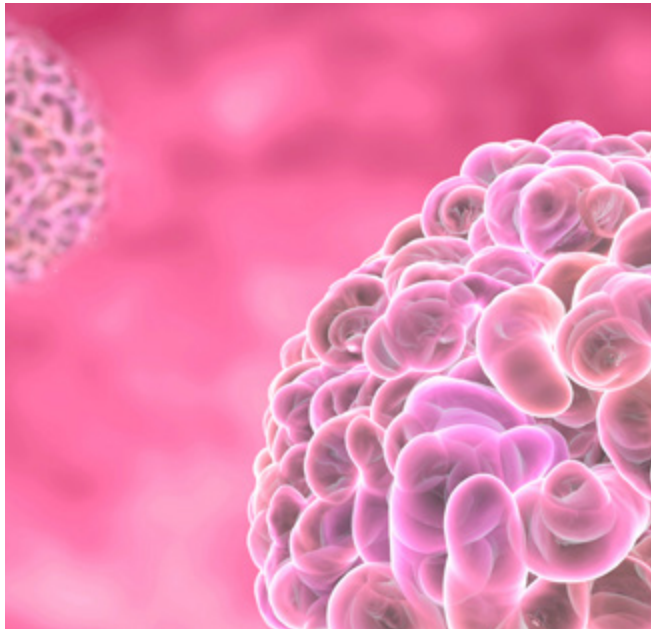
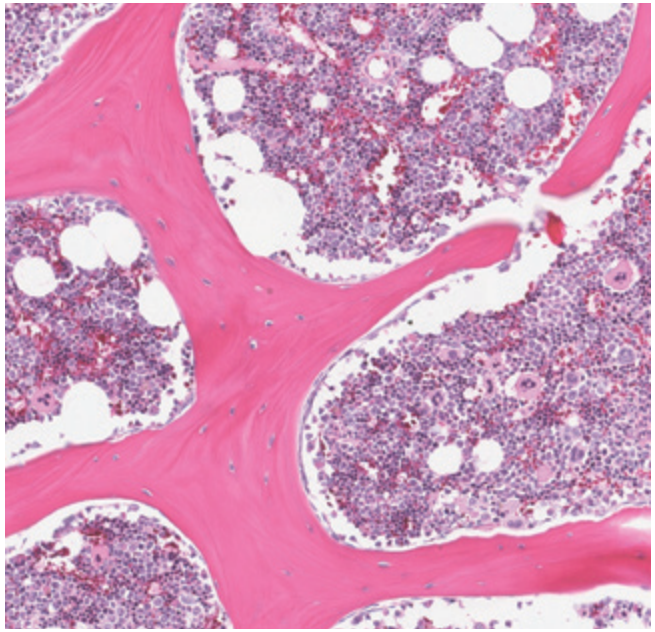
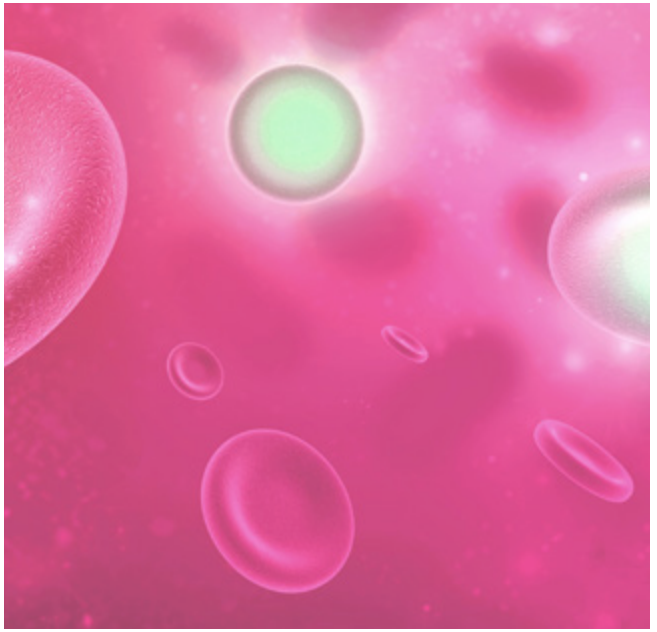
ALLCELLS®

