2015-2020 Biologics Monographs 4 – Antibiotics Expert Committee (BIO4 EC)
February 21-22, 2018
USP – U.S., Rockville

Agenda - Draft

Goals and Anticipated Outcomes

- See goals under each agenda item

Attendees

Attendee list provided on the day of the meeting

Wednesday, February 21, 2018

[CLOSED to all Observers and Government Liaisons]

8:30 a.m. **1. Procedural Matters and Standards of Conduct**

a.	Call Meeting to Order	Dr. Anger
b.	Establish Quorum	Ms. Casino
c.	Identification of Observers and Confidential Information	Dr. Anger
d.	Conflict of Interest, Confidentiality, Code of Ethics	Ms. Casino
e.	Review of the Agenda	Dr. Anger

[END of CLOSED section]

9:00 a.m. **2. Open Procedural Matters**

a.	Welcome	Dr. Anger
b.	Meeting Center Announcements	Ms. Fletcher
c.	Announce Changes to the Attendee List, Confirm Quorum	Dr. Anger
d.	Introductions of New Staff and Observers	All
e.	Approval of Agenda and Minutes of the Previous Meeting	Dr. Anger
f.	Open Action Items from Previous Meetings	Dr. Kibbey

9:15 a.m. **3. USP Strategy Updates**

Goal: To inform EC of USP Initiatives and Council of Experts Activities

a.	USP Quality Institute: Antimicrobial Resistance Program	Dr. Levy
b.	Council of Experts (CoE) October Meeting Update	Dr. Anger
c.	Discussion	All

10:00 a.m. **4. BIO4 EC Work Plan Update**

Goal: To update EC of the near-term RS and monograph revisions planned

a.	Documentary Standard Update and Timeframes	Dr. Han
b.	Reference Standards Update and Ballot Expectations	Dr. Zhang
c.	Discussion	All

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

10:45 a.m. **5. Reference Standard Candidate Evaluation Packages (RSCEPs)**

Goal: To understand the USP RS Collaborative Process and to prepare to review RSCEPs in the future

a. RS Collaborative Testing and Approval Process — Dr. Kibbey
b. Discussion — All

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

1:00 p.m. **6. General Chapter <81> *Antibiotics—Microbial Assays***

Goal: To understand previous requests for revisions and determine next steps

a. Review of chapter and previous revision requests from stakeholders — Dr. Han
b. Feedback from Laboratories running the tests — Ms. Reid and Guthrie
c. Recommended changes for calculations and statistical analyses — Mr. Walfish
d. Discussion and next steps — All

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

2:45 p.m. **7. Monograph Revision and Omission Processes**

Goal: To understand the monograph review process, stakeholder outreach to support modernization, and best practices to advance PF proposals

a. Review of USP internal review processes, mechanisms for stakeholder outreach, and laboratory studies performed prior to *PF* publication of a revision proposal — Dr. Kibbey
b. USP's internal process to support monograph omissions prior to *PF* and BIO4 EC's support — Dr. Kibbey
c. Discussion and decisions — All

4:15 p.m. **8. USP General Chapters for Impurities**

Goal: To understand USP revision proposals for chapters that support impurity control

a. USP General Chapters <476> and <1086> — Dr. Hernandez-Cardoso
b. Discussion — All

4:45 p.m. **9. Meeting Wrap-up**

a. Summary of Day 1 — Dr. Anger

5:00 p.m. Meeting adjourns, Bus transportation to Cambria Hotel & Suites

6:00 p.m. EC Dinner (Location TBD)

Thursday, February 22, 2018

8:30 a.m. **10. Gentamicin Drug Substance and Products**

Goal: To learn about the deficiencies in the family of monographs and plan future revisions

a. BIO4 EC member review summary — Drs. Han and Yuan
b. Discussion — All

9:30 a.m. **11. Bacitracin Drug Substance and Products**

Goal: To understand monograph deficiencies and determine next steps

a. Manufacturers' Control Strategy and Monograph Reviews — Dr. Klasson
b. USP Monograph Review and Proposed Revision Summary — Dr. Han

c. Discussion and next steps — All

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

10:45 a.m. **12. Colistimethate Drug Substance and Products**

Goal: To understand monograph deficiencies and determine next steps

a. Manufacturers' Control Strategy and Monograph Reviews — Dr. Klasson
b. USP Monograph Review and Proposed Revision Summary — Dr. Zhang
c. Discussion and next steps — All

11:30 a.m. **13. USP General Chapter <1223.1> *Validation of Alternative Methods to Antibiotic Microbial Assays***

Goal: To understand USP guidance for converting <81>-based potency assays to HPLC assays and plan for laboratory studies

a. Chapter review — Dr. Kibbey
b. Biologics Bioassay Bridging Case Studies — Dr. Kibbey
c. Near-term Drug Products that may be evaluated for conversion — Dr. Zhang
d. Discussion and Next Steps — All

12:30 p.m. **Lunch**

1:00 p.m. **14. Erythromycin Drug Substance and Products**

Goal: To understand monograph deficiencies and determine next steps

a. Monograph Reviews — Ms. Deneau and Dr. Zhang
b. Discussion — All

1:45 p.m. **15. Meeting Wrap-up**

a. Summary of Day 2 — Dr. Anger

2:00 p.m. **Meeting Adjourns**