

2015–2020 General Chapters–Biological Analysis (GCBA) Expert Committee
Monday, September 16, 2019
USP – U.S., Rockville

Agenda - Draft

Goals and Anticipated Outcomes

Goals are provided under individual agenda items.

Attendees

Attendee list is provided on the day of the meeting

Day 1

Monday, September 16, 2019

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|-----------|---|---|
| 8:30 a.m. | <p style="color: red; margin: 0;">[CLOSED to All Observers and Government Liaisons]</p> <p>1. Procedural Matters and Standards of Conduct</p> <ul style="list-style-type: none"> a. Call Meeting to Order, Establish Quorum b. Identification of Observers and Confidential Information c. Conflict of Interest, Confidentiality, Code of Ethics d. Review of Agenda for Specific Conflicts of Interest/Need for Recusal | <p>Dr. Workman</p> <p>Dr. Workman</p> <p>Ms. Casino</p> <p>Dr. Workman</p> |
| | [END CLOSED Session] | |
| 8:45 a.m. | <p>2. Open Procedural Matters</p> <ul 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 | <p>Dr. Workman</p> <p>Ms. Fletcher</p> <p>Dr. Workman</p> <p>All</p> <p>Dr. Workman</p> <p>Dr. Workman</p> <p>Dr. Workman</p> <p>Dr. Bhattacharya</p> |
| 9:00 a.m. | <p style="color: red; margin: 0;">[CLOSED to All Observers]</p> <p>3. Update on General Chapter <1049.1> <i>Design of Stability Studies for Biotechnology Product Development and Lifecycle Management</i></p> <p><i>Goal: Review updates made based on GCBA EC comments and vote to move to Pharmacopeial Forum</i></p> <ul style="list-style-type: none"> a. Updates Based on GCBA EC Member Comments b. Discussion c. Final Discussion and Vote to Move to PF | <p>Mr. Schmidt</p> <p>All</p> <p>Non-Conflicted Members</p> |
| 9:30 a.m. | <p>4. Public Comments Resolution</p> <p><i>Goal: Discuss public comments received and approve chapters to move to ballot</i></p> <ul style="list-style-type: none"> a. Resolution of remaining public comments for chapters <1235>, <1238> and <1239> from last GCBA EC meeting b. Discussion | <p>Dr. Saha</p> <p>All</p> |

c. Final Discussion and Vote to Move to Ballot

Non-Conflicted
Members

[END CLOSED Session]

10:15 a.m. **5. Updates on Round Robin Study**

Goal: Update GCBA EC on collaborative testing status of the study

- a. Updates on Round Robin Study on <198> Identification of Bacterial Polysaccharides using Nuclear Magnetic Resonance Spectroscopy
- b. Discussion

Mr. Basha

All

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

11:00 a.m. **6. Vaccine Related Activities**

Goal: Update GCBA EC on current and future activities related to vaccine chapters

- a. Addition of NMR Identity Testing Protocol, O-acetyl Quantification by NMR in Chapter<198>
- b. Addition of qNMR Protocol for Quantification of Standards (RSs to quantify saccharide content)
- c. Discussion

Dr. Jones

Dr. Jones

All

11:45 a.m. **7. Cell and Gene Therapy Update**

Goal: Inform EC of USP's latest Round Tables and future plans

- a. Update on Round Tables and Standard Development
- b. Discussion

Dr. Richardson

All

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

[CLOSED to All Observers]

1:00 p.m. **8. Status Update on <1042> Cell Banking**

Goal: Update EC on the status of the chapter and public comments received

- a. Update from the Expert Panel
- b. Discussion for Path Forward

Dr. Potts

All

1:15 p.m. **9. Public Comment on <1102> Immunological Test Methods-
General Considerations**

Goal: Discuss public comment with EC and approve to move to ballot

- a. Discuss Public Comment Received
- b. Final Discussion and Vote to Move to Ballot

Dr. Bhattacharya

Non-Conflicted
Members

[END CLOSED Session]

1:30 p.m. **10. Future Revisions of General Chapters**

Goal: Identify General Chapters for revision and assign action items to committee members

- a. Introduction and Goal
- b. Discussion and Chapter Assignments

Dr. Workman/Dr.
Bhattacharya

All

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



Spalding Auditorium Joint Session

3:00 p.m. **11. Overview of New Standard Development Activities**

Goal: Inform EC on new standards and collaborations

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

Dr. McCarthy
Dr. McCarthy
All

4:15 p.m. **12. Wrap-up of Day 1**

- a. Summary of Day 1

Dr. Workman/Dr.
Mulkerrin

4:30 p.m. Meeting recesses; 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

Goals and Anticipated Outcomes

Goals are provided under individual agenda items.

Attendees

Attendee list provided on the day of the meeting.

Day 2

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 Dr. Atouf/ Dr. McCarthy
- b. 2020-2025 Cycle – structure and expertise Dr. Carrick
- c. Discussion All

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

Goal: To update EC members on new general chapter

- a. Update on Expert Panel activities Mr. Schmidt
- b. Discussion All

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

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

Goal: To discuss mAb standard development and get EC feedback on next steps

- a. Bulk Characterization and Collaborative Testing Plan Dr. Jing
- b. cIEF Analysis Ms. Peckham
- c. Discussion All

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

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

Goal: To discuss development data and get EC feedback on next steps

- a. CEX Column Qualification Standards Ms. Liu
- b. SEC Column Qualification Standards Dr. Tu
- c. Development of a high molecular weight (HMW) impurity
performance reference standard for HMW characterization Ms. Yan
- d. Fc Binding Assays Dr. McCarthy
- e. Discussion All

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

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

Goal: To discuss potential new standards

- a. Higher Order Structure
- b. Predigested mAb Standard
- c. Brainstorming and Prioritization of Other Standards

Dr. McCarthy
Dr. McCarthy
All

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

- a. Summary

Drs. Workman &
Mulkerrin

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