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REDUCTION OF N-GLYCAN PROFILE VARIATION BY USING CAPACITANCE PROBES FOR OPTIMIZED PROCESS CONTROL

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The glycan profile of therapeutic monoclonal antibodies frequently plays an important role in their biological function and pharmacokinetics. Therefore, improved control of the glycosylation profile of biopharmaceutical monoclonal antibodies has become an increased priority during late stage and commercial manufacturing of New Biological Entities as well as biosimilars. Two ways to obtain better control are through process parameter optimization and/or through addition of media supplements to the production reactor. Cell culture supplementation with mycophenolic acid is one method to efficiently manipulate N-glycan profiles of monoclonal antibodies, notably the level of fucosylation. We have observed at least for some CHO-based cell culture processes, that the timing of mycophenolic acid addition to the cell culture process relative to the cell growth profile is important to fine-tune the effect on the glycoprofile. This poster presents a case study where batch-to-batch variation of the N-glycan content of fucose for a monoclonal antibody at harvest could be correlated to the mycophenolic acid dose timing relative to the viable cell volume profile measured online by use of capacitance probes in 15 kL large-scale manufacturing bioreactors. Scale-down runs performed at 3 L scale with different timing of mycophenolic acid addition supported these observations. These data demonstrates how online capacitance probe measurements potentially could be used to optimize the process parameter mycophenolic acid dose timing, and thereby, further improve control of product N-glycan profile for this process.