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The FDA's Quality Management Maturity Program

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The FDA's Quality Management Maturity (QMM) Program continues to evolve in response to the escalating challenge of therapeutic drug shortages. This article examines the rollout of the program and reports on results from the initial QMM pilot studies and industry stakeholders' feedback, recommendations, and consensus opinions that informed the agency's launch of the QMM Prototype Assessment Protocol Evaluation Program scheduled to begin later in 2024. The article also addresses the potential impact of the QMM program.

Keywords – quality management maturity, FDA, pharmaceutical

Introduction

In the early 2000s, the US Food and Drug Administration (FDA) and others, including many legislators, drug manufacturers, physicians, and the public, began noticing shortages in the availability of certain classes of FDA-approved, commercially marketed drugs for treating a range of clinical indications.[1] Although the reasons for the shortages were not well understood, it was clear that the causes needed to be identified. Since then, the FDA and the drug industry have made steady progress in identifying the causes of drug shortages and the systemic changes needed to improve the quality and reliability of drug supplies. After more than a decade of these efforts, the FDA is nearing the point of implementing a full suite of recommended regulatory and industry solutions. This article provides a brief chronology of the steps taken to identify the shortages and the challenges they present and assesses the status of the FDA's novel regulatory QMM program, which could enhance the reliability of the global drug supply. It also examines how this information can be used in the development of the agency's QMM Prototype Assessment Protocol Evaluation.

Drug supply improvement initiatives

Beginning in the mid-2000s and through 2019, the FDA launched a concerted effort to investigate and better understand the causes of the growing trend in

drug shortages affecting patients in the US and globally.[2,3] The FDA led fact-finding studies that included many stakeholders, including patient advocacy and academic groups, industry professionals, and regulators. The initial investigative stage yielded insights into possible changes to reduce the incidence of drug shortages in the US and globally. Problem root causes were identified, and recommendations by the various governmental and public/private teams were evaluated to address the issue.[4,5]

Results from these early FDA-sponsored fact-finding investigations and a later report compiled by the Interagency Drug Shortage Task Force in 2019 revealed that three primary factors substantially contribute to these shortages.[6] Broadly speaking, they relate to: [6]

- Economic disincentives in manufacturing generic drugs;
- Manufacturers are not encouraged to participate in QMM because they are not recognized and rewarded for adhering to the requirements, and conversely, there are no penalties for those who do not participate in the program; and
- Difficulties for manufacturers to recover following a disruption, for example, when a company moves production to a foreign site and logistic and regulatory challenges make it difficult to maintain production levels or easily increase production to offset the shortages.

Once the root causes of the shortages had been identified, the focus shifted to which of the recommended changes to FDA policies and industry practice should be implemented and how the changes should occur. The FDA implemented several initiatives to address these next steps, including:

- The collection of key quality metrics from industry to evaluate product manufacturing quality, starting in 2015;
- Collaborative research with the University of St. Gallen in 2016 on how the agency can use those metrics to improve the effectiveness of its quality inspections; and
- A quality benchmarking study in 2020 by St. Gallen with Dunn & Bradstreet to gauge manufacturing performance and quality practices.[7,8,9]

The QMM program

Another initiative launched by the FDA was the QMM program, intended to address one of the recommendations from the Interagency Drug Shortages Task Force to incentivize drug manufacturers to invest in maturing their quality management systems.[6] The term *quality management system* (QMS) describes a collection of business processes focused on consistently meeting expectations related to the quality of a product and expressed as the organizational goals and aspirations, policies, processes, documented information, and resources needed

for implementing and maintaining quality. The term *quality management maturity* (QMM) used in context with QMS describes the stage at which a drug manufacturer attains "consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement."[10] The QMM program includes the development of a rating system, expressed as a score, to incentivize manufacturers to adopt more mature quality management practices.

QMM refers to both being compliant with established laws and regulations related to current good manufacturing practice (cGMP) and how management integrates and optimizes its QMS with nonregulated practices and business processes such as human resources, the drugs supply chain, finance, information technology, and other non-GMP systems that affect the quality and availability of a drug. These factors are typically outside the scope of a cGMP quality audit and are often overlooked by site management (see section on QMM pilot studies).[11] The QMM program was established to address this by encouraging drug manufacturers to go beyond minimum compliance with cGMP regulations to: [12]

- Promote a focus on quality culture,
- Identify organizations that use advanced quality management practices and acknowledge establishments that continually improve quality,
- Identify weaknesses and suggest opportunities for improvement, and
- Reduce risks to product availability to assure supply chain resiliency.

