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United States Pharmacopeia: 2014 Excipients Stakeholder Forum

Wrap-Up—June 18, 2014
Meeting #2

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, Global Education and Verification programs.

What we heard?

- ▶ The stakeholders can impact both resolutions and key initiatives of the Expert Committee.
- ▶ The key initiatives and resolutions (2,3,and 5) relating to the Excipient Expert Committee pertain to monograph modernization and pharmacopeial harmonization in the 2010-2015 revision cycle
- ▶ Collaboration with FDA, industry and other stakeholders is key to advancing the resolutions and initiatives.
- ▶ These efforts can only begin with open dialogue and information sharing as seen today in regards to the gelatin monograph and round table discussion; these discussions were a first step in identifying and addressing key issues and a forum that allows for open discussion and stakeholder feedback in an effort to update and modernize excipient compendial standards.

1. Identify a list of excipient monographs that can be retrospectively harmonized with pharmacopeias outside the PDG process.
2. To address the problem that arises when an excipient monograph such as pregelatinized starch exists as more than one monograph in different regulatory regions and compendia (partially pregelatinized starch and pregelatinized starch), garner input from the IPEC clusters and other stakeholders on how to move forward with harmonization for pregelatinized starch.
3. Markus Lipp, Sr. Director of Foods to schedule a teleconference with stakeholders for ways to address the current concern on the outdated reference to the FCC in the CFR.

▶ The future direction:

- Industry & regulatory agencies to work together- utilizing and sharing each others resources, experience and knowledge.
- Further understanding of the excipient global supply chain
- Communicate with and educate stakeholders on key issues relating to excipient monograph specifications so each can provide input into updating these standards
- Development/strengthening of compendial standards

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

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- ▶ <https://callforcandidates.usp.org/node?destination=node>

2015 Convention

- ▶ <http://www.usp.org/2015-convention>

Resolutions

- ▶ www.resolutions.usp.org

Global Education & Training

- ▶ <http://www.usp.org/meetings-courses/courses>

Spectral Library Project

- ▶ <http://www.usp.org/spectral-library>

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>



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Thank You