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FMEA
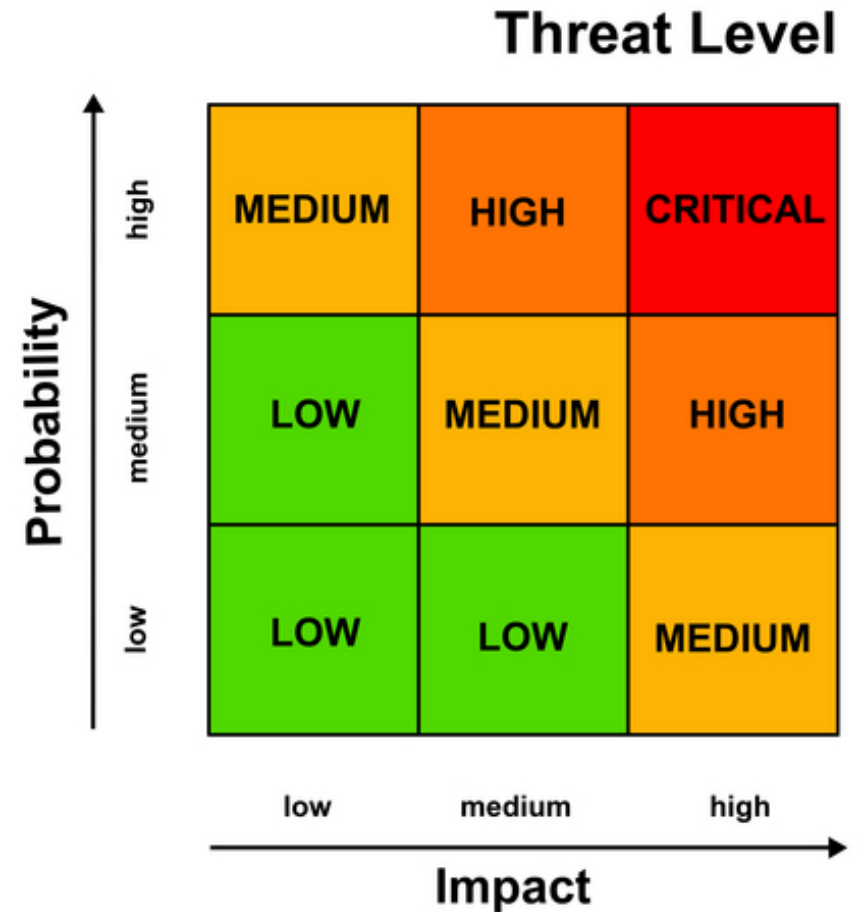
Agenda

1. FMEA: What is it ?

2. FMEA purpose and benefits

3. How to perform FMEA analysis

4. Takeaways

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Introduction

What is it ?

FMEA is a highly effective method of lowering the possibility of failure.
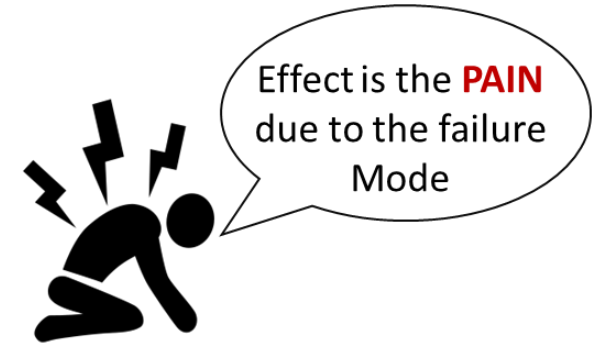

Threat Level

Introduction

Purpose and Benefits

Failure at the modes is how a process can fail. **Effects are the ways** that these failures can lead to waste, defects, or harmful outcomes for the customer.

Failure Mode and Effects Analysis is designed to **identify, prioritize,** and **limit these failure modes.**

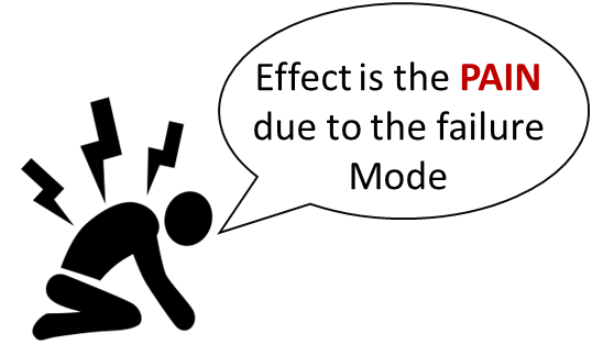Effect is the **PAIN** due to the failure Mode

1. What is the **PAIN** that is felt by the end user ?

2. What is the **PAIN** felt by downstream manufacturing or assembly operations ?

Introduction

Purpose and Benefits

Methodology aimed at allowing organizations to **anticipate failure** during the **design stage** by identifying all the **possible failures** in a process design or manufacturing process.

FMEA is **not a substitute** for good engineering. Rather, it enhances good engineering by applying the knowledge and experience of a **cross-functional team** to review the design progress of a product or process by **assessing its risk of failure.**

Effect is the **PAIN** due to the failure Mode

1. What is the **PAIN** that is felt by the end user ?

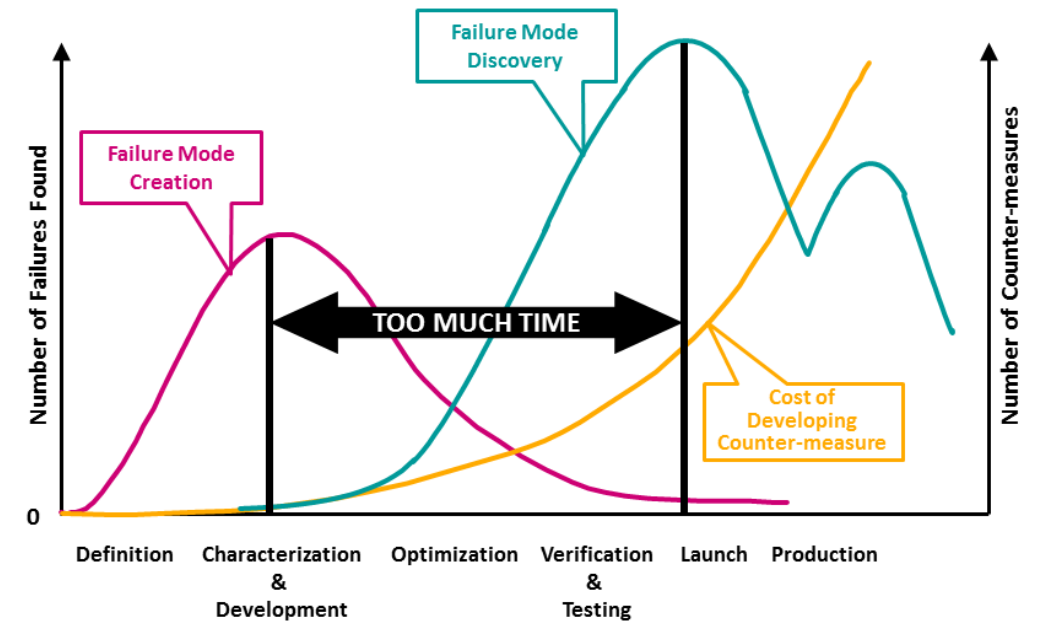2. What is the **PAIN** felt by downstream manufacturing or assembly operations ?

