

Quality Management in Practice

Quality Management Maturity (QMM) at CDER

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Agenda

What is Quality Management Maturity (QMM)?

Why is CDER developing its QMM Program?

Lessons Learned from Cohorts 1 & 2

Case Study

What is Quality Management Maturity (QMM)?

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



Why is CDER Developing its QMM Program?

The Report was updated on 2/21/20 to include revised economic analysis about production increases and supply restoration after a shortage. See the [FDA Archive for the original Report](#).

Drug Shortages:

Root Causes and Potential Solutions

2019

U.S. Food and Drug
Administration



FDA U.S. FOOD & DRUG
ADMINISTRATION



- **Root Cause:** The market does not recognize and reward manufacturers for **mature quality management systems** that focus on **continuous improvement** and **early detection** of supply chain issues.
- **Enduring Solution:** Incentivize drug manufacturers to invest in QMM.



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

CDER's QMM Program



Assessment Tool

- Prototype protocol (series of questions)
- Prototype rubric (guide for scoring)



QMM Scores

- Responses substantiated for full credit
- Inter-rater variability monitored and resolved



Assessments performed in teams

- Teams of three assessors to minimize bias



Onsite, Hybrid, Remote

- 5-day assessments

CDER's QMM Program



QMM Assessment Report

- Contains scores, strengths, and opportunities to improve



Post-assessment engagements

- Develop and discuss improvement goals
- Track progress toward these goals

19 assessments performed & 18 reports issued by September 30, 2026



Continual Improvement

- Lessons learned from cohorts 1 and 2
- Protocol refinements
- Adjusted rubric from 5 levels (cohort 1) to 4 levels (cohort 2)

A QMM Assessment...

Evaluates behaviors and practices that sustain an establishment's quality culture, promote supply chain reliability, and enhance the operation of the quality system.

Does not evaluate compliance with CGMPs and consequently cannot be used in lieu of or as a surrogate for establishment inspections or drug quality sampling and testing.

Reflects maturity of an establishment's quality mindset and quality management behaviors and practices.

Five QMM Practice Areas



Cohort 1 QMM Prototype Assessment Protocol Evaluation Program Scores (scored on a **1-to-5** scale)

Establishment	Management Commitment to Quality	Business Continuity	Advanced Pharmaceutical Quality System	Technical Excellence	Employee Engagement and Empowerment
A	2.8	2.7	2.6	2.7	3.4
B	4.8	4.3	4.2	3.6	4.9
C	4.2	4.4	3.6	3.6	4.5
D	4.0	3.8	3.7	4.3	4.1
E	4.6	4.5	4.7	4.4	4.9
F	4.5	4.4	4.4	4.3	4.7
G	2.2	2.5	2.2	2.7	2.4
H	3.7	3.8	3.5	3.7	4.0
I	3.8	3.8	3.6	3.4	3.8

Cohort 2 QMM Prototype Assessment Protocol Evaluation Program Scores (scored on a **1-to-4** scale)

Establishment	Management Commitment to Quality	Business Continuity	Advanced Pharmaceutical Quality System	Technical Excellence	Employee Engagement and Empowerment
A	3.7	3.6	3.8	3.5	3.8
B	3.2	3.2	3.2	3.1	3.3
C	2.8	2.9	3.1	3.1	2.3
D	3.4	2.9	3.6	3.3	2.7
E	3.4	3.1	3.3	3.1	2.9
F	3.5	3.5	3.1	3.4	3.2
G	2.6	2.8	2.6	2.5	2.1
H	3.3	2.9	3	3.2	2.9
I	3.7	3.5	3.5	3.4	3.8

Lessons Learned

- The QMM prototype assessment protocol and rubric measured differences in maturity between practice areas and between establishments.
- Both Cohorts 1 and 2 had higher scores in management commitment to quality (management responsibility).
- Both Cohorts 1 and 2 had their lowest scores in advanced PQS (quality risk management) and technical excellence (knowledge management, data excellence).
- According to the ICH Q10 model, quality risk management and knowledge management are enablers of the PQS. Hence, strengthening these areas may improve the function of the PQS.

Quality Management in Practice

A Case Study

Advanced Pharmaceutical Quality System (APQS)



Assessment Team evaluated the robustness of the Quality Risk Management (QRM) approach with respect to formality, the use of QRM tools, and stakeholder engagement to evaluate risk and manage subjectivity/bias.

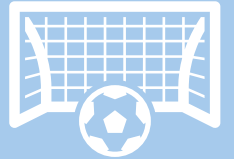
OPPORTUNITY FOR IMPROVEMENT

The QRM approach applied the same level of rigor, documentation, and stakeholder involvement regardless of the level of risk, criticality, or impact of the decision.



Advanced Pharmaceutical Quality System (APQS)

IMPROVEMENT GOALS



Modify QRM approach using the ICH Q9(R1) framework to ensure the level of rigor, documentation, and stakeholder engagement are commensurate with the level of risk by:

- Considering the level of uncertainty, complexity, and importance as a guide
- Apply QRM tools based on fitness-for-use with respect to the specific risk problem
- Minimize the impact of subjectivity or bias on QRM activities

Why this matters: QRM is a foundational PQS enabler that influences the consistency and rigor of risk-based decisions across the product lifecycle.

From Assessment to Implementation

- 1 Gap assessment** Compare current QRM practices with desired framework
- 2 Redesign approach** Update SOPs, scoring definitions, and tool-selection criteria
- 3 Build capability** Train relevant personnel and initiate pilot implementation
- 4 Deploy** Implement across the site and integrate into routine PQS processes
- 5 Verify effectiveness** Effectiveness check and follow-up gap assessment

Implementation does not stop at document revision.
It covers process design, understanding the benefits and limits of tools, training, governance, monitoring, and verification of effectiveness.

