The Future of Quality Management Maturity

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

Quality Management Maturity Workshop
May 24-25, 2022

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.

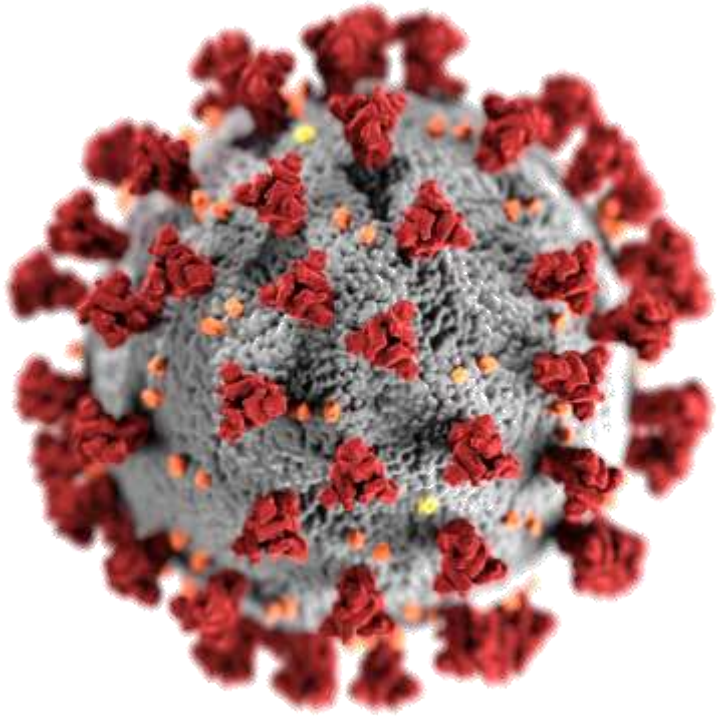

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is

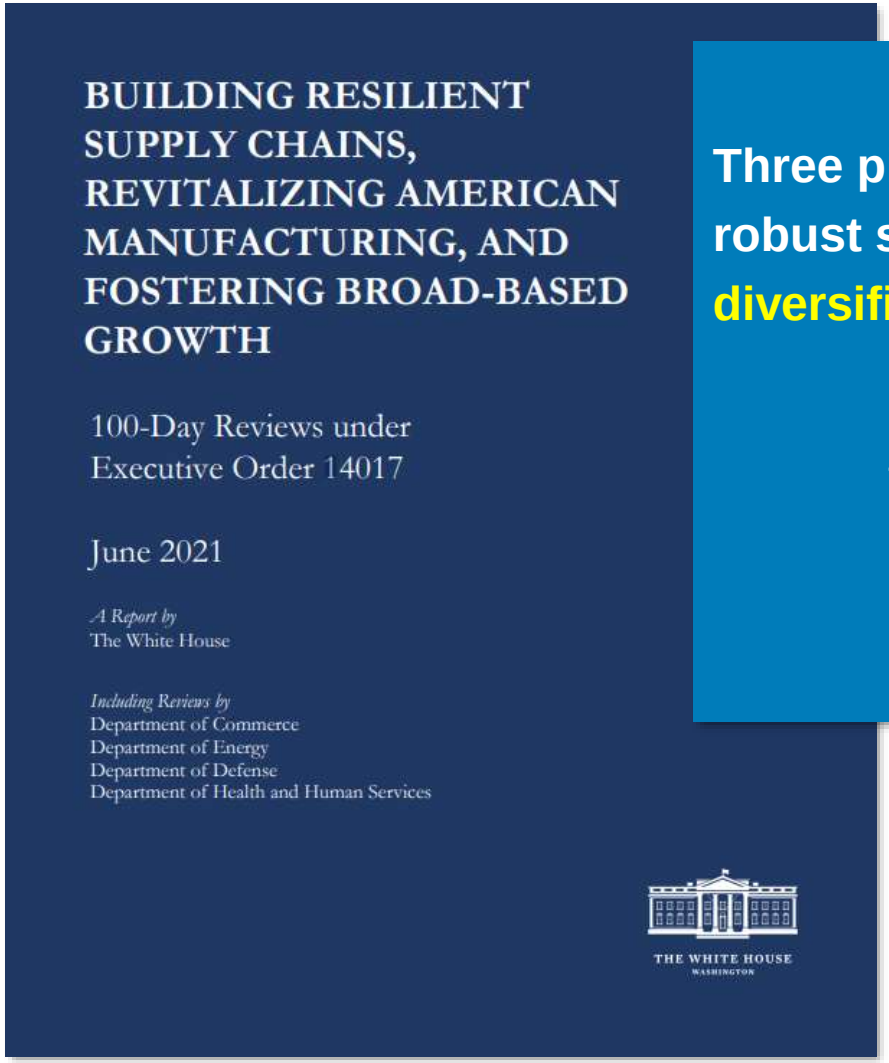
assuring *every* dose is safe and effective, free of contamination and defects.


