

The Future of Quality Management Maturity

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Quality Management Maturity Workshop

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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.

A close-up photograph showing a hand holding an orange pill bottle, pouring three white, oval-shaped pills into the palm of another hand. The background is blurred, focusing attention on the action of taking medication.

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

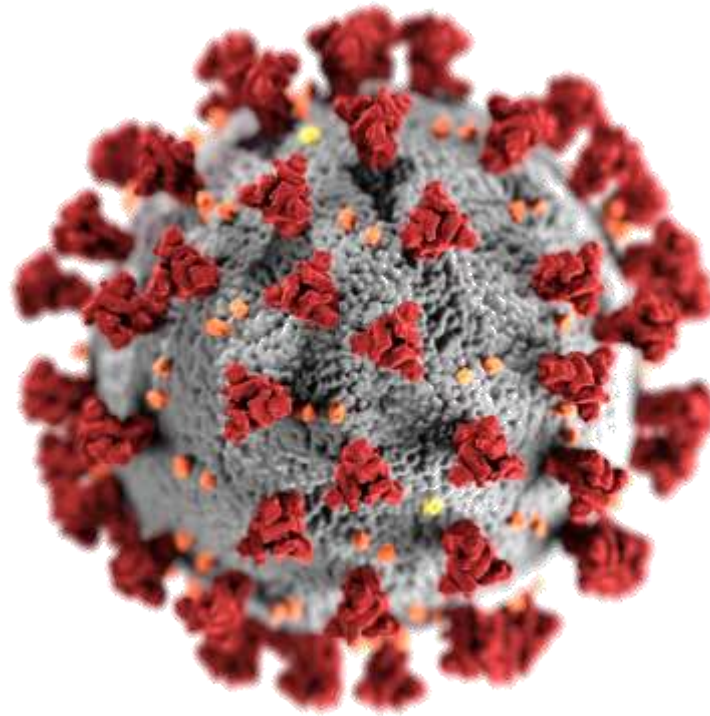


Pharmaceutical quality is assuring *every* dose is safe and effective, free of contamination and defects.



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

A Different Kind of Contagion



The Three Pillars

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

100-Day Reviews under
Executive Order 14017

June 2021

A Report by
The White House

Including Reviews by
Department of Commerce
Department of Energy
Department of Defense
Department of Health and Human Services



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

– 100-Day Report by
The White House



THE WHITE HOUSE
WASHINGTON

Challenge: Transparency

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

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

– 100-Day Report by
The White House



Quality Management Maturity

US FDA Center for Drug Evaluation and Research

Quality Management Maturity (QMM) is the state attained when drug manufacturers have consistent, reliable, and robust **business processes** to achieve quality objectives and promote continual improvement.

An Array of Quality



Pharmaceutical Quality

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

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

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

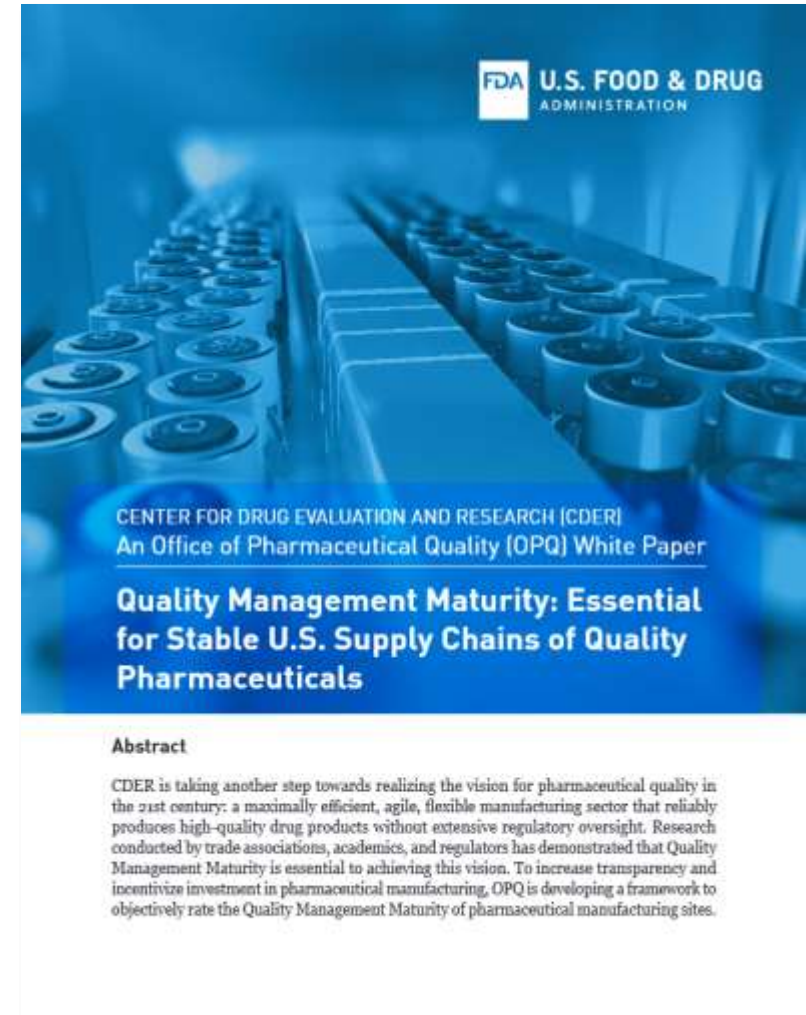
Productivity Optimization (5S)

QMMM \neq QM

QMMM = f(QM, x, y, z...)

