Key Words: alternating tangential flow (ATF), enzyme replacement therapy (ERT), glycoprotein, perfusion

Novel antibody therapeutics (mAbs) dominate the biologics portfolio today. Commercial late-stage antibody therapeutics development went from 39 candidates in Phase 3 studies as of late 2014 to 53 as of late 2015\(^1\). The advantages of this robust pipeline in mAbs has allowed companies to build well established platform technologies using fed-batch processes with high titers and online cell culture process monitoring to yield high quality products.

Contrast this with the development of complex glycoprotein therapeutics, these processes have cell lines with significantly lower productivity and products with tenuous stability, making straightforward fed-batch platform processes insufficient for manufacture. In these instances, biopharmaceutical manufacturers turn to more labor intensive perfusion cell culture techniques. Here we present the successful development and scale up of a semi-automated long duration perfusion process using alternating tangential flow (ATF) for production of a novel enzyme replacement therapy (ERT).

References: