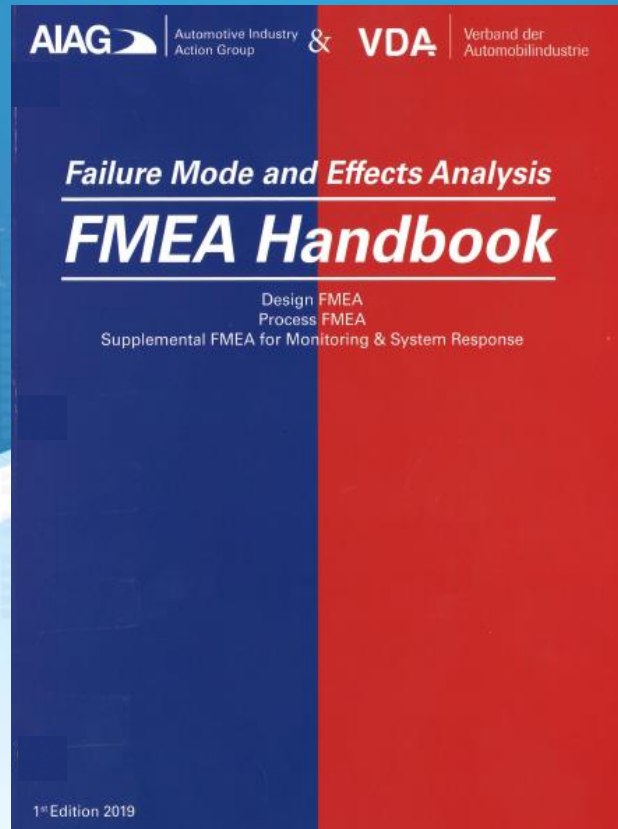


# Introduction to AIAG VDA FMEA Handbook (An Executive Overview)



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# Course Objectives

- Provide an overview on need for FMEA and its integration in the company.
- Provide an understanding of the 7 Step approach in the New AIAG VDA FMEA 1<sup>st</sup> Edition.
- Provide an overview on the role of Senior Management in the Development and maintenance of FMEA.
- Emphasize on the collaboration of Customer (OEM), Tier N, and Supplier in Developing a FMEA.
- Provide a summary on changes and its rationale.

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# Agenda

1. Introduction to Failure Modes and Effects Analysis (FMEA)
  - a. What is FMEA
  - b. Types of FMEA
  - c. System FMEA Vs. Design FMEAs
2. Changes Summary
  - a. General Changes
  - b. 7 Step Changes with Rationale (using DFMEA)
  - c. Summary
  - d. References
3. How to Develop / Implement AIAG VDA FMEA
  - a. The FMEA Team
  - b. Conducting an FMEA
  - c. Basic Structure of an FMEA
4. Transition Strategy to AIAG VDA FMEA
5. Omnex Workshops on AIAG VDA FMEA

# A BRIEF INTRODUCTION TO OMNEX

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# 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. OHSAS 18001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
  - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.





# About Omnex

- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 400 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for IATF16949.
- Served on committees that wrote QOS, ISO 9001:2000, QS-9000 and it's Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).





