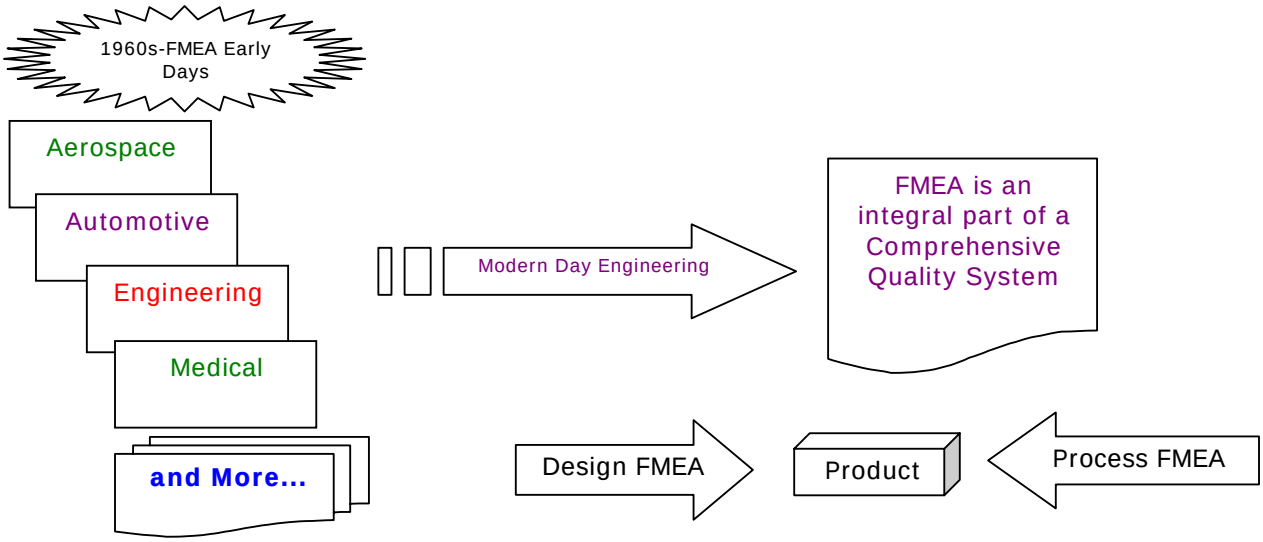
Failure Mode and Effects Analysis (FMEA)

Quantum Age provides onsite consulting services on Failure Mode Effects Analysis (FMEA) for identifying and solving product design and production process problems.

Our broad ranging experience in handling a large number of product designs and production of such designs allows us to assist your design and production teams to gauge the potential failure modes and work out solutions to minimize such failure modes.



What is FMEA?

Failure Mode and Effects Analysis (FMEA) is a tool that examines potential product or process failures, evaluates risk priorities, and helps determine remedial actions to avoid identified problems.

An FMEA is a form of Brainstorming that generally follows a **Cause and Effect Analysis** or a Process mapping and it is usually followed by a Pareto Analysis. It is a granular analysis of a process, a system or a product design for the purpose of identifying possible deficiencies. It is generally conducted by a cross functional group with all the participants having a stake or knowledge about the process, system or product being assessed.

Methodology

Describe Product or Process

Define Functions

Identify Potential Failure Modes

Describe Effects of Failure

Determine Causes

Detection Methods / Current Controls

Calculate Risk

Take Action

Assess Results

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Failure Mode and Effects Analysis (FMEA)

When conducting a process or system FMEA, the first step should consist mapping the system or the process and then listing all the steps of the process to be implemented before brainstorming the potential problems that can cause undesired effects at every stage of the process.

When the FMEA is done in relation with a New Product Development, the listing of the items to be assessed will include all the critical parts of the product and their interactions.

