Chemical Medicines Monographs 3 Expert Committee
October 5–6, 2016
USP–U.S.
Rockville, MD

Executive Summary

A quorum was present and Dr. Bernard Olsen, Chair, presided over the Chemical Medicines Monographs 3 Expert Committee (CHM3 EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the CHM3 EC, grouped by topic.

1. **CHM3 Portfolio and Work Plan Overview:** Expert Committee (EC) members discussed the CHM3 EC Work Plan.

2. ***USP 40–NF 35, First Supplement* Ballot Items:** EC members reviewed and discussed ballot proposals for the *First Supplement* to *USP 40–NF 35*.

3. **Drug Structures Update:** EC members received a presentation on USP's internal efforts to update its impurity files.

4. **Photo Diode Array (PDA):** Attendees discussed the advantages and disadvantages of using PDA-based identification methods in monographs.

5. **General Chapter Updates:** EC members received updates on the status of the following General Chapters:
    - <476> *Organic Impurities in Drug Substances and Drug Products* and <1086> *Impurities in Drug Substances and Drug Products*
    - <232> *Elemental Impurities–Limits,* <233> *Elemental Impurities–Procedures*, and <2232> *Elemental Contaminants in Dietary Supplements*
    - <785> *Osmolality and Osmolarity*, <857> *Ultraviolet-Visible Spectroscopy* and <1857> *Ultraviolet-Visible Spectroscopy–Theory and Practice*
    - <197> *Spectrophotometric Identification Tests*
    - <11> *Reference Standards*
    - <2251> *Adulteration of Dietary Supplements with Drugs and Drug Analogs*

6. **Updates and Overviews:** EC members received updates on and overviews of the following:
    - Chemical Medicines Collaborative Group (CHMCG) recommendations
    - *USP–NF Style Guide*
    - Development of global health monographs
    - Potential removal of the Packaging & Storage Statement from drug substance and drug product monographs
    - RS Continued-Suitability-for-Use program
    - Strategic Marketing Program Office
    - Development of non-traditional reference standards
    - Food fraud portfolio
    - Prospective harmonization of monographs for which the CHM3 EC is responsible