

BIOLOGICS AND BIOSIMILARS & BIOPHARMA & BIOTHERAPEUTICS

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Using SPOT™ and SLIM™ technology in our CHO^{BC}® platform to reduce cost of goods of biosimilars

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Innovative cell line generation and early process development are the cornerstones of the success of a biosimilar antibody since the costs of goods (COGs) needs to be very low. To achieve this, a high producing cell line in combination with a modulatory upstream processing (USP) strategy to meet similarity to the originator that do not limit productivity are obligatory. The major strategy generally used in USP to optimize productivity, is an elevation of viable cell density (VCD) in the fermenter. This USP solution however creates difficulties in downstream processing (DSP), since clarification will be difficult and in addition host cell related impurities will be high. Since Bioceros recognizes the biosimilar process as USP and DSP together, we have a different USP strategy for productivity optimization. Ultimately COGs are determined by USP and DSP together. Therefore, we create using our SPOT™ technology to increase Qp values, already during the cell line generation. The high Qp values facilitate high volumetric productivity at low VCD of these cell lines which enables a simple and efficient DSP process. Alongside we observed that irrespective of the VCDs, cell lines with a high productivity had a very high demand for oxygen, agitation, gas-flow and nutrients. These high demands result in process issues, like oxidation of the product, shear stress, high sparging rates and high costs. Furthermore, these high demands will limit the ultimate innovations to further increase productivity. To avoid these issues we applied metabolic engineering and developed the SLIM™ technology on our CHOBC® platform. The SLIM™ technology decreases oxygen and feed consumption and also decreases sparging and agitation rates in the bioreactors showing the high efficiency of these process on which the SLIM™ technology was applied. Together, SPOT™ and SLIM™ technology in our CHOBC® platform reduce the cost of goods of biosimilars.

Biography

Louis Boon received his PhD in Biochemistry at the University of Amsterdam. In 2003 he was one of the founders of Bioceros BV where he currently holds a position of CSO. In addition, he held positions as CSO for 4AZA Bioscience NV and for FF Pharma: he was VP Preclinical for PanGenetics BV and Tanox. He is an author of over 280 papers in international scientific journals in the field of medical biotechnology. Bioceros generates production cell lines and production processes for the industry and uses its proprietary CHOBC® platform and its SPOT™ technology to generate a portfolio of cell lines producing biosimilar monoclonal antibodies. He developed a complete process modulation toolbox to fit biosimilar CQAs. Currently, he is also involved in the development of innovative new molecular antibody entities, which now within the Polpharma Biologics group can be progressed to GMP production and clinical testing

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