Balancing
Risks
Part 2 of 3

Agenda

Other risk management tools – FMEA

When to use FMEA and when not

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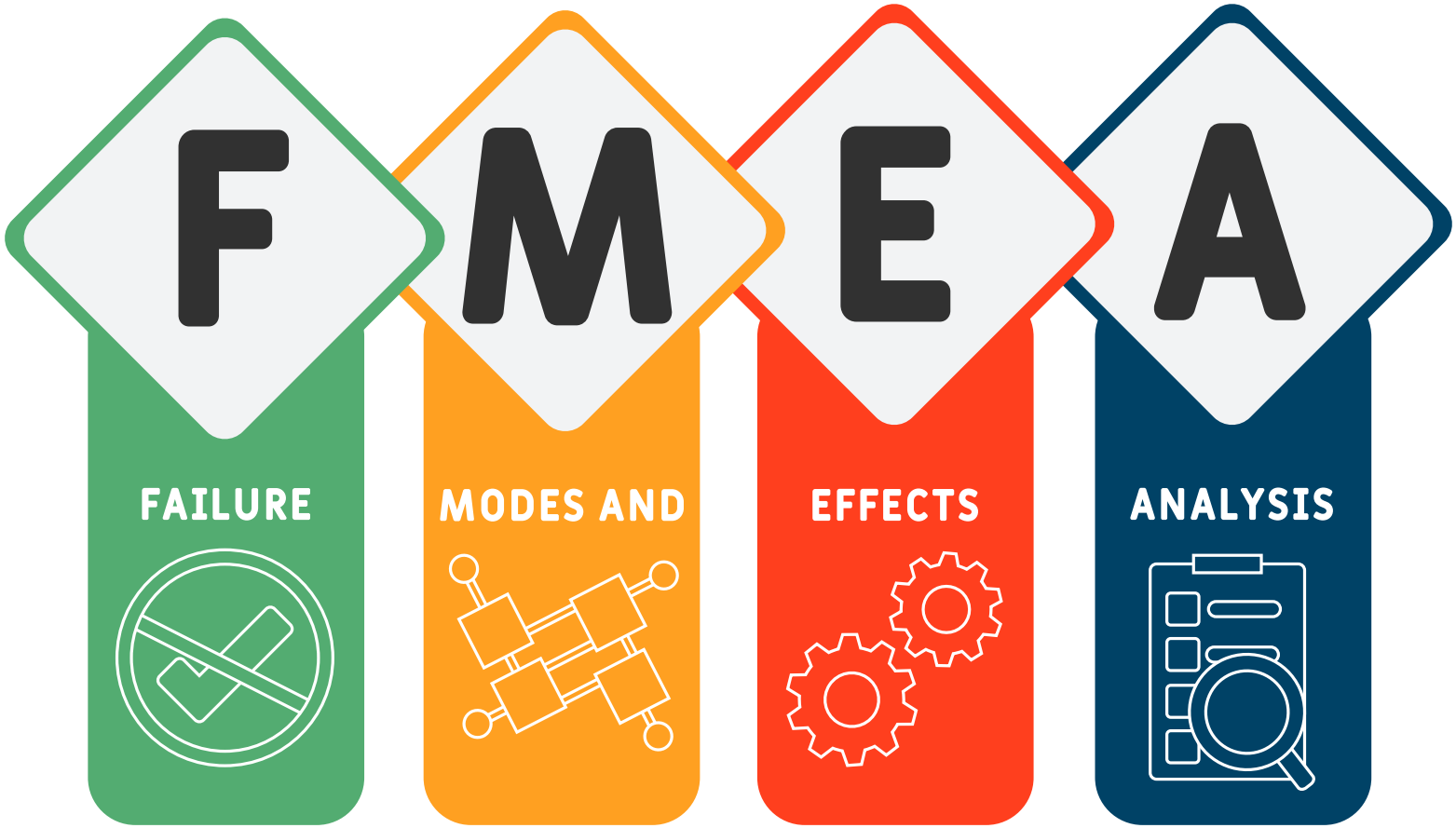

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What is a FMEA ?

FMEA

- Failure Mode and Effects Analysis (**FMEA**) is a structured approach to discovering potential failures that may exist within the design of a product or process. Failure modes are the ways in which a process can fail. Effects are the ways that these failures can lead to waste, defects or harmful outcomes for the customer.

