



Continuous Improvement Toolkit

FMEA

Managing Risk

PDPC
FMEA RAID Logs
Fault Tree Analysis
Risk Assessment*

Traffic Light Assessment
Lean Measures KPIs
OEE Capability Indices

MSA RTY Descriptive Statistics
Cost of Quality
Reliability Analysis

Understanding Performance

Benchmarking
Focus groups Interviews
Photography Check Sheets
Observations Questionnaires

Data Collection
Critical Incident Technique

Deciding & Selecting

Pros and Cons
Break-even Analysis
Force Field Analysis
Decision Tree
QFD Matrix Diagram
Kano Analysis
Critical-to Tree
Cause and Effect Matrix
Confidence Intervals
Probability Distributions
Graphical Analysis
Run Charts
Control Charts
Sampling
Brainstorming
Analogy
Nominal Group Technique
Affinity Diagram
Lateral Thinking

Importance-Urgency Mapping
Cost Benefit Analysis
Voting Pugh Matrix
TPN Analysis
Prioritization Matrix
Paired Comparison
Pareto Analysis
ANOVA
Hypothesis Testing
Scatter Plot
Correlation
5 Whys
Chi-Square Test
Fishbone Diagram
TRIZ***
SCAMPER***
Mind Mapping*

Tree Diagram**
Simulation
Mistake Proofing
Pull Systems
JIT
Ergonomics
Work Balancing
Automation
Bottleneck Analysis
Flow
Value Analysis
Waste Analysis
Time Value Map
Process Redesign
SIPOC
Flow Process Chart
Process Mapping
Flowcharting
Service Blueprints

TPN Analysis
PDCA Control Planning
Hoshin Kanri Kaizen
How-How Diagram
Standard work
TPM
Visual Management
5S
SMED
Value Stream Mapping
Process Mapping
Service Blueprints

Creating Ideas**

Planning & Project Management*

RACI Matrix Stakeholder Analysis
PEST PERT/CPM Activity Diagram
Roadmaps Project Charter Gantt Chart

Gap Analysis
Control Planning
Hoshin Kanri Kaizen
How-How Diagram
Standard work

Understanding Cause & Effect
Mistake Proofing
Pull Systems
JIT
Ergonomics
Work Balancing
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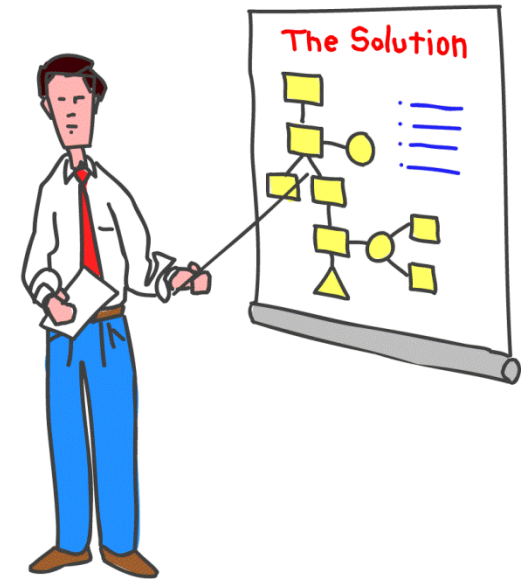
Identifying & Implementing Solutions***
TPM
Visual Management
5S
SMED
Value Stream Mapping
Process Mapping
Service Blueprints

Designing & Analyzing Processes

Designing & Analyzing Processes

- FMEA

- ❑ **Failure Modes** are the manners in which a process could potentially fail to meet the improvement intent.
- ❑ Failure Mode and Effect Analysis (**FMEA**) is a risk Analysis tool.
- ❑ FMEA is a systematic approach that identifies potential failure modes in:
 - ❑ **A process.**
 - ❑ A product.
 - ❑ A system.



- FMEA

- ❑ **Product FMEA:**

Analyze the function, design and potential failure of each component of a product.

- ❑ **Process FMEA:**

Analyze the key outputs and the potential failure of each step of a process.

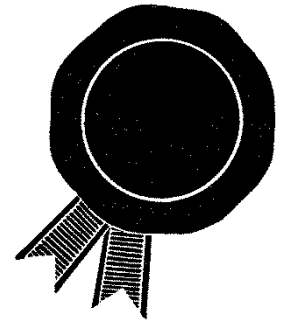
- ❑ Process FMEA considers the effect of process failure on the product or service concerned.



- FMEA

Benefits:

- ❑ Provides a basis for identifying root failure causes and developing effective corrective actions.
- ❑ Early identification and elimination of potential process failure modes.
- ❑ Prioritize product/process deficiencies.
- ❑ Emphasizes problem prevention.
- ❑ Documents risk and actions taken to reduce risk.
- ❑ Provides a foundation for other maintainability, safety, testability, and logistics analyses.
- ❑ Improves process reliability and quality.



