

2ND INTERNATIONAL CONFERENCE ON CELL SCIENCE AND REGENERATIVE MEDICINE



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Development an iPSC-Derived Mesenchymal Product: Toward a Consistent Allogeneic Cell Therapy Product with Reduced Donor Variability

Abstract: The intrinsic heterogeneity of donor-derived mesenchymal stromal cells (MSCs) presents a significant challenge for the manufacturing of standardized allogeneic cell therapy products. To address this limitation, we established and characterized an induced pluripotent stem cell (iPSC) bank as a renewable, well-defined material for the generation of MSCs with reduced donor variability.

iPSC lines were generated under xeno-free conditions and subjected to rigorous quality control, including karyotype analysis, pluripotency marker expression, and genomic integrity. Selected iPSC clones were then differentiated into MSCs using a defined, scalable protocol. The resulting iPSC-derived MSCs (iMSCs) underwent a release testing panel commonly applied in cellular therapies, including identity (CD73⁺, CD90⁺, CD105⁺, CD45⁻, CD34⁻), potency (through immunomodulatory assays), and purity (via flow cytometry and residual pluripotency marker exclusion).

Beyond standard release testing, comparative analyses were performed to assess the mechanistic functionality of iMSCs versus donor-derived MSCs in relation to their known modes of action in vivo. These included assays for cytokine secretion profiles and modulation of inflammatory signalling pathways. iMSCs demonstrated consistent and reproducible functional activity.

These findings support the possible use of iPSC-derived MSCs as a reliable and mechanistically active allogeneic cell therapy platform, with potential for improved manufacturing control and predictable in vivo performance.

Keywords: iPSC, MSC, allogeneic, donor-variability and manufacturing.

Biography: Celia Martínez Prieto is currently working as a Cell Therapy Production Technician at Takeda, with an academic background in Clinical Laboratory Science and Biomedical Science. He has extensive experience in biomedical research and a strong focus on cell culture.

Throughout his career, he has worked with various cell types, especially induced pluripotent stem cells (iPSCs), including their culture, differentiation, and characterization. He brings solid technical expertise and a proactive, innovative mindset, always looking to implement new techniques to optimize and advance current processes in the field of regenerative medicine.