

# Production Chemical Custom Packaging Services

## Overcoming rapid growth challenges with process liquid preparation

### Situation

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

Management estimated the process liquid and buffer preparation demand would exceed the capacity of the site's existing resources within two 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 customer as well as a significant capital expenditure (CapEX) to expand the warehouse by an estimated 10,000ft<sup>2</sup>.

### Solution

To better assess the customer's needs, Thermo Fisher Scientific conducted a Process Walk of the company's weigh-dispense-hydration (formulation) workflow to analyze the current state of the process liquid and buffer preparation area. Utilizing the lean principles of the 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 process liquid and buffer preparation area.
- Inefficient sterile connection technology resulted in wasted time and effort, as well as adding additional costs for expensive equipment.

To address the operational and business expansion challenges observed, Thermo Fisher proposed **Production Chemical Custom Packaging Services** to help maximize productivity and outputs by streamlining the process liquid preparation steps; thereby, enabling the CDMO to meet current and future production demands without additional capital investments.

### Results



**\$2.7M CapEX Avoidance**

Space & equipment



**\$2.4M OpEX Annual Savings**

Manufacturing & maintenance resources



**\$330.8K Annual Savings**

Raw material costs



## Ready-to-use process liquids

By collaborating with Thermo Fisher, the CDMO was able to directly source process liquids and buffers for their eight highest volume buffers in 100L bioprocess containers of their choosing through Production Chemical Custom Packaging Services. This tailored solution, unique to the customer's specific weigh-dispense-hydration (formulation) workflow requirements, simplified their process liquid and buffer preparation by alleviating the time and resources required for sterile connections. De-bottlenecking the workflow with ready-to-use process liquids enabled the customer to optimize their schedule for campaign runs. By leveraging Production Chemical Custom Packaging Services, the customer benefited from the procurement of larger lot sizes that were not capable of being handled within their facility resulting in annual savings for raw materials. Most significantly, the customer avoided capital and operational expenditures totaling \$5.1 million in the first year for facility and capacity expansions.

## Results

The CDMO achieved both long- and short-term needs to focus their resources on core manufacturing activities while avoiding significant expenditures for eight high-volume solutions prepared through Production Chemical Custom Packaging Services. Specifically, the customer experienced:

### **\$2.7M CapEX avoidance**

for facility expansion and equipment for process liquid and buffer preparation, and additional warehouse space

### **\$2.4M Annual savings in OpEX**

to support manufacturing and maintenance

### **\$330.8K Annual savings**

in raw material costs

### **56% Time savings**

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

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

Operational Readiness  
Program Manager

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