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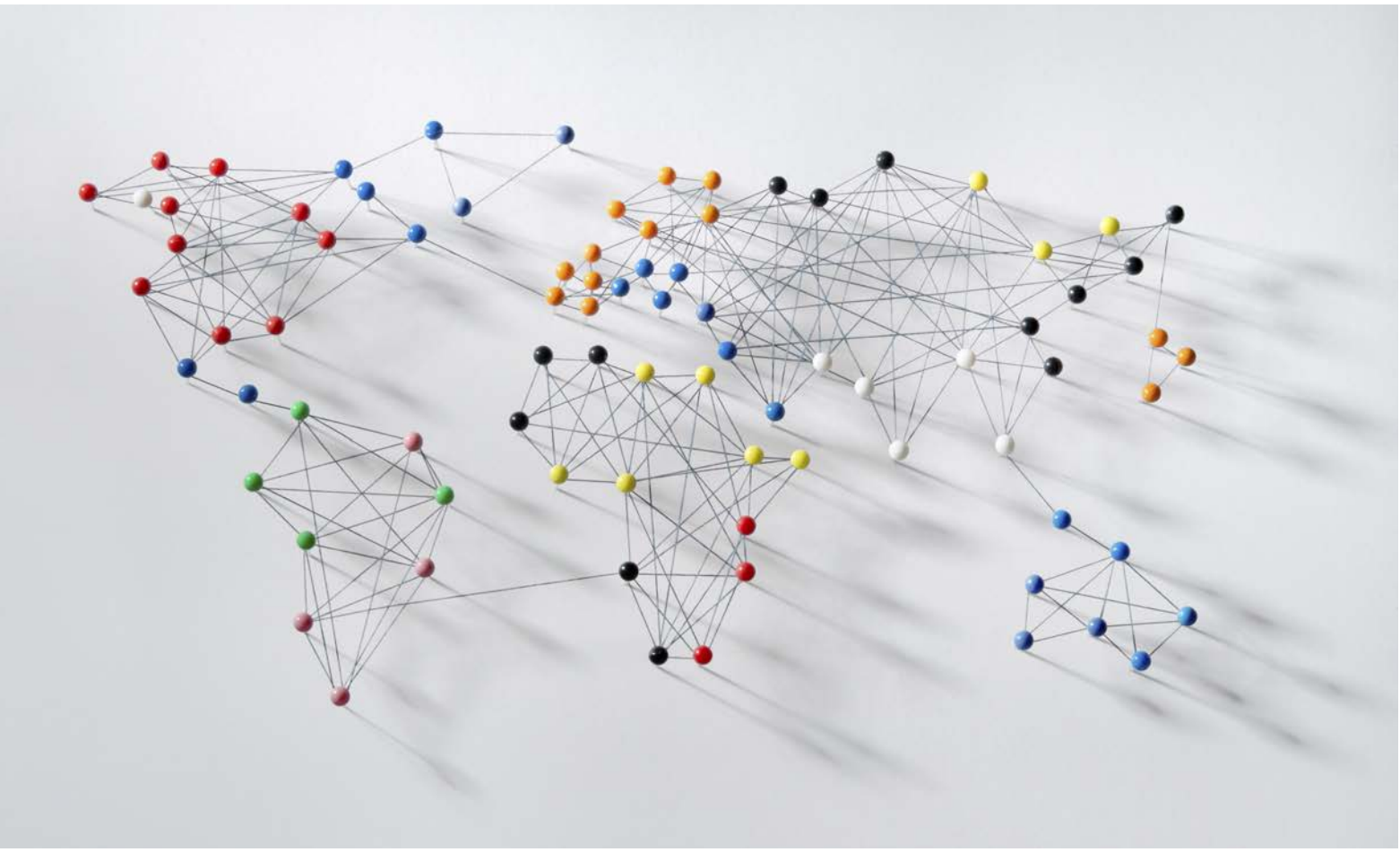

MADE WITH SPEED & SCALE

WHITEPAPER

# Bulletproof your supply chain: Hope for the best, prepare for the worst

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• API • BIOLOGICS • VIRAL VECTOR SERVICES • EARLY & LATE PHASE DEVELOPMENT • CLINICAL TRIAL SOLUTIONS • LOGISTICS SERVICES • COMMERCIAL MANUFACTURING

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# Abstract

Hope is not a strategy in drug manufacturing. You need a contingency plan to protect your company and your customers if the worst-case scenario occurs. In formulating this plan, it is critical to assess where your company's supply chain is vulnerable and to take the necessary steps to address those risks.

