The Importance of Quality Throughout the Drug Supply Chain

Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting

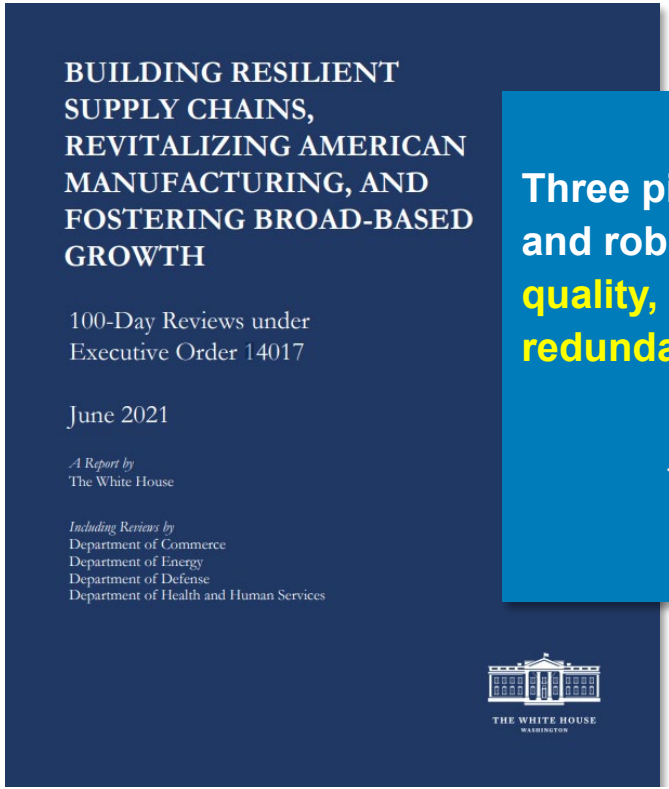
November 2, 2022

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Supply Chain Vulnerabilities

US FDA Center for Drug Evaluation and Research

The Three Pillars

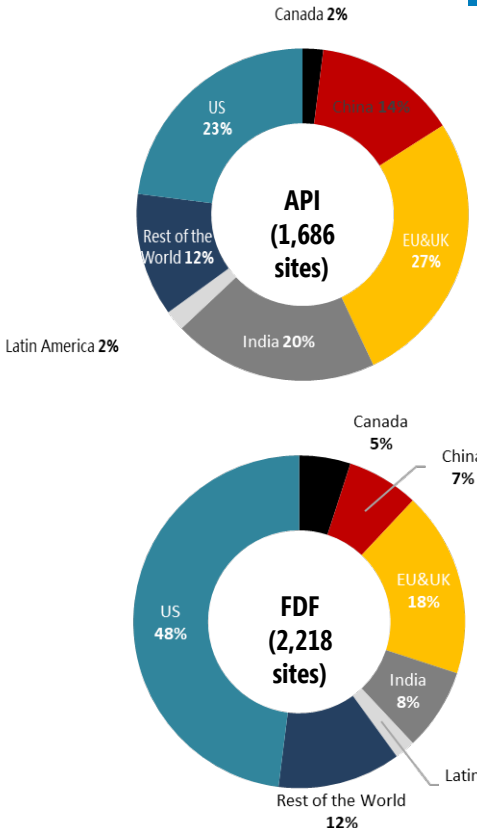


Three pillars of a secure and robust supply chain are quality, diversification, and redundancy.

– 100-Day Report by The White House

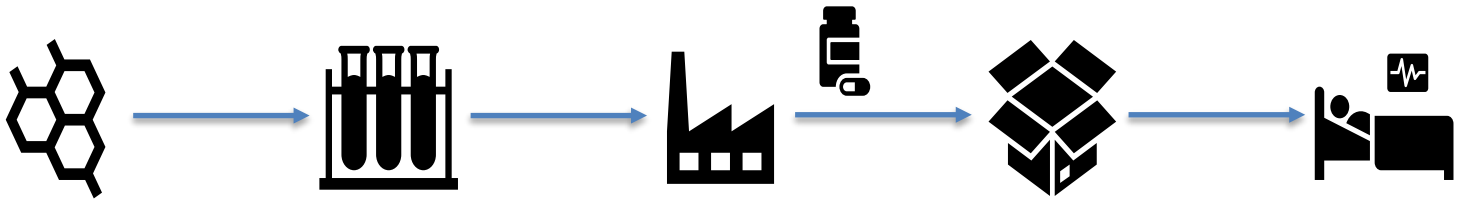
Quality: A Global Challenge

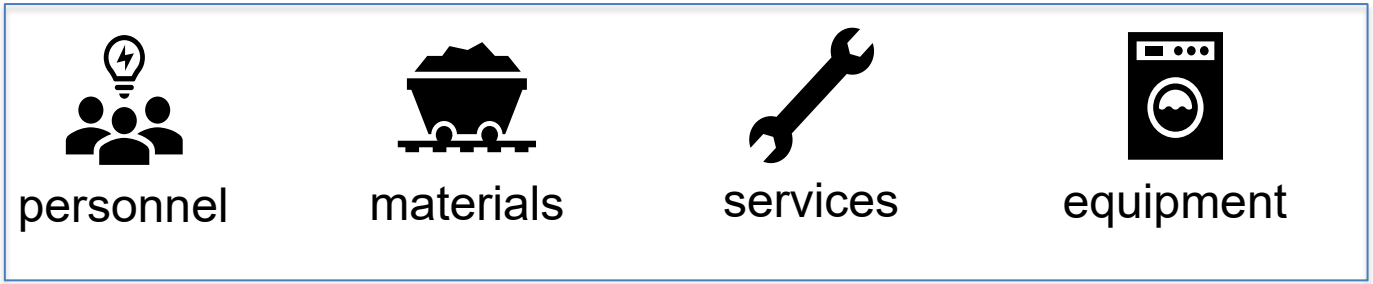
- **More than 75%** of active pharmaceutical ingredient (API) sites are outside of the US
- **More than 50%** of finished drug formulation (FDF) sites are outside of US
- Many products **launch** globally
- Regulatory strategies must be **data-driven** and **risk-based**



**FY2021 Report on the State of Pharmaceutical Quality*

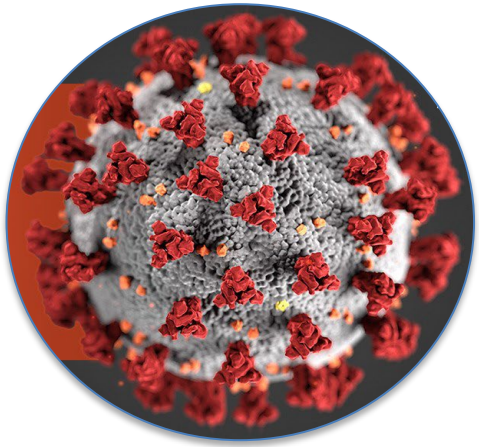
Supply Chains in the Era of COVID





Challenges from COVID

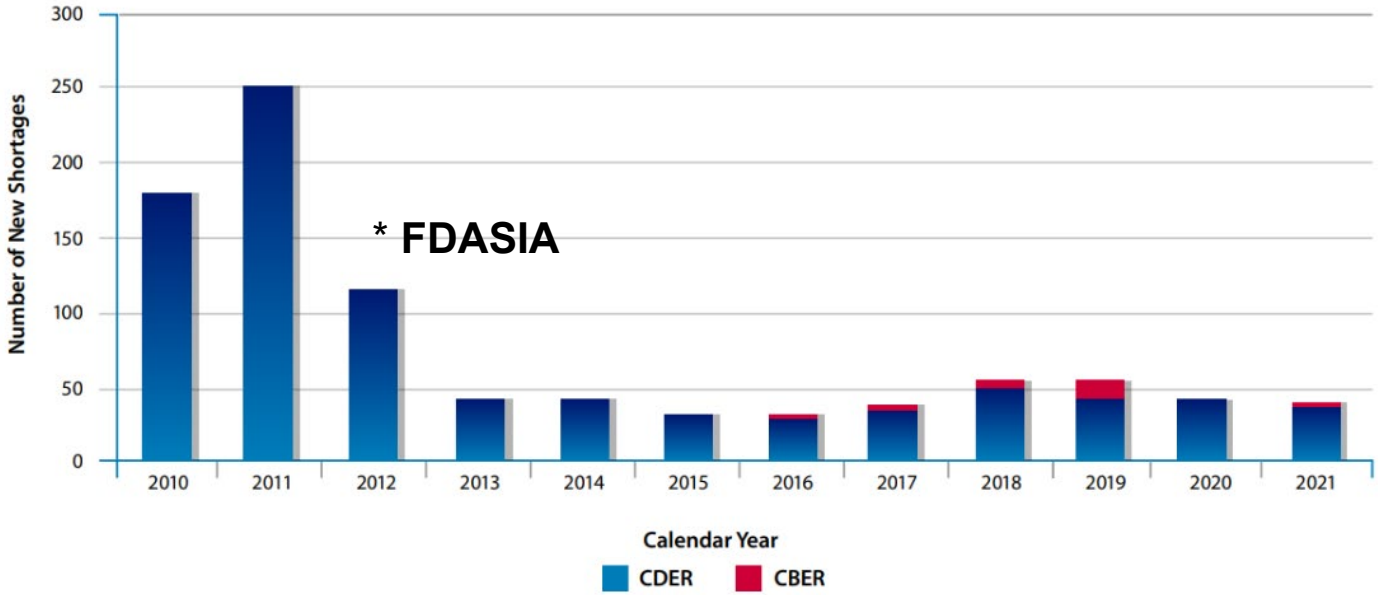
- ❑ Sudden, increased, local demand
- ❑ Competition on manufacturing lines in facilities due to limited capacity
- ❑ Supply of manufacturing components and other commodities
- ❑ Manpower and logistical challenges posed by public health safety measures



