

Quality Management Maturity (QMM)



Djamila Harouaka, PhD
Senior Scientific Advisor

Office of Quality Surveillance
Office of Pharmaceutical
Quality
CDER | US FDA

SBIA
April 12, 2023



Agenda

- 
- A dark blue horizontal bar with rounded ends, positioned above the first agenda item.
- Quality Management Maturity (QMM)

- 
- A light blue horizontal bar with rounded ends, positioned above the second agenda item.
- QMM Program Development

Quality Management Maturity (QMM)

Drug Shortages - A Potential Solution

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



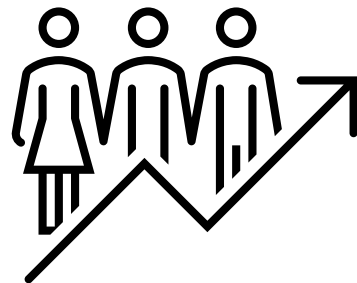
FDA U.S. FOOD & DRUG
ADMINISTRATION



- 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: *Developing a rating system to incentivize drug manufacturers to invest in QMM*

Understanding QMM

Drug manufacturers achieve higher levels of QMM when they successfully integrate business and manufacturing operations with quality practices and technological advancements to optimize product quality, enhance supply chain resiliency, 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

Continual Improvement

Risk Management

Manufacturing Strategy and Operations

Productivity Optimization (5S)

QMM is 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
 - PDA Quality Culture Initiative
 - ISPE Advancing Pharmaceutical Quality Program
 - 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

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

Quality means different things to different people. For the public, the idea of pharmaceutical quality means 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 resistant 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.

2021

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

2022

“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

QMM Program Development

Recent Milestones and Publications

- Two QMM Pilots: completed in 2022
- SBIA Workshop: May 24-25, 2022
- 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 Swatek³ · 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 Lundt¹ · Marcus Yambot¹ · Alex Viehmann¹ · Neil Stiber¹ · Kevin Gonzalez¹ · Lyle Canida¹ · Lucinda Buhse¹ · Michael Kopcha¹

April 2022

FDA 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

Program Under Development - 2023

Designed as a VOLUNTARY program!

