

Cell and Gene Therapy Biomanufacturing Market - A Global and Regional Analysis: Focus on Product Type, Application, Usage, End User, and Region - Analysis and Forecast, 2022-2031

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Abstracts

Global Cell and Gene Therapy Biomanufacturing Market Industry Overview

The global cell and gene therapy biomanufacturing market was valued at \$12.31 billion in 2022 and is anticipated to reach \$29.76 billion by 2031, witnessing a CAGR of 10.31% during the forecast period 2022-2031. The growth in the global cell and gene therapy biomanufacturing market is expected to be driven by the increased number of approved therapies and growing infrastructure requirements. In addition, expansion in target indications for cell and gene therapies creates a demand for large-scale biomanufacturing.

Market Lifecycle Stage

The global cell and gene therapy biomanufacturing market is in progressing phase. The cell and gene therapy market is developing rapidly due to its potential to target chronic and rare/orphan diseases that earlier had limited treatment options. Cell and gene therapies available in the market or in the pipeline are the result of years of pioneering research. Currently, there are more than 25 cell and gene therapies approved by the FDA in the last 10 years. These factors are expected to drive the demand for consumables, equipment, and software solutions required for manufacturing cell and gene therapy, thereby augmenting the growth of the cell and gene therapy biomanufacturing market.

Moreover, manufacturers began to produce application-specific cell and gene therapy

equipment in recent years.

Impact

The field of medicine is transformed with the commercialization of cell and gene therapies. With the advent of time and introduction of new technologies, cell and gene therapy areas are flourishing. There is constant ongoing research for the development of novel cell and gene therapies. According to the American Society of Gene + Cell Therapy (ASGCT), as of February 2023, there are more than 2,000 clinical trials in the pipeline. The robust clinical pipeline for novel cell and gene entities is expected to create a lucrative opportunity for manufacturers and boost the growth of the cell and gene therapy biomanufacturing market.

Impact of COVID-19

In December 2019, Wuhan, a city in the Hubei region of China, was the site of the first detection of the COVID-19 outbreak. Following the classification of COVID-19 as novel pneumonia due to a cluster of unexplained pneumonia cases, efforts to pinpoint the culprit causing the outbreak and outline its genomic sequence got underway right once. The virus has already spread to every country on the globe, and researchers, governments, and business leaders are working to find answers to the crisis at a scale and speed that has never been seen. Testing for SARS-CoV-2 in the populace is one of the main steps that has been put into place globally, among many other measures used to stop the spread of the disease. The most crucial benefit of testing is that it offers evidence of illness, enabling individuals and those they have come into contact with to take the required precautions, including quarantining, to minimize community exposure.

The COVID-19 pandemic has substantially interrupted social, economic, and political activity around the world due to its unparalleled size and intensity. As a result, the cell and gene therapy (CGT) sector, which has historically struggled with tremendous complexity in the supply of materials, production, and logistical operations, has been disrupted by COVID-19.

The research, production, clinical development, and market introduction of CGTs for diseases unrelated to COVID-19 have all been significantly disrupted as a result of the COVID-19 pandemic. A lack of manufacturing material supplies, challenges with clinical studies, and delay in the creation of regulatory dossiers are all significant reasons. This has emphasized the significance of tackling the difficulties in CGTs' supply chain and production to increase resilience during the crisis.

To prevent CGTs' market access from being significantly disrupted, manufacturing resilience, digitalization, telemedicine, value-based pricing, and creative payment systems may be progressively tapped.

Market Segmentation:

Segmentation 1: by Product Type

Consumables

Equipment

Software Solutions

Based on product, the consumables segment in the global cell and gene therapy biomanufacturing market dominated in FY2021. The equipment has a shelf life of five to seven years and software solutions also require a one-time investment with yearly maintenance costs. However, consumables are required more frequently and in large quantities for the production of cell and gene therapies.

Segmentation 2: by Usage

Commercial Stage Manufacturing

Research Stage Manufacturing

Based on usage, the global cell and gene therapy biomanufacturing market was dominated by the research stage manufacturing segment in FY2021.

Segmentation 3: by Application

Upstream Processing

Harvesting

Downstream Processing

Based on application, the downstream processing segment accounted for the largest share of the global cell and gene therapy biomanufacturing in FY2021.

