

INSIGHT REPORT

MITIGATING RISK WITH FMEA & QUALITY MANAGEMENT SOFTWARE

INTELEX

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Problems cost money. The sooner a potential problem or error is anticipated and resolved, the less it will ultimately cost an organization. This includes direct costs like warranty claims and recalls, and in more serious terms, the long-term costs associated with lost business and damage to a company's reputation. Fortunately, these challenges can be anticipated and addressed proactively using hazard analysis and risk management tools.

Failure Mode and Effects Analysis (FMEA) is one powerful engineering tool that can be used to prevent quality, reliability, and safety problems. When applied consistently and comprehensively, FMEA can reduce or eliminate the cost of failures and other errors. Failures are prioritized according to the severity of the consequences, the frequency of occurrence, and the difficulty of detection. FMEA can be used at the design stage to identify potential issues that can be resolved by improving the product design, to incorporate risk-based thinking into the design of a new production process, or to improve an existing production process in a risk-aware way.

The FMEA process also documents current knowledge and actions about the risks of failures, which can be used in continuous improvement activities. As a "living document," FMEA can reveal hidden issues in both products and services. It can also be used not only to explore and identify issues, but to prioritize responses to them. Organizations use FMEA to:

- incorporate [risk-based thinking](#) into new product design
- identify Critical to Quality (CTQ) characteristics for business or customers
- decide when and if to launch corrective or preventive actions
- decide when and if to deploy improvement projects to production
- determine whether to accept, avoid, mitigate, or transfer risks, and
- prioritize and allocate resources to risk mitigation efforts.

Although most commonly used in manufacturing environments, the powerful FMEA approach is broadly applied across many industries. It can be used to reduce medical errors in hospitals, to anticipate and reduce the incidence of software bugs, and to enhance non-functional requirements like reliability and serviceability. FMEA has also been used to examine hazards associated with drug delivery, to understand system safety, and to prevent fatalities in the aerospace industry. Organizations in transportation and logistics, facilities management, the military, energy/utilities, oil and gas, and chemical process industries also commonly incorporate FMEA into their risk assessment practice.

In addition to protecting people and assets, properly applied FMEA can help shorten product development times, reduce the costs of prototyping and testing, and reduce or eliminate issues due to low quality. It can help prevent accidents caused by material failures, protect against mistakes introduced by operators, and be used to anticipate events like the introduction of foreign objects that can have serious (or even catastrophic) consequences.

FMEA is a creative and collaborative process that brings stakeholders together to resolve problems before they can happen. It is a cornerstone for risk analysis in most organizations and can be used in conjunction with other methods including Fault Tree Analysis (FTA), Process Hazard Analysis (PHA), Hazard and Operability (HAZOP) studies, and Event Tree Analysis (ETA).

FMEA: A PROACTIVE APPROACH TO RISK MANAGEMENT

Risk management is a foundational component for any quality system. In [ISO 9001:2015](#), risk-based thinking is a central requirement: identifying, analyzing, and evaluating risks (6.1.1) must be done in the context of the relevant issues and requirements of the core business (4.1, 4.2, and 4.3). Action plans must be integrated into QMS processes and effectiveness of those actions must be tracked (6.1.2).

The Baldrige Criteria for Performance Excellence, administered by the Malcolm Baldrige National Quality Award (MBNQA) program and the U.S. National Institute of Standards and Technology (NIST), also requires that risks and opportunities are systematically addressed. This includes creating an environment conducive to intelligent risk-taking (1.1), using risks to catalyze innovation (5.2), and pursuing strategic opportunities based on risk identification (6.2).

FMEA can be leveraged as part of any quality system, or even in Six Sigma projects during the “Improve” phase. The FMEA technique is often applied in new product development (often referred to as D-FMEA to reflect design), to examine production processes (P-FMEA to reflect emphasis on the process), or even to manage supply chain risk. The Production Part Approval Process (PPAP) used to qualify suppliers in the automotive industry requires, at some of its levels, that suppliers share FMEA results or allow their customers to review the results.

BENEFITS OF FMEA SOFTWARE

“Doing an FMEA can require a huge effort. If, for example, you have a safety programmable logic controller (PLC), you very easily have between 500 and 1,000 components on the circuit boards; if each component has three failure modes, you can easily end up with an FMEA table of 3,000 rows. ‘It’s really hard work to do this,’ says Maier (principal engineer, functional safety, at Underwriters Laboratories) [footnote: <https://www.automationworld.com/article/primer-understanding-fmea-tool-testing-functional-safety>]

Centralized software to store and manage risk-related information and related quality data will carry significant benefits for any organization, including:

- streamlining data collection, risk assessment and reporting across sites and facilities
- eliminating duplicate data
- deploying active notifications based on built-in risk reduction policies and threshold limits
- reducing costs through improved risk management processes, including more effective identification of (and response to) failure modes
- streamlining quality management processes that incorporate risk considerations
- providing real-time access to corporate quality performance metrics
- reducing the resources required to complete tasks and communicate across departments, and
- creating control plans and control plan templates to document the process control strategies that will ensure requirements are met.

