INDUSTRIALLY-RELEVANT EXAMPLES USING A DATA ANALYTICS STRATEGY TO EFFECTIVELY ADDRESS COMPLEX PERFORMANCE CHALLENGES

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Manufacturing processes that produce biotherapeutic medicines rely heavily on chemical engineering principles alongside deep biological understanding. With the invent of high-speed, high-throughput data acquisition capability of recent years, there is a need for high-speed data analytics and visualization to get the most value out of the data. Yet, most processing is still done in user-specific spreadsheets with highly time-consuming, manual inputs and calculations. Further, when challenges arise, it becomes necessary to couple reams of disparate data sources, often in multiple iterations, to better understand the complex bioreactor or purification dynamics. It is not uncommon for a technical team to need to leverage significant historical data to enable small-scale model verification and provide insights into various scale-up challenges, all within a very tight product development timeline. This old-fashioned way of handling data is especially problematic due to the rapidly increasing number of cell therapies that need to be transitioned from a proof-of-concept phase to a scale and quality suitable for commercial production, with even more limited resources and time. The right data, including a way to assess it quickly and easily in collaboration with colleagues, is needed to understand the potential effect that process scaling may have on product comparability. Since this session focuses on process scale-up and characterization, this presentation will focus on how to implement a data analytics strategy that can put a more holistic “molecule development view" right at our fingertips. The approach, using industrially-relevant case studies, will highlight how to better assess all of the data gathered in order to more rapidly advance promising molecules, while using fewer resources and ultimately seeing new patterns and relationships that otherwise would have remained unknown. In this presentation, we will focus on case studies that illustrate how scientists rapidly achieved these specific improvements: 1) uncovered important issues related to bioreactor scale up, including rapid comparisons of key process steps across multiple batches at the 3L, 100L and 1000L scale, 2) enabled rapid data analytics efforts to be able to dig deeper into the physics of a process and explore data in a new way for both upstream and downstream processes, 3) developed a methodology that provided a framework for comparing outcomes across upstream and downstream processes, all within the same application environment, and 4) facilitated inter-department collaboration during an investigation phase. By replacing the old time-consuming approaches typically used for analyzing data, there is more opportunity to develop quality insight into the key performance indicators, thus supporting a more holistic “molecule-development view” when scaling a process. Using a streamlined data analytics strategy enables the development of a truly robust understanding of the physical situation from early development through commercialization.

Reference: Graham, L.J. (Alkemy Innovation, Inc.), and T. Barreira (Merrimack Pharmaceuticals, Inc.) "Leveraging a Data Strategy with Seeq to Create the Optimal Biotherapeutic Development Process," poster presentation at the Bioprocessing Summit Conference, Boston, MA, August 15-19.