

North America Recombinant Cell Culture Supplements Market Segmented By Product (Recombinant Albumin, Recombinant Insulin, Recombinant Epidermal Growth Factors, Recombinant Transferrin, Recombinant Trypsin, Others), By Application (Regenerative Medicine & Bio-Production), By Expression System (Mammalian Expression System, E.Coli Expression System, Yeast Expression System, Others), By End-User (Academic & Research Institutions, Biotechnology & Pharmaceutical Companies, Others), By Country, Competition, Forecast & Opportunities, 2018-2028

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## **Report description:**

North America Recombinant Cell Culture Supplements Market has valued at USD 193.31 million in 2022 and is anticipated to project robust growth in the forecast period with a CAGR of 9.44% through 2028. The North America Recombinant Cell Culture Supplements Market is a crucial segment of the broader biotechnology and cell culture industry. It encompasses the production and sale of cell culture supplements derived from recombinant sources, primarily used in the growth and maintenance of cells for various applications in research, drug development, biomanufacturing, and regenerative medicine.

The North America Recombinant Cell Culture Supplements Market is one of the largest and most mature in the world, driven by substantial investments in research and development (R&D), pharmaceuticals, and biotechnology. The market has experienced steady growth in recent years, primarily due to the increasing demand for biopharmaceuticals, vaccines, and regenerative medicine products.

#### Key Market Drivers

Increasing Demand for Biopharmaceuticals

The increasing demand for biopharmaceuticals is a significant market driver for the North America Recombinant Cell Culture Supplements Market. This demand is driven by various factors and understanding it in detail is crucial for businesses operating in this sector. The aging population in North America is more susceptible to chronic diseases and conditions that often require advanced therapeutic interventions. Biopharmaceuticals offer effective treatment options for conditions like cancer, diabetes, autoimmune disorders, and cardiovascular diseases, driving their demand. Biopharmaceuticals are known for their precision and specificity in targeting disease mechanisms. They are designed to interact with specific molecular targets, minimizing side effects and enhancing therapeutic outcomes. This precision is particularly valuable in treating complex diseases. Advances in biopharmaceutical research have paved the way for personalized medicine. By tailoring treatments to an individual's genetic makeup and specific disease characteristics, biopharmaceuticals offer the potential for more effective and patient-centered therapies. As patents for some biologic drugs expire, it opens the door for the development of biosimilars, which are highly similar versions of the original biologics. Biosimilars often require recombinant cell culture supplements for production, increasing the demand for these supplements. The prevalence of chronic diseases, such as cancer, autoimmune diseases, and rare genetic disorders, is on the rise. Biopharmaceuticals are increasingly being used to manage and treat these conditions, leading to a sustained demand for cell culture supplements. The growing demand for biopharmaceuticals necessitates larger-scale production, often involving mammalian cell culture systems. Recombinant cell culture supplements, such as growth factors, media, and serum alternatives, are vital for supporting cell growth and protein expression during biopharmaceutical production. The demand for biopharmaceuticals directly translates into increased demand for cell culture supplements. This growth in demand benefits manufacturers and suppliers in the Recombinant Cell Culture Supplements Market, as they can expand their product offerings and capture a larger share of the market. To meet the specific requirements of biopharmaceutical production, manufacturers of cell culture supplements are innovating and customizing their products. This includes developing specialized media and supplements optimized for the growth and expression of specific cell lines used in biopharmaceutical manufacturing. Businesses that can consistently provide high-quality and reliable cell culture supplements to support biopharmaceutical production gain a competitive advantage. They become preferred partners for biopharmaceutical companies and contract manufacturing organizations seeking to ensure product quality and regulatory compliance.

Technological Advancements in Cell Culture Techniques

Ongoing advancements in cell culture techniques, including cell line engineering, media optimization, and bioprocess automation, are revolutionizing biomanufacturing. These innovations enhance cell culture efficiency, productivity, and scalability, reducing production costs and improving product quality.

Businesses in North America's Recombinant Cell Culture Supplements Market must adapt to these technological advancements by offering specialized supplements tailored to novel cell culture methods. Market players that invest in research and development to create innovative culture supplements gain a competitive edge and capture a larger market share.

Growing Research and Development Activities

Robust research and development (R&D) activities in the biotechnology and pharmaceutical sectors drive the demand for recombinant cell culture supplements. Companies are continuously exploring new therapeutic targets, leading to an increasing number of cell-based assays and preclinical studies.

