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Evolving biosimilars regulatory landscape: US and EU

The regulatory landscape for the development of biosimilars in the US and EU is dynamic as many of the guidelines issued by European Medicines Agency (EMA) have undergone revisions and in 2015, the FDA issued number of revised guidelines for Quality and Scientific Considerations as well as updated Questions and Answers documents that lend much clarity as to FDA expectations. The thinking of the regulators both in the EU and US has evolved over the years and there is a great deal of convergence. 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 a Vice President and Head, Global Biosimilars Regulatory Strategy. She has over 25 years of work experience in the healthcare industry, including the last 17 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. She has a PhD in Nutrition/Nutritional Biochemistry, Master of Public Health and Regulatory Affairs Certification.

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