



General Chapters Chemical Analysis Expert Committee (GC-CA EC)
Tuesday, January 21, 2020
10:00 a.m. – 12:00 p.m.
Teleconference

Agenda - Draft

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

- 10:00 a.m. **1. Opening, Procedural, and Administrative Matters**
(Informational & Decision-making)
- a. Welcome, Opening Remarks, Introduction Ms. Lewen
 - b. Roll Call Mr. Freebern
 - c. Establish Quorum All
 - d. Conflicts of Interest, Confidentiality, Code of Ethics
and Recording Policy Mr. Freebern
 - e. Approval of Agenda Ms. Lewen
 - f. Approval of Minutes of Previous Meeting Ms. Lewen
 - g. Action Items from Previous Meeting Mr. Freebern
- 10:05 a.m. **2. Expert Committee Ballot Items**
(Informational)
- a. General Chapters
 - i. <1430.3> Analytical Methodologies
Based on Scattering Phenomena
- Dynamic Light Scattering Dr. Hammond, Dr. Biba
 - ii. <1430.6> Analytical Methodologies
Based on Scattering Phenomena
- Particle Counting via Light Scattering Dr. Biba
 - iii. <1430.7> Analytical Methodologies
Based on Scattering Phenomena
- Nephelometry and Turbidimetry Dr. Rockstroh, Dr. Biba
- 10:10 a.m. **3. Regulatory** Dr. Pappa
(Discussion)
- a. The Analytical Procedure Lifecycle Expert Panel
 - b. <1224> *Transfer of Analytical Procedures*

- 10:20 a.m. **4. Spectroscopy**
(Discussion)
- a. Quantitative Nuclear Magnetic Resonance Ms. Botros
 - b. <852> and <1852> Atomic Absorption Spectroscopy Mr. Shelbourn, Dr. Biba
- 10:40 a.m. **5. Chromatography**
(Discussion)
- a. Stimuli Article-Residual Solvents Determination by SIFT-MS Dr. Biba
See Harmonization section: <621>
- 10:50 a.m. **6. Impurities**
(Discussion)
- a. <232> Elemental Impurities - Limits Dr. Schweitzer, Dr. Zaidi
 - b. Water Requirements for <233> Elemental Impurities-Procedures Mr. Shelbourn, Mr. Hernández-Cardoso
 - c. USP Element Specific Chapters Ms. Lewen, Dr. Zaidi
 - d. Stimuli Article on Elemental Impurities Mr. Shelbourn
 - e. Organic Impurities in Drug Substances and Drug Products Dr. Swiss, Mr. Hernández-Cardoso
- 11:10 a.m. **7. Wet Chemistry**
(Discussion)
- a. <191> Identification Test—General Ms. Botros
- 11:20 a.m. **8. Water** Dr. Soli, Dr. Bevilacqua, Mr. Slabicky
(Discussion)
- a. <1231> *Water for Pharmaceutical Purposes*
See Harmonization section: Sterile Water for Injection Monograph
- 11:30 a.m. **9. Quality Standards for Pharmaceutical Continuous Manufacturing Expert Panel** Ms. Botros, Dr. Matos, Dr. Biba
(Discussion)
- 11:35 a.m. **10. Analytical Methodologies Based on the Light Scattering Phenomena Expert Panel** Dr. Swiss, Dr. Biba
(Informational)
- a. <1430.3> Analytical Methodologies Based on Scattering Phenomena-Dynamic Light Scattering
 - b. <1430.6> Analytical Methodologies Based on Scattering Phenomena- Particle Counting by Light Scattering
 - c. <1430.7> Analytical Methodologies Based on Scattering Phenomena-Nephelometry and Turbidimetry

11:40 a.m. **11. Harmonization Topics**
(Discussion)

- a. <233> *Elemental Impurities-Procedures*
- b. <621> *Chromatography*
- c. Sterile Water for Injection

Dr. Zaidi
Dr. Pappa
Mr. Hernandez-Cardoso

11:50 a.m. **12. Workplan and Legacy Document Review**
(Informational & Decision-making)

- a. Workplan
- b. Legacy Document

Ms. Gaitán
Mr. Freebern

12:00 p.m. **Adjourn**