PROCESS INTENSIFICATION: CASE STUDIES WITH A CHO-BASED MONOCLONAL ANTIBODY PRODUCTION PROCESS

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Standard platform technologies for cell culture processing provide simple and robust strategies to meet rapid timelines for early process development and ease of manufacturing. However, when there is a need to achieve high antibody titers due to high product demand, both culture media and feed strategies must be customized for specific cell lines. Two case studies will describe the strategies employed as part of a process intensification effort to overcome the limitations of a platform Phase III cell culture process. The first case study will demonstrate an intensified fed-batch process development effort performed to maximize production of a CHO-based monoclonal antibody, while maintaining product quality comparability with the original Phase III process. The second case study will describe the evaluation of a concentrated fed-batch process using alternating tangential flow filtration to retain the protein in the bioreactor, and achieve even higher titers in support of the high product demand forecast. These case studies will show that the intensified fed-batch process improved titers by 50%, and the concentrated fed-batch process improved titers by 100% relative to the fed-batch platform.