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Nucleic Acid Therapeutics CDMO Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2019-2029 Segmented By Type (Gene Therapy, RNA-based Therapies), By Service (Process Development & Optimization, Manufacturing Services, Analytical and Quality Control Services, others), by Application (Oncology, Genetic Disorders, Infectious Diseases, others), by region, and Competition

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Abstracts

Global Nucleic Acid Therapeutics CDMO Market was valued at USD 10.96 billion in 2023 and is anticipated to witness an impressive growth in the forecast period with a CAGR of 9.10% through 2029. Nucleic Acid Therapeutics CDMO (Contract Development and Manufacturing Organization) is a specialized service provider in the biopharmaceutical industry that offers expertise and infrastructure for the development and production of nucleic acid-based therapies. Nucleic acid therapeutics are a class of drugs that utilize DNA or RNA molecules to treat various diseases, including genetic disorders, cancer, infectious diseases, and rare conditions. CDMOs in this field offer essential support to biotech and pharmaceutical companies in the development, manufacturing, and testing of these therapies. CDMOs provide expertise in the design and development of nucleic acid-based therapies. This includes optimizing the sequences, structures, and formulations of DNA or RNA molecules to ensure their safety and efficacy. They are equipped to produce nucleic acid therapeutics at scales suitable for clinical trials. This involves adhering to good manufacturing practices (GMP) to meet regulatory requirements and ensure product quality. CDMOs offer capabilities for large-scale commercial production of nucleic acid therapies. They have the infrastructure to handle the complexities of scaling up manufacturing processes to meet

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market demands. Continuous advancements in nucleic acid therapeutics, such as mRNA vaccines, gene therapies, and RNA-based drugs, have fueled the demand for CDMO services. These therapies offer innovative solutions for various diseases, including cancer, genetic disorders, and infectious diseases. The shift toward personalized medicine, which involves tailoring treatments to an individual's genetic makeup, has led to a growing demand for customized nucleic acid therapeutics. CDMOs support the development of personalized therapies. The COVID-19 pandemic highlighted the importance of rapid vaccine development and production. mRNA vaccines, developed with the assistance of CDMOs, showcased the potential of nucleic acid-based platforms for infectious disease control.

Key Market Drivers

Advancements in Nucleic Acid Therapeutics

mRNA (messenger RNA) vaccines have gained widespread attention due to their rapid development and success, particularly in the case of COVID-19 vaccines. These vaccines work by introducing a small piece of mRNA that encodes a viral protein, stimulating an immune response. This technology is being explored for other infectious diseases and cancer. CRISPR-Cas9 and other gene editing techniques have revolutionized the ability to modify genes with precision. These technologies hold great promise for the treatment of genetic disorders and the correction of disease-causing mutations. RNA Interference (RNAi) Therapy is a mechanism that can silence or "turn off" specific genes. RNAi-based therapies, such as small interfering RNA (siRNA), are being developed to treat various genetic and chronic diseases by reducing the expression of disease-causing genes.

Antisense Oligonucleotides (ASOs) are short sequences of nucleic acids that can bind to RNA and regulate gene expression. They have been used to treat conditions like spinal muscular atrophy and Duchenne muscular dystrophy. Exon skipping is a technique that involves altering the splicing of pre-mRNA to exclude specific exons. It is used in the treatment of certain genetic diseases like Duchenne muscular dystrophy. Nucleic acid-based cancer immunotherapies, such as CAR-T cell therapy, are being developed to enhance the body's immune response against cancer cells. This approach has shown remarkable success in some cancer patients. Advances in viral vectors, such as adeno-associated viruses (AAV) and lentiviruses, have improved the efficiency and safety of delivering nucleic acid therapies to target cells in the body.

Non-viral delivery methods, including lipid nanoparticles and other nanocarriers, are

being developed to transport nucleic acid therapies safely and efficiently into cells. These technologies are critical for reducing potential immune responses and side effects. Regulatory agencies have adapted to the unique characteristics of nucleic acid therapies, creating streamlined approval processes, and offering support for their development. This has paved the way for more rapid adoption of these treatments. Researchers are exploring combinations of nucleic acid therapies with other drugs and treatment modalities to enhance their effectiveness and address complex diseases. Long non-coding RNAs (lncRNAs) are gaining attention for their roles in gene regulation and disease. Studies are ongoing to investigate their potential as therapeutic targets. This factor will help in the development of the Global Nucleic Acid Therapeutics CDMO Market.

