VIA ELECTRONIC SUBMISSION

March 12, 2024

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

Re: Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request (FDA-2023-D-4974)

Dear Sir/Madam:

On behalf of the United States Pharmacopeia (USP), I appreciate the opportunity to offer our comments to the Food and Drug Administration (FDA) on the Advanced Manufacturing Technologies Designation Program draft guidance ("draft guidance"). USP is an independent, scientific, global non-profit organization founded in 1820 and is dedicated to building trust in medicines through rigorous science and public quality standards. USP standards are developed through an open, transparent, science based, expert-led process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology. A core pillar of USP's mission is to help strengthen the global supply chain so that the medicines people rely on for their health are available when needed and meet quality standards as expected and required.[1]

For many years, USP has been supportive of efforts that enable innovative approaches and increased adoption and implementation of advanced manufacturing technologies (AMTs). AMTs such as continuous, additive, and distributive manufacturing technologies, can improve manufacturing efficiency, reduce production costs, reduce environmental footprints, and facilitate supply chain resilience. We commend FDA's ongoing efforts related to AMT and engagement of stakeholders to identify and address impediments to AMT adoption and implementation.

USP appreciates that the draft guidance recognizes that novel technologies may include the use of new or established techniques or technologies in a novel way to substantially improve the manufacturing process for a drug while maintaining or improving drug quality. This approach aligns with USP's position that a multifaceted approach to policy reforms which include appropriate flexibility is needed to support a diversity of advanced and innovative technologies, products, and processes.[2] For example, the challenges or opportunities for manufacturers producing active pharmaceutical ingredients are different from those producing finished drug products, in particular the associated process improvements. Allowing for various types of novel technologies and approaches to be designated as part of the program will help to encourage engagement with the program by a breadth of developers and help to ensure developers and the FDA are maximizing the potential benefits of the program.

[1] The Federal Food, Drug, and Cosmetic Act of 1938 created the statutory requirement that medicines sold in the United States generally must adhere to USP's public quality standards to help ensure the quality of medicines and the safety of patients.

[2] U.S. Pharmacopeia. Recognizing Challenges and Opportunities to Support Adoption of Advanced Manufacturing Technologies for Medical Products: USP Public Policy Position. January 2024. Accessed at https://www.usp.org/sites/default/files/usp/document/public-policy/USP%20AMT_PositionPaper_2024.pdf on Feb. 1, 2024.

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As the Advanced Manufacturing Technologies Designation Program launches and the first AMTs are designated and developers participate in the program, it is vital that the program criteria or other program guidelines are set appropriately to ensure the intent of the program is being met. Lessons learned from the program, as well as ongoing industry experiences and insights, can help to inform the landscape for AMT and whether some aspects of the program may need to be updated to reflect the current understanding and scientific and technological environment. USP recommends that FDA regularly review the program and update the program guidance to ensure it is meeting the needs of both program participants, applicants, and the cross-disciplinary teams at FDA working on the program.

AMT represents a paradigm shift in pharmaceutical production with unique technical and practical considerations. USP is committed to working with FDA and interested manufacturers and developers to help accelerate the adoption of designated technologies through standards, technical guides, and other collaborative efforts. In 2023, USP released the first in a planned series of technical guides for pharmaceutical continuous manufacturing (PCM), which covers the development control strategies for continuous manufacturing of solid oral dose drug products. The technical guide aims to share knowledge and best practices for those involved in the development of continuous manufacturing platforms. Practices outlined in the guide are intended to serve as a detailed conceptual and practical illustration of the process for these products made with PCM technology. As such, they are not intended to be binding or considered the only acceptable approach. Furthermore, collaborations such as public-private partnerships between industry academia, and government stakeholders to bridge knowledge gaps and the development of resources like the PCM technical guides may help stakeholders bring to market more quality products made with novel technologies and processes for the benefit of patients.

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We welcome the opportunity to further discuss how USP can support the FDA in developing standards and policies needed to support designated technologies and the adoption and implementation of AMTs. For more information, or if you have questions regarding these comments, please contact Hilary Daniel, Senior Regulatory Affairs Policy Manager at hilary.daniel@usp.org.

Sincerely yours,

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