General Chapters–Biological Analysis Expert Committee  
September 16, 2019  
USP–U.S.  
Rockville, MD

Executive Summary–Draft

A quorum was present, and Dr. Wes Workman, Chair, presided over the General Chapters–Biological Analysis Expert Committee (GCBA EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the GCBA EC, grouped by topic.

1. **General Chapter <1042> Cell Banking**: In closed session, EC members received an update on resolution of public comments for <1042> from the Cell Banking Expert Panel.


3. **General Chapter <1102> Immunological Test Methods—General Considerations**: In closed session, EC members reviewed public comments on <1102>.

4. **General Chapter <1239> Vaccines for Human Use—Viral Vaccines**: In closed session, EC members reviewed public comments on <1239>.

5. **Round Robin Study**: EC members received an update on a round robin study to establish performance standards for bacterial polysaccharides used in vaccine manufacturing. A final study report is expected in January 2020.

6. **Vaccines**: EC members received updates on the collaborative studies to establish identification and quantification standards for bacterial polysaccharides used in vaccine production.

7. **Cell and Gene Therapy**: USP staff provided updates on USP’s development of physical and documentary standards in the field.

8. **Performance Standards**: In a joint session with members from Biologics 2–Proteins, EC members received progress reports on studies regarding the following: monoclonal antibodies, capillary isoelectric focusing, multi-angle light scattering, capillary electrophoresis–mass spectroscopy, multi-attribute methods, Fc binding assays, high molecular weight impurities, column qualification, and host cell proteins.
Joint Session of the General Chapters–Biological Analysis and Biologics Monographs 2–Proteins Expert Committees
September 17, 2019
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Executive Summary–Final

A quorum was present and Dr. Mike Mulkerrin, Chair, presided over the Joint Session of the General Chapters–Biological Analysis Expert Committee (GCBA EC) and Biologics Monographs 2–Proteins (BIO2) EC face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the Expert Committees, grouped by topic.

1. **General Chapter <1049.1> Design of Stability Studies for Biotechnology Product Development and Lifecycle Management:** EC members reviewed the GCBA EC decision in response to the recommendation from the Biologics Stability Expert Panel.

2. **Performance Standards:** EC members received progress reports on studies regarding the following: monoclonal antibodies, capillary isoelectric focusing, multi-angle light scattering, capillary electrophoresis–mass spectroscopy, multi-attribute methods, Fc binding assays, high molecular weight impurities, column qualification, and host cell proteins.

3. **Non-Glycosylated Heavy Chain:** EC members agreed to discontinue the development of a non-glycosylated heavy chain standard.

4. **USP Collaborations:** EC members received an update on USP’s collaborations with BioPhorum, the Alliance for Regenerative Medicine, The National Institute for Innovation in Manufacturing, the Standards Coordinating Body, and the Complex Carbohydrate Research Center at the University of Georgia.