Understanding Core Tools: DFMEA

Design Failure Modes and Effect Analysis (DFMEA)

Course Objectives

This one day core tools overview employs a hands on approach to provide a general understanding of APQP product development processes and their relationship to APQP phase II deliverables including:

- The Design Failure Mode Effects Analysis (DFMEA)
- The Design Verification Plan and Report (DVP&R)
- Development linkages to the Process FMEA

Course Agenda

- Chapter 1: APQP Phases: Key Deliverables (Outputs)
- Chapter 2: Design Failure Mode and Effects Analysis (DFMEA) Introduction
- Chapter 3: DFMEA Preparation
- Chapter 4: Developing the DFMEA
  - **Breakout Exercise 1: Starting the DFMEA & Design Failure Modes**
  - **Breakout Exercise 2: Potential Design Causes**
  - **Breakout Exercise 3: Design Controls**
  - **Breakout Exercise 4: Design Effects & Classification**
  - **Breakout Exercise 5: RPNs, Risk and Criticality, and Improvements**
- Chapter 5 – Design Verification Plan and Report (DVP&R)

A BRIEF INTRODUCTION TO OMNEX

Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
  - Integrated management system solutions.
  - Elevating the performance of client organizations.
  - Consulting and training services in:
    - Quality Management Systems, e.g., ISO 9001, IATF 16949, AS9100, QOS
    - Environmental Management Systems, e.g., ISO 14001
    - Health and Safety Management Systems, e.g., ISO 45001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
  - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.

Omnex Worldwide Offices

Omnex is headquartered and operates from the United States through offices in Michigan.

The company maintains international operations in many countries to provide comprehensive services to clients throughout Western Europe, Latin America and the Pacific Rim.

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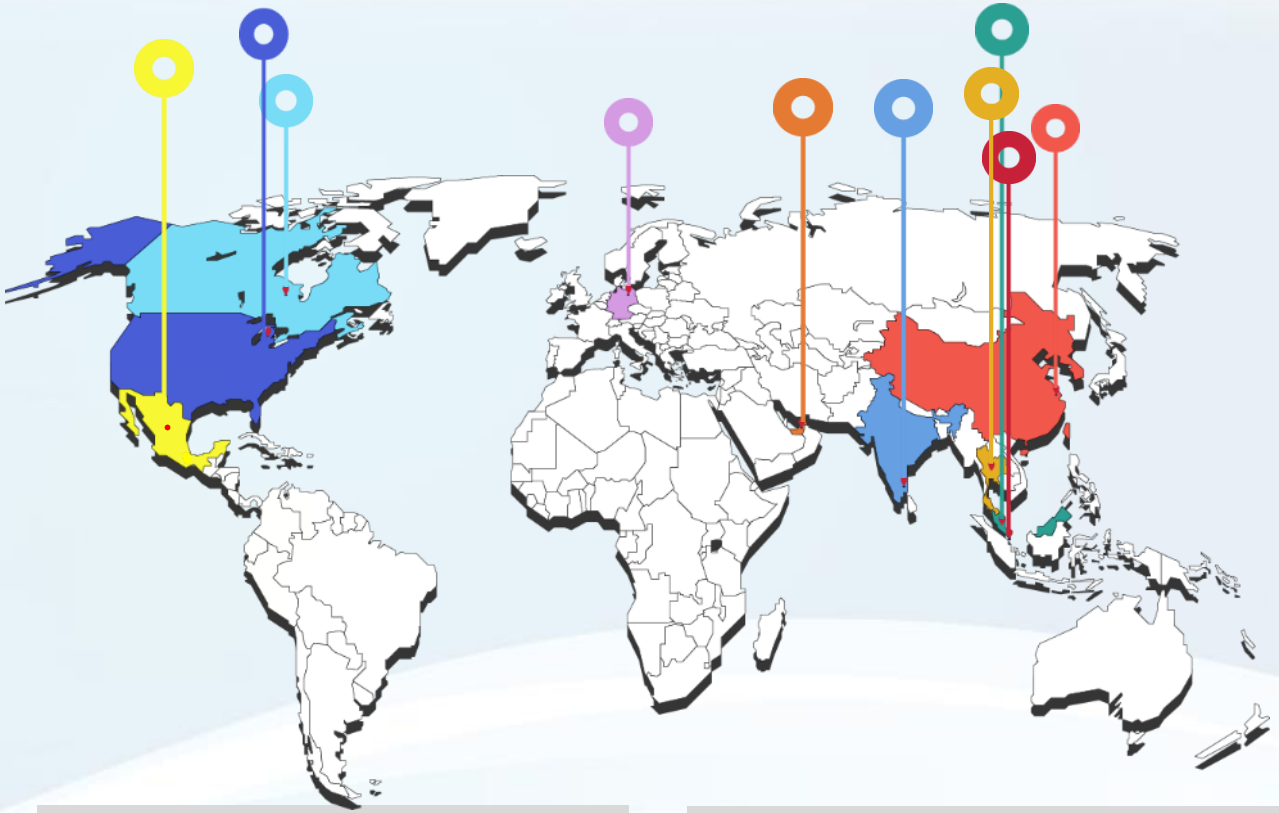
info@omnex.com



- Omnex Global Head Quarters (Michigan, USA)
  West Coast Operations (San Jose, CA)
- Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)
- China (Shanghai, Guangzhou, Wuhan, Chengdu)
- Canada (Mississauga)
- Europe (Berlin, Germany)
- Middle East (Dubai, Saudi Arabia, Bahrain)
- Thailand (Bangkok)
- Mexico (Monterrey)
- Singapore
- Malaysia (Kuala Lumpur)

Rules of the Classroom

- ✓ Start and end on time
- ✓ Return from breaks and lunch on time
- ✓ All questions welcome
- ✓ Your input is valuable and is encouraged
- ✓ Don’t interrupt others
- ✓ One meeting at a time
- ✓ Listen – and respect others’ ideas
- ✓ No “buts” – keep an open mind
- ✓ Phones in Do Not Disturb (silent) mode
- ✓ No e-mails, texting or tweeting during class

If you must take a phone call or answer a text please leave the room for as short a period as possible

Icebreaker

- Instructor Information:
  - Name
  - Background
- Student Introductions:
  - Name
  - Position / Responsibilities
  - Your involvement in the APQP or Product Design process?
  - Do you manage or use a DFMEA or DVP&R?
  - What do you expect to take away from this class?
  - Please share something unique and/or interesting about yourself.

Chapter 1

APQP Phases:
Key Phase Deliverables (Outputs)

Chapter 1: APQP Phases (Outputs) — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Identify the phase(s) in which key product development deliverables are created
- Explain the benefit of concurrent engineering and APQP

Chapter Agenda

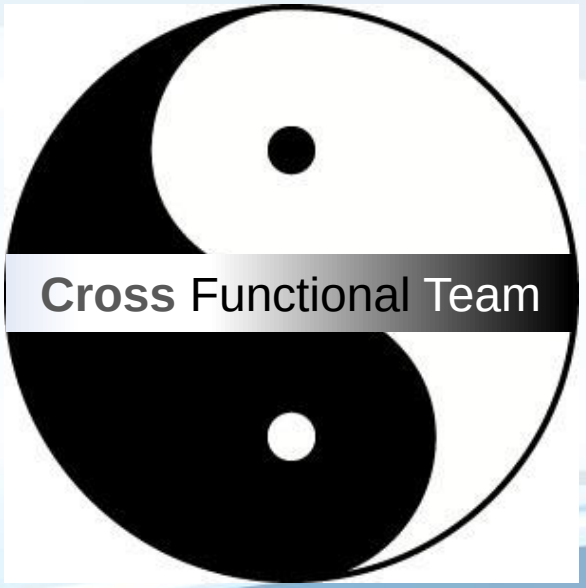
- Yin/Yang of Concurrent Engineering
- APQP Phases
- APQP Deliverables
- Special Characteristics

“Yin/Yang” of Concurrent Engineering

Concurrent (or Simultaneous) Engineering is basic to:

- Stimulate knowledge sharing between all key functions to achieve common goals
- Integration of customer expectations into product and process design
- Alignment of design attributes with manufacturing capabilities
- Reduce ‘time to market’ through overlap of phases

Changes in either development activity may have profound impact on the counterpart development activity—they are two halves of the same process.



Another Look at Concurrent Engineering

During design reviews, the teams identify the linkages between Product Design and Process Design/Development.

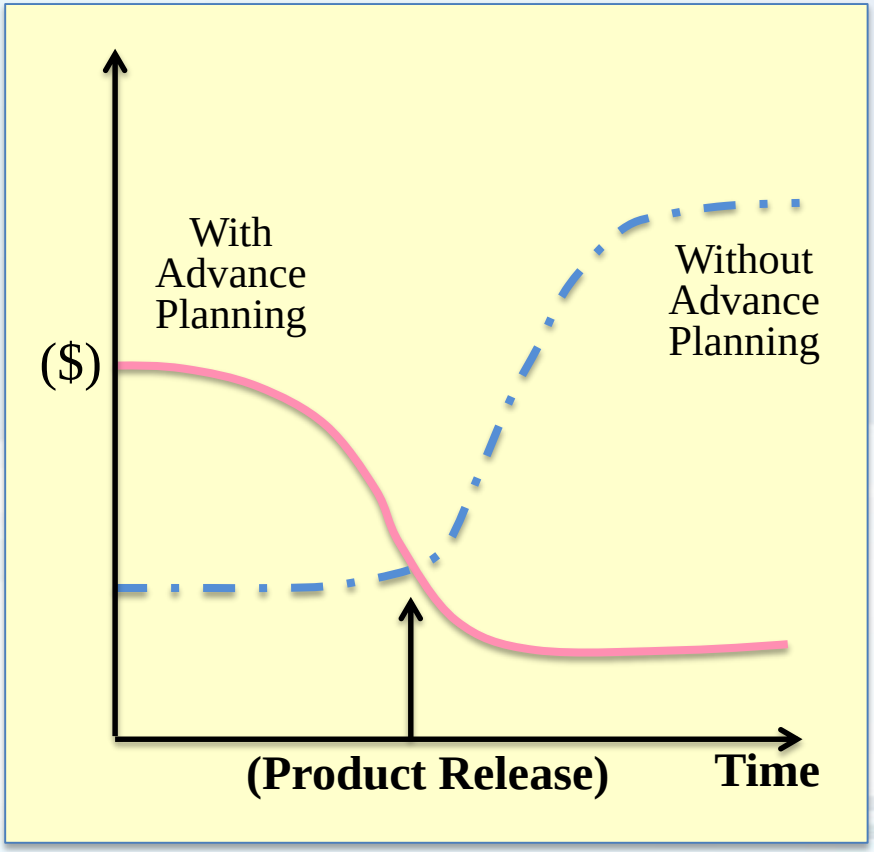
Design reviews are coordinated with manufacturing process design and development; includes all affected functional areas.

Remember DFM/A

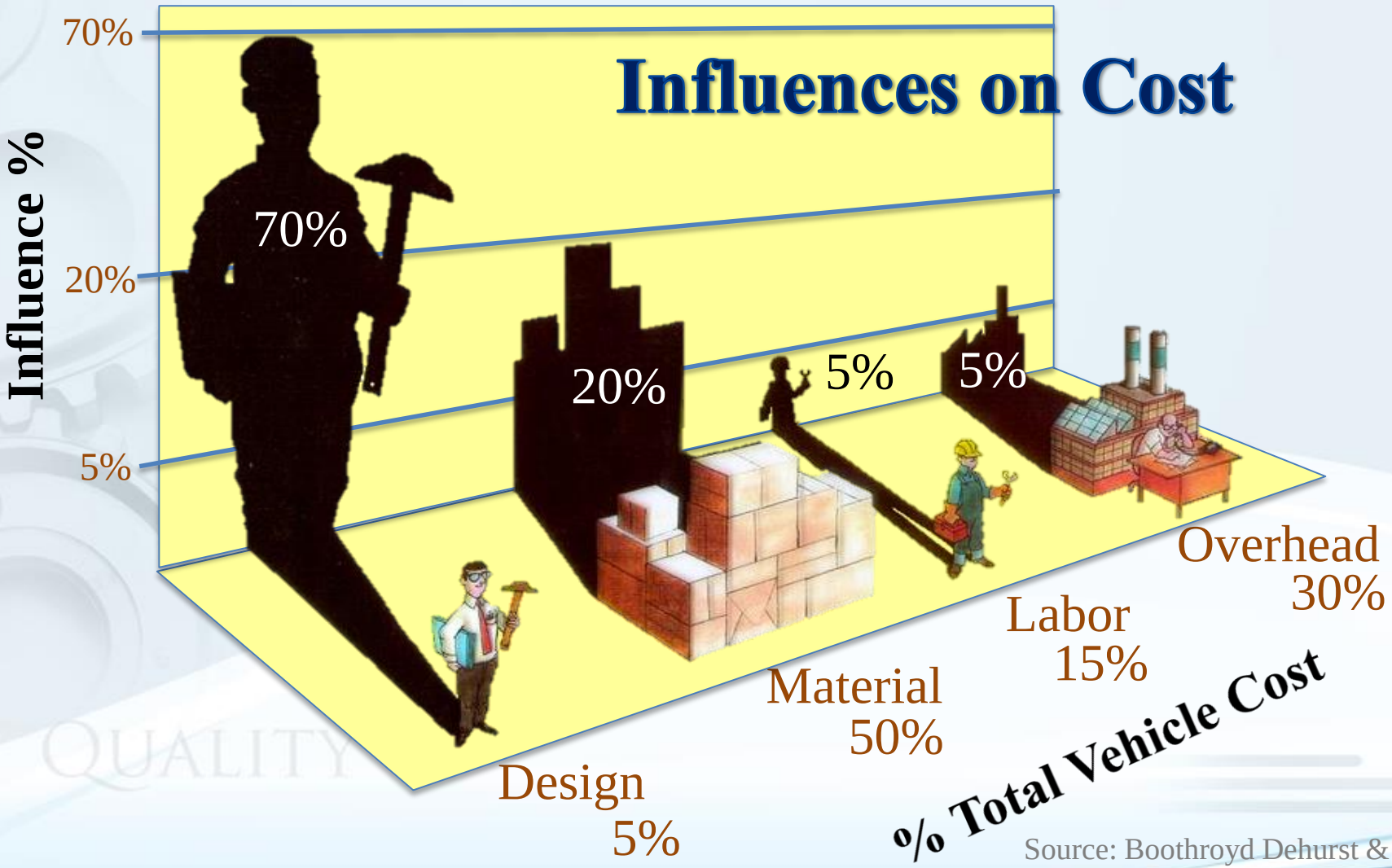
Advance Planning: Concurrent Engineering

Benefits

- Resources are focused on customer satisfaction
- Required changes are identified early
- Changes close to or after product launch are minimized
- Process can accommodate unavoidable changes
- Reflects the Yin/Yang reality of development



