

Sterile Injectable Contract Manufacturing - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2024 - 2029)

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Abstracts

The Sterile Injectable Contract Manufacturing Market size is estimated at USD 14.44 billion in 2024, and is expected to reach USD 28.5 billion by 2029, growing at a CAGR of 12% during the forecast period (2024-2029).

The increasing pipeline and approvals of injectable drugs are significant drivers of the sterile injectable contract manufacturing market. Pharmaceutical companies are developing injectable drugs due to their advantages, including faster onset of action, precise dosing, and improved patient compliance. For instance, according to the FDA report published in January 2023, CDER approved 37 novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biological products under Biologics License Applications (BLAs) in 2022. These drugs include injectables, and hence, a strong pipeline is expected to increase the demand for contract manufacturing for commercial and research purposes, thereby contributing to market growth.

The burgeoning demand for cellular and genetic treatments propels the expansion of the market. As the pipeline of these therapies expands, there is a growing need for specialized manufacturing capabilities, which contract manufacturing organizations (CMOs). For instance, according to ClinicalTrials.gov, as of March 2024, more than 581 clinical trials were investigating the potential of cell therapies and related approaches for treating various diseases in North America. Therefore, the high amount of research in clinical development for cell-based therapy is expected to boost contract manufacturing over the forecast period.

Moreover, strategic activities by the market players, such as the expansion of sterile

manufacturing facilities, collaboration, and partnership, are expected to contribute to the market growth over the forecast period. For instance, in November 2023, private equity firm NorthEdge invested in a Torbay Pharmaceuticals sterile injectable contract manufacturer and license holder to support its next phase of international growth after acquiring it from Torbay and Devon NHS Foundation Trust. In March 2023, PCI Pharma Services unveiled plans for a USD 50 million expansion at its Rockford, Illinois, sterile injectables site. The project will add a 200,000-square-foot facility to boost the plant's capacity for injectable drug-device combination products.

Hence, the growing demand for cell and gene therapy in the product pipeline and the expansion of sterile manufacturing facilities are expected to boost market growth over the forecast period. However, challenges related to quality control and high operational costs are anticipated to restrain the market's growth.

Sterile Injectable Contract Manufacturing Market Trends

The Cancer Segment is Expected to Hold a Significant Share Over the Forecast Period

Cancer therapies necessitate meticulous manufacturing techniques that guarantee drug stability and effectiveness. Sterile injectable contract manufacturers with expertise in handling complex formulations and biologics are well-positioned to meet the unique challenges of oncology drugs. Many cancer treatments involve complex biologics and novel therapeutic approaches. Sterile injectables provide a reliable and effective means of delivering these advanced therapies, contributing to the expansion of the sterile injectable contract manufacturing market.

The Canadian Cancer Society's (CCS) 2023 report highlighted that cancer poses a significant healthcare burden in Canada, with its incidence steadily rising. Thus, the high burden of cancer is creating opportunities for new sterile injectables CMO in the country, driving the segment's growth. The same source stated that 239,100 cancer cases were reported in Canada in 2023. Thus, the growing burden of cancer is expected to create demand for contract manufacturing services, likely contributing to segmental growth.

The robust growth in outsourcing practices is projected to fuel segment expansion throughout the forecast period. Pharmaceutical companies, including those focused on oncology, are increasingly outsourcing manufacturing activities to streamline operations, reduce costs, and leverage the specialized capabilities of contract manufacturers. This trend has contributed to the growth of the sterile injectable contract manufacturing

market within the cancer segment.

Hence, growing cancer prevalence and the increasing trend of outsourcing are expected to boost the segment's growth over the forecast period.

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

In North America, the sterile injectable contract manufacturing market is expected to grow due to the establishment of contract manufacturing facilities, the rise in chronic diseases, and the development of advanced biologics. Sterile injectables are crucial for delivering complex therapies, and contract manufacturing provides a scalable solution for meeting this demand.

The increasing emphasis on biologics and biosimilars, which often require sterile injectable formulations, contributes significantly to the growth of the contract manufacturing market. For instance, according to a report by the Food and Drug Administration published in March 2023, 15 biologics were approved in 2022; of this, six were indicated for the treatment of a diversity of cancers. An anticipated surge in biologics drug approvals is projected to boost market growth during the forecast period.

Strategic activities by the market players, such as manufacturing facility expansion, collaboration, partnerships, and acquisitions, are expected to boost the market's growth over the forecast period. For instance, in October 2023, Sharp acquired Berkshire Sterile Manufacturing (BSM), a contract development and manufacturing organization (CDMO) in Massachusetts that offers clinical and commercial sterile injectable products. Additionally, in March 2022, Sandoz Canada announced the completion of the sale of its Boucherville, Quebec, manufacturing plant to Delpharm, a CMO. This plant is Canada's largest sterile injectable production facility and provides strategic and potentially lifesaving medicines to the Canadian and US healthcare systems, primarily hospitals.

Thus, collaborations with or outsourcing manufacturing to CMOs in the region contribute to the overall growth of the market.

Sterile Injectable Contract Manufacturing Industry Overview

The sterile injectable contract manufacturing market is consolidated and consists of a few major players. In terms of market share, certain major players currently dominate the market. Market players adopt various strategies such as expanding manufacturing facilities, collaborating, and partnering to stay competitive. Some of the companies currently dominating the market are Baxter, Catalent Inc., Vetter Pharma, Recipharm AB, and Aenova Group.

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