

**2015–2020 General Chapters–Biological Analysis (GCBA) Expert Committee
Wednesday – Thursday, August 23-24, 2017
USP – U.S., Rockville**

Agenda - Final

Goals and Anticipated Outcomes

1. Review the progress of new Expert Panels
2. Determine if revisions of official documentary standards are needed
3. Review proposals published in the *Pharmacopeial Forum (PF)* and resolve public comments
4. Update the Expert Committee's 2015-2020 Work Plan

Attendees

Attendee list to come

Wednesday, August 23, 2017

8:45 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> <ol style="list-style-type: none"> a. Call Meeting to Order b. Establish Quorum c. Identification of Observers and Confidential Information d. Conflict of Interest, Confidentiality, Code of Ethics e. Review of the Agenda <p style="color: red; margin: 0;">[END CLOSED session]</p>	<p>Dr. Workman</p> <p>Ms. Gould-Kostka</p> <p>Dr. Workman</p> <p>Ms. Gould-Kostka</p> <p>Dr. Workman</p>
9:00 a.m.	<p>2. Open Procedural Matters</p> <ol style="list-style-type: none"> a. Welcome b. Meeting Center Announcements c. Announce Changes to the Attendee List, Confirm Quorum d. Introductions of New Staff and Observers e. Approval of Agenda and Minutes of the Previous Meeting f. Action Items from the Previous Meetings 	<p>Dr. Workman</p> <p>Ms. Fletcher</p> <p>Dr. Workman</p> <p style="text-align: right;">All</p> <p>Dr. Workman</p> <p>Dr. Arora</p>
9:15 a.m.	<p>3. Biologics Policy and Strategy Update</p> <p><i>Goal: To inform EC of USP's latest strategic initiatives in biologics</i></p> <ol style="list-style-type: none"> a. Strategic Directions for Biologics b. Discussion 	<p>Dr. Atouf</p> <p style="text-align: right;">All</p>
9:45 a.m.	<p>4. Revision Proposals of General Chapters</p> <p><i>Goal: To understand the scope of new chapters and revision of existing chapters that are commonly used to characterize biologics</i></p> <ol style="list-style-type: none"> a. Proposed revision of Chapter <1024> <i>Bovine Serum</i> b. Proposed revision of Chapter <90> <i>Fetal Bovine Serum – Quality Attributes and Functionality Tests</i> c. Discussion 	<p>Dr. Workman</p> <p>Dr. Potts</p> <p style="text-align: right;">All</p>
10:15 a.m.	Break	

- 10:45 a.m. **5. Status Update on USP General Chapters in Progress**
Goal: To understand the progress on the revision of the vaccine chapters
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| a. Review of General Chapter on Cell Banking | Dr. Bell/Dr. Arora |
| b. Review of General Chapter <1237> <i>Virology Test Methods</i> | Dr. Bell/Dr. Huang |
| c. Review of General Chapter on Stability | Dr. Mire-Sluis/
Mr. Schmidt |
| d. Review of General Chapter on Validation of Commercial Test Kits | Dr. Miller/ Dr. Curti |
| e. Update on <1055> <i>Peptide Mapping</i> | Dr. Arora |
| f. Discussion | All |
- 12:00 p.m. **Lunch and Group Photo**
- 1:15 p.m. **6. 2015-2020 Cross-EC Topics: Development and Revision of non-GCBA Chapters of Interest for Biologics**
Goal: To understand the scope of new related chapters and activities
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| a. Status Update on Validation and Verification of Compendial Procedures | Dr. Horacio Pappa |
| b. Status Update from Continuous Manufacturing Expert Panel | Dr. Horacio Pappa |
| c. Discussion | All |
- 2:00 p.m. **7. Scope of USP General Chapters <476> and <1086> and Biologics**
Goal: To inform EC about scope of USP GCs <476> and <1086>, revisions by Organic Impurities in Drug Substance and Drug Product Expert Panel and how these relate to Biologics Product Classes
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| a. Status Update on revisions on GC <476>and <1086> | Dr. Hernandez -
Cardoso |
| b. Discussion | All |
- 2:30 p.m. **Break**
- 3:00 p.m. **8. Status Update from Round Table on Higher Order Structure**
Goal: To inform EC of the status of USP Round Table on HOS
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| a. Higher Order Structure- Stimuli article- Status update and next Steps | Dr. Huang |
| b. Discussion | All |
- [Session 9 is scheduled in Spalding Auditorium - open to USP Staff]**
- 3:30 p.m. **9. Points of Consideration in Biologics- where will it be in the future?**
Goal: To inform EC of multi attribute models and digital standards and brainstorm new topics of interest for GCBA EC
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| a. Multi-attribute Measurement Models | Dr. Huijuan Li |
| b. Reference Standards of the Future | Dr. Workman |
| c. Discussion | All |
- 5:00 p.m. **10. Wrap-up of Day 1**
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| a. Summary of EC Consensus/Action Items | Dr. Workman/ Ms.
Palmer |
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- 5:15 p.m. Meeting adjourns, Bus transportation to hotel
 6:05 p.m. Depart from hotel lobby to restaurant
 6:15 p.m. EC dinner at TBD

