Prescription/Non-Prescription Stakeholder Forum Webinar Meeting

Monday, April 2, 2018
Stakeholder Forum Overview

Priscilla Zawislak, Co-Chair

International Pharmaceutical Excipients Council (IPEC)
Action Items from 2017 Forum

Phyllis Walsh, Co-Chair

*International Pharmaceutical Excipients Council (IPEC)*
Action Items from 2017 Forum

- Frequency of Meetings
- Implementation of a Packaging Work Group
Thank You

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USP Prescription/Non-Prescription Stakeholder Forum
Monday, April 2, 2018

USP Updates from the Previous PNP SF

Desmond Hunt, Ph.D.
Principal Scientific Liaison
Plastic Work Group

- Johnson & Johnson
- Eli Lilly and Company
- GlaxoSmithKline
- AbbVie
- Novartis
- Pfizer
- Janssen
- CoE Representative
- Expert Committee Observers
- United States Food and Drug Administration - Center for Biologics Evaluation and Research
- United States Food and Drug Administration - Center for Drug Evaluation and Research
- Perrigo
- Tolmar
- BioPharmaDev, Inc.
- Bilcare Research Incorporation.
- Merck
Thank You

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USP Prescription/Non-Prescription Stakeholder Forum
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USP Updates from the Previous PNP SF

Jessica Simpson, M.P.H.
Manager, Compendial Operations
Team first met in 2006, most recently met in 2016

The purpose of this Project Team will be to continue a dialogue between stakeholders and USP regarding the USP-NF General Notices to:

- Propose revisions to USP’s General Notices
- Review and provide feedback on revisions to General Notices
- Consider communication of General Notices-related initiatives to industry, regulatory, and other stakeholders

We are re-starting the Project Team this Spring

- If you are interested in participating please contact Jacqueline Starkes @ jws@usp.org
- Selection based on current representation
Thank You

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Discussion
Updates to the USP-NF Subscription Model and New Platform Launch
Trey White, Ph.D., Senior Director, Documentary Standards
Rebecca Cambronero, MBA, MSL, PMP, Director, Documentary Standards
USP-NF Online Demo
Welcome!

- Legacy platform
- Features
- Setting expectations
- Demo on dev site

Get Ready for the New USP–NF Online!
New document Storage Architecture

Siloed vs. shared USP-NF content storage

- **Legacy System**

- **New USP-NF Online**

Sets the foundation for use of DOIs
Legacy USP–NF Online Main Page
New Features and Functionality

New *USP-NF* online platform

- Comprehensive Search Tool
- Simplified Navigation
- Bookmarks & My Viewing Activity
- E-mail notifications on revisions
- Search across selected publications
- Centralized location of official content
Setting Expectations

- Currently in development
- Look and feel not final
- Not all functions work
- *USP41-NF36* content only
Demo of new platform

- Dashboard
- Navigation Bar
- Search Tool
- Search Results
- Official Status
- Document View
Thank You

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Discussion
Next Meetings: USP Prescription/Non-Prescription Stakeholder Forum

- Next Webinar Meeting
  Monday, July 9, 2018, 1:00 p.m. – 3:00 p.m.

- Next Face-to-Face Meeting
  Thursday, October 18, 2018, 9:00 a.m. – 5:00 p.m.

Phyllis Walsh, Co-Chair
International Pharmaceutical Excipients Council (IPEC)
Thank You

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