

Cell culture process development of a biosimilar monoclonal antibody-Case study

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Biosimilars are biologic medicinal products whose active drug substance are made by a living organism or derived from a living organism by means of recombinant DNA or controlled gene expression methods. Biologics such as recombinant proteins, fusion proteins and monoclonal antibodies are much more complex than small molecule pharmaceutical drugs. Due to this complexity, quality and consistency of the biologic product are dependent on manufacturing process ("process is product"). Galactose, fucose and mannose content of monoclonal antibodies are critical quality attributes while demonstrating biosimilarity. Present case study is about cell culture process development a biosimilar monoclonal antibody with respect optimizing galactose, fucose and mannose content.

Biography

Bala Reddy has completed his Master's degree in Microbiology from Indian Council of Agricultural Research (ICAR) India. He has over 12 years of experience in biosimilars development, manufacturing and commercialization. He is the Head of Biologics Operations at Hetero Drugs Ltd. for the past 4 years. Hetero is one of the top 10 pharmaceutical companies in India with manufacturing and marketing presence across the globe. At Hetero, he is responsible for designing and establishing the R&D and manufacturing infrastructure and to develop and manufacture biosimilars for Indian and global markets. Before joining Hetero, he was with Intas Biopharmaceuticals Ltd. for over 6 years and was responsible for biosimilar process and product development.

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