CellGenix

Now part of Sartorius

High Quality GMP Reagents for Cell and Gene Therapy Manufacturing

Safe | GMP Compliant | Reliable

About Sartorius CellGenix

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Sartorius CellGenix is a leading global supplier of high quality raw materials for the expanding cell and gene therapy and regenerative medicine space. We develop, manufacture and market human cytokines and growth factors in preclinical and GMP quality along with GMP serum-free media for further manufacturing of ATMPs. Our products are used by academia and industry partners in clinical trials and commercial manufacturing throughout the world.

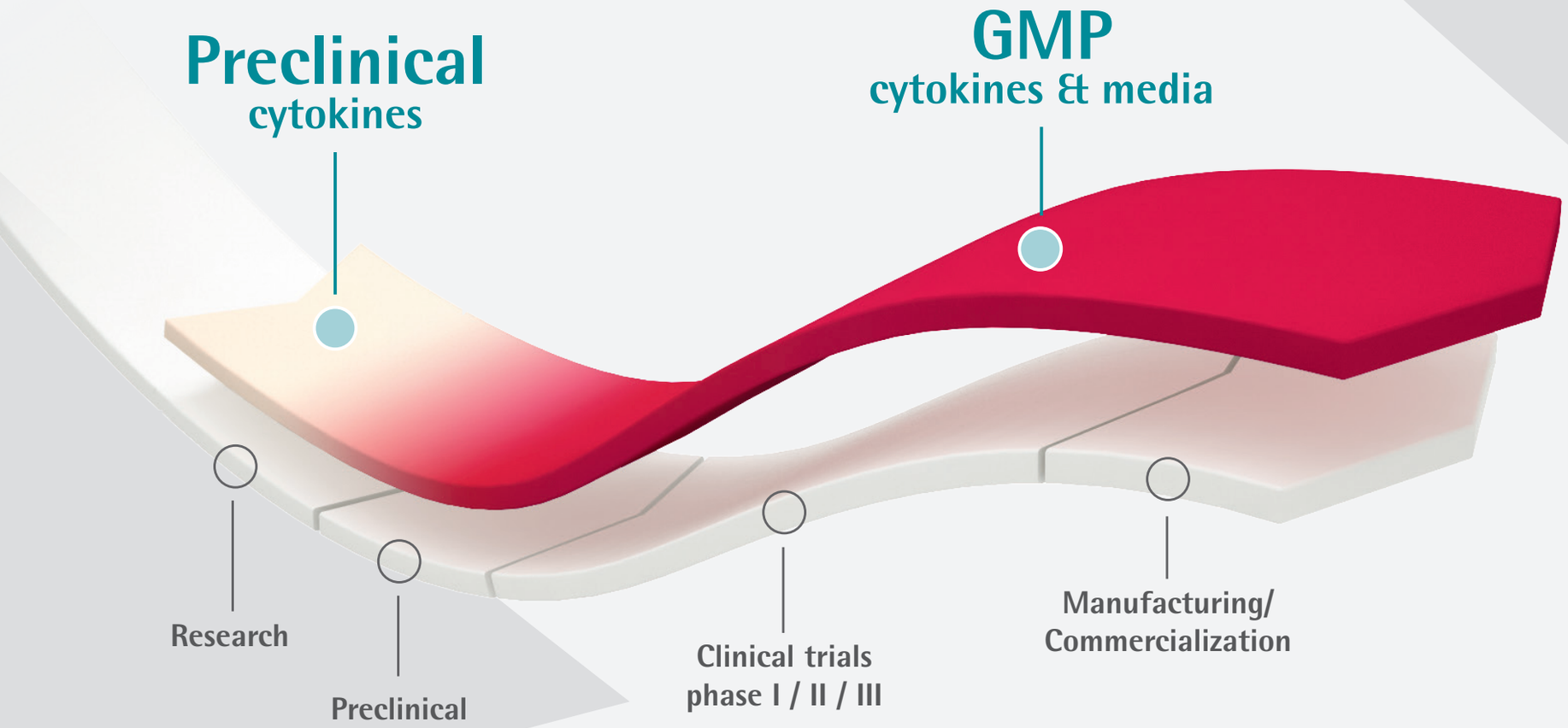
With almost 30 years of experience we are experts in the GMP manufacturing of raw materials for the cell and gene therapy space. As an ATMP developer and manufacturer we gained in-depth cell culture knowledge and superior regulatory expertise. With this unique background we understand the high requirements our customers face during product development and the regulatory approval process. By offering expert technical and regulatory support we can help simplify raw material qualification and validation efforts.

Sartorius CellGenix is headquartered in Freiburg, Germany.
In Juli 2021 the life science group Sartorius acquired a majority stake in CellGenix.

