CASE STUDY

Production Chemicals and Services

Production Ready Services

CapEX avoidance with improved operational efficiencies

Situation

A mid-size biopharmaceutical company was faced with the need for capital expenditures to expand their direct raw material warehouse, and to construct an additional cleanroom to meet the growing needs of their commercial product pipeline. Some of the new materials added to the production schedule required raw material sampling and additional regulatory requirements.

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 ft^2 current Good Manufacturing Practices (cGMP) warehouse facility and expansion of the current cleanroom.

Management was interested in considering alternatives that might allow them to avoid these significant capital and operating expenses, 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 the partnership with Thermo Fisher.

Key observations and findings during the engagement 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 materials. In addition, there were significant constraints in resources, space, and equipment.
- Upgrade investments would be required for warehouse expansion and to meet regulatory requirements.
- Material release time was impacted by:
  - Increased volume of raw material sampling causing a longer sampling lead time from 1 week to 8 weeks.
  - Inefficient operations with Warehouse personnel applying Material Label and Quality personnel 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.

Results

$5.6M Savings

Warehouse & Cleanroom cost avoidance

$433K Annual Savings

Cleanroom & Warehouse activities

$99K Annual Savings

QA release activities

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To address the business challenges observed, Thermo Fisher proposed two key components of **Thermo Fisher Production Ready Services.**

- **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 normal sampling supplies and create sample labels.
  - Storage of larger material lot sizes at a Thermo Fisher cGMP warehouse to reduce the number of sampling events and reduce QC testing costs.
- **Production Material Release Service:**
  - Customer released material was stored as customer-owned inventory in a Thermo Fisher cGMP warehouse by customer part and lot number to support production demand.
  - Thermo Fisher warehouse team applied customer material label to product containers and performs100% inspection.
  - Material was delivered with a one-day lead time for Just In Time (JIT) deliveries based on customer inventory pull system.

Results

By taking advantage of the **Production Ready Services** offered by Thermo Fisher, including the **cGMP Distribution Services** and 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 also realized in addition to a reduction in final material release time with 1-day JIT delivery of QA released material from the Thermo Fisher warehouse. As a result, the customer experienced:

$5.6M CapEX Savings

$5M CapEX in building additional 30,000 ft² facility to construct additional warehouse and store additional material

$433K annual savings CapEX and OpEX associated with the warehouse and cleanroom

$99K savings in activity costs associated with Quality FTE costs for sampling, QC testing, labeling for QA released material

1-Day JIT delivery of QA released local inventory from the Thermo Fisher warehouse

Reduced final material release time by eliminating raw material sampling at the customer site and changing how product labeling of Quarantine and QA release material was conducted

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/productionready**

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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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