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Advanced Therapy Medicinal Products CDMO Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Product (Gene Therapy, Cell Therapy, Tissue Engineered, Others), By Phase (Phase I, Phase II, Phase III, Phase IV), By Indication (Oncology, Cardiology, Central Nervous System, Musculoskeletal, Infectious disease, Immunology & inflammation, Others), By Region, and By Competition

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Abstracts

Global Advanced Therapy Medicinal Products CDMO Market has valued at USD 4.77 billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 12.15% through 2028. The Global Advanced Therapy Medicinal Products Contract Development and Manufacturing Organization (CDMO) Market is a dynamic and rapidly evolving sector within the pharmaceutical and biotechnology industries. This market encompasses organizations that provide specialized services for the development and manufacturing of advanced therapy medicinal products (ATMPs), which include gene therapies, cell therapies, and tissue-engineered products.

Key Market Drivers

Proliferation of Advanced Therapies

The healthcare landscape is witnessing a revolution as advanced therapies, including gene therapies, cell therapies, and tissue-engineered products, emerge as groundbreaking treatments for previously incurable diseases. This paradigm shift in

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medicine is driving the demand for specialized services provided by Contract Development and Manufacturing Organizations (CDMOs).

The advent of advanced therapies has expanded therapeutic horizons, offering new hope to patients suffering from rare and debilitating conditions. These therapies target the root causes of diseases at the genetic and cellular levels, promising higher efficacy and fewer side effects compared to traditional treatments. As more conditions become treatable through advanced therapies, the demand for CDMO services to develop and manufacture these products increases.

Pharmaceutical companies, biotechnology firms, and academic institutions are investing heavily in advanced therapy research and development. This surge in investment translates into a growing pipeline of potential therapies. CDMOs are integral to this process, providing the expertise and infrastructure needed to advance these therapies from the laboratory to clinical trials and eventual commercialization.

The development and manufacturing of advanced therapies come with complex regulatory challenges. Regulatory bodies like the FDA and EMA have stringent requirements to ensure the safety and efficacy of these novel treatments. CDMOs specializing in advanced therapies possess the regulatory expertise to help clients navigate this intricate landscape, ensuring compliance throughout the product lifecycle. This support streamlines the regulatory approval process, accelerating market entry.

Scaling up the production of advanced therapies for clinical trials and commercialization is a significant challenge. CDMOs offer scalable manufacturing solutions, enabling companies to transition smoothly from small-scale production for clinical trials to large-scale manufacturing for broader patient populations. This scalability is essential for meeting the increasing demand for advanced therapies.

The Global Advanced Therapy Medicinal Products CDMO Market is characterized by its global reach. Leading CDMOs operate across regions, making advanced therapies accessible to a wider patient base. Global presence also allows for diversification into different markets, ensuring a steady demand for CDMO services.

The healthcare industry is increasingly adopting a patient-centric approach, focusing on personalized medicine. Advanced therapies align perfectly with this trend as they can be tailored to individual patients' genetic and biological profiles. As personalized medicine gains prominence, the demand for advanced therapies and CDMO services tailored to their development and manufacturing is poised to soar.

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The competitive landscape of the ATMP CDMO market fosters innovation and efficiency. Established CDMOs and emerging players continuously enhance their capabilities, drive down costs, and improve manufacturing processes. This competitive environment benefits clients by making advanced therapy development and production more accessible and cost-effective.

Increased Investment in Research and Development

The world of healthcare is witnessing a profound transformation, largely driven by the relentless pursuit of innovative treatments and therapies. Among these, advanced therapy medicinal products (ATMPs) such as gene therapies, cell therapies, and tissue-engineered products are emerging as the future of medicine. Fueling this transformation is the substantial increase in investment in research and development (R&D), which has a profound impact on the Global Advanced Therapy Medicinal Products Contract Development and Manufacturing Organization (CDMO) Market.