Segmentation 4: by End User

Life Science Companies

Contract Research Organizations (CROs)

Contract Manufacturing Organizations (CMOs)

Cell Banks

Based on end user, the global cell and gene therapy biomanufacturing market is dominated by the life sciences companies segment in FY2021.

Segmentation 5: by Region

North America

Europe

Asia-Pacific

Latin America

Middle East and Africa

In 2021, the North America cell and gene therapy biomanufacturing market dominated the global market with a 44.70% market share, and it is expected to hold its dominance throughout the forecast period 2022-2031. However, the Asia-Pacific (APAC) region, constituting several emerging economies, is expected to register the highest CAGR of 17.88% during the forecast period 2022-2031.

Recent Developments in the Global Cell and Gene Therapy Biomanufacturing Market

In January 2023, Sartorius AG collaborated with Roosterbio Inc. to advance its downstream purification processes for the development of exosomes.

In February 2022, Sartorius AG completed the acquisition of Novasep's chromatography division to complement its own product portfolio.

In August 2022, Merck KGaA launched VirusExpress 293 Adeno-Associated Virus (AAV) Production Platform to speed up the development of cell and gene therapies.

In June 2022, Lonza Group AG and Adva Biotechnology Ltd. entered into a license agreement that provides the latter access to the former's core intellectual property enabling the expansion of automated bioreactors worldwide.

In June 2022, Becton, Dickinson and Company launched FACSDiscover S8 Cell Sorter featuring CellView Image Technology.

In January 2023, Bio-Techne Corporation launched RNAscope plus assay to advance its gene therapy development.

In September 2021, Thermo Fisher Scientific Inc. launched the integrated Gibco AAV-MAX Helper Free AAV Production System for AAV vector production.

Demand - Drivers and Limitations

The following are the demand drivers for the global cell and gene therapy biomanufacturing market:

Increasing Number of Approved Therapies and Growing Infrastructure Requirements Creating an Upsurge Demand for Cell and Gene Therapy Biomanufacturing Products

Expansion in Target Indications for Cell and Gene Therapies Creating a Demand for Large-Scale Biomanufacturing

Entry of New Market Participants in Cell and Gene Therapies Driving the Demand for Biomanufacturing Facilities and Equipment

Increasing Investments and Fundings in Cell and Gene Therapy Fuelling the Growth of Cell and Gene Therapy Biomanufacturing

The market is expected to face some limitations due to the following challenges:

High Set-Up Cost of Biomanufacturing Facilities

How can this report add value to an organization?

Workflow/Innovation Strategy: The cell and gene therapy biomanufacturing market (by product type) has been segmented into consumables, equipment, and software solutions. Moreover, the study provides the reader with a detailed understanding of the different applications of cell and gene therapy biomanufacturing in upstream processing, harvesting, and downstream processing.

Growth/Marketing Strategy: Cell and gene therapy biomanufacturing is being used for upstream processing, harvesting, downstream processing, and other applications. Various companies are providing consumables and equipment aid in the manufacturing of various cell and gene therapies, which is also the key strategy for market players to excel in the current cell and gene therapy biomanufacturing market.

Competitive Strategy: Key players in the global cell and gene therapy biomanufacturing market have been analyzed and profiled in the study, including manufacturers involved in new product launches, acquisitions, expansions, and strategic collaborations. Moreover, a detailed competitive benchmarking of the players operating in the global cell and gene therapy biomanufacturing market has been done to help the reader understand how players stack against each other, presenting a clear market landscape. Additionally, comprehensive competitive strategies such as partnerships, agreements, and collaborations will aid the reader in understanding the untapped revenue pockets in the market.

Key Companies Profiled

Becton, Dickinson and Company

Bio-Rad Laboratories, Inc.

Bio-Techne Corporation

Danaher Corporation

Endress+Hauser Group Services AG (Analytik Jena GmbH)

General Electric Company (GE Healthcare)

Getinge AB

Infors AG

Lonza Group Ltd

Merck KGaA

Miltenyi Biotec B.V. & Co. KG

PIERRE GUERIN

Sartorius AG (Sartorius Stedim Biotech S.A.)

Thermo Fisher Scientific Inc.

WuXi AppTec

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