

# FROM LAB TO LAUNCH: STRATEGIES FOR OVERCOMING SUPPLY CHAIN FRAGILITY



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Life Sciences

Nearly 40% of the US pharma research budget, roughly \$7 billion a year, is spent on clinical trials, with patient recruitment alone consuming nearly \$1.89 billion.<sup>1</sup> However, this significant investment is often undermined by supply chain fragilities, which play a large part in why 80% of clinical trials do not finish on schedule.

These delays, stemming from disruptions such as raw material shortages, logistical hurdles and prolonged delivery times, directly contribute to the escalating drug shortage crisis. The first quarter of 2024 saw 323 active drug shortages in the US, the highest levels recorded since 2001,<sup>2</sup> highlighting the urgent need to address supply chain vulnerability issues hindering trial completion and impacting drug availability.

The disruptions are particularly problematic for emerging pharmaceutical companies developing groundbreaking therapies and transitioning from R&D to early commercialization. Such companies are likely to have limited resources to manage rapid growth expectations; additionally, they do not have the infrastructure, supplier networks or financial resources that established organizations use to withstand market volatility.

This whitepaper examines how supply chain fragility affects life sciences companies and outlines practical steps that can be taken to strengthen resilience for 2025 and future years.

## THE HIDDEN COSTS OF SUPPLY CHAIN FRAGILITY

The impact of supply chain disruptions exceeds the inconvenience of delayed shipments.

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The most significant issue for pharmaceutical companies is obtaining recertification from the FDA. If problems arise at their production sites, it can create a major bottleneck, hindering their ability to return to previous production levels after the incident. This is a crucial concern that often arises.

**Ceiry Fox, Managing Director of Operations, Life Sciences Practice, Area Senior Vice President, Gallagher**

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In the life sciences industry, such disruptions can trigger a cascade of adverse effects, impacting everything from clinical trial timelines to market entry strategies and, ultimately, a company's bottom line.

### The threat of cybersecurity

As life sciences companies increasingly adopt advanced technologies like AI, the Internet of Things (IoT) and blockchain to enhance supply chain efficiency, they face heightened cybersecurity risks. A breach in a supplier's system can have far-reaching consequences, potentially compromising sensitive research data and proprietary manufacturing specifications and even allowing counterfeit materials to infiltrate the supply chain.

This can ultimately jeopardize intellectual property and product integrity while posing significant financial and reputational risks.

### Delayed clinical trials

A single missing component, a delay in delivery of materials or a logistical logjam can not only postpone the delivery of potentially life-saving therapies to patients but also incur substantial financial burdens.

Delayed clinical trials also increase research personnel expenses, prolong facility usage and require patient appointments to be rescheduled. A single day of clinical trials costs approximately \$40,000, and the longer the delay, the more this cost accumulates.<sup>3</sup>

### **Perishable materials**

The global cold chain logistics market is expected to reach \$862.33 billion by 2032.<sup>4</sup> Many life sciences products, such as biologics, cell therapies and gene therapies, are highly sensitive to temperature and require strict cold chain management. Maintaining the integrity of the cold chain demands specialized equipment, rigorous monitoring and meticulous documentation, as a single temperature excursion can render a product unusable.

### **Lost revenue**

Delays in bringing a therapy or drug to market can allow competitors to seize the opportunity, capture market share and establish a dominant position. The opportunity cost of delayed market entry can be significant in a competitive therapeutic area where first-mover advantage is crucial.

According to the National Library of Medicine, each day of a clinical trial delay can cost sponsors anywhere from \$600,000 to \$8 million in lost sales.

### **Political climate and tariffs**

The current political climate, characterized by shifting trade policies and the imposition of tariffs, can negatively impact supply chains. Suppliers may face uncertainty as they navigate new regulations and consider alternative sourcing strategies to mitigate the impact of tariffs.

This includes increased costs for raw materials and finished goods, as well as disruptions in the flow of goods across borders.

