Dinesh Palanivelu, J Bioanal Biomed 2016, 8:5(Suppl)
http://dx.doi.org/10.4172/1948-593X.C1.023

Evolution of structure-function paradigm in biopharmaceutics based on global regulatory needs

Dinesh Palanivelu
Biocon Research Centre, Bangalore, India

Protein biopharmaceuticals has become a major focus in biotechnology industry for treating various life-threatening diseases. Unraveling their structural complexity represents a biggest analytical challenge. In the past decade, the state-of-the-art analytical tools have been developed to dissect primary and higher order structures, PTM modifications, purity and impurity profiles and pharmacokinetic properties to provide Structure-Activity Relationship (SAR), specifically in the field of biosimilars. Biosimilars are defined as follow-on-biologics that have been shown to have comparable quality, safety, and efficacy to the innovator products. Regulatory approval for a biosimilar version is provided on the basis of its comparability to an innovator product. The complexity of the manufacturing process, analytical methods, structural heterogenity and the possibility of severe immunogenicity reactions makes evaluation of similarity between an innovator and the biosimilar version a great challenge for the scientific community and regulatory agencies. Biosimilar development involves an iterative target-directed approach, driven by thorough understanding of the structure and its biological function of a target molecule. This includes understanding batch-to-batch consistency, stability, and whether variants or aggregates can be linked to safety and efficacy. The role of Higher-Order-Structure (HOS) has become a major investigation tool for establishing Structure-Function relationship. Differences in HOS provides potential clues to any observed biological and/or immunological differences between proteins and variant forms. What is required to integrate HOS into existing biopharmaceutical processes? Will doing so prove worth the cost, time, and effort? Here, we present the pleothera of HOS tools designed for biosimilar programs to understand the purity and impurity profiles to establish its SAR across several orthogonal analytical methods. Extensive HOS characterization datasets adds value to the totalilty of evidence which helps the regulatory agencies in the decision making process. In summary, the paradigm shift in structure-function relationship is the current requirement for global regulatory approvals for biosimilars.

Biography

Dinesh Palanivelu has completed his PhD in the field of Structural Biology from Biozentrum, University of Basel, Switerland and Post-doctoral studies from University of California, San Francisco, Cardiovascular Research Insitute, San Francisco USA. He is the Scientific Manager - Team Leader in Analytical and Molecular Characterization Division, Biocon Research Centre, Biocon Limited, Bangalore, a premier Biopharamceutical Organization in India. He has published several papers in the field of Structural Biology and Protein Chemistry in internationally reputed journals.

dinesh.palanivelu@biocon.com

Notes: