

Biosimilar Pipeline and Global Market Prospects Key Factors, Comparative Analysis and 2022 Forecast

Global Biosimilar Pipeline Market Prospects report provides a detailed analysis of the regulatory pathways in key geographies and also in-depth analysis of the biosimilar pipeline as well as forecasts for biosimilars in the market and those in late stages of development with high market potential.

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Browse report spread across 117 pages available at @ <http://www.reportsnreports.com/reports/956891-global-biosimilar-pipeline-and-market-prospects-addressing-production-complexities-through-risk-management-and-quality-by-design.html> .

In depth, it provides the following -

- o Assess the drivers and restraints of growth in the global biosimilars market. It includes detailed information on how the issue of interchangeability continues to slow down growth in the global biosimilars market.

- o Provides a detailed analysis of the regulatory pathways in key geographies including the US, Europe, Japan and China and concludes with case studies of successful biosimilar approvals, and their path through regulatory frameworks, in key markets.

- o Covers the various steps in the manufacturing of biologics and biosimilars. A comparison of timeline and development costs for both types of products is provided. It also covers the Good Manufacturing Practices (GMP) for large molecules.

- o Covers the strategies that some of the major pharmaceutical companies have adopted in order to compete in the biosimilars market. Furthermore, it also discusses common entry strategies for emerging markets and a summary of biosimilar manufacturing considerations in order to increase the chances of a successful development program.

- o Provide an in-depth analysis of the biosimilar pipeline as well as forecasts for biosimilars in the market and those in late stages of development with high market potential.

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Government support for biosimilars is increasing in key geographical markets, given the cost saving opportunities that these products represent for national healthcare budgets. A biosimilar is a bio-therapeutic that is clinically highly similar to an approved innovative product (reference product) in terms of active ingredients, and has no meaningful differences in efficacy and safety.

The complexities of manufacturing a biological drug also apply to biosimilars. The complex requirements are manifold and have been a significant barrier to the further expansion of the biosimilars market. One of the key challenges biosimilar manufacturers face is the knowledge gap under which these products are developed. This challenge arises from the fact that the innovator

product information remains proprietary and must adopt a reverse engineering process. They also need to adopt the latest technology and quality initiatives, such as QbD, DoE and PAT techniques. Organizations also need to adopt a proactive approach in risk mitigation through risk-management-plans (RMP) and long-term studies and through being cognizant of adverse events and adopting production best practices outlined by industry associations and regulatory agencies.

A number of biologics will go off patent before 2020, which presents a huge opportunity for biosimilar manufacturers. Pricing discounts for these products usually fall by 30-50% compared with the innovator product. The cost advantages will lead to greater access to these drugs, and significantly reduce the cost of healthcare in many countries.

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Scope

Global biosimilar pipeline in 2017

oWhat is the distribution of pipeline biosimilars by stage of development?

oWhich are the therapy areas set to benefit the most from biosimilar drugs in development?

oIn biosimilar development, what are the most common molecular targets for key therapy areas?

oHow many companies are currently involved in biosimilar drug development, which are the most active and what is the level of specialization across the development landscape?

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