

ACCELERATING ATTRIBUTE-FOCUSED CELL CULTURE PROCESS DEVELOPMENT THROUGH THE DEPLOYMENT OF AN AUTOMATIC ASSAY PREPARATION PLATFORM

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Key Words: Walkup, Efficiency, Real-time, Quality, Sample Prep Platform

Evolving business and patient needs necessitate rapid and efficient process development to ensure accelerated advancement of therapeutic molecules. Rigorous attribute focus is critical for the development of robust processes that can consistently deliver high-quality product and automated high-throughput analytical approaches to rigorously characterize product quality facilitate product commercialization. To accelerate our attribute-focused development of drug substance processes to produce biotherapeutics, we have developed an automated analytical platform that includes multiple attribute capabilities to enable a high resolution understanding of product quality. Specifically, we have developed a turn key solution called the Automatic Assay Preparation Platform (A2P2) system that is co-located in a cell culture laboratory for easy analysis of protein concentration, aggregation, charge variants, post-translational modifications (PTMs), glycans, and metabolites. This solution is designed to be used by scientists with minimal analytical expertise and employs qualified analytical methods that provide high fidelity results. This approach allows cell culture scientists to gain valuable process insights in near real-time that can be directly leveraged to guide subsequent experiments without waiting for analytical results from the lab. We have piloted this concept and have realized significant improvements from the A2P2 affinity sample cleanup system (*Figure 1*) with 45-73% reduction in result turnaround time, 91-97% reduction in staff hands-on time, and up to 357% increase in sample processing capacity compared to typical Tecan-Atoll processes. Product quality attribute assays will be integrated into the A2P2 platform for more efficiency enhancements. Overall, the innovative A2P2 platform with integrated analytics and its co-location within a cell culture laboratory significantly improves the efficiency and throughput of multiple product quality attribute assays to enhance and accelerate cell culture process development.

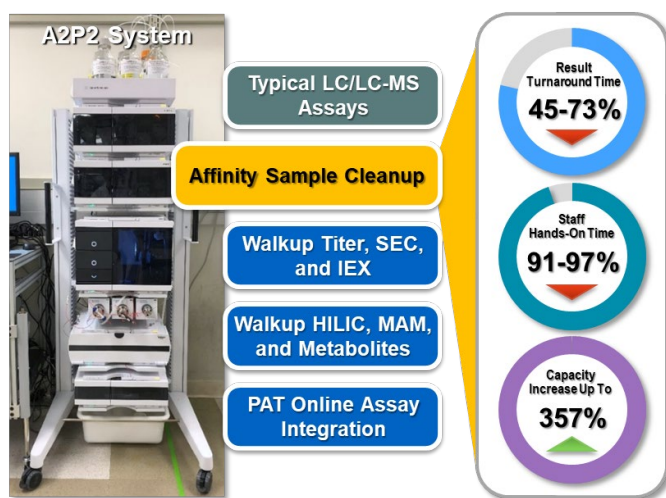


Figure 1 - A2P2 System Capabilities and Efficiency Gains from A2P2 Affinity Sample Cleanup Process