Product Cost and Product Design



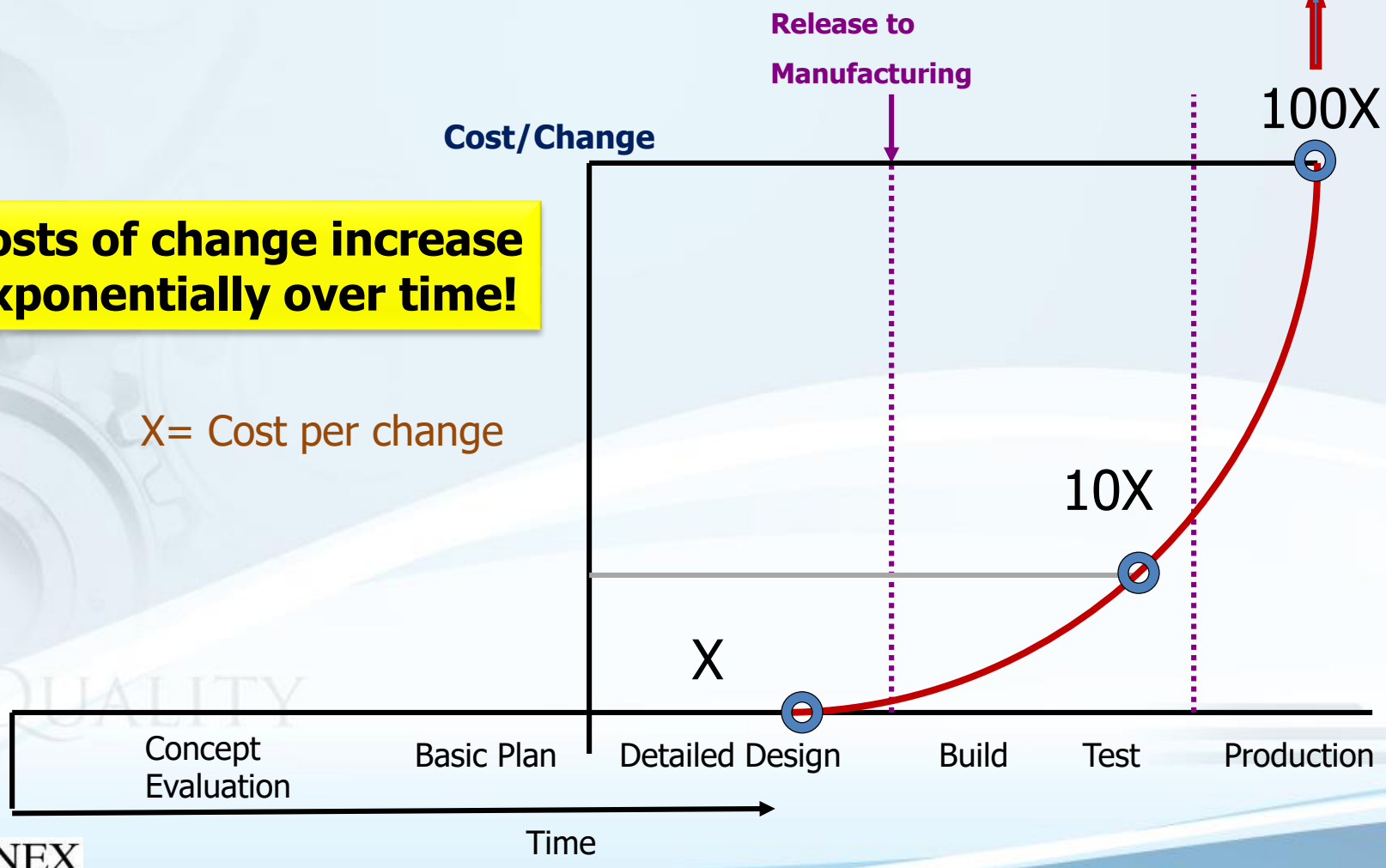
Source: Boothroyd Dehurst & Ford

Design Engineering: Cost of Change/Failure

∞!

Costs of change increase exponentially over time!

X= Cost per change



FMEA: The Value of Timeliness

*"One of the most important factors for the successful implementation of an FMEA program is **timeliness**. It is meant be a **before-the-event action**, **not an after-the-fact exercise**."*

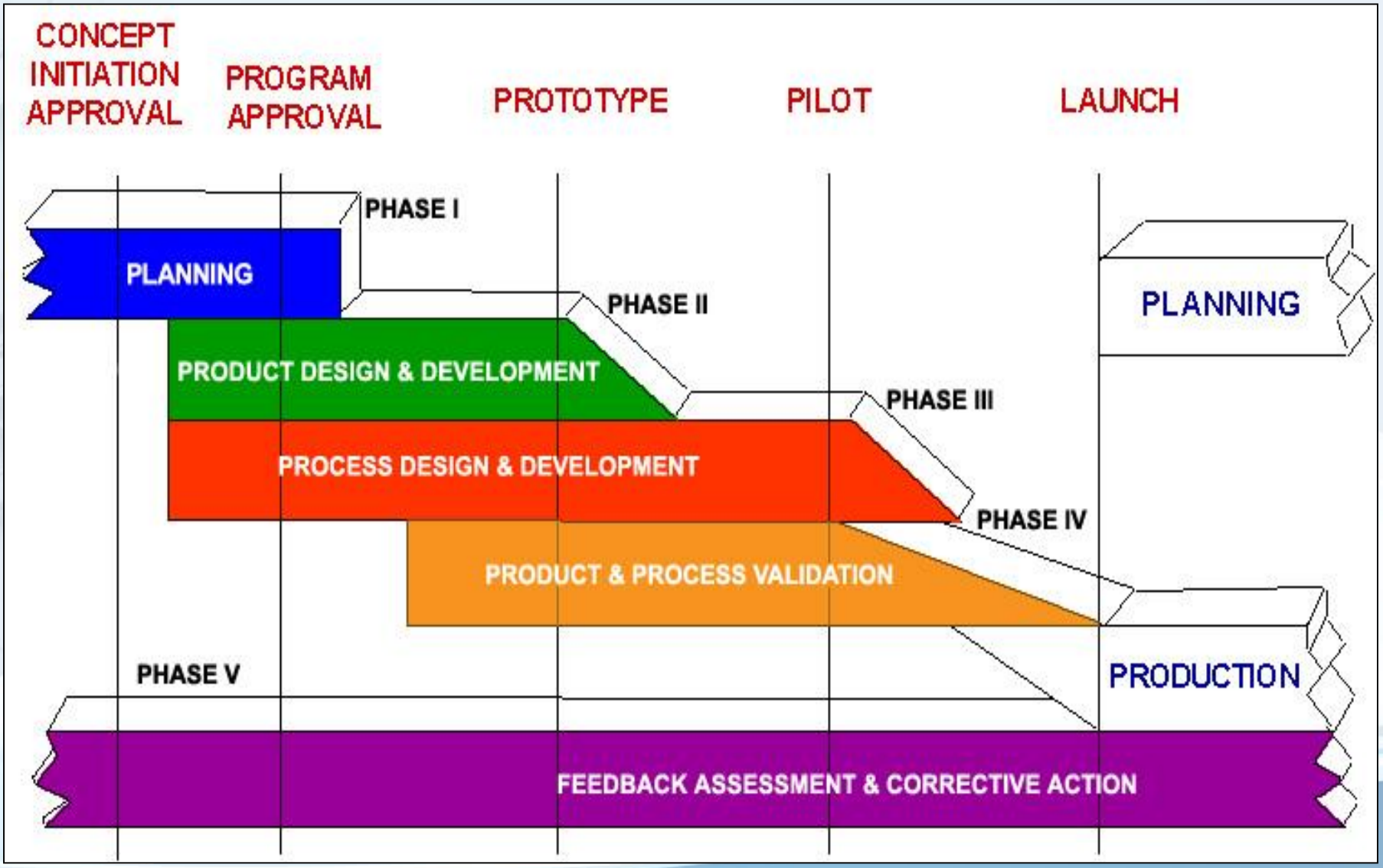
The most value is achieved when the FMEA is complete before a failure mode has been incorporated into the product or process.

Early preventive changes to the design (product or process) are the easiest and least expensive to implement.

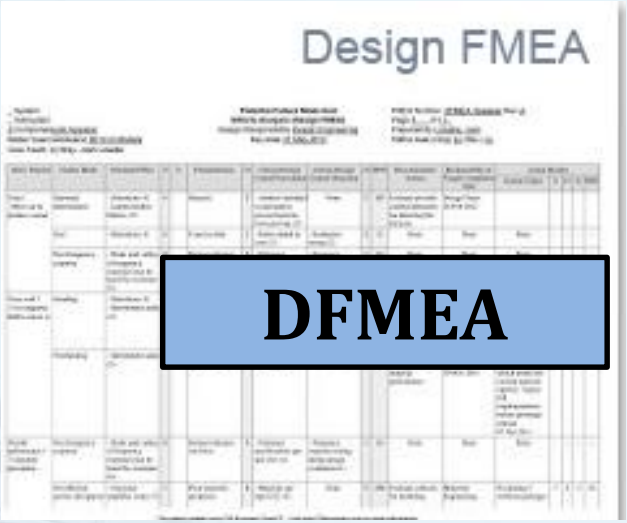
*"The DFMEA should be **initiated before or at design concept finalization** and be **fundamentally complete before production drawings are released** for tooling."*

– AIAG FMEA 4th Ed.

Alignment of APQP Processes



APQP Phase II: Design Responsible Outputs



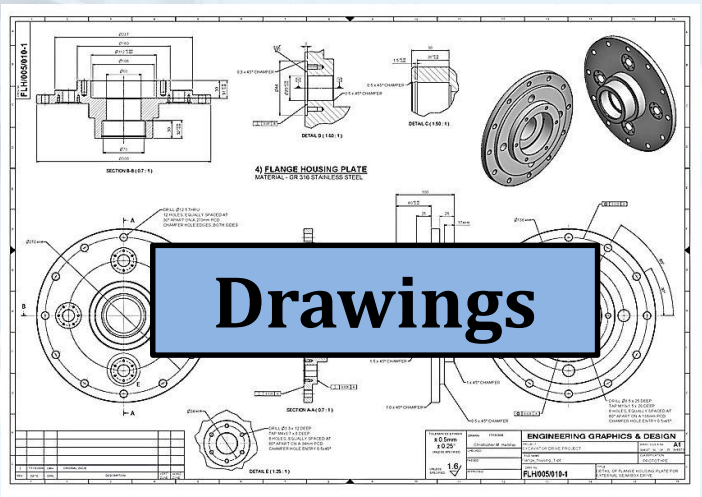
DFMEA

Properties | FMEA | DVP&R

Test Request #	Test/ Specification Method	Acceptance Criteria	Assigned To	Planned Test Phase	Planned Sample Size	Planned Start
1	Vehicle durability test.	95% reliability (i.e. no corrosion) at XXX miles of operation.	Test Lab	95% reliability	Per Established Test Plan	10/14/2016
2	Laboratory accelerated corrosion test.	Accelerated life data analysis estimates 95% reliability (i.e. no corrosion) at YYY miles of operation.	Accelerated Test Lab	Accelerated life data ana	10 Vehicles	7/13/2016
3	Design of Experiments on wax thickness.	Determine the optimal wax thickness.	Reliability Engineering and Test Lab	Determine the optimal wax	TBD	6/1/2016
4	Physical and chemical lab test.	The wax formulation is sufficient to prevent corrosion for this application.	Materials Engineer	The wax formulation is su	N/A	5/11/2016
				st be able to sition	N/A	6/1/2016

Worksheet

DVP&R



Drawings

	Chemistry							
	Grade 55		Grade 60		Grade 65		Grade 70	
Thickness	C	Mn	C	Mn	C	Mn	C	Mn
3/16" thru 1/2"	.18	.60/.90	.21	.60/.90	.24	.85/1.20	.27	.85/1.20
>1/2" thru 2"	.20	.60/1.20	.23	.85/1.20	.26	.85/1.20	.28	.85/1.20
>2" thru 4"	.22	.60/1.20	.25	.85/1.20	.28	.85/1.20	.30	.85/1.20
>4" thru 8"	.24	.60/1.20	.27	.85/1.20	.29	.85/1.20	.31	.85/1.20
>8"	.26	.60/1.20	.27	.85/1.20	.29	.85/1.20	.31	.85/1.20

P	S					V'	Cb'
.035	.035					.03	.02

Material Specs

Etc.

Chapter 1: APQP Phases (Outputs) — What We Covered

Learning Objectives

You should now be able to:

- Identify the phase(s) in which key product development deliverables are created
- Explain the benefit of concurrent engineering and APQP

Chapter Agenda

- Yin/Yang of Concurrent Engineering
- APQP Phases
- APQP Deliverables
- Special Characteristics

Chapter 2

Design Failure Mode and Effects Analysis (DFMEA) Introduction

Chapter 2: DFMEA Introduction — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Identify the purpose of a DFMEA
- Explain the DFMEA link to PFMEA

Chapter Agenda

- What is an FMEA?
- DFMEA Purpose
- DFMEA Objectives
- New Products
- Linkages

An FMEA is…

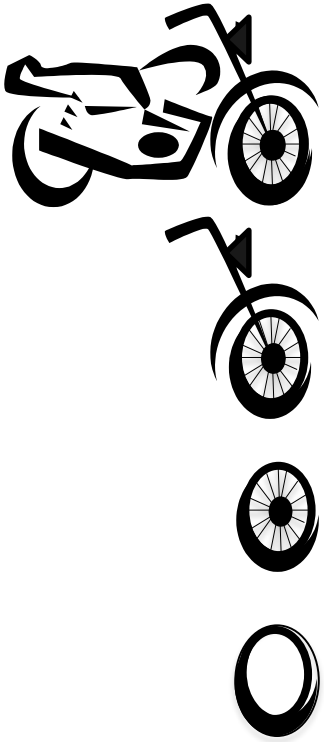
A disciplined analytical process that allows a team to anticipate failures and prevent their occurrence through product and process design.

Design FMEA

Analyzes products prior to release of design to production. Design review teams look at ***potential failure modes of the product due to design deficiencies, risks, or errors***.

