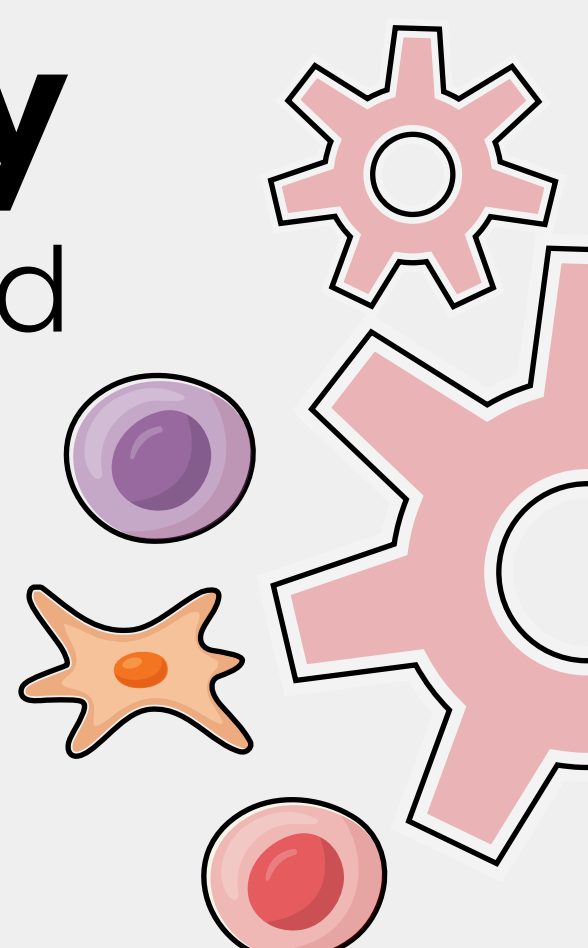


Stem cell therapy

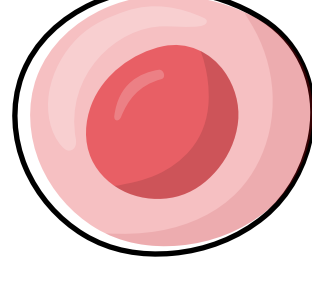
Building reproducible and scalable workflows

Stem cell therapy development is increasingly guided by manufacturing mindset principles: robustness, reproducibility and risk mitigation. As the field matures, the integration of standardized workflows, defined materials and early scalability considerations will be essential for successful translation.



Stem cell platforms for therapy development

Each platform comes with specific process considerations that must be controlled to ensure reproducibility and scalability.

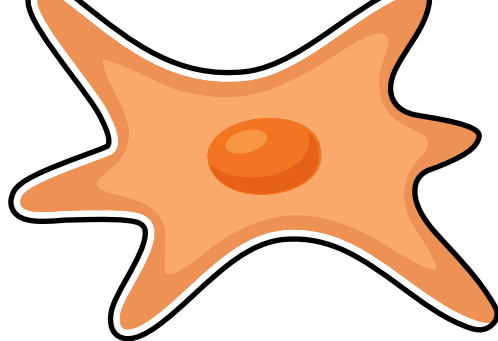


iPSC-derived cells

Enable the generation of defined therapeutic cell types (e.g., cardiomyocytes, neurons, retinal cells).

Key considerations

- Achieving controlled differentiation
- Ensuring purity

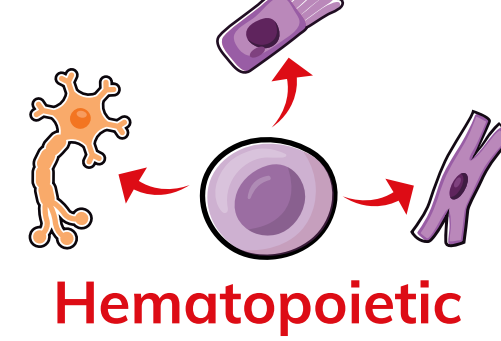


Mesenchymal stromal cells

Widely explored in regenerative and immunomodulatory applications.

