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Cell and Gene Therapy Contract Development and Manufacturing Organization Market Size and Forecast (2021 - 2031), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By Service Type (Drug Development and Manufacturing, Testing and Regulatory Services, and Others), Product Type (Gene Therapy and Cell Therapy), End User (Pharmaceutical Companies, Biopharmaceutical Companies, and Others), and Geography

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Abstracts

According to our new research study on “Cell and Gene Therapy Contract Development and Manufacturing Organization Market Forecast to 2031 –Global Analysis – by Service Type, Product Type, End User, and Geography,” the market is anticipated to grow from US$ 6.22 billion in 2024 and is projected to reach US$ 31.86 billion by 2031; it is expected to register a CAGR of 26.4% during 2025–2031. Increasing clinical trials for innovative therapies and surging regulatory approvals and commercialization are contributing to the growing cell and gene therapy contract development and manufacturing organization market size. However, the high manufacturing complexities hampers the cell and gene therapy contract development and manufacturing organization market growth. Further, rising integration of AI and digital transformation is expected to bring in new cell and gene therapy contract development and manufacturing organization market trends in the coming years.

In terms of revenue, North America dominated the market in 2024. It is estimated to dominate the global market during the forecast period. The US is the largest market for cell and gene therapy contract development and manufacturing organization in the

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world. The US is observing growing advancements in biotechnology, an increasing prevalence of genetic diseases, and surging demand for specialized manufacturing services. As per the estimates of the US Government Accountability Office published in October 2021, ~25 to 30 million people suffer from rare diseases in the country. As per the Food and Drug Administration (FDA), more than 7,000 rare diseases affect over 30 million people in the country. The growing understanding of these diseases has led to a surge in gene therapy development. CDMOs play a crucial role in this space by providing specialized services for the development and manufacturing of gene therapies targeting rare genetic disorders.

In 2023, the US FDA approved numerous cell and gene therapies, including gene-editing treatments targeting rare diseases. Therapies such as exagamglogene autotemcel (Casgevy) and lovotibeglogene autotemcel for sickle cell disease, as well as valoctocogene roxaparvovec for severe hemophilia A, have received FDA approval, highlighting the potential of gene therapies in addressing rare disease challenges. The accelerated regulatory pathways, such as the Regenerative Medicine Advanced Therapy (RMAT) designation, have spurred biotechnology companies to partner with CDMOs for scaling production.

Investments in manufacturing infrastructure have bolstered the market growth. The National Cell Manufacturing Consortium, established through collaboration between 15 academic institutes, over 25 companies, and government agencies, aims to enable cost-effective, large-scale manufacturing of cell therapies. In addition, strategic collaborations between CDMOs, academic institutions, and biopharma companies also contribute to market growth.

Cell and Gene Therapy Contract Development and Manufacturing Organization Market Analysis

Access to Specialized Facilities and Technologies to Provide Market Opportunities in Future

The demand for cell and gene therapies is driving biopharmaceutical companies toward CDMOs that can provide cutting-edge facilities and technologies, which are required to scale up production while ensuring quality, compliance, and regulatory approval. These specialized capabilities are essential 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, require specialized facilities equipped with the latest

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technologies. The production of viral vectors used in gene therapies requires GMP standard facilities to ensure the safety, consistency, and quality of the final product. These facilities should be equipped to handle complex biological materials, such as live cells and genetically modified organisms, in controlled and monitored environments. The increasing adoption of automated cell culture systems, continuous manufacturing, and digital quality monitoring systems enhances the growth and efficiency of gene therapy production. For instance, in March 2025, Bharat Biotech invested US$ 75 million in its first cell and gene therapy facility in the southern India which is expected to launch new therapies in next 3 years for oncology and rare disease.

The need for specialized facilities creates a substantial opportunity for CDMOs. It is cost-effective and efficient for biopharma companies to collaborate with CDMOs that have the required technology and facilities. For instance, in 2023, Bristol-Myers Squibb collaborated with a CDMO for the production of its CAR-T cell therapy, Breyanzi. This therapy involves harvesting, modifying, and expanding a patient's T-cells, a process requiring specialized technology and facilities to ensure the desired therapeutic effect. By leveraging CDMO expertise in specialized facilities, Bristol-Myers Squibb was able to scale production while ensuring regulatory compliance and quality. Thus, the soaring need for advanced manufacturing capabilities with advanced technology is expected to create future growth opportunities for the cell and gene therapy contract research and development organization market.

Cell and Gene Therapy Contract Development and Manufacturing Organization Market Report Segmentation Analysis

Key segments that contributed to the derivation of the cell and gene therapy contract development and manufacturing organization market analysis are service type, product type, and end user.

Based on service type, the cell and gene therapy contract development and manufacturing organization market is segmented into drug development and manufacturing, testing and regulatory services, and others. The drug development and manufacturing segment held the largest share of the market in 2024.

In terms of product type, the cell and gene therapy contract development and manufacturing organization market is bifurcated into gene therapy and cell therapy. The cell therapy segment dominated the market in 2024.

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By end user, the cell and gene therapy contract development and manufacturing organization market is categorized into pharmaceutical companies, biopharmaceutical companies, and others. The biopharmaceutical companies segment dominated the market in 2024.

Cell and Gene Therapy Contract Development and Manufacturing Organization Market: Competitive Landscape and Key Developments

WuXi Biologics Inc, Charles River Laboratories International Inc, Catalent Inc, Lonza Group AG, Thermo Fisher Scientific Inc., AGC Biologics AS, Takara Bio Inc, FUJIFILM Holdings Corp, Pluri Inc, SK pharmteco Inc, Aenova Holding GmbH, and Minaris Advanced Therapies are among the key companies operating in the cell and gene therapy contract development and manufacturing organization market.

Statistics Canada, World Population Prospectus, Globocan, Brazilian Health Regulatory Agency (ANVISA), Alliance for Regenerative Medicine (ARM), and the Food and Drug Administration (FDA) are among the primary and secondary sources referred to while preparing the cell and gene therapy contract development and manufacturing organization market report.

Reason to buy

Save and reduce time carrying out entry-level research by identifying the growth, size, leading players, and segments in the cell and gene therapy contract development and manufacturing organization market.

Highlights key business priorities in order to assist companies to realign their business strategies.

The key findings and recommendations highlight crucial progressive industry trends in the cell and gene therapy contract development and manufacturing organization market, thereby allowing players across the value chain to develop effective long-term strategies.

Develop/modify business expansion plans by using substantial growth offering developed and emerging markets.

Scrutinize in-depth market trends and outlook coupled with the factors driving

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the market, as well as those hindering it.

Enhance the decision-making process by understanding the strategies that underpin security interest with respect to client products, segmentation, pricing, and distribution.

The List of Companies - Cell and Gene Therapy Contract Development and Manufacturing Organization Market

WuXi Biologics Inc

Charles River Laboratories International Inc

Catalent Inc

Lonza Group AG

Thermo Fisher Scientific Inc.

AGC Biologics AS

Takara Bio Inc

FUJIFILM Holdings Corp

Pluri Inc

SK pharmteco Inc

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