Laboratory 2

An FMEA should be the guide to the development of a complete set of actions that will reduce risk associated with the system, subsystem, and component or manufacturing/assembly process to an acceptable level.

The primary objective of an FMEA is to improve the design.

- ✓ For **System** FMEAs, the objective is to improve the design of the system.
- ✓ For **Design** FMEAs, the objective is to improve the design of the subsystem or component.
- ✓ For **Process** FMEAs, the objective is to improve the design of the manufacturing process.

Design FMEA

Design FMEA (DFMEA) explores the possibility of product malfunctions, reduced product life, and safety and regulatory concerns derived from [2]:

- ✓ Material Properties.
- ✓ Geometry.
- ✓ Tolerances.
- ✓ Interfaces with other components and/or systems.
- ✓ Engineering Noise: environments, user profile, degradation, systems interactions.

Process FMEA

Process FMEA (PFMEA) discovers failure that impacts product quality, reduced reliability of the process, customer dissatisfaction, and safety or environmental hazards derived from [2]:

- ✓ Human Factors.
- ✓ Methods followed while processing.
- ✓ Materials used.
- ✓ Machines utilized.
- ✓ Measurement systems impact on acceptance.
- ✓ Environment Factors on process performance.

Why Perform FMEA?

Historically, the sooner a failure is discovered, the less it will cost. If a failure is discovered late in product development or launch, the impact is exponentially more devastating.

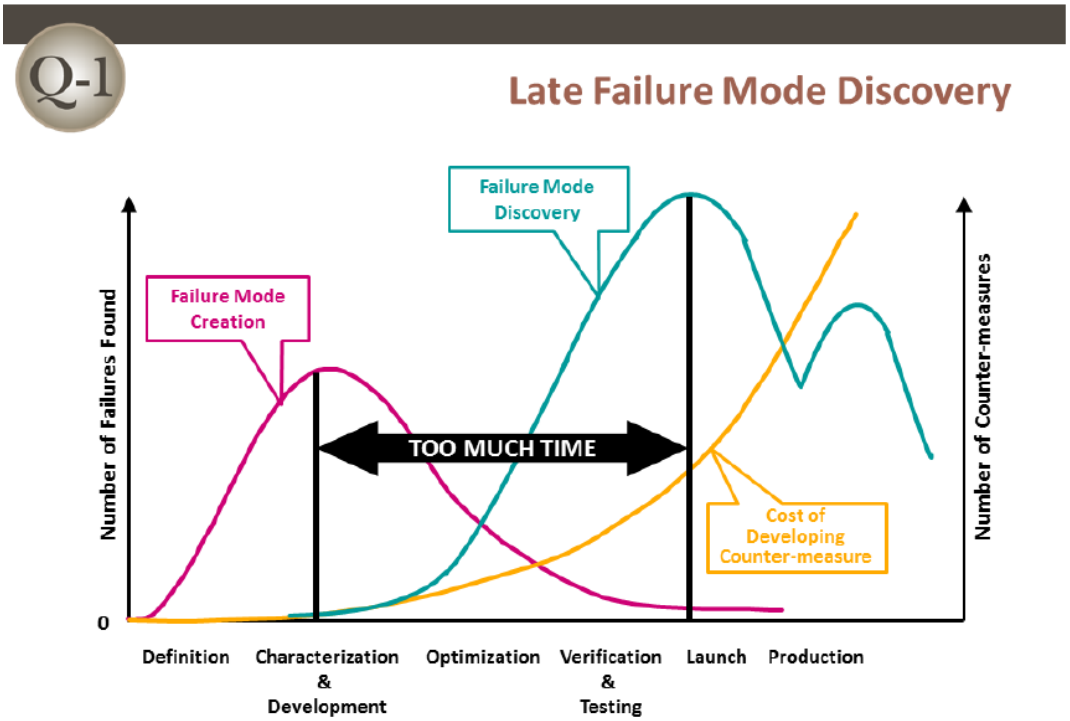
FMEA is one of many tools used to discover failure at its earliest possible point in product or process design.