Quality Cells for Quality Science







GMP PRODUCT CATALOG 2022

ALLCELLS®

Increasing Need for High Quality GMP Raw Material to Support the Cell and Gene Therapy Industry

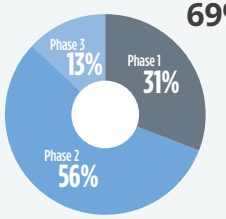
The global cell and gene therapy (CGT) clinical trials market size is rapidly expanding and expected to reach USD 45.4 billion by 2028. As more allogeneic therapeutics transition from the laboratory to late-stage clinical trials and beyond, CGT candidates must meet stringent regulatory requirements, which starts with the raw cellular material acquired from donors.

With a lack of standardization of starting raw cellular materials, choosing a supplier with expertise in GMP-specific regulatory requirements for donor selection and tissue processing, enabling a seamless transition into clinical trials and commercialization. As only a few GMP suppliers understand the complexity of the supply chain logistics and are able to navigate through the challenges, securing a trusted partner early on in the process eases development and paves the way for successful approval without costly delays.

Cell and Gene Therapy Market Trends

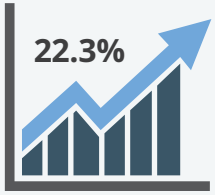
1,220 CGT Clinical Trials in 2020

69% in Phase 2/3



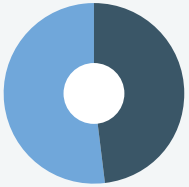
Data: Alliance for Regenerative Medicine 2020 Report