FMEA

The Cost of Failure

The sooner we discover a failure, the less it will cost. If we discover late a failure 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.
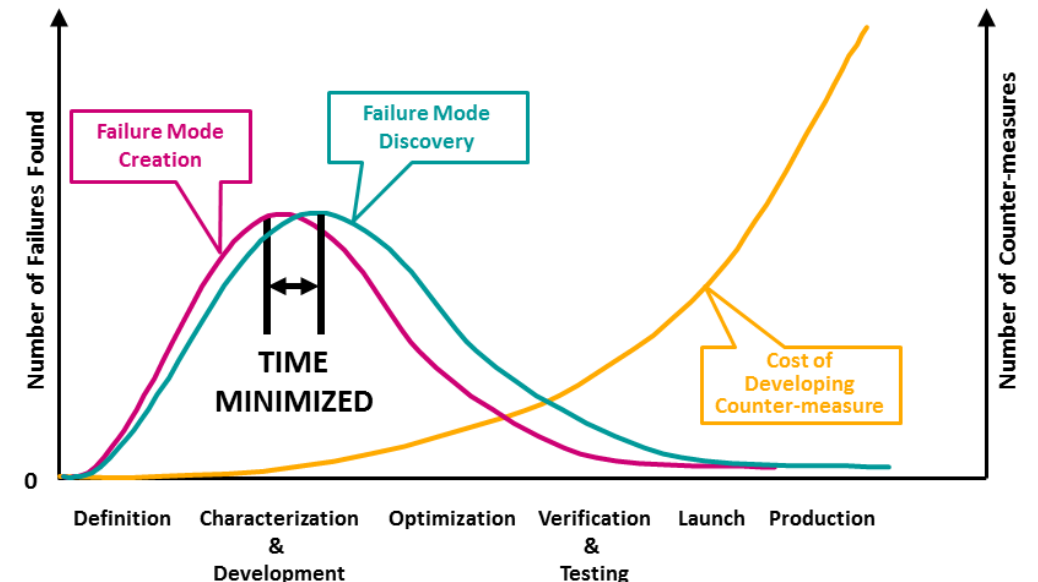
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FMEA

The Cost of Failure

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

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FMEA

PFMEA

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

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

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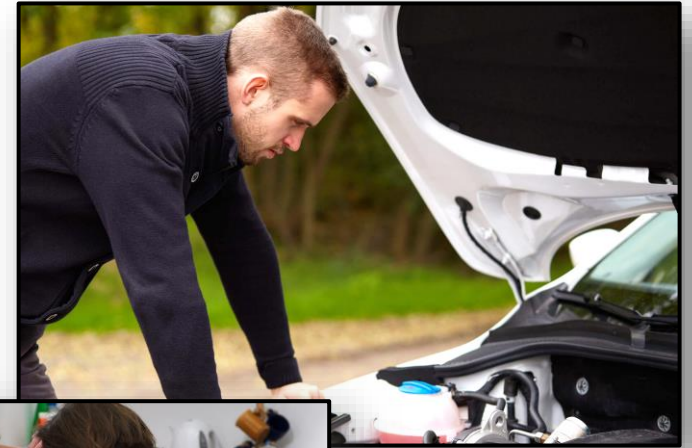
FMEA

DFMEA

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

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

FMEA

When to perform FMEA analysis:

- When we are designing a **new product**, **process,** or **service.**

- When we are planning on performing an **existing process** in a different way.

- When we have a **quality improvement** goal for a specific process.

- When we need to **understand** and improve the failures of a process.

- Occasionally throughout the **lifetime** of a process.

