



# Next Generation MSC and Exosome Production

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Efficient and scalable bioreactor cultivation of stable telomerized Mesenchymal Stromal Cells (MSC/TERT)

## The Case for Stable MSC lines

Telomerized Mesenchymal Stromal Cells (MSC/TERT) provide key advantages such as stable growth performance and phenotype over many generations. Products derived from these stable cell lines can theoretically be supplied from one Master Cell Bank (MCB) throughout the whole product life cycle. Most importantly, MSC/TERT and extracellular vesicles (EV) or exosomes secreted from them show highly comparable biological properties compared to primary MSCs and their secretome<sup>1</sup>.

- Reproducible quality products over the whole product life cycle
- Less variability
- Better manufacturing (consistency, productivity, cost of goods)

<sup>1</sup> Data available upon request

In collaboration with Evercyte GmbH we have several MSC/TERT lines from different tissue sources available. These R&D cell lines are fully documented and ready for GMP cell banking.

Table 1: MSC/TERT lines developed from different tissues

Code	Tissue Source	GMP ready
Ad-MSC/TERT	Adipose tissue	Yes
BM-MSC/TERT	Bone marrow	Yes
WJ-MSC/TERT	Wharton's Jelly	Yes
P-MSC/TERT	Placenta	Yes
CP-MSC/TERT	Chorionic Plate	Yes

## Manufacturing Platform

We have developed a scalable bioreactor-based manufacturing systems for consistent cell expansion and efficient EV / exosome production over extended time frames.

**Cell yields between 0.2 – 1.0 x 10<sup>9</sup>** have been reached so far with the MSC/TERT lines **per 0.25 L bioreactor unit** and with the proprietary Phoenestra bioreactor setup.

With these cell densities we reach **particle concentrations exceeding 1 x 10<sup>9</sup> particles / mL . day** (4 MSC/TERT lines from different tissues tested so far).

Considering a certain fraction of particles which are therapeutically non-relevant and some downstream processing losses, we produce exosome quantities **providing 4 – 40 clinical doses from a single 250 mL bioreactor unit and in 20 – 30 days, depending on the respective cell line.**