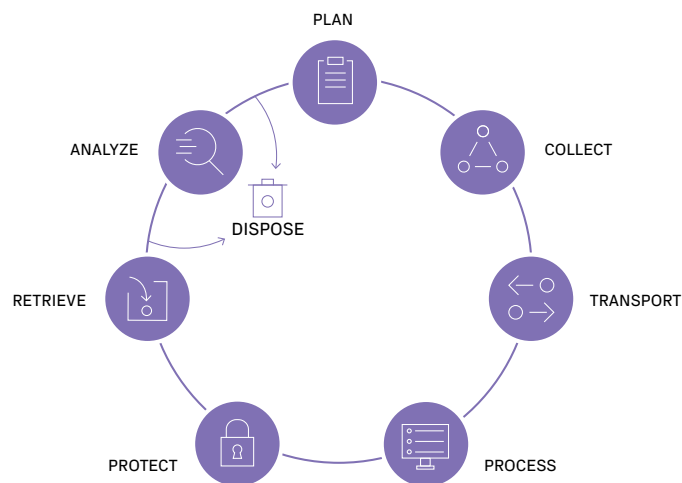


Cell and Gene Therapy Clinical Trial Services



Azenta Life Sciences stands at the forefront of innovative and comprehensive clinical trial sample services and automated solutions for cell and gene therapy, with expertise in cold chain maintenance below the glass transition temperature. Our goal is to improve study timelines, increase sample value, enable sample re-use, and provide a scalable solution for our clients by handling the entire sample management workflow, ultimately gaining approval for your therapeutic candidate.



Study Initiation

Our team of experienced project managers is dedicated to meeting client-specific requirements and provides transparent communication every step of the way.



- Standard and client-specific operating procedures
- Project definition capturing specific requirements for each sample group
- Collection kit design
- Site training and manuals
- Project-specific KPIs (key performance indicators) and KQIs (key quality indicators)
- Consulting services

Pre-Analytical Services

- Sample accessioning (manual or electronic registration)
- Aliquoting and reformatting
- Blood fractionation
- PBMC isolation and cryopreservation
- Stool processing
- DNA/RNA and cell-free nucleotide extraction
- Tissue sectioning



Sample Storage

- Automated and manual storage solutions to support:
 - Short-term storage (STS)- Active/prospective clinical trial samples to batch and prepare for planned and unplanned testing requirements
 - Long-term storage (LTS)- Legacy samples for future use or regulatory retention samples
- Storage temperature capabilities:
 - Electromechanical (ambient to -80°C)
 - LN₂-based (-20°C to cryogenic -196°C)
- 24/7 secure storage in our GxP compliant repositories



Analytical Services

Working together with in-line laboratories, we ensure acceleration of clinical trial timelines and streamlining the process, leading to fewer touchpoints. Our analytical services include RUO, GLP, and CLIA regulated solutions for:



- Genetic & genomic services
- Bioinformatics
- Histology & pathology services

Cell and Gene Therapy Clinical Trial Services



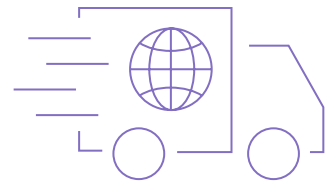
Sample Support Services

- Consent management
- Pathology report redaction

Sample Retrieval & Shipment

Our customers trust Azenta Life Sciences as their cold-chain logistics experts specializing in biological shipment regulations around the globe. We manage the sample from receipt to delivery at the end-user site. Our processes protect sample identity and integrity.

- Rapid retrieval, with 24-hour turnaround time available
- Fast deliveries for time-sensitive therapies, with expedited service options
- Accurately annotated chain of custody ensures samples securely reach their destination
- Standard and custom labeling services
- Custom sorting and blinding services



Sample Management Logistics Solutions

- Robust infrastructure with multiple redundancies to keep samples safe
- Electronic sample, inventory, and asset management systems capture chain of custody and full audit trail with 21 CFR, Part 11 compliant software
- Proven risk mitigation strategies to keep irreplaceable assets secure
- Licenses, accreditations, and memberships include (but not limited to): CLIA, CAP, FDA, ISO, ISCT and ISBER
- Superior informatics platform with full visibility to inventory 24/7 from anywhere around the world
- Real-time access to quality data and corresponding samples



Biorepository Locations

Our global network of interconnected biorepositories and sample bioprocessing laboratories accelerates pre-clinical and clinical research timelines, reduces sample administration costs, and maximizes the value of your samples.

- Cleveland, OH, USA
- Fresno, CA, USA
- Indianapolis, IN, USA
- Beijing, China
- Griesheim, Germany
- Montreal, Canada
- Singapore, Singapore



Sample management support available at customer locations.

