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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5706]

Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a limited number of drug manufacturing establishments to participate in the third year of the voluntary Quality Management Maturity (QMM) Prototype Assessment Protocol Evaluation Program. The Center for Drug Evaluation and Research (CDER) is implementing this voluntary program for manufacturers of CDER-regulated drug products to gain additional experience with the assessment tool and process. The continuation of this voluntary program is needed to assure that these assessments enable consistent and meaningful evaluations of establishments' quality management practices and provide useful feedback for the establishments. This notice outlines the types of establishments FDA is seeking for participation and the process for submitting a request to participate in the program.

DATES: FDA intends to accept requests to participate in the voluntary QMM Prototype Assessment Protocol Evaluation Program through April 13, 2026. See the "Participation" section of this document for instructions on submitting a request to participate and for information about the selection process.

FOR FURTHER INFORMATION CONTACT: For questions about the voluntary QMM Prototype Assessment Protocol Evaluation Program, 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. To

submit a request to participate in the program, contact Conchetta Newton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Rm. 4144, 240-402-6551, CDER-QMM@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

QMM refers to the extent to which drug manufacturing establishments implement quality management practices that prioritize patients, drive continual improvement, and enhance supply chain reliability through the strategic integration of business decisions and manufacturing operations with quality practices and technological advancements. CDER has developed a voluntary QMM program to encourage drug manufacturers to implement quality management practices that go beyond current good manufacturing practice (CGMP) requirements.[1]

Following completion of the first year of the program, CDER refined the prototype QMM assessment tool (including both a protocol and rubric), which is used to evaluate how effectively establishments monitor and manage quality and quality systems.[2] In CY 2026, CDER intends to continue the voluntary QMM Prototype Assessment Protocol Evaluation Program to evaluate a drug manufacturing establishment's quality management practices and provide actionable feedback for the establishment. This notice announces CDER's intent to continue the QMM Prototype Assessment Protocol Evaluation Program, outlines the types of establishments CDER is seeking for participation, and describes the process for submitting a request to participate in the program.

In 2024, CDER evaluated nine establishments during the initial year of the voluntary QMM Prototype Assessment Protocol Evaluation Program.[3] CDER used a standardized prototype assessment protocol and rubric to evaluate each establishment's practices, behaviors,

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[1] FDA has solicited comments to inform the development of this program. See 88 FR 63587, September 15, 2023.
[2] For additional information, see *CDER's Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development* (2023), available at https://www.fda.gov/media/171705/download?attachment.
[3] See 89 FR 4950, January 25, 2024.

and responses to specific questions. Feedback from participants in the first year of the program indicated that the QMM report, engagement with the assessment team, and the ability to have open discussions provided value to establishments and highlighted strengths and opportunities for improvement. In addition, participating establishments were able to share challenges and successes related to their manufacturing sectors.

The 2024 QMM program provided CDER with experience in the successful application of the standardized prototype assessment protocol and rubric at nine drug manufacturing establishments. The nine establishments represented a range of manufacturing sectors (e.g., generic drug manufacturers, contract testing laboratory, brand drug manufacturers) in the pharmaceutical industry. The prototype assessment protocol and rubric distinguished differences in maturity levels between practice areas at a single establishment. Differences in maturity levels were also clearly discerned between establishments. Using the insights gained from these experiences, CDER streamlined the QMM assessment tool to make the prototype protocol and rubric clearer and more concise.

CDER is now evaluating the refined assessment tool at more establishments in the second year of the QMM Prototype Assessment Protocol Evaluation Program, which is ongoing. Through this announcement, CDER is offering an opportunity for additional establishments to volunteer to participate. This will allow CDER to gain further experience with the assessment tool, expand our knowledge of quality management practices in the industry, and provide additional drug manufacturing establishments with actionable feedback.