FMEA

FMEA
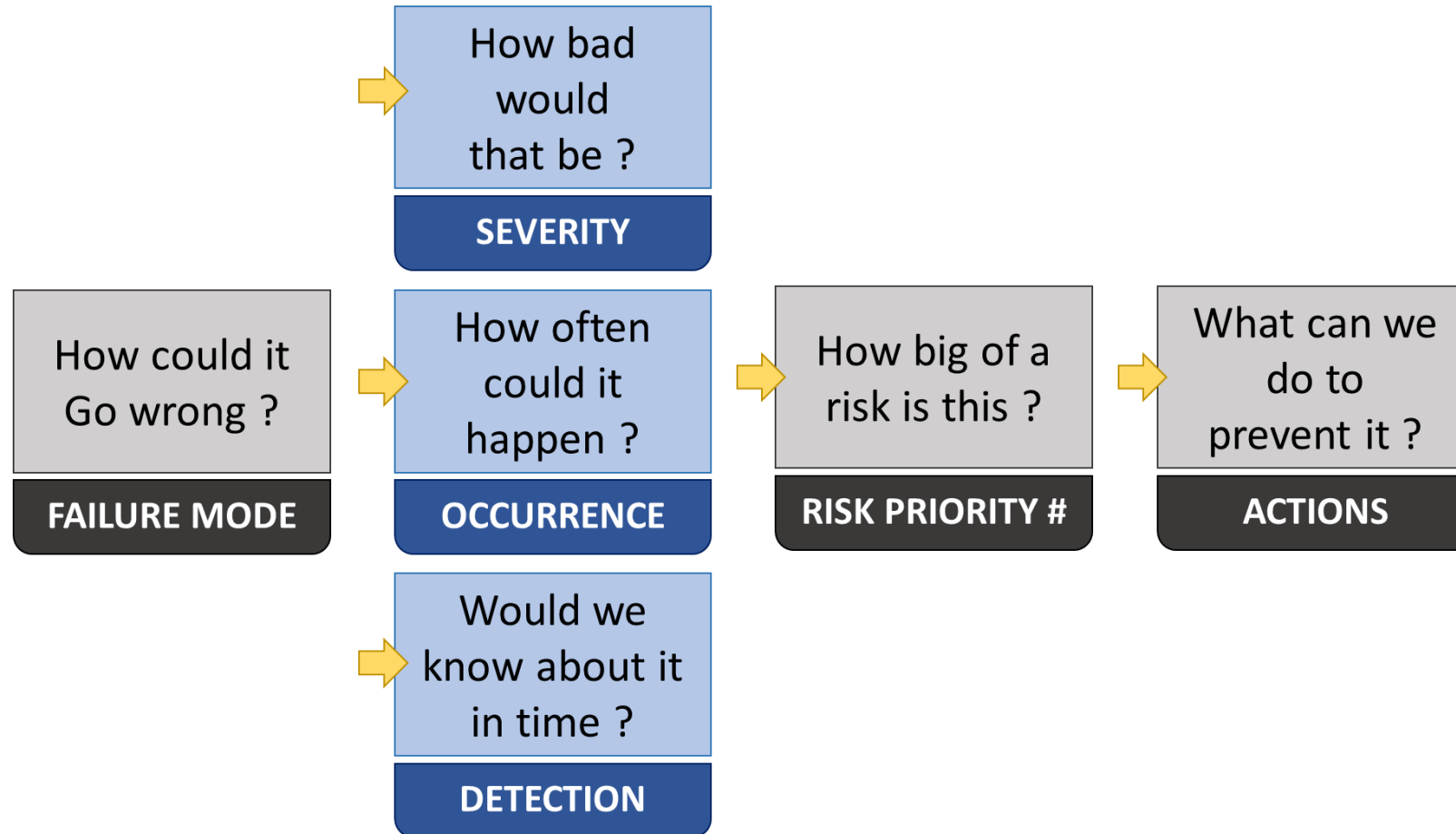
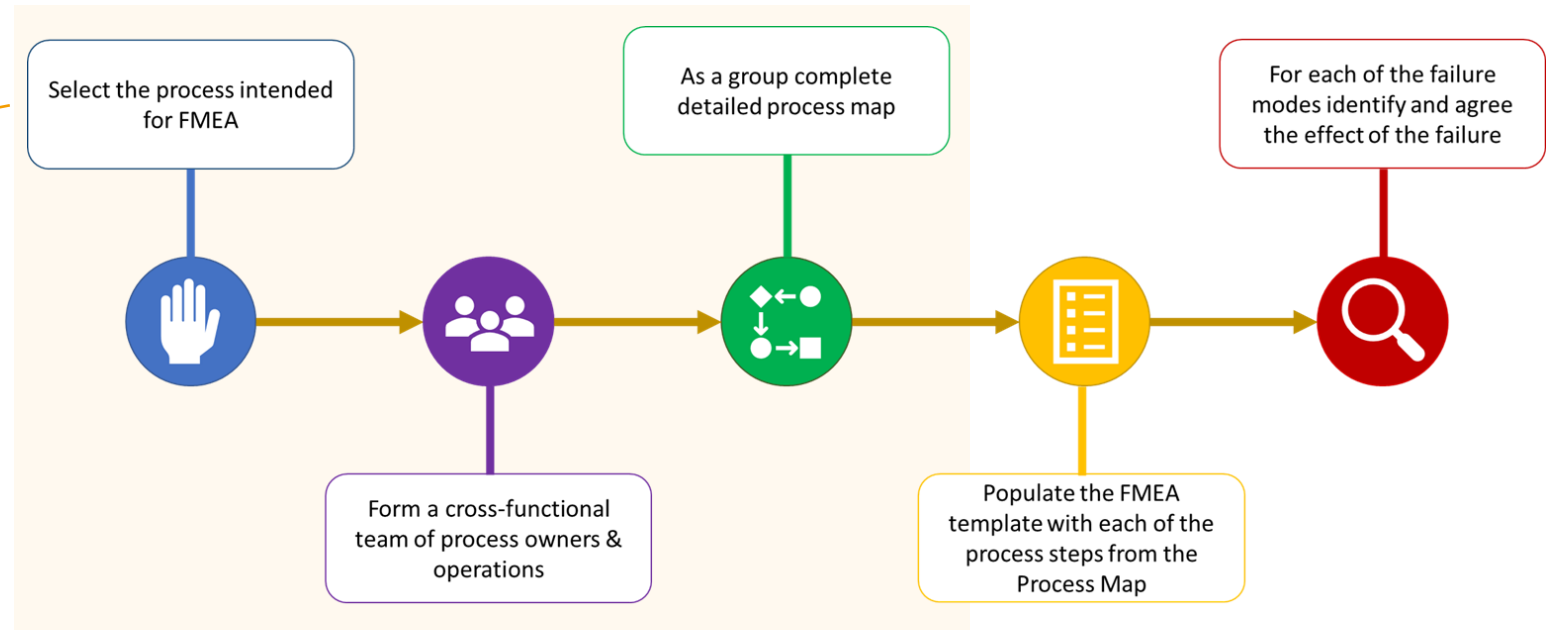**How to perform FMEA analysis:**

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

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FMEA

How to perform FMEA analysis:

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

Select the process intended for FMEA

Form a cross-functional team of process owners & operations

As a group complete detailed process map

Populate the FMEA template with each of the process steps from the Process Map

For each of the failure modes identify and agree the effect of the failure

FMEA

How to perform FMEA analysis:

Pre-work involves the **collection** and **creation of key documents**. FMEA works smoothly through the development phases when an investigation of past failures and preparatory documents is performed from its onset. Preparatory documents may include:

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FMEA

How to perform FMEA analysis:

Pre-Work Team Assembly

1

- Process Flow Diagram (For the PFMEA).

- Characteristics Matrix (For the PFMEA).

- Use a process flowchart to identify each process component.

- List each process component in the FMEA table.

- If it feels like the scope is too big, it probably is. This is a good time to break the Process Failure Mode and Effects Analysis into more manageable chunks.

FMEA

How to perform FMEA analysis:

Severity Ranking

2

This step comprises inserting the functions, **failure modes**, **effects** of failure and **Severity** rankings.

Write functions in v**erb-noun** context. Each function must have an **associated measurable**.

Effects result from failure, where each individual effect is given a **Severity ranking**.

