XDR-500 MO—SINGLE-USE FERMENTOR FOR MICROBIAL PROCESSES

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Single-use bioreactors are well-established in production of biopharmaceuticals in mammalian expression systems. However, a similar technology breakthrough for microbial/yeast-based productions is still awaiting due to the unique requirements associated with such high-cell density cultivations, including high oxygen transfer capacity and efficient heat removal.

Here, we present the single-use Xcellerex™ XDR-500 MO stirred-tank fermentor system specifically designed for microbial/yeast applications. The performance of the fermentor was evaluated using an *E. coli* fed-batch process producing a domain antibody (dAb) as a model system. The process was originally developed for a lab-scale conventional stainless steel system. This work describes the transposition and scale-up strategy of the process to the XDR-500 MO system together with obtained results.

Critical process parameters such as dissolved oxygen (DO) level, pH, and induction conditions were maintained as in the initially developed process, while parameters such as DO control, substrate feed strategies, as well as medium and feed preparations were adapted to the single-use technology.

Results from the scaled-up process, using the XDR-500 MO system, revealed that cell growth and productivity were comparable across scales and the system performance was similar to conventional stainless steel systems.

Additionally, an *in silico* study on the basis of the described *E.coli* dAb process was conducted, comparing process economy of the XDR-500 MO system with conventional fermentors.

Results from the successful transfer of the dAb process to the XDR-500 MO system as well as data from the process economy comparison indicate that under defined conditions, single-use technology can be a feasible alternative to conventional stainless steel-based processes.