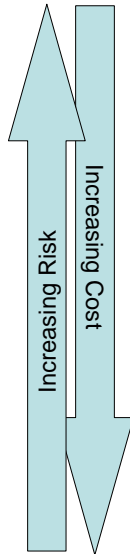


Managing Questionable Supply Chains



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What are the Tools for Managing Supply Chains?



	Quality System	Design Validation	Product Validation	Field Audits
Basic	Supplier Questionnaire/risk analysis	Design Review/ materials analysis	ETL Listing; CB Scheme	Follow-up services on ETL listed/non listed
Moderate	Customized audit/ 3rd Party QMS certification	Durability; Life test; Failure Analysis	Finished Product Test; QPM (Quality & Performance Mark)	Checklists / random sampling
Thorough	Customized development program; On-call task-force; Capabilities study	Full DFMEA/HM; AST	Factory audits; Periodic Re-testing	Retail-level sampling; Receiver or POE Sampling; Full re-test or checklist

The modern supply chain is becoming more complex, with many different levels of skill and oversight in the suppliers and the purchasing companies. Some suppliers have excellent design and quality control skills while others need help with fundamental issues and constant supervision. Some suppliers do an excellent job of implementing lessons learned and maintaining a high level of quality, production and safety. These companies only need a basic level of supplier management, designed to document their level of excellence in quality, design, production and safety. Some suppliers must be guided through all levels of design, quality, production and safety and most have constant monitoring to ensure they have not drifted from good practices.

Three Levels of Oversight:

- **Basic:** Minimal oversight, spot checking. Assumes supply chain has good design, quality and production processes in place, little oversight needed.
- **Moderate:** Detailed oversight with in-depth checks on design, quality and production.
- **Thorough:** Detailed design, production, shipping, auditing and oversight. Assumes the supply chain does not have basic skills and all details must be guided and checked.

In this paper three levels of oversight will be discussed, from the perspectives of: **Quality Systems** - contributed by Calin Moldovean, Vice President of Intertek’s System Certification business; **Design Validation** - contributed by Alex Porter, Chief Engineer for Programs, Performance and Durability; and **Product Validation** - contributed by Larry Todd, Chief Engineer for Electrical.

Basic Level- Quality Systems

At the basic level, the supplier is assumed to have an effective quality management system and deliver lower-risk products or services. The initial supplier selection process is the key component in minimizing risk in the supply chain. At this stage, Intertek assists by designing, distributing and analyzing a custom supplier self-evaluation questionnaire on behalf of the customer. With the results of this survey, we develop a risk-based analysis and include supplier selection recommendations. The customer can then use this validated information to make informed choices. The results of the survey can also be used to determine if a Basic level of oversight is sufficient, or if a higher level of oversight is needed for some of the surveyed suppliers.

Basic Level- Design Validation

At the basic level, the assumption is made that the supplier has good design capabilities. Therefore, the tools used to manage the oversight are focused on ensuring that their good design capabilities are directed toward the proper goals.

At this level, the risks to the design are poor packaging, inaccurate claims, incorrect/wrong features and wrong functionality. Notice that these problems are not associated with an inability to design properly, but misdirected design efforts (wrong functions) or tertiary problems (such as packaging).

Several tools can be used to verify that a good design team is addressing the correct deliverables and taking care of tertiary details. A design review that compares the details of the deliverable to the design can eliminate incorrect features and wrong functions. Extending the design review to include packaging and labeling can avoid inaccurate claims. This, combined with simple package testing, can ensure that the design meets expectations and will be properly packaged.

At this level, materials testing can be very helpful. Even though the design is well done and has been reviewed to meet expectations, over time the product will be produced using materials sources that may change. Materials testing on the finalized design can document the characteristics of the materials (both raw and as fabricated) so that production can control the characteristics going forward. The details of material properties are a design element that is often overlooked near the end of a design process.

Basic Level – Product Validation

At the basic level of Product Validation, the assumption is made that the supplier is interested in meeting qualification rules and legal requirements for safety. The supplier wants to verify that the product meets current safety rules and wants to be able to identify that minimum safety fact to buyers and end-users of the product. The tools for this vary based on the country into which the product is being marketed. The basic tools to meet this level of product validation is the Country Certification, such as the ETL Listing for North America, and the use of the CB Scheme test program to facilitate acceptance in many other countries.

