

**Compounding Expert Committee (CMP EC)
Friday, September 29, 2017
USP-US
Rockville, Maryland
Preliminary Agenda**

Goals and Anticipated Outcomes

- Discuss and review Subcommittee activities and Workplan

Attendees

Attendee list provided on the day of the meeting

Breakfast for Volunteers at the Hotel**CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS**

- 8:30 a.m. **1. Procedural Matters and Standards of Conduct** Ms. Davidson
The meeting will be called to order, and procedural matters addressed.
- Call Meeting to Order
 - Establish Quorum
 - Identification of Observers and Confidential Information
 - Conflicts of Interest
 - Update on General Chapters

END CLOSED SESSION

- 9:30 a.m. **2. Open Procedural Matters**
- Welcome Ms. Davidson
 - Meetings Center Announcements Ms. Fletcher
 - Announce Changes to Attendee List, Confirm Quorum Ms. Davidson
 - Introductions All
 - Approval of Agenda and Previous Meeting's Minutes Ms. Davidson
 - Procedural Announcements Ms. Ammerman
- 9:45 a.m. **3. Subcommittee Update: <795> Pharmaceutical Compounding – Nonsterile Preparations** Dr. Shrewsbury
(Informational and Discussion)
The EC will receive an overview of the proposed revision and discuss next steps
- Proposed Revision Draft
 - Discussion
 - Next Steps
- 10:45 a.m. **4. Subcommittee Update: Monograph Development** Dr. Bassani/
Dr. Serumaga
(Informational)
The EC will receive an update on monograph development efforts and review new monograph proposals.
- New Monograph Proposals for PF
 - Status FY2018 Contract Studies
 - Status Monograph Donation Program

11:00 a.m. **Break**

- 11:15 a.m. **5. Subcommittee Update: <1163> Quality Assurance in Pharmaceutical Compounding** Dr. Parr/
Dr. Musil
(Informational and Discussion)
The EC will receive an overview of the proposed revision and discuss next steps
a. Proposed Revision Draft
b. Discussion
c. Next Steps
- 11:30 a.m. **6. Subcommittee Update: <1168> Compounding for Phase 1 Investigational Studies** Dr. Parr
(Informational and Discussion)
The EC will receive an overview of the public comments received on the chapter and discuss next steps.
a. Summary of the public comments and commentary
b. Next Steps
- 12:00 p.m. **7. Overview of General Chapter Proposals in the Pharmacopeial Forum** Dr. Sun
(Informational)
The EC will receive an overview of the upcoming proposals in the PF for public comment
a. Revisions to General Chapter <1160> *Pharmaceutical Calculations In Pharmacy Practice*
b. Revisions to General Chapter <1176> *Prescription Balances And Volumetric Apparatus Used In Compounding*
- 12:15 p.m. **Lunch**
- 1:15 p.m. **8. USP Standards: Education & Implementation** Ms. Jinga/
Mr. Emrick
The EC will receive an overview of activities of the Strategic Marketing and Program Operations team.
a. Education updates
b. Haz App update
- 1:30 p.m. **9. Update on Compounding – Radiopharmaceuticals Expert Panel** Dr.
Ravichandran
(Informational)
The EC will receive a status update of the Compounding – Radiopharmaceutical Expert Panel and new proposal of General Chapter <825> *Compounding – Radiopharmaceuticals*
- 1:45 p.m. **10. Update on Parenteral Nutrition Safety Expert Panel** Ms. Sullivan
The EC will receive an overview of the Parental Nutrition Safety Expert Panel and development of <799> *Parental Nutrition Safety*
- 2:00 p.m. **11. Subcommittee Update: <797> Pharmaceutical Compounding – Sterile Preparations** Ms. Davidson
(Informational and Discussion)
The EC will discuss the revision timeline of the chapter, public comments received, and next steps.
a. Overview of Discussion Forum on Administration and Urgent-Use
b. Review of <797> Sections
- 2:45 p.m. **Break**
- 3:00 p.m. **12. Subcommittee Update: <797> Pharmaceutical Compounding – Sterile Preparations (Continued)** Ms. Davidson
- 4:15 p.m. **13. Action Items and Wrap Up** Ms. Ammerman
- 4:30 p.m. **14. Adjourn - Next face-to-face meeting: April 11, 2018**