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Challenges in quality control of biosimilars in India: Role of National Institute of Biologicals

Subhash Chand, J P Prasad, Surinder Singh
National Institute of Biologicals, India

The global biosimilars market is USD 5.95 billion and expected to reach USD 23.63 billion by 2023 growing at a CAGR of 31.7% driven by the patent expiration of blockbuster biologic drugs. A biosimilar product is the one, similar in terms of quality, safety and efficacy to an already licensed reference bio-therapeutic product. Human Insulin, the recombinant DNA (rDNA) technology first drug was developed in 1980s, lead the foundation for the development of rDNA technology based Biotherapeutics. Omnitrope (Somatropin) was the first biosimilar product approved by European Medicines Agency (EMA) in 2006. In India, the first Biosimilar Guidelines were released in June 2012 and were revised by Department of Biotechnology and Central Drugs Standard and Control Organisation (CDSCO) in March 2016, which addresses the pre-marketing and post-marketing regulatory requirements, manufacturing process and quality control. The use of biopharmaceuticals is continuously increasing and has resulted in a huge market. During the development phase, any inevitable change in manufacturing processes may significantly affect the quality attributes like physical, chemical or biological property of the biosimilar. There are multiple challenges at every stage of biosimilar development like development and expression of clones; development, processing, purification, characterization of product and bioanalytical methods etc. Similarly, there are several challenges in the clinical development phase including study indication and design, patient recruitment, Immunogenicity, regulatory approvals, safety assessment and Post marketing study. The advancement in science & technology has helped to effectively combat the challenges and keeping the biosimilar development at a rapid pace. National Institute of Biologicals (NIB) is as an apex autonomous Institute under the Ministry of Health and Family welfare, Government of India; which ensures the quality of biological drugs including biosimilars by undertaking high end quality control testing. CDSCO forwards various biological products including biosimilars for quality evaluation at NIB before marketing authorisation or post marketing surveillance to ensure the quality, safety and efficacy of the various biological products marketed in India.

subhash.b08@gmail.com