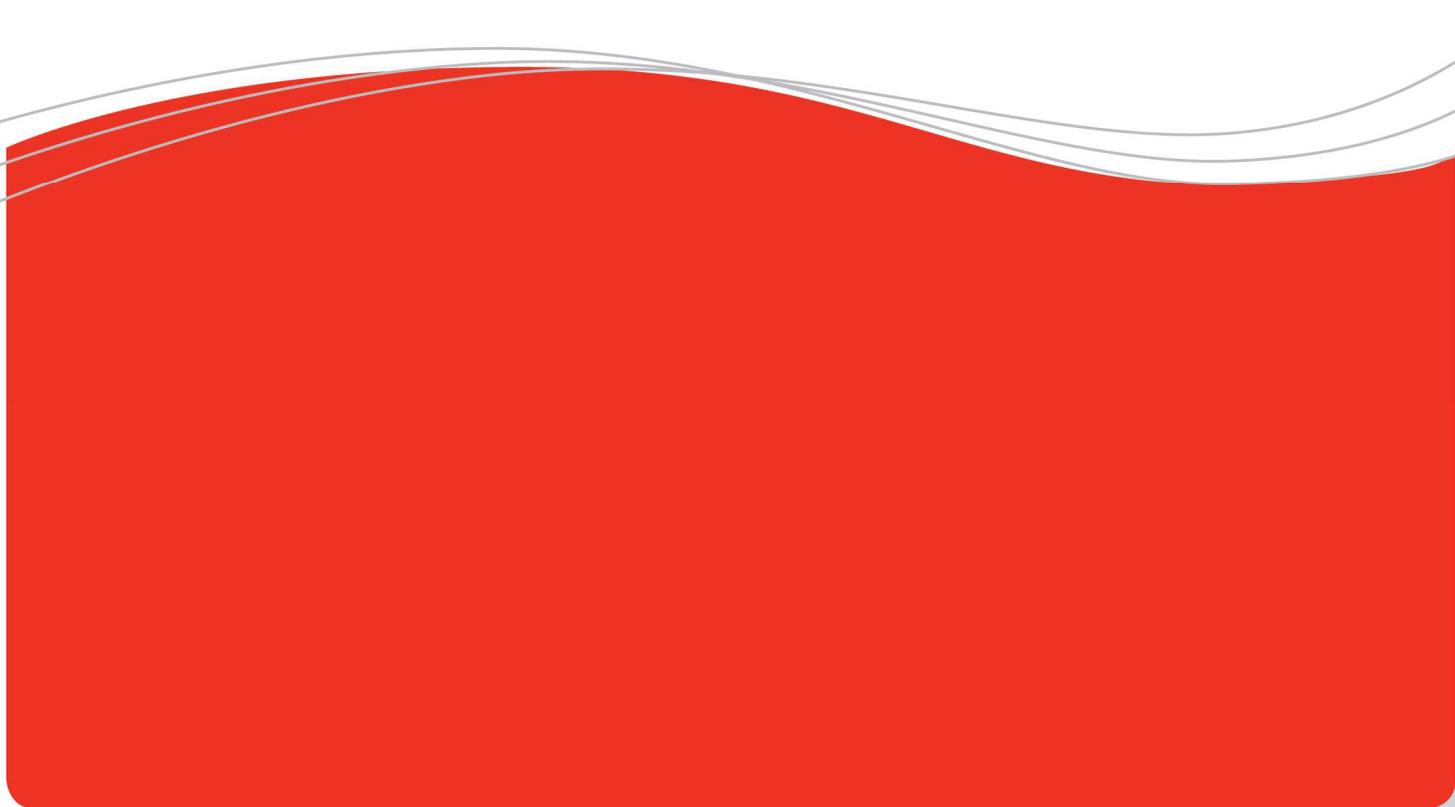




Managing FMEA's



By Steve Murphy and Marc Schaeffers





Managing FMEA

Introduction

Let's say your team has performed a couple of FMEA and the outcomes have been very positive. In fact the results have been so positive that you want to roll out the technique across your whole organization. How are you going to manage this? This article will help you with this. We have broken the process into two stages. Stage one contains the steps you will need to perform once to create your FMEA framework. Stage two consists of the steps you need to take for each individual FMEA.

Stage one setting up the FMEA framework

Define the techniques applied

De facto most companies start their FMEA programs by performing Process FMEA's. They often learn quite quickly that a lot of production problems can be prevented by better design. Correcting problems by design is also more cost effective. So at the start of your FMEA program you need to decide if you are going to make design FMEA's and/or process FMEA's or maybe even system FMEA's. So the hierarchy of FMEA's need to be established. If you decide to make design FMEA's you will also need the Design Verification Plan & Report (DVP&R). When you make process FMEA's you will likely also need to make Control Plans.

It is definitely not necessary to start with all the variants at the same time. However before starting the project you should have a good idea of the total scope and which techniques will be applied.

