

Accelerating SARS-CoV-2 immunotherapy speed to clinic with pre-made process liquids

Situation

A clinical stage biopharmaceuticals company was working diligently to expedite their development of a SARS-CoV-2 (COVID-19) immunotherapy but was challenged to scale their manufacturing operations with existing resources. To support the desired rapid pace of development without expanding in-house buffer manufacturing, the company had decided to outsource ten different buffers as their capacity within the weigh-dispense-hydration suites was becoming increasingly limited.

The company reached out to another chemical supplier for the production and delivery of the necessary buffers to alleviate resources within the weigh-dispense-hydration suites so they could focus on their other, core-manufacturing needs. However, the chemical supplier was not responsive to the urgency of their buffer needs and capacity constraints—the biopharmaceuticals company would receive delayed communications specifically regarding lead time issues and any small volume (<200L) requests from the supplier. Upon these realizations and fearing first-in-human (FIH) trial delays, management explored alternative partners who could reliably supply the outsourced process liquids and buffers to advance their development of a SARS-CoV-2 immunotherapy without incurring additional capital (CapEX) and operational (OpEX) expenditures.

Solution

To efficiently address the customer's needs, Thermo Fisher Scientific collaborated with the company's Chief Scientific Officer and Purification Manager to better understand the unique needs for their highest priority buffers.

Key observations included:

- Operational inefficiencies in the weigh-dispense-hydration suites while preparing process liquids and buffers, causing delays
- Inefficient supply chain and lack of communications regarding poor lead times affecting planned development timelines
- Warehouse was over capacity and unable to support storage of process liquids and buffers, a 10,000 ft² expansion would be needed to support the scale-up

To address the observed challenges with scaling and internal capacity, Thermo Fisher proposed **Process Liquid Preparation Services** to provide pre-made process liquids ready-to-use in manufacturing. This offering enabled tailored solutions to streamline the preparation steps for process liquids of various volumes to meet advanced timeline demands for development of a SARS-CoV-2 immunotherapy.

Results



\$2.2M CapEX avoidance

Raw materials and finished goods warehousing, equipment, space, and facility upgrade



\$368K OpEX annual savings

Manufacturing resources



36% Reduction in lead times



Ready-to-use process liquids

By partnering with Thermo Scientific™ Production Chemicals and Services, the customer received pre-made process liquids and buffers 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 process liquid and buffer preparation needs.

By leveraging Process Liquid Preparation Services, the customer could focus their valuable resources on the SARS-CoV-2 immunotherapy development for FIH trials without expanding capacity, investing in new equipment, or increasing head count; therefore, resulting in significant annual savings. Additionally, the process liquids were delivered on a pre-determined schedule aligned with capacity availability, thereby avoiding significant capital expenditures while also significantly improving lead times from 14 weeks to 9 weeks—a 36% reduction.

Results

The biotherapeutics company avoided additional expenditures for facility and capacity expansions, enabling them to focus

their resources on accelerating SARS-CoV-2 immunotherapy development for their FIH trials. Specifically, the customer experienced:

\$2.2M CapEX avoidance

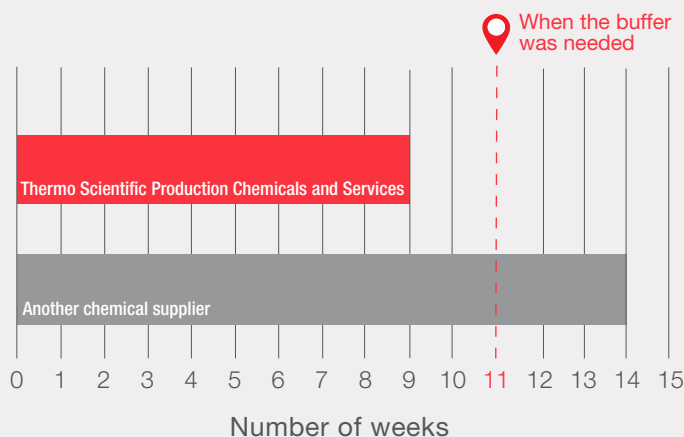
\$1.7M for facility expansion including warehouse space to store buffers and raw materials

\$0.5M for equipment, space, and facility upgrades

\$368K OpEX annual savings

to support current manufacturing resources without increasing head count by three technicians and one manager

36% Reduction in lead times



Thermo Scientific Production Chemicals and Services works with biologic developers and manufacturers who want to do what matters most, innovate and produce life-changing therapeutics. With over 30 years of experience delivering production chemicals and direct material supply chain solutions, we deliver risk mitigation, improved operational efficiencies, and reduced total cost of ownership so our customers can accelerate their speed to market, speed to clinic, and improve productivity.

Find out more at: thermofisher.com/simplifybufferprep

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