

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.



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

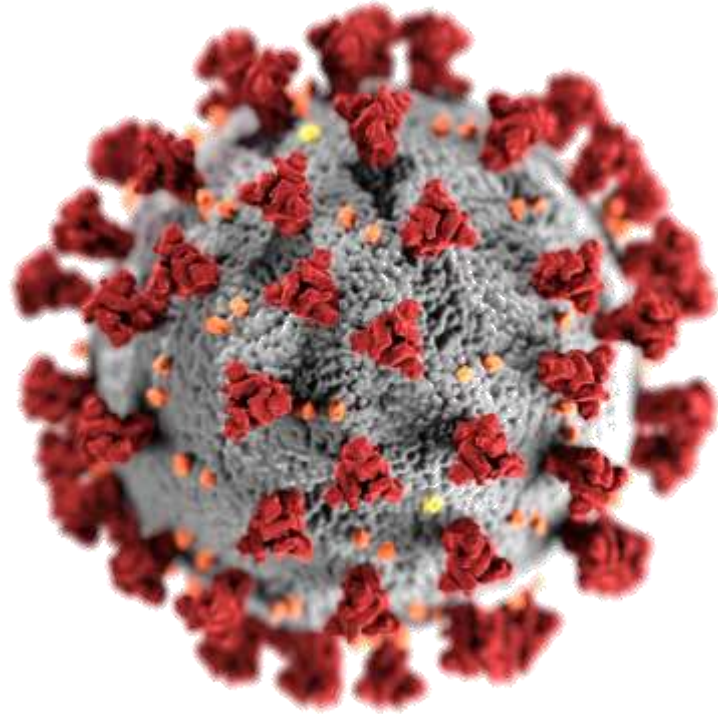


Pharmaceutical quality is assuring *every* dose is safe and effective, free of contamination and defects.



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

100-Day Reviews under
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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

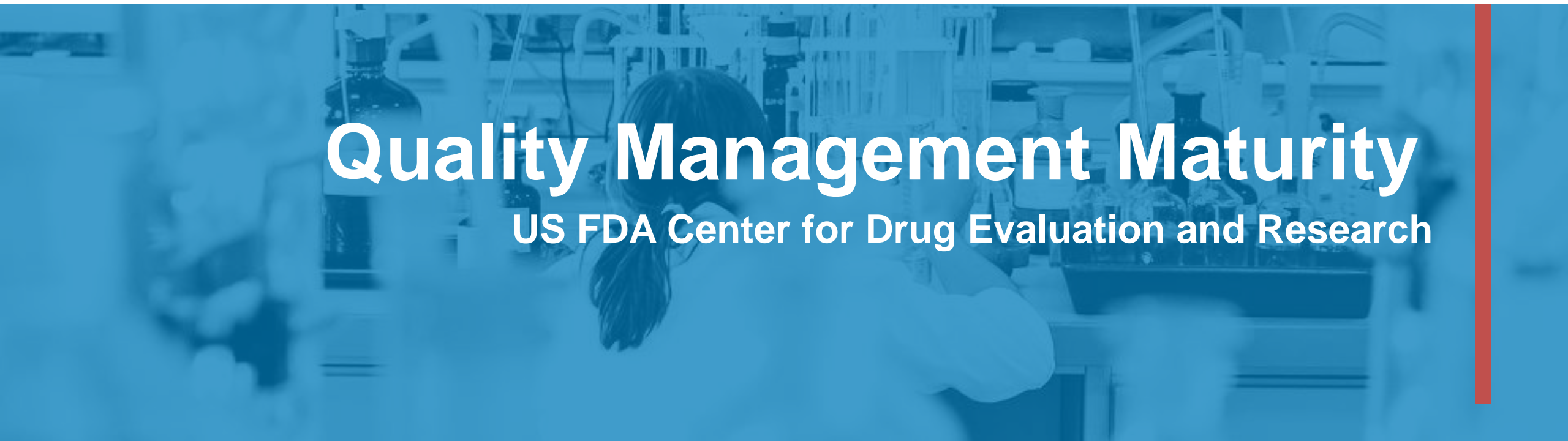


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WASHINGTON



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>	QUALITY MANAGEMENT <i>CDER Confidence: Low</i>	Performance and patient focus identifies areas of improvement and implements changes
<i>Gives manufacturers confidence in every batch they release</i>	PROCESS QUALITY <i>CDER Confidence: High</i>	Manufacturing risks are controlled to provide a quality drug product
<i>Gives patients confidence in every dose they take</i>	PRODUCT QUALITY <i>CDER Confidence: High</i>	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...)