- It is primarily a reliability tool.

- Originally developed by the US military but now used in various forms by a range of industries.

FMEA

- ‘Go to’ tool for engineers
- Assesses process failure and is primarily a reliability tool
- Whilst generally applied to processes, FMEA can be applied to a range of areas these include systems, design, software and manufacturing.

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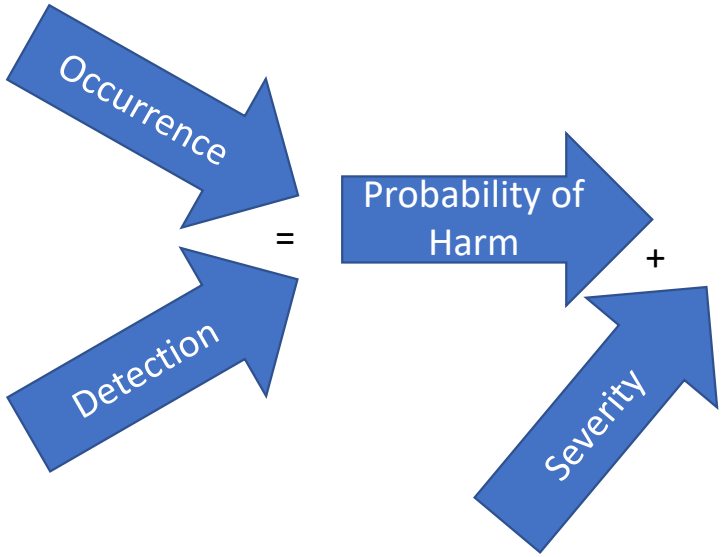
How risk is derived for a FMEA



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FMEA

- There is an International Standard on how to perform a FMEA.

- *IEC60812: 2018 Failure modes and effects analysis (FMEA and FMECA)*

- There are a vast range of training modules and variation on how to perform FMEA based on the range of groups who consider they own the tool:
  - Process Excellence
  - Lean
  - Engineering
  - Quality

- This training is based on guidance in the International Standard.

Different forms of FMEA

SYSTEM / FUNCTIONAL FMEAS

DESIGN FMEAS

PROCESS FMEAS

SERVICE FMEAS

SOFTWARE FMEAS

MANUFACTURING FMEAS

FMEA

- For each FMEA you break the design, system, process into component elements.

- You go through and assess the potential ways each element could fail and the cause of the failure.

You then quantify:

- The consequence of the failure ie: the Severity
- The probability of occurrence: the Occurrence
- The ways that you would detect and contain the failure if it happened ie: Detection

Purpose of FMEA

- The main purpose of the FMEA is to take actions to eliminate or reduce failures.
- In addition to the identification of risk a FMEA also documents current knowledge and actions about the risks of failures.
- FMEA is used during product design to prevent failure and identify attributes that need verification and validation activities performed to ensure the medical device or diagnostic performs against predetermined expectations

When to use a FMEA

- When a process, product, or service is being designed or redesigned.
- When an existing process, product, or service is being applied in a new way.
- Before developing control plans for a new or modified process.
- When improvement goals are planned for an existing process, product, or service.
- When analysing failures of an existing process, product, or service.
- Periodically throughout the life of the process, product, or service.

When <u>not</u> to use a FMEA

- When you are assessing the risk of product performance in the field during use, unintended use or product failure classical risk management should be used, which is based on ISO14971:2019.

- The output of your FMEA **may** feed into assessment of risk using the classical model if new or increased failures are identified.

Team

- A team lead should be identified to lead and facilitate the FMEA exercise. This individual should be experienced in use of the FMEA tool.
- A cross-functional team of people with diverse knowledge about the process, product or service, and customer needs should be formed to take part in the FMEA exercise. Functions that may be needed include design, manufacturing, quality, testing, maintenance, purchasing, sales, marketing and customer service.
- The FMEA tool is only as powerful as the expertise of the individuals completing the exercise.

Key concepts in FMEA…

RPM

Probability of Harm

Control Measures

Cause

Occurrence

Detection

Effects Analysis

Failure Mode

Gemba

Severity

Scoping the FMEA

- Prior to completing the FMEA the team should scope the boundaries of the exercise and ask the questions:

"Is it for a concept, system, design, process, or service ? "

" What are the boundaries ? "

" How detailed should we be ? "

- If the the FMEA is too high level it will miss failure modes.