Increased R&D investment has broadened the horizons of therapeutic possibilities. It has enabled the discovery and development of ATMPs for a wide range of diseases, including rare genetic disorders, cancers, and autoimmune conditions. As more therapeutic targets are identified and explored, the demand for CDMO services to facilitate their development and production surges.

The infusion of capital into ATMP R&D programs has significantly shortened development timelines. As a result, promising therapies are progressing rapidly through preclinical studies, clinical trials, and regulatory approvals. CDMOs play a pivotal role in this acceleration, offering their expertise in process development, manufacturing, and regulatory compliance to expedite the journey from laboratory discovery to patient treatment.

Pharmaceutical companies, biotechnology startups, and academic institutions are actively seeking collaboration with CDMOs to leverage their specialized capabilities. The increased R&D funding fosters more partnerships, as organizations pool their resources and expertise to advance ATMPs. CDMOs, acting as strategic partners, help navigate the complexities of ATMP development, including manufacturing scale-up and regulatory hurdles.

Investment in ATMP R&D often involves significant financial risk. Collaborating with CDMOs can help mitigate some of this risk. CDMOs offer cost-effective and efficient

solutions for process development and manufacturing, allowing organizations to optimize their R&D budgets and manage expenditures more effectively.

Developing and manufacturing ATMPs require specialized expertise, as these therapies are at the cutting edge of science and technology. CDMOs have honed their capabilities in this niche field, attracting organizations seeking to tap into their knowledge and experience. This expertise accelerates the development process and ensures adherence to regulatory requirements.

Scalable Manufacturing Solutions

The landscape of healthcare is undergoing a revolutionary transformation with the advent of advanced therapy medicinal products (ATMPs). These innovative therapies, which include gene therapies, cell therapies, and tissue-engineered products, have the potential to treat previously incurable diseases. As the demand for these groundbreaking treatments continues to surge, scalable manufacturing solutions provided by Contract Development and Manufacturing Organizations (CDMOs) are playing a pivotal role in fueling the growth of the Global Advanced Therapy Medicinal Products CDMO Market.

The rise in the popularity of ATMPs has created a significant demand for large-scale production. Scalable manufacturing solutions offered by CDMOs are essential to meet this growing demand. These solutions enable the transition from small-scale clinical production to large-scale commercial manufacturing, ensuring a steady and reliable supply of advanced therapies for patients.

One of the primary advantages of scalable manufacturing is its ability to reduce time to market. By efficiently scaling up production processes, CDMOs help pharmaceutical companies and biotech firms bring their ATMPs to market more quickly. This accelerated timeline is critical for patients who urgently need these life-saving therapies.

CDMOs specialize in flexible manufacturing solutions that can adapt to the changing needs of their clients. Scalability allows for the adjustment of production volumes as clinical trials progress and the demand for ATMPs increases. This flexibility ensures that clients have the manufacturing capacity required at every stage of development.

Scalable manufacturing is not solely about increasing production volumes; it also involves optimizing and fine-tuning manufacturing processes. CDMOs excel in process development and optimization, ensuring that the transition from laboratory-scale

production to large-scale manufacturing is smooth and efficient. This expertise streamlines the manufacturing process, reducing costs and improving product quality.

The Global Advanced Therapy Medicinal Products CDMO Market operates on a global scale. Leading CDMOs have a presence in various regions, allowing them to serve clients worldwide. This global reach not only supports international collaborations but also ensures that ATMPs are accessible to a diverse patient population across the globe.

Patient-Centric Healthcare

The landscape of healthcare is evolving, with a growing emphasis on patient-centric approaches that prioritize individualized care and treatment. This transformation is particularly evident in the realm of advanced therapy medicinal products (ATMPs), which include gene therapies, cell therapies, and tissue-engineered products. Patient-centric healthcare is emerging as a driving force behind the growth of the Global Advanced Therapy Medicinal Products Contract Development and Manufacturing Organization (CDMO) Market.

