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Point-of-Care Cell and Gene Therapy Manufacturing Market - A Global and Regional Analysis: Focus on Technology, Therapeutic Area, End User, and Regional Analysis - Analysis and Forecast, 2025-2035

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Abstracts

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This report will be delivered in 7-10 working days.Point-of-Care Cell and Gene Therapy Manufacturing Market Overview

Point-of-care (POC) cell and gene therapy manufacturing refers to the decentralized production and processing of cell and gene therapies directly at or near the patient's location, such as in hospitals or specialized treatment centers. This approach enables faster, more personalized therapeutic interventions by streamlining the manufacturing process, reducing transportation times, and minimizing delays associated with centralized production facilities

The Point-of-Care (PoC) Cell and Gene Therapy Manufacturing Market is projected to grow significantly driven by key advancements in automation, decentralized manufacturing, and personalized medicine. PoC manufacturing is revolutionizing the production of cell and gene therapies directly at hospitals, clinics, and research centers, bypassing the need for centralized bioprocessing facilities. The market's growth in 2024 is fueled by the rising approval rates of cell and gene therapies, an increase in clinical trials, and the adoption of automated cell processing systems, all of which contribute to reducing costs, improving accessibility, and enhancing patient outcomes. Support from regulatory bodies like the FDA and EMA is accelerating the adoption of decentralized manufacturing. By 2035, PoC manufacturing is expected to become a standard practice, particularly for treatments targeting oncology, autoimmune diseases, and rare

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genetic disorders. Innovations in closed system bioreactors, 3D tissue printing, AI-driven bioprocessing, and mobile processing units will further increase production efficiency, scalability, and affordability in the sector.

The rapid increase in FDA and EMA approvals for cell and gene therapies is a key driver of the Point-of-Care (PoC) manufacturing market. In 2023, the FDA approved more than 10 new cell and gene therapies, with many others in Phase III clinical trials. These drugs rely on complex manufacturing processes that are well-suited to PoC production models. The Alliance for Regenerative Medicine (ARM) predicts that over 20 new gene therapies will gain regulatory approval by 2025, further increasing the demand for decentralized and PoC manufacturing solutions. Additionally, the growing number of clinical trials focused on oncology, autoimmune disorders, and rare genetic diseases is driving the adoption of PoC manufacturing. Hospitals and biotech companies are investing in PoC solutions to meet the rising need for rapid and cost-effective cell therapy production.

Moreover, the development of mobile processing units that enable on-site production at hospitals and clinics is expected to drive the market over a forecast period, These units integrate closed-system bioreactors, automated cell expansion, and real-time monitoring, facilitating the rapid manufacturing of personalized therapies. Companies like Orgenesis are leading the way with mobile PoC manufacturing solutions that reduce dependence on centralized facilities and lower production costs. Additionally, the U.S. National Institutes of Health (NIH) is funding research into mobile CGT production platforms. This innovation enhances accessibility, particularly in regions with limited biomanufacturing infrastructure, while also reducing the turnaround time for critical therapies, such as CAR-T cell treatments. By 2035, mobile manufacturing units are anticipated to become a standard practice, especially in oncology and regenerative medicine.

However, one of the main challenges in Point-of-Care (PoC) cell and gene therapy manufacturing is ensuring regulatory compliance. Unlike traditional centralized manufacturing, PoC production must adhere to Good Manufacturing Practice (GMP) and current GMP (cGMP) standards, which can differ across regions. For instance, FDA guidelines for cell therapies mandate strict contamination control, complicating decentralized production. Similarly, the EU GMP Annex 1 regulations require sterility testing, adding to compliance costs for hospitals adopting PoC manufacturing models. Additionally, scaling PoC models while ensuring consistent product quality and safety poses a significant hurdle. As regulatory agencies such as the FDA, EMA, and Japan’s PMDA update guidelines for decentralized biomanufacturing, companies will need to

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invest heavily in compliance and validation processes. Despite these challenges, collaboration between the industry and regulatory bodies is expected to help streamline approval processes for PoC therapies.

