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Nucleic Acid Therapeutics CDMO Market - A Global and Regional Analysis: Focus on Chemical Synthesis Method, Product, Technology, Disease Type, End User, and Region - Analysis and Forecast, 2023-2033

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Abstracts

Intro on Nucleic Acid Therapeutics CDMO

The global nucleic acid therapeutics CDMO market was valued at $3.88 billion in 2022 and is expected to reach $14.19 billion by 2033, growing at a CAGR of 12.55% during the forecast period 2023-2033. The key factors driving the growth of the global nucleic acid therapeutics CDMO market include the growing demand for nucleic acid therapeutics applications to treat chronic and genetic diseases, manufacturing advancement for producing nucleic acid by CDMO (a contract development and manufacturing organization), increasing FDA (Food and Drug Administration) approvals of nucleic acid therapeutics, and increasing investment for the expansion of CDMO manufacturing units.

Market Introduction

CDMO: An organization that offers services including medication development, manufacturing, and pharmaceutical packaging that incorporates serialization and aggregation is known as a contract development and manufacturing organization or a CDMO. Based on their designs, formulas, and specifications or those of their clients, these businesses offer support services to several businesses.

Therapeutic Nucleic Acid: According to the National Centre for Biotechnology Information (NCBI), therapeutic nucleic acids (TNAs) are a subset of nucleic acids that are closely related compounds used to cure disease through the sequence-specific

recognition of endogenous nucleic acids. The therapeutic use of nucleic acids can be broadly divided into two categories, i.e., DNA therapies (including gene therapy, DNA aptamers, and antisense oligonucleotides) and RNA therapeutics (micro RNAs, short interfering RNAs, ribozymes, RNA decoys, and circular RNAs).

Nucleic Acid Therapeutics CDMO Market: According to BIS Research, the nucleic acid therapeutics CDMO market refers to the products and services provided by CDMO companies for the manufacturing of nucleic acid therapeutics. These therapeutics can be produced by either CDMO companies or pharmaceutical companies.

Impact

Nucleic Acid Therapeutics has made an impact in the following ways:

Nucleic acids in cancer therapy- A flexible framework to comprehend and treat complicated genetic illnesses like cancer has been made possible by significant advancements in the field of RNA therapies. For instance, RNA interference (RNAi) enables the ability to silence specific genes that are responsible for the disease or that encourage it. For cancer immunotherapy, on the other hand, mRNA medicines can encode tumor-associated antigens. This section gives a general review of nucleic acid therapies, mostly for the treatment of cancer.

Nucleic acids therapeutics for combating infectious disease- Millions of people around the world lose their lives to infectious diseases each year, posing a serious threat to public health. Millions of people have died, specifically from the COVID-19 pandemic brought on by the brand-new SARS-CoV-2 coronavirus. The creation of vaccines has significantly aided in the control and prevention of infectious diseases and annually saves thousands of lives. Smallpox has been completely eradicated thanks to extensive vaccination use, but cases of several infectious diseases have increased.

RNA therapeutics for lung disorders - Recently, new polymeric complexes and cationic LNPs were used to transfer nucleic acids to the lungs. The lungs are easily accessible for localized drug administration by inhalation, even though these methods have started to develop targeting the lungs with the systemic distribution of nucleic acids. The three main techniques for pulmonary medication administration are Dry powder inhalers and pressurized metered-dose inhalers (pMDIs) (DPIs),

Nucleic acid therapeutics for ocular diseases- The first clinical uses of nucleic acid treatments were for the treatment of nervous system disorders, which frequently take

the form of uncommon hereditary diseases. The creation of nucleic acid therapies offers an exciting case study in eye diseases. The developed and specialized cells that make up the retina normally serve as the tissue of interest in the eye as an extension of the central nervous system (CNS).

Nucleic acid therapeutics for neuromuscular diseases- Beyond the protected immunological environment of the inner eye, scientists have considered using nucleic acids to treat a variety of hereditary nervous system illnesses. Recent research has concentrated on creating therapies that simultaneously decrease aberrant splice variants of critical genes and introduce a necessary protein using gene therapy. Unfortunately, some neurodegenerative diseases can cause neuronal loss and muscular weakening.

