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Comprehensive functional & biological characterization of biosimilar monoclonal antibodies

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Approval of biosimilar molecules requires a comparability package to be presented to the regulatory authorities, to ensure a high degree of similarity with the reference molecule. These packages include two types of assays-physiochemical and biological. Of these assays, the biological analysis provides the most critical parameters of a product, yet are the most challenging to perform. Today, there are a variety of different methods to measure the biological activity of the different aspects of the molecule. Biooutsource, provides a complete biological characterization and comparability testing program for biosimilar manufacturers with particular emphasis on the biological activity.

This presentation will discuss the format of biological characterization of a Humira biosimilar molecule for comparability studies. Measuring the affinity and avidity of the binding of these molecules to the target (TNFα) is most usefully measured using SPR techniques. In addition, the *in vitro* biological characterization assays will be discussed including L-929, ADCC, CDC and a new assay will be presented, to measure the effectiveness of this molecule, by measuring apoptosis. The variability of the batches of innovator molecule is critical to understanding where the biosimilar version sits regarding similarity. The results from the current batches of data biooutsource that are available will be presented along with pertinent conclusions.

Biooutsource recommends a layered approach, to the application of biological activity testing to a biosimilar such as Humira. Starting from the simplest assays and delving into the minor or less well understood biological functions which will finally resolve the questions around the comparability of biosimilars.

Biography

Daniel Galbraith founded BioOutsource in 2007 with a team which included some former colleagues from Q-One Biotech, Europe's leading CRO biosafety provider. Initially he worked as Head of Operations and more recently has taken the role as Chief Scientist where he has developed a successful team which is now seen as one of the leading providers for bioanalytical services globally and has gained a reputation for successful contract research in the biosimilar industry. Prior to founding BioOutsource he headed up the Biotechnology Service for Covance Laboratories Europe where he was in charge of their Biosafety Team. It was during this time in Covance that he first became involved with the bioanalysis of complex biologic molecules and eventually went on to develop services for biosimilar molecules. He has also held senior positions in the fields of contract research (BioReliance Europe) and manufacturing (MedImmune) for some of the largest players within the Biotechnology industry. He has a keen interest in biosimilars and from his time with MedImmune working on the FluMist project he has retained an interest in virus vaccines and their testing to meet regulatory guidelines.

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