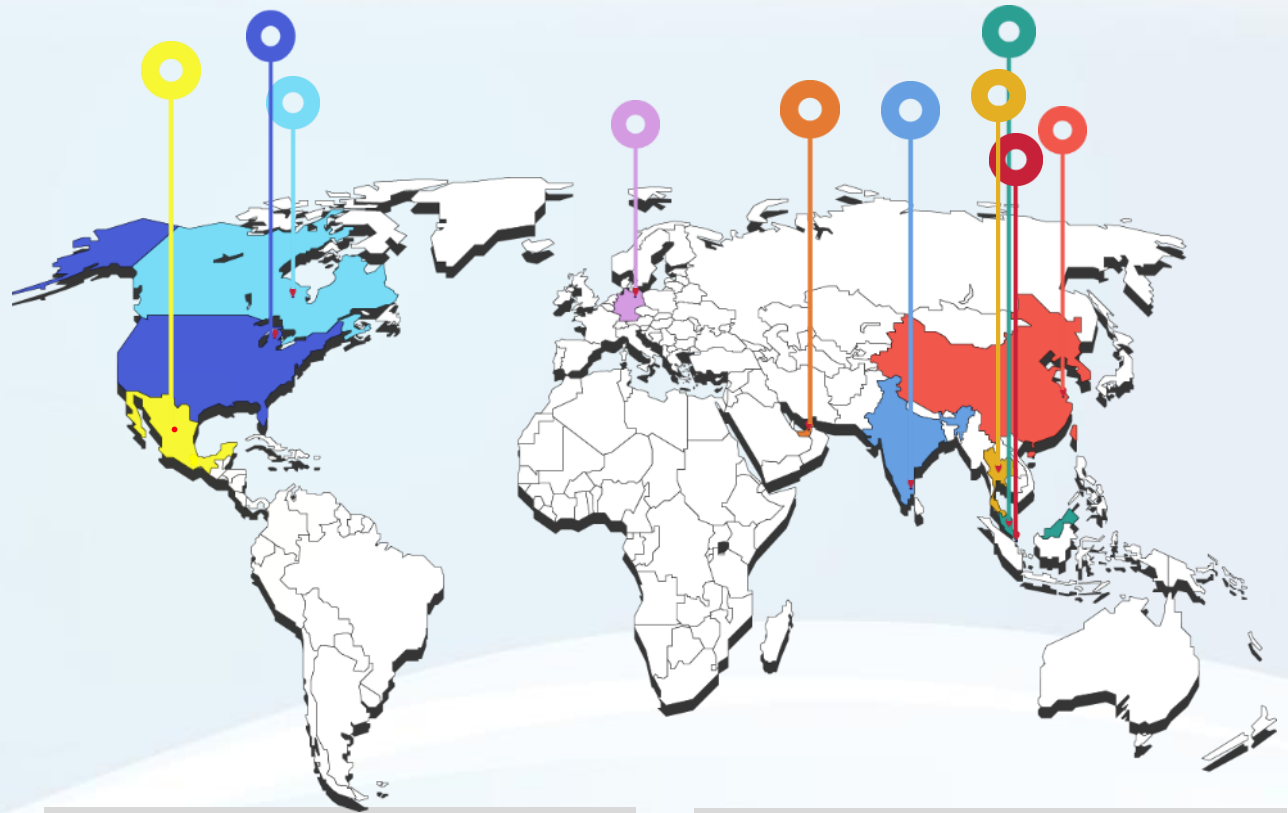
# Omnex Worldwide Offices



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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● Thailand (Bangkok)

● Mexico (Monterrey)

● Singapore

● Malaysia (Kuala Lumpur)



# Chapter 1

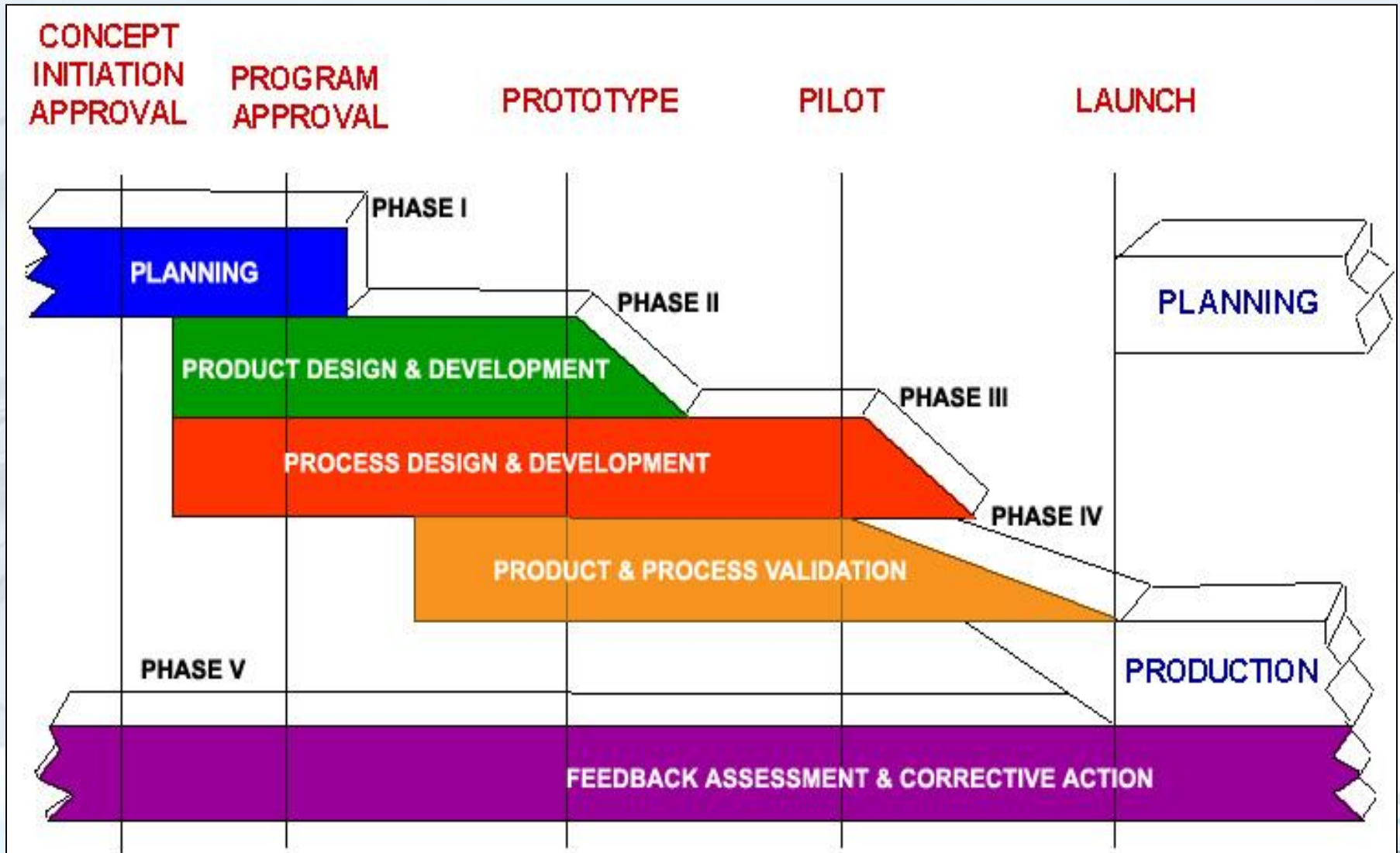
## Introduction to Failure Mode Effects Analysis (FMEA)

