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Biosimilar of protein therapeutics

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Protein therapeutics, including monoclonal antibodies and cytokines, have become mainstream treatments in a number of clinical settings starting from pain control, cardiovascular to oncology. All these biological drugs are expensive.In order to develop inexpensive patients' treatments, biosimilar of these branded drugs are required. Formulation, manufacturing and various other chemistry, manufacturing and controls (CMC) information of the branded drugs are different from biosimilar. Manufacturing of the biological drugs are long multistep processes and complex. During formulation and manufacturing processes the drug product may be associated with product-related, process-related, and/or host-related impurities through degradation, deamidation, misfolding, or aggregation. When it is administered within the body, these impurities may also produce antibodies in addition to the antibody of drug substances. Moreover, protein aggregation in particular has long been associated with increased immunogenicity. Repeated administration of drug product may cause a break in immune tolerance that can adversely affect pharmacokinetics and clinical response. In addition, neutralizing antibodies that cross reacts with nonredundant proteins may be a cause of autoimmune reaction. Well designed formulation coupled with good protein purification scheme may sometimes reduce the formation of product related impurities and increase the stability of drug product. One of the best remedy will be to purify the drug product to homogeneity or near homogeneity retaining its stability and functional activity, which may not trigger immunogenicity or other clinical issues due to negligible content of impurities. At the same time more discussions with Agency are required for quicker review and approval like FDA's "breakthrough therapy pathway" for the drug used in life threatening more serious illness. Near homogeneous protein and frequent discussion with agency may open up the easier regulatory pathway for biosimilar approval. Interchangeability and price reduction issues may be solved at that time.

Biography

Alok Bandyopadhyay, PhD, RAC is a consultant with more than 15 years of pharmaceutical experience. He held positions at several pharmaceutical companies and has published more than 75 articles and abstracts.

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