


TISSUE SOURCING  
CELL ISOLATION AND CRYOPRESERVATION  
GMP MANUFACTURING  
CLINICAL TRIAL SUPPORT



OrganaBio's vertically integrated capabilities and data-driven operations facilitate the ability to move quickly and work with a single partner who can scale with your program. From tissue sourcing, contract process development and manufacturing, to supporting clinical trial management, our client-focused team and purpose-built infrastructure are specifically designed to support global drug developers throughout all stages of the therapeutic development lifecycle. With strategically placed tissue collection and cell processing centers, coupled with in-house, advanced cell isolation and cryopreservation capabilities, OrganaBio is poised to support all phases of clinical development and commercialization.



**JUSTIN IRIZARRY**  
CEO, OrganaBio

# 500+ Combined Years of Experience

Our team has 500+ combined years of “in the field” experience working in a range of environments, from academic institutions to start-ups, small and large biotech, and pharmaceutical enterprises.

# 1,000+ Birth Tissue and Apheresis Donors

OrganaBio provides access to over 1,000 qualified donors for birth tissue and apheresis materials. Our pool of recallable donors grows weekly as we actively screen and qualify more donors.



The Cell and Gene Therapy (CGT) industry is highly dynamic and requires agility and flexible solutions. OrganaBio grants its clients unique access to critical resources and solutions for CGT developers, catalyzing clinical translation and commercialization of life-altering and lifesaving cures. Founded in 2018, OrganaBio remains driven to become the central hub for tissue sourcing, cell isolation, GMP manufacturing, clinical sample processing, and crypreservation services to support CGT of today – and beyond. At its core, OrganaBio continually applies a rigorous data-driven approach to derive meaningful insights across strategically located facilities to deliver results to clients where they matter most.

## The Benefits of Partnering with OrganaBio

- **Client-Centric:** Focus on meeting each client’s unique specifications through a high-touch model, custom-built products and services, and rapid turnaround time (TAT) for all inquiries and projects.
- **Agile & Scalable:** Leverage vertical integration of business units to quickly pivot, meeting client’s current demands and scaling requirements from preclinical to commercialization.
- **Data-Driven:** Apply best-in-class service through continual, data-driven processes that seek optimal outcomes while mitigating risks and predicting desired results. This is achieved through hyper-control, sterling delivery rates, and on-time, in-full (OTIF) completion for all services.



# The Central Hub to Support CGT of Today, and Beyond



# Strategic Locations

With a bicoastal presence, OrganaBio offers flexibility, customization, and unparalleled TAT. In addition, OrganaBio can provide access to highly diverse populations of clinical trial participants and donor tissues. OrganaBio has multiple locations across the country in close proximity with clinical trial epicenters to shorten time from sample collection to processing and cryopreservation. OrganaBio plans to expand its reach to at least five more locations to create additional capacity for therapeutic developers. These locations are **Houston, Chicago, Detroit, Nashville, and Atlanta.**

## Irvine

- Cell Processing
- Cryopreservation
- Dedicated Long-Term Storage

## Miami

- Birth Tissue Collection Network
- Leukapheresis Center
- Cell Processing
- Cryopreservation
- Dedicated Long-Term Storage
- ISO 7 Cleanrooms for current good manufacturing practices (cGMP) Manufacturing
- QC/Analytical Testing core

## Our Clients

OrganaBio dedicates its advanced expertise and facilities to help pharmaceutical and biotechnology companies of all sizes to scale towards commercialization. By understanding the criticality of proper methodologies and tight timelines, sponsors of clinical trials and auxiliary stakeholders, such as investors and data analysts, partner with OrganaBio throughout all stages of their drug development – from preclinical to commercialization of next-generation therapeutics. OrganaBio's clients are comprised of three distinct categories, and they are:

- **Cell Processing & Cryopreservation Services (CPC Services):** Contract Research Organizations, Pharmaceutical Companies, and Biotechnology firms with assets in clinical trials.
- **Sourcing of Critical Tissue and Cellular Starting/Raw Materials:** Developers of CGT therapies from preclinical development through commercialization of next-generation drugs.
- **Contract Development and Manufacturing Organization (CDMO):** Early-stage companies with drug candidates in early-phase development, developers entering Phase I or II clinical trials, and biomedical researchers requiring customization and internal expertise with industry-specific infrastructure.