Rise in Vaccine Development and Pandemic Preparedness

The COVID-19 pandemic highlighted the need for rapid vaccine development in response to emerging infectious diseases. Nucleic acid technologies, particularly mRNA-based vaccines, demonstrated their potential for accelerated vaccine production. CDMOs specializing in nucleic acid therapeutics played a pivotal role in developing and manufacturing these vaccines in record time. Nucleic acid vaccines, especially mRNA vaccines, offer flexibility in vaccine design. This allows for faster adaptation to new strains of viruses, making them valuable tools for pandemic preparedness. CDMOs can quickly adjust production processes to meet evolving vaccine requirements. Nucleic acid vaccine platforms have the potential to significantly reduce vaccine development timelines. This speed is essential for addressing emerging infectious diseases and ensuring timely access to vaccines for global populations. CDMOs have the capacity to scale up the production of nucleic acid vaccines rapidly. This scalability is critical in pandemic scenarios when there is a need to produce large quantities of vaccines within a short timeframe. The ongoing threat of infectious diseases and the potential for future pandemics have heightened awareness of the importance of preparedness and rapid response. Nucleic acid therapeutics, including vaccines and antiviral treatments, are central to these efforts.

Governments around the world have initiated funding and partnerships to support the development and manufacturing of nucleic acid vaccines for pandemic preparedness. Public and private investments have driven innovation and capacity building in this field. Regulatory agencies have played a role in expediting the development and approval of nucleic acid vaccines in response to public health emergencies. Streamlined regulatory pathways have facilitated the rapid deployment of these vaccines. Collaboration among governments, organizations, and pharmaceutical companies has been crucial in

coordinating efforts for pandemic preparedness. Nucleic acid vaccine development is often a collaborative effort with international partners. Nucleic acid vaccines offer a promising approach to addressing global vaccine accessibility, as they can be manufactured in diverse locations, allowing for more equitable distribution to areas in need during a pandemic. Beyond infectious disease vaccines, nucleic acid therapeutics have applications in cancer and rare disease treatment. The expertise developed in pandemic vaccine development can also benefit research and development in these areas. This factor will pace up the demand of the Global Nucleic Acid Therapeutics CDMO Market.

Increasing Demand Personalized Medicine

Personalized medicine relies on genetic information to understand an individual's susceptibility to diseases, response to treatments, and potential genetic mutations that may cause diseases. Nucleic acid therapeutics, such as gene therapies and RNA-based treatments, can be designed to address specific genetic mutations and variations, making them highly relevant for personalized medicine. Nucleic acid therapeutics can be customized to target the root causes of diseases at the genetic level. By addressing the unique genetic characteristics of each patient, these therapies offer the potential for more effective and precise treatment. Personalized medicine is particularly significant in the treatment of rare and genetic diseases. Nucleic acid therapies can be tailored to address the specific genetic mutations responsible for these conditions. The demand for such therapies is driven by the need for more targeted and curative treatments for these patient populations. The field of oncology benefits greatly from personalized medicine. Nucleic acid therapeutics, including targeted gene therapies, can be designed to address specific genetic alterations in cancer cells. This approach enhances the effectiveness of treatments while minimizing side effects.

Patients are increasingly seeking more personalized and patient-centric care. Nucleic acid therapeutics align with this trend by offering treatments that are tailored to individual patients, thereby improving treatment outcomes and patient satisfaction. By targeting therapies to the patient's unique genetic makeup, the potential for adverse effects and treatment non-responsiveness can be minimized. This is especially important in cases where traditional treatments may have significant side effects. Personalized medicine often includes the use of companion diagnostics to identify the most suitable treatment for a patient. These diagnostics can involve genetic testing to guide the choice of nucleic acid therapeutics. Personalized medicine integrates pharmacogenomic information to determine the most effective and safe drug regimens for individuals. Nucleic acid therapies can be tailored to align with these regimens. The

demand for nucleic acid therapeutic development for personalized medicine has led to increased research and clinical trials in this field. CDMOs play a critical role in these trials by providing development and manufacturing services for these personalized treatments. Regulatory agencies have recognized the importance of personalized medicine and nucleic acid therapeutics. They are adapting to accommodate these treatments through specialized regulatory pathways and support. This factor will accelerate the demand of the Global Nucleic Acid Therapeutics CDMO Market.

