OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Biowaivers & Biosimilars
September 23-25, 2013 Hilton Raleigh-Durham Airport at RTP, NC, USA

Biosimilar characterization and comparability assessments-Experiences from a CRO GMP protein chemistry laboratory

Leonard Bell
Covance Laboratories, UK

The originators detailed biopharmaceutical 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 biopharmaceuticals. Conversely CMOs & CROs are now rapidly building extensive experience and expertise for this testing across a diverse range of biopharmaceutical 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 Bell 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 biopharmaceutical products, with the goal of delivering bespoke analytical methods appropriate for the particular phase of biopharmaceutical drug development, and that are consistent with regulatory expectations.

Leonard.Bell@covance.com