

Outsourcing trusted-weight dry powder chemicals to support expansion

Situation

The gene therapy division of a major pharmaceutical manufacturer was looking for ways to overcome capacity constraints due to the increased production demands for process liquids and buffers. In order to sustain growth, non-core manufacturing activities, including the weigh and dispense steps in the process liquid and buffer preparation, were identified as bottlenecks impacting the overall production schedule.

After a self-assessment, management concluded that outsourcing their process liquid and buffer preparation activities would be the best path to meet the increasing demand for process liquids without adding significant capital (CapEX) and operational (OpEX) expenditures. With recent investments in their water for injection (WFI) system, they opted to keep hydration (formulation) steps in-house. They reached out to one of their chemical suppliers for trusted-weight dry powders to be dispensed into a specific container that was validated in their process; however, the supplier was not willing to deviate from their standard bioprocess containers (BPCs).

Solution

To efficiently address the customer's needs, Thermo Fisher Scientific collaborated with the company's Head of Engineering and Manufacturing Operations to better understand the specific processes and demands within their weigh and dispense area (dry suites).

Key observations included:

- Operational inefficiencies and capacity constraints in the dry suites causing delays in production schedules
- Inefficient supply chain planning for just-in-time deliveries, sometimes resulting in expediting shipments
- Warehouse was over capacity and unable to support receipt of additional raw materials, a 10,000 ft² expansion would be needed to support the business growth

To address the operational and business expansion challenges observed, Thermo Fisher proposed **Process Liquid Preparation Services** to provide ready-to-hydrate, trusted-weight dry powder chemicals. The open architecture design resulted in a tailored solution, streamlining the customer's process liquid preparation steps prior to hydration to meet current and future production demands.

Results



\$3.6M CapEX Avoidance

Space & equipment



\$434.4K OpEX Annual Savings

Manufacturing & maintenance resources



\$409K Annual Savings

Raw material, sampling, & QC testing costs



Trusted-weight dry powder chemicals

By collaborating with Thermo Fisher, the customer found the most value-added solution was to receive four trusted-weight dry powders packaged into their preferred BPCs (ILC Dover EZ BioPac® bags) through Process Liquid Preparation Services. The open architecture and flexibility of this service allows customers to select any chemical and any container type, in any brand or format to meet their unique weigh-dispense-hydration workflow needs.

By leveraging Process Liquid Preparation 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 and QC testing. Additionally, the dry powder chemicals were delivered on a pre-determined schedule so valuable facility space did not need to be used and a warehouse expansion was avoided.

Results

The gene therapy division avoided additional expenditures for facility and capacity expansions and focused their resources on core manufacturing activities while avoiding significant

expenditures for four trusted-weight dry powders packaged in their preferred BPCs.

\$3.6M CapEX avoidance

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

\$434.4K Annual savings in OpEX

to support manufacturing and maintenance

\$409.9K Annual savings

in raw material, sampling, and QC testing costs

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