Drug Shortages

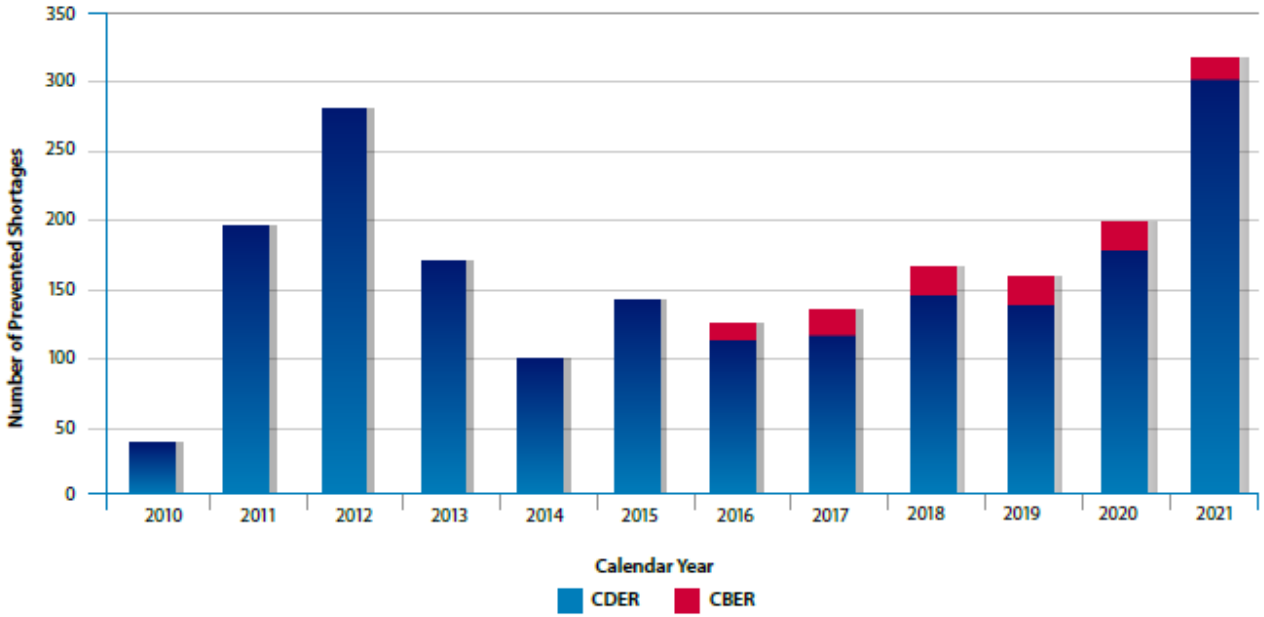
US FDA Center for Drug Evaluation and Research

Historical Drug Shortages



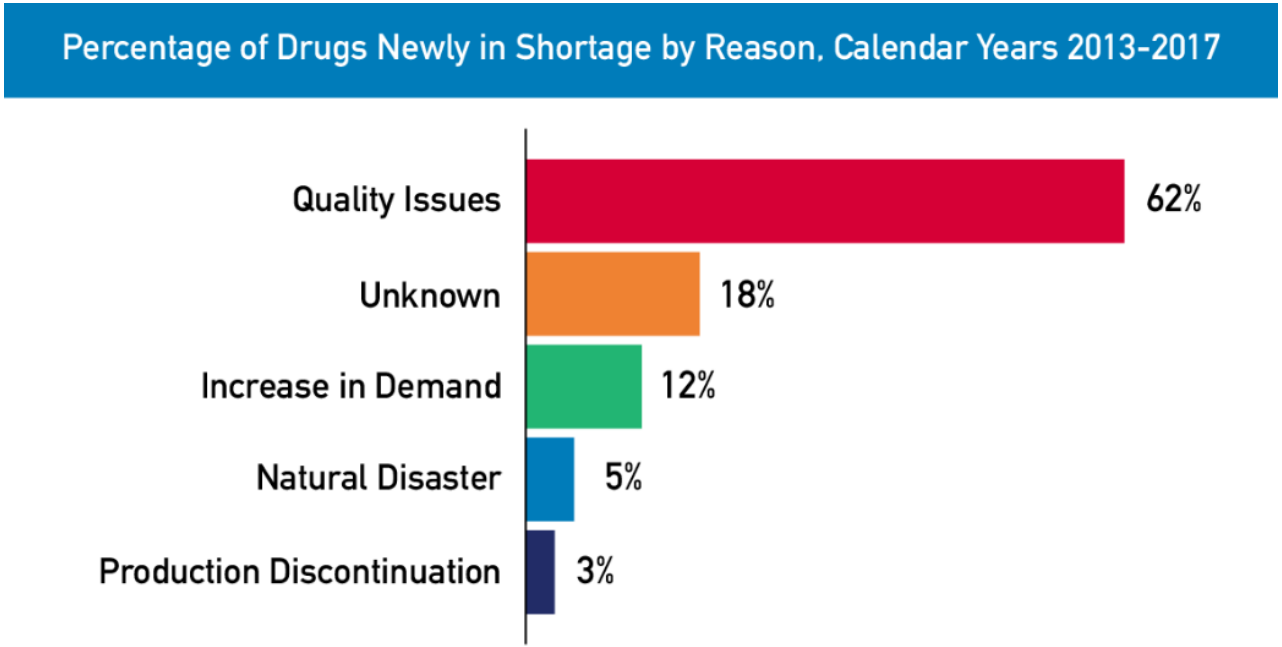
**FDASIA – Food and Drug Administration Safety and Innovation Act*
FDA Report to Congress - Drug Shortages for Calendar Year 2021

Historical Drug Shortages



FDA Report to Congress – Drug Shortages for Calendar Year 2021

Historical Reasons for Drug Shortages



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

Source: Internal FDA Data

Root Causes and Potential Solutions

- **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

- **Recommendation**

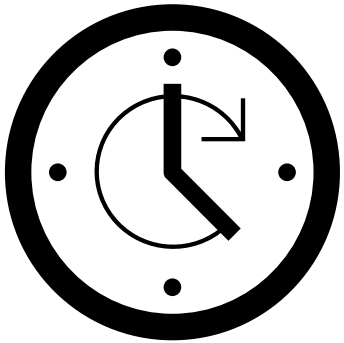
  Developing a rating system to incentivize drug manufacturers to invest in QMM

In Closing

US FDA Center for Drug Evaluation and Research

The Future: Proactive Regulation

- ❑ CDER's Emerging Technology Program
- ❑ Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative
- ❑ Holistic Supply Chain Understanding
- ❑ International Regulatory Convergence
- ❑ QUALITY MANAGEMENT MATURITY PROGRAM




FDA
Patients deserve quality medicines that are available when they need them.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ADMINISTRATION

The Future of Pharmaceutical Quality

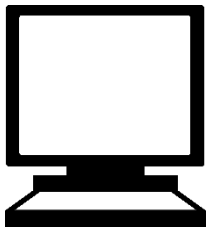
Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting

November 2, 2022

Michael Kopcha, Ph.D., R.Ph.
Director
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.



Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.

Drugs are no different.


FDA
Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is

assuring *every* dose is safe and effective, free of contamination and defects.


It is what gives patients confidence
in their *next* dose of medicine.

An Array of Quality

Pharmaceutical Quality

*Gives patients confidence in their **next** dose of medicine*

*Gives manufacturers confidence every batch will be **acceptable to release***	**QUALITY MANAGEMENT**	Performance and patient focus identifies areas of improvement and implements changes
*Gives manufacturers confidence in every batch they **release***	**PROCESS QUALITY**	Manufacturing risks are controlled to provide a quality drug product
*Gives patients confidence in every dose they **take***	**PRODUCT QUALITY**	Every dose is safe and effective and free of contamination and defects

CDER's Office of Pharmaceutical Quality

- ❑ Assessment
- ❑ Surveillance
- ❑ Inspection
- ❑ Research
- ❑ Policy

CDER's Site and Product Catalog

Sites:

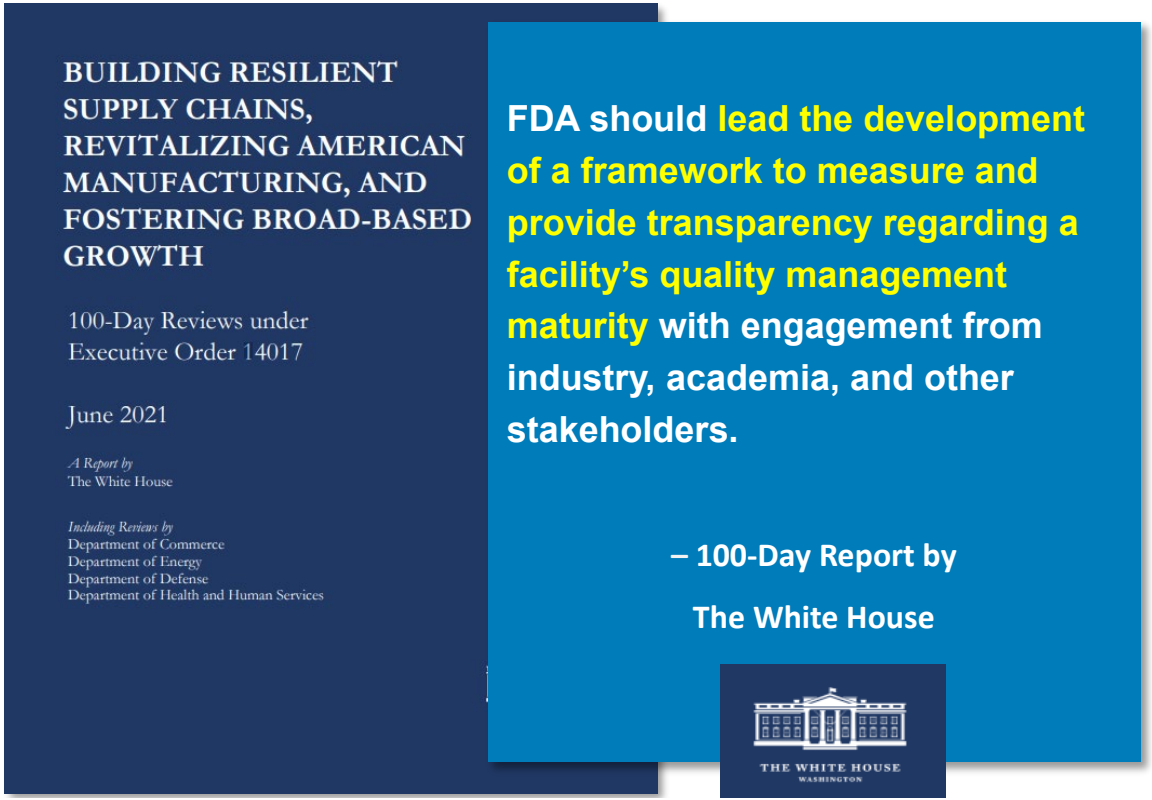
- ❑ **7,000** human drug manufacturing sites of obligation
- ❑ **2,000** medical gas manufacturers (nearly all in U.S.)
- ❑ **600** hand sanitizer sites
- ❑ Includes **active pharmaceutical ingredient** and **finished dosage form** sites

