Clinical iPSC Services For Cell Therapy Manufacturing



Regulatory Compliant iPSCs

REPROCELL's StemRNA[™] Clinical iPSCs provide a benchmark for clinical grade iPSCs. These high-quality iPSCs provide a foundation for various cell therapy programs, ensuring safety, consistency, and regulatory compliance. REPROCELL is a trusted partner for cell therapy developers who are seeking robust, high-quality clinical iPSC banks that meet industry standards.

Your GMP Partner

- StemRNA[™] Clinical Reprogramming: footprintfree iPSC generation
- Ready-to-use clinical iPSCs and custom iPSCs
- Unique evaluation period of Clinical iPSC Clones
- StemEdit[™]: Clinical Gene Editing
- Cell Therapy Manufacturing
- Simple commercial license (one-time royalty only)



Our Clinical Stem Cell Project Workflow

REPROCELL's StemRNA™ Clinical Seed iPSCs are generated utilizing an in-house developed proprietary, footprint-free RNA reprogramming technology, eliminating the risk associated with retention of reprogramming vectors and drastically enhancing the safety profile for clinical applications.

To meet the highest global standards, the donor material and the resulting clinical iPSCs undergo rigorous quality control to ensure compliance with the FDA, EMA and PMDA. These processes include extensive informed consent and donor screening under IRB-approved ethical guidelines to ensure donor eligibility. Additionally, the usage of media and reagents, process controls, and cell bank characterization comply with set guidelines, all monitored through Good Documentation Practices.

Sponsors can choose between various clones and evaluate these to select the best clone for further GMP MCB generation and downstream cell therapy manufacturing.

From our bank of Clinical Seed Clones, we manufacture the corresponding Pilot Clones, allowing you to develop and evaluate your own protocols in a cost-effective manner.

REPROCELL has capability in Europe and in the US to manufacture GMP Master Cell Banks (MCBs) from your chosen clones, providing all the necessary quality and regulatory documents to help you move forward with your cell therapy product.



Three Ways to Access iPSC Clones

- 1. We offer a bank of ready-to-use **StemRNA™ Clinical iPSC Seed Clones** for evaluation.
- 2. We provide corresponding **StemRNA[™] Clinical iPSC Pilot Clones** from these Seed Clones for method development.
- 3. We can create exclusive **StemRNA™ Clinical Seed Clones** matching your donor criteria.

The difference between Seed Clones and Pilot Clones



StemRNA[™] Clinical iPSC Seed Clones (Clinical Use)

These cells are suitable for clinical use through subsequent regulated and approved processes, including activities resulting in a GMP Master Cell Bank and Working Cell Bank. **StemRNA™ Clinical iPSC Seed Clones** are generated following the principles of GMP, and they are covered by a rigorous quality control (QC) process that is compliant with US FDA, European EMA, and Japanese PMDA regulations.

StemRNA[™] Clinical iPSC Pilot Clones (Research Use)

These cells are intended for evaluation purposes only, and they are NOT suitable for downstream therapeutic applications. The *ready-to-use* **StemRNA™ Clinical iPSC Pilot Clones** are created in a research setting from our StemRNA™ Clinical iPSC Seed Clones. These Pilot Clones offer a more cost-effective way to explore the potential of our Clinical Seed iPSCs for developing and optimizing your processes.



The Advantages of the StemRNA[™] Clinical Approach

🖉 Extensive QC at every step of manufacturing ensures compliance with FDA, EMA, and PMDA

Footprint-free clinical RNA reprogramming technology eliminates risks of vector retention

Evaluation phase allows selection of best iPSC clone for GMP manufacturing

Simple commercial license with a one-time royalty fee only and no restriction on any differentiated cell type

Pilot Clones offer a cost-effective bridge from research to GMP manufacturing

Find out more: www.reprocell.com/clinical-stem-cell-services





REPROCELL BRANDS

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