GMP Cell Therapy Consumables Market Forecast to 2028 - COVID-19 Impact and Global Analysis by Product (Kits, Reagents/Molecular Biology Reagents, Growth Factors/Cytokines and Interleukins, and Others), Cell Therapy (NK Cell Therapy, Stem Cell Therapy, T-Cell Therapy, and Others), Process (Cell Collection and Characterization/Sorting and Separation, Cell Culture and Expansion/Preparation, Cryopreservation, Cell Processing and Formulation, Cell Isolation and Activation, Cell Distribution/Handling, Process Monitoring and Control/Readministration/Quality Assurance, and Others), and End Use (Clinical, Commercial, and

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Report description:

The GMP cell therapy consumables market is expected to grow from US$ 11,031.25 million in 2021 to US$ 59,985.89 million by 2028; it is estimated to grow at a CAGR of 27.5% from 2022 to 2028.

The market growth is attributed to a rise in research & development and drug discovery and an increase in strategic collaborations. However, stringent regulatory policies hamper the market growth.
Good Manufacturing Practices (GMP) ensure that products are consistently produced and controlled according to quality standards. Cell therapy manufacturing processes are complex and require an underpinning pharmaceutical quality system and quality control (QC) laboratory. Also, all aspects of cell therapy manufacturing require trained personnel. As the process is

complex, there may be chances of contamination; therefore, GMP in cell therapy is becoming mandatory. Also, the increasing use of cell therapy to treat various diseases is propelling the demand for cell therapy consumables manufactured according to GMP regulations.

The companies in the GMP cell therapy consumables market is making strategic collaborations for the development of new products and cell therapy treatments. A few strategic collaborations in the GMP cell therapy consumables market is mentioned below:

- In October 2022, Pluristyx, panCELLa, and Implant Therapeutics management announced the corporate merger, pending shareholder approval. The merged company will combine complementary portfolios to offer end-to-end customer support and provide increased access to a wide range of induced pluripotent stem cell (iPSC)-related products and services. The integrated technology and service offerings will greatly accelerate the development and delivery of revolutionary cell therapies to patients.
- In November 2021, Laurus Labs signed an investment agreement with Immunoadoptive Cell Therapy Private Limited (ImmunoACT), an advanced cell and gene therapy company, to acquire a 26.62% stake (fully diluted basis), subject to the fulfillment of certain conditions.

The increase in strategic collaborations among market players for cell therapy development has propelled the use of GMP cell therapy consumables to achieve the desired products, which drives the growth of the GMP cell therapy consumables market. Moreover, the past five years have been the rebirth period for cell and gene therapy (CGT) innovations, and the COVID-19 pandemic accelerated the pace of these developments. As per the 2019 US Food and Drug Administration (FDA) report, in the last two years, CGT developers submitted about 500 applications to the FDA to initiate clinical trials. Out of those applications, the FDA predicts that ~10 to 20 CGT products will be approved annually by 2025. In 2021, FDA approved Breyanzi. Breyanzi is a cell-based gene therapy to treat patients suffering from certain types of large B-cell lymphoma cancer. Each dose is a customized treatment that uses the patient's T-cells to fight relapsed or refractory disease.

FDA checks the quality of medication products and ensures it by carefully monitoring manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The approval process for new therapy/drug marketing applications includes a review of the manufacturers' compliance with the CGMPs. Therefore, the outlook of the CGT field is promising due to the increased rate of FDA approvals and patient enthusiasm. In addition, continued advances in CGT following GMP will transform the disease treatment processes and modify healthcare delivery on individual and industry levels.

Process Insights

Based on process, the GMP cell therapy consumables market is segmented into cell collection and characterization/sorting and separation, cell culture and expansion/preparation, cryopreservation, cell processing and formulation, cell isolation and activation, cell distribution/handling, process monitoring and control/readministration/quality assurance, and others.. The cell collection and characterization/sorting and separation segment held the largest market share in 2021. However, the cryopreservation segment is expected to register the highest CAGR during the forecast period. Cryopreservation has become a significant aspect of the manufacturing process for many cellular therapies. It occasionally comes before cell culture (conserving the starting cellular material before moving forward with large-scale manufacturing) and generally follows cell expansion therapies. The ability to store cells at different points during the manufacturing process enables the creation of a customized workflow. Selecting GMP-grade or suitable cryoprotective agents (CPAs) and controlled-rate freezing equipment with appropriate cooling profiles for immune cells is one of the best practices adopted to help generate high-quality cells. Sartorius designs NutriFreez cell freezing solutions for the cryopreservation of cells manufactured in compliance with GMP services.

Asia Pacific is one of the fastest-growing regions in the GMP cell therapy consumables market. India is expected to register the highest CAGR in the regional market during the forecast period. Pharmaceutical companies in India highly adopt GMP cell therapy consumable products owing to the need for aseptic and sterile production machineries and spaces. The increase in the development of biosimilars, cell therapy, and combination products; high demand for GMP testing at both clinical and preclinical stages; and constant focus of manufacturing companies to fulfill requirements of regulatory bodies concerning GMP are among the factors supporting the market growth. In the US, leukemia treatment using CAR T-cell therapy costs around US$ 800,000 to US$ 900,000. However, Indian start-ups and pharmaceutical companies are focusing on offering this treatment at a lower cost by reducing the treatment time and increasing the effectiveness of cell therapy. Also, the government is investing in cell therapy for leukemia treatment. For instance, in June 2021, the Department of Biotechnology (DBT) supported the first CAR T-cell therapy

conducted at ACTREC, Tata Memorial Center in Mumbai. This increased the demand for cell therapy consumables in India as Phase I/II trials were carried out in the country.
The World Health Organization (WHO), US Food and Drug Administration (FDA), US Centers for Medicare & Medicaid Services, and Johns Hopkins University are among the primary and secondary sources referred to while preparing the report on the GMP cell therapy consumables market.

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