Millipore®
CTDMO Services

MERCK

Case Study

Scale your Process Directly from 3 L to 2,000 L

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 solutions and decades of expertise in biologics manufacturing allows us to conceptualize and implement accelerated paths to compress processes while minimizing risk and ensuring product quality.

The Challenge

Once a robust upstream process is established, scalability is critical to support demand for drug substance during clinical development. A typical scaling initiative takes a 3 L process and increases it to 2,000 L with intermediate volumes and pilot runs 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 3 L bioreactor to 2,000 L 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 2,000 L scale as were developed for the 3 L bioreactor. By leveraging our deep understanding of process dynamics and sophisticated Mobius® bioreactors, process scale-up from 3 L bench scale bioreactors to 2,000 L becomes faster, more predictable, and consistent. The need for intermediate scale steps at 200 L and 1,000 L, 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.

For clients seeking an outsourcing partner, we provide a streamlined experience to cover the entire value chain from pre-clinical to commercial phases. Our integrated Millipore® CTDMO Services offering combines our expertise in contract testing, development, and manufacturing to accelerate solutions for clients and patients. Our technical leadership, regulatory know-how, testing services and manufacturing expertise are tightly aligned with our supply network to offer total solutions for our clients. We leverage 30+ years of global success with dedicated sites around the world. We are the industry's experienced choice, built to serve pioneers.

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MK_DS11960EN 46669 04/2023