Joint Event on

18th European Biosimilars Congress

35th Annual European Pharma Congress

April 14-15, 2025

Webinar

J Bioanal Biomed 2025, Volume 17

Evolution of biosimilar regulation in Saudi Arabia

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The increasing demand for cost-effective biologic therapies has positioned biosimilars as a critical component of healthcare systems worldwide. In Saudi Arabia, the landscape of biosimilars has evolved significantly, guided by robust regulatory frameworks and advancements in scientific evaluation. This talk will explore the journey of biosimilar regulation in Saudi Arabia, with a focus on the evolution of regulatory requirements for biosimilar approval. The talk will discuss the scientific principles underpinning biosimilar development, including comparability studies, clinical evaluation, and the importance of pharmacovigilance in the post-marketing phase. Emphasis will be placed on the key milestones in the regulatory journey, from the early adoption of international guidelines to the development of tailored national policies that support local needs and innovation. By highlighting the progress made and challenges faced in the biosimilar regulatory landscape, this talk aims to provide a comprehensive understanding of the regulatory strategies that have enabled the integration of biosimilars into Saudi Arabia's healthcare system. The provide insights into how these efforts align with global trends and contribute to the national vision for enhancing patient access to high-quality, affordable medicines.