Several business sectors unrelated to the pharmaceutical industry have grappled with similar quality issues and successfully resolved the supply problems by integrating QMM principles into their operations.[11] The benefits associated with enhanced QMM practices and the lessons learned in those cases informed the FDA about the potential value of QMM model in drug manufacturing.[11]

QMM pilot studies: Third-party assessments

In 2020, the FDA launched QMM pilot studies to gather information on assessing a manufacturer's QMS for maturity. [13] The study assessments were done by third-party contractors and observed by FDA staff to guide them in the future development of an agency QMM evaluation and rating system.[13] Two vendors were competitively selected to drive the QMM pilot studies. One assessed seven US-based sites that manufactured finished dosage form products, and the other assessed eight foreign sites that manufactured active pharmaceutical ingredients (APIs) used in finished drugs marketed in the US.[13] All the participating sites had volunteered for the program but were required to meet minimum cGMP compliance in which there were no regulatory actions for the previous five years.[13]

Each vendor developed their own assessment protocols, methodologies, and rating systems that minimally covered topics listed in the Federal Register, such as supply chain management, manufacturing strategy, and risk management, among others.[5] At the completion of the pilot studies in 2022, each vendor submitted a final report compiling the results of the assessments and recommendations for rating the sites based on their protocol criteria.[13] Feedback obtained during discussions with the pilot study participants and through comments on a QMM program proposal in 2023 indicated that the assessments helped the participating manufacturers identify their strengths, weaknesses, and new areas for improvement that had not been previously identified during internal audits or FDA regulatory inspections.[13] The pilot studies also provided the FDA with important takeaways, such as the scoring approach for determining the QMM ratings assigned to each site, assessor behaviors, and participant perceptions regarding the assessment questions and reports, which they planned to incorporate into the next phase – generating the QMM Prototype Assessment Protocol Evaluation Program.[13]

Many stakeholders seem to be adopting a cautiously optimistic stance regarding the value of the QMM program.[14,15] While they generally support it, many of those responding to the call for comments noted specific aspects of the program that need more deliberation. We can glean much from:

- Post-assessment feedback from drug and API manufacturers that participated in the initial round of pilot studies during 2020-2022,[13] and
- The public comments and published opinions regarding the FDA's September 2023 QMM program proposal.[16]

However, until the FDA completes its current round of assessments as part of its QMM prototype evaluation program (see the section, QMM prototype assessment), the amount of empirical information regarding the degree of public support for the QMM program is limited. The assessment is expected to be completed in 2025.

Post-assessment feedback from pilot participants

When queried post assessment, the overall sentiment of pharma manufacturers participating in the QMM pilots was positive.[13] Several pilot study participants offered feedback about the overall benefits of the program, including that it:[17]

- Prompted them to take a wholistic, "big picture" look at their systems, which was not always the case with audits,
- Got them to consider certain topic areas they had not previously addressed,
- Helped identify site strengths and weaknesses;

- Would be beneficial to sites' continuous improvement program and help manufacturers identify and focus on where they are and where they need to go; and
- Could allow for the QMM score to inform decisions about reducing the frequency of and time spent on vendor audits.

In addition, a poll on the perceived benefits of participating in the QMM program, taken during a 2022 CDER workshop that included several pilot participants, showed that participants ranked benefits such as being able to identify continuous improvement opportunities and improving supply chain insights higher than receiving regulatory incentives from the FDA.[17]

In November 2022, the FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee voted unanimously for establishing a QMM program following presentations from FDA representatives and industry stakeholders.[12,20]

Comments on the proposed QMM program

On 15 September 2023, the FDA published a notice in the Federal Register to solicit comments from the public regarding its proposed QMM program.[16] The comment period ended on 14 December 2023 and yielded 23 responses from interested individuals, industry groups, patient advocacy organizations, and drug manufacturers.[18] A few commentators expressed mild to strong reservations about an FDA-run QMM program, but in general, the comments were cautiously positive, with almost all respondents expressing measured support for certain aspects of the QMM initiative. Many noted similar advantages of participating in the QMM program, including that:[18]

- Using QMM scores as a marketing tool might lead to improved market reputation and customer perceptions of the company;
- Implementing QMM within a manufacturer's supply chain might improve transparency with suppliers and reduce the risk of supply interruptions;
- The efficient processes resulted in fewer errors, customer complaints, and recalls, leading to cost savings;
- It facilitated shared learning and benchmarking across the pharmaceutical sector;
- It resulted in robust risk management and decision making; and
- It fostered a quality-based organization focused on proactive continual improvement.

