

North America Cell and Gene Therapy Manufacturing Services Market Forecast to 2030 - Regional Analysis - by Type [Cell Therapy (Autologous and Allogenic) and Gene Therapy (Viral and Non-Viral Vector)], Indication (Cancer, Orthopedics, and Others), Application (Clinical Manufacturing and Commercial Manufacturing), and End User [Pharmaceutical and Biotechnology Companies and Contract Research Organization (CROs)]

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Abstracts

The North America cell and gene therapy manufacturing services market is expected to grow from US\$ 4,153.27 million in 2022 to US\$ 14,711.72 million by 2030. It is estimated to grow at a CAGR of 17.1% from 2022 to 2030.

Increasing Popularity of Outsourcing Cell and Gene Therapy Manufacturing Drives North America Cell and Gene Therapy Manufacturing Services Market

Cell and gene therapy manufacturing is a complex process, which makes the proper execution and overseeing of the operation crucial. Cell and gene therapy manufacturers have a limited number of qualified personnel who know biological and process engineering. Moreover, for experienced teams, managing the attempts to reach the first clinical trial using a manual, and open manufacturing method and then building a more commercially suitable process can be tricky. Therefore, these enterprises choose to work with contract development and manufacturing organizations (CDMOs) to accelerate their clinical studies and commercialization process. CDMOs provide product development, manufacturing, clinical trial support, and commercialization services to cell and gene therapy companies on a contract basis. Partnering with a CDMO enables scalability, speed to market, access to technical expertise without overhead costs, and

cost efficiencies for cell and gene therapy manufacturers. In April 2022, ThermoGenesis established a CDMO facility in California, US to provide CDMO services to cell and gene therapy manufacturers, using its expertise in T-cell receptor (TCR), chimeric antigen receptor-T cell (CAR-T cell), tumor-infiltrating leukocyte (TIL), iPSC, natural killer cell (NK), and mesenchymal stem cell (MSC) manufacturing. Outsourcing cell and gene therapy manufacturing to CDMOs proves cost-effective for manufacturers. Thus, the increasing preference for outsourcing growing cell and gene therapy manufacturing to CDMOs fuels the North America cell and gene therapy manufacturing services market growth.

North America Cell and Gene Therapy Manufacturing Services Market Overview

Cell and gene therapies (CGTs) treat patients suffering from serious and rare diseases with unaddressed therapeutic needs. Manufacturing CGTs is a highly complex process, with the insufficiency of infrastructure and expertise being a major limiting factor. Logistical challenges associated with intermediates and the final product also limit the CGT manufacturing capacity of companies. The CGT manufacturing process involves the extraction of autologous cells through "apheresis," dispatching them to specialized labs, and sending them back to clinics for administration into patients, all of which must be performed with strict quality control. The US Food and Drug Administration (USFDA) has approved only 7 CGT drugs, with the pipeline of new products reaching ~1,200 experimental therapies. Half of these are in Phase 2 clinical trials, with estimates of annual sales growth accounting for 15% for cell therapies and ~30% for gene therapies, as per the estimates of the Chemical & Engineering News report 2022. On March 31, 2022, CELL Technologies Inc. announced the submission of the clinical data of its stem cell program in pain and arthritis for approval by Health Canada to help patients access evidence-based and regulatory-approved stem cell procedures across Canada. Thus, the abovementioned factors are expected to promote the cell and gene therapy manufacturing services market growth during the forecast period. Thus, the abovementioned factors are responsible for the growth of the North America cell and gene therapy manufacturing services market.

North America Cell and Gene Therapy Manufacturing Services Market Revenue and Forecast to 2030 (US\$ Million)

North America Cell and Gene Therapy Manufacturing Services Market Segmentation

The North America cell and gene therapy manufacturing services market is segmented into type, indication, application, end user, and country.

Based on type, the North America cell and gene therapy manufacturing services market is bifurcated into cell therapy and gene therapy. In 2022, the cell therapy segment registered a larger share in the North America cell and gene therapy manufacturing services market. The cell therapy segment is further segmented into autologous and allogenic. The gene therapy segment is further segmented into viral and non-viral

vector.

Based on indication, the North America cell and gene therapy manufacturing services market is segmented into cancer, orthopedics, and others. In 2022, the cancer segment registered the largest share in the North America cell and gene therapy manufacturing services market.

Based on application, the North America cell and gene therapy manufacturing services market is segmented into clinical manufacturing and commercial manufacturing. In 2022, the commercial manufacturing segment registered the largest share in the North America cell and gene therapy manufacturing services market.

Based on end user, the North America cell and gene therapy manufacturing services market is bifurcated into pharmaceutical and biotechnology companies and contract research organization (CROs). In 2022, the pharmaceutical and biotechnology companies segment registered a larger share in the North America cell and gene therapy manufacturing services market.

Based on country, the North America cell and gene therapy manufacturing services market is segmented into the US, Canada, Mexico. In 2022, the US registered the largest share in the North America cell and gene therapy manufacturing services market.

Catalent Inc, Charles River Laboratories International Inc, FUJIFILM Holdings Corp, Lonza Group AG, Merck KgaA, National Resilience Inc, Nikon Corp, Oxford BioMedica Plc, Takara Bio Inc, Thermo Fisher Scientific Inc, and WuXi AppTec Co Ltd are some of the leading companies operating in the North America cell and gene therapy manufacturing services market.

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