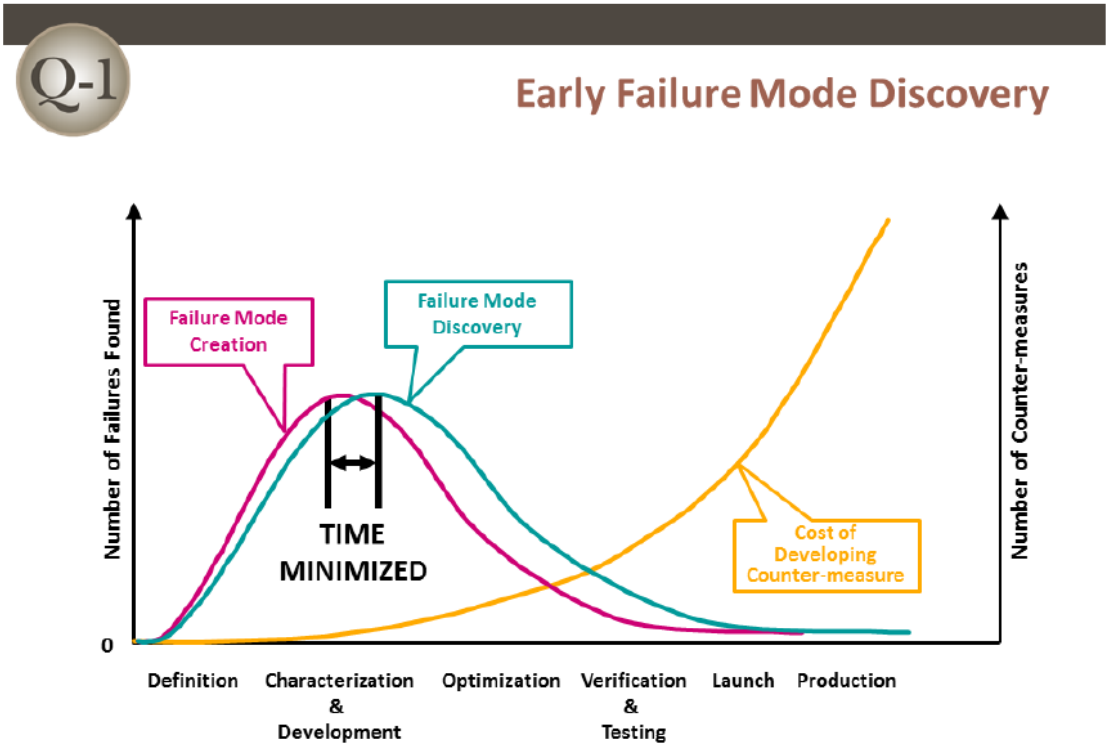
Discovering a failure early in Product Development (PD) using FMEA provides the benefits of:

- ✓ Multiple choices for Mitigating the Risk.
- ✓ Higher capability of Verification and Validation of changes.
- ✓ Collaboration between design of the product and process.
- ✓ Improved Design for Manufacturability and Assembly.

- ✓ (DFM/A).
- ✓ Lower cost solutions.
- ✓ Legacy, Tribal Knowledge, and Standard Work utilization.

Ultimately, this methodology is effective at identifying and correcting process failures early on so that you can avoid the nasty consequences of poor performance.





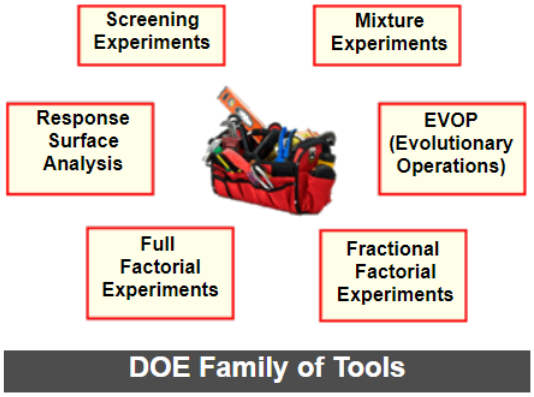
Typically, the main elements of the FMEA are [3]:

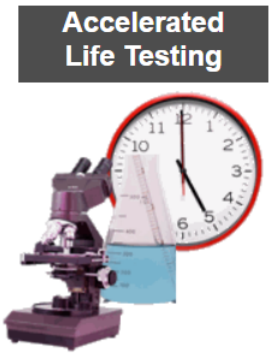
- ✓ The ***failure mode*** that describes the way in which a design fails to perform as intended or according to specification;

- ✓ The ***effect*** or the impact on the customer resulting from the failure mode; and
- ✓ the ***cause***(s) or means by which an element of the design resulted in a failure mode.