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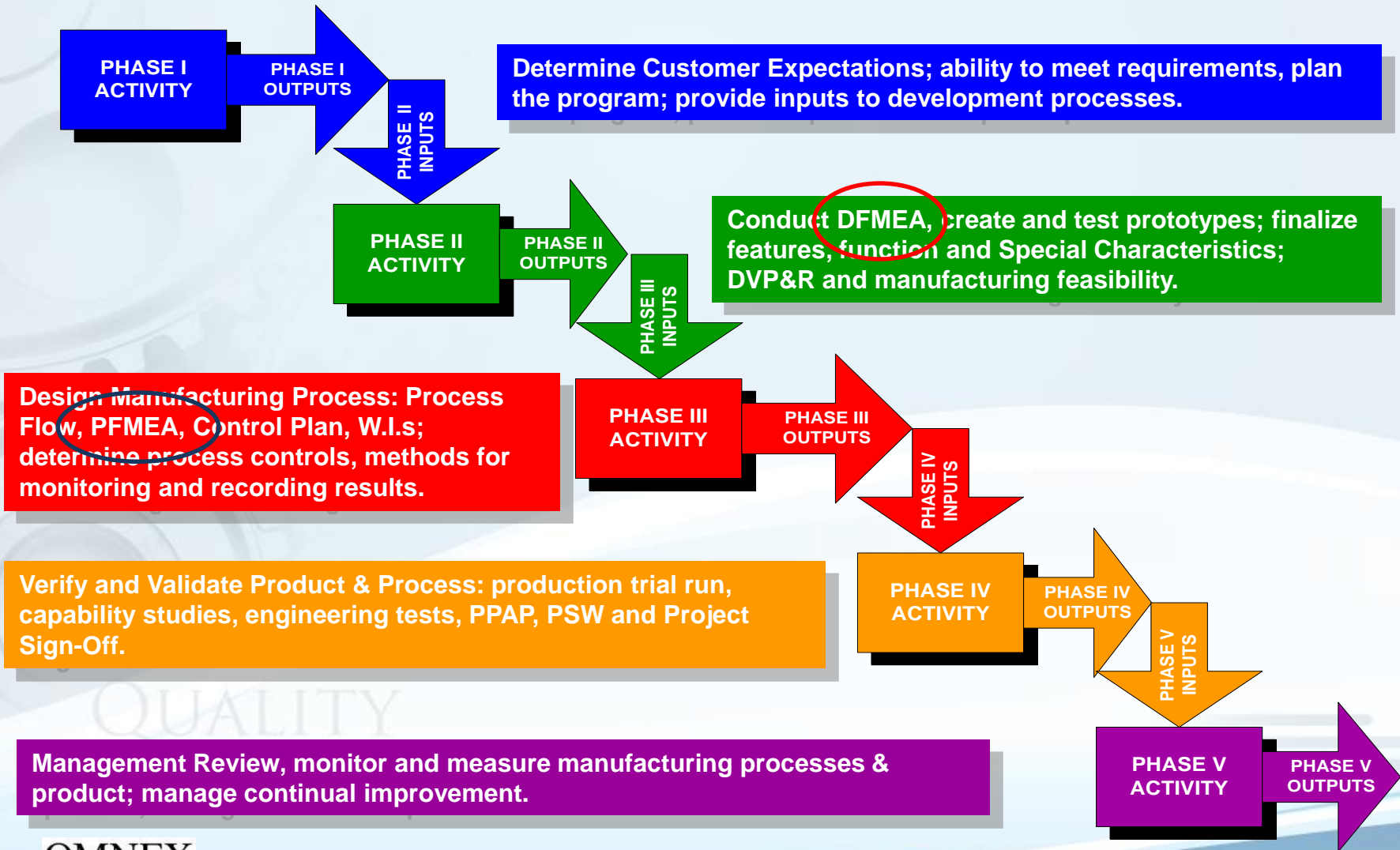
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# Alignment of APQP Processes