This whitepaper provides insights into why it is critical to manage, optimize, and streamline a supply chain. It also explores how to incorporate flexibility in planning to overcome potential challenges, the value of having a contingency plan, and how to use a risk-based approach to determine where a contingency plan is needed. Experts describe how to best combine supply chain management and logistics expertise to build a nimble and efficient operation that can help to mitigate risks, such as those brought on by the COVID-19 pandemic.

## Supply interruption probability is increasing

Supply chain interruptions can affect the pharmaceutical and healthcare industries in several ways. First and foremost, supply chain disruptions—be they product stock-outs, limited supply, delayed clinical trials, or stalled marketing launches—can negatively impact the lives of patients who rely on access to much needed and, in some cases, life-saving medication.

Unforeseen supply chain disruptions can be felt globally, regionally, and locally, and result from numerous factors such as natural disasters, transportation events like port strikes, and pandemics. For instance, the unprecedented COVID-19 pandemic is an example of an event that caused major supply chain interruptions in 2020 and heightened the debate about the location of API manufacturing and where raw materials are sourced1. A 2019 report from FDA's Center for Drug Evaluation and Research estimated 72% of API manufacturers supplying the US market were located overseas, with 13% of those sites located in China[2]. COVID-19 management strategies highlighted challenges with logistics and human resources, manufacturing shutdowns, and export constraints—all of which disrupted a wide range of services and supplies in various manufacturing industries worldwide[3]. In the global pharmaceutical market, resilience and redundancy are key factors in addressing future needs[4, 5].

COVID-19 is not the only unforeseen event that has disrupted supply chains globally in recent history. In 2011, a magnitude 9.0 earthquake off the coast of Japan resulted in the 50-foot Fukushima tsunami that caused flooding and destruction, costing over $10 billion in global economic loss. Pharmaceutical companies reported significant damage: one lost 9.0 billion yen, a second 5.5 billion yen, and a third 4.5 billion yen[6].

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Extreme weather and natural disasters are becoming increasingly common. The US National Ocean Atmosphere Association (NOAA) reported that as of October 7, 2020, 16 weather/climate disaster events affecting the US had taken place since the beginning of that year[7]. For the period 1980–2019, the annual average is 6.6 events, but for the most recent five years (2015–2019) is 13.8.

## A framework for supply chain contingency planning

With such increasing risk, it is essential to have contingency plans and backup solutions in place to minimize the impact of any supply chain interruptions. The framework for supply chain contingency planning can be considered to be a three-step process that starts with identifying risks, continues with risk assessment, and ends with developing an appropriate response to each identified and quantified risk.

### Step 1: Identifying the risks

First, prepare an end-to-end supply chain map (Figure 1) that identifies all the pieces of the supply chain. This includes investigational medicinal products and precursors as well as ancillary items, their respective vendors and locations, and where materials are handed off between vendors. In addition, the lead times required for moving materials from one point to another are determined and the total time to move through the entire process is calculated. Once the map is completed, the next step is to identify potential vulnerabilities. For example:

- Is packaging performed at only one location?
- Are the ancillary supplies only obtained from a single vendor?
- How many handoffs are there and what can be done to ensure that there are no delays or other issues during these handoffs?
- Who is responsible for your transportation in each region and is there a backup company for this?

### Step 2: Assessing the risks

Quantify the risks identified from the supply chain map, then determining the probability, impact, and proximity of each risk. First, assess how likely is each risk to happen—probability. For example:

- Are any portions of the supply chain located in a high-risk zone for political unrest or weather events?
- Are there extended transit times or extensive lead times?

