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Immunoassays in drug development – Comparing and contrasting different platforms

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The drug development process requires sensitive and robust assays to enable PK/PD and Immunogenicity assessment of biologics. Immunoassays are commonly employed to this purpose, utilising the target-specific properties of antibodies to detect the analyte of interest. With the rapid advances in technology, the range of immunoassay platforms available is growing whilst existing platforms are becoming more refined, enabling bioanalytical scientists to choose a platform that is tailored to their needs. Various factors can influence the choice of platform, these can be either assay related such as sensitivity or assay type (quantitative/immunogenicity), or more general factors such as time and cost effectiveness. The Meso Scale Discovery® platform has become established as a reliable platform, particularly for immunogenicity assessment whereby a homogenous solution phase incubation of the sample with the capture and detection reagents provides a simple, easy to perform assay. The GyrolabTM is a largely automated platform that provides a time effective option allowing quick turnaround for analysis of samples. The CiraTM immunoassay platform from Aushon Biosystems, Inc. provides highly sensitive assays that are ideal for Biomarker analysis and also specialises in multiplexing capabilities, making it an attractive option for pharmacodynamics assessment. Carefully selecting the appropriate platform can improve the likelihood of successfully navigating biologics through the drug development process.

Biography

Kabir Hussain has a BSc degree in Cancer Biology & Immunology from the University of Bristol, UK. As part of the Clinical Pharmacology and DMPK group, he is responsible for the development, validation and execution of Immunoassays used in the analysis of samples from clinical and non-clinical studies, including GLP toxicology studies. He works in a GLP certified laboratory and consequently has experience working in accordance with the OECD principles of Good Laboratory Practice. He is a Principle Investigator for GLP multi-site studies and a Study Director for method validation studies. He previously worked at a CRO developing and validating immunoassays.

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