AABB Cell and Gene Therapy Pharmacy Accreditation Consulting

Last reviewed October 2026 · https://www.integralhs.com/aabb-cell-gene-therapy-pharmacy-accreditation

What to have ready

- A purchased copy of the AABB Cell and Gene Therapy Standards for Pharmacy, 1st edition, effective October 1, 2025 (AABB [https://www.aabb.org/standards-accreditation/standards/cell-and-gene-therapy-standards-for-pharmacy]; prices on AABB Purchase Standards [https://www.aabb.org/standards-accreditation/standards/purchase-standards]).
- A list of every CGT product you receive, store, handle or dispense, matched to AABB's CGT pharmacy activity definition (Accreditation Activities, Version 3 [https://www.aabb.org/docs/default-source/default-document-library/accreditation/aabb-accreditation-activities.pdf]).
- Written policies, processes and procedures (AABB abbreviates them PPPs) that cover every standard, and a way to show staff work from them (AABB Accreditation Process [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/accreditation-process]).
- Records showing staff follow those procedures, since the on-site visit tests practice against the written procedures (AABB [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/cell-and-gene-therapy-pharmacies]).
- A written boundary between pharmacy handling and clinical administration, since AABB places administration, manufacturing and starting-material collection outside the standards (AABB [https://www.aabb.org/standards-accreditation/standards/cell-and-gene-therapy-standards-for-pharmacy]).
- Evidence of at least 6 months of operation in the activity before you start (AABB Accreditation Process [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/accreditation-process]).
- The location and current CGT activity details AABB asks for with the Institutional Membership Application (AABB [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/cell-and-gene-therapy-pharmacies]).
- A named owner for the APEX self-assessment (AABB [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/cell-and-gene-therapy-pharmacies]).
- A process for a Corrective Action Plan and Post-Assessment Questionnaire if non-conformances are found (AABB [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/cell-and-gene-therapy-pharmacies]).
- A communications hold: nothing that advertises an AABB relationship until your facility or new activity is accredited and the certificate is issued, per AABB's process page (AABB Accreditation Process [https://www.aabb.org/standards-accreditation/accreditation/become-accredited/accreditation-process]).