

Compounding Expert Committee (CMP EC)
Wednesday, April 11, 2018
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

END CLOSED SESSION

- 8:45 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
 - Review of Action Items Dr. Sun
 - Procedural Announcements Ms. Ammerman
- 9:00 a.m. **3. Subcommittee Update: Monograph Development** Dr. Bassani/
(Informational) Dr. Serumaga
- 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
- 9:15 a.m. **4. Subcommittee Update: <795> Pharmaceutical Compounding – Nonsterile Preparations** Dr. Shrewsbury/
(Informational) Dr. Sun
- The EC will receive an update on the revision proposal published for public comment PF 44(3) May/June 2018 (pre-post March 30)
- Electronic Form for Public Comments
 - Open Microphone Session
 - Next Steps

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| 9:30 a.m. | 5. Update on Compounding – Radiopharmaceuticals Expert Panel
(Informational)
The EC will receive a status update of the Compounding – Radiopharmaceutical Expert Panel and new proposal of General Chapter <825> <i>Compounding – Radiopharmaceuticals</i> | Dr.
Ravichandran |
| 9:45 a.m. | 6. USP Standards: Education & Implementation
a. Update on Exchange of Compounded Drug Preparation Information in Health IT Systems
b. HazRx Mobile App update
c. Education updates | Ms. Jinga/
Mr. Emrick |
| 10:30 a.m. | Break | |
| 10:45 a.m. | 7. Update on USP’s Inaugural Compounding Workshop on May 21 and 22, 2018 | Dr. Serumaga |
| 11:00 a.m. | 8. Overview of Public Comments Received in the Pharmacopeial Forum
(Informational)
The EC will receive an overview of the proposals in PF for public comment
a. Revisions to General Chapter <1160> <i>Pharmaceutical Calculations In Pharmacy Practice</i>
b. Revisions to General Chapter <1176> <i>Prescription Balances And Volumetric Apparatus Used In Compounding</i> | Dr. Sun |
| 11:15 a.m. | 9. Subcommittee Update: <797> Pharmaceutical Compounding – Sterile Preparations (Discussion)
The EC will discuss remaining action items, finalize the revision proposal, and next steps. | Ms. Davidson |
| 12:00 p.m. | Lunch | |
| 1:00 p.m. | 10. Subcommittee Update: <797> Pharmaceutical Compounding – Sterile Preparations (Continued) | Ms. Davidson |
| 3:00 p.m. | Break | |
| 3:15 p.m. | 11. Subcommittee Update: <797> Pharmaceutical Compounding – Sterile Preparations (Continued) | Ms. Davidson |
| 4:15 p.m. | 12. Action Items and Wrap Up
a. Call for Candidates | Ms. Ammerman |
| | 13. Adjourn - Next face-to-face meeting: April 11, 2018 | |