

MANAGING RISK IN OUTSOURCED PRODUCT DEVELOPMENT AND MANUFACTURING

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ABSTRACT

In today's litigious society, products used by consumers can become the source of product liability lawsuits. Outsourcing product development and manufacturing can create additional risk because the electronics manufacturing services (EMS) provider's practices may come under scrutiny in this type of lawsuit. What checks and balances should be built into this relationship? What elements should be built into the outsourced product development and manufacturing to help minimize this element of risk?

Syncro Corporation has been an EMS provider for more than two decades and has been manufacturing proprietary automotive aftermarket products since the 1960s. This paper discusses its systems and processes for supporting robust product development and production of high quality products for clients in the automotive, medical and upscale consumer product sectors, who often have enhanced needs for traceability or regulatory reporting support. In particular, it will look at:

- Critical design process review points
- Product validation elements such as Failure Modes and Effects Analysis (FMEA), process control plans and mutually acceptable product acceptance criteria
- Quality assurance processes and recordkeeping
- Likely traceability support requirements.

INTRODUCTION

One of the positive elements of our legal system is that it provides a viable way for consumers injured by poorly designed and built products to receive compensation. However, the system can also allow consumers to receive compensation even when their injury is a result of deliberate misuse of a well designed and built product, in part because a jury of non-technical people decides the outcome based on their perception of the credibility of the parties presenting testimony and evidence.

How do companies defend themselves and their products in an atmosphere of emotional appeal? The answer is to be able to present a track record of good due diligence in design and manufacturing processes, and to be cognizant of the way even relatively benign documentation can become a weapon for the opposing legal team in a product liability lawsuit.

In addition to its EMS activities, Syncro Corporation also manufactures proprietary brake controllers used in towing applications. It has successfully defended these products in a number of lawsuits over the years and its internal systems and processes within the design and manufacturing realm have helped in this defense.

CONSIDERING THE HUMAN FACTOR IN DESIGN

It is virtually impossible to design a product that can't be misused in ways that cause some injury. Besides the obvious product safety benefits, design processes which demonstrate a focus on trying to minimize that risk can be helpful in defending product liability lawsuits arising from consumer misuse.

The first step in that process is asking the question: "Who is the non-typical user and how could they misuse this product?" This leads to the formal Design Failure Modes and Effects Analysis. The end goal of this process should be to identify the hazards and consequences, and the ways these potential hazards can be avoided.

This information may not only drive design considerations, but it may also help determine the requirements for warning labels placed on the product or in the user manual. Attention to detail in this area helps demonstrate that the OEM is serious about product safety. Human factors experts generally recommended a three part approach to the process which includes:

- Ensure safety by design whenever possible
- Install guards on areas of the product which can cause injury if handled improperly
- In the event a risk exists that can't be designed out or reasonably guarded against, use persuasion to highlight the misuse risk.

From the EMS provider perspective, writing the user manual or determining necessary warning labels is typically the OEM customer's responsibility. However, it may be part of the outsourced product development process. In the Company's system, a third-party human factors design consultant is contracted when needed to support their internal engineering teams in this area of product development or product redesign efforts. However,

ultimately the OEM is responsible for final approval of the product design and any accompanying packaging elements.

DOCUMENTATION GENERATION / RETENTION CONSIDERATIONS

Documentation is often the single most important factor in winning or losing a product liability lawsuit. The types of documents generated and internal policies related to document retention may be as important as the actual content of the documentation because a plaintiff's lawyers may be looking to show breakdowns in internal systems that suggest a bad product may have been produced.

Records that "tell the story" of a robust design process include:

- Engineering drawings and schematics
- Performance test requirements and results
- Design FMEAs
- Notes from design reviews.

A good document retention policy defines the documents that will be generated and the period of time those records are retained. Conscientious companies may ask the question: "If I'm doing everything possible to ensure product safety, why should I be worried about documentation content or retention?" The answer is that even the most innocuous documents may be used to sway a jury. For example, a promotion announcement may be used to demonstrate that an engineer or manager lacked a key competency needed for that particular product. An overly detailed cost/benefit analysis may list low probability potential risks which carry unsupportable redesign costs and those may be used as examples of an OEM sacrificing safety for profit. A member of the engineering team may write a speculative email about a failure mode risk that is subsequently proven to be inaccurate and just the original email may be presented. Analysis of document destruction records may show inconsistent adherence to retention time policies or a focus on destroying documents related to the product under scrutiny. A document generation policy that limits the creation of unnecessary documents and a track record of consistent storage/destruction activities minimizes the possibility that technically irrelevant documents may be used to sway a jury's opinion.

From an outsourcing perspective, an OEM with good procedures in these areas could still face issues if its design house or EMS provider were inconsistent in their practices because all companies involved in design and production may have their records and procedures scrutinized. OEMs with higher liability products should consider this area in supplier selection audits.

The Company's records procedure specifies that every quality record is listed and that list includes the name of the individual responsible for maintenance of that record, where it is archived and its retention period.

PRODUCTION CHECKS AND BALANCES

A robust quality management program, clearly defined operator skill requirements, methodology for identifying and correcting defects, supplier certification process and a system for ensuring production lot traceability are all important elements of a good manufacturing process. They are all key elements in minimizing product liability because they create a foundation for both "proving" that systems were in place to ensure good product is consistently built and assisting in rapidly recalling products that are found to be defective in the field.

