Executive Summary–Final

A quorum was present and Dr. Ed Chess, Chair, presided over the Biologics Monographs 3–Complex Biologics Expert Committee (BIO3 EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the BIO3 EC, grouped by topic.

1. **Biologics Strategy:** EC members learned about the refreshed USP Global Biologics Strategy. Among other activities, the EC will aim to maintain USP Heparin standards; develop standards for plasma-derived and recombinant blood products, as well as cell, gene, tissue therapies; and identify critical biologics raw materials for standards development.

2. **EC Work Plan:** EC members reviewed the BIO3 EC’s portfolio and reviewed their assignments. EC members will review high-priority monographs and general chapters and evaluate them according to criteria determined by the USP Up-to-Date Initiative.

3. **Heparin Sodium Bovine:** EC members reviewed the results of a round robin study of bovine heparin quality attributes using the USP Heparin RS, a porcine mucosa standard. They also reviewed a draft documentary standard for Heparin Sodium Bovine which is in progress.

4. **Ancillary Materials:** USP will convert ancillary material general chapters (e.g., <92> Growth Factors and Cytokines Used in Cell Therapy Manufacturing and <90> Fetal Bovine Serum—Quality Attributes and Functionality) into monographs and group them in a new section of USP–NF. USP will work with industry to determine which new ancillary standards need to be developed.

5. **Cellular Therapies Working Group:** The EC reviewed the Working Group’s proposed revisions of General Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products that will be published in PF 43(3) [May–Jun. 2017]. The EC also reviewed revisions the Working Group is considering for <1046> Cellular and Tissue-Based Products Revision, targeted for publication in PF 43(5) [Sep.–Oct. 2017].

6. **Monograph Updates:** EC members reviewed the following:
   - Dextran 40 monograph in progress
   - Acarbose Tablets monograph revisions targeted for publication in PF 43(5) [Sep.–Oct. 2017]
   - Scaffold Human Amnionic Membrane Allograft monograph
   - Scaffold Human Placental Connective Tissue Matrix Allograft monograph

7. **Review of Public Comments:** EC members reviewed public comments on the Enoxaparin Sodium monograph and the Fondaparinux Sodium for Injection monograph in closed session.
8. **Reference Standards:** In closed session, EC members reviewed the testing plan for the Albumin Human RS. EC members also learned about the RS Up-to-Date initiative that is evaluating USP RSs.

9. **Coagulation Topics:** A Coagulation Expert Panel will be formed to investigate and develop assays for potency determination and impurities for coagulation factors, specifically factor VIII (FVIII) and coagulation factor IX (FIX) products (recombinant and plasma derived) and review monographs for coagulation factors. The Call for Candidates will be issued soon.

   EC members received an overview of immunoglobulin issues. They also learned about the Global Working Group that is developing guidance for harmonized test methods and generating appropriate reference materials.

10. **Cell and Tissue Topics:** The EC received an overview of a quantitative *in vitro* assay to measure the potency and quality of hematopoietic stem cell therapeutic products. EC members also learned more about the 21st Century Cures Act and the U.S. Food and Drug Administration Office of Tissues and Advanced Therapies.