

Global Formulation Development Outsourcing - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2025 - 2030)

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Report description:

The Global Formulation Development Outsourcing Market size is estimated at USD 28.20 billion in 2025, and is expected to reach USD 38.02 billion by 2030, at a CAGR of 6.16% during the forecast period (2025-2030).

Amid the COVID-19 pandemic, countries' health systems are rapidly investing in research and development to combat the virus, having a significant impact on the formulation development outsourcing market. For instance, in October 2020, AiPharma joined a global consortium of pharmaceutical, manufacturing, and distribution leaders to advance oral antiviral Avigan/Reeqomus for COVID-19. As a part of the consortium, AiPharma commercializes all formulations of favipiravir, a broad spectrum oral antiviral drug that targets COVID-19 and 11 other infectious diseases. Thus, the onset of the pandemic has significantly benefitted the formulation development outsourcing market. Moreover, as per an article titled 'Pharmaceutical Technology, 2021 Outsourcing Resources Supplement', published in August 2021, the pharmaceutical outsourcing market has seen a growth in vaccine development and manufacturing activity in the past year, particularly due to the industry's response to the COVID-19 pandemic. As a result of which, there has been an increase in the formulation development outsourcing activities, thereby contributing to the market growth.

Furthermore, the major factors fueling the market growth are the increasing trend of patent protection expiration of major drugs and the rising number of pharmaceutical and biopharmaceutical companies outsourcing their services. The increasing trend of patent protection expiration of major drugs is driving the market growth. For instance, as per a 2021 update by the Generics and Biosimilar Initiative, as part of ongoing action to improve the quality of generics and ensure an efficient and competitive generics market, the Korean Ministry of Food and Drug Safety (MFDS) announced that 158 patents for pharmaceutical products were anticipated to expire in 2021. As per the same source, the MFDS's Green List (a list similar to the US Food and Drug Administration's (FDA) Orange Book) shows that 44 of the patents will be ready for immediate generics entry, having no other

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patents on the products involved. Thus, this increases the need for formulation development outsourcing for newer candidates, thereby contributing to the market growth.

However, structural changes in the pharmaceutical industry and insufficient funding to perform the drug development process through formulation development are the major factors hindering the market growth.

Formulation Development Outsourcing Market Trends

The Oncology Segment is Expected to Witness Significant Growth over the Forecast Period

By application, the oncology segment is anticipated to hold a major share of the market. This can be attributed to the rising incidence rates of cancer cases globally. According to the World Health Organization (WHO), cancer accounted for approximately 10 million deaths in 2020. Additionally, as per the 2021 statistics by the American Cancer Society, by 2040, the global burden of cancer is expected to grow to 27.5 million new cases and 16.3 million cancer deaths.

Formulation development plays a vital role in anti-cancer drugs, as formulation issues, including stability, solubility, and bioavailability, are important considerations for the drug development process. Hence, most pharma service companies are focused on oncology formulation development to provide end-to-end solutions for oncology drug development. For instance, in November 2021, Oncology Pharma Inc. revealed plans for the development of a lead drug candidate in a co-development project with NanoSmart Pharmaceuticals Inc. Likewise, in October 2021, Metrics Contract Services, the US-based contract pharmaceutical development and manufacturing division of Mayne Pharma entered a development and manufacturing agreement with ESSA Pharmaceuticals. Metrics will provide formulation development, analytical services, and manufacturing to support the ongoing clinical development of an orally administered oncology drug as a part of the agreement.

Thus, the high incidence rates of cancer cases and the increasing focus on cancer therapeutics by biopharmaceutical companies are expected to aid in the growth of the segment over the forecast period.

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

Within North America, the United States is expected to hold a major share of the market. This can be attributed to the growing burden of chronic diseases and the presence of key players in the region, especially in the United States. As most of the major drugs are in the stage of patent expiration, key players are involved in novel drug development. In this context, to save time and investment on a series of clinical trials and evaluation studies in formulation development, pharmaceutical companies are outsourcing formulation development services to CROs, which may drive market growth in the region.

Additionally, amid the COVID-19 pandemic, several collaborative research programs are looking to fast-track their process in terms of advancing therapeutics and vaccines by collaborating with institutions, such as the Biomedical Advanced Research and Development Authority (BARDA) and Coalition for Epidemic Preparedness Innovations (CEPI). For instance, in May 2020, the United States Department of Commerce's National Institute of Standards and Technology (NIST) funded around USD 8.9 million to the highly impacted biopharmaceutical manufacturing projects in response to the emerged outbreak. Therefore, such initiatives are contributing to the increasing outsourcing for formulation development, thereby contributing to the market growth.

Moreover, several market players are engaged in the implementation of strategic initiatives, thereby contributing to market growth. For instance, in January 2022, Recro Pharma Inc., a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development, reported being awarded a new formulation development and cGMP manufacturing contract from a key department of the United States government.

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Thus, due to the above-mentioned factors, the market is expected to witness significant growth over the forecast period.

Formulation Development Outsourcing Industry Overview

The formulation development outsourcing market is moderately competitive. In terms of market share, a few companies, such as Charles River Laboratories, Aizant Drug Research Solutions Private Limited, Catalent Inc., Laboratory Corporation of America Holdings, and Syngene International Ltd, among others, hold the largest market shares. Key market players are evolving through various strategic alliances, such as acquisitions, collaborations, and new product launches, to expand their global product portfolios and secure their positions in the global market.

Additional Benefits:

- The market estimate (ME) sheet in Excel format
- 3 months of analyst support

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