



Partner Organization Report

Partner Organization:	USP
Committee Name (if applicable):	
ISCT Representative(s):	Joseph C. Laning
Role of ISCT Representative:	Voting ISCT Representative at 2015 Convention
Last Committee Report Submitted on:	
Date of Upcoming Board of Directors Meeting for Submission:	June 20, 2018

1. How often has this committee met during the last 12 months?

- a. The USP has 25 expert committees that meet regularly, however not all expert committees have direct bearing on issues relevant to the objectives important to ISCT. The main expert committee which actively works on topics of interest to ISCT is the Biologics Collaborative Group and the BIO3-Complex Biologics Expert Committee. This committee meets once per year with the Meeting Executive Summaries being posted on the USP website. Committee Details are as follows;

Focus Areas

- Anticoagulants and protamine, GAGs, carbohydrates, blood and blood products, cells, and tissue monographs and reference standards
- Selected general chapters that pertain to the anticoagulants and protamine, GAGs, carbohydrates, blood and blood products, cells, and tissue monographs

Expert Committee Charge

The Biologics Monographs 3 – Complex Biologics Expert Committee is responsible for the development and revision of *USP–NF* monographs and their associated USP Reference Standards in the following therapeutic categories: Anticoagulants and protamine, GAGs, carbohydrates, blood and blood products, cells, and tissue.

Key Issues

- Work with other Biologics Expert Committees, FDA and stakeholders
 - to improve existing complex biologics monographs
 - to develop new product monographs in the area of coagulation factors
 - on standards for cellular therapeutics

2. What was accomplished during the meeting(s)? (To answer this question, you may attach conference call reports or meeting minutes.)
 - a. Please see Appendix B for posted meeting summaries
 - b. Of note would be the following;
 - i. General Chapter <127> Flow Cytometric Enumeration of CD34+ Cells: To be revised and prepare it for balloting.
 - ii. CD34+ Cell Enumeration System Suitability RS, recommendations to be prepared
 - iii. EC recommended the formation of a Tissue-based Products Expert Panel to develop tissue-based product standards, including amniotic membrane-derived product monographs
 - iv. Cell therapy working group to finalize revisions to General Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products PF 43(3) [May–Jun. 2017], and to General Chapter <1046> Cellular and Tissue-Based Products PF 43(5) [Sep.–Oct. 2017].
 - v. 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
 - vi. EC received an overview of a quantitative in vitro assay to measure the potency and quality of hematopoietic stem cell therapeutic products and learned about the 21st Century Cures Act and the U.S. Food and Drug Administration Office of Tissues and Advanced Therapies
 - vii. EC members reviewed the testing plan for the Albumin Human RS
 - viii. Cell and Gene Therapy Standards: EC members received overviews of the gene therapy market and challenges in analytical analysis and product manufacturing. EC members discussed the need for a rapid, small scale performance assay for current compendial assays
3. What are the key goals and initiatives for the next 6 months to 1 year?
 - a. Dextran 40 monograph revisions
 - b. Immunoglobulin product quality
 - c. Gene therapy rapid, small scale product performance assay development
 - d. Tissue product monographs
4. Are there any activities within this time period that ISCT should be aware of or take part in? Specifically, are there activities that any ISCT Committees can comment on?
 - a. Be particularly aware of changes made to <1043>, <1046>, <92>, and <90> as standards and monographs within these USP documents for materials and reagents commonly used in cell therapy processes or designated as testing standards or test method standards for should certainly be of high quality but also be functional in the context of the complex therapeutics being developed in this industry. (See

Appendix C)

5. Additional comments or feedback: N/A

Respectfully Submitted,

Joseph C. Laning, PhD

