Preclinical characterisation of biological drugs

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During the recent decades considerable efforts have been made to develop biological drugs and this diverse line of research is expected to continue its growth. The methods used for investigating the ADME-Tox properties of the biological drugs are different than those traditionally used for small molecules. In the preclinical development of biological drugs, various analytical techniques are needed and thorough structural characterisation of biological drug candidates forms an essential part of the development process.

Traditionally the analytical techniques of biological drugs have been dependent on immunoassays. It is notable that the current LC/MS systems provide a good selection of tools not only for comprehensive structural characterisation, but also for quantification of biological drug candidates and process-related impurities. The clear advantage of LC/MS assays over immunoassays is that they are not dependent on having an antibody/antigen for the target.

Other noteworthy points of characterisation are protein-protein interactions for example to evaluate the specificity and binding kinetics. As the neonatal Fc receptor (FcRn) play a big role in the pharmacokinetics of the Fc-containing proteins it is recommendable to investigate and optimise the binding of the compound to this receptor. In addition to evaluating potential immunogenicity by utilising human originating cell lines, investigation of Fc gamma receptor (FcγR)-binding may be used to evaluate antibody-dependent cellular cytotoxicity (ADCC).

The solutions for obtaining high-quality scientific data to support preclinical development of biological drugs will be demonstrated in this poster presentation.