- FMEA

- ❑ It is widely used in industrial, medical and business areas.
- ❑ Requires considerable knowledge of system operation and engineering.
- ❑ It is used to rank and prioritize the possible causes of failures to develop and implement preventative actions.
- ❑ It identifies critical or significant process characteristics that require special controls.



- FMEA

- ❑ FMEA helps identifying every possible failure mode then determine the **frequency** and **impact** of the failure.
- ❑ FMEA helps recommend actions to reduce the impact and/or likelihood of problems.

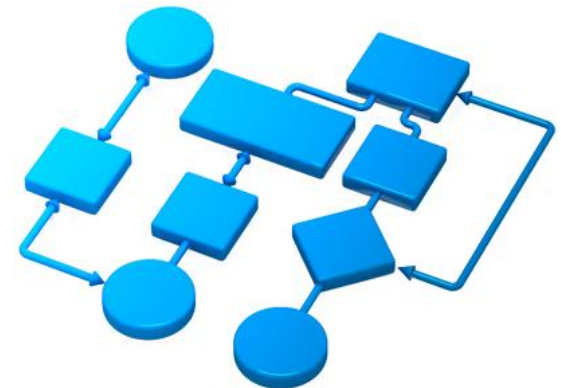
- ❑ **To reduce the risk:**
 - ❑ Reduce the failure effect severity.
 - ❑ Lower the probability of the failure.
 - ❑ Both.



- FMEA

Approach:

- ❑ Describe the process and its function.
- ❑ Identify the process steps (process mapping).
- ❑ List the different failure modes that can occur (brainstorming).
- ❑ Rate their severity (SEV).
- ❑ For each failure mode, consider the potential causes that might cause the failure (brainstorming).
- ❑ Rate their occurrence (OCC) or how likely they are to occur.



- FMEA

Approach:

- ❑ For each potential cause, consider the controls in place to prevent it happening (or to detect the failure if the cause occurs).
- ❑ Rate the likelihood of detection (DET).
- ❑ Calculate the **Risk Priority Number** (RPN).
- ❑ Assign actions to tackle the highest RPN's (Act on the results).
- ❑ After actions have been taken, re-assess the severity, probability and detection to re-evaluate the failures.
- ❑ Update the FMEA as the process changes.

- FMEA

Step	Failure	Effect	S E V	Causes	O C C	Controls	D E T	R P N	Action	Who	When	R P N



Completed during the first draft



Used to track actions

- FMEA

Non-manufacturing Example:

Failure Mode and Effect Analysis (FMEA)														
Project #:				Project Title:					Date:					
Process/Product:				Process Owner:					Revision:					
First Draft									Recommended Corrective Actions					
Process step / product part	Potential Failure Mode	Potential Failure Effect	Potential Causes	Current Controls	S E V	O C C	D E T	R P N	What	Who & When	S E V	O C C	D E T	R P N
Take order	Missing of some info.	Incorrect order	Lack of attention	Using of an order-taking checklist	3	4	2	24	Provide stronger validation (order taking system)					
Prepare order	Wrong amount of ingredients	Defective product	Broken of equipment	Periodic inspection of equipment	4	1	3	12						
Deliver order	Takes too long to deliver	Delayed delivery	Traffic jam or too many orders	Using of GIS technology	3	3	3	27	Hire more people to delivery & buy more delivery cars					

- FMEA

Tips:

- ❑ The FMEA is meant to be a "before the failure" action.
- ❑ Upon completing the FMEA, a report is written to document the team's accomplishments.
- ❑ It's a living document and therefore it should be continually updated as changes occur or more information is gained.
- ❑ The ratings are usually on a scale of 1 to 10.
- ❑ Apply your rating scales consistently.

- FMEA

Severity Rating:

- ❑ (1-2) Minor failure which is not noticed by the customer.
- ❑ (3-4) Failure that could be noticed by the customer without negatively affecting customer satisfaction.
- ❑ (5-6) Moderate failure that may result in some customer dissatisfaction.
- ❑ (7-8) Major failure that may generate high level of customer dissatisfaction.
- ❑ (9-10) Safety issue, adverse impact on end-user, etc.



- FMEA

Occurrence Rating:

- ❑ (1-2) The cause of the failure is unlikely to occur.
- ❑ (3-4) The cause of the failure occurs sometimes.
- ❑ (5-6) An occasional occurrence of the cause of the failure.
- ❑ (7-8) A frequent occurrence of the cause of the failure.
- ❑ (9-10) The occurrence of the cause of failure is very probable.



- FMEA

Detection Rating:

- ❑ (1-2) Reliable detection control to detect failure mode.
- ❑ (3-4) High likelihood that the current control will detect failure mode.
- ❑ (5-6) Moderate likelihood that the current control will detect failure mode.
- ❑ (7-8) Low likelihood that the current control will detect failure mode.
- ❑ (9-10) No control available to detect failure mode or ineffective control.

