HCT/P Tissue Establishment Compliance Consulting (21 CFR Part 1271)

Last reviewed October 2026 · https://www.integralhs.com/hctp-tissue-establishment-cgtp-compliance

What to have ready

Each item ties to 21 CFR Part 1271 [https://www.ecfr.gov/current/title-21/part-1271] as in force on September 30, 2026, or to FDA's CGTP guidance (December 2011, Final) [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells-tissues-and].

1. Your counsel's written classification of each product against the section 1271.10(a) criteria.
2. If you rely on the same-surgical-procedure exception in section 1271.15(b), counsel's confirmation that it applies.
3. Your registration and HCT/P listing records, and the date of your last December update under section 1271.21(b).
4. A list of the manufacturing steps you perform, using the steps named in section 1271.150(a): recovery, donor screening, donor testing, processing, storage, labeling, packaging and distribution.
5. The SOP for each of those steps, with its current version and approval date.
6. Your donor-eligibility procedures and records (Subpart C).
7. Your current deviation, tracking and reporting procedures (Subparts D and E).
8. A copy of FDA's CGTP guidance, the version your procedures were written against.
9. Names of the tissue specialists who will review and approve technical content.