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CHO expression platform technology for cell line development of biosimilars

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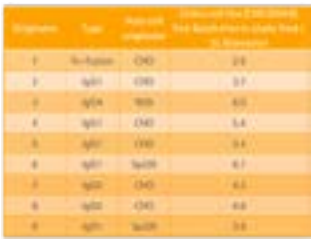
The market for therapeutic proteins including biosimilars is steadily growing, resulting in an increased demand for fast and efficient cell line and process development platforms. Additionally, new challenges arise due to strict requirements for biosimilars regarding quality and productivity. Sartorius Stedim Cellca's CHO expression platform comprises a potent vector system and a highly productive host cell line combined with tailored chemically-defined media and upstream process design. The expression system is suitable for high-titer production of biosimilars with variation of glycan structures. Sartorius Stedim Cellca has established a biosimilar cell line development approach including a first selection based on glycan profile already on pool level. Following, 48 clones are screened in fed-batch for productivity and protein quality using the ambr15 system. Moreover, individual media and process modifications using the ambr15 and ambr250 system to achieve similarity to the originator are available. The fed-batch performance of the technology is directly transferable from small scale systems to large scale bioreactors not only in terms of process performance but also achieving robust protein quality. Sartorius Stedim Cellca has an excellent track record in the generation of biosimilar cell lines. Several high producing (>3 g/L in a standard fed-batch process) biosimilars with the target protein quality profile were successfully generated for customers. In cooperation with Sartorius Stedim BioOutsource not only protein quality but also binding assays and functional assays such as ADCC (antibody-dependent cell-mediated cytotoxicity) were performed. In this line, Sartorius Stedim BioOutsource offers in depth innovator analytics and bioassay development for biosimilars. Consequently, Sartorius Stedim Biotech offers the whole cell line and process development process including master and working cell bank generation, analytics as well as bioassays.



Recent Publications

1. Neves A T, Otte M, Schwartz C, Lindner C, Pabst O Yu P and Voehringer D (2015) The extracellular domains of IgG1 and T cell-derived IL-4/IL-13 are critical for the polyclonal memory IgE response *in vivo*. PLoS Biology. 13(11):e1002290.
2. Lindner C, Thomsen I, Wahl B, Ugur M Sethi M K et al. (2015) Diversification of memory B cells drives the continuous adaptation of secretory antibodies to gut microbiota. Nature Immunology. 16(8):880-888.
3. Lindner C, Wahl B, Föhse L, Suerbaum S, Macpherson A J, Prinz I and Pabst O (2012) Age, microbiota, and T cells shape diverse individual IgA repertoires in the intestine. Journal of Experimental Medicine. 209(2):365-377.
4. Pott J, Stockinger S, Torow N, Smoczek A, Lindner C et al. (2012) Age-dependent TLR3 expression of the intestinal epithelium contributes to rotavirus susceptibility. PLoS Pathogens. 8(5):e1002670.

Biography

Cornelia Lindner received a Doctoral Degree in Immunology in 2013 from the Hannover Medical School, Germany. During her PhD project she characterized antibodies and their sequence repertoires using immunological assays as well as Next Generation Sequencing. Following, she worked for 3 years in the field of experimental antibody therapy gaining experience in cell line development. Thereby, establishing CHO cell lines for production of antibodies and fusion proteins as well as downstream purification and protein characterization was her focus. She joined Sartorius Stedim Cellca GmbH, Germany in 2016. She currently leads one of four teams in the Operations Department organizing the whole cell line and process development process for customer projects based on Sartorius Stedim Cellca's cell line development platform. She and her team in cooperation with Sartorius Stedim BioOutsource recently completed a very successful biosimilar cell line development project.

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