

**2015–2020 Biologics Monographs 2 – Proteins (BIO2) Expert Committee**  
**Monday, September 16, 2019**  
**USP – U.S., Rockville**

**Agenda**

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**Goals and Anticipated Outcomes**

Goals are provided under individual agenda items.

**Attendees**

*Attendee list to come*

**Monday, September 16, 2019**

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. | <b>1. Procedural Matters and Standards of Conduct</b><br>a. Welcome, Opening Remarks, Introduction<br>b. Conflicts of Interest, Confidentiality, Code of Ethics<br>c. Review of Agenda for Specific Conflicts of Interest/Need for Recusal | Dr. Mulkerrin<br>Ms. Gould-Kostka<br>Dr. Mulkerrin |
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**[END CLOSED SESSION]**

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|-----------|---|---|
| 8:45 a.m. | <b>2. Open Procedural Matters</b><br>a. Welcome<br>b. Meeting Center Announcements<br>c. Recording Policy and any other Procedural Announcements<br>d. Roll Call and Introduction of Members, Government Liaisons, Staff and Observers<br>e. Establish Quorum<br>f. Approval of Agenda<br>g. Approval of Minutes of Previous Meeting<br>h. Action Items from Previous Meeting | Dr. Mulkerrin<br>Ms. Fletcher<br>Ms. Gould-Kostka<br>All<br><br>Dr. Mulkerrin<br>Dr. Mulkerrin<br>Dr. Mulkerrin<br>Dr. McCarthy |
|-----------|---|---|

**[CLOSED TO ALL OBSERVERS]**

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|-----------|--|------------------|
| 9:00 a.m. | <b>3. Trypsin Bovine Reference Standard</b><br><i>Goal: To review RSCEP for new reference standard</i><br>a. Review of Trypsin Bovine RSCEP<br>b. Discussion | Dr. Menon<br>All |
|-----------|--|------------------|

**[END CLOSED SESSION]**

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|-----------|---|---|
| 9:45 a.m. | <b>4. Enzymes</b><br><i>Goal: To inform EC of expert panel activities and new enzyme reference standards in development</i><br>a. Enzyme Expert Panel Update<br>b. Heparinase Reference Standards<br>c. Hyaluronidase Reference Standard<br>d. Discussion | Dr. Carrière<br>Dr. Curti<br>Dr. Curti<br>All |
|-----------|---|---|

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

11:00 a.m. **5. Path Forward for New Standards**

*Goal: To discuss and obtain EC feedback on new standards in development*

- a. Host Cell Protein
- b. TNF alpha
- c. Discussion

Dr. McCarthy  
Dr. McCarthy  
All

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

1:00 p.m. **6. Raw Materials Standards**

*Goal: To identify and discuss new raw materials standards*

- a. Standards for Trace Metals in Media
- b. Brainstorming and Prioritization of Other Raw Materials Standards
- c. Discussion

Dr. McCarthy  
Dr. McCarthy  
  
All

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

3:00 p.m. **7. Overview of New Standard Development Activities**

*Goal: To inform on new standards and collaborations*

- a. Overview of New Standards Pipeline
- b. Collaborations
- c. Discussion

Dr. McCarthy  
Dr. McCarthy  
All

4:15 p.m. **8. Wrap-up**

- a. Summary

Dr. Mulkerrin/ Dr.  
Workman

4:30 p.m. Meeting adjourns, Bus transportation to hotel

6:00 p.m. Depart from hotel lobby to restaurant

6:30 p.m. EC dinner

**Joint Session of the Biologics Monographs 2 – Proteins (BIO2) Expert Committee  
and General Chapters – Biological Analysis (GCBA) Expert Committees  
Tuesday, September 17, 2019  
Spalding Auditorium  
USP – U.S., Rockville**

**Agenda - Draft**

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**Goals and Anticipated Outcomes**

Goals are provided under individual agenda items

**Attendees**

*Attendee list to come*

**Tuesday, September 17, 2019**

8:15 a.m. Arrive at USP

8:30 a.m. **1. Biologics Update**

*Goal: To inform EC members of 2020-2025 committee structure and recruiting progress*

- a. Strategy Update
- b. 2020-2025 Cycle – Structure and Expertise
- c. Discussion

Dr. Atouf/ Dr. McCarthy  
Dr. Carrick  
All

9:15 a.m. **2. <1049.1> Design of Stability Studies for Biotechnology  
Product Development and Lifecycle Management**

*Goal: Update EC members on new general chapter progress*

- a. Update on Expert Panel Activities
- b. Discussion

Mr. Schmidt  
All

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

10:30 a.m. **3. Characterization of Three Monoclonal Antibody Standards**

*Goal: Discuss mAb standard development and get EC feedback on next steps*

- a. Bulk Characterization
- b. Collaborative Testing Plan
- c. Analysis using Multiple-Attribute Methods
- d. Discussion

Dr. Jing  
Dr. Jing  
Dr. McCarthy  
All

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

1:00 p.m. **4. New Uses of Three Monoclonal Antibody Standards**

*Goal: Discuss development data and get EC feedback on next steps*

- a. cIEF Analysis
- b. SEC-MALS
- c. Update on Column Qualification Standards
- d. Discussion

Dr. McCarthy  
Dr. Yan  
Dr. McCarthy/Dr. Tu  
All

3:00 p.m. **Break**

3:30 p.m. **5. New Standards Under Consideration**

*Goal: Discuss potential new standards and get EC feedback on proof of concept study*

- a. Higher Order Structure
- b. Fc Binding Assays
- c. Discussion

Dr. McCarthy  
Dr. McCarthy  
All

4:30 p.m. **6. Wrap-up**

- a. Summary

Dr. Workman & Dr.  
Mulkerrin

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

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