

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

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Abstracts

The South & Central America Cell and Gene Therapy Contract Development and Manufacturing Organization (CDMO) market is projected to grow significantly, reaching an estimated US\$ 586.7 million by 2031, up from US\$ 158.4 million in 2024. This growth represents a compound annual growth rate (CAGR) of 20.6% from 2025 to 2031, indicating a robust expansion in this sector.

Executive Summary and Market Analysis

The cell and gene therapy CDMO market in South & Central America is primarily divided into three regions: Brazil, Argentina, and the Rest of South & Central America. Governments in these countries are actively promoting biopharmaceutical innovation through regulatory reforms and investments in biotechnology infrastructure. This governmental support has fostered a favorable investment climate, encouraging collaborations between local CDMOs and global biotech firms.

A significant driver of market growth is the rising prevalence of genetic and rare diseases in the region, which has created an urgent demand for advanced therapies. With limited local capacity to produce highly specialized treatments, many biopharmaceutical companies are turning to CDMOs for efficient development and delivery of cell and gene therapies that meet regional health needs. Furthermore, improvements in healthcare infrastructure, partnerships between companies and local entities, and the development of skilled scientific talent across South & Central America are enhancing the region's ability to support complex processes involved in cell and gene therapy, such as vector manufacturing, cell modification, and clinical trial support.

Strategic Insights

Market Segmentation Analysis

The South & Central America CDMO market for cell and gene therapy can be segmented by 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 held the largest market share.

By Product Type: The market is categorized into Gene Therapy and Cell Therapy, with Gene Therapy dominating the market share in 2024.

By End User: The end users include Pharmaceutical Companies, Biopharmaceutical Companies, and Others, with Biopharmaceutical Companies holding the largest share in 2024.

Market Outlook

The increasing demand for cell and gene therapies is driving biopharmaceutical companies to seek out CDMOs that can provide state-of-the-art facilities and technologies necessary for scaling up production while ensuring quality, compliance, and regulatory approval. These specialized capabilities are crucial for the production of complex and personalized therapies, which require advanced infrastructure to maintain high manufacturing standards.

Cell and gene therapies, including gene editing, viral vector production, and personalized medicine, necessitate specialized facilities equipped with the latest technologies. The production of viral vectors, essential for gene therapies, requires Good Manufacturing Practice (GMP) standard facilities to ensure the safety, consistency, and quality of the final product. These facilities must be capable of handling complex biological materials, such as live cells and genetically modified organisms, in controlled environments.

The adoption of automated cell culture systems, continuous manufacturing, and digital quality monitoring systems is enhancing the efficiency and growth of gene therapy production. The need for specialized facilities presents a significant opportunity for

CDMOs, as it is often more cost-effective for biopharma companies to collaborate with CDMOs that possess the necessary technology and infrastructure. For example, in 2023, Bristol-Myers Squibb partnered with a CDMO for the production of its CAR-T cell therapy, Breyanzi, which involves harvesting, modifying, and expanding a patient's T-cells. This process requires specialized technology and facilities to ensure the desired therapeutic outcomes. By leveraging CDMO expertise, Bristol-Myers Squibb was able to scale production while maintaining regulatory compliance and quality standards.

Country Insights

The market is further segmented by country, with Brazil, Argentina, and the Rest of South & Central America being the key regions. Brazil is expected to hold the largest market share in 2024.

The Brazilian government has played a crucial role in advancing the cell and gene therapy sector. According to a report titled "First Gene Therapy Products Approved in Brazil," Brazil became the first Latin American country to approve gene therapy products. The Brazilian Health Regulatory Agency (ANVISA) granted marketing authorization for Novartis' gene therapy products, Luxturna and Zolgensma, which have also received approval from the Brazilian Technical Commission of Biosafety (CTNBio). This regulatory initiative has facilitated the introduction of innovative treatments into the market and attracted international CDMOs to establish operations in Brazil.

The demand for cell and gene therapies in Brazil is further supported by its large patient population and the prevalence of genetic disorders. Studies indicate that approximately 53,746 live births in Brazil are affected by rare genetic diseases, and around 13.2 million individuals suffer from rare diseases. This substantial demand for innovative therapies is a key factor driving the growth of CDMOs in the region.

Company Profiles

Key players in the South & Central America CDMO market for cell and gene therapy 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.

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