

CELL PROCESSING & CRYOPRESERVATION SERVICES

From acting as a cell processing hub for whole blood specimens to cryopreservation of autologous apheresis materials, to cold chain storage and logistics, we offer our pharma partners and CROs an array of services that enable speed, geographic flexibility, and risk mitigation in the development, manufacturing, and deployment of innovative cell therapies and vaccines.



CPC Services is a multi-center clinical sample processing hub with readily available services such as routine plasma and cell isolation from whole blood (e.g. PBMC), analytical testing of blood samples and cells, cryopreservation of donor material (e.g. autologous leukopaks), and cold storage solutions.

Full Project Oversight

- Dedicated project managers
- Timely and clear communication with sponsors and clinical sites
- Inventory management
- Robust data capture including sample receipt, processing, storage, and shipment metrics for tracking and trending

Cell Isolation from Whole Blood

- Processing of clinical trial samples within hours of sample receipt
- Cell isolation from patient blood samples
- Cryopreservation of cells from patient blood samples
- Technology transfer of client processes for processing and analytical testing

Sample Cryopreservation

- Cryopreservation of patient apheresis material for autologous and allogeneic use
- Controlled rate freezing
- Standardized and customer-specific cryopreservation protocols, wholly owned birth tissue and leukapheresis supply chain for procurement of allogeneic tissues for training, validation, and other purposes

Cold Storage & Logistics

- Dedicated short and long term biospecimen storage
- Ambient temperature and cold storage
- Static and dynamic environmental monitoring & temperature control
- Validated shipping protocols

Analytical Testing & Validation

- Cell enumeration and viability
- 6-part differential CBC
- 8-color flow cytometry
- DNA extraction and PCR

Quality & Regulatory Compliance

- Qualified and trained staff
- High quality and safety standards
- IRB approved, FDA registered and inspected
- GMP compliant, US FDA and EU compliant







99.9%

Processing accuracy across all samples

Over a 24-month period, OrganaBio collected and processed over 2,000+ samples, achieving a 99.9% success rate through the processing stages.

Demonstrated Success

OrganaBio's unique Hub Processing model is vital to Sponsors' clinical trial success through fast and efficient sample processing and cryopreservation. Exceptional track record, an experienced trained and qualified team, along with consistent quality management system across geographies ensure efficient technology transfer and proven accuracy. OrganaBio's client-centric and data-driven approach enables seamless operations between Sponsors, clinical sites, and OrganaBio's dedicated staff.

2,000+
Patient samples processed

30 min

Average from sample receipt to process initiation

99.1% Average

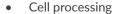
cell viability 2.94e6

PBMC/ml average recovery

Bi-coastal Geographies

Co-located with areas of high density for research and clinical trials, OrganaBio is readily capable of commissioning a facility with full-service capabilities within a matter of weeks. Additional locations planned in Houston, Chicago, Detroit, Memphis, Nashville, and Atlanta to create additional capacity for therapeutic developers.





- Cryopreservation
- Dedicated long-term storage options

Miami

- Cell processing
- Cryopreservation
- Dedicated long-term storage options
- ISO 7 cleanrooms available if needed





GMP Compliant Processes & State of the Art Equipment

Sample Processing & Cryopreservation

- Controlled rate freezing (including protocol transfer and validation)
- Customer-specific options for either mechanical or LN2 freezers at -150°C
- Refrigerated centrifuges
- Automated cell counting
- Sterile welding and sealing
- Plasma extraction
- BSL2 biological safety cabinets

Equipment Validation & Qualification

- Training and SOPs
- Technology transfer
- Preventive maintenance and equipment redundancy
- Qualified vendors, reagents, and materials
- Data security

Quality Oversight of Products & Processes

- Validated electronic quality management system (eQMS), unified across all business units and geographic locations
- Quality assurance
- Regulatory compliant storage and use of clinical sample
- GMP compliance
- 21 CFR Part 11 compliant software

"CPC Services has become our 'go-to' cell processing hub. The team's attention to detail and stellar execution, from sample processing to management of clinical sites, to coordination of logistics, eases the burden on our team and ensures successful data capture. CPC Services is showing us how this work should be done."

Manager, Vaccines R&D of Large Cap Global Pharmaceutical Company

Contact us at sales@organabio.com or call 305.676.2586 to schedule a consultation.