A supplier who does not meet the basic level of product validation runs the risk of, at a minimum, low market acceptance, to outright blockage from a market. The CB Scheme leading to a CE Mark for Europe and certifications in other countries is a minimum to even enter many countries. In North America, the safety certifications available are not required for entry for many products, but markets and retailers willing to accept products without a safety certification, like the ETL Mark, are limited. In some cases installation of your product could be blocked without a proper listing, or at a minimum require additional testing and evaluation at the installation site.

The tools of ETL Listing and CB Scheme are similar in part of what they provide the supplier. In each case the product is thoroughly evaluated for construction and test requirements so that the product complies with safety requirements. This evaluation covers fire hazards, electrical shock hazards and casualty hazards. The additional advantage of an ETL Listing is a descriptive report is written to verify on a regular basis that the product is being built the same way, assuring compliance with the safety requirements.

The listing mark of ETL, as a Nationally Recognized Test Lab (NRTL), is a sign that the product complies with safety requirements required by hundreds of retailers and as defined in the National Electrical Code, the law used for installation of electrical building equipment in the US. These listing marks open the markets for your product. In a similar way, the CB scheme report means that testing and evaluation is only done once, and then facilitates the submittal of your product to other certification bodies around the world for the necessary local certifications.

Moderate Level - Quality Systems

At the Moderate level, the supplier usually has a Quality Management System (QMS) in place - but there may still be delivery delays or high quality costs, which are signs that the QMS is ineffective. The supplier may lack an understanding of key customer and regulatory requirements; this is frequently an issue when working internationally (there may be differences between two cultures on what each thinks is acceptable). Lastly, the products or services being supplied are of a higher risk, and thus a simple survey may not provide the required level of confidence.

One solution that can help mitigate these risks is a second-party supplier auditing program. With the help of an independent (second-party) auditing provider such as Intertek, the customer develops a proprietary audit program that is customized to address the needs of their product and their QMS. The second-party will then audit the suppliers against those unique criteria and provide a findings report. By leveraging the second-party's established auditor pool, the customer saves money on travel time and expenses, and is assured that the audits are performed by competent local auditors who know the language and culture.

The supplier audit program can also be supplemented by customer-specific supplier training programs and workshops. Often, supplier issues are rooted in poor communications with the customer, and not a lack of technical ability on the part of the supplier. If the customer finds a better way to communicate what their expectations are, and the suppliers have a forum in which to voice their concerns and exchange best practices, then it is a win-win situation for all – particularly in today's competitive international market.

Finally, at the Moderate level, many customers require their suppliers to hold third-party QMS certification, to a standard such as ISO 9001. However, a certificate by itself may not provide the assurance the customer is looking for.

Moderate Level - Design Validation

At the moderate design validation level, the assumption is made that the supplier has some design ability but only moderate knowledge of the long-term characteristics of the design. Therefore, the tools used to manage the oversight are focused on the performance, durability, longevity and field performance of the product.

At this level, the supplier is will often design a product that meets the basic deliverables but will have challenges with field failures, warranty claims and long-term performance

of the product. The supplier may not have a history of field experience with the product that provides lessons learned in designing the product.

Applying durability tests and life tests to early prototypes provides information to validate if the design has any apparent weaknesses that should be addressed before production starts. Performance testing can evaluate how well the different performance targets are met before, during and after the product is exposed to durability and life cycle testing. Using these methods, the design can be iterated to eliminate most design flaws.

Analyzing field failures can provide additional feedback to the design during production ramp and after production starts. Failure analysis is the mechanical, physical and chemical investigation into the root cause and sequence of events that leads to a product condition in which the product no longer meets expectations. Failure analysis is using materials science to solve a mystery: Why did the product fail? By answering this question, failures that result in warranty claims can be eliminated.

Moderate Level – Product Validation

At the moderate level of Product Validation, we assume that the supplier is meeting the minimum safety requirements but now wants to verify some performance levels of his product not relating to safety. This might be to determine that continuity of quality levels and performance is maintained. If you want your customers to know they can trust your quality level, this is the level for you. Testing of your marketed product at some place along the supply chain and the Intertek Quality & Performance Mark (QPM) are two levels within this Moderate level to validate your products.

If your products vary in quality items, such as fit and finish, output, box quality, even the printing on the box or whatever is a major concern for your supply chain, then finding a way to verify that the product you design and produce makes it to the end user as expected would be important. Another risk is that after you do all this quality work, it is not as noticed as you would like. Returns of your product to the retailer or distributor because they do not meet expectations are costly and hurt the reputation you have worked so hard to build. Making sure your product get to the end use in proper operating fashion is an important trait in a quality manufacturer.