# FMEA is one of the APQP deliverables



# Also, FMEAs are PPAP requirements

## Product Definition

- 1 Design Record
- 2 Engineering Change Documents
- 3 Customer Engineering Approval

## PPAP Core Elements

- 4 **DFMEA**
- 5 Process Flow
- 6 **PFMEA**
- 7 Process Control Plan (Prototype)
- 8 Measurement Systems Analysis
- 9 Dimensional Results
- 10 Material Performance Tests

## PPAP Core Elements

- 11 Initial Process Studies
- 12 Qualified Laboratory Documentation
- 13 Appearance Approval Report
- 14 Sample Production Parts
- 15 Master Sample
- 16 Checking Aids
- 17 Customer Specific Requirements
- 18 Part Submission Warrant

## PPAP Approval

- 19 PPAP Review and Sign-Off

# WHAT IS FMEA?

Purpose and Benefits





# FMEA: Process Definition

- The FMEA process is a disciplined analytical process that allows the design team to anticipate potential failures and prevent their occurrence early in product design, and manufacturing process development.
- The FMEA is integrated into the work of the design and development teams (departments) and aimed at system optimization and risk mitigation.

**Risk Assessment and  
Knowledge Management**



# Why Perform FMEA?

- Prevention is the only effective way to achieve zero defect launch goals.
- S/D/P FMEA are used extensively in the automotive industry to effectively reduce defect levels:
  - Many automotive manufacturers are at <20 ppm.
  - Automotive industry average is 0.23% defects.
  - Aerospace industry average is 2% defects.
- FMEA enables building an engineering knowledge base providing shorter lead times and fewer delays.
- FMEAs are integral in Problem Solving

**We Need a Paradigm Shift from Detection to Prevention**

# Purposes and Benefits of FMEA

- The FMEA process is a structured approach to...
  - Improve the quality, reliability, and safety of products, processes, and services.
  - Increase customer satisfaction.
  - Reduce development timing and cost.
  - Document and track actions taken to reduce risk.

## *Concept*

Identify ways the product or process can fail

Then plan to prevent those failures

# Risk Reduction & FMEA

- FMEA distinguishes between System, Subsystem, and Component design risk.
- Prevention is built into the FMEA format for S/DFMEA and PFMEA.
- FMEA links with controls and strives for better and earlier controls in design; e.g., DFMEA with DVP&R and PFMEA with Control Plans.
- Links PFMEA with Control Plans to shop floor controls.
- FMEA focus is on improvement actions to reduce risk.

# TYPES OF FMEA

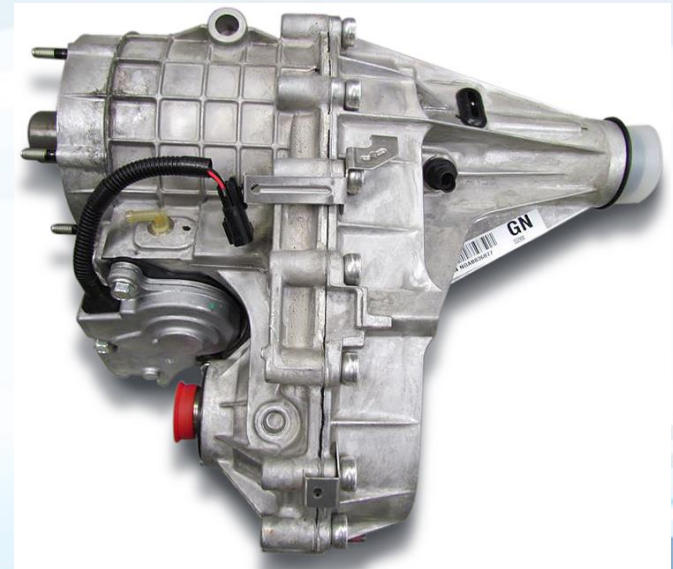
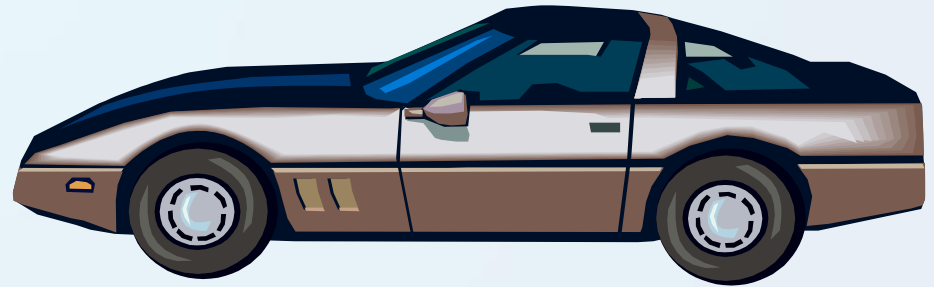
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# Primary Types of FMEAs

- **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. O.m.n.ex
- **Design 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.
  - Note: VDA uses the terms Product FMEA versus Design FMEA
- **Process FMEA:** Used to analyze processes before they are released for use in serial production..
  - Focuses on potential failure modes associated with the deliverables of a process due to design and operation.

