Quality Management Maturity (QMM)

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Pharmaceutical Quality Symposium 2023


Everyone deserves
confidence in their *next* dose
of medicine.
Pharmaceutical quality
assures the
availability,
safety,
and efficacy
of *every* dose.


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

A Potential Solution to Drug Shortage

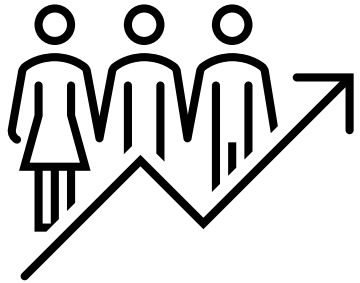
- Root Cause: ***The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues***

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

Participation in the QMM Program will be Voluntary!

Understanding QMM

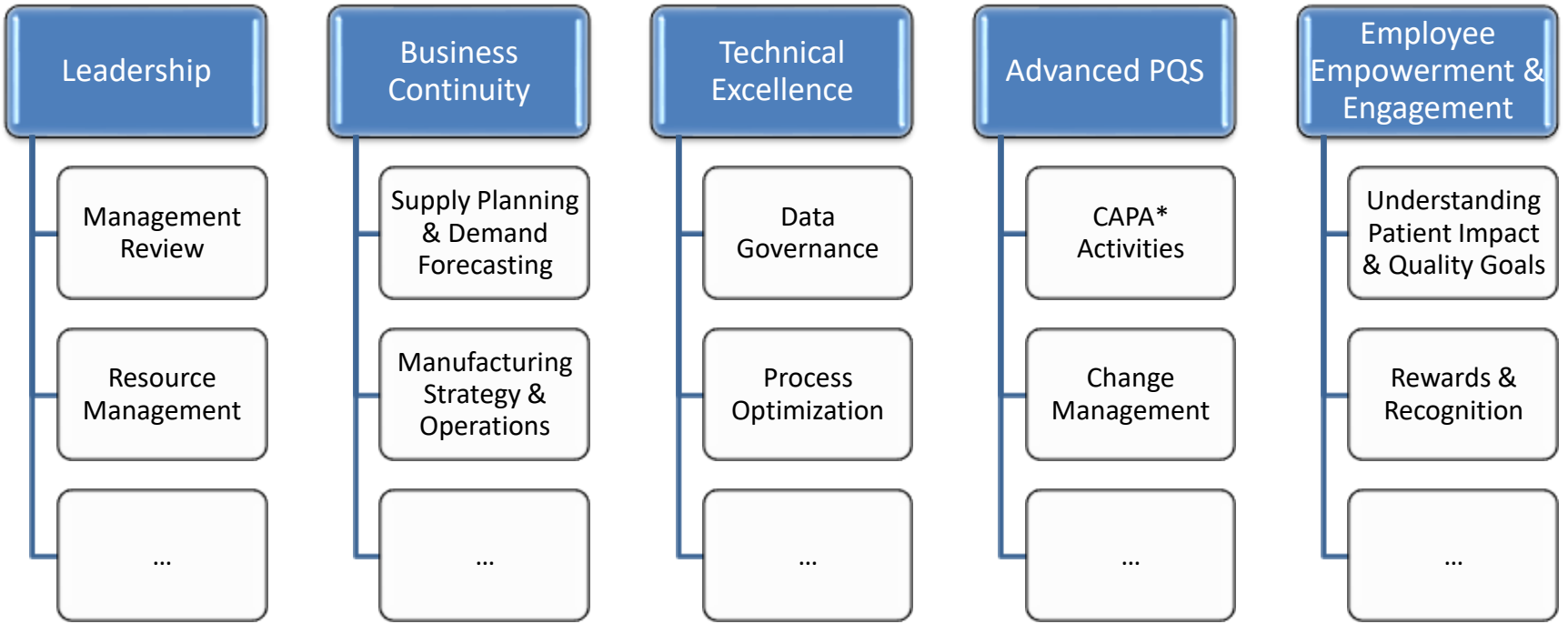
Drug manufacturers achieve higher levels of maturity when they successfully integrate business and manufacturing operations with quality practices and technological advancements to optimize product quality, enhance supply chain reliability, and drive continual improvement.




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

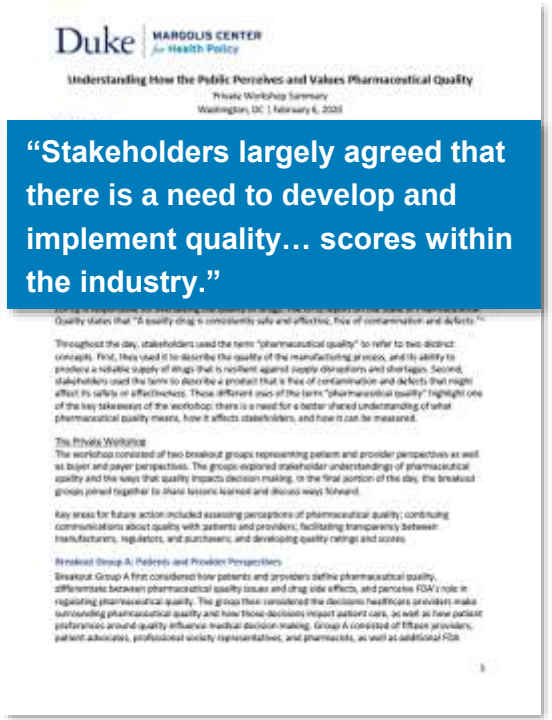
- "Quality always costs less" – W. Edwards Deming
  - Achieving quality outcomes requires investment
  - Good quality does not imply higher costs
  - Organizations whose quality practices are the most sophisticated are not necessarily the ones that spend the most
- Cost of poor quality – Loss of production, 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

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."