Design/Process FMEA: Identify ways the product design or manufacturing process could fail and then plan how best to prevent failures

FMEA Hierarchy

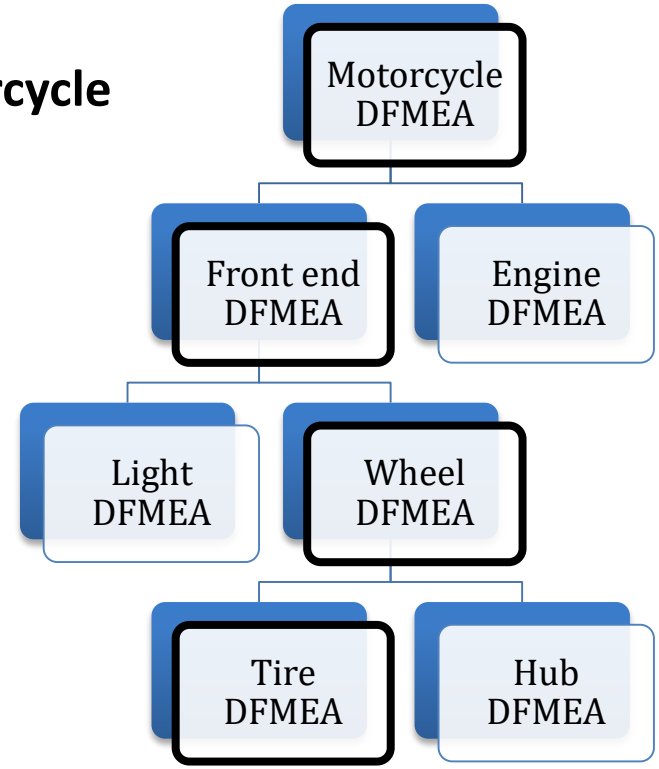


Highest System Level – Motorcycle

System Level – Front end

Sub-system Level – wheel

Component Level – Front tire



Primary Types of Design FMEAs

Highest Level System FMEA: Used to analyze the expected deliverables of the product to the customer

- Focuses on potential failure modes of the **overall product** caused by the **design process**. (Product misses customers' expectations)
- This may be a qualitative analysis

System FMEA: Used to analyze systems and subsystems in the early concept and design stages

- Focuses on potential failure modes associated with the **functions and interfaces** of a system caused by **design** (Interface/system failures)

Component FMEA: Used to analyze products before they are released to production

- Focuses on potential failure modes associated with the **functions** of a product caused by **design** (Part failures)

When to Create a DFMEA

Case 1: New Designs, New Technology, or New Process

- The scope of the FMEA is the complete design, technology or process

Case 2: Modifications to Existing Design or Process

(assumes there is an effective FMEA for the existing design or process)

- The scope should focus on the modification to design or process, possible *interactions* due to the modification, and field history

Case 3: Existing Design or Process used in a New Way or Environment *(assumes there is an effective FMEA for the existing design or process)*

- The scope should focus on the implications of the new use or environment

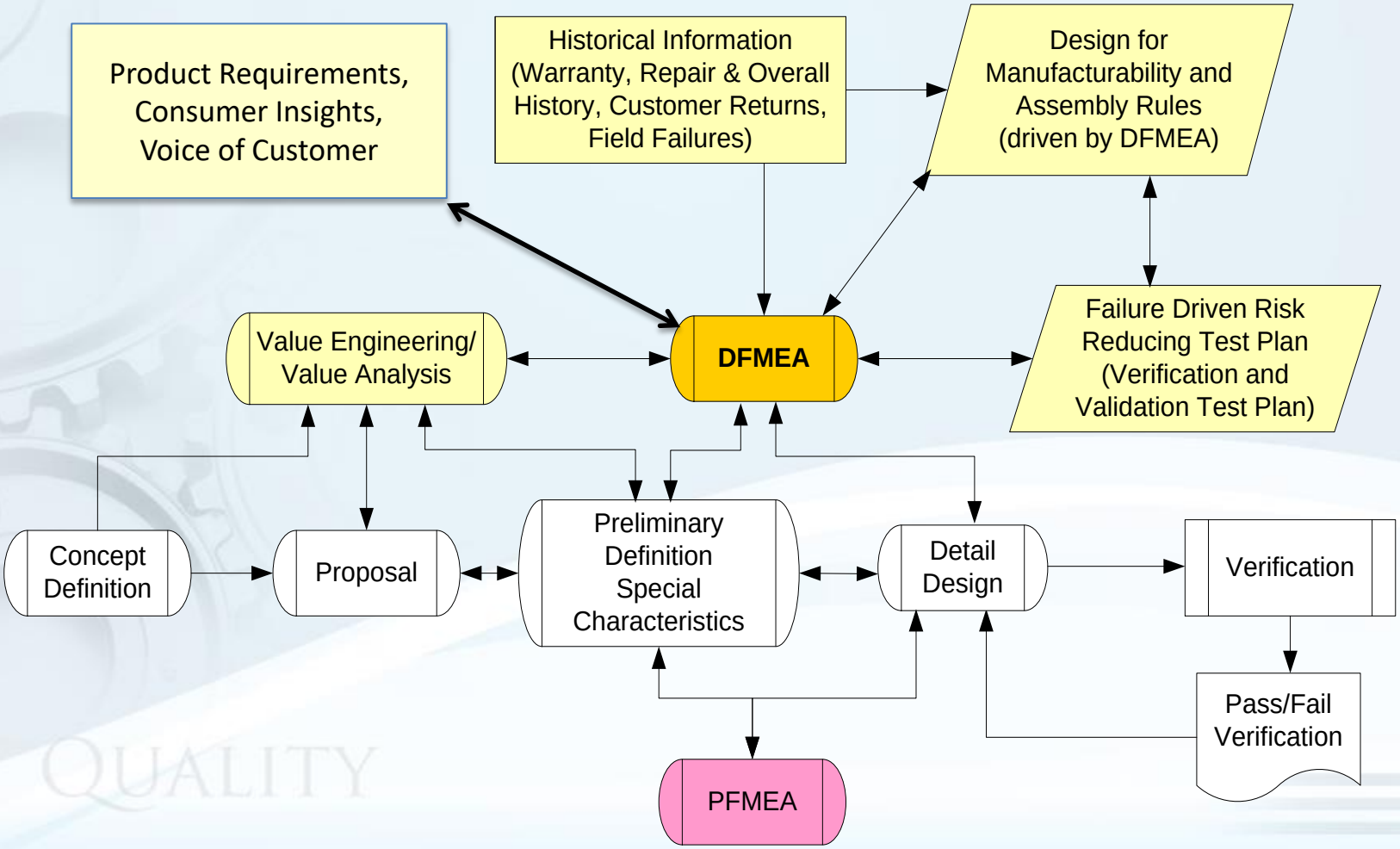
Design FMEA Objectives

Ensure Robust Design and Effective Design Review & Verification Process

- Identify and Mitigate Risk
  - An analytical technique utilized by a design-responsible engineer and design review team
  - Ensure that potential failure modes and associated causes / mechanisms are considered and addressed
  - **Standardized method of identifying, evaluating, and prioritizing risks from design causes**
  - **Minimize the "customer" experiencing failure modes**
  - Meet product / customers' expectations
  - Ensure manufacture and assembly processes are appropriate for the design

Knowledge Management

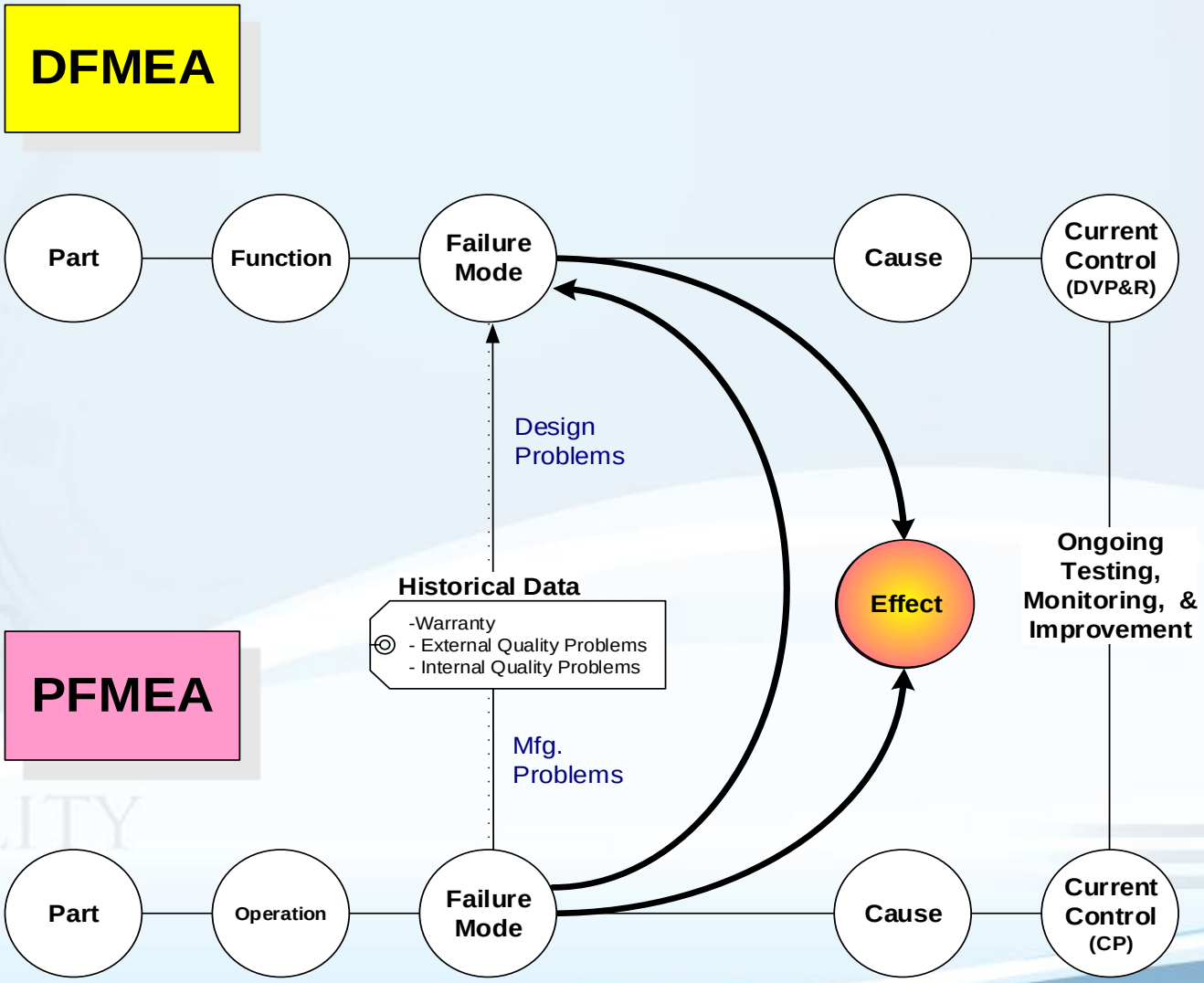
Development DFMEA Links



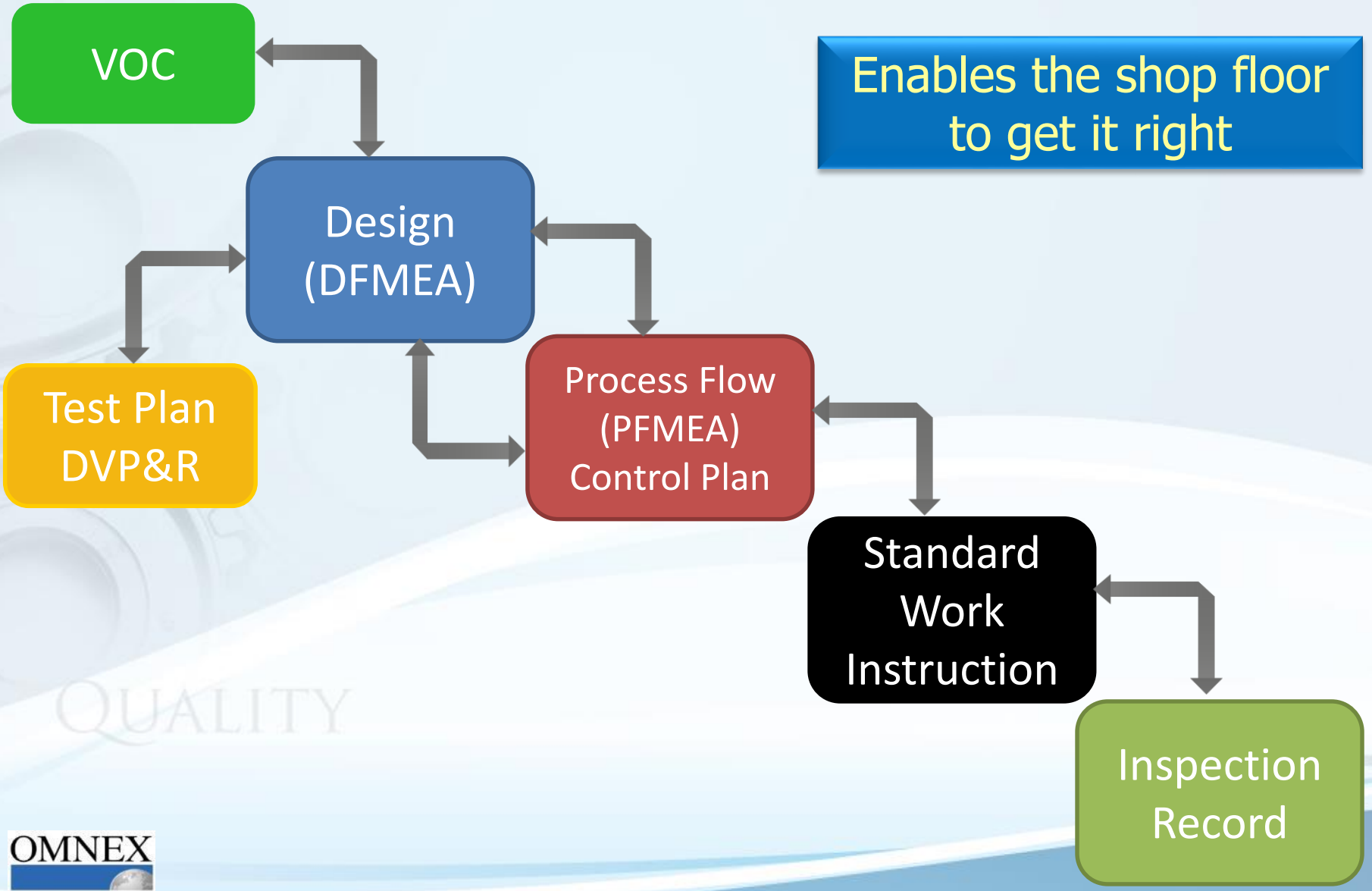
DFMEA Documents Living Information

- Initiated before design concept finalization
- Updated as changes occur or additional information is obtained throughout the phases of product development
- Fundamentally completed before the production design is released
- Source of lessons learned for future design iterations
- Updated as Severity, Occurrence, and Detection are affected by design changes

Design and Process FMEA Links



Voice of Customer to Test Plan and Shop Floor



Chapter 2: DFMEA Introduction — What We Covered

Learning Objectives

You should now be able to:

- Identify the purpose of a DFMEA
- Explain the DFMEA link to PFMEA

Chapter Agenda

- What is an FMEA?
- DFMEA Purpose
- DFMEA Objectives
- New Products
- Linkages

Chapter 3

DFMEA Preparation

Chapter 3: DFMEA Preparation — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Define the "*Customer*"
- Evaluate "*Function*"
- Identify Requirements
- Create input documents for a DFMEA
  - Boundary Diagram
  - Parameter Diagram
- Recognize the links from VOC to Product Validation

