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Analytics in biosimilar development: Comparability and similarity

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In past two decades, biopharmaceutical industry has made significant foot-print in pharmaceutical industry. At present, major contributions are from innovator manufacturers. Due to patent exclusivities are reaching to their end, lot of competition is growing to manufacture these off-patent biologics. As in case of biologics, "Process is the Product", it becomes critically important to evaluate products manufactured by different routes. On the other hand, because of the complexity in structures and the structure–function relationship of biological therapeutics, such changes may lead to changes in molecular structures, which may adversely affect the quality, safety, or efficacy of the drug. Drug manufacturers must demonstrate the comparability of their products after process and formulation changes to ensure similar quality, safety, and efficacy. Biosimilars also require evaluation of their equivalency to the innovators' products. By complementing traditional biochemical methodologies, biophysical characterization, using a variety of methodologies, can enhance product knowledge in terms of higher order structure, molecular size distribution, and the properties of aggregates. This article presents three case studies that show the advantages of applying state-of-the-art biophysical techniques in comparability assessments.

Biography

Alok Sharma got his Doctoral degree in Molecular Microbiology from G.B. Pant University of Agriculture and Technology, Panatnagar. He was awarded PhD student fellowship from German Research Centre for Biotechnology, Braunschweig, Germany. Later he joined Dr. Victor Wray's lab for postdoctoral research at Division of Structure Biology at Helmholtz Centre for Infection Biology, Germany. He is the Head of Analytical Development Team, Biotech Division, Lupin Limited. He has published more than 20 papers in reputed international journals in the field of protein structure–fuction relationship and serving as a reviewer of many peer reviewed journals. He is serving as the Expert Panel Member of United States Pharmacopeia Convention (USP) Therapeutic Proteins" for 2011-2015.

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