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Challenges in development of biologics and biosimilars: An overview

The global prescription drug market is expected to grow by 6% to reach nearly USD 1.05 trillion by 2022. The top 20 drugs are manufactured by 14 companies and account for a total 10% of global prescription drug market in 2016. The total revenue generated by top 20 products was estimated to be USD 0.128 trillion. Biologic drugs are cost effective opportunity for patients in the area of oncology, diabetes, inflammatory disorders, Autoimmune diseases, cardiovascular diseases and represent a total market value of more than \$50 billion. There are 150 marketed biologic products worldwide, with almost 500 products under development. About 21 important biologics will loose patent protection by the year 2019. The biopharmaceuticals show much greater efficacy and efficiency when compared to conventional pharmaceuticals. The use of biopharmaceuticals is continuously increasing and has resulted in a huge market demand. Biological drug products including Biosimilars, are larger in size and more complex than conventional small molecule drugs and the majority of these originate from living organisms. During the product development phase, some of the process changes are inevitable such as Cell line change, Critical Raw Material change, Primary packaging components change, Scale up/ down, Process parameter change, Formulation, Presentation, Device and Form Change Site Change or Critical Equipment change. Multiple complex manufacturing processes involved in biologics drug product development may significantly affect the product quality attributes, product development process and the product safety and/or efficacy. These may also affect the other quality attributes such as physical, chemical, biological, or microbiological property of the biologic drug product. There are multiple challenges at every stage of development of high quality biologics drug products. These include the initial clone development, clone expression, product development, processing, purification, characterization, post translation modifications, sensitive bioanalytical methods and stringent regulatory expectations. Similarly, there are several challenges in the clinical development phase also. These include Study Indication, Study Design, reference product, regulatory approvals, patient recruitment, Inclusion and Exclusion Criteria, Statistical consideration, Immunogenicity, Safety assessment and Post marketing study requirement. The advancement in the technology and availability of scientific approaches have helped to a great extent in effectively combating the challenges and keep the biologics drug development process at a rapid pace. The presentation on challenges in developing Biologics and Biosimilars gives an overview of scope for Biologics and Biosimilars drugs, various challenges and methods to overcome many of these challenges.

Biography

Dixit (graduate from University of Illinois) is a scholastic personality with several patents and publications to his credit and with more than 25 years of rich experience in pharmaceuticals, biopharmaceutical and CRO industries in the area of drug discovery and bio-analytical services. He has extensively worked on method development and validation of various assay platforms such as LC-MS, ELISA, MSD, SPR, RIA/RIPA and Cell based assays for Immunogenicity and pharmacokinetics evaluation of non-clinical and clinical study samples under GLP and GCLP compliant practices for regulatory submission studies. As a test facility management and head of bioanalytical laboratory he has successfully faced multiple sponsor's and regulatory audits. Dr. Dixit with his expertise is currently guiding the team biologics in the delivery of quality compliant bioanalytical and Characterization services for biologics and biosimilars for submission studies

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