The basic process is to take a description of the parts of a system, and list the consequences if each part fails. In most formal systems, the consequences are then evaluated by three criteria and associated risk indices:

- severity (S),
- likelihood of occurrence (O), and (Note: This is also often known as probability (P))
- inability of controls to detect it (D)

Each index ranges from 1 (lowest risk) to 10 (highest risk). The overall risk of each failure is called Risk Priority Number (RPN) and the product of Severity (S), Occurrence (O), and Detection (D) rankings: RPN = S × O × D. The RPN (ranging from 1 to 1000) is used to prioritize all potential failures to decide upon actions leading to reduce the risk, usually by reducing likelihood of occurrence and improving controls for detecting the failure.

Since the purpose of an FMEA is to forestall failures, after determining the list of potential failures and their RPNs, the next step should be the planning of the actions to take to avert their occurrence. The strategic actions to take are above all based on the nature of the failures but their presence is contingent upon the RPN. After finishing the first phase of the FMEA, preventive tasks are assigned to stakeholders according to their aptitude, but the priority of execution should be subject to the RPN ranking.

History

The FMEA process was originally developed by the US military in 1949 to classify failures "according to their impact on mission success and personnel/equipment safety". FMEA has since been used on the 1960s Apollo space missions. In the 1980s it was used by Ford to reduce risks after one model of car, the Pinto, suffered a fault in several vehicles causing the fuel tank to rupture and it to subsequently burst into flames after crashes.

When to use it?

Failure mode and effect analysis is primarily a quality-planning tool. It is useful in developing features and goals for both products and processes, in identifying critical product/process factors and designing countermeasures to potential problems, in establishing controls to prevent process errors, and in prioritizing process subunits to ensure reliability.

Applications

FMEA is most commonly applied but not limited to design (Design FMEA) and manufacturing processes (Process FMEA).

Design Failure Modes and Effects Analysis (DFMEA) identify potential failures of a design before they occur. DFMEA then goes on to establish the potential effects of the failures, their cause, how often and when they might occur and their potential seriousness.

Process Failure Modes and Effects Analysis (PFMEA) is a systemized group of activities intended to:

1. Recognize and evaluate the potential failure of a product/process and its effect,
2. Identify actions which could eliminate or reduce the occurrence, or improve detect ability,
3. Document the process, and
4. Track changes to process-incorporated to avoid potential failures.

Failure Mode and Effects Analysis (FMEA)

Salient Features of FMEA

- First Time Right
- Identifies inadequacies in the development of the product
- Test and trial may be limited to a few products
- Regulatory Reasons
- Continues Improvement
- Preventive (not Corrective) Approach
- Team Building
- Required by Procedures

FMEA Benefits

The FMEA analysis procedure is a tool that has been adapted in many different ways for many different purposes. It can contribute to improved designs, products and processes, resulting in:

- Reducing the likelihood of customer complaints
- Reducing the likelihood of campaign changes
- Reducing maintenance and warranty cost
- Reducing the possibility of safety failure
- Reducing the possibility of extended life or reliability failure
- Reducing the likelihood of Product Liability claim

Limitations

FMEA is useful mostly as a survey method to identify major failure modes in a system. It is not able to discover complex failure modes involving multiple failures or subsystems, or to discover expected failure intervals of particular failure modes. For these, a different method called fault tree analysis is used.

Back Ground Task for PFMEA (Process FMEA)

1. Details of the manufacturing process/Process flow chart
2. List of critical process parameters (Temperature, Pressure, etc.)
3. Properties of device material (brittleness, density etc.)
4. Manufacturing environment details
5. Manufacturing Tool details
6. Batch to batch variation

Back Ground Task for DFMEA (Design FMEA)

1. Detail design of Device
2. Principle/Basis of design (Deagglomeration Principle, punching mechanism of capsule etc.)
3. Part/Component list
4. Functions of components
5. Theory/principle for the positioning of different components at their respective places (pin, sieve etc)
6. Operating environment conditions (Humidity level, Pressure, Temp etc)
7. Design Specifications (with Tolerances)
8. Details of operating methods (pin movement fidelity, fatigue effects etc)
9. Critical parameters of design and its dimensions

Failure Mode and Effects Analysis (FMEA)

List of End-User Usage Failures
1.
2.

List of Quality Checks
1.
2.

Packaging Details
1.
2.

Transportation Details
1.
2.

List of Product Design Robustness Expectations/Parameters
1.
2.