CASE STUDY

When good processes don't reduce product risk

When process becomes a checkbox: how an established manufacturer lost sight of product risk and business performance

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Executive summary

An established global consumer product manufacturer had invested significantly in its quality system over the years and its processes were well established. With around 200 employees, a broad product portfolio, its own assembly plant, a dedicated product quality team and in-house testing facilities, the business had many of the elements expected to support effective product risk management.

It was ISO 9001 certified, underwent regular audits and had documented procedures for everything from product development processes to risk assessments, testing, problem solving and corrective action.

However significant product quality problems were persisting. At the time when the project outlined in this case study took place, some products faced potential global recalls and poor product reviews were damaging sales and reputation. The business had also been unprofitable for the previous five years.

A technical product audit, looking at all processes related to the design, manufacturing and improvement of the products, revealed that many of the processes intended to manage product risk were not delivering their intended outcomes. Risk assessments consumed considerable resources without consistently identifying the most important risks. Investigations often failed to establish root causes, manufacturing approvals were frequently granted under deviation, and market information was outdated, incomplete or not prioritised appropriately.

A corrective action programme was designed to address the weaknesses identified. Procedures we revised and training was delivered to help staff understand and apply the changes.

The business was sold a short while after this work. Consequently, the longer-term impact of the corrective action programme on product performance or business results could not be established. However, the fact-based assessment of the product and process risks was able to support better informed management decision-making and it was acknowledged that this work was valued by the leadership team.

The case illustrates an important lesson: having documented processes, quality systems and formal risk assessments does not necessarily mean that a business is effectively managing its product risks.

The business: **established systems, persistent problems**

The manufacturer was an established international business with a reputation for producing high-quality consumer products. It had its own assembly plant, a product development team, customer service functions, a dedicated product quality team and in-house testing facilities.

Product development followed defined stages, with formal gates, risk assessments and highly detailed verification plans. Procedures documented how activities were expected to be performed, and the business operated within an established and certified ISO 9001 quality management system.

On paper, many of the necessary elements were present.

However, the business continued to experience significant quality problems. Some products were facing the possibility of global recalls and negative reviews were affecting sales and reputation. Additionally, the business had not turned a profit for 5 years and was facing a restructure.

These problems raised questions about whether the existing processes were identifying the right risks, whether the information reaching decision-makers was adequate, and whether identified problems were being resolved effectively.

The issue was not simply a lack of procedures or technical resources. It was whether the systems in place were helping the business make the decisions and take the actions needed to manage product risk.

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The warning signs: **activity was not translating into effective action**

The business had invested considerable effort in its processes. Risk assessments could involve many people and take days to complete. Meetings could include around 30 participants, decisions were often slow and responsibility for taking action was not always clear.

The quality team was under significant pressure, with limited capacity and gaps in the resources or competencies available to address major quality issues. Different departments tended to focus on their own objectives, making it difficult to resolve problems that crossed functional boundaries.

The result was a system in which substantial activity did not necessarily translate into better risk management.

Risk assessments were being completed, but important risks associated with consumer use and the wider product lifecycle could still be missed. Corrective action processes existed, but investigations did not consistently identify root causes or result in effective solutions. Market information was available, but it was not always sufficiently current, complete or appropriately prioritised.

In some cases, procedures appeared to have become an exercise in completing the required documentation rather than a practical tool for making decisions and controlling risk.

This distinction matters. A process can be followed as written and still fail to achieve its purpose. The existence of a completed risk assessment, approved document or closed corrective action does not, by itself, demonstrate that the underlying risk has been adequately addressed.

The technical product audit: **identifying the underlying weaknesses**

A technical product audit was conducted to assess how effectively the business's existing product focused processes managed product development, compliance, manufacturing, quality and product risk.

The audit examined product verification plans, regulatory and material testing, internal product testing, risk assessments, production part approval process (PPAP), Control Plan documentation, warranty and customer feedback, corrective action processes, engineering change requests, common product failure modes and physical products, including printed materials (user instructions, packaging and product labelling).

