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General Chapters Prospectus Process Update

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- ▶ Anticipated outcomes
- ▶ Background and goals of process
- ▶ Process implementation and status
- ▶ Discussion

- ▶ Provide update on status of implementation
- ▶ Share some of USP's experiences
- ▶ Receive stakeholder input to inform disposition of pilot

Stakeholders want to inform major publications

- ▶ EC Work Plans and Executive Summaries are useful but not formally interactive
- ▶ PF is perceived as too far downstream for major course changes
- ▶ Stakeholders proposed GC Project Team to give early input
- ▶ USP action to consider recommendation

- ▶ Provide window to early thinking on a high-impact standards (i.e., general chapters)
- ▶ Enable input opportunity that is:
 - Early in process
 - Informative to USP staff and expert volunteers
- ▶ Keep it simple and efficient
- ▶ Satisfy CoE need for ways to foster collaboration through better information sharing



General Chapter Prospectus Process

USP to Pilot Process for Early Input on General Chapters

Type of Posting	General Announcement
Posting Date	26-Feb-2016

Based on feedback from stakeholders, USP is implementing a process intended to provide interested stakeholders with the opportunity to submit input on general chapters during the early stages of their development.

General chapters are often identified as high-impact standards. They may be applied to numerous articles or affect major activities in the pharmaceutical supply chain, the practice of pharmacy, or other disciplines. In addition, the broad scope of some general chapters can be related to other guidance for industry and practitioners, such as Good Manufacturing Practices, sanctioned industry standards, and practice standards. Robust input at the early stages of general chapter development has the potential to benefit USP staff and volunteers by suggesting modifications to scope and content that can streamline the development process, save time and effort, and minimize delays in reaching an official publication.

To accomplish this, USP Expert Committee members will develop a brief prospectus for new general chapters or major general chapter revisions prior to their publication in Pharmacopeial Forum (PF). Each prospectus will include information available at the time of its drafting, and thus the contents of each prospectus may differ. The prospectus will be posted to the work plan web page of the associated Expert Committee (<http://www.usp.org/expert-committees>) and to the USP-NF Compendial Notices web page (<http://www.usp.org/usp-nf/notices>). USP will announce the prospectus posting through its Compendial Updates email service and accept input for one month following the announcement. The Compendial Notice posting will be retired after completion of the input period. This process will be monitored on an ongoing basis to ensure that its goals are being met.

The input received from the prospectus process will be considered as advisory only. The Expert Committees will not publish or respond to all input received on prospectus notices. The Expert Committees may, at their discretion, choose to contact submitters or address certain aspects of provided input in the briefing of a general chapter's PF proposal. Formal comments on subsequent PF proposals must be submitted separately at the time of publication in PF.

Should you have any questions, please contact Horacio Pappa, Ph.D., Director, General Chapters (301-816-8319, hp@usp.org).

- ▶ Initiated February 2016
- ▶ 8 GCPs posted by 6 SLs
 - 2 progressed to PF
 - 5 more with upcoming deadline
- ▶ 14 comments received

General Chapter Prospectus

As part of a pilot process, USP Expert Committee members will develop a brief prospectus for new general chapters or major general chapter revisions prior to their publication in Pharmacopeial Forum (PF). The purpose of these is to solicit input during the early stages of general chapter development. The input received from the prospectus process will be considered as advisory only. Formal comments on subsequent PF proposals must be submitted separately at the time of publication in PF.

Below is a listing of the currently active general chapter prospectus notices:

- <87> Biological Reactivity, In Vitro, <88> Biological Reactivity, In Vivo, and <1031> The Biocompatibility of Materials used in Drug Containers, Medical Devices and Implants (posted 30-Dec-2016; deadline 30-Jan-2017)
- <381> Elastomeric Closure for Injections (posted 30-Dec-2016; deadline 30-Jan-2017)
- <382> Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems (posted 30-Dec-2016; deadline 30-Jan-2017)
- <1381> Evaluation of Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems (posted 30-Dec-2016; deadline 30-Jan-2017)
- <1382> Assessment of Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems (posted 30-Dec-2016; deadline 30-Jan-2017)

▶ Benefits

- Generally a helpful exercise
- Majority of input received is potentially meaningful

▶ Challenges

- Timing relative to PF
- Each case is different
- Visibility of process to stakeholders
- Understanding of how it works
- SL level of effort not insignificant

- ▶ Utility to stakeholders?
- ▶ Simplicity of input submission?
- ▶ Other feedback?



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Thank You