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U.S. Pharmacopeial Convention

United States Pharmacopeia: 2016 Excipients Stakeholder Forum

Wrap-Up—September 29, 2016

Excipient Stakeholder Forum Purpose

Overarching Purpose…

- To provide a forum for manufacturers, distributors, and users of excipients to discuss key issues/topics in an open forum setting.
- To encourage excipients constituencies to work openly and directly with USP as well as collaborate with fellow stakeholders.

Specifically…

- *Extending opportunities* for participation to a broad range of excipients stakeholders to ensure industry-wide input to USP, so that we can further understand excipient issues that will facilitate update and development of excipient monographs .
- *Educating stakeholders* on USP activities and initiatives that might affect excipients stakeholders, for example the USP/NF standard setting process, harmonization, Global Education, and Verification programs.

What we heard?

- The Excipients Project Team formed under the Excipient Stakeholder Forum has helped with the USP monograph up-to-date initiative in strengthening the Gelatin monograph.
- Collaboration with FDA and key stakeholders is essential in efforts to update and modernize excipient compendial standards.
- The route of administration, such as for injection, is not currently considered when determining specifications for certain monographs. For example, the composition of polysorbate 80 is complex and there are safety and stability concerns when it is used for injection.
- Industry and regulators should agree on approaches and guidances for controlling Atypical Active quality and appropriate GMPs.
- USP has worked closely with the ICH, FDA, and Industry to ensure alignment of standards for elemental impurities with the ICH Q3D Guideline for Elemental Impurities.

Action Items

1. Consider the route of administration when establishing excipient monograph specifications for intended use.

2. Further discussion needed with stakeholders to understand the challenges related to Atypical Actives.

3. Create and awareness among stakeholders to prepare for implementation of <232> *Elemental Impurities—Limits* and <2232> *Elemental Contaminants in Dietary Supplements* by January, 2018.

4. Call for Volunteers to Stakeholders for planning and implementing the next Excipients Stakeholder Forum. Contact Jessica Simpson at jcs@usp.org.

Moving Forward

- The future direction:
  - Industry & regulatory agencies working together- utilizing and sharing each others resources, experience and knowledge (Gelatin is a good example).
  - Collaborate with stakeholders in development/strengthening of compendial standards.
  - Communicate with and educate stakeholders on key issues relating to excipient monograph specifications so each can provide input into updating these standards.
  - Further understanding of the challenges faced in developing quality excipients standards within a complex excipient global supply chain.

The excipient stakeholder forum planning committee addresses key issues identified through its stakeholders.

USP Informational Links

Global Education & Training
- http://education.usp.org/

USP General Information
- http://www.usp.org/usp-nf

Monograph Modernization
- http://www.usp.org/usp-nf/key-issues/monograph-modernization

USP Donor Program
- http://www.usp.org/usp-nf/development-process/donor-program

USP Verification Services
- http://www.usp.org/usp-verification-services

Information on our Call for Candidates process
- https://callforcandidates.usp.org/

Resolutions
- http://www.usp.org/2015-convention/resolutions

Thank You