Enhance the cost-effectiveness of your cGMP chemical supply chain

Supply chain issues have real, quantifiable impacts on biomanufacturers. Today, manufacturers face a host of challenges to making new, life-saving therapies and vaccines a reality. In particular, increased shortages of several raw materials are hampering production efforts.

Costs associated with supply chain issues are part of the total cost of ownership, or TCO. Unlike the material cost, supply chain costs (and thus the TCO) are well within an organization's power to contain and control. Accurate accounting and management of TCO can help companies achieve new levels of cost efficiency, minimize risk, and accelerate their ability to bring vital products to market.

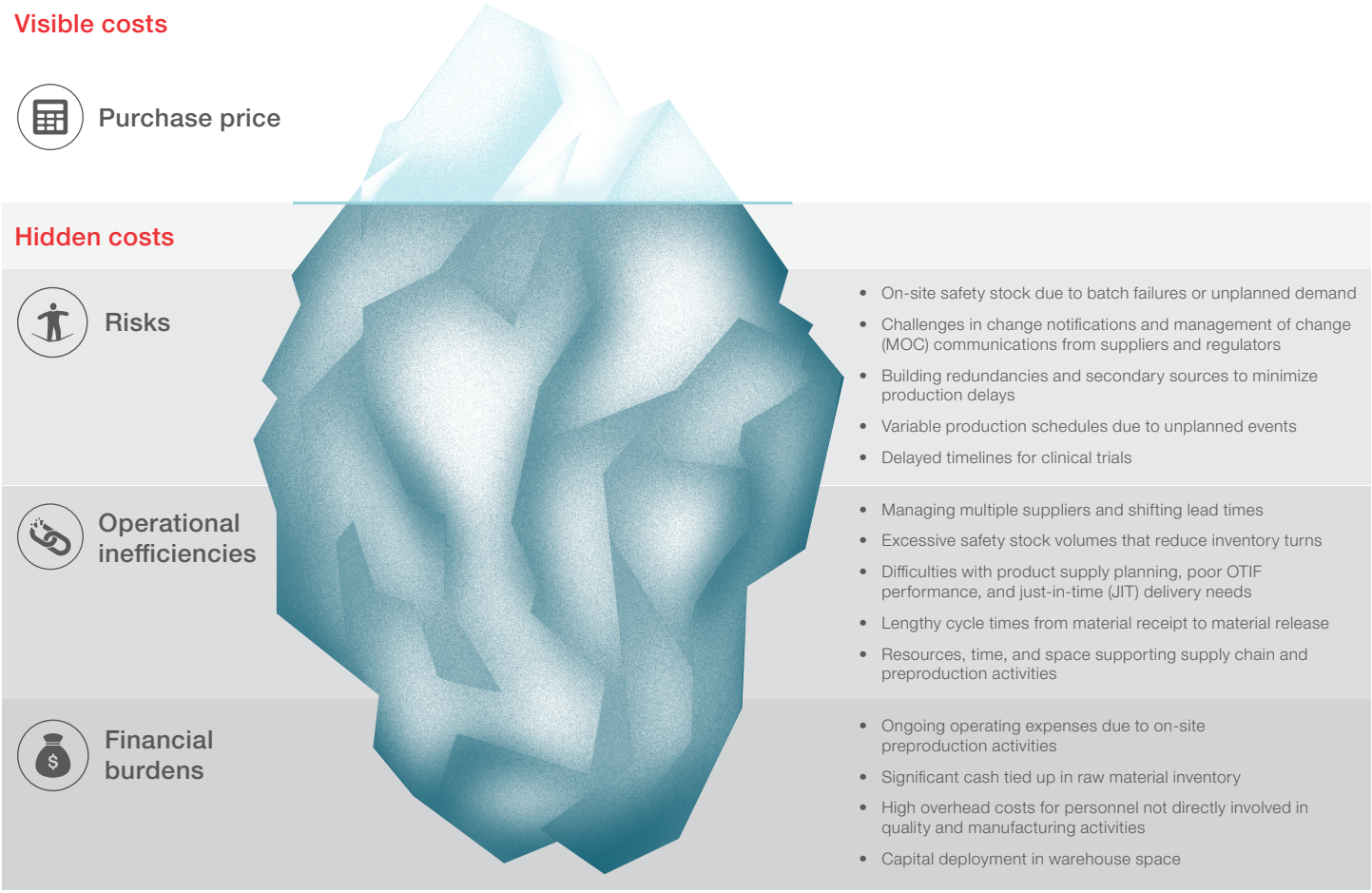

Figure 1. TCO touches several areas that can adversely impact speed to market.

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Inclusions for total cost of ownership

Generally, manufacturers include the face value of process chemicals and core labor that are compliant with current good manufacturing practices (cGMP) when calculating TCO. But TCO accounts for so much more, as detailed in Figure 1.