Failure Modes = Cause of the failure or one way the system can fail.

Process FMEA

- **You can't perform a Process FMEA is you don't have a process map !**

- This should be based not only on documentation describing the process but review of the process directly how it is executed in practice ie: at the Gemba. This should be available visually throughout the FMEA exercise.

- It is **critical** that individuals who directly execute the process form part of the mapping exercise but also play a direct role in the FMEA activity.

Identification of Failure Modes

- For each step / change in the process, identify all the ways failure could happen.

- Identify all the potential consequences on the system, related systems, process, related processes, product, service, customer, or regulations. These are potential effects of failure.

- Ask the following questions: " What does the customer experience because of this failure ? What happens when this failure occurs ? ". Do not take into account the probability of these events occurring. Capture all potentially realistic failure modes.

- For each failure identify all the potential causes.

SEVERITY, OCCURENCE AND DETECTION ASSESSMENT

COMPONENT	SCORE	DEFINITION
SEVERITY (Consequence of harm)	**5**	Affects a parameter or characteristic **critical** for product quality and/or efficacy and/or safety and / or:- The deviation has a **critical** impact on continued regulatory compliance.
	3	The deviation affects a parameter or characteristic that is **not critical** for product quality and/or efficacy and/or safety and / or:- The deviation has a **non-critical** impact on continued regulatory compliance.
	1	The deviation does not affect product quality, efficacy or safety and / or The deviation has a **negligible** impact on continued regulatory compliance.
OCCURRENCE	**5**	Almost certain to occur regularly based on on historical data and knowledge of the process.
	3	Likely to occur and would not be surprised if it occurred based on on historical data and knowledge of the process.
	1	Very unlikely to occur, would be surprised if it occurred based on historical data and knowledge of the process.
DETECTION	**5**	The defect has gone or is going undetected.
	3	Level of containment and detection though manual systems. Defect detected through sampling methods.
	1	High degree of containment and detection through automated, error-proofed systems or verification with a high degree of redundancy. Highly unlikely the defect will go undetected. 100% inspection.

DECIDING WHICH RISKS TO MITIGATE

The product of Severity x Occurrence x Detection generates the Risk Priority Number (RPN)

But which RPNs require mitigation ?

