

# Improving Efficiency and Effectiveness of FMEA Studies

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This paper discusses the challenges engineering teams face in conducting Failure Modes Effects Analysis (FMEA) studies and the best practices for meeting those challenges.

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## Executive Summary

This paper discusses the challenges engineering teams face in conducting Failure Modes Effects Analysis (FMEA) studies and the best practices for meeting those challenges. This paper focuses on the specific topic of improving the efficiency and effectiveness of FMEA studies.

Modern economic needs and increased business competition require engineers to constantly develop newer and better solutions within shorter timeframes and tighter margins. In addition, documentation requirements for meeting standards / regulatory compliance and

**FMEA studies significantly reduce costs and improve productivity when properly conducted.**

customer needs are becoming increasingly complex and verbose. Managing open actions and continuous improvement activities across all projects, product variations, and processes in addition to daily engineering tasks is cumbersome, time consuming, and is susceptible to errors, omissions, and non-conformances.

FMEA studies are proven methods for improving products and processes while subsequently reducing engineering workload and improving machine and resource availability through a preemptive, systematic approach of identifying, analyzing, and improving high-risk components. If implemented correctly, FMEA studies significantly reduce costs and improve productivity.

However, the value of an effective FMEA is often shrouded by a lack of clarity and structure, misconceptions, and previous experiences and, as such, FMEA studies are frequently grouped with the other required information and documented retrospectively in preparation of customer requirements or audits. Performing studies in this way only adds cost to a project and perpetuates the misnomer that FMEA studies are not value-added activities.

This paper discusses the benefits of effective FMEA studies, the challenges related to conducting FMEA studies, best practices for efficiently overcoming challenges via structure and automation, and the benefits of implementing those practices.

## Benefits of conducting effective FMEA studies

The goal of completing effective FMEA studies is to improve products and processes through a systematic approach of reducing risk and the limiting opportunities for product/process failure. Effective FMEA studies are powerful tools that benefit the organization, customers, and end users by:

- ✓ Improving yield and profit margins
- ✓ Reducing time to market
- ✓ Increasing machine and human resource availability
- ✓ Ensuring employee and customer safety
- ✓ Meeting industry specific standards compliance and customer requirements



- ✓ Identifying necessary controls and developing test procedures
- ✓ Supporting due diligence claims in legal disputes

Completing FMEA studies efficiently has the additional benefits of freeing up valuable engineering time, reducing the 'cost of quality', and most importantly, obtaining the team buy-in which likely ensures studies will be conducted more regularly and helps drive continuous improvement activities.

As well as being a reliable tool for preventing potential risks in the subject design or process, the process of developing an FMEA provides the environment to identify improvements for similar designs and processes. Cost savings across multiple product lines may be realized while conducting a single FMEA study.

## FMEA challenges created by lack of clarity

While developing products and processes, engineers instinctively plan for potential physical and financial risks which may jeopardize a design. Although FMEA is simply a method for engineers to document their thought process and the FMEA's logical flow itself lends naturally to the engineering environment, there is still a reluctance and tendency to postpone FMEA studies; But why?

### Planning – Defining the scope of the study

The FMEA process can be daunting and out of the comfort zone for engineers. FMEA documents created after a project is complete may expose weaknesses in the product or process design which is frustrating for the team who invested so much time. Poorly defined document scopes, unsuitable team selection, and a general misunderstanding of the FMEA process also contribute to weak study results and a discouraged team. An FMEA study's timing and clear scope play a critical role in its success.

**An FMEA study's timing  
and clear scope play a  
critical role in its  
success.**

Conducting the FMEA prior to a project and reviewing it as the project progresses will save your team time, help reduce development costs, and will be seen by the team as a value-added support rather than a hindrance.

In the past, FMEAs were expected to be an extensive document detailing every aspect of a product design or process. In the modern approach, there is far more flexibility in the functionality of the study. Existing 'family level' FMEA documentation, for example, may address a broad range of products or processes. Certain components of the product or aspects of the process which are considered extremely low-risk or trivial may be unnecessary to detail. Therefore, the scope of the FMEA may be defined to focus only on potential high-risk aspects of the design or process such as a new technology, safety critical features, or complex components which merit additional thought and preparation. Defining a



manageable scope will gain team support and help focus efforts on the areas of greatest concern.

### Planning – Identifying the team

The document scope plays an integral role in determining the appropriate team. While an FMEA team may include representation of the customer requirements, key disciplines involved in the product or process design and implementation, test engineering, reliability engineering, and/or quality engineering, only people directly involved in the product or process in the scope of the FMEA should be involved in its creation.

"The more; the merrier" is not an applicable phrase when it comes to selecting an FMEA team. If a team has too many members, it may limit individual contributions and inspire impertinent conversations which removes focus from the task at hand and leads to longer study completion times.