CAGR 2021 to 2028

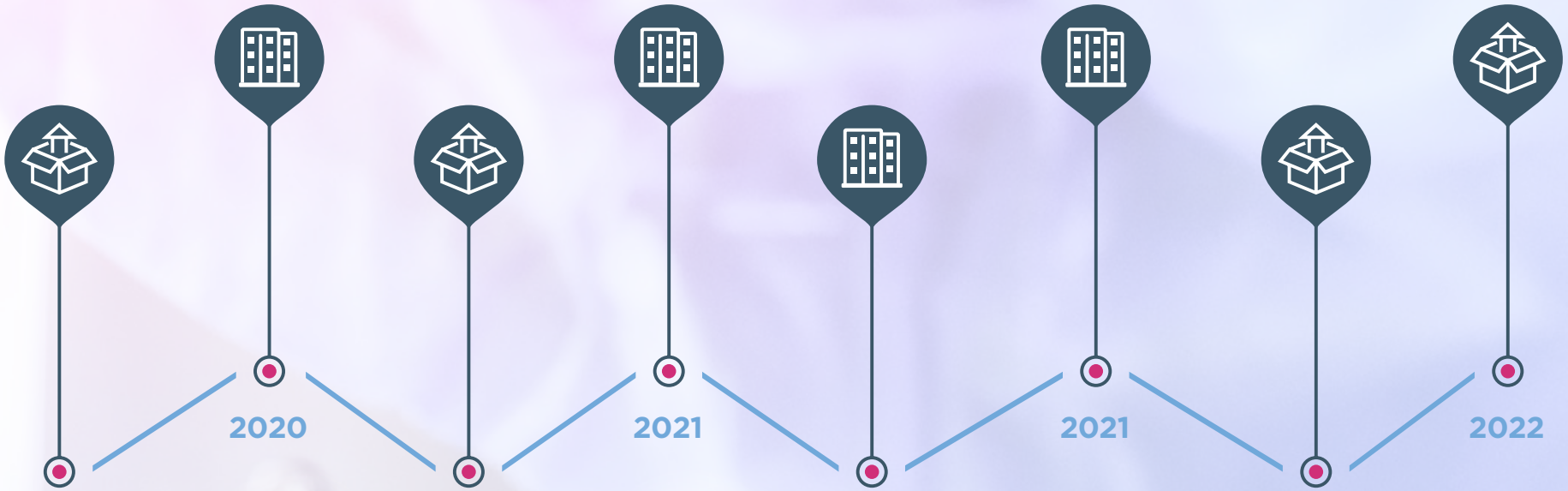


$45.4 billion
by 2028

48.3% CGT market share in North America



AllCells is continuously at the forefront of the market requirements providing the highest quality products and services.



2016

PRODUCT RELEASE

GMP-compliant Fresh Leukopak and Bone Marrow Aspirate

2020

FACILITIES EXPANSION

Expanded capability for whole leukopak cryopreservation

2020

PRODUCT RELEASE

Research Use Only Cryopreserved Leukopak

2021

FACILITIES EXPANSION

Completion of Class A and B GMP-compliant cleanroom

2021

FACILITIES EXPANSION

Addition of donor collection facility in Houston

2021

FACILITIES EXPANSION

Expanded capability of donor collection facility in Quincy for GMP-compliant fresh product

2021

PRODUCT RELEASE

GMP-compliant Cryopreserved Leukopak

2022

PRODUCT RELEASE

GMP-compliant PBMCs

more to come...

Qualified & Reliable

GMP-COMPLIANT CRYOPRESERVED LEUKOPAK

- High cell viability and cell recovery product
- Scalable and flexible supplier
- Dependable cold chain logistics

NOW AVAILABLE

ALLCELLS®

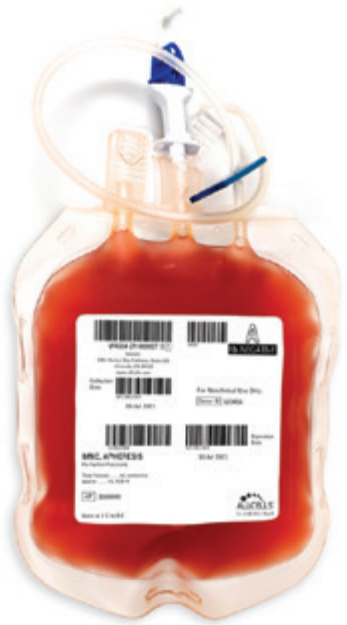
Quality Cells for Quality Science

Fresh GMP-compliant Leukopak

A leukopak is an enriched leukapheresis product collected from normal peripheral blood, which contains a concentrated fraction of mononuclear cells like lymphocytes and monocytes. Ideal for regenerative medicine and cell therapy applications requiring isolated hematopoietic stem cells (HSCs) and immune cells (i.e., T cells, NK cells) (Fig 1).

AllCells' GMP-compliant Leukopak products are collected are collected from qualified, healthy and consenting donors per IRB-approved protocols by our team of experienced clinicians and processed in our FDA-registered, GMP-compliant and accredited collection and processing clean room facilities. Stringent quality systems ensure r egulatory compliance requirements are met. All our GMP-compliant products are subjected to an extensive quality review and are provided with supporting extended documentation during batch release.

