

ToThePoint

Managing Product Integrity Through the Supply Chain

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In today's global economy, the supply chains of materials, components, manufacturing services, and logistics that bring products to market are complex. Liability and product safety are ever-present concerns, pointing to the need to verify your supply chain risk management approach to product integrity and quality assurance.

What are Supply Chains?

Products are often brought to market through supply chains, **composed of distinct companies** aligned to produce, handle, and distribute specific products. A supply chain can be made up of a few companies in a tight geographical area, or it can be a broad international network.

Legal and Regulatory Protections

Wherever your supply chain partners are located, they will most likely be subject to **standards and regulations**, including customs requirements for companies importing into your market. However, if problems arise, expectations can change and legal remedies may not be adequate to resolve them. Within the supply chain, the protection provided by risk transfer mechanisms like insurance and the ability of legal systems to impose obligations can vary greatly from one country to the next.

Supply chain challenges can be especially complex when they span geographic jurisdictions. Contract terms and conditions may not respond the same way, possibly requiring **different approaches for certain jurisdictions**. This can be especially true when sourcing

products from other parts of the world where traditional methods of protection may not apply. For example, you may not be able to effectively subrogate against suppliers in countries with developing systems of laws and regulations. In cases like these, it is prudent to find alternative ways to **decrease your risk against safety, performance, and quality issues**, which might include directly managing quality, design specifications, testing, and auditing.

Supply Chain Risk Assessment

From a product integrity standpoint, regardless of your company's role in the supply chain, it is important **to assess and document critical expectations of product safety, quality, compliance, and performance** with your supply chain partners. Here are several supply chain risk factors for consideration:

- **Significant differences in regulatory climates from a health and safety perspective**
 - Regulatory oversight that is developing or lacking
 - Regulatory differences for a specific product class (for example, toys, automotive, aviation, energy, life sciences, tech products)
 - Contractual risk transfer mechanisms that may not be recognized in the supplier's jurisdiction
- **Products that may be highly vulnerable to tampering or quality deviations**
 - Food
 - Pharmaceuticals
 - Technology products

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- **Commodity materials, components or subassemblies that are difficult to identify and trace**
 - The potential risk of recall across many different products (for example, consumer electronics, food ingredients) that would be required to either correct the problem or take the product out of the stream of commerce
 - The part in question may be difficult to identify from competitors' parts
- **Safety-critical products**
 - Especially if potential emotional impact, such as children's car seats and cribs
 - The risk that a failure of the material, part or product could lead to a complete product failure, such as a fire, electrical shock, chemical release or an ensuing loss
- **Products highly vulnerable to counterfeiting**
 - Structural hardware (such as bolts)
 - Automotive parts
 - Consumer goods

Assessing Your Suppliers' Hazard Reduction Controls

As part of your assessment of each vendor within your supply chain, it is prudent to **evaluate how your suppliers recognize and mitigate their own product safety risks**. Ideally, suppliers with high hazard critical risk factors will have more robust product safety programs.

If your company is the final product manufacturer, you might have to verify that hazard reduction techniques are being implemented throughout your supply chain, using in-house or third-party auditing processes.

When evaluating hazard reduction techniques, each supplier should be able to clearly articulate their approach for the following areas. A lack of response could be a red flag for product safety issues.

- **Risk Awareness** – Understanding of industry, product safety standards, incident history
 - Recalls of similar products
 - Pending legislation

- Safety awareness and training
- How the product is the same as or different from competitors' products
- **Risk Measurement** – Testing against specifications, safety surveillance
 - Standards compliance (meets or exceeds mandatory and voluntary standards)
 - Quality control and/or quality assurance measures
 - Field and customer service
- **Risk Communication** – Clearly communicating performance expectations and inherent risks
 - Within the company
 - Within the supply chain (both directions)
 - With customers (marketing, labels, manuals, website)
 - In recall plan communication
- **Risk Management** – Organizational structure to support product quality and safety
 - Management commitment to and active involvement in the program
 - Planning, organization and control
 - Engineering and compliance
 - A safety team involving all departments in the company
- **Risk Reduction** – Ability to address and respond to incidents to mitigate loss
 - A system for measurement, corrective action and status reporting
 - Contractual risk transfer (certificates of insurance, hold harmless agreements, additional insured status)
 - Customer and field service
 - Recall plan and testing
 - Risk assessment for new and modified products
 - Legal defenses

Assessing Product Safety

Understanding the complexity of the supply chain and its impact on product safety is an important starting point in determining the requirements you may need to place on your suppliers. Materials, components, and subassemblies sourced from developing countries often present moderate to severe exposure; however, it's important to be objective when it

comes to anticipated risks and regulatory requirements associated with your suppliers.

Consider your organization's approach to supplier qualification: performed directly, via third-party testing services or a combination of both. **If you use third-party testing services**, you will want to find out:

- Does the lab accreditations that indicate they have been qualified for the testing they will be performing? Labs will generally have an overall accreditation and then be validated for their abilities to test to certain standards.
- What is the testing agency's experience in performing the tests you are seeking?

Verifying the testing agency's outcomes via regular internal or qualified third-party audit will go a long way to mitigating supply chain product safety risk.

Proactive Risk Management in Action

Be proactive and engaged in managing supply chain risk.

Implement best practices (including but not limited to) implementing measures such as the following:

- **Qualify the vendor**, even if working with an import/export firm.
- Visit your supplier's facility. It can be important to appreciate a company's culture, business practices and facility operational management.
- Determine the supplier's procedures for responding to customer complaints and quality issues.
- Use Internet news feeds to **research suppliers**, both during initial qualification and on-going.
- Assess the regulatory climate of the sourcing country as it affects your product. Educate your suppliers when there are regulatory gaps that could influence product integrity.
- **Establish clear quality standards for product and component acquisition.** Identify when quality should override price considerations.

- **Seek domestic references** and follow up with these references.
- Ensure contracts between you and each supplier are written and formalized. **Contracts should include quality metrics and recourse if the metrics** are not met. Methods of recourse should include those that are enforceable within the source country.
- **Require written notice** if work is to be further subcontracted out, and stipulate that any change orders or change requests by the supplier must first be approved by you.
- Know what contract terms are enforceable in the source country.
- **Have a recall plan** and request one from your suppliers.
- Plan for how to respond to quality issues and enforce your plan when a problem is identified.
- Engage a **qualified and reputable third-party testing lab**.
- Ensure you have direct access to a decision maker at the supplier who can stand behind promises.
- Don't assume that your suppliers have the same concept of adequate quality and safety as you do.

Think of your supply chain as part of your company. Seek the same level of quality that you strive for in your own organization because, from your customer's perspective, responsibility for the integrity of your product rests with you.

Resources

Consumer Products Safety Commission (CPSC) Business and Manufacturing Portal: <http://www.cpsc.gov/en/Business--Manufacturing/>

U.S. Occupational Safety and Health Administration (OSHA) listing of Nationally Recognized Testing Labs (NRTL): <https://www.osha.gov/dts/otpca/nrtl/nrtllist.html>