FMEA

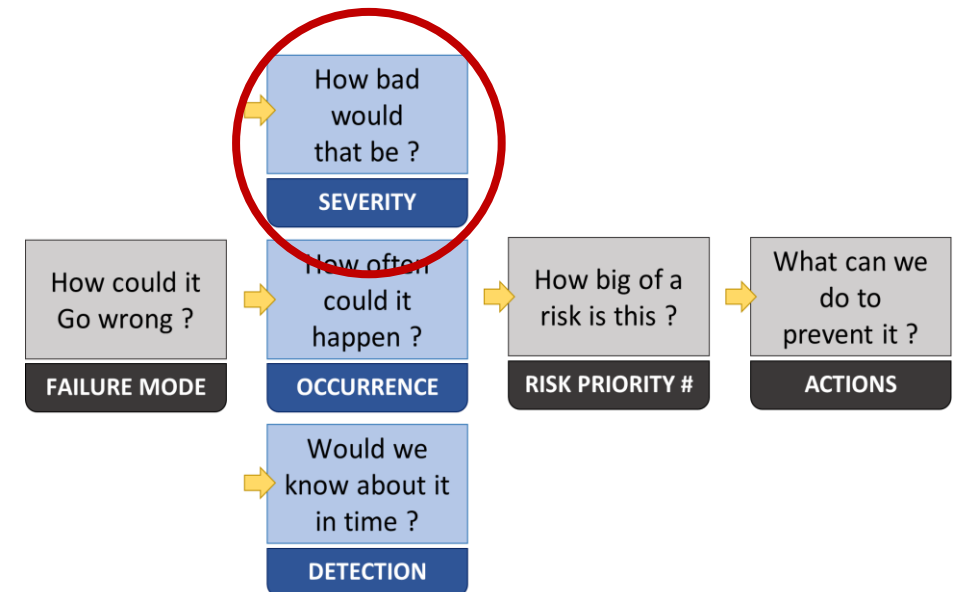| DFMEA		
Effect	**SEVERITY OF EFFECT ON PRODUCT (CUSTOMER EFFECT)**	**RANK**
Failure to meet safety and/or regulatory requirements	Failure affects safety of product and to the consumer. Involves noncompliance with government regulations without warning	10
Failure to meet safety and/or regulatory requirements	Failure affects safety of product and to the consumer. Involves noncompliance with government regulations with warning	9
Loss or Degradation of primary function	Loss of primary function: product inoperable, but doesn't affect safety on customer	8
Loss or Degradation of primary function	Degradation of primary function: product operable, but at reduced level of performance	7
Loss or Degradation of Secondary functions	Loss of secondary funtions: product operable, but other functions are inoperable or not acceptable by the customer	6
Loss or Degradation of Secondary functions	Degradation of secondary function: product operable, but at reduced level of performance	5
Annoyance	Appearance and operability is acceptable, but product doesn't conform with more than 75% of the customers	4
Annoyance	Appearance and operability is acceptable, but product doesn't conform with 50% of the customers	3
Annoyance	Appearance and operability is acceptable, but product doesn't conform with 25% of the customers	2
No effect	No discernible effect	1

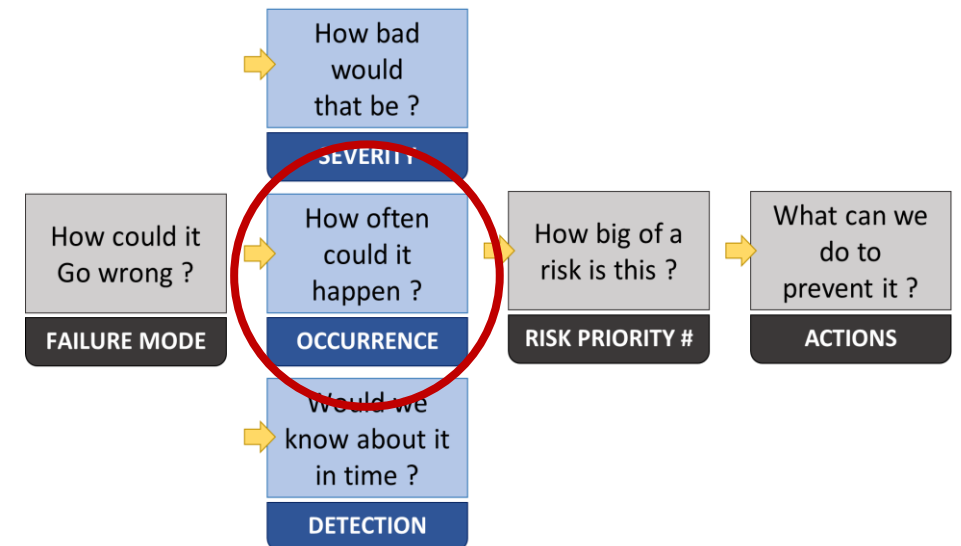| PFMEA		
Effect	**SEVERITY OF EFFECT ON PRODUCT (MANUFACTURING)**	**RANK**
Failure to meet safety and/or regulatory requirements	May endanger consumer, operator or surroundings areas without warning	10
Failure to meet safety and/or regulatory requirements	May endanger consumer or operator with warning	9
Major Disruption	100% of the product have to be scrapped. Line shutdown or stop shipments will be necessary	8
Significant Disruption	A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or adedd additional manpower may be required	7
Moderate Disruption	100% of the production run may have to be reworked off line and accepted	6
Moderate Disruption	A portion of the production run may have to be reworked off line and accepted	5
Low Disruption	100% of the production run may have to be reworked in station before operation can proceed	4
Low Disruption	A portion of the production run may have to be reworked in station before operation can proceed	3
Minor Disruption	Slight inconvenience to the process, operation or operator	2
No effect	No discernible effect	1

FMEA

How to perform FMEA analysis:

Occurrence Ranking

This step comprises inserting the functions, **occurrence modes**, **effects** of failure and **Occurrence** rankings.

Effects result from failure, where each individual effect is given an **Occurrence ranking**.

FMEA

DFMEA		
Likelihood of Failure	**OCCURRENCE OF CAUSE**	**RANK**
VERY HIGH	New Technology / New design with no history	10
HIGH	Failure is inevitable with new design, new application or change in duty cycle/operation conditions	9
	Failure is likely with new design new application or change in duty cycle/operation conditions	8
	Failure is uncertain with new design new application or change in duty cycle/operation conditions	7
MODERATE	Frequent failures associated with similar designs or in design simulation and testing	6
	Occasional failures associated with similar designs or in design simulation and testing	5
	Isolated failures associated with similar designs or in design simulation and testing	4
LOW	Only isolated failures associated with almost identical designs or in design simulation and testing	3
	No observed failures associated with almost identical design or in design simulation and testing	2
VERY LOW	Failure is eliminated through preventive controls	1

| PFMEA		
Likelihood of Failure	**OCCURRENCE OF CAUSE**	**RANK**
VERY HIGH	More than 100 per 1,000 or more that 1 per 10 (More than 10%)	10
HIGH	50 per 1,000 or 1 in 20 (5%)	9
	20 per 1,000 or 1 in 50 (2%)	8
	10 per 1,000 or 1 in 100 (1%)	7
MODERATE	2 per 1,000 or 1 in 500 (0.2%)	6
	0.5 per 1,000 or 1 in 2,000 (0.05%)	5
	0.1 per 1,000 or 1 per 10,000 (0.01%)	4
LOW	0.01 per 1,000 or 1 in 100,000 (0.0015)	3
	Less than 0.001 per 1,000,000 (Less than 0.0001%)	2
VERY LOW	Failure is eliminated through preventive controls	1

FMEA

How to perform FMEA analysis:

Detection Ranking (step 4)

The next step is to add the **Detection Controls** that verify that the design meets requirements (for Design FMEA) or cause and/or failure mode, if undetected, may reach a customer (for Process FMEA).

