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FDA/EMA current thinking on total evidence for development of biosimilars

The regulatory landscape for the development of biosimilars in the US and EU is dynamic as many of the guidance issued by European Medicines Agency (EMA) have recently undergone revisions and the FDA has issued number of revised guidelines for quality and scientific considerations as well as updated questions and answers documents that lend much needed clarity. FDA has also issued final guidelines for nonproprietary naming of biological products as well as draft interchangeability guidance. This session is designed to provide current status of biosimilar guidelines in the US and EU. The focus will be to identify major updates in order to help sponsors navigate through the complex requirements for the regulatory approval of biosimilars in the US and EU.

Biography

Kamali Chance is the Vice President and Head of Global Biosimilars Regulatory Strategy, Biosimilars Center of Excellence. She has over 25 years of work experience in the healthcare industry, including the last 18 years in regulatory affairs/regulatory strategy. She has extensive experience working with the FDA and EMA. She advises pharmaceutical and biotechnology companies in the development of region specific and/or global regulatory strategy for the development of biosimilar products. She has authored/co-authored number of articles on the development of biosimilars and has PhD in Nutrition/Nutritional Biochemistry and Masters of Public Health and Regulatory Affairs Certification.

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