This level can be provided with services such as spot-checking of products at the time of original shipment, at port of entry and even on the retailer’s shelves. Working with the



supplier is critical in this step to find the quality issues and come up with a cost-effective way to check and verify the product makes it though its travels from manufacturer to end user and meets all requirements. This kind of testing can include statistical analysis, checklist reviews of a product upon arrival at retailer's facility or checks all the way through the process.

The second way to look at a moderate effort is to use a labeling program that provides your product with verification of the qualities of your product. Saying your product is best is sometimes a hollow claim, but being able to place a third party label on the product identifying where your product is the best is a great way to verify your marketing claims and show the consumer that your product really is worth "extra" because of the benefits it provides.

The Intertek Quality and Performance Mark (QPM) is a means of communicating the quality and performance of the end product to the consumer. The QPM verifies a product's quality and performance and is only issued after a product passes a battery of tests. This provides independent, third party assurance that each passing product meets a benchmarked level of quality & performance.

Thorough Level - Quality Systems

The quality systems risks at the Basic and Moderate levels were mostly internal issues, such as supplier selection and training. At the heart of the thorough level are methods needed to mitigate the external risks that have the most impact on our customers, our brand image, and our bottom line: field product failures, product recalls, and production delays. At the same time, safety and regulatory compliance risks cannot be overlooked.

One way to mitigate these risks is to design and administer customized Supplier Development Programs that address supplier audits, supplier selection, performance monitoring, and most importantly, supply chain improvement. These programs can be customized for the customer's needs, the industry and the international marketplace.

The customer can also take advantage of Intertek's "on-call" supplier troubleshooting task force. For example, suppose the customer were experiencing a spike in product failure and warranty claims, and were able to trace the issues back to a particular supplier. An Intertek expert would perform a root cause analysis to determine what happened (whether it was a problem with the product or with the supplier's QMS) and identify ways to improve that supplier.

Finally, the customer could perform supplier process capability studies, to ensure continued capability and identify areas of improvement.

All of the quality management tools outlined in this paper take a holistic approach to supply chain management. Business partners such as Intertek can manage the process for you from top to bottom – helping you to strengthen your supply chain performance while saving money, staying on schedule, *and* freeing up your resources for higher value-added and end-customer focused activities.

Thorough Level – Design Validation

At the thorough level of design validation, the assumption is made that the supplier has very little or no experience designing the product. This doesn't mean that the supplier is inexperienced with design, but may mean that the technology is brand new, the end use environment is new, or both. Therefore, the tools used to manage the oversight are focused on determining fundamental characteristics about the technology and the end-use application so that the design can be completed in a knowledgeable way.

With new technology or new applications, warranty claims resulting from design flaws are likely. The durability and life cycle performance of the product is unknown. The nuances of underlying assumptions that make the product work have not been explored.

To address these problems, the first step is to enumerate all of the hypothesis that must be true for the product to work. This is accomplished through a Design Failure Modes Effect Analysis (DFMEA), which is a common tool used to document all of the failures, their effect, the mechanisms that cause them, the design controls that will be used to prevent them and the detection method that will be used to verify if the design control was successful. A DFMEA has limitations; specifically it relies heavily on the experiences of the team putting the DFMEA together. So for new technology, the DFMEA can be a weak tool.

To mitigate this weakness, a Hypothesis Matrix is also conducted. The Hypothesis Matrix cross-references all of the failure modes that are identified against all the mechanisms that could precipitate them. The result is a matrix of hypotheses that captures all of the assumptions that must be true for the product to work. These can then be analyzed to verify that all attributes have a proactive design control and that all hypotheses have a test to verify they are true. This technique has been used to successfully achieve zero design-related warranties on new technology.

Finally, the use of accelerated stress test methods such as Highly Accelerated Life Test (HALT) and Failure Mode Verification Testing (FMVT) are used to verify what failure modes actually exist in the design, what precipitates the failures and how they rank compared to service conditions and other failure modes. This information along with the Hypothesis Matrix can be used to ensure that the product is robust before being put into service, even when there is no experience with the technology or final application.