Patient-centric healthcare places the patient at the center of decision-making and treatment planning. Personalized medicine, a key component of this approach, tailors medical interventions to the specific genetic, molecular, and clinical characteristics of each patient. ATMPs align perfectly with this paradigm, as they can be customized to target the unique biological factors driving a patient's disease.

The shift toward personalized medicine has led to a surge in the demand for tailored therapies. Patients with rare genetic disorders, cancers, and other challenging conditions are seeking treatments that address the root causes of their diseases. ATMPs, which have the potential to provide precisely such treatments, are thus gaining popularity and fueling growth in the ATMP CDMO market.

To create truly patient-centric therapies, collaboration between pharmaceutical companies, biotech startups, academic institutions, and CDMOs is essential. CDMOs bring specialized expertise in ATMP development and manufacturing to the table, enabling organizations to navigate the complexities of personalized therapies more effectively. As collaborations increase, so does the demand for CDMO services.

Patient safety and product quality are paramount in patient-centric healthcare. ATMPs must meet stringent regulatory standards to ensure efficacy and safety. CDMOs

specializing in advanced therapies have the expertise to help clients meet these regulatory requirements, ensuring that patient-centric treatments adhere to the highest standards of quality and safety.

While patient-centric therapies are tailored to individual patients, they still need to be scalable to serve broader populations. CDMOs offer scalable manufacturing solutions that can transition from small-scale clinical production to large-scale commercial manufacturing. This scalability ensures that successful therapies can reach a wider patient base.

Key Market Challenges

High Costs

The development and manufacturing of advanced therapies are resource-intensive endeavors. The costs associated with research, development, and manufacturing can be prohibitively high. CDMOs must find ways to manage costs effectively while maintaining the high-quality standards required for ATMPs.

Talent and Expertise

The specialized nature of ATMPs demands a skilled workforce with expertise in various fields, including molecular biology, bioprocessing, and regulatory affairs. Attracting and retaining top talent can be a challenge, especially when competing with other sectors of the biopharmaceutical industry.

Supply Chain Complexity

The supply chain for ATMPs can be complex, involving the sourcing of raw materials, manufacturing, storage, and distribution. Ensuring a secure and efficient supply chain is essential for maintaining product integrity and patient safety. CDMOs must establish robust supply chain strategies to mitigate potential disruptions.

Key Market Trends

Increased Collaboration and Partnerships

Collaboration is a cornerstone of innovation in the ATMP sector. CDMOs are forming strategic partnerships with pharmaceutical companies, biotech startups, and academic

institutions. These collaborations facilitate knowledge sharing, resource pooling, and the co-development of cutting-edge therapies. The trend of collaborative ventures is expected to accelerate as stakeholders seek to leverage collective expertise and resources.

Shift Towards Allogeneic Therapies

While autologous therapies, which use a patient's own cells, have been prevalent, there is a growing shift towards allogeneic therapies, which use donor cells. Allogeneic therapies offer advantages in terms of scalability, cost-effectiveness, and shorter manufacturing timelines. CDMOs are adapting their capabilities to accommodate this shift, including the development of standardized, off-the-shelf allogeneic products.

Automation and Process Optimization

Automation and process optimization are becoming increasingly crucial in ATMP manufacturing. CDMOs are investing in state-of-the-art automation technology to enhance process efficiency, reduce variability, and ensure product quality. These advancements not only reduce production costs but also accelerate the time to market for advanced therapies.

Segmental Insights

Product Insights

Based on the category of Product, the gene therapy sector emerged as the dominant force in the market, boasting the highest revenue share in 2022. This supremacy can be attributed to the surge in financial backing and the escalating number of clinical trials focused on gene therapies, both of which are fueling the demand for Contract Development and Manufacturing Organization (CDMO) services. In the initial three quarters of 2020, gene therapies globally secured over USD 12 billion in funding, concurrently with the commencement of approximately 370 clinical trials. Additionally, as of mid-2022, around 2,000 gene therapies were in the developmental pipeline, targeting various therapeutic areas such as neurological, cancer, cardiovascular, blood, and infectious diseases.

