International Pharmaceutical Excipients Council of the Americas

Janeen Skutnik-Wilkinson
Chair

April 21, 2021

Desmond Hunt
Principal Scientific Liaison
United States Pharmacopeial Convention
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Cc: Catherine Sheehan
John Giannone
Pallavi Nithyananandan

Re: General Chapter <1xxx> Supplier Qualification Prospectus

Dear Dr. Hunt,

Members of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) are interested in continued dialog and collaboration in the development of meaningful public standards that ensure patients' safety and access to quality medicines. This letter is in response to the Prospectus posted March 26, 2021 for General Chapter <1xxx> Supplier Qualification.

IPEC-Americas Background

IPEC-Americas represents more than 50 excipient manufacturers, distributors and pharmaceutical/biopharma companies to support the safe production and use of excipients. This letter represents the IPEC-Americas membership. A complete list of IPEC-Americas member companies can be found at: https://ipecamericas.org/what-ipec-americas/member-companies. IPEC-Americas is dedicated to working closely with regulatory authorities, industry organizations and scientific bodies (globally) to advance public health on matters relating to the quality, safety, manufacture, distribution, use and functionality of excipients. IPEC is the sole association representing excipients.

IPEC-Americas Comments

1. IPEC-Americas recognizes the efforts of USP to continually improve, modernize, and harmonize compendial monographs and general chapters. We are concerned, however, with the direction USP is taking on topics and general chapters that are not directly related to standards setting. FDA and industry guidelines already exist for supplier qualification. USP's priorities should be aligned with those of FDA and industry to modernize monographs and general chapters identified as being most at risk due to outdated analytical methods or having inadequate tests. IPEC-Americas recommends that USP focus efforts to improve patient safety on risks identified by FDA and increase opportunities for industry stakeholder involvement in the development of new/revised standards prior to publication in the Pharmacopeial Forum.

2. It is well recognized that practically all modern supply chains are global. Therefore, the creation of a supplier qualification guidance should be developed by ICH to ensure global applicability. Further, it is important to note that while USP General Chapters over 1000 are intended by USP to be "informational only", global users, especially in countries without individual pharmacopeia, often adopt the content of chapters > 1000 as requirements. Therefore, to prevent potential for lack of international harmonization, USP should not proceed independently with creation of new GxP general chapters. Issuance of guidelines for supplier qualification and good supply practices in general is more appropriate for ICH than any single pharmacopoeia.
3. Over the past several years, the responsibilities of scientific liaisons have broadened such that availability to engage in meaningful dialogue with industry stakeholders has become extremely limited. The development of new informational guidelines on supplier qualification does not seem to provide significant value and potentially provides distraction from other primary standard setting activities for the development of new and revision of outdated scientific standards.
4. IPEC-Americas generally supports the approaches to supplier qualification described in Xavier Health's *Good Supply Practices for the 21st Century.* However, Xavier Health's strategy is extremely broad and is intended for makers of finished drug products. There are significant supply chain differences and supplier qualification requirements for packaging components, bulk excipients, contract manufactured drug product, computer software, etc. which may not be adequately addressed in the development of proposed General Chapter. Further, efforts to create new > 1000 general chapters should focus on key topics for which there is a lack of guidance information. Creating new USP general chapters based on existing guidance documents does not add value, especially where the USP general chapter cannot be as comprehensive.
5. Lastly, IPEC-Americas wishes to express concern over potential bias and/or conflict of interest in the development of a USP general chapter for supplier qualification given that USP generates income from the USP Ingredient Verification Service, which is essentially a supplier qualification program.

In summary, IPEC-Americas values the opportunity to partner with USP, FDA, and other stakeholders for collaboration on the development of global standards which ensure the quality and safety of excipients. However, due to competing priorities, lack of international harmonization and potential conflict of interest, IPEC-Americas recommends that USP not independently pursue creation of a general chapter for supplier qualification. We believe that this is not a single compendial topic and that an international guidance should be developed under ICH.

Respectfully yours,

Janeen A Skutnik

Janeen Skutnik-Wilkinson
Chair, IPEC-Americas