



11th EDITION
GLOBAL PHARMACEUTICAL
QUALITY SUMMIT

Quality Management Maturity (QMM): Regulatory Expectations and Industry Readiness

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Next 30 minutes...

- What is FDA's QMM Program?
 - Why QMM is a good business strategy?
 - Is the industry mature enough?
- Disclaimer: The opinions and the points presented here are of the speaker and speaker alone, and not necessarily of his organization & PDA. Some slides have data derived from publicly available sources, and the sources are referenced in the same slide. No claim is made for the accuracy of the information taken from publicly available sources, please check the relevant website or source for the accuracy of the information.





What is FDA's QMM Program?

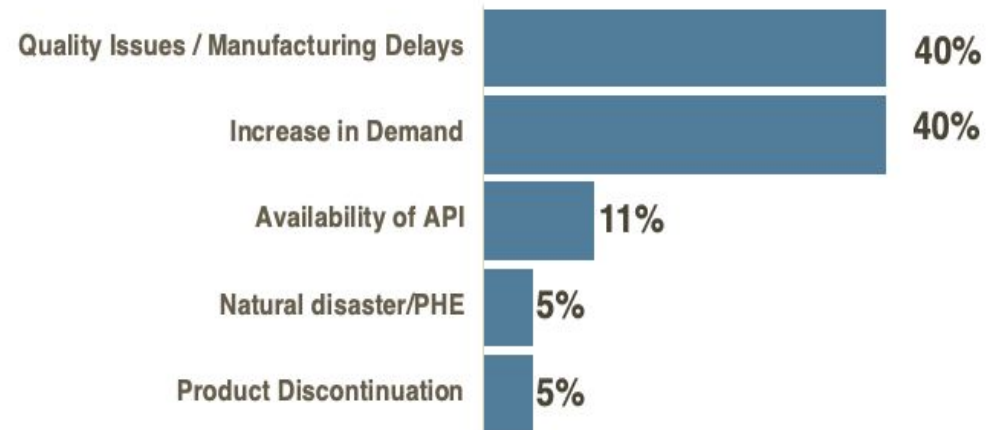
What is Quality Management Maturity (QMM)?

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.



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

Ref: “CDER’s Quality Management Maturity (QMM) Program”; Jennifer Maguire, PhD, Director, Office of Quality Surveillance (OQS), Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), speaking at PDA India Chapter meeting, 4 December 2025

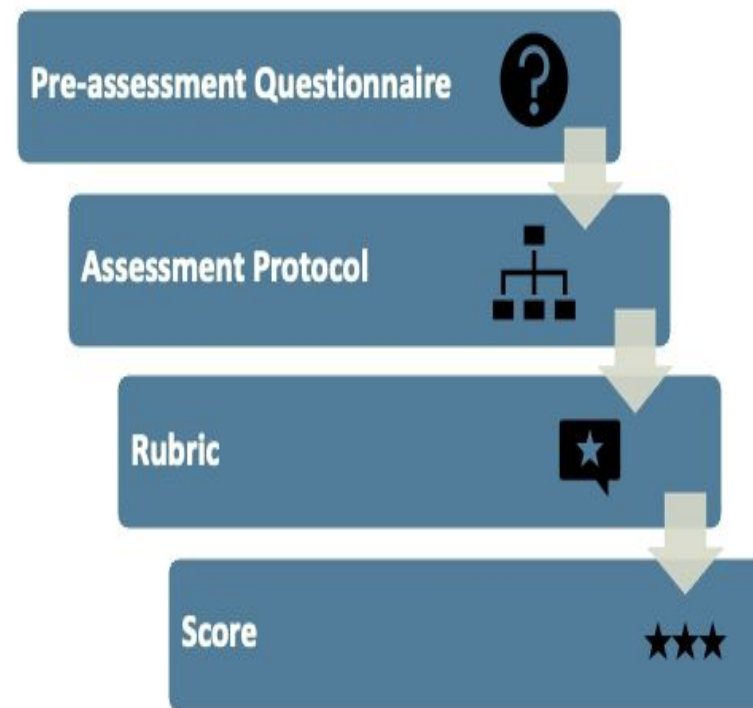


What is FDA's QMM Program?

Five QMM Practice Areas



Overview of Prototype Assessment Process



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Ref: "An Overview of CDER's Quality Management Maturity (QMM) Program"; Jennifer L. Huntington, DVM, MPH
Regulatory Specialist, Office of Quality Surveillance, Office of Pharmaceutical Quality, CDER | U.S. FDA, speaking



Why QMM is a Good Business Strategy?

