

Reducing lead time, delivering >99.5% OTIF

CGMP- and GDP-compliant inventory management

Situation

A midsize contract development and manufacturing organization (CDMO) was confronted with a potential increase in capital expenditure related to expanding its direct raw material warehouse capacity to support customer portfolio growth. Holding large volumes of safety stock, or extra inventory, was necessary to address long lead times for critical raw materials and variable on-time in-full (OTIF) performance from suppliers. This put the CDMO in a suboptimal working capital position.

Management was anxious about the company's ability to build and validate a new warehouse in time to accommodate the required inventory growth. They estimated that a 15,000 ft² expansion was necessary to meet business objectives. Options that would reduce the need for capital expenditure were a high priority.

Solution

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

- Assessed raw material inventory levels required for production by product SKU to evaluate supply availability based on the unique interplay between the company's projected demand and supplier lead times

Key observations and findings included:

- Variable and poor OTIF performance from direct suppliers
- Lengthy lead times from direct suppliers (up to 85 days for some raw materials)
- Excessive safety stock held to compensate for long and variable supplier lead times

- Frequent manufacturing interruptions and campaign changes
- Frequent need to expedite shipments
- Warehouse at >95% capacity

To address these business challenges, Thermo Fisher proposed a stocking agreement for critical and routine chemicals. Under the agreement, the materials would be held in a Thermo Fisher warehouse* that complied with Current Good Manufacturing Practices (CGMP) and Good Distribution Practices (GDP) for off-site inventory management.

The solution included:

- Analyzing and documenting critical material lead times and OTIF performance
- Aligning the company's projected demand with the material lead times entered in its enterprise resource planning (ERP) system
- Calculating the amount of safety stock that would need to be held in a Thermo Fisher CGMP warehouse to enable one-day lead times and eliminate expedited shipping fees
- Executing the defined safety stock agreement between Thermo Fisher and the CDMO
- Thermo Fisher ordering and holding safety stock for just-in-time (JIT) delivery

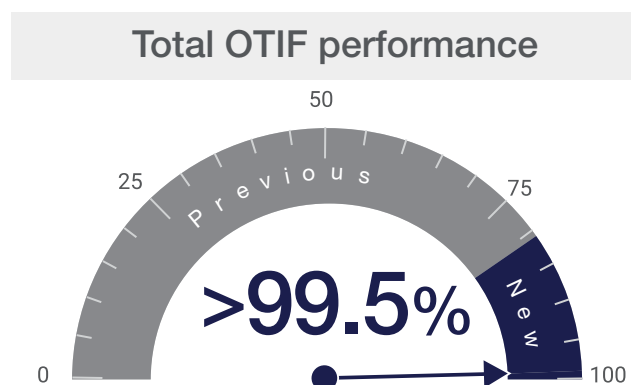
* Certified ISO 9001:2015 Quality Management System incorporating applicable elements of 21 CFR Parts 210 and 211 and the IPEC Good Distribution Practices Guide.

Result

By taking advantage of the chemical inventory management services offered by Thermo Fisher, which included a safety stock agreement and holding inventory in a CGMP-compliant warehouse, the CDMO reduced its capital requirements for inventory and warehouse expansion. Collaborating with Thermo Fisher significantly reduced the need for on-site warehouse capacity and associated CGMP and hazardous material storage compliance. It also helped significantly reduce material lead times and improved OTIF performance to >99.5%. Reducing the company's on-site inventory storage requirements enabled more efficient use of warehouse space and full-time equivalent (FTE) savings on material handling. This allowed the CDMO to allocate its human and financial resources more effectively to support customer portfolio growth.

As a result, the company experienced:

- **\$2.5 million cost avoidance in one-time capital expense** due to cost avoidance for new warehouse expansion
- **>99.5% OTIF delivery**, representing a 17% improvement
- **\$359,000 annual savings** in warehouse operating expense (OpEx) to support material storage and handling
- **\$120,000 annual savings** in inventory carrying costs
- **\$120,000 annual savings** through elimination of expedited shipping fees



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