

**Additional Information Regarding the January 25, 2024 Federal Register Notice titled:  
Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program  
[Docket No. FDA–2023–N–5706]**

Questions and Answers:

- 1) What does participation in this Prototype Assessment Protocol Evaluation Program entail?
  - It includes a virtual orientation, completion of the pre-interview questionnaire, assessment (up to five days), and opportunities for post-assessment collaboration.
- 2) How can selected establishments prepare for participation?
  - FDA will convene a virtual orientation session for establishments that are selected to participate in the 2024 program, at least six weeks prior to the start of the assessments, to share information regarding timelines and expectations.
  - Participating establishments will receive the pre-interview questionnaire, which provides sample questions in each practice area and is designed to assist the establishment in preparing for the assessment.
- 3) How will the pre-interview questionnaire be used?
  - The pre-interview questionnaire will help the participating establishments understand the topic areas that will be covered during the assessment and consider which examples they choose to share to demonstrate their practices.
  - The pre-interview questionnaire will also help FDA to streamline the assessment.
- 4) Who needs to be present during the onsite portion of an assessment?
  - It is at the discretion of participating establishments to determine who needs to be present during their assessments. They will receive an agenda in advance of their assessment so they can ensure the appropriate people are available at the requested times. FDA does not believe that the entire leadership team needs to be present for the full assessment. If necessary, personnel may participate remotely as the establishment deems appropriate.
- 5) How many FDA staff and contractors will perform the assessment?
  - Assessment teams will be composed of three individuals -- two FDA staff and one FDA-hired contractor. Contractors will be held to the same standard as FDA staff in maintaining confidentiality and protecting nonpublic information.
- 6) Which FDA staff will participate in the assessment teams?
  - The assessment teams will be staffed from CDER's Office of Pharmaceutical Quality and will not include FDA personnel currently involved in inspections or CGMP compliance.
- 7) What is the expected output from the assessment?
  - After the assessment, participating establishments will receive a 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. The report will also describe expectations for reaching the next level of maturity.

- 8) Are there opportunities to consult with CDER after the assessment is complete?
- Yes. We encourage participating establishments to select at least one area they feel would be most important to focus on for their continual improvement and develop a plan for achieving it. If participating establishments share this improvement plan with CDER, we will host a virtual meeting with the establishment to discuss it and the path forward.
- 9) Where should additional questions be sent?
- Please send any additional questions to [CDER-QMM@fda.hhs.gov](mailto:CDER-QMM@fda.hhs.gov).