Foundation of Science



PDA PAPER
Quality Culture Survey Report
 PRESHI PATEL¹, DENYSE BAKER², DEE BURDICK³, CYLIA CHEN⁴, JONATHAN HILL,⁵
 MORGAN HOLLAND⁶, and ANE SARANT⁷

ABSTRACT: The Pharmaceutical Association conducted an anonymous global survey of quality culture in the pharmaceutical industry to determine whether there is a relationship between certain quality behaviors and certain quality attributes, and whether these quality attributes in turn predict quality outcomes. Other studies have shown that quality of compliance issues seen by sites and regulatory notice attributes are driving good behavior, and the distance of the geographic location of the site. Even the current state of quality culture then survey responses suggest a p-value = 0.07, 1-Tail. The top five quality culture items (1) Management communication that quality is important, (2) Clear performance expectations, (3) Clear performance included in at least half of all hands meetings, and (5) 4 means quality attributes are related to management review central quality system reviews of ICH Q10, and therefore in regulatory inspections. Additional research and data in the pharmaceutical industry and regulators are being.

RESEARCH
The Impact of Quality Culture on Operational Excellence—An Empirical Study from Pharmaceutical Industry
 THOMAS FRIEDL¹, SWA BUEHLER², STEPHAN HÖRNER³, CYLIA CHE DENYSE BAKER⁴

ABSTRACT: Quality culture as an enabler of high-quality performance and advantage is increasingly discussed among operational excellence (OPX) experts as an aspect of quality culture on performance, especially on the so-called Total Quality Management (TQM) indicators. A central challenge is the lack of practical and accepted metrics to assess culture. In 2014, the Pharma quality culture survey within the pharmaceutical industry. The results indicate that quality culture behavior of a production site's employees and the maturity of the quality system in place. As the maturity of the quality system increases, the positive correlation between quality culture behavior and OPX indicators is strengthened. This paper explores the comprehensive St. Gallen OPX database for pharmaceutical analysis and shows that high-performing production sites, regarding finally a higher level of both quality system maturity and quality culture behavior.

Introduction
 In their 2017 article, "The Future of Pharmaceutical Quality and the Path to Go There," Yas and Kapta (1) show that the pharmaceutical industry still has a long way to go to improve quality. A comparison with other sectors confirms that the pharmaceutical industry is lagging in quality despite significant improvements in process and product understanding. While the electronic and automobile industry achieves a level of Six-Sigma (equivalent to more than 3.4 defects per one million parts), the pharmaceutical industry is still operating at a level of two- to three-sigma. In general, however, is rarely achieved (1).

Following Janet Woodcock, Director of the US Food and Drug Administration (FDA) Center for Drug Evaluation and Research, the pharmaceutical industry is still operating at a level of two- to three-sigma. In general, however, is rarely achieved (1).

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 Volume 16
 Issue 1 Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape
 Linking Data, Analytics, Knowledge and Risk
 Level 3
 Article 8
 12-15-2021

"Holistic Risk-based Site Surveillance Site Quality Risk Identification and Pharmaceutical Industry"
 Matteo Bernasconi
 Institute of Technology Management, University of St. Gallen
 Thomas Friedl
 Institute of Technology Management, University of St. Gallen
 Nuala Cahnan (edPoc)
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Journal of Pharmaceutical Innovation
 ORIGINAL ARTICLE
Quantitative Analysis of the QMS for Pharmaceutical Manufacturing
 Genan Wang^{1,2}, Weibang Wang³, Qiang Zhang^{4,5}