**"The more; the merrier"  
does not apply to  
FMEA team selection**

Before an FMEA revision or version is finalized, consider sending it to the team members for approval. Including the team in the approval process gives ownership of the document to the team, reminds relevant team members of open actions, and demonstrates to the team that their input is valuable.

### Structuring the approach & managing time

Even with a properly defined document scope and a well assembled team, a significant amount of time is often lost during the 'brainstorming' process – when the team is researching and documenting the information for the study. The researching process is often unstructured, manual and dependent solely on the experiences and expertise of the current team members. Data entry may also be tedious and slow using traditional spreadsheet templates.

#### Structured approach

An unorganized approach to an FMEA study (i.e. filling in fields in a random order, poor preparation, etc.) leaves the study vulnerable to erroneous or incomplete information. Even if a systematic approach is adopted, the selected method plays an instrumental role in the team's performance – quality, quantity, and pace.

To demonstrate the variance in potential productivity depending on the chosen method, consider the following table. If the table is completed one item at a time, entering the size and color before moving on to the next item, the thought process must shift from column to column which slows down the pace of the document. To illustrate the amount of time it takes, complete the table below using this first method – entering a vegetable, its size, its color; then enter another vegetable, its size, and its color; and so on.



Category	Item	Size	Color
Vegetables			
Large Animals			
Items found in the office			

The efficiency of the team may be significantly improved by altering the approach. To demonstrate how productivity may be improved, complete the following table one *column* at a time instead of row by row. For example, list three types of fruit, then list the size of each, then the color of each fruit. Then list three small animals, then the size of each, then their color.

Category	Item	Size	Color
Fruits			
Small Animals			
Items found at home			

The same principle may apply for creating FMEA documents. For example, start by listing the various items or process steps. This may be done quite effectively by reviewing the product diagram or process flow. Next, determine all of the failure modes for each of the previously listed items or process steps, indicating the severity of each. The potential causes for each failure mode should then be listed. Utilizing this method to complete the document helps keep the team focused and maintains the flow of the document.

Keeping the team focused on similar types of information will improve their performance. By following this second method, not only should the pace of the document increase, the information entered for each column should be more consistent, as well.

**Managing time**

With a well-selected team, the ideas should flow steadily. Spending too much time on a particular entry may disrupt the pace of the document and result in longer study completion times. Often the cause of delays is due to a lack of available information or lack of detail. Where additional information is required but not currently available, it is recommended to maintain the team’s momentum by simply assigning an action to complete the information at a later time and moving on to the next entry.

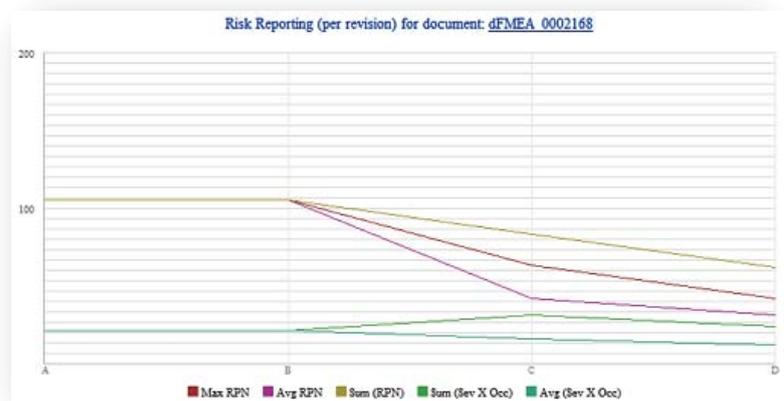


## Leveraging existing knowledge

While 'brainstorming' is important for identifying and discussing new ideas, there's no need to "re-invent the wheel" when documenting existing knowledge in FMEA studies. Time may be saved by reviewing other documents created for similar products and processes. Using previously created documents as a resource will reduce the amount of time spent trying to remember information, will help ensure all relevant information is considered in the current study, and will promote the use of consistent language in the documents in order to convey a clear message and facilitate reporting and future research.

## Continuous improvement & action follow-up

Too frequently, documents are left to collect dust. By regularly reviewing and updating your FMEA documents, the time to complete the updates may be reduced. This may sound like something that is more easily corrected in theory; however, in practice, there are a number of effective and efficient opportunities to review your FMEA documents--when another document for the same or similar part or process is updated, at regular review meetings, and when a change has been made to the part or process.



Consider reviewing open actions regularly – at weekly meetings, for example. Addressing open actions with the team provides a forum for discussion. Setting interim targets or milestones for complex open actions, if applicable, helps make a project manageable and provides metrics to quantify progress.

Graphing key metrics (i.e. 'average Risk Priority Number (RPN)' or 'the mathematical product of Severity and Occurrence') over time for a particular document is another method for visualizing and quantifying improvement to a product or process.