Assessment & Rubric

Scoring System

Operational Decisions

Communications

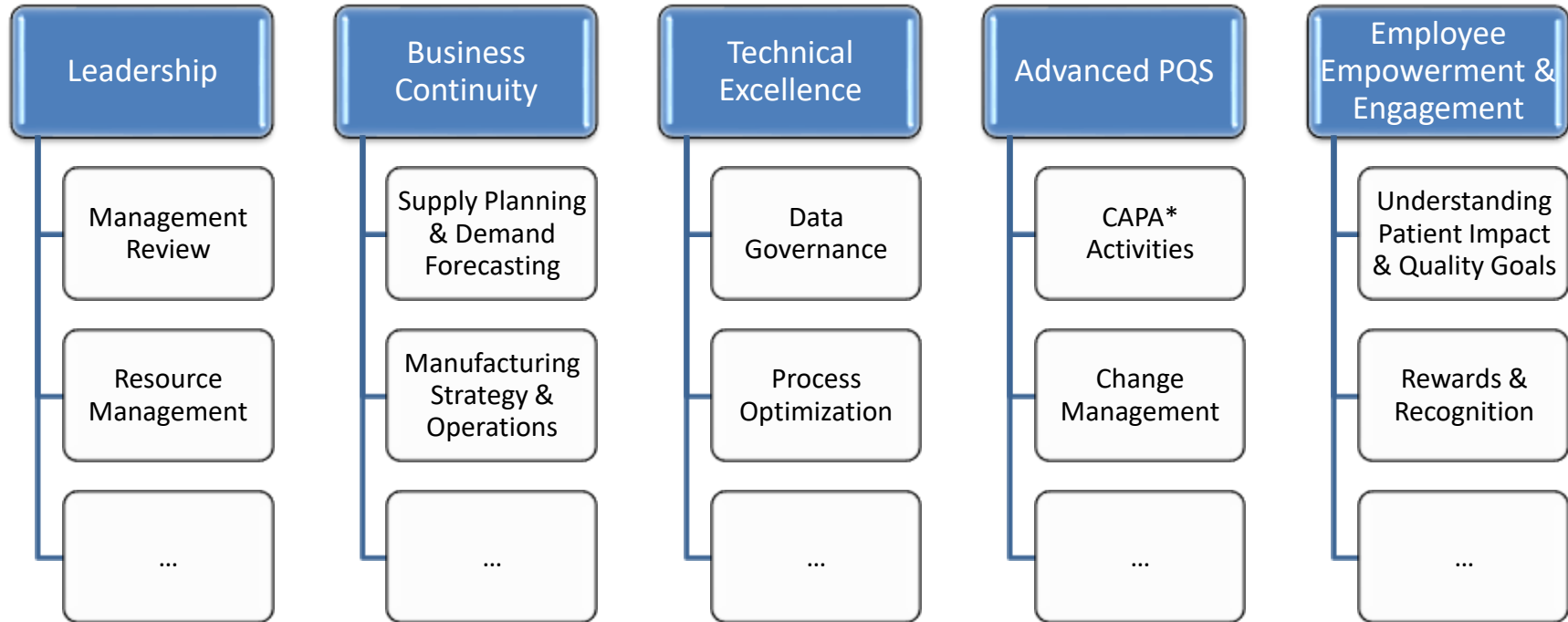
Guidance Development

IT Development

Implementation Planning

Assessment & Rubric

Practice Areas will be assessed according to a defined rubric.



*CAPA – Corrective Action and Preventive Action

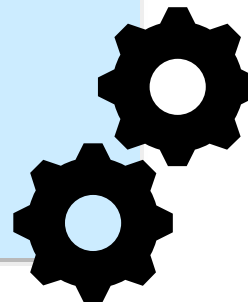
Scoring System

Scores need to be meaningful to participants indicating areas of strength and areas for improvement

- Develop scores for each practice area and an overall score for the site.
- Develop objective algorithm to score each Practice Area of the assessment
- Determine weighting for each Practice Area
- Provide scores and a benchmark against peers