Products:

- ❑ **170,000** finished dosage forms
- ❑ **19,000** active pharmaceutical ingredients
- ❑ **1,500** medical gases
- ❑ Includes **new drugs** and **biologics**, **generics**, **biosimilars**, **over-the-counter** drugs

**Based on June 2022 CDER Site & Product Catalogs and unique NDCs*

Challenge: Transparency



Quality Management Maturity

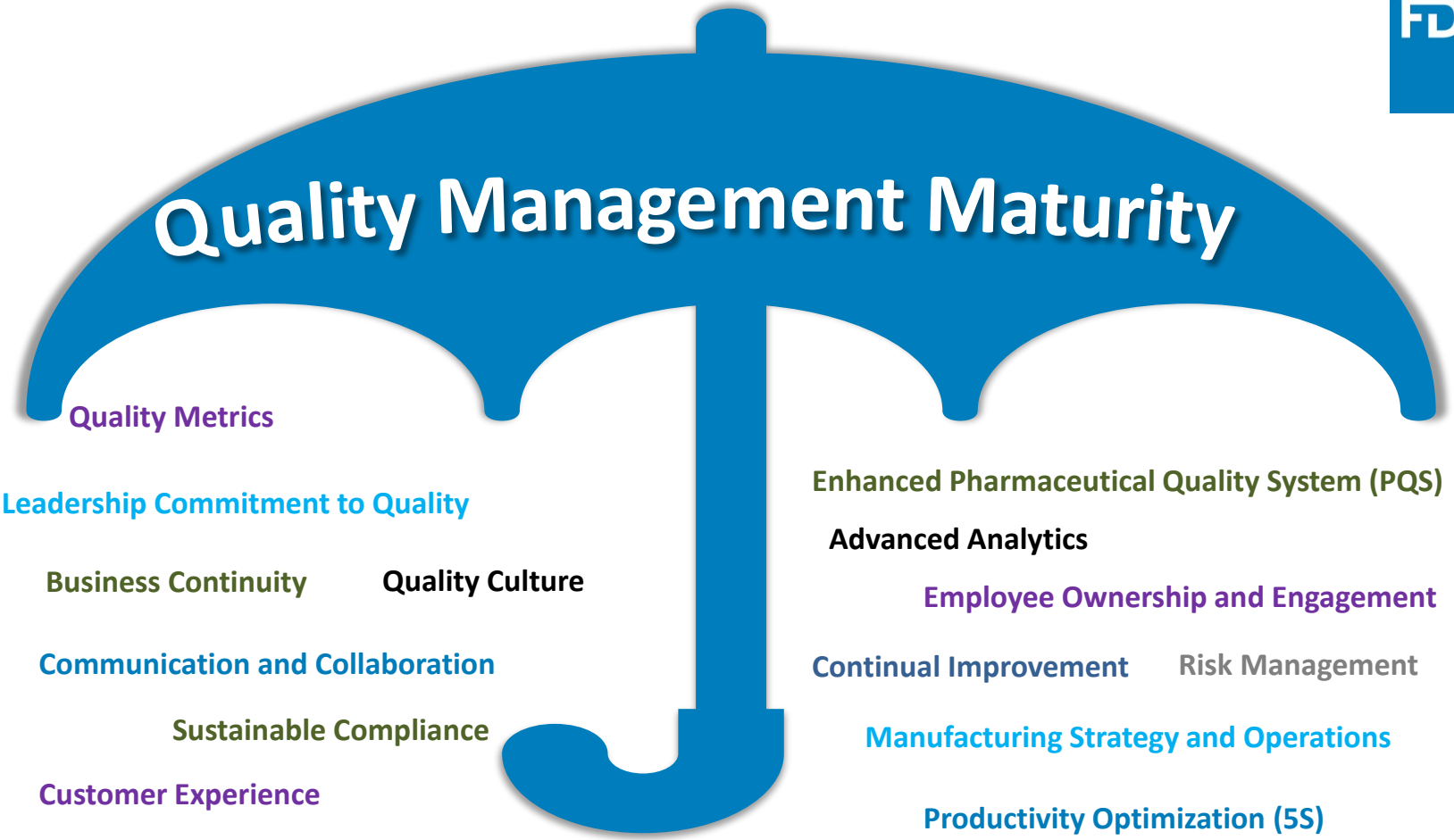
US FDA Center for Drug Evaluation and Research

Data for Regulatory Innovation

LAGGING INDICATORS → LEADING INDICATORS

- Quality Defect Reports
- Drug Sampling and Testing Results
- External data
- Application data
- Inspection Data

- Quality Management Maturity Ratings
- Quality Metrics


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)

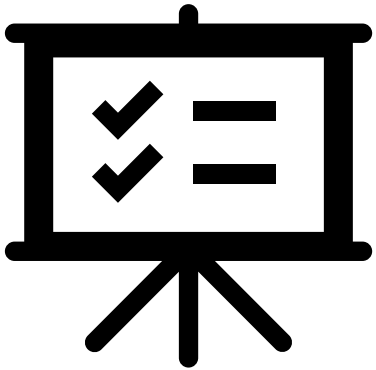
QMM ≠ QM

QMM =f(QM, x, y, z…)

Foundation of Science

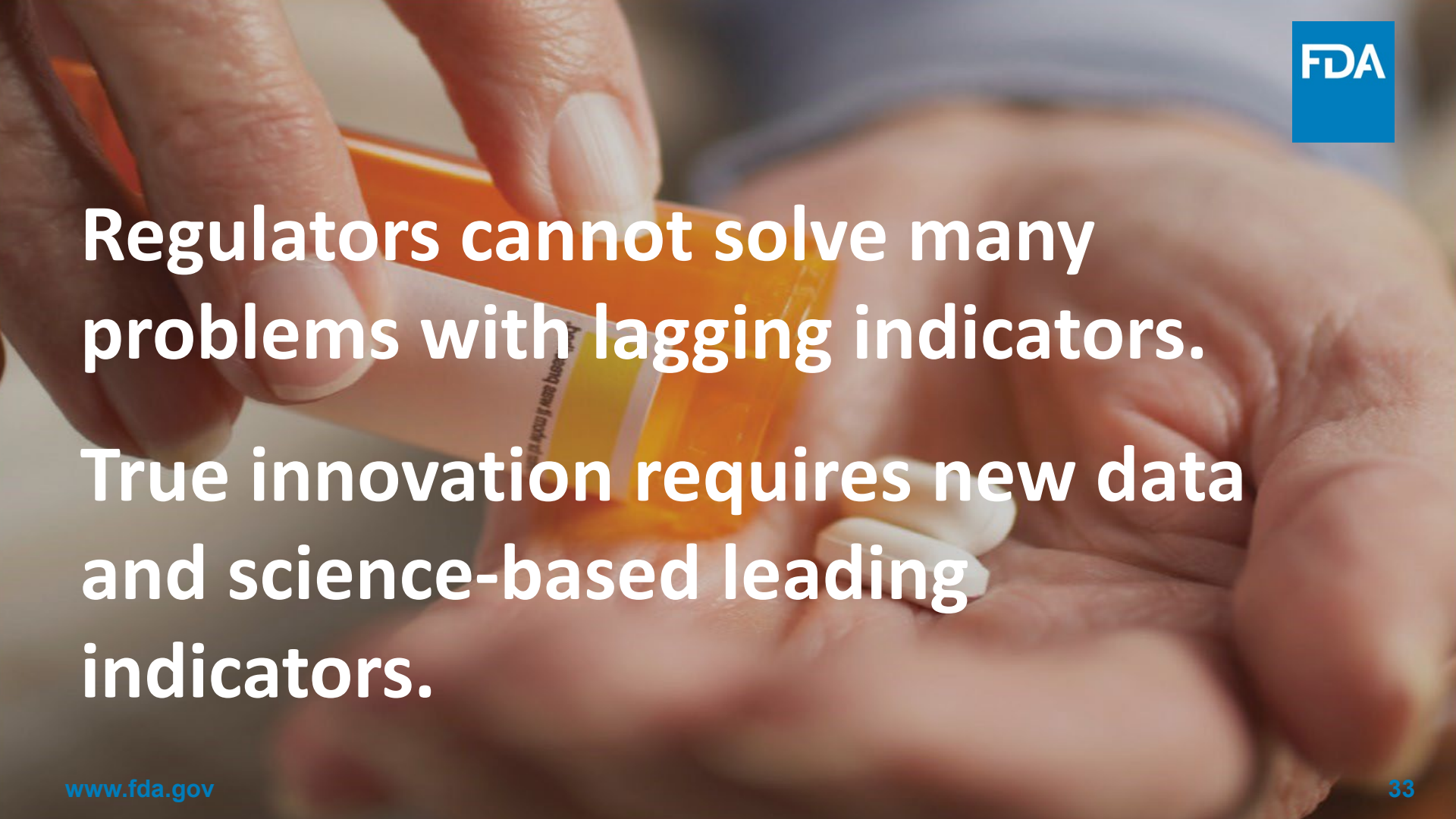
Today's Agenda Topics

- ❑ Lessons learned from FDA's QMM program
- ❑ Stakeholder perspectives
- ❑ FDA's vision for QMM
- ❑ Potential benefits to stakeholders and FDA



In Closing

US FDA Center for Drug Evaluation and Research



Regulators cannot solve many problems with lagging indicators.

