

# **Cell and Gene Therapy Manufacturing QC Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Therapy Type (Cell Therapy, Gene Therapy), By Offering (Instruments, Consumables, Others), By Process (Raw Material Preparation, Upstream Processing, Downstream Processing, Packaging), 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, Others), By Application (Safety Testing, Potency Testing, Identity Testing, Stability and Genetic Fidelity Testing, Others), By Region and Competition, 2019-2029F**

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## **Abstracts**

Global Cell and Gene Therapy Manufacturing QC Market was valued at USD 1.04 Billion in 2023 and is anticipated to project steady growth in the forecast period with a CAGR of 6.85% through 2029. The Global Cell and Gene Therapy Manufacturing Quality Control (QC) market encompasses the rapidly evolving sector focused on ensuring the safety, efficacy, and reliability of cell and gene therapy products. Quality

control is a critical component in the production process, involving rigorous testing and validation of manufacturing protocols to meet strict regulatory standards. The QC market is driven by the burgeoning demand for advanced therapies targeting complex diseases and relies heavily on cutting-edge technologies for analytics and process standardization.

## Key Market Drivers

### Rise in Prevalence of Cancer & Cardiovascular Diseases

Cell therapy focuses on different illnesses at the cellular level, either by rejuvenating a specific cell group or by utilizing cells as carriers for therapeutic agents. Whereas gene therapy seeks to impact the progression of various genetic and acquired conditions at the genetic level. It is expected that cardiovascular ailments will propel the demand for cell and gene therapies which will in turn drive the growth of cell and gene therapy manufacturing QC market in the forecast period. One possible treatment which have emerged as a leading option for management of cardiac arrhythmias are approaches which can improve the action potential conduction and electrical excitability in the heart.

Stem cell therapy has the significant potential to treat cardiac diseases mainly heart failure and coronary heart diseases. Numerous clinical trials have depicted that stem cell therapies are safe to use and acquire the extensive capability to improve the heart function thereby reducing the chances of adverse cardiovascular events. Cancer have also prevailed as a leading morbidity over past few years. In two latest clinical trials which were conducted in 2022, it has been proved that CAR T-cell therapy can also be used for management of non-Hodgkin lymphoma in patients whose cancer returned after initial stage. Therefore, development of new cell and new therapies which are making new additions in treatment techniques of serious chronic diseases are also anticipated to bolster the growth of cell and gene therapy manufacturing QC market in the forecast period.

### Growth in Pharmaceutical Research & Development

Cell and gene therapies are a rapidly expanding domain of medicine with the capability to cure a broad spectrum of ailments. Nevertheless, these therapies are also inherently complex and require rigorous quality assurance (QA) measures to ensure their well-being and effectiveness. Research and development in the quality control of cell and gene therapies is concentrated on developing novel approaches and technologies that can enhance the precision, effectiveness, and

promptness of quality control testing. Many new methods have been developed in recent years to facilitate the QC of cell and gene therapies. Scientists at the University of Pennsylvania created a novel technique for characterizing the efficacy of cellular and genetic treatments. This technique is known as functional evaluations which enables the quantification of cells' capacity to carry out designated functions, such as combating infections or generating proteins.

### Increasing Pipeline of Therapies

The burgeoning pipeline of innovative therapies, particularly in the realm of cell and gene therapy, is catalyzing a surge in demand for robust quality control (QC) solutions worldwide. With an increasing number of biopharmaceutical companies focusing on developing cutting-edge cell and gene therapies to address a diverse array of diseases, there's a pressing need for stringent QC measures to ensure safety, efficacy, and consistency of these treatments. The complexity of cell and gene therapies, often tailored to individual patients, necessitates meticulous QC protocols throughout the manufacturing process. T

The demand for specialized QC technologies and services tailored to the unique requirements of cell and gene therapy manufacturing is on the rise. This trend is driving significant growth in the global Cell and Gene Therapy Manufacturing QC Market, as companies seek reliable QC solutions to navigate the intricate regulatory landscape and bring innovative therapies to market efficiently and safely.

### Manufacturing Scale-up

The process of scaling up manufacturing operations for cell and gene therapies is presenting a formidable challenge, one that significantly amplifies the demand for robust quality control (QC) solutions on a global scale. As promising therapies progress from early-stage development to commercial production, the need for stringent QC measures becomes paramount to ensure product quality, safety, and consistency at larger scales. Manufacturing scale-up introduces complexities such as optimizing production processes, increasing batch sizes, and maintaining uniformity across multiple manufacturing sites—all of which require meticulous QC protocols. Consequently, biopharmaceutical companies are increasingly investing in advanced QC technologies and expertise tailored specifically for cell and gene therapy manufacturing. This surge in demand for QC solutions is propelling the growth of the global Cell and Gene Therapy Manufacturing QC Market, as companies strive to meet regulatory requirements, minimize risks, and accelerate the commercialization of life-saving

therapies.

