LABEL-FREE CHARACTERISATION OF BIOLOGICAL DRUGS IN PLASMA

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Abstract Text

The effects of immunogenicity are only detectable and measured after phase II trials and in rare cases after phase I trials. The major causes for immunogenetic reactions are in some cases related to the drug product and various modifications thereof but it can also be related to the patient and to the dosing of the drug product. Issues with both safety and efficacy can be related to anti-drug antibodies (ADA) arising after administration of biological drugs to patients.

By using Asymmetric-Flow Field Flow Fractionation (AF4), in-depth characterisation of both monomer and higher aggregated form of antibodies can be accomplished and this can studied on patient basis allowing more in-depth knowledge of drug behaviour in the individual patient.

Using the AF4 methodology in combination with label-free technologies allows us to distinguish between monomers and higher aggregates in complex tissues such as plasma, blood and cerebrospinal fluid (CSF). We also believe that this combination of technologies allows for a track and trace system setup in order to study drug dissolution from complex carrier systems such as viral capsids, nanoparticles and liposomes. The system not only allows the study of drug-drug interactions but also drug-target and drug-particle interaction.

This allows investigation of several of the causes leading to immunogenicity such as aggregation, degradation, and modification. By using this ex vivo sampling methodology, we believe that problems leading to immunogenetic reactions can be studied in human tissues in pre-clinical settings before putting patient at risk at various stages during dosing regiments.

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