Advantages of participation

Leading industry trade organizations expressed qualified support for the QMM program, though they all recognized QMM as a valuable resource for continual improvement and advancing cultural excellence. For example, one industry

association noted that QMM could provide small companies or resource-constrained manufacturers a roadmap in developing their own formal quality maturity program, and another noted it would enhance a culture of proaction across organizations.[18]

A public-private partnership organization also voiced support for adopting the QMM program mentioning opportunities for benchmarking and proactively building quality management systems instead of reacting to audit findings. A consortium of experts across academia, private industry, and governmental agencies emphasized the value of QMM along with other initiatives as a comprehensive approach to address drug shortages and provided other policy recommendations to focus on drug supply chain resilience.[18]

Several comments were submitted by individual domestic manufacturers who were supportive of QMM. They noted the value of collaboration in developing a positive relationship with the FDA and the potential incentives this can incur. Examples they referenced include increased regulatory flexibility with postapproval changes and reduced inspection frequency using a risk-based approach, among others, which will encourage manufacturer participation.[18]

Foreign drug associations and manufacturers located in India and the Netherlands generally supported the program, noting the market advantages that participation in the QMM program may provide, including fostering trust and collaboration with clients and purchasers. Some foreign respondents also noted that QMM could be implemented within their own supply chain to enhance vendor engagement and the vendor qualification program.[18]

Contract manufacturing organizations (CMOs) and a CMO trade group provided insights on QMM but had differing opinions about its benefits and concerns. One CMO supported QMM and identified opportunities resulting from participation in the program, such as improved visibility of risks and gaining a strong competitive advantage by building customer trust through transparency with QMM scores. Although the trade group noted potential opportunities such as shared learning and improved product quality, it emphasized that continuous improvement initiatives are a collaborative effort with clients. It noted that CMOs are often restricted by contracts in implementing changes that might require previous approval from client drug manufacturers and that their efforts to improve processes might be stymied because of such contractual limitations.[18]

Several patient advocacy groups and purchasing organizations concurred with industry in supporting the FDA's initiative to remedy the dire drug shortage situation and recognized the dual benefits of improving supply chain reliability and enhancing supply chain transparency. They noted that QMM scores would enable purchasers to identify and mitigate potential risks, verify information

provided by manufacturers as part of contract negotiations, and make more informed purchasing decisions.[18]

Critiques and recommendations

While most comment responders endorsed QMM, many also expressed clear reservations with various aspects of the program, which they recommended should be amended to serve the program's objectives better and avert unintended and counterproductive consequences that would unfairly harm certain companies, potentially exacerbating the drug supply problem.[18]

Commenters responded largely along industry lines on public disclosure of the FDA's QMM assessment outcomes. Most respondents representing purchasers or the healthcare industry preferred to have the QMM ratings shared publicly to assist in making informed purchasing decisions and to provide transparency during contract negotiations with suppliers. However, respondents representing the manufacturing sector wanted the scores to remain confidential or to be disclosed only at the discretion of the assessed company. It is interesting to note that one of the international associations representing professionals within the manufacturing industry said that some sort of public disclosure is needed to create the economic incentive for manufacturers to invest in QMM.[18]

Respondents who opposed revealing QMM scores were concerned the ratings might be confused as indicators of cGMP compliance or product quality, leading to biased decision making by purchasers, causing supply distortions, and/or having unintended consequences such as forcing companies to exit the market, leading to more drug shortages. The FDA has asserted that QMM score transparency is critical to ensure that drugs sold in the US meet quality requirements and are safe and effective but acknowledges that QMM scores should be more closely defined to avert potential misconceptions.[10,18]

Another concern among respondents was whether participation in the QMM program would be mandatory. While nearly all respondents indicated they would prefer keeping the program voluntary, there were also concerns that insufficient participation could make benchmarking meaningless and disincentivize participation. However, several respondents noted concerns that a mandatory program could add regulatory burdens and costs for manufacturers without the corresponding benefit of improving supply. In a 2023 FDA whitepaper, the agency pushed back on that view, stating that participation in the QMM program is voluntary even though the agency's inspection authority is required under the law for compliance purposes. The agency also noted that QMM is already part of a company's quality system rather than an additional burden or requirement. Many organizations already have the same practices and processes that QMM evaluates, in which maturity is attained through the site's natural proactive continual improvement efforts. In addition, improving quality systems should lead to long-term cost savings, although costs may initially be short-term cost increases.[18,19]

