

## VIA ELECTRONIC SUBMISSION

December 13, 2021

ICH/European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands  
[ich@ema.europa.eu](mailto:ich@ema.europa.eu)

**Re: ICH guideline Q13 on continuous manufacturing of drug substances and drug products**

Dear Sir/Madam,

The United States Pharmacopeia (USP)<sup>1</sup> appreciates the opportunity to comment on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q13 harmonized guideline draft. We sent similar comments to the Food and Drug Administration (FDA) in response to the issuance of the FDA Draft Guidance for Industry, “Q13 Continuous Manufacturing of Drug Substances and Drug Products.”<sup>2</sup>

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.<sup>3</sup> This includes engagement with a broad group of stakeholders, including academic research centers and manufacturers, to identify

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<sup>1</sup> 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.

<sup>2</sup> FDA Draft Guidance, “Q13 Continuous Manufacturing of Drug Substances and Drug Products,” <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q13-continuous-manufacturing-drug-substances-and-drug-products>.

<sup>3</sup> For additional information on USP’s involvement in supporting continuous manufacturing, see <https://www.usp.org/supply-chain/advanced-manufacturing>.

and subsequently develop relevant standards and practices. We look forward to collaborating further with ICH on this topic.

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USP remains committed to supporting continuous manufacturing, and we look forward to continuing to engage with ICH and other stakeholders. We are further interested in collaborating with 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](mailto:atul.dubey@usp.org); (301) 816-8205.

Sincerely yours,



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