

Regulatory Affairs Committee

CHAIR: Kathleen Hopping, BS,MS

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 March 29, 2025

Name	Roles
Chair	
Kathleen Hopping, BS,MS	
Consultant	
Anne Chenoweth	
Junior Committee Member	
Jennifer Vrieze, BS	
Joanna Casimir, DrPH	
Liaison	
Nina Sen, SBB(ASCP)	BB/TS AC Liaison
Aasawari Bapat, CABP(H),MD,PHD	Quality, Regulatory, and Management Subsection Liaison
<u>Member</u>	
Valery Freeman-Allen, MSC	
Richard Bewley, MLT(ASCP)	
Jessica Lantz, BSC	
Mrs Susan Sullivan, CQA(ASQ),MBA,MT(ASCP)SBB	
Todd Riemer, BS,MT(ASCP)	
Jeremy Puckett, BA	
Monisha Dey, MLS(ASCP),MS	
Staff Liaison	
Karen Palmer, CQA(ASQ),MT(ASCP)	

Time Commitment:

To learn about the time commitments for this committee, please contact the staff liaison listed in the roster above.