# SFMEA vs. DFMEA

- A system is a complete “product”; e.g.,
  - At the top level system = Automobile
  - At the WP (work product) level system = “System” or Structure

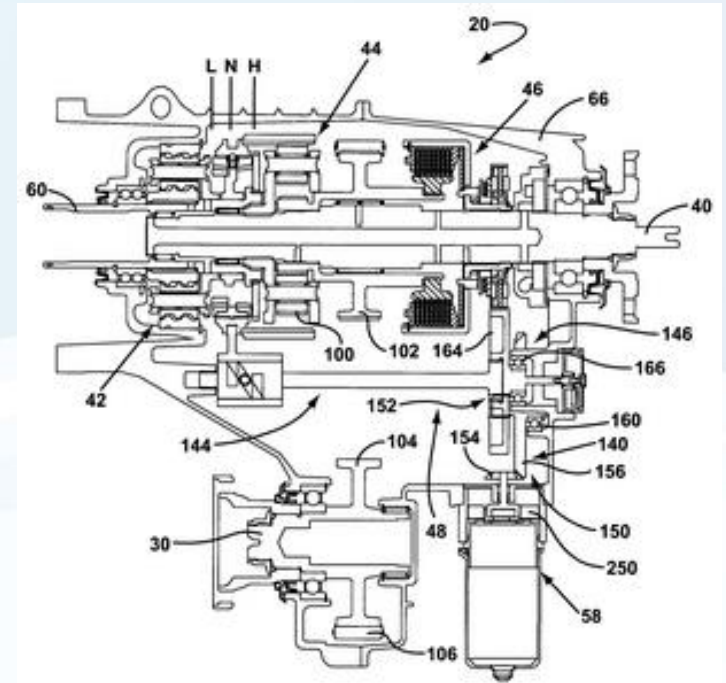
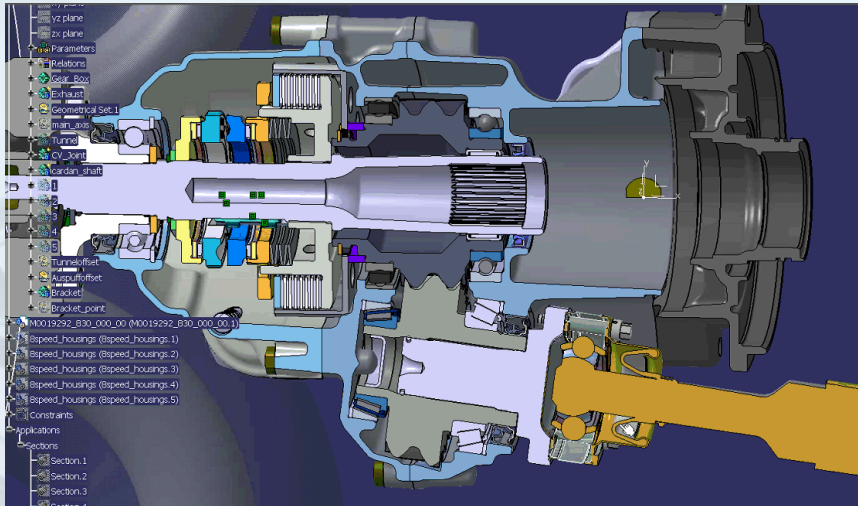


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# SFMEA vs. DFMEA

An SFMEA includes the analysis of the interfaces **among** the related subsystems / components.



A DFMEA focuses on the analysis of the requirements and interfaces **within** a subsystem / component.



# SFMEA vs. DFMEA

- The process for a System FMEA is generally the same as the development of other FMEAs.
- **Major differences:**
  - The System level FMEA focuses on functions and relationships that are unique to the system as a whole (i.e., do not exist at lower levels).
  - The System level FMEA includes failure modes associated with ***interfaces and interactions*** in addition to considering single point failures which is the primary focus of product level FMEAs.
  - The DFMEA is at the item/feature level and is an effective design input tool; design output should have characteristics that address all the critical items or features

# Classification of System, Subsystem and Component

- A **System DFMEA** is comprised of various subsystems and components which are represented as system elements (items).
- **System and subsystem** analyses are dependent on the viewpoint or responsibility. Systems provide functions at the vehicle level. These functions cascade through subsystems and components.
- For purpose of analysis, a sub-system is considered the same way as a system. Interfaces and interactions among systems, subsystems, the environment and the customers (e.g. Tier N, OEM, and end user) may be analyzed in System FMEAs.
- Within a system there may be software, electronic, and mechanical elements. Examples of systems include: Vehicle, Transmission System, Steering System, Brake System or Electronic Stability Control System, etc.
- A **component DFMEA** is a subset of a system or subsystem DFMEA. For example, an Electrical Motor is a component of the Window Lifter, which is a subsystem of Window Lifter System. A Housing for the Electrical Motor may also be a component or part. For this reason, the terms "system element" or "item" are used regardless of the level of analysis.