Impact of COVID-19

The COVID-19 pandemic had a low impact on the nucleic acid therapeutics contract development and manufacturing organization (CDMO) sector. The demand for nucleic acid-based COVID-19 vaccines and therapies has led to an increased demand for CDMO services. Many CDMOs have experienced an uptick in orders for services such as nucleic acid synthesis, formulation, and manufacturing of viral vectors.

The future impact of COVID-19 on the demand and supply across the global nucleic acid therapeutics CDMO market depends on the abilities of stakeholders to withstand unforeseeable scenarios in the future. The intensity of impact due to COVID-19 in the future will depend on the current efforts being made by companies to equip their supply chains with the necessary components and processes to remain responsive.

Market Segmentation:

Segmentation 1: by Product Type

- Standard Nucleic Acid
- Micro-Scale Nucleic Acid
- Large-scale nucleic acid
- Custom Nucleic Acid

Modified Nucleic Acid

Primers

Probes

Other Nucleic Acid

Other Services

Standard Nucleic Acid to Continue Dominating the Nucleic Acid Therapeutics CDMO Market (by Products)

Products comprise standard nucleic acid, micro-scale nucleic acid, custom nucleic acid, modified nucleic acid, primers, probes, other nucleic acid, and other services.

Standard nucleic acid: Standard nucleic acids refer to naturally occurring nucleic acids that have a fixed basic structure without any modifications. These nucleic acids are in high demand for the production of various therapies associated with them. They form the foundation for the development of several biotechnology products and treatments in the healthcare industry. By using standard nucleic acids, researchers can better understand the natural functions of these molecules and develop effective treatments for various genetic disorders and diseases.

Micro-scale nucleic acid: Micro-scale nucleic acid refers to small fragments of DNA or RNA molecules that are typically less than 50 base pairs in length. These fragments are used in a variety of research applications, including PCR (polymerase chain reaction) amplification, sequencing, and gene expression analysis. The use of micro-scale nucleic acids allows for highly specific and sensitive detection of genetic material in samples, which is important for many applications in the fields of biotechnology, medicine, and agriculture. The ability to work with micro-scale nucleic acids is also essential for the development of new diagnostic tools and therapies that target specific genetic markers associated with the disease.

Large-scale nucleic acid: Large-scale nucleic acid production is a critical component of the global nucleic acid therapeutics CDMO industry, enabling the synthesis, purification, and characterization of nucleic acids at a commercial scale to meet the increasing demand for gene therapies and RNA-based therapeutics. It supports the advancement

of precision medicine worldwide by delivering high-quality nucleic acids for therapeutic use, driving the development of innovative nucleic acid therapies for patients globally.

Custom nucleic acid: Custom nucleic acid refers to synthetic DNA or RNA molecules that are designed to have specific sequences and properties based on the researcher's needs. These sequences can be designed to match specific genes, mutations, or other genetic markers of interest, making them valuable tools for a variety of research applications, such as gene editing, gene therapy, and synthetic biology. Custom nucleic acids can be produced using various techniques, including chemical synthesis and gene synthesis, and can be modified with different functional groups and labels to enable specific interactions and detection.

Modified nucleic acid: Modified nucleic acids, also known as 'clickmers' or xeno nucleic acids, can be easily adapted with almost any azide-bearing functional group through copper-catalyzed azide-alkyne cycloaddition. These modifications allow the incorporation of large chemical moieties, such as long carbohydrate chains and polycyclic compounds, which are usually incompatible with polymerase-mediated evolution methods. The resulting modular nucleic acid templates have various applications in gene therapy, molecular diagnostics, and gene editing, providing improved efficiency, specificity, and safety for these technologies. Additionally, chemical modifications can alter the properties of nucleic acids, such as stability and resistance to enzymatic degradation, making them valuable tools in many fields.

