THE Ribosome
TRANSLATING STANDARDS INTO QUALITY
USP U.S. Pharmacopeial Convention

New Developments in Performance and Raw Materials Standards

USP's biological standards support its mission of promoting public health. The early standards for biologics included in the *USP* covered antitoxin products, and evolved over time to a wide range of biological products including complex extracts, peptides, proteins, vaccines, blood products, cell, and tissue based products.

The development process for standards involves collaborating with practitioners, industry, and government agencies. In the current landscape and based on feedback received from its stakeholders, USP is broadening its portfolio of biologics standards to include performance standards which support biologics analytical testing throughout the product lifecycle. Performance standards are used to ensure and demonstrate methods performance and can be applicable to product families (e.g., insulins) or classes (e.g., mAbs). In general, the procedures are written into general chapters in the *USP-NF*. In addition to performance standards, the USP biologics program is also evaluating the types of raw materials that are considered to be critical for the manufacturing of biologics, and exploring the possibilities for developing analytical procedures and/or associated reference materials to test for the quality of these raw materials. It is important to highlight that the performance and raw materials standards to be generated in this context will be developed in collaboration with USP's stakeholders using the same quality systems used for product specific standards. Comments and queries should be addressed to Fouad Atouf.

Upcoming USP Workshops

7th Bioassay Workshop – Bioassay: A Lifecycle Approach
September 25 – 26, 2017, USP-Rockville, MD USA

USP's 7th Bioassay Workshop will examine how the principles in the USP Bioassay chapters are applied throughout the life cycle of a bioassay. The role and requirements of the bioassay shift as a product emerges from research and evolves through development, commercialization, transfer, maintenance, monitoring, and retirement. Decisions are made throughout the lifecycle of the bioassay using appropriate statistical approaches to understand the impact and risks of specific choices in assay design, development, analyses and validation strategies. Read more…

Call for Abstracts deadline extended to **March 31.** Read **here** for details.

Products & Services

Recently Released Reference Standards

- Exenatide (NEW)
- Calcitonin Salmon Related Compound A
- Corticotropin
- Dextran 40
- Dextran Vo Marker
- Dextran 10 Calibration
- Fondaparinux Sodium for Assay
- Pancreatin Lipase

Reference Standards Coming Soon

- Coagulation Factor VIIa (NEW)
- Erythropoietin (NEW)
- Bile Salts
- Chymotrypsin
- Dermatan Sulfate

See also:
Reference Standard Development Process

Reference Standard Release Notification

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Control and Determination of Visible and Sub-visible Particulate Matter in Biologics, June 26 - 27, 2017, USP-Rockville, MD USA

This workshop will be a forum for discussing the control and determination of undesired visible and sub-visible particulate matter and also characterization ofinherent particle species in biopharmaceuticals. **Click for more info and registration.**

4th Peptide Workshop, November 6 – 7, 2017, USP-Rockville, MD USA

USP is bringing its **4th USP Workshop on Synthetic Therapeutic Peptides: Regulations, Standards and Quality** back again in 2017 for a more in-depth program which will examine GMP manufacturing considerations, analytical characterizations, CMC and formulation for diverse delivery systems, and USP updates. **Click here for more information.**

Call for Abstracts deadline is **April 28, 2017.** Read **here** for details.

General Chapters Biological Analysis Expert Committee Update

USP's General Chapters Biological Analysis Expert Committee (GCBA EC) has been very busy since their last face-to-face meeting last August (see the Executive Summary.) The Chair and Vice Chair of the EC, Wes Workman and Wendy Saffell-Clemmer, have been facilitating the advancement of many activities of the EC including formation of a new Expert Panel, under the leadership of member Ken Miller, to develop a general chapter describing best practices for validation of test kits. An outline is under development and will be posted on the USP website for early comment by stakeholders.

