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Challenges faced in developing biosimilars-Maximizing productivity and performance of mammalian expression systems

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Biotherapeutics play a critical role in the treatment of diseases that affect the human condition. The biological activity of the great majority of these therapeutic proteins depends on correct posttranslational modifications best achieved by mammalian expression systems.

Protein production essentially has four steps:

1. Constructing a suitable vector containing the gene(s) of interest
2. Production of materials for preclinical evaluation
3. Creation of stable clones expressing the protein of interest and
4. Media development to optimize nutrient levels for the production clone

This expression system can then be utilized in process development and scale-up studies for cGMP manufacturing.

Recent progress in biopharmaceuticals has been led by the rapid growth in development of monoclonal antibody (mAb) products. Significant progress has been made on both the molecule & process fronts leading towards greatly improved manufacturing plants productivity. Biotherapeutic molecules have always been selected for the target clinical properties, but now also are engineered for stability & suitability for productive production processing. Better balance of media components & feeds has allowed higher cell densities & higher viability late in cell culture processes. Product recovery & purification have been substantially standardized & optimized.

The combination of these advances has resulted in several fold decrease in cost of goods & much higher output for a standard plant. Scaled down experimental cell culture models promise to provide optimal process conditions faster.

Biography

Ganesh Kumraj is a Post Graduate in Industrial Microbiology from University of Pune, India and has completed his Ph.D. from University of Rajasthan, Jaipur India. He is the Managing Director of BioBridge Healthcare Solutions, a pharma and biotech companies consulting service organization. He has over 23 years of experience and has worked at various senior level positions in the pharmaceutical and biotechnology industry and has handled key positions in quality and operations management; technology transfer, scale-up and optimization, corporate quality assurance, quality control, validations, production and project management functions. He has had earlier stints with premier government institutions before moving to private sector.

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