Primers: Primers are short, single-stranded DNA or RNA molecules that are used as starting points for DNA synthesis. They serve as complementary sequences to the template DNA or RNA strand and are essential components in several molecular biology techniques, including polymerase chain reaction (PCR), quantitative PCR (qPCR), and DNA sequencing. Primers are designed to be specific to the target sequence of interest, allowing for the amplification or detection of a particular gene or genetic marker. Accurate primer design is critical for the success of these techniques, as it can affect the specificity, sensitivity, and reproducibility of the results.

Probes: Probes are short, single-stranded DNA or RNA molecules that are used to detect and quantify specific nucleic acid sequences in a sample. They are designed to be complementary to the target sequence and are labeled with a detectable signal, such as a fluorescent or radioactive label. Probes are widely used in molecular biology techniques, such as PCR, qPCR, and DNA sequencing, and are valuable tools for disease diagnosis, genetic testing, and research. Accurate probe design is crucial for achieving high sensitivity and specificity in nucleic acid detection and quantification.

Other nucleic acid: The other nucleic acid category of the product involved within the global nucleic acid therapeutics CDMO market comprises products/services, including DNA origami reagents, WellRED Oligos, next-generation sequencing oligos, custom-locked nucleic acid oligonucleotides, antisense oligonucleotides, single-stranded DNA Extremer, double-stranded DNA Extremer and CRISPR RNA Synthesis, among others.

Other services: The other services segment under the products offered within the global nucleic acid therapeutics CDMO market includes services such as chemical development, analytical services, qualification and validation services, validation services, stability testing, and stability studies

Segmentation 2: by Technology

Column-Based Method

Microarray-Based Method

Column-Based Method to Register Maximum Share in the Market

Column-Based Method: The column-based technology for oligonucleotide synthesis, which involves the use of solid-phase phosphoramidite chemistry, has been a traditional method for synthesizing oligonucleotides. This technique utilizes separate columns that enable the iterative addition of nucleotides on the controlled-porosity glass beads (CPG) matrix in a programmable manner, with reagents being pumped through the columns. This results in the synthesis of one sequence per column. With commercially available column-based oligo synthesizers, it is possible to synthesize 96-768 oligonucleotides, each containing 10 nmol to 2 ?mol simultaneously. These oligonucleotides have been utilized in several studies as modules for DNA constructions by assembly methods.

Microarray-Based Method: The microarray-based oligonucleotide synthesis method involves in-situ synthesis or deposition of pre-synthesized oligonucleotides that range in size from 25- to 60-mers. Thousands of distinct features on the microarray chips enable the simultaneous synthesis of unique oligonucleotide sequences, with one per chip feature. The resulting product is a pool of sequences containing every oligonucleotide synthesized on the array, which requires further processing to isolate the desired oligonucleotide sequences for subsequent gene synthesis.

Segmentation 3: by Disease Type

Genetic Disease

Infectious Disease

Genetic Disease segment: Highest share in the market due to the high number of FDA approvals of nucleic acid drugs treating genetic diseases.

Genetic Disease: Nucleic acid therapeutics are a diverse range of sequence-programmable medications that provide an effective and clinically practical method to modify expression or fix genetic abnormalities that cause disease with the help of intuitive engagement with genome sequences made possible by nucleic acid therapies, many diseases can now be directly targeted at their genetic source.

Infectious Disease: Nucleic acid therapeutics for infectious diseases has demonstrated considerable promise. They offer a fresh method to fight infections since they can target certain viruses by interfering with their genetic material or by blocking crucial viral proteins.

Segmentation 4: By Chemical Synthesis Method

Solid-Phase Oligonucleotide Synthesis

Liquid-Phase Oligonucleotide Synthesis

Solid-Phase Oligonucleotide Synthesis to Dominate the Global Nucleic Acid Therapeutics CDMO Market (by Chemical Synthesis Method)

Solid-Phase Oligonucleotide Synthesis: Solid-phase oligonucleotide synthesis is a highly efficient and widely used method for synthesizing oligonucleotides. This technique involves the use of solid support held between filters within columns that allow reagents and solvents to pass through freely. Traditional solid-phase synthesis uses polymer or specialized glass beads that are not affected by reaction conditions. Solid-phase synthesis yields high-purity products rapidly, and the entire process can be easily automated and controlled using computer systems, making it cost-effective. Custom oligonucleotide production benefits significantly from solid-phase synthesis,

allowing the rapid and cost-effective synthesis of highly pure oligonucleotides tailored to specific research or therapeutic needs.