In many organizations, FMEA results are recorded on grids that follow a recognized format, captured either on paper or in Excel spreadsheets. It can be a tedious and rigorous process. Teams that complete the FMEA have to rely on their personal knowledge to identify potential failure modes, causes, and effects. It is difficult (and often impossible) to search through multiple FMEAs to find failure modes shared between parts, or between products, making the creation of each new FMEA a daunting and time-consuming exercise.

With each new FMEA that is created, the knowledge base within an FMEA software system can be continuously grown and improved, ensuring that your organizational knowledge is captured and shared. This also means that it’s easier for teams to build a new FMEA, because they have access to consistent records, including:

- catalogs of parts or products
- catalogs of process steps
- catalogs of commonly encountered failure modes, and
- catalogs of commonly encountered root causes.

Because FMEA results are commonly reported in a standard gridded format that can have up to 20 columns of information, manually creating and editing the grids can be painstaking. FMEA software can generate those grids for you and produce new ones whenever there are updates to the failure modes, root causes, or associated controls or actions.

FMEA software implemented consistently across sites and facilities can resolve nearly all the challenges associated with FMEA analysis, including capturing the relative importance of SOD (severity, occurrence, detection) variables, reducing the subjectivity of SOD estimates, and making SOD variables easier to determine. (Liu et al, 2013) This approach can also help you identify conditions for use that would be beyond the limits of established engineering specifications, or changes in product design that might disrupt its ability to function for your customers.

FMEA + QUALITY MANAGEMENT SOFTWARE = AMPLIFIED VALUE

When FMEA is embedded within a quality management software system, the benefits are amplified even further. The relationships between RPN estimates and the effectiveness of corrective actions can be tracked, providing a solid basis for determining the impact of corrective actions. In addition, occurrence estimates from an FMEA can be compared to (or directly sourced from) records of quality events such as nonconformances. The quality management system can also keep track of:

- root cause analysis details used to identify the causes listed in the FMEA
- control plans that emerge from FMEA due diligence
- actions to prevent causes or detect failure modes, and
- historical actions taken to ensure follow-through on all risk reduction efforts.

Sharing information across other applications, such as customer complaints and corrective action plans, will also strengthen the integrity of your risk management approach. Risks can also be assessed against actual observations to close the loop and validate the significance of your risk prioritization.

Flexibility is also critical. A flexible FMEA software system can be configured with SOD scales that are appropriate to the problem at hand. For example, Six Sigma process improvement projects may require tracking occurrence in terms of defects per million opportunities (DPMO).

The most significant driver of value for FMEA capabilities integrated into your quality management software, however, is the preservation of brand equity. This asset is the most vulnerable to damage from public perception amidst recalls, bad press, or social media attention to poor quality. Product recalls, for example, can tarnish years of work building your brand -- and shake the confidence of stakeholders, compromise brand identity, endanger the health and safety of consumers, or lead to litigation. Through effective integrated FMEA management, you can protect your organization from [damage or destruction](#).

CONCLUSION

Save time, save money, and preserve organizational knowledge when FMEA capabilities are integrated into your quality management software. Through centralized data, well-defined and structured tools, and a consistent practice for incorporating risk-based thinking into quality management, it is easier for organizations to protect themselves from the threat of failure.

As failure costs are reduced through effective application of FMEA, quality management software will pay for itself in cost savings and other efficiency gains. The added peace of mind that comes from continuously improving safety, reliability, and effective function is priceless.

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APPENDIX:

AIAG/VDA UPDATES TO FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

The Automotive Industry Advisory Group (AIAG) and Verband der Automobilindustrie (VDA) in Germany are publishing an update to their widely used FMEA Manual in early 2019. It includes significant changes from the 4th Edition that was released in 2008. The changes were motivated by discrepancies between the German and North American approaches to FMEA in the automotive industry, which made it difficult for supply chain partners in different countries to use FMEA for supplier selection and relationship management.

The revision presents three main changes. First, a rubric has been added to facilitate assessment of Severity (S), Opportunity (O), and Detection (D) for each failure mode. Also, a new method for prioritization is proposed that eliminates the Risk Priority Number (RPN) in favor of Action Priority (AP), and finally, the FMEA tasks are situated within a six-step process that will already be familiar to many organizations who use FMEA. There will be considerable growing pains associated with the shift away from RPN in this industry; despite its shortcomings, it is the most well-known of the methods to prioritize risks reported on FMEA forms.

Even though the AIAG/VDA FMEA manual was designed for the automotive industry and supports identification of “special characteristics” that must be controlled as a regulatory or safety requirement, it is versatile enough to be applied to risk management scenarios in other industries. FMEA software must be able to adapt to industry changes like this.

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