Chapter Agenda

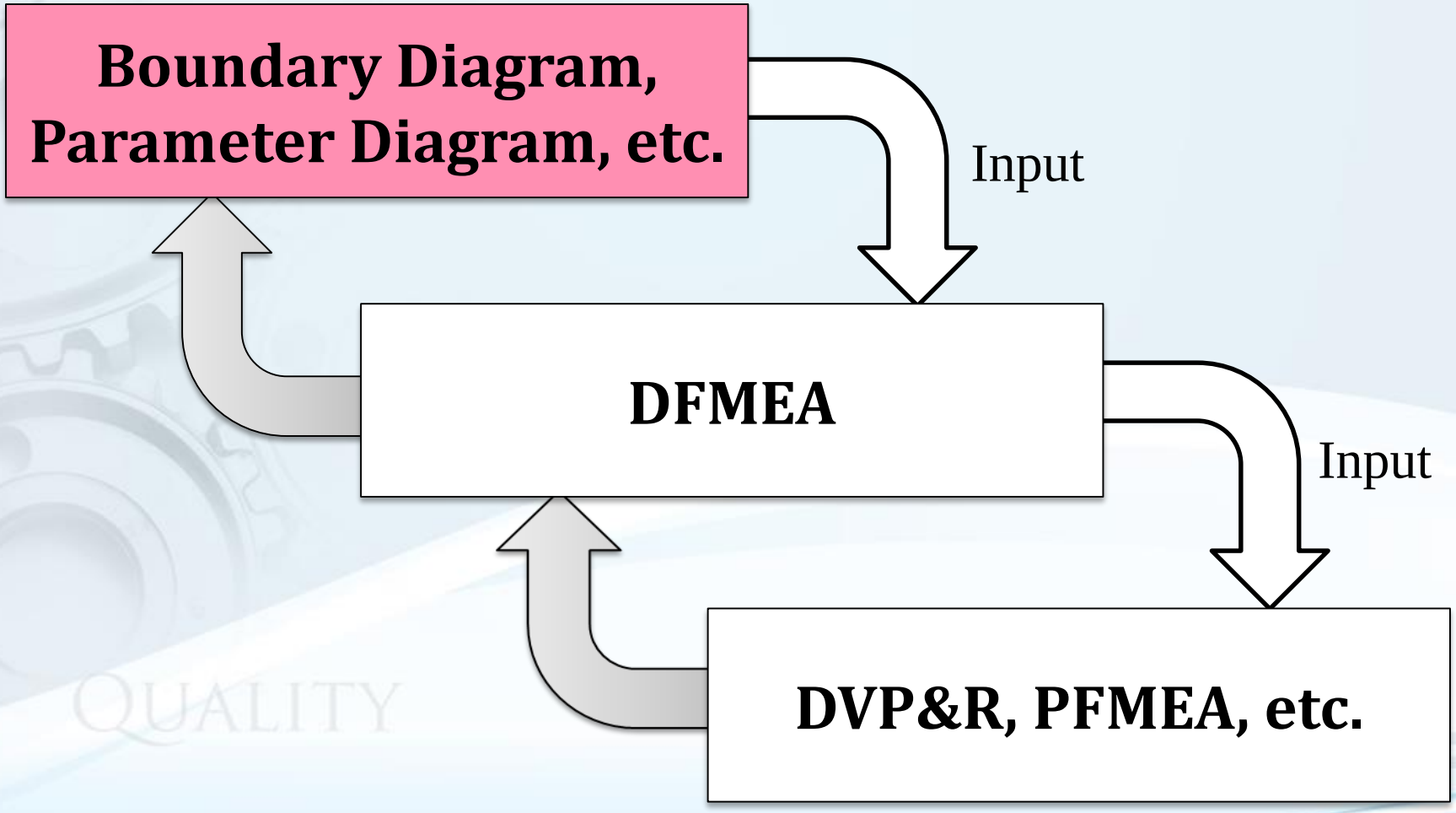
- Define the Customer
- Identify Specific Functions and Requirements
- Robust Designs
- Other Inputs to DFMEA

Who is the Customer?

Some customers to consider:

- End User (consumer)
- Customer (who you supply)
  - OEM Assembly
  - Manufacturing Centers (plants)
- Supply Chain Manufacturing
- Regulators
- Assembly
- Production
- Logistics
- Service
- Others …

Robust Designs: Inputs and Feedback



Scope of DFMEA: Boundary (Block) Diagrams

Before the FMEA can begin, a clear understanding of the scope establishes the boundary of the FMEA analysis.

The scope needs to be established at the start of the process to ensure consistent direction and focus.

The following may assist the team in defining the scope of the FMEA:

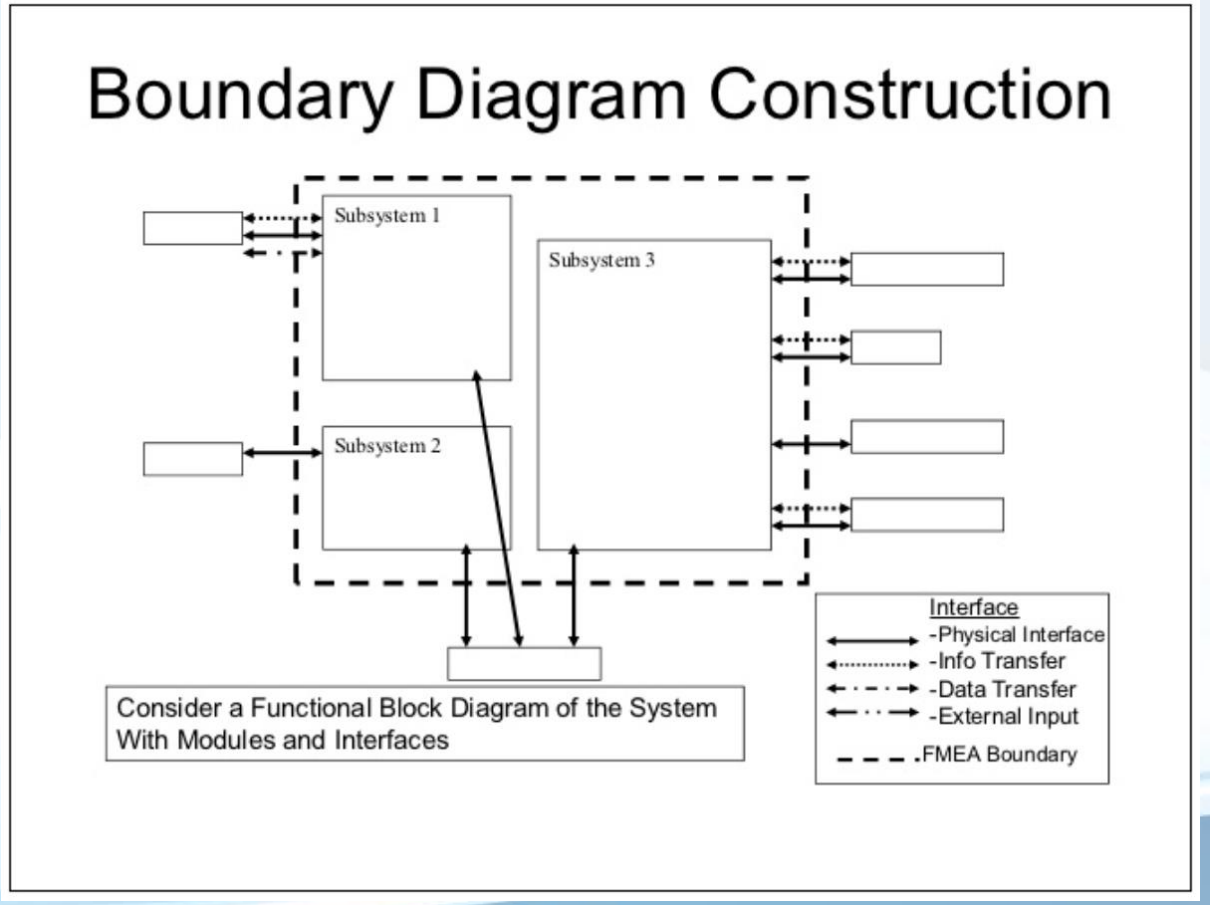
- Function Model
  Block (Boundary) Diagrams
- Parameter (P) Diagrams
- Interface Diagrams
  Process Flow Diagrams
- Interrelationship Matrices
- Schematics
- Bill of Materials (BOM)

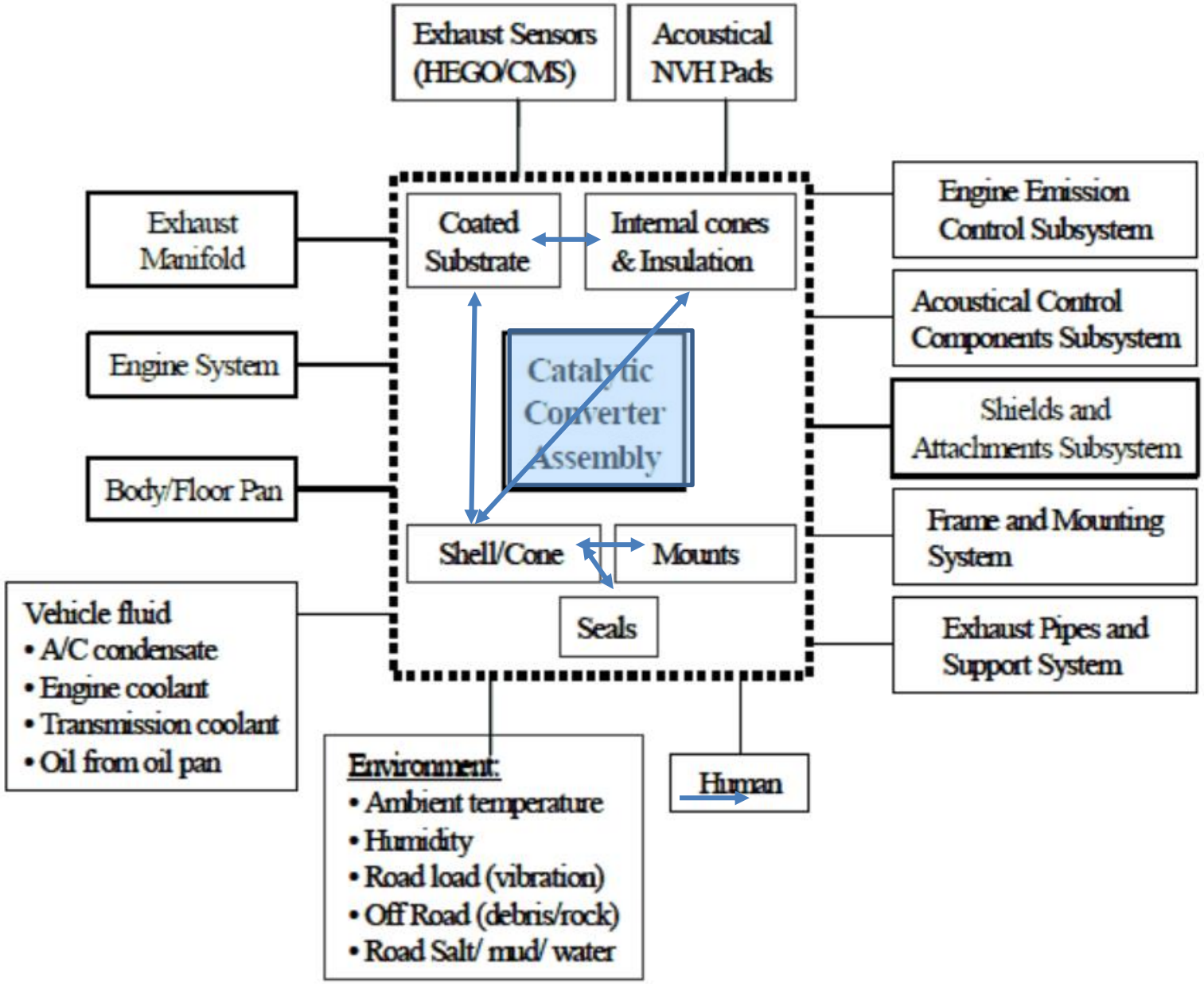
Scope of DFMEA: Boundary (Block) Diagrams

A Boundary Diagram defines what is included and excluded:

- Determined based on the type of FMEA being developed, i.e., system, subsystem, or component

What to exclude can be just as important as what to include in the analysis





Generic Catalytic Converter Assembly Boundary Diagram

Sample Boundary Diagram example from Ford Motor Company

Scope of DFMEA: Parameter (P) Diagrams

The **Parameter Diagram** (**P-Diagram**) takes the inputs from a system / customer and relates those inputs to desired outputs of a design that the engineer is creating while also considering non-controllable outside influences.

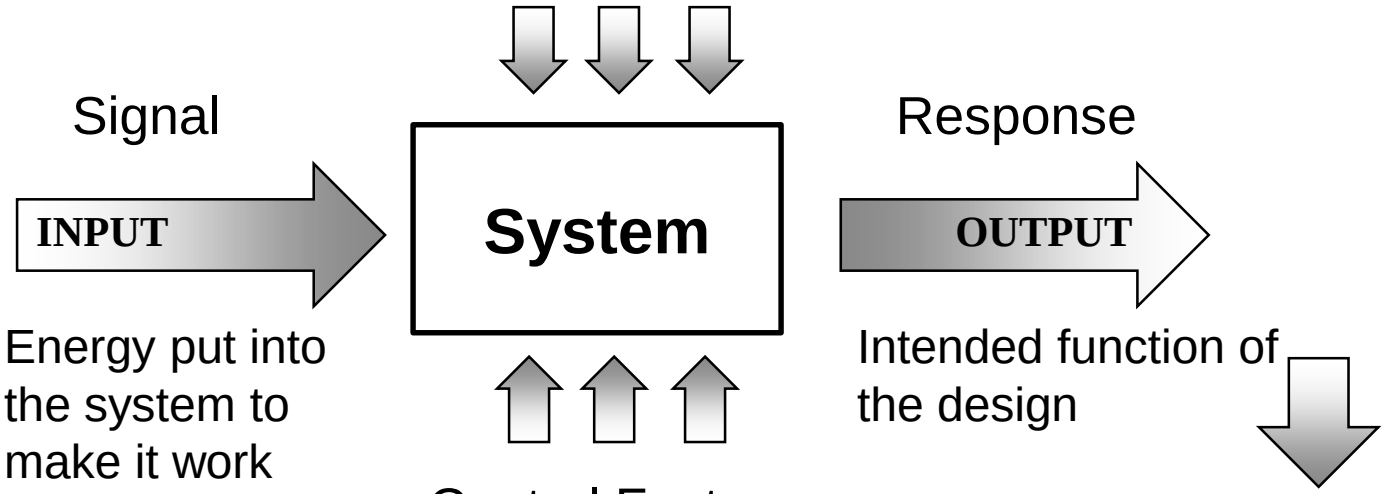
The **P-Diagram**, is a useful tool in brainstorming and documenting Signal Factor(s).

