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Evaluation of immunogenicity in biotherapeutics

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Unwanted immunogenicity is a significant issue affecting most biotherapeutic products, including biosimilars. Anti-Drug Antibodies (ADA), also known as anti-therapeutic antibodies (ATA) can be associated with adverse reactions and can impact clinical efficacy and PK/PD profile. Neutralizing antibodies can bind to the active part of the biomolecule thereby blocking the therapeutic effect of the biomolecule, and may inhibit the activity of corresponding endogenous factor. There is a clear need to be able to detect these potential culprits early on and testing for its presence has become a regulatory requirement. Prediction, minimizing and assessment of immunogenicity are challenges faced by the biologics industry. The industry standard, regulatory acceptable testing strategy for ADA is step-wise: Screening for total ADA, confirmation, and neutralizing activity testing. There is a critical need to understand sensitivity and specificity of ADA assays. Furthermore, major challenges in development of immunogenicity assays are designing a good sensitive ADA assays, overcoming the interference of free drugs, having appropriate controls, setting up cut off points, and good clinical protocol for collection of blood samples. To understand and overcome immunogenicity problem an appropriate study design is of paramount importance, Quantimmune foresee its involvement early on in study designs and development of these assays may be in pre-clinical stages of drug development. In addition to overview of ADA assays this presentation will address the involvement of different component of immune system involved in immunogenicity and enable investigators to work out an immunogenicity testing strategy for regulatory success and to ensure that their drug is both safe and efficacious.

Biography

Surendra J Chavan has over 25 years of biotechnology experience. He has successfully led drug development research programs at Memorial Sloan Kettering Cancer Center (NY, USA), Celtaxsys Inc., (GA, USA), Forest Life Sciences (CA, USA) and Bioquant (CA, USA) which resulted in 10 US patents. He has earned his MSc (Biotechnology) from IIT (Mumbai) and PhD in Biochemistry from the Advanced Centre for Treatment, Research and Education in Cancer, formerly known as Cancer Research Institute, Mumbai, India. He has over 50 publications in peer-reviewed journals and has been an important contributor to various scientific meetings throughout North America.

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