Optimizing Supply Chain Management

Strategies to mitigate supply chain disruptions

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Global Optimization

In today's global economy, life science and technology companies rely on an increasing number of both domestic and foreign-based suppliers to meet production requirements. Supply chain management becomes crucial to avoid potential business disruptions, particularly in industries producing critical products such as COVID-19 vaccines. For example, many of the companies that produce key precursor materials used in COVID-19 vaccines are located in China and Korea. A disruption in transportation such as the blockage of the Suez Canal, a main artery for transporting goods between Asia and Europe, could have significant consequences.

Even after the initial impacts of pandemic-related disruptions subside, effects on the supply chain related to the COVID-19 vaccine rollout are predicted to last a minimum of 1-2 years. The supply chain will be strained as we attempt to manufacture and distribute 14 billion doses of the vaccine worldwide. Pharmaceutical companies will need to assess the patient populations that their products serve and prioritize products accordingly. For example, a company that produces insulin is serving a patient population that relies on their product. Identifying "business-critical" products, and then assessing their specific vulnerabilities such as warehousing, logistics and transportation for example, can help narrow down the most important areas to focus on specifically.

A surge in consumer demand fuelled in part by the global pandemic, along with an increase in storms and other natural disasters, continues to pose significant supply chain risks. Transportation constraints including a global shortage of container capacity, high rates of cargo transportation cancellations, and slower handling speeds due to labour shortages at ports, have resulted in supply chain disruptions and delivery delays, exposing companies to complex and costly risks. These exposures can be substantially reduced by optimizing customized risk mitigation strategies.

This article is designed to assist life science and technology companies in evaluating their exposures and seeking legal or specialized consultant advice on implementing measures to protect themselves against potentially complex and costly litigation arising from breeches to their supply chain. The paper will outline steps involved in Supply Chain Management including sourcing optimization, warehousing, and logistics, as well as transportation. Strategies to identify critical risk factors in each aspect of the supply chain provide a roadmap to successfully mitigating potential supply chain disruption.

Sourcing Optimization

To begin, identify your key suppliers and prioritize those who are critical to the operation. Use an assessment tool to evaluate suppliers based on their geographic location, management practices including business continuity, planning and attitude. Developing relationships with suppliers is important and designating individuals within your organization to manage supplier relationships is an essential element of supply chain management.

Risk Mitigation Strategies

When working with key suppliers, it is critical to have risk mitigation strategies in place, so you are prepared should an issue arise along the supply chain. The following is a list of risk mitigation steps and considerations, with each addressed more fully below:

1. Supply Chain Team
2. Contractual Risk Transfer
3. Written Contracts
4. Insurance Policies
5. Supplier Evaluation
6. Supplier Monitoring
7. Logistics Optimization

Supply Chain Team

Establish a Supply Chain Management Team to oversee the supply chain process. The goal for this team is to assure delivery of products and goods while managing relationships and maintaining inventory.

This dedicated team develops information to tier suppliers, maintain relationships and effectively leverage cost and compliance with terms and agreements.

Contractual Risk Transfer

Risk transfer refers to a risk management technique in which risk is transferred to a third party. One party assumes the liability of another party in one of two ways:

1. Within a contract between two or more parties to manage risk
2. Through an insurance policy with one party and the insurance carrier

We recommend organizations consult with their risk manager, legal counsel, or insurance risk control specialist with any questions regarding contractual risk transfer.

Written Contracts

A written contract is not just a legal document — it is also a tool for doing business. A detailed, negotiated contract has several advantages over a Supplier Agreement or Purchase Order (PO) with language attempting to limit liability and allocate various risks. First, the process of negotiating the contract may reveal risk issues that otherwise might go unnoticed. Also, a contract covering all aspects of the arrangement with the supplier will enable both parties to structure their relationship in ways that advance strategic business goals. Finally, a fully negotiated contract that specifically allocates risk and liability makes enforcement simpler and more predictable, whereas a purchase order lacking contractual detail could result in unanticipated judicial remedies.

During the negotiation process, it is important to consider every aspect of the proposed business arrangement from different perspectives. Thus, in addition to undergoing legal review, the contract should be examined by regulatory, clinical, and other scientific departments for provisions that may affect their own functioning.

