



BIO3 Complex Biologics Expert Committee Update

The BIO3 EC is responsible for the development of USP-NF general chapters and monographs and their associated physical reference standards (RSs) for complex biologics, which includes plasma derivatives, recombinant blood products, heparin products, tissue products, cell therapies, gene therapies, and ancillary materials. The First BIO 3 face-to-face meeting took place in March 2016, with the primary objective of developing a work plan for the 2015-2020 cycle. Key projects being pursued include developing new monographs for Eptacog alfa activated, Bovine heparin and scaffold human amniotic membrane, as well as improving and modernizing monographs for legacy products in the blood products area, such as Albumin Human and Factor IX complex. In addition, BIO3 EC will develop standards to address the quality of ancillary materials, which are materials used during product manufacturing, not intended to be in the final product but residuals may remain. For BIO3 EC updates and additional information, [read more here](#).

BIO3 approved the formation of an Expert panel (EP) on Coagulation factor assays. The scope of the EP is to develop General chapters for coagulation assays and monographs for coagulation factors. BIO3 EC is also the sponsor for the Bovine Unfractionated Heparin EP (BUFH). The goal of this expert panel is to develop appropriate standards, both documentary and physical, for the potential reintroduction of Bovine heparin in the US market. In this capacity, the BUFH EP has designed and conducted a large scale evaluation of methods using bovine heparin obtained from the current manufactures. Additionally, a sub-group of BIO3 experts is working on revisions to general chapters <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products and <1046> Cellular and Tissue-Based Products to be



General Chapter Prospectus

[<1xxx> Fc Function Assays](#)

Input deadline: November 28, 2016

[New Chapter Downloads Available:](#)

<89.1> Collagenase I

<89.2> Collagenase II

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

[\[Glu13\]-Exenatide](#)

[\[Met\(O\)14\]-Exenatide](#)

[\[N-Acetyl-His1\]-Exenatide](#)

[Prekallikrein Activator](#)

[CD34+ Cell Enumeration System Suitability](#)

[Collagenase I](#)

[Collagenase II](#)

and *more...*

- [Recently Released](#)
- [Under Development](#)

published soon in the Pharmacopeial Forum.

The next [face-to-face meeting for BIO3](#) will be held on March 7-8, 2017 at the USP-USA Rockville location. Please check the 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 General Chapters Biological Analysis (GCBA) Expert Committee update in the next e-newsletter.



PepTalk The Protein Science Week

January 9-13, 2017



Dr. Fouad Atouf will present the topic "Detection of Impurities: Use of Pharmacopeia Reference Standards" at [PepTalk The Protein Science Week](#) in San Diego, CA, January 9-13, 2017.

Meet with Dr. Atouf and our Strategic Marketing Senior Director, Meyer Gladstone, to learn about USP's work in therapeutic proteins and explore opportunities to collaborate or volunteer.

WCBP 2017

21st Symposium on the Interface of Regulatory & Analytical
Sciences for Biotechnology Health Products
January 24-26, 2017, Washington, DC

Be sure to visit the USP exhibit at WCBP 2017. Exchange ideas and explore opportunities with Dr. Salah Kivlighn and Meyer Gladstone from Strategic Marketing, and scientists Dr. Maura Kibbey, Dale Schmidt and Dr. Rebecca Potts.



13th Annual PEGS The Essential Protein Engineering Summit

May 1-5, 2017



Meet Dr. Maura Kibbey and Dr. Steven Walfish at [PEGS 2017](#) in Boston, MA, May 1-5, 2017. Dr. Kibbey's presentation topic will be "New USP Initiatives for Biophysical Characterization of Biologics", and Dr. Walfish will speak about "Lifecycle Management for Bioassay Development and Validation." In addition, Dr. Kibbey and Dr. Walfish are conducting a **short course** on May 4:

Title: New USP Initiatives for Characterization and Release of Biologics

Topics include:

- USP Stimuli Article on Higher Order Structure Characterization of Biologics
- Case studies developing biologics monographs and potency assays

- [Release Notification](#)

[For complete list and information about USP](#)

[Reference Standards](#)

Documentary Standards Proposed

Published in PF 42(5), comments due Nov 30

- Fondaparinux Sodium
- Fondaparinux Sodium Injection
- <509> Residual DNA Testing [NEW]
- Insulin Aspart
- Teriparatide Injection
- Teriparatide for Injection

[Current Biologics Standards in Development](#)

[Current Biologics Standards in USP-NF](#)



Save the Date!

- **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 Dr. Tina Morris Nov 17, 2016 at [2016 AAPS Annual Meeting & Exposition](#) Nov. 13-17 in Denver, Colorado.

Published by:

Tina Morris, Ph.D.
Senior Vice President
Science—Global Biologics

[Contact Tina Morris](#)

Questions?

Contact Us: www.usp.org/contact-us

Phone: +1-800-227-8772

Website: <http://www.usp.org>

- Updates on USP bioassay-related chapters and activities

Click [here](#) for the list of opportunities to connect with USP staff speaking at conferences.



Upcoming Expert Committee Meetings, Agendas & Info

[BIO1 Peptides and Insulins, Nov 16-17](#)

[BIO2 Proteins, Nov 29-30](#)

[BIO3 Complex Biologics, March 7-8, 2017](#)

GCBA, August 23-24, 2017

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