Liquid-Phase Oligonucleotide Synthesis: Liquid-phase oligonucleotide synthesis is a method for synthesizing oligonucleotides on a large scale that utilizes soluble polymer support. The technique requires three reaction steps and 4-5 precipitation steps per nucleotide addition, making it more time-consuming and labor-intensive than solid-phase synthesis. However, LPOS offers several advantages over solid-phase syntheses, such as easy purification of the final product by removing interfering compounds through precipitation or membrane filtration.

Segmentation 5: By End User

- Pharmaceutical Companies
- Academic Research Institute
- Diagnostic Laboratories

Pharmaceutical companies have been dominating the nucleic acid therapeutics CDMO market for a long time and hold the largest market share currently, followed by academic research institutes.

Segmentation 6: by Region

- North America - U.S., Canada
- Europe - Germany, U.K., France, Italy, Spain, and Rest-of-Europe
- Asia-Pacific - China, Japan, India, Australia, and Rest-of-Asia-Pacific
- Rest-of-the-World

North America has witnessed the increase in investment for the production of nucleic acid therapeutics by CDMO. Furthermore, the presence of several established companies and startups, as well as the FDA approvals, resulted in this region holding the maximum share in the global nucleic acid therapeutics CDMO market in 2022,

followed by Europe.

Recent Developments in the Nucleic acid therapeutics CDMO Market

In June 2021, Danaher Corporation acquired Aldeveron for $9.6 billion. Through this acquisition, the company will expand its manufacturing capacity in plasmid DNA and mRNA.

In January 2023, Agilent Technologies, Inc. invested $725 million to increase its manufacturing capacity for therapeutic nucleic acids.

In March 2022, IMM, a partner of VGXI, has recently announced that it received a $12 million grant from the National Institutes of Health (NIH) to support the Phase 1 clinical trial of a DNA vaccine aimed at preventing Alzheimer's disease. The vaccine will be manufactured using VGXI's expertise in contract manufacturing of DNA plasmids for human clinical trials, produced in accordance with GMP standards.

In April 2022, BACHEM partnered with Eli Lilly and Company to develop and manufacture active pharmaceutical ingredients based on oligonucleotides, a rising new class of complex molecules.

In September 2021, AGC Biologics expanded the company’s Heidelberg facility to increase manufacturing capacities for plasmid-DNA (pDNA) and messenger RNA (mRNA) projects.

In August 2022, Codexis and Molecular Assemblies announced the execution of a commercial license and enzyme supply agreement for an optimized TdT enzyme for enzymatic DNA synthesis.

In June 2020, OliX Pharmaceuticals, Inc. partnered with LGC Biosearch Technologies Inc. to scale up the production of OliX’s OLX301D therapeutic candidate.

Demand – Drivers and Limitations

Market Demand Drivers:

Growing demand for nucleic acid therapeutics applications to treat chronic and genetic diseases: There is a growing demand for nucleic acid therapeutics due to their potential in treating chronic and genetic diseases. Nucleic acids, such as DNA and RNA, are essential molecules that play a key role in the regulation of gene expression and protein synthesis in cells. In recent years, researchers have made significant progress in developing new techniques for the delivery of nucleic acids to specific cells and tissues in the body, which has opened new avenues for the development of targeted therapeutics.

Increasing FDA or European Medicines Agency (EMA) approvals of nucleic acid Therapeutics: Nucleic acid therapeutics, including RNA and DNA-based treatments, have seen a significant increase in approval and development in recent years. This is largely due to advances in technology and the understanding of the genetic mechanisms that underlie many diseases. For instance, nucleic acid therapeutic that has gained approval is Onpattro (patisiran), which is a small interfering RNA (siRNA) therapy for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR). This was the first RNA interference (RNAi) therapy to receive approval from the U.S. FDA in 2018.