True innovation requires new data and science-based leading indicators.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QMM Lessons Learned

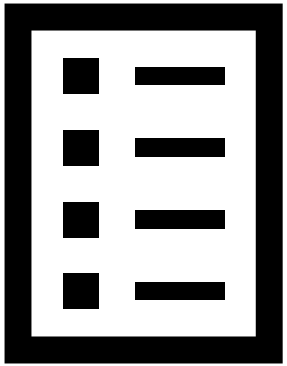
Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting

November 2, 2022

Jennifer Maguire, Ph.D.
Director
Office of Quality Surveillance
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

AGENDA

- ❑ Understanding Quality Management Maturity (QMM)
- ❑ FDA's Pilot Programs and related activities – Lessons Learned
- ❑ Economic Analysis – Key Findings



Understanding Quality Management Maturity (QMM)

US FDA Center for Drug Evaluation and Research

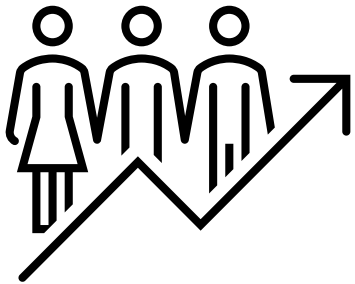
Why Develop a QMM Program?

The Report on Drug Shortages: Root Causes and Potential Solutions (2019) identified one potential root cause of drug shortages was that *the market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues.*

An enduring solution proposed was to *develop a rating system to incentivize drug manufacturers to* ***voluntarily*** *invest in 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.



FDA's QMM Pilot Programs and Related Activities – Lessons Learned

US FDA Center for Drug Evaluation and Research

QMM Pilot Programs (2021-2022)

- **Two pilots:**
  - Finished Dosage Form Pilot Program – 7 domestic sites
  - Active Pharmaceutical Ingredient Pilot Program – 8 foreign sites
- **Assessments should enable:**
  - Establishing best practices and identifying continuous improvement opportunities
  - Protocols and associated scoring that maximize inter-rater reliability and provide a quantitative overall rating
  - Cross-sectional comparison against industry peers
- **Assessed multiple practice areas:**
  - Leadership and Governance
  - Stakeholder Engagement and Satisfaction
  - Quality Culture
  - Continual Improvement
  - Workforce Engagement
  - Sustainability

FDA's Role

FDA participated in the pilot as spectators to observe and learn. Lessons learned from the pilots will be used to help FDA:

- ✓ Identify mature quality management practices
- ✓ Develop assessment framework
- ✓ Develop scoring system
- ✓ Perform assessments
- ✓ Provide QMM assessment scores
- ✓ Provide reports to participants

QMM Assessment Protocol – Key Learnings

Preparation

- Orient participants, set expectations, schedule appropriate staff
- Provide examples of documentation used to substantiate QMM score

Protocols

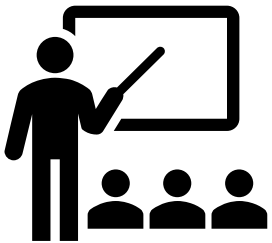
- Streamline topic areas and number of questions
- Consider sector-specific questions
- Separate questions for corporate vs. site staff

Discussion

- Speak with management and staff separately

Time Management

- Strict time limit per question was not effective strategy

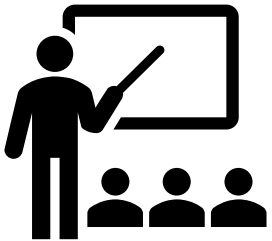


Developing a Rubric to Score QMM Assessments

- The QMM pilot program contractors independently developed rubrics used to define criteria for how scores were assigned.
- Scores were generated for each practice area in addition to a final aggregated score reflecting all practice areas.
- Development of the rubric is dependent on the practice areas that will be evaluated and verification of participant responses through suitably identified supporting information.

Pilot Scoring Approach – Key Learnings

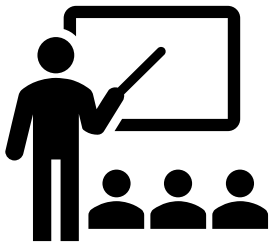
- **Objective criteria to discern between levels are critical**
  - Multiple assessors may be needed to minimize bias
  - Need objective approach for managing conflicting scores to reduce bias
- **Streamline scoring rubric to allow less room for interpretation and improve scoring precision**
  - Maximize inter-rater reliability
  - Maximize consistency in scoring



Assessor Behaviors – Key Learnings

Training

- ❑ Distinguish above-the-bar behaviors from CGMP* compliance
- ❑ Interview skills – avoid leading questions, put staff at ease
- ❑ Remain neutral – do not impose opinions
- ❑ Understand the audience
- ❑ Repeat questions when necessary
- ❑ Allow enough time for staff to respond
- ❑ Stay on topic



**CGMP – Current Good Manufacturing Practice*

Examples of Participant Feedback

Pilot participant feedback shows positive sentiment for the program

The assessment results will be used for the improvement of processes and programs and for communication within the corporate organization.

In the same way that QMM data is useful in assessing a potential API supplier, the data could be useful in assessing a contract lab or other contract facility.*

We could envisage using the QMM score to reduce the frequency, content, and time spent on vendor audits.

We will look at various behaviors/actions listed in each maturity level and strive to move to the next level.

**API – Active Pharmaceutical Ingredient*

Economic Analysis

OPQ funded research with the University of Maryland through the FDA's Centers of Excellence in Regulatory Science and Innovation (CERSI) program.

- **Goal:** Identify effects of a quality rating system on drug product market structure including dis/incentives for manufacturers to strengthen their processes.
- **Findings:**
  - Market is characterized by an asymmetric information problem.
  - Absent a standardized methodology to assess differences in manufacturing quality, the market is unable to differentiate drug products based on manufacturing quality.
  - Despite a market characterized by price inelasticity, the analysis suggests that quality ratings should incent manufacturers to invest in quality.

Impact of QMM on Supply Networks

FDA applied a systems thinking approach to study possible direct and indirect effects of a QMM program on the end-to-end supply network.

- Engaged with offices including ORA, OQS, OPMA, DSS, and OMQ.
- Analyzed priorities and relationships between stakeholders.

Lessons Learned:

- Increased FDA's awareness of external factors that may affect stakeholders in the supply chain.
- It may be important to consider sector-specific incentives.

In Summary

- Lessons learned from the QMM Pilot Programs will help guide development and operational decisions in conjunction with findings from research initiatives and continued engagement with industry partners and other stakeholders.

- Sentiment about the QMM program has been overall positive!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Stakeholder Perspectives

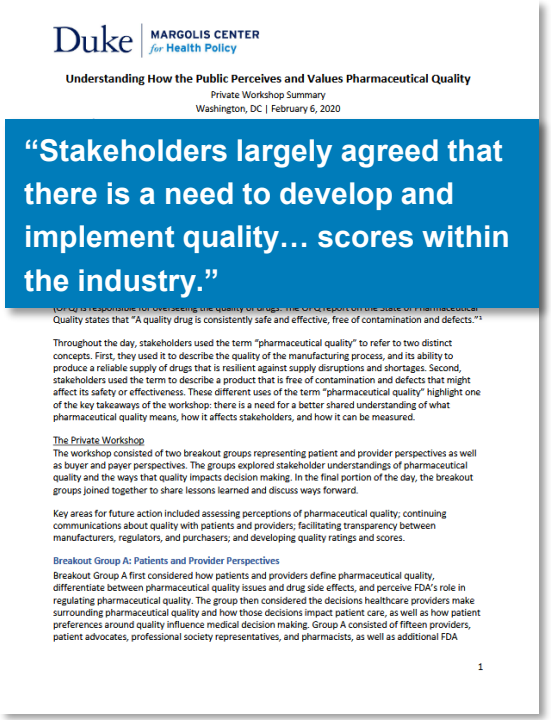
Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting

November 2, 2022

Adam Fisher, Ph.D.
Director, Science Staff—Immediate Office
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Road to a 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."