Drafting a Comprehensive Contract

The following provisions, among others, should be included in a contract:

Duties of the parties

A contract between a purchaser and supplier should expressly allocate responsibility for every aspect of the business relationship, including:

- Developing the manufacturing process
- Designing packaging and storage materials
- Determining label content
- Paying the upfront costs for raw materials
- Securing FDA or other relevant regulatory approval
- Shipping the product

Contracts should outline compliance with current Good Manufacturing Practices (cGMP) and other relevant regulatory requirements, in addition to adverse event reporting or quality issues.

Warranties and Remedy for Breach

The contract should specify any warranties provided by the parties, and what the remedy is for breach of such warranties. The supplier may warrant, for example, that its products will be in conformity with the terms of the agreement and applicable U.S. regulations. The contract also can limit the remedy for a breach of this warranty by stating that in the event of a manufacturing problem, the supplier owes only a refund of the money paid for that batch of defective products.

The parties should also consider a provision allowing for liquidated damages in the event of a material breach. This may prevent a lengthy and expensive trial to determine the amount of damages.

Dispute Resolution Mechanisms

Contracts can specify such key points as what law would be applied in interpreting the contract, whether disputes should be settled by arbitration or judicial proceedings, how costs are to be allocated, and where disputes can be adjudicated. Contracts can also provide for a more informal dispute resolution mechanism, such as an independent third-party examiner with authority to determine whether the supplier's goods conform to the contract's specifications.

Establishing a dispute resolution mechanism is of importance when dealing with a foreign company which may not be subject to legal process in the U.S. The Hague Service Convention, an international treaty signed by many countries, provides a method for obtaining jurisdiction over foreign individuals and corporations. However, not all countries have joined this treaty and enforcement of its provisions is sometimes problematic for a variety of other reasons such as cost and delay. It may be advisable to have a foreign company waive its Hague Convention rights in this respect or agree outright that it can be sued in the U.S.

Indemnity Clauses

An indemnity clause allows a contracting party to shift the costs of a claim or lawsuit onto the other party if that is where the fault lies. This type of clause is essential whenever there is a possibility that the other party's negligence or product defect could subject one's own company to liability.

In general, it is wise to specify the types of fault covered by this provision, such as a manufacturing or design defect. Many contracts include reciprocal indemnity clauses which are generally intended to ensure that neither party will be held liable for the actions of the other. These provisions should also address other issues, such as which party is entitled to direct and control the litigation and whether one party has the authority to settle the case on behalf of the other.

These clauses should not be entered into lightly, as illustrated by a recent case in which a foreign drug manufacturer agreed to indemnify its American distributor for any injuries resulting

from the use of its drug. Years later, a verdict of over $500 million was entered against both parties, divided between the two. However, due to the indemnity clause, the manufacturer was required to pay the whole amount, including several million dollars in punitive damages that the jury had assessed against the distributor.

Insurance Coverage

Especially in situations involving potentially large exposure, consider requiring the other party to obtain an insurance policy, naming one's own company as an additional insured. This is an especially important consideration when the contracting party is based in a country whose laws make it potentially difficult to obtain or enforce a monetary judgment. Refer to Insurance Policies section for additional detail.

Recall of Defective Products

Any contract for the provision of goods or components should address the issue of a potential product recall. As recalls are often very costly, the parties should decide who will bear the expense in varying circumstances — for instance, if the recall is based on a design flaw versus a manufacturing flaw. The contract should also state whether one or both of the parties can authorize a voluntary recall if one is deemed necessary and mandate cooperation and coordination between the parties.

Note that recalls are usually not covered under general commercial or product liability policies. Therefore, after assessing the potential risks and costs of a recall, consider obtaining a special "recall policy," and require that the other party purchase one as well, naming one's own company as an additional insured, and/or self-insuring with the understanding that losses will be paid out of pocket.

Contracting with international suppliers can help businesses expand production and boost profits. However, it is essential to understand and address the associated liability exposures. By negotiating a comprehensive, carefully reviewed contract with the supplier, and discussing the risks with one's insurer, organizations can minimize the prospect of catastrophic loss, even in the event of a product defect or similar occurrence.

