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Immunogenicity of protein biotherapeutics: Case studies on ADA methods

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Which the advent of Biotechnology more and more human recombinant protein biotherapeutics have replaced the animal derived drug products. This has helped in global availability of quality drug products at a competitive price. The advantages of the recombinant protein biotherapeutics are high purity, high specific activity, steady supply and batch-to-batch consistency. All protein biotherapeutics are potentially immunogenic and hence could elicit immunogenicity response. These responses could be of different types such as binding antibodies or neutralizing antibodies. Immunogenicity of protein biotherapeutics is a major concern especially when the biological function of the drug and the endogenous counterpart are neutralized by antidrug antibodies (ADA). Hence the regulatory agencies insist that the immunogenicity response be characterized. An effort has been made in this presentation to discuss on immunogenicity to protein biotherapeutics, regulatory concerns, strategy to evaluate the immunogenicity, overview of methods available, factors influencing immunogenicity and to share the experience of developing an ADA method using ELISA and GYROS assay format to assess immunogenicity of two drug products.

Biography

Dixit (graduate from University of Illinois) is a scholastic personality with several patents and publications to his credit and with more than 25 years of rich experience in pharmaceuticals, biopharmaceutical and CRO industries in the area of drug discovery and bio-analytical services. He has extensively worked on method development and validation of various assay platforms such as LC-MS, ELISA, MSD, SPR, RIA/RIPA and Cell based assays for Immunogenicity and pharmacokinetics evaluation of non-clinical and clinical study samples under GLP and GCLP compliant practices for regulatory submission studies. As a test facility management and head of bioanalytical laboratory he has successfully faced multiple sponsor's and regulatory audits. Dr. Dixit with his expertise is currently guiding the team biologics in the delivery of quality compliant bioanalytical and Characterization services for biologics and biosimilars for submission studies.

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