

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 Dr. Chess a. Welcome, Opening Remarks, Introduction b. Conflicts of Interest, Confidentiality, Code of Ethics Ms. Casino c. Review of Agenda for Specific Conflicts of ΑII Interest/Need for Recusal **END CLOSED SESSION** 2. Open Procedural Matters 8:45 a.m. Dr. Chess a. Welcome b. Meeting Center Announcements Ms. Fletcher c. Recording Policy and any other Procedural Ms. Casino Announcements d. Roll Call and Introduction of Members, Government Ms. Casino Liaisons, Staff and Observers e. Establish Quorum Dr. Chess Dr. Chess f. Approval of Agenda g. Approval of Minutes of Previous Meeting Dr. Chess h. Action Items from Previous Meeting Dr. Potts 9:00 a.m. 3. Fondaparinux Sodium for Injection

b. Path Forward for Revision

a. Information from Manufacturers

revision

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

c. Discussion All

Mr. Basha

Mr. Basha



9:30a.m. **4. Dextran Monograph Revisions**

Goal: Provide an update on the revision of the Dextran monographs and inform about a proposal with the Dextran Reference Standards

a. Update on the Dextran Monograph Revisions

Mr. Basha

b. Dextran Reference Standards

Dr. Bhattacharya

c. Discussion

All

10:00 a.m. **5. Gene Therapy Workshop**

Dr. Heidaran

Goal: Inform the EC about the upcoming Gene Therapy Workshop

a. Discussion

All

ΑII

10:15 a.m. **Break**

10:45 a.m. **6. Update from the Chair**

Goal: Inform the EC of the Biologics Stakeholder forum and updates from the COE

a. Biologics Stakeholder Forum (January 10, 2020)b. Updates from the COEDr. Chess

c. Discussion

11:15 a.m. 7. Flexible Volunteer Model

Goal: Inform on flexible model to be piloted with Advanced Therapies EC next cycle

a. Discussion Ms. Bellon

11:30 a.m. **8. Updates on Biologics Department and 2020-2025 Cycle**

Goal: Update on Biologics department, review 2020-2025 EC structure, and discuss applications for the next cycle

a. Biologics Department Updates

Drs. Carrick/McCarthy

b. 2020-2025 EC Structure and Applications

Dr. Carrick

c. Discussion

All

12:00 p.m. Lunch & Group Photo

1:00 p.m. 9. Update for Coagulation Factors Expert Panel

Goal: Inform the EC on the Expert Panel face-to-face meeting and the scope of the proposed work from the Expert Panel

a. Coagulation Factors Expert Panel Meeting Summary

Dr. Alai

b. Scope of Chapters to be Written by the Coagulation Factors Expert Panel

Dr. Alai

c. Discussion

All

1:30 p.m. **10. Heparin**

Goal: Discuss Anti Factor IIa and Xa testing for Heparin and LMWH, tests to identify the species for Heparin, and if the USP Heparin monographs should be revised

a. Anti Factor IIa and Xa Testing on Heparin and

Dr. Viskov



	LMWHb. Heparin Methods, Potential Chapters and Need for Species Identification Testsc. Discussion	Dr. Gray All
2:30 p.m.	Break	
	 11. Legacy Document/Prioritization of Revisions the EC on the plans for and ongoing work on revisions of documents d through the EC review a. BIO3 Accomplishments this Cycle b. Identified Revisions Needed/Prioritization c. Ongoing Work/Future Plans for Revisions and Assignment of Work d. Discussion 	ary standards that Dr. Potts Dr. Potts Dr. Potts
3:45 p.m. Goal: Update	12. Update on Omission of Immune Globulin Monographs the EC on the status of the Immune Globulin monographs proposed a. Summary of Monographs Proposed for Omission b. Discussion	d for omission Dr. Bhattacharya All
4:00 p.m. Goal: Inform t Therapy Man	13. Revision of <92> Growth Factors and Cytokines Used in Cell Therapy Manufacturing the EC of the planned revision of <92> Growth Factors and Cytokine ufacturing a. Revision of General Chapter <92> b. Discussion	es Used in Cell Dr. Potts 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. Goal: Update	15. Revision Proposal for Acarbose Monographs the EC with more information on the revision proposal for the Acarb a. Proposed Revisions of Acarbose Monographs	oose monographs Dr. Skasko

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

b. Discussion

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

ΑII



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
 b. Physical Reference Standards that Could be Developed
 c. Discussion

Dr. Heidaran
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
 b. Heparinases
 c. Discussion
 Dr. Richardson
 Dr. Curti

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

a. Reminder of Next EC Meeting Dr. Chess

12:00 p.m. Adjourn & Lunch