TCO also includes support personnel, equipment, facility footprint, and time required to complete all processes from procurement through preparing product to be used in manufacturing. The cost of inefficiencies is also part of the TCO, and this can quickly compound—in some cases even growing to overshadow visible costs. These hidden costs—from poor on-time, in-full (OTIF) performance from suppliers to facility inspection failures—impact the ability to mitigate risk and optimize operational efficiencies.

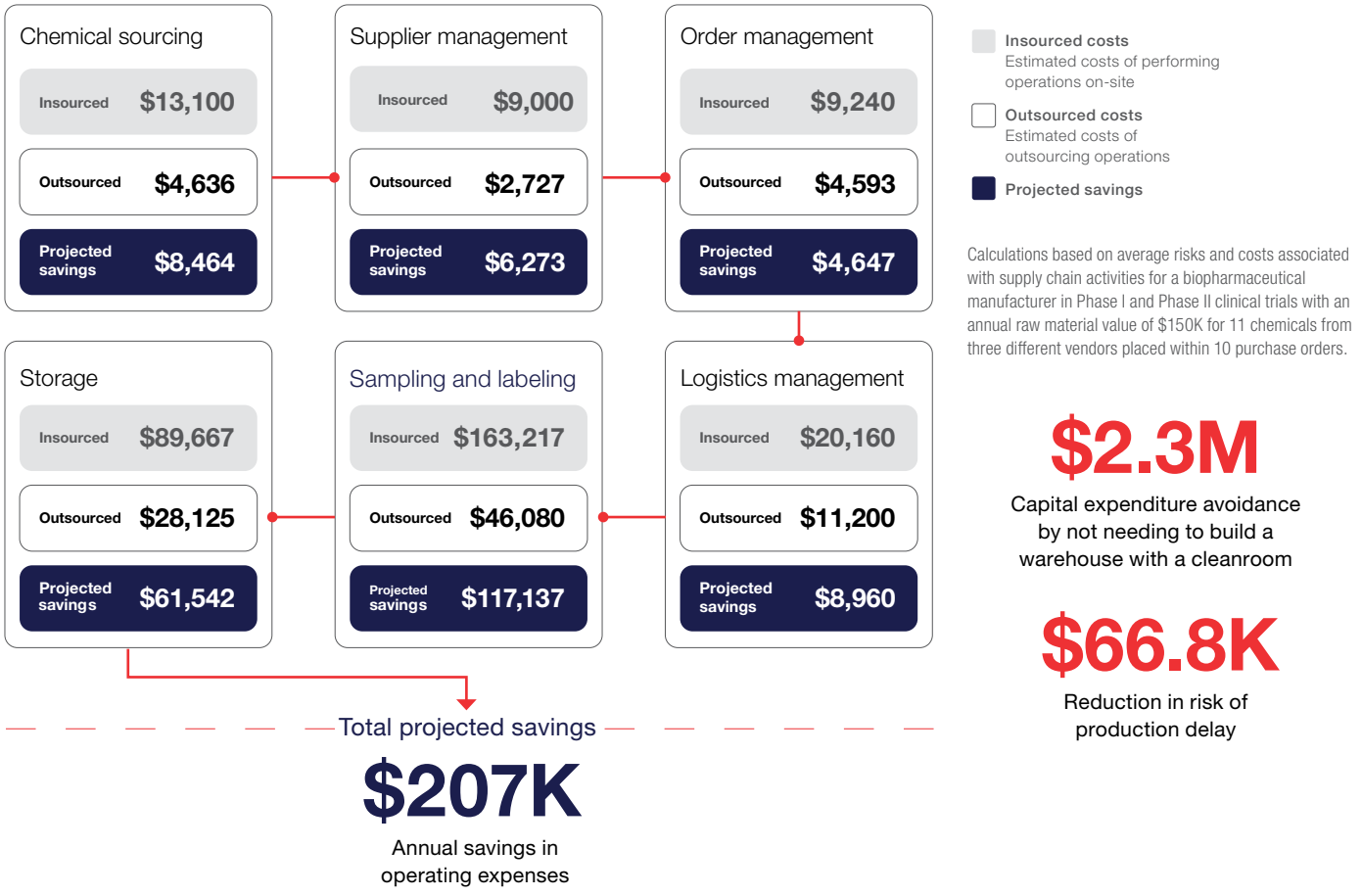
Calculating TCO for cGMP chemical supply chain

While TCO varies from facility to facility, there are some clear costs that are associated with certain activities in a biomanufacturer's cGMP chemical supply chain. Figure 2 below shows an example of costs observed throughout the supply chain, based on a biopharmaceutical manufacturer preparing product for Phase I and Phase II clinical trials.

