

International Pharmacy Conference

July 14-15, 2016 Philadelphia, USA

Biosimilar of protein therapeutics

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Biopharmaceuticals like monoclonal antibodies are widely used in clinical medicine for various therapies e.g. cancer, inflammatory and autoimmune diseases. Several biosimilar drugs, supposed to be economical version of branded biological drugs, are in the process of drug development for market approval. Unfortunately, biosimilar manufacturing is often different from the brand name drug due to variation in manufacturing processes. As a result, such variations may trigger unwanted clinical issues, which may limit the use of biopharmaceuticals. Well engineered cells, well designed formulation coupled with good manufacturing scheme may sometimes reduce some of the extrinsic and intrinsic factors and increase the stability of drug product. One of the proposals for remedies is to purify the drug product to homogeneity or near homogeneity retaining its stability and functional activity. Due to its low or negligible content of impurities clinical issues may not be triggered and may get a relief from rigorous clinical studies. In addition, incorporation of risk based approach, which considers both probability of induction of clinical issues and expected clinical consequences followed by risk mitigation during drug development, may provide better regulatory pathway for market approval.

Biography

Alok Bandyopadhyay is a Senior Global Consultant at AB consulting. He started his scientific career working on immunoglobulin and received his PhD from University of Calcutta. Later he came to USA to work on molecular biology of proteins using Fulbright Travel grant. He took training as a Post-doctoral fellow from US universities. After training, he held several academic positions and worked in molecular biology of proteins. He published several scientific papers in various peer reviewed journals and received awards. In 1990s, he joined industry in drug development area and at the same time, he held Adjunct Faculty Position in Medicine at Thomas Jefferson Medical College, and subsequently Stony Brook University Medical College, NY. He worked with various famous people in the protein research. After joining industry, he gained experience in project management, advancing product innovation from conception through commercialization. He worked in various areas of drug development including Research, Quality and Regulatory. He was involved in various global submissions of IND, NDA, BLA, ANDA, pre-approval, and post approval. He worked in drug development of CNS, immunology, endocrinology, and oncology. He is a certified regulatory professional and proficient in US/EU regulations. He is successful interfacing with FDA reviewers. He is attached with several professional associations e.g. RAPS, DIA and AAPS.

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