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Global GMP-Grade iPSC Master Cell Bank Market Growth (Status and Outlook) 2026-2032

https://marketpublishers.com/r/G7A4F593E3D0EN.html
Date: October 2026
Pages: 87
Price: US$ 3,660.00 (Single User License)
ID: G7A4F593E3D0EN

Abstracts

The global GMP-Grade iPSC Master Cell Bank market size is predicted to grow from US$ 279 million in 2025 to US$ 794 million in 2032; it is expected to grow at a CAGR of 16.2% from 2026 to 2032.

GMP-grade iPSC master cell banks (MCBs) are clinical-grade induced pluripotent stem cell repositories established under GMP or equivalent quality systems. They are derived from donor-derived somatic cells through ethical sourcing (informed consent and donor screening), followed by reprogramming, clone selection, expansion, cryopreservation, and full release testing. These MCBs serve as stable starting materials for the generation of working cell banks (WCBs), gene-edited iPSC lines, directed differentiation products, and downstream cell therapy manufacturing. Their value lies in compliant donor traceability, non-integrating reprogramming methods, genetic stability, sterility and adventitious agent testing, full batch traceability, regulatory documentation readiness, and long-term cryogenic storage management. The estimated gross margin is approximately 58%.

Demand is primarily driven by allogeneic iPSC-based cell therapies, regenerative medicine products, disease modeling platforms, and drug discovery systems. As clinical programs in immune cells, cardiomyocytes, neurons, retinal cells, and other iPSC-derived lineages advance toward late-stage development, developers increasingly prefer GMP-compliant starting materials from the earliest stages. This reduces the risk of re-establishing cell lines, repeating process development, or facing regulatory setbacks later in the development pipeline.

The supply landscape is evolving from standalone cell banking services toward integrated platforms offering clinical-grade seed clones, master cell banks, working cell

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banks, gene editing services, and regulatory submission documentation packages. Core competitive factors include donor compliance and traceability, non-integrating reprogramming methods, low-passage expansion strategies, genomic and karyotypic stability, viral and adventitious agent testing, closed-system GMP manufacturing workflows, DMF or IND/CTA-ready documentation packages, and demonstrated comparability between research-grade and GMP-grade cell lines.

Regionally, North America, Europe, and Japan lead in regulatory experience, clinical-grade banking infrastructure, and CDMO capabilities. China and South Korea are rapidly scaling domestic GMP iPSC platforms. Key risks include donor authorization complexity, intellectual property constraints, divergent regulatory interpretations across jurisdictions, long release-testing cycles, and high batch production costs. Key opportunities lie in off-the-shelf HLA-matched cell banks, hypoimmunogenic gene-edited iPSC libraries, automated manufacturing systems, and standardized regulatory documentation ecosystems.

Report Scope

LPI (LP Information)' newest research report, the “GMP-Grade iPSC Master Cell Bank Industry Forecast” looks at past sales and reviews total world GMP-Grade iPSC Master Cell Bank sales in 2025, providing a comprehensive analysis by region and market sector of projected GMP-Grade iPSC Master Cell Bank sales for 2026 through 2032. With GMP-Grade iPSC Master Cell Bank sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US$ millions of the world GMP-Grade iPSC Master Cell Bank industry.

This Insight Report provides a comprehensive analysis of the global GMP-Grade iPSC Master Cell Bank landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on GMP-Grade iPSC Master Cell Bank portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms’ unique position in an accelerating global GMP-Grade iPSC Master Cell Bank market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for GMP-Grade iPSC Master Cell Bank and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced

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view of the current state and future trajectory in the global GMP-Grade iPSC Master Cell Bank.

This report presents a comprehensive overview, market shares, and growth opportunities of GMP-Grade iPSC Master Cell Bank market by product type, application, key players and key regions and countries.

Segmentation by Type:

Off-the-Shelf GMP iPSC MCB

Custom GMP iPSC MCB

Customer-Owned Line GMP Banking

Technology-Transfer GMP MCB Manufacturing

Segmentation by Starting Cell Source:

CD34+ Cord Blood-Derived iPSC MCB

Peripheral Blood-Derived iPSC MCB

Fibroblast-Derived iPSC MCB

T Cell-Derived iPSC MCB

Other Somatic Cell-Derived iPSC MCB

Segmentation by Quality Documentation Level:

Basic GMP-Released iPSC MCB

Extended Characterized iPSC MCB

Viral Safety-Tested iPSC MCB

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Filing-Ready iPSC MCB

DMF-Supported iPSC MCB

Segmentation by Engineering Status:

Unedited iPSC MCB

Reporter or Selection-Marker Edited iPSC MCB

Disease-Model or Corrected iPSC MCB

Immune-Evasion Edited iPSC MCB

Other Engineered iPSC MCB

Segmentation by Application:

Immune Cell Therapy Development

Regenerative Cell Therapy Development

Gene-Edited Platform Cell Development

Disease Modeling and Drug Screening

Toxicology and Safety Evaluation

Other Clinical Research

This report also splits the market by region:

Americas

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United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

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Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

FUJIFILM Cellular Dynamics

REPROCELL

Cellistic

I Peace

LineaBio

Catalent

Applied StemCell

CiRA Foundation

Ubrigene

Minaris Advanced Therapies

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