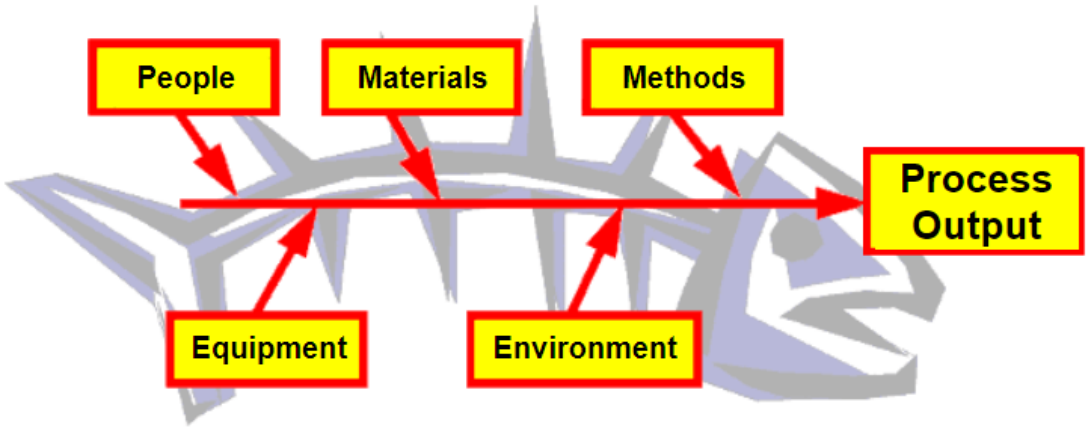
A Design-FMEA involves a study of a specific product. A Process-FMEA is a study of a process that may produce products or provide a service. While the principles and strategy of a Design-FMEA and a Process-FMEA are essentially the same, the tactics used in some of the steps will differ somewhat [4].

1. A primary objective of a Design-FMEA is to uncover potential failures associated with the product such as those that could cause product malfunctions, a shortened product life or a safety hazard while using the product [4]. At the beginning of the process for designing a new product, we can look at how the design process itself might fail. Study of the design process could show us where we need to use design tools such as Design of Experiments (DOE) or Accelerated Life Testing to explore potential failure modes. Incorporation of design aids can lead to more robust design [4].





2. Process-FMEAs are used to uncover process problems related to the manufacture of a product or a series of products. When conducting a Process-FMEA, you need to think about how failures from the many process inputs or causes can affect process outputs such as product quality, processing efficiency and safety [4].



While both focus on identifying risks, conducting a Process-FMEA differs from conducting a Design-FMEA in several ways.

Issue	DFMEA	PFMEA
Customer	End-user plus related design teams & mfg	End-user plus downstream operations
Team Make-Up	Design Team	Process Team
Review	Blueprint or Schematic	Flowchart or Traveler
Intended Function(s)	Design Requirements	Operating parameters & product specs
Controls	Focus on product & design process	Manual, gages, & mistake- proofing
Ranking Criteria	Differs primarily in Severity & Detection Evaluation Criteria	

While this is not intended as a comprehensive checklist, this comparison of a typical team representation involved in a DFMEA versus a PFMEA does demonstrate that the make-up of an FMEA team requires careful thought [4].

Another difference between DFMEAs and PFMEAs is the type of controls used to prevent or detect the effects or causes of failures. PFMEA controls can be categorized into three types listed in increasing order of power: manual controls, gages, and mistake-proofing (also known as error-proofing). DFMEA controls focus on the design process and on the product itself [4].

DFMEA	
Rank	**Design Control**
10	No control or will not detect
9	
8	
7	
6	
5	
4	
3	
2	
1	Almost certain to prevent

PFMEA			
Rank	**Mistake-Proofed**	**Gaging**	**Manual Inspection**
10			x
9			x
8			x
7			x
6		x	x
5		x	
4	x	x	
3	x	x	
2	x	x	
1	x		

1 = Best control; 10 = Poorest control

Severity, occurrence and detection ranking scales are all used for both DFMEAs and PFMEAs although the descriptions of the ranking scales are a little different. In either case, however, the ranking scales should be customized for your organization [4].