

## **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 November 22, 2024**

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