



2015-2020 Chemical Medicine 2 Expert Committee
Monday–Tuesday, December 16-17, 2019
USP Headquarters, Rockville, Maryland

Preliminary Agenda

Goals and anticipated outcomes

- Metrics and portfolios updates
- Collaborate Group update and End of Cycle Discussions
- Expert Committee specific case studies and monographs of interest
- Impurities Update
- USP Labs Case Studies
- 2020 Call for Candidates update

Attendees

Attendee list is provided on the day of the meeting

**Day 1, Chemical Medicines Monographs 2 EC
Monday, December 16, 2019**

8:20 a.m.	CHM2 EC Members, Government Liaisons, and Observers arrive at USP and check in	
8:30 a.m.	1. Opening and Procedural Matters	
	A. Meeting Center announcements	Ms. White
	B. Welcome and call meeting to order	Dr. Parente
	C. Introduction of EC members, Government Liaisons, Observers and Staff	All
	D. Procedural Announcements and Guide to Observers	Dr. Austgen
	E. Approval of Previous Draft Minutes	Dr. Parente
	F. Approval of CHM2 EC Preliminary Agenda	Dr. Austgen
	G. Previous F2F Meeting Action Items review	Dr. Austgen
	CLOSED SESSION to Government Liaisons and Observers	
8:35 a.m.	2. Conflict of Interest Review	Dr. Parente
	END OF CLOSED SESSION	
8:40 a.m.	3. Collaborative Group Update	Dr. Virgili
8:50 a.m.	4. General Chapters: Impurities Update	Mr. Hernandez-Cardoso
9:20 a.m.	5. Reporting Threshold Update	Dr. Gump
9:30 a.m.	6. Genotoxic Impurities Update	Dr. Muldoon Jacobs
10:00 a.m.	<i>Break</i>	
10:15 a.m.	7. Nitrosamine Impurities and the Recalls – Background, Learnings and Action Plans	Dr. Min
11:00 a.m.	8. FDA Presentation	Dr. Zhang
Noon	<i>Lunch</i>	

1:00 p.m.	9. Impurity Control Strategy in Cilostazol Tablets Monograph	Dr. Bililign
1:40 p.m.	10. 2020-2025 Call for Candidates Update	Ms. Bellon
2:00 p.m.	11. RS Labs Pilot Project	Dr. Reddy
2:30 p.m.	<i>Break</i>	
3:00 p.m.	12. ATP Introduction and Update	Mr. Johnson
3:30 p.m.	13. CHM 2 Hot Topics / Impurities Summary	Dr. Virgili
4:30 p.m.	14. Recap/Action Items Review	Dr. Austgen
4:45 p.m.	<i>Adjourn for day Transportation for CHM 2 EC Members to hotel and then to restaurant</i>	
6:30 p.m.	Dinner: Founding Farmers, 12505 Park Potomac Ave, Potomac, MD 20854	

**Day 2, Chemical Medicines Monographs 2 EC
Tuesday, December 17, 2019**

8:15 a.m.	CHM2 EC Members, Government Liaisons, and Observers arrive at USP and check in	
8:30 a.m.	15. Procedure Improvement for the test of Limit of Perindopril Related Compound A and Imidazole	Ms. Wu, Drs. Huang, and Min, and Mr. Li
9:00 a.m.	16. Scientific Liaison Updates	
	a. Non-Biological Complex Documentary Standard Development: Polidocanol and Polidocanol Injection	Dr. Y Yang
	b. Benzonatate Monograph Revision: Path Forward	Dr. W Yang
10:00 a.m.	<i>Break</i>	
10:30 a.m.	17. CHM 6 OTC Monograph Transition	Dr. Chang
11:00 a.m.	18. End of Cycle Discussion	Dr. Austgen
11:45 a.m.	19. Recap/Action Items Review	Dr. Austgen
12:00 p.m.	<i>Adjourn and Lunch Chair/CSO Discussion</i>	Drs. Parente/Venema