

FEDERAL AND INDUSTRY REGULATIONS
Regulatory Oversight and Standards for Tissue Donation

Food and Drug Administration (FDA)

“Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement (21 CFR Parts 16, 1270 and 1271)”

- The FDA requires organizations involved in human cell and tissue-based products to follow “current good tissue practice.” CGTP governs the methods used in, and the facilities and controls used for, the manufacture of the tissue products as well as its record keeping and the establishment of an overall quality program. These and other actions are intended to help protect the public health.
- Tissue recovery agencies fall under these regulations. They are part of the manufacturing process.
- Comprehensive audits of each recovery agency are conducted by local FDA staff, typically on an annual basis. Audits include, but are not limited to, review of medical records, clinical and administrative policy, and observation of recovery and equipment storage.

American Association of Tissue Banks (AATB)

- The AATB is a scientific, not-for-profit, peer group organization founded in 1976 to facilitate the provision of transplantable cells and tissues of uniform high quality in quantities sufficient to meet national needs.
- The AATB publishes standards to help ensure that the conduct of tissue banking meets acceptable norms of technical and ethical performance, and provides technical information that describes procedures to foster reasonable and responsible approaches to recovery, processing, preservation and distribution of transplantable tissue.
- AATB routinely inspects and accredits tissue organizations and certifies personnel to ensure that tissue banking activities are being performed in a professional and high quality manner consistent with standards of the Association. Just 10 percent of all tissue-related organizations possess the accreditation.