The need for consistent and reliable cell culture supplements in R&D efforts necessitates a steady supply from manufacturers. This demand fuels the growth of the market, with suppliers catering to both large pharmaceutical corporations and smaller research institutions.

## Stringent Regulatory Requirements

The pharmaceutical and biotechnology industries operate under strict regulatory frameworks to ensure product safety and efficacy. Regulatory agencies, such as the FDA in the United States, mandate compliance with Good Manufacturing Practices (GMP) and quality standards.

To meet these stringent requirements, manufacturers of recombinant cell culture supplements must invest in quality control, documentation, and traceability. Businesses that can consistently provide high-quality, GMP-compliant supplements gain a competitive advantage as they become preferred partners for drug manufacturers seeking regulatory approval. Key Market Challenges

High Cost of Production

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The production of recombinant cell culture supplements involves complex biotechnological processes and stringent quality control measures. The cost of sourcing raw materials, maintaining sterile production facilities, adhering to regulatory requirements, and conducting extensive quality testing all contribute to the high production costs.

The elevated cost of production translates into higher prices for cell culture supplements. This can deter smaller biotech companies, research institutions, and academic labs from using these supplements, limiting market penetration. Additionally, cost-sensitive pharmaceutical manufacturers may explore alternative, more cost-effective technologies or source supplements from low-cost regions, affecting local suppliers.

Regulatory Hurdles and Compliance Challenges

The North American biopharmaceutical industry operates within a stringent regulatory environment, necessitating compliance with Good Manufacturing Practices (GMP) and quality standards. Achieving and maintaining compliance is resource-intensive and requires continuous monitoring and documentation.

Companies in the Recombinant Cell Culture Supplements Market must invest significantly in regulatory compliance. Failure to do so can result in production delays, fines, or even product recalls. Smaller manufacturers may struggle to meet these requirements, limiting their market access, while larger players must allocate substantial resources to navigate the complex regulatory landscape.

Supply Chain Vulnerabilities

The cell culture supplement market relies on a complex global supply chain, with raw materials often sourced from various regions. Factors such as natural disasters, geopolitical tensions, and disruptions like the COVID-19 pandemic can disrupt the supply chain, leading to shortages and delays in production.

Supply chain vulnerabilities can lead to unpredictable fluctuations in the availability of critical raw materials. This can hinder manufacturers' ability to meet customer demand consistently, impacting their reputation and potentially leading to the loss of customers. Businesses must invest in supply chain diversification, redundancy, and risk mitigation strategies to counteract these challenges.

#### Key Market Trends

Growing Emphasis on Animal-Origin-Free and Chemically Defined Supplements

There is an increasing demand for cell culture supplements that are free from animal-derived components and precisely defined chemically. This trend arises from concerns related to the potential transmission of animal-borne diseases, batch-to-batch variability, and the need for greater control and reproducibility in cell culture processes.

Manufacturers are developing and marketing supplements that are entirely free of animal-derived ingredients, offering researchers and biopharmaceutical companies alternatives that reduce the risk of contamination and ensure consistency. Chemically defined supplements provide better control over cell culture conditions, leading to improved cell growth, protein expression, and overall product quality.

Rise of Serum-Free and Xeno-Free Culture Media

Serum-free and xeno-free culture media are gaining traction due to concerns about the use of fetal bovine serum (FBS) in traditional cell culture. Serum-free media eliminate FBS, while xeno-free media also exclude other animal-derived components, addressing ethical, safety, and regulatory issues associated with FBS.

The adoption of serum-free and xeno-free culture media aligns with the industry's commitment to reducing variability and ensuring the safety of biopharmaceutical products. As a result, suppliers of recombinant cell culture supplements are shifting their product offerings to cater to this growing demand, providing researchers and manufacturers with reliable alternatives. Focus on Sustainability and Environmental Responsibility

Sustainability concerns are permeating various industries, including biopharmaceuticals. Businesses are increasingly conscious of their environmental impact and are seeking sustainable alternatives in their processes and products. This trend extends to the North America Recombinant Cell Culture Supplements Market.

Manufacturers are investing in sustainable production processes, including the use of renewable energy sources and environmentally friendly materials. Additionally, there is a push to reduce single-use plastics in bioprocessing. Suppliers that prioritize sustainability in their operations and offer eco-friendly packaging are likely to attract environmentally conscious customers and align with regulatory efforts promoting sustainability.

