Carmine Lanni, J Bioequiv Availab 2012, 4:7
http://dx.doi.org/10.4172/0975-0851.S1.006

OMICS Group Conferences
Accelerating Scientific Discovery

International Conference and Exhibition on
Biowaivers & Biosimilars

September 10-12, 2012 Hilton San Antonio Airport, USA

Bioanalytical challenges in development of biosimilars

Carmine Lanni
Bioanalytical Development Services, USA

Biosimilars are to proteins what generics are to small molecules. However, due to the complexity of proteins especially if the protein is glycosylated, the regulatory agencies (EMA and FDA) see them as novel proteins and require that they be evaluated as such. The Opportunity with biosimilars and biobetters is that the clinical utility of the drug has been demonstrated and thus the risk is small. In addition, by manipulating the protein you have the opportunity to improve on the innovator's drug. There are a number of opportunities as a number of biologics are going off patent. As with proteins, there are several unique challenges to supporting their development. To determine the dose and regimen, the pharmacokinetics of the protein must be demonstrated, thus this requires the development of a bioanalytical method, usually an immunoassay. This requires the appropriate selection of reagents and formats that will measure the intact drug not its metabolite or fragment. In addition, for some molecules it may be total drug, bound drug, or free drug to determine what fraction of the dose is bioavailable. The PK assay method must be able to permit demonstration of bioequivalence of the biosimilar. The inherent instability of most proteins in human matrix also requires that the molecule is stable during sample collection and processing. The mere presence of an Fc region does not ensure stability in biologic matris. In addition, the immunogenicity of the molecule must be demonstrated, requiring the design of an immunogenicity testing process. The design of the immunogenicity testing process is dependent on the risk level of and type of molecule and can be quite complex. In summary while the bioanalytical support for development of biologics is more complex than small molecules, the high probability of success makes it cost effective.

Biography

Lanni has worked for 30 years in a number of pharmaceutical, and biotechnology companies, as well as CROs in drug discovery (10 years) and Development and GLP bioanalysis (20 years). These companies Include, RW Johnson Research Institute, Abbott Laboratories, Amgen Inc, Allergan, Quest Diagnostics Clinical Trials and MPI Research he is currently Chief Scientific Officer and Co-founder of a Bioanalytical CRO specializing in biologics called Biologic Development Services. Lanni received his doctorate in biochemistry and biophysics from the Medical College of Virginia where his research focused on phospholipid metabolism of alveolar macrophages. His postdoctoral work, conducted over two years at the Department of Pathology at the University of Connecticut Health Center, involved the activation of phospholipid metabolizing enzymes during an inflammatory response. Lanni has over 50 publications and has chaired several workshops and conference sessions at national and international conferences. He has participated in the development on five molecules in a variety of therapeutic areas that have obtained FDA approval.

clan4956@gmail.com