

Sterile Injectable Contract Manufacturing Market Size, Growth, Industry Trends | Emergen Research

The Sterile Injectable Contract Manufacturing Market is expected to grow from an estimated USD 16.54 bn in 2024 to USD 34.77 bn in 2033, at a CAGR of 8.50%.

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/EINPresswire.com/ -- The global [sterile injectable contract manufacturing market](#) is projected to grow from USD 16.54 billion in 2024 to USD 34.77 billion by 2033, achieving a robust CAGR of 8.50%. This growth is fueled by the rising demand for biologic drugs and biosimilars, which are critical for treating chronic illnesses such as cancer, diabetes, and autoimmune diseases.



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Key Growth Drivers

Biologic drugs, including monoclonal antibodies, vaccines, and therapeutic proteins, require complex manufacturing processes to ensure sterility and integrity. These drugs have become essential in managing chronic conditions, driving the need for specialized manufacturing. Government approvals are increasing, with the U.S. Food and Drug Administration (FDA) approving 47 new biologics in 2022 alone. Similarly, the European Medicines Agency (EMA) has reported a rise in biologic drug applications, indicating a growing market demand for contract manufacturers equipped to meet these requirements.

The growing market for biosimilars is another significant factor boosting the industry. As patents for branded biologics expire, biosimilars offer cost-effective alternatives without compromising therapeutic efficacy. This trend is particularly prominent in the U.S. and Europe, where health agencies promote biosimilar adoption to reduce healthcare costs.

Technological Advancements Powering the Market

The adoption of advanced technologies in sterile manufacturing is revolutionizing the industry. Automation, high-speed filling systems, and the use of artificial intelligence (AI) for quality control are enhancing production efficiency and safety. Regulations such as the FDA's Current Good Manufacturing Practices (CGMP) encourage manufacturers to implement cutting-edge technologies to meet stringent quality standards.

Additionally, single-use technologies are gaining traction, simplifying production processes and reducing contamination risks. Reports suggest a 40% rise in the use of single-use systems since 2020, significantly lowering production costs and timelines. As demand for personalized medicine grows, contract manufacturers are investing in small-batch production capabilities to cater to complex formulations.

Challenges to Market Growth

Despite its growth potential, the market faces challenges, including high capital and operational costs associated with sterile manufacturing facilities. Building and maintaining sterile environments requires specialized equipment, rigorous quality checks, and compliance with strict regulatory standards, driving up costs.

Smaller manufacturers, particularly in developing regions, struggle to compete due to these barriers. The need for continuous facility upgrades to meet evolving regulations further compounds cost pressures, slowing market growth in emerging economies.

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Therapeutic Applications Driving Demand

The sterile injectable contract manufacturing market is segmented by therapeutic applications, with cancer treatments leading the way. The increasing prevalence of cancer globally, along with the rise of injectable therapies like chemotherapy, immunotherapy, and targeted treatments, is driving demand. The World Health Organization (WHO) reports that cancer accounted for 9.6 million deaths globally in 2018.

The cardiovascular segment is also experiencing rapid growth due to the rising incidence of

heart disease, which remains the leading cause of death worldwide. Advances in injectable therapies, including monoclonal antibodies and anticoagulants for heart conditions, are expected to fuel this segment further.

Some of the key companies in the global Sterile Injectable Contract Manufacturing market include:

Baxter

Catalent, Inc.

Vetter Pharma

Recipharm AB

Aenova Group

Fresenius Kabi AG

Unither Pharmaceuticals

FAMAR Health Care Services

Cipla Inc.

NextPharma Technologies

Sterile Injectable Contract Manufacturing Latest Industry Updates

In December 2023, Cipla also filed a patent for a stable, ready-to-use, extended-release injectable formulation of aripiprazole aimed at treating schizophrenia and related disorders. This novel formulation is designed to maintain its stability over six months in sealed, sterile conditions, with a low level of impurities, ensuring its effectiveness for long-term treatment. In October 2022, Recipharm AB announced plans to install a high-speed filling line at its Wasserburg facility in Germany. This new line will significantly enhance the company's capacity to fill and finish sterile liquid and lyophilised products, supporting the development and manufacture of advanced therapies and vaccines. The initiative reflects Recipharm's commitment to meeting the increasing global demand for high-quality pharmaceutical products.

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Sterile Injectable Contract Manufacturing Market Segmentation Analysis

Molecule Type Outlook (Revenue, USD Billion; 2020-2033)

Small Molecule

Large Molecule

Therapeutic Application Outlook (Revenue, USD Billion; 2020-2033)

Cancer

Diabetes

Cardiovascular Diseases

Central Nervous System Diseases

Infectious Disorders

Musculoskeletal

Anti-viral

Others

Route of Administration Outlook (Revenue, USD Billion; 2020-2033)

Subcutaneous (SC)

Intravenous (IV)

Intramuscular (IM)

Others

End-use Outlook (Revenue, USD Billion; 2020-2033)

Pharmaceutical Companies

Biopharmaceutical Companies

Others

Regional Outlook (Revenue, USD Billion; 2020-2033)

North America

United States

Canada

Mexico

Europe

Germany

France

United Kingdom

Italy

Spain

Benelux

Rest of Europe

Asia-Pacific

China

India

Japan

South Korea

Rest of Asia-Pacific

Latin America

Brazil

Rest of Latin America
Middle East and Africa
Saudi Arabia
UAE
South Africa
Turkey
Rest of MEA

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