



**Excipient Monographs 1 Expert Committee (EM 1 EC) Meeting**  
**Thursday – Friday, November 14 – 15, 2019**  
**8:30 a.m. – 5:00 p.m. (Thursday), 8:30 a.m. – 3:00 p.m. (Friday)**  
**Briggs Parker, Wiley, Marshall Rooms**  
**USP Headquarters, Rockville, Maryland**

**Agenda – Draft**

---

**Goals and Anticipated Outcomes**

- Expected Outcomes in Agenda for each topic

**Attendees**

*Attendee list provided on the day of the meeting*

**Day 1**

**Thursday, November 14, 2019**

8:15 a.m. Arrive at USP, register and check in

**CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS**

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

- a. Welcome, Opening Remarks, Introduction
- b. Conflicts of Interest, Confidentiality, Code of Ethics
- c. Review of Agenda for Specific Conflicts of Interest/Need for Recusal

Dr. Koo  
Dr. Koo  
All

**END CLOSED SESSION**

8:45 a.m. **2. Open Procedural Matters**

- 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 Previous Meeting Minutes ([October 16](#))
- h. Review of Previous Meeting Action Items

Dr. Koo  
Ms. White  
Mr. Lew  
All  
Dr. Koo  
Dr. Koo  
Dr. Koo  
Mr. Lew

9:20 a.m. **3. FY19 Four Year EM1 EC Accomplishments**

Expected Outcome: Update the EC

- a. PF publications and Approved Standards – *USP40-NF 35 1S, USP40-NF35 2S, USP41-NF36*

Dr. Sheehan/  
Dr. Wang

9:45 a.m. **4. Review and Update EM1 usp.org Work Plan**

Expected Outcome: Update the EC and align on deliverables

- a. FY20 Work Plan prioritization and deliverables
- b. Work beyond FY20 that will need EC support at some point

Dr. Sheehan/Dr.  
Wang



- and Milestones
- i. Consequential Standards
  - ii. Lab Projects

- 10:05 a.m. **Break**
- 10:20 a.m. **5. Potential Pharmasci Excipient Programs [BRAINSTORM]** Dr. Sheehan/Dr. Wang  
Follow-up to Excipient Science Strategy from August 2018 F2F meeting – Potential scientific topics/venues  
Expected Outcome: EC Brainstorm
- 11:00 a.m. **6. Call for Candidates Application Process** Ms. Bellon  
Expected Outcome: Discuss how to update the expert profile and reapply to the EC
- 11:15 a.m. **7. Expert Advisors** Ms. Bellon  
Expected Outcome: Update on the Expert Advisor and their role in the 2020-2025 Cycle
- 11:30 a.m. **8. USP Science Strategy Update** Dr. Jeff Moore  
Expected Outcomes: Update the EC on the USP Science Strategy
- 12:00 p.m. **Lunch (Group Photo)**
- CLOSED TO ALL OBSERVERS**
- 1:00 p.m. **9. Monograph Discussion – Starches** Dr. Delaney  
Expected Outcomes: Discuss and seek EC feedback
- a. Dextrates
  - b. Liquid Glucose
  - c. Hydrogenated Polydextrose
  - d. Maltodextrin
- 1:45 p.m. **10. Monograph Discussion – PLGA/PLA Strategy and Fellowship Program** Dr. Zhang/Dr. Chesterman  
Expected Outcomes: Discuss the PLGA Strategy and Fellowship Project Update
- a. PLGA/PLA Monographs Development Strategy
  - b. Fellowship Project Update
- END CLOSED SESSION**
- 2:30 p.m. **Break**
- 2:45 p.m. **11. BREAKOUT: When and how do we include/exclude tests for microbial endotoxins with regard to injectables?** Dr. Holloway/All  
Expected Outcome: Outcome will be shared with Microbial EC to help develop a list of criteria
- a. Summer Intern Project
  - b. Expected Outcome: Outcome will be shared with Microbial EC to help develop a list of criteria
  - c. Examples to use: BHT, MCT, Cholesterol
- Dr. Liu



- d. Break-Out Activity (Instructions: 3 Breakout groups: Assign EC Leads to work with SLs and members) (30 min)
- e. Share Results (30 min)

**CLOSED TO ALL OBSERVERS**

- 3:45 p.m. **12. Monograph Discussion – GPC Study of Methacrylate Copolymers** Dr. Zhang  
Expected Outcome: Research project update and Discuss and seek feedback from EC  
**END CLOSED SESSION**
- 4:30 p.m. **13. Chemical Information Update** Dr. Prasad  
Expected Outcomes: Update the EC
- 5:00 p.m. **Adjourn – Day 1, Transportation to Hotel**
- 6:00 p.m. **Dinner at:**  
*Trapezaria (walkable from the Hotel)*  
*11 N Washington St*  
*Rockville, MD 20850*

**Day 2**  
**Friday, November 15, 2019**

- 8:30 a.m. **[CLOSED TO ALL OBSERVERS]**  
**14. Monograph Modernization** Dr. Yarkala  
Expected Outcome: Discuss monograph updates  
a. Carrageenan
- 9:30 a.m. **15. Monograph Modernizations** Dr. Saladi  
Expected Outcome: Discuss monograph updates  
a. Cetyl alcohol  
b. Stearyl alcohol  
**[END CLOSED SESSION]**
- 10:30 a.m. **Break**
- 10:45 a.m. **16. Consequential Standards – Lactoses Update** Dr. Moreton  
Expected Outcome: Provide update and seek guidance
- 11:20 a.m. **17. Consequential Standards – Polysorbates Update** Mr. Dominic Moore  
Expected Outcome: Discuss and seek feedback from EC
- 12:00 p.m. **Lunch**
- 1:00 p.m. **18. Call for Candidates – Collaborative Recruiting Group Update** Dr. Sheehan  
Expected Outcome: Update and determine if there is any needed or missing expertise for upcoming ECs
- 1:20 p.m. **19. Consequential Standards – Polyethylene Glycol (PEG) Update** Dr. Wang



Expected Outcome: Status update and next steps  
a. Awaiting PDG comments on Stage 1 draft

**CLOSED TO ALL OBSERVERS**

- |           |  |              |
|-----------|--|--------------|
| 1:45 p.m. | <b>20. Element Specific Chapters Update</b><br>Expected Outcome: Update and discuss revised roadmap and discuss comments from JS.<br><b>END CLOSED SESSION</b> | Dr. Holloway |
| 2:30 p.m. | <b>21. Legacy Document Discussion</b><br>Expected Outcome: Overview of Legacy document and schedule  | Mr. Lew      |
| 2:45 p.m. | <b>22. Meeting Wrap-Up</b>   | Dr. Koo      |
| 3:00 p.m. | <b>Adjourn</b>   |              |

DRAFT