Kamali Chance, J Bioanal Biomed 2014, 6:2
http://dx.doi.org/10.4172/1948-593X.S1.013

OMICS Group Conferences
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3rd International Conference and Exhibition on
Biowaivers, Biologics & Biosimilars

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

Comparison of US/EU biosimilar guidelines

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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) are undergoing revisions and the FDA has issued another guidance on clinical pharmacology this year. 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 the similarities and differences between FDA and EMA guidelines 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 Senior Director and Head, Global Biosimilars Regulatory Strategy. She has over 25 years of work experience in the healthcare industry, including the last 16 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, Masters of Public Health and Regulatory Affairs Certification.

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