



Avoid CapEX with improved operational efficiencies

Helping to expedite quality release processes

Situation

A mid-size biopharmaceutical company was faced with the need for capital expenditures (CapEX) to expand their direct raw materials warehouse and to construct an additional cleanroom to meet the growing demands of their commercial product pipeline. Some of the new materials added to the production schedule necessitated raw material sampling, and there were additional regulatory requirements to be implemented.

Management was challenged with the decision to fund the construction and operation of a new warehouse and cleanroom and to add the required warehouse and quality personnel to handle the increased activities. They estimated the need for a 30,000 ft² current good manufacturing practices (CGMP) warehouse facility and expansion of the existing cleanroom.

Management was interested in considering alternatives that might allow them to avoid these significant capital and operating expenses (OpEX), while still achieving their overall business goals.

Solution

The customer engaged Thermo Fisher Scientific to evaluate and propose potential solutions to address their situation. They were already utilizing the CGMP Distribution Services of Thermo Fisher for a portion of their raw materials requirements, so they were familiar with the capabilities and value of their collaboration with Thermo Fisher.

Key observations and findings during the evaluation included:

- Warehouse utilization was over 85%.
- Current warehouse space could not be expanded to add another cleanroom.
- Current cleanrooms were not qualified to manage the new material requirements, including the need to handle flammable substances. In addition, there were significant constraints in resources, space, and equipment.
- Upgrade investments would be necessary for warehouse expansion and to meet regulatory requirements.
- Material release time was impacted by:
 - Increased volume of raw material sampling, which increased the sampling lead time from 1 week to 8 weeks.
 - Inefficient operations in which warehouse personnel were applying material labels and quality personnel were applying a release label.
- Lot size was not optimized for QC testing efficiency and cost-effectiveness.
- There were not enough warehouse and quality resources to perform the number of sampling activities required.

To address the business challenges observed, Thermo Fisher proposed two key solutions:

- **Chemical raw material sampling service:**

- Perform raw material sampling in a validated cleanroom environment according to the Thermo Fisher quality system, industry best practices, and customer-specific protocols.
- Conduct monthly environmental monitoring.
- Execute cleaning and maintenance work instructions.
- Provide standard sampling supplies and create sample labels.
- Store larger material lot sizes at a Thermo Fisher GMP- and GDP-compliant warehouse to reduce the number of sampling events and decrease QC testing costs.

- **Material release:**

- Customer-released material was stored as customer-owned inventory in a Thermo Fisher GMP- and GDP-compliant warehouse by customer part and lot number to support production demand.*
- The Thermo Fisher warehouse team applied customer material labels to product containers and performed relevant inspections.
- Material was typically delivered with a one-day lead time for just-in-time (JIT) deliveries based on the customer inventory pull system.

Results

By taking advantage of sampling offered by Thermo Fisher, including the use of the Thermo Fisher warehouse to hold inventory, the customer was able to avoid a major capital investment for construction of a warehouse and cleanroom. This allowed the customer to realize significant savings in the associated capital and operating expenses. Likewise, substantial

savings in the QA release activities associated with raw material sampling, QC testing, risk exposure, and QA release labeling were realized. As well, there was a reduction in final material release time with 1-day JIT delivery of QA-released material from the Thermo Fisher warehouse.

The company experienced:

\$5.6M CapEX avoidance
for facility expansion

\$433K annual savings
in operating expenses

\$99K savings
in working capital

1-day JIT delivery
of QA-released inventory

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* Certified ISO 9001:2015 Quality Management System incorporating applicable elements of 21 CFR Parts 210 & 211 and the IPEC Good Distribution Practices Guide.

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