Sourcing and managing cGMP chemicals can be resource-intensive—requiring investments in cGMP-compliant space, skilled personnel, equipment, time, and more—throughout the supply chain. When a company insources chemical supply chain management by working directly with the individual suppliers, the company will increase their TCO and assume all risks, which will in turn hinder valuable resources, like those previously mentioned. Alternatively, outsourcing supply chain management activities can help companies realize a reduction in their assumed level of risk and TCO, as well as realize an increase in operational efficiencies with resources no longer encumbered.

Overall, projected savings from the outsourcing of biomanufacturing activities can run into the millions of dollars, from annual savings of $207,000 for operating expenses and $66,800 from reducing the risk of production delays to $2.3 million in capital expense avoidance.

Figure 2. Cost-effective cGMP chemical sourcing and supply chain management



CASE STUDY

Improving cGMP chemical supply with outsourcing assistance

Mitigating cGMP chemical supply disruptions with an outsource service provider can bring significant benefits to a biomanufacturer, including significant reductions in TCO.

A midsize contract development manufacturing organization (CDMO) was holding high volumes of safety stock inventory to address the variability in critical raw material lead time and supplier OTIF performance. Site leadership was challenged to consider building a new 15,000 square-foot warehouse to meet massive customer demand.

To better understand the situation's impact on the CDMO's operations, lean specialists from Thermo Fisher Scientific facilitated a Gemba walk of the company's process ecosystem to uncover potential areas for improvement. Observations from the Gemba found that in addition to the CDMO's high volume of inventory and poor OTIF performance from direct suppliers, they were also experiencing the following:

- Extremely variable lead times (up to 85 days) with nonproactive and nonresponsive suppliers
- Frequent manufacturing interruptions and campaign changes
- Recurring needs to expedite shipments
- A nearly full warehouse, running at >95% capacity

In response, Thermo Fisher worked with the CDMO to document critical material lead time and OTIF performance that aligned with the forecasted demand reflected in Enterprise Resource Planning (ERP) software. This enabled the CDMO to calculate and plan the precise amount of safety stock required to be held at a Thermo Fisher cGMP warehouse for JIT delivery. Additionally, a custom stocking agreement was established for critical cGMP chemicals to be stored also at a Thermo Fisher cGMP warehouse, alleviating space constraints at the CDMO's site. This combination of cGMP Distribution Services and Assurance of Supply Services from Thermo Scientific™ Production Chemicals and Services enabled the CDMO to focus its resources on core manufacturing activities.

As a result, the CDMO reduced their capital requirement for inventory and warehouse expansion, significantly reduced the need for on-site warehouse capacity, cut material lead times, and improved OTIF performance to >99.5%. This translated into $2.5M savings in one-time capital expenses by avoiding the cost of a new warehouse, $359K annual savings in warehouse operating expenses, $120K annual savings in inventory carrying costs, and $120K in annual savings from eliminating expedite fees.

This CDMO—and dozens of others who have engaged Thermo Fisher—ultimately came to understand the entirety of their calculated TCO and how both direct and indirect decisions can significantly affect it.

Results

$2.5M savings
Warehouse expansion avoided

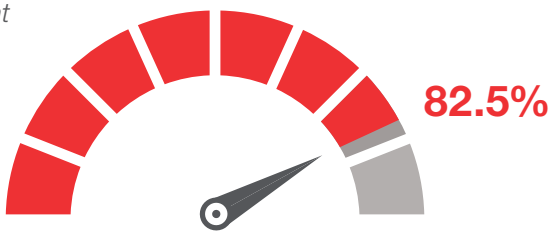
$359K annual savings
Warehouse operating expenses

$120K annual savings
Inventory carrying costs

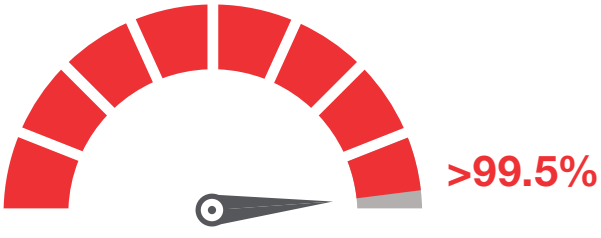
$120K annual savings
Expedite fees eliminated

>99.5% OTIF performance
17% improvement

Improvement in OTIF



Starting OTIF performance



Ending OTIF performance

How we can help

Thermo Scientific Production Chemicals and Services can help reduce TCO. As in the case of the CDMO mentioned here, our lean specialists can conduct an on-site Gemba walk through your cGMP chemical supply chain.

In a world of accelerating breakthroughs and meeting patient needs, Thermo Scientific Production Chemicals and Services enables biologics developers and manufacturers to do what they do best: produce life-changing therapeutics and vaccines.

Find out more at **thermofisher.com/tco**

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