Parameter (P) – Diagram

Noise Factors

Sources that disrupt response that can not be controlled

● Piece to Piece ● Changes over Time/Usage ● Customer Usage
● External Environment ● Subsystem Interaction



Energy put into the system to make it work

Intended function of the design

Control Factors

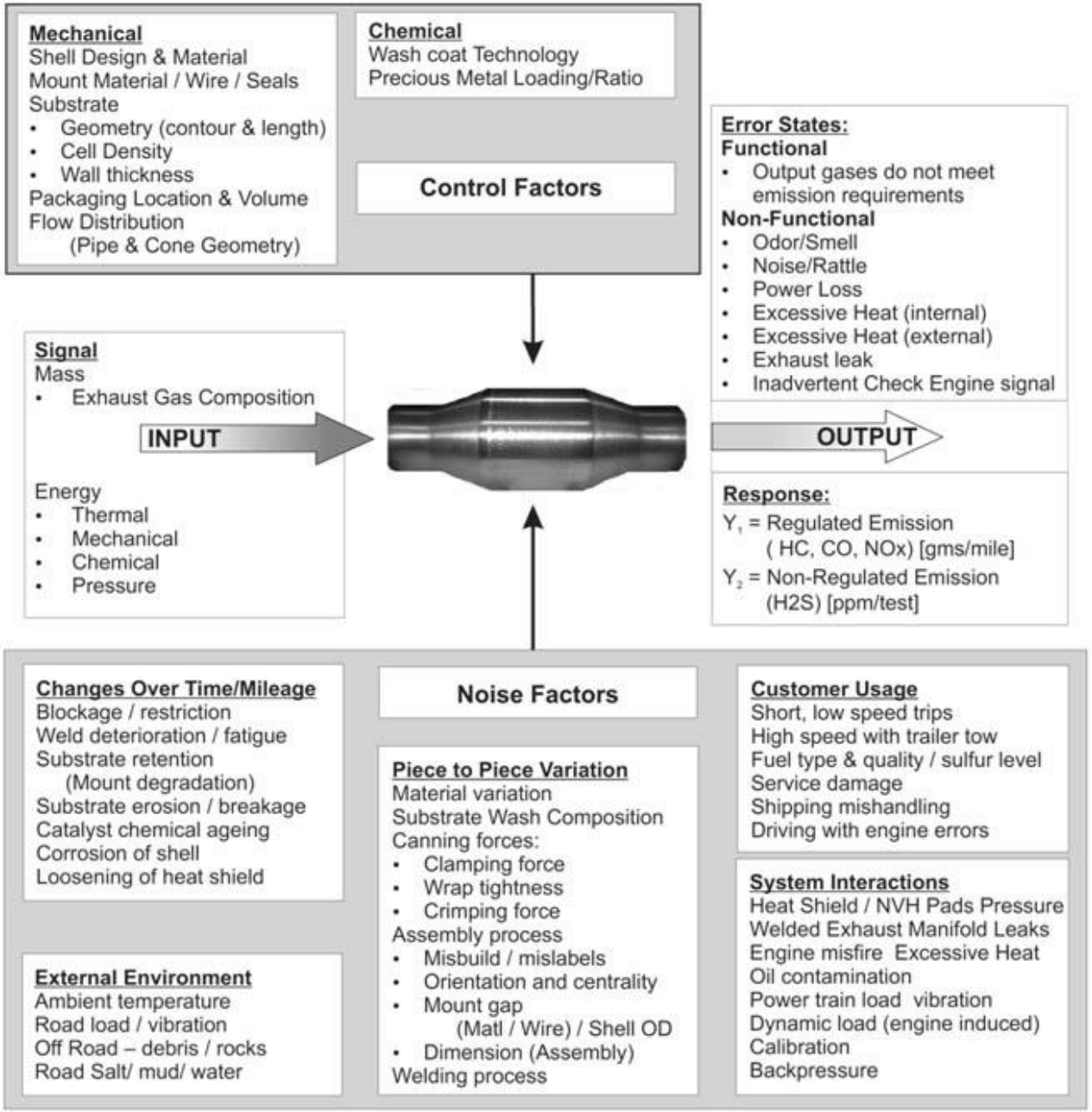
Features of the design that can be controlled or changed as a part of the design process

Error States

Undesirable output or Failure Modes

- Compliance
- Functional
- Annoyance

Parameter (P) – Diagram



Other Inputs to Design FMEA

Similar Product Performance Indicators:

- House of Quality (HoQ)
- Lessons Learned from previous design cycles
- Warranty information
- Historical campaign data
- Customer complaints and returns data
- Corrective and/or preventive actions
- Design FMEAs for similar products and processes
- Design Matrices for similar products/processes
- Product Benchmarks

Chapter 3: DFMEA Preparation — What We Covered

Learning Objectives

You should now be able to:

- Define the "*Customer*"
- Evaluate "*Function*"
- Identify Requirements
- Create input documents for a DFMEA
  - Boundary Diagram
  - Parameter Diagram
- Recognize the links from VOC to Product Validation

Chapter Agenda

- Define the Customer
- Identify Specific Functions and Requirements
- Robust Designs
- Other Inputs to DFMEA

Chapter 4

Developing the DFMEA

Chapter 4: Developing the DFMEA — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Conduct an effective DFMEA, identifying:
  - Functions and Requirements
  - Design Failure Modes
  - Effects of Failure
  - Design Causes
  - Preventive and Detective Controls
- Quantify and Evaluate Relative Risk
- Develop an Action Plan

Chapter Agenda

- Starting the DFMEA Form: Item, Function, Requirements, Failure Modes:
  - **Breakout Exercise 1**
- Potential Design Causes
  - **Breakout Exercise 2**
- Potential Controls & Prevention
  - **Breakout Exercise 3**
- Potential Effect & Severity
  - **Breakout Exercise 4**
- Action Planning
- Evaluating and Maintaining DFMEAs

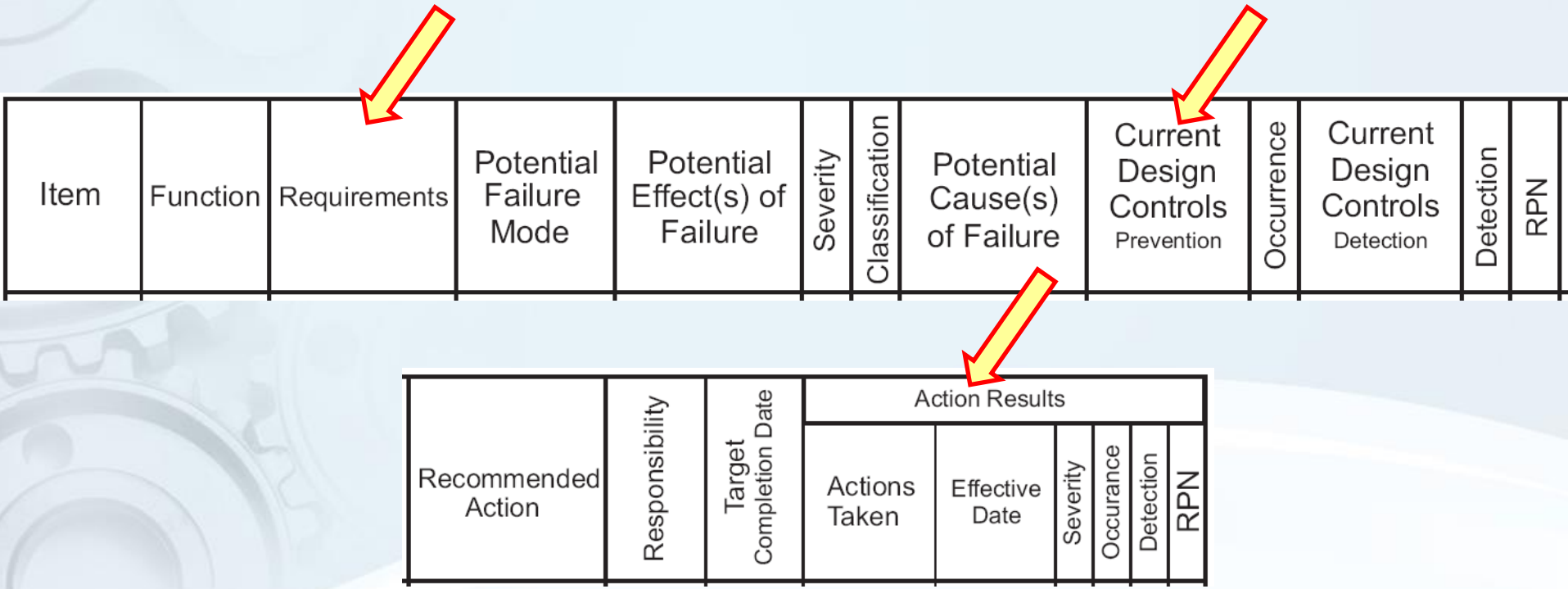
DFMEA Form Examples

Item	Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detection	RPN

Recommended Action	Responsibility	Target Completion Date	Action Results					
			Actions Taken	Effective Date	Severity	Occurance	Detection	RPN

Standard* DFMEA Form

= Significant Focus



There are several format options in FMEA 4th Ed.
This is the one Omnex recommends.

Identify the Functions

- What **SHOULD** the product/service ideally do?
- What are the Functional Deliverables?
- What do we expect to see, in terms of:
  - Performance?
  - Efficiency?
  - Effectiveness?
  - Under what conditions?
  - For each customer:

Buyer	Management
User	Government
Manufacturing	Society
Handling, etc.	

Consider the conditions

Storage
Transport
Normal Use
Excessive Use
Abuse
Extreme Conditions
Etc. …

Identify Specific Requirements

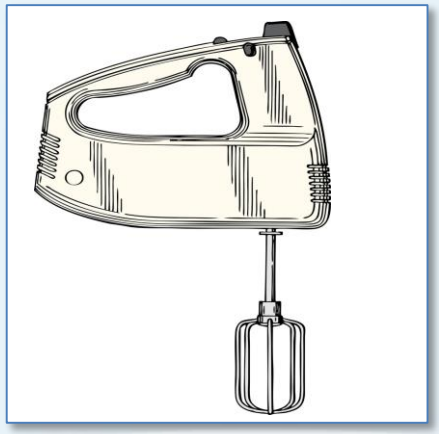
Requirements identify the conditions under which the functions hold true.

- Requirements are generally provided by a document such as a product specification or duty cycle, or are converted from a process known as a **Quality Function Deployment (QFD)** or **House of Quality (HoQ)**. If you are a supplier, your customer may dictate the product requirements to you.
- Requirements must be measurable and should have test methods defined. If requirements are poorly written or nonexistent, design work may be wasted.

Product Function: What is Required?

Heat bread to specified level

Spin at **200 rpm** and **400 rpm**



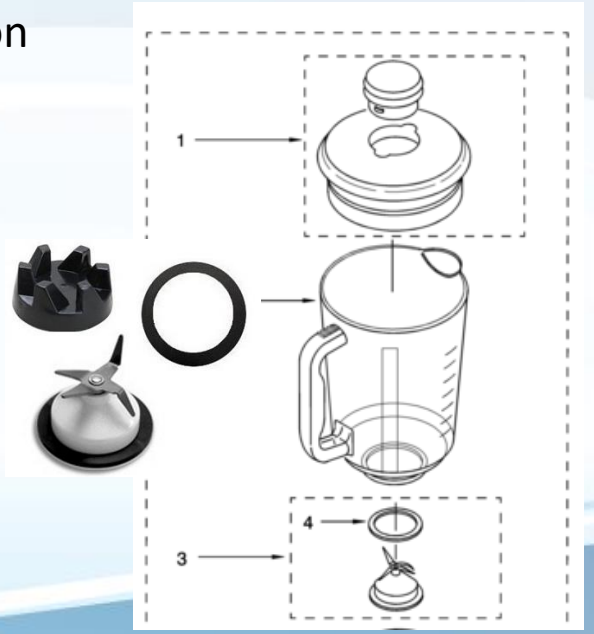
Achieve 100°C (boil) in 60 sec

Fully Charge battery in **30 min**

Requirements

The Requirements column describes the conditions or the extent to which the function must conform.

- The requirements are either provided by a document such as a product specification or duty cycle, or are converted from a process known as a **Quality Function Deployment (QFD)** or **House of Quality (HoQ)**.
- The requirement must be measurable and should have test methods defined.
  - If requirements are poorly written or nonexistent, design work may be wasted. Sometimes a recommended action (column ‘n’) will be to investigate, clarify, or create the requirements for the function.



Example:

No leaks on life cycle test - (SP-13200x)

Example: Function — Requirement Worksheet

Function – Requirement Worksheet

	Function	When	How much
1	Leak-free Steering	Operated at 90 Bar and during Idle condition	Zero amount of oil over 300 seconds
2	Quiet Steering	Accelerated to full throttling	Less than audible noise (~ 75 decibals)
3	Steering with Road feel / grip	At 100 km/h speed	Zero play

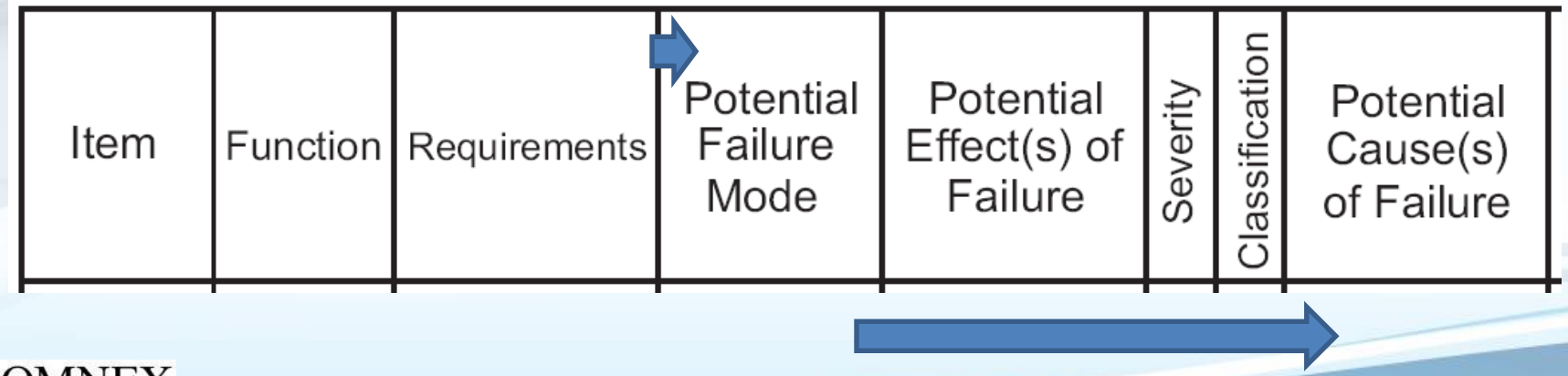
Requirements:
When = under what conditions

How Much = acceptance criteria

Thinking about Functions and Requirements

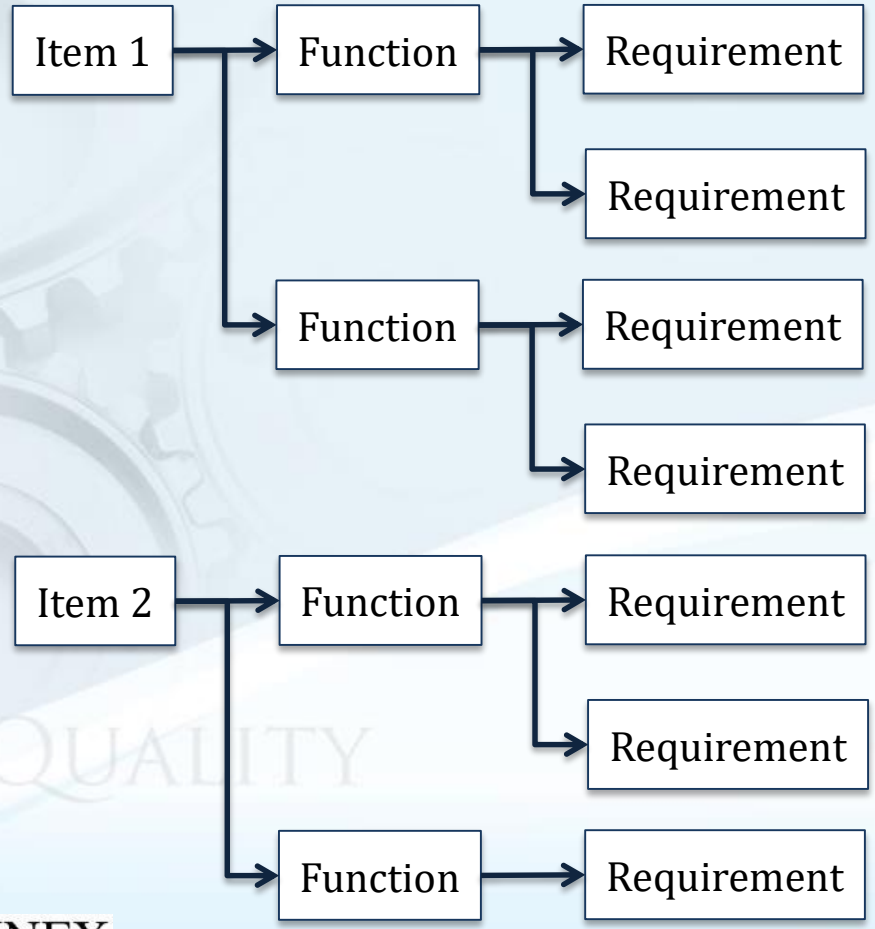
- If the function has more than one requirement with different potential modes of failure, list each of the requirements separately.