ABSTRACT
Purpose: To propose a statistical methodology for quantitative analysis of the quality management system (QMS) of pharmaceutical manufacturing.
Methods: (1) Based on the manufacturing data from two established active pharmaceutical ingredients (API) manufacturers in China from 2016 to 2019, the linear regression with Pearson correlation coefficient is used to find the correlation between the proposed QMS operation indicators and performance indicators. (2) A stepwise multiple linear regression is used to identify the independent operation indicators with the biggest impact on a given performance indicator. (3) The Akaike Information Criterion is used to predict the performance indicators based on the operation indicators.
Results: (1) Deviations in the right-first-time rate correlates strongly with various changes and deviations; the customer complaints correlate with changes, deviations, and CAPAs; the deficiency rate of foreign inspections correlates with deviations and CAPAs; and the CAPA on-time completion rate correlates with changes, deviations, and the rate of employee in quality. (2) Impact: the right-first-time rate and the customer complaints are mostly impacted by the total deviation rate; the deficiency rate of foreign inspections is mostly impacted by deviations in equipment and instrument, and deviations due to human error. The CAPA on-time completion rate is mostly impacted by deviations in facility and utilities. (3) Predictability: the right-first-time rate, the customer complaints, the deficiency rate of foreign inspections, and the CAPA on-time completion rate can all be predicted based on the existing data with statistical significance.

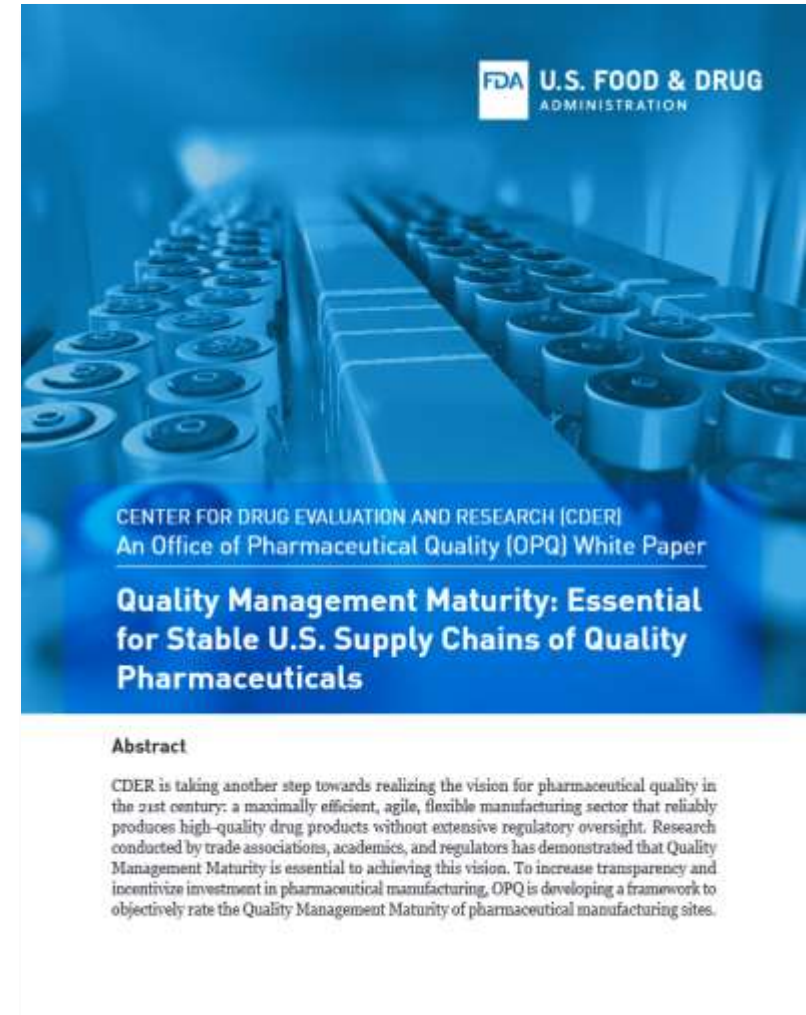
Conclusions: Deviations emerge as a key leading indicator for the performance of QMS. The proposed statistical methodology provides a basis for the data-driven quality management and regulation, whose visibility and predictability are likely to progress as the data accumulation.
Keywords: QMS; Pharmaceutical manufacturing; Statistical modeling; Performance; Deviations

