



Uninterrupted supply to meet demand

Chemical procurement, order management, and quality management in CGMP- and GDP-compliant environments

Situation

A large biopharmaceutical company was facing added complexity and higher costs in its direct material supply chain operations due to a significant increase in campaign volume at its manufacturing site. Management was concerned about the heightened risk of production delays and took specific actions to mitigate it. They allocated more full-time equivalent (FTE) resources to supply chain operations and quality management, and they invested a significant amount of capital in raw material inventory. Management was also concerned about on-site warehouse capacity for direct receipt of raw materials in the event that campaign manufacturing volume continued to increase.

Solution

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

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

Key observations and findings included:

- Operational inefficiency in managing multiple suppliers and distributors
- Operational inefficiency in product supply planning
- Poor on-time in-full (OTIF) delivery performance from direct suppliers
- Significant quality management activity related to product nonconformances
- Evidence of excessive supply chain expenditures for noncore activities
- Warehouse above 90% capacity
- Instances of direct material overflow in the warehouse

- Supply chain operations negotiating with suppliers to hold product shipments due to space constraints, with mixed results
- Supply chain operations requiring expedited shipments
- Supply chain management securing bids for off-site storage

To address these business challenges, Thermo Fisher offered to consolidate production sourcing. This included:

- **Supplier management**—reducing supplier management complexity and resource requirements by facilitating pricing, supplier audits, quality agreements, and ongoing supplier management
- **Order management**—reducing the amount of time and resources associated with managing supplier orders; resolving issues and changes in expected ship dates; improving communication about OTIF performance; and facilitating alternative supply sourcing when needed
- **Material receipt, material handling, and outbound logistics management**—managing vendor errors as part of the inbound receipt process; consolidating shipments; and reducing the time and cost associated with warehouse activities at the time of receipt
- **Quality management system**—providing management of change (MOC) and change notifications; managing quality agreements; and resolving quality issues identified during inbound product receipt to reduce the overall time and cost associated with supplier errors, poor quality, and corrective and preventative action (CAPA)
- **Procurement**—providing the company with flexible ship dates; leveraging a CGMP-compliant warehouse for short-term storage of inventory to address limitations in warehouse capacity and flexibility; and reducing the need for expedited shipping

Result

By taking advantage of the procurement and order management services offered by Thermo Fisher along with our validated quality management system* (QMS), technology systems, and CGMP- and GDP-compliant warehouse, the company was able to reduce the complexity and cost of production chemical management and significantly reduce the risk of production delays. The company was also able to reallocate supply chain FTE resources, reduce its operating and working capital expenditures, and mitigate capacity constraints in its facility. Collaborating with Thermo Fisher enabled the company to dedicate more human and financial resources to managing its growing campaign manufacturing volumes to meet patient demand.

The company experienced:

\$345K savings

by reduction in production delays

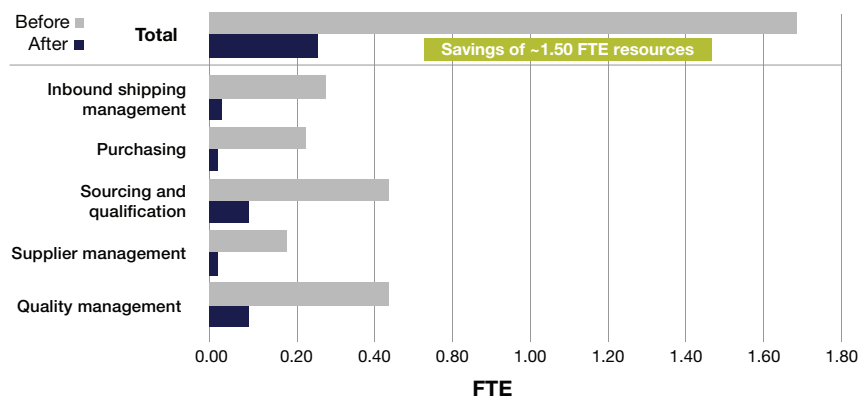
\$123K savings

in FTE costs

\$120K savings

in working capital

Client FTE resource savings: Before and after implementing Thermo Fisher support



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

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