

Sartorius CellGenix 總部位於德國佛萊堡，專門提供細胞治療、基因治療和再生醫學所需的高品質原料，含 Cytokine、Growth factors、Serum-free medium 等，並具備完善的法規支持。





Pre-clinical vs GMP

Pre-clinical 以及 GMP 等級的 Cytokines / Growth factors，採用相同的生產步驟及表達系統，保證一致的品質與效果，確保臨床前階段順利銜接至臨床階段！

提供學術研究單位、臨床單位以及工業生產單位更彈性的選擇，節省成本及時間。

Preclinical

rh Cytokines

經濟
實惠



於 GMP 設施生產

適合臨床前使用

GMP

rh Cytokines



符合 GMP 品質標準

更加全面的 QC 測試

法令遵循與合規管理

遵循法規：USP <1043>,
Ph. Eur. 5.2.12, ISO TS 20399

法規支援：包含 eCTD Drug Master Files
(需事先詢問)，現場審核 & 客製化文件

Quality Attributes	Preclinical grade	GMP grade
Quality Management System: Manufactured, tested, released & distributed under ISO 9001:2015	yes	yes
Adherence to GMP guidelines	no	yes
Batch documentation	yes	yes
Regulatory compliance: USP <1043>, Ph. Eur. 5.2.12, ISO TS 20399	N/A	yes
Process validation by 3 consistency batches	no	yes
Determination of DNA content	no	yes
Sterility testing	yes	Ph. Eur.
Purity	≥ 95%	≥ 97%
Identity of product confirmed	one method	≥ two methods
Endotoxin testing	< 1000 EU/mg	≤ 50 EU/mg or ≤ 25 EU/mg
Determination of host cell protein	no	yes
MCB/WCB fully characterized	yes*	yes
Supplier and raw material control	yes*	yes
Regulatory support: DMF, on-site audits, change notifications, quality agreements, etc.	no	yes

*All measures are applied for our preclinical grade, but these quality attributes cannot be verified in an audit

Please refer to Technote "CellGenix® rh Cytokines – Preclinical vs GMP" for a complete overview

細胞培養 CellGenix 產品組合



Cell Type	CellGenix® rh Cytokines	CellGenix® serum-free GMP Media
T Cells	IL-2, IL-7, IL-15, IL-21, TGF-β1	TCM Medium
Natural Killer Cells (NK cells)	IL-2, IL-15, IL-21	SCGM Medium
Dendritic Cells (DC)	GM-CSF, IL-4, IL-1β, TNF-α, IL-6, IL-10, IFN-γ*	DC Medium
Hematopoietic Stem Cells (HSC)	SCF, TPO, Flt-3L, IL-3, IL-6	SCGM Medium
Pluripotent Stem Cells (iPSC, ESC)	EGF, FGF-2, Activin A, OSM*, HGF*, TGF-β1	
Mesenchymal Stem Cells (MSC)	EGF, FGF-2, PDGF-BB, TGF-β1	
Chondrocytes	FGF-2, PDGF-BB	

All CellGenix® products are available in GMP and Preclinical grade, except *) Preclinical only

產品列表

品名 Recombinant Human	規格及貨號	
	GMP	Preclinical
	50 µg	1 mg
IL-3	1002-050	1402-050
IL-4	1003-050	1003-1000
IL-6	1004-050	1004-1000
TNF-α	1006-050	1406-050
PDGF	1009-050	1409-050
IL-7	1010-050	1410-050
IL-1b	1011-050	1411-050
GM-CSF	1012-050	1012-1000
IL-15	1013-050	1413-050
IL-10	1014-050	1414-050
FLT-3L	1015-050	1015-1000
EGF	1016-050	1016-1000
TPO	1017-050	1017-1000
SCF	1018-050	1018-1000
IL-21	1019-050	1419-050
IL-2	1020-050	1020-1000
FGF-2	1021-050	1021-1000
Activin A	1022-050	1422-050
TGF-β1	1026-050	1426-050
OSM		1423-050

CellGenix® GMP Dendritic Cell Medium (DCM) 適用於培養 DC	
規格	貨號
500mL Bottle, w / Phenol Red	20801-0500
500mL Bag, w / Phenol Red	20901-0500
500mL Bottle, w/o Phenol Red	20805-0500
500mL Bag*, w/o Phenol Red	20905-0500
CellGenix® GMP Stem Cell Growth Medium (SCGM) 適用於培養 HSC/CIK cells/NK cells	
規格	貨號
500mL Bottle, w/ Phenol Red	20802-0500
500mL Bag, w/ Phenol Red	20902-0500
500mL Bottle, w/o Phenol Red	20806-0500
500mL Bag*, w/o Phenol Red	20906-0500
CellGenix® GMP T Cell Medium (TCM) 適用於培養 T cells	
規格	貨號
500mL Bottle, w/o Phenol Red	20814-0500
1000mL Bag, w/o Phenol Red	20914-1000

*On Request

