

CDER's Quality Management Maturity (QMM) Program

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GRx + Biosims
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Agenda

What is quality management maturity (QMM)?

Why develop CDER's Quality Management Maturity Program?

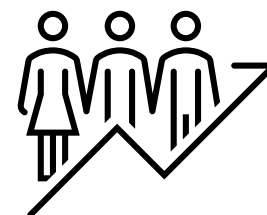
What was learned from the 2024 QMM Prototype Assessment Protocol Evaluation Program?

What comes next?

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 Develop CDER's 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



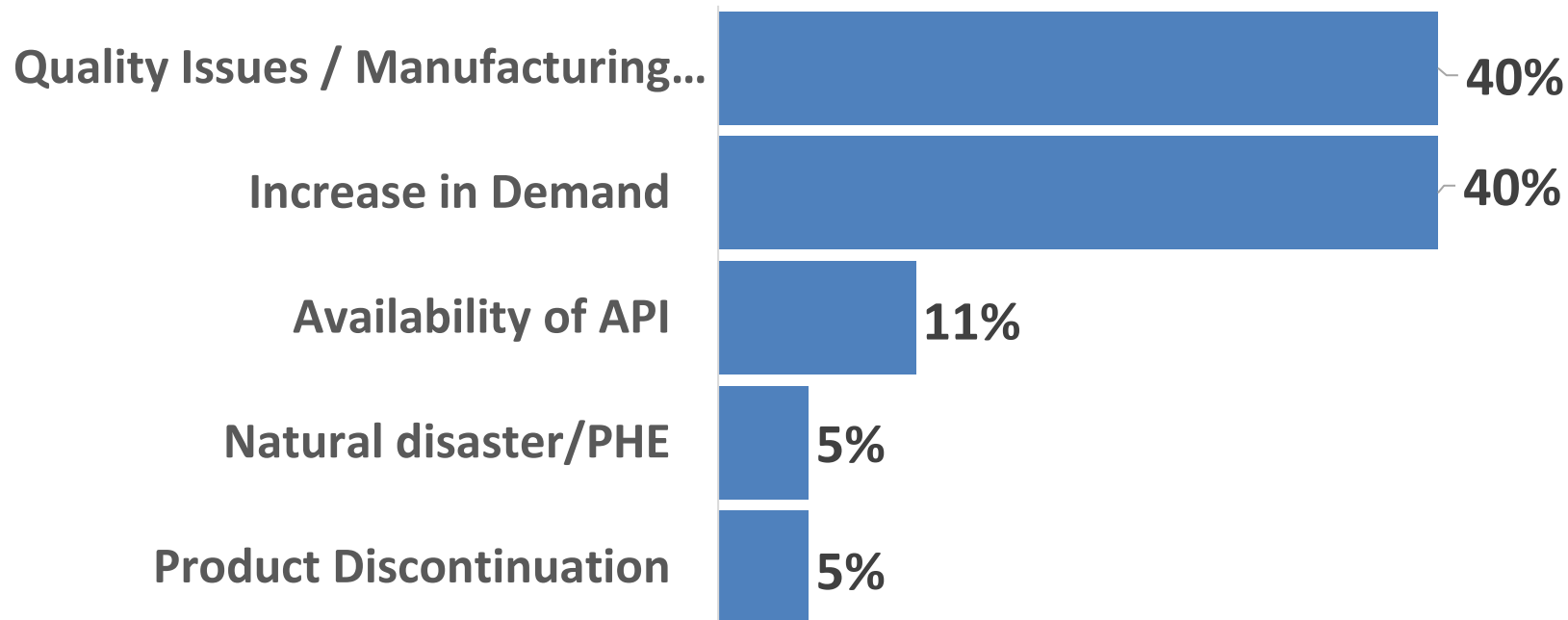
 **U.S. FOOD & DRUG**
ADMINISTRATION

- **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.

