

2015-2020 Chemical Medicines Monographs 6 Expert Committee
Thursday - Friday, October 17th - 18th, 2019
USP Headquarters, Rockville, Maryland

Agenda

Goals and Anticipate Outcomes

- Pilot Study for Complex Formulations
- General Chapters - Impurities Update
- Collaborative Group Update
- End-of-Cycle Discussion Update

Attendees

Attendee list is provided on the day of the meeting

Day 1, Thursday, Oct 17

3:20 p.m. CHM 6 EC, GL and Observers check in

3:30 p.m. **CLOSED SESSION to Government Liaisons and Observers**

Conflict of Interest Review

Dr. Walter

END of CLOSED SESSION

- | | | |
|------------|---|--|
| 3:35 p.m. | 1. Opening and Procedural Matters <ol style="list-style-type: none">a. Meeting Center Announcementsb. Call Meeting to Order, Opening and Welcoming Remarksc. Introduction of Expert Committee Members, Government Liaisons, Observers and Staffd. Guide to Observers and Procedural Announcementse. Outstanding Action Items Reviewf. Approval of Meeting Agendag. Approval of Previous Meeting Minutes | Ms. White
Dr. Walter
All

Dr. Austgen
Dr. Austgen
Dr. Walter
Dr. Walter |
| 3:45 p.m. | 2. USP-FDA-CHPA Roundtable Wrap-up
Recap/Analysis
Next Steps | Dr. Gump
All |
| 4:30 p. m. | 3. Day 1 Wrap up
Action items review | Dr. Austgen |
| 4:40 p.m. | <i>Adjourn and transportation to hotel and restaurant
(shuttle leaves at 6:10 p.m. for dinner)</i> | |
| 6:30 p. m. | CHM6 Dinner at That's Amore, Rockville, MD | |

Day 2, Friday, Oct 18

8:45 a.m.	CHM6 Expert Committee Members, Government Liaisons and Observers arrive at USP and check in	
9:00 a.m.	4. 2020-2025: Chemical Medicines 6 Expert Committee a. Background b. New Volunteer Model c. Discussion	Dr. Chang Dr. Ramakrishna All
10:00 a.m.	5. Formation of New Subcommittee/Working Group for Pilot Study for Complex Formulation Diphenhydramine monograph family	Dr. Walter Dr. Whitaker
10:45 a.m.	<i>Break</i>	
11:00 a.m.	6. General Chapters <476> and <1086> PF 45(1) Update	Mr. Hernandez-Cardoso
Noon	<i>Lunch</i>	
1:00 p.m.	7. Collaborative Group Update	Dr. Seibert
1:15 p.m.	8. End-of-Cycle Discussion	Drs. Austgen and Chang
2:15 p.m.	<i>Break</i>	
2:45 p.m.	9. Call for Candidates Update	Ms. Bellon
3:15 p.m.	10. CHM 6 Workplan and Metrics Updates	Dr. Chang
3:30 p.m.	11. SL Workplan Updates FY '20 a. Dr. Bililign b. Dr. Chang c. Dr. Anthony d. Mr. Nguyen	
4:30 p.m.	12. Day 2 Wrap-up and Action Items Review	Dr. Austgen
4:40 p.m.	<i>Adjourn</i>	