

North America Cell and Gene Therapy Contract Development and Manufacturing Organization Market Size and Forecast (2021 - 2031)

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Abstracts

The North America Cell and Gene Therapy Contract Development and Manufacturing Organization (CDMO) market is poised for significant growth, with projections indicating that it will reach approximately USD 15,571.7 million by 2031, up from USD 3,012.9 million in 2024. This growth trajectory reflects a compound annual growth rate (CAGR) of 26.6% from 2025 to 2031, underscoring the increasing demand for specialized manufacturing services in the biotechnology sector.

Executive Summary

The North American market for cell and gene therapy CDMOs encompasses the United States, Canada, and Mexico, with the U.S. expected to dominate the market share. The robust growth in this sector is primarily driven by the rising prevalence of genetic disorders, advancements in biotechnology, and an escalating demand for specialized manufacturing capabilities.

Technological innovations are pivotal in this growth, particularly the integration of artificial intelligence (AI) and automation into manufacturing processes. These advancements enhance efficiency, scalability, and cost-effectiveness. For example, companies like OmniaBio are utilizing AI to streamline production workflows, thereby improving both the speed and quality of manufacturing. Furthermore, the consolidation of CDMOs through mergers and acquisitions is expanding their capabilities and geographic reach, which in turn enhances service offerings and operational efficiency.

Market Segmentation Analysis

The North America Cell and Gene Therapy CDMO market can be segmented based on service type, product type, and end user:

By Service Type: The market is divided into Drug Development and Manufacturing, Testing and Regulatory Services, and Others. In 2024, Drug Development and Manufacturing is expected to hold the largest market share.

By Product Type: The market is categorized into Gene Therapy and Cell Therapy, with Gene Therapy anticipated to dominate in 2024.

By End User: The market is segmented into Pharmaceutical Companies, Biopharmaceutical Companies, and Others, where Biopharmaceutical Companies are projected to hold the largest share in 2024.

Market Outlook

Cell and gene therapies necessitate highly specialized manufacturing processes, including the production of viral vectors, transduced cells, and other specialized biological materials. These therapies often target rare or complex diseases, such as genetic disorders, cancer, and autoimmune diseases. As of 2024, there are approximately 1,975 ongoing clinical trials for cell and gene therapies (CGTs), marking a critical year for approvals, with many more therapies in the pipeline. This surge in clinical trials is driving the demand for CDMOs, as biopharmaceutical companies, particularly small and medium-sized enterprises, often lack the necessary infrastructure and expertise for manufacturing these complex therapies.

The partnership between Autologus Therapeutics and AGC Biologics Milan, initiated in 2020, exemplifies the collaboration needed to develop, manufacture, and supply viral vectors for Autolus' CAR-T product candidate, AUCATZYL. Such collaborations are essential for bringing innovative therapies to market efficiently. Additionally, technological advancements, including AI, are optimizing manufacturing processes for clinical trials, enabling more efficient and cost-effective production methods that are crucial given the complexities involved in cell and gene therapy manufacturing.

Country Insights

The North American market is further segmented by country, with the United States, Canada, and Mexico being the primary regions. The U.S. is expected to hold the largest

market share in 2024, driven by advancements in biotechnology, a rising prevalence of genetic diseases, and an increasing demand for specialized manufacturing services. According to the U.S. Government Accountability Office, approximately 25 to 30 million people in the U.S. suffer from rare diseases, with over 7,000 rare diseases identified by the FDA. This growing understanding of rare diseases has catalyzed the development of gene therapies.

The approval of advanced therapies is a significant market driver. In 2023, the FDA approved several cell and gene therapies, including gene-editing treatments for rare diseases, such as exagamglogene autotemcel (Casgevy) for sickle cell disease and valoctocogene roxaparvovec for severe hemophilia A. The accelerated regulatory pathways, such as the Regenerative Medicine Advanced Therapy (RMAT) designation, have encouraged biotechnology companies to partner with CDMOs to scale production effectively.

Company Profiles

Key players in the North America Cell and Gene Therapy CDMO market include Charles River Laboratories International Inc, Catalent Inc, Lonza Group AG, WuXi Biologics Inc, Pluri Inc, Aenova Holding GmbH, Takara Bio Inc, FUJIFILM Holdings Corp, AGC Biologics AS, Thermo Fisher Scientific Inc., Minaris Advanced Therapies, and SK pharmteco Inc. These companies are employing various strategies, including expansion, product innovation, and mergers and acquisitions, to enhance their market presence and offer innovative solutions to their clients.

In conclusion, the North America Cell and Gene Therapy CDMO market is on a robust growth path, driven by technological advancements, increasing clinical trials, and a rising demand for specialized manufacturing services. As the market evolves, CDMOs will play a crucial role in the development and commercialization of innovative therapies targeting complex diseases.

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