Reasons for New Drug Shortages



Percentage of Drugs Newly in Shortage by Reason Calendar Years 2022-2023

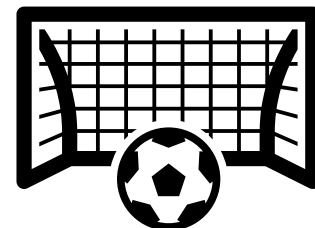


Note: Percentages do not equal 100% due to rounding.
Source: Internal FDA Data

CDER's QMM Program Goals



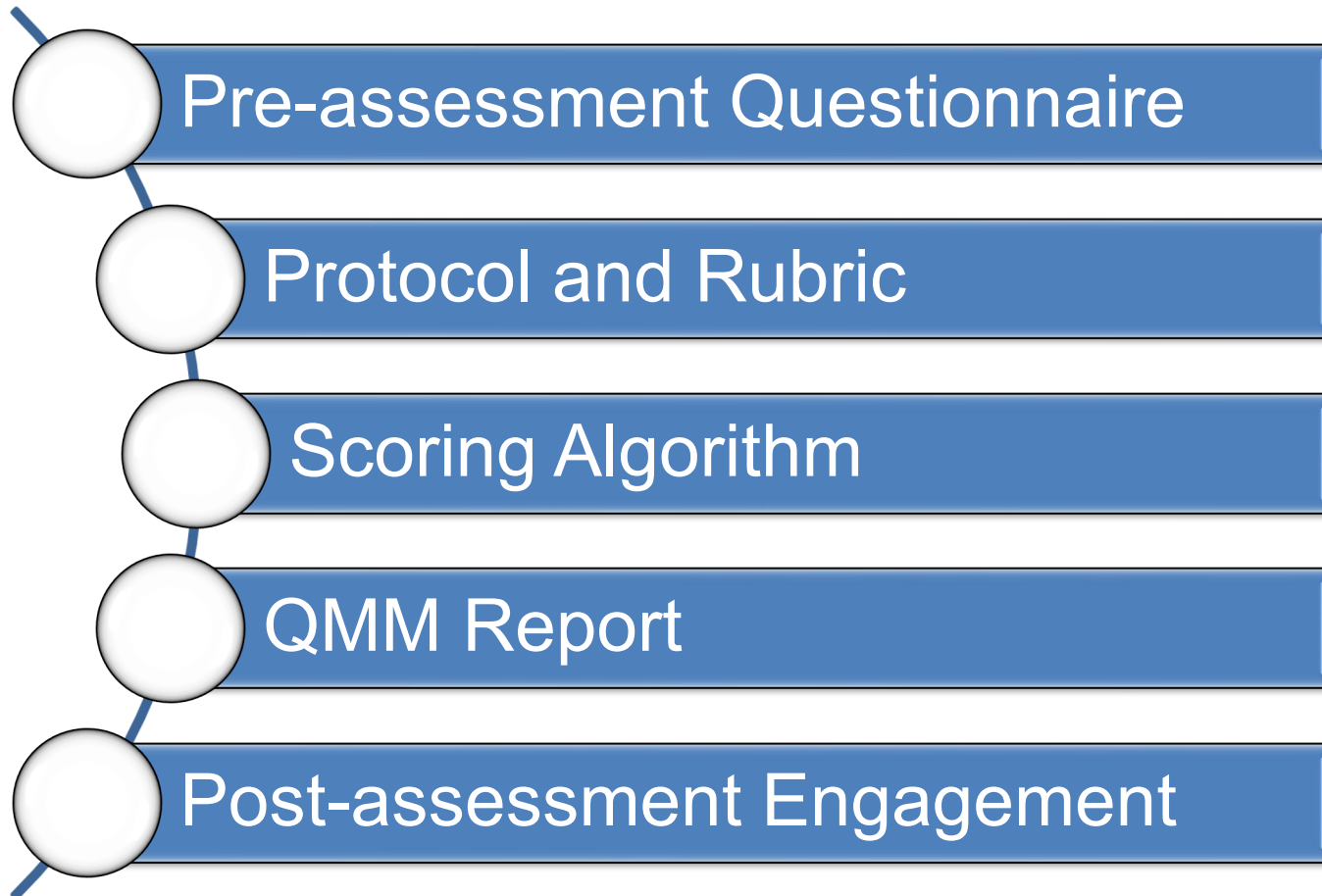
- ✓ Foster a strong quality culture mindset.
- ✓ Recognize establishments with advanced quality management practices and acknowledge establishments that strive to continually improve quality management practices.
- ✓ Identify areas where quality management practices can be enhanced and provide suggestions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



