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Cell and Gene Therapy Manufacturing QC Market - A Global and Regional Analysis : Focus on Therapy Type, Offering, Process, Technology, Application, and Region - Analysis and Forecast, 2023-2033

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Abstracts

Global Cell and Gene Therapy Manufacturing QC Market Industry Overview

The global cell and gene therapy manufacturing QC market was valued at $1.95 billion in 2022 and is anticipated to reach $10.65 billion by 2033, witnessing a CAGR of 16.85% during the forecast period 2023-2033. The growth in the global cell and gene therapy manufacturing QC 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-based therapies creates a demand for large-scale manufacturing and QC.

Market Lifecycle Stage

The global cell and gene therapy manufacturing QC market is in progressing phase. The cell and gene therapy manufacturing QC market is experiencing rapid growth due to the increasing adoption of innovative therapies such as CAR T-cells and others. Robust quality control processes are essential to ensure the safety, efficacy, and consistency of cell and gene-based treatments. The FDA has approved more than 25 cell and gene-based therapies in the last 10 years. These factors are expected to drive the demand for consumables, instruments, and software solutions required for manufacturing cell and gene therapy, thereby augmenting the growth of the cell and gene therapy manufacturing QC market.

Impact

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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 and 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 QC and boost the growth of the cell and gene therapy manufacturing QC market. In addition, the entry of several established players, such as Lonza., Merck KGaA, Charles River Laboratories International Inc., Eurofins Scientific, and others, is expected to aid the market growth.

The field of cell and gene therapy manufacturing QC is witnessing several trends and advancements that are expected to have a significant impact on the market. Some of the trends include the adoption of automation QC processes, advanced analytical technologies, process analytical testing (PAT) and quality risk management (QRM), and others. These trends and advancements in cell and gene therapy manufacturing QC are expected to drive improvements in product quality, manufacturing efficiency, regulatory compliance, and patient safety. They are expected to play a crucial role in supporting the growth and success of the cell and gene therapy industry, making QC an integral part of the development and commercialization of these advanced therapies.

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 those who are tested 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

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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 cell and gene-based therapies (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 a delay in the creation of regulatory dossiers are all significant reasons for the manufacturing of cell and gene therapy. 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 Therapy Type

Cell Therapy

Gene Therapy

Based on therapy type, the cell therapy segment dominated the global cell and gene therapy manufacturing QC market in FY2022. The increasing adoption of cell-based therapies, such as CAR-T cell therapy and stem cell therapy, contributed to the prominence of the cell therapy segment. Cell therapy is a type of medical treatment that involves the transplantation or infusion of live, healthy cells into a patient's body to treat or cure a disease or disorder. The goal of cell therapy is to restore or replace damaged or malfunctioning cells with healthy ones or to use the therapeutic properties of the transplanted cells to stimulate the body's own natural healing processes.

Segmentation 2: by Offering

Products

Services

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Based on offering, the services segment dominated the global cell and gene therapy manufacturing QC market in FY2022. This segment encompassed a range of vital services, including quality control testing, analytical services, process development, validation, and regulatory compliance. Within the services segment, there is a further division into various categories, including safety testing, potency testing, sterility testing, identity testing, stability and genetic fidelity testing, and others.

Segmentation 3: by Process

- Raw Material Preparation
- Upstream Processing
- Downstream Processing
- Packaging

Based on process, the global cell and gene therapy manufacturing QC market was dominated by the upstream processing segment in FY2022. The dominance of the upstream processing segment can be attributed to several factors, including advancements in bioprocessing technologies, optimized cell culture media, and improved bioreactor systems.

Segmentation 4: by Application

- Safety Testing
- Potency Testing
- Identity Testing
- Stability and Genetic Fidelity Testing
- Others

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Based on application, the safety testing segment accounted for the largest share of the global cell and gene therapy manufacturing QC market in FY2022. This segment encompasses a range of tests, including sterility testing, endotoxin testing, and among others. Furthermore, some of the key players, such as Lonza., Thermo Fisher Scientific Inc., Charles River Laboratories International, Inc., Eurofins Scientific, and Merck KGaA, offer safety testing, potency testing, and other services in the global cell and gene therapy manufacturing QC market.

Segmentation 5: by Technology

- Polymerase Chain Reaction (PCR)
- Flow Cytometry
- Limulus Amebocyte Lysate (LAL)
- Enzyme-Linked Immunosorbent Assay (ELISA)
- Chromatography
- Mass Spectrometry
- Western Blotting
- Next-Generation Sequencing (NGS)
- Electrophoresis
- Other Technologies

Based on technology, the global cell and gene therapy manufacturing QC market is dominated by the PCR segment in FY2022. It plays a vital role in various QC (quality control) processes, including gene expression analysis, viral vector detection, and genetic stability assessment. PCR is used in a variety of tasks in cell and gene therapy manufacturing, including detecting contaminants, measuring gene expression and viral vector integration, and assessing gene editing success. Different types of PCR systems, such as real-time PCR and digital PCR, are used depending on the specific application and process requirements.

