December 14, 2018

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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Subject: Docket No. FDA-2018-D-1609: Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management; International Council for Harmonisation; Draft Guidance for Industry.

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance: Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.

USP is an independent, scientific, nonprofit organization dedicated to protecting and improving public health. We collaborate with regulators, clinicians, other practitioners, manufacturers, and other stakeholders to develop public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP shares the goal of FDA and the International Council for Harmonisation (ICH) in advancing and promoting patient safety across medicines by strengthening quality assurance.

FDA's and ICH's efforts to develop a harmonized approach regarding technical and regulatory considerations for product lifecycle management will benefit patients, industry and regulatory authorities alike. The concepts outlined in Q12 align with a critical vision for harmonizing pharmaceutical quality approaches that integrates risk management thinking and emphasizes science.

Pharmacopeias and the public standards they provide have a critical role in supporting regulatory authorities and in the life cycle approach—transitioning to a more flexible and adaptable approach to measuring and defining quality. By providing testing approaches and standards, as well as guidelines for key analytical parameters and transitions, pharmacopeias help implement, apply, and maintain the quality intent of the regulators. Involvement of pharmacopeias will be critical for the evolution and establishment of these new quality paradigms.

USP would like to highlight one aspect of the chapter that particularly resonates with a quality standard approach. As indicated in 3.2.3.2, established conditions related to analytical procedures are focused on performance criteria that determine fit for purpose. This is consistent with the conclusions of the USP Expert Panel on validation that recommends a structured approach for the assessment of fit for purpose. This work is also relevant to support chapter 8 in the proposed Q12 guidance.

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We appreciate the opportunity to provide these comments for your consideration, and we would welcome the opportunity to discuss these issues. We look forward to our continued discussion with the Agency, and the ICH Assembly with regards to the continuing dialogue on the ICH Quality Strategy for the advancement of public health.

If you have questions or would like additional information, please contact Kevin Moore, Ph.D. Senior Manager, Pharmacopeial Collaboration at ktm@usp.org or (301) 816-8369.

Sincerely,

Jaap Venema, Ph.D.
Executive Vice President and Chief Science Officer