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

A Different Kind of Contagion



The Three Pillars

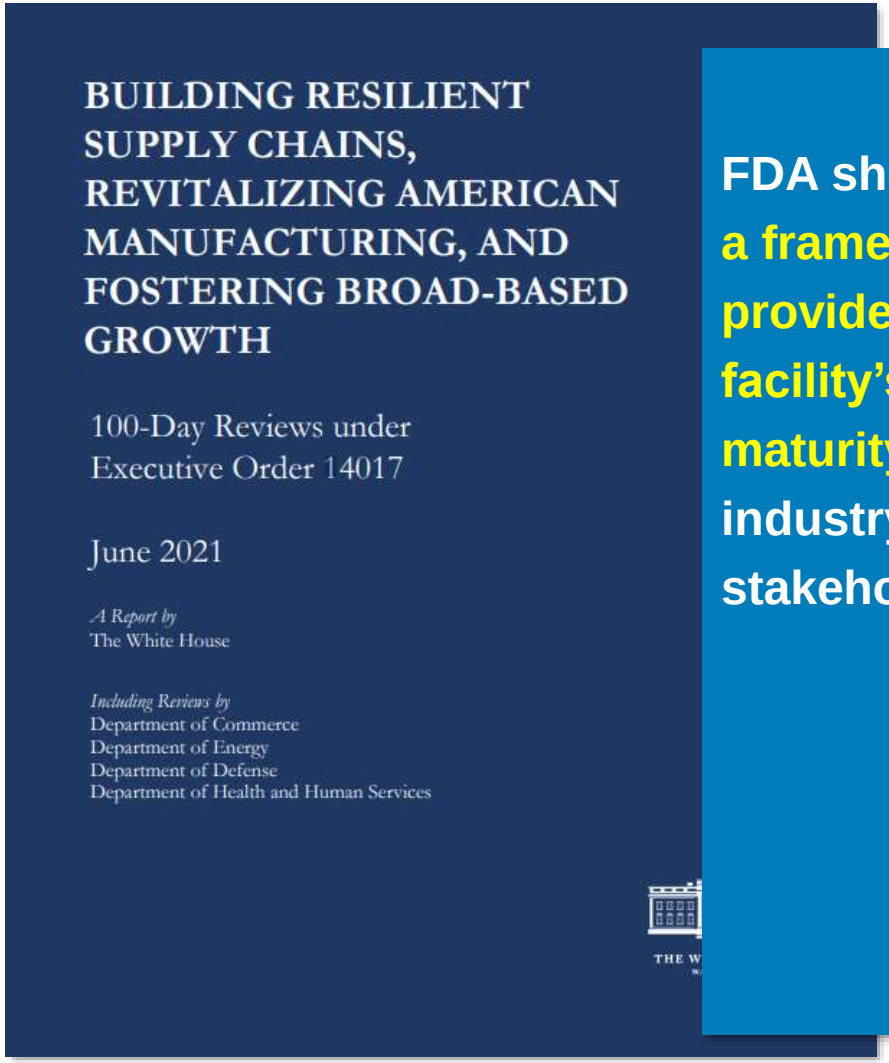


Three pillars of a secure and robust supply chain are quality, diversification, and redundancy.

