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New analytical methodology in assessing comparability of biosimilars

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The regulation of biosimilars is founded on the scientific principal of comparability. This talk will present a new analytical methodology in assessing product comparability between innovator and biosimilar rituximab products from United States, Europe and Indian markets. A novel methodology with SpeB based middle-down proteolysis coupled with imaged capillary isoelectric focusing (iCIEF) and capillary gel electrophoresis (CGE) will be presented to characterize difference in post translational modifications, process related modifications and impurity profiling among the three marketed products. Forced stress conditions were applied to these three products, and difference in their degradation profiles and degradation rates will be presented.

Biography

Julia Ding has completed her PhD from Emory University and Post-doctoral studies from University of California at Berkeley. She is currently the Manager at PPD Labs®, a premier contract research organization.

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