

Establishing a resilient cGMP chemical supply chain

Today's biopharmaceutical innovators and contract development and manufacturing organizations (CDMOs) face no shortage of challenges in their current good manufacturing practices (cGMP) chemical supply chain operations. Materials can suddenly be in short supply, leaving manufacturers to compete for increasingly scarce, yet vital, materials.

There are many approaches to enhancing the resiliency of a supply chain and identifying inefficiencies and added costs in a biomanufacturing workflow. It's important to arrive at a total cost of ownership (TCO), which only emerges from a holistic examination of your total workflow. Arriving at TCO can be made easier by applying Lean Six Sigma™ methods or another process framework to the totality of your supply chain. A chain is only as strong as its weakest link; that is why the entirety of your supply chain should be considered before building resilience into your workflow. Here are the most important considerations to make.

Start with sourcing

Biomanufacturers are increasingly concerned about price and supply pressures. Sourcing is one of the critical starting points for many companies looking to purchase directly through a supplier or a distributor.

But sourcing doesn't end with the identification of chemicals and management of multiple suppliers. Successful sourcing means that a chemical will be delivered in the desired quantity, at the specified quality, where and when it is needed. This helps keep your workflows and production schedules intact. Visibility and transparency from suppliers and distributors are crucial. A trusted service provider with decades of experience can help with the much-needed analysis of your whole supply chain, as well as planning ahead for production scale-up and subsequent commercialization. This analysis includes the identification of alternate suppliers to mitigate your risks associated with supply disruptions.

Check your cGMP supply resiliency

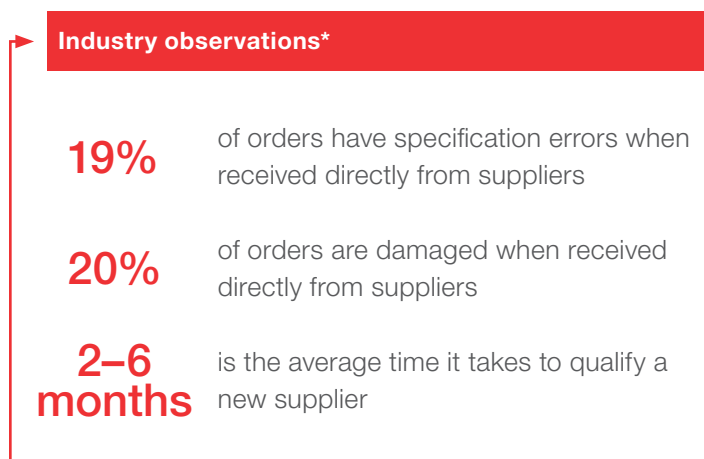
- Do your suppliers have support teams dedicated to understanding and improving your sourcing strategies of key cGMP chemicals?
- Are your suppliers' quality management systems (QMS) appropriately focused and adapted to meet your requirements?
- When there have been changes in your orders and lead times, have your suppliers' communications been more proactive than reactive?
- Are your suppliers delivering quality-compliant product to meet your order and supply planning needs?

An organization that increases supply chain resiliency every day for a broad range of chemical classes can make a difference. Such a service provider understands how to work with both primary and secondary sources, as well as help forecast demand to avoid supply disruptions.

Biomanufacturers in 2018 and 2019 saw global, industry-wide supply shortages for sodium hydroxide, amino acids, isopropanol, and guanidine thiocyanate. In 2020 and 2021, some of these shortages have persisted, with extended lead times of up to 52 weeks for basic chemicals. A trusted service provider can mean the difference between a fulfilled order and an extremely delayed one.

Map the supply chain

When cGMP chemicals do not conform to your specific quality requirements, it results in added expenses and resources. These problems can arise when companies choose to manage several individual suppliers on their own without establishing an alternative sourcing strategy.



Trusted support from an experienced service provider can help mitigate these very real risks. Such a provider can conduct a Gemba Walk, which will effectively “map” your chemical supply chain to identify its potential risks, bottlenecks, and inefficiencies.

A fact-based assessment of processes can assist in the development or improvement of cGMP chemical sourcing workflows—from procurement to delivery—that can help companies realize significant savings and efficiencies.

Gain peace of mind

By anticipating manufacturing needs, it is possible to reduce risk and avoid the prospect of supply disruptions, from supply for scale-up to production demand.

But not all service providers are alike. Typically, a supplier is focused solely on the transaction. An exceptional supplier, however, draws on decades of applying qualified systems and processes to meet your cGMP chemical sourcing requirements. Such a supplier is a timely communicator—especially around the management of changes or change notifications—and has an excellent record of compliance with customers’ purchase and storage requirements. They also bring tested training protocols and documentation practices to the table.

Thermo Fisher Scientific works with customers to manage the totality of their supply chain challenges, from sourcing through delivery. We offer a robust suite of supply chain services surrounding the cGMP chemicals our customers need, including the aforementioned service features as well as:

- Primary and alternative sourcing assistance
- Order and supplier management
- Supply chain transparency and documentation
- Customer-focused QMS

Drawing on more than 30 years in the industry, Thermo Scientific™ Production Chemicals and Services take on the work of right-sizing your key cGMP chemical orders and delivering on it. Together, we can help identify and design resilient supply chain processes to help meet your cGMP chemical needs for your bioprocessing workflow.

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

Connect with us to start building your resilient cGMP supply chain at thermofisher.com/innovateproductivity

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