OUR CLIENTS



## The CGT Ecosystem

Change is perennial for the CGT industry and drug developers need to quickly adapt and stay at the forefront of innovation. By leveraging OrganaBio's portfolio of solutions for next-generation therapeutics and keen industry acumen, drug developers can stay ahead of emerging healthcare trends.

### How OrganaBio Addresses Industry Pain Points:

- Scalability & Speed
- Data and Analytics
- Serving Larger Patient Populations
- Rapid Delivery & The One Partner Approach

**By staying at the forefront of industry trends, OrganaBio develops solutions for impediments to CGT progress.**





# Cell Processing & Cryopreservation (CPC) Services

Rapid sample processing ensures safety, quality of product, compliance, and data integrity. From acting as a cell processing hub for clinical trial samples to cryopreservation and cold chain logistics, OrganaBio offers its partners cell processing & cryopreservation services that enable speed and flexibility for CGT and vaccine clinical trials.

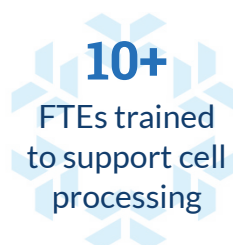
- Meet clinical timelines with ease
- Achieve geographic and demographic diversity
- Cell isolation and processing
- Assay development, analytical testing, and validation
- Cryopreservation for autologous and allogenic use
- Storage and logistics

**"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*

## Demonstrated Success

OrganaBio's unique Hub Processing model is vital to the success of Sponsors' clinical trial collection and processing function for immediate onsite processing and subsequent cryopreservation of participant samples. The function is performed more efficiently and faster than the required six-hour window, ensuring consistency and validity of sample viability data. OrganaBio's client-centric and data-driven approach enables seamless operation and timely delivery of crucial clinical trial participant samples.





# Tissue Sourcing & Catalog Products

OrganaBio provides adult leukapheresis products from a diverse and engaged donor pool, Peripheral Blood Mononuclear Cells (PBMCs), ethically sourced birth tissue, cord blood-derived hematopoietic stem cells (HSCs), and immune cells to enable pharmaceutical companies to develop and manufacture innovative cell therapies and vaccines.

- LeukoPAC™ Apheresis-Derived Products
- HematoPAC™ HSCs and Cord Blood
- ImmunoPAC™ Cord Blood-Derived Immune Cells
- NeoPAC™ Umbilical Cord and Placenta Tissue
- MesenPAC™ MSCs and Paired Bioprocess Media



SOURCING & PRODUCTS

LeukoPAC™	LeukoPAC-FRSH	Healthy adult peripheral blood-derived leukopak, fresh
	LeukoPAC-FRZN	Healthy adult peripheral blood-derived leukopak, cryopreserved
	LeukoPAC-PBMC-PB	Healthy adult leukapheresis-derived mononuclear cells
	LeukoPAC-T-PB	Healthy adult leukapheresis-derived T cells
	LeukoPAC-NK-PB	Healthy adult leukapheresis-derived Natural Killer cells
HematoPAC™	HematoPAC-HSC-CB	Umbilical cord blood-derived Hematopoietic Stem Cells
	HematoPAC-CB-FRSH	Human umbilical cord blood from healthy, full-term births
ImmunoPAC™	ImmunoPAC-T-CB	Umbilical cord blood-derived T cells
	ImmunoPAC-NK-CB	Umbilical cord blood-derived Natural Killer cells
NeoPAC™	NeoPAC-PL	Human placenta from healthy, full-term births
	NeoPAC-UC	Human umbilical cord from healthy, full-term births
	NeoPAC-PL-UC	Human placenta and umbilical cord from healthy, full-term births
MesenPAC™	MesenPAC-MSCs	Placenta-, or umbilical cord-derived Mesenchymal Stromal Cells
	GroPAC-MSC-CGM	Optimized complete growth medium for MesenPAC™-MSCs in a batch 2D process

Experts committed  
to our One Partner  
Approach



# Contract Development and Manufacturing Organization (CDMO)

OrganaBio's flexible process development capabilities and internal manufacturing services leverage inherent CGT expertise through the medium of contract or hybrid manufacturing. These capabilities are bolstered by a cGMP-compliant, state of the art, 19,000 square foot facility – catalyzing the clinical translation of cell and gene therapies.

