

# Prescription/Non-Prescription Stakeholder Forum Webinar Meeting

Monday, April 2, 2018



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

## Stakeholder Forum Overview

Priscilla Zawislak, Co-Chair

*International Pharmaceutical Excipients Council (IPEC)*



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## 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 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 Updates from the Previous PNP SF**

Jessica Simpson, M.P.H.  
*Manager, Compendial Operations*



# General Notices Project Team



- ▶ 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](mailto:jws@usp.org)
  - Selection based on current representation

# Thank You



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# Discussion



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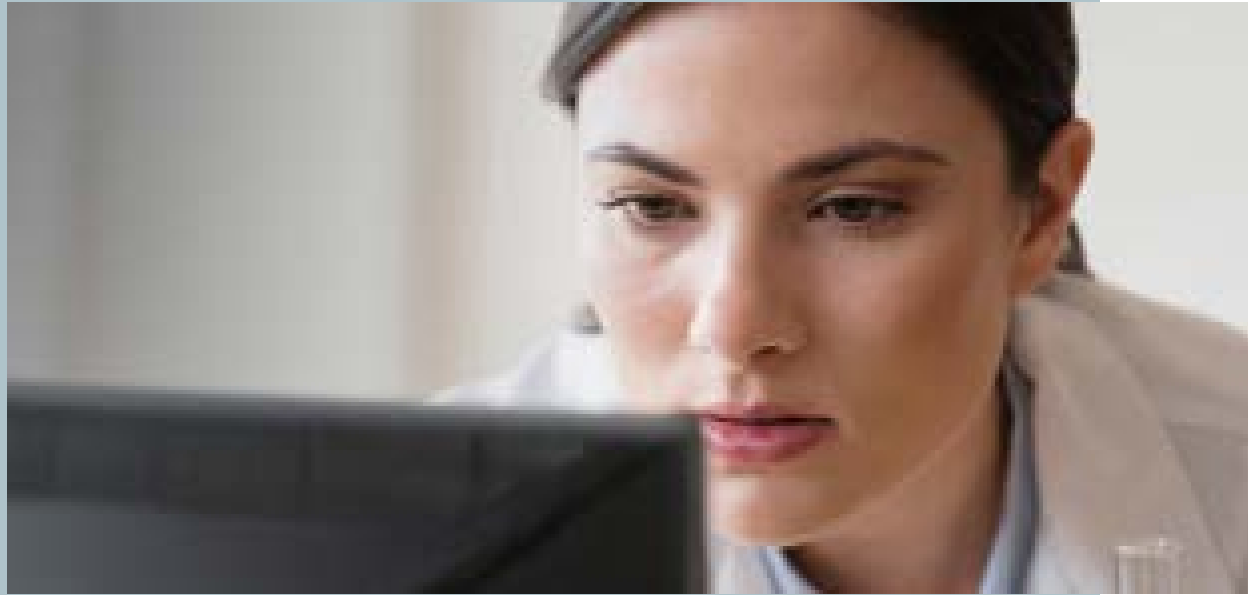
## Updates to the USP-NF Subscription Model and New Platform Launch

Trey White, Ph.D., Senior Director, Documentary Standards  
Rebecca Cambroner, MBA, MSL, PMP, Director, Documentary  
Standards



