Min Zhang, J Bioanal Biomed 2015, 7:5
http://dx.doi.org/10.4172/1948-593X.C1.017

OMICS International
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4th International Conference and Exhibition on
Biologics & Biosimilars
October 26-28, 2015 Baltimore, USA

Overcome challenges in manufacture of biosimilars through media/feed screening and cell culture process optimization

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In the biosimilar journey of drug development through regulatory approval, the product quality attributes of the biosimilar protein must compare within defined limits to those of the innovator product. Unlike small molecule drugs, whose structure can usually be completely defined and entirely reproduced, biologicals are typically more complex and are almost unlikely to be shown to be structurally identical to an innovator product. Therefore, biosimilarity is generally demonstrated as having matched product quality attributes, comparable *in vitro* biological activity, and no clinically meaningful differences between the bio-similar drug and innovator product. The complexity of recombinant protein manufacturing processes, including expression systems (i.e., host cell line, expression vector, cell line development process), cell culture process conditions and related nutrient systems,such as cell culture media and feeds, present significant challenges to achieve the required product quality for biosimilars. To address these challenges, Fujifilm Diosynth Biotechnologies (FDB) has developed a systematic approach of combining media toolbox methodology and bioprocess "know-how" to screen and optimize manufacturing conditions that promote the desired product quality profiles of recombinant proteins. Case studies will be presented to highlight the efficacy of this approach and successful implementation in manufacture of biosimilar recombinant monoclonal antibodies.

Biography

Min Zhang has over 10 years of experience in mammalian cell culture, from cell line engineering, media development, bioprocess development and bio-manufacturing, bioprocess characterization, Quality-by-Design (QbD) and therapeutic protein commercialization. He is currently a Principal Scientist and Group Leader at Fujifilm Diosynth Biotechnologies USA, Inc. (FDBU) where he leads a cell culture team to support upstream process development and cGMP manufacturing for cell culture programs at various development and clinical phases. Prior to joining FDBU, he had tenures in Cell Culture Development Department at Eli Lilly and Company and SAFC (Sigma-Aldrich). He was a Staff Scientist and did his Post-doc research at University of California at Berkeley after he received his Doctorate in Molecular Cell Biology from Institute of Genetics at Fudan University.

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