

**2015-2020 General Chapters Chemical Analysis Expert Committee  
Tuesday-Wednesday, October 3 - 4, 2017  
9:00 am - 5:00 pm, 9:00 am - 2:00 pm  
USP – U.S., Rockville**

**Draft Agenda**

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**Goals and Anticipated Outcomes**

The primary goal of this meeting is to go over action items generated during the previous meeting to monitor their status, update the Committee on activities involving the different Subcommittees, and introduce new topics for discussion according to the work plan.

**Attendees**

*Attendee list provided on the day of the meeting*

**Day 1**

**Tuesday, October 3, 2017**

**CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS**

9:00 a.m.	<b>1. Procedural Matters and Standard of Conduct</b> (Informational) <ul style="list-style-type: none"> <li>a. Call Meeting to Order</li> <li>b. Establish Quorum</li> <li>c. Identification of Observers and Confidential Information</li> <li>d. Conflicts of Interest</li> </ul>	Ms. Lewen
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**END OF CLOSED SESSION**

9:15 a.m.	<b>2. Opening and Procedural Matters</b> (Informational & Decision-making) <ul style="list-style-type: none"> <li>a. Meetings Center Announcements</li> <li>b. Welcome</li> <li>c. Introductions</li> <li>d. Minutes of the Previous Meeting</li> <li>e. Approval of the Agenda</li> <li>f. Procedural Announcements</li> </ul>	Ms. Hawkins Ms. Lewen All Ms. Lewen Ms. Lewen Mr. Freebern
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9:30 a.m.	<b>3. Expert Committee Ballot Items</b> (Informational) <ul style="list-style-type: none"> <li>a. General Chapters</li> <li>b. Reference Standards Replacement Lots</li> </ul>	Dr. Zaidi Dr. Tang
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9:45 a.m.	<b>4. Reference Standards Development</b>	Dr. Tang
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10:00 a.m.	<b>5. Analytical</b> (Discussion) <ul style="list-style-type: none"> <li>a. &lt;41&gt; <i>Balances</i></li> <li>b. &lt;1251&gt; <i>Weighing on an Analytical Balance</i></li> </ul>	Mr. Brown
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10:15 a.m.	<b>6. Regulatory</b> (Discussion) <ul style="list-style-type: none"> <li>a. Validation and Verification Expert Panel</li> </ul>	Mr. Martin, Dr. Pappa
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- b. <1226> *Verification of Compendial Procedures –  
Addition of Solution Stability Statement*

Dr. Pappa

10:45 a.m. **Break**

11:00 a.m. **7. Spectroscopy**  
(Discussion)

- a. <197> *Spectrophotometric Identification Tests* Dr. Schweitzer, Dr. Biba  
 b. <855> *Nephelometry and Turbidimetry* Dr. Swiss, Dr. Biba  
 c. <856>and <1856> *Near Infrared Spectroscopy* Mr. Hammond, Dr. Zaidi  
 d. <857> and <1857> *Ultraviolet-Visible  
Spectroscopy* Mr. Hammond, Dr. Marques  
 e. <858> and <1120> *Raman Spectroscopy* Mr. Hammond, Dr. Zaidi

12:00 p.m. **Group Photo**

12:05 p.m. **Lunch**

1:00 p.m. **8. Chromatography**  
(Discussion)

Dr. Quattrocchi, Dr. Biba

- a. <467> *Residual Solvents*  
 b. <1467> *Residual Solvents–Verification of Compendial  
Procedures and Validation of Alternative Procedures*

1:30 p.m. **9. Impurities**  
(Discussion)

- a. An above 1000 chapter on Elemental Impurities Ms. Lewen, Dr. Zaidi  
 b. Elemental Impurities and Packaging Chapters,  
<661> series Ms. Lewen, Dr. Zaidi  
 c. Other USP Element Specific Chapters Ms. Lewen, Dr. Zaidi  
 d. Organic Impurities in Drug  
Substances and Drug Products Dr. Swiss, Mr. Hernández-Cardoso  
 e. <801> *Polarography* Dr. Swiss, Mr. Hernández-Cardoso

2:30 p.m. **Break**

3:00 p.m. **10. Wet Chemistry**  
(Discussion)

- a. <541> *Titrimetry* Dr. Marques  
 b. <785> *Osmolarity and Osmolality* Dr. Marques  
 c. <301> *Acid Neutralizing Capacity* Dr. Helmut, Dr. Zaidi

3:45 p.m. **11. Water**  
(Discussion)

- a. Water for Pharmaceutical Purposes Dr. Soli, Mr. Hernández-Cardoso  
 b. Water for Analytical Purposes Dr. Soli, Mr. Hernández-Cardoso  
 c. Revision to 4 Sterile Packaged Waters Dr. Soli, Mr. Hernández-Cardoso

5:00 p.m. **Meeting Day 1 Adjournment**

6:30 p.m. **Dinner**

**Day 2**

**Wednesday, October 4, 2017**

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| 9:00 a.m.  | <b>12. Continuous Manufacturing Expert Panel</b><br>(Discussion)  | Drs. Matos, Biba                      |
| 10:00 a.m. | <b>13. Analytical Methodologies Based on the Light Scattering Phenomena</b><br>(Informational)  | Dr. Swiss, Dr. Biba                   |
| 10:30 a.m. | <b>Break</b>  |                                       |
| 11:00 a.m. | <b>14. Harmonization Topics</b><br>(Discussion)   |                                       |
|            | a. <233> <i>Elemental Impurities-Procedures</i>   | Dr. Zaidi                             |
|            | b. <644> <i>Electrical Conductivity of Solutions</i><br>(G-03) Stage 4  | Dr. Bevilacqua, Mr. Hernández-Cardoso |
|            | c. <621> <i>Chromatography</i>  | Dr. Pappa                             |
| 11:30 a.m. | <b>15. Workshops</b><br>(Informational)   |                                       |
|            | a. Computer modeling for in vitro and in vivo studies<br>(October 23-25, 2017)  | Dr. Marques                           |
|            | b. PQRI / USP Workshop on Implementation Status of ICH Q3D<br>Elemental Impurities Requirements - Analytical and Risk<br>Assessment Challenges (November 2 – 3, 2017) | Dr. Zaidi                             |
|            | c. Workshop on Lifecycle Approach of Analytical Procedures<br>(Spring 2018)   | Dr. Pappa                             |
|            | d. HPLC 2018 – Washington DC  | Dr. Marques                           |
| 12:00 p.m. | <b>Lunch</b>  |                                       |
| 1:00 p.m.  | <b>16. Review of 2015-2020 Work Plan</b><br>(Decision-making)   | Ms. Lewen                             |
| 1:30 p.m.  | <b>17. General Chapter Decision Tree</b><br>(Discussion)  | Ms. Lewen                             |
| 2:00 p.m.  | <b>Meeting Adjourns</b>   |                                       |