

2015–2020 Biologics Monographs 2 – Proteins (BIO2) Expert Committee
Thursday November 1, 2018
USP – U.S., Rockville

Agenda

Goals and Anticipated Outcomes

1. To update EC on path forward for monographs, RS, and performance standards
2. To review revision proposals, reference standards, and EP activities
3. To discuss topics related to Biologics Performance Standards

Attendees

Attendee list to come

Thursday, November 1, 2018

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

[CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS]

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| 8:30 a.m. | 1. Procedural Matters and Standards of Conduct <ol style="list-style-type: none"> 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. Mulkerrin
Ms. Gould-Kostka
Dr. Mulkerrin |
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[END CLOSED SESSION]

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| 8:45 a.m. | 2. Open Procedural Matters <ol style="list-style-type: none"> 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. Mulkerrin
Ms. Fletcher
Ms. Gould-Kostka
All

Dr. Mulkerrin
Dr. Mulkerrin
Dr. Mulkerrin
Dr. McCarthy |
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9:00 a.m. 3. Path Forward for BIO2 EC

Goal: To discuss with the EC and obtain feedback on USP's path forward for biological standards

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|----|-----------------------------------|--------------|
| a. | Approach to Monographs | Dr. Carrick |
| b. | Approach to Performance Standards | Dr. McCarthy |
| | i) Scope and Process | |
| | ii) Expectations from EC | |
| c. | Next Cycle | Dr. McCarthy |
| d. | Discussion | All |

10:00 a.m. 4. Fc Function

Goal: To inform EC of progress on Fc Function Chapter

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|----|--------------------------------------------|-----------------------|
| a. | Expert Panel Update on Fc Function Chapter | Dr. Crouse-Zeineddini |
| b. | Performance Standards for Fc Assays | Dr. Arora |

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

11:00 a.m. **5. Human Chorionic Gonadotropin (HCG)**

Goal: To inform EC of progress on Fc Function Chapter

- a. HCG Monograph Revision
- b. Discussion

Dr. Arora
All

12:00 p.m. **Lunch and Group Photo**

1:00 p.m. **6. 2020-2025 Call for Candidates**

Goal: To inform EC members of the open Call for Candidates and the Recruitment Ambassador program

- a. Overview of Application Process
- b. Recruitment Ambassador Program
- c. Discussion

Ms. Bellon
Ms. Bellon
All

1:30 p.m. **7. Interferon Beta 1a**

Goal: To inform EC on progress on Interferon Beta 1a standards

- a. Update on Monograph Methods
- b. Proposal for Bioassay Standard
- c. Discussion

Dr. Huang
Dr. Potts
All

2:00 p.m. **8. Enzymes**

Goal: Update EC on enzyme panel activities

- a. Enzyme Panel Update
- b. Discussion

Dr. Carrière
All

[CLOSED to all observers and government liaisons]

2:30 pm **9. Final Decisions on Monographs**

Goal: To discuss and conduct voting on monographs

- a. Discussion
- b. Final deliberations and decision

All
All

[END CLOSED session]

2:45 p.m. **Break**

3:15 p.m. **10. Performance Standard Updates**

Goal: Update the EC on new performance standard development

- a. Characterization of mAb Bulk Materials
- b. Raw Materials Standards: PEGs
- c. Discussion

Dr. McCarthy
Dr. Menon
All

4:45 p.m. **11. Wrap-up**

- a. Summary

Dr. Mulkerrin

5:00 p.m. Meeting adjourns, Bus transportation to hotel

5:45 p.m. Depart from hotel lobby to restaurant

6:00 p.m. EC dinner