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Technical challenges in developing biosimilar antibodies

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Since originator recombinant proteins are getting off patent, biosimilar molecules are entering the market. Although the overall costs of bringing a biosimilar product to the market is in general much lower than for an originator, the technical challenges to reach biosimilarity compared to originator product are significant. There is also a strong push to bring down the cost of goods to manufacture these products. Strategies will be presented to reach technical proof of similarity of specific antibodies while reducing production costs. These include innovative concepts to increase antibody titers on our CHOBC® platform using our SPOT™ technology and our USP toolbox to modulate relevant post-translational modifications like glycosylation and charge variants. In addition, these include, selection of new Protein A resins to decrease cost of goods while maintaining product quality, the development of high throughput methods, including Multi-Attribute Methods (MAM), to increase efficiency, and the extensive characterization of antibody charge variants (eg oxidation, deamidation, fucosylation, lysine truncation etc.) and disulfide linkage analysis to increase product knowledge.

Recent Publications

1. Van Corven E (2014) Recombinant protein and mAb biopharmaceuticals to become a commodity? Pharmaceutical Bioprocessing. 2(2):107-109

Biography

Emile Van Corven pursued MSc in Biology/Chemistry at Leiden University, Netherlands. He got his PhD in 1987 at Nijmegen University and was a Postdoc Fellow at The Netherlands Cancer Institute in Amsterdam, Netherlands. He is currently the Chief Development Officer at Bioceros, Head of Downstream Process and Analytical Development. He has a track record of more than 25 years in the biopharmaceutical industry: Principal Consultant CMC (Xendo), Director and Global Head of process development and pilot plant GMP manufacturing of vaccines (Crucell/J&J), and development of recombinant proteins (Pharming). He also worked for the Dutch Regulatory Authorities as Head of Control Lab for the Release Of Blood Products/Vaccines, and Head of the Regulatory Group for review of Biotech CMC Dossiers. He has published over 30 peer-reviewed scientific articles, chapters in textbooks, and is Co-inventor of various patents. From 2012-2015, he was a Member of the Editorial Board of *Pharmaceutical Bioprocessing*.

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