System Level

Item:  
Jet engine

Function:  
provide propulsion  
on demand

Requirements:  
Fuel combustion on  
demand xxxx

Failure Mode  
Combustion without  
demand

Cause:  
Design allows  
internal leak  
(pooling of fuel  
outside  
chamber)

Effect:  
Uncontained  
Failure

Sub-System Level

Item:  
Fuel Transfer  
Ass'y

Function:  
transfer fuel to  
combustion  
chamber on  
demand

Requirements:  
XXXXXXXXXX

Failure Mode  
Fuel transfer  
external to  
chamber

Cause:  
Ass'y design  
allows integrity  
failure due to  
function or  
manufacturing

Effect:  
Internal leak

Component

Item:  
Fuel Tubing

Function:  
Contain fuel from  
storage to chamber

Requirements:  
XXXXXXXXXX

Failure Mode  
Leakage external  
to chamber

Cause:  
tube design  
allows integrity  
failure due to  
function or  
manufacturing

Effect:  
integrity failure  
of tube ass'y

Component Mfg

Step xx

Function:  
Form Tubing

Requirements:  
XXXXXXXXXX

Failure Mode  
Out of Spec:  
Geometry or wall  
thickness

Cause:  
\* Fixture setup;  
\* incoming material  
\* Excess forming  
pressure applied

Effect:  
integrity failure  
of tube

# Other Scopes of FMEAs

- **Process Design FMEA:** Used to improve process design; capability, efficiency, productivity, reliability.
- **Maintenance FMEA:** Used to improve maintenance process and Overall Equipment Effectiveness (OEE).
- **Machinery FMEA:** Used to improve the design of plan machines and equipment.
- **EHS FMEA:** Used to reduce risk of accident and injury experience to those operating the process, as well as reduce damage to the process, facilities and equipment.
- **Inspection Process FMEA:** Used to analyze and improve the inspection process.
- **Logistics / Shipping FMEA:** Used to improve the logistics / shipping process.

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# Chapter 2

## Changes Summary

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# Change Point Summaries

## AIAG 4th Edition FMEA Reference Manual to AIAG & VDA FMEA Handbook

- The AIAG & VDA FMEA method is described by a 7-Step approach.
- The steps are the synthesis of AIAG and VDA DFMEA process steps.
  - For example, Block/Boundary Diagrams are shown as Step 2 of the 7-Step approach and the same deliverable is shown as a prerequisite in the 4th Edition.
- Special Characteristics are removed from DFMEA but stay in PFMEA,
  - Refer Annex 01 Special Characteristics.
- For continuous Improvement a History/Change Authorization column is added
- The linkage between DFMEA and PFMEA is explained and FMEA Collaboration
  - (Customer Tier n- Tier n+1).



# 1st Step: Planning and Preparation

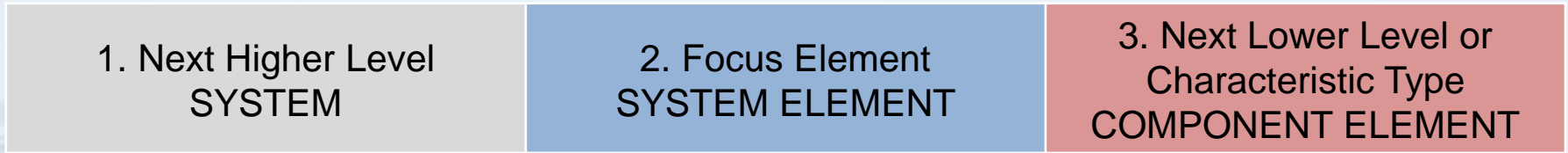
- Preparation is partly considered in the 4th Edition General FMEA Guidelines, Chapter II Overview of FMEA, and Chapter III DFMEA.
- Step 1 includes definition of the "5T's": InTent, Timing, Team, Task, and Tool to be used to document the analysis as well as identification of the analysis subject and baseline DFMEA as appropriate.
- FMEA Form Sheet header is defined within Step 1 and the following changes apply:
  - i. Company Name added
  - ii. Marking of System, Subsystem or Component removed
  - iii. Engineering Location added
  - iv. Customer Name added
  - v. Model Year(s)/Program(s) changed to Model Year/Platform
  - vi. Subject added
  - vii. Key Date removed
  - viii. Revision Date added
  - ix. FMEA Number changed to DFMEA ID Number
  - x. Page Number of Page Number removed
  - xi. Prepared By changed to Design Responsibility
  - xii. FMEA Date (orig.) changed to Start Date
  - xiii. Core Team changed to Cross-Functional Team
  - xiv. Confidentiality Level added

