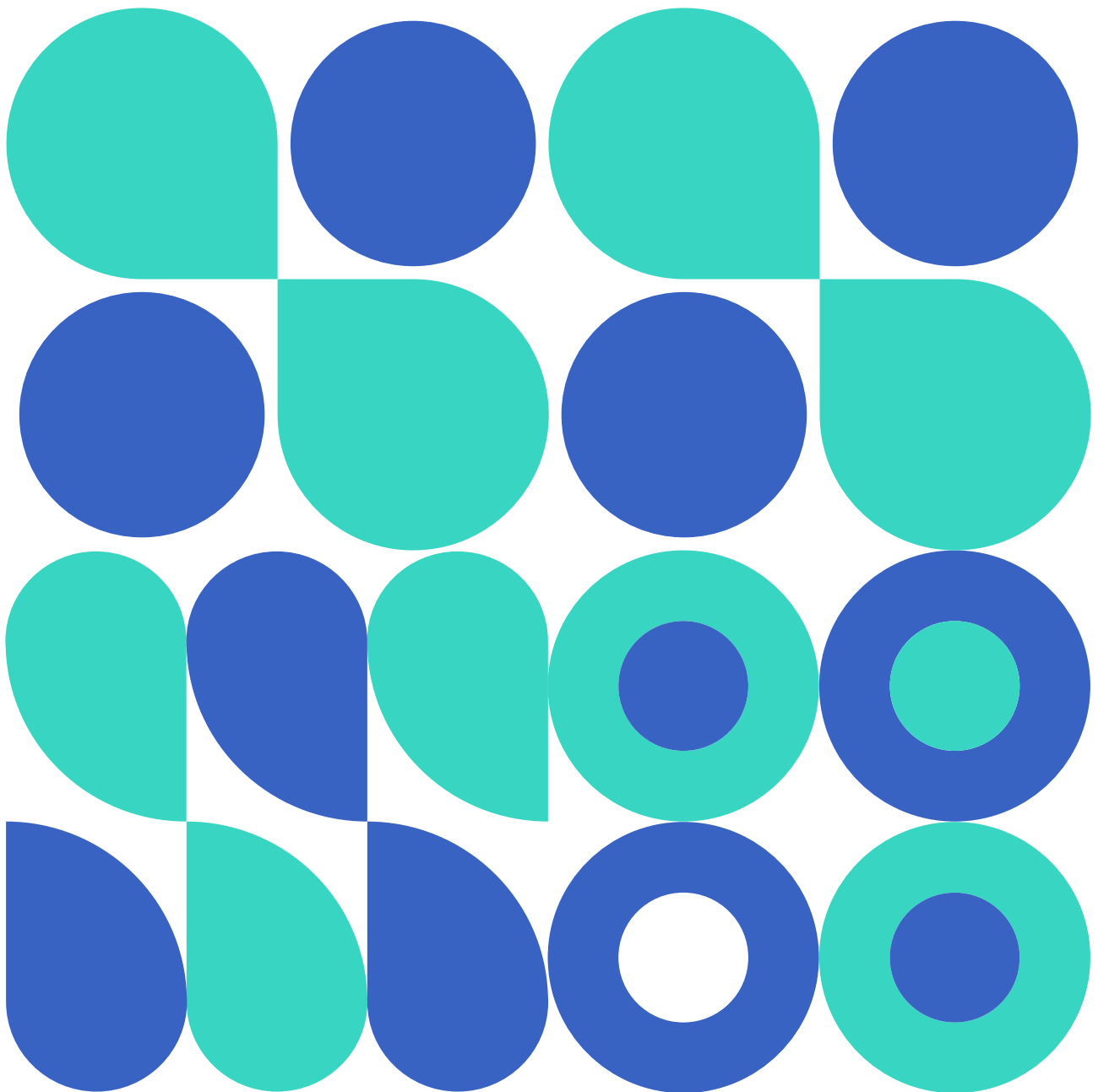


Human Biological Materials for Cell and Gene Therapy Manufacturing

BioSupplies

Biological material solutions

Cell Therapy



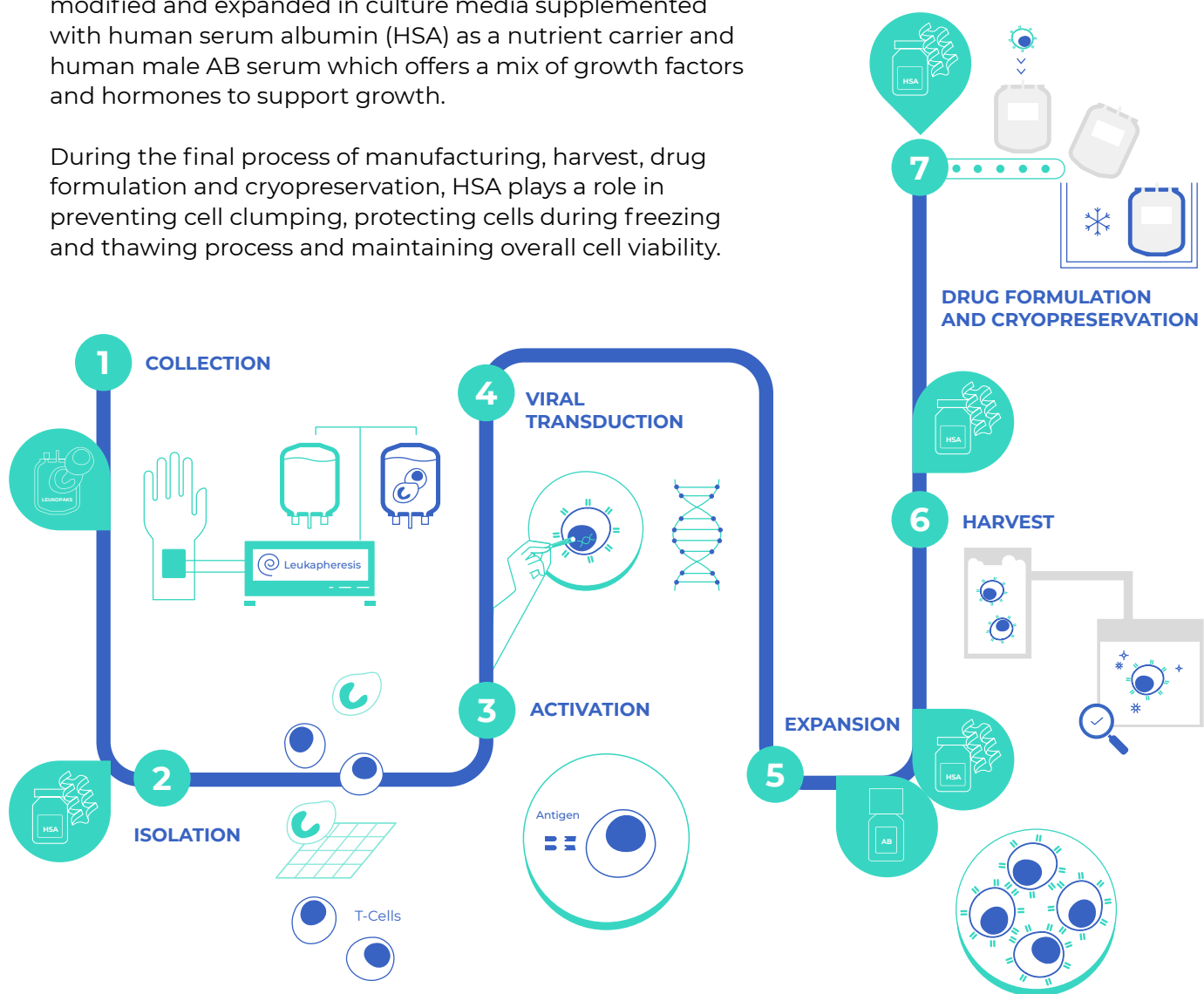
GRIFOLS

Human Biological Materials for Cell and Gene Therapy Manufacturing

In the evolving global landscape of cell therapy development, selecting human raw materials is crucial to ensure the quality, efficacy, and safety of these treatments.

Leukopaks are the starting point in the collection and isolation of immune cells. These cells are then activated and modified and expanded in culture media supplemented with human serum albumin (HSA) as a nutrient carrier and human male AB serum which offers a mix of growth factors and hormones to support growth.