Conversely, the cell therapy segment is projected to experience the most rapid growth throughout the forecast period. The field of cellular therapeutics is in a constant state of evolution, as it integrates new cell types, thereby presenting abundant opportunities for

companies to bolster their market positions. Moreover, the market is drawing new entrants due to the substantial unmet demand for cell therapy manufacturing, recent approvals of advanced therapies, and the proven efficacy of these products.

Indication Insights

Based on Indication, the oncology sector has taken a commanding position in the market and is poised for substantial growth in the coming forecast period. This projected growth is primarily driven by the heavy burden of disease, strategic initiatives implemented by key industry players, and the availability of advanced therapies for treating various forms of cancer. As of January 2021, it was estimated that there were approximately 18,000 to 19,000 potential patients for the treatment of cancer using cell and gene therapy products like Kymriah (manufactured by Novartis AG) and Yescarta (developed by Gilead Sciences, Inc.), with an even larger pool of around 124,000 patients for potential treatment.

Conversely, the cardiology segment is expected to exhibit significant expansion during the forecast period. This growth can be attributed to the escalating prevalence of cardiovascular diseases and collaborative research efforts aimed at advancing therapies. For example, in February 2021, Trizell GmbH partnered with Catalent, Inc. to develop phase 1 cell therapy for the treatment of micro- and macroangiopathy. Trizell's medication falls under the category of Advanced Therapy Medicinal Products (ATMPs) and employs regulatory macrophages, which are a platform technology originating from Germany.

Regional Insights

North America seized the largest market share in 2022. This can be attributed to the growing trend of outsourcing activities and an increasing awareness of advanced therapy. The United States, in particular, has consistently held a leading position in the research and development of advanced treatments, and this dominance is expected to persist throughout the forecast period. Recent approvals of products like Kymriah and Yescarta have further catalyzed investments in the regional Contract Development and Manufacturing Organization (CDMO) market for advanced therapy medicinal products. Furthermore, in March 2021, the U.S. Food and Drug Administration (FDA) granted approval for Abecma, marking the first approval of CAR-T cell therapy for combating cancer.

On the other hand, the Asia Pacific region is projected to be the fastest-growing

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segment during the forecast period, primarily due to the surging demand for innovative Advanced Therapy Medicinal Products (ATMPs) and increased research and development activities aimed at creating novel therapies. Additionally, the growth of the advanced therapy medicinal products CDMO market in this region is driven by the continual expansion of CDMO services. Numerous local players have collaborated with biotech firms from other countries engaged in mesenchymal stem cell research and therapy development. Furthermore, in September 2022, Takara Bio, Inc. introduced CDMO services for gene therapy products utilizing siTCR technology for its genetically modified T-cell therapy products.

Key Market Players

Celonic AG

Bio Elpida

Rentschler Biopharma SE

AGC Biologics GmbH

Catalent Inc

Lonza Group AG

WuXi Advanced Therapies

Minaris Regenerative Medicine

Patheon Inc

Cell and Gene Therapy Catapult

Report Scope:

In this report, the Global Advanced Therapy Medicinal Products CDMO Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Advanced Therapy Medicinal Products CDMO Market, By Product:

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Gene Therapy

Cell Therapy

Tissue Engineered

Others

Advanced Therapy Medicinal Products CDMO Market, By Phase:

Phase I

Phase II

Phase III

Phase IV

Advanced Therapy Medicinal Products CDMO Market, By Indication:

Oncology

Cardiology

Central Nervous System

Musculoskeletal

Infectious disease

Immunology & inflammation

Others

Advanced Therapy Medicinal Products CDMO Market, By Region:

North America

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United States

Canada

Mexico

Europe

Germany

United Kingdom

France

Italy

Spain

Asia-Pacific

China

Japan

India

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

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South Africa

Saudi Arabia

UAE

Kuwait

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Advanced Therapy Medicinal Products CDMO Market.

Available Customizations:

Global Advanced Therapy Medicinal Products CDMO 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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