Recommended Actions should address weakness in the testing and/or control strategy.
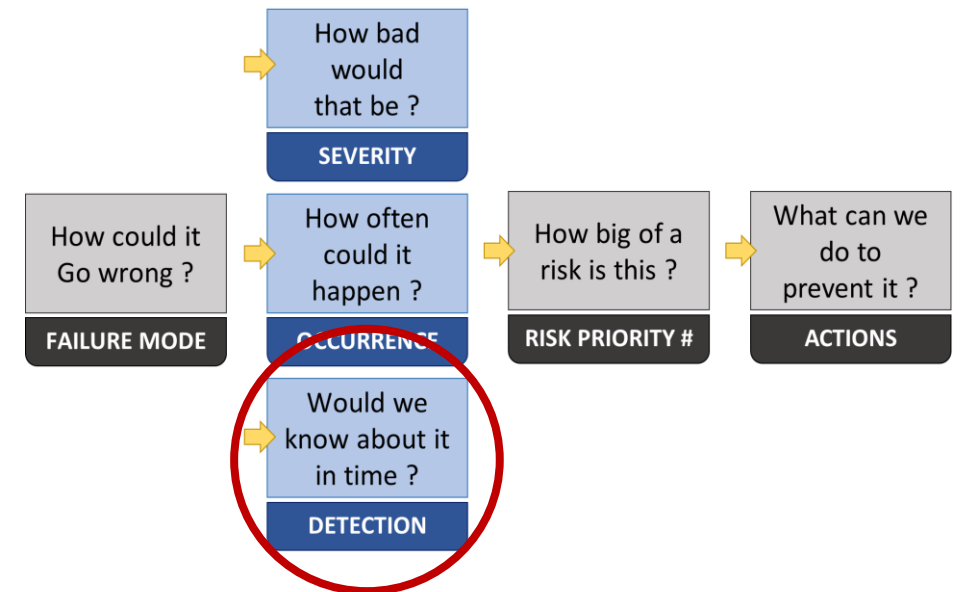
FMEA

DFMEA		
Opportunity of Detection	LIKEHOOD OF DETECTION BY DESIGN CONTROL	RANK
No detection opportunity	No current design control; cannot detect or is not analyzed	10
Not likely to detect at any stage	Design controls have **weak** detection capability and the analysis is not correlated to expect actual operating conditions	9
Post design freeze and prior launch	Product verification after design freeze prior to launch with **pass/fail** testing	8
	Product verification after design freeze prior to launch with test to **failure** testing	7
	Product verification after design freeze prior to launch with **degradation** testing	6
Post design freeze	Product validation (reliability, development, validation test) prior to design freeze using **pass/fail** testing	5
	Product validation (reliability, development, validation test) prior to design freeze using test to **failure** testing	4
	Product validation (reliability, development, validation test) prior to design freeze using test to **degradation** testing	3
Analysis correlated	Design controls have **strong** detection capability and the analysis is highly correlated to expect actual operating conditions	2
Detection not applicable; failure prevention	Failure cause or mode cannot occur because it is fully prevented through the design solutions	1

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FMEA

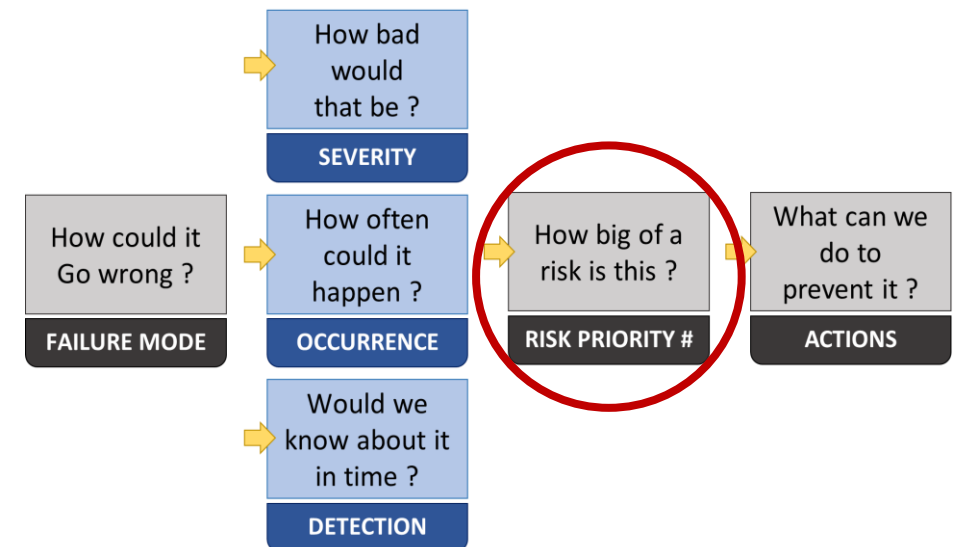| Likelihood of Detection	Opportunity for Detection	PFMEA LIKELIHOOD OF DETECTION BY PROCESS CONTROL	RANK
Almost impossible	No detection opportunity	No current process control; Cannot detect or is not analyzed	10
Very remote	Not likely to detect at any stage	Failure Mode and/or error (cause) is not easily detected	9
Remote	Problem detection post processing	Failure mode detection post-processing by operator through visual/tactile/audible means	8
Very low	Problem detection at source	Failure mode detection post-processing by operator through the use of visual/tactile/audible means or post-processing through the use of attribute gaguing (go/no-go)	7
Low	Problem detection post processing	Failure mode detection post-processing by operator through the use of variable gauging or in-station by operator through the use of attribute gaguing (go/no-go)	6
Moderate	Problem detection at source	Failure mode or cause detection in-station by operator through the use of variable gaugung or by automated controls in-station that will detect failures. Gauging performed on setup and first-piece check (during start-up).	5
Moderate high	Problem detection post processing	Failure mode detection post-processing by automated control that will detect defective part and lock it to prevent further processing	4
High	Problem detection at source	Failure mode detection in-station by automated controls that will detect defective part and automatically lock part in-station to prevent further processing	3
Very high	Error detection and /or problem prevention	Error or cause detection in-station by automated controls that will detect error and prevent defective part from being made	2
Almost certain	Detection not applicable; Error detection	Error or cause prevention as a result of fixture design, machine design or part design. Defective part cannot be made because item has been error proofed by process/product design	1

FMEA

How to perform FMEA analysis:

Action Priority Assignment

5

The Actions that were previously determined in Paths 1, 2 or 3 are assigned a **Risk Priority Number (RPN)** for action follow-up.

