

**2015–2020 Biologics Monographs 2 – Proteins (BIO2) Expert Committee**  
**Wednesday – Thursday, September 27-28, 2017**  
**USP – U.S., Rockville**

**Agenda**

---

**Goals and Anticipated Outcomes**

1. To update EC's 2015-2020 work plan
2. To update new proposals, revision proposals and EP activities
3. To discuss topics related to Biologics Performance Standards

**Attendees**

*Attendee list to come*

**Wednesday, September 27, 2017**

8:15 a.m. Arrive at USP, register and check in

8:30 a.m. **[CLOSED to all observers and government liaisons]**

- |           |   |   |
|-----------|---|---|
| 8:30 a.m. | <b>1. Procedural Matters and Standards of Conduct</b> <ol style="list-style-type: none"> <li>a. Call Meeting to Order</li> <li>b. Establish Quorum</li> <li>c. Identification of Observers and Confidential Information</li> <li>d. Conflict of Interest, Confidentiality, Code of Ethics</li> <li>e. Review of the Agenda</li> </ol> | Dr. Mulkerrin<br>Ms. Gould-Kostka<br>Dr. Mulkerrin<br>Ms. Gould-Kostka<br>Dr. Mulkerrin |
|-----------|---|---|

**[END CLOSED session]**

- |           |   |   |
|-----------|---|---|
| 8:45 a.m. | <b>2. Open Procedural Matters</b> <ol style="list-style-type: none"> <li>a. Welcome</li> <li>b. Meeting Center Announcements</li> <li>c. Announce Changes to the Attendee List, Confirm Quorum</li> <li>d. Introductions of New Staff and Observers</li> <li>e. Approval of Agenda and Minutes of the Previous Meeting</li> <li>f. Action Items from the Previous Meetings</li> </ol> | Dr. Mulkerrin<br>Ms. Fletcher<br>Dr. Mulkerrin<br><br>All<br>Dr. Mulkerrin<br>Dr. Potts |
|-----------|---|---|

9:00 a.m. **3. Work Plan for 2015-2020 Cycle**

*Goal: To update EC of the work plan*

- |  |   |                               |
|--|---|-------------------------------|
|  | <ol style="list-style-type: none"> <li>a. Work Plan and Book Ballot Items</li> <li>b. Reference Standard Ballot Items</li> <li>c. Discussion</li> </ol> | Dr. Potts<br>Dr. Potts<br>All |
|--|---|-------------------------------|

9:15 a.m. **4. Revision Proposals**

*Goal: To inform EC of progress on draft proposals and EC activity and seek EC feedback*

- |  |   |   |
|--|---|---|
|  | <ol style="list-style-type: none"> <li>a. Human Chorionic Gonadotropin (HCG)           <ol style="list-style-type: none"> <li>i. Chorionic Gonadotropin And Chorionic Gonadotropin for Injection</li> <li>ii. Development of HPLC Identification Method</li> <li>iii. Development of HPLC Identification Method</li> <li>iv. Monograph Revision Proposal</li> <li>v. HCG Monograph Revisions</li> </ol> </li> </ol> | Dr. Arora<br><br>Ms. Chillara<br>Dr. Groisman / Dr. Balanian<br>Dr. Arora<br>Dr. Wolfenson / Dr. Di Nardo |
|--|---|---|

- vi. Discussion All
- 10:30 a.m. **Break**
- 10:45 a.m. b. Filgrastim Revision  
 i. Monograph Revision Dr. Potts  
 ii. RS Update Dr. Menon  
 iii. Discussion All
- 11:15 a.m. **5. Enzyme Standards Setting Update**  
*Goal: Update EC on recent work with enzyme standards*
- a. Trypsin Revision and RS Dr. Chang  
 i. Discussion All  
 b. Pancreatin Revision Dr. Carrick /Dr. Potts  
 i. Discussion All  
 c. Chymotrypsin Revision Dr. Menon  
 i. Discussion All  
 d. Enzyme Panel Update Dr. McCarthy  
 i. Discussion All
- 12:15 p.m. **Lunch and Group Photo**
- 1:15 p.m. **6. New Monograph Proposals**  
*Goal: Update the EC on new monograph proposals*
- a. Interferon Beta-1A Monographs Dr. Huang  
 i. Glycan Method Update  
 b. Pegfilgrastim Monograph and Pegfilgrastim RS Dr. Menon  
 c. Somatropin Revision and New Monograph Dr. Arora  
 d. Somatropin New Monograph Proposal Ms. Jespersen  
 e. Discussion All
- [CLOSED to all observers and government liaisons]**
- 2:45 p.m. **7. FDA Naming Guidance and USP Monographs**  
*Goal: To inform on USP perspective on biologics monograph naming with new FDA guidance*
- a. FDA Guidance and Naming of Biologic Monographs Ms. Devine  
 b. USP's Perspective Ms. Devine  
 c. Discussion All
- [END CLOSED session]**
- 3:15 p.m. **Break**
- 3:30 p.m. **8. Fc Function EP Update**  
*Goal: To inform EC of the EP activity*
- a. Fc Function Update Dr. Crouse-Zeineddini
- 4:00 p.m. **9. USP Biologics Workshops**  
*Goal: To inform the EC of Biologics workshops*
- a. Summary of Bioassay Workshop Dr. Mulkerrin
- 4:30 p.m. **10. Wrap-up of Day 1**
- a. Summary of EC Consensus/Action Items Dr. Mulkerrin/ Mr. Podolsky
- 4:45 p.m. Meeting adjourns, Bus transportation to hotel

5:45 p.m. Depart from hotel lobby to restaurant  
6:00 p.m. EC dinner at TBD

### Thursday, September 28, 2017

8:30 a.m. **11. USP's Performance Standards and Raw Materials**

*Goal: To have in-depth discussion on development of biologic performance standards*

- a. USP Performance Standards
  - i. Oligosaccharide Standards
  - ii. mAb Standards

Dr. Carrick  
Mr. Schmidt

9:15 a.m. **12. Ideas for New Performance Standards and Raw Materials Standards**

- a. Protein A
- b. Standards for PEGs
- c. Bioassay Standards

Dr. Mulkerrin  
Dr. Menon  
Dr. Crouse-Zeineddini

10:00 a.m. **Break**

10:15 a.m. **13. Brainstorming Session Performance and Raw Materials Standards**

*Goal: To develop ideas for new performance standards*

- a. Brainstorming session—Ideas for new standards
  - i. System Suitability Standards
  - ii. Assay standards
  - iii. Limit or Impurity Standards

All  
All  
All  
All

12:00 p.m. **14. Path Forward**

- a. Recommendations for standards and projects to initiate
- b. Type of materials to acquire and studies to characterize the material

All  
All

12:15 p.m. **15. Meeting Summary and Action Items**

- a. Planning Future Meetings: Face-to-Face and Teleconferences
- b. Action Items
- c. Summary

Dr. Potts  
Mr. Podolsky  
Dr. Mulkerrin

12:30 p.m. **Adjourn and Lunch**