

# **mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Application (Viral Vaccines, Protein Replacement Therapies, Cancer Immunotherapies), By Indication ( Infectious Diseases, Metabolic & Genetic Diseases, Cardiovascular & Cerebrovascular Diseases), By End user (Biotechnology & Pharmaceutical Companies, Academic & Research Institutions, Others), By Region and Competition**

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## **Abstracts**

Global mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market has valued at USD 8.51 Billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 7.11% through 2028. The realm of medicine has witnessed significant advancements in recent years, and one of the most revolutionary breakthroughs is the development of mRNA therapeutics. These cutting-edge treatments, which leverage the power of messenger RNA (mRNA), have the potential to tackle a wide range of diseases, from cancer to infectious diseases. As this field continues to grow, so does the demand for contract development and manufacturing organizations (CDMOs) specializing in mRNA therapeutics.

Messenger RNA (mRNA) therapeutics represent a novel approach to treating diseases by instructing the body's own cells to produce therapeutic proteins. This technology has been at the forefront of the fight against the COVID-19 pandemic, with the development and successful deployment of mRNA-based vaccines by companies like Pfizer-

BioNTech and Moderna. Beyond vaccines, mRNA therapeutics hold immense potential in the treatment of various genetic disorders, rare diseases, and even certain cancers. As the promise of mRNA therapeutics becomes increasingly evident, the demand for specialized CDMOs has surged. CDMOs play a pivotal role in the development and manufacturing of mRNA-based drugs, offering expertise in formulation, production, quality control, and regulatory compliance. This market segment is expanding rapidly to meet the growing needs of pharmaceutical and biotechnology companies, both established players and startups, who are investing heavily in mRNA-based therapies.

### Key Market Drivers

#### Growing Investment in Research and Development is Driving the Global mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market

The surge in investment in R&D within the mRNA therapeutics sector has been a driving force behind the growth of the mRNA CDMO market. Several factors contribute to this increased investment. The remarkable success of mRNA-based COVID-19 vaccines has bolstered investor confidence in the technology. This has led to substantial funding for companies engaged in mRNA research and development. The mRNA therapeutics pipeline has expanded rapidly, with candidates in various stages of development for a wide range of diseases. Investors see the potential for mRNA to transform the treatment landscape across multiple therapeutic areas, spurring greater investment. Biopharmaceutical companies are forming partnerships and collaborations with CDMOs to accelerate the development and manufacturing of mRNA therapies. These partnerships often come with substantial financial commitments. Governments worldwide recognize the importance of mRNA therapeutics in addressing public health challenges. As a result, they are allocating significant funding to support research and development efforts in this field.

#### Expanding Therapeutic Applications is Driving the Global mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market

One of the primary factors propelling the mRNA therapeutics CDMO market's growth is the increasing number of therapeutic applications. Initially, mRNA technology gained prominence for its potential in developing vaccines, as seen in the rapid development of COVID-19 vaccines by Pfizer-BioNTech and Moderna. However, its utility extends far beyond vaccines.

mRNA therapeutics are being explored for cancer treatment, with the ability to trigger an immune response against cancer cells or directly target them with specific therapies. mRNA can be used to correct genetic mutations responsible for rare diseases, offering hope to patients who previously had limited treatment options. mRNA technology can be adapted to create vaccines and treatments for various infectious diseases, from influenza to HIV. mRNA can be harnessed to modulate the immune system's response and treat autoimmune conditions like multiple sclerosis and rheumatoid arthritis. Researchers are investigating mRNA therapies to combat heart diseases by targeting specific genes associated with these conditions. mRNA therapeutics hold promise in treating neurological disorders, including Alzheimer's and Parkinson's disease.

As research continues to uncover new therapeutic opportunities, the demand for mRNA therapeutics CDMOs is expected to surge, as these organizations play a pivotal role in translating research into market-ready therapies. Contract development and manufacturing organizations specializing in mRNA therapeutics are crucial to the industry's success. These CDMOs provide essential services to biopharmaceutical companies, startups, and research institutions, allowing them to leverage mRNA technology without building their own production capabilities from scratch.

CDMOs can synthesize mRNA molecules tailored to specific therapeutic targets, ensuring precise and effective treatments. They optimize mRNA production processes, improving efficiency, scalability, and cost-effectiveness. CDMOs have the infrastructure and expertise to manufacture mRNA therapeutics at scale, meeting the growing demand. Ensuring that mRNA therapies meet rigorous quality and regulatory standards is vital, and CDMOs excel in this area. CDMOs expedite the development and production of mRNA therapeutics, allowing treatments to reach patients faster.

