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Biosimilar development cost: Role of analytics

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A biosimilar product is a biological product that is approved based on showing that it is highly similar to the reference product, with no clinically meaningful differences in terms of safety, efficacy and quality from the reference product. Biosimilar development is more time consuming and costlier than that of generic development due to complex manufacturing process and product. While generics takes only couple of years to develop with a cost of about 5-10 millions, biosimilar takes 8-10 years to develop with the cost of 100-300 millions. Typical steps in Biosimilar development are to characterize US licensed reference product, define target product profile, reverse engineer the biosimilar, define critical quality attributes, perform analytical comparability between proposed biosimilar and reference product, optimize the process until high analytical similarity between reference and biosimilar is achieved and address the residual uncertainties with analytical, non-clinical and clinical studies. A deep knowledge of critical quality attribute of reference and biosimilar product is the critical step for the development of biosimilar. It is important to understand how CQA links to the manufacturing process (critical process parameter and critical material attributes) and clinical performance of product (safety, efficacy and immunogenicity). A biosimilar product is not exact copy of reference product but similar to reference product. However, if biosimilar critical quality attributes are highly similar to reference product CQA, there is a great possibility that clinical performance of biosimilar will be similar to innovator product. Thorough understanding of product quality attributes can be achieved by analytical characterization and testing. The comparison between critical quality attributes can also be performed by analytical comparability studies. Analytics also allow the detection of changes in quality attributes due to change in molecule or process. There are a great number of tools which can even detect minor differences in carbohydrate structures. Additionally, there is a whole array of biological assays available, which can detect if change is clinically meaningful or not. Higher analytical capability (Product Knowledge and analytical tools) is the key to reducing the development time and cost of Biosimilar.

Biography

Dipti Gulati completed her PhD from Allahabad University and Postdoctoral studies from Indian Institute of Sciences, India and Albert Einstein College of Medicine on Protein-Carbohydrate Interactions, USA. Currently, she is the President of PJI Biotech, a Consulting Services Organization. Previously, she held various management positions at Amgen, BioMerieux, Emergent Bio Solutions, Diosynth and SmithKline Beecham Pharmaceuticals. She has published more than 25 papers in reputed journals and is serving as a Committee Member for several groups of PDA.

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