Essentially there are two approaches

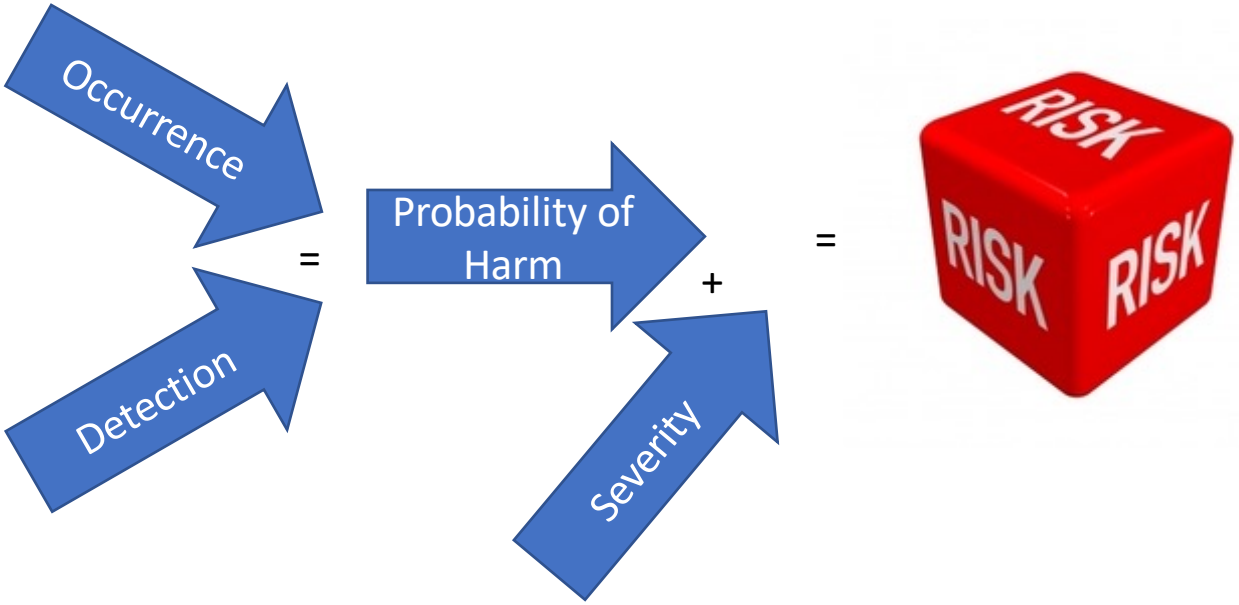
Approach 1: Preassigned cut-off

A value is set prior to completing the FMEA by the team, above which risks will be mitigated.

Limitations:
(a) Highly subjective.
(b) Can be subject to abuse as risks are scored to bring them under the cut-off.

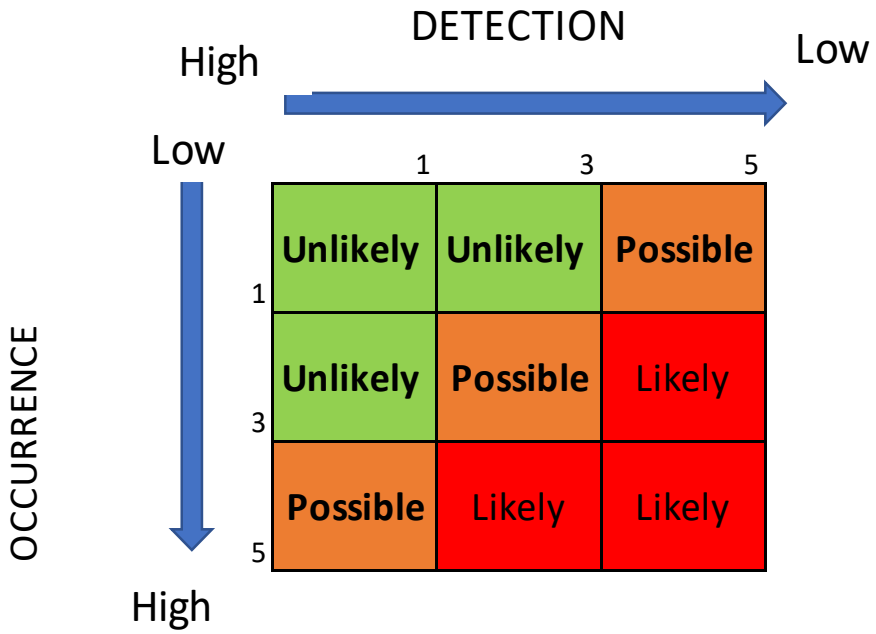
DECIDING WHICH RISKS TO MITIGATE

Approach 2: The criteria for how Severity and Occurrence and Detection translate to Risk Band is predefined in the process.



CALCULATION OF PROBABILITY OF HARM

The two components of Severity and Detection are multiplied to determine the Probability of Harm for any given failure mode based on the matrix below.



CALCULATION OF RISK LEVEL – CRITICALITY ANALYSIS

The combination of Probability of Harm and Severity will be used to determine the Criticality of the issue and whether the unmitigated risk is either High, Medium or Low,

The product of the Severity, Occurrence and Detection components constitutes the Risk Priority Number (RPN). The RPN will be used to prioritise risk control measures.

SEVERITY

Low → High

PROBABILITY OF HARM

Low ↓ High

	1	3	5
Unlikely	**LOW**	**LOW**	**MEDIUM**
Possible	**LOW**	**MEDIUM**	**HIGH**
Likely	**MEDIUM**	**HIGH**	**HIGH**

Example… You will need to set your own risk criteria

- Risk control measures shall be considered for all causes that generate risks classified as **High** or **Medium**.
- Where it is reasonably practical risk reduction should also be considered for risks classified as **Low**.
- The following risk control measures will be considered in order of priority – CAPA – 5RS

Limitations of FMEA

- When used at too high a level tool it will miss failure modes.
- When used at too fine a detail level it will be challenging to complete.
- If you don't have the correct expertise you will miss failure modes. Unknown – unknowns.
- It treats Severity, Occurrence and Detection as equally weighted.
- The RPN scale is not linear ie: 5 inconveniences ≠ death or serious injury.

