DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3721]

Quality Management Maturity Program for Drug Manufacturing Establishments;

Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to solicit comments that will assist the Agency in developing a Quality Management Maturity (QMM) program for establishments manufacturing human drugs, including biological products, regulated by the Center for Drug Evaluation and Research (CDER).

DATES: Submit either electronic or written comments on the notice by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to ensure that the Agency considers your comment.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments may not be considered. Electronic comments must be submitted on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:
Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2023-N-3721 for “Quality Management Maturity Program for Drug Manufacturing Establishments; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted
as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the
Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that
you do not wish to be made publicly available, submit your comments only as a
written/paper submission. You should submit two copies total. One copy will
include the information you claim to be confidential with a heading or cover note that
states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The
Agency will review this copy, including the claimed confidential information, in its
consideration of comments. The second copy, which will have the claimed
confidential information redacted/blacked out, will be available for public viewing
and posted on https://www.regulations.gov. Submit both copies to the Dockets
Management Staff. If you do not wish your name and contact information to be made
publicly available, you can provide this information on the cover sheet and not in the
body of your comments and you must identify this information as “confidential.”
Any information marked as “confidential” will not be disclosed except in accordance
with 21 CFR 10.20 and other applicable disclosure law. For more information about
FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015,
or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-

Docket: For access to the docket to read background documents or the electronic and
written/paper comments received, go to https://www.regulations.gov and insert the docket
number, found in brackets in the heading of this document, into the “Search” box and follow the
prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville,
MD 20852, 240-402-7500.
FOR FURTHER INFORMATION CONTACT: Djamila Harouaka, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, Rm. 4160, Silver Spring, MD 20993-0002, 240-402-0224, CDER-QMM@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Drug manufacturers can achieve higher levels of QMM by successfully integrating business and manufacturing operations with quality practices and technological advancements to optimize manufacturing process performance and product quality, enhance supply chain reliability, and foster proactive continual improvement. CDER is developing a voluntary program to promote QMM at drug manufacturing establishments. The goals of this program are: (1) to foster a strong quality culture mindset; (2) recognize establishments that have advanced quality management practices and acknowledge establishments that strive to continually improve those practices; (3) identify areas where quality management practices can be enhanced and provide suggestions for growth opportunities; and (4) minimize risks to product availability to assure reliable market supply.

The QMM assessment is designed to appraise an establishment’s quality culture mindset, behaviors, and commitment to adopting best practices to effectively meet the needs of patients and consumers. QMM assessments would not be used to evaluate compliance with current good manufacturing practice (CGMP).

QMM assessments would be conducted by trained assessors, who would engage directly with establishments, either onsite or in a hybrid (onsite/remote) environment, for 2 to 5 business days. The QMM assessment will cover five practice areas: (1) management commitment to quality; (2) business continuity; (3) advanced pharmaceutical quality system; (4) technical excellence; and (5) employee engagement and empowerment. Within each practice area, the assessors would explore key elements to better understand an establishment’s QMM. Examples of elements covered under each practice area could include: management review and resource
management (management commitment to quality practice area), supply planning and demand forecasting (business continuity practice area), data governance and process optimization (technical excellence practice area), effectiveness of the corrective action and preventive action process (advanced pharmaceutical quality system practice area), and rewards and recognition (employee engagement practice area). Each establishment’s responses, executed practices, and behaviors would be assessed using a standardized assessment protocol and an objective rubric, which is currently under development, to help identify areas of strength and potential areas with opportunities for improvement.

At a November 2, 2022, meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee, FDA sought to determine the support of academic and industry experts for CDER’s development of a QMM program. By a vote of 9-0, the committee affirmed that CDER should establish a QMM program to incentivize investments in mature quality management practices. During deliberations, committee members advised the Agency to continue to seek stakeholder input throughout the program’s development. Further information about the November 2022 Advisory Committee meeting, including event materials, is available on FDA’s website at https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-2-3-2022-pharmaceutical-science-and-clinical-pharmacology-advisory-committee-meeting. For further information about QMM, relevant research, and previously conducted pilot programs, please see CDER’s QMM webpage at https://www.fda.gov/drugs/pharmaceutical-quality-resources/cder-quality-management-maturity. FDA has verified the website addresses, as of the date this document publishes in the Federal Register, but websites are subject to change over time.

II. Request for Comments

FDA is opening a docket to solicit additional feedback from the public on CDER’s planned, voluntary QMM program. The public is invited to provide detailed comments on all aspects described in this notice. To facilitate this input, FDA has developed a list of questions.
These questions are not exhaustive, and FDA welcomes other pertinent information the public would like to share on this topic. In all cases, FDA encourages the public to provide the reasoning and specific basis for any comments.

1. If you are a manufacturer, please identify the types of drug(s) produced in your establishment (e.g., active pharmaceutical ingredients, innovator drugs, innovator biologics, generics, biosimilars, or OTC monograph drugs). If you are not a manufacturer, please specify whether you are a purchaser, payor, pharmacy, healthcare provider, patient, regulator, supplier, distributor, contract service provider, or other (please describe).

2. What advantages do you anticipate that your sector (i.e., your organization and others like yours) would gain from CDER’s voluntary QMM program?

3. How would participation in a QMM program benefit you or your specific organization?

4. How would you use information from a QMM assessment if it were provided to your organization? For example, if your organization acts as a supplier or contract organization, would you consider sharing information from a QMM assessment with a potential client? If your organization enters into contracts with purchasers, would you consider sharing information from a QMM assessment with a purchaser? If your organization is a purchaser, would you consider requesting information from a QMM assessment?

5. What, if any, unintended consequences, roadblocks, or other concerns do you anticipate with a voluntary QMM program? What barriers to participation do you anticipate? Please explain. Which of these unintended consequences might be unique to stakeholders like you? Why?

6. FDA anticipates that each establishment would be provided with a detailed report following their QMM assessment. What would you want such a report to contain?

7. With respect to the outcomes of a QMM assessment, what are your thoughts about making outcomes public? Would your thoughts be different if the outcomes were generally qualitative (e.g., descriptive information) versus quantitative (e.g., a numerical rating)?
8. What other feedback would you like the FDA to consider for a voluntary QMM program?

III. References

The following references are on display with the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at https://www.regulations.gov as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the Federal Register, but websites are subject to change over time.


Lauren K. Roth,

*Associate Commissioner for Policy.*

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