Other considerations to review when negotiating contracts to ensure you have proper legal provisions as well as limit of liability within the contract are:

- Total cost of the contract

- How many units of a product will be sold and to which countries — USA vs. rest of the world (Note: the more USA-centric, the larger the limit of liability and proper legal provision addressing US jurisdictions and legal concerns)
- If there is a product exposure, does this product represent a higher-than-normal potential for class action (see consideration note above)

Insurance Policies

Stock Through Put (STP), Parametric, or Supply Chain policies[1] are financial risk transfer mechanisms. These are used in mitigating risk associated with a supply chain entity. While risk transfer is a critical component to a risk management strategy, it should not be the primary

focus. Rather, the primary focus is developing a risk mitigation strategy to address the supply chain integrity and asset resilience with firms who specialize in risk modeling supply chains.

Analyze Key Coverage Provisions Within an Insurance Policy to Ensure Coverage Applies

We recommend a qualified insurance professional or an attorney who specializes within the life science or technology industry and international law conduct a thorough review of the entire insurance policy including all additional insured language provisions, whether contained within the base policy or by an endorsement. In reviewing the policy, it is important to ensure you are comfortable with any limitations or exclusions that may apply to the operation, including services being rendered or provided on behalf of a foreign entity. Definitions must also be carefully scrutinized as they may contain provisions that narrow coverage.

Additional Insured status typically extends coverage to a third-party performing service or selling product(s) on behalf of the foreign entity (named insured) but does not apply to sole negligence of the third-party.

As long as your insured is performing the duties outlined within the contract or agreement, and more importantly adhering to the limitations within the policy, they should be afforded coverage subject to the concerns outlined within the collectability section. Some key provisions to review in an insurance policy include vendors, contractual obligations and traditional additional insured language provisions by endorsement or embedded within the base policy. Medical professional sales consultants should be reviewed to determine if there is a potential exposure from their operation, and whether such would be excluded under a professional services exclusion, even if they may otherwise qualify as additional insureds.

83% of organizations experienced a third-party incident over the past 3 years, costing an average of $7.5 million for remediation costs.[2]

Considerations to ensure potential insurance collectability

When considering whether to work with a foreign entity, it is important to evaluate the potential insurance collectability should an issue arise. For example:

- Does the foreign entity's insurance policy have a USA territory provision?
- Who is the insurance carrier of the foreign entity? Do they have any operations within the U.S. or are they listed as a non-admitted carrier? Are they listed within AM Best?
- Does the foreign entity have any operations within the U.S.?

When working with a foreign entity, request a semi-annual certificate of insurance evidencing coverage and limits and, if possible, confirm whether the limits are still intact or if there has been erosion from claims activity. If there has been erosion, you should inquire into the cause to assess whether the claims activity may be systemic and expose you to potential liability. If you suspect a systemic issue, seek immediate assistance from a qualified insurance professional as well as a qualified attorney.

If there is no confidence with the enforceability or collectability of the foreign entity's insurance policy, an alternative to consider is using a different type of financial product for protection against liability exposure. For example, an evergreen letter of credit can serve as collateral or a performance bond could be used in the event of a breach of

[1] Stock throughput (STP) insurance covers your company's goods against physical loss or damage while in your control anywhere in the global supply chain, in transit and in storage as a company owned inventory. STP policy insures a company's inventory and the flow of goods from the source of production to its final destination, whether at a place of storage or a retail store.

[2] https://loricca.com/cyber-supply-chain-risk-management-c-scrm

contract or a claim arising from the actions of the foreign entity.

There is no scientific approach or mathematical formula to assist you in in determining the appropriate limits when requesting additional insured status under the foreign entity's insurance policy. However, there are some steps to consider including:

- Determine the actual services or product being rendered by the foreign entity and whether they are critical to your operation.
- Understand the downstream effects that would arise to your operation should a defect materialize and whether you could assess a dollar amount.
- Evaluate your ability to inspect 100% of all services or products provided by the foreign entity to ensure quality.
- Perform appropriate due diligence involving the heads of your Regulatory Affairs, Clinical Affairs, Legal/General Counsel, Sales and Marketing, Quality Assurance, Manufacturing or any other relevant departments, on the foreign entity to ensure they have the capabilities and overall quality controls necessary to provide you the product or service according to your specification or agreement.
- Ensure the foreign entity is following the Foreign Corrupt Practice Act and has no unresolved FDA or foreign similar concerns.
- Know the market share, market cap and total assets of your insured as well as the foreign entity.