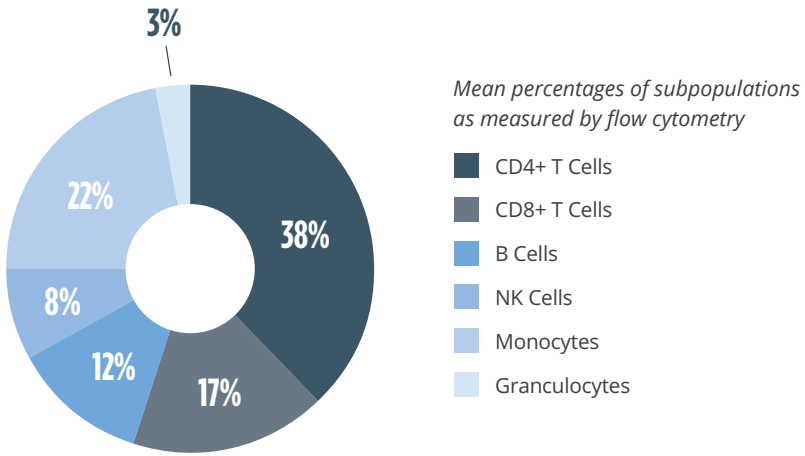
GMP-compliant Leukopaks are collected from healthy human donors using the Spectra Optia Apheresis System directly into ACD-A anticoagulant. GMP-compliant Leukopak products are quality controlled for: volume, viability, total nucleated cell count, and sterility (USP71). The product is shipped using a validated shipping container.



SPECIFICATIONS

- Anti-coagulant: ACD-A
- Volume: ≥280mL
- Viability: ≥90%
- TNC Concentration (x106 cells/mL): ≥26
- Sterility Test (USP71): No growth
- Shipping: Validated shipping container

Fig 1: Cell Supopulations in Fresh Leukopak



Product Portfolio

GMP-compliant Cryopreserved Leukopak

CRYOPRESERVED LEUKOPAKS DEMONSTRATE COMPARABILITY TO FRESH LEUKOPAKS

In studies comparing fresh and post-thaw cryopreserved Leukopaks, cell count (Fig 2a) and viability (Fig 2b) as well as the mean percent of subpopulations (T cells, B cells, NK cells and monocytes) (Fig 2c) were comparable.

SPECIFICATIONS

- Anti-coagulant: ACD-A
- Format: 70mL CS250 bag with 2 retention vials*
- Pre-cryopreservation Total Nucleated Cell count per bag: ≥2.5 Billion cells
- Cryopreservation media: CS10*
- Pre-cryopreservation viability %: ≥95
- Sterility Test (USP71): No growth
- Shipping: GMP-compliant shipping container

