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Recommendations from the AAPS LBABFG biosimilars action program committee for the validation of pharmacokinetic and immunogenicity assays in support of biosimilar drug development

Aparna Kasinath
Syngene International Limited, India

While, the development of Biologics is complicated and a strategy driven approach, mainly owing to the complexity and nature of the molecule, development and commercialisation of a biosimilar is two-fold challenging. The biosimilar is not only required to meet safety and efficacy end points as with all biologics, but also must demonstrate comparability with its innovator. Demonstration of comparability requires robust developed and validated assays that are able to pick out bio-analytical differences between the biosimilar and innovator. Pharmacokinetic and Immunogenicity assays are the major measurement platforms for safety and efficacy data arising from non-clinical and clinical studies. Currently there are no regulatory guidelines that clearly define the process/ path to be taken for designing comparability assays. This talk is aimed at discussing the recommendations made by the AAPS Ligand Binding Assay team for a harmonized strategy for biosimilar assay development and a One or Two assay bioanalytical strategy. This discussion is tailored to all biosmilar manufacturers and biosimilar bioanalytical scientists in particular.

Biography

Aparna Kasinath is currently Head of Test Facility Management, Regulated Bioanalytical Laboratory, Syngene International Limited, Bangalore, India. She has more than 14 years of assay experience which includes close to a decade of 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 bioanalytical Practices with Global Regulatory Requirements, but also strives to bring out the Indian Bioanalytical Perspective on to a Global Platform for effective Harmonization of best practices.

aparna.kasinath@syngeneintl.com

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