2015-2020 Chemical Medicines Monographs 6 Expert Committee  
Tuesday-Wednesday, October 30-31, 2018  
USP Headquarters, Rockville, Maryland  

Preliminary Agenda

Goals and anticipate outcomes
- Provide recap of the USP-FDA-CHPA Roundtable Retreat, Part III
- Provide overview of CHM6 metrics and forecasting
- 2020-2025 Cycle planning
- Valsartan case study—perspectives from Industry, Authorities and Pharmacopeia
- Provide <476> and <1086> updates
- Provide perspectives on dissolution tests
- Provide external collaborations update

Attendees
Attendee list is provided on the day of the meeting

Day 1  
Tuesday, October 30, 2018

8:30 a.m.  CHM6 Volunteers arrive at USP and check in

CLOSED SESSION to Government Liaisons and Observers

8:45 a.m.  1. Conflict of Interest Review  
Dr. Walter

END of CLOSED SESSION

8:50 a.m.  2. Opening and Procedural Matters  
A. Meeting Center Announcements  
Ms. Hawkins
B. Opening and Welcoming Remarks  
Dr. Walter
C. Introduction of Volunteers, Government Liaisons, Observers and Staff  
All
D. Guide to Observers  
Lynette
E. Approval of previous F2F Meeting Minutes  
Dr. Walter
F. Approval of today’s meeting Preliminary Agenda  
Dr. Walter

9:00 a.m.  3. OTC Drug Products Working Group Update  
Dr. Gilmor  
A. Outcomes from the OTC Round Table Retreat  
B. Directions for the 2020 – 2025 cycle

10:00 a.m.  4. USP-FDA Collaboration  
Drs. J. Yang (FDA) & Anthony

10:30 a.m.  Break
10:45 a.m. 5. CHM6 EC Work Plan – metrics to date Dr. Santos

11:00 a.m. 6. CHM6 Work Plan for the last two years of the Cycle CHM6 SLs
Timing and what to put in PF for the new type of monographs

Noon Lunch

1:00 p.m. 7. 2020-2025 Cycle Planning Drs. Walter &
A. Last appeals for the APAP monographs and Volunteers’
   conflict of interest Whitaker
B. Recruiting Ambassadors
C. What will be different for CHM6
D. What will be the same for CHM6
E. When the “rules” for CHM6 be set

2:00 p.m. 8. Valsartan Case study Dr. Gonzalez
A. Perspective from a generic manufacturer
B. Lesson learned: perspectives from Authorities, EC,
   Pharmacopeia
   USP Valsartan Team

3:30 p.m. Break

4:00 p.m. 9. RS Development Dr. Reddy

4:30 p.m. 10. USP Standards for OTC: Current State and Next Steps (USP Summer Intern Work) Dr. Ramakrishna

5:00 p.m. Adjourn

6:30 p.m. Dinner at Mykonos, Rockville, MD

Day 2

Wednesday, October 31, 2018

8:30 a.m. Chair meeting with Dr. Jaap Venema Dr. Walter

8:45 a.m. Volunteers arrive and check in

9:00 a.m. 11. Performance tests: The need for multiple dissolution tests in USP monographs, historical perspectives and strategy Dr. Marques

9:30 a.m. 12. <476> and <1086> Statuses update Mr. Hernandez-Cardoso

10:00 a.m. Break

10:30 a.m. 13. Chlorpheniramine Maleate and its Organic Impurities Mr. Nguyen
   (Collaborative Work with Microsolv and Challenges)
<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>11:00 a.m.</td>
<td>14. Collaborative Work With Instrument Manufacturers For Inorganic Monograph Modernization</td>
<td>Dr. Chang</td>
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<td>11:30 a.m.</td>
<td>15. Chair’s Recap</td>
<td>Dr. Walter</td>
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<td>11:55 a.m.</td>
<td>16. Next Steps and Action Items Review</td>
<td>Dr. Santos &amp; Lynette</td>
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<td>12:00 p.m.</td>
<td>Meeting Adjourn and lunch</td>
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