

CellGenix[®] Preclinical & GMP Cytokines Portfolio

High Quality Raw Materials
for Cell and Gene Therapy
Manufacturing



Product Information

Growth factors and cytokines are small signaling proteins crucial in regulating cell growth, differentiation, and function. CellGenix[®] growth factors and cytokines are designed as raw | ancillary materials for cell and gene therapies and regenerative medicine. They are added to cell cultures to promote the proliferation and differentiation of various human cells towards the desired target cell type, like immune cells (e.g., T cells) or stem cells (e.g., human mesenchymal stem cells). To ensure a seamless transition from preclinical development to commercial manufacturing, we offer CellGenix[®] cytokines in GMP and preclinical grade.

Features and Benefits

- Seamless transition from early development to clinical stages with consistent product quality & performance
- Exceptional batch-to-batch consistency to ensure optimal cell expansion and differentiation
- Manufactured in compliance with applicable GMP guidelines. Regulatory support available for GMP products.

Introduction


CellGenix® growth factors and cytokines combine optimal quality and safety with excellent performance due to state-of-the-art production, stringent quality control, and expert regulatory support. The growth factors and cytokines are manufactured in a dedicated animal-free facility to ensure the highest safety level.

CellGenix® growth factors and cytokines are available in preclinical and GMP grades, produced under the same conditions in a ISO-certified facility, using identical production steps and expression systems. This ensures consistent product quality and performance during scale-up.

GMP cytokines come with documented evidence of purity, potency, sterility, and stability (including methods and results). Expert regulatory support includes auditing of our production site and providing reference to our Drug master Files (DMFs) filed at FDA.

Relevant Applications

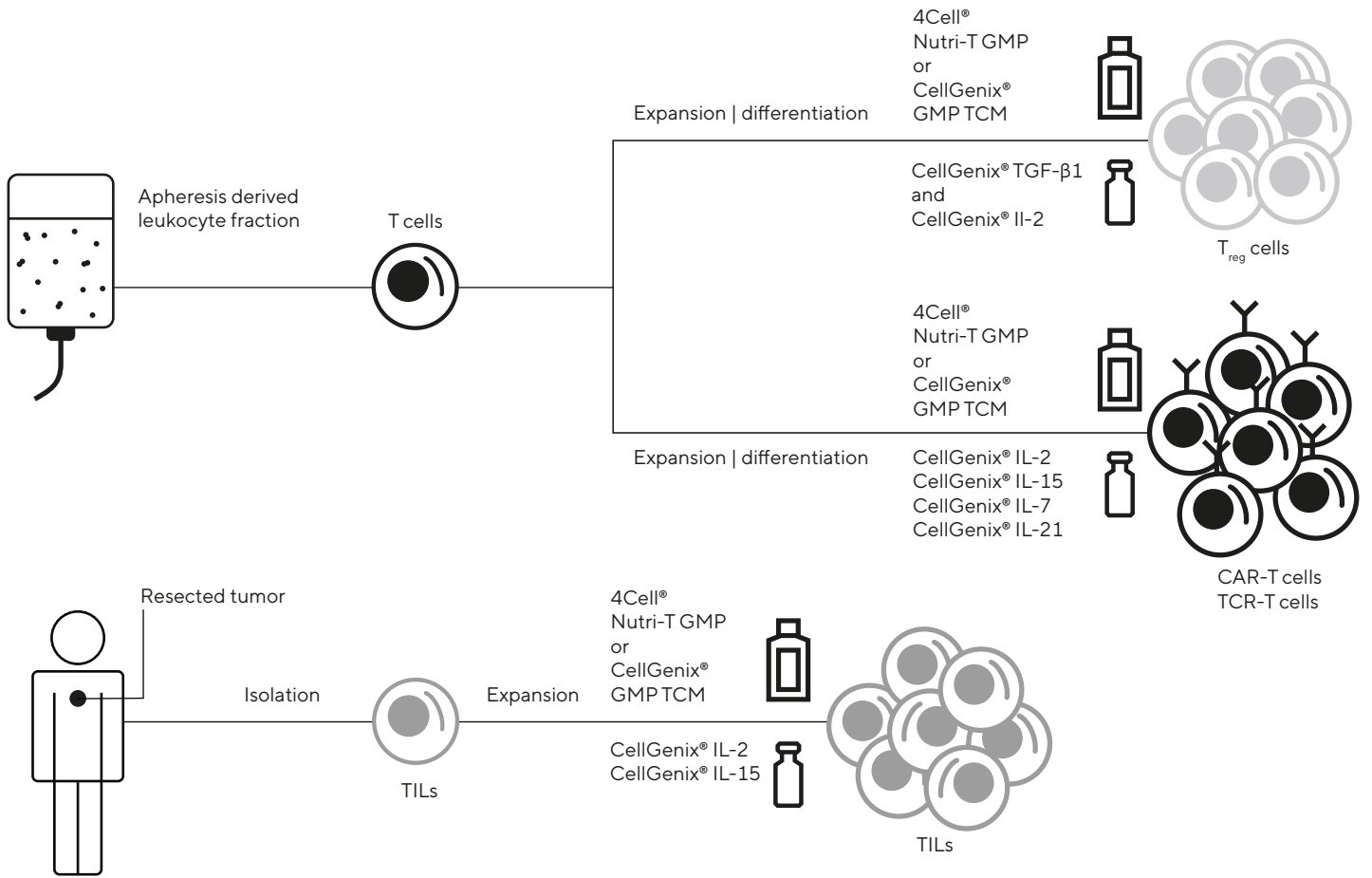
CellGenix® growth factors and cytokines are ideal for activating, expanding, and differentiating human cells for ex vivo (outside the human body) cell culture. To ensure a seamless transition from preclinical development to commercial manufacturing, we offer CellGenix® cytokines and growth factors in GMP and preclinical grade. Customized solutions, including bulk requests, can be provided to meet special manufacturing needs.