During the final process of manufacturing, harvest, drug formulation and cryopreservation, HSA plays a role in preventing cell clumping, protecting cells during freezing and thawing process and maintaining overall cell viability.



Grifols: Your Partner in Cell Therapy

FROM PHARMA TO PHARMA. FROM SCIENCE TO SOLUTIONS

At Grifols Bio Supplies, we believe cell therapy is the future of medicine. Backed by 115+ years in plasma science, we provide high-quality, ethically sourced biological materials to help pharma and biotech companies develop life-changing therapies.

Our mission is aiming to ensure every patient, anywhere, can access the best therapies to improve their health and quality of life. This is why we supply trusted human-derived materials that accelerate cell therapy research and development.

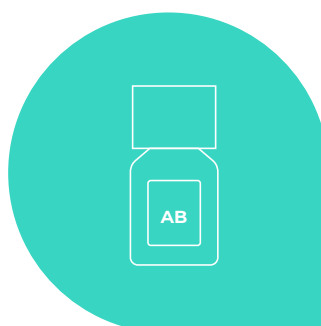
As a leading pharmaceutical company specialized in human biological materials, we stand for excellence, safety, innovation, collaboration, and community – values that guide our work and ensure reliability and safety for our clients.

To accelerate cell therapy, we rely on two main product lines:



CELL SOURCING

Providing a reliable and scalable cell supply, ensuring consistency, minimizing variability^{1,2} and reducing production delays.



CELL CULTURE SUPPLEMENTS

Optimizing cell culture performance³ and ensuring well-regulated, stable, and efficient conditions for cell expansion.



Apheresis and Human Plasma-Based Materials Supporting Advanced Therapies

CELL SOURCING: LEUKOPAKS

Grifols leukopaks provide a **reliable and well-controlled source of leukapheresis-derived starting materials**, combining **donor oversight, regulatory-aligned testing, and scalable supply** to support advanced therapy programs from research through manufacturing.

KEY ADVANTAGES:

- **Established US and EU donor network**
Sourced from collection centers in the **United States and Europe**, leveraging donors with **prior plasma donation history** to enhance donor knowledge, monitoring, and safety.
- **Supply continuity and donor availability**
Backup donor scheduled for every collection, with **recallable donors** available upon request.
- **Regulatory-aligned donor testing**
All donors are tested for viral markers in line with **US FDA or EMA requirements**.
- **RUO and GMP quality grades**
Available to support development across the full product lifecycle, from research to manufacturing.
- **Documentation provided**
Delivered with certificate of analysis (CoA) and donor demographic information.
- **Flexible product formats**
Available as:
 - **Fresh** – offered in full or half formats
 - **Split**
 - **Cryopreserved**



GMP: Good manufacturing practices
US FDA: United States Food and Drug Association
EMA: European Medical Association

Apheresis and Human Plasma-Based Materials Supporting Advanced Therapies

CELL CULTURE SUPPLEMENTS: HUMAN SERUM ALBUMIN

Grifols human serum albumin (HSA) is manufactured under strict quality standards to provide a highly pure and consistent **therapeutic-grade**, combining broad **regulatory compliance**, **robust global supply** and **comprehensive documentation** to support manufacturing process of cell therapies.

KEY ADVANTAGES:

- o **Dual market release**

Approved and available in **both Europe and the United States**, ensuring broad compliance and global applicability.

- o **Robust supply infrastructure**

Extensive global network of facilities and strong scalability to meet growing demand and support customer production needs.

- o **Therapeutic-grade quality**

Manufactured under EP/USP standards with rigorous safety protocols.

- o **Comprehensive regulatory documentation package**

Enables global regulatory submissions with a full set of documents including CoA, BSE/TSE, nitrosamines, melamines, residual solvents statements, viral safety studies, annually updated plasma master file (PMF), and complete supporting dossiers for IND/MA applications.

- o **Multiple formats**

Supporting transition from early research to large-scale manufacturing with vials and bags. Available as:

- o Vials: 25% HSA in 100-ml bottles
- o Bags: 25% HSA in 100-ml bags



EP/USP: European pharmacopeia/ United states pharmacopeia

BSE: bovine spongiform encephalopathy

TSE: transmissible spongiform encephalopathy

IND: Investigational new drug application

MA: Marketing authorization

Apheresis and Human Plasma-Based Materials Supporting Advanced Therapies

CELL CULTURE SUPPLEMENTS: HUMAN MALE AB SERUM

Grifols human male AB serum provides a **consistent and scalable** human-derived supplement, combining **strict manufacturing controls**, global standard **compliance**, and reliable supply to support robust **cell culture and expansion** processes.

