

Regulatory Affairs Committee

CHAIR: Scott Webber

PURPOSE: Serve as a resource to AABB on Transfusion Medicine and Cellular Therapy related regulatory issues.

CHARGES: 1. Provide input for the development of position statements for the Food and Drug Administration (FDA)

and Centers for Medicare and Medicaid (CMS).

- 2. Review FDA/CMS documents and notices and provide input on the operational and technical implications.
- 3. Develop, revise and review documents and toolkits for alignment with FDA regulations and recommendations.
- 4. Review AABB Standards to identify areas where the addition of regulatory references would be relevant and useful.
- 5. Assist with developing content for the Ask the FDA and CMS/CLIA session at Annual Meeting.

Current Personnel as of May 08, 2024

| Name | Roles |
|------------------------------------|---|
| Chair | |
| Scott Webber | |
| Consultant | |
| Anne Chenoweth | |
| Junior Committee Member | |
| Richard Bewley | |
| Jennifer Vrieze | |
| Liaison | |
| Nina Sen, SBB(ASCP) | BB/TS AC Liaison |
| Dr. Aasawari Bapat, CABP(H),MD,PHD | Quality, Regulatory, and Management Subsection Liaison |
| <u>Member</u> | |
| Janice Habel | |
| Roxanne Tata, MT(ASCP)SBB | |
| Jean Reece | |
| Valery Freeman-Allen | |
| Jessica Lantz | |
| Mrs Susan Sullivan | |
| Staff Liaison | |
| Karen Palmer | |

Time Commitment: To learn about the time commitments for this committee, please contact the staff liaison listed in the roster

above.