

## Crisis Management

### COVID-19 exposes supply risks for emerging Life Sciences companies



As an emerging company, does your team have the framework and experience to manage suppliers during major disruptions?

Many emerging life sciences companies are ill-equipped--compared with larger companies--to deal with major disruptions like the COVID-19 pandemic. They often have limited budgets, capabilities, staff and systems, so depend more on suppliers to quickly scale up and meet business objectives. For some of these companies, the COVID-19 crisis exposed their inability to manage procurement and supply chain operations, adversely impacting business performance.

Although the world is anxious to see vaccines deployed and a return to some level of normalcy, it will take time for population (herd) immunity to develop – perhaps well into 2022, according to the World Health Organization (WHO). In the meantime, companies must continue working with suppliers to achieve their targets.

During the past year we have worked with emerging life sciences clients to help them adjust their overall supply chain framework to successfully manage through this crisis. While each company used a framework unique to its own needs, successful companies initiated the following actions:

1. Analyzed COVID-19's impact on their supply chain and operations
2. Strengthened collaboration with critical suppliers
3. Assessed the strategic role of procurement and sourcing for their organization

## 1. Analyzed COVID-19's impact on their supply chain and operations

As an example: a spike in global demand for glass vials and packaging materials needed for the COVID-19 vaccine directly impacted three downstream supply markets: (1) vials and packaging material for all vaccines and medicines, (2) raw material for the vials and packaging materials, and (3) logistics services (cold chain and others) needed to move materials through the supply chain.

Global supply chain disruption for all goods and services caused major unanticipated supply market consequences.

To address this disruption, we helped our clients understand and address potential shortages of any “vial like material” in their own supply chain to enable them to pre-purchase and stockpile critical raw materials. Although many companies were in “survival mode” early in this crisis, they learned to evaluate their supply chain processes, policies and systems and develop a **systematic** approach as opposed to a **reactive** and resource intensive approach. In some cases, this evaluation revealed a need to change how procurement, legal, finance and technical operations staff worked together to negotiate, amend and execute supply agreements.

Enactment of legislation to ensure security of supply for API, excipients and packaging materials for US based companies.

This crisis made both the industry and the US Government more aware of the risk of offshoring key technical drug development and manufacturing knowledge—such as the decades long outsourcing of fluorination chemistry to China and India primarily for cost savings. To counteract the risk of critical material shortages because of such sourcing decisions, Congress incorporated financing into the CARES ACT of 2020 (and other legislation) to authorize funding of US produced API and other critical pharmaceutical material.

As a result, executives and their procurement teams realized that decisions to offshore production of strategic materials to low-cost countries needed to change, particularly for essential chemical compounds. Although changing suppliers from offshore to onshore takes time to evaluate, negotiate and qualify, our clients now see the importance of preparing for supply market changes, and have the tools to identify US suppliers and evaluate good sourcing options based on capability, cost and risk.

## 2. Strengthened collaboration with critical suppliers

Most established life sciences companies have long-term, collaborative supplier relationships that can help them manage through crises. In contrast, early-stage companies, by their nature, generally have only short-term relationships, which can limit their ability to solve problems in a crisis.

As an illustration of pandemic induced market volatility, from March through May, supply of many products varied daily from shortage to surplus as the market adjusted to the crisis.

As governments such as China and India prioritized distribution of essential drug material for their own healthcare needs, they placed export restrictions on those key raw materials and supplies for the US. Other services like clinical trials required coordinating work with CRO's and the use of CTMS software to incorporate COVID regulations to manage patients, facilities, and clinical supplies. While clients and their suppliers expended significant resources to address these shortages, as the pandemic continued, several took the lead to develop a better supplier collaboration process.

A company in the pre-clinical stage that focused on small molecule development took stock of its relationships with strategic suppliers and decided to strengthen those relationships, recognizing the need for supplier/client collaboration as it grew. By undertaking this effort, they were able to anticipate potential issues in a number of areas and strengthen supplier management processes around risk management in both drug development with CRO’s and indirect purchases of lab supplies.

### 3. Assessed the strategic role of procurement and sourcing for their organization

Just as this crisis jump-started the use of connectivity/collaboration technology across society to help deal with quarantine requirements, it also pushed clients to assess the strategic role of procurement and sourcing, and how it should be organized. In an emerging company, knowledge of qualified suppliers usually starts with executives and department leaders, but as the company grows, oversight of the supply base needs to be institutionalized into a formal procurement and supply chain function.