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**Identify risk: Where is your supply chain vulnerable?**

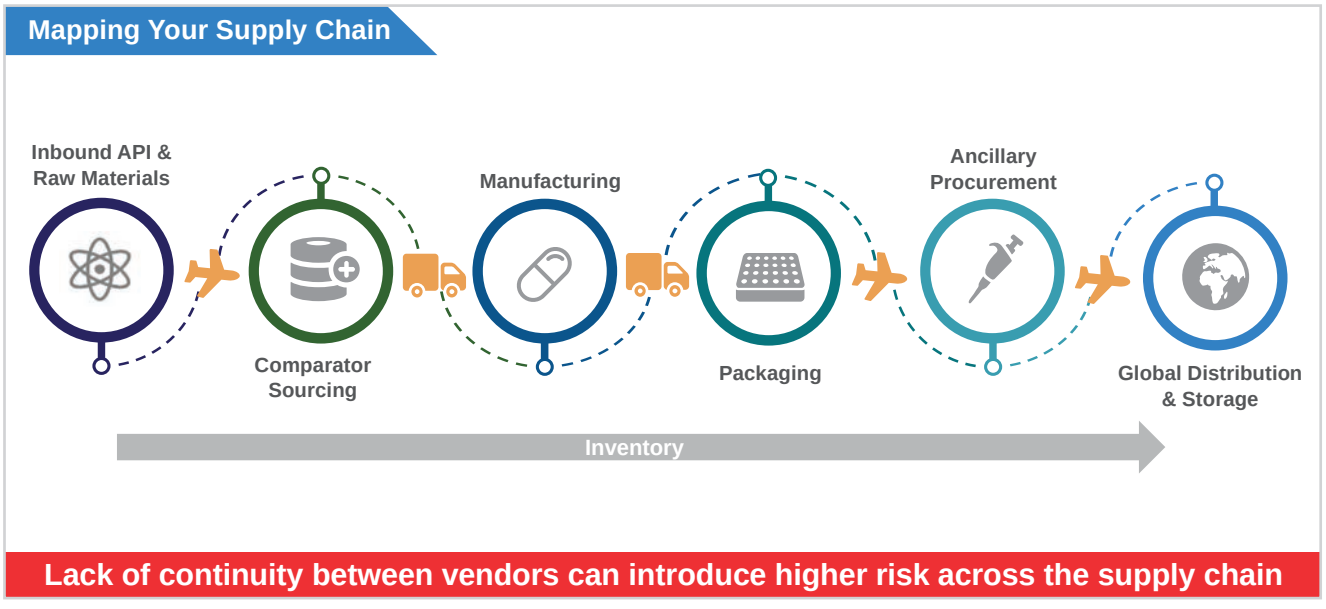


Figure 1

Next, determine what the outcomes of each risk could mean for your business impact. For example:

- How long would it take to recover from a delay or loss?
- What would happen if there was an issue with your only source for material?

Then, identify when each risk is likely to happen—proximity. For example:

- Is a risk unpredictable and could happen at any time without warning, such as a disease outbreak?
- Is it seasonal, such as increased wildfires in summer?
- Is it set for a certain time in the future, like a regulatory deadline?
- How soon does each risk need to be addressed?

Finally, once the risks have been quantified along these three parameters, the assessment can be summarized in a risk register, which can then be charted as shown in Figure 2. In this example, a bubble is drawn at the intersection of risk proximity and risk probability, where the soonest and highest risks are found in the lower left-hand corner, the latest and lowest risks are found in the upper right-hand corner, and the risk impact is proportional to the bubble size.

### Step 3: Developing an appropriate response

Last, determine which risks must be mitigated and the actions needed to address them. Note that not all supply chain risks pose a threat; some may be neutral while others may even present opportunities to improve the supply chain.

Mitigating actions reduce the probability, or impact, of the risk. For example, when shipping to the clinic, if there is no buffer in your packaging timelines any delay might affect the scheduling of your first patient. While the probability and proximity of this event might be low, the impact could be very high, perhaps affecting the achievement of corporate targets. Action may be needed to reduce the risk—such as agreeing to expedited timelines with your packaging vendor.

