



MANAGING COMPONENT SAFETY THROUGH THE SUPPLY CHAIN

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In the context of product safety, a manufacturer, distributor, or importer seeks to be united with all members of the supply chain as a team with a common goal. While the manufacturer's brand is generally most visible to consumers and the general public, an effective product safety plan depends upon all members of the team remaining closely aligned to achieve and maintain product safety. In this article we share some strategies to protect your brand through effective management of component safety through the supply chain, which include: (1) setting expectations at the outset and reaffirming

KEY TAKEAWAYS

- Managing component safety is a team effort involving all members of the supply chain.
- The strategies herein can help protect your brand through effective management of the supply chain.

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those expectations throughout the relationship; (2) establishing written protocols and procedures for supplier quality in design and manufacturing; (3) conducting routine audits applying risk management theory to address potential issues in the supply chain; and (4) creating a plan for management of problems arising from potential breaches of supply chain agreements.

Vetting potential suppliers

- Set expectations at the outset and reaffirm throughout the relationship.

The first step to managing component safety in the supply chain is to fully vet potential suppliers based upon their understanding of product safety and the applicable regulatory processes. It is important to work with companies who are committed to supplying safe and compliant products.

Recognizing that cost is a powerful driver in supplier selection decisions, an effective product safety plan considers that the cost of a relationship with a supplier includes more than the price of the product and distribution expenses. The true cost of the relationship may also include future litigation and recall costs associated with an unsafe component. As such, when vetting component suppliers, you should consider the following:

- Whether the supplier has an appropriate product safety plan that includes appropriate testing, auditing, and quality control processes;
- Whether the supplier agrees to purchase the appropriate level of insurance for its components;
- Whether the supplier has been involved in litigation over quality issues; and
- Whether the supplier takes appropriate steps to preserve intellectual property.

Vetting suppliers at the outset of the relationship and avoiding those suppliers with a history of safety issues helps to ensure that you are only partnering with suppliers that share your common goal of creating a safe product.

Reaffirming supplier commitment

In addition to employing a stringent vetting process to select appropriate suppliers, you can also reaffirm your commitment to product safety, and thereby your commitment to ensuring your component suppliers have a commitment to product safety, throughout the relationship in various ways.

Some suggested methods for reaffirming the commitment to product safety include:

- Use the contract and contract negotiations with the supplier to establish the expectation that all members of the team work together to mitigate risk. Negotiate indemnification provisions in your supply contracts which require the supplier to indemnify you for litigation and recall costs arising out of the failure or other issues with its components. This provides an additional incentive to the supplier to ensure that the products it supplies to you are safe and compliant. Additionally, you may also consider including contractual provisions that specify material usage, allow for you to perform site visits, and/or allow for periodic spot-checking of products to test for compliance with safety requirements.
- Establish a form or system of communication where suppliers are required to provide information regarding potential product failures discovered during pre-production testing.
- Establish expectations for supplier involvement in the event of a corrective action or recall related to the applicable component. Such a protocol should address

the supplier's responsibility for handling any root-cause investigations, follow-up testing, collecting and storing of recalled products, and handling of claims related to the recall.

- Establish written protocols and procedures for supplier quality in design and manufacturing.

Materials and quality control methods

Your product safety plan should also establish written protocols and procedures for suppliers regarding the quality of materials and quality control methods for manufacture, especially for components that are safety critical. The following processes can help ensure quality in design and manufacturing:

- Establish a Production Part Approval Process (PPAP) for safety critical components. The repercussions of unapproved and unevaluated changes to safety critical components can result in product quality and/or safety issues. As such, it is important that you establish a PPAP where unapproved changes to safety critical components are prohibited and the prohibitions are enforced through appropriate actions.
- Establish Non-Conforming Material procedures to have a step-by-step protocol that reduces uncertainty when a non-conforming component is identified.
- Require component suppliers to provide test results sufficient to make the required product certifications, such as a general conformity certificate or children's product certificate.
- Distribute a Quality Manual to component suppliers that covers product specifications and the safety and compliance requirements that those components are required to meet.
- Conduct routine audits applying risk management theory to address potential issues in the supply chain

While conducting routine audits of all suppliers in the supply chain to ensure product safety is desirable, it may be unrealistic if you have numerous component suppliers. However, you can employ risk-management theory to assess priorities for conducting routine audits within the supply chain.

This process will identify which suppliers might pose the most risk. A high priority supplier might be a supplier that manufactures safety-critical components of your product or a supplier with a weaker history of safety and quality.

Once you have identified high-priority suppliers, you can assess the potential consequences of those risks and identify the appropriate actions to mitigate those risks. For high priority suppliers that manufacture safety-critical components of your product, you might subject them to more rigorous and frequent audit routines.

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Over time, trusted suppliers might be able to have the audit routine reduced, but safety critical components should always be subjected to some level of audit which will be more rigorous than non-safety critical components.

Breach of supply chain agreement

- Responding to a potential breach of supply chain agreement.

Even with effective management of the supply chain, components in your product may still have a quality and/or safety issue.

When a product safety issue arises because of a component failure, the manufacturer, distributor, or importer will still be the face of the problem and the first line of responsibility.

When encountering a potential product issue, you should conduct a risk assessment and determine what steps should be taken to identify the nature and extent of the problem.

In particular, you may consider whether it is necessary to invest in conducting a root cause investigation or whether

the failure mode effects analyses (“FMEA”) documentation you routinely collect from your suppliers is sufficient in helping you identify the problem.

Regardless of the method you choose to identify the problem, you can protect your legal right to seek potential recovery from the supplier of the failed component.

You may need to determine early on whether you should send a breach letter to the supplier(s) upon discovery that components are failing so the suppliers can assist with the investigation.

Once you have determined the cause of the component failures, you may have various considerations to weigh before deciding whether to seek recovery from the supplier. It may be important to protect your legal right to pursue recovery by placing the supplier on notice of the potential right to recovery and requesting the preservation of evidence.

Conclusion

Managing component safety is a team effort that requires the members of the supply chain to remain closely aligned toward the common goal of achieving product safety.

The strategies set forth above will help a manufacturer, distributor, or importer protect your brand through effective management of the supply chain.

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