Key Market Challenges

Quality Control and Safety

Nucleic acid therapeutics involves complex and intricate manufacturing processes. The synthesis and purification of nucleic acids, as well as the production of viral vectors for gene therapies, require precision and control to ensure product quality and safety. The risk of contamination in nucleic acid therapeutics is high, and even minor contaminants can compromise product safety and efficacy. Ensuring aseptic and sterile manufacturing environments is crucial. Nucleic acid therapeutics must be thoroughly characterized to ensure their identity, quality, and consistency. This includes verifying the sequence, structure, purity, and concentration of the nucleic acids. Nucleic acid therapies often require specialized analytical methods for quality control. This includes advanced techniques for assessing stability, impurities, and secondary structures. Scaling up the production of nucleic acid therapeutics for clinical trials and commercial use while maintaining product quality can be challenging. CDMOs must ensure that the scalability of manufacturing processes does not compromise quality or safety. Ensuring patient safety is paramount. Any impurities or deviations in the quality of nucleic acid therapeutics could lead to adverse effects, making quality control and safety a top priority.

Manufacturing Scalability

The manufacturing of nucleic acid therapeutics involves complex and intricate processes, including the synthesis, purification, and formulation of RNA or DNA molecules. Scaling up these processes while maintaining product quality and consistency can be challenging. Nucleic acid therapeutics are often customized to target specific diseases or genetic variations in patients. Scaling up while preserving the individualized nature of these therapies can be complex. Maintaining the same rigorous quality control standards as production scales up is a critical challenge. Ensuring that the product meets safety and efficacy standards at larger volumes is essential. Sterility

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and aseptic conditions are paramount in nucleic acid therapeutic manufacturing. Ensuring that these conditions are maintained at larger scales is challenging and requires advanced facilities and equipment. Gene therapies often use viral vectors (e.g., adeno-associated viruses) for delivery. Scaling up the production of these vectors and ensuring their quality and safety is complex. Scaling up manufacturing often involves significant capital investment. Managing costs while achieving scalability is crucial for the commercial viability of nucleic acid therapeutics.

Key Market Trends

Increased Outsourcing

Nucleic acid therapies, including gene therapies and RNA-based drugs, are technically complex to develop and manufacture. Outsourcing to specialized CDMOs with expertise in this field allows pharmaceutical companies to tap into specialized knowledge and capabilities. Many pharmaceutical and biotechnology companies lack in-house expertise in nucleic acid therapeutics. Outsourcing to CDMOs with a proven track record in this area is a practical way to access the necessary expertise. The transition from laboratory-scale to clinical-scale and commercial-scale production of nucleic acid therapeutics can be challenging. CDMOs often have established infrastructure and facilities that can scale up production efficiently. Outsourcing can help expedite the development and production of nucleic acid therapies, reducing the time-to-market. CDMOs are equipped to handle specific aspects of the development process, allowing pharmaceutical companies to focus on core activities. CDMOs can offer flexible services that cater to the specific needs of pharmaceutical clients. They can customize their services to match the requirements of individual projects, whether they involve viral vector production, RNA synthesis, or analytical testing. Outsourcing to CDMOs can help spread the financial and regulatory risks associated with nucleic acid therapeutic development. CDMOs are often well-versed in navigating the regulatory landscape and managing compliance.

Segmental Insights

Type Insights

In 2023, the Global Nucleic Acid Therapeutics CDMO Market largest share was held by RNA-based therapies segment and is predicted to continue expanding over the coming years. The development of mRNA (messenger RNA) vaccines, such as those for COVID-19, garnered significant attention and demonstrated the potential of RNA-based

therapies. This spotlight on mRNA vaccines increased the demand for CDMO services to manufacture these innovative products. RNA-based therapies have a wide range of applications, including mRNA vaccines, small interfering RNA (siRNA) for gene silencing, and antisense oligonucleotides (ASOs) for gene expression modulation. This versatility makes RNA-based therapies attractive for addressing various diseases, driving their popularity. RNA-based therapies have shown promising results in clinical trials for a variety of conditions, including genetic disorders, rare diseases, and certain cancers. Positive clinical outcomes have encouraged further investment in RNA-based therapeutics. RNA-based therapies are known for their relative speed and efficiency in development and production. mRNA vaccines can be rapidly designed and manufactured, making them well-suited for responding to emerging infectious diseases. Patients and healthcare providers are increasingly seeking innovative therapies, and RNA-based treatments offer a new approach for addressing unmet medical needs.

