Understanding the hidden value of quality

by James Fell

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Like most businesses, biomanufacturers must allocate their finite resources to the best uses to be successful. While quality-related activities are not necessarily thought of as revenue generating, they are resource-intensive and certainly critical for success. An experienced distribution and service provider can help reduce the cost of quality while maximizing the chance of success. Thermo Fisher Scientific knows that attention to quality in the beginning mitigates risks, improves operational efficiencies, and reduces the costs of poor quality (COPQ).

The raw materials supply chain is too vital to leave to chance. Entrusting supply chain management to an organization with deep supply chain experience—one that can anticipate potential pitfalls, mitigate those risks, and provide operational efficiencies—can help insulate companies from COPQ. This allows those companies to concentrate on allocating their resources to what they do best: producing life-changing drugs.

A reconsideration of quality management

Here are the elements of quality management that can make all the difference when collaborating with an organization that views quality as a value-add activity:

- **Quality Management System**—A quality management system (QMS) identifies and manages processes and resources to meet customer requirements. Ultimately, the quality of an organization's services is determined by their ability to satisfy customer needs and by the value and benefit perceived by the customer.
- **Order and supply chain management**—Effective order and supply chain management helps ensure compliance to customer requirements at every step: from order, to storage, to shipment, to delivery, and beyond. This is facilitated through a deep understanding of regulated raw material requirements and complex supply chain requirements. Key components are the alignment of material processes with customer requirements and expectations, and the drive to exceed those expectations.
- **Material receipt**—A documented, multistep material inspection upon receipt verifies conditions and compliance to the customers' requirements to identify non-conformances (flaws or errors). Non-conformances are immediately tracked, reviewed, and resolved in collaboration with the vendor before the material is ever delivered to the customer, thereby becoming an integral part of vendor management.
- **Handling and storage**—The raw material is stored in a cGMP warehouse under controlled conditions according to product and customer requirements. The material is segregated for chemical compatibility and to prevent comingling of product. Non-conforming products are electronically and physically isolated to prevent inadvertent shipment.
- **Picking and shipping**—Picking and shipping are optimized through documented processes that utilize continuous improvement. State-of-the-art scanning technology is used to locate, pick, and verify materials. Additionally, a three-way match helps complete the confirmation of picking accuracy and compliance to customer requirements.

COPQ cannot be overstated. Our experience indicates there is about a 9% chance that an inbound shipment has an order error of some sort (e.g., incorrect material, quantity, or missing customer requirements), and it is equally probable that the material received is damaged or has label quality issues.* A distributor with a robust QMS can help effectively shield customers from these issues, maximizing a company's operational efficiencies by minimizing time-consuming and expensive corrective and preventative actions (CAPA). The average cost today to implement a CAPA is conservatively $3,000*—never mind the production delays due to lack of raw material. It does not take long to realize the value of a distributor with an effective QMS.

9%

Chance an inbound shipment has an error of some sort

$3,000

Average cost to resolve an order error (e.g., incorrect material or quantity, damaged shipment, labeling error)

Case study

Minimizing COPQ

Recently, a biopharmaceutical company was facing increased campaign volumes. Management, concerned about potential increased risk of production delays, contacted Thermo Fisher Scientific.

To better assess the company's needs, we reviewed their chemical bill of materials (BOM) and facilitated a Gemba walk that revealed:

- Operational inefficiencies in managing multiple suppliers
- Poor on-time-in-full (OTIF) performance from direct suppliers
- Significant quality management activities due to material non-conformances
- A warehouse at >90% capacity
- A supply chain requiring expedited shipments

Taking advantage of our documented processes, the company helped reduce the complexity of managing their suppliers. Our team was able to resolve quality issues identified during inbound product receipt prior to the product reaching the customer. Our process experts were also able to introduce more flexible shipping dates by leveraging the cGMP warehouse for short-term inventory holding.

As a result, the company realized $345,000 in savings due to reduced production delays, $123,000 in resource cost savings, and $120,000 in working capital savings.

