Global Biosimilar Pipeline and Market Prospects: Addressing Production Complexities Through Risk Management and Quality by Design

**Description:**

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 biotherapeutic 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.

The report "Global Biosimilar Pipeline and Market Prospects: Overcoming Production Complexities Through Risk Management and Quality by Design" provides an in-depth assessment of the current trends in the global biosimilars market, with a particular focus on manufacturing complexities and the strategies being implemented to overcome them. Furthermore, it also positions current biosimilar regulatory frameworks and guidelines implemented in the US, Europe, Japan and China, recent updates regarding the key issue of interchangeability, and case studies of successful biosimilar approvals in recent years.

In depth, it provides the following:

- 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.
- 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.
- 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.
- 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.
- 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.

**Scope**

- Global biosimilar pipeline in 2017
- What is the distribution of pipeline biosimilars by stage of development?
- Which are the therapy areas set to benefit the most from biosimilar drugs in development?
- In biosimilar development, what are the most common molecular targets for key therapy areas?
- How 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?
- Global biosimilar clinical trials in 2017
- What was the volume of biosimilar clinical trials from 2006 to 2016, by therapy area and stage of development?
- What is the average biosimilar clinical trial size and duration across different stages of development, and across the immunology and oncology therapy areas?
- How much revenue will promising biosimilar drugs in the market, and in development, record to 2022?
- What are the key factors driving growth in the global biosimilars market?
- How important are the cost saving opportunities for national healthcare budgets?
- How much will biosimilar manufacturers benefit from the biologic drugs patent cliff?
- How does legislation regarding biosimilar interchangeability differ among key geographical markets?
- What are the factors restraining the growth of global biosimilar market?
- How do manufacturing challenges affect the market?
- What are the legal issues impacting the biosimilar market?
- How are competition and patient recruitment issues slowing growth in the market?
- What are the regulatory pathways for biosimilars in the US, Europe, Japan and China?
- Manufacturing processes for biosimilar drugs
- How does molecular weight and complexity pose a challenge to biosimilar production?
- What is the impact of environmental factors on production complexity?
- How significant is the knowledge gap in the process of manufacturing a biosimilar drug?
- What are the best practice guidelines and strategies to overcome production complexities?
- How do development timelines and costs differ between biologics and biosimilars?
- What is the impact of immunogenicity in the production process?

Key Reasons to Purchase

This report will allow you to:

- Gain insightful analyses and comprehensive understanding of the global biosimilar R&D and commercial landscape
- Assess biosimilar production processes, key issues and ways to mitigate development risk
- Understand the most important driving and restraining forces in the global biosimilars market
- Learn about biosimilar strategies being adopted by leading pharmaceutical companies.
- Understand the future outlook and prospects for biosimilar drugs

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