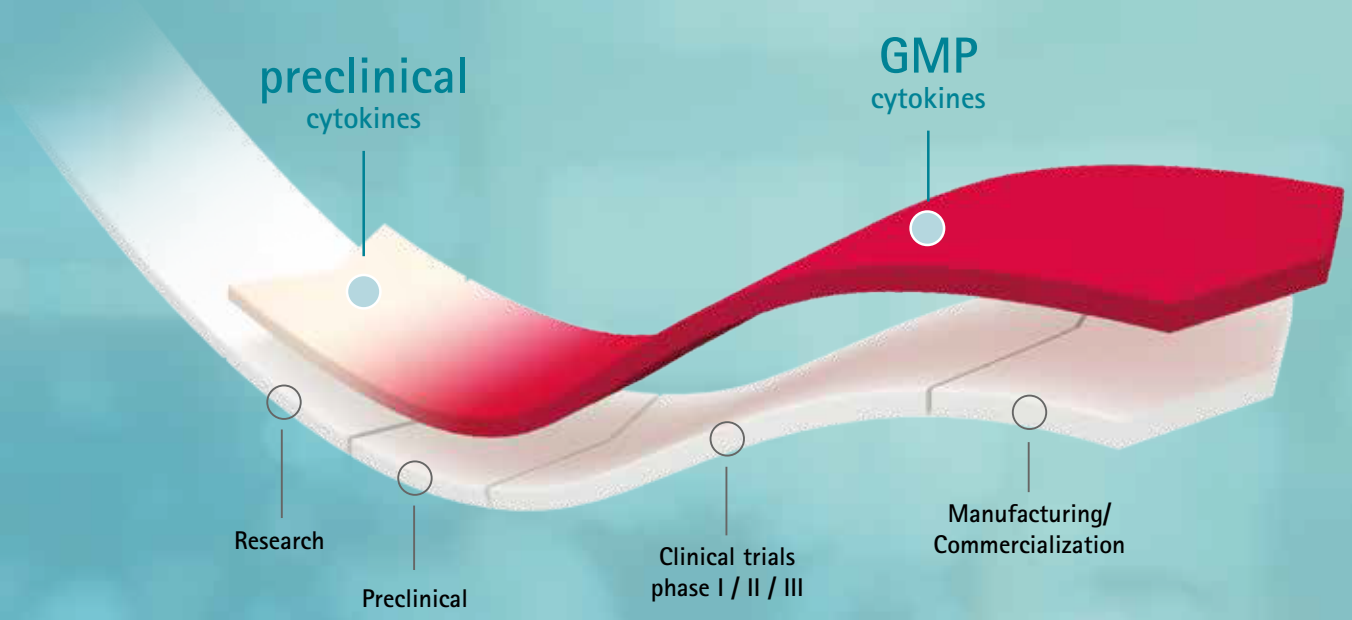
CellGenix

CellGenix Cytokines & Growth Factors



On the path from research to cell & gene therapy manufacturing

Preclinical rh Cytokines

Produced in GMP facility

Cost efficient – preclinical phase

Intended for preclinical *ex vivo* use

Preclinical vs GMP

CellGenix

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

GMP rh Cytokines

More comprehensive QC testing

GMP quality standard

Regulatory compliance & support

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

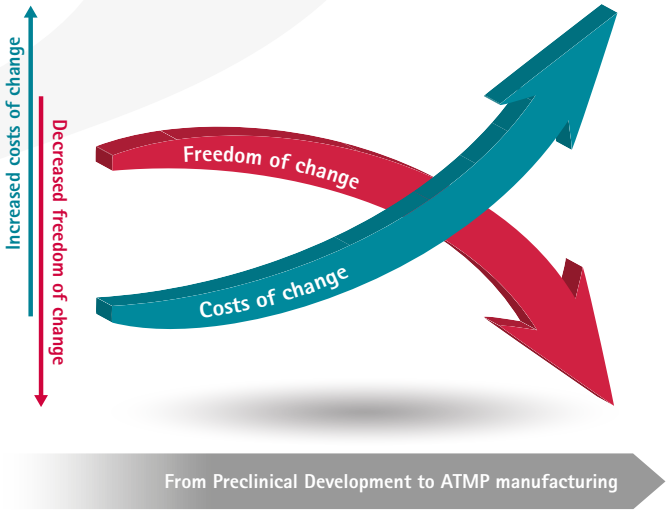
Switching to GMP grade raw materials prior to clinical development offers an economic benefit and saves time

To enable a seamless and cost-effective transition to the clinical stage we recommend identifying the appropriate GMP grade raw materials already during early stage preclinical research.

Switching to the required GMP grade raw materials directly after preclinical development, will prevent the need for expensive and time-consuming clinical comparability studies to prove the raw material changes do not alter the final ATMP.

A study performed by the Tufts Center for the Study of Drug Development (CSDD) estimated that the costs of an amendment for a Phase III trial are more than three times as much as an amendment for a Phase II trial. They estimated the average direct cost to make changes to the protocols of phase III trials tops $1 million per study.[1]

Translation from Preclinical Development to ATMP



[1] Getz KA, Stergiopoulos et al. Ther. Innov. Regul. Sci. 50 (4) 436-441 (2016)

FLY-ZY-003b | 03/2020

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