Road to a QMM Program

- **Pilot Programs**
 - Domestic FDF sites
 - Foreign API sites
- **QMM White Paper**
- **QMM Stakeholder Workshop**
- **QMM Advisory Committee**





Key Challenges

US FDA Center for Drug Evaluation and Research



Key Challenges to Achieving QMM



- **Define Scope**
- **Consider QMM in Decision Making**
- **Distinguish QMM Appraisals**
- **Understanding the Supply Chain**
- **Reward for Higher QMM**
- **Potential Risks**



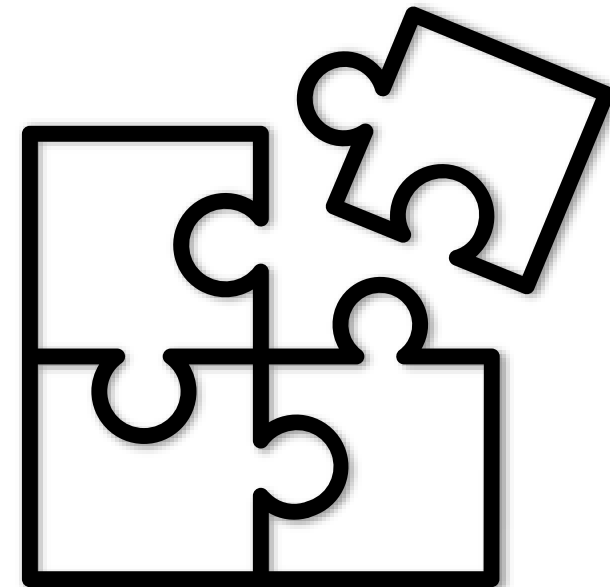
Key Elements

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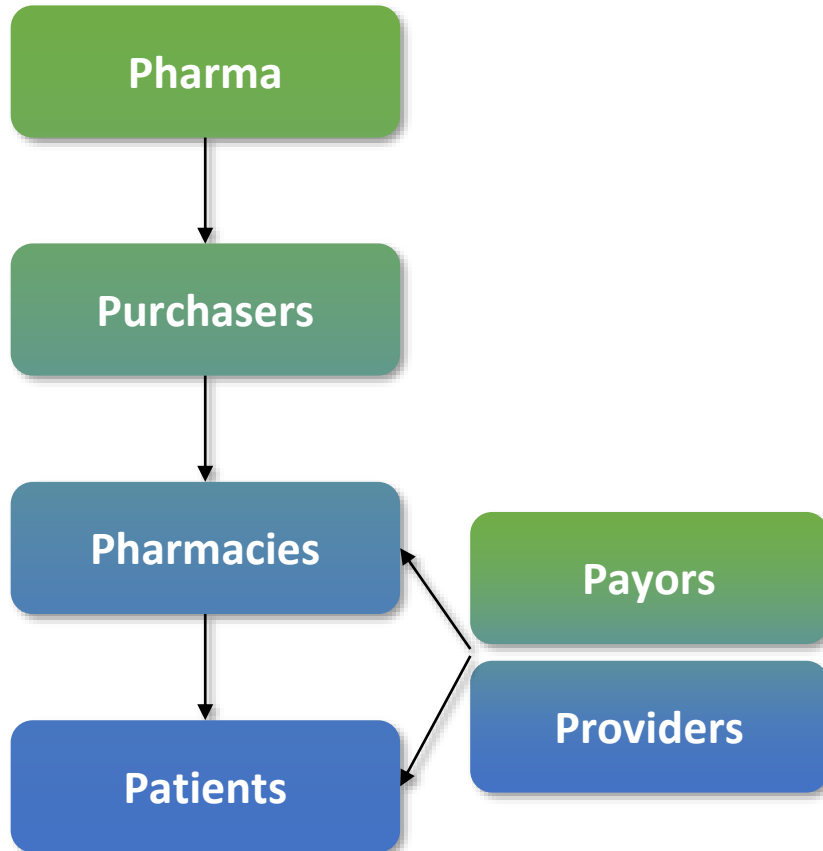
Key Elements of a QMM Program



- **Foundation of Quality Culture**
- **Assessment Tools**
 - Objective and Consistent
 - Standardized and Validated
- **Clear Incentives**
- **Transparency**



“6 Ps” Impacted by QMM Ratings



Stakeholder	Benefits
Pharmaceutical Manufacturers	<ul style="list-style-type: none">✓ Positive and proactive performance acknowledged✓ “Good actors” rewarded
Purchasers ³	<ul style="list-style-type: none">✓ Improved supply chain transparency for decision-making✓ Quality ratings backed by FDA insight and non-public data
Pharmacies	<ul style="list-style-type: none">✓ Improved supply chain transparency✓ Less risk of failing to meet demand and medication error
Payors	<ul style="list-style-type: none">✓ Improved supply chain transparency for decision-making✓ Less need to respond to drug shortage
Providers	<ul style="list-style-type: none">✓ Less risk of drug shortage impacting their patients✓ More confidence in the supply of drugs they prescribe
Patients	<ul style="list-style-type: none">✓ Less risk of drug shortage impacting their care✓ More confidence in drug availability



Everyone comes away with more confidence in their *next* dose of medicine.



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