## cGMP Facility Features

- Controlled and secured access to ISO 7 cleanrooms (with ISO 5 BSCs) and individual HVACs with 24-hour environmental monitoring
- Analytical testing (QC) core
- Part 11 compliant eQMS
- Cold-storage space, materials receipt, warehousing, and inventory control

## Process Development Services

- Consistent processing for RUO and GMP equivalents
- All processes performed under approved SOPs and Batch Records and reviewed by Lab Director and quality
- Quality management systems

## Consultative Services

- Quality assurance
- Environmental monitoring
- Regulatory expertise
- Logistics
- Information technology

- Assay development and quality control
- Qualified vendors, reagents, and materials

## How We Work

OrganaBio is committed to strengthening and accelerating the deployment and commercialization of cell-based therapies. By simplifying technology transfer and scale-up between preclinical and translational phases through commercialization, OrganaBio has pioneered a unique end-to-end solution that spans research and discovery to cGMP-compliant manufacturing.

## Unique Benefits

- **Rapid turnaround time:** Work can begin in as little as 24 hours from ideation to execution.
- **High quality products:** Reduces failure rates, speeds up production time, and creates superior results.
- **High touch:** Extensive experience across a broad spectrum of cell types and manufacturing platforms, providing fully tailored process development, cGMP manufacturing, and analytical testing services and solutions.
- **Donor recruitment and tissue sourcing:** Diverse and highly recallable donor pool managed; ability to customize donor recruitment and testing to meet specific program needs.





## Vertical Integration

OrganaBio is the nexus for rapid tissue sourcing, cell processing, manufacturing, and cryopreservation services. Our vertically integrated business model allows for faster turnaround times, quality and regulatory assurance, and advanced data tracking. By having a completely in-house and integrated supply chain from start to finish, **OrganaBio is the one source needed for all next-generation therapeutics – cell and gene therapies, vaccines, and regenerative medicine.**

Partners can advance their programs knowing that OrganaBio's unique, vertically integrated model will mature and scale alongside them at each phase.



▼  
**Tissue Sourcing**

▼  
**Cell Isolation and  
Cryopreservation**

▼  
**GMP Manufacturing**

▼  
**Clinical Trial Support**

▼  
**CUSTOMERS**



## Data-Driven Processes

OrganaBio maintains their best-in-class service through a continual data-driven process that seeks optimal outcomes for their clients, while mitigating risks and predicting desired results. OrganaBio delivers excellence that is repeatable, predictable, and measured at every step. Clients benefit from OrganaBio's data-driven approach in terms of hyper-control, sterling delivery rates, and OTIF for all services rendered.



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delivers excellence  
that is repeatable,  
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DATA-DRIVEN  
PROCESSES



Benefits of OrganaBio's data-driven approach include hyper-control over processes and products, meeting milestones on tight deadlines, and delivery timelines for OTIF outcomes. By constantly striving to be at the forefront of the industry with quality, logistics, and sustainability, OrganaBio aims to be on the cutting edge of regenerative medicine and next generation therapies.

## Client-Centric

OrganaBio has a strategy and a culture of doing business that focuses on creating the best experience for clients, and, as a result, builds brand loyalty. Clients' needs are at the center of the business's philosophy, operations, and product/service portfolio. These are exhibited by a high-touch model, products and services that are purpose-built for custom needs, as well as rapid TAT for all inquiries and projects.

OrganaBio's vertically integrated business and processing models are designed to quickly pivot as clients' demands change and projects scale from preclinical to commercialization. In a productive and cost-effective way, OrganaBio has rapidly deployable resources and project management teams that have been pressure-tested to deliver results without compromising quality.

