How to Plan for the Unplannable – preparing for threats to supply chain security and brand protection in the pharmaceutical industry

Life sciences and healthcare organizations must have comprehensive risk management and crisis management plans that can provide for proactive risk scenario planning and a rapid response to supply chain emergencies. They also need to develop a detailed roadmap for supply chain risk management (SCRM) to ensure supply continuity and protect the ultimate stakeholder: the patient.[1]

Why It's Dire

Supply chain disruptions and ambiguity are persistent challenges: Geopolitical uncertainty is disrupting shipping routes in the Red Sea, and the U.S. Presidential Administration is rapidly implementing higher tariffs and changing trade policy.

Such disruptions are costly. Over the course of a decade, the average company can expect to lose nearly one-half of one year's profits because of supply chain disruptions, according to a 2021 study[1]. In a subsequent study[2], nine out of ten respondents stated that they had encountered supply chain challenges in 2024. Supply chain instability is likely to remain the norm, not the exception.

Supply chain disruptions in the pharmaceutical industry can lead to dire consequences - from negative business implications, like budget and workforce reductions - to patient safety threats the pose risk to patient health. The list of potential threats to the pharmaceutical supply chain is seemingly endless: natural disasters, infrastructure failures, geopolitical decisions, labor strife, political instability, cargo theft, cybersecurity threats, counterfeiting, supplier insolvency, supplier procedural failures, and so on. Manufacturers, distributors, logistics providers, health care providers, and patients are all vulnerable.

Product safety and supply chain security are prominent risks within the industry. Despite ongoing vigilance from regulatory agencies, drug diversion and counterfeiting undermine supply chains, jeopardizing patient safety. The World Health Organization estimates that at least one in ten medicines in low-and-middle-income countries are substandard or falsified and that countries spend an estimated $30.5 billion per year on substandard and falsified medical products. Additionally, parallel trade poses its own set of challenges, as it involves transporting and repackaging products in the language of the importing country. This practice can inadvertently allow dangerous, adulterated, or counterfeit drugs to infiltrate legitimate distribution channels and markets, posing risks to brand recognition, societal trust, and patient safety.

How to Invest in Readiness and Response – Now and Later

The McKinsey Global Supply Chain Leader Survey demonstrates that unprecedented, major investments that organizations made in supply chain resiliency in the post COVID-19 pandemic era are translating into tangible outcomes, with seventy-three percent of survey respondents reporting that they have made progress on dual-sourcing strategies and sixty percent of respondents indicating they are acting to regionalize their supply chains. This also includes two-thirds of respondents indicating that they have made progress in the implementation of advanced planning and scheduling systems which combined with advancements in data collection, synthesis, and visualization, enable robust scenario planning and the ability to proactively plan for, respond to, and mitigate the impact of supply chain disruptions.[3]

Investments in supply chain tools including digital twins, procurement and supplier management solutions, warehouse management systems, transportation management systems, and data-lake solutions can provide advanced planning solutions with real-time data and visibility to enable advanced scenario planning solutions that can proactively identify risks and avoid disruption as well as quickly identify disruptions and take remedial action.

Where to Invest

1. **Supplier Risk Management**

   Life sciences and healthcare organizations must audit their key suppliers to qualify their operations, assess their performance, and quantify the potential costs of risk associated with supply disruptions. These costs can include lost revenue due to stock-outs, regulatory penalties, contractual penalties, and damage to brand reputation (e.g., from compromised product quality, product diversion, etc.) - all of which are damaging to holistic profitability. Through the audit process, organizations gather and analyze a comprehensive array of financial and compliance information from their suppliers and service providers to inform development of robust risk mitigation and business continuity plans.

2. **Operational Continuity Assurance**

   Organizations should rigorously evaluate the production assets involved with manufacturing and packaging pharmaceutical products, including infrastructure and technology components to mitigate risks to product quality, operations, and patient safety. Technology should enable quality control measures, such as validation and revalidation of active pharmaceutical ingredients, with thorough documentation.

3. **Life Sciences and Pharmaceutical Industry Logistics and Product Protection**

   Organizations must expect logistics partners to fully understand the products they handle, their risk profile, and the environmental conditions necessary for preserving product quality and efficacy. Failing to meet these conditions can lead to significant losses and invite regulatory - or even criminal - consequences.

Pharmaceutical organizations should audit logistic partners' capabilities and compliance requirements to ensure product integrity, including import and export capabilities, strategic routing practices, packaging compliance, appropriate storage condition maintenance, and standard operating procedure good distribution, and good documentation practice adherence. Formal auditing practices should extend to freight forwarders and import/export services providers, particularly in our current environment where port delays could increase the risk to product quality or security. It is imperative to understand the environment and constraints where products may be stored and work with logistics services provider to ensure they have adequate storage and controls in the event of a delay, particularly for temperature-controlled products and controlled substances.

Looking Ahead

Supply chain risks are often unexpected, like the massive power outage across the Iberian Peninsula (occurring the week of April 28, 2025) that's disrupting flights, trains, subways, mobile phones, and more. Rx-360 facilitates close collaboration among our member organizations who identify and monitor a wide array of potential supply chain risks, legislative initiatives, and approaches to improve supply chain resiliency that can enable proactive and reactive risk management.

[1]Susan Lund, McKinsey & Company, Building National Supply Chain Resilience, July 11, 2021
[2]Knut Alicke, Tacy Foster, Vera Trautwein, McKinsey & Company, Supply Chains: Still Vulnerable, October 14, 2024
[3]Jamie Hintlian, Ryan Kelly, Pharmaceutical Processing World, A Roadmap for Risky Territory, October 15, 2014

Why Integrate Supply Chain Security and Risk Management with Business Strategy

Proactive Risk Management
By anticipating and addressing supply chain vulnerabilities, organizations can better safeguard their operations.

Enhanced Compliance and Performance
A robust supply chain risk management program can improve compliance with regulations and enhance operational efficiencies.

Value Creation

Successful risk management strategies support compliance and continuity and optimize processes and stakeholder relationships – all leading to greater, more demonstrable business value.

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10 Actions to Mitigate Supply Chain Risk

1. Qualify Suppliers Establish governance to assess suppliers based on financial stability, compliance, ethics, and having an effective quality management system (QMS).

2. Review Sourcing Risks Identify all inputs for production and assess sourcing risks to implement effective controls for risk identification and risk management.

3. Understand Supplier Networks Ensure that primary suppliers have robust business continuity plans with sufficient redundancy and that secondary suppliers are not relying on the same primary suppliers.

4. Maintain Service Level Agreements Create financial incentives and penalties for suppliers to meet performance standards and actively manage supplier performance via weekly, monthly, and annual scorecards.

5. Collaborate Across Networks Optimize supplier management through partnership and collaboration to proactively identify risks, communicate quickly, improve quality, reduce costs, and enhance service levels.

6. Review Equipment and Packaging Assess critical production dependencies and establish comprehensive maintenance plans and response service-level agreements, making sure to include alternative equipment, suppliers, and service providers.

7. Create Redundancy, Business Continuity, and Disaster Recovery Plans Develop backup strategies for essential equipment to minimize downtime during malfunctions and detailed plans and metrics to trigger actions and effectively manage the incident and return to operations as normal.

8. Confirm Adequate Stock Ensure stock and safety stock levels are adequate for continuity during disruptions.

9. Guard Against Counterfeiting Implement security measures and authentication technologies to protect products from counterfeiting and ensure brand protection.

10. Integrate New Regulations Develop robust compliance procedures, ensuring adaptability to regulatory changes within sourcing, trade, and logistics via effective contract management.

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