- The more precisely the desired product function(s) and requirements are identified, the easier it is to identify potential failure modes, effects, and related causes for preventive/corrective action.



Conducting a DFMEA

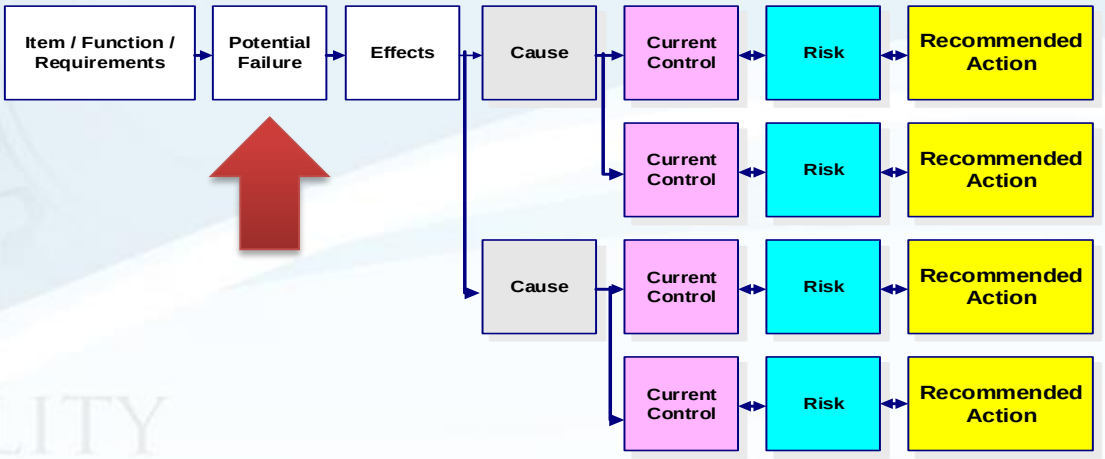
1. List all the Item Details, Functions, and Requirements



As information is added, 'branches' will evolve.

Conducting a DFMEA

1. List All the Item Details, Functions and Requirements
2. For Each Requirement
   - **Identify Potential Design Related Failure Mode(s)**



Potential *Design* Failure Mode

- Defines how the output of the design process could fail to:
  - Meet the functional requirements
  - Meet the design intent (fit, form)
  - Meet the processing intent
- General types of failure modes for the functional approach include:
  - Failure to operate or interact at the prescribed time
  - Intermittent operation or interaction
  - Premature operation or interaction
  - Failure to stop operating or interacting at the prescribed time
  - Degraded operation or interaction

Potential Failure Mode

- **For each requirement** – a description of what would be seen, heard, felt, etc. if the deliverable does not meet the identified requirement…
  - Why would the item be unacceptable?
  - How would the item not conform to the customer requirements?
  - What would the customer consider unacceptable?
  - How does the item fail to meet regulatory compliance?

Related Malfunctions

1. **No function**
2. **Partial function**
3. **Over function**
4. **Under / degraded function**
5. **Intermittent function**
6. **Unintended function**

Failure Modes are the details of the malfunction as applied to the requirement

Example

Item	Function	Requirement	Failure Mode
Disk Brake system	Stop vehicle on demand (considering environmental conditions such as wet, dry, etc.)	Stop vehicle traveling on dry asphalt pavement within specified distance of demand	vehicle does not stop
			vehicle stops in excess of yy feet
			activates with no demand; vehicle movement impeded
			Continues to activate with no demand – no movement
		Stops vehicle with less than specified force on occupants	Stops vehicle with more than xx g's of force

Failure Mode Brainstorming

- *If the prerequisites are not complete,* or as a cross-check on the team's discussions, brainstorming can be used to identify failure modes…
  - What is the product supposed to do?
  - What is the product not supposed to do?
  - What is the measure of meeting objectives?
  - How can this design fail?
  - Regardless of specification/prints, what else could be objectionable?
  - What could happen during manufacture / assembly / field use?
  - If we don't satisfy the function, what will we see happen in the product?

Focus on physical / technical terms — NOT the symptoms

Breakout Exercise 1

Starting the DFMEA Form

Item, Function, Requirements, Failure Modes

Breakout Exercise 1: Starting the DFMEA Form

Instructions

1) Using the provided example, complete the Item, Function and Requirements columns on the supplied DFMEA form.
2) Take item (a) and (b) below, and identify known or potential failure modes, creating a separate branch for each.

Function: Requirement

a. Transmit Torque & Position: **Transmit 50Ft-lbs 1 million cycles**
b. Mate to Crank: **Maximum Assembly force of XXX**

3) Remember DFM/A requirements!

HINT

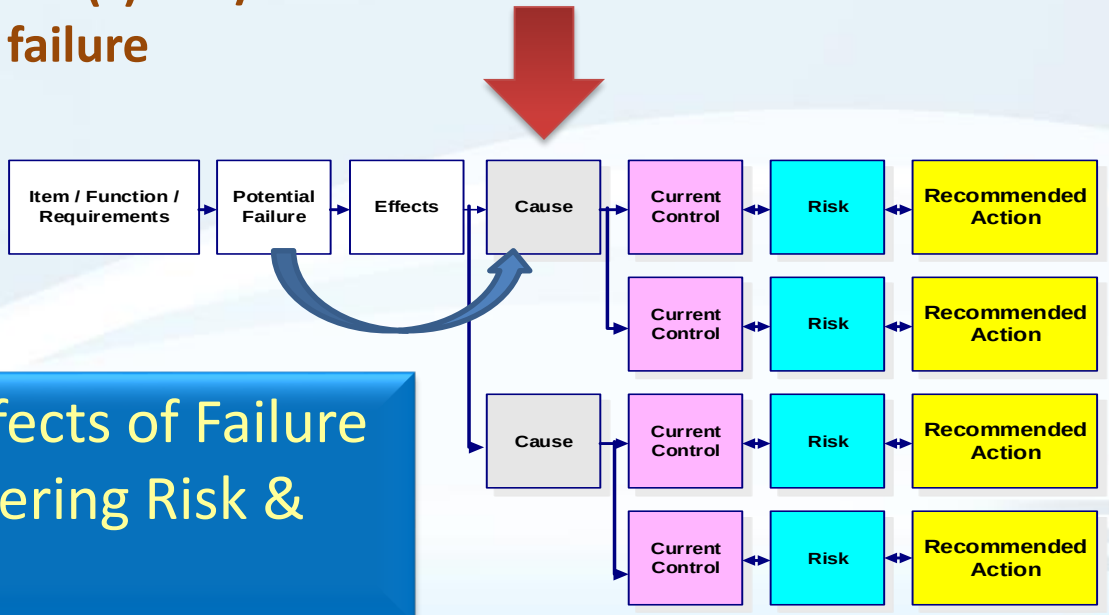
- There will only be one Item (Handle Stem). Identify the functions and requirements for the part completing the Item, Function, Requirements and potential failure modes columns.
- Do not complete any other column!!

Be prepared to share and discuss your output with the class

Breakout Exercise 1: Answer

Conducting a DFMEA

1. List All the Item Details, Functions and Requirements
2. For Each Requirement
   - Identify Potential Design Related Failure Mode(s)
3. **For Each Failure Mode**
   - **Identify the Cause(s) and/or mechanism of failure**



We will explore Effects of Failure later, when considering Risk & Criticality

Potential Causes of Failure (In Design)

- Potential cause of failure is defined as an indication of design weakness; the consequence of which is the failure mode
- Described in terms of something that can be ***corrected or controlled***
- For each failure mode, list all known causes and/or failure mechanisms
- Each cause assignable to a failure mode should be listed and considered separately

Cause vs. Mechanism of a Failure Mode

- A failure mechanism is the physical, chemical, electrical, thermal, or other process that results in the failure mode.
  - For a system, the failure mechanism is the process of error propagation following a component failure which leads to a system failure.
  - A product or process can have several failure modes which are correlated to each other because of a common failure mechanism behind them.
- Causes are the circumstances that induce or activate a failure mechanism.
- Failure mechanisms are used to determine and understand the causes of a failure mode.
- Control methods and improvement actions are focused on the causes, not failure mechanism.

Potential Causes of Design Failure

- Determined by the FMEA team using subject matter knowledge and experiences
- Potential failure causes can be determined directly or by understanding the mechanisms of failure

Incorrect Material Selected	Tolerance Stack Error
Incorrect Algorithm	Incorrect coating specified
Inadequate Travel Specification	Incorrect geometry specified
Incorrect surface finish spec.	Incorrect parameters specified
Improper Software Parameters	Missing specification
Incompatible material specified	Incorrect mating dimension

Breakout Exercise 2

Potential Design Causes

Breakout Exercise 2: Potential Causes

Instructions

Working with the DFMEA form from the previous breakout:

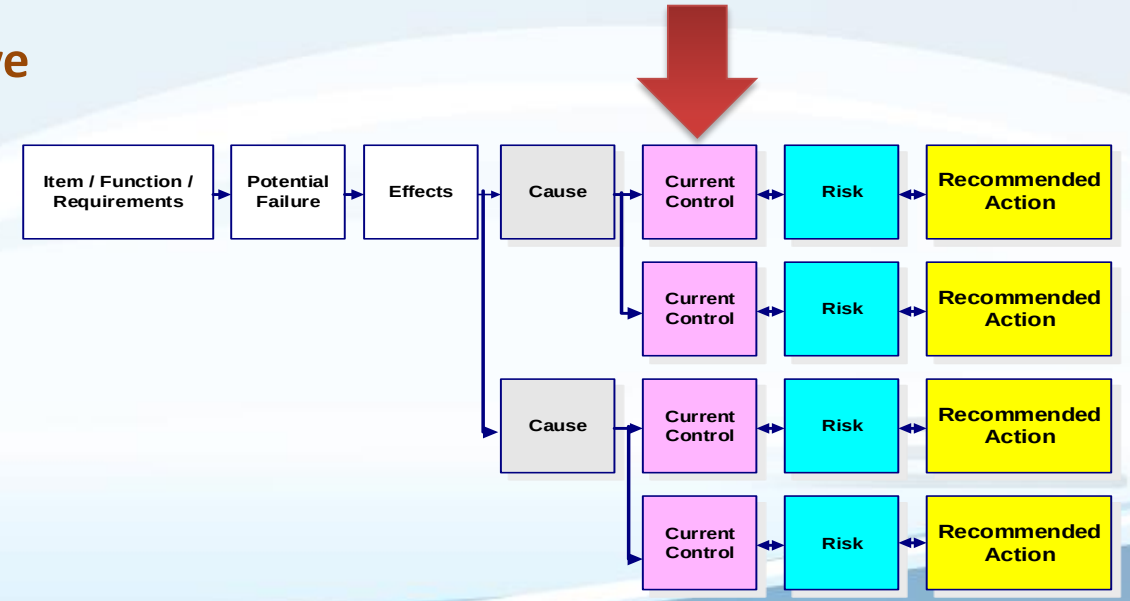
1) For the Failure Modes listed in Exercise 1, identify potential design causes of the failure mode(s); determine mechanism(s) of failure and design cause(s).
2) Since there may be more than one mechanism/cause for each failure mode, create a separate branch for each cause identified.

Be prepared to share and discuss your output with the class

Breakout Exercise 2: Answer

Conducting a DFMEA

1. List All the Item Details, Functions and Requirements
2. For Each Requirement
   - Identify Potential Design Related Failure Modes
3. For Each Failure Mode
   - Identify the Cause(s) and/or mechanism of failure
4. **For Each Cause**
   - **Identify What Preventive and Detective Controls in the Design Process are/will be in place**



Design Controls

"Current Design Controls are those activities conducted as part *of the design process* that have been completed or committed to and that will assure the design adequacy for the design functional and reliability requirements under consideration."

Source: FMEA Fourth Edition, 2008

Two Types of Design Controls:

Prevention (P):

- **Prevent the cause thus preventing the failure mode**

Detection (D):

- **Detect the cause**
- **Detect the failure mode**

Prevention Controls in Design

Prevention Controls may include analysis, testing, reviews, and other activities that will assure the design adequacy.

- Fail-safe designs/proven design solutions
- Analysis of concepts to establish design requirements
  - Studies on similar designs, phased testing from prototype through production, lessons learned and feedback loops
  - Designed Experiments to understand the variation model of the function
  - Simulation studies / virtual analysis consistent with real life
- Benchmarking studies
- Design and Material standards (internal and external)
- Documentation – records of best practices, lessons learned, etc. from similar designs

Occurrence (OCC)

Occurrence is an index linked to the likelihood that a specific cause will occur, resulting in the failure mode within the design life.

- A consistent scale must be used to ensure continuity.

- Occurrence is directly related to the sensitivity of the design to the identified (special) causes.
  - If the process capability and performance is unacceptable then this will impact the Occurrence ranking.

- The likelihood of occurrence ranking number has a relative meaning rather than an absolute value.