Service Insights

In 2023, the Global Nucleic Acid Therapeutics CDMO Market largest share was held by manufacturing services segment and is predicted to continue expanding over the coming years. Nucleic acid therapeutics, such as mRNA vaccines, gene therapies, and antisense oligonucleotides, often involve complex manufacturing processes. These processes require specialized expertise, infrastructure, and quality control measures, making CDMOs a crucial partner in the production of these therapies. As nucleic acid therapeutics progress from early-stage development to clinical trials and commercialization, there is a need for efficient and scalable manufacturing solutions. CDMOs are well-equipped to handle the scale-up of production, ensuring a consistent supply of these therapies. Manufacturing nucleic acid-based products often requires specialized equipment and facilities, including bioreactors, purification systems, and cleanrooms. CDMOs are equipped with these resources, allowing biopharmaceutical companies to avoid the significant capital investment required for in-house manufacturing. Nucleic acid therapeutics are subject to rigorous regulatory standards to ensure product safety and quality. CDMOs are experienced in navigating the complex regulatory landscape, and their facilities are designed to meet these requirements, expediting the approval process.

Application Insights

In 2023, the Global Nucleic Acid Therapeutics CDMO Market largest share was held by oncology segment in the forecast period and is predicted to continue expanding over the coming years. The global incidence of cancer has been steadily increasing, making

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oncology one of the most significant therapeutic areas in healthcare. Nucleic acid therapeutics, such as RNA-based treatments and gene therapies, have shown promise in targeting and treating various types of cancer. Nucleic acid therapeutics can be designed to target specific genetic mutations or pathways involved in cancer. This targeted approach is more effective and can lead to fewer side effects compared to traditional chemotherapy. The trend towards precision medicine has led to the development of personalized cancer therapies. Nucleic acid therapeutics can be customized to an individual patient's genetic profile, increasing their effectiveness in treating cancer. Many nucleic acid therapeutics, particularly RNA-based therapies and gene editing techniques have demonstrated clinical success in treating various types of cancer. Positive clinical trial results have increased investment in these therapies. Nucleic acid therapeutics are crucial in the field of cancer immunotherapy. They can be used to modify a patient's immune cells to better recognize and attack cancer cells, leading to innovations such as CAR-T cell therapies.

Regional Insights

The North America region dominates the Global Nucleic Acid Therapeutics CDMO Market in 2023. North America, particularly the United States, is home to a robust biotechnology and pharmaceutical industry. Many major biopharmaceutical companies, as well as numerous innovative startups, are based in this region. These companies often require CDMO services for the development and production of nucleic acid therapeutics. North America has a long history of investment in research and development, making it a hub for innovation in the life sciences sector. This culture of innovation has led to the development of cutting-edge nucleic acid therapeutics, which, in turn, drives the demand for CDMO services. The United States has well-established regulatory agencies like the U.S. Food and Drug Administration (FDA) that have paved the way for the development and approval of nucleic acid therapeutics. The regulatory framework provides a level of confidence for companies looking to invest in this sector. The region offers access to significant financial resources, including venture capital and public funding. This financial support enables biotech startups and established companies to invest in nucleic acid therapeutic development, including outsourcing to CDMOs.

Key Market Players

Catalent Inc.

Thermo Fisher Scientific

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Lonza Group AG

FUJIFILM Diosynth Biotechnologies

Cognate BioServices

Eurofins Genomics

Sirion Biotech

Oxford Biomedica

Danaher (Aldevron)

Report Scope:

In this report, the Global Nucleic Acid Therapeutics CDMO Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Nucleic Acid Therapeutics CDMO Market, By Type:

Gene Therapy

RNA-based Therapies

Nucleic Acid Therapeutics CDMO Market, By Service:

Process Development & Optimization

Manufacturing Services

Analytical and Quality Control Services

Others

Nucleic Acid Therapeutics CDMO Market, By Application:

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Oncology

Genetic Disorders

Infectious Diseases

Others

Nucleic Acid Therapeutics CDMO Market, By region:

North America

United States

Canada

Mexico

Asia-Pacific

China

India

South Korea

Australia

Japan

Europe

Germany

France

United Kingdom

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Spain

Italy

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies presents in the Global Nucleic Acid Therapeutics CDMO Market.

Available Customizations:

Global Nucleic Acid Therapeutics 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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16.9. Danaher Corp. (Aldevron)
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