Results

$345K
saved due to reduced production delays

$123K
saved in resource costs

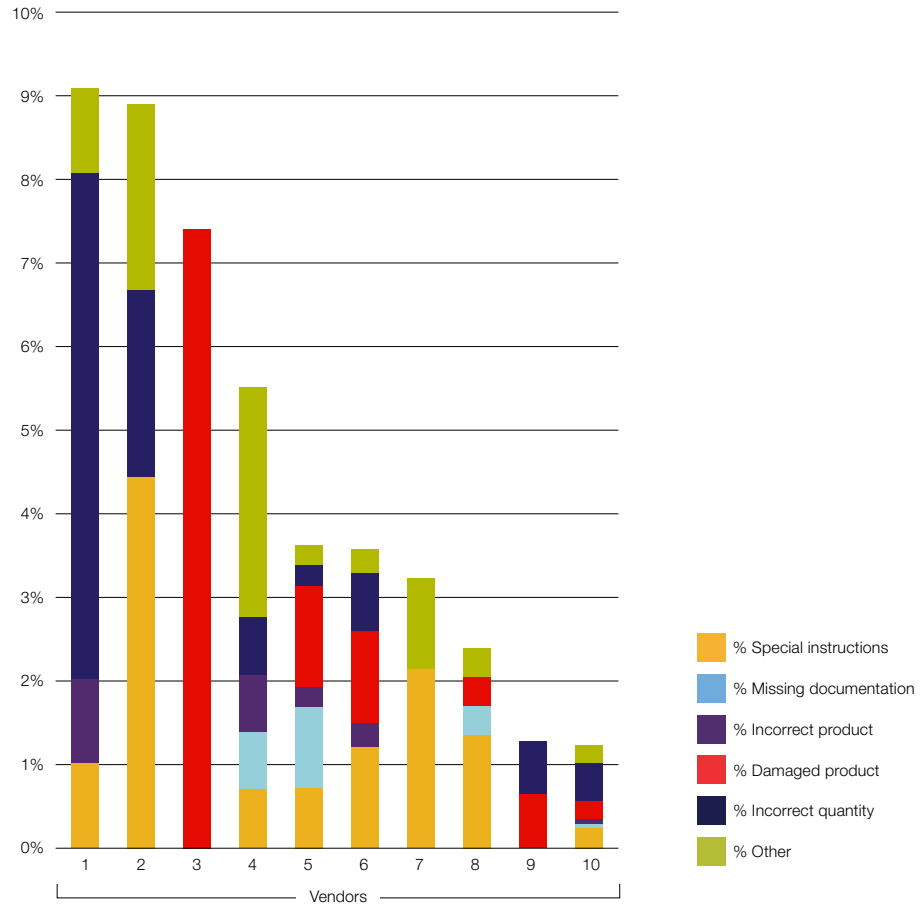
$120K
saved in working capital

This scenario is common and occurs within many companies. In our decades of supply experience, we have seen contingency stock inherently increase when demand across the industry increases in anticipation of problems in the supply chain. Figure 1 shows the most prevalent errors we observed in Q4 of 2020 during the recent pandemic and ramp up for vaccine and therapeutics production.

Non-conformances are an unfortunate inevitability. The first quarter of 2021 revealed that 4.5% of chemicals received by our Production Chemicals and Services team had some type of non-conformance. Of those errors, 27% were traced to mixed lots or incorrect lot numbers, 20% to damaged materials, and 19% to non-compliance to customer requirements.*

