADMINISTRATION