An Update on CDER's Quality Management Maturity Program

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Agenda

- What is CDER's QMM Program?
- Why develop CDER's QMM Program?
- What were the Lessons Learned from First Cohort of the QMM Prototype Assessment Protocol Evaluation Program?
- Next Steps

What is CDER's QMM Program?

CDER's Quality Management Maturity (QMM) Program encourages drug manufacturers to implement quality management systems and practices that go beyond current good manufacturing practice (CGMP) requirements.

The QMM Program evaluates and scores a drug manufacturing establishment's level of maturity in five practice areas.

CDER's QMM Program Goals

- Foster a strong quality culture mindset.
- Recognize establishments with advanced quality management practices and acknowledge establishments that strive to continually improve quality management practices.
- Identify areas where quality management practices can be enhanced and provide suggestions for opportunities for growth.
- Minimize risk to product availability to assure reliable market supply.

Five QMM Practice Areas

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 Develop CDER's QMM Program?

- 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.
- Enduring Solution: Incentivize drug manufacturers to invest in QMM.

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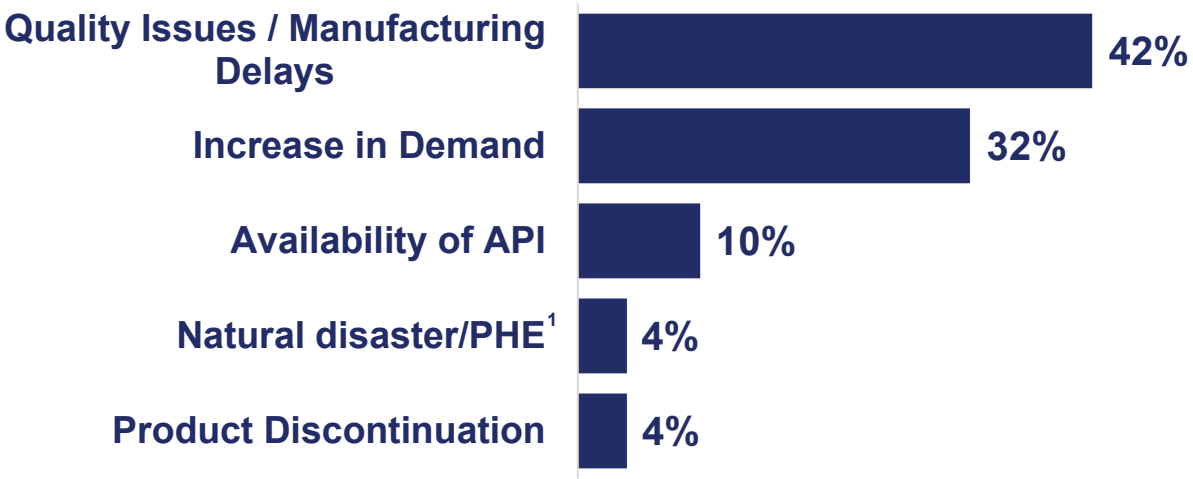
Reasons for New Drug Shortages

Percentage of Drugs Newly in Shortage by Reason
Calendar Years 2022-2024



[1] PHE = Public Health Emergency

Note: Percentages do not equal 100% due to rounding.