Five QMM Practice Areas



QMM Program Development



Milestones and Publications



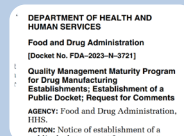
Two QMM Pilots ([API](#) & [FDF](#)) completed in 2022



[CDER White Paper #2](#)
August 2023



[CDER White Paper #1](#)
April 2022



[FRN announcing docket of public/stakeholder feedback](#)
September 2023



[Small Business and Industry Assistance \(SBIA\) Workshop](#)
May 24-25, 2022



[FRN announcing 2024 QMM Prototype Assessment Protocol Evaluation Program](#)
January 2024



[Article on benchmarking quality practices with D&B](#)
October 2022



[2024 QMM Prototype Assessment Protocol Evaluation Program](#)
June-December 2024



[FDA Advisory Committee](#)
November 2, 2022



[FRN announcing 2025 QMM Prototype Assessment Protocol Evaluation Program](#)
April 2025



[Article on lessons from pilot programs](#)
January 2023



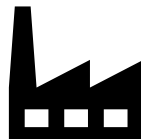
[Quality Management Initiatives in the Pharmaceutical Industry: An Economic Perspective](#)
July 2025

2024 QMM Prototype Assessment Protocol Evaluation Program

FDA



The screenshot displays the Federal Register website interface. At the top, there is a navigation bar with links for Sections, Browse, Search, Reader Aids, and My FR, along with a search box labeled "Search Documents". Below the navigation bar, the "FEDERAL REGISTER" logo is prominently displayed, accompanied by the text "The Daily Journal of the United States Government" and the National Archives seal. A blue banner with a white "N" icon and the word "Notice" is visible. The main heading of the notice is "Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program". Below this, it states "A Notice by the Food and Drug Administration on 01/25/2024". The document is identified as "PUBLISHED DOCUMENT: 2024-01423 (89 FR 4950)". Under the "DOCUMENT HEADINGS" section, the text reads: "Department of Health and Human Services", "Food and Drug Administration", and "[Docket No. FDA-2023-N-5706]". The "AGENCY:" field is also visible. On the left side, there is a sidebar with icons for PDF, Document Details, Document Dates, and Table of Contents.



9 establishments selected

2024 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 tools and process

What was Learned from the 2024 QMM Prototype Assessment Protocol Evaluation Program?



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

2024 QMM Assessment Scores Advanced PQS



What were the highest scoring practice areas?

Employee Engagement and Empowerment
Management Commitment to Quality

2024 QMM Assessment Scores Advanced PQS



What were the highest scoring practice areas?

Employee Engagement and Empowerment
Management Commitment to Quality

What were the lowest scoring practice areas?

Advanced Pharmaceutical Quality System
Technical Excellence

What Comes Next?

Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program

A Notice by the Food and Drug Administration on 04/23/2025



PUBLISHED DOCUMENT: 2025-06968 (90 FR 17069)

DOCUMENT HEADINGS

Department of Health and Human Services
Food and Drug Administration
[Docket No. FDA-2023-N-5706]

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Notice.

PDF

Document Details

Document Dates

Table of Contents

Related Documents

Public Comments

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.

Questions?



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