

2015-2020 BIO1- Peptides & Insulins Expert Committee
Wednesday - Thursday, November 7-8, 2018
USP – U.S., Rockville

Agenda

Goals and Anticipated Outcomes

- Update the Expert Committee on 2015-2020 Work Plan
- Review progress of Expert Panels
- Review proposals published in the *Pharmacopeial Forum (PF)* and resolve public comments
- See goals under agenda items

Attendees

Attendee list is provided on the day of the meeting

Wednesday, November 7, 2018

[CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS]

- 8:30 a.m. **1. Closed Procedural Matters and Standards of Conduct**
- a. Welcome, Opening Remarks, Introduction Dr. De Felippis
 - b. Conflicts of Interest, Confidentiality, Code of Ethics Ms. Gould-Kostka
 - c. Review of Agenda for Specific Conflicts of Interest/Need for Recusal Dr. De Felippis
- [END CLOSED SESSION]**
- 8:45 a.m. **2. Open Procedural Matters**
- a. Welcome Dr. De Felippis
 - b. Meeting Center Announcements Ms. Fletcher
 - c. Recording Policy and any other Procedural Announcements Ms. Gould-Kostka
 - d. Roll Call and Introduction of Members, Government Liaisons, Staff and Observers All
 - e. Establish Quorum Dr. De Felippis
 - f. Approval of Agenda Dr. De Felippis
 - g. Approval of Minutes of Previous Meeting Dr. De Felippis
 - h. Action Items from Previous Meeting Dr. Huang
- 9:00 a.m. **3. USP Updates**
- Goal: To inform EC of Biologics Program Unit and Council of Experts Activities*
- a. USP and Biologics Program Unit Update Dr. Atouf
 - b. Council of Experts Meeting Update Dr. De Felippis
 - c. 2020-2025 Call for Candidate Update Ms. Bellon
 - d. Discussion All

10:15 a.m. **Break**

10:30 a.m. **4. BIO1 EC Work Plan Update**

Goal: To update EC of the Work Plan

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| a. Work Plan Update and Ballot Items | Dr. Huang |
| b. Outreach for donation of new monographs and materials | Drs. De Felippis/Huang |
| c. Discussion | All |

11:00 a.m. **5. Update from SC and Expert Panels**

Goal: To review progress of Subcommittee and Expert Panels

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|---|---------------------------|
| a. Synthetic Peptide General Chapter | Drs. Srivastava/Curti |
| b. Discussion | All |
| c. Final discussion and decision on approval for PF | Non-conflicted EC members |
| d. Insulin Expert Panel | Drs. Boux/McCarthy |
| e. Glatiramer Expert Panel | Drs. Gratzl/Curti/Metta |
| f. Discussion | All |

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

1:00 p.m. **6. Monographs for Recombinant and Synthetic Peptides**

Goal: To discuss topics related to synthetic peptides and standardize expectations for adding synthetics to peptide monographs

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| a. Introduction | Dr. De Felippis |
| b. Regulatory perspectives | Dr. Fisher |
| c. Product and process related impurities for synthetic peptides | Drs. Rode/Srivastava |
| d. Case study of Calcitonin Salmon and recent stakeholder requests | Dr. Huang |
| e. USP monograph pending revision process | Ms. Bladen |
| f. Discussion | All |

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

[CLOSED TO ALL OBSERVERS]

3:00 p.m. **7. Monograph Revisions**

Goal: To review public comments and decide on path forward for ballot or for PF

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|---|---------------------------|
| a. Glucagon Monographs | Dr. Curti |
| b. Teriparatide Monographs | Dr. Huang |
| c. Discussion | All |
| d. Final discussion and decision on approvals | Non-conflicted EC members |

[END CLOSED SESSION]

4:30 p.m. **8. Wrap-up of Day 1**

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| a. Summary of Day 1 | Dr. De Felippis |
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4:45 p.m. Meeting adjourns, bus transportation to hotel

5:50 p.m. Depart from hotel lobby to restaurant

6:00 p.m. EC Dinner at restaurant

Thursday, November 8, 2018
8:30 a.m. 9. Reference Standard Characterization

Goal: To review peptide chirality characterization and provide input for RS collaborative study plans

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| a. Peptide chirality characterization – Introduction | Dr. Verlander |
| b. Peptide chirality characterization – TWIMS-MS | Mr. Han |
| c. Peptide chirality characterization – GC-MS | Dr. Gerhardt |
| d. RS study plan for Gonadorelin Acetate and Related Compounds | Mr. Schmidt |
| e. RS study plan for Bivalirudin and Related Compounds | Mr. Schmidt |
| f. Peptide impurities standards | Mr. Metta |
| g. Discussion | All |

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

[CLOSED TO ALL OBSERVERS]

10:15 a.m. 10. New Monographs

Goal: To review new monograph proposal

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|---|---------------------------|
| a. Lanreotide Acetate Monograph | Lanreotide WG/Dr. Huang |
| b. Update on Lanreotide Injection Monograph | Dr. Huang |
| c. Discussion | All |
| d. Final discussion and approve to PF | Non-conflicted EC members |

10:50 a.m. 11. New Reference Standards

Goal: To review RSCEP and approve to ballot

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|---|---------------------------|
| a. RSCEP Review: Triptorelin Acetate | Dr. Curti |
| b. Discussion | All |
| c. Final discussion and approve to ballot | Non-conflicted EC members |

[END CLOSED SESSION]

11:30 a.m. 12. Peptide Workshop Debrief

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| a. Review of feedback from attendees | Dr. De Felippis |
| b. Future workshop: need and schedule | Drs. De Felippis/Kibbey |
| c. Discussion | All |

12:15 p.m. 13. Meeting Wrap-up

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| a. Summary and Next EC Meeting | Dr. De Felippis |
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12:30 p.m. **Adjourn and Lunch**