Biologics Monographs–Complex Biologics 3 Expert Committee (BIO3 EC)
March 5, 2019
USP–U.S.
Rockville, MD

Executive Summary

A quorum was present and Dr. Ed Chess, Chair, presided over the Biologics Monographs – Complex Biologics 3 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. **Immunoglobulin Standards:** USP plans to publish the proposed omission of the following monographs in *PF* 45(4) [Jul.–Aug. 2019]:
   - Immune Globulin
   - Tetanus Immune Globulin
   - Rho (D) Immune Globulin
   - Hepatitis B Immune Globulin
   - Rabies Immune Globulin
   - Varicella-Zoster Immune Globulin
   - Vaccinia Immune Globulin
   - Pertussis Immune Globulin

   USP has received initial support of the omissions from stakeholder groups. USP will continue to seek feedback on the impact of the omissions from manufacturers.

2. **Dextran Monographs:** The EC tabled revision of these monographs due to the absence of a sponsor.

3. **Vector Copy Number (VCN) Standards:** USP is collaborating with a partner to produce a set of VCN genomic DNA standards that could be used to standardize product characterization assays. VCN performance standards could be used to validate in-house transduction assays, cell product release, and patient monitoring.

4. **mRNA Roundtable:** A summary of the USP Roundtable on mRNA Products held in November 2018 is available on USP.org.

5. **Enoxaparin Sodium Monograph:** USP will conduct additional laboratory studies on marketed enoxaparin sodium products to evaluate the potential inclusion of hydrogen (^{1}H)-nuclear magnetic resonance (NMR) in the Enoxaparin Sodium monograph.

6. **Factor Xa Standards:** USP discussed development of a Bovine Factor Xa Reference Standard (RS) for use with General Chapter <208> *Anti-Factor Xa and Anti-Factor IIa Assays for Unfractionated and Low Molecular Weight Heparins.*

Coagulation Factors Expert Panel: The Expert Panel will develop a suite of chapters on potency for use with coagulation assays. For example, the Expert Panel plans to develop a proposed general chapter numbered above 1000 that provides best practices for potency assays for coagulation factors.