



Chemical Medicines Monographs 3 Expert Committee

December 9–10, 2015

USP–U.S.

Rockville, MD

Executive Summary

A quorum was present and Dr. Bernard (Bernie) Olsen, Chair, presided over the Chemical Medicines Monographs 3 Expert Committee (CHM3 EC) 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. **Appointment of Vice Chair:** The Chair appointed Dr. Joseph Stowell to serve as the CHM3 EC Vice Chair for a 1-year term.
2. **USP 39–NF 34, Second Supplement, Pre-Ballot Discussion:** The EC met in Closed Session and discussed upcoming ballot items for the *Second Supplement to USP 39–NF 34*.
3. **CHM3 Portfolio and Work Plan Overview:** EC members received an overview of the monographs assigned to the CHM3 EC and discussed the EC's Work Plan.
4. **USP–NF Up-to-Date Overview:** EC members received a presentation of the purpose, history, strategies, and path forward for monograph modernization.
5. **U.S. Food and Drug Administration Center for Veterinary Medicine (CVM) Overview:** EC members received a presentation on CVM's core mission, organization, regulatory authority, and collaborations with USP.
6. **Prospective Harmonization Overview:** EC members received an overview of the scope, recently completed and ongoing projects, challenges, and the path forward for prospective harmonization of monographs.
7. **General Chapter <621> Chromatography:** EC members received an overview of recent and upcoming revisions to <621>.
8. **General Chapters <476> Organic Impurities in Drug Substances and Drug Products and <1086> Impurities in Drug Substances and Drug Products Update:** EC members received an update on the status of <476> and <1086>.
9. **USP's Role on Dissolution/Disintegration/Drug Release Tests:** EC members received an overview of monograph dissolution, disintegration, and drug release tests.
10. **Reference Standards Evaluation:** EC members received an overview of the USP Reference Standards Evaluation process.
11. **USP Monograph Revision Process:** EC members received an overview of the USP monograph revision process.

- 12. Ballot Process and CoE Portal Update:** EC members received an update on the balloting process and the CoE portal.