

Cell and Gene Therapy Manufacturing Market Forecasts to 2032 – Global Analysis By Therapy Type (Cell Therapy, Gene Therapy, Tissue-Engineered Products, Combination Regenerative Therapies and Other Therapy Types), Scale, Workflow, Mode, Technology, End User and By Geography

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Abstracts

According to Statistics MRC, the Global Cell and Gene Therapy Manufacturing Market is accounted for \$6.004 billion in 2025 and is expected to reach \$19.35 billion by 2032 growing at a CAGR of 18.2% during the forecast period. Cell and Gene Therapy (CGT) Manufacturing refers to the complex process of producing therapeutic products that involve modifying or using human cells or genetic material to treat diseases. It encompasses the sourcing of raw biological materials, cell isolation, genetic modification, expansion, purification, formulation, and quality control to ensure safety, efficacy, and consistency. Manufacturing can be autologous (patient-specific) or allogeneic (off-the-shelf) and often requires specialized facilities, advanced bioreactors, and strict regulatory compliance. CGT manufacturing integrates biotechnology, molecular biology, and engineering to create innovative therapies for conditions such as cancer, rare genetic disorders, and degenerative diseases.

Market Dynamics:

Driver:

Rising incidence of chronic and rare diseases

Conditions such as cancer hemophilia and neurodegenerative disorders require

targeted and durable treatments that conventional drugs cannot address. Platforms support autologous and allogeneic cell processing viral vector production and ex vivo gene editing across therapeutic pipelines. Integration with personalized medicine and orphan drug programs enhances clinical relevance and regulatory alignment. Demand for curative and precision therapies is rising across aging populations and underserved disease areas. These dynamics are propelling infrastructure expansion and platform deployment across advanced therapy manufacturing ecosystems.

Restraint:

Supply chain and logistics issues

Cold chain requirements short shelf life and patient-specific workflows complicate transportation and inventory management. Raw material sourcing equipment availability and skilled labor shortages disrupt production timelines and quality assurance. Regulatory compliance across multi-site and cross-border operations adds to complexity and operational risk. Enterprises face challenges in aligning manufacturing with clinical demand and reimbursement cycles. These constraints continue to hinder platform maturity and global accessibility across cell and gene therapy programs.

Opportunity:

Increased investment in biopharmaceutical R&D

Governments venture capital and strategic partnerships are funding platform scale-up process optimization and regulatory engagement. Platforms support closed-system automation digital batch records and AI-driven quality control across upstream and downstream workflows. Demand for scalable and GMP-compliant manufacturing is rising across oncology rare diseases and regenerative medicine. Integration with CDMOs academic centers and hospital networks enhances flexibility and geographic reach. These trends are fostering growth across innovation-driven and investment-backed manufacturing ecosystems.

Threat:

Limited manufacturing infrastructure

Many regions lack GMP facilities trained personnel and validated equipment for high-

volume and high-complexity therapies. Autologous workflows require decentralized and patient-specific setups that challenge traditional manufacturing models. CDMOs face bottlenecks in vector production cell expansion and release testing due to limited capacity and high demand. Regulatory delays and technology transfer issues further constrain scalability and commercialization. These limitations continue to restrict platform deployment across emerging markets and high-growth therapeutic areas.

Covid-19 Impact:

The pandemic disrupted supply chains clinical trials and facility operations across cell and gene therapy manufacturing. Lockdowns and resource reallocation delayed equipment delivery patient recruitment and regulatory review. However post-pandemic recovery emphasized resilience digitization and advanced therapy acceleration across healthcare systems. Investment in modular cleanrooms remote monitoring and decentralized manufacturing surged across biopharma and CDMO networks. Public awareness of genetic medicine and personalized therapies increased across consumer and clinical segments. These shifts are reinforcing long-term investment in cell and gene therapy infrastructure and global manufacturing capacity.

The viral vector platforms segment is expected to be the largest during the forecast period

The viral vector platforms segment is expected to account for the largest market share during the forecast period due to their foundational role in gene delivery across therapeutic applications. Platforms support AAV Lentivirus and retrovirus production for in vivo and ex vivo gene therapies. Integration with scalable upstream processing purification and analytics enhances yield potency and safety. Demand for high-performance and regulatory-grade vectors is rising across oncology ophthalmology and rare disease pipelines. Vendors offer modular platforms closed systems and digital QC tools to support GMP compliance and tech transfer. These capabilities are boosting segment dominance across gene therapy manufacturing workflows.