### Assess risk: Which risks should concern you the most?

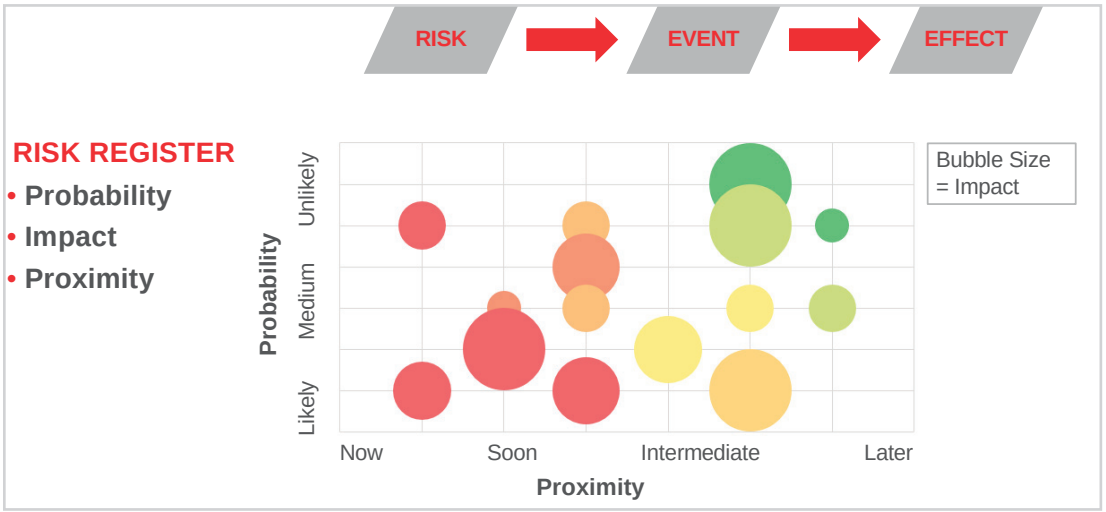


Figure 2

Sometimes there is little that can be done about a risk except to identify and monitor it, and make a conscious decision to accept, reject or share the risk. Take the example of having a sole source API vendor. If the vendor cannot supply, then delays or study failures may ensue—high impact.

The proximity will depend on when supply is needed, and the probability will be related to how hard it is to source your API. If this is truly the only source, then you may have to accept the risk or examine the possibility of sharing it with your vendor.

Capitalizing actions are aimed at proactively taking advantage of the opportunity the risk introduces. In the event of having only a single transportation vendor, for example, any closure will result in missed supplies and delays. Identifying this early and qualifying an additional shipping route provides extra safety for your organization.

## Strategies for responding to risks

When developing a strategy to respond to or proactively prepare for risks such as the COVID-19 pandemic, Brexit, increasing weather events, political unrest, or unforeseen events, one of the most useful strategies is building redundancy. Until you need it, redundancy will always seem like overplanning. However, it is critically important to build as much redundancy as possible into your supply chain. This means developing and qualifying a primary plan A, a backup plan B, and even a plan C. Qualifying multiple locations and ensuring they are all listed in site documentation for regulatory and investigational medicinal product dossier (IMPD) purposes is essential.

Redundancy can be built into many aspects of your supply chain—from sourcing, to manufacturing, to distribution. It pays to look for suppliers who have redundancy built into their own networks.

For example, when choosing a clinical trials partner, if built-in redundancy is not an option, then it can be created by qualifying multiple suppliers. Incorporate these redundancy plans into your supply chain by listing the alternate plans in all applicable contracts and regulatory documentation.

Redundancy is an important part of building your global transportation supply chain. A transportation network should not only cover the geographies you require, but also provide you flexibility and redundancy. Since no single transportation carrier is immune to disruption, redundancy must be built into the transportation supply chain—either by engaging with a partner with built-in redundancies, or by qualifying multiple transportation carriers.

**Capitalizing actions are aimed at proactively taking advantage of the opportunity the risk introduces.**

Furthermore, no single transportation carrier is superior in every region. In order to ensure that you have full global coverage, you may want to work with a vendor to track carrier performance and pricing to ascertain who performs best regionally. By contracting with a provider who has a network of carriers, or by directly contracting multiple carries yourself, you can reduce risk and gain flexibility for each region.

Where you keep your inventory really matters and another useful supply chain strategy when responding to risk is to use a top-down inventory distribution model. In this approach, the buffer at each level—primary, secondary, and final—is assessed to evaluate the flexibility of inventory at each point and how it can move around.