Key players in the Point-of-Care (PoC) Cell and Gene Therapy Manufacturing Market are actively advancing their technologies and expanding their operations to enhance decentralized therapy production. Here are some notable developments. For instance, In January 2024, Orgenesis Inc. acquired full control of Octomera LLC, aiming to advance its immuno-oncology portfolio and streamline decentralized CGT production. This strategic move aligns with Orgenesis's mission to make advanced therapies more accessible and cost-effective. Such initiatives are expected to positively impact the market growth.

Key players in the market are Orgenesis Inc., Miltenyi Biotec, Vineti, Lonza, SQZ Biotechnologies Company, Ori Biotech Ltd, RoosterBio, Inc., Oxford BioMedica plc, Invetech, Wilson Wolf, etc.

Market Segmentation:

Segmentation 1: by Technology

- Microfluidics
- 3 D Printing
- Closed System Bioreactors
- Automated Cell Processing Systems
- Others

Automated Cell Processing Systems to Lead Global Point of Care Cell and Gene Therapy Manufacturing Market (by Technology)

Automated cell processing systems are revolutionizing cell therapy production by enhancing scalability and reducing human error. Miltenyi Biotec's CliniMACS Prodigy platform exemplifies this innovation. This all-in-one system automates complex processes such as cell separation, washing, and genetic modification within a closed,

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GMP-compliant environment, streamlining workflows and ensuring consistent product quality. Similarly, Ori Biotech has developed the IRO platform, which automates key stages of cell therapy manufacturing, including activation, transduction, expansion, and harvest. Launched in collaboration with the Cell Therapy Manufacturing Center (CTMC), a joint venture between Resilience and MD Anderson Cancer Center, the IRO platform facilitates rapid scaling from clinical to commercial production, addressing critical bottlenecks in cell therapy manufacturing.

Segmentation 2: by Therapeutic Area

- Metabolic and Autoimmune Diseases
- Renal Diseases
- Oncology
- Neurological Diseases

Segmentation 3: by End User

- Biotech Companies
- Hospitals and Research Institutes
- Specialty Clinics & Standalone Clinical Setting

Hospitals and Research Institute to Lead the Global Point of Care Cell and Gene Therapy Manufacturing Market (by End User)

Hospitals and research institutes are spearheading the adoption of PoC manufacturing models to meet the growing demand for personalized regenerative therapies. The University of Texas MD Anderson Cancer Center, for instance, launched the Institute for Cell Therapy Discovery & Innovation in 2024, backed by over $80 million in funding. This institute aims to accelerate the development and clinical application of cell therapies for cancer, autoimmune diseases, and infections by integrating advanced manufacturing techniques directly within the clinical setting. Such initiatives exemplify how leading medical centers are investing in PoC models to enhance treatment

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accessibility and efficacy.

Segmentation 4: by Region

- North America
- Europe
- Asia-Pacific
- Latin America
- Middle East and Africa

North America to Lead the Global Point of Care Cell and Gene Therapy Manufacturing Market (by Region)

North America is expected to lead the PoC Cell and Gene Therapy Manufacturing Market due to several key factors. The U.S. boasts a robust research and development infrastructure, with prominent biotech firms, academic institutions, and healthcare centers driving the adoption of PoC manufacturing. Regulatory support from the FDA, including fast-tracked approvals for personalized therapies and endorsement of decentralized manufacturing, further accelerates market growth. Additionally, the U.S. stands as the largest investor in regenerative medicine, with initiatives such as the Cancer Moonshot Program fostering the development of novel therapies. Strategic collaborations between companies like Orgenesis and Lonza and hospitals are also driving the creation of automated, on-site cell therapy production platforms, positioning the U.S. as a leader in the sector.

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Contents

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5. REGION

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6. COMPETITIVE BENCHMARKING AND COMPANY PROFILES

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