



FMEA

? What is It

Is an effective method of lowering the **possibility of failure**. **Failure at the modes** is how a process can fail. **Effects** are how these failures can lead to waste, defects, or harmful outcomes for the customer.

🕒 When

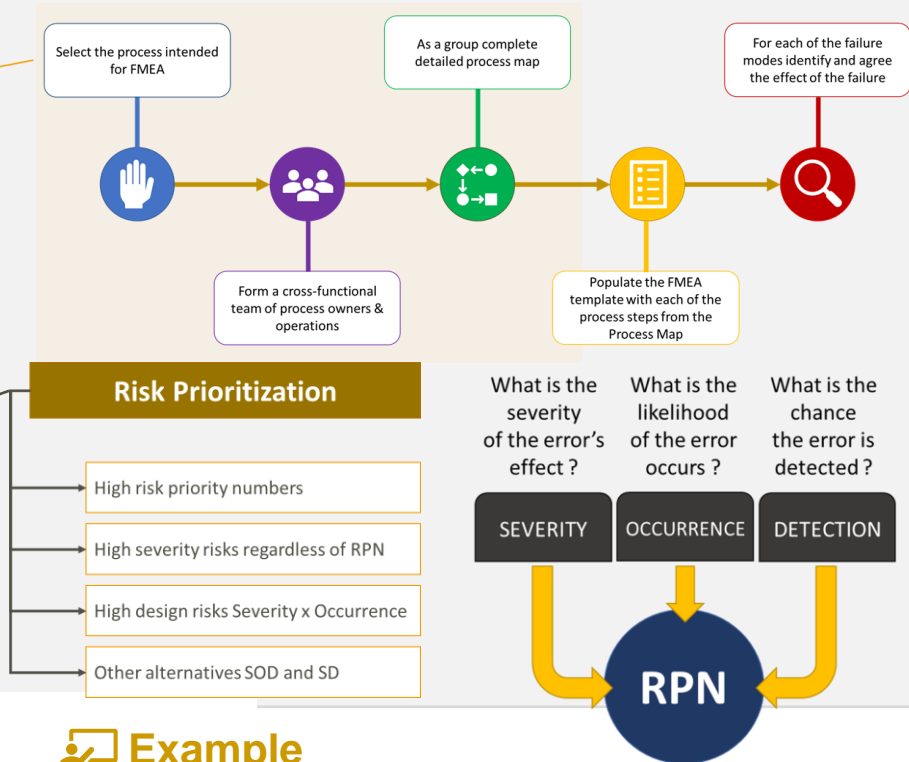
- Process design focused on **risk mitigation**.
- To improve **process reliability**.
- To improve **product quality**.
- Used in the **Analyze** phase of the **DMAIC**.

🎯 Goals

- **Assess risk**, move from subjective to a quantifiable risk rating.
- Carry out **proactive corrective actions** before a failure occurs.
- **Support good process design**.

📊 How

- 1 Pre-Work Team Assembly
- 2 Severity Ranking
- 3 Occurrence Ranking
- 4 Detection Ranking
- 5 Action Priority Assignment
- 6 Actions Taken
- 7 Re-ranking RPN Closure



💡 Hints

- The **process map** guides the FMEA method's best practice.
- FMEA may need **Cause-Effect diagrams** to evaluate the potential causes of failure.
- The ranking tables must be **well thought** before performing the FMEA.

📄 Example

Operation: BUILDING & PACKAGING		Responsibility: Jan		FMEA number: 123456								
Model: E-UMent		Prepared by:		Pgs: 1 of 1								
Care Team:				FMEA Date (Orig): 25/Mar/21								
				Rev: 1								
Process Function	Potential Failure Mode	Potential Effect(s) of Failure	Cause(s) of Failure	Current Process Controls	Recommended Action(s)	Responsibility and Target Completion Date	Action Results					
							S	O	D	R	F	N
Filling out batch record	Missing recordal information or information on the record is not correct	Delay or stop the products from being released.	The person who fill out the record is not trained properly.	7	Get reviews the BR and provide back to production team for correction	0	252					0
Storage space for milled product					6	Further information required	0					0
Milling capacity					6	Further information required	0					0
Blending	Added the wrong strain into the blend	Not suitable batch, potential disposal of large quantity of product	Miscommunication and/or no formal instructions to operator, no start-up procedure	8	none	8	276					0
Blending	Added the wrong strain quantity into the blend	Not suitable batch, potential disposal of large quantity of product	Not tracking/documenting during blending process.	8	none	9	448					0