The goal is to understand whether inventory can only go to specific levels—e.g., from primary to secondary, or from secondary to final, or if it can move back and how difficult it would be. This enables the identification of sites between which inventory can be moved, to determine the timelines required and to ensure that inventory is kept in the locations where it is most flexible.

When the timelines required to move material between sites are determined, it is important to look for opportunities to shorten these timelines, particularly because there is a correlation between lead times and the amount of inventory that must be maintained to meet demand fluctuations (Figure 3). Reducing lead time allows you to hold less inventory during normal operations, gives greater flexibility to meet demand fluctuations, and improves response time during a crisis.

## Conclusion

In summary, pharmaceutical companies must safeguard their supply chain to ensure consistent availability of much needed clinical trials materials, drug products, and therapeutics. A supply chain safety net is becoming increasingly necessary in an uncertain world. The framework for supply chain planning begins with identifying the risks by preparing an end-to-end supply chain map that includes locations, transitions, and vulnerabilities. Then, by assessing the risks by building a risk register that identifies the probability, impact, and proximity of those risks. Finally, by implementing a strategy to bulletproof the supply chain by building redundancy and flexibility in manufacturing and packaging, inventory and lead times, and global logistics. Take the necessary steps to help your company prepare for increased complexities to deliver your drug to the right place at the right time, every time.

**Respond to risk: Reduce your lead time to improve your responsiveness**

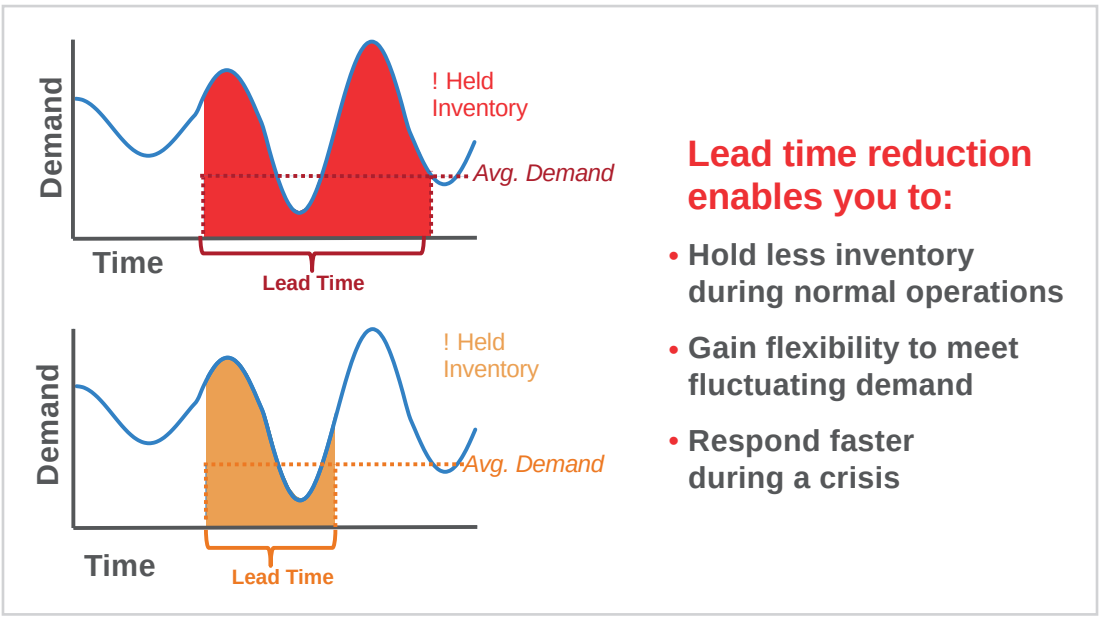


Figure 3

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## About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. We give pharma and biotech companies of all sizes instant access to a global network of facilities and technical experts across the Americas, Europe, Asia and Australia. Our global leadership is built on a reputation for scientific and technical excellence. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. As a leading pharma services provider, we deliver unrivaled quality, reliability and compliance. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.


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Jason Mieding currently serves as the senior director responsible globally for Thermo Fisher Scientific's Total Transportation Management (TTM) service. Bringing more than 20 years of supply chain expertise to the business, Jason is responsible for designing and leading a global transportation network that provides customers and suppliers with efficient and effective transportation solutions.


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