The RPN is **calculated by multiplying** the **Severity**, **Occurrence** and **Detection** Rankings for each potential failure / effect, cause, and control combination.
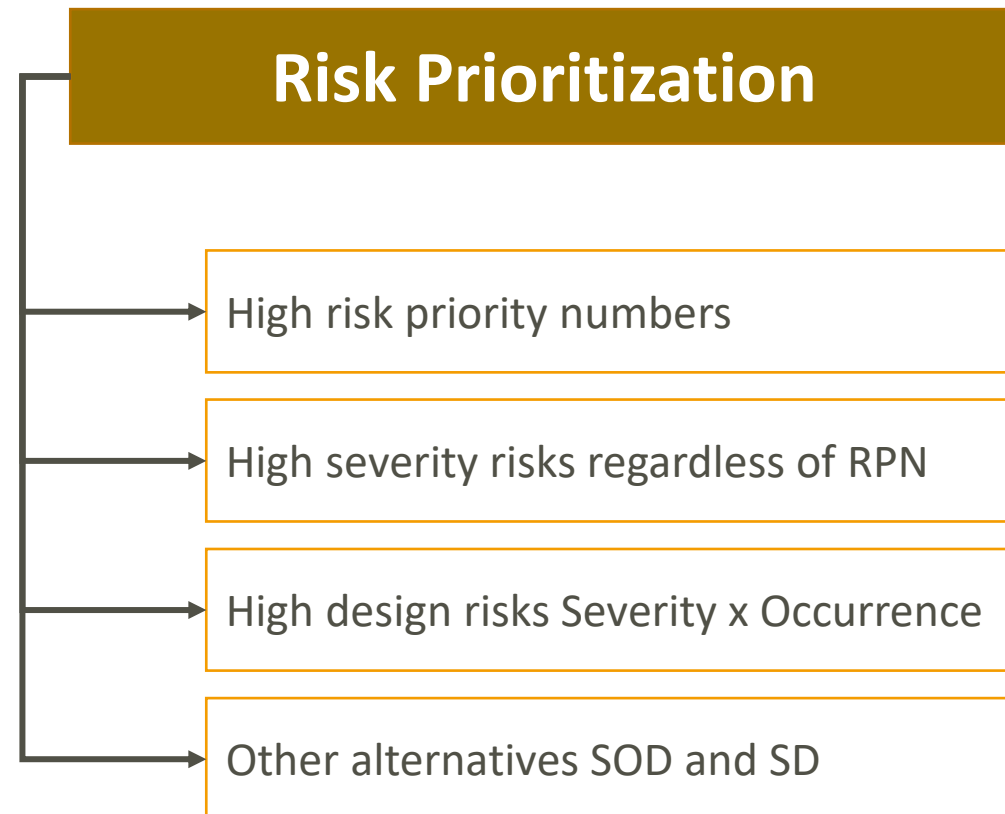
Actions **should not be determined based** on an RPN threshold value.

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FMEA

How to perform FMEA analysis:

5 Action Priority Assignment

Risk Prioritization

High risk priority numbers

High severity risks regardless of RPN

High design risks Severity x Occurrence
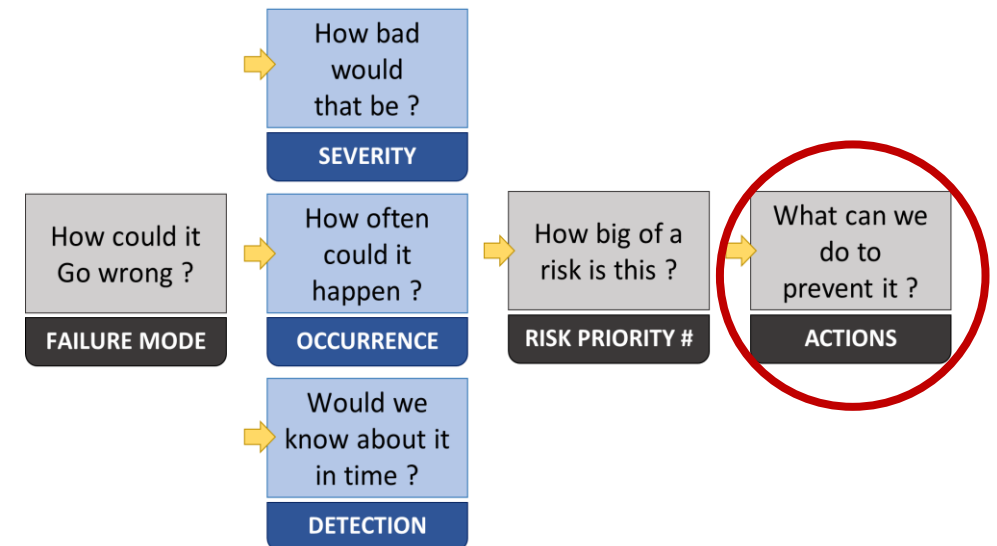
Other alternatives SOD and SD

FMEA

How to perform FMEA analysis:

Actions Taken
6

- Review Recommended **Actions** and assign RPN for additional follow-up.
- Assign Actions to the **core team**.
- Assign action **due dates**.

How bad would that be ?
SEVERITY

How could it Go wrong ?
FAILURE MODE

How often could it happen ?
OCCURRENCE

How big of a risk is this ?
RISK PRIORITY #

What can we do to prevent it ?
ACTIONS

Would we know about it in time ?
DETECTION
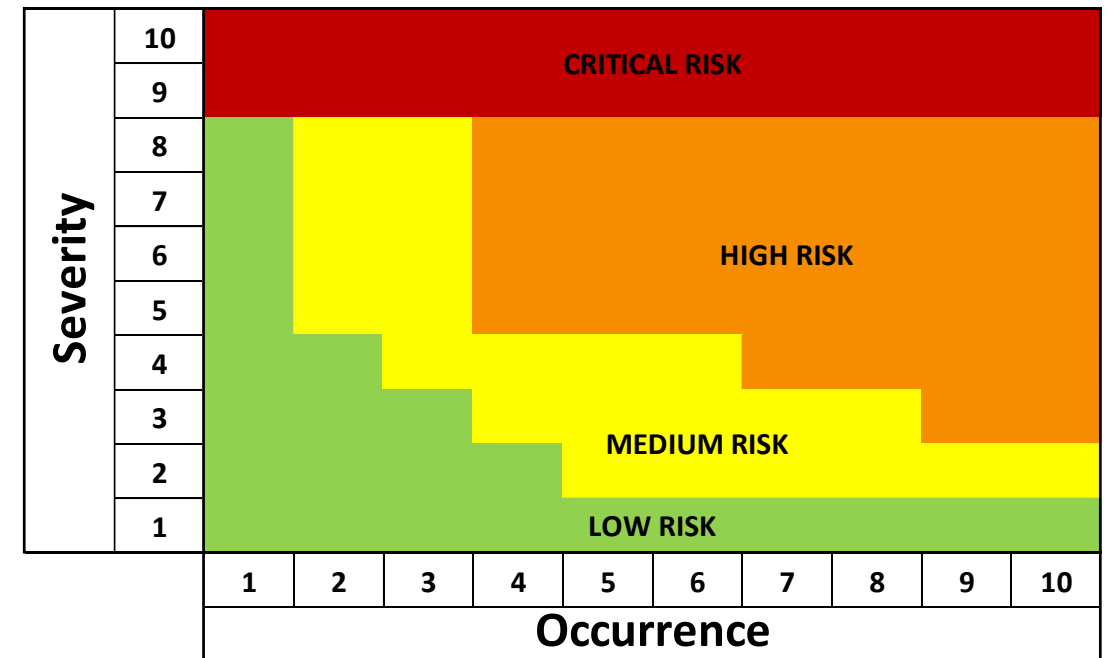
FMEA

How to perform FMEA analysis:

Actions Taken

6

FMEA Actions are closed when **countermeasures** have been taken and are successful at reducing risk.