Advancements in manufacturing units for producing nucleic acid by CDMO: There have been several recent advancements in manufacturing technology that CDMOs can utilize to improve efficiency and reduce costs.

One such advancement is the use of continuous manufacturing processes. This method involves running reactions in a continuous flow rather than batch processing, which can be time-consuming and requires a significant amount of equipment. Continuous manufacturing allows for faster processing times and reduces the need for large amounts of starting materials and reagents. Another advancement is the use of automated systems for nucleic acid purification and analysis. Automation can help to reduce errors and increase accuracy, as well as improve efficiency and reduce costs. These systems can also be used to improve the scalability of nucleic acid production, making it easier for CDMOs to produce large quantities of nucleic acids for research or commercial use.

Market Restraints:

Substantial variation in nucleic acid leads to complications in therapeutic classification: The large variation in nucleic acids, specifically in DNA and RNA sequences, can indeed make therapeutic classification difficult. This is because the specificity of a drug

to a particular sequence or target is critical for its effectiveness and safety. However, because of the vast diversity of nucleic acid sequences, it can be challenging to develop a drug that targets a specific sequence or gene without affecting other unrelated sequences. Several forms of nucleic acid medications have different molecular weights (ranging from 2,400 to 16,000 amu), sizes (single or double-stranded), numbers of nucleotides, and negative charges. As the drug molecules interact with the target mRNAs, cells, and tissues, these variations lead to a wide range of different modes of action.

Lack of expertise in developing nucleic acid therapeutics: the production of peptides and nucleic acids differs significantly. Large amounts of solvents and reagents are used during the synthesis in flow-through columns; thus, the facility infrastructure will be increased adequately. Moreover, because oligonucleotides are extremely water-soluble and negatively charged, aqueous solutions must be handled during the entire downstream process. The oligonucleotide APIs, in particular double-stranded molecules, are also much larger than peptides and provide difficulties from an analytical standpoint.

Market Opportunities:

Continued Research and Development Activities for Manufacturing Innovative Nucleic Acid Therapeutics Forcing Pharmaceutical Companies to Expand their Businesses: Nucleic acid therapeutics, including RNA-based therapies such as messenger RNA (mRNA) vaccines and small interfering RNA (siRNA) drugs, are a rapidly growing area of pharmaceutical research and development. These therapies have the potential to treat a wide range of diseases, including genetic disorders, infectious diseases, and cancer, by targeting specific genes and proteins.

Pharmaceutical Firms Becoming More Outsourcing-Oriented: The trend of pharmaceutical firms becoming more outsourcing-oriented can be an opportunity for contract development and manufacturing organizations (CDMOs). Pharmaceutical companies are increasingly looking to outsource various aspects of their operations to external partners, including drug development, manufacturing, and clinical trials. This trend has been driven by factors such as cost reduction, increasing complexity of drug development, and the need for specialized expertise.

How can this report add value to an organization?

Product/Innovation Strategy: The global nucleic acid therapeutics CDMO market has

been extensively segmented based on various categories, such as product, chemical synthesis method, disease type, technology, and end users. This can help readers get a clear overview of which segments account for the largest share and which ones are well-positioned to grow in the coming years.

Growth/Marketing Strategy: Synergistic activities and product business expansion accounted for the maximum number of key developments, i.e., nearly 38.54% of the total developments in the global nucleic acid therapeutics CDMO market, as of February 2023.

Competitive Strategy: The global nucleic acid therapeutics CDMO market is competitive, with around four key players accounting for a large market share. Key players in the global nucleic acid therapeutics CDMO market analysed and profiled in the study involve established players that offer various kinds of nucleic acid therapeutics CDMO products.

The global nucleic acid therapeutics CDMO market has witnessed several investments for the expansion of CDMO manufacturing units by the market players. The expansion is aimed at increasing the manufacturing capacity. To meet the growing demand for their services, CDMOs are expanding their manufacturing units and investing in new technologies. 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

The companies that are profiled have been selected based on inputs gathered from primary experts and analysing company coverage, product portfolio, and market penetration.

Key Companies Profiled

- Agilent Technologies, Inc.
- AGC Biologics
- Asymchem Inc.
- BACHEM

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