## Segmental Insights

Product Insights

Based on the category of Product, the Recombinant growth factors segment emerged as the dominant player in the North America market for Recombinant Cell Culture Supplements in 2022. This segment plays a pivotal role in supporting cell growth, proliferation, and protein expression, making it a critical component in various biopharmaceutical and biotechnology applications. Consequently, Recombinant growth factors, such as various types of cytokines and growth-promoting proteins, are indispensable for promoting cell proliferation and ensuring cell viability in vitro. These factors mimic the natural cellular environment, facilitating the growth of mammalian cells, including those used in the production of biopharmaceuticals.

Growth factors play a vital role in enhancing the expression of recombinant proteins in cell cultures. They stimulate cells to produce more proteins, including therapeutic proteins and antibodies, which are crucial for the biopharmaceutical industry. The production of monoclonal antibodies (mAbs) is a significant driver of the biopharmaceutical industry. Recombinant growth factors are extensively used to optimize cell lines used for mAb production, resulting in higher yields and improved product quality. The development of vaccines, especially viral vaccines and subunit vaccines, relies on the efficient growth of host cells in culture. Recombinant growth factors are essential to support the expansion of these cells and the production of viral antigens or subunits. Manufacturers of recombinant growth factors offer a wide range of specialized formulations tailored to specific cell lines and applications. This customization allows biopharmaceutical companies to fine-tune their cell culture processes for maximum productivity and efficiency. Recombinant growth factors are crucial for optimizing the growth of specific cell lines used in biopharmaceutical production. This enables companies to achieve higher cell densities and protein expression levels, leading to increased yields and cost-effectiveness. These factors are expected to drive the growth of this segment. Application Insight

Based on the category of Application, the bio-production segment emerged as the dominant player in the North America market for Recombinant Cell Culture Supplements in 2022. Biopharmaceuticals, including monoclonal antibodies, vaccines, gene therapies, and recombinant proteins, are in high demand due to their efficacy in treating various diseases. This demand is driven by factors such as an aging population, increasing prevalence of chronic diseases, and the need for innovative therapeutic solutions.

The production of biopharmaceuticals relies heavily on cell culture techniques, and therefore, the demand for cell culture supplements, including growth factors, media, and other supplements, is substantial. The bio-production segment caters to this demand by providing the necessary tools and resources to support the growth and expression of cells used in biopharmaceutical manufacturing.

The biomanufacturing industry in North America has experienced significant growth in recent years. This expansion is driven by the increasing number of biopharmaceutical products in development and the need for efficient and scalable production processes. The bio-production segment plays a pivotal role in meeting the requirements of the growing biomanufacturing industry. It provides specialized cell culture supplements and solutions that are essential for optimizing cell growth, protein expression, and bioprocess efficiency, thereby contributing to the overall growth of the industry.

Biopharmaceutical production often involves specific cell lines, expression systems, and process conditions. These variables require customized solutions to maximize yields and product quality. The bio-production segment offers tailored cell culture supplements designed to meet the unique requirements of bioprocessing applications. This customization includes the development of media formulations, growth factors, and supplements optimized for particular cell lines and biopharmaceutical products, ensuring optimal results in the production process. These factors are expected to drive the growth of this segment. Expression System

Based on the category of Expression System, the mammalian expression system segment emerged as the dominant player in the North America market for Recombinant Cell Culture Supplements in 2022. Mammalian expression systems, such as Chinese hamster ovary (CHO) cells and human embryonic kidney (HEK) cells, are preferred for the production of complex proteins, including monoclonal antibodies, enzymes, and glycoproteins. These systems enable the correct folding, post-translational modifications, and assembly of intricate protein structures. The use of mammalian expression systems necessitates specialized cell culture supplements to support the growth and productivity of these cells. The demand for high-quality and precisely formulated supplements is significantly higher when working with mammalian cells, contributing to the dominance of this

#### segment.

Biopharmaceuticals, especially monoclonal antibodies (mAbs), are a major driver of the biopharmaceutical industry. Mammalian expression systems are the preferred choice for producing mAbs due to their ability to produce correctly folded and glycosylated antibodies, which is crucial for therapeutic efficacy. The production of mAbs using mammalian expression systems relies heavily on specialized cell culture supplements, including growth factors and culture media optimized for mammalian cells. As the demand for mAbs continues to grow, so does the need for supplements tailored to mammalian expression systems. Mammalian expression systems are particularly valuable when producing biopharmaceuticals that closely resemble human proteins. Since they are derived from human or closely related mammalian cells, these systems are capable of producing proteins with similar post-translational modifications and biological activity to native human proteins. The need for biopharmaceuticals that closely mimic human proteins is driving the use of mammalian expression systems. This, in turn, fuels the demand for cell culture supplements optimized for mammalian cells to achieve the desired protein quality and functionality. These factors are expected to drive the growth of this segment.