## Key Market Challenges

### Shortage Of Professionals Skilled in Advanced Manufacturing & Quality Control of Gene & Cell Therapies

Strict adherence to quality assurance (QA) standards within the cell and gene therapy manufacturing sector may paradoxically decrease the demand for traditional quality control (QC) solutions globally. As regulatory agencies enforce stringent QA requirements to ensure the safety and efficacy of therapies, companies are compelled to implement comprehensive QA measures throughout the manufacturing process. This robust QA framework often incorporates built-in quality control mechanisms, reducing the need for separate QC systems. Advancements in manufacturing technologies and process optimization allow for greater consistency and reliability, minimizing the occurrence of errors and deviations that typically necessitate extensive QC interventions. There may be a shift towards integrated QA-QC approaches, where QC functions are seamlessly embedded within QA processes, leading to a potential decrease in the demand for standalone QC solutions in the cell and gene therapy manufacturing market as companies prioritize holistic quality assurance strategies.

### High Cost of Quality Control

The high cost associated with quality control (QC) processes in cell and gene therapy manufacturing could potentially decrease the demand for QC solutions globally. While QC is crucial for ensuring the safety, efficacy, and consistency of therapies, the significant expenses involved. The complexity of cell and gene therapies, often requiring specialized QC technologies and expertise, can further inflate the costs of QC implementation and maintenance. Companies might opt to prioritize cost-saving measures or alternative QC strategies, such as outsourcing QC functions or utilizing less expensive QC technologies, potentially leading to a decreased demand for traditional QC solutions in the cell and gene therapy manufacturing market. This cost-conscious approach could shape the dynamics of the QC market as companies balance the need for quality assurance with financial constraints.

## Key Market Trends

### Strict Adherence to QA Standards

The stringent adherence to quality assurance (QA) standards within the cell and gene therapy manufacturing sector is playing a pivotal role in driving the demand for advanced quality control (QC) solutions on a global scale. As regulatory agencies impose rigorous requirements to ensure the safety, efficacy, and consistency of these groundbreaking therapies, biopharmaceutical companies are under increasing pressure to implement comprehensive QA measures throughout the manufacturing process. Strict adherence to QA standards necessitates robust QC protocols to detect and mitigate any deviations or discrepancies promptly. Consequently, there's a growing demand for specialized QC technologies and services tailored specifically for the unique challenges of cell and gene therapy manufacturing. This escalating demand for QC solutions is fueling the expansion of the global Cell and Gene Therapy Manufacturing QC Market as companies prioritize compliance with QA standards to navigate regulatory complexities, uphold product quality, and accelerate the development and commercialization of transformative therapies.

### Use of Technologies like AI In QC Systems

The integration of cutting-edge technologies, such as artificial intelligence (AI), into quality control (QC) systems, is revolutionizing the cell and gene therapy manufacturing landscape and significantly bolstering the demand for advanced QC solutions worldwide. AI-powered QC systems offer unprecedented capabilities for data analysis, predictive modeling, and real-time monitoring, enabling biopharmaceutical companies to enhance the efficiency, accuracy, and reliability of their QC processes. By leveraging AI algorithms to analyze vast datasets and identify patterns or anomalies, these systems can streamline QC protocols, accelerate decision-making, and mitigate risks during the manufacturing of complex cell and gene therapies. There's a surging demand for AI-driven QC technologies and services tailored specifically for the unique requirements of cell and gene therapy manufacturing. This increasing reliance on AI in QC systems is driving the growth of the global Cell and Gene Therapy Manufacturing QC Market as companies recognize the transformative potential of technology to optimize production processes, ensure regulatory compliance, and expedite the development and commercialization of innovative therapies.

### Segmental Insights

#### Therapy Type Insights

Based on Therapy Type, gene therapy has gained rapid growth in the global cell and

gene therapy manufacturing quality control (QC) market in 2023. This growing trend can be attributed to several factors. The increasing approval of gene therapy products by regulatory authorities has provided a strong foundation for the sector's expansion. Substantial investments in research and development (R&D) have fuelled advancements in gene therapy, leading to breakthrough treatments and therapies. The rising demand for regenerative medicine has further fuelled the growth of gene therapy as it offers the potential to address the root causes of genetic disorders. The impact of gene therapies goes beyond conventional treatments, as they are revolutionizing the fight against previously untreatable conditions.

