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Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Docket Number: **FDA-2023-N-3721**

Dear FDA Dockets Management Staff,

I am submitting comments to Docket Number FDA-2023-N-3721, **Quality Management Maturity Program for Drug Manufacturing Establishments; Request for Comments** on behalf of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL). NIIMBL, a part of the ManufacturingUSA network, is a public private partnership of approximately 200 members in academia, government service, and across the biopharmaceutical supply chain. NIIMBL collected feedback on this whitepaper from its membership and aggregated the responses.

NIIMBL, on behalf of our community, recognizes the individual efforts involved in developing this Program and we appreciate the opportunity to comment. We acknowledge that assessment of quality culture as an additional consideration in a quality systems management approach is important and impactful. There is value in promoting quality culture in the regulated industry and identifying areas that require attention. We have the following general comments that may improve the utility and implementation of the program:

General Comments:

- **Purpose**. The purpose of the QMM program is unclear and program goals are unclear as described in the text. If the purpose is to manage patient risk, this purpose would be better served by amending current guidance or regulation. If the purpose is to assess and score companies and publish such assessments, there may be unintended consequences that may arise from perceived favoritism or punishment of organizations. Further, entangling QMM, which is important for quality assurance, with questions of FDA's authority as related to pricing, capacity management and shortages, requirements published as guidance rather than rule, or divergent practices in review of and standards for 351(a) applications could have negative consequences.

- **FDA Center Collaboration.** The excellent principles of practice published in CDER MAPP 5014.1 on CDER's Risk Based Site Selection Model, CDER MAPP 5015.13 on Quality Assessments for Products in Expedited Programs, and CDER MAPP 5017.2 which discusses using risk-based assessments dependent upon clinical relevance, all acknowledge that quality assurance is dependent on the type of product, product development and manufacturing history, and totality of the evidence. The CDER QMM program should not walk back or diverge from these principles of practice.

  We suggest the QMM Program be approached as an FDA (e.g. Field Compliance Program) initiative rather than a CDER program. We recommend that CDER work with ORA and other Centers to integrate this into published Field Compliance Programs to assure a shared understanding of expectations during post launch assessments. It is unclear how this assessment would be applied to biologics or combination products that are reviewed and

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inspected by different Centers, which can unintentionally introduce further divergence in quality oversight of vaccines, therapeutic proteins, devices, and branded, unbranded, and generic oral dosage forms.

- **Educational Program.** We suggest that the QMM Program could be established as an educational program for the regulated industry on continued improvement in quality assurance rather than be implemented as an assessment. Excellent quality culture programs have been established within the industry through, for example the Parenteral Drug Association and the International Society for Pharmaceutical Engineering. Such an educational program would benefit from benchmarking the successes and hurdles to deployment experienced by these existing programs and incorporating them into a general framework which organizations can leverage as part of their internal improvement efforts.

Feedback on specific questions:

1. **Identity of respondents.** NIIMBL compiled responses from our member community, which includes approximately 200 members in academia, government service, and across the biopharmaceutical supply chain. Respondents primarily represented large biopharmaceutical manufacturers, however many of these organizations also manufacture other drugs.

2. **Advantages - Sector.** All organizations would benefit from a universal definition of the different levels of quality management maturity with clear indicators of each level for more precise benchmarking. More awareness and education can lead to a more resilient supply chain to deliver medicines to patients on time. An additional benefit to the sector could result from improved consistency of expectations around quality management which may facilitate more efficient manufacturing agreements between organizations, e.g., partnerships between primary manufacturers or contracts between primary manufacturers and CDMOs.

3. **Benefits - Organization.** Feedback on areas for continuous improvement would be valuable within an organization. Participation in this program could be used to drive continuous improvement and consistency within an organization, proactively building QM systems instead of defaulting to a reactive approach based on audit findings.

4. **Use of QMM Assessment.** The QMM assessment data can be used within an organization to understand the different levels of maturity associated with the five practice areas defined by the QMM Program and to develop internal continuous improvement plans for their QM systems. Many respondents felt strongly that if the QMM assessment becomes perceived as a business edge, it can result in unintended consequences (see #7 below).

5. **Concerns.** Many of the concerns fall into two main categories, both tactical. The first is if there is a lack of critical mass participating in the program, the benchmarking data will not be meaningful or useful. The second is that it is, in practice, challenging to separate the measure of the maturity of quality from compliance. Education opportunities could mitigate the second challenge.

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6. **Report contents.** The QMM assessment should contain operational definitions of what is being assessed and the rationale/criteria for each level of maturity. The report can highlight industry best practices and what needs to be done to improve from one level of maturity to the next. The report should also include the results of the assessment which highlight the positives as well as how an organization can progress to the next level of QM maturity.

7. **Public outcomes.** There was a strong feeling that QMM assessment outcomes should be kept confidential. Advertising a QMM rating could be perceived as a business edge that may unintentionally harm smaller organizations and vendors that may be fully compliant but may have a less mature QMS due to limited resources. Because NIIMBL's mission is focused on adoption of new biopharmaceutical manufacturing technologies, we have concerns that publicly sharing a QMM rating may discourage manufacturers from implementing new technologies due to perceived regulatory and business risk.

8. **Additional feedback**. It would be beneficial for the document to include a statement around how adoption of disruptive and innovative technologies can be a strength for quality maturity and compliance. Additionally, several respondents suggested industry incentives for participation, such as performing cGMP and QMS inspections at the same time, with inspection frequency related to risk status.

In summary, we suggest that the CDER QMM Program be advanced as an educational program for the regulated industry, be incorporated into Field Compliance Program assessments, or be revisited through established pathways for multi-Center guidance and rulemaking.

We appreciate this opportunity to provide feedback to this request and would be happy to follow up.

Kind Regards,

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