BioReliance®

Pharma & Biopharma Manufacturing & Testing Services

MilliporeSigma

Mini Case Study

Scale your Process Directly from 3L to 2000L

Time is of the essence. In the biotech industry, you need to move quickly and use resources efficiently to advance a drug candidate into the clinic and ultimately onto the market. Being able to quickly produce a batch at the right time and at the right size is essential to support development and get to the finish line faster.

The combination of our innovative, custom solutions and decades of expertise in biologics manufacturing allows us conceptualize and implement innovative approaches to accelerate and compress processes while minimizing risk and ensuring product quality.

The Challenge

Once a robust upstream process established, scalability is critical to support demand for drug substance during clinical development. A typical scaling initiative takes a 3L process and increases it to 2000L with intermediate volumes and pilot runs in-between. This stepwise approach can require up to three months and can slow progress towards important milestones. We explored strategies to accelerate this scale-up process while ensuring safety, efficiency and robustness.

Our Approach

We developed a strategy to enable a direct, efficient and robust tech transfer of a monoclonal antibody production process from a 3L bioreactor to 2000L without the need for any intermediate volumes. The knowledge generated during process development, as well as a specific model designed to keep the oxygen mass transfer coefficient (KLa) stable in any bioreactor, were key factors in our success. In addition, we conducted a clone stability study and defined process tolerances for volume, gas level, pH, feed and other parameters as all system characteristics must be considered. Mixing efficiency, sparging efficiency and fluid movement and gas/liquid interaction can all vary among bioreactor sizes and were modeled and evaluated.

The Outcome

Our approach allowed us to achieve similar conditions for production at the 2000L scale as were developed for the 3L bioreactor. By leveraging our deep understanding of process dynamics and sophisticated Mobius® bioreactors, process scale-up from 3L bench scale bioreactors to 2000L becomes faster, more predictable, and consistent. The need for intermediate scale steps at 200L and 1000L, for example, along with pilot runs become obsolete. Elimination of these intermediate steps can significantly shorten the scale-up process – accelerating the time to market and delivering a competitive advantage.

BioReliance® End-to-End Solutions is an adaptable CDMO partner for small biotechs and start-ups needing to develop and commercialize biologics. We do this by balancing speed, risk and cost through custom solutions, by leveraging our bioprocessing technologies and process development expertise, and by allowing our clients to transfer their process and knowledge to their end point at any step of their drug development. To learn more, please visit **EMDMillipore.com/adaptive-CDMO**

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