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Complexities of Biosimilar Product

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Abstract

Biosimilar Act, passed in 2007 under 351(k), states that a biosimilar product should be “highly similar” to prior approved reference product (RLD) and will have “no clinically meaningful differences” in their safety or efficacy. FDA also published three guidance to support this biosimilar project. However, the biosimilar processes are not so smooth. The biological molecules, manufacturing processes, and impurities profile are complex; leaving various issues in deriving different sections of CMC work. Due to relative complexities in producing biosimilar product small differences in the design and execution of manufacturing process can have a large influence of product related-, process related-,or host related impurities protein profile of a finished product, which may trigger immunogenicity and changes the clinical profile requiring elaborate animal studies and human clinical studies. FDA’s guidance are not very clear to drive the product into regulatory pathway for approval. Complexities still exist in clinical studies as clinicians like to review the details of data from three phase 3 trials and payors wish to see more stringent data regarding safety and efficacy.

One of the remedies is that if the biosimilar product is purified to homogeneity or near homogeneity, and if it is stabilized and restores the functional activities, the impurities protein content will be negligible or minimum, which may not trigger the immunogenicity or other clinical issues. With more advancement of science, research and development may solve these issues and open 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 has held positions at several pharmaceutical companies and published several articles and abstracts.