• Business Strategy Steps:

- Defining Clear Vision & Purpose
- Identify Competitive Advantage
- Set Measurable Goals (KPIs)
- Develop Actionable Plans
- Execute and Monitor

• QMM Practice Areas

- Management Commitment to Quality
- Technical Excellence
- Advanced PQS
- Business Continuity
- Employee Engagement & Empowerment

Ref: "Mature Quality Organizations make an average \$156 million (YoY) more than their peers", 5 Stats on the ROI of Quality as a Strategic Business Initiative, A Survey of 300 C-suite leaders, across manufacturing, IT, ITES, F&B and Life Sciences. www.etq.com





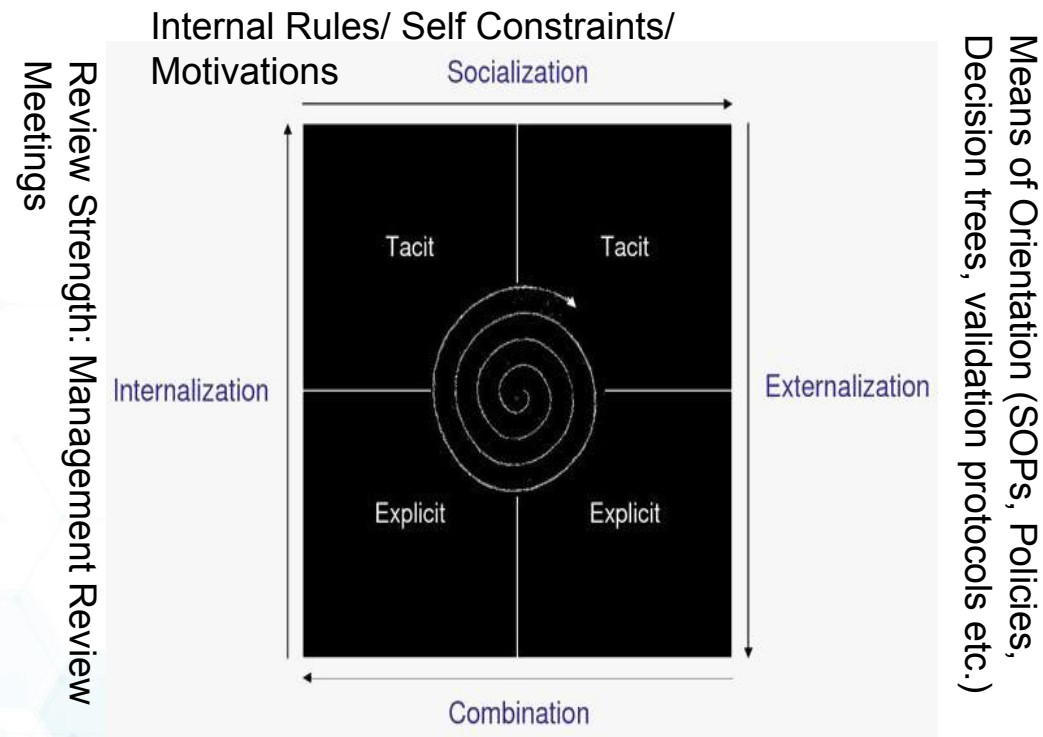
Is Industry Mature Enough?

- Yes & No
- Revisiting Dr. McGuire's statement quoted above, *“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.”*
- The challenge we face as leaders and cannot outsource our responsibility is, **“Integrate business and manufacturing operations with Quality Management”**



People make or break Integration

- Identify people capability to integrate business and manufacturing operations with Quality Management Systems.
- One of the tools is SECI model of Knowledge Transfer (Nonaka & Takeuchi model).



Process mapping: Current Process vs Improvements required (OEE, RFT, Quality Improvement Projects)

Quality Management Maturity & Supply Chain Resilience (2024)



Annual Meeting (2024) Maintaining Quality and Compliance



PDA ANNUAL MEETING 2025



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From Framework to Action: Revised PDA QMM Model and the New Playbook. Wednesday, 25 February 2026, Free Webinar Registration

https://events.teams.microsoft.com/event/840c7402-1442-4cc0-b68f-3c5bc484858c@f17bc40a-fafd-43b9-95aa-cc5d95009e6a?utm_campaign=14751069-S%26RA%20Interest%20Group%20VM%20Invites%202025&utm_medium=email&hsenc=p2ANqtz-9sDkkRLk1mNA4NfyMhsXNN3svzhVoh9MvchRgdszJYhV68KWMoljgpuyimU9IBHoJvKaD86T1OM5wqykT_vlCbMvdT_w&_hsmi=404750939&utm_content=404750939&utm_source=hs_email



Thank You