

Bioprocessing

Overcoming rapid growth challenges with buffer preparation

Introduction

A growing contract development manufacturing organization (CDMO) was challenged with the need to quickly expand their buffer preparation capacity in order to meet the demand for one of their client's recently approved therapeutics. This need for additional capital and operational expenditures (CapEX and OpEX) resulted from a sudden increase in campaign volumes that subsequently increased the demand for buffers.

CDMO management estimated the buffer preparation demand would exceed the capacity of the site's existing resources within 2 months, including weigh-dispense-hydration equipment, storage space, and personnel. These resource constraints would result in production delays, potentially impacting their supply of finished drug product to their client as well as requiring a significant CapEX to expand the warehouse by an estimated 10,000 ft².

Assessment

To better assess the customer's needs, Thermo Fisher Scientific conducted a Gemba process walk of the company's, i.e., the CDMO's, weigh-dispense-hydration (formulation) workflow to analyze the current state of the buffer preparation area. Utilizing the lean principles of the Gemba process walk, the team identified multiple areas of potential improvement and waste elimination. Key observations during the engagement included:

- Limited availability and size of mixing equipment impacted manufacturing by creating bottlenecks in the buffer preparation area.
- Inefficient sterile connection technology resulted in wasted time and effort, as well as additional costs for expensive equipment.

“By outsourcing common buffer formulations, we reduced our buffer prep load by 56%, which gives us a chance to keep up with the projected growth.”

-Operations Readiness
Program Manager

Solution

To address the operational and business expansion challenges observed, Thermo Fisher proposed that Gibco™ Process Liquid Preparation Services help increase productivity and outputs by simplifying the process liquid preparation steps. Streamlining the steps enabled the CDMO to meet current and future production demands without additional capital investments.

Ready-to-use process liquids and buffers

By collaborating with Thermo Fisher using the Process Liquid Preparation Services, the CDMO was able to directly source process liquids and buffers in 100 L bioprocess containers of their choosing to supply their 8 highest-volume buffers. This tailored solution, unique to the CDMO's specific weigh-dispense-hydration (formulation) workflow requirements, simplified their buffer preparation by alleviating the time and resources required for sterile connections. De-bottlenecking the workflow with ready-to-use process liquids and buffers enabled the CDMO to optimize their schedule for campaign runs.

By leveraging Process Liquid Preparation Services, the customer benefited from the procurement of larger lot sizes that were not capable of being manufactured within their facility, which resulted in annual savings for raw materials. Most significantly, the customer avoided CapEX and OpEX totaling \$5.1 million in the first year for facility and capacity expansions.

Results

The CDMO met both long- and short-term needs to focus their resources on core manufacturing activities while avoiding significant expenditures for 8 high-volume solutions prepared through Process Liquid Preparation Services. Specifically, this customer experienced:

\$2.7 million CapEx avoidance

for facility expansion, equipment for process liquid and buffer preparation, and additional warehouse space to support manufacturing and maintenance

\$2.4 million annual savings

in OpEx

\$330,800 annual savings

in raw material costs

56% time savings

in process liquid and buffer preparation by de-bottlenecking the weigh-dispense-hydration area

Contact your technical specialist or [use this form](#) to request more information.

Find out more at thermofisher.com/simplifybufferprep

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