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Risk assessment: A pragmatic approach to develop biosimilars

Harish Shandilya
INTAS Biopharmaceuticals Ltd., India

Therapeutic proteins and antibodies are one of the most important and rapidly growing segments of the pharmaceutical industry. By 2016, yearly spending on brand biologics will reach $60 billion. But affordability of these life-saving drugs is a challenge specifically in the developing world. There is a pragmatic solution on the horizon for safe, affordable, biosimilar versions of these critical therapies. Biosimilars have been proved safe and efficacious in Europe for last seven years but in USA the guidelines from US FDA to develop biosimilars is still awaited. As we know the genesis of Biosimilars is providing cheap, affordable drugs for the masses, specifically in emerging markets where affordability of critical drugs is a major concern. In this presentation, the author will focus on how to design the development in a cost effective way keeping a close watch on Critical Quality Attributes (CQAs) of the drug. What and how much is required to establish the Biosimilarity of the drug is more important. There is a huge improvement in assays available during the development of innovator molecules and assays available now. It is now possible to accurately quantitate the chemical status of each residue in a protein molecule and measure minute structural variance using various orthogonal approaches. On top of that the relevance and extent of clinic trails for innovators and for biosimilars will be discussed too.

Biography

Harish Shandilya is heading Biocharacterization of therapeutic proteins at INTAS Biopharmaceuticals Ltd., Ahmedabad. He is working with INTAS for last 7 years now. Prior to this assignment, he has developed clones for many biotherapeutic proteins. He is a molecular biologist by training and has worked at various prestigious institutions in India and abroad. He did his Postdoctoral work at Vanderbilt University Medical Center, Nashville, USA. Before joining Intas, he was associated with University of Pittsburgh, USA. He has done his PhD degree (1999) from India. He has published more than 20 research papers in reputed journals. He has experience of coordinating multiple Biosimilar product development programs for domestic and regulated market projects.

harish_shandilya@intaspharma.com