Key considerations

- Ensuring consistent expansion
- Maintaining phenotype stability
- Achieving reproducible functional characterization



Hematopoietic stem/progenitor cells

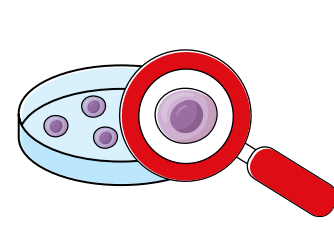
Established therapeutic platform in cell therapy, particularly for blood and immune-related disorders.

Key considerations

- Identifying robust markers for cell identity
- Optimizing viability
- Enhancing engraftment potential

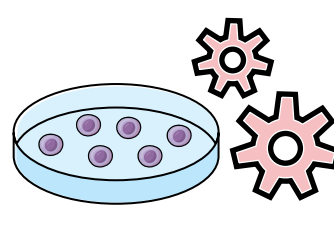
The end-to-end development workflow

Explore the key stages of stem cell therapy development and the critical steps needed to ensure consistency, scalability and functionality throughout the workflow.



Cell sourcing and qualification

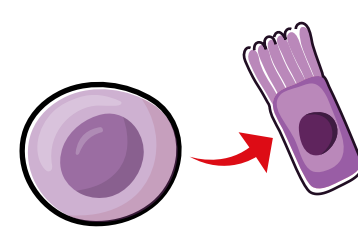
Ensure traceability, documentation and donor variability assessment.



Expansion and culture optimization

Select defined media, consider serum-free or animal component-free systems.

Control seeding densities, monitor doubling time and assess morphology.



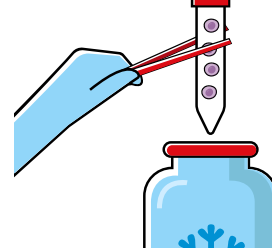
Differentiation or priming

Maintain tight control of timing, supplements, and environmental cues.



Quality control

Assess identity, purity, potency, sterility and functional consistency.



Cryopreservation and recovery

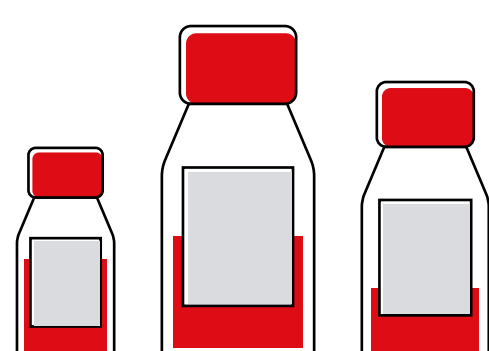
Standardize freeze-thaw protocols to ensure post-thaw performance.



Harvest and formulation

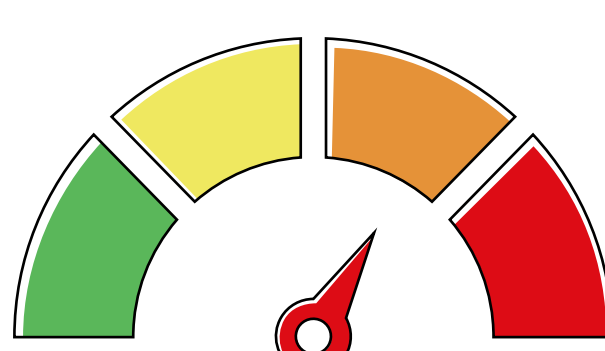
Use gentle handling to preserve phenotype and functionality.

What are the key challenges in stem cell workflows?



Process variability

Differences in media lots, serum-containing reagents, supplements and handling conditions can affect phenotype and potency.



Scale-up pressure

Expanding cells without altering functional characteristics requires careful parameter control.



Potency definition

Functional assays must reflect the intended therapeutic mechanism while remaining reproducible.



Cryopreservation impact

Post-thaw viability does not always equal preserved functionality.

How do I prepare for industrial readiness?



Define critical process parameters early (density, passage number, feeding schedule).



Consider transitioning to serum-free or ACF systems at research stage to support later GMP alignment.



Lock reagent specifications before scale-up to avoid later comparability studies.



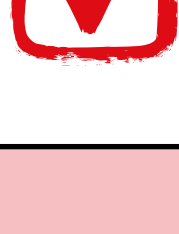
Use bridging experiments when changing media or supplements.



Standardize thawing and recovery timelines before functional testing.



Separate development assays from release assays to ensure clarity.



Plan for documentation and traceability from the beginning.