The commercial manufacturing segment is expected to have the highest CAGR during the forecast period

Over the forecast period, the commercial manufacturing segment is predicted to witness the highest growth rate as cell and gene therapies transition from clinical trials to market authorization and global distribution. Platforms support scale-up batch release and regulatory documentation across approved and late-stage therapies. Integration with

CDMOs hospital networks and logistics providers enhances throughput and geographic coverage. Demand for cost-efficient and compliant manufacturing is rising across CAR-T gene editing and regenerative medicine programs. Enterprises are aligning commercial readiness with payer engagement and post-market surveillance strategies.

Region with largest share:

During the forecast period, the North America region is expected to hold the largest market share due to its advanced biopharma ecosystem regulatory engagement and infrastructure maturity across cell and gene therapy manufacturing. Enterprises and CDMOs deploy platforms across oncology rare disease and regenerative medicine programs with integrated analytics and automation. Investment in GMP facilities workforce development and digital manufacturing supports scalability and compliance. Presence of leading therapeutic developers academic centers and regulatory bodies drives innovation and standardization. Firms align manufacturing strategies with FDA guidance NIH funding and commercialization roadmaps.

Region with highest CAGR:

Over the forecast period, the Asia Pacific region is anticipated to exhibit the highest CAGR as healthcare modernization biotech investment and disease burden converge across regional economies. Countries like China India Japan and South Korea scale manufacturing platforms across public health academic research and commercial therapy programs. Government-backed initiatives support infrastructure development CDMO expansion and international collaboration across advanced therapies. Local firms offer cost-effective and regionally adapted solutions tailored to regulatory frameworks and patient needs. These trends are accelerating regional growth across cell and gene therapy manufacturing innovation and deployment.

Key players in the market

Some of the key players in Cell and Gene Therapy Manufacturing Market include Thermo Fisher Scientific Inc., Lonza Group AG, Catalent Inc., Fujifilm Diosynth Biotechnologies Inc., WuXi Advanced Therapies Inc., Samsung Biologics Co., Ltd., AGC Biologics Inc., Minaris Regenerative Medicine GmbH, Oxford Biomedica plc, Charles River Laboratories International Inc., Recipharm AB, Merck KGaA, Takara Bio Inc., Miltenyi Biotec B.V. & Co. KG and BioNTech SE.

Key Developments:

In July 2025, Lonza confirmed that its \$1.2 billion acquisition of Genentech's Vacaville facility (2024) drove CHF 3.1 billion in H1 2025 CDMO sales, with 23.1% growth at constant exchange rates. The 330,000-liter bioreactor site significantly boosted Lonza's biologics capacity and margin resilience, outperforming peers like WuXi and Samsung. This acquisition positioned Lonza as a global CDMO leader in large-scale cell and gene therapy manufacturing.

In April 2025, Thermo Fisher launched Gibco™ CTS Viral Vector Production System, a closed modular solution for AAV and lentiviral manufacturing. The system enabled scalable, GMP-compliant production for clinical and commercial gene therapies. It integrated with Thermo's bioprocessing and analytics platforms, supporting faster turnaround and reduced contamination risk in cell and gene therapy workflows.

Therapy Types Covered:

Cell Therapy

Gene Therapy

Tissue-Engineered Products

Combination Regenerative Therapies

Other Therapy Types

Scales Covered:

Research & Development

Clinical-Scale Manufacturing

Commercial Manufacturing

Workflows Covered:

Vector Production

Cell Processing

Cell Banking

Regulatory Compliance & Validation

Other Workflows

Modes Covered:

In-House Manufacturing

Contract Manufacturing (CDMOs)

Hybrid Manufacturing Models

Technologies Covered:

Viral Vector Platforms

Non-Viral Delivery Systems

Cell Expansion & Banking Technologies

Quality Control & Release Testing Tools

Other Technologies

End Users Covered:

Biopharmaceutical Companies

Academic & Research Institutes

CROs & CDMOs

Hospitals & Clinics

Cell & Gene Therapy Startups

Other End Users

Regions Covered:

North America

US

Canada

Mexico

Europe

Germany

UK

Italy

France

Spain

Rest of Europe

Asia Pacific

Japan

China

India

Australia

New Zealand

South Korea

Rest of Asia Pacific

South America

Argentina

Brazil

Chile

Rest of South America

Middle East & Africa

Saudi Arabia

UAE

Qatar

South Africa

Rest of Middle East & Africa

What our report offers:

- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2024, 2025, 2026, 2028, and 2032
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market

estimations

- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

Free Customization Offerings:

All the customers of this report will be entitled to receive one of the following free customization options:

Company Profiling

Comprehensive profiling of additional market players (up to 3)

SWOT Analysis of key players (up to 3)

Regional Segmentation

Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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