Quality states that "A quality drug is consistently safe and effective, free of contamination and defects."[1]

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

THE WHITE HOUSE
WASHINGTON

2022

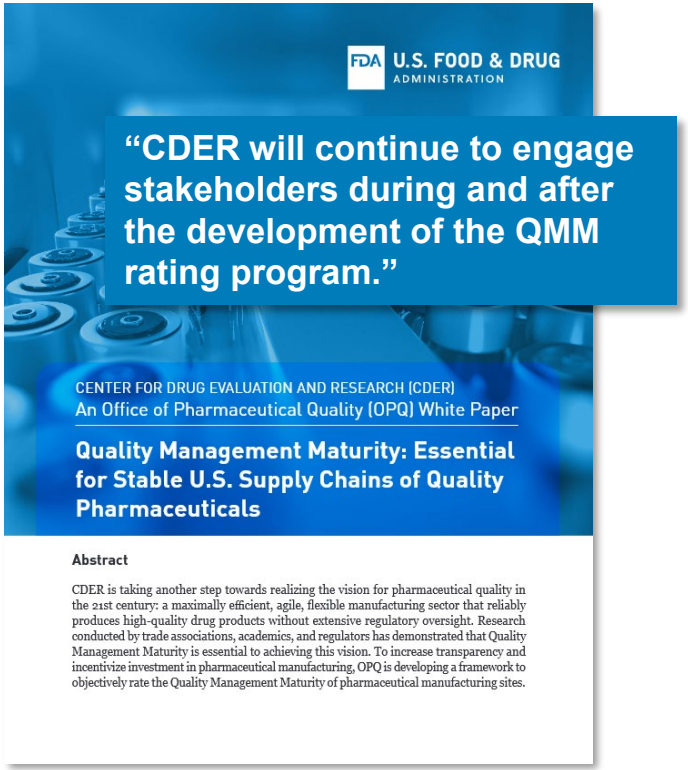
The National Academies of
SCIENCES · ENGINEERING · MEDICINE

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."

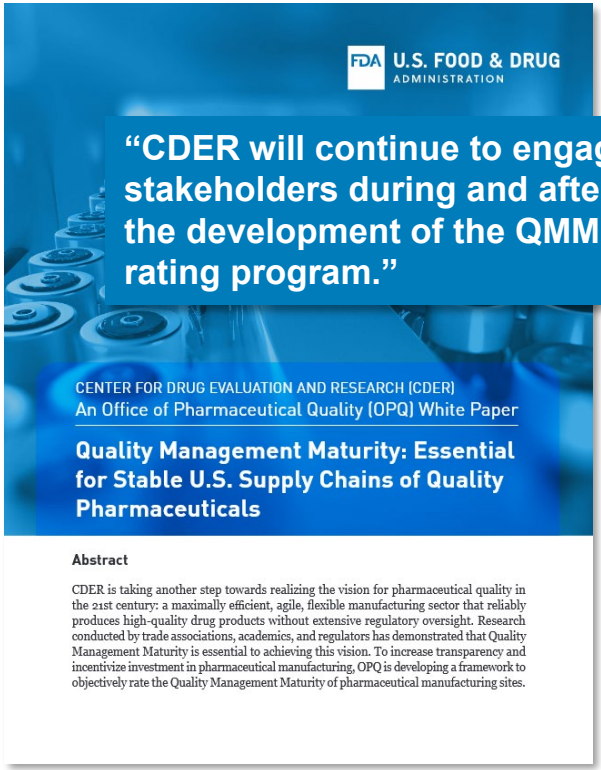
MEDICAL PRODUCT SUPPLY CHAINS

Engagements on the Road to QMM



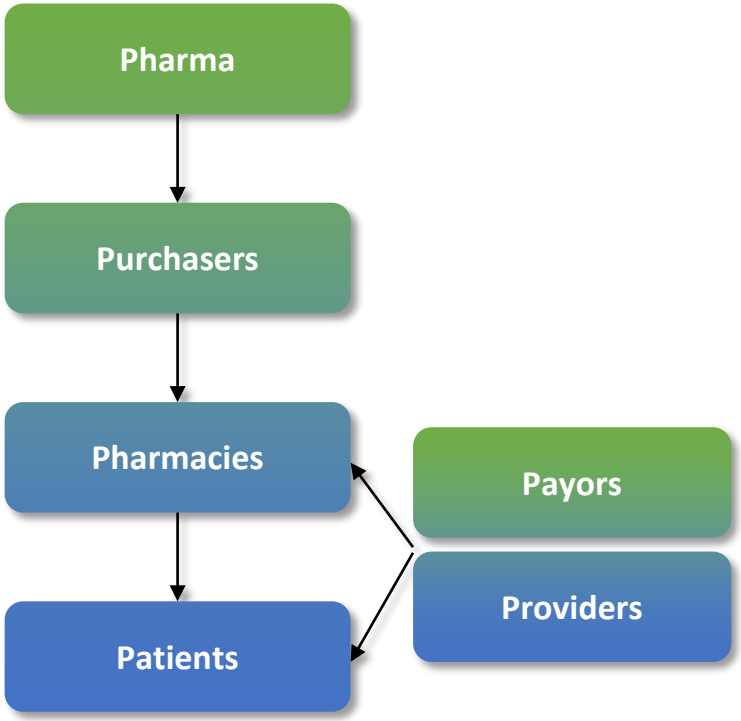
- **Stakeholder Meetings**
  - E.g., Duke-Margolis (Feb 3, 2020)
- **QMM Stakeholder Workshop**
  - May 24-25, 2022
- **Pharmaceutical Science and Clinical Pharmacology Advisory Committee**
  - Today

Engagements on the Road to QMM



- ❑ Key Challenges Identified with Stakeholders
- ❑ Key Elements of a Program Identified with Stakeholders
- ❑ Feedback from Workshop Stakeholders

“6 Ps” Impacted by QMM Ratings



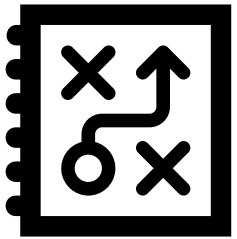
Key Challenges Identified with Stakeholders

US FDA Center for Drug Evaluation and Research

Key Challenges to Achieving QMM

Clearly defining the scope and meaning of QMM ratings

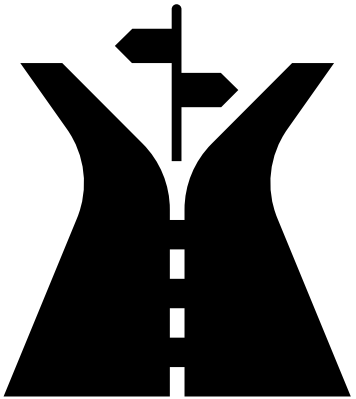
- ❑ Stakeholders use “pharmaceutical quality” in different ways (e.g., product, process, facility, supply chain)
- ❑ Ratings will reflect the QMM at a manufacturing site and not the quality of the product or process
- ❑ High QMM ratings will not be a “guarantee” for a site’s products

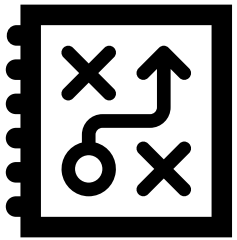


Key Challenges to Achieving QMM

Convincing purchasers to consider QMM in decision-making

- ❑ Perception that QMM exists if the drug has been approved by FDA
- ❑ Describe the value of using QMM in purchasing decisions

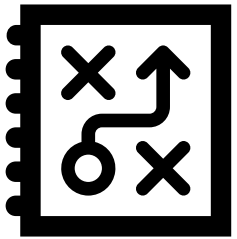




Key Challenges to Achieving QMM

Separating QMM assessments from CGMP* inspections

- ❑ Transparency, engagement, and collaboration are critical
- ❑ QMM assessments will be a CDER surveillance function

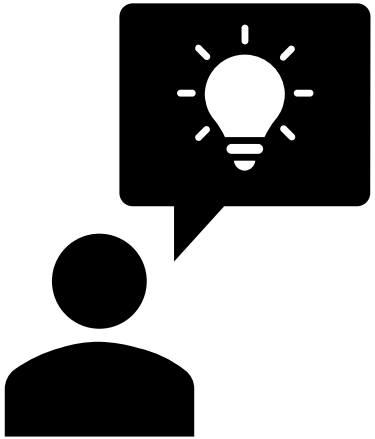


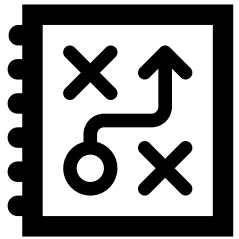
*CGMP – Current Good Manufacturing Practice

Key Challenges to Achieving QMM

Relying on purchasers to understand their supply chains

- ❑ Purchasers must know the specific facilities manufacturing the drugs or components they purchase (esp. APIs*)
- ❑ FDA may not be able to disclose specific information about the drug product supply chain
- ❑ Most purchasers already require supply chain site information as part of their decision-making process



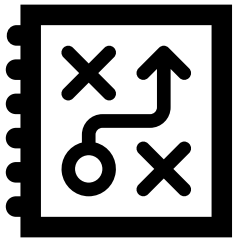


**APIs – Active Pharmaceutical Ingredients*

Key Challenges to Achieving QMM

Relying on the market to reward facilities with higher QMM

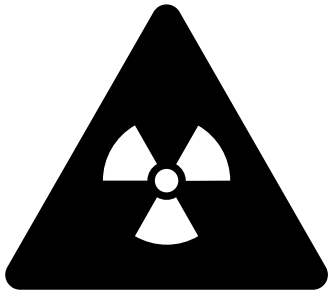
- ❑ QMM ratings should incentivize continual improvement
- ❑ But not over-consolidate the market and/or markedly raise purchasing costs
- ❑ Research may be needed to avoid unintended consequences, such as market over-consolidation

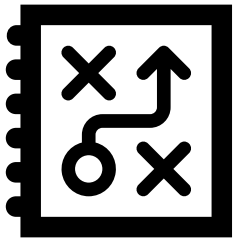


Key Challenges to Achieving QMM

Addressing potential risks of QMM in decision-making

- ❑ Healthcare professional responsibility/liability
  - Ratings based on manufacturing sites not products
- ❑ Use of QMM ratings in marketing





