An Innovative, Scalable, Single-Use Bioreactor Platform

A Reliable and Scalable Single-Use Bioreactor System is Needed for Large-Scale Manufacturing of Cell Therapy Products

- Stirred-type mixing can result in a high degree of hydrodynamic shear stress and an uneven gradient of energy dissipation, negatively affecting cell yield and differentiation efficiency, quality, and potency
- Vertical-Wheel™ Technology Enables Superior, Scalable Expansion and Differentiation Performance for Numerous Types of Cell Therapy Products

Fig 1. A Representative, Large-Scale Cell Manufacturing Process Scheme Using the Family of Vertical-Wheel Bioreactors

Serial passaging of cells into progressively larger Vertical-Wheel bioreactors while maintaining high levels of cell growth and pluripotency

Scalable Expansion of MSCs Grown on Microcarriers

Fig 2. Process Optimization and Scale-Up of eMSCs Grown on Microcarriers

- Optimal medium feeding conditions for engineered MSCs grown on microcarriers can result in over 1 Million cells/ml at both 0.5L and 3L scales

Fig 3. Comparable hMSC Growth Profile During Scale Up and Robustness of Process Across Donors

- (A) Small scale 0.1L culture process (n=3) was successfully scaled up to 3L development scale (n=3), 15L pilot scale (n=3), and 50L production scale (n=2) in Vertical-Wheel bioreactors
- (B) The culture process works for multiple donors and can be robustly scaled to 50L production scale

Superior Scalability and Robustness of Cell Therapy Manufacturing Using Vertical-Wheel Bioreactors

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**Conclusion**

- Vertical-Wheel bioreactors provide the ideal conditions of homogeneous energy dissipation distribution, complete particle suspension with minimal power input, and low hydrodynamic shear stress for various types of cell therapy products
- For processes involving cells grown on microcarriers such as MSCs, Vertical-Wheel bioreactors provide superior performance of cell expansion as well as rapid, in-vessel cell dissociation and harvesting
- For processes involving cells grown as aggregates such as ESCs and iPSCs, Vertical-Wheel bioreactors provide unmatched control of cell aggregate size and morphology, leading to superior performance of cell expansion (while maintaining pluripotency) and subsequent differentiation efficiency
- Vertical-Wheel bioreactors have demonstrated unparalleled scalability across a full range of vessel sizes, enabling the scale up of cell therapy manufacturing to meet commercial production needs

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