### **ESG and sustainability pressures**

The growing emphasis on sustainability and Environmental, Social and Governance (ESG) standards is putting businesses under more pressure to maintain moral and responsible supply chain policies.

Regulatory bodies and investors are scrutinizing the environmental impact and ethical conduct of supply chains, making companies vulnerable if a supplier is found violating labor laws, environmental standards or ethical sourcing expectations.

Such violations can lead to regulatory penalties, brand reputational damage and investor confidence loss, resulting in significant financial and operational costs.

### **Regulatory complexity across borders**

Companies sourcing internationally must contend with diverse customs regulations, varying quality requirements, tariffs and export controls, which can lead to significant unforeseen delays and compliance challenges. Emerging companies, in particular, may underestimate the complexity and variability of these regulations, resulting in costly disruptions.

These regulatory hurdles can also necessitate additional resources for compliance management, including legal expertise and specialized logistics support, further driving up operational costs.

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R&D companies, especially those that don't yet have a product approved by the FDA and are still in the research or clinical stage, tend to have a very nimble supply chain. It is rare for these companies to have a lot of redundancy in their manufacturing capabilities. More often than not, they rely on single suppliers, single contract manufacturers and even single storage facilities. Having suppliers in different geographic regions can mitigate the impact of localized disruptions.

**Mary Broderick, Area Executive Vice President — Property Practice, Gallagher**

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## LOOKING AHEAD: PROACTIVE STRATEGIES FOR 2025 AND BEYOND

The life sciences industry is driven by technological advancements, regulatory changes and increasing global interconnectedness. Emerging pharmaceutical companies must prioritize building a resilient supply chain that can anticipate and mitigate potential disruptions and keep the flow of critical materials and therapies uninterrupted.

### Strategic inventory management

By strategically storing inventory at multiple geographic locations, companies can minimize the risk of supply chain disruptions caused by regional events such as natural disasters or political instability. Based on the volume, such inventory management can help keep production moving, depending on where in the supply chain the event occurs. Additionally, vulnerabilities are significantly decreased once the inventory crosses six months or more worth of the finished drug product.

### Diversification of suppliers and strategic partnerships

Relying on a single supplier for critical components is now considered a considerable risk. Diversification is not just about having backup options but also about building a robust network of reliable partners.

Furthermore, establishing redundant supply lines by identifying multiple suppliers for each component is key. Part of this process is ensuring the chosen suppliers can meet the required quality standards and have the capacity to scale in line with growth needs.

### Implementation of a robust risk management framework

By regularly assessing supplier, logistical and regulatory risks and identifying potential vulnerabilities in your supply chain, action can be taken before disruptions occur. It is essential to develop detailed contingency plans for each identified risk.

To help establish these plans, it can be helpful to conduct a scenario planning exercise to simulate different disruption scenarios and test the effectiveness of the contingency plans. This could include alternative source strategies, emergency logistics plans and communication protocols.

Additionally, implementing a system that enables the organization to continue critical business functions during a disruption is a key factor to consider.

### Invest in advanced technologies

Leveraging artificial intelligence and machine learning can improve demand forecasting and inventory management, helping to anticipate fluctuations in demand and avoid stockouts.

Incorporating blockchain technology can enhance traceability and transparency throughout the supply chain. It helps track the movement of materials and products, promoting authenticity and preventing counterfeiting.

To ensure product integrity, utilization of the IoT will help to monitor critical parameters such as temperature, humidity and location throughout the supply chain.

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If you're considering a storage facility specializing in cold storage, there are a few key factors to remember. First, check if they have multiple power feeds to the grid. This is important because if one feed goes down, the facility can still maintain operations through the others. Inquire about backup generators. Some facilities may specify that only a portion of their units — say, 25% — can utilize backup power, and it may only cover certain areas. If that is the case, determine which facility areas you want to agree on for your product.

