



**Biologics Monographs 3 – Complex Biologics Expert Committee (BIO3 EC)
Tuesday–Wednesday, November 19–20, 2019
USP – U.S., Rockville**

Agenda - Draft

Goals and Anticipated Outcomes

Goals are listed under individual agenda items.

Attendees

Attendee list provided on the day of the meeting

Day 1

Tuesday, November 19, 2019

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

**CLOSED TO ALL OBSERVERS AND GOVERNMENT
LIAISONS**

8:30 a.m. **1. Closed Procedural Matters and Standards of
Conduct**

- a. Welcome, Opening Remarks, Introduction
- b. Conflicts of Interest, Confidentiality, Code of Ethics
- c. Review of Agenda for Specific Conflicts of
Interest/Need for Recusal

Dr. Chess
Ms. Casino
All

END CLOSED SESSION

8:45 a.m. **2. Open Procedural Matters**

- a. Welcome
- b. Meeting Center Announcements
- c. Recording Policy and any other Procedural
Announcements
- d. Roll Call and Introduction of Members, Government
Liaisons, Staff and Observers
- e. Establish Quorum
- f. Approval of Agenda
- g. Approval of Minutes of Previous Meeting
- h. Action Items from Previous Meeting

Dr. Chess
Ms. Fletcher
Ms. Casino
Ms. Casino
Dr. Chess
Dr. Chess
Dr. Chess
Dr. Potts

9:00 a.m. **3. Fondaparinux Sodium for Injection**

*Goal: Provide information from manufacturers with the EC and discuss the path forward for the
revision*

- a. Information from Manufacturers
- b. Path Forward for Revision
- c. Discussion

Mr. Basha
Mr. Basha
All



- LMWH
- b. Heparin Methods, Potential Chapters and Need for Species Identification Tests Dr. Gray
 - c. Discussion All

2:30 p.m. **Break**

3:00 p.m. **11. Legacy Document/Prioritization of Revisions**

Goal: Inform the EC on the plans for and ongoing work on revisions of documentary standards that were identified through the EC review

- a. BIO3 Accomplishments this Cycle Dr. Potts
- b. Identified Revisions Needed/Prioritization Dr. Potts
- c. Ongoing Work/Future Plans for Revisions and Assignment of Work Dr. Potts
- d. Discussion All

3:45 p.m. **12. Update on Omission of Immune Globulin Monographs**

Goal: Update the EC on the status of the Immune Globulin monographs proposed for omission

- a. Summary of Monographs Proposed for Omission Dr. Bhattacharya
- b. Discussion All

4:00 p.m. **13. Revision of <92> Growth Factors and Cytokines Used in Cell Therapy Manufacturing**

Goal: Inform the EC of the planned revision of <92> Growth Factors and Cytokines Used in Cell Therapy Manufacturing

- a. Revision of General Chapter <92> Dr. Potts
- b. Discussion All

4:30 p.m. **14. Wrap-up of Day 1**

4:45 p.m. **Adjourn – Day 1, Transportation to Hotel**

Day 2

Wednesday, November 20, 2019

8:45 a.m. **15. Revision Proposal for Acarbose Monographs**

Goal: Update the EC with more information on the revision proposal for the Acarbose monographs

- a. Proposed Revisions of Acarbose Monographs Dr. Skasko
- b. Discussion All

9:15 a.m. **16. Development of a New Chapter for Plasmid DNA as a Raw Material in Cell Gene Therapy (CGT) Products**

Goal: Inform the EC on topics that could be covered in a new, above 1000 general chapter on plasmid DNA

- a. Discuss Topics for a New General Chapter on Plasmid DNA as a Raw Material for CGT Dr. Richardson



- b. Discussion All

10:00 a.m. **17. Comparability in Gene Therapy**

Goal: Discuss comparability in gene therapy products and explore the potential for development of a general chapter

- a. Comparability in Gene Therapy Dr. Heidaran
- b. Physical Reference Standards that Could be Developed Dr. Heidaran
- c. Discussion All

10:30 a.m. **Break**

11:00 a.m. **18. Update on Performance Standards**

Goal: To inform the EC of performance standards in development.

- a. Performance Standards in the Pipeline for Development Dr. Richardson
- b. Heparinases Dr. Curti
- c. Discussion All

11:45 a.m. **19. Meeting Summary**

- a. Reminder of Next EC Meeting Dr. Chess

12:00 p.m. **Adjourn & Lunch**