

FMEA: Failure Mode and Effects Analysis as the basis for low-risk processes

FMEA (Failure Mode and Effects Analysis) is a systematic method for identifying potential failures in products and processes before they occur. It originated in the aerospace and automotive industries and is today a standard element of quality management and supplier evaluation. For buyers, the FMEA is a central tool for identifying supplier risks at an early stage, agreeing binding quality requirements and controlling inspection effort along the value chain.

Key facts

- The FMEA assesses failures systematically according to probability of occurrence, severity and probability of detection.
- In the automotive industry, the FMEA is frequently demanded from the supplier contractually via standards such as AIAG-VDA.
- A distinction is typically made between system FMEA, Design FMEA (DFMEA) and Process FMEA (PFMEA).
- Assessment is frequently carried out using the Risk Priority Number (RPN) or the more recent Action Priority (AP) format.
- FMEAs are living documents: they are updated when there are changes to product, process or supplier.
- For procurement, the FMEA is an early indicator of supplier risk and the effort required for incoming inspection and goods inspection.

Definition: FMEA

The FMEA is a preventive analysis method of quality management that systematically records and assesses all conceivable failure modes of a product or process, together with their causes and effects. The aim is to identify risks before the start of serial production or process release and to derive appropriate preventive and detection measures.

Types of FMEA

Three forms are common. The system FMEA considers the interplay of components and interfaces, the Design FMEA (DFMEA) design-related failures of a component or assembly concept, and the Process FMEA (PFMEA) failures in the manufacturing and assembly process. For buyers, the supplier's DFMEA and PFMEA are especially relevant, as they show how reliably its design and manufacturing can actually maintain the agreed quality.

Distinction from other methods

The FMEA is not a root cause analysis carried out after a failure has occurred, but a forecasting method applied before the failure. It complements tools such as value stream analysis, which looks at material flow, or cost driver analysis, which breaks down cost drivers. While 8D reports and complaints

processes operate reactively, the FMEA is part of failure prevention and is therefore closely linked to process optimisation in procurement, for example in supplier selection and development.

Process and assessment methodology

An FMEA is ideally produced by an interdisciplinary team comprising design, manufacturing, quality and procurement. The process follows a proven seven-step scheme that systematically separates structure, function, failure, assessment and measures.

The assessment criteria

Each potential failure is assessed according to three criteria: occurrence (O), severity (S) and detection (D), each typically on scales of 1 to 10. Classically, the values are multiplied together to give the Risk Priority Number (RPN), with thresholds such as 100 or 125 frequently serving as action limits in practice. The more modern AIAG-VDA format replaces pure multiplication with the Action Priority (AP), with the levels High, Medium and Low, as this takes account of individual high ratings – such as a safety-related characteristic – more reliably.

From risk to action

For each failure, preventive measures (such as modified design or process parameters) and detection measures (such as 100% inspection or automated optical inspection) are derived. Once implemented, a reassessment is performed. Important for buyers: measures must be scheduled, assigned to responsible parties and agreed on a binding basis within project plans or quality assurance agreements.

Significance of the FMEA for procurement

For procurement organisations, the FMEA is far more than a quality document: it provides rational insights into the risk profile of a product and its supply chain, and is thus a basis for procurement decisions.

Supplier selection and release

In the context of enquiries such as the Request for Proposal (RFP) and subsequent supplier qualification, a bidder's FMEA can provide information about its quality competence: anyone who analyses failures systematically generally also works in a more process-oriented manner. For critical components, the FMEA complements customary instruments such as supplier classification and the supplier certificate, as it shows how the supplier specifically controls risks.

Risk and procurement strategy

FMEA results feed into overarching supplier risk management: high RPN or AP ratings on a single-source component are a clear signal to develop second sources or hold safety stock. The FMEA also provides a criterion for supplier segmentation: suppliers with high quality potential deserve more intensive support than commodity suppliers with standardised, low-risk processes.

Contractual anchoring

FMEA obligations, update obligations in the event of changes and the right of access should be enshrined in framework supply agreements and quality assurance agreements. In addition, penalty clauses and complaints arrangements can set out the consequences of a breach of agreed measures – although legal wording should be reviewed on a case-by-case basis.

FMEA in projects: APQP, safe launch and production ramp-up

The FMEA is not an isolated document but part of the entire launch and change management process. It sits at the beginning and extends through to serial production monitoring.

FMEA and control plan

In the automotive and supply industry, the FMEA is typically produced as part of APQP (Advanced Product Quality Planning) and feeds directly into the control plan. The inspection characteristics specified there determine the scope and frequency of quality inspection at the supplier and in the buyer's own incoming goods department – and thus also the inspection effort the buyer must factor in.

Safe launch and launch monitoring

For components with high FMEA risks, the safe launch has become established: during the launch phase, the supplier is obliged to maintain increased inspection depth and enhanced identification for a limited period. In practice, a period of several weeks to a few months is typically agreed, after which a gradual return to the normal inspection regime takes place. Procurement should negotiate and document the additional costs involved at an early stage.

Key KPIs relating to the FMEA

The benefit of an FMEA is reflected in measurable quality and process metrics. Procurement should track these regularly and evaluate them jointly with quality colleagues.

Complaint and failure metrics

Key indicators are the parts-per-million defect rate (ppm), the scrap rate and the number of recurring failures. If complaints fail to materialise despite high FMEA risks, this indicates effective preventive and detection measures. If the figures rise, the FMEA or control plan may be outdated or incomplete.