– 100-Day Report by

The White House

Challenge: Transparency



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.

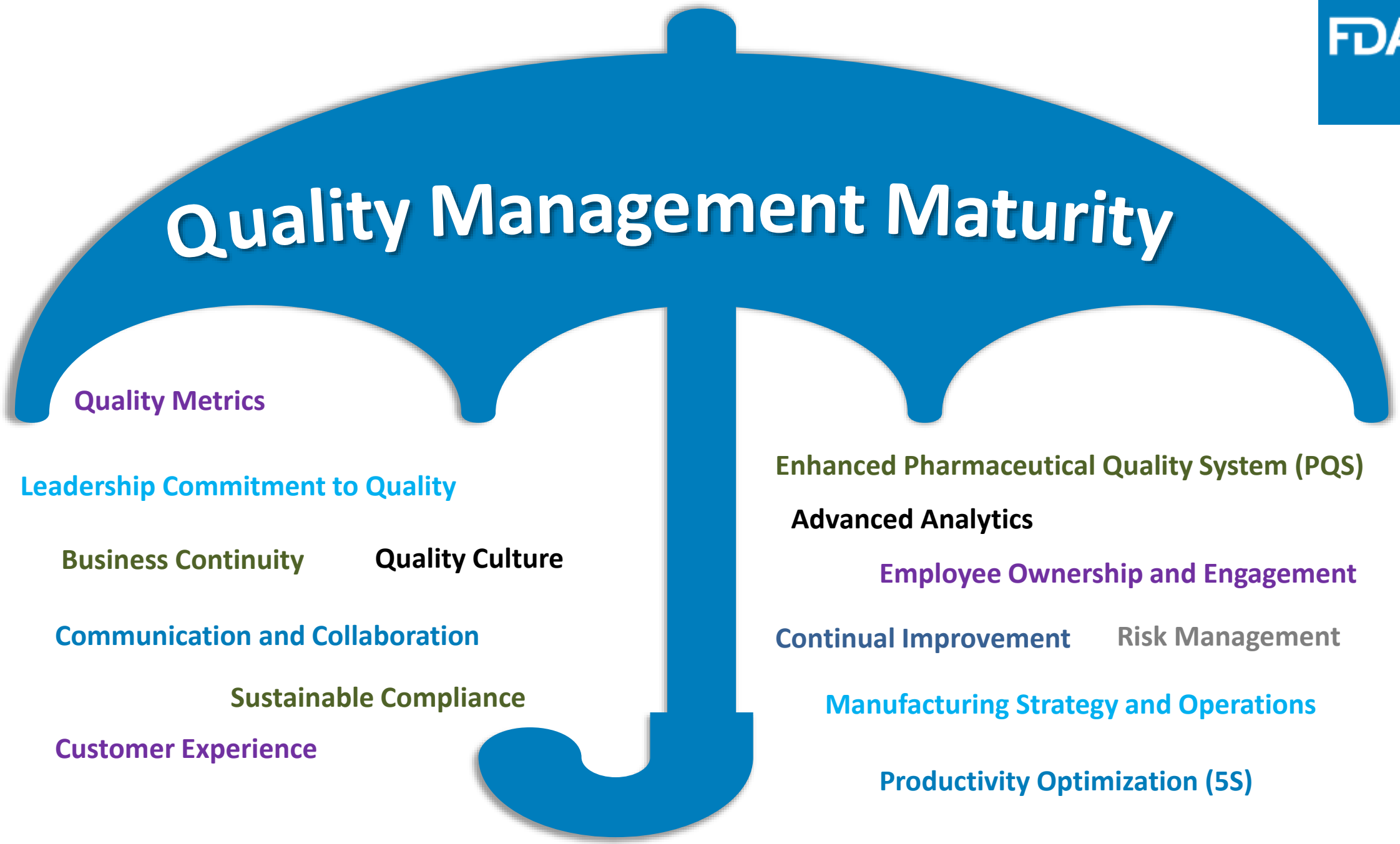
An Array of Quality

Pharmaceutical Quality