Introduction
 Quantitative characterization of the quality management system (QMS) for pharmaceutical manufacturing has been a research subject of academia, industry, and regulator for years. A successful characterization usually requires a large amount of real-world manufacturing quality data and a systematic statistical approach.
 Much of Georgetown University and Nickerson at Washington University studied manufacturing quality risks based on the US Food and Drug Administration (FDA) site inspection data for the purpose of prioritizing GMP inspections to manufacturing sites with high-quality risks (1). They also included site operation data of manufacturing facility, human resources, deviation management, and manufacturing performance. Data was collected by using survey questionnaire to 50 active pharmaceutical ingredients (API) and related drug sites (FDA's manufacturing sites). The data was product-based, i.e., data was collected for each product for each site, on a monthly basis from 1999 to 2005. The statistical analysis using linear regression and Pearson correlation coefficient is site-based by aggregating data of all the products for each site. They found that larger sites

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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

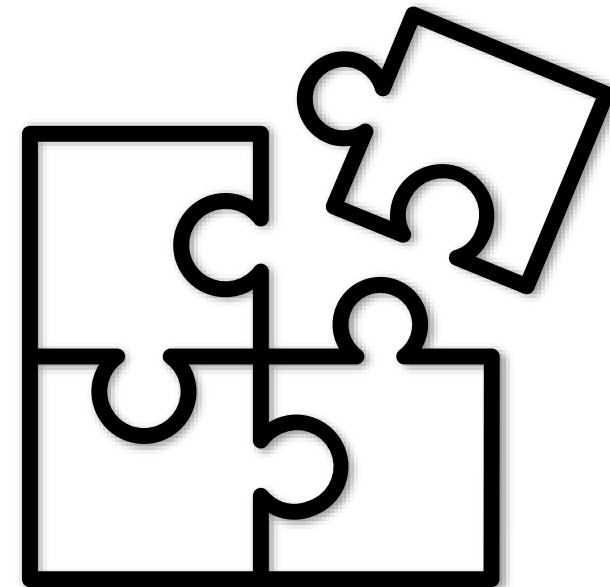
US FDA Center for Drug Evaluation and Research



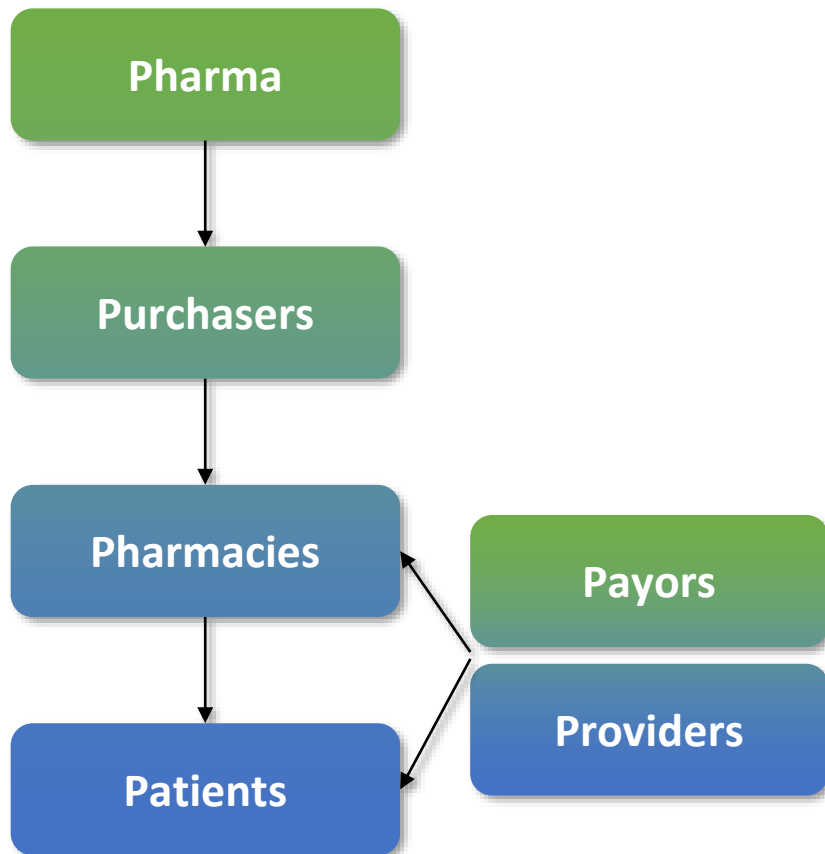
Key Elements of a QMM Program



- **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	<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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