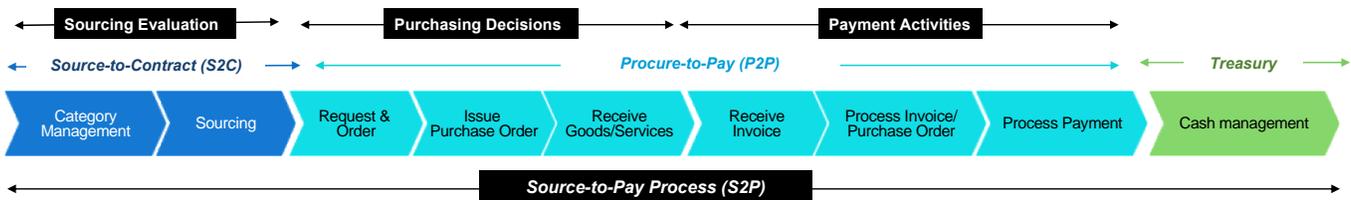
A client working on cell and gene therapy realized during this crisis that its supplier contracts were less than favorable in terms of cost and production flexibility. In reviewing their sourcing process, they saw that over the past couple of years, different functions had been trying to “negotiate the best deal” on their own. By failing to look at sourcing agreements from a “strategic supplier management” perspective, their procurement framework had become neither efficient, collaborative nor cost effective.

As a result, they devised a plan to restructure their current sourcing process across organizational responsibilities, systems, policies and metrics in ways that supported their strategy, providing a clearer understanding of the resources required to source and manage suppliers.

#### The art of creating a scalable procurement framework

Consider the change in an emerging company’s procurement phases as it moves from pre-clinical to clinical and eventually, commercialization. In a 12–18-month period it can grow from managing 100-250 suppliers to managing 1,000-1,500 suppliers. Such rapid growth puts pressure on staff and supplier relationships, creating risk across the supply base.

To mitigate this risk and build a scalable procurement and supply management function, a company must understand the steps, actions and levers needed to efficiently purchase goods and services. The diagram below presents those steps:



*By strategically deploying the following levers, companies can build a scalable operating model to efficiently manage suppliers, costs and risks*

Lever	Scope
Organization Structure	Procurement & supporting staff structure responsibilities needed to purchase goods & services
Process & Policies	Steps and requirements involved in the purchase of goods & services
Systems & Tools	Templates and systems (ERP and e-Procurement) needed to efficiently purchase goods and services
Metrics	Supplier performance, financial, risk and procurement metrics needed to efficiently manage the S2P process

Although the idea of scalable procurement is easy to understand, as a company finds itself rapidly growing its supply base, a poor process can quickly become challenging to manage. To build a scalable and efficient procurement framework, many companies use the following levers to successfully manage suppliers, cost and risk.

Reaping the benefits: As a result of several successful product launches, one company, focused in rare disease treatment, was experiencing the kind of rapid sales growth described earlier. While they had elements of a procurement process in place – contract management, policies and a finance system to pay invoices—they saw a need for an integrated and scalable “procurement framework”. Working with their finance, legal, compliance, IT and department leaders to deploy this framework, they realized the following benefits:

- Improved levels of trust with stakeholders and suppliers to develop supply contracts
- Integration of sourcing process and policies with the corporate risk management process
- Financial savings and improved budget management to meet quarterly and annual fiscal goals

While COVID-19 impacted all aspects of business and in some cases created significant hardship, our client’s ability to strategically look at their suppliers and procurement process allowed them to maintain their growth and meet their business targets.

## About Tunnell Consulting

Founded in 1962, Tunnell is an employee-owned company that is exclusively focused on Life Sciences companies and healthcare related government agencies. As such, Tunnell supports the mission and objectives of a variety of organizations, including start-ups / emerging companies, established bio/pharmas, CMOs, the U.S. Government, and investors. We integrate strategic, technical, process, quality, regulatory, organizational, manufacturing and staffing expertise to design and implement sustainable solutions that meet our clients’ needs. Headquartered in King of Prussia, PA with offices in Cambridge, MA and Bethesda, MD, Tunnell combines deep industry knowledge and scientific credentials that result in measurable results that boost the operating performance of each unique client.

For more information please contact:

**Dave Stowe**  
(847) 530-9081

[david.stowe@tunnellconsulting.com](mailto:david.stowe@tunnellconsulting.com)

**Bill Connell**  
(610) 662-6615

[bill.connell@tunnellconsulting.com](mailto:bill.connell@tunnellconsulting.com)

**Jonathan Horn**  
(865) 577-4440

[jonathan.horn@tunnellconsulting.com](mailto:jonathan.horn@tunnellconsulting.com)