

# 3<sup>rd</sup> International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

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## Bioanalytical strategy for biosimilars: Recommended steps for establishment of comparability

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Bioanalytical comparability is an important step in establishing biosimilarity between a biosimilar and its reference therapeutic. Results from bioanalytical analyses determine the final efficacy of a biosimilar drug compared to its reference therapeutic; in a head to head trial. Ligand binding assays are one of the most popular and routinely used analytical techniques for the bioanalysis of biosimilars. For dependable results, drug specific ligand binding assay development and fit for purpose validation should follow unique strategies for comparison of any two specific drugs. Owing to the complexity in the structure of biosimilars, adequate study of the two drugs in the development and validation phases should be done before designing sample analysis studies. Appropriate statistical tools should be employed in interpreting assay results to ensure that differences, if any, are called out on time. In this discussion, recommendation on appropriate and systematic strategies for comparability of Biosimilars using ligand binding assays will be made based on the author's experience and current regulatory expectations.

### Biography

Aparna Kasinath is currently the Head and Test Facility Management of the Regulated Bioanalytical Laboratory at Clinigene International Limited. She has more than 12 years of assay experience which includes more than 7 years of experience in Immunoassay Development/Transfer, Validation and Sample analysis in support of PK and Immunogenicity studies for novel biologics and biosimilars. She has a PhD from Sardar Patel University, Gujarat, India and was selected as a UNESCO fellow to the Czech Academy of Sciences, Prague- as a part of her PhD program. She is an active member of various Bioanalytical Groups and works to not only to synchronize Indian Bioanalytical Practices with Global Regulatory Requirements, but also strives to bring out the Indian Bioanalytical Perspective on to a Global Platform for effective Harmonization.

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