## Key Market Challenges

### Regulatory Hurdles

One of the most significant challenges in the mRNA therapeutics CDMO market is navigating complex regulatory landscapes. mRNA-based therapies represent a new frontier in medicine, and regulatory agencies worldwide are continually updating and adapting their guidelines. Manufacturers must ensure that their production processes and facilities meet stringent regulatory standards, which can vary from one region to another. Achieving regulatory compliance is a resource-intensive and time-consuming task that can delay product development and market entry.

## Scalability Issues

Scalability is another major challenge faced by CDMOs in the mRNA therapeutics market. The production of mRNA vaccines and therapies requires state-of-the-art manufacturing facilities and equipment. Scaling up production capacity quickly to meet high demand, as seen during the COVID-19 pandemic, can be a logistical nightmare. Furthermore, mRNA therapies often involve complex and delicate processes that must be carefully controlled to maintain product quality and efficacy during scale-up.

## Supply Chain Vulnerabilities

The global supply chain is vulnerable to various disruptions, including geopolitical tensions, natural disasters, and unexpected events like the COVID-19 pandemic. These disruptions can lead to shortages of critical raw materials, equipment, and skilled personnel needed for mRNA production. CDMOs must develop resilient supply chains, diversify sourcing options, and establish contingency plans to mitigate these risks.

## Intellectual Property and Licensing

The mRNA therapeutics market is characterized by a complex web of intellectual property rights and licensing agreements. Many key technologies and patents are held by different companies and institutions, making it challenging for CDMOs to navigate the landscape. Negotiating licensing agreements, royalty payments, and compliance with various patents can add significant complexity and costs to mRNA therapy development.

## Cost and Pricing Pressures

Developing and manufacturing mRNA therapies can be costly, especially in the early stages when technologies are still being optimized. Pricing pressures, both from healthcare systems and patient advocacy groups, can limit the profitability of mRNA CDMOs. Balancing the need for affordable treatments with the costs of research, development, and manufacturing poses a constant challenge.

## Competitive Landscape

The rapid growth of the mRNA therapeutics market has attracted numerous players, increasing competition among CDMOs. Smaller CDMOs may struggle to compete with larger, more established firms that have greater resources and expertise. Differentiating

services and establishing a reputation for quality and reliability are vital for success in this highly competitive industry.

### Technological Innovation

The mRNA therapeutics field is continuously evolving, with new discoveries and technologies emerging at a rapid pace. CDMOs must invest in research and development to stay at the forefront of innovation. Staying updated with the latest advancements is crucial, as outdated technologies can quickly become obsolete, impacting the competitiveness of a CDMO.

### Key Market Trends

#### Technological Advancements

The field of medicine and pharmaceuticals is constantly evolving, and one of the most exciting advancements in recent years has been the development of mRNA therapeutics. These groundbreaking therapies have shown immense potential in treating various diseases, from cancer to infectious diseases. As the demand for mRNA therapeutics continues to grow, so does the need for contract development and manufacturing organizations (CDMOs) specialized in this field.

The rapid expansion of technological advancements in mRNA therapeutics has been a driving force behind the growth of the CDMO market. mRNA production methods have become more efficient and scalable. Continuous innovations in lipid nanoparticles (LNPs) and microfluidic technologies have significantly enhanced the formulation and encapsulation of mRNA molecules, allowing for the development of more stable and effective therapies. Advancements in sequencing and gene editing technologies have enabled the development of personalized mRNA therapies. CDMOs are now better equipped to tailor mRNA treatments to individual patients, opening up new possibilities in precision medicine. CDMOs have fine-tuned their manufacturing processes to increase yields and reduce production costs. This has made mRNA therapies more accessible and economically viable for a broader range of medical conditions. Collaboration between pharmaceutical companies, research institutions, and CDMOs has accelerated the development of mRNA therapies. These partnerships bring together expertise in mRNA technology, drug development, and manufacturing.

