

COMMERCIALIZATION OF A 2ND GENERATION INTENSIFIED PERFUSION PROCESS DURING LIFE CYCLE MANAGEMENT

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Continuous biomanufacturing provides many advantages for the production of therapeutic proteins through process integration, automation and intensification. Sanofi is currently developing robust cell culture processes using ATF perfusion technology to achieve improved volumetric productivity with consistent product quality. This presentation is a case study on how we applied intensified process technology on product commercialization. Using QbD approach, we successfully implemented an intensified perfusion process coupled with continuous capturing on a commercial product life cycle management. For the 2nd generation process, entire production and capturing stage is fully integrated and automated. The new perfusion process comprises of high cell density and achieves significant increase in volumetric productivity, which allows a substantial footprint reduction and increases flexibility in a new facility. More importantly, product quality was remarkably comparable with the 1st generation process. Dramatic improvement in process robustness and consistency were demonstrated as well. Facilitated by computational fluid dynamics (CFD) simulation, we successfully scaled up to commercial scale. In support of technology transfer and manufacturing, process control strategy was drafted based on the results of bioreactor characterization using univariate and multivariate studies.