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Japan's Reprocell launches GMP master cell bank manufacturing for clinical iPSCs

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Integrated workflow including clinical seed production and StemEdit gene editing services



Japan-based Reprocell has announced the launch of its US FDA compliant Good Manufacturing Practice (GMP) Master Cell Bank (MCB) manufacturing service for human induced pluripotent stem cells (iPSCs). Operating from its Beltsville, Maryland facility, in the US, Reprocell now offers a comprehensive, end-to-end workflow for clinical iPSC manufacturing.

This integrated service spans from StemRNA™ clinical seed iPSC manufacturing and StemEdit gene editing to GMP Master Cell Bank (MCB) production in compliance with FDA standards. By unifying these critical steps, Reprocell enables cell therapy developers to accelerate IND submissions while reducing regulatory and manufacturing uncertainty.

As part of this platform, the StemRNA Clinical iPSC Seed Clone – LLF-34-F3, derived from US sourced donor material, is supported by an active FDA Drug Master File (DMF). This clone has been expanded into a GMP MCB using FDA-compliant closed system processes. This off-the-shelf GMP iPSC MCB is now available for commercial use, providing ready-to-use clinically validated starting material.

For sponsors requiring European alignment, Reprocell also offers MCB/WCB manufacturing through its partner, Histocell. This service operates with a GMP certificate and authorisation from the Spanish Agency for Medicines and Medical Devices (AEMPS) under European Medicines Agency (EMA) oversight.