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

THE WHITE HOUSE

2022


The National Academies of SCIENCES · ENGINEERING · MEDICINE

CONSENSUS STUDY REPORT

MEDICAL PRODUCT SUPPLY CHAINS

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

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 Fellows[1] · Thomas Friedli[2] · Ye Li[3] · Jennifer Maguire[3] · Nandini Rakala[3] · Marten Ritz[2] · Matteo Bernasconi[2] · Mark Seiss[1,4] · Neil Stiber[3] · Mat Swatek[1] · Alex Viehmann[3]

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

January 2023

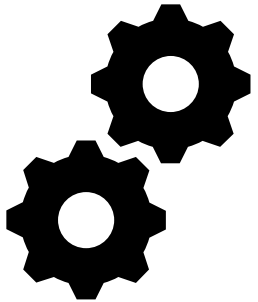
COMMENTARY

Lessons from CDER's Quality Management Maturity Pilot Programs

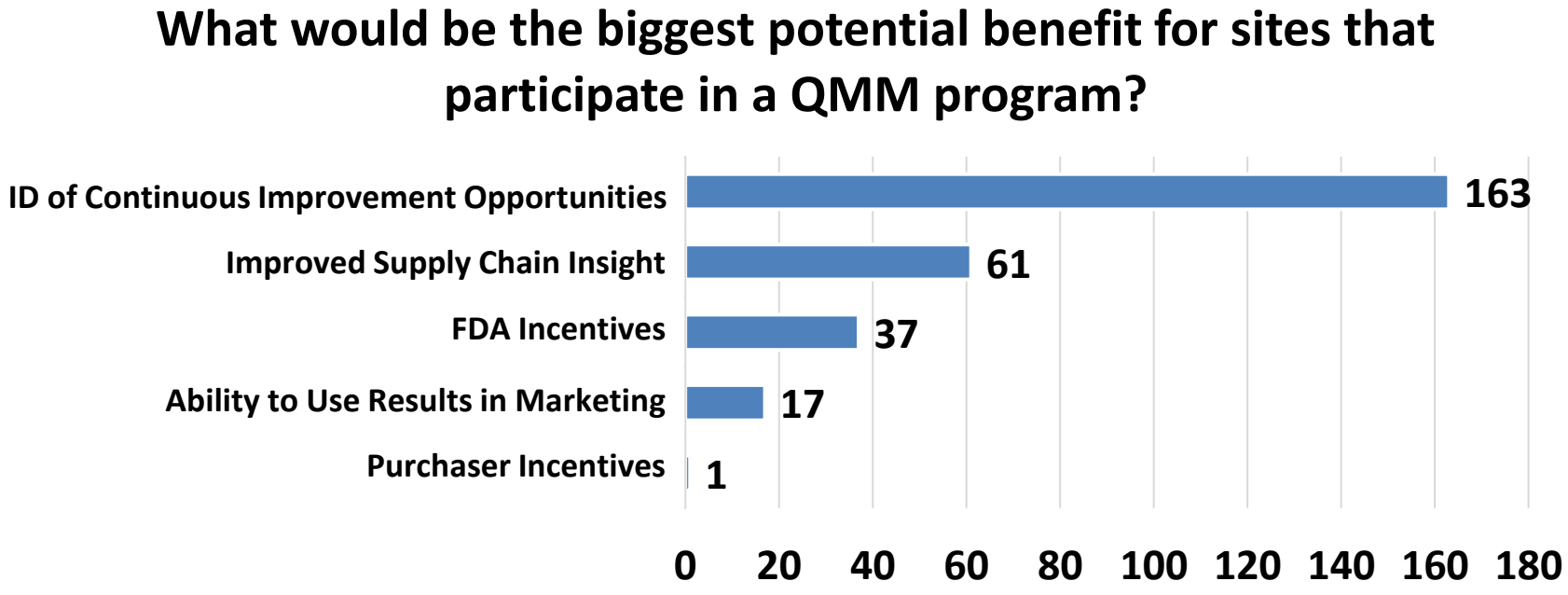
Jennifer Maguire[1] · Adam Fisher[1] · Djamila Harouaka[1] · Nandini Rakala[1] · Carla Lundi[1] · Marcus Yambot[1] · Alex Viehmann[1] · Neil Stiber[1] · Kevin Gonzalez[1] · Lyle Canida[1] · Lucinda Buhse[1] · Michael Kopcha[1]

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



Addressing Common Misconceptions

QMM ≠ QM; QMM = ƒ(use of quality metrics, x, y, z…)

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

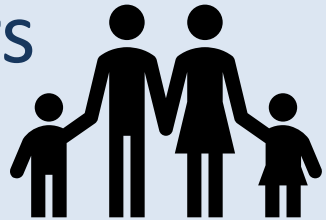
*CGMP – Current Good Manufacturing Practice

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

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