Working with International Suppliers: Sound Contracts Minimize Risk

The first step in evaluating organizational exposure is to understand what the current policy does and does not cover. Ask the insurer or broker about foreign business considerations, as well as policy limits and exclusions. If the existing insurance policy cannot meet today's global sourcing needs, consider what adjustments are required to protect the business from possibly catastrophic losses resulting from overseas events.

In addition, before finalizing any business plans, it is a good idea to ask an insurance representative to review the proposed venture. The insurer can help evaluate the risks arising from the business arrangement and determine whether they would be covered under existing policies, or whether a new type of insurance is needed. This step is especially important if the proposed deal involves indemnifying another entity, a provision often included in overseas manufacturing contracts (as discussed above).

Supplier Evaluation

Evaluating suppliers is a critical component of your supply chain. Criteria to include in this evaluation includes quality, geographic location, cost, and social responsibility. Suppliers are more than a source for procurement. Companies are now considering the environmental impact when selecting a supplier to assure they are socially responsible and taking action to reduce their carbon footprint and act sustainability.

Supplier Monitoring

Monitoring supply chain includes physical audits of key suppliers as well as administering questionnaires and setting performance standards. Tools are available to assist in monitoring established metrics on the risk profile of suppliers. Companies should begin with analyzing data they have available, capturing that data on a dashboard to categorize suppliers from high to low risk. The Internet of Things (IoT) optimizes monitoring supply chain data. Using this data helps identify supply chain risk enabling factors which could adversely impact suppliers such as geopolitical, financial or climate risk.

Supply chain relationships are critical. Suppliers are no longer seen as transactional, but rather collaborative partners critical to driving outcomes.

> *"As supply chains become ever more distributed and complex, so does the need for effective tools that model future risks to business continuity posed by factors such as production quality issues and natural disasters."*
>
> **Libbe Englander**
> CEO & Founder PHARM3R

Logistics Optimization

Logistics encompasses warehousing, storage, transportation and delivery optimization. Logistics optimization — where companies seamlessly connect with their customers to deliver product in a timely and affordable manner — is

a key differentiator for most companies. Artificial intelligence and IoT devices provide real-time data from product inventory to delivery to optimize logistics.

How Sompo Global Risk Solutions (GRS) Can Help

Supply chain risk management needs to be a proactive practice. Companies build systems to be efficient and to work in a perfect environment; but the importance of assessing possible supply chain risk exposures is critical.

At Sompo GRS, we have tools available to enhance and support supply chain management. Our team of experts can show you how to mitigate supply chain risk factors and eliminate potential loss. Our robust business continuity planning programs establish steps to mitigate disruptions.

As members of the RiscAuthority in the UK, we have access to their Business Continuity Supply Chain tool kit, which can be used by our U.S. and other global clients to manage supply chain risks. Clients can log in and create their own account and supply chain analysis. The toolkit enables the creation of a web portal that can be configured with company-specific supplier details. The toolkit then automatically determines the risk rating of suppliers, based on the responses received to a set of multiple-choice questions. These questions cover gross profit dependency, supplier resilience to disruption and the mitigation options available to the business. Once supply chain weaknesses are identified, the risks can be mitigated using standard methods.

Risk mitigation strategies can be expensive but having this resiliency can be far less costly in the long run should your company be exposed to a supply chain risk. At Sompo GRS, we believe the future of supply chain management is a holistic approach encompassing the full circle of service from your partners.

About Sompo GRS Underwriting and Risk Control Teams

Sompo GRS is dedicated to all aspects of supply chain management and our underwriting and risk control team members are a key contributor to this effort. Comprised of highly trained professionals specializing in industries including Life Science, Technology, Real Estate, Financial Institutions, Professional Services and Hospitality. We have proven risk assessment benchmarking tools to help customers mitigate potential supply chain risk and work with them to develop comprehensive risk management strategies to mitigate potential supply chain interruptions.

If you would like to hear more about how our risk control specialist can help your organization maximize your supply chain management, please contact us at GRSRiskControlQuestions@sompo-intl.com