



**General Chapters—Chemical Analysis Expert Committee (GCCA EC)
September 15–16, 2016
USP—U.S., Rockville, MD**

Executive Summary

A quorum was present and Ms. Nancy Lewen, Chair, presided over the General Chapters—Chemical Analysis Expert Committee (GCCA EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the GCCA EC, grouped by topic.

- 1. Vice Chair:** The Chair announced that Dr. Oscar Quattrocchi will continue serving as Vice Chair until June 30, 2017.
- 2. Ballot for *First Supplement to USP 40–NF 35*:** The EC reviewed General Chapters and monographs to be included in the ballot.
- 3. Balances:** The EC formed a Working Group to revise General Chapters <41> *Balances* and <1251> *Weighing on an Analytical Balance*.
- 4. Spectroscopy**
 - Revised <197> *Spectrophotometric Identification Tests* was published in *PF* 42(5) [Sep.–Oct. 2016].
 - The Analytical Technologies Based on the Light Scattering Phenomena Expert Panel is revising General Chapter <855> *Nephelometry, Turbidimetry, Visual Comparison*.
 - The Spectroscopy Subcommittee is addressing comments received on General Chapters <856> *Near Infrared Spectroscopy*, <858> *Raman Spectroscopy*, and <1120> *Raman Spectroscopy*.
 - Revised General Chapters <857> *Ultraviolet-Visible Spectroscopy* and <1857> *Ultraviolet-Visible Spectroscopy—Theory and Practice* were published in *PF* 42(4) [Jul.–Aug. 2016].
- 5. Validation and Verification:** The Validation and Verification Expert Panel is working on new General Chapter <1220> *Analytical Procedures Lifecycle* and will publish the draft as a *Stimuli* article “Analytical Target Profile: Structure and Application throughout the Analytical Lifecycle” in *PF* 43(1) [Jan.–Feb. 2017].
- 6. General Chapter <1058> *Analytical Instrument Qualification*:** The Regulatory Subcommittee has addressed comments on revised <1058>, which was published in *PF* 42(3) [May–Jun. 2016]. The EC began discussing its next revision of the General Chapter.
- 7. General Chapter <467> *Residual Solvents*:** The Residual Solvents Expert Panel has addressed comments on revisions published in *PF* 41(5) [Sep.–Oct. 2015].
- 8. Water**
 - **Revision to Four Sterile Packaged Water Monographs:** USP is convening a roundtable with multiport bag manufacturers to address the Total Organic Carbon (TOC) limit in sterile packaged water monographs. The EC formed a Working Group to develop a TOC Test Decision Tree.

- **Joint Educational Forum with FDA:** The Waters Expert Panel is preparing the USP-FDA Pharmaceutical Waters Course to be held October 17, 2016, at USP–U.S., Rockville.

9. Wet Chemistry

- **<541> Titrimetry:** The Titrimetry Subcommittee is revising <541>.
- **<785> Osmolarity and Osmolality:** Revised <785> was published in *PF* 42(4) [Jul.–Aug. 2016].

10. Impurities: A Subcommittee will review all element-specific general chapters in *USP–NF* to determine if these chapters should remain or be omitted. The Elemental Impurities Expert Panel published a *Stimuli* article “Future of Element-Specific Chapters in the *USP–NF*” in *PF* 42(4) to communicate the Subcommittee’s approach.

11. Analytical Methods Based on the Light Scattering Phenomena: The Analytical Technologies Based on the Light Scattering Phenomena Expert Panel is preparing an informational general chapter numbered above 1000 on this topic.

12. Continuous Manufacturing Roundtable: The Continuous Manufacturing (CM) Expert Panel will report to the GCCA EC. The Expert Panel will work on the CM standard starting with *Stimuli* articles.

13. Work Plan Review

EC members prioritized General Chapters scheduled for review during the cycle and added the following to their Work Plan:

- Spectral Libraries
- USP FDA Water Course
- Standards for Other Types of Water
- Response to the European Medicines Agency document on Water for Injection