

cGMP* Distribution Services

Uninterrupted supply to meet demand

Situation

A large biopharmaceutical company faced added complexity and operational costs within its direct material supply chain operations, as a result of significantly increased campaign volumes at their U.S. manufacturing site.

Management was concerned about the potential increased risk for production delays and as a result, was taking specific actions to mitigate this risk. This included increasing Full Time Equivalent (FTE) resources within supply chain and quality, as well as investing significant capital in raw material inventory. Additionally, they were concerned about the site's warehouse capacity for direct raw materials – especially if the campaign volume continued to increase.

Solution

To better assess the customer's needs, Thermo Fisher Scientific:

- Performed a GEMBA walk to analyze current state process flow from raw material sourcing to the manufacturing suites
- Reviewed the chemical bill of materials (BOM)

Key observations and findings during the engagement included:

- Operational inefficiencies in managing multiple suppliers/distributors
- Operational inefficiencies with product supply planning
- Poor On Time In Full (OTIF) from direct suppliers
- Significant quality management activities due to product nonconformances
- Evidence of excessive supply chain expenses for non-core activities
- Warehouse at >90% capacity
- Instances of direct material overflowing warehouse racking
- Supply chain working with suppliers to hold product shipment due to space constraints with mixed success
- Supply chain requiring expedited shipments
- Supply chain management securing bids for off-site storage

To address the business challenges observed, Thermo Fisher proposed that the customer aggregate their sourcing of production chemicals leveraging the Production Chemicals and Sourcing Services, and cGMP Distribution Services offered by the company. This solution included:

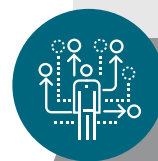
- **Supplier management** – Reducing the customer's supplier management complexity and resource requirements by facilitating pricing, supplier audits, quality agreements, and ongoing supplier performance management.
- **Order management** – Reducing the time and resource costs associated with managing supplier orders, and resolve issues and changes to expected ship dates, improve customer-related communication to OTIF performance, as well as facilitate alternative sources of supply as needed.

Results



\$345K Savings

Reduced risk of production delays



\$123K Savings

FTE resource reallocation



\$120K Savings

Working capital availability



- **Material Receipt & Handling and Outbound Logistics Management** – Managing vendor errors as part of the inbound receipt process and create freight synergies via shipment consolidation, reducing the time and costs associated with customer warehouse activities at time of receipt.
- **Quality Management System** – Providing management of change (MOC) and change notification, manage customer quality agreements, and resolve quality issues identified during inbound product receipt to reduce the overall time and costs associated with supplier errors, poor quality, and CAPA management.
- **Procurement** – Providing the customer with the flexibility to move ship-dates, leveraging the cGMP warehouse for short-term inventory holding, to address customer warehouse capacity and flexibility constraints, as well as reduce the need for expedited shipping.



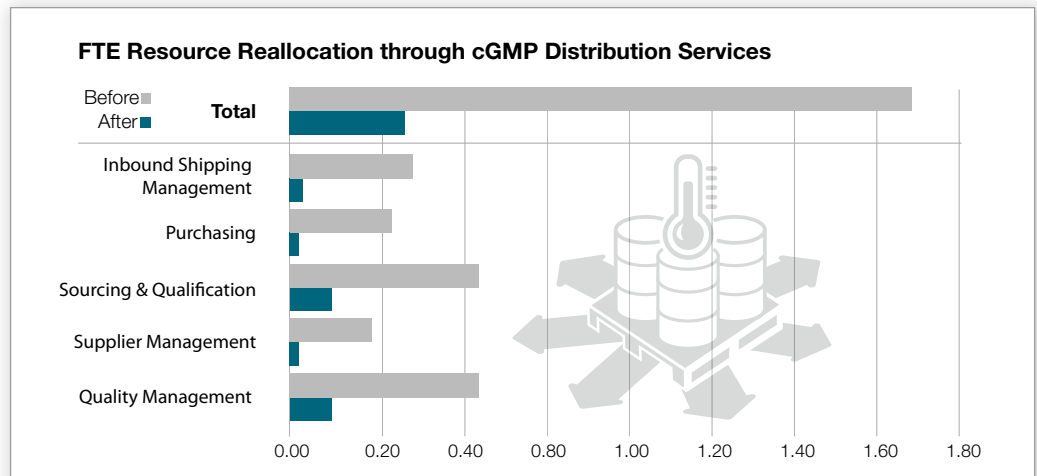
Result

By taking advantage of the cGMP Distribution Services offered by Thermo Fisher, including validated Quality Management System, Technology Systems, cGMP warehouse facilities, order management, procurement, material receipt and handling, and outbound logistics management, the customer reduced the complexity and operational costs associated with the management of their production chemicals, as well as significantly reduced the risk of production delays. Specifically, the customer was able to reallocate supply chain FTE resources, reduce operating expenses, reduce working capital, as well as mitigate the increasing capacity constraints on their GMP raw material warehouse. Overall, the customer's human and financial resources could now be more effectively dedicated towards managing the increasing campaign volumes in the manufacturing suite to meet patient demand.



As a result, the customer experienced:

- **\$345K savings due to reduced production delays**
- **\$123K savings in FTE resource costs**
- **\$120K savings in working capital**



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/cgmpdistribution

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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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