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Overcoming the challenges of biosimilar development as a mid-size player

The market for biosimilars is evolving, rapidly. Based on the growing confidence in biosimilars, many players are entering this market, including mid-size companies. Such players with a more local focus have many opportunities in the future biosimilar market because of their strong local presence, flexibility and nimbleness. However, there are challenges regarding development costs, timelines and risk. To address these challenges, mid-size players require a clear strategy for product design, development and market launch right at the project start. In the first place, the product design has to reflect the requirements from all stakeholders. Pharmacists can provide valuable input to product design as they have a holistic view in terms of quality, usability, economics of treatment, supply chain and other aspects. Secondly, for product development, there are essential prerequisites such as robust funding, an expert team and a strong partner network. However, the development costs for biosimilars are significant and the development time up to approval exceeds five years in most cases. Hence, efficient development programs are needed without compromising quality. The biosimilar concept provides tools to make the development efficient. Accordingly, biosimilarity is established at the analytical and functional levels and confirmed by clinical studies. Thus, a thorough analytical and functional data set using state-of-the-art methods is required as well as highly specific and sensitive clinical study designs to detect clinically relevant differences. The biosimilar concept approach allows for high-quality data, and helps making development efficient, thereby supporting mid-size players to overcome the challenges of biosimilar development.

Biography

Ruediger Jankowsky was appointed as the Managing Director of Cinfa Biotech in 2014. He is responsible for the set-up and leadership of Cinfa Biotech's international organization. He has over 15 years of experience in the pharmaceutical industry, where he held various international executive positions in global and mid-size pharmaceutical companies. During this time, he developed an expertise in medicinal product development and business development. Before joining Cinfa Biotech, he was responsible for the global management of biosimilar development projects at a leading biopharmaceutical manufacturer. He holds a PhD in Protein Biochemistry.

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