**Mary Broderick, Area Executive Vice President — Property Practice, Gallagher**

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## Emphasis on cold chain logistics

A fundamental factor in avoiding delays and interruptions is partnering with qualified cold chain logistics providers with proven expertise in handling temperature-sensitive products. Invest in validated cold chain infrastructure, including temperature-controlled storage facilities, refrigerated trucks and real-time temperature monitoring systems to track the temperature of products throughout the supply chain.

Contingency plans need to be developed for handling temperature excursions, such as backup power generators, separating products in different freeze chambers and quarantining affected products to contain the spread of contaminants.

## Serialization

Serialization is the process of assigning a unique, traceable identifier to each individual unit of a product. It is a powerful tool in the fight against counterfeit drugs. By verifying a product's serial number, its authenticity can be determined, and fake medication can be prevented from entering the supply chain.

It provides end-to-end visibility for tracking a product's movement and location at every stage. In the event of a product recall, serialization enables the rapid and precise identification of affected units, minimizing the scope of the recall and reducing risk to patients.

## Talent and vendor management gaps

A robust supply chain is not solely dependent on materials but also on the expertise and effectiveness of the people managing it. Early-stage life sciences companies often face challenges due to gaps in procurement and vendor management capabilities, which can hinder their ability to vet suppliers thoroughly, monitor performance and negotiate favorable terms.

To address these gaps proactively, it is imperative to build strong procurement and vendor management teams equipped with the necessary skills and knowledge to navigate complex supply chain dynamics. This includes providing training and development opportunities to enhance their expertise in supplier evaluation, contract negotiation and performance monitoring.

## Insurance and risk transfer solutions

Companies can effectively transfer supply chain risks by utilizing various insurance products and risk transfer strategies. These solutions include cargo insurance to protect against loss or damage during transit, clinical trial insurance to safeguard against potential liabilities in research phases and business interruption policies to cover financial losses from operational disruptions.

Additionally, companies can explore other risk transfer techniques tailored to address specific supply chain vulnerabilities, such as contingent business interruption insurance or liability coverage for supplier defaults.

## MITIGATING RISKS THROUGH PROACTIVE PARTNERSHIPS

A fragile supply chain can be the difference between making significant progress or suffering significant setbacks in reliably bringing lifesaving and life-improving therapies to patients.

Emerging pharmaceutical companies can navigate these challenges and build resilience in the supply chain by embracing proactive strategies and forging strategic partnerships. This is where Gallagher's expertise becomes invaluable. We understand the unique pressures and complexities companies face transitioning from R&D to commercialization and offer tailored risk management solutions to address these specific needs.

Through comprehensive risk assessments, we help you identify potential vulnerabilities in your supply chain, enabling you to anticipate and mitigate disruptions before they occur. Our insurance solutions provide financial protection against unforeseen events, safeguarding your investments and ensuring business continuity.

At Gallagher, we believe in building flexible and scalable solutions that grow with your company. Our team works closely with you to create a customized risk management plan that aligns with your specific goals and objectives, allowing you to focus on your core business.

<sup>1</sup>Considerations For Improving Patient Recruitment Into Clinical Trials, *Clinicalleader.com*.

<sup>2</sup>National Drug Shortages: January 2001 to December 2024, *Ashp*, accessed 25 Mar 2025.

<sup>3</sup>Smith, Zachary P, et al. New estimates on the cost of a delay day in drug development, *Pubmed*, 21 May 2024.

<sup>4</sup>Cold Chain Logistics Market Size, Share & Industry Analysis, PDF. 03 March 2025.

## Connect with us

### **Ceiry Fox**

Managing Director of Operations,  
Senior Vice President  
Life Sciences

115 Federal Street, Suite 800, Boston,  
MA 02110  
M: (617) 646-0286  
E: ceirya\_fox@ajg.com

### **Mary Broderick**

Area Executive Vice President  
Property

115 Federal Street, Suite 800, Boston,  
MA 02110  
M: (617) 204-6709  
E: mary\_broderick@ajg.com

### **Tony Farias**

Senior Risk Control Consultant  
National Risk Control

M: (831) 210-9551  
E: tony\_farias@ajg.com