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Segmentation 6: by Region

- North America
- Europe
- Asia-Pacific
- MEA
- LATAM

North America cell and gene therapy manufacturing QC market is expected to have the highest market share in 2022 and is currently the leading contributor to the market. However, the Asia-Pacific region, constituting several emerging economies, is expected to register the highest CAGR of 18.01% during the forecast period 2023-2033.

Recent Developments in the Global Cell and Gene Therapy Manufacturing QC Market

- In March 2023, Thermo Fisher Scientific Inc. collaborated with Arsenal Biosciences to assist in the clinical manufacturing of autologosus T-cell therapies.

This partnership combined Thermo Fisher's cell therapy manufacturing expertise with Arsenal Biosciences' innovative technologies, with the goal of advancing the development and accessibility of personalized T-cell therapies.

- In January 2023, Sartorius AG collaborated with Roosterbio Inc. to enhance their downstream purification methods in the field of exosome development.
- In February 2023, Charles River Laboratories International, Inc. partnered with Purespring Therapeutics. This partnership would advance gene therapies for kidney diseases and provide innovative treatment options for patients by leveraging Charles River's eXpDNA plasmid platform.
- In January 2023, Bio-Techne Corporation launched MauriceFlex, a new product

under its ProteinSimple brand. MauriceFlex is a versatile system that facilitates protein charge variant fractionation along with routine cIEF (capillary isoelectric focusing) and CE-SDS (capillary electrophoresis-sodium dodecyl sulfate) assays. This innovative system offered a comprehensive solution for protein characterization, streamlining workflows in protein analysis.

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

In April 2023, Danaher. (Cytiva) launched X-platform bioreactors, which aim to streamline single-use upstream bioprocessing operations. These versatile bioreactors can be used for producing monoclonal antibodies, protein-based drugs, cell and gene therapies, and viral vectors. They offer flexibility and efficiency in bioprocessing, facilitating the development and manufacturing of various therapeutic products.

Demand - Drivers and Limitations

Market Demand Drivers:

Growing Cell and Gene Therapy Production Leading to Increased Demand for Quality Control (QC)Testing

Increasing Number of Approvals Leading to an Upsurge in Demand for Cell and Gene Therapies QC Testing

Rise in Investment for the Development of Cell and Gene Therapies Increasing the Demand for QC Products and Services

Market Restraints:

Limited Adoption of Cell and Gene Therapy due to High Manufacturing and QC Costs

Market Opportunities:

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Continuous Entry of New Market Participants in Cell and Gene Therapies to Create an Opportunity for the Expansion of Manufacturing Facilities and QC Testing Services

Introduction of Technologically Advanced Products in QC Testing for Cell and Gene Therapies

How can this report add value to an organization?

Workflow/Innovation Strategy: The cell and gene therapy manufacturing QC market (by offering) has been segmented into products and services. Moreover, the study provides the reader with a detailed understanding of the different applications of cell and gene therapy manufacturing QC in raw material preparation, upstream processing, downstream processing, and packaging.

Growth/Marketing Strategy: Cell and gene therapy manufacturing QC is being used for raw material preparation, upstream processing, downstream processing, and packaging. Various companies are providing products and services to aid in the manufacturing and QC of various cell and gene therapies, which is also the key strategy for market players to excel in the current cell and gene therapy manufacturing QC market.

Competitive Strategy: Key players in the global cell and gene therapy manufacturing QC 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 manufacturing QC 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 Market Players and Competition Synopsis

Cell and gene-based therapies have sparked efforts to promote treatments such as chimeric antigen receptor (CAR)-T cell therapy has gained significant attention in the field of oncology for its potential to treat certain types of cancer. The need to cater to the clinical and commercial production of cell-based therapies has increased the demand

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for quality control (QC) testing during the manufacturing of cell and gene-based therapies. The increased demand for treatments in the healthcare sector is fuelling the expansion of the cell and gene therapy manufacturing QC market and helping the market to spread out across different regions.

Key Companies Profiled:

Bio-Techne Corporation

bioM?rieux SA

Danaher. (Cytiva)

F. Hoffmann-La Roche Ltd

Lonza.

Miltenyi Biotec B.V. & Co. KG

Sartorius AG

Thermo Fisher Scientific Inc.

WuXi AppTec

AGC Biologics.

Charles River Laboratories International, Inc.

Catalent, Inc

Eurofins Scientific

Merck KGaA

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10 GLOBAL CELL AND GENE THERAPY MANUFACTURING QC MARKET (BY REGION)

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