EXPERIENCES AND CHALLENGES DURING THE COMMERCIALIZATION OF A LICENSED-IN MONOCLONAL ANTIBODY

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Key Words: commercialization, process robustness, tech transfer, scale-down model qualification, MVDA

A variety of scientific and regulatory challenges may be encountered during the commercialization of a monoclonal antibody process. These challenges may be compounded when the product is licensed-in. In this work, we present case studies detailing a series of experiences and lessons learned during the commercialization of a licensed-in monoclonal antibody process. The work will cover topics including qualification of scale-down models, troubleshooting scale-up and tech transfer, mitigation strategies for process performance variability, and demonstration of clonality. A variety of experimental and statistical methodologies were implemented to address these concerns, including application of multivariate data analysis. Details of the methodologies will also be provided to demonstrate their application to troubleshooting of commercial upstream fed-batch production processes.