



Quality Management Maturity (QMM)

Nandini Rakala, Ph.D., M.S., B.S.

Visiting Associate & Data Scientist

Office of Quality Surveillance, Office of Pharmaceutical Quality
CDER | U.S. FDA

Pharmaceutical Quality Symposium 2023

Everyone deserves confidence in their *next* dose of medicine.

Pharmaceutical quality assures the availability, safety, and efficacy of *every* dose.

A close-up photograph of a person's hands. The left hand holds an orange plastic pill container, tilted to pour three white, oval-shaped pills into the palm of the right hand. The background is softly blurred, showing a person's arm in a light blue sleeve.

Reliable supply chains provide quality drugs when and where patients need them.

A Potential Solution to Drug Shortage

The Report was updated on 2/21/20 to include revised economic analysis about production increases and supply restoration after a shortage. See the [FDA Archive for the original Report](#).

Drug Shortages:

Root Causes and Potential Solutions

2019

U.S. Food and Drug
Administration



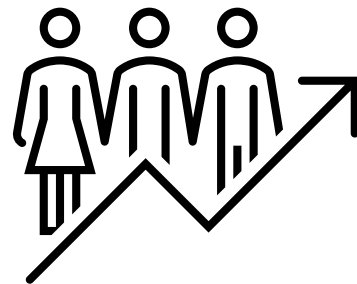
FDA U.S. FOOD & DRUG
ADMINISTRATION

- 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*

Participation in the QMM Program will be Voluntary!

Understanding QMM

Drug manufacturers achieve higher levels of maturity 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.



Quality Management Maturity

Quality Metrics

Leadership Commitment to Quality

Business Continuity

Quality Culture

Communication and Collaboration

Sustainable Compliance

Customer Experience

Enhanced Pharmaceutical Quality System (PQS)

Advanced Analytics

Employee Ownership and Engagement

Risk Management

Continual Improvement

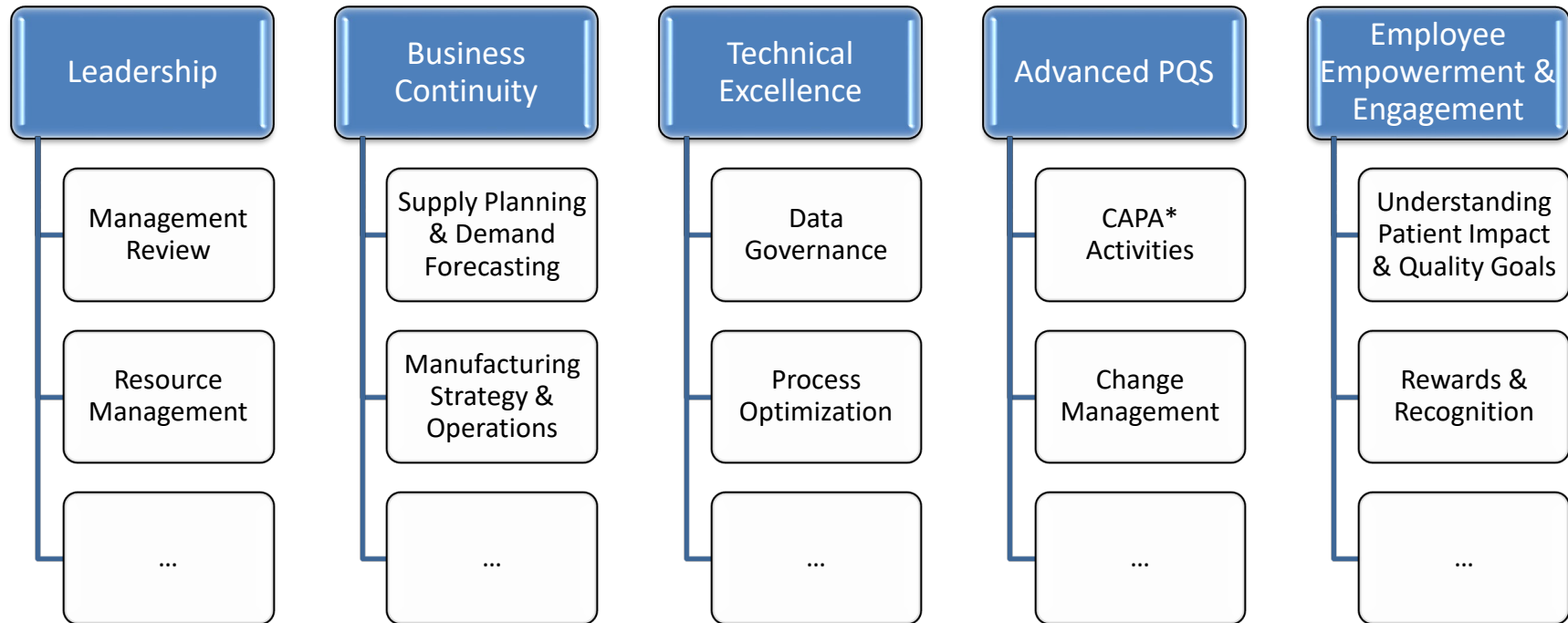
Manufacturing Strategy and Operations

Productivity Optimization (5S)

Prototype of Protocol:

Examples of Assessment Practice Areas

Practice Areas will be assessed according to a defined rubric.



