CellGenix
Now part of Sartorius

TECHNOTE

CellGenix® rh Cytokines – Preclinical vs GMP

To allow for a seamless transition from preclinical development to the clinical stage, we offer both preclinical and GMP cytokines. Both product grades are produced under the same conditions in a GMP facility, using identical production steps and expression systems. This ensures an equal product quality and performance.

The difference between both quality levels is that we offer a more comprehensive QC testing including tighter specifications and documentation for our GMP products. Our preclinical grade products therefore offer a cost efficient alternative for the early development phase when safety and quality of raw materials have a lower priority.

Preclinical grade: Intended for preclinical *ex vivo* use

GMP grade: Intended for *ex vivo* use in clinical trials and commercial ATMP manufacturing

Quality Attributes	Preclinical grade	GMP grade
MCB/WCB fully characterized	no	yes
All processes according to released SOPs	yes	yes
Batch documentation	yes	yes
Change control, OOS and deviation procedures	yes*	yes
Production and QC equipment qualified	no	yes
Cleaning validation for production equipment	yes*	yes
Process validation by 3 consistency batches	no	yes
Validation of all analytical methods	no	yes
Determination of DNA content	no	yes
Sterility testing	yes	Ph. Eur.
Purity	≥ 95%	≥ 97%
Endotoxin testing (all cytokines except IL-2, IL-7, IL-15 and IL-21)	< 1000 EU/mg	≤ 50 EU/mg
Endotoxin testing (IL-2, IL-7, IL-15 and IL-21)	< 25 EU/mg	≤ 25 EU/mg
Expiry date on CoA	yes	yes
Validation of shelf life by accelerated and real time testing	no**	yes
Identity of product confirmed	one method	≥ two methods
Supplier and raw material control	no	yes
Activity value on CoA	minimum	specific
Determination of host cell protein	no	yes
Regulatory support: DMF, on-site audits, change notifications, etc.	no	yes
Regulatory compliance	no	USP <1043> Ph. Eur. 5.2.12 ISO TS 20399

* All measures are applied for our preclinical grade production batches. We however don't send change notifications for our preclinical grade cytokines and these quality attributes cannot be verified in an audit.

**Shelf life is determined according to data generated through stress tests in which the impurity profile is analyzed under forced degradation conditions.

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 & 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. 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.

ZY-TI-009d | 12/2021
Subject to change without notice

HQ: Sartorius CellGenix GmbH | Am Flughafen 16 | 79108 Freiburg | GERMANY | Phone +49 761 888 89-0 | Fax +49 761 888 89-830
US: CellGenix Inc. | One New Hampshire Avenue, Suite 125 | Portsmouth, NH 03801 | USA | Phone +1 603 373 0408 | Fax +1 603 373 8104
www.cellgenix.com | info@cellgenix.com