DFMEA Occurrence Table

Likelihood of Failure	Criteria: Occurrence of Cause – DFMEA (Design Life / Reliability of Product)	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/operating conditions	**9**
	Failure is likely with new design, new application, or change in duty cycle/operating conditions	**8**
	Failure is uncertain with new design, new application, or change in duty cycle/operating 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 design or in design simulation and testing	**4**
Low	Only isolated failures associated with almost identical design 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 control	**1**

Prevention Controls affect the Occurrence ranking

Design Controls Detection

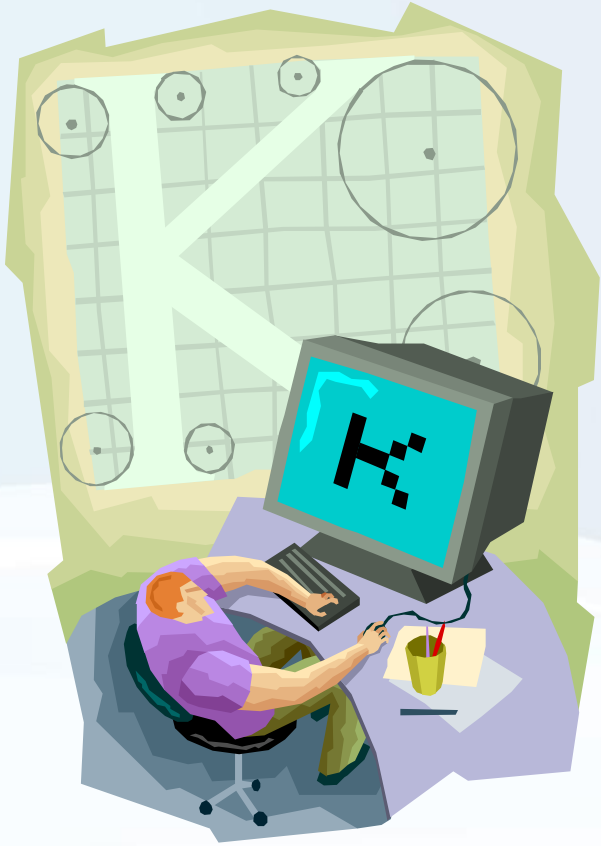
- Design Controls Detection refers to the activities conducted as a part of the design process to verify safety and performance requirements will be achieved.
  - This generally involves tests and evaluations intended to prove the design is capable as aligned to the causes and failure modes identified.

Examples of Design Controls Detection may include:

- **Verification / Validation Testing (DV or PV)**
  - **Life Testing or Test to Failure (durability testing)**
  - **Degradation Testing**
  - **Vibration Testing**
  - **Thermo-shock Testing**
  - **Qualification Testing**

Detection Controls in Design

- **Design Analysis Techniques**
  (to detect causes)
  - Analysis of the specifications to establish conformance to design requirements
    - Designed Experiments
    - Proven Modeling / Simulation / Virtual Analysis
  - Tolerance Stack-up
  - Material Compatibility
  - Design Review
  - Design Verification / Validation
  - Testing



Detection Controls are used to verify a Specification

Example

Failure Mode	Cause	Preventive	Detective
Vehicle does not stop	Mechanical linkage break due to environmental corrosion	Designed per material standard MS-845	Environmental stress test 03-9963
	Master cylinder vacuum lock due to seal design	Carry-over design with same duty cycle requirements	Pressure variability testing – system level
	Loss of hydraulic fluid due to incorrect connector torque specification	Designed per Torque requirements - 3993	Vibration step-stress test 18-1950
	Loss of hydraulic fluid due to hydraulic lines crimped / compressed; inappropriate tube material specified	Designed per material standard MS-1178	DOE – tube resiliency

The controls must relate to the cause or failure mode

Detection (DET)

Detection is the index associated with the best detection control shown in the Current Control column.

- When more than one control is identified, it is recommended that the Detection ranking of each control be included as part of the description of the control; record the value with the lowest (most effective) ranking.
  - Only detection controls are ranked and recorded.

DFMEA Detection Tables

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control		Rank	Likelihood of Detection
No detection opportunity	No current design control; Cannot detect or is not analyzed.		**10**	**Absolute Uncertainty**
Not likely to detect at any stage	Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g., CAE, FEA, etc.) is **not correlated** to expected actual operating conditions.		**9**	**Very Remote**
Post-Design Freeze and Prior to Launch	Product verification/validation after design freeze and prior to launch with **pass/fail** testing (e.g., Sub-system or system testing with acceptance criteria such as ride and handling, shipping evaluation, etc.)		**8**	**Remote**
	Product verification/validation after design freeze and prior to launch with **test to failure** testing (e.g., Sub-system or system testing until failure occurs, testing of system interactions, etc.)		**7**	**Very Low**
	Product verification/validation after design freeze and prior to launch with **degradation** testing (Sub-system or system testing after durability test, e.g., Function checks, etc.)		**6**	**Low**

DFMEA Detection Tables

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control		Rank	Likelihood of Detection
Prior to Design Freeze	Product validation (reliability testing, development or validation tests) prior to design freeze using **pass/fail** testing (e.g., acceptance criteria for performance, function checks, etc.)		**5**	**Moderate**
	Product validation (reliability testing, development or validation tests) prior to design freeze using **test to failure** (e.g., until leaks, yields, cracks, etc.)		**4**	**Moderately High**
	Product validation (reliability testing, development or validation tests) prior to design freeze using **degradation** testing(e.g., data trends, before/after values, etc.)		**3**	**High**
Virtual Analysis – *Correlated*	Design analysis/detection controls have a strong detection capability. Virtual Analysis (e.g., CAE, FEA, etc.) **is highly correlated** with actual and/or expected operating conditions prior to design freeze.		**2**	**Very High**
Detection not Applicable; Error Prevention	Failure cause or failure mode can not occur because it is fully prevented through design solutions (e.g., proven design standard/best practice or common material, etc.)		**1**	**Almost Certain**

Breakout Exercise 3

Design Controls
Prevention and Detection

OMNEX

Breakout Exercise 3: Design Controls

Instructions

Working with the DFMEA form from the previous breakout:

1) For each cause of failure identified in Exercise 3, identify current design controls, placing them, as appropriate, in the Prevention and Detection columns.
2) Note that a current design control which operates by detecting the presence of the Cause is listed in the Detection column.

Remember…

"Current Design Controls are those activities conducted as part *of the design process* that have been completed or committed to and that will assure the design adequacy for the design functional and reliability requirements under consideration."

Source: FMEA Fourth Edition, 2008

Breakout Exercise 3: Design Controls

Instructions – Ranking

Referring to the Occurrence and Detection Tables:

1) Rank each "Prevention" control and record.

   Since there is a greater or lesser likelihood of occurrence for each cause, provide a separate occurrence ranking for each.

2) Rank each "Detection" control and record.

   Select the ranking for the most effective (lowest number) control.

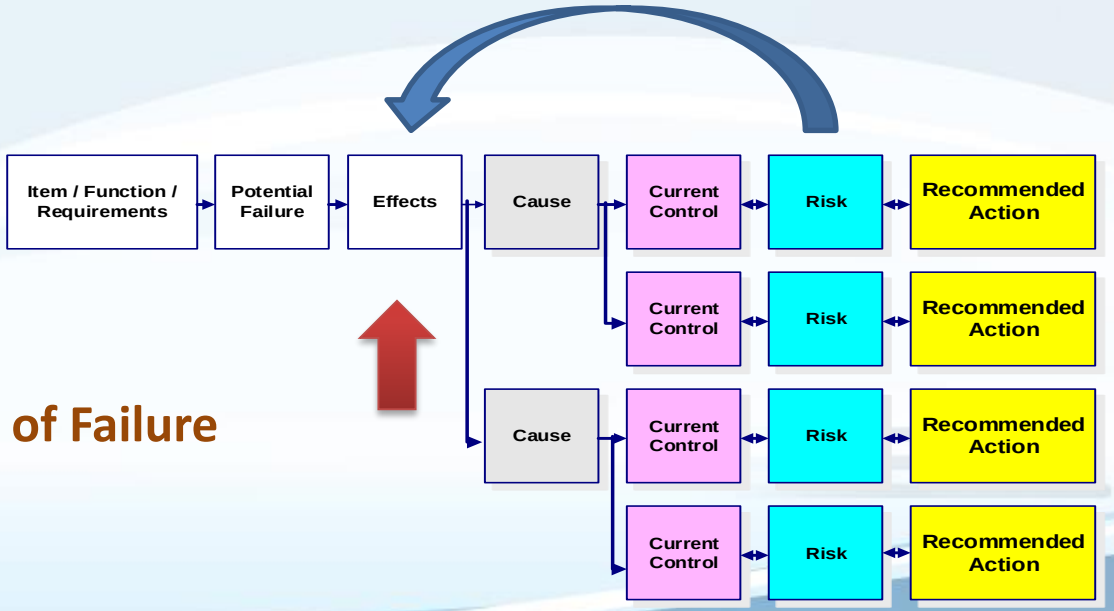
   Note: the same controls may operate for different causes, and are repeated.

Be prepared to share and discuss your output with the class

Breakout Exercise 3: Answer

Conducting a DFMEA

1. List All the Item Details, Functions and Requirements
2. For Each Requirement
   - Identify Potential Design Related Failure Modes
3. For Each Failure Mode
   - Identify the Cause(s) and/or mechanism of failure
4. For Each Cause
   - Identify What Preventive and Detective Controls in the Design Process are/will be in place
5. **For Each Failure Mode**
   - **Assess Potential Effects of Failure**



Potential Effect(s) of Failure

The Potential Effects of a Failure on any of multiple possible customers are listed in this column. Many effects could be possible for any one failure mode.

- All effects should appear in the same cell or grouped next to the corresponding failure mode.

Describe the effects of the failure in terms of what the customer might notice or experience, remembering that the customer may be an internal customer as well as the ultimate end user.

Source: FMEA Fourth Edition, 2008

Examples:

Fluid gets on countertop

Fluid enters motor housing shorting motor

Ask: So what?

Example Effects – Effective Descriptions

- Fisheyes on class A surface
- Uneven color / streaking
- Vision impaired due to oil spray; hazard
- Cannot be fastened to mating part
- Loss of steering control due to drop in hydraulic pressure
- Loss of Power – hazard
- Fading brakes – potential hazard
- Will not lock
- Intermittent operation – potential hazard
- Noise (metal to metal) > 75 db
- Erratic operation cause loss of control (hazard)
- Unstable shelf life; loss of adhesion
- Misalignment due to rough mating surface
- Unpleasant odor
- Thermal event
- Regulatory nonconformance to ISI 686-7
- Electromagnetic Capability (EMC) sporadic due to Radio Frequency Interference (RFI)

Severity (SEV)

The Severity of each effect is selected based on the **most serious** effect to the customer. The severity ranking is between 1 and 10.

The highest severity is chosen from the many potential effects and recorded in the Severity column.

- If a recommended design action is identified to reduce the severity, it is placed in the Recommended Actions column of the DFMEA.
- If a design improvement is shown to reduce the severity, the new severity is recorded in the Severity column after the recommended action is implemented.

DFMEA Severity Table

Effect	Criteria: Severity of Effect	Rank
Hazardous Without Warning	Potential failure mode affects product operation and/or involves noncompliance with government regulation without warning	**10**
Hazardous With Warning	Potential failure mode affects product operation and/or involves noncompliance with government regulation with warning	**9**
Very High	product inoperable (loss of primary function)	**8**
High	product operable but at a reduced level of performance. Customer very dissatisfied	**7**
Moderate	product operable but comfort/convenience feature(s) inoperable. Customer dissatisfied	**6**
Low	product operable but comfort/convenience feature(s) operable at a reduced level of performance. Customer somewhat dissatisfied	**5**
Very Low	Component does not conform to fit and finish/squeak and rattle requirements. Defect noticed by most customers (greater than 75%)	**4**
Minor	Component does not conform to fit and finish/squeak and rattle requirements. Defect noticed by 50% of customers	**3**
Very Minor	Component does not conform to fit and finish/squeak and rattle requirements. Defect noticed by discriminating customers (less than 25%)	**2**
No	No discernible effect	**1**

Characteristics Classification

DFMEAs deal with functions and requirements not characteristics

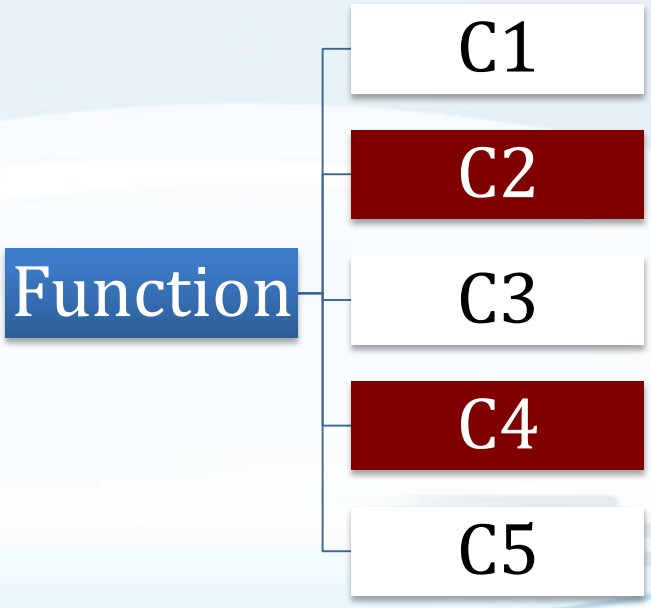
- The **Classification** column may be used to highlight high-priority features/requirements or failure modes and their associated causes.
- As a result of this analysis, the team may use this information to identify special characteristics ***in the design record***.
- A characteristic designated in the design record as special without an associated design failure mode identified in the DFMEA is an indication of a weakness in the design process.

Classification: Linkages Between Design & Process

Special Requirements (Form, Fit, Function, Finish, Safety)

For **Special Requirements**, identify **Special Product Characteristics** in design record or via the PFMEA.

Process Owners designate key process parameters that can have a significant impact on Key Characteristics called out in the design record



Key Requirements

Identification of Key Requirements

Criteria	
Severity = 9 or 10	Safety Related
Severity = 5 to 8 and Occurrence = 4 to 10	Candidate

Note: Use customer specific symbols/designations as required

Breakout Exercise 4

Potential Effect & Severity Classification (Class) — Special Characteristics

Breakout Exercise 4: Potential Effects and Severity Classification

Instructions

Working with the DFMEA form from the previous breakout:

1) For each cause of failure, identify Potential Effects of Failure, Severity (ranking), and any Classifications (Special Characteristics) completing through Sev column on the supplied DFMEA form.

Be prepared to share and discuss your output with the class

Breakout Exercise 4: Answer

Risk and Criticality: RPN

The Risk Priority Number (RPN) is the product of the three previously selected rankings:

RPN = Severity x Occurrence x Detection

- The DFMEA RPN is a relative risk ranking used to identify weaknesses in the design process and prioritize which design controls and severity items need improvement actions.

Cautions

"The use of an RPN threshold is NOT an acceptable practice for determining the need for recommended actions."

Source: FMEA Fourth Edition, 2008

- There is no RPN value that requires mandatory action.
- Applying thresholds assumes that RPNs are an accurate measure of relative risk (which they often are not) and that continuous improvement is not required (which it is).

RPN Assessment Weighting

S	O	D	RPN
7	2	5	70
2	7	5	70
5	7	2	70
7	5	2	70
2	5	7	70

S	O	D	RPN
10	2	2	40
3	10	4	120
2	5	10	100

Alternatives / Additions

- SO (S x O)
- Concatenation
  - SOD
  - SO
  - SD

S	O	D	RPN	SxO	SOD	SO	SD
7	7	3	147	49	70703	707	703
7	3	7	147	21	70307	703	707
3	7	7	147	21	30707	307	307

Equal RPN Values

Very Different Scenarios

Recommended Actions

The Recommended Actions column is used to record potential improvement activities within the Design FMEA document.

