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Biosimilar assays: Guiding principles (PK, ADA and Nab) for a bioanalytical scientist for a one or two assay choice

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For a biologic therapeutic, Pharmacokinetics (PK) and Immunogenicity are two important measurements in support of safety and efficacy. While PK measure the drug in the system, Immunogenicity qualitatively determines the binding and the neutralizing antibody presence induced by the drug. In case of Biosimilars, the study is made for the Biosimilar drug in a head to head comparison with the reference drug. Assays for Biosimilarity study support have to be developed and validated for their intended use. Well-studied assays yield accurate and reliable results which help in making critical clinical decisions for a therapeutic. Considering that the assay needs to selectively and specifically consider and detect minor changes in the reference and Biosimilar product, it the responsibility of the bioanalytical scientist to make informed decisions about the assay formats, reagents and validation parameters. This talk will be specially designed to compare and contrast one or two assay choices based on the nature and availability of critical reagents. We will explain experiments to be made for development and validation as per FDA/EMA guideline requirements. We will also be able to share our experience of more than a decade in PK, ADA and cell based neutralizing antibody assays and hold discussions with the audience for best practices.

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