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iPSCs and MSCs:
key considerations for development and manufacturing

Induced pluripotent stem cells (iPSCs) and mesenchymal stem cells (MSCs) have great therapeutic potential in regenerative medicine and cell and gene therapy. However, both cell types present unique challenges during development and manufacturing.

iPSCs

Reprogramming efficiency and consistency

Reprogramming somatic cells into iPSCs can be inefficient and variable, leading to inconsistencies in cell quality and characteristics.

Genetic stability

iPSCs may acquire genetic mutations during reprogramming and expansion, which can affect their safety and efficacy in therapeutic applications.

Differentiation control

Achieving precise and reproducible differentiation into specific cell types is challenging, requiring optimized protocols and conditions.

Scalability

Large-scale production of iPSCs for clinical applications requires robust and scalable manufacturing processes that maintain cell quality and functionality.

Regulatory compliance

Due to their pluripotent nature and potential for tumorigenicity, iPSC products must meet regulatory standards for safety and efficacy.

MSCs

Source variability

MSCs can be isolated from various tissues meaning their properties may vary depending on the source, affecting consistency in therapeutic applications.

Expansion and senescence

MSCs can undergo senescence during *in vitro* expansion, reducing their regenerative potential and therapeutic efficacy.

Differentiation control

Although MSCs are multipotent, directing their differentiation into specific cell types can be challenging, requiring precise and carefully controlled culture conditions.

Immunogenicity and safety

Ensuring that MSCs do not elicit adverse immune responses or cause unwanted side effects is crucial for their safe use in therapies.

Standardization and quality control

Establishing standardized protocols for MSC isolation, expansion and characterization is essential to ensure consistent quality and therapeutic efficacy.

Expert Tips from Sartorius

Automation

Cell therapy manufacturing is still highly manual. Implementing automated solutions can enhance process robustness, improve reproducibility and reduce labor-intensive steps.

Raw materials

Selecting high-quality, regulatory-compliant raw materials from the outset helps optimize processes and minimize complexity as development progresses.

Scalability

Adopt scalable technologies, especially for cell harvesting, to ensure that small-scale methods can be easily transitioned to large-scale manufacturing.

Explore Sartorius cell and gene solutions

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