The findings revealed weaknesses across several connected areas.

Regulatory compliance processes resulted in unnecessary testing

The audit found that not all legal requirements relating to toxicity were being addressed. Internal testing was also inconsistent across products.

The existing material compliance system contained multiple documents covering different materials, often with substantially the same testing requirements. When requirements changed, numerous documents needed updating. Some were not updated, leaving outdated information in circulation.

The system also applied generic requirements to materials even where a particular chemical was not expected to be present. This could result in unnecessary testing. In other cases, requirements exceeded what applicable legislation or standards required, contributing to nonconformances and concessions.

The business arranged and paid for all testing, adding to the cost of the process.

These findings highlighted a problem beyond test selection. The system needed to maintain current requirements, distinguish between materials and their relevant risks, and establish a more effective basis for demonstrating compliance.

The corrective action programme therefore included work to centralise requirements, make testing more material-specific, establish realistic requirements based on applicable laws and standards, and improve the use of supplier compliance evidence supported by random testing.

Risk assessments consumed resources without delivering sufficient value

The risk assessment process was another significant area of concern.

The Failure Mode and Effects Analysis (FMEA) performed required substantial effort, but their focus was primarily on individual components. Risks associated with consumer use and production process set-up were not consistently identified, even though such problems could later emerge in the market or on the production line.

The audit also found that some high-severity risks were not being addressed.

This raised a fundamental question about the purpose of the assessment. A risk assessment should help the business understand what could go wrong, the potential consequences and what action is needed.

The corrective programme included improving both the efficiency and the effectiveness of the FMEA process, broadening the focus beyond components and strengthening the treatment of high-severity risks, while reducing the time used to perform the assessments.

Manufacturing approvals had little value and corrective actions were ineffective

The audit identified weaknesses in production controls and problem-solving processes.

Production Part Approval Process (PPAP) submissions were frequently approved under deviation. When deviations become routine, approval can lose its value as evidence that the manufacturing process and associated controls are ready and effective.

The audit also found that 8D (a problem solving method) investigations seldom identified the true root cause, while Engineering Change Requests (ECRs) seldom resolved the actual problem.

These findings pointed to a recurring pattern: the business had established processes for investigating and correcting problems, but the processes were not consistently achieving their intended outcomes.

An investigation may document a problem and record an action without establishing why the failure occurred. A change may then address the immediate symptom while leaving the underlying cause in place.

The corrective action programme included improvements to PPAP, Control Plan, 8D and ECR processes, with the aim of strengthening manufacturing controls and the effectiveness of problem-solving.

Market information was not being used effectively

The audit also examined how the business collected and used information from products already in the market.

Market reports were not always prioritised according to risk, and much of the available information was outdated or incomplete.

Warranty data, customer feedback, incident reports and recurring failures can provide important evidence about how products behave in real-world conditions. That evidence should inform decisions about products already on sale, as well as future design, verification and risk assessments.

If information is incomplete, out of date or not prioritised appropriately, the business can struggle to recognise emerging patterns and determine which problems need urgent attention.

The corrective programme therefore included improvements to the collection, assessment and response to customer feedback, along with better connections between in-market issues, corrective action, engineering changes and product risk assessments.

The wider issue: **processes were not working as a connected system**

Taken together, the findings showed that the challenges were not confined to a single procedure or department.

The business had established processes for compliance, testing, risk assessment, production approval, problem-solving and customer feedback. However, weaknesses in these individual processes, combined with siloed working and slow decision-making, reduced their overall effectiveness.

A risk identified during product development might not be adequately addressed. A problem arising in production or in the market might not be investigated to its root cause. Lessons from one product might not be captured and applied to others.

The organisation was also carrying a substantial documentation and process burden. Yet the quantity of documentation did not reliably indicate whether the most important risks were being controlled.

This is an important distinction for business leaders. A quality management system can provide structure, consistency and accountability, but certification and regular system audits do not guarantee that every product risk is identified or that every process is effective in practice.