**Reason for change:**  
To use common terms and include necessary information for record management



## 2nd Step: Structure Analysis

- For DFMEA, ITEM is expanded to SYSTEM, SYSTEM ELEMENT, and COMPONENT ELEMENT with SYSTEM as Next Higher Level, SYSTEM ELEMENT as Focus Element, and COMPONENT ELEMENT as Next Lower Level or Characteristic Type.
- Collaboration between customer and supplier is defined and added.



Reason for change:

To correctly identify the system, subsystem, component and/or characteristic in relation to the item (focus element) being analyzed.

This information is needed for Step 3, Function Analysis.

# 3rd Step: Function Analysis

- AIAG 4TH Edition Form Sheet A and C: Item/Function and Requirement are split so that Item is part of Step 1 and Function and Requirement space is available for each of the levels defined in Step 2.
- The description is more detailed how to formulate functions.
- Detailed definition of requirements | characteristics and usage of P-Diagram explained.
- Collaboration between engineering teams is described.

1. Next Higher Level  
Function and Requirement

2. Focus Element Function  
and Requirement

3. Next Lower Level  
Function and Requirement or  
Characteristic

Important note:

AIAG Form Sheet A and C: Item/Function needed correction due to instances where customers have received DFMEAs showing an Item description and Failure Mode with no Function or Requirement identified. The expectation is that a Function and Requirement are necessary for an understanding of how the Function could fail.

Reason for change:

To establish the functions for each Item/System Element to demonstrate an understanding of how each level contributes to the functionality of the next higher level.

Considering and listing the positive Functions and Requirements of the Product leads to listing the negatives, the Effect of Failure, and the Causes of Failure.

# 4th Step: Failure Analysis

- Concept of FOCUS ELEMENT establishes the focus of the analysis.
  - i. Potential Failure Mode changed to: Failure Mode {FM} of the Focus Element
  - ii. Potential Failure Effect changed to: Failure Effects {FE} to the Next Higher level Element and/or End User
  - iii. Potential Failure Cause changed to: Failure Cause {FC} of the Next Lower Element or Characteristic
  - iv. Order of columns changed from FM, FE, FC to FE, FM, FC

Important note:

Although the order of columns changed, the order of creating the analysis using a spreadsheet remains the same. It is necessary to identify first the (FM), then either the (FE) or (FC) depending on the team. When using FMEA-dedicated software the team may perform the DFMEA in a different way e.g. identifying failures and then linking them in a proper failure chain of (FE), (FM), (FC).

- Identify failures by systematic description of question approach.
- More detailed description how to formulate failure effects, failure mode and failure cause with examples.
- Relationship is shown between PFMEA and DFMEA.
- Collaboration between customer and supplier explained.

1. Failure Effect (FE) to the Next Higher Level System and/ or End User

2. Failure Mode (FM) of the Focus Element

3. Failure Cause of the Next Lower Level Element or Characteristic

Reason for change:

To promote the cause and effect analysis in terms of a chain of potential events. The structure, function, and failure sections of the form sheet are designed using a pattern that leads to three levels of a failure chain (FE), (FM), (FC).

# 5th Step: Risk Analysis

- The term "ranking" replaced by "rating" because each failure is rated according to the criteria defined in the rating charts. Each rating chart has a new column to add company-specific examples
  - i. Severity rating- Ten-point scale with similar definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA, PFMEA, and FMEAMSR when rating the (FE) to the end user level.
  - ii. Occurrence rating- Ten-point scale with added emphasis on Prevention Controls as input to the Occurrence rating.
  - iii. **Detection** rating- Ten-point scale that considers Ability to Detect, Detection Method Maturity, and Opportunity for Detection.
  - iv. **Action Priority (AP)** is offered as a replacement for Risk Priority Number (RPN) Reference AP table for High-Medium-Low assignments. There is a common AP table for DFMEA and PFMEA.
  - v. **Classification** replaced with **Filter Code (Optional)**- The Filter Code column may be used to flag potential special characteristics or other information designated by the company
- Classification of failures as shown on product drawings and/or specifications (standard or special type) is not a requirement of DFMEA, therefore the column was removed and replaced with a Filter Code column, as optional.
- Current Controls, even if the implementation is in the future, are part of Risk Analysis.
- More detailed evaluation tables for occurrence and detection with examples.
- Collaboration between customer and supplier explained.

