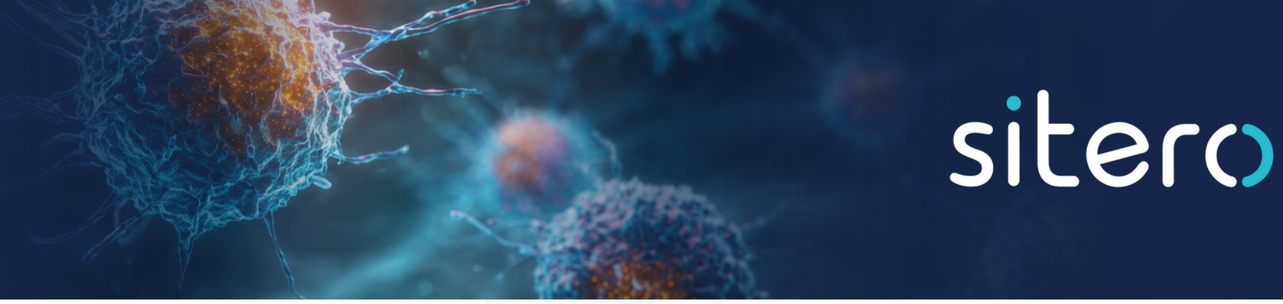
CGT Biosafety Services Snapshot:
What We Can Support Today



sitero

Sitero Biosafety Services In Cell and Gene Therapy

Clear, defensible biosafety decisions for cell and gene therapy programs, from R&D through clinic, without over-promising regulatory outcomes.

Risk assessments

- Vector-specific risk assessments (AAV, lentivirus, retrovirus, adenovirus, etc.)
- NIH Guideline applicability and IBC scope clarification
- BSL/ABSL determinations
- Environmental and viral shedding risk evaluations

IBC services & documentation

- Local IBC services for institutions needing external support
- Protocol drafting and review for IBC submissions
- Containment and Appendix-aligned language for protocols and SOPs
- Support in responding to IBC stipulations and committee questions

CGT-focused training

- CGT-specific biosafety fundamentals and viral vector handling
- Role-based training for lab, manufacturing, and clinical staff
- Flexible delivery: virtual, in-person, or on-demand modules

Inspection & audit readiness

- Pre-inspection gap assessments focused on CGT workflows
- Mock inspections and corrective action planning
- Organization and packaging of biosafety documentation for site/regulatory visits

Talk with a biosafety expert

Tell us about your cell and gene therapy program and explore how Sitero can help you strengthen biosafety, reduce rework, and improve inspection readiness.