# CellGenix® Preclinical and GMP Cytokines Offer a Seamless Transition from Preclinical Development to the Clinical Stage

No one can deny the rise of cell and gene therapies (CGTs) and their potential to cure diseases. CGTs are however complex to develop and CGT developers face many different manufacturing challenges. One major challenge is to enable a safe and effective translation from the preclinical development phase to the clinical stage. In the late clinical phases GMP grade raw materials are required, which are often not available, or they have different product characteristics as the research raw materials. Changing raw materials in your clinical development requires process optimization and time consuming and expensive comparability studies to prove that the raw material changes do not alter your CGT. By using our preclinical cytokines in your development phase, you can avoid spending time on optimizing your manufacturing process and you will not need to do clinical comparability studies.

Our preclinical grade products offer a cost-efficient alternative for the early development phase when regulatory compliance of raw materials has a lower priority.

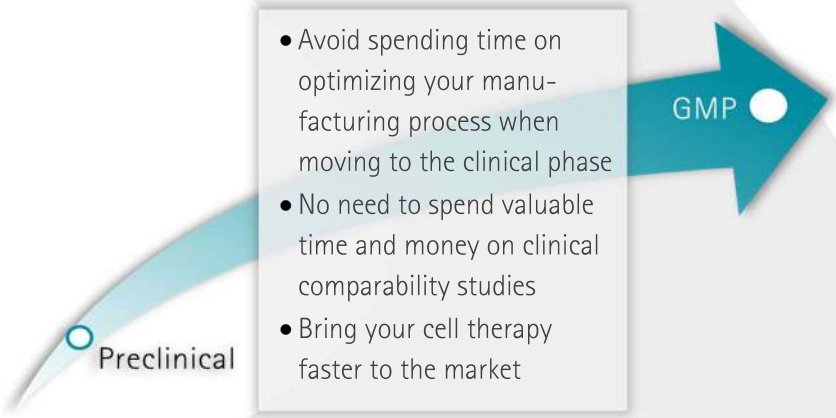
Visit our website for a full overview of our preclinical vs. GMP cytokines.

## CellGenix® preclinical and GMP cytokines share the following quality attributes

- Quality Management System: Manufactured, tested, released & distributed under ISO 9001:2015
- Master Cell Bank/Working Cell Bank fully characterized
- All processes according to released SOPs
- Batch documentation
- Change control, OOS, and deviation procedures
- Supplier and raw material control

To ensure a seamless transition to the clinical stage, both our preclinical and GMP cytokines are produced under the same conditions in our GMP facility. We use identical production steps and expression systems and can therefore guarantee equal product quality and performance.

## Seamless transition from preclinical to GMP




- Avoid spending time on optimizing your manufacturing process when moving to the clinical phase
- No need to spend valuable time and money on clinical comparability studies
- Bring your cell therapy faster to the market

✓ Adherence to GMP guidelines

✓ Regulatory compliance
USP <1043>
Ph. Eur. 5.2.12
ISO TS 20399

✓ Regulatory support
incl. eCTD Drug Master Files,
on-site audits,
& customized documentation

**When you are ready to enter a GMP environment, all you need to do is switch to our GMP cytokines.**

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