It is also important to consider what language you are going to use. Often FMEA's and DVP&R will be developed by high level teams and will be in English. It is likely that Control Plans will be used on the shop floor and will be in the local language.

Distinguish between standard and customer specific FMEA's, DVP&R and Control Plans

FMEA is an important and effective way to establish process knowledge. To optimize the benefit of this knowledge it is useful to create standard FMEA's for individual or groups of process steps. The same can be done for design requirements. To create customer specific FMEA's you can call up the standard FMEA's and add the customer specific requirements. Using standard FMEA's in this way ensures process knowledge is not lost and every customer benefits from your increased process knowledge.



Organization of FMEA

This brings us to “Who is going to do what?”

There are too many differences between companies to define a standard approach for FMEA deployment and management. For example it may seem obvious that the Quality Manager should take overall responsibility for FMEA. However some organizations find it is more effective to assign this responsibility to the Engineering manager. Then each section manager is responsible for the designs/processes in his section and each engineer is responsible for the FMEA for his designs/processes. However other groups have a part to play not just in the roll out but also in generating the FMEA and completing the actions. Make sure they are included in the rollout and make sure they know and accept their roles and responsibilities.

- Training, maintenance, manufacturing staff, production planning and finance.
- Who will trigger the FMEA? The Quality Manager or the Process/Design Engineer?
- Who is responsible for following up the recommended actions?
- Who is responsible for budget, staffing and training of the resources?
- The senior management, Will you have an overall steering committee that say reviews the progress of the FMEA rollout?
- How will the senior management review the FMEA after the rollout?

Software selection worksheets and ranking criterion

It's likely that you performed your first FMEA using Excel and this worked fine. You have used Excel for templates and worksheets before and instinctively you can see some problems.

- Ensure everybody uses the agreed template.
- Ensure the documents are all stored in an easy to access database.
- Version control can be problematic.
- Do you want to produce design FMEA as well as Process FMEA?
- How do we distinguish between standard and customer specific items without copying items?
- Link between design FMEA and DVP&R and between process FMEA and Control Plans

There are plenty of good FMEA software products on the market. Use your first Excel trials and the decision processes you use to help you define the criterion that are important to you. Use these to select your package.

In Excel it is straightforward to produce a worksheet for everybody to use. You can download one from the web. You can also download some scoring sheets for Severity,



Occurrence and Detection However there are some questions you may need to ask yourself.

- We supply to one or more specific industries, is the layout of the worksheet consistent with the requirements in these industries?
- If we supply multiple industries do we need multiple formats?
- Do the scoring sheets make sense for your organization? Do you have the information that allows you to say that this problem occurs for one part in a thousand? Does it make more sense to say this problem occurs one a month?

The more intuitive and relevant the ranking sheets are to your organization the more likely it is that they will be accepted and used by your teams.

FMEA training

If you have come up through an engineering background then it is likely that FMEA seems straightforward to you. Maybe you'll think all the training required will be to send some key players on a one day course and everybody else will pick it up as we go along. Consider this, as part of the FMEA rollout you'll be involving a whole range of staff with totally different backgrounds. Training and Finance have very different mind sets to process engineering. To ensure your team have the knowledge required to play their role in the FMEA process you may need a spectrum of training programs, for example

- Detailed training explaining the 14 steps for the quality, process and design engineers that includes time to practice and quickly moves them to "Unconscious competence".
- A light version for the senior staff which includes emphasis on their governance responsibilities.
- A lighter version for the support staff who actively contribute to the FMEA.

Legal consideration

Today there is a lot of transparency between suppliers and customers. Customers will have access to a range of performance metrics including scrap, cycle time and process capability. Be very careful who has access to your FMEA. A good FMEA will contain all your "dirty laundry". It will be a list of all the things that are good enough but could be a lot better. Now imagine this information in the hands of a litigation expert. This expert's role is to convince a jury that you are responsible for a client's injury or



losses with the resulting financial and reputational damage. To minimize the risk consider the following:

- Clear policies on who can view FMEA particularly customers and third parties.
- Insist on a confidentiality agreement for any third party who views the FMEA.
- Some companies will not allow an FMEA to be released to a third party without the written consent of the senior technical and legal officers.

Meetings

Meetings! Much as you may consider meetings the bane of company life I am afraid there is no getting away from them. Without some meetings there will be no FMEA. I won't reiterate basic meeting skills here but I think it is useful to consider some things specific to FMEA.

- Debates will occur but to prevent them from taking up the whole meeting place a time limit on them. For example after two minutes we will take a vote or take the issue off line and come back with a proposal at the next meeting...
- Have a dedicated time keeper to ensure the above happens.
- Use a software system that allows you to update the FMEA as you go along. Review the progress at the end of the meeting.
- Invite at least one contrary but constructive person with good process knowledge to prevent "group think" from taking hold.