The question is not simply whether a process exists or whether people have followed it. It is whether the process provides the information, decisions and actions needed to achieve its intended purpose.

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From audit findings to a corrective action programme

Following the initial audit, a 9-month Corrective Action Programme was implemented to address the weaknesses identified. The programme improved the effectiveness of the existing system rather than simply adding more documentation.

Its main areas of work included:

Strengthening product compliance requirements. The material compliance system was improved so that requirements were easier to maintain, relevant to the materials being used and grounded in applicable legislation and standards. The programme also addressed the use of supplier compliance evidence and appropriate verification testing.

Improving risk assessment. The FMEA process was changed to be more effective at identifying risks beyond individual components, including risks associated with consumer use and production processes. The programme also changed how high-severity risks were addressed.

Improving manufacturing controls and problem-solving. Changes to PPAP, Control Plans, 8D investigations and ECR processes improved the effectiveness of production approvals, root-cause investigations and corrective action.

Making better use of market feedback. The programme included improvements to how customer feedback and market information were collected, assessed, prioritised and acted upon. It also strengthened the links between in-market problems and the relevant engineering and risk management activities.

Retaining organisational knowledge. New guidelines for product and printed-material development made relevant requirements and lessons more accessible to staff.

Training was an important part of this work. Revised procedures alone cannot resolve weaknesses if people do not understand their purpose, how to apply them or when a situation requires further investigation or escalation. The programme required attention to both the technical processes and the organisational factors that influence whether those processes work in practice.

Supporting management decisions

An important part of the contribution to this business was providing fact-based assessments to support management decision-making.

Technical risk information is most useful when it enables decision-makers to understand the nature and significance of a risk, consider the available options and determine what action is appropriate. It should support decisions.

At the end of the project, the business's leadership provided a written recommendation acknowledging the value of the work and its contribution to management decision-making.

The business was sold a short while after the work was completed. Consequently, it was not possible to establish the longer-term impact of the corrective action programme on product quality, the frequency of failures or the business's financial performance.

What can be demonstrated is the scope of the audit, the weaknesses it identified, the corrective action programme developed in response, and the recognition received for the work and its contribution to management decision-making.

Lessons for product businesses

This case illustrates why business leaders should look beyond the existence of formal processes when evaluating how effectively product risks are managed.

A business can have a quality management system, documented procedures, detailed risk assessments and extensive testing, yet still fail to identify or address its most significant product risks.

There are several questions worth asking:

- **Are we assessing the right risks?** Do our assessments consider the product's intended use, foreseeable consumer behaviour, manufacturing processes and experience in the market, or are they focused too narrowly on individual components?
- **Are our processes producing useful decisions?** Do risk assessments help people determine what action is needed, or have they become documentation exercises?
- **Are we resolving problems at their source?** Do investigations establish root causes and verify that corrective actions address them?
- **Are we learning from products already in the market?** Is customer feedback and failure data current, complete and used to inform decisions about existing and future products?
- **Can people act on what they find?** Are responsibilities clear, decisions made in a timely manner, and sufficient expertise and resources available to address significant risks?

These questions help shift the focus from process compliance alone to process effectiveness.

The objective is not to create more procedures or make every assessment more complicated. It is to ensure that the processes a business already relies on are helping it identify the right risks, make informed decisions and take effective action.

The central question is not simply, “Do we have a product risk management process?”

It is, **“How do we know our processes are helping us make better decisions and manage the risks our products create?”**

About Global Product Confidence

Global Product Confidence delivers leadership and business support for product businesses operating or expanding globally. Through 25+ years working in product development and manufacturing, Fiona van Petegem, founder of Global Product Confidence, developed The Smart Risk Framework, to help product businesses remain profitable as complexity increases. She has also published a book on this topic.

Many leaders of product businesses find they spend the majority of their time responding to crises rather than focusing on business strategy and growth. We help them solve that by helping them understand product risk, what drives it and what to do about it. Our ultimate goal is to make it easy for businesses to confidently take exceptional products to global customers.

Want to learn more about the Smart Risk Framework? Contact us to book an initial conversation.

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