 **For further information, visit**
Cytokines and Growth Factors

Technical Specifications

Attributes	Preclinical Grade	GMP Grade
Intended use	Intended for preclinical ex vivo use	Intended for ex vivo use in clinical trials and commercial Cell and Gene Therapy products manufacturing
Volume	50 µg	50 µg and 1 mg for selected cytokines
Access to batch documentation	No	Yes
Identity of product confirmed	One method	≥ two methods
Activity value on CoA	Minimum	Specific
Regulatory support, DMF, on-site audits, change notifications, etc.	No	Yes
Regulatory compliance	USP <1043>, Ph. EUR 5.2.12	USP <1043>, Ph. EUR 5.2.12, ISO 20399:2022

Figure 1: Workflow Examples for T Cell Therapies



Note. T cells play a central role in cell-mediated immunity. Immunotherapy based on these powerful cells is a rapidly growing field with promising results. Current therapies use one of the four following technologies: chimeric antigen receptor (CAR) bearing T cells, tumor-infiltrating lymphocytes (TILs), regulatory T cells (Treg) and T cell receptor (TCR) engineered T cells.

Ordering Information

Growth Factors & Cytokines	Format	Amount	Quantity	Order Number
CellGenix® Preclinical rh GM-CSF	Lyophilized, glass vial	50 µg	1	1412-050
CellGenix® GMP rh GM-CSF	Lyophilized, glass vial	50 µg	1	1012-050
CellGenix® GMP rh GM-CSF	Lyophilized, glass vial	1 mg	1	1012-1000
CellGenix® Preclinical rh IL-4	Lyophilized, glass vial	50 µg	1	1403-050
CellGenix® GMP rh IL-4	Lyophilized, glass vial	50 µg	1	1003-050
CellGenix® GMP rh IL-4	Lyophilized, glass vial	1 mg	1	1003-1000
CellGenix® Preclinical rh TNF-α	Lyophilized, glass vial	50 µg	1	1406-050
CellGenix® GMP rh TNF-α	Lyophilized, glass vial	50 µg	1	1006-050
CellGenix® Preclinical rh IL-1β	Lyophilized, glass vial	50 µg	1	1411-050
CellGenix® GMP rh IL-1β	Lyophilized, glass vial	50 µg	1	1011-050
CellGenix® Preclinical rh IL-10	Lyophilized, glass vial	50 µg	1	1414-050
CellGenix® GMP rh IL-10	Lyophilized, glass vial	50 µg	1	1014-050
CellGenix® Preclinical rh IFN-γ	Lyophilized, glass vial	50 µg	1	1425-050
CellGenix® Preclinical rh SCF	Lyophilized, glass vial	50 µg	1	1418-050
CellGenix® GMP rh SCF	Lyophilized, glass vial	50 µg	1	1018-050
CellGenix® GMP rh SCF	Lyophilized, glass vial	1 mg	1	1018-1000
CellGenix® Preclinical rh TPO	Lyophilized, glass vial	50 µg	1	1417-050
CellGenix® GMP rh TPO	Lyophilized, glass vial	50 µg	1	1017-050
CellGenix® GMP rh TPO	Lyophilized, glass vial	1 mg	1	1017-1000
CellGenix® Preclinical rh FLT-3L	Lyophilized, glass vial	50 µg	1	1415-050
