

INTEGRATION OF XCell™ ATF PERFUSION WITH SINGLE COLUMN CAPTURE CHROMATOGRAPHY FOR PRODUCTION OF MONOCLONAL ANTIBODIES

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Perfusion cell culture processes have demonstrated higher productivity than fed-batch due to the ability to generate and maintain high cell densities over long process durations. When using a perfusion system, like the Repligen XCell™ ATF, a clarified cell free stream of product is continuously generated and is ready for downstream purification. Similarly, continuous or semi-continuous capture chromatography of monoclonal antibodies (mAbs) can provide significant advantages over batch processes such as higher productivity, improved product quality, lower equipment footprint, and reduced purification cost. Integrating a perfusion system with a continuous downstream purification system could achieve all these advantages over a batch system. Multicolumn based chromatography systems (MCC) have been widely evaluated and show tremendous benefit when integrated with perfusion processes for continuous purification of mAbs. However, adoption of MCC within the biotech industry has been slow due to complexity of the systems which can be challenging to set-up, qualify and come with a higher risk of process failures. In this work, we have combined a single capture chromatography column containing a high capacity Protein A resin, Purolite Praesto® Jetted A50, with a Repligen XCell™ ATF perfusion cell culture system. The performance and productivity of this single column capture integrated system were compared with MCC approaches. The high performance single-column system simplifies the downstream capture process and is scalable to > 5 kg mAb per day process without the need for complicated MCC equipment or operation.