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

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

Quality Management Maturity



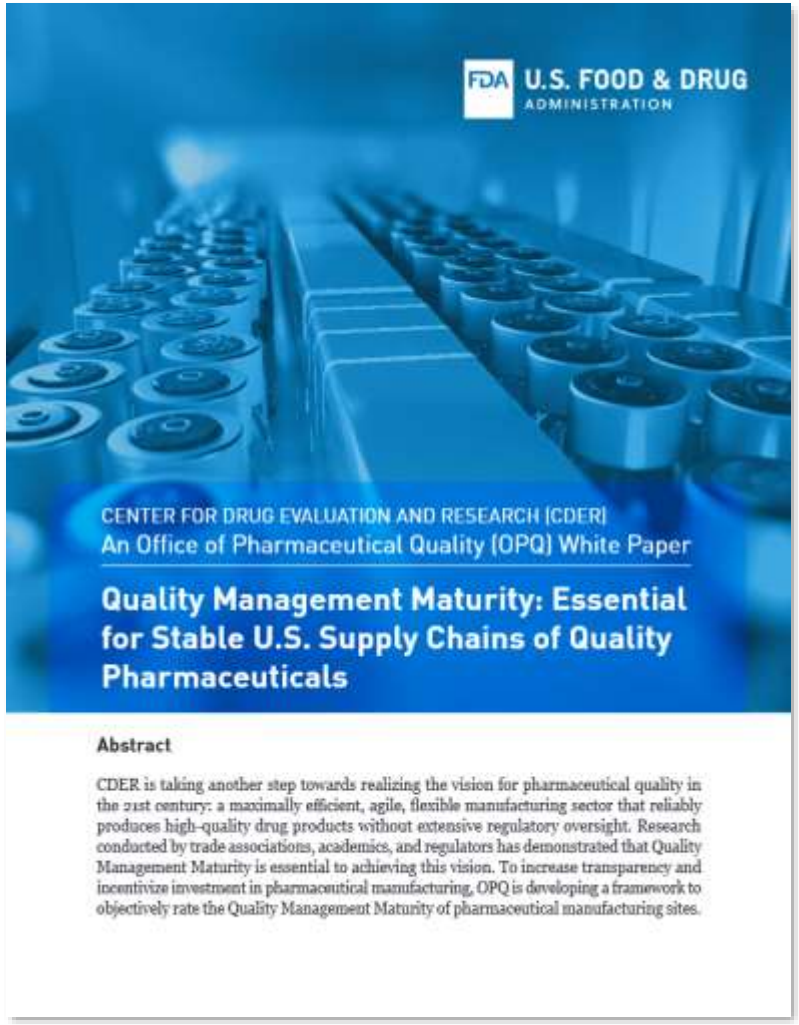
QMM ≠ QM

QMM =f(QM, x, y, z…)

