



**2015-2020 Joint Meeting of the Chemical Medicines 4 and 5 Expert Committees  
Monday-Wednesday, April 8-10, 2019  
USP Headquarters, Rockville, Maryland**

**Preliminary Agenda**

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**Goals and anticipated outcomes**

- Metrics and portfolios updates
- Chemical Medicines Monographs 4 Radioactive Drugs Expert Panel update
- Collaborate Group update
- Expert Committee specific case studies
- FDA update
- USP new PF platform update
- Dissolutions update
- General Chapters updates
- USP Labs update
- Chairs topics
- 2020 Call for Candidates update

**Attendees**

*Attendee list is provided on the day of the meeting*

**Day 1, Chemical Medicines Monographs 4 EC only  
Monday, April 8, 2019**

CHM4 EC Members, Government Liaisons , and Observers  
arrive at USP and check in

Noon *Lunch*

**CLOSED SESSION to Government Liaisons and Observers**

1:00 p.m. 1. Conflict of Interest Review for CHM4 EC Members Ms. Huynh-Ba

**END OF CLOSED SESSION**

1:15 p.m. 2. **Opening and Procedural Matters**

A. Meetings Center Announcements	Ms. Hawkins
B. Welcome, Call Meeting to Order	Ms. Huynh-Ba
C. Introduction of EC members, Government Liaisons, Observers and Staff	All
D. Guide to Observers	Dr. Austgen
E. Approval of CHM 4 EC Preliminary Agenda for April 8, 2019	Ms. Huynh-Ba Ms. Huynh-Ba
F. Approval of Draft Minutes of Previous Meeting—to be done with CHM5 Volunteers on second day	
G. Procedural Announcements, Conflict of Interest,	Dr. Austgen

Confidentiality

1:30 p.m.	3. Radioactive Drugs Expert Panel Update	Dr. Ponto
2:00 p.m.	4. Metrics Update	Ms. Beltran
2:15 p.m.	5. Work Plan and Portfolio Update	Dr. Joyce
2:30 p.m.	6. Impurities limits and FDA comments on proposals	Staff
3:00 p.m.	<i>Break</i>	
3:30 p.m.	7. Case study: Atropine Sulfate	Dr. Joyce
4:00 p.m.	8. Aerosol Drug Products Update	Dr. Ravichandran
4:30 p.m.	9. New Online <i>PF</i> Platform	Staff
5:00 p.m.	<i>Adjourn and transportation to hotel and restaurant</i>	
6:30 p.m.	<i>Dinner at Thai Pavilion, Rockville, MD</i>	

Day 2, Chemical Medicines Monographs 4 & 5 ECs (Joint Meeting)  
Tuesday, April 9, 2019

8:05 a.m.	<i>CHM4 Chair Meeting with Dr. Jaap Venema (Visitor's Lounge)</i>	Ms. Huynh-Ba
8:30 a.m.	CHM4 & CHM5 EC Members, Government Liaisons , and Observers arrive at USP and check in	
	<b>CLOSED SESSION to Government Liaisons and Observers</b>	
8:45 a.m.	10. Conflict of Interest Review	Ms. Karren
	<b>END OF CLOSED SESSION</b>	
9:00 a.m.	11. Opening and Procedural Matters	
	A. Meeting Center announcements	Ms. Hawkins
	B. Welcome and call meeting to order	Ms. Karren
	C. Introduction of EC members, Government Liaisons, Observers and Staff	All
	D. Guide to Observers	Lynette
	E. Approval of previous Joint CHM4 & CHM5 ECs Joint Meeting draft Minutes	Ms. Huynh-Ba & Ms. Karren
	F. Previous F2F Meeting Action Items review	Dr. Austgen
	G. Approval of CHM4 & CHM5 ECs Joint Meeting Preliminary Agenda	Ms. Huynh-Ba & Ms. Karren
9:15 a.m.	12. USP Leadership in Chemical Medicines	Mr. Alemayehu
9:30 a.m.	13. Collaborative Group Update	Dr. Xia & Dr. Seibel
10:00 a.m.	14. FDA Update	TBD

10:30 a.m.	<i>Break</i>	
11:00 a.m.	15. Dissolution Equations guideline	Dr. Garito
11:30 a.m.	16. GCs <476> and <1086> Updates	Mr. Hernandez-Cardoso
Noon	<i>Lunch</i>	
1:00 p.m.	17. Reagent Linking Update	Dr. Marques
1:30 p.m.	18. General Chapters <232> and <233> A. USP Update B. Industry Practice C. Breakout sessions and Report out	Dr. Zaidi Dr. Xia
3:00 p.m.	<i>Break</i>	
3:30 p.m.	19. USP Adapt.Transform.Progress (ATP)	Staff
4:00 p.m.	20. OTC Update	Dr. Reddy
4:30 p.m.	21. USP Lab Work • Lab processes • International Labs	Staff
5:00 p.m.	22. Call for Candidates • Ambassador Program Update	Ms. Bellon Ms. Karren
5:15 p.m.	23. Meeting Wrap-up and Action Items Review	Ms. Huynh-Ba Dr. Austgen
5:30 p.m.	<i>Adjourn</i> <i>Transportation for CHM4 EC Members to airport (or hotel)</i> <i>Transportation for CHM5 EC Members to hotel and then to restaurant</i>	
6:30 p.m.	<i>Dinner at La Tasca, Rockville, MD</i>	

**Day 3, Chemical Medicines Monographs 5 EC only  
Wednesday, April 10, 2019**

8:05 a.m.	<i>CHM5 Chair Meeting with Dr. Jaap Venema (Visitor's Lounge)</i>	Ms. Karren
8:30 a.m.	CHM5 EC Members, Government Liaisons , and Observers arrive at USP and check in	
8:45 a.m.	24. Metrics Update	Ms. Beltran
9:00 a.m.	25. Work Plan and Portfolio Update	Dr. Koleck
9:30 a.m.	26. Impurities Limits and FDA Comments on Proposals	Staff
10:00 a.m.	<i>Break</i>	

10:30 a.m.	27. Topic: TBD	TBD
11:00 a.m.	28. Chair Topic	Ms. Karren
11:30 a.m.	29. New Online <i>PF</i> Platform <ul style="list-style-type: none"><li>• Input from Users</li></ul>	TBD
Noon	30. Meeting Wrap up and Action Items Review	Ms. Karren Lynette
12:15 p.m.	<i>Adjourn and Lunch</i>	