Most of the respondents also raised the ambiguity or lack of sufficient incentives for industry to participate in QMM, such as those available in the Center for Devices and Radiological Health's Voluntary Improvement Program. (The CDHR incentives include pre-announced or reduced inspection frequencies and reduced review timelines for change submissions, among others.) Some respondents even suggested that potential financial incentives from government bodies such as the Centers for Medicare and Medicaid Services for grants or tax incentives should be explored. Although the FDA has alluded to potential incentives in its Office of Pharmaceutical Quality whitepaper, such as providing regulatory flexibility in making postapproval changes or reduced inspection frequencies, they have not yet solidified a firm position for future participation in the program.[10] However, the FDA mentions in the same whitepaper that the market will need to play a key role in incentivizing manufacturers by using QMM scores in their purchasing decisions to reward products from facilities that should likewise encourage continual improvement in the long term.[18]

Some respondents raised concerns over large companies or innovator manufacturers having unfair advantages over smaller companies or generic manufacturers that may need more human or discretionary capital resources for maintaining a highly mature quality organization. Many noted it may be challenging for resource-constrained companies to go beyond what is required for cGMPs, causing them to be excluded from the market if they do not score well enough or do not participate in the QMM program. Respondents also noted that those are the same demographics of organizations that can benefit the most from enhanced QMM if they were to participate, giving them a competitive advantage over larger companies, and reducing supply interruptions for the generic drug industry that contribute to a majority of the drug shortages. The FDA recognizes this as a consideration in the QMM program, in which they deem maturity as independent of an establishment's size or age and instead, a reflection of the quality mindset and practices that are implemented.[18,19]

Several nonprofit respondents, industry groups, and a healthcare improvement company supported improving quality and supply chain reliability but had alternate recommendations for tackling the endemic drug shortages. One respondent believed the QMM program should be run by an independent third party modeled after organizations such as the US Pharmacopeia or the Joint Commission, a US-based nonprofit organization, in which it could increase flexibility, market responsiveness, and transparency while maintaining oversight by the federal government. Other respondents believed that using industry-led or site-established programs to advance continued improvement would allow for a more focused effort in relevant areas without the potential unintended consequences of the additional burdens that the QMM program presents, resource challenges, and external visibility leading to misinterpretation of QMM ratings. Furthermore, some respondents suggested that existing quality

programs and tools should be improved rather than relying on the QMM program for quality management. They cited as examples the analytic tools and models maintained by the FDA's Office of Quality Surveillance to provide real-time data for making purchasing decisions and pursuing existing statutory options such as priority pathways for the review of drug shortage applications or extending shortage reporting requirements to API manufacturers, among others, as part of the CARES Act. [18]

Several other concerns were expressed, such as the handling of confidential information, potential training and variability between assessors, and collaboration amongst global regulators, but none that the FDA has not already addressed through literature or other forums or that will provide a foreseeable roadblock to implementation of the program. [18]

QMM prototype evaluation

In January 2024, the FDA announced its QMM Prototype Assessment Protocol Evaluation Program (PEP) for its newly developed QMM assessment tool. The agency invited drug and API manufacturers to submit applications for nine available spots to participate voluntarily in its trial run of the tool.[21] The development of the tool was informed by the assessment findings from the two QMM pilot studies and the feedback and comments solicited from the industry. The results from the PEP studies will guide the agency on which aspects of the tool, if any, need refining to ensure the effectiveness of the QMM program.

Members of senior management at the participating manufacturers will have to complete pre-assessment questionnaires to help them prepare them for the evaluation process. The assessment by a three-member team of CDER and/or contractor QMM assessors will take four to five days. Once the assessment has been completed, the agency and each participant will receive a confidential QMM report summarizing areas of strength and growth opportunities based on the QMM parameters. About six months after the assessment, the assessor team will conduct a follow-up virtual meeting with participant senior staff to solicit additional feedback on the assessment process and any actionable recommendations for improving the QMM process and performance.[21] The five areas of QMM assessment are: [21]

- Management commitment to quality
- Business continuity
- Advanced pharmaceutical quality system
- Technical excellence
- Employee engagement and empowerment

This most recent phase in the QMM program development process is expected to be completed in early 2025.

Conclusion

FDA has garnered broad but tentative support from the drug industry and other stakeholders for its QMM program. Earlier root cause evaluations by independent analysts indicate that by addressing non-cGMP aspects of drug manufacturing (e.g., vendor selection, greater communication between and among suppliers and manufacturers in the production processes, and improved inter-departmental alignment of operations), senior management can better influence the drug supply output and reliability. The FDA has invested considerable time in investigating the causes of drug shortages and soliciting input from the pharmaceutical industry and public at large and now has a clearer perspective on the changes needed to mitigate the quality-related drug shortage problem.

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