II. Participation

A. Establishment Characteristics

CDER will consider the following establishment characteristics when identifying potential participants for the third year of the QMM Prototype Assessment Protocol Evaluation Program:

- The potential participant is an establishment as defined in 21 CFR 207.1 that registers with FDA under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and manufactures, prepares, propagates, compounds, or processes drugs, or APIs used in such drugs, subject to approval or licensure under section 505 of the FD&C Act or section 351 of the Public Health Service Act, or that are marketed pursuant to section 505G of the FD&C Act without an approved application under section 505 of the FD&C Act (often referred to as over-the-counter (OTC) monograph drug products).
- The establishment received at least one human drug surveillance inspection.[4]
- The current inspection classification for the establishment at the time of the request to participate is No Action Indicated (NAI) or Voluntary Action Indicated (VAI).
- The establishment manufactures, prepares, propagates, compounds, or processes at least one CDER-regulated drug (API or finished drug product) that is currently in commercial distribution in the U.S.
- The establishment is willing to participate in an onsite or hybrid assessment.

B. Requests to Participate

Drug product manufacturers that meet the establishment characteristics described in section II.A and are interested in participating in the voluntary QMM Prototype Assessment Protocol Evaluation Program should submit a request directly to Conchetta Newton (see FOR FURTHER INFORMATION CONTACT). To be considered for this program, a request should include all the following information:

(1) A contact person (name and email)

(2) Manufacturing establishment address

[4] Inspections conducted by FDA or by Mutual Recognition Agreement (MRA) partners and classified by FDA would fulfill this criterion.

(3) Establishment FDA Establishment Identifier (FEI) and Data Universal Numbering System Numbers (DUNS)

(4) A brief description of the business operations (e.g., manufacturing, testing, re/packaging, re/labeling, sterilizing, storing, distributing, or salvaging) conducted at the establishment. Please indicate whether the establishment produces active pharmaceutical ingredients (APIs), generic drugs, innovator drugs, over-the-counter (OTC) drugs, biological drug products, and if the establishment is a contract manufacturing or contract testing organization.

(5) Confirmation that the establishment features the characteristics discussed in section II.A of this notice.

C. Selection Process

CDER intends to select participants that reasonably reflect the diversity of the industry. CDER intends to notify each establishment of a decision on their request to participate within 60 days of receipt. CDER intends to select up to nine volunteer participants for this program.

D. FDA-Participant Interactions

CDER intends to notify participants of their selection and confirm their willingness to participate. Selected participants will receive orientation materials which will contain additional information about program timelines, milestones, and expectations. Participating establishments will also receive a pre-assessment questionnaire, which will provide them with specific topic areas that will be covered during the assessment. The pre-assessment questionnaire is intended to help establishments prepare for the assessment and identify the relevant subject matter experts to support the assessment. CDER will also provide each establishment with options for dates and times to schedule the assessment which may take up to five days.

Each assessment will be conducted by a team of three assessors. The assessment team will be composed of CDER staff and will not include FDA personnel from the Office of

Inspections and Investigations charged with the responsibility of ensuring CGMP compliance. In advance of the assessment, the establishment will receive an agenda so that they can assure the appropriate subject matter experts are available at the requested times. The entire leadership team does not need to be present for the full assessment. If necessary, personnel may participate remotely as the establishment deems appropriate.

Following completion of the assessment, each participating establishment will receive a QMM assessment report that provides their score in each practice area and underlying topics covered along with context for how the score was determined. The report will highlight 2-3 areas of strength and 2-3 actionable opportunities for improvement in each practice area. Participating establishments are encouraged to select at least one opportunity for improvement identified in the QMM assessment report and develop a plan to implement improvement(s). Establishments are requested to share their improvement plan with CDER, and a meeting will be scheduled to discuss the proposed plan 3 months after the assessment. Approximately 6 months after the assessment, CDER will schedule a final check-in meeting to discuss any progress made toward the improvement goals. CDER will solicit feedback from each establishment on the assessment, the QMM assessment report, and invites any suggestions or input to improve the program. This information will help CDER evaluate the QMM assessment tool and process to determine whether it enables a meaningful assessment of the establishment's quality management practices and if feedback for the establishment is actionable.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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