

High Potency API Contract Manufacturing - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2024 - 2029)

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Abstracts

The High Potency API Contract Manufacturing Market size is estimated at USD 7.99 billion in 2024, and is expected to reach USD 13.14 billion by 2029, growing at a CAGR of 9% during the forecast period (2024-2029).

The market is growing due to increased drug pipelines, expansion of HPAPI facilities, and outsourcing API. The rise in targeted therapies, especially in oncology and other specialized areas, has increased demand for HPAPIs. These APIs are crucial in manufacturing highly potent drugs that specifically target particular molecular pathways or cellular mechanisms; enhancing treatment efficacy while minimizing side effects will likely contribute to market growth during the forecast period.

For instance, according to the data updated by the Spanish Network of Cancer Registries (REDECAN) in January 2023, an estimated 279,260 new cases of cancer were expected to occur in Spain by the end of 2023, out of which 42,721 new cases of colorectal cancer, 31,282 cases of lung cancer, and 21,694 cases of urinary bladder cancer were expected to occur in Spain in 2023. The surge in chronic diseases like cancer and HPAPIs plays a vital role in these therapeutic areas, driving demand for contract manufacturing services during the forecast period.

Moreover, the growing expansion of high-potency API facilities is expected to positively impact the high-potency API contract manufacturing market. This expansion indicates an increasing demand for specialized facilities that produce high-potency APIs. For instance, in June 2022, MilliporeSigma, the United States and Canada Life Science business of Merck KGaA, doubled its HPAPI production capacity by expanding its facility in Verona, near Madison.

Similarly, in September 2022, Lonza celebrated the expansion of its HPAPI multipurpose manufacturing suite in Visp, boasting enhanced capabilities for antibody-drug conjugate (ADC) payload production. Expanded facilities allow contract manufacturers to offer a more comprehensive range of high-potency APIs, catering to a broader spectrum of pharmaceutical products and therapies. Thus, they are expected to boost the high-potency API contract manufacturing market during the forecast period.

Hence, the CMO companies' favorable regulatory scenario and expansion of HPAPI facilities are expected to boost the market during the forecast period. However, significant investments and complicated safety and handling specifications associated with the production of HPAPIs are expected to restrain the market during the forecast period.

High Potency API Contract Manufacturing Market Trends

The Oncology Segment is Expected to Hold a Significant Share During the Forecast Period

HPAPIs are an increasingly important part of the drug development pipeline driven by the rise in treatments that focus on specific targets, particularly in oncology. HPAPIs are important in small-molecule cancer treatments targeting specific cell parts such as kinase inhibitors. The increasing demand for HPAPIs creates excellent opportunities for companies that manufacture and provide clinical support for these drugs. According to the article published by Contract Pharma in September 2023, 25% of all drugs manufactured worldwide are considered highly potent, and 60% of oncology drugs contain HPAPIs. Hence, the increasing demand for HPAPI in oncology is expected to boost the demand for contract manufacturing services in the pharmaceutical industry.

The surge in the prevalence of cancer is fuelling the demand for advanced and effective therapeutics, leading to new investments by companies and other stakeholders, like governments, for the identification, testing, and development of novel cancer therapeutics. For instance, in July 2023, according to the data updated by the Santé Publique France, it was estimated that over 433 thousand new cancer diagnoses were expected in 2023, comprising 57% in males and 43% in females. The source also stated that new cancer cases in women are increasing faster, with the median age of diagnosis being 68 years old (compared to 70 years old for men). Thus, the growing burden of cancer is expected to create a demand for contract manufacturing services, likely contributing to segment growth.

The increasing demand for HPAPI due to their potential against cancer, so the market players engaging in strategic activities, is likely to boost the segment growth. For instance, in May 2023, Cerbios-Pharma SA (Cerbios) announced the regulatory approval of its new manufacturing facility by SwissMedic. The facility is dedicated to GMP-compliant production of highly potent molecules (HPAPIs) for clinical and commercial use. HPAPIs manufactured at the facility will comprise cytotoxic linker payloads for ADC antibody-drug conjugates employed in cancer therapies. In June 2022, Merck invested EUR 59 million in a high-potency API manufacturing facility to address demand for critical cancer therapies.

Hence, the increasing application of HPAPI demand in cancer drugs and strategic activities made by the market players are anticipated to drive market growth during the forecast period.

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

North America has emerged as a critical destination for contract developers with expertise in high-potency drug engineering. This has resulted in many projects being outsourced to the region. Additionally, the region's strict regulations regarding product manufacturing and quality are expected to create favorable growth opportunities for contract manufacturing services, particularly in the United States.

The high-potency API contract manufacturing market is expected to flourish due to the growing expansion of specialized facilities equipped to handle the production of high-potency APIs. This indicates an increasing demand for such facilities, which, in turn, will have a positive impact on the market. For instance, in July 2022, Piramal Pharma Solutions established an advanced API manufacturing facility in Aurora, Ontario, Canada, featuring High Potency API (HPAPI) capabilities. The facility, constructed with an investment of CAD 30 million (USD 23 million), provides an additional 10,000 square feet of manufacturing space. It houses two new reactor suites, expanded filtration and drying capabilities, and enhances the company's clinical-scale to commercial-scale API production capacity. Notably, the plant can handle HPAPIs with an occupational exposure limit (OEL) of 1 mcg/m³, ensuring safe and compliant production of potent active pharmaceutical ingredients.

A collaborative agreement between the market players to expand the high potency API manufacturing services is expected to contribute to market growth. For instance, in May 2023, Evonik and Heraeus expanded the range of services for highly potent active pharmaceutical ingredients. Evonik specializes in mid-to large-scale, later clinical phase HPAPIs. Leveraging the distinct HPAPI expertise of both companies, the collaborative endeavor offers customers a comprehensive solution from pre-clinical research to commercial production.

Thus, increasing HPAPI facility expansion and strategic collaboration will boost the North American high-potency API contract manufacturing market during the forecast period.

High Potency API Contract Manufacturing Industry Overview

The high-potency API contract manufacturing market is fragmented and has several major players. Market players adopt strategies such as expanding manufacturing facilities, collaborating, and partnering to stay competitive. In terms of market share, a few significant players are Piramal Pharma Solutions, Lonza, Catalent Inc., VxP Pharma Inc., and Pfizer CentreOne.

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