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Operational and technical challenges for drug development, scale up, scale down & higher scale manufacturing of biosimilars

Sumant Chaubey
3B BIO-TECH, Gujarat, India

The global biosimilars market estimated worth of $2.3 billion in 2015, and is expected to grow at a CAGR of 22.1% by 2020. Various factors contributed for the rise in demand for biopharmaceutical products e.g. drop in healthcare expenditure, growing demand for cost-effective generics, growing occurrence of chronic diseases, and growing aging population. Biosimilars industry is divided into recombinant nonglycosylated proteins, recombinant glycosylated proteins, and recombinant peptides. The recombinant nonglycosylated proteins includes insulin, granulocyte colony-stimulating factor (G-CSF), interferons, and human growth hormones and the recombinant glycosylated proteins includes erythropoietin and monoclonal antibodies. Biologics and biosimilar market is dominated by products from mammalian cell cultures (>75%). There is great opportunities in biopharmaceuticals, novel biologics & biosimilar r-proteins, Vaccines development and process parameter set up. Different scale-up criteria have been practiced depending on the type of fermentation and bioreactors. Growing mammalian cells in fermenters/bioreactors and to produce the protein of interest is a very cautious and tricky process. Process parameters e.g. pH or dissolved oxygen concentration, toxic byproduct concentration need to be controlled very strictly to corroborate the consistency of a product. Minor deviations of the predefined process parameters causes abrupt changes of product critical quality attributes (CQA) like glycosylation, aggregation, c-terminal clipping or acidic variation, which can affect the pharmacokinetics of the protein e.g. case study for eryhtropoetin, Darbepoetin, Mabs, etc. Concept of QbD and PAT was introduced as per international guidelines (ICH, USFDA, Global Guidelines) to control the quality of biologics / biosimilars by strict IPQC methods. In reality scale-up of laboratory and pilot-plant data to commercial size industrial bioreactors is complicated. Problem of dead zone, improper distribution of air/oxygen, uneven distribution of media, growth pattern causes the great impact on product formation and quality at higher scale of operation. No actual data or correlation or exisiting formula is fixed for scale-up. Different Biopharma giants e.g. Amgen, Dr. Reddy Lab, Biocon, Biogen, Merck Sereno, uses different scale-up criteria to design commercial size bioreactor systems. In fermentation or cell culture based biopharma industry there are a lot of trade secrets on scale-up of bioreactors and fermentors and very few published results.

Sumant.biopharmaexpert@gmail.com