

Supply chain mapping and monitoring

Actions for pharmaceutical and packaging manufacturers to mitigate disruption and boost supply chain resiliency in 2024 and beyond

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Supply chain disruptions are nothing new to pharma manufacturers. From shortages of drugs for attention deficit hyperactivity disorder (ADHD) to shortages of critical cancer drugs, at some stage every manufacturer will face shortages caused by disruptions several tiers down the supply chain. Monitoring showed that the life sciences industry experienced the highest number of disruption alerts of all industries tracked in 2023.¹

The year 2023 also saw a notable increase in pharmaceutical drug recalls. Disruptions were widespread in the US, in particular, with shortages caused by raw materials' shortages, manufacturing quality issues and increased demand.² However, organisations worldwide have struggled to ensure continuity of supply and this is likely to continue throughout 2024. Pharma companies should expect drug supply disruption to worsen unless they take proactive steps to strengthen their supply chains.

Develop a bird's-eye overview through supply chain mapping

A complete bird's-eye view of the supplier network is crucial to responding quickly and efficiently in the face of disruption. Currently, many pharma manufacturers in Europe and the US are single-source dependent on China and India. Unfortunately, critical failure points in these regions are common and the biggest threat to business continuity. As long as pharma



manufacturers lack transparency into impacted locations and materials, the door to further disruption remains wide open.

Data shows that factory fires have been the number one cause of supply chain disruption for five years in a row for all sectors, including the pharma industry.

For example, a factory fire at Kwality Pharmaceuticals Facility in Amritsar of the Punjab region in India caused significant disruption to the exports of liquid oral products, powder for oral suspension, tablets, capsules, and sterile powder for injections.³ Another recent example of a fire at Solara Active Pharma Sciences in Kalapet,

India, caused the production of active pharmaceutical ingredients (APIs) to be taken offline, including albendazole, bumetanide, cetirizine dihydrochloride and chlorpromazine.⁴ In both of these cases, production was further delayed due to incident reporting, cleaning, repairs and quality control.

Mapping can provide manufacturers with a clearer view of high-risk sites. Supply chain practitioners often focus on tracking the top 20% of suppliers that make up 80% of spend. Instead, they should shift their focus



to the remaining 80% of suppliers that comprise 20% of spend. This is because research shows that 85% of disruptions happen in the indirect (tier 2+) supply chain.⁵ Mapping the supply chain down multiple tiers – even to material origin – is key to exposing critical failure points. It is only then that practitioners can better predict where



disruptions occur and what products are likely to be impacted.

Resilient supply chains made possible through 24/7 monitoring

Simply put, there are no shortcuts on the road to a robust and resilient supply chain. However, early detection of supply chain issues is crucial to making tangible progress. AI-powered, 24/7 monitoring solutions can enable manufacturers to see what disruption is currently occurring and what may disrupt supply in the future, through comprehensive oversight of millions of news and social feeds. This shifts the dial in supply chain management from reactive to resilient.

Supplier risk assessments are another effective tactic for resiliency. These enable manufacturers to use analytics to highlight problem areas, calculate scores and anticipate future trends. By identifying gaps in supplier processes, pharma manufacturers can encourage better management practices. In addition, through increased collaboration, manufacturers can rest assured that they have selected the most suitable suppliers for their needs, with transparent safety standards and robust backup plans to ensure continuity of supply.

Better quality control requires reliable manufacturing practices

Enhanced quality control can help pharma manufacturers decrease

disruptions. The Food and Drug Administration (FDA) recalls approximately 4,500 drugs and medical devices every year in the US. The most common reason for recalls in 2022 and Q1 2023 was contamination, followed by deviations from current Good Manufacturing Practice-approved (cGMP) sterility procedures.⁶ The presence of microbial species has resulted in FDA recalls of injections used to treat metabolic acidosis, eye drops, allergy pills and magnesium citrate, as well as cGMP recalls of over-the-counter pain relievers, hand sanitisers, antibiotic ointment and losartan potassium tablets.⁷ Furthermore, products with emergency use authorisation (EUA) have faced particularly high rates of recall.⁷ The safety of pharmaceutical products has also become a growing concern in cardiovascular medicine, which has been recalled by the FDA, the European Medicines Agency (EMA) and others, as a result of safety concerns due to impurities.⁸

Manufacturing errors may occur, but a lack of supplier oversight means pharma companies cannot rule out the presence of contaminated – or even counterfeit or falsified – medicines in their supply chain. However, proper sterility and quality control in drug manufacturing is only possible through greater transparency of suppliers, multiple tiers deep in the supply chain. Downstream manufacturers in

PMPS



Europe and the US will inevitably feel the ripple effects of product recalls such as sodium bicarbonate injections, eye drops and allergy pills, owing to a lack of compliance among upstream manufacturers in particular. This only highlights the need to have full visibility into every step and every product in their supply chain.

Economic uncertainty requires resilient solutions

Future disruption is inevitable. According to a recent article, the global economy is expected to remain weak in 2024, with high inflation continuing to eat away at pharmaceutical profits.⁹ Recent proprietary data indicates that bankruptcy alerts surged by 196% year-on-year globally in the first half of 2023, while profit warnings soared by 300%. It should be noted that there is a real cost to these numbers; when three major UK pharmaceutical manufacturers went into administration, 1,000 jobs were lost, disrupting established supply networks.¹⁰

The generics industry has also been hit particularly hard, shaken by high production costs and small profit margins.¹¹ This has resulted in limited supply, leading to global disruption to supplies of treatments such as ADHD medications, impacting organisations like the NHS in the UK. Manufacturers must act in advance of disruption

to minimise future damage to their supplies of generics, with escalating costs likely to impact standard pharmaceutical practices including the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS).

In summary, to combat future disruptions, pharma manufacturers must first invest in technology to map the supply chain down to sub-tier levels in order to gain transparency. Next, they must proactively address weaknesses via 24/7 supply chain monitoring. Whether it is factory fires, quality control issues, or economic uncertainty, supply chain monitoring gives manufacturers an edge in ensuring their supply network is compliant and resilient.

By mapping the supply chain in depth, and monitoring millions of news feeds worldwide, manufacturers can move towards resilience in their supply chains. With this visibility, they can track where disruptions may occur, take steps to mitigate risk, and organise alternative suppliers where necessary, thereby gaining a competitive edge while reducing risk, shortages and disruptions.

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