Thursday, August 24, 2017

[CLOSED to all observers]

8:30 a.m. **11. Review Public Comments**

Goal: To review and resolve public comments and determine if the revision of chapter ----

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| a. <198> NMR Spectroscopy Identification of Bacterial Polysaccharides Use in Vaccine Manufacture | Dr. Jones/
Dr. Saha |
| b. Anthrax vaccine | Dr. Saha |
| c. BCG vaccine monograph | Dr. Saha |
| d. Discussion | All |

[END CLOSED Session]

9:30 a.m. **12. Vaccines General Chapters**

Goal: To understand the progress on the revision of the vaccine chapters

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| a. Review of Chapter <1235> Vaccines for Human Use – General Considerations | Dr. Jones /Dr. Saha |
| b. Review of Chapter <1238> Vaccines for Human Use Bacterial Vaccines | Dr. Jones/ Dr. Saha |
| c. Review of Chapter <1239> Viral Vaccines | Dr. Zablackis/ Dr. Saha |
| d. Discussion | All |

10:00 A.M. **Break**

10:30 a.m. **13. New Vaccine Analytical Chapters for Consideration**

Goal: To review the scope and background for the proposal of New Vaccine Analytical Chapters for Consideration

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| a. Review of Vaccine Subcommittee recommendations and updates | Dr. Jones/Dr. Huang |
| b. Discussion | All |

11:00 a.m. **14. Review of Official Chapter <1102> Immunological Test Methods – General Considerations and <1103> Immunological Test Methods – Enzyme-linked immunosorbent assay (ELISA)**

Goal: To review the revisions for chapters <1102> and <1103>

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| a. Proposed Revisions | Dr. Arora |
| b. Discussion | All |

11:30 a.m. **15. 2015-2020 Cross-EC Workshops**

Goal: Status update and review of future USP meetings with external stakeholders to help inform the Expert Committee's work plan

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| a. (Sub)Visible Particulates in Biologics: Report | Dr. Kibbey |
| b. Bioassay Workshop: Planning with BIO2 and Statistics | Dr. Potts |
| c. Consideration of any future GCBA-sponsored workshops? | All |

12:00 p.m. **16. Review of Official Chapters: Planning**

Goal: To inform EC of the timeframe for each official chapter and seek volunteer reviewers

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| a. 5-year review cycle and items for Year 3 | Dr. Arora |
| b. Discussion and assignment of volunteers | All |

12:15 p.m. **17. Meeting Summary and Action Items**

Goal: To plan future activities and review near-term action items

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| a. Action Items | Ms. Palmer |
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b. Summary

Dr. Workman

12:30 p.m.

Box Lunches and Adjourn