

**CELL AND GENE THERAPY SERVICES FOR PHARMACY STANDARDS
COMMITTEE**

PURPOSE: To develop, maintain and update standards for the handling of approved cell and gene therapy products within pharmacy.

CHARGES:

1. Review existing requirements from the Standards for Cellular Therapy Services and identify standards applicable to activities within pharmacy. Where necessary craft new standards surrounding the receipt, handling, storage, or dispensing of cell and gene therapy products through pharmacy.
2. In coordination with AABB staff, develop guidance for the Standards for Cell and Gene Therapy Services for Pharmacy and create records of rationales for changes to existing requirements, as applicable.
3. Review and respond to requests for clarification and variances to the Standards as needed.
4. Develop interim/emergent standards as needed for submission to the AABB Board of Directors.
5. Monitor the development of new practices and technologies with potential application to cell and gene therapies and develop or modify standards when appropriate.

PERSONNEL:

<u>Role</u>	<u>Chair</u>
	Beth Shaz
	<u>Members</u>
	Jodi Sibell
	Kim Tedesco
	Maribeth Bettarelli
	Joe DePinto
	Marissa Szymala
	Eric Balmir
	Jill Blind
	Kim McConnell
	Phil Wilson
	Chiara Cerati
	Brenda Alder
	Mary McLeod
	<u>Consultant</u>
	Linda Barnes
	<u>Representatives</u>

Food and Drug Administration (Office of Therapeutic Products)	TBD
	<u>Liaisons</u>
CT Standards Committee	Katherine Browne
CT Accreditation Committee	Corinne Goldberg