- The purpose of the DFMEA is to identify potential failure risks.
- Once identified, risk issues must be addressed as appropriate.
- Actions must be detailed to the point that they make sense when stood alone in a risk register or actions list.
- As the document is updated to reflect activity in the **Recommended Actions** columns, consider changes that will:
  - Eliminate the cause of the failure mode
  - Eliminate the failure mode
  - Mitigate the effect
  - Change the design related to the product characteristic (geometry, material, etc.)
  - Change the effect of failure mode on the product performance

Recommended Actions (Improvement)

Intent of any recommended action is to reduce any or all of the occurrence, severity, and/or detection rankings.

To Reduce:	Consider This Action:	To Accomplish this:
Severity	Change the design	Eliminate or reduce the severity of the failure mode
Occurrence	Change the design or improve engineering specification	Prevent the cause or failure and its effect from occurring
Detection	Change the design or improve engineering specification	Detect that the cause has occurred and take corrective action Detect that the failure mode has occurred and correct

If no actions are recommended, indicate "*None at this time*"

Recommended Actions

Recommended Actions	Responsibility and Target completion Date	Actions Taken	SEV	OCC	DET	RPN
NONE at this time	-	-	-	-	-	-
Implemented Corrosion Test SEC 3-A-1 48 Hours	P. Cauffin 2/22/06	Conducted test with no failures.	6	3	2	36
Open Plating Surface Tolerances and harden surfaces	P. Cauffin 9/4/2005	Prototype complete and retested 9/4/2005	6	2	2	24

Class Discussion

- As a group, identify and list some potential improvement actions based on your analysis and resulting risk assessment:

Considerations / Key Learnings

- Only **current** controls are included in the DFMEA Control columns.
  - Recommended Actions are where additional/new controls are brainstormed.
- Prevention controls in design only affect the ***occurrence*** of cause of design failure. Prevention controls should lead to the correct design specification.
- Test validation is **NOT** a “discovery process”. Validation is intended to prove that the design is correct (functional requirements are met).

A-1 DESIGN FMEA CHECKLIST

Customer or Internal Part No _____ Revision Level _____

	Question	Yes	No	N/A	Comment / Action Required	Person Responsible	Due Date
1	Was the DFMEA prepared using the *Chrysler, Ford, and General Motors Potential Failure Mode and Effects Analysis (FMEA)* reference manual, and applicable customer specific requirements?						
2	Have historical campaign and warranty data been reviewed?						
3	Have best practices and lessons learned from similar part DFMEAs been considered?						
4	Does the DFMEA identify Special Characteristics?						
5	Have pass-through characteristics (glossary) been identified and reviewed with affected suppliers for FMEA alignment and appropriate controls in the supply base?						
6	Have special characteristics designated by the customer or organization been reviewed with affected suppliers to assure FMEA alignment?						
7	Have design characteristics that affect high risk priority failure modes been identified?						
8	Have appropriate corrective actions been assigned to high risk priority numbers?						
9	Have appropriate corrective actions been assigned to high severity numbers?						
10	Have risk priorities been revised when corrective actions have been completed and verified?						

SR Checklist

Revision Date: _____

Source: APQP Reference Manual 2nd Edition © 2008

Prepared By: _____

Maintaining DFMEAs

The DFMEA is a living document and should be reviewed whenever there is a design related failure, a design change, or a change in use/application, and updated as necessary.

- DFMEAs should include a periodic review of the rankings
  - When improvements have been made either through product changes or improvements in design controls
  - Where field issues occur, the SOD rankings should be revised accordingly

Continually enhance Organizational Knowledge

Chapter 4: Developing the DFMEA — What We Covered

Learning Objectives

You should now be able to:

- Conduct an effective DFMEA, identifying:
  - Functions and Requirements
  - Design Failure Modes
  - Effects of Failure
  - Design Causes
  - Preventive and Detective Controls
- Quantify and Evaluate Relative Risk
- Develop an Action Plan

Chapter Agenda

- Starting the DFMEA Form: Item, Function, Requirements, Failure Modes:
  - **Breakout Exercise 1**
- Potential Design Causes
  - **Breakout Exercise 2**
- Potential Controls & Prevention
  - **Breakout Exercise 3**
- Potential Effect & Severity
  - **Breakout Exercise 4**
- Action Planning
- Evaluating and Maintaining DFMEAs

Chapter 5: DVP&R

Design Verification Plan and Report

Chapter 5: DVP&R — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Itemize all tests necessary to assure design criteria and targets can and will be met
- Document test results and progress made toward design targets
- Ensure verification of the design so that the program and Project Team can move forward

Chapter Agenda

- Objectives of DVP&R
- DVP Format & Flow
- DVP&R Format
- Management Responsibility for DVP
- Challenges to Development

Design Verification Plan

Objectives

- Itemizes all tests necessary to assure criteria and targets can and will be met
  - Specifies test responsibilities, quantities and timing requirements
- Provides test results and progress made toward design targets
- Allows the program/project to move forward

Uses

- Product development tool to layout plan to meet all requirements and present results
- Product assurance tool and working document to aid engineering personnel
- Test Schedule

Design Verification Plan

Test Plan

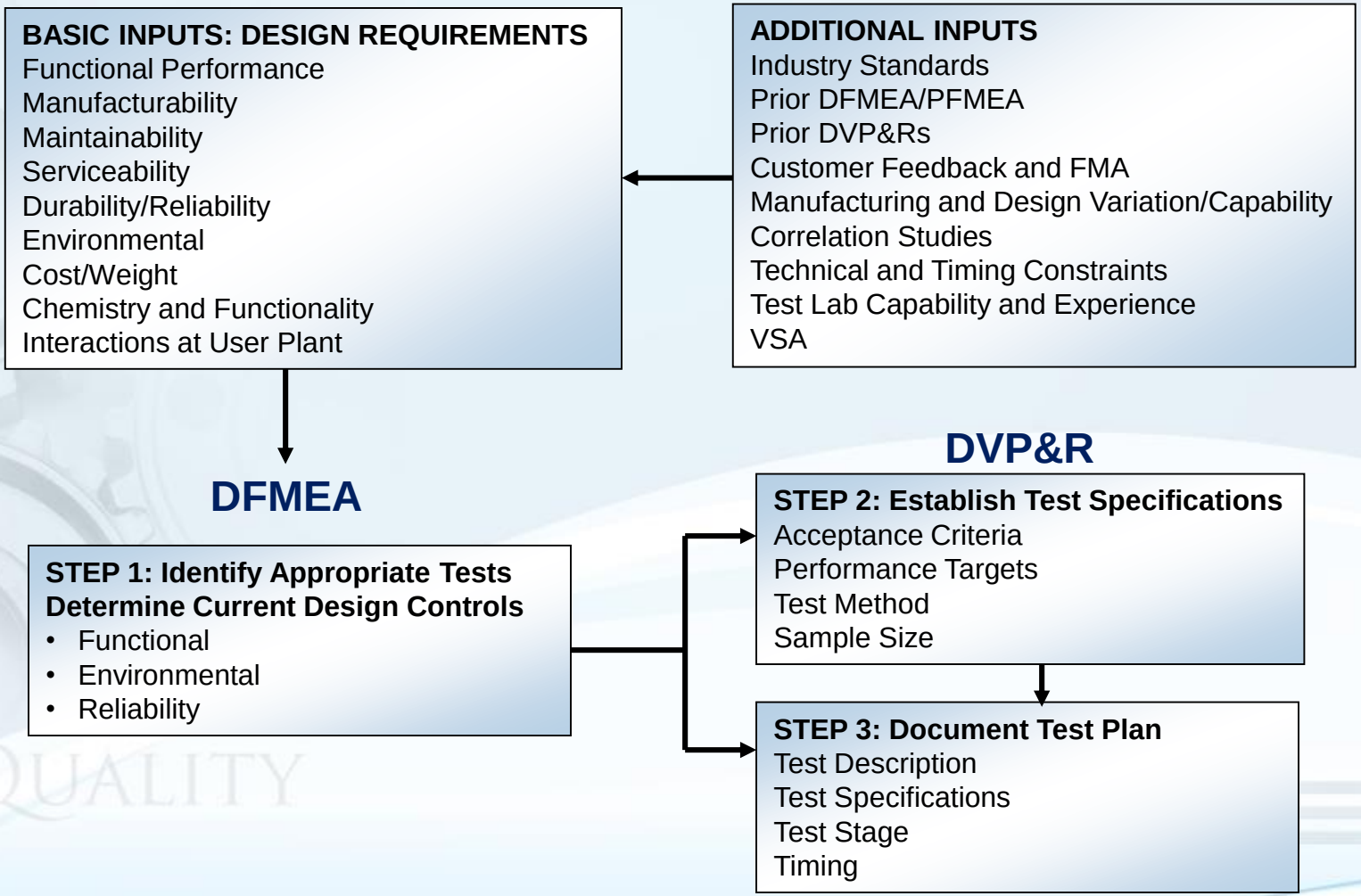
- Test plan documents test activities during each phase of product development

Test Plan Development

- Developed early in design phase of all new products
- **Incorporates Detection Controls from the DFMEA**
- Revised based on significant changes in environment, design, government regulations, or customer requirements

DVP without input from DFMEA can fail to detect significant design risks

Test Plan Flow Format



Sample Test Plan (DVP)

TEST PLAN

Item No.	Procedure or Standard	Test Description	Acceptance Criteria	Target Requirements	Test Responsibility	Test Stage	Sample		Timing	
							Qty	Type	Start	Comp.
1		Inherent Reliability Prediction	1000 Hours	R 95	ABC	DV			8/30/xx	9/30/xx
2	PF 99	Opening Effort	Max & Min Range Sec 4-8-2	No Failures Cp > 1.33 & No Failures Cpk > 1.33	ABC ABC ABC ABC	DV PV CC	5 30	B D E	8/30/xx 10/19/xx 1/30/xx	9/2/xx 10/22/xx
				ures ures	ABC ABC	DV PV	5 5	B D	8/30/xx 10/18/xx	9/2/xx 10/22/xx
				0 0	ABC	DV	6	B	8/28/xx 10/19/xx	9/5/xx 10/22/xx
5	PF 99	PG Test	30 K VE Sec 5-A-3	Four Consecutive Successes						

TEST STAGE CODES

ED	Engineering Development
DV	Design Verification
PV	Production Validation
CC	Continuing Conformance

SAMPLE TYPE CODES

A	Prototype (Handmade)
B	Prototype (Tooled)
C	Program Level
D	Initial Production
E	Full Volume Production

Sample Test Report (&R)

TEST REPORT				Notes
Samples Tested			Actual	
Qty	Type	Phase		
			R96	MIL - HDBK - 217 Prediction Test Report # 24375
5 30	B D	I I	No Fail No Fail Cp = 1.8	Test Report # 98476 Test Report # 4876
5 5	B D	I I	No Failures No Failures	Test Report # 9487
6 6	B D	I I	R93 C90 R93 C90	6 Tests to Failure (Weibull Analysis) 6 Tests to Failure (Weibull Analysis)
8	D	I	No Failures	Test Report # 02943

DVP&R Summary & Considerations

Metrics

- Number (%) DV planned actions versus completed
- Number of test results that do not meet requirements

Skills and Tools

- Trained team members in all of design verification analytical techniques such as reliability tests, DFMEA, design of experiments
- Team members with understanding of DFMEA/DVP linkage
- Use of software to create, link and track documentation

Chapter 5: DVP&R — What We Covered

Learning Objectives

At the end of this chapter, you will be able to:

- Itemize all tests necessary to assure design criteria and targets can and will be met
- Document test results and progress made toward design targets
- Ensure verification of the design so that the program and Project Team can move forward

Chapter Agenda

- Objectives of DVP&R
- DVP Format & Flow
- DVP&R Format
- Management Responsibility for DVP
- Challenges to Development

Thank You!

Questions?

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Appendix

FMEA Tables

DFMEA Severity Classification

Effect	Criteria: Severity of Effect	Rank
Hazardous Without Warning	Potential failure mode affects product operation and/or involves noncompliance with government regulation without warning	**10**
Hazardous With Warning	Potential failure mode affects product operation and/or involves noncompliance with government regulation with warning	**9**
Very High	product inoperable (loss of primary function)	**8**
High	product operable but at a reduced level of performance. Customer very dissatisfied	**7**
Moderate	product operable but comfort/convenience feature(s) inoperable. Customer dissatisfied	**6**
Low	product operable but comfort/convenience feature(s) operable at a reduced level of performance. Customer somewhat dissatisfied	**5**
Very Low	Component does not conform to fit and finish/squeak and rattle requirements. Defect noticed by most customers (greater than 75%)	**4**
Minor	Component does not conform to fit and finish/squeak and rattle requirements. Defect noticed by 50% of customers	**3**
Very Minor	Component does not conform to fit and finish/squeak and rattle requirements. Defect noticed by discriminating customers (less than 25%)	**2**
No	No discernible effect	**1**

RPN = severity X occurrence X detection

DFMEA Occurrence Table

Likelihood of Failure	Criteria: Occurrence of Cause – DFMEA (Design Life / Reliability of Product)	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/operating conditions	**9**
	Failure is likely with new design, new application, or change in duty cycle/operating conditions	**8**
	Failure is uncertain with new design, new application, or change in duty cycle/operating 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 design or in design simulation and testing	**4**
Low	Only isolated failures associated with almost identical design 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 control	**1**

DFMEA Detection Table

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control		Rank	Likelihood of Detection
No detection opportunity	No current design control; Cannot detect or is not analyzed.		**10**	**Absolute Uncertainty**
Not likely to detect at any stage	Design analysis/detection controls have a weak detection capability; Virtual Analysis (e.g., CAE, FEA, etc.) is **not correlated** to expected actual operating conditions.		**9**	**Very Remote**
Post-Design Freeze and Prior to Launch	Product verification/validation after design freeze and prior to launch with **pass/fail** testing (e.g., Sub-system or system testing with acceptance criteria such as ride and handling, shipping evaluation, etc.)		**8**	**Remote**
	Product verification/validation after design freeze and prior to launch with **test to failure** testing (e.g., Sub-system or system testing until failure occurs, testing of system interactions, etc.)		**7**	**Very Low**
	Product verification/validation after design freeze and prior to launch with **degradation** testing (Sub-system or system testing after durability test, e.g., Function checks, etc.)		**6**	**Low**

DFMEA Detection Table

Opportunity for Detection	Criteria: Likelihood of Detection by Design Control		Rank	Likelihood of Detection
Prior to Design Freeze	Product validation (reliability testing, development or validation tests) prior to design freeze using **pass/fail** testing (e.g., acceptance criteria for performance, function checks, etc.)		**5**	**Moderate**
	Product validation (reliability testing, development or validation tests) prior to design freeze using **test to failure** (e.g., until leaks, yields, cracks, etc.)		**4**	**Moderately High**
	Product validation (reliability testing, development or validation tests) prior to design freeze using **degradation** testing(e.g., data trends, before/after values, etc.)		**3**	**High**
Virtual Analysis – *Correlated*	Design analysis/detection controls have a strong detection capability. Virtual Analysis (e.g., CAE, FEA, etc.) **is highly correlated** with actual and/or expected operating conditions prior to design freeze.		**2**	**Very High**
Detection not Applicable; Error Prevention	Failure cause or failure mode can not occur because it is fully prevented through design solutions (e.g., proven design standard/best practice or common material, etc.)		**1**	**Almost Certain**