ISO 10993-6_2026 VS ISO 10993-6_2016

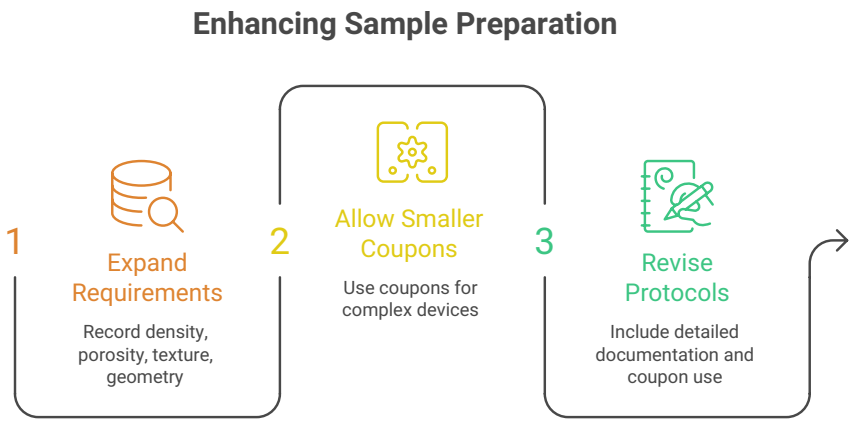
GAP Assessment – Consolidated Conclusion Summary
Based on the clause-by-clause comparison, the 2026 edition introduces **expanded requirements for sample preparation, control selection, animal model use, and absorbable material evaluation**. The changes emphasize **Good Laboratory Practices (GLP), detailed documentation of physical properties, broader reference standards, and refined study protocols**, moving beyond the 2016 baseline. The major gaps requiring action are summarized below, with parameters highlighted for implementation.

1. Animal Testing and GLP

- 2026 mandates GLP or recognized QA systems for all animal studies; 2016 allowed broader flexibility. **Action:** Update protocols to enforce GLP compliance and facility quality system documentation.

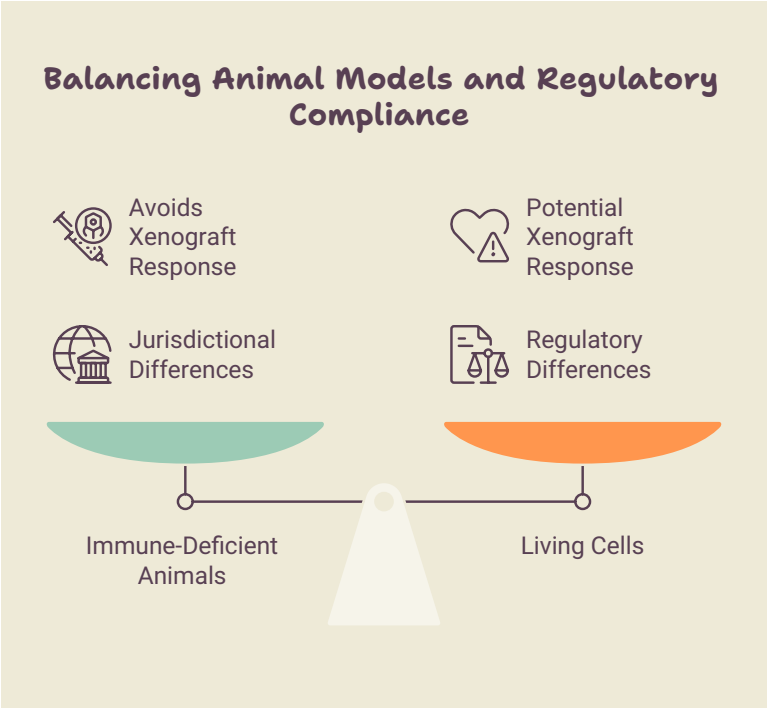
2. Sample Preparation

- Expanded requirements: record density, porosity, texture, and geometry; allow smaller coupons for complex devices. **Action:** Revise DHF protocols to include detailed property documentation and coupon use for multi-material devices.



3. Scaffold Materials

- Clarifies immune-deficient animal use to avoid xenograft response; notes jurisdictional differences for living cells. **Action:** Update risk files to reflect immune-deficient animal option and regulatory definitions.



4. Control Samples

- New requirement: comparative controls must match geometry, porosity, and absorption rates; reference materials specified. **Action:** Document control selection, justify deviations, and align with ISO 10993-12 and ISO/TS 37137-1.