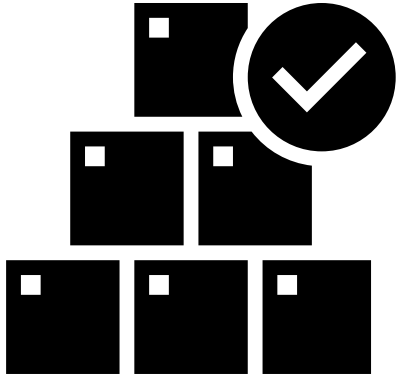
Key Elements of a Program Identified with Stakeholders

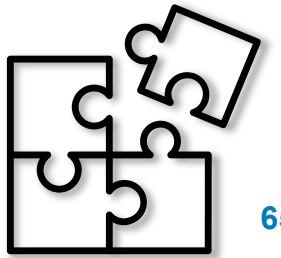
US FDA Center for Drug Evaluation and Research

Key Elements of a QMM Program

Quality culture must be foundational

- ❑ Culture must be led from the top
- ❑ Objectives drive quality
  - Integrated business and quality objectives

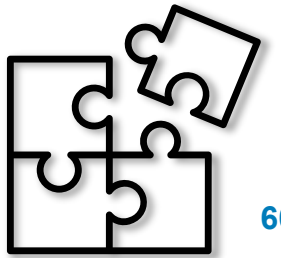




Key Elements of a QMM Program

Assessment must be objective, consistent, standardized, and validated

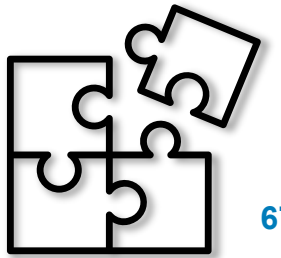
- ❑ True whether carried out by FDA or contractor
- ❑ Scope must be distinct from determining CGMP compliance



Key Elements of a QMM Program

Transparency is critical

- ❑ Understanding the intentions of the program and the impact on drug shortages and patient/consumer outcomes
- ❑ Must be clear that all drugs sold in the U.S. are of adequate quality and considered safe and effective
- ❑ A universal understanding will be needed
  - Broad communication to the public

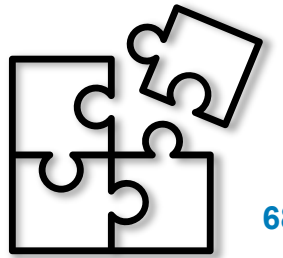


Key Elements of a QMM Program

There must be clear incentives

- ❑ Reduced inspection frequency, increased regulatory flexibility for postapproval changes (ICH* Q12), and improved supply chain insight
- ❑ There is a cost to supply disruptions and shortages
- ❑ Healthcare professionals, pharmacies, and patients may need to advocate for the use of QMM ratings

★★★



*ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Feedback from Workshop Stakeholders

US FDA Center for Drug Evaluation and Research

QMM Workshop Feedback

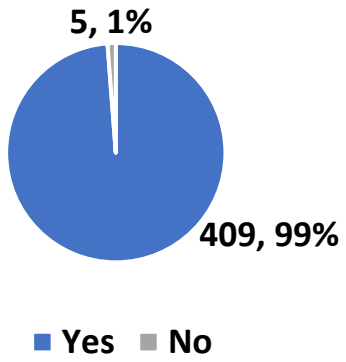
VIRTUAL

Quality Management Maturity Workshop

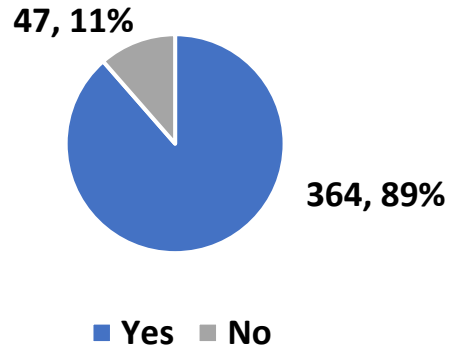
MAY 24 - 25, 2022

Stakeholders on a QMM Program

Should purchasers of drug products or active pharmaceutical ingredients consider the quality management maturity of the facility/manufacturer that manufactures them?

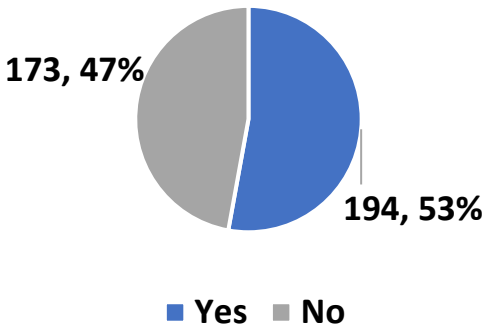


Do you believe that information on the quality management maturity of facilities making drug products or active pharmaceutical ingredients will improve decision-making in the pharmaceutical supply chain?

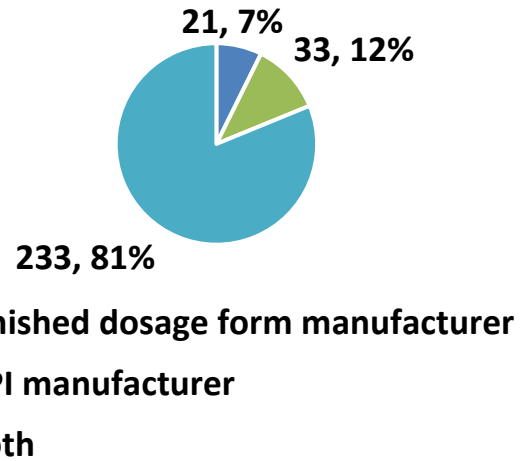


Stakeholders on Shortages

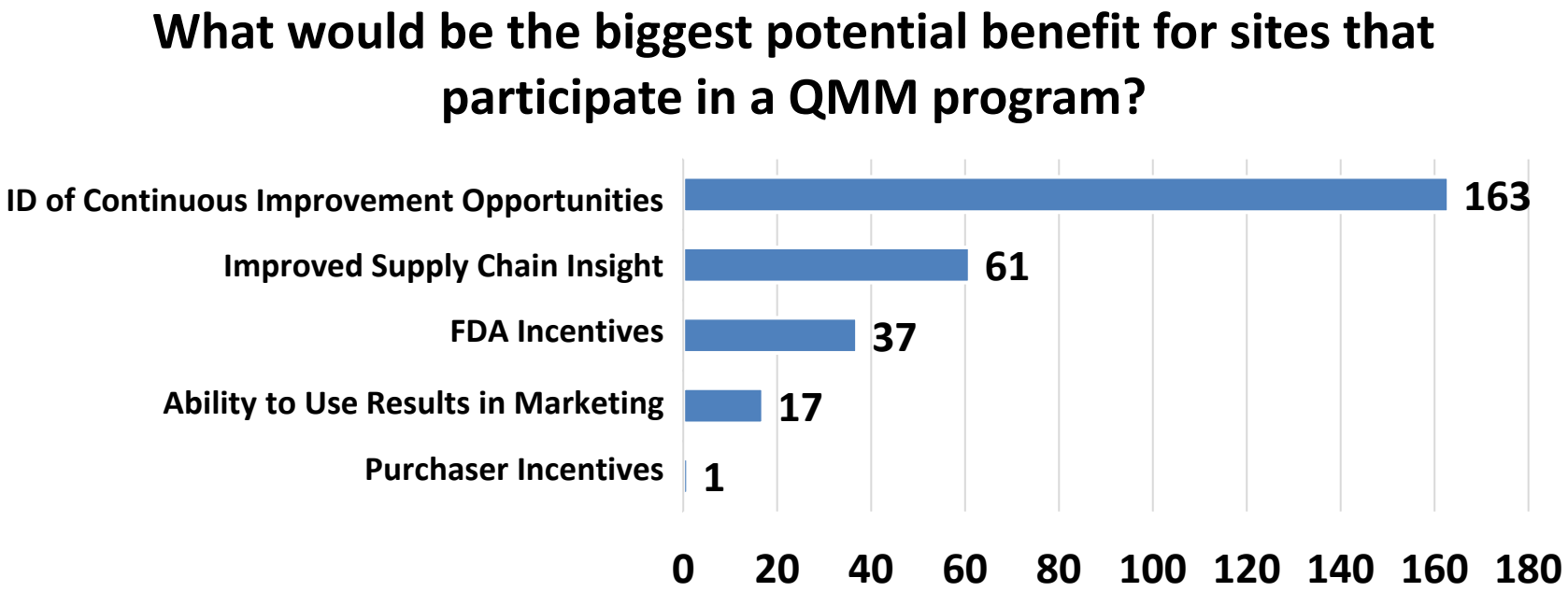
Do you believe that giving purchasers information on the quality management maturity of facilities making drug products or active pharmaceutical ingredients will reduce drug shortages in the long term?



Which QMM ratings will be most valuable to prevent shortage?



