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Biological and functional characterization of anti-TNF α biosimilar durgs

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Biological comparability of biosimilars is closely related to the clinical effectiveness. Potency assays mimic the *in vivo* biological activities expected from the drug. Some biological activities are extremely complex to measure, this is however related to the reason some monoclonal antibodies are successful as drugs is because of the many different pathways these molecules can act on to treat disease. Remicade's (Rituximab) critical function is to link the Fc portion of Remicadeto natural killer cells and mediate antibody dependent cell cytotoxicity and complement dependent cytotoxic, Rituximab also increases MHC II and adhesion molecules, it elicits shedding of CD23, it down regulates the B cell receptor and it induces apoptosis. All of these biological processes are able to be assessed using *in vitro* assays. Biosimilar manufacturers challenge is to assess the variability of the innovator molecules in these assays using different batches and then to assess their biosimilar version and making the argument that these are "similar". The presentation will discuss a number of key assays which form the critical quality attributes and are used as an "off-the-shelf" analytics to allow developers to compare their molecule against the relevant innovator molecules. The Innovator library of data allows the data generated from the biosimilar batches to be assessed in the context of a long history of testing batches of innovator molecule. Humira (Adalimumab) has been chosen as the model biosimilar for this presentation and this shall be set as the reference monoclonal antibody.

Biography

Daniel Galbraith founded BioOutsource in 2007 with a team which included some former colleagues from Q-One Biotech. As chief scientist, 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. He has also held senior positions in the fields of contract research (BioReliance Europe) and manufacturing (MedImmune). 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.

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