** customization available*

Fig 2a: Average % Viability
Pre-Freeze vs. Post-Thaw

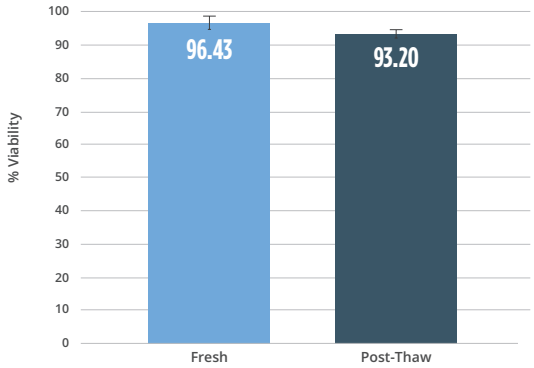


Fig 2b: Average Viable Cell Count
Pre-Freeze vs. Post-Thaw

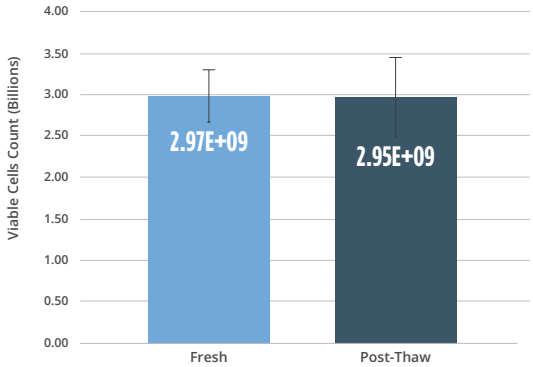
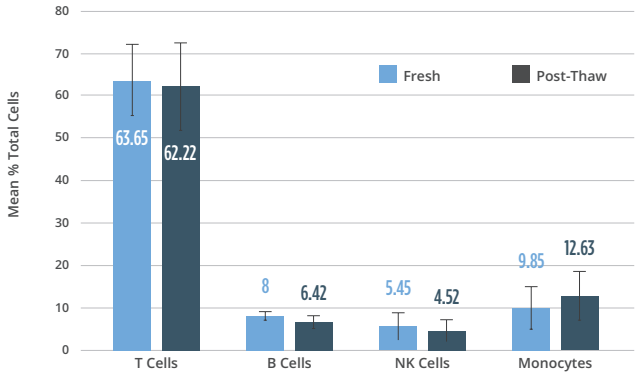
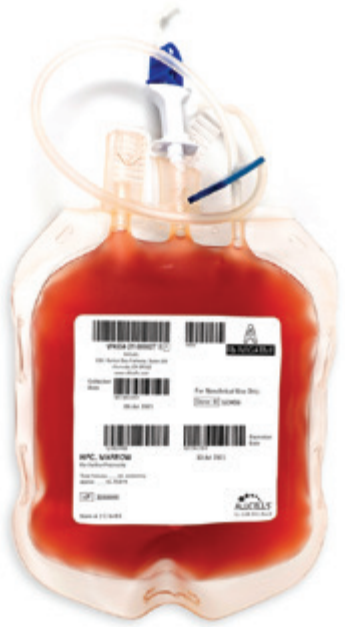


Fig 2c: Distribution of Cell Subpopulations
Pre-Freeze vs. Post-Thaw



GMP-compliant Bone Marrow

Bone Marrow aspirate products are a rich source of CD34+ cells, Mesenchymal Stem Cells (MSCs) and other leukocytes. GMP-compliant Bone Marrow is collected from healthy, human donors by needle aspiration from the posterior iliac crest with heparin. GMP-compliant bone marrow products are quality controlled for: volume, viability, total nucleated cell count, and sterility (USP71). Available in fresh format only.



SPECIFICATIONS

- Anti-coagulant: Heparin
- Volume: 100mL
- Viability: ≥90%
- TNC Concentration (x106 cells/mL): ≥8
- Sterility Test (USP71): No growth
- Shipping: Validated shipping container

PRODUCT UPDATE

We have recently implemented a proprietary process change to improve our bone marrow aspiration protocol that delivers a higher viable Total Nucleated Cells (TNCs) and CD34+ yield from a single donor ensuring sufficient cells for your downstream workflow, minimizing experimental variability, compared to our previous protocol (Table 1). Additionally, this method reduces cell contamination from red blood cells and granulocytes. Overall, these are attributed to a higher quality bone marrow aspirate product.

Table 1

NUMBER OF SAMPLES WITH:	PREVIOUS METHOD (N=28)	NEW METHOD (N=29)	CONCLUSION
≥ 15 million TNCs/mL	50%	86%	**72%** increase in donor samples with more than 15 million TNCs/mL
≥ 20 million TNCs/mL	18%	45%	**150%** increase in donor samples with more than 20 million TNCs/mL

High Quality Starting Material

FOR YOUR PRECLINICAL TO COMMERCIAL APPLICATIONS

AllCells maintains the same high quality material and stringent protocols for both RUO and GMP-compliant products to provide end-to-end solutions for the entire cell therapy workflow. AllCells GMP products provide a seamless transition from Research-Grade products with minimal variability.

	PRE-CLINICAL PHASE RESEARCH USE ONLY	CLINICAL PHASES I / II / III GMP-COMPLIANT MATERIAL	COMMERCIALIZATION GMP-COMPLIANT MATERIAL
Donor Assessment and Testing	Eligible donors are screened against HIV, Hepatitis B, and Hepatitis C.	Donors are subject to viral testing per FDA-mandated 21 CFR 1271 as well as CDC, NIH, and AABB recommendations. Donors also undergo a MD-administered physical exam.	
Donor Consent (IRB Approved)	For research use only.	For commercial and research use.	
Operational SOPs	Validated SOPs/e-batch records.	GMP operational SOPs and extensive batch records.	
Regulatory Compliance	Research Use Only	GMP/GTP, 21 CFR 1271 Parts A–C.	
Quality	E-documentation, product specifications based on process experience, certificate of analysis.	QMS-governed GMP documentation e.g. batch records, equipment validation, stability studies, to support product for further manipulation.	
Processing Facility	GMP-like collection and processing facilities.	Class A and B clean room.	
Packaging Protocol and Packaging	Commercial Grade	Packaging validated to ISTA standards including temperature logger.	
Sterility Testing	Bioburden Test (Cryo products only)	Sterility Testing (USP71)	