By targeting the underlying genetic mechanisms, gene therapies offer new hope and possibilities for patients who have long struggled with debilitating disorders. This revolutionary approach has garnered significant interest from both the public and private sectors, driving further investment and research in this field. As the field of gene therapy continues to evolve, it holds immense promise for the future of medicine. With ongoing advancements, we can look forward to more targeted and effective treatments that could potentially transform the lives of countless individuals worldwide.

### Offering Insights

Based on the Offering, within the global Cell and Gene Therapy Manufacturing Quality Control (QC) market, the Instruments segment is currently dominating in terms of market share. Cell and gene therapy manufacturing entails complex processes that demand precise quality control measures at each stage. Instruments are vital in guaranteeing the quality, purity, and effectiveness of therapeutic products, rendering them indispensable for manufacturers. Regulatory bodies impose rigorous quality control standards to ensure the safety and efficacy of cell and gene therapy products. Instruments provide dependable and standardized methodologies to meet these regulatory requirements, making them indispensable for achieving compliance and securing market approval. The rapid progress of technology has spurred the creation of advanced instruments tailored specifically for cell and gene therapy manufacturing QC. These instruments offer heightened sensitivity, accuracy, and throughput, empowering manufacturers to identify and rectify quality issues more efficiently. Automation plays a pivotal role in optimizing manufacturing processes and minimizing human error. Instruments equipped with automation capabilities facilitate streamlined sample processing, data analysis, and reporting, thereby enhancing overall QC effectiveness and productivity.

### Regional Insights

North America has firmly established itself as the dominating region in the global market for cell and gene therapy manufacturing quality control (QC). This leadership position can be attributed to its highly advanced biotechnology infrastructure, which includes state-of-the-art research facilities, cutting-edge manufacturing capabilities, and a robust talent pool of scientists and experts. Substantial investments in research and development have propelled North America to the forefront of innovation in this field.

North America boasts a comprehensive regulatory framework that ensures the highest standards of safety and efficacy in therapeutic practices. These regulatory frameworks, meticulously designed and continuously updated, provide a solid foundation for the development and manufacturing of cell and gene therapies. The stringent regulations and rigorous quality control measures in place inspire confidence in the safety and effectiveness of these therapies, not only within North America but also internationally.

With its unwavering commitment to excellence and continuous advancements in technology, North America continues to raise the bar in the field of cell and gene therapy manufacturing quality control. The region's relentless pursuit of breakthroughs, coupled with its collaborative ecosystem of academia, industry, and regulatory bodies, fosters a fertile ground for innovation and ensures that North America remains at the forefront of this rapidly evolving field.

## Regional Insights

In January 2023, Bio-Techne Corporation launched MauriceFlex, a novel addition to its ProteinSimple product line. MauriceFlex is a versatile platform designed to facilitate the separation of protein charge variants, expanding upon standard cIEF (capillary isoelectric focusing) and CE-SDS (capillary electrophoresis-sodium dodecyl sulfate) tests. This innovative system provides comprehensive protein characterization, streamlining examination procedures.

## Regional Insights

Bio-Techne Corporation

Biomerieux SA

F. Hoffmann-La Roche Ltd

Lonza Group Ltd.

Miltenyi Biotec India Pvt Ltd.

Sartorius AG

ThermoFisher Scientific Inc.

AGC Inc.

Charles River Laboratories International, Inc.

Merck KGaA

#### Report Scope:

In this report, the Global Cell and Gene Therapy Manufacturing QC Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Cell and Gene Therapy Manufacturing QC Market, By Therapy Type:

Cell Therapy

Gene Therapy

Cell and Gene Therapy Manufacturing QC Market, By Offering:

Instruments

Consumables

Others



### Cell and Gene Therapy Manufacturing QC Market, By Process:

Raw Material Preparation

Upstream Processing

Downstream Processing

Packaging

### Cell and Gene Therapy Manufacturing QC Market, 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

Others

### Cell and Gene Therapy Manufacturing QC Market, By Application:

Safety Testing

Potency Testing

Identity Testing

Stability and Genetic Fidelity Testing

Others

Cell and Gene Therapy Manufacturing QC Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

## Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Cell and Gene Therapy Manufacturing QC Market.

## Available Customizations:

Global Cell and Gene Therapy Manufacturing QC Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

## Company Information

Detailed analysis and profiling of additional market players (up to five).

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