



# **EVscale™ - Scalability and Consistency for the Future of Extracellular Vesicles / Exosomes**

Phoenestra GmbH  
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# The Challenge with Extracellular Vesicles (EV) and how Phoenestra has addressed it



## Problem Statement

- Primary MSC are highly variable
- Extracellular Vesicles (EV) / exosomes from primary MSC are highly variable
- Scalability issues
- Intrinsic complexity
- All this impacting clinical supplies and translation into clinical efficacy

## Our Approach

- Stable MSC lines (MSC/TERT)
- Xeno- and Virus-free
- MCB/WCB concept
- Scalable Bioreactor technology and Downstream-processing
- Advanced analytical methods and approaches to address EV complexity

## The Solution\*: EVscale™

- Library of MSC/TERT lines from different human tissues (GMP-ready)
- Patented, scalable bioreactor setup for adherent cell lines
- Scalable Downstream processing
- Functional bioassays (Potency)
- -omics-based composition-function relationships

\* in collaboration with



# The Key Benefits of EVscale™



- ✓ Stable GMP-grade MSC lines (MSC/TERT) (licensed from Evercyte)
- ✓ Oncogene and virus-free cell line generation
- ✓ Tiered Cell Banking possible (MCB/WCB concept)
- ✓ Xeno-free and serum-free cultivation media
- ✓ High productivity from small bioreactor footprints which is scalable
- ✓ Gentle and scalable Downstream processing of EV / exosomes
- ✓ Proven biological functionalities, in-depth characterization (with Evercyte, TAmiRNA)



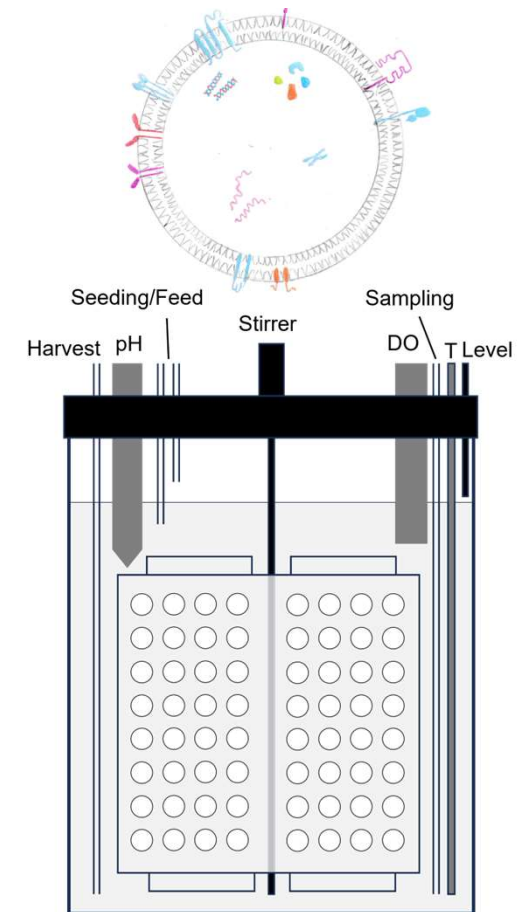
**Less Variability and Better Consistency, Scalability and high Productivity  
Compared to Conventional MSC-EV Technologies**

# The EVscale™ Platform Technology



## The Importance of Advanced Manufacturing Technologies

- State-of-the-art unit operations which are **scalable**
- Perfusion bioreactor cultivation ensures **controlled** nutrient supply, metabolite removal and continuous EV harvest
- Membrane and chromatography-based Downstream processing for **defined** EV / exosome preparations
- **Systematic** process and analytical development
- Basis for successful translation into **clinical efficacy**
- Basis for **cost leadership**



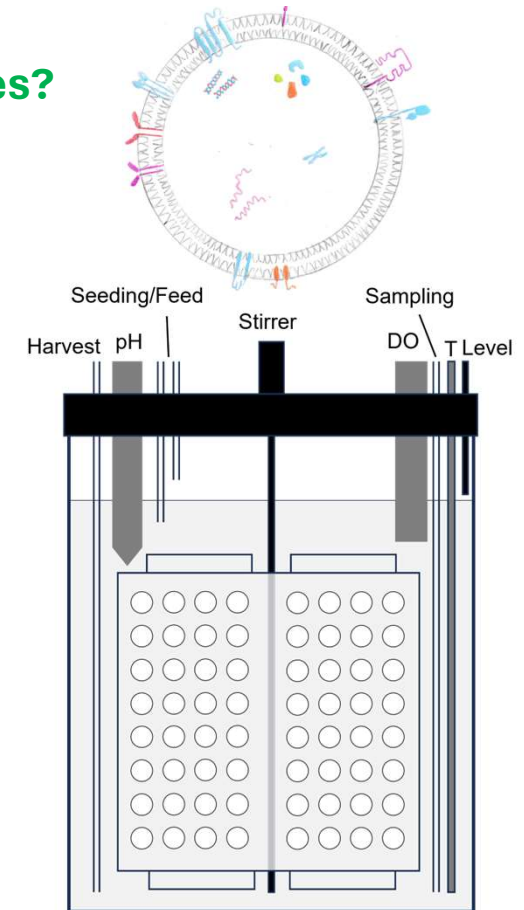
# The EVscale™ Platform Technology – Consistency and Scalability by Design



