

**2015–2020 Biologics Monographs 3 – Complex Biologics Expert Committee
(BIO3 EC)**

**Tuesday – Wednesday, March 6-7, 2018
USP – U.S., Rockville**

Agenda - Draft

Goals and Anticipated Outcomes

- Reviews Monographs published in *PF 43(4)* and *PF 43(5)* and path forward.
- Update on Performance Standards.

Attendees

Attendee list is provided on the day of the meeting

Tuesday, March 6, 2018

- 8:15 a.m. Arrive at USP, register and check in
- 8:30 a.m. **[CLOSED to all observers and government liaisons]**
- 1. Procedural Matters and Standards of Conduct**
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| a. Call Meeting to Order | Dr. Chess |
| b. Establish Quorum | Ms. Casino |
| c. Review of Observer List and Confidential Information | Dr. Chess |
| d. Conflict of Interest, Confidentiality, Code of Ethics | Ms. Casino |
| e. Review of the Agenda | Dr. Chess |
- [END CLOSED session]**
- 8:45 a.m. **2. Open Procedural Matters**
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|---|--------------|
| a. Welcome | Dr. Chess |
| b. Meeting Center Announcements | Ms. Fletcher |
| c. Announce Changes to the Attendee List, Confirm Quorum | Dr. Chess |
| d. Introductions of New Staff and Observers | All |
| e. Approval of Agenda and Minutes of the Previous Meeting | Dr. Chess |
| f. Action Items from the Previous Meetings | Dr. Carrick |
- 9:00 a.m. **3. USP Strategy Updates**
- Goal: To inform EC of Biologics Program Unit and Council of Experts Activities*
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| a. Biologics Program Unit Update | Dr. Atouf |
| b. Council of Experts (CoE) May Meetings Updates | Dr. Chess |
| c. Discussion | All |
- 9:45 a.m. **4. BIO3 EC Work Plan Update**
- Goal: To update EC of the work plan*
- | | |
|--|-------------|
| a. Work Plan Update and Book Ballot Items | Dr. Carrick |
| b. Reference Standards Update and Ballot Items | TBD |
| c. Discussion | All |
- 10:00 a.m. **Break**

10:30 a.m.	5. Update from Expert Panels, Subcommittees, and Workshops	
	<i>Goal: To review progress of EP, SC, and WS</i>	
	a. Coagulation Factors Expert Panel	Dr. Carrick
	b. Heparin workshop	Dr. Gray
	c. Cell Therapy subcommittee	TBD
	d. Procoagulant working group	TBD
	e. Discussion	All
11:30 a.m.	6. Update on USP GC <85> Bacterial endotoxins	Dr. Tirumalai
	<i>Goal: To inform EC on work bacterial endotoxins</i>	
11:45 a.m.	Lunch and Group Photo	
1:15 p.m.	7. Monograph reviews	
	<i>Goal: To update EC on results of monograph reviews</i>	
	a. Tissue product monographs	TBD
	b. Discussion	All
	[CLOSED to all observers]	
2:00	8. <1043> Public Comments	
	<i>Goal: To present response to public comments to EC</i>	
	a. Public comments and response	TBD
	b. Discussion	All
2:15 p.m.	9. Monograph Revisions	
	<i>Goal: To review proposed revisions</i>	
	a. Fondaparinux sodium and Fondaparinux sodium for injection	TBD
	b. <162> Diphtheria antitoxin potency	TBD
	c. Discussion	
3:15	Break	
3:30 p.m.	10. Monograph Revisions	
	<i>Goal: To review proposed revisions</i>	
	a. Arcarbose tablets	Dr. Arora
	b. Enoxaparin sodium	Dr. Basha
	c. Discussion	All
	[END CLOSED session]	
4:30 p.m.	11. Wrap-up of Day 1	
	a. Summary of Day 1	Dr. Chess
4:45 p.m.	Meeting adjourns, bus transportation to hotel	
5:50 p.m.	Depart from hotel lobby to restaurant	

6:00 p.m. EC Dinner at restaurant

Wednesday, March 7, 2017

8:30 a.m. 12. Gene Therapy Overview and Industry perspectives

Goal: To inform and discuss the current state of Gene Therapy and

- a. Current Market overview
- b. Gene Therapy Industry perspective #1
- c. Gene Therapy Industry perspective #2
- d. Discussion

USP Staff
Dr. Bergelson
TBD
ALL

10:15 a.m. Break

10:45 a.m. 13. Performance Standards Brain Storming

Goal: To obtain feedback from EC on development of performance standards

- a. Performance standard overview
- b. Industry perspective Blood products
- c. Industry perspective Cell therapy
- d. Discussion

USP Staff
TBD
TBD
All

12:00 p.m. 14. Meeting Wrap-up

- a. Summary and Next EC Meeting

Dr. Chess

12:30 p.m. Adjourn and Lunch