



GMP
COMPLIANT
ALLOGENEIC
CLINICAL
PRODUCTS





GMP Compliant Allogeneic Clinical Grade Provider.

AllCells is the leading provider of high quality human primary cells from peripheral blood and bone marrow.

AllCells collects from bi-coastal owned and operated LeukoLab – Donor Care and Management Facilities. Clinical grade products are collected and processed in our California facilities.

We partner with global life science researchers and bio-manufacturing organizations to develop immunotherapies, vaccines, and cell and gene therapy starting material.



AllCells Clinical Grade product line is for further manufacturing of allogeneic cell based therapies.



DONOR SCREENING & TISSUE COLLECTION

Donors from our extensive research donor pool are further qualified for donation of clinical grade products through extensive FDA specified viral screening by CLIA approved laboratories, AABB derived health history verifications and physical assessments completed by our medical team.

We value our donor's privacy and follow strict HIPAA guidelines to safeguard their personal information. We also obtain their consent through processes outlined by the NIH and approved by an independent IRB.

AllCells IRB approved screening protocols are adaptable to your scientific requirements.

AllCells rigorous screening limits the risk of donor failures and the potential expense of not being able to utilize your internal or outsourced production capacity.



SUPERIOR QUALITY

Meeting specific operational requirements, selecting and reserving quality donors, and navigating the complexities of critical supply chain logistics are all addressed during our consultative approach to ensure superior quality.

AllCells comprehensive operational facility SOPs, QMS, QAAs, documented training, GMP collection documentation, localized chain of custody from donor to shipment, validated release assays, compendial testing, rigorous QA review and demonstrated stability; provide the assurances needed.

Global Experience, with a Proven Team Approach.

Experienced in Clinical Grade Collections, AllCells has developed a proven approach to delivering Clinical Grade cells with the highest level of compliance.

1. Donor pool: Active, recallable, healthy, and diverse.
2. Customized to your needs.
3. Project Management with a team approach.
4. Experienced in delivering GMP/GTP compliant Clinical Grade products for allogeneic use to customers around the world.

CLINICAL GRADE PRODUCT OFFERINGS

Fresh Whole Bone Marrow

A rich source of adult stem cells such as CD34+ hematopoietic stem and progenitor cells. Cells from Bone Marrow have shown to have therapeutic potential in translational and regenerative medicine.

Fresh Leukopak

Containing a high concentration of all major lymphocyte populations, T cells, B cells, NK cells and monocytes.

High-quality starting materials are the foundation for downstream process development.

At AllCells, we test sterility of Bone Marrow and Leukopak Clinical Grade products through compendial testing by qualified laboratories.

At AllCells, our validated, small format recyclable packaging eliminates risk of transient temperature excursions during shipment from AllCells, California to your facility or CMO, world-wide.



AEROSAFE PACKAGE

AllCells has partnered with AeroSafe Global to provide a validated, insulated and reusable shipping packaging in accordance with ISTA 7D standards in summer and winter profiles. The AeroSafe shipping package will maintain a safe temperature range to ensure that the highest quality

primary cell products are protected, with the integrity and viability that you have come to expect from AllCells.

Product Quality: Shipping temperature range maintained for up to 96 hours after packaging.

Sustainable Shipping: Reusable and recyclable packaging components reduce landfill and disposal within your facility.

Integrity: Proven package integrity – over \$9 billion dollars' worth of valuable product shipped in this configuration with no excursions from AeroSafe.

Learn more at www.allcells.com

Cell and Gene Therapy starting material requires extensive quality assurance documentation. AllCells GMP-Compliant products follow rigorous quality system oversight that meet all regulatory standards and protocols.

AllCells Advanced Capabilities and Quality Systems - Define the Difference:

- Donor Qualification
- Optimized Apheresis Cell Collections
- Vendor, Materials, and Equipment Qualification
- Validation and Maintenance Protocols
- Controlled Documentation and Record Management
- Temperature and Environmental Monitoring
- Continued Process Improvement Protocols

+ Products intended for further manufacturing to support clinical and commercial use.

REGULATORY OVERSIGHT

Comprehensive understand of both FDA and EU regulations for the collection of tissues and cells for human application. Donors are screened and tissues are collected in accordance with GMP, FDA, CFR 21CFR1271 and EU directives 2004/23/EC and 2006/17/EC.



AllCells Alameda

1301 Harbor Bay Parkway
Suite 200
Alameda, CA 94502
510.726.2700

AllCells Quincy

500 Congress Street
Unit 1A
Quincy, MA 02169

info@allcells.com
www.allcells.com