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Strategy for the global development of biosimilars: Putting it all together

Growing numbers of companies are pursuing a global development of biosimilars for multiple markets. This global approach presents multiple challenges from selecting a reference product for biosimilar development to designing and conducting a clinical trials including a marketing strategy development and pharmacovigilance program. How to ensure that the global development results in successful marketing authorization in each jurisdiction? How to incorporate specific country requirements for biosimilar development at the early stages of biosimilar program? The strategic approach to the alignment of product development, regulatory activities and clinical program provides an answer to these questions. This presentation will discuss strategy of the biosimilar product development through earlier development to regulatory approval and provide some practical examples.

Biography

Oxana Iliach is a PhD in Pharmaceutical Science from St. Petersburg Chemical and Pharmaceutical Academy, Russia and the Senior Director Global Regulatory Strategy and CMC at the Biosimilar Center of Excellence, QuintilesIMS, Canada. She has more than 15 years' experience in healthcare industry, including the last 10 years in regulatory affairs. Her expertise lies in the development of global regulatory strategy for biosimilars with the focus on overall quality and CMC compliance. She has a particular focus and expertise in regulatory and CMC requirements for biosimilars and regularly presents and writes on the topic. Presently, she is a Professor at Seneca College of Applied Arts and Technology, Toronto, Canada and a Member of CAPRA (Canadian Association of Professionals in Regulatory Affairs) and RAPS.

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