*CAPA – Corrective Action and Preventive Action

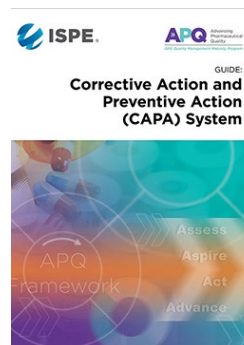
Benefits of Quality Are Nothing New

- “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



Complementary Efforts

- Learn from efforts to date
 - ISPE Advancing Pharmaceutical Quality Program
 - PDA Quality Culture Initiative
 - University of St. Gallen Operational Excellence Research
 - FDA/CDRH Case for Quality Pilot Program
 - Dun & Bradstreet Quality Benchmarking Study



dun & bradstreet

Road to FDA's QMM Program

2020

Duke | MARGOLIS CENTER
for Health Policy

Understanding How the Public Perceives and Values Pharmaceutical Quality

Private Workshop Summary
Washington, DC | February 6, 2020

“Stakeholders largely agreed that there is a need to develop and implement quality... scores within the industry.”

Context is responsible for overseeing the quality of drugs. The first report on the state of pharmaceutical quality states that “A quality drug is consistently safe and effective, free of contamination and defects.”

Throughout the day, stakeholders used the term “pharmaceutical quality” to refer to two distinct concepts. First, they used it to describe the quality of the manufacturing process, and its ability to produce a reliable supply of drugs that is resilient against supply disruptions and shortages. Second, stakeholders used the term to describe a product that is free of contamination and defects that might affect its safety or effectiveness. These different uses of the term “pharmaceutical quality” highlight one of the key takeaways of the workshop: there is a need for a better shared understanding of what pharmaceutical quality means, how it affects stakeholders, and how it can be measured.

The Private Workshop

The workshop consisted of two breakout groups representing patient and provider perspectives as well as buyer and payer perspectives. The groups explored stakeholder understandings of pharmaceutical quality and the ways that quality impacts decision making. In the final portion of the day, the breakout groups joined together to share lessons learned and discuss ways forward.

Key areas for future action included assessing perceptions of pharmaceutical quality, continuing communications about quality with patients and providers, facilitating transparency between manufacturers, regulators, and purchasers, and developing quality ratings and scores.

Breakout Group A: Patients and Provider Perspectives

Breakout Group A first considered how patients and providers define pharmaceutical quality, differentiate between pharmaceutical quality issues and drug side effects, and perceive FDA's role in regulating pharmaceutical quality. The group then considered the decisions healthcare providers make surrounding pharmaceutical quality and how those decisions impact patient care, as well as how patient preferences around quality influence medical decision making. Group A consisted of fifteen providers, patient advocates, professional society representatives, and pharmacists, as well as additional FDA

1

2021

**BUILDING RESILIENT
SUPPLY CHAINS,
REVITALIZING AMERICAN
MANUFACTURING, AND
FOSTERING BROAD-BASED
GROWTH**

“FDA should lead the development of a framework to measure... a facility's quality management maturity with engagement from industry, academia, and other stakeholders.”

Department of Health and Human Services
Department of Health and Human Services



THE WHITE HOUSE
WASHINGTON

2022

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

CONSENSUS STUDY REPORT



“Establishing a quality rating system... is a long-term initiative that will have to be developed in collaboration with business partners and with stakeholders.”

**MEDICAL PRODUCT
SUPPLY CHAINS**

Recent Milestones and Publications

- Two QMM Pilots: completed in 2022
- SBIA Workshop: May 24-25, 2022
- FDA Advisory Committee: November 2, 2022

The AAPS Journal (2022) 24:111
<https://doi.org/10.1208/s12248-022-00761-7>

October 2022

RESEARCH ARTICLE



Benchmarking the Quality Practices of Global Pharmaceutical Manufacturing to Advance Supply Chain Resilience

Matt Fellows¹ · Thomas Friedli² · Ye Li³ · Jennifer Maguire³ · Nandini Rakala³ · Marten Ritz² · Matteo Bernasconi² · Mark Seiss^{1,4} · Neil Stiber³ · Mat Swatek¹ · Alex Viehmann³