The Company uses ISO 9001:2000 as its primary quality management system and has very specific procedures to enhance its ability to support customer needs for ensuring documented quality and traceability. Examples include:

- *Supplier certification procedures* – Procurement policies include detailed procedures for choosing and evaluating suppliers. Material acceptance procedures segregate the supply base to reduce non-value added inspection, while ensuring that critical parts are closely monitored. In addition, both suppliers and parts are certified, meaning that a supplier must be both certified as an approved supplier as well as the approved vendor list (AVL) source for a given part.
- *Material storage and handling procedures* – All received material has specific procedures for incoming inspection, handling and storage. As parts are received, the computer flags those with specialized handling and storage requirements, such as moisture or ESD sensitivity and they receive special color-coded labels. Storage shelf life is tracked by date code. There is also specialized tracking related to parts with low volume consumption, associated with end of life production support or with repair depot relative to shelf life, storage location and/or incoming inspection procedures.
- *Work order processing* – Product documentation, MRP and work orders are electronically integrated. Product documentation is electronically updated and work orders will automatically reference the latest revision in the system. Consequently, when an engineering change notification (ECN) is approved and entered in the system, it is immediately clear to all production personnel that a new revision is in effect and the work order will automatically reference that revision. The MRP system then assigns parts based on work order requirements. Material is verified as it is picked to ensure it is the right material for the work order. There

is also a first article inspection process on production setup.

- *Operator Training and Certification* – Industry-standard training programs such as the IPC J Standard C Solder Training / Certification program are used in operator training. Operators are certified based on a skills matrix and certifications are tracked by badge number. The time/attendance monitoring system will not allow an operator to clock into a production work cell unless he/she has the certification needed to perform the operations in the work cell. In the event a PCN/ECN changes the processes in a given work cell to the point where operators require additional skills training, they will not be able to clock in until the system recognizes that they have been certified in the new skills.

- *Production Part Approval Process (PPAP)* – Although PPAPs are typically an automotive industry requirement, many other industries with liability concerns require similar levels of product acceptance documentation. The PPAP is used to verify manufacturing capability and product performance prior to product shipment. While not every EMS customer requires the full PPAP documentation process, the discipline is in place to generate whatever levels of verification documentation a given OEM requires. Typically, a complete PPAP documentation package includes:
 - Design records
 - Engineering changes
 - Engineering approvals
 - Design FMEA
 - Process FMEA
 - Dimensional results
 - Records of material/performance test results
 - Initial process studies
 - Measurement system analysis studies
 - Qualified laboratory documentation
 - Control plan
 - Part Submission Warrant (PSW)
 - Appearance Approval Report (AAR)
 - Sample production parts
 - Master sample.

- *Traceability* – A number of records are tracked to each work order including:
 - Raw material lot used including manufacture lot and date code
 - Test data
 - Operators performing the work
 - Attribute tracking including yields.

- *Measurement and continuous improvement* – Data collection includes:

- Selective use of SPC
- Customized performance validation testing
- Regular collection and on-line reporting of key performance metrics
- Customized reporting for customers.

There are also weekly communications and monthly reviews of quality metrics used to drive improvement targets.

CUSTOMER FEEDBACK LOOPS

Clear communication between OEM and EMS providers is essential. While ultimate product liability rests with the customer, in a product liability investigation all parties involved in the product development, manufacturing and distribution process are scrutinized.

While the exact acceptance process may vary slightly by customer, under the Company's processes, customers approve designs, AVL changes, ECNs and first articles.

Most projects involve at least weekly project status calls with customers and more formalized design or program reviews may be held less frequently. In some cases, groups of suppliers have been brought in for a focused customer day.

Project performance data is tracked internally for all programs. Some customers also rate performance on key metrics via a supplier scorecard.

The end goal is to provide a range of measurements that ensure that the customer is the final point of acceptance of any product change and keep all team members informed of any needed corrective actions or performance issues.

CONCLUSION

Product liability lawsuits are time-consuming and typically involve committing significant technical staff resources to document research, depositions and testing. Consistent procedures relative to document generation and retention, and product testing/analysis combined with robust traceability systems help demonstrate a commitment to designing and building quality products and ultimately benefit consumers by helping to ensure high quality, safe products. In addition, evidence of process discipline can be a deterrent to legal teams with weak cases because the inconsistencies that could support an emotional appeal are less likely to be found

early in the process. Most law firms won't waste significant time on liability cases that are perceived unlikely to be won in court.

The challenge for minimizing this liability in outsourced product design and development is twofold. From an OEM perspective, its EMS providers should have systems in place that ensure they are not the weak link in the manufacturing chain either in terms of their actual activities or the way they document those activities. OEMs producing consumer product with inherent liability risks should consider this in initial supplier selection audits. From the EMS provider standpoint, the customer must continue to own the design and the bulk of the liability because they also receive the bulk of the margin associated with the end product. Internal approval systems should reflect this relationship element.

Taking a proactive approach to addressing product safety considerations as a joint focus from product design through manufacturing helps minimize the risk for both parties.