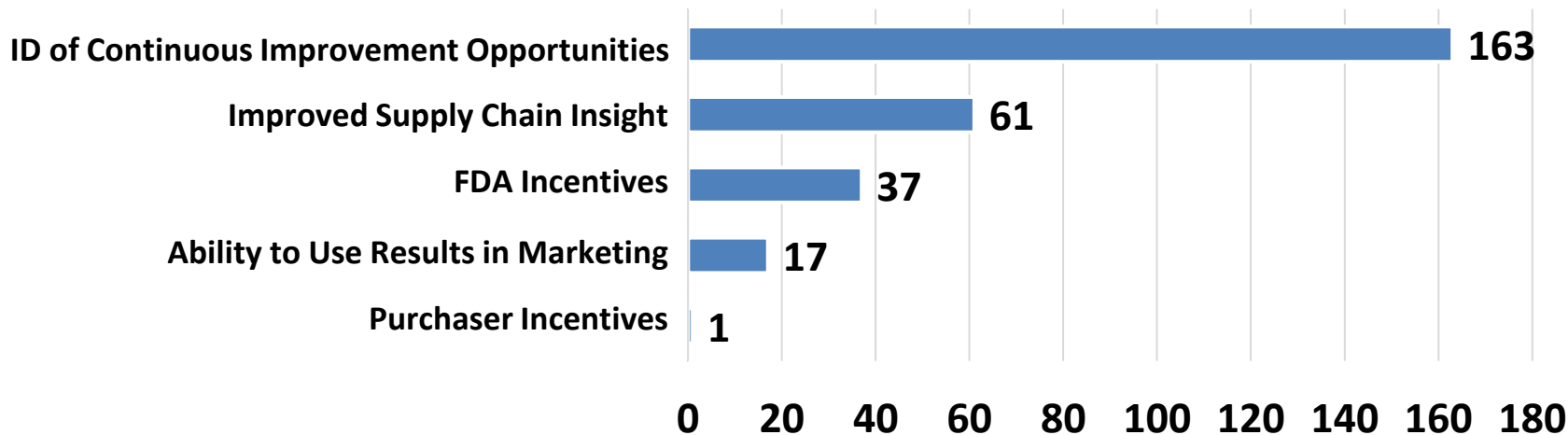
Operational Decisions

- Eligibility criteria (e.g., manufacture at least one CDER-regulated product)
- Executed by FDA and/or contractor
- Executed virtually and/or on-site
- Level of transparency
- Reassessment period
 - Shelf-life of assessment
 - Modified protocol
- Assigning a final rating
- Incentives for participation



Stakeholder Feedback on Incentives

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





Should QMM Ratings be Public?

There are key considerations for making a rating public:

- Publicizing ratings for a voluntary program might disincentivize participation
- Supply chain benefits the most if the least mature sites are incentivized to participate in the program
- Public information may be misinterpreted, e.g., establishment performance may be conflated with product quality
- Manufacturers could share ratings directly with purchasers

Communications

- Maximize benefits of the program
- Prevent unintended consequences
- Engage stakeholders to understand drivers and challenges
- Transparent development process
- Combat misconceptions





A QMM assessment is:

NOT intended to be used in lieu of, or as a surrogate for, establishment inspections. Does not evaluate CGMP* compliance.

A QMM rating is:

NOT a measure of product quality. It is an evaluation of an establishment's behaviors and quality practices.

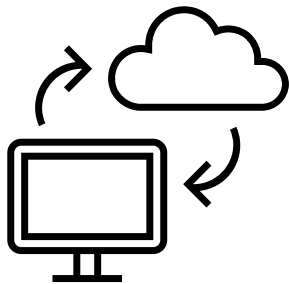
*CGMP – Current Good Manufacturing Practice

Guidance Development

- Drafting guidance to address topics such as
 - Eligibility criteria for voluntary participation
 - Components of the program
 - Incentives
- Opportunity for public comment

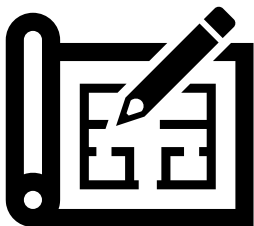


IT Development



- Developed an IT Roadmap to facilitate design and development in FY2024 and FY2025
- An IT system will:
 - Manage eligibility screening and scheduling of voluntary participants
 - Receive, exchange, and store data
 - Automate assessment scoring
 - Share final reports and visualizations

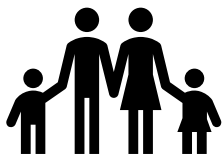
Implementation and Planning



- Funding
- Hiring
- Training
- Business process development

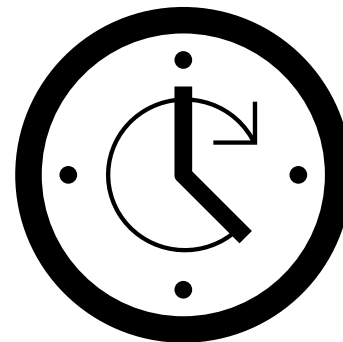
QMM is Valuable to All

- **Patients and Consumers** – Strengthens availability of drugs with fewer recalls and shortages
- **Manufacturers** – Enables continual improvement, promotes a robust supply chain, and informs selection of contract sites
- **Purchasers and Payers** – Enhances supply chain transparency and market knowledge with less need to respond to shortages
- **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
- **FDA** – Enhanced risk-based allocation of surveillance tools



The Future: Proactive Regulation

- QMM is one piece of achieving supply chain resiliency
- Other programs also move toward proactive regulation:
 - CDER's Emerging Technology Program
 - CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative
 - Holistic Supply Chain Understanding
 - International Regulatory Harmonization



No one can do this alone...



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