Consistent information and evaluation of risk criteria across all of an organization's FMEA studies is often a challenge. Reporting on common items or process steps across all documents for an organization and confirming the appropriate level of detail is documented may be tedious and time consuming. Similarly, reviewing high-risk metrics across all of the organization's FMEA studies periodically, although highly effective for ensuring consistency and identifying outliers, may be impractical in traditional spreadsheet based applications.

## Additional post-study challenges

Once a study has been documented new challenges arise. Identifying which document revision is the most recent, preventing documents from being accidentally overwritten, and



distinguishing related documents for each product or process are issues which still need to be addressed.

## Meeting challenges through efficiency, structure and automation

Software has become the key to improving the team's performance and unlocking the team's potential to save significant amounts of time and money for each project. Although spreadsheet software applications have been used to document FMEA studies, the preferred method is to utilize a software package dedicated to FMEA and related documentation, such as QA Assistant Studio™ or QA Assistant Studio Flex™.

### The spreadsheet approach

Spreadsheet software applications are intended to be used for computing mathematical equations on numeric tables – not as templates for FMEA. Using spreadsheet software to document FMEA studies creates its own challenges in maintaining momentum and facilitating a structured approach. For example, the team may spend substantial amounts of time performing tedious tasks such as inserting rows and merging cells, researching lessons learned across multiple documents, and ensuring information is consistent.

Using spreadsheet software to document FMEA studies creates its own challenges

Spreadsheet software also limits company-wide reporting and monitoring the status of actions. Specifying team access to the studies and controlling various document revisions may require additional software. As a result, assigning ownership to actions and reviewing open actions across multiple FMEA studies becomes very complex, time consuming, and susceptible to error.

### Preferred solution for efficient and effective FMEA studies



QA Assistant Studio™ software effectively addresses each challenge identified in this paper—facilitating efficient FMEA studies, obtaining the team's buy-in for continuous improvement activities, and reducing development and production costs while meeting customer requirements.

The QA Assistant software is dedicated to FMEA and related Advanced Product Quality Planning (APQP) documents. It includes a number of tools to ensure FMEA studies are completed quickly and easily. The software provides clarity in document terms, assists in defining the team and structuring the approach for documents, and automates researching of lessons learned across all documents created by the company – substantially reducing the time needed for FMEA studies and improving study results.



QA Assistant Studio also provides for actions to be directly assigned to individual document cells to facilitate action follow-up and continuous improvement. It may even send email notices to remind action owners of outstanding issues.

In addition to allowing project milestones to be planned and tracked, the project tools enable documents to be linked either to individual products and processes or to product and process families – allowing the changes made in one document to instantly propagate to all relevant projects.

Revision control, including obtaining approvals for documents before they are finalized, is easy using QA Assistant Studio's built-in version control and document integrity tools. Audit preparation is also simplified as teams are clearly identifiable and each change a person makes to a document is automatically logged and available for review.

The reporting tools included with QA Assistant Studio help the team identify high-risk areas, address open actions, and verify continuous improvement results. The reports may also be used to check for missing or out-of-bounds criteria in documents.

QA Assistant Studio's ease of use obtains the engineers' buy-in and its quantifiable results continuously impress managers and customers.

## Conclusion

While FMEA studies have the potential to move a product from conception to production efficiently and mitigate development and production costs, there are many challenges in documenting FMEA studies which not only adversely affect the current projects but may also hinder future timelines for similar projects. However, with dedicated software solutions such as QA Assistant Studio™ and QA Assistant Studio Flex™, these challenges may easily be overcome while obtaining team support for FMEA and, through active continuous improvement activities, setting one organization apart from its competitors.

**QA Assistant Studio effectively addresses every challenge associated with FMEA studies.**

## About QA Assistant LLC

QA Assistant is dedicated to saving our customers time and money by making the creation, maintenance, and control of quality documentation faster and easier.



QA Assistant is based in the US with representation in 16 countries throughout Europe, and the Americas. We work closely with our suppliers and resellers to ensure the best services are available to our customers.

Our headquarters and development center is ISO / IEC 27001 compliant.

### **Quality Software from Quality Engineers**

At QA Assistant we combine the latest software development technology with years of experience in using and implementing quality tools to deliver products that meet the needs of Quality Technicians, Engineers, Managers and Directors in the Global Markets.

"QA Assistant is committed to designing world-class quality systems solutions which, through their simplicity, functionality, and robustness, empower our customers to meet the demands of their dynamic markets."

-QA Assistant Director of Engineering

Our focus and commitment to Quality goes beyond our meticulous engineering and testing methodology; It extends to our first-class support resources and our personalized interaction with our clients.

The QA Assistant company culture is evident in our professionalism with our clients, our attention to detail, and our pursuit of excellence in our products.

Many thanks to Mary Bray (Key Account Manager, QA Assistant LLC ) for her promotion and commitment to the success of this white paper.