Thorough Level – Product Validation

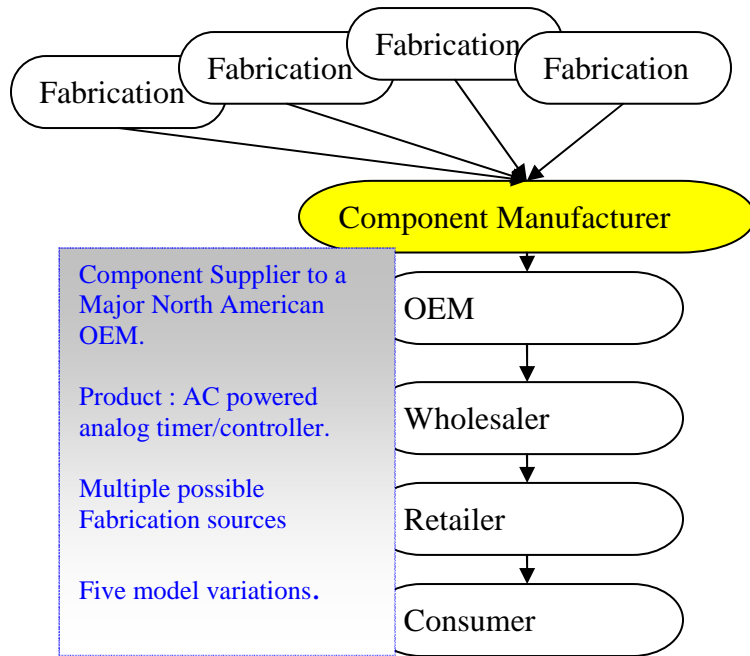
At the thorough level of product validation, we are assuming that the supplier wants to have a high quality product and wants to better control the supply chain process. Doing extra at each end of the supply chain adds to the consistency and quality of the product and verifies that the product is keeping up with requirements and that changes have not been made in the process. In this level, additional, more complete factory audits may be more frequent or involve additional items than what is done in the basic level safety audit. This might involve actually checking performance and energy use during the manufacturing process. The other option here is to re-test samples of the product on a regular basis to show that changes in the parts used or manufacturing process have not affected the quality of the product.

If you make a quality product and set high standards for it, then you don't want to run the risk that changes in your manufacturing process in non-safety related components or changes in speed of production affect your product in ways the customer will notice. Keeping close checks on manufacturing, not only of the end-product but of the components used, might be a useful way to limit possibilities of changes. If many small changes have been made, how that will affect the overall product in performance or energy use or other trait that is important to you and your customers?

The factory audits, like any part of this program, can be developed to specifically meet your needs. Multiple manufactures can be verified against one another, visits to factories and verification that parts and techniques used in the construction of your product meet your guidelines can be done at a frequency based on need and number of products produced. Testing and re-testing to an appropriate level of desire to meet specifications can be done at intervals that provide consistency to your product, without overtaxing the system with unnecessary testing. Programs testing different facets of your products' specifications can be done at different times to provide quick and simple results to show that your products are still at the same quality level you desire for your customers or your customers desire of your products.

Composite Case Study

Following is a composite case study compile from a range of projects to illustrate how the different levels of quality, design and product validation can be used to address given situation.



Risks:

- 1) Does the product meet the functional requirements of the OEM purchasing the components?
- 2) Does the product comply with safety requirement so that it can easily be used in the end product?
- 3) Can the manufacturers hold quality over multiple runs, multiple model variations?
- 4) Materials supplied to the manufacturers are from multiple unknown sources. How will the material properties be controlled?
- 5) The supplier is responsible for all warranty. Warranty charge from the OEM will be part cost plus service call. A service call is estimated to cost ten times the part cost.

Solutions:

- 1) Does the product meet the functional requirements of the OEM purchasing the components?
- 2) Does the product comply with safety requirement so that it can easily be used in the end product?

Checking that a given design meets the OEM requirements requires simply the basic design validation. This would include reviewing packaging and basic deliverables as well as a “check list” of validation. For safety and regulatory requirements a basic product validation would include safety certification for listing of the product.

- 3) Can the manufacturers hold quality over multiple runs, multiple model variations?

This would require a more thorough product validation including factory audits and periodic sampled testing. A moderate review of the quality systems including customized audits and possible training. Basic field audits would also be used. Finally quarterly inspections to verify same basic safety components are not varied.

- 4) Materials supplied to the manufacturers are from multiple unknown sources. How will the material properties be controlled?

A basic design validation on the materials would include materials testing for baseline material properties on the original designs, followed by periodic materials testing on incoming materials. This would combine with the basic quality systems evaluation of the supplier selection and evaluation process.

- 5) The supplier is responsible for all warranty. Warranty charge from the OEM will be part cost + service call. A service call is estimated to cost 10 times the part cost.

A moderate to thorough design validation would include hypothesis matrix on the product followed by Accelerated Stress Testing (AST) to uncover failure modes and non-intuitive design flaws. Forensic failure analysis would be used on any failure modes found. Any failures from the field would be rigorously investigated so the root cause can be eliminated. This would be combined with a thorough quality systems including supplier troubleshooting.

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