Stakeholders on Incentives

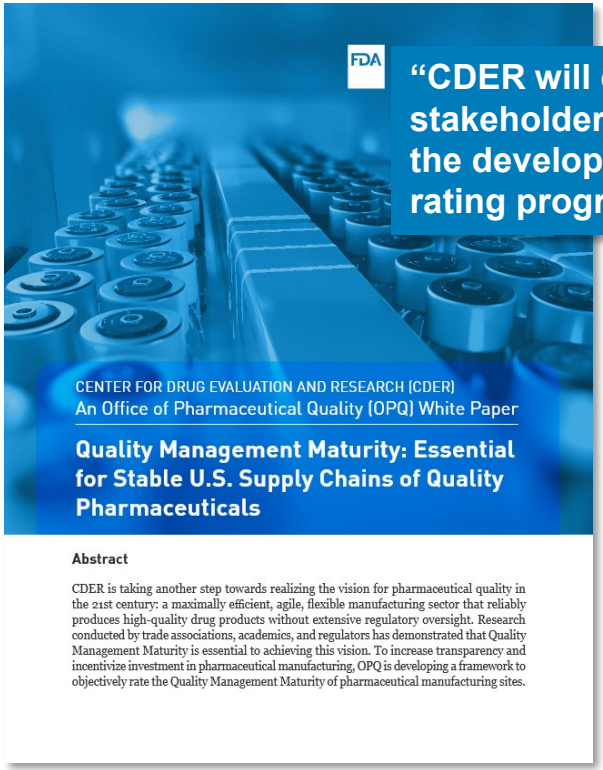


Key Concerns from Workshop

From discussions and Q&A:

- Timeline
- Incentives
- Cost burden to participate
- Unintended consequences and impact on industry
- Drug cost
- Feasibility of all firms achieving QMM
- Measuring program success
- Transparency

Engagements on the Road to QMM



"CDER will continue to engage stakeholders during and after the development of the QMM rating program."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ADMINISTRATION

FDA's Vision for Quality Maturity Management

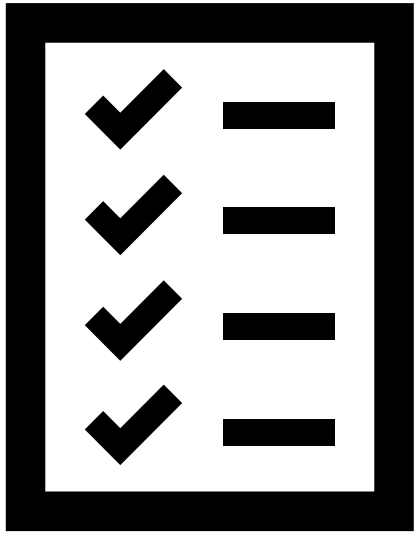
Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting

November 2, 2022

Alex Viehmann
Director, Division of Quality Intelligence II
Office of Quality Surveillance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

AGENDA

- ❑ Background: The Business Case for QMM
- ❑ Operational Considerations
- ❑ Assessment Framework

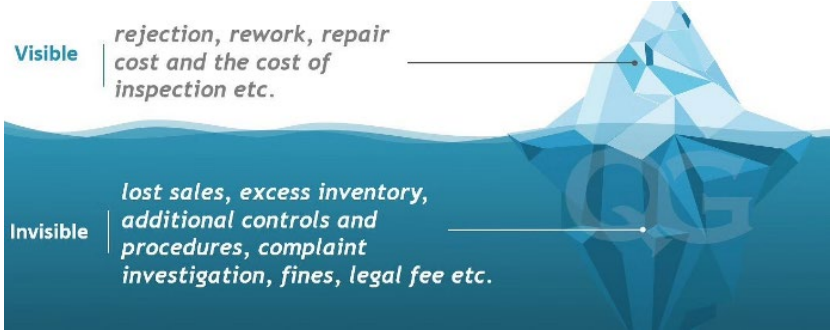


Background: The Business Case for QMM

US FDA Center for Drug Evaluation and Research

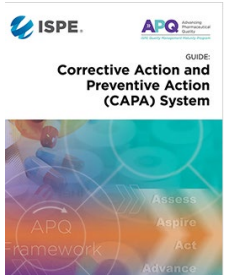
“QMM is Nothing New”

- “Quality always costs less” – W Edwards Deming
  - Good quality doesn’t have to mean higher costs
  - Achieving quality outcomes requires investment
  - Organizations whose quality practices are the most sophisticated are not necessarily the ones that spend the most
- Cost of poor quality
  - Internal and external failures
    - Loss of production, rework, scrap, loss of business
- Cost of quality
  - Inspection and prevention costs
    - Labor costs for audits, preventive/predictive maintenance, training, design improvements, implementation of advanced control mechanisms (e.g., SPC)
- High levels of QMM will lead to:
  - Higher revenues
  - Greater customer satisfaction
  - Operational efficiencies – increase in productivity



Parallel Efforts

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



Business Case from other Industries

Quality ratings are successfully used in many industries:

CARFAX® revolutionized used car buying
- Widespread adoption of used car reports and quality-based estimators

Centers for Medicare and Medicaid Services (CMS) established a 5-star quality rating for nursing homes
- Prices for highest rated nursing homes rose 5-6% over lowest rated facilities

Federal agencies regulating the safety and soundness of depository institutions (banks, thrifts and credit unions) develop and apply CAMELS* ratings
- Ratings have been highly successful for federal regulators managing safety and soundness of banking sector

**CAMEL – Capital adequacy, Asset quality, Management, Earnings, Liquidity, and Sensitivity*

A QMM Assessment is NOT…

The QMM assessment is not intended to be used in lieu of or as a surrogate for establishment inspections and does not evaluate compliance with CGMP*.

A QMM assessment is not a reflection of product quality. It is an evaluation of an establishment's quality practices.

**CGMP – Current Good Manufacturing Practice*

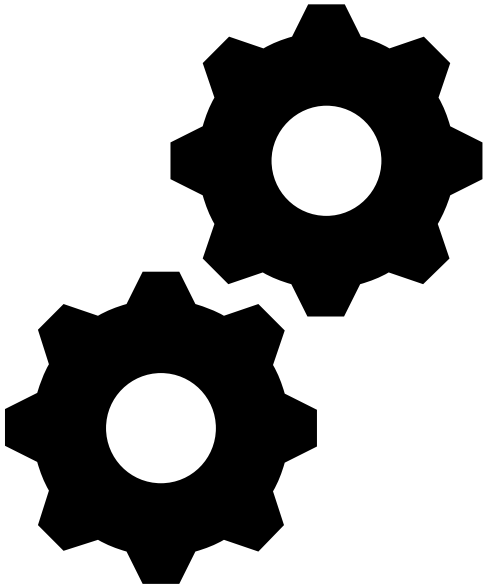
A QMM Assessment DOES…

- ❑ Identify and evaluate above-the-bar behaviors
- ❑ Identify opportunities for continual improvement
- ❑ Allow participants to become eligible for incentives
- ❑ Promote benefits from continual improvement

Operational Considerations

US FDA Center for Drug Evaluation and Research

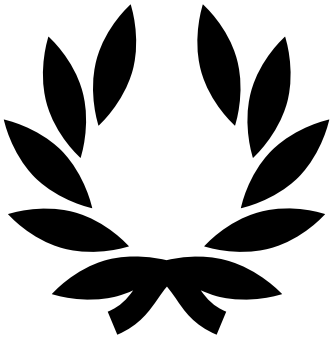
Operationalizing a QMM Program



- ❑ Executed by FDA or contractor?
- ❑ Executed virtually or on-site?
- ❑ Reassessment period?
  - Shelf-life of assessment and related incentives
  - Conditions of factors for reassessment
- ❑ Assigning a final rating
  - Considering assessment scores plus other factors
- ❑ Communicating the QMM rating

Incentives Under Consideration

- ❑ Regulatory flexibility
  - Inform PQS* assessments to support ICH Q12 implementation
  - Post-market activities (e.g., supplements)
- ❑ Inspection decisions – frequency and scope
  - Surveillance
  - Pre-approval
- ❑ Sector specific incentives
  - Innovators, generics, OTCs, biologics…

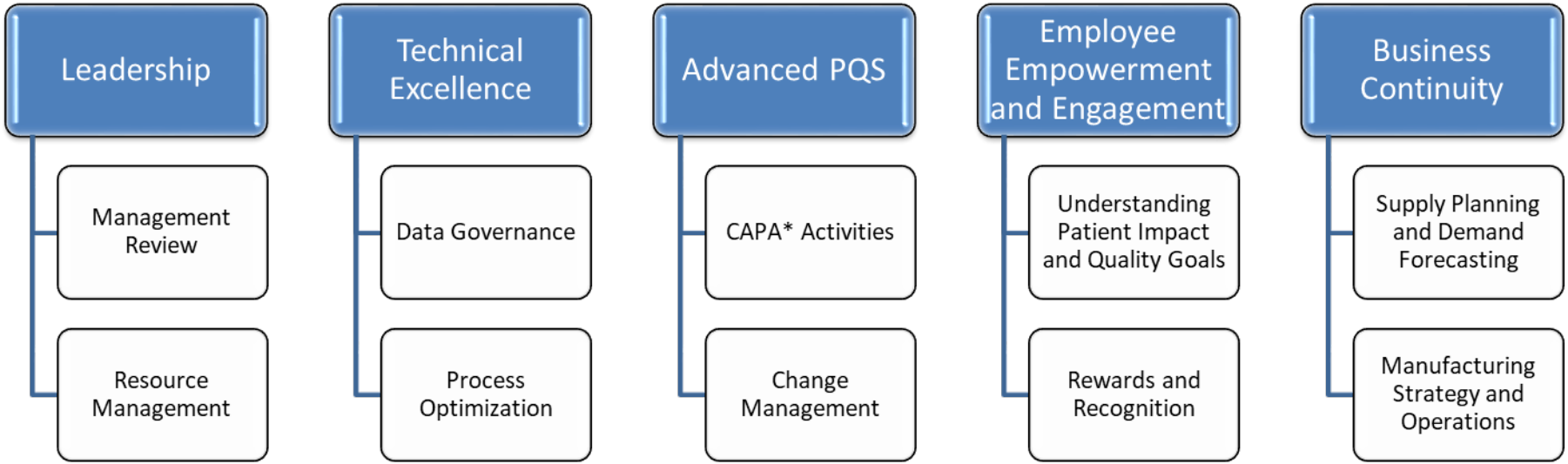


PQS – Pharmaceutical Quality System

Assessment Framework

US FDA Center for Drug Evaluation and Research

Example Practice Areas and Elements



**CAPA – Corrective and Preventive Action*

QMM Program – Moving Forward

- ❑ Develop protocol for QMM assessments
- ❑ Develop rubric for scoring the assessments
- ❑ Operational considerations
- ❑ Final rating considerations (integration of relevant data)
- ❑ Coordinate with government partners – inform reimbursement/procurement decisions