Differences between FMEA and classical risk assessment

Classical Management of Risk **Eg: ISO14971: 2019**	**FMEA** **IEC60812: 2018**
Is used **early** in the design process and starts with identifying Hazards.	Is used **late** in the design process. By definition a detailed process or functional map is already available.
Considers risk from normal use, unintended use and failure.	Considers only failures.
Severity is based on harm to the patient.	Severity can be based on impact of the failure on whatever you want ie: safety, cost, compliance etc.
Used to manage all risks.	Is focused on assessing and improving reliability.

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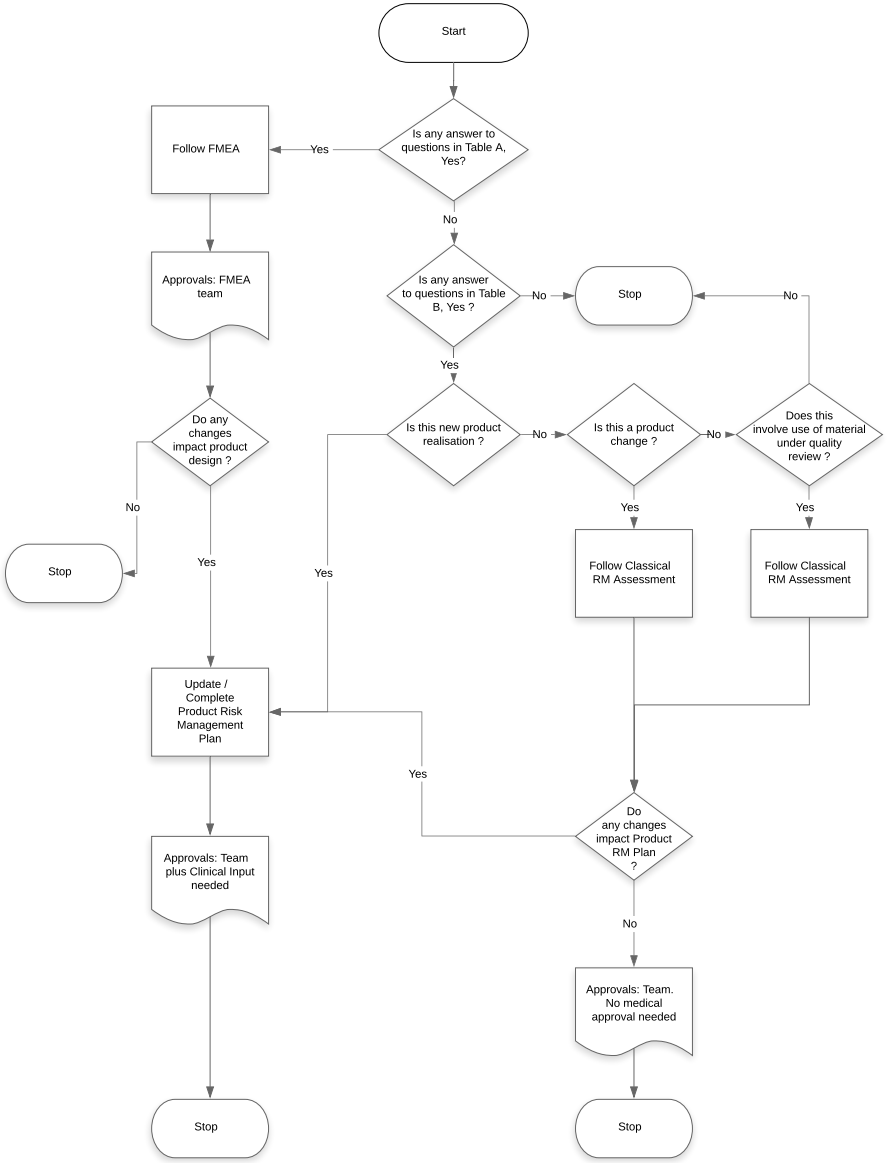
Which tool to use.
Example flow-chart to help you

Failure Modes Effect Analysis FMEA – Process Change	Yes	No
Is the change a process change ?	☐	☐
Will the change impact the reliability of a process ?	☐	☐
Will the change create potential failure modes in a process ?	☐	☐
Are you assessing the reliability of a process ?	☐	☐

Table A: Is it an FMEA ?

