



Chemical Medicines Monographs 5 Expert Committee
December 7–8, 2015
USP–U.S.
Rockville, MD

Executive Summary

A quorum was present and Ms. Amy Karren, Chair, presided over the Chemical Medicines Monographs 5 Expert Committee (CHM5 EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the CHM5 EC, grouped by topic.

1. **Appointment of Vice Chair:** The Chair appointed Mr. Michael Skibic to serve as Vice Chair.
2. **Monograph Portfolio and Work Plan:** USP staff reviewed the portfolio of monographs the CHM5 EC is responsible for, including new monographs, planned revisions, and the overall modernization effort.
3. **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>.
4. **USP Monograph Revision Process:** EC members received an overview of the USP monograph revision process.
5. **Reference Standards Evaluation and Joint-Standards Setting Subcommittees (JS3s):** EC members received an overview of the USP Reference Standards Evaluation process, and the role of JS3s in approving Reference Standards Replacement and Continuation Lots.
6. **USP–NF Up-to-Date Overview:** EC members received a presentation of the purpose, history, strategies, and path forward for monograph modernization.
7. **USP’s Role on Dissolution/Disintegration/Drug Release Tests:** EC members received an overview of monograph dissolution, disintegration, and drug release tests.
8. **General Chapter <621> *Chromatography:*** EC members received an overview of <621>, which promotes a flexible approach to select high-performance liquid chromatography column dimensions.
9. **Research and Innovation (R&I) Initiatives:** EC members received an overview of the USP R&I Strategic Initiative, which includes four major areas:
 - Mobilizing a Culture of Innovation Across the Organization
 - Forward-looking Mentality
 - Technological Advancement
 - Performance-driven and Revenue-generating