### End-User Insights

Based on the category of End-User, the biotechnology and pharmaceutical companies segment emerged as the dominant player in the North America market for Recombinant Cell Culture Supplements in 2022. Biotechnology and pharmaceutical companies are at the forefront of biopharmaceutical research and development. These organizations invest heavily in discovering and developing novel biologics, such as monoclonal antibodies, vaccines, gene therapies, and recombinant proteins. The development and production of biopharmaceuticals heavily rely on cell culture techniques and the use of cell culture supplements, including growth factors and culture media. As biopharmaceutical development continues to expand, these companies require a consistent and reliable supply of high-quality supplements.

Biotechnology and pharmaceutical companies are responsible for large-scale biomanufacturing of biopharmaceutical products. This includes producing commercial quantities of drugs for clinical trials and eventual market distribution. Large-scale biomanufacturing demands substantial quantities of cell culture supplements to support cell growth, protein expression, and the overall bioprocess. Suppliers catering to biotechnology and pharmaceutical companies must meet the volume and quality requirements essential for such production.

Regulatory agencies, such as the FDA in the United States, impose stringent quality and safety standards on biopharmaceutical products. Compliance with Good Manufacturing Practices (GMP) and other quality assurance requirements is crucial. Biotechnology and pharmaceutical companies prioritize regulatory compliance and quality assurance to ensure the safety and efficacy of their products. They rely on suppliers of cell culture supplements that can provide GMP-compliant and consistently high-quality products, creating a robust demand for these supplements. These factors collectively contribute to the growth of this segment.

#### **Regional Insights**

United States emerged as the dominant player in the North America Recombinant Cell Culture Supplements market in 2022, holding the largest market share in terms of value. The United States is the largest economy in North America and a global leader in the biopharmaceutical industry. Its economic strength, robust healthcare infrastructure, and significant investments in healthcare and life sciences contribute to its dominance in the market. The U.S. is home to a large number of biotechnology and pharmaceutical companies, including major players in the biopharmaceutical sector. These companies drive the demand for cell culture supplements due to their extensive biomanufacturing operations. The U.S. hosts numerous research institutions, universities, and academic centers engaged in biopharmaceutical research and development. These organizations require cell culture supplements for their studies and often collaborate with industry players. The U.S. has a well-established and rigorous regulatory framework for biopharmaceuticals. Compliance with regulatory standards, such as Good Manufacturing Practices (GMP), necessitates the use of high-quality cell culture supplements.

The Canada market is poised to be the fastest-growing market, offering lucrative growth opportunities for Recombinant Cell Culture Supplements players during the forecast period. Factors such as Canada's biopharmaceutical sector is experiencing growth, with a rising number of biotech startups, research collaborations, and investments in biomanufacturing facilities. The Canadian government offers incentives, grants, and support for biopharmaceutical research and development. These initiatives encourage innovation and contribute to market growth. Canada has a well-educated and skilled workforce in the life sciences

sector, attracting international companies and fostering local biopharmaceutical growth. Canada's strategic location provides easy access to both North American and international markets, making it an attractive destination for biopharmaceutical manufacturing. Canada often collaborates with U.S. biotech firms and research institutions, further boosting its biopharmaceutical activities.

**Key Market Players** Merck KGaA Thermo Fisher Scientific Inc. Corning Incorporated FUJIFILM Irvine Scientific, Inc. Lonza Group AG Novus Biologicals, LLC **BBI Solutions OEM Limited** Gemini Bioproducts, LLC Report Scope: In this report, the North America Recombinant Cell Culture Supplements Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below: □ Recombinant Cell Culture Supplements Market, By Product: o
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Mammalian Expression System o
E.Coli Expression System o[]Yeast Expression System o∏Others ☐Recombinant Cell Culture Supplements Market, By End-User: onAcademic & Research Institutions o
Biotechnology & Pharmaceutical Companies o[]Others □ Recombinant Cell Culture Supplements Market, : o<sub>
Hospital Pharmacies</sub> o Retail Pharmacies o[]E-stores o[]Hypermarkets/supermarkets ☐Recombinant Cell Culture Supplements Market, By Country: o∏United States o∏Canada o∏Mexico **Competitive Landscape** Company Profiles: Detailed analysis of the major companies present in the North America Recombinant Cell Culture Supplements Market. Available Customizations:

North America Recombinant Cell Culture Supplements 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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