For Your Preclinical to Commercial Applications

RELIABLE AND TRUSTED GMP SUPPLIER

With over 5 years of GMP expertise and over 20 years in the industry, AllCells is your reliable and trusted supplier of high-quality GMP compliant starting material to support your cell therapy commercialization journey.

ROBUST AND ASSURED SUPPLY CHAIN

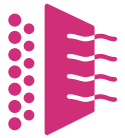
AllCells' dynamic and continuously expanding donor pool and facilities provides you continuous and assured access to high-quality starting material to support scalability throughout your product lifecycle.

INTEGRATED PROJECT MANAGEMENT

Our dedicated GMP team of scientists, clinicians, quality and logistics experts will partner with you to define, design and manage your project to deliver a product that meets your specific needs.

LARGEST RECALLABLE GMP DONOR DATABASE

AllCells cultivates the largest repository of healthy, recallable donors to fulfill a diversity of clinical parameters selected in compliance with FDA current Good Tissue Practices (cGTP) regulations under 21 CFR 1271.



GMP-compliant
Clean Room

FDA-registered,
AABB Compliance

Extended Virals

Competitive
Pricing

Donor Management Services

Recruitment
Ongoing and client-specific donor recruitment efforts.

Screening
Standard viral screening and/or client-specific protocols.

Monitoring
Premier access to AllCells donor database to identify donors with study-specific attributes.

Retention
Active donor engagement to foster repeat/recallable donors; maintain minimum client-specific donor pool size.

MEETING YOUR SPECIFIC DONOR REQUIREMENTS

At AllCells, we understand that donors meeting the stringent regulatory criteria is just as critical as meeting the specific project needs for the success of the product and subsequent application. We maintain an exclusive and GMP-qualified donor pool that is highly characterized from viral screening to HLA typing and beyond in order to ensure that we are able to meet certain required criteria. We have developed and use proprietary software that enables us to optimize our processes from recruitment, screening, monitoring and retention, ultimately empowering us to provide the right donor for every project with the shortest lead times in the market.

Our diverse, dynamic and continuously expanding donor pool enables AllCells to provide the match customers need to successfully complete their study.

- Healthy Donors
- Recallable, repeat or unique donors
- HLA type (low and high resolution)
- CMV status (negative or positive)
- Blood type
- Demographics (gender, age, ethnicity)
- Specific lifestyle characteristics (BMI, smoking status, and more)
- Additional custom criteria (screening or testing)
- Dedicated donor pools

All collections are from donors who are qualified for participation in accordance with the IRB approved informed consents and meet AllCells' quality standards.

The Right Donors for Every Project

PREMIER ACCESS TO OUR DONOR REPOSITORY

AllCells has the largest, most diverse donor pool in the industry, with three facilities strategically located in the Bay Area, California, Boston, Massachusetts, and Houston, Texas.

- FDA registered, AABB-compliant facilities
- Experienced technical and clinical team
- Strict IRB compliance, regulatory oversight
- Donors meeting FDA 21 CFR 1271 requirements

ALLCELLS®

Quality Cells for Quality Science

AllCells Alameda
1301 Harbor Bay Parkway, Suite 200
Alameda, California 94502

AllCells Quincy
1250 Hancock Street, Suite 120S
Quincy, Massachusetts 02169

AllCells Houston
3509 Elgin Street, Suite 300
Houston, Texas 77004

510.726.2700
orders@allcells.com
www.allcells.com