The purpose of an FMEA is to **discover and mitigate risk**.

FMEAs which **do not find risk** are considered being weak and **non-value added**.
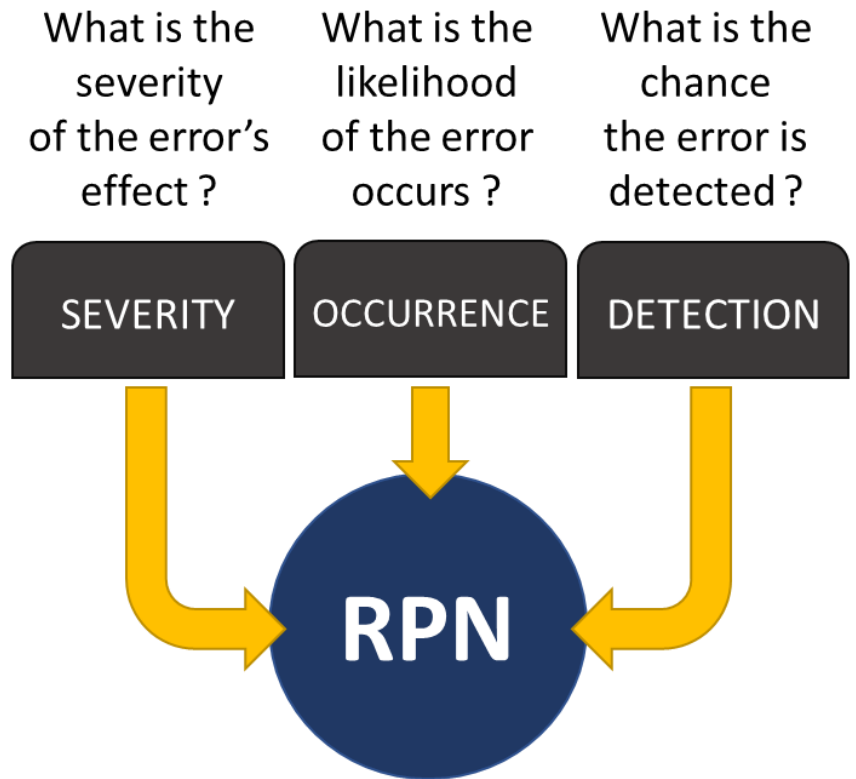
FMEA

How to perform FMEA analysis:

Re-ranking RPN Closure

After successful confirmation of **Risk Mitigation Actions**, the Core Team or Team Leader will **re-rank** the appropriate ranking value (Severity, Occurrence or Detection).

The new rankings will be multiplied to attain the **new RPN**.

The original RPN is **compared to the revised RPN** and the relative improvement to the design or process has been confirmed.
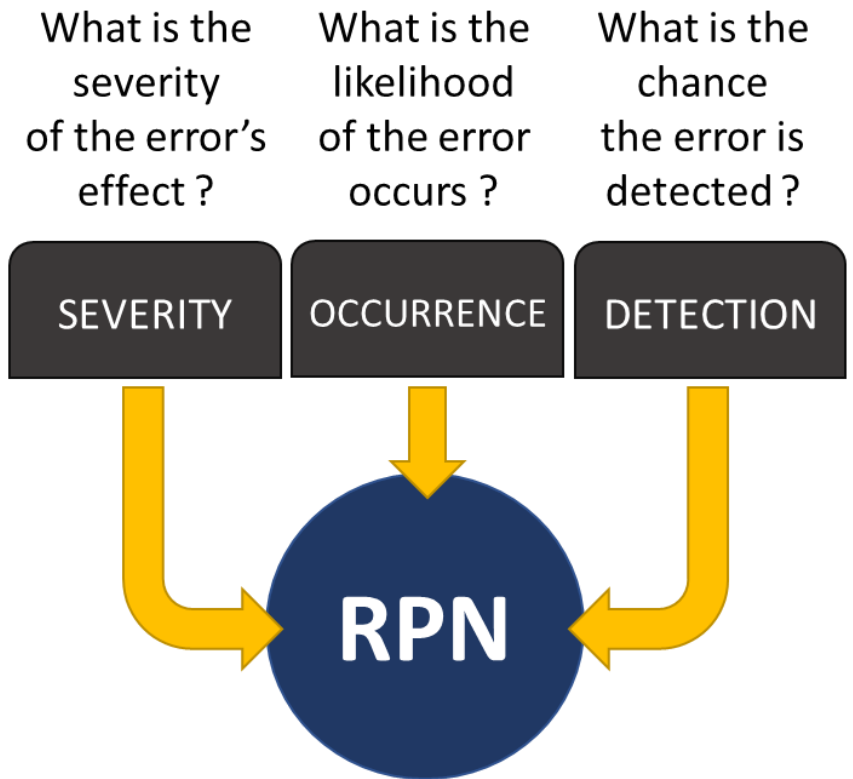
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FMEA

How to perform FMEA analysis:

Re-ranking RPN Closure (7)

Columns completed in this step:

- Re-ranked Severity
- Re-ranked Occurrence
- Re-ranked Detection
- Re-ranked RPN
- Generate new Actions, repeating Step 5, until risk has been mitigated
- Comparison of initial RPN and revised RPN

What is the severity of the error's effect ?   What is the likelihood of the error occurs ?   What is the chance the error is detected ?

