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Single-Cell Sequencing for the Characterization of Mesenchymal Cell Therapy Products: A Tool to Assess Batch-to-Batch Variability in Allogeneic Manufacturing

Abstract: Comprehensive characterization of cell therapy products is crucial to ensure product consistency, quality, and safety, particularly in the context of allogeneic manufacturing. In this study, we implemented a single-cell RNA sequencing (scRNA-seq) platform that integrates the Chromium system (10x Genomics) with Illumina sequencing to enable transcriptomic profiling of mesenchymal stromal cells (MSCs) at single-cell resolution. This approach enables the identification of transcriptionally distinct subpopulations within MSC products and provides insights into their functional heterogeneity. The platform was applied to multiple production batches of allogeneic MSCs to investigate inter-batch variability. Our results reveal differences in cell composition and gene expression signatures between batches, highlighting the presence of variable proportions of subpopulations potentially associated with immunomodulatory capacity, proliferation, or differentiation potential.

Our findings demonstrate the value of scRNA-seq as a high-resolution tool for batch comparability assessments and the identification of critical quality attributes (CQAs) in MSC-based products. The integration of this technology into manufacturing workflows supports the development of robust quality control strategies, facilitates more predictable production outcomes, and contributes to more cost-effective manufacturing of allogeneic cell therapies.

Keywords: Cell therapies, donor-variability and Single-cell Sequencing.

Biography: Roberto Moreno Vellisca is a Cell Therapy Production Technician at Takeda, with a titulation as a Histopathology and Cytology Technician. He has extensive experience in biomedical research and specializes in Next Generation Sequencing, with a particular focus on single-cell RNA sequencing (scRNA-Seq). His work centers on optimizing sequencing workflows and applying cutting-edge technologies to support the development of advanced cell-based therapies. He brings a strong combination of technical expertise and a deep interest in innovation and translational science.