In Closing

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ADMINISTRATION

Potential QMM Benefits to Stakeholders and FDA

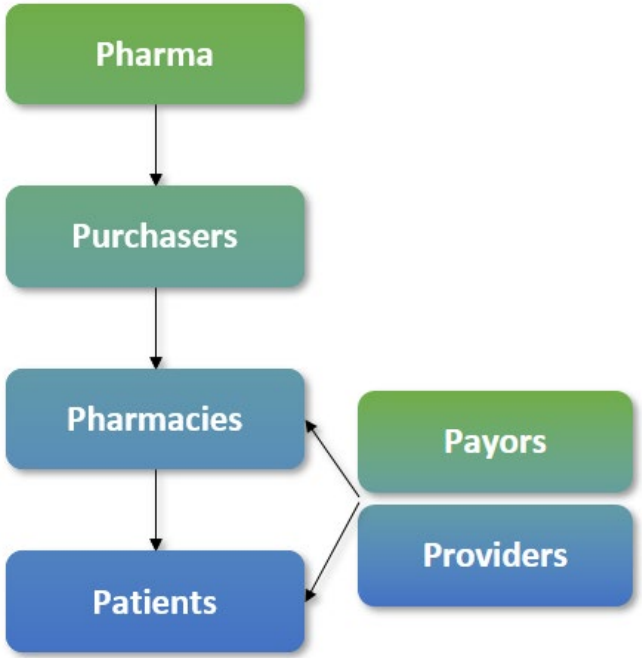
Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting

November 2, 2022

Lucinda (Cindy) Buhse, Ph.D.
Deputy Director, Operations
Office of the Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

AGENDA

- ❑ Benefits to Stakeholders:
  - Industry
  - Purchasers and Payers
  - Healthcare Professionals
  - Pharmacies
  - Patients and Consumers
- ❑ Benefits to FDA



Benefits to Industry

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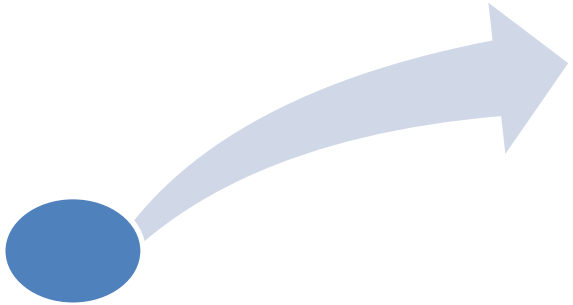
Industry

- Facilitates the use of ICH Q12 (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management) regulatory flexibilities.
- Informs decision-making for applicants/ manufacturers in the selection of contract sites.
- Is an important element of oversight and controls over the manufacture of drugs to ensure quality (section 501 FD&C* Act).
- Enables continual improvement of
  - process performance,
  - product quality, and
  - the pharmaceutical quality system (PQS).



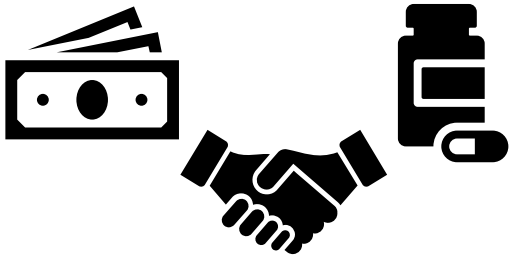
FD&C – Federal Food, Drug, and Cosmetic Act

Industry

- Fewer recalls resulting in improved corporate image.
- Leader to quality system efficiencies and cost savings.
- A more robust drug supply chain and greater commitment to quality in pharmaceutical manufacturing.
- Positive and proactive performance is acknowledged.
- “Good actors” are rewarded through potential commercial and regulatory incentives.

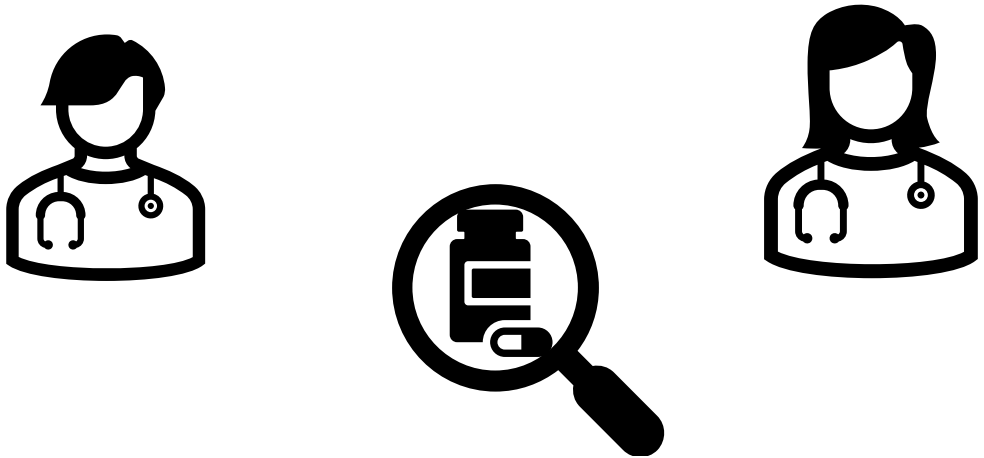
Purchasers and Payers

- ❑ Provides greater transparency into the market overall.
- ❑ More insight into the supply chain.
- ❑ Quality ratings have insight from FDA including incorporation of non-public data.
- ❑ Less need to respond to drug shortages.



Healthcare Professionals

- Less risk of drug shortages impacting their patients.
- More confidence in the supply of drugs they prescribe and/or dispense.



Pharmacies

- ❑ Improved supply chain transparency.
- ❑ Less risk of failing to meet demand.
- ❑ Reduced risk of medication errors.

Benefits to Patients and Consumers

US FDA Center for Drug Evaluation and Research

Patients and Consumers

More reliable availability of important drug products.

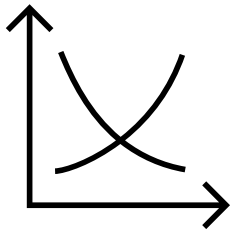
- ❑ Fewer recalls.
- ❑ Fewer quality-related drug shortages.


Greater confidence in their *next* dose of medicine.

Benefits to FDA

- ❑ Better informed about the quality management practices at sites.
- ❑ Better able to identify factors leading to supply disruption.
- ❑ Improved effectiveness of inspections.
- ❑ Enhanced risk-based allocation of surveillance tools.
  - Improved risk-based resource allocation for quality surveillance.
  - Better resource allocation decisions (e.g., inspection timing and frequency) and regulatory flexibility (e.g., related to postapproval changes).

Benefits to FDA



- Additional quantitative and objective insight into the state of quality for facilities.
- Advance FDA efforts toward performance-based regulation.
- Streamline the process of regulating post approval changes.
- Support FDA efforts to engage industry toward implementation of ICH Q12.

In Closing

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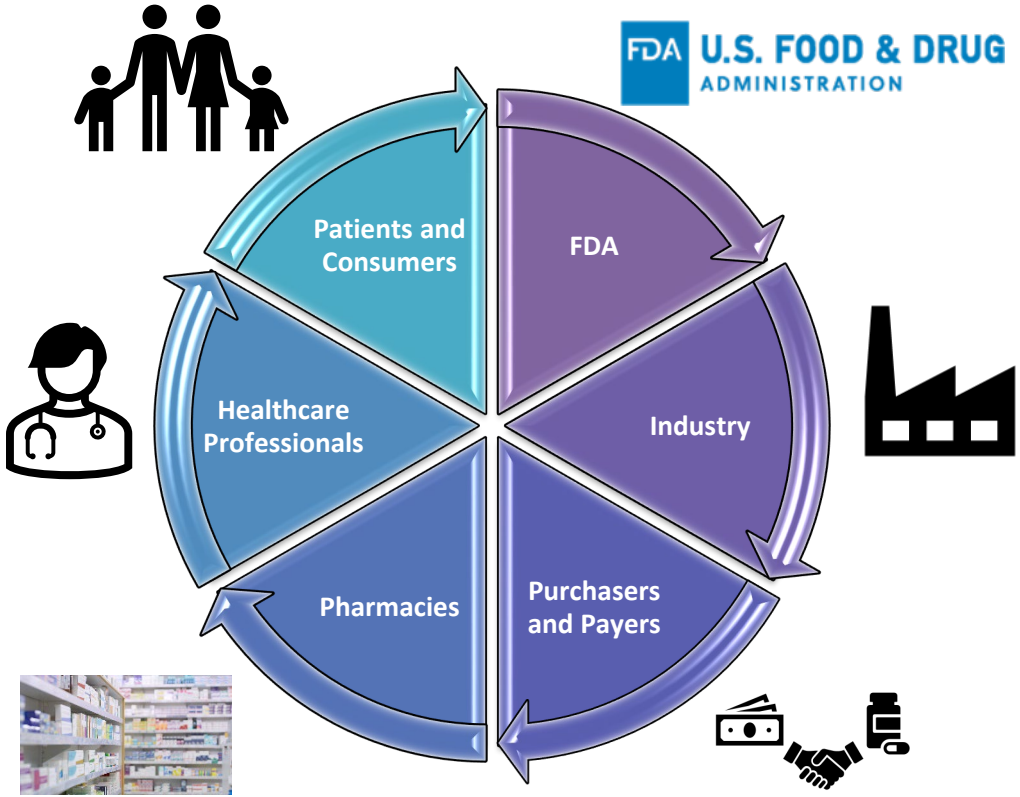
QMM is Important to All

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