EVALUATION OF AMBR® 250 PERFUSION BIOREACTOR SYSTEM AS A MODEL FOR HIGH-THROUGHPUT PERFUSION CELL CULTURE PROCESS DEVELOPMENT

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The efficient development and delivery of high-quality therapeutic products necessitates the need for high-throughput process development (HTPD) tools. In recent years, fed-batch process development timelines have been significantly reduced as industry has implemented fully automated mini bioreactor systems such as the ambr® 250 HT. More recently, as continuous processing for biologics has gained traction, driven by novel technology and economic pressure to significantly improve monoclonal antibody (mAb) production over the standard fed-batch process, more efficient, cost effective, and environmentally sustainable mAb processes are expected. Traditionally, perfusion process development work requires a combination of deep-well plates and small-scale stirred tank bioreactor (STR), both of which are labor intensive and time consuming. The established ambr®250 HT platform has recently been integrated with perfusion capabilities to enable rapid continuous perfusion process development (PD). In this work, we present the results from our assessment of the automated disposable perfusion bioreactor system for high throughput upstream PD activities, including clone selection and process optimization. In addition, several high stress conditions were also examined here to identify optimal operation ranges for the current system. The studies conclude that ambr® 250 perfusion reactor is able to generate process performance and product quality profiles equivalent to bench-top bioreactors for a high cell density perfusion process.