CONTROLLING MONOCLONAL ANTIBODY PRODUCT QUALITY USING HIGH THROUGHPUT SYSTEMS (HTS)

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Enhancing throughput of bioprocess development has become increasingly important to rapidly screen and optimize cell culture process parameters. The need to conduct large numbers of experiments has resulted in the use of miniaturized high-throughput (HT) technology for bioprocess development.

Advanced Microscale Bioreactors (ambr™) is an automated micro-bioreactor system with miniature single-use bioreactors with a 10-15 mL working volume controlled by an automated workstation. We used Ambr15 to perform cell culture studies to optimize and control product quality attribute of monoclonal antibody. The large number of samples produced from these experiments greatly exceeded the capacity of traditional analytical assay so we used the LabChip® microfluidics platform to analyze the product quality of the monoclonal antibody. The microfluidic LabChip provided a high-throughput workflow for data generation and analysis of sample purity and quantification with the capability to resolve low level impurities under reducing and non-reducing conditions.