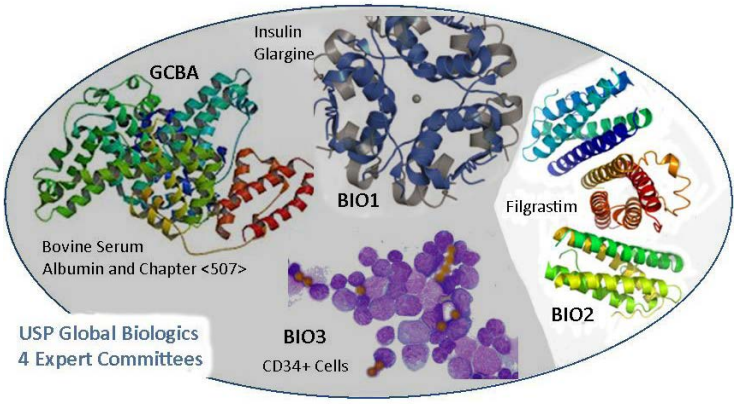
Global Biologics e-Newsletter



BIO2 Proteins Expert Committee Update

The BIO2 EC is responsible for the development of USP-NF general chapters and monographs and their associated physical reference standards (RSs) for recombinant and naturally derived proteins, which include monoclonal antibodies, protein hormones, cytokines, enzymes, and complex extracts. The first BIO2 EC face-to-face meeting took place in February 2016, with the primary objective of developing a work plan for the 2015-2020 cycle. Key projects being pursued include developing new monographs and associated RSs for Epoetin, Interferon beta-1a, Interferon beta-1a Injection and Pegfilgrastim as well as improving and modernizing legacy protein monographs, such as monograph family for Pancreatin and Pancrelipase. In addition, BIO2 EC aims to develop standards to address the quality of raw materials used in biopharmaceutical manufacturing. For BIO2 EC updates and additional information, read more here.

BIO2 EC also approved the formation of two Expert Panels (EP), Enzymes and Fc Function Assays. The scope of the Enzymes EP is to modernize current USP enzyme monographs, and to develop new standards for pharmaceutical enzymatic preparations as well as standards for the pancreatic and gastric enzymes used in new dissolution assays mimicking gastrointestinal tract. The Fc Function Assays EP will develop a general chapter to address development and validation of Fc function assays including assays measuring low affinity FcγR interactions as well as impact of glycosylation on antibody effector function. Additionally, BIO2 EC members joined BIO1 EC members to form a new Insulin Expert Panel to develop documentary standards and RSs for Insulin and Insulin analogues. Furthermore, BIO2 EC is working in collaboration with the General Chapters

Expert Committee Meetings, Agendas & Info
GCBA, August 23-24
BIO1 Peptides and Insulins, Nov 16-17
BIO2 Proteins, Nov 29-30

Visit our website for convenient downloads:
<127> Flow Cytometric Enumeration of CD34+ Cells

"The US Regulatory and Pharmacopeia Response to the Global Heparin Contamination Crisis", published in **Nature Biotechnology**
and *more…*

Read Newsletter Online

General Links

- USP–NF Online
- PF Online
- Commentary
- Errata
- Key Issues
- Donor Program
- Chromatographic Columns
- Calendar of Events

Reference Standards

CD34+ Cell Enumeration System Suitability
Collagenase I
Collagenase II
Prekallikrein Activator *(Released soon)*
and more…

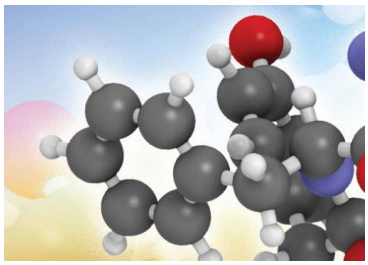
- Recently Released

—Statistics Expert Committee to organize the USP 7th Bioassay workshop to be held at USP-USA Rockville location, MD on Sept. 25-26, 2017.

The next face-to-face meeting for BIO2 EC will be held on November 29-30, 2016 at the USP-USA Rockville location. Please check USP website for the meeting agenda (currently under development) and consider registering as an observer for this upcoming face-to-face meeting. Look here for the BIO3 Complex Biologics update in the next e-newsletter.

3rd Synthetic Therapeutic Peptides Workshop – Regulations, Standards and Quality

Nov. 14-15, 2016, USP-Rockville, MD



Peptides represent one of the fastest growing segments in the biopharmaceutical market. Being able to manufacture peptides with consistent high quality is an important priority for manufacturers of this drug class. As the global manufacturing landscape continues to transform, public standards for the quality of peptides will play a growing role in the supply chain integrity of these drugs.

After a successful program in 2015 focused on raw material control strategy, the types of impurities and appropriateness of impurities methods, peptides in vaccines, conjugated peptides, and regulatory considerations, USP is bringing its Synthetic Therapeutic Peptides Workshop back again in 2016 for a more in-depth program that will examine manufacturing considerations, impurities, specifications, novel peptide therapeutics, and regulatory considerations.

For details and to **register** | Submit abstracts **due August 15.**

Pre-Conference Workshop at CHI's Bioprocessing Summit

August 15, 2016

Dr. Fouad Atouf and Dr. Maura Kibbey conducted a pre-conference workshop entitled "New USP Initiatives and Standards for Biologics" at the CHI Bioprocessing Summit in Boston, MA, August 15-19, 2016.

This short course detailed new USP standards for legacy products and the qualification of biologic raw materials. The course started with a look at biological standards and future directions in the Pharmacopeia, followed by Chapters to assess viral clearance of starting materials and recombinant product; development of new Chapters for cell banking and cryopreservation, and modernization of monographs for animal- and human-

- Under Development
- Release Notification

For complete list and information about USP Reference Standards

Documentary Standards Proposed

General Chapter Prospectus — Cell Banking
(Comments due August 29, 2016)

Published in PF 42(4), comments due Sept 30

- Eptifibatide (NEW)

Published in PF 42(3), comments due July 31

- Goserelin Implants (NEW)
- <126> Somatropin Bioidentity Tests
- Insulin Glargine
- Insulin Glargine Injection

Current Biologics Standards in Development
Current Biologics Standards in USP–NF

- **Visible and Subvisible Particulate Matter in Therapeutic Proteins**
  June 26-27, 2017 in Rockville, MD
  Read on for details and **call for abstracts**.

USP Staff at Conferences

Meet USP CSO Dr. Jaap Venema in North Bethesda, MD where he will address "Comparative Analytics" at the The GPhA Biosimilars Council Conference, Sept 7-8, 2016.

Meet Dr. Tina Morris Sept. 27-28, 2016 at EDQM's "Ph. Eur. : Tackling Future

derived biologics.

In addition to the workshop, Dr. Kibbey addressed “Best Practices for Host Cell Protein Measurement: USP Chapter <1132>”. Dr. Atouf spoke on ”Defining and Qualifying Raw Materials for Use in Cell Therapies.”

Click ***here*** for the list of opportunities to connect with USP staff speaking at conferences.

Challenges of the Quality of Medicines Together" in Tallinn, Estonia.

Meet Dr. Rebecca Potts in Memphis, TN where she will address CD34+ Cell Enumeration at the ISCT North American Regional Conference, Sept. 30-Oct.2, 2016.

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