### Segmental Insights

## Application Insights

Based on the category of Application, Viral Vaccines emerged as the dominant player in the global market for mRNA Therapeutics Contract Development & Manufacturing (CDMO) in 2022. The dominance of viral vaccines in the mRNA Therapeutics CDMO market bodes well for public health, as it promises the rapid development of vaccines for emerging infectious diseases and the potential for breakthroughs in cancer immunotherapy. It also highlights the critical role CDMOs play in translating mRNA technology into tangible treatments, ultimately benefiting patients worldwide. Regulatory agencies such as the U.S. FDA have recognized the potential of mRNA technology and are streamlining the approval process for mRNA-based vaccines and therapeutics. This support encourages further development and manufacturing in this space.

Pharmaceutical giants and biotech startups alike are pouring substantial investments into mRNA-based therapies. The race to develop mRNA vaccines for various diseases and conditions has created a booming market for CDMOs specializing in viral vaccine production. mRNA-based cancer vaccines and immunotherapies are gaining momentum in the biopharmaceutical industry. These therapies leverage the body's immune system to target cancer cells specifically. As research in this field advances, CDMOs are increasingly involved in the manufacturing of personalized cancer vaccines tailored to individual patients. Beyond COVID-19, mRNA vaccines have demonstrated promise in addressing other infectious diseases. CDMOs are playing a vital role in developing mRNA vaccines for influenza, Zika virus, and other pathogens. The versatility of mRNA technology allows for rapid adaptation to new viral strains, making it an attractive option for vaccine development.

## End User Insights

The Biotechnology & Pharmaceutical Companies segment is projected to experience rapid growth during the forecast period. Biotechnology and pharmaceutical companies are at the forefront of mRNA therapeutic research and development. They invest heavily in identifying new therapeutic targets, designing mRNA sequences, and conducting pre-clinical studies to evaluate the safety and efficacy of these therapies. These companies have the resources and infrastructure to initiate and manage large-scale clinical trials, which are crucial for gaining regulatory approvals. mRNA therapies have shown immense promise in treating various diseases, and pharmaceutical giants are keen to capitalize on this potential. Biotechnology and pharmaceutical companies have established distribution networks and relationships with healthcare providers, making it easier for them to bring mRNA therapies to market once they receive regulatory approval. This access is crucial for ensuring that these innovative treatments reach

patients in need. While CDMOs specialize in manufacturing, biotechnology and pharmaceutical companies often have their own manufacturing facilities or strategic partnerships with CDMOs. This enables them to scale up production quickly when a promising mRNA therapy advances through clinical trials.

## Regional Insights

North America emerged as the dominant player in the global mRNA Therapeutics Contract Development & Manufacturing (CDMO) market in 2022, holding the largest market share in terms of value. One of the primary reasons for North America's dominance in the mRNA therapeutics CDMO market is its thriving biotechnology ecosystem. The region boasts a rich network of biotech companies, academic institutions, research centers, and startups. These entities collaborate to advance mRNA technology, develop innovative therapies, and provide comprehensive CDMO services. Key cities like Boston, San Francisco, and San Diego have become global hubs for biotech innovation, housing numerous companies at the forefront of mRNA research and development. The presence of world-class talent, research infrastructure, and capital investment has allowed North America to push the boundaries of mRNA therapeutics. Another pivotal factor in North America's leadership is the strong government support and regulatory framework in place. Government agencies such as the Food and Drug Administration (FDA) in the United States have paved the way for mRNA therapies by streamlining regulatory processes, expediting approvals, and providing funding for research and development. In response to the COVID-19 pandemic, Operation Warp Speed in the United States accelerated the development and manufacturing of mRNA vaccines. This initiative showcased the agility and potential of mRNA technology and further solidified North America's position as a leader in the field.

## Key Market Players

Danaher corporation (Aldevron)

Recipharm AB

Biomay AG

Samsung Biologics

Lonza Group AG

Catalent , Inc

Bio-Indication Inc

Kaneka Eurogentec S.A

TriLink BioTechnologies

BioNTech SE

Report Scope:

In this report, the Global mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market,  
By Application:

Viral Vaccines

Protein Replacement Therapies

Cancer Immunotherapies

mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market,  
By Indication:

Infectious Diseases

Metabolic & Genetic Diseases

Cardiovascular & Cerebrovascular Diseases

mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market,  
By End user:

Biotechnology & Pharmaceutical Companies



Academic & Research Institutions

Others

mRNA Therapeutics Contract Development & Manufacturing (CDMO) 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 presents in the mRNA Therapeutics Contract Development & Manufacturing (CDMO) Market.

Available Customizations:

Global mRNA Therapeutics Contract Development & Manufacturing (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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