



USING FMEA AS
A RISK ASSESSMENT
TECHNIQUE



INTRODUCTION

Failure mode effects analysis (FMEA) is a form of risk assessment using a step-by-step approach to identify possible failures in a design, process, and/or product enabling analysis to eliminate or reduce future failures. This type of assessment was first used by the US military in the 1940s and further developed by the aerospace and automotive industries. Although engineers have performed various forms of FMEA on their designs and processes for years, it has just recently become a regular technique for risk assessment in the pharmaceutical industry.

Failure modes and effects analysis is meant to be a preventative action, a pre-assessment tool. FMEA should be implemented before a process or product is designed or redesigned or being applied in a new way. Failure modes determine the ways in which a product or process might fail, and effects analysis is used to study the consequences of those failures. By doing this, potential failures can be prioritized according to their consequences, how frequently they may occur, and how easily they may be detected. Then, the purpose would be to take action to eliminate or reduce potential failures. The entire process documents current knowledge and actions for use in continuous improvement of the process or product and control before and during the process or product. It can also be used to prevent potential failures with future processes or products.

The pharmaceutical manufacturing industry is continuously enhancing procedures in order to provide safe, cost-effective medicines to customers whenever possible. The FDA states FMEA “provides for an evaluation of potential failure modes for processes and their likely effect on outcomes and/or product performance. Once failure modes are established, risk reduction can be used to eliminate, contain, reduce, or control the potential failures. FMEA relies on product and process understanding. FMEA methodically breaks down the analysis of complex processes into manageable steps. It is a powerful tool for summarizing the important modes of failure, factors causing these failures, and the likely effects of these failures.” Using FMEA as a disciplined technique in order to identify and help minimize potential risk is extremely important.

Piramal Pharma Solutions – Lexington, KY uses many different risk management methods, but FMEA has been used sparingly. The technique can be intimidating to someone not having used it before or often. As a technical writer for Piramal – Lexington, I broke apart the process into manageable steps and held training sessions for my fellow employees in anticipation of this technique being used more often as our company grows. Below are the general steps used to complete a FMEA. This is subjective as the document is a living document that can be designed, changed, and completed in many different ways.

1. Assemble a team of people from different departments with diverse knowledge about the process or product and client needs. It is important to start with all departments involved. As the process evolves, some departments may become unnecessary. It is important to have as many alternative viewpoints as possible to catch all potential failure modes. Although an individual is usually responsible for the preparation of the FMEA, input should be a team effort. Bring all participants together for a brainstorming session.

2. Develop a detailed description of the process/product. Describe both the desirable and undesirable uses or outcomes of the process/product. Remember: If anything can go wrong, it will.

3. Develop a workflow or block diagram of the process/product. This provides an overview of the major components or steps and how they are related. This is also helpful in developing the list of functions in the FMEA document and should be included with the FMEA document. Also, identify the scope of the FMEA. Depending on the process/product, the FMEA can be extremely detailed or very simple. The scope must be determined before starting the FMEA. When the scope is determined, the rating key should also be determined. There are several different rating keys, but all should have a rating for severity of effect, likelihood of occurrence, and ability to detect. This key should be agreed upon and used by all involved in the FMEA process.

4. Determine the template to use for the FMEA document. Several are available on the internet depending on how detailed the FMEA is going to be. Also, the company may have a required template to use. A template can also be created in Word or Excel. The document should specify the process/product the FMEA is focused on, who is responsible for preparing the document, and the date the FMEA was started on.

5. With the brainstorming team, identify all the functions of the process/product. These should be listed with a verb followed by a noun in a column labeled "Functions." Break the process/product into separate subsections, items, parts, assemblies, and/or steps and identify the function of each. Use a different row for each function.

6. For each function, identify all of the ways failure could happen and list in a separate column labeled "Potential Failure Mode," same row as the function. Depending on the determined scope of the FMEA, each function could have several failure modes, just one failure mode, or several of the functions could have the same failure mode. It may be necessary to rewrite the function with more detail.

7. For each failure mode, assuming the failure has occurred, describe what might be experienced or noticed by personnel, clients, and/or customers. This needs to go in a column labeled "Potential Failure Effects," same row as the failure mode. These should be as detailed as possible, and depending on the scope of

the FMEA, could be several for each failure mode. Two types of effects should be considered: local and global. Local effects do not affect other components. Global effects can affect other functions or components.

8. Using the agreed upon rating key, determine how serious the potential failure effects are. Assign a number based from the key based on severity. If a failure mode has more than one failure effect, only the highest severity rating is used. This should go in a column labeled "SEV" in the same row as the failure mode the effects represent.

9. In a fifth column labeled "Potential Root Causes," determine all potential root causes of each failure mode. This should be listed on the same row as the potential failure mode it represents. Use the knowledge and experience from the brainstorming team. List all possible causes for each failure mode. A root cause is a defect in design, process, quality, part, or application which is the underlying cause of a failure or which initiates a process leading to a failure.

10. In a new column labeled "OCC," using the rating key, determine the occurrence rating for each potential root cause. This rating estimates the probability of the failure occurring for that particular reason during the lifetime of the process/product. This number should be placed in the same row as the root cause.

11. Identify current process controls for each potential root cause and list in a seventh column labeled "Current Controls," same lines as the cause on the FMEA form. These are tests, procedures, and/or mechanisms currently in place to detect either the cause or its failure mode after it has happened but before the client/customer is affected.

12. Determine the detection rating (the ability to detect the failure) using the rating key for each current control. This should be listed in the eighth column labeled "DET," same row as the current control.

13. Calculate the risk priority number (RPN) by multiplying the severity rating by the rate of occurrence by the detection rating ($SEV \times OCC \times DET = RPN$). Place the total in the ninth row labeled "RPN," in the same row as each current control. These numbers provide the guidance for ranking potential failures in the order they should be addressed. The higher the number, the larger the risk. Depending on the pre-determined scope of the FMEA, just some of the high numbers will be addressed or all of the ratings will be addressed.

14. After the potential failures are ranked, the team should identify recommended actions, the parties responsible for the actions, and target completion dates. These actions may be design or process changes to lower severity of occurrence. They may also be additional controls to improve detection.

15. Note actions as they are completed with results and date on the FMEA document. Also, note any changes to the severity, occurrence, detection ratings, and RPN.

FMEA is a working document. It is constantly changing and updating and is important to have someone assigned as a responsible party to ensure the form stays up-to-date with the process/product design. The need for taking appropriate preventative actions with

follow-ups is extremely important. With the implementation of this risk management technique, quality and safety is improved, client satisfaction is increased, and product development timing and costs are reduced. Increased knowledge on FMEA is just another way Piramal – Lexington is striving to put our clients first and continuously improve with the industry.





Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies and Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs, Antibody Drug Conjugation and are well versed in technologies such as Bio-catalysis, Route Scouting etc. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.



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