KEY ADVANTAGES:

◦ Biological compatibility and reduced immunoreactivity

- **AB blood type** donor sourcing eliminates anti-A and anti-B antibodies, and **male only donor** collection avoids rhesus factor antibodies, together reducing immunoreactivity and minimizes interference during cell culture
- Reduced immunoreactivity supports improved **cell viability and expansion** resulting in enhanced biocompatibility

◦ Supply and logistic capabilities

A robust global supply with scalable sourcing and production capacity to support development through clinical and commercial manufacturing.

◦ Features supporting safe and consistent cell culture

Male AB serum includes features designed to support safety and consistency in cell therapy cell culture processes, including:

- **Heat inactivation** to reduce complement activity and limit immune-related interference
- **Gamma irradiation** to provide an additional viral-reduction step for applications requiring regulatory-aligned safety

- **Xeno-free product design** based on the use of human thrombin to defibrinate plasma, removing xenogeneic risk while enabling fully human and regulatory-preferred culture conditions

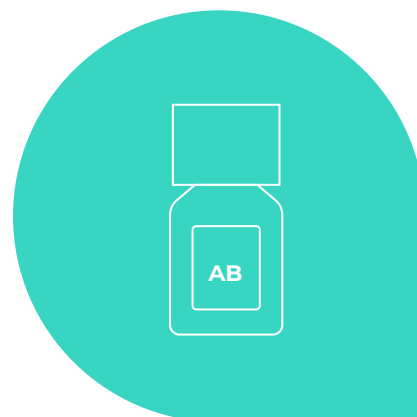
◦ Comprehensive documentation package

Enables global regulatory submissions with a full set of documents including certificates of analysis (CoA), certificates of origin (CoO), safety testing reports, such as viral markers, mycoplasma, endotoxin.

◦ Grade, formats and packaging

Supplied in GMP grade with flexible packaging options:

- 100-mL bottles
- 500-mL bottles



Your Ally in Cell therapy

Quality and Safety

Guided by decades of pharmaceutical experience, Grifols operates with a quality-driven mindset that emphasizes rigorous standards, strong safety oversight, and regulatory awareness. This approach supports consistent product quality, regulatory compliance, and smooth global market access across applications.

- Manufacturing process governed by strict **GMP** protocols and compliance with **US FDA** and **EMA** standards
- End-to-end oversight from donation to delivery, supporting **traceability and quality control** throughout the supply chain
- Comprehensive **regulatory documentation** and product information to support global submissions and smooth market access

Diverse donor network

Grifols Bio Supplies relies on a broad and well-characterized donor network that provides diverse sourcing options, while stringent screening and monitoring support safety, traceability, and flexibility in donor selection.

- **Broad donor network** across multiple collection sites
- **Well-characterized donor profiles** enabling donor selection based on age, sex, HLA type, demographic, CMV status, blood type, and phenotype
- **Recallable donors** and back up donors
- Stringent donor screening, continuous monitoring, and extensive historical data to provide an **extra layer of safety** and traceability

Strong supply capability

Grifols Bio Supplies has a reliable and scalable supply through a robust global infrastructure designed to maintain consistency and quality, supporting the transition from early development to full commercial production.

- Strategic locations in the US and Europe to support **global delivery**
- Robust, **global supply infrastructure** designed to meet the demands of time-sensitive workflows and complex cell therapy workflows

We stand for trust.
The certainty that when
you choose the best,
you are in the best hands.

**Choose Grifols
and enhance your
cell culture processes
with a trusted partner**

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2. Gómez I, Schaffer JM, Winterstein K, et al. Optimizing cell sourcing for cell therapy by reducing donor variability with recallable leukopak donors for enhanced standardization. *Cytotherapy.* 2025;27(5 Suppl):S141.
3. Díez JM. AB male human serum: cell proliferation assays. Barcelona: R&D Bioscience Industrial Group. Grifols; 2017.

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GRIFOLS

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