The EC has also finalized a Stage 4 revision of the harmonized chapter <1055> on peptide mapping that should be published later this year. The EC also reviewed the public comments received from the PF proposal of chapter <509> *Residual DNA Testing*. The comments to be incorporated are minor in nature so this chapter will move to the EC ballot later this year once the 2 new RS's for E. coli and CHO genomic DNA are released for sale. The EC is also considering some new analytical chapters and RS's to support the vaccine industry. The Biologics Stability Expert Panel is making good progress on their new general chapter and a public prospectus should be posted soon for early comment by stakeholders.

The EC's next face-to-face meeting will be held at USP's Rockville office August 23-24, 2017. The agenda for the meeting will be posted on our USP website approximately 2 months before the meeting. Anyone who wishes to attend the meeting can apply by completing a simple observer form.

Products & Services

Documentary Standards in PF

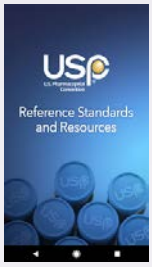
In PF 43(2)
Published March 1,
Comments due May 31, 2017

- <198> Nuclear Magnetic Resonance Spectroscopy Identity Testing of Bacterial Polysaccharides Used in Vaccine Manufacture (NEW)
- Chymotrypsin
- Chymotrypsin for Ophthalmic Solution

In PF 43(3)
To be published May 1,
Comments due July 31, 2017

- Triptorelin Pamoate (NEW)
- Desmopressin Acetate

See Official Text in *USP-NF*



Free App *Just Released!*

This ***free app*** puts the latest, real-time RS data at your fingertips, such as newly released reference standards, reference standards in development, lot numbers and valid use dates. Locate products through fully-searchable alphabetical listings or use the built-in bar code scanner. Download now:
For Android **For iOS**

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USP Staff at Speaking Events

CPhI North America/InformEx

Come to **CPhI North America** and see the keynote address featuring **USP's CEO, Dr. Ronald T. Piervincenzi** as well as attend other presentations by distinguished speakers from USP.

Afterwards, stop by the **USP lounge** to learn more about how USP has laid the foundation for quality in healthcare and health products worldwide. USP is an Official Conference Partner of the inaugural **CPhI North America** in Philadelphia taking place on May 16 – 18, 2017.

PEGS 2017

Short Course on New Initiatives

Meet Maura Kibbey and Steven Walfish at **PEGS 2017** in Boston on May 1-5, 2017. Dr. Kibbey will speak about "New USP Initiatives for Biophysical Characterization of Biologics", and Mr. Walfish will cover "Lifecycle Management for Bioassay Development and Validation." In addition, they are conducting a **short course** on May 4 entitled "NEW USP Initiatives for Characterization and Release of Biologics".

Be sure to stop by **booth 202**, meet the USP Biologics Team, and learn about their latest developments in protein standards.

ExcipientFest

USP Workshop will be Conducted

Don't miss USP's workshop on Excipient Qualification and the Impact on Excipient Variability in Pharmaceutical Manufacturing on April 24th, 2017 at **ExcipientFest Americas** in Providence, Rhode Island.

Catherine M. Sheehan, M.S., M.S., Sr. Director, Science, Excipients and John Giannone, Senior Director of Strategic Marketing and Program Operations, Excipients at USP, will lead presentations and group discussions on topics such as raw materials variability and the latest news from FDA and USP's February workshop on "Standards for Pharmaceutical Products: Critical Importance of Excipients in Product Development".

TIDES 2017

Oligonucleotide and Peptide Therapeutics

Visit USP's **booth 110** at **TIDES 2017** April 30th – May 3, 2017 in San Diego, California, and learn about recent USP advances in peptide standards.

Call for Candidates: BIO4 Antibiotics Expert Committee

Applications due April 10, 2017

Read here for details and to apply

Published by:
Fouad Atouf, Ph.D.
Vice President
Science–Global Biologics
Contact Fouad Atouf

Questions?
Contact Us:
www.usp.org/contact-us
Phone: +1-800-227-8772
Website: http://www.usp.org