VIA ELECTRONIC SUBMISSION

November 12, 2024

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

Re: Strategy Document on Innovative Manufacturing Technologies (FDA Docket No. FDA-2024-N-3945)

Dear Sir/Madam:

The United States Pharmacopeia (USP) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) recent publication, "Strategy Document on Innovative Manufacturing Technologies" (Strategy). USP is an independent, scientific, global non-profit organization founded in 1820 and dedicated to building trust in medicines through rigorous science and public quality standards. We are guided by approximately 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention. A core pillar of USP's mission is to help strengthen the global supply chain so that medicines are available when needed and meet quality standards as expected and required.

General Comments

USP appreciates the opportunity to comment on FDA's Strategy Document on Innovative Manufacturing Technologies. A resilient pharmaceutical supply chain is critical to public health, and advanced manufacturing technologies (AMTs) play a crucial role in strengthening this resilience. AMTs such as continuous manufacturing, additive manufacturing, and distributed manufacturing have the potential to improve manufacturing efficiency, reduce production costs, reduce environmental footprints, and support supply chain resilience. These technologies can speed the production of drug products and, when combined with a Quality-by-Design (QbD) approach using process analytical technologies (PAT), can improve medicine quality and facilitate rapid technology transfer and scale-up – critical levers to mitigate drug shortages and facilitate pharmaceutical supply chain reliability.

For many years, USP has supported efforts that enable innovative approaches and increased adoption and implementation of advanced manufacturing technologies. We strongly support FDA's efforts identified in the Strategy to update the 2017 Emerging Technology Program (ETP) guidance and to establish program goals for the Emerging Technology Team (ETT), as well as building the CBER Advanced Technologies Team (CATT) 2.0. These initiatives are essential for monitoring technology readiness, engaging with stakeholders, and fostering international collaboration. Enhancing these programs through updated guidance and other feedback from stakeholders will help to address ongoing as well as unanticipated challenges and identify opportunities for advancement.

USP also looks forward to the final guidance document on FDA's Advanced Manufacturing Designation Program by the end of the calendar year. As noted in our comments on the draft guidance, we believe that a multifaceted approach involving regulatory support and collaborative efforts is necessary to fully realize the potential of AMTs in strengthening our

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pharmaceutical supply chain. USP supports a range of policies that enable increased adoption and implementation of AMTs,[1] such as:

1. Promotion of public-private partnerships to accelerate the adoption of AMTs. These collaborations can help bridge knowledge gaps and address technical and regulatory uncertainties.
2. Enhancement of regulatory harmonization efforts. We urge increased collaboration between FDA and international regulatory bodies to harmonize regulatory expectations for advanced manufacturing technologies. This could include developing shared guidelines, mutual recognition agreements, uniform post-approval changes, or joint inspection programs—building on existing work at International Coalition of Medicines Regulatory Authorities (ICMRA)—to reduce barriers for global implementation of AMTs.
3. Work with Congress to ensure adequate and sustainable funding for the Centers of Excellence in Advanced and Continuous Manufacturing.

Additionally, USP is actively developing public quality standards that can help to accelerate the adoption of AMTs and the development of detailed guidelines and solutions to advance three key foundational areas of innovative manufacturing – 1) Process Analytical Technologies (PAT), 2) digital frameworks and AI/ML applications, and 3) comprehensive material property knowledge. Our Continuous Manufacturing Knowledge Center (CMKC) provides a platform for information sharing and discussion among stakeholders.[2] Further, USP contributed to the ICH Q13 harmonized guidance on continuous manufacturing – an effort led by FDA and PMDA. We stand ready to support FDA's efforts through our standards-setting activities and to collaborate with FDA and other stakeholders to address the challenges and opportunities in advanced pharmaceutical manufacturing.

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Thank you for considering these comments. USP looks forward to continued engagement with FDA to advance these critical initiatives. Should you need additional information about USP's response, please contact Brett Howard, Senior Director, U.S. Regulatory Policy, at brett.howard@usp.org or (301) 692-3296.

Sincerely,

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[1] USP Global Policy Position: Recognizing Challenges and Opportunities to Support Adoption of Advanced Manufacturing Technologies for Medical Products. 2023; https://www.usp.org/sites/default/files/usp/document/public-policy/USP%20AMT_PositionPaper_2024.pdf.

[2] USP, Continuous Knowledge Manufacturing Center, available at https://cmkc.usp.org/.