

## **NEXT GENERATION PERFUSION PROCESS DEVELOPMENT FOR PRODUCTION OF BIOLOGICS**

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Process intensification by perfusion cell culture at the N-1 seed and N-stage production steps has been developed for biomanufacturing in the pharmaceutical industry recently. In this case study, a traditional fed-batch cell culture process is currently used in manufacturing of a monoclonal antibody. To address much higher projected drug substance demands at peak sale years, different process intensification strategies are being evaluated as next generation process options for future mAb manufacturing. These strategies include N-1 seed perfusion, steady state perfusion, and non-steady state dynamic perfusion at N production step. Data on productivity improvement, comparability of different quality attributes, scale-up method, facility fit, and cost of goods will be presented to compare different next generation perfusion process options.