Managing biologics

How allograft tissue is regulated

When your OR is selecting allograft tissue, how do you know which federal regulations govern their safety?

The US Food and Drug Administration (FDA) uses a tiered approach to regulating these materials, explains Scott Brubaker, CTBS, chief policy officer for the American Association of Tissue Banks (AATB).

Minimally processed tissue

Conventional allografts, such as bone, tendons, ligaments, skin, and fascia lata, are regulated solely under Section 361 of the Public Health Service (PHS) Act (42 USC 264), which covers human tissues and cellular and tissue-based products (HCT/Ps), as long as they meet 4 criteria:

• are minimally manipulated
• are intended for homologous use
• are not combined with another article
• do not have a systemic effect or depend on the metabolic activity of living cells for their use.

Tissue establishments that perform any manufacturing function for tissue regulated under Section 361 must meet requirements of 21 CFR 1271, which include the FDA’s current Good Tissue Practice Rule, and Donor Eligibility Final Rule and Guidance. These focus on preventing disease transmission during each step from donor screening and tissue recovery to tissue distribution. There are donor eligibility and testing requirements; controls for tissue recovery; and expectations for tissue tracking, handling, labeling, and recordkeeping. Establishments must also have a quality program and comply with registration and reporting responsibilities. But unlike medical devices, conventional tissue allografts do not require FDA clearance (510k) or premarket approval (PMA).

Tissue as a medical device

Biologics that go beyond any of these criteria, such as gels, pastes, and putties with demineralized bone matrix (DBM) or implants combined with biologics, are regulated under a higher tier: Section 351 of the PHS Act and the Federal Food, Drug, and Cosmetic Act, which covers drugs, biological products, and medical devices.

Manufacturers of these products must meet FDA’s Good Tissue Practice rule as well as the Good Manufacturing Practice (GMP) regulation and, for products designated as medical devices, the Quality Systems Regulations (QSR).

Basically, the manufacturer must demonstrate safety and effectiveness before the product can be widely marketed, either through the FDA’s 510k
process, in which the company demonstrates equivalence to a product already on the market, or a PMA.

**Regulating DBM-based materials**

The FDA decided to include DBM-based materials under Section 351 after long deliberations, Brubaker says. Manufacturers argued that DBM is no different than the original bone material with the minerals removed using simple processing steps and that its action is homologous without a systemic effect. There was agreement to regulate DBM as a “361 product,” but if DBM is combined with another article, the product is ‘kicked up’ to a higher regulatory tier as a tissue device.

---

**Reference**