Figure 1

Q4 2020 vendor performance—percent flawed receipts by vendor issue

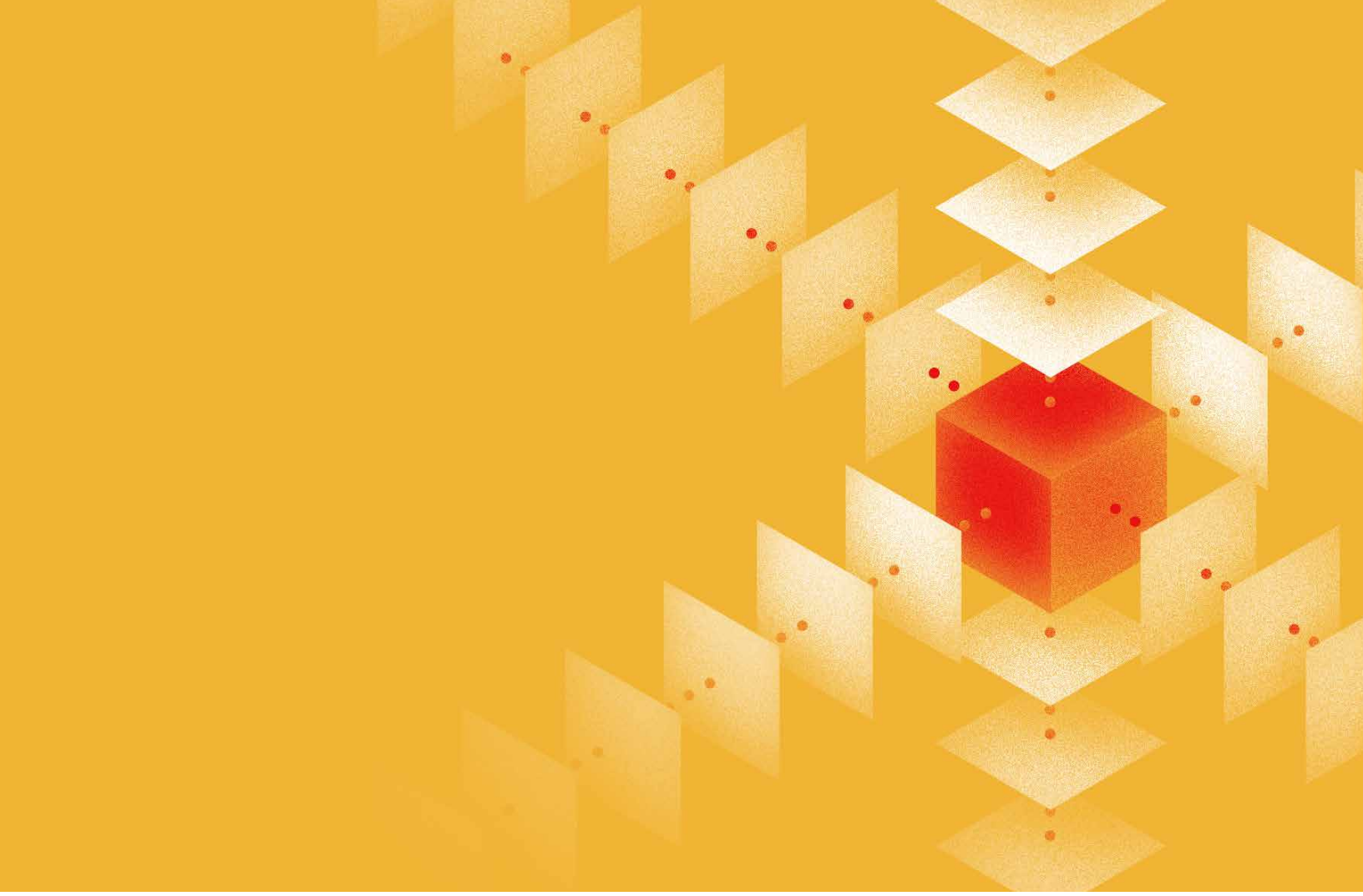


Quality and non-conformance issues intercepted by Thermo Fisher Scientific, Q1 2021

19%
of flawed orders had specification errors when received directly from suppliers

20%
of flawed orders were damaged when received directly from suppliers

27%
of flawed orders were traced to mixed lots or incorrect lot numbers



Trust and experience

The Production Chemicals and Services team can help simplify and streamline your supply chain processes at various stages. Startups may need extra support with strategies to scale up manufacturing, though larger organizations are not immune to these challenges. By working with us, you can start thinking of your supply chain as a resource, rather than a risk. This perspective can allow your organization to do what it does best: innovate and produce life-changing drugs.

* Derived from Thermo Scientific™ Production Chemicals and Services reports and studies.

Find out more about our supply chain services at
thermofisher.com/supplychain

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