Ashesh Kumar, J Bioanal Biomed 2013, 5:4
http://dx.doi.org/10.4172/1948-593X.S1.011

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Biowaivers & Biosimilars
September 23-25, 2013 Hilton Raleigh-Durham Airport at RTP, NC, USA

Novel methods for improved biologics productivity by integrated process techniques

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Efficient production of therapeutic protein requires an integrated upstream and downstream process. Further, process analytical techniques (PAT) are utilized to control variations and to modulate flexibility in the system to operate it efficiently. Use of GMP compatible, scalable process as well as genetically stable clones facilitates consistent titers and quality of desired product. Any changes for improving the upstream process which results into higher fermentation/ bioreactor yields are always a challenge for the downstream purification team to follow it through to achieve high product yields.

In a unique effort, we have studied and demonstrated that changes in the fermentation at scale up level can be systematically visualized at microscopic level with the help of optimized method of preparation of cells under electron microscopy (EM) techniques. These subtle changes in the fermentation can be then fine-tuned to have higher productivity which is very difficult (if not impossible) to achieve. The study also allowed, quantifying the level of production of inclusion bodies and their densities, and to relate them to number of cells expressing them after induction. A novel method thus allows, better optimized fermentation conditions, for achieving higher titers. Study indicates that availability of genetically stable and robust clone for production of therapeutic protein helps in the integrations.

Biography

Ashesh Kumar is Director-Biologics & Licensing at Paras Biopharmaceuticals Finland. Prior to this, he was Head of Biopharmaceuticals at Medipolis GMP Oy Finland for six years, where he led a team of process scientists and was responsible for development of a scalable production technology for a biosimilar analog insulin technology, and successfully licensing it to a European partner. He is a Ph.D. in Biosciences & Biotechnology from Indian Institute of Technology, Roorkee, India with 15 years of Biopharma industry experience on biosimilars and their scale up production. His research is published in peer reviewed international journals. He has also authored and edited a number of books and is member of various international groups in USA and EU.

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