SEVERITY   OCCURRENCE   DETECTION

RPN

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FMEA

How to perform FMEA analysis:

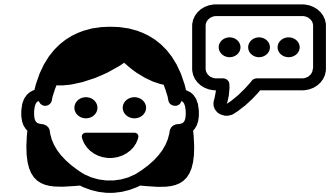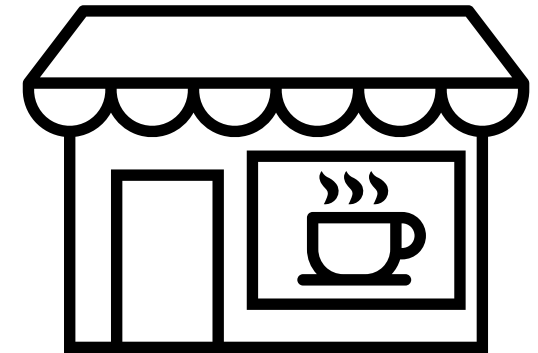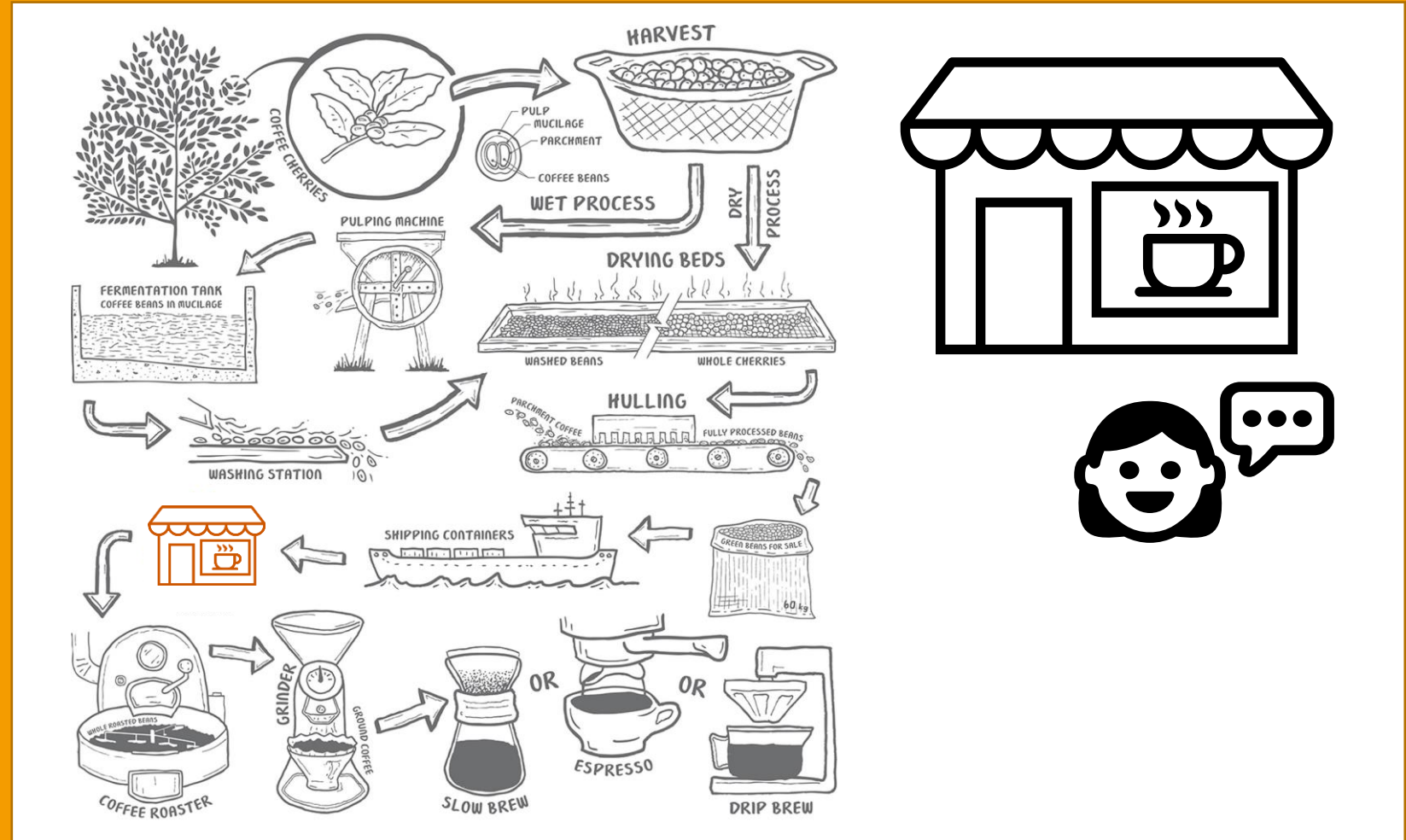The Failure Modes in a FMEA are equivalent to the Problem Statement or Problem Description in **Problem Solving**.

Causes in a FMEA are equivalent to potential **root causes** in Problem-solving.

LEARNING HUB

FMEA Coffee Shop

TOOLBOX

FMEA Template
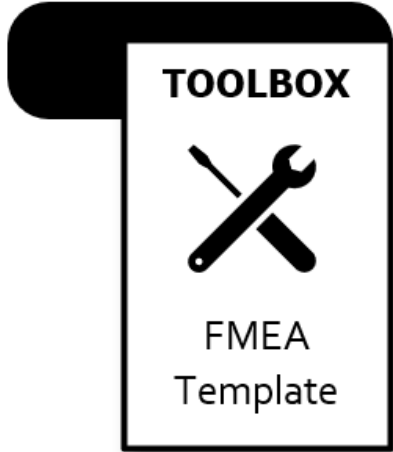
PathStone Group	PSF Process Failure Modes Effect Analysis			

Operation:	BLENDING & PACKAGING	Responsibility:	Jen	FMEA number:	123456
Model:	Current	Prepared by:		Page :	1 of 1
Core Team:				FMEA Date (Orig):	23-Mar-21 Rev: 1

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s)/ Mechanism(s) of Failure	Occur	Current Process Controls	Detec	RPN	Recommended Action(s)	Responsibility and Target Completion Date	Action Results			
												Actions Taken	Sev	Occ	Det	RPN
Filling out batch record	Missing records/ information or information on the record is not correct	Delay or stop the products from being released.	6		The person who fill out the record is not trained properly.	7	QA reviews the BR and circled back to production team for correction	6	252							0
Storage space for milled product									0	Further information required	Bal (Eng)					0
Milling capacity									0	Further information required	Bal (Eng)					0
Blending	Added the wrong strain into the blend	Non usable batch, potential disposal of large quantity of product	9		Misscommunication and/or no formal instructions to operator, no start-up procedure	8	none	8	576	Process Control Sheet, Line clearance, Recipe 5S Blending room layout	Edgar Sona Cedric & Jen Adam (Prod) Eng					0
Blending	Added the wrong strain quantity into the blend	Non usable batch, potential disposal of large quantity of product	9		Not tracking/documenting during blending process,	8	none	9	648	Process Control Sheet, "automate" calculations (recipe) Line cleanace 5S Blending room layout	Edgar Sona Cedric & Jen Adam (Prod) Eng					0

Takeaways

- **Data collected** from problem solving is placed into an FMEA for future planning of **new products** or **process quality**. This allows an FMEA to consider actual failures, categorized as failure modes and causes, making the FMEA **more effective** and **complete**.

- **Problem solving methods** are completed faster by utilizing easy to locate, pre-brainstormed information from an FMEA.

- Possible causes in an FMEA are immediately used to jump start **Fishbone diagrams**.

- The design or process controls in an FMEA are used in verifying the root cause and **Permanent Corrective Actions**.

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Thank You

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FMEA

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TRANSFORMATION

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