

# Plasmid DNA Contract Manufacturing - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2024 - 2029)

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## Abstracts

The Plasmid DNA Contract Manufacturing Market size is estimated at USD 5.52 billion in 2024, and is expected to reach USD 12.44 billion by 2029, growing at a CAGR of 14.5% during the forecast period (2024-2029).

The growing disease prevalence, investment in research studies, and popularity of gene therapy are the key factors driving the growth of the market. The ever-increasing popularity of gene therapy drives the demand for plasmid DNA contract manufacturing due to the essential role of plasmids in the gene therapy process. Plasmids serve as carriers for introducing therapeutic genes into target cells. As more gene therapy treatments advance through clinical trials and into commercial production, there is an increasing need for large-scale, high-quality production of plasmid DNA. For instance, in August 2023, Charles River established a world-class HQ plasmid manufacturing center of excellence to combat supply scarcity and fulfill the escalating demands of the cell and gene therapy industry.

The increasing disease burden, characterized by diverse health challenges ranging from chronic diseases to infectious threats, increases the demand for plasmid DNA contract manufacturing services. According to the British Heart Foundation's January 2024 England Factsheet, approximately 7.6 million individuals in England had cardiovascular diseases in 2022. As per the same source, around 620 million people live with heart and circulatory diseases (cardiovascular diseases) across the world in 2022; this number has been rising since then due to changing lifestyles, aging, and the growing population. Thus, with the rise in the prevalence of chronic diseases, there is a corresponding increase in demand for novel therapeutics and treatments. Plasmid DNA contract manufacturing is poised to benefit from this by meeting the requirements of

biotech and pharmaceutical companies that are developing advanced therapies for chronic conditions.

As per the report published by WHO in March 2023, approximately 39.0 million people were living with HIV by the end of 2022, including 1.5 million children. Moreover, 29.8 million people living with HIV were receiving antiretroviral therapy globally. Plasmid DNA is crucial in gene therapy and vaccine development, gaining traction in treating chronic diseases. Gene therapies often utilize plasmid DNA to deliver therapeutic genes into cells, targeting genetic disorders associated with chronic conditions. Hence, the growing burden of chronic diseases is expected to boost the market's growth over the forecast period.

The players in this market are continuously expanding their operations to accommodate the growing demand for plasmid DNA. They are vigorously advancing their capabilities to serve as a fully integrated one-stop-shop by offering various plasmid services, including process development and optimization, plasmid design, plasmid engineering, plasmid construction, and GMP plasmid manufacturing.

For instance, in January 2023, Catalent inaugurated a novel commercial-grade plasmid DNA (pDNA) production facility within its European Center of Excellence for Cell Therapies in Gosselies, Belgium. The facility has 12,000 square feet (1,100 m<sup>2</sup>) of development and manufacturing space across multiple cleanrooms for CGMP-grade pDNA production for clinical and commercial-phase supply.

Thus, the growing demand for cell and gene therapy and strategic activities from the market players is expected to boost the market's growth over the forecast period. However, the need for advanced infrastructure for manufacturing in particular developing countries and quality issues associated with contract manufacturing are anticipated to restrain the market growth over the forecast period.

## Plasmid DNA Contract Manufacturing Market Trends

### The Cell & Gene Therapy Segment is Expected to Grow Significantly Over the Forecast Period

The cell & gene therapy market is anticipated to expand due to the growing number of contract development organizations (CDOs) adding cell and gene-based plasmid DNA manufacturing services to their offerings. For instance, in October 2022, Ray Therapeutics and contract development and manufacturing organization (CDMO) Forge

Biologics extended their agreement to manufacture clinical-stage plasmid DNA, supporting Ray Therapeutics' groundbreaking optogenetics gene therapy program. Moreover, in October 2023, BioCina Pty Ltd announced a new partnership with GenomeFrontier Therapeutics AU Pty Ltd to support GenomeFrontier with process development and GMP manufacturing for Minicircle DNA and Plasmid DNA to support the CAR-T cell therapy product.

The technological advancement of the plasmid DNA platform and the introduction of advanced technologies by contract manufacturing are expected to increase the outsourcing demand, thereby boosting the segment's growth. For instance, in January 2023, Charles River Laboratories International Inc. launched its eXpDNA plasmid platform, established from the company's contract development and manufacturing (CDMO) and biologics testing experience. The platform significantly reduces plasmid development and production timelines while streamlining the development journey for cell and gene therapy and vaccine developers, focusing on product quality and consistency.

Gene therapy developers often collaborate with these specialized manufacturing facilities to leverage their expertise, infrastructure, and regulatory compliance to meet the increasing demand for plasmid DNA in gene therapy treatments. This outsourcing allows gene therapy companies to focus on the clinical and regulatory aspects of their treatments while ensuring the efficient and reliable production of plasmid DNA at a commercial scale. In June 2023, INADcure Foundation and Charles River Laboratories collaborated on the production of high-quality plasmid DNA (pDNA) for Phase I/II clinical trials of a gene therapy targeting Infantile Neuroaxonal Dystrophy.

Hence, the growing demand for cell and gene therapy and strategic activities by the market players are expected to contribute to the segment's growth over the forecast period.

### North America is Expected to Hold a Significant Share of the Market Over the Forecast Period

In North America, the plasmid DNA contract manufacturing market is expected to grow owing to factors such as established research facilities, increasing investment in R&D for cell therapy, and the growing burden of chronic diseases. The growth of the plasmid DNA contract manufacturing market can be attributed to the increasing number of

product launches, the high number of ongoing clinical trials, and the potential application of cell therapies in the treatment of autoimmune diseases, cancer, and infectious diseases.

The growing demand for cell and gene therapy is expected to boost the market's growth over the forecast period. As of October 2023, more than 581 clinical trials focusing on cell therapies were conducted to interpret the potential of these therapies for treating various disease indications in North America. Therefore, the increasing research in clinical development is expected to boost the plasmid DNA contract manufacturing market over the forecast period.

The growing trend of outsourcing and strategic activities by the market players is expected to contribute to the market's growth over the forecast period. For instance, in October 2022, Forge Biologics launched plasmid DNA (pDNA) manufacturing services to support its AAV clients after closing a USD 90 million Series C funding round. Similarly, in May 2022, Avantor signed an agreement with Cytovance Biologics (a contract development and manufacturing organization specializing in plasmid DNA) in order to manufacture research-grade and GMP-grade plasmids for viral vectors and mRNA-based vaccines and therapeutics.

Hence, the increase in the number of clinical research for cell and gene therapy, expansion of plasmid DNA manufacturing facilities, and strategic collaboration by the market players are expected to boost the market over the forecast period.

## Plasmid DNA Contract Manufacturing Industry Overview

The plasmid DNA contract manufacturing market is moderately competitive, with the presence of both small and large players who are involved in strategic activities such as the expansion of services, partnerships, collaborations, and mergers and acquisitions. PlasmidFactory GmbH & Co. KG, Lonza, BioCina, Charles River Laboratories, and Catalent Inc. are among the notable key players in this market.

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