## Quality & Regulatory Assurance

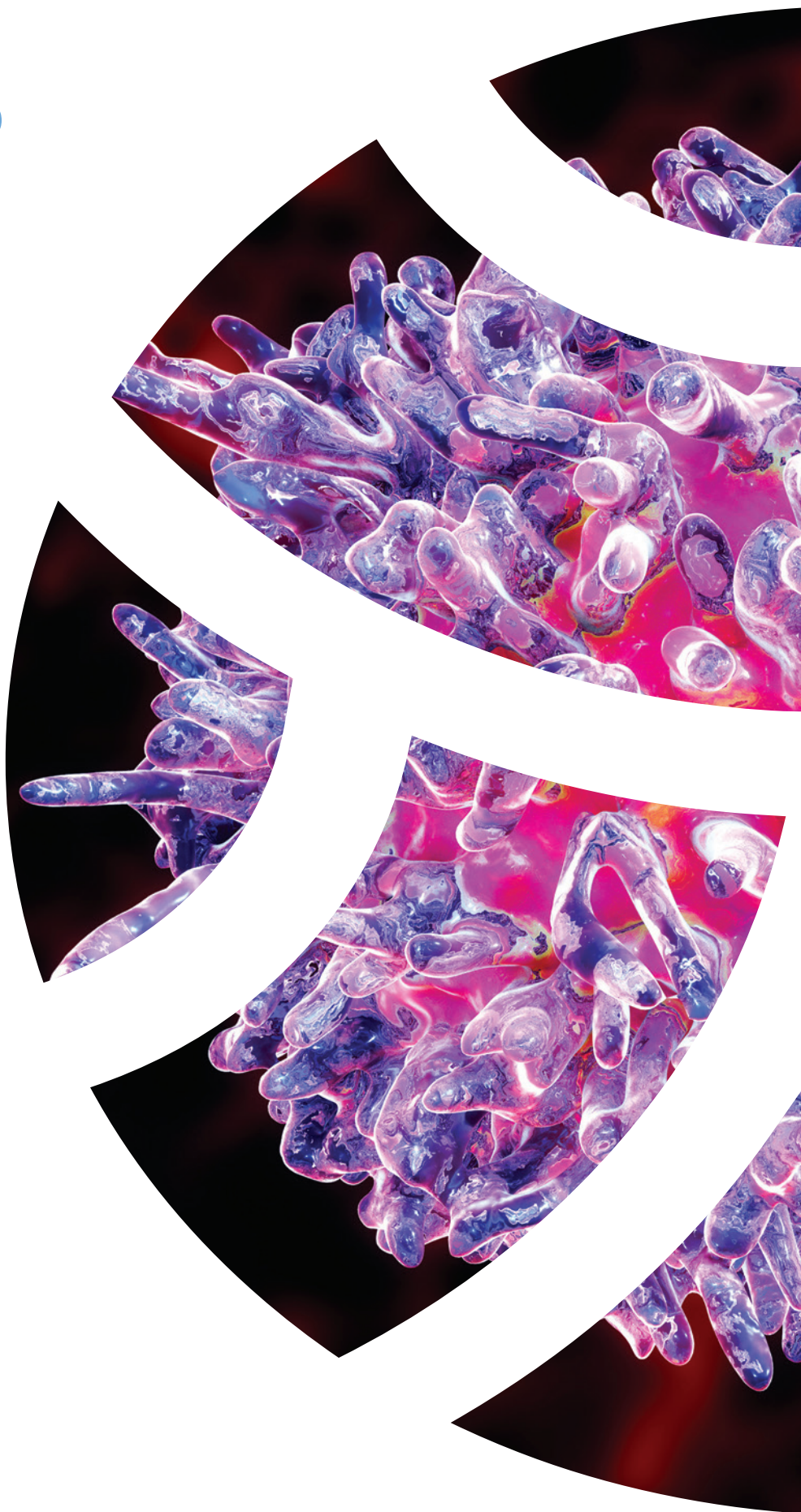
OrganaBio prioritizes quality in all aspects of its business, including ethics within its tissue sourcing process. OrganaBio offers both Research Use Only (RUO) and cGMP tissues and cells for clinical trials, including but not limited to: cancer research, immunotherapy, cell therapy, tissue engineering, vaccines, and regenerative medicine therapeutic developers. All tissues are ethically sourced from fully consented, healthy donors who have been recruited, screened, and qualified under the Institutional Review Board (IRB), with approved protocols and in accordance with US FDA 21 CFR 1271. All perinatal tissues are collected in adherence to the American College of Obstetrics and Gynecology (ACOG) delayed cord clamping guidelines and sourced from mothers who have consented weeks before delivery. OrganaBio's wholly owned tissue supply subsidiaries, OrganaBio, GaiaGift and HemaCenter, are FDA-registered blood and tissue establishments. OrganaBio has been carefully, critically, and successfully FDA inspected and approved for all regulations and in accordance with federal law.







QUALITY &  
REGULATORY  
ASSURANCE



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