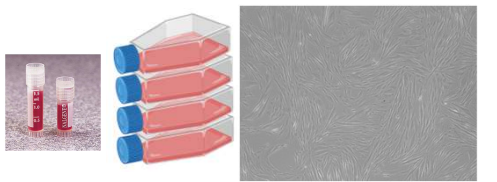
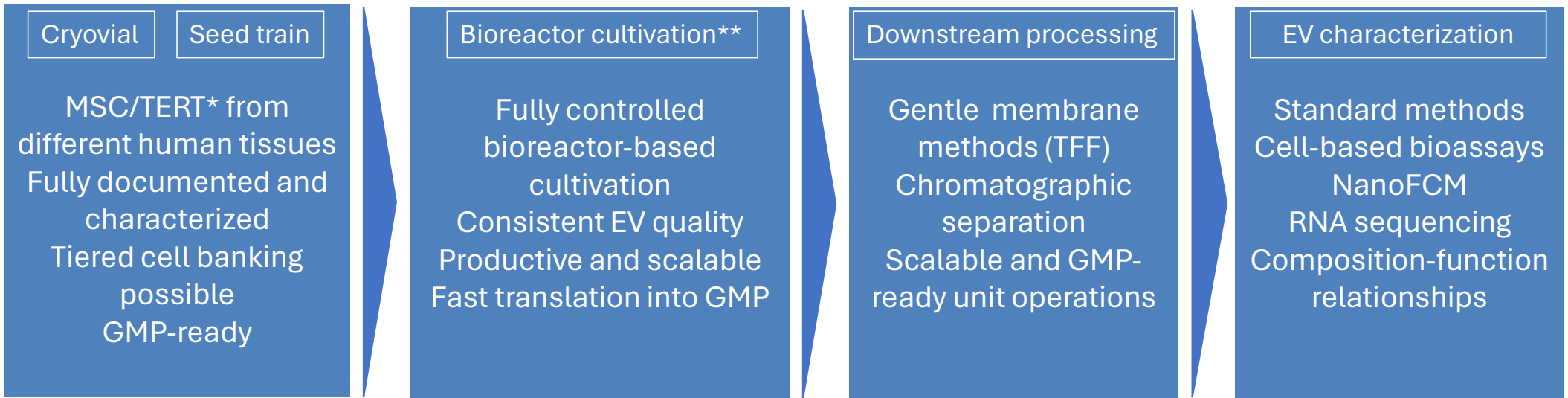
What differentiates EVscale™ from other EV production technologies?  
Clinical and commercial success in mind from the start!

- We can **supply the whole product life-cycle** (pre-clinical / clinical / commercial phases) with one Master Cell Bank
- By design we **avoid sources of variability** (different donors, complex, serum containing media)
- By design we enable adherent - and sometimes delicate - **cell lines to grow well** and under **fully controlled** conditions
- We employ innovative and scalable downstream processing and analytical tools for **EV characterization and product definition**

Therefore, if anyone can supply **consistent EV / exosome preparations** from relevant cell sources – **WE CAN**



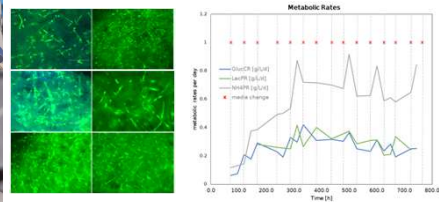
# EVscale™: The Novel End-to-end Approach for the Manufacturing of EV-based therapeutics



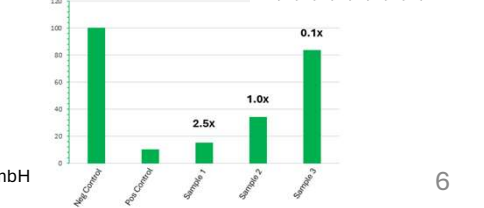
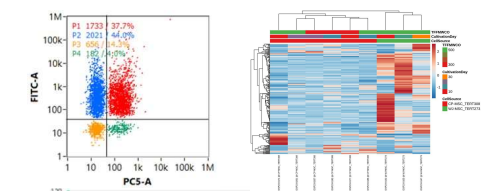
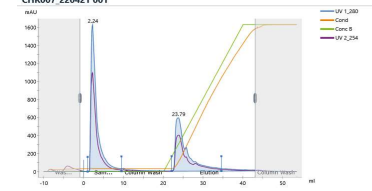
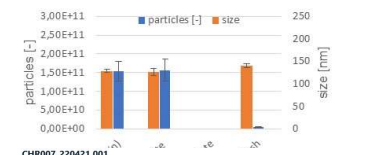
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\*\*Patent pending



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**Get in touch and let us know your thoughts!**



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