A real "As is" Process Flow

For a process FMEA a crucial component is the Process Flow. You may already have a process flow in the form of a batch traveler with all the process steps on it. Or it could be incorporated in your Manufacturing Execution System. This is useful as a start but what we really need is an "as is" process flow. You can generate this by walking through the flow on the shop floor with the production personnel. The sort of steps that frequently get missed out in process flows but can be significant sources of variation:

- Transportation steps, these can easily be a source of damage.
- Any hold step after cleaning.
- Any time delays



- Any storage step when the product or raw materials is subject to the variations in the weather.
- Rework steps, formal and informal.
- Sources of incoming raw material. Does the raw material come from a bulk delivery or the stores?

Also consider where your process flow starts. If it starts on the production line then you may not be considering any variation that occurs in the stores or at the kitting steps.

While making the process flow you need to distinguish between the standard processes and specific process activities required for specific customers.

Incorporating current failure information

You may not realize it but you already have a huge amount of information on failure modes and potential causes. These include details of field failures and customer returns, inline NCR issues, problems identified by OEE, SPC out of control points and maintenance and breakdown reports. Frequently the Severity is known but what needs to be discussed are the Occurrence and the Detection. If this information is collected beforehand then the FMEA meeting can be used constructively to discuss these issues.

Steps to be followed for each FMEA project

Determine the Scope of the FMEA

Having decided to run for example a Process FMEA there is still some ground work to do before running the first meeting. It is important to define the scope of the FMEA. It is useful to consider the following:-

- Exactly where are you going to start? In the stores or the kitting department? At the holding step after the previous process?
- If you have machines that run a range of processes will you start with the process that runs the most products?
 - Or the process that generates the most defects?
 - Or the steps in the process that generate the most customer returns?

For your first few FMEA it is useful to limit the scope to a region of the line so that it gives insight into some problems that you are currently working on or your customers are reporting.



Make the Scope Visible

The basic steps are covered in FMEA framework under the A real “As is” Process Flow section. What is essential is to have this flow available in the FMEA meetings. If you have a large printer for CAD use then print off a large version and stick it on the wall for reference during meetings.

Bringing the team together

After you have established the process flow and transferred this to the FMEA template you can start to think about the team. It is important to remember this, FMEA is a team process and the FMEA will only be as good as the team. So you will need a good team. There should be a core team who own the FMEA. After that there will be the experts and knowledge owners who contribute as required. So let’s start with a core team. We’ll need;

- The FMEA owner
- An expert in running the FMEA process
- Representatives from Process and Equipment Engineering, Manufacturing, Quality representing the customer.

Think of the personal characteristics of the team. It is useful to look at Belbins team roles <http://www.belbin.com/rte.asp?id=8> . If you have no “Completer/Finishers” and no “Team workers” then your team could flounder. It’s likely that your organization has its own team building experts and it would be useful to consult with these are you are putting your team together.

Typically the core team will be between 5 and 7 people. It’s useful to define team roles for people to keep the meeting going smoothly. To complete the FMEA as you go along you’ll need a scribe and to keep the meeting on course you’ll need a timekeeper.

Basic meeting skills have been covered under FMEA framework. Most companies have developed their own meeting norms and usually these will be fine for your FMEA meetings.

As the FMEA develops you may need to pull in specialists. For example an expert in robotic handling or the chemical processing that is taking place.

Establish the role of suppliers

Your suppliers will have a huge amount of knowledge that will be relevant to the FMEA. They will understand issues other customers have had and the sources of variation within their product. Be tactful and they will share this with you and you can



incorporate this into the FMEA. Organize a specific FMEA meeting to assess their impact on your product quality.

For example:

- Chemical suppliers
- Variations in composition.
- Variations in contamination levels
- Raw Materials
- Variations in mechanical properties
- Variations in visual properties.
- Components and subsystems
- Interface requirements
- Reliability

Gather information

Make sure all the current information gathered under “Incorporating current failure information” is easily available during the meeting. There is nothing worse than hunting around on the server for the file half way through a meeting. Distribute this information to the team beforehand to give them time to review it. It will provoke thought and help to generate new ideas.

Conclusion

FMEA is deceptively simple. Performing one high quality FMEA for a problem process can be taxing. Meetings can get bogged down in debates over Severity rankings. The documented process flows can be very different to actual process flows. When you come to roll the process out to the whole organization these problems can multiply.

In this white paper we have offered solutions into a range of issues you will come across when introducing a FMEA framework for a whole organization and when performing specific FMEA.

About the authors

Steve Murphy has 30 years of experience within high tech manufacturing including senior roles within the semiconductor, aerospace and oil and gas sectors.

Marc Schaeffers has 25 years of experience with the implementation of quality systems in industry and is the designer of the DataLyzer FMEA software system.

Both are working with DataLyzer International, a software and consultancy company specialized in the implementation of FMEA, SPC, MSA and OEE.