Source: Internal FDA Data

2024 QMM Prototype Assessment Program Evaluation Program

9 establishments selected and assessed

Milestones

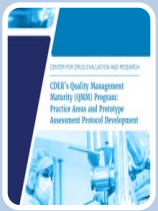
Cohort #1

FRN announcing 2024 QMM Prototype Assessment Protocol Evaluation Program

2024 QMM Prototype Assessment Protocol Evaluation Program

June-December 2024

Cohort #2



FRN announcing 2025 QMM Prototype Assessment Protocol Evaluation Program

2025 QMM Prototype Assessment Protocol Evaluation Program

September 2025-April 2026

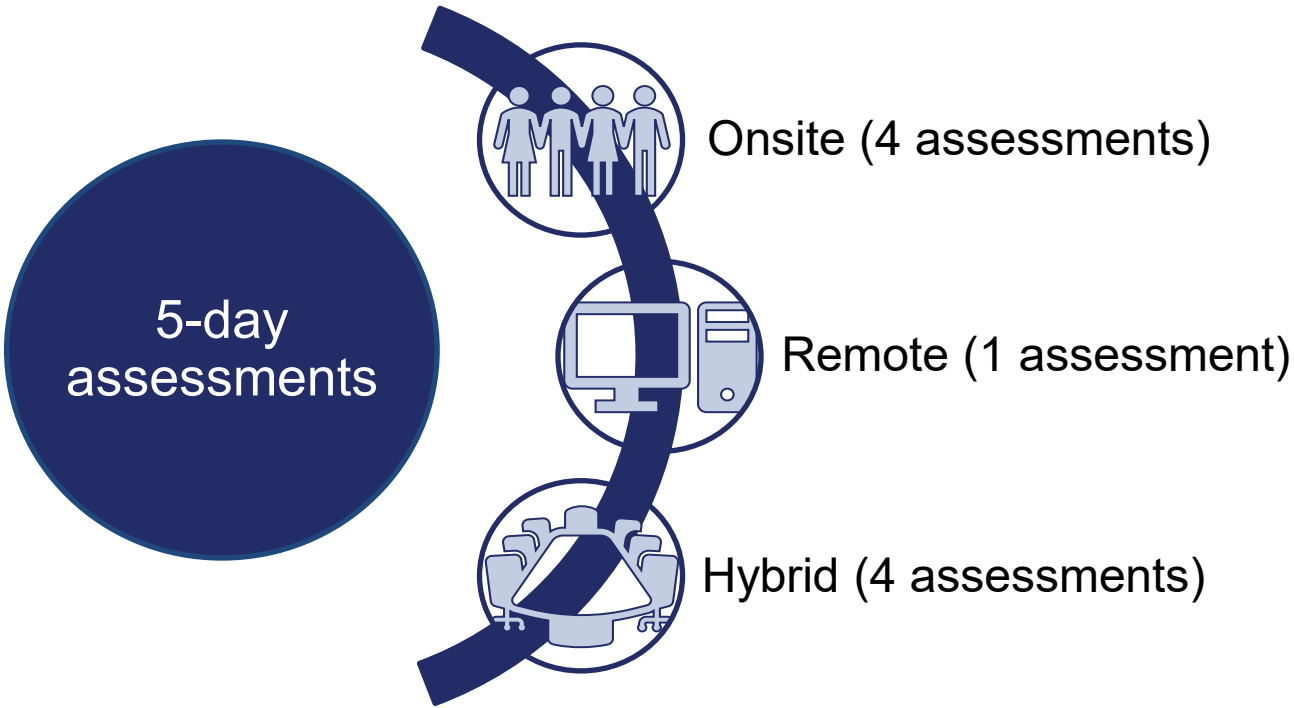
2024

2025-2026

2024 QMM Prototype Assessment Protocol Evaluation Program Goals

- Gain experience with the prototype assessment tool and process to ensure it is fit for use
- Inform refinement of the prototype assessment tool and process

2024 Assessment Formats



Protocol and Rubric

Standard protocol with questions in 5 QMM practice areas

Rubric defined maturity across 5 levels

Question and Corresponding Rubric - Example

Q. How does the establishment use risk management to inform decision-making?

Level 1	Risk is not considered in decision-making.
Level 2	Risk is inconsistently considered in decision-making.
Level 3	Risk is systematically considered in decision-making for commercial manufacturing.
Level 4	Risk is systematically considered in decision-making at all stages of the product lifecycle.
Level 5	Risk based decision-making has been optimized at all stages of the product lifecycle.

Scoring Algorithm

Assessments were performed in teams

- Teams of three assessors to minimize assessor bias

Used standardized protocol and rubric

- Protocol was aligned to ISO standards, guidance documents
- Assessors rated establishments using defined rubric

Scores

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

QMM Assessment Report

- Numerical scores for each practice area and underlying elements
- Strengths
- Improvement Opportunities

Post-assessment Engagements

Establishment selects at least one improvement opportunity

Establishment develops goals that are objective and measurable

Establishment provides brief update to QMM assessment team 1 week before each meeting

1st Post-assessment meeting

2nd Post-assessment meeting

2024 QMM Prototype Assessment Protocol Evaluation Program Scores[1]

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

[1]Scores are out of 5.

Highest Scoring[1] Practice Areas

	Management Commitment to Quality			Employee Engagement and Empowerment		
Establishment	Management Responsibility	Communication	Personnel Management	Ownership and Empowerment	Communication	Rewards and Recognition
A	3.1	2.2	3.2	3.6	3.1	3.6
B	4.6	5	4.9	4.8	4.8	5
C	4.2	4.3	4.1	4.7	4.8	4.2
D	4.6	3.6	4	4.5	3.7	4.1
E	4.5	4.8	4.6	4.9	4.8	4.9
F	4.6	4.3	4.4	4.9	4.5	4.8
G	2.5	2.1	2	2.6	2.8	1.8
H	4	3.4	3.6	3.7	3.8	4.5
I	3.9	4.2	3.5	4.1	3.6	3.8

[1]Scores are out of 5.

Lowest Scoring[1] Practice Areas

	Advanced PQS		Technical Excellence			
Establishment	Quality Risk Management	Continual Improvement	Technological Advancement	Data Excellence	Knowledge Management	Process Optimization
A	2.5	2.7	2.4	2.8	2.9	2.7
B	3.3	5	3.9	3.2	3.4	3.8
C	3.3	4	3.6	3.3	3.5	3.8
D	3.1	4.2	4.7	4.5	4	4.1
E	4.8	4.6	4.7	3.8	4.4	4.6
F	4.1	4.8	4.8	3.2	4.8	4.6
G	2.2	2.3	2.8	2.8	2.4	2.8
H	3	4.1	4	3.7	3.6	3.8
I	3.2	3.9	3.9	3.2	3.1	3.6

[1]Scores are out of 5.

Lessons Learned

- The QMM prototype assessment protocol and rubric distinguished measurable differences in maturity between practice areas and between establishments.
- The QMM assessments provided establishments with actionable feedback that they used to develop improvement plans.
- Some rubrics needed to be simplified to reduce scoring inconsistencies between assessors.
- Some questions needed to be simplified to clarify their intent and guide the establishment to answer with the appropriate information.

Next Steps

2026 QMM Prototype Assessment Protocol Evaluation Program (Cohort #3)

- FRN (Docket No. FDA-2023-N-5706; 2026-02768) dates:
  - February 11 to April 13, 2026
- Gain experience with the refined assessment tool and process to ensure it is fit for use
- Foster mature quality management practices through identification of strengths and opportunities to improve


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

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Questions?

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