What Changed in the QRM Framework?

Formality commensurate with the level of risk

QRM triage considers uncertainty, complexity, and importance.

Three formality levels were defined to guide the level of effort, documentation, stakeholder involvement, and approvals.

Fit-for-purpose tools

The framework expands the use of tools beyond FMEA/FMECA to tools such as SME assessment, checklists, risk ranking & filtering, PHA, FTA, HACCP, and HAZOP.

No single methodology is suitable for every situation.

Objectivity & governance

Risk estimates and assumptions are supported by objective evidence where possible.

Multidisciplinary expertise, facilitation, calibration exercises, and training are used to reduce subjectivity and improve consistency.

The revised workflow ensures risk controls are appropriate, residual risks are evaluated, and risks are communicated and periodically reviewed.

How Progress and Effectiveness Are Tracked

Adoption

% adoption of the new formality framework

Tool use

Use of fit-for-purpose QRM tools

Capability

Training completion and competency assessment

Implementation

Review scoring consistency, documentation, and correct application (RFT)

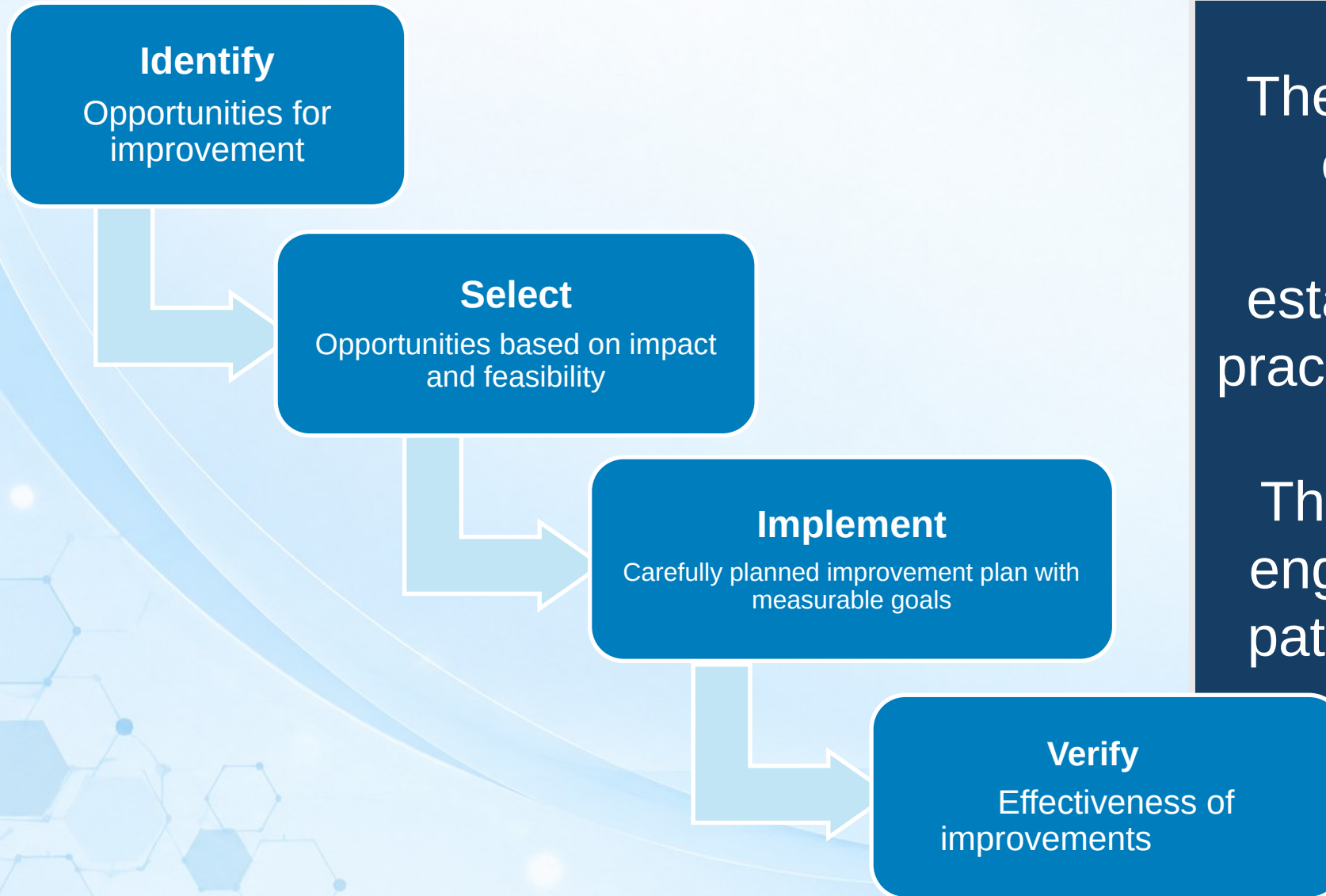
Governance

Monthly project reviews, dashboards, Site Quality Review Board, and Management Review

Success is defined by sustained use and effectiveness—not simply by issuing a revised SOP + read and understand training.

QMM in Practice:

Assessment → Action → Continual Improvement



The QMM assessment evaluates a drug manufacturing establishment's quality practices and behaviors.

The post-assessment engagements create a pathway for actionable improvement.

Questions?

Contact us at: CDER-QMM@fda.hhs.gov