CellGenix® GMP rh FLT-3L	Lyophilized, glass vial	50 µg	1	1015-050
CellGenix® GMP rh FLT-3L	Lyophilized, glass vial	1 mg	1	1015-1000
CellGenix® Preclinical rh IL-2	Lyophilized, glass vial	50 µg	1	1420-050
CellGenix® GMP rh IL-2	Lyophilized, glass vial	50 µg	1	1020-050
CellGenix® GMP rh IL-2	Lyophilized, glass vial	1 mg	1	1020-1000
CellGenix® GMP rh IL-2	Liquid, syringe	1 mg in 1 mL	1	1520-1000 available soon
CellGenix® Preclinical rh IL-6	Lyophilized, glass vial	50 µg	1	1404-050
CellGenix® GMP rh IL-6	Lyophilized, glass vial	50 µg	1	1004-050
CellGenix® GMP rh IL-6	Lyophilized, glass vial	1 mg	1	1004-1000
CellGenix® Preclinical rh IL-7	Lyophilized, glass vial	50 µg	1	1410-050
CellGenix® GMP rh IL-7	Lyophilized, glass vial	50 µg	1	1010-050
CellGenix® Preclinical rh IL-15	Lyophilized, glass vial	50 µg	1	1413-050
CellGenix® GMP rh IL-15	Lyophilized, glass vial	50 µg	1	1013-050
CellGenix® Preclinical rh IL-21	Lyophilized, glass vial	50 µg	1	1419-050
CellGenix® GMP rh IL-21	Lyophilized, glass vial	50 µg	1	1019-050
CellGenix® Preclinical rh IL-3	Lyophilized, glass vial	50 µg	1	1402-050
CellGenix® GMP rh IL-3	Lyophilized, glass vial	50 µg	1	1002-050
CellGenix® Preclinical rh OSM	Lyophilized, glass vial	50 µg	1	1423-050
CellGenix® Preclinical rh TGF-β1	Lyophilized, glass vial	50 µg	1	1426-050
CellGenix® GMP rh TGF-β1	Lyophilized, glass vial	50 µg	1	1026-050

Growth Factors & Cytokines	Format	Amount	Quantity	Order Number
CellGenix® Preclinical rh PDGF-BB	Lyophilized, glass vial	50 µg	1	1409-050
CellGenix® GMP rh PDGF-BB	Lyophilized, glass vial	50 µg	1	1009-050
CellGenix® GMP rh PDGF-BB	Lyophilized, glass vial	1 mg	1	1009-1000 (please enquire)
CellGenix® Preclinical rh FGF-2	Lyophilized, glass vial	50 µg	1	1421-050
CellGenix® GMP rh FGF-2	Lyophilized, glass vial	50 µg	1	1021-050
CellGenix® GMP rh FGF-2	Lyophilized, glass vial	1 mg	1	1021-1000
CellGenix® Preclinical rh EGF	Lyophilized, glass vial	50 µg	1	1416-050
CellGenix® GMP rh EGF	Lyophilized, glass vial	50 µg	1	1016-050
CellGenix® GMP rh EGF	Lyophilized, glass vial	1 mg	1	1016-1000
CellGenix® Preclinical rh Activin A	Lyophilized, glass vial	50 µg	1	1422-050
CellGenix® GMP rh Activin A	Lyophilized, glass vial	50 µg	1	1022-050



Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

Sartorius CellGenix GmbH
Am Flughafen 16
79108 Freiburg
Phone +49 761 88889 0
Fax + 49 761 88889 830
info@cellgenix.com

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

 **For further information, visit**
www.sartorius.com