Foundation of Science

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

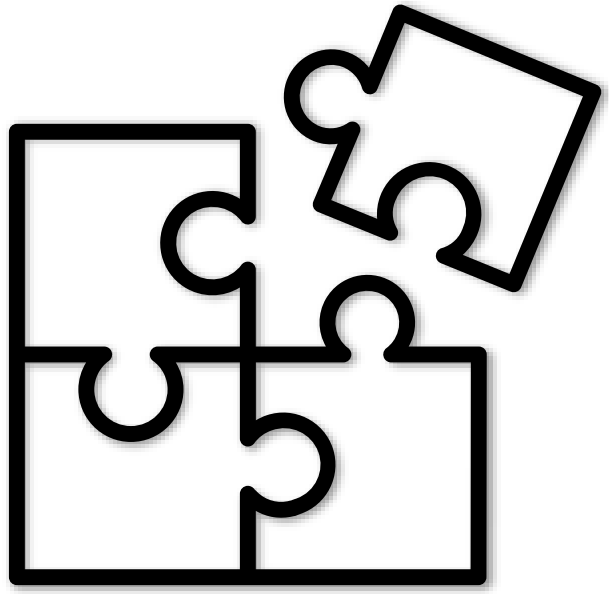
- Define Scope
- Consider QMM in Decision Making
- Distinguish QMM Appraisals
- Understanding the Supply Chain
- Reward for Higher QMM
- Potential Risks

Key Elements

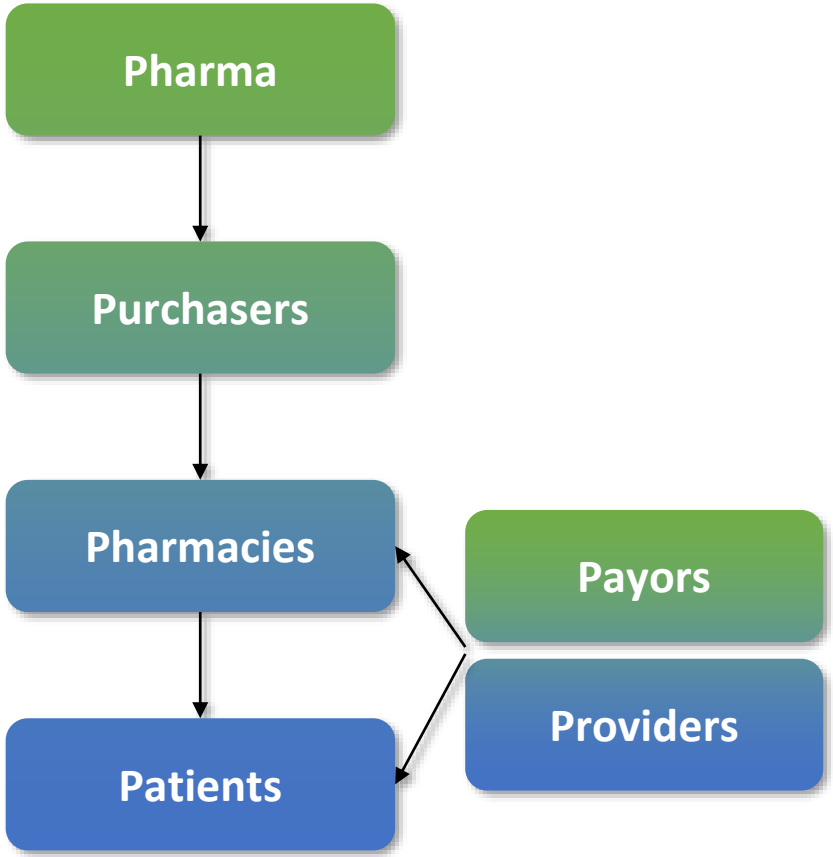
US FDA Center for Drug Evaluation and Research

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	✓ Positive and proactive performance acknowledged ✓ “Good actors” rewarded
Purchasers[3]	✓ Improved supply chain transparency for decision-making ✓ Quality ratings backed by FDA insight and non-public data
Pharmacies	✓ Improved supply chain transparency ✓ Less risk of failing to meet demand and medication error
Payors	✓ Improved supply chain transparency for decision-making ✓ Less need to respond to drug shortage
Providers	✓ Less risk of drug shortage impacting their patients ✓ More confidence in the supply of drugs they prescribe
Patients	✓ 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.


FDA
U.S. FOOD & DRUG
ADMINISTRATION