VIA ELECTRONIC SUBMISSION

December 13, 2021

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

Re: Docket No. FDA-2021-D-1047 for "Q13 Continuous Manufacturing of Drug Substances and Drug Products"

Dear Sir/Madam,

The United States Pharmacopeia (USP)[1] appreciates the opportunity to comment on the Food and Drug Administration's (FDA) Draft Guidance for Industry, "Q13 Continuous Manufacturing of Drug Substances and Drug Products," also known as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q13 harmonized guideline draft. We will be sending similar comments to ICH on this guideline.

USP is an observer organization to ICH and participated in the expert working group that developed this guideline. The issuance of this draft document is a significant milestone for facilitating the implementation of the continuous manufacturing of drug substances and drug products.

Continuous manufacturing has the potential to lower manufacturing costs and reduce the physical footprint of manufacturing facilities compared to traditional batch manufacturing. It also has the potential for fostering greater quality control, lowering the variability in manufactured products, and providing enhanced flexibility in production quantity and utilization of manufacturing lines.

USP supports the development of advanced manufacturing technologies, including continuous manufacturing, and its associated analytical tools, to help ensure a robust and reliable supply of quality medicines. We are working to develop continuous manufacturing technologies.[2] This includes engagement with a broad group of stakeholders, including academic research centers and manufacturers, to identify and subsequently develop relevant standards and practices. We look forward to collaborating further with FDA on this topic.

[1] USP is an independent, scientific, nonprofit organization dedicated to improving public health for medicines, foods, and dietary supplements. USP public standards are developed through an open, transparent, expert-based process, offering the ability to confront public health emergencies, adapt to new industry practices, and support evolving science and technology.

[2] For additional information on USP's involvement in supporting continuous manufacturing, *see* https://www.usp.org/supply-chain/advanced-manufacturing.

USP Headquarters
12601 Twinbrook Parkway | Rockville, MD 20852, USA
+1-301-881-0666 | usp.org

Additionally, we note that FDA's draft guidance, "Quality Considerations for Continuous Manufacturing,"[3] describes FDA's current thinking on continuous manufacturing of small molecule, solid oral drug products that are regulated by the Center for Drug Evaluation and Research and request clarification on how the ICH guideline, when finalized, will affect this draft guidance.

* * *

USP remains committed to supporting continuous manufacturing, and we look forward to continuing to engage with FDA, ICH, and other stakeholders. We are further interested in collaborating with FDA and ICH on providing resources and training on continuous manufacturing.

Thank you again for the opportunity to comment. For more information, please contact Atul Dubey, PhD, Principal Investigator (Pharmaceutical Continuous Manufacturing) at atul.dubey@usp.org; (301) 816-8205.

Sincerely yours,

Jaap Venema, Ph.D.
Executive Vice President and Chief Science Officer
jpv@usp.org
(301) 230-6318

[3] FDA draft guidance, "Quality Considerations for Continuous Manufacturing," at https://www.fda.gov/media/121314/download (Feb. 2019).