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Biosimilar characterization and comparability assessments – Experiences from a CRO GMP Protein chemistry laboratory

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Abstract

The originators detailed biopharmaceautical characterization competes with the competitions goal of demonstrating biosimilar comparability within regulatory expectations. Many originator and biosimilar manufacturers have specific experience in this. However, this is usually applied to only a limited selection of biopharmaceauticals. Conversely CMOs & CROs are now rapidly building extensive experience and expertise for this testing across a diverse range of biopharmaceautical products. With a growing knowledge of both the short cuts and pit falls associated with the different approaches to demonstrate comparability in accordance with regulatory expectations. There is substantial scope for the sharing of good practice and analytical expectations between all parties. Examples are presented from both successful and unsuccessful comparability assessment experiments for a selection of different originator / biosimilar candidates using a variety of analytical methods. These techniques include image capillary electrophoresis, glycan analysis, and Surface Plasmon Resonance. The experiences from additional in house characterization and comparability work using Trastuzumab as a model compound is also presented. To illustrate the actual complexities and limitations of the data obtained from different analytical methodologies considered essential for the demonstration of biosimilarity. With a focus towards specialist characterization techniques including LC-MS, intact mass, peptide mapping and glycan analysis.

Biography

Leonard after initially worked as peptide chemist in industry, and subsequently returned to university to complete his Ph.D from University of Sunderland. Following postdoctoral work at the University of Liverpool he rejoined the biotechnology industry. He is a senior scientist (Biochemistry) in the Protein Chemistry Department at a Global Contract Research Organization. His particular interest is in applying new, and existing well established, techniques to a variety of Biopharmaceautical products. With the goal of delivering bespoke analytical methods appropriate for the particular phase of Biopharmaceautical drug development, and that are consistent with regulatory expectations.