# *USP-NF Online Demo*





Get Ready for the New *USP-NF Online!*

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

# Welcome!

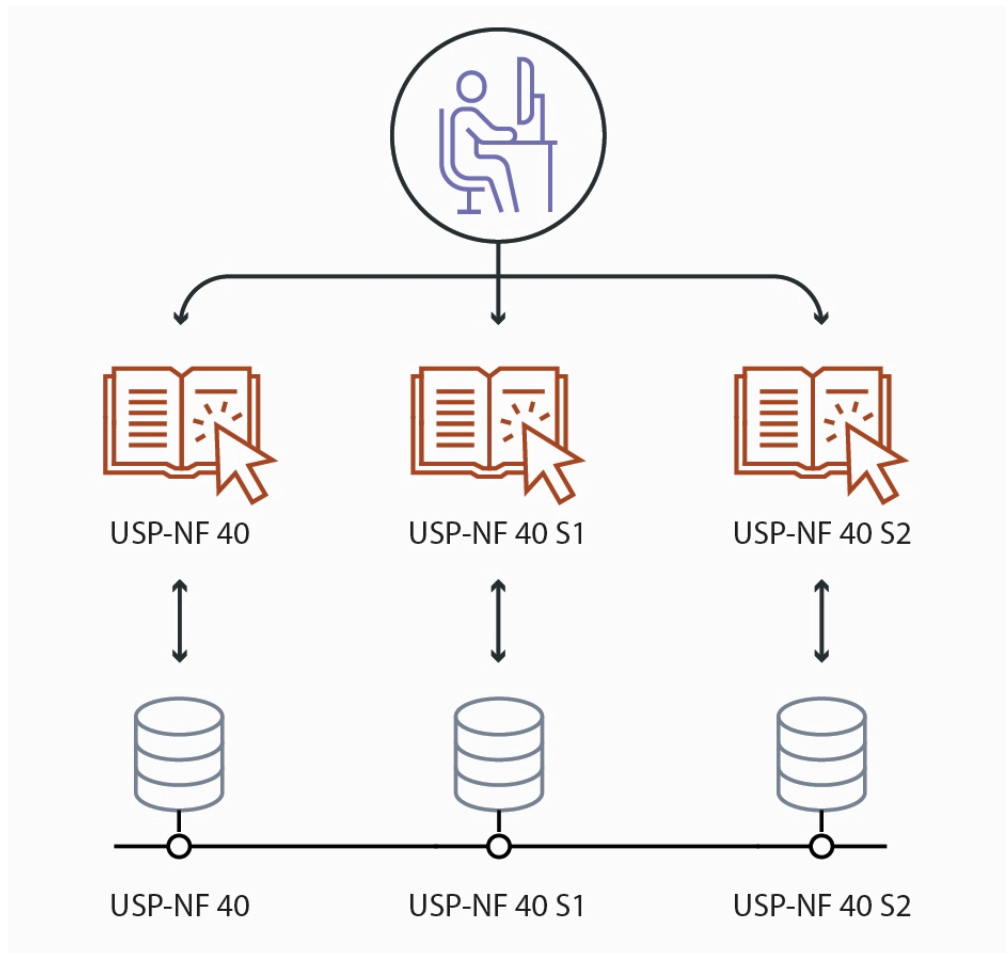
# New document Storage Architecture



## Siloed vs. shared USP-NF content storage

### ▶ Legacy System

### ▶ New USP-NF Online




Sets the foundation for use of DOIs



# Legacy *USP–NF* Online Login



 | **USP-NF Online**

Click the USP-NF version listed below that you would like to access. [LOG OUT](#)

CURRENTLY OFFICIAL	NOT YET OFFICIAL	NOT YET OFFICIAL
<b>USP 40–NF 35 through First Supplement</b> Information in this edition of USP–NF remains official until December 1, 2017	<b>USP 40–NF 35 through Second Supplement</b> Information in this edition of USP–NF will become official on December 1, 2017  Before December 1, 2017, use this information to prepare for compliance.	<b>USP 41–NF 36</b>  Information in this edition of USP–NF will become official on May 1, 2018  Before May 1, 2018, use this information to prepare for compliance.

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# Legacy USP–NF Online Main Page



The screenshot shows the USP-NF Online main page. At the top left is the USP logo with the tagline "Global Expertise, Trusted Standards, Improved Health" and "U.S. Pharmacopoeial Convention". To the right of the logo is the text "USP–NF | Online". On the far right of the top navigation bar is a search box with "Quick Search" and "Go" buttons, and a link to "Advanced Search". Below the search bar are buttons for "USP-NF HOME", "USP LINKS", "HELP", and "LOGOUT".

On the left side, there is a vertical navigation menu with the following items: My USP-NF, Bookmarks, Searches, USP40-NF35 S2, New Official Text, Front Matter, Admissions, Annotated Lists, General Notices, General Chapters, Dietary Supplements Chapters, Reagents, Reference Tables, USP Monographs, GH Monographs, Dietary Supplements, NF Monographs, Chromatographic Columns, Glossary, Contact USP, USP Home Page, Technical Support Site, Email Software Tech Support, and Email Customer Service.

The main content area has a heading "Welcome To The USP-NF" and a row of icons for document operations. Below this, there are two columns of text:

**USP–NF Online features icons to identify and link to new official text.** The icons help users identify and access *Revision Bulletins*, *IRAs*, and *Errata*, as well as *Stage 6 Harmonization* notices, and are added to monographs, General Chapters, and reagents that have new official text that has not yet published in the *USP–NF* or its Supplements. When you click on an icon, it will link you to the page on the USP website where new official text can be viewed. Icons will appear for monographs, General Chapters, and reagents only. For new official text updates to all other content, please check the appropriate new official text page on the USP website.

**Errata, IRAs, Revision Bulletins, and Stage 6 Harmonization Notices:** *USP–NF* is continuously revised. Revisions occurring through USP's Standard Revision Process are presented annually as Standard Revisions in the *USP–NF* and in twice-yearly Supplements. Revisions also may occur more frequently through one of USP's Accelerated Revision Processes: *Errata*, *Interim Revision Announcements (IRAs)*, and *Revision Bulletins*. *Errata*, *IRAs*, and *Revision Bulletins*, and *Stage 6 Harmonization* notices are posted on the USP website in the *USP–NF* section.

*Errata*, *IRAs*, and *Revision Bulletins* posted as New Official Text supersede standards in the on-line publication and in the *USP–NF* or Supplement. To access *Errata*, *IRAs*, and *Revision Bulletins*, [click here](#). To access *Stage 6 Harmonization* notices, [click here](#).

USP has developed a Cumulative List of *USP–NF* Revisions to assist users in tracking revisions to *USP–NF* content. This list was first posted in December 2015 and includes information on the status of all proposed revisions that have been in progress since July 2015, including information on *In-Process Revisions*, *Revision Bulletins*, *Interim Revision Announcements*, *Errata* and redesigned monographs. Users may access the cumulative list of revisions here: [http://www.usp.org/sites/default/files/usp\\_pdf/EN/USPNF/cumulative\\_ballot\\_results.xlsx](http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/cumulative_ballot_results.xlsx)

2017  
U.S. Pharmacopeia  
National Formulary

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USP 40  
NF 35  
through Second Supplement

# 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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