The AAPS Journal (2023) 25:14
<https://doi.org/10.1208/s12248-022-00777-z>

January 2023

COMMENTARY



Lessons from CDER's Quality Management Maturity Pilot Programs

Jennifer Maguire¹ · Adam Fisher¹ · Djamilia Harouaka¹ · Nandini Rakala¹ · Carla Lundi¹ · Marcus Yambot¹ · Alex Viehmann¹ · Neil Stiber¹ · Kevin Gonzalez¹ · Lyle Canida¹ · Lucinda Buhse¹ · Michael Kopcha¹

April 2022



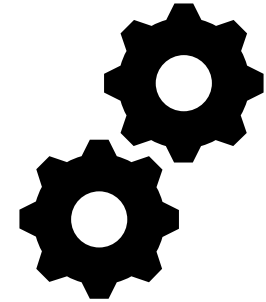
U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
 An Office of Pharmaceutical Quality (OPQ) White Paper

**Quality Management Maturity: Essential
 for Stable U.S. Supply Chains of Quality
 Pharmaceuticals**

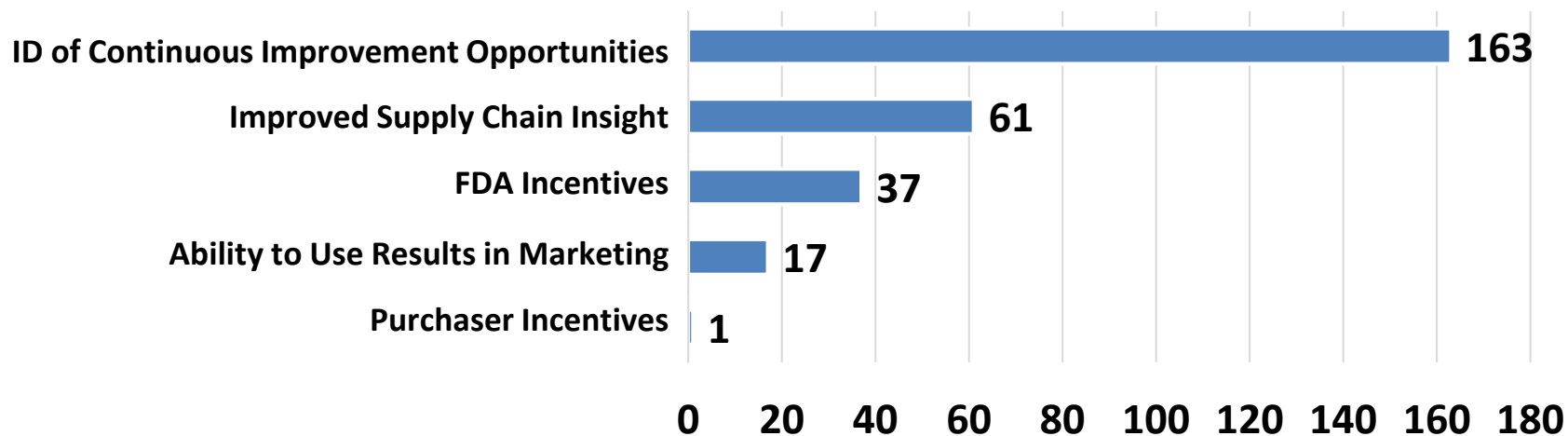
Future Operational Considerations

- Eligibility criteria
- Executed by FDA or 3rd party
- Executed remotely vs on-site components
- Incentives for participation
- Reassessments:
 - Periodicity
 - Depth of reassessment coverage
- Determining how to present the assessment outcome
- Level of transparency around site assessment outcomes
 - What information, if any, should be made public?
- Metrics to assess program success and impact on quality



Stakeholder Feedback on QMM Benefits

What would be the biggest potential benefit for sites that participate in a QMM program?



Addressing Common Misconceptions

QMM \neq QM; QMM = $f(\text{use of quality metrics, } x, y, z\dots)$

A QMM assessment is **NOT** intended to be used in lieu of an establishment inspection and does not evaluate compliance with CGMP*

A QMM outcome is **NOT** a measure of product quality. It is an evaluation of an establishment's, culture, mindset, behaviors, and quality practices

QMM is Valuable to All

- **FDA** – Promotes continual improvement and enables potential regulatory flexibility for postmarket CMC changes
- **Patients and Consumers** – Strengthens availability of drugs with fewer recalls and shortages
- **Manufacturers** – Enables continual improvement, promotes a more robust supply chain, and informs selection of contract sites
- **Healthcare Professionals** – Increases confidence in the supply of drugs prescribed and/or dispensed with less risk of drug shortages
- **Pharmacies** – Reduced risk of failing to meet demand because supply chain is more robust and transparent
- **Purchasers and Payers** – Potential to enhance supply chain transparency and market knowledge with less need to respond to shortages



No one can do this alone...



Let us work together to assure global pharmaceutical quality to improve the lives of patients and consumers