Management of Risk - Product Realisation or Product Change	Yes	No
Will the change impact the composition of the medical device ?	☐	☐
Will the change impact how the device is used by the end-user ?	☐	☐
Will the change impact the functionality of the device ?	☐	☐
Will the change impact how the device is transported or stored ?	☐	☐

Table B: Is it Management of Risk ?



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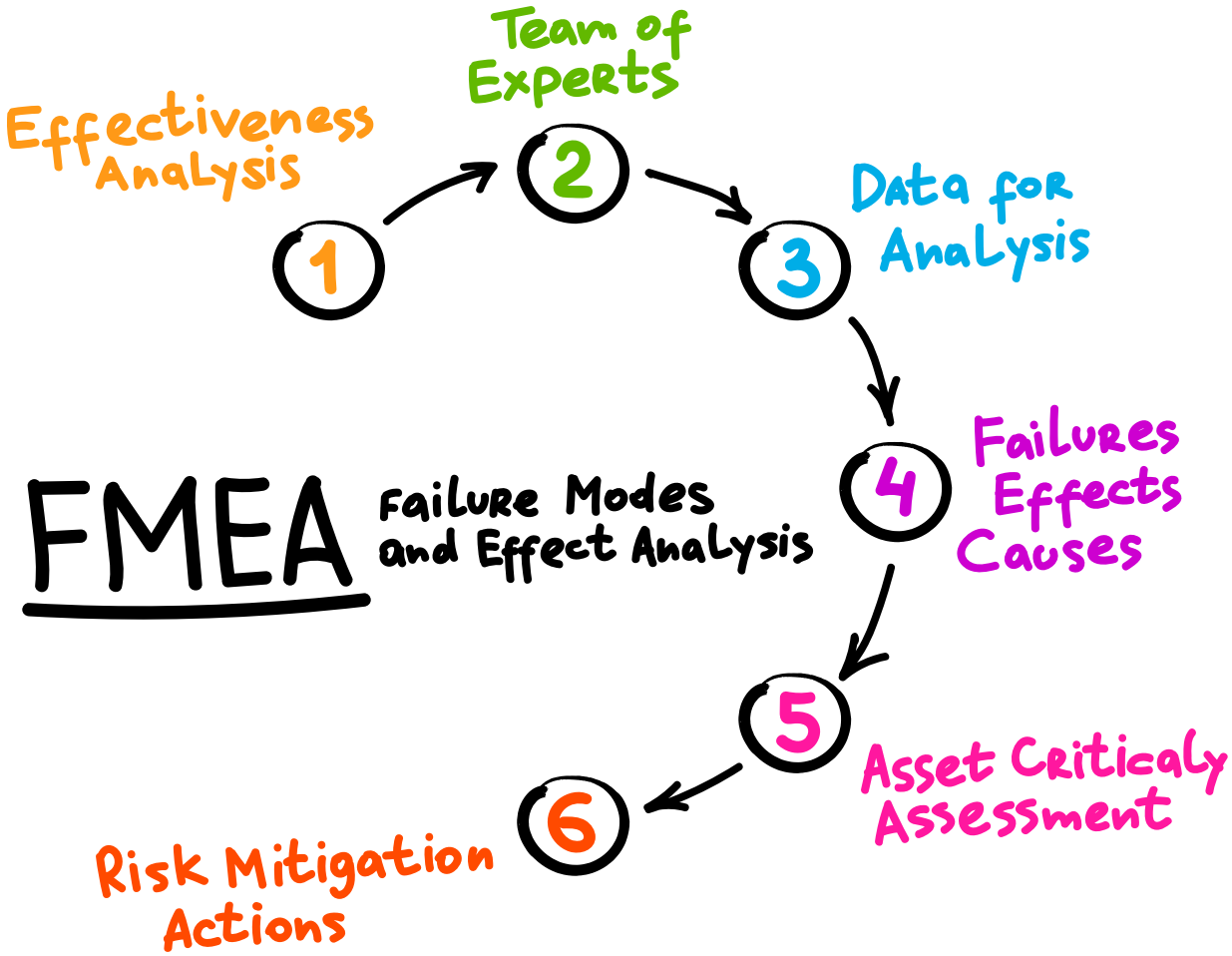

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