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10 October 2022

Dockets Management Staff (HFA-305),
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Reference: Docket No. FDA-2022-N-1777 for "*Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting*," Request for Comments.

Dear Madam or Sir,

PDA appreciates the opportunity to provide comments to FDA as the agency further refines the FDA Quality Management Maturity program. In general, the QMM program will provide useful information that will be of help to the industry. PDA would like to express our continued support for the FDA QMM program and the fact it was developed based on research findings and pilot programs. In our attached comments, PDA offers specific comments that we believe will be helpful in the further development of this importance program to ensure the best possible outcomes for industry and FDA that will maximize the benefit to patients.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in fields of pharmaceutical, biological, device manufacturing, and quality. Our comments have been prepared by a committee of PDA members with expertise in the areas covered in the Public Docket on behalf of PDA's Quality Management Maturity Task Force Team and Board of Directors.

If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,

Richard Johnson
President and CEO

cc. Glenn Wright, PDA; Carrie Horton, PDA

Parenteral Drug Association (PDA)

PDA is a non-profit international professional association of

- more than 10,000 individual member scientists
- having an interest in fields of pharmaceutical, biological, device manufacturing, and quality

Since its founding in 1946 PDA has been committed

- to developing scientifically sound, practical technical information and expertise
- to advance pharmaceutical/biopharmaceutical manufacturing science and regulation
- to enable PDA members to better serve patients

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PDA recognizes positive elements in the current FDA QMM Program proposal.

- FDA recognizes that metrics alone are not sufficient to ensure a mature quality management system and this program emphasizes that quality culture is foundational.[1]
- The program is designed to differentiate and recognize those sites who demonstrate mature approaches to quality systems from others focused solely on compliance and cost minimization.
- The FDA QMM program was developed based on industry and academic research into quality culture as well as pilot experiences.[2,3]
- FDA aspires to bring transparency around pharmaceutical quality systems into purchasing decisions for HCPs, patients and payors.

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1. https://www.fda.gov/media/157432/download
2. https://public-inspection.federalregister.gov/2020-22976.pdf
3. https://public-inspection.federalregister.gov/2020-22977.pdf

Areas which require greater clarification

Incentives for industry:

- With a fully voluntary program, industry needs a better understanding of the benefits of participation to embrace program. E.g. how will QMM ratings enable the regulatory flexibility in PAC reporting created by ICH Q10 and Q12?

Choice of program attributes:

- FDA should choose the mature quality attributes carefully in order to assure that these drive the right behaviors as well as driving more mature quality systems.
- PDA recommends that FDA continue to work with academic and industry experts in determining the attributes that would drive the right behaviors based on research findings.

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Areas which require greater clarification

Execution of the program: PDA has significant experience with quality culture maturity assessments[1] and has found that:

- A method of collecting “shopfloor” feedback is essential to properly understanding the maturity level at a site.
- Assessors must be trained to evaluate attributes of quality culture and mature quality attributes and understand how this is different from a compliance audit.
- An over-emphasis on a model with scoring precision may drive the process towards compliance and KPIs which are more easily quantified and drive away from assessing behaviors which are critical to understanding culture and maturity.

Public and Payor Perception: PDA believes it will be challenging for the public and payors to understand the OPQ distinctions between product quality, process quality, and quality management and make informed purchasing decisions; particularly if they have no information source to link specific products they are purchasing with sites being evaluated in the QMM model.

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1. https://www.pda.org/pda-letter-portal/home/full-article/how-to-measure-quality-management-maturity

In Conclusion

PDA is ready and willing to support further dialogue between industry, academia, and FDA to resolve the outstanding questions and build a strong and successful QMM program which benefits patients.

These comments have been prepared by members of the PDA Quality Management Maturity Task Force.

Thank you for the opportunity to present today to the Pharmaceutical Science and Clinical Pharmacology Advisory Committee

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