For more information, visit cellgenix.com

From Research to ATMP –

Your Dedicated Partner in Cell and Gene Therapy



Growth Factors, Cytokines and Serum-Free Media

ADCF and Serum-free Policy

ADCF Level 2

Animal-Free Facility:
No ADC in product and production process

- **Highest safety level:** no exposure to animal or human components or byproducts
- **Save time & money:** no viral safety studies needed

ADCF Level 1

ADC Production Area:
No ADC in product, but ADC in production process

- Require animal or human expression system or ADC in production process
- **Safety:** documented evidence of viral/prion safety

Regulatory Excellence

CellGenix® GMP products are based on three major quality standards:

- **Safety** – Safe and qualified raw materials in compliance with our animal-derived component-free and serum-free policy.
- **GMP Compliance** – Manufacturing and quality control following all applicable GMP guidelines to provide documented evidence of purity, potency, consistency and stability.
- **Regulatory Compliance and Support** – GMP products are manufactured, tested, released and distributed under an ISO 9001:2015 certified Quality Management System and allow for the safe use in accordance with USP Chapter <1043>, Ph. Eur. General Chapter 5.2.12. and ISO Technical Standard 20399:2022. GMP cytokines are tested and released according to USP Chapter <92> as applicable.
  We offer expert regulatory and technical support as well as FDA Drug Master Files for most of our products. Customized solutions can be provided to meet special compliance needs.

Dendritic Cells

DCs represent unique antigen-producing cells capable of sensitizing T cells to antigens. They play a central role in the regulation of innate and adaptive immunity. DC therapy represents a new and promising immunotherapeutic approach for treatment of different types of cancer.

rh Cytokines

CellGenix® GM-CSF, IL-4, IL-1β, TNF-α, IL-6, IL-10, IFN-γ

(GMP/preclinical grade)

Medium

CellGenix® GMP DC

Embryonic Stem Cells & Induced Pluripotent Stem Cells

ES and iPS cells can differentiate into all cell types of the human body and have the capacity to self-renew. Potential therapeutic applications include basic research, drug testing and regenerative medicine.

ES and iPS cells are in addition used as new cell sources for the generation of DC and T cell therapies.

rh Cytokines

CellGenix® EGF, FGF-2, Activin A, OSM, HGF, TGF-β1

(GMP/preclinical grade)

(OSM & HGF: preclinical grade only)

Hematopoietic Stem and Progenitor Cells

HSCs are widely used for transplantation after high-dose chemotherapy of lymphoma, leukemia and certain immune-deficiency illnesses.

rh Cytokines

CellGenix® SCF, TPO, Flt-3L, IL-3, IL-6

(GMP/preclinical grade)

Medium

CellGenix® GMP SCGM

T Cells

T cells play a central role in cell-mediated immunity. T cell immunotherapy for cancer, chronic infection and autoimmunity is a rapidly growing field with very promising results in clinical trials. There are currently four types of therapies: chimeric antigen receptor (CAR), tumor-infiltrating lymphocytes (TILs), regulatory T cells (Treg) and T cell receptor (TCR) engineered T cells.

rh Cytokines

CellGenix® IL-2, IL-7, IL-15, IL-21, TGF-β1

(GMP/preclinical grade)

Medium

CellGenix® GMP TCM

Natural Killer Cells

NK cells are a subset of cytotoxic lymphocytes involved in the innate immune system. They play a major role in the host-rejection of both tumors and virally infected cells. Immunotherapy, based on NK cell infusion is a potential adjuvant treatment for many cancers.

rh Cytokines

CellGenix® IL-2, IL-15, IL-21

(GMP/preclinical grade)

Medium

CellGenix® GMP SCGM

Mesenchymal Stem Cells

MSCs are multipotent stem cells that can be differentiated into a variety of cell types, including osteoblasts, chondrocytes, myocytes, adipocytes, pancreatic islets cells and neuronal cells.
They hold great therapeutic promise in the field of cell-based tissue engineering and regenerative medicine. MSCs are being used for the prevention or treatment of GvHD after allogeneic blood stem cell transplantation. Their immunomodulatory properties are furthermore employed in autoimmune diseases such as diabetes and Crohn's disease.

rh Cytokines

CellGenix® EGF, FGF-2, PDGF-BB, TGF-β1

(GMP/preclinical grade)

Chondrocytes

Chondrocytes are the only cell type resident in the cartilage. Chondrocytes are, for example, used for the generation of articular cartilage injuries in the knee (Autologous Chondrocyte Transplantation, ACT).

rh Cytokines

CellGenix® FGF-2, PDGF-BB

(GMP/preclinical grade)

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