Costs and effort

FMEA work costs time and therefore money; at the same time, it reduces quality costs and the risk of expensive special transport, such as air freight cost components for short-notice replacement procurement. An economic appraisal can be carried out using cost driver analysis by comparing inspection costs, complaint costs and risk costs.

Risks and typical errors in the FMEA

In practice, the value of the FMEA often fails less because of the method than because of its application. Anyone who knows the following pitfalls can avoid them deliberately.

Token documents and lack of currency

A common occurrence is that the FMEA is produced once at the start of the project and then no longer maintained – a classic audit problem. Changes to design, tooling or process should only be accepted with an updated FMEA and an agreed change notification. Procurement should check this on a sample basis as part of due diligence and supplier audits.

Formalism instead of analytical rigour

The second danger: the assessment is mechanically 'trimmed' to low values in order to fall below

thresholds without genuine improvements having been implemented. Interdisciplinary teams, clear responsibilities and a critical eye, even on 'unlikely' failures, prevent this. Detection measures should never substitute for preventive measures.

Current developments: AIAG-VDA, software and digitalisation

The FMEA methodology was fundamentally revised with the harmonised AIAG-VDA handbook: the seven-step approach and the Action Priority assessment are replacing classic RPN thinking in many places. At the same time, FMEA software solutions are gaining ground that support version control, teamwork and linking to control plans and design requirements.

FMEA in the supply chain

Increasingly, the FMEA is being extended beyond the organisation's own system boundary: supplier analysis and supply chain risks are included in the assessment, for example raw material availability or logistical disruptions. This perspective complements classic instruments such as supplier risk scoring and capacity planning at the supplier – including detailed planning of procurement capacities in tight market situations.

Linking FMEA and procurement metrics

Modern procurement organisations link FMEA insights to their procurement metrics and dashboard systems so that quality risks are managed visibly alongside cost and delivery metrics. In this way, the FMEA evolves from a quality document into a steering instrument for procurement decisions and supplier development.

Typical metrics

RPN threshold: frequently $\leq 100\text{--}125$

Common action limit in practice; above it, measures are mandatory.

Parts-per-million defect rate (ppm): < 50 ppm for critical parts

Industry-dependent; significantly stricter for automotive serial parts.

Safe launch duration: typically 4–12 weeks

Period of increased inspection depth after launch, followed by gradual reduction.

FMEA update rate: $> 95\%$

Proportion of FMEAs that have been traceably updated following changes.

Practical example

A medium-sized mechanical engineering company procures a hydraulic valve housing from a new foundry supplier for the first time. Prior to release, the buyer requests the supplier's process FMEA and, together with the in-house quality team, determines that a shrinkage defect in a critical area would only be detected through quarantine samples – a high detection risk. On the basis of this insight, concrete countermeasures are negotiated and documented.

- Modifying the casting process with additional simulation as a preventive measure prior to release.
- Agreeing a safe launch phase with 100% X-ray inspection and enhanced identification for three months.
- Anchoring the FMEA obligation and update arrangements in the framework supply agreement,

including a right of inspection.

- Including the results in supplier risk scoring and supplier classification as a basis for future tenders.

Conclusion

For technical buyers, the FMEA is a central instrument for assessing quality risks relating to products and suppliers in a structured, traceable and early manner. Its value arises not from the document itself but from the consistent derivation of measures, their monitoring and their anchoring in contracts and supplier processes. Anyone who integrates FMEA results with procurement decisions, supplier strategy and inspection effort measurably reduces complaint costs and launch risks. The prerequisites are well-maintained, up-to-date analyses and an honest approach to assessments. Combined with complementary instruments such as the control plan, safe launch and supplier audits, the FMEA thus becomes an effective building block of modern risk management in procurement.

Frequently asked questions

What does FMEA mean in simple terms?

FMEA (Failure Mode and Effects Analysis) is a method that enables teams to systematically identify, assess and prevent potential failures in products or processes before they occur. Occurrence, severity and detection of the failure are typically assessed. Preventive and inspection measures are then derived from this.

What is the difference between DFMEA and PFMEA?

DFMEA (Design FMEA) analyses design-related failures of a product or component. PFMEA (Process FMEA) examines failures in the manufacturing and assembly process, for example incorrect tool settings or inadequate inspection steps. In practice, the two complement each other: quality is only stable once both design and process are under control.

How is the Risk Priority Number (RPN) calculated?

Classically, the ratings for occurrence (O), severity (S) and detection (D), each on scales of 1 to 10, are multiplied together to give the RPN with a maximum value of 1000. In practice, thresholds serve as action limits. The AIAG-VDA format replaces multiplication with the Action Priority (AP), with the levels High, Medium and Low, assessing the criteria in a combinatorial manner.

When must an FMEA be created or updated?

It is customary to produce the FMEA during development or before serial release approval. It must be updated whenever there is any significant change to design, process, tooling or location, as well as after serious failure events. Many customers contractually require the supplier to be actively prompted to update it.

Is an FMEA required by law or by contract?

There is no general statutory obligation; however, it may become necessary on the basis of product liability and regulatory requirements in safety-critical industries. In the automotive and medical technology industries, the FMEA is frequently required contractually via customer standards and certifications. The specific obligation arises case by case and should be regulated contractually.

What benefits does an FMEA offer to procurement?

The FMEA makes a supplier's quality potential and risks transparent before complaints arise. It provides

arguments for supplier selection, incoming goods inspection effort and safe launch arrangements. In addition, the results feed into supplier risk management and supplier segmentation.