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# 5th Step: Risk Analysis

1. Failure Effect (FE) to the Next Higher Level System and/ or End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause of the Next Lower Level Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)
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## Reason for change:

Rating charts revised for global use by automotive OEMs and suppliers to encourage more effective and efficient DFMEAs by using common rating criteria. The AP table considers the importance of Severity, then Occurrence, then Detection when prioritizing actions for risk reduction as described in the AIAG 4th Edition FMEA Manual. The AP (H-M-L) considers the ratings of S, O, and D at the same time and applies logic to determine the priority of action. The table also makes recommendations on how work through the three AP levels.

# 6th Step: Optimization

- The definition of optimization is detailed in the AIAG & VDA FMEA Handbook.
  - Recommended Action split into two columns: **Preventive Action and Detection Action**
  - New: **Status** (Suggested status levels: Open, Completed, Discarded)
  - Changed: **Action Taken with Pointer to Evidence**
  - New: **Remarks** (for DFMEA team or internal use)
- New assessment or action effectiveness defined.
- Continual improvement described.
- Collaboration between FMEA team, management, customer and supplier explained.

DFMEA Prevention Action	DFMEA Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Remarks
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## Reason for change:

The information helps the user with visual management to be sure each piece of information is included and correct. Important is the "Pointer to Evidence" for follow-up reasons.





# 7th Step: Result Documentation

- Step 7 summarizes the scope and results of the DFMEA in a report for review by internal management and/or the customer.
- The AIAG 4th Edition FMEA manual indicates that management owns the FMEA process and has the ultimate responsibility of selecting and applying resources and ensuring an effective risk management process including timing.
- These statements are found in Chapter 2, Strategy, Planning, Implementation. However, the 4<sup>th</sup> Edition does not provide additional guidance on how to engage management in the DFMEA team.
- Step 7 provides recommendations for what to include in results documentation.
- This report should indicate the technical risk of failure as a component of the development plan and project milestones.

## Reason for change:

The involvement of senior management in the FMEA Development and maintenance process has been reinforced through this Step 7 using the reporting of FMEA.



# Summary

- Similar rationale for changes have been clarified by AIAG VDA for PFMEA and Supplement FMEA to MSR in Appendix F of AIAG VDA FMEA.
- This joint publication is the culmination of more than three years of collaboration between OEM and Tier 1 supplier members of the Automotive Industry Action Group (AIAG), and the Verband der Automobilindustrie (VDA).
- The text has been completely rewritten, and the FMEA method has been revised in a few key areas. The intent is to provide a common foundation for FMEA across the sectors of the automotive industry which are represented by these organizations.
- While every effort was made to achieve consensus, it may be necessary to refer to individual corporate publications or Customer-Specific Requirements (CSR).
- A new method, Supplemental FMEA for Monitoring and System Response (FMEA-MSR), has been added. It provides a means for the analysis of diagnostic detection and fault mitigation during customer operation for the purpose of maintaining a safe state or state of regulatory compliance.
- This handbook supersedes AIAG 4th Edition FMEA and VDA, "Product and Process FMEA" Volume 4.

# References provided in AIAG VDA FMEA

- IATF 16949: 2016 Quality management systems Particular requirements for the application of ISO 9001 for automotive production and relevant service part organizations
- ISO 9001 Quality management systems- Requirements
- ISO 26262 Road vehicles - Functional safety
- SAE<sup>o</sup> J1739 Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)
- VDA Volume 2 Quality Assurance of Supplies
- VDA Maturity Level Assurance for New Parts
- AIAG APQP Advanced Production and Quality Planning
- AIAG PPAP Production Part Approval Process

# Chapter 3

## How to Develop / Implement AIAG VDA FMEA

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**Process Applicable to Any Type of FMEA**



# THE FMEA TEAM

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# Team Approach

- Conducting an FMEA is a “creative” process involving a cross-functional team.
- A large portion of the benefit of the FMEA process comes from the increase in knowledge generated by team discussions and related activities. O-M-N-E-X
- ***This, in itself, is sufficient justification for using the FMEA process.***

Who / which function should be part of the FMEA Team?

# Roles on the FMEA Team

- **Team Leader**
  - Typically the responsible engineer
- **Facilitator / Moderator**
  - Is an FMEA process expert
    - Skilled in the FMEA methodology and facilitation methods
  - Not a requirement for every team
    - May not need a full-time facilitator
    - Applicable for novice teams
- **Team Members**
  - Core Team
  - Expanded Team
- **Scribe or Recorder**
  - Skilled in the use of the appropriate software
  - Role should be rotated, if possible

What is the role of the Management then?



# Management Responsibility

**“Ultimately, management has the responsibility and ownership for development and maintenance of the FMEAs”**

*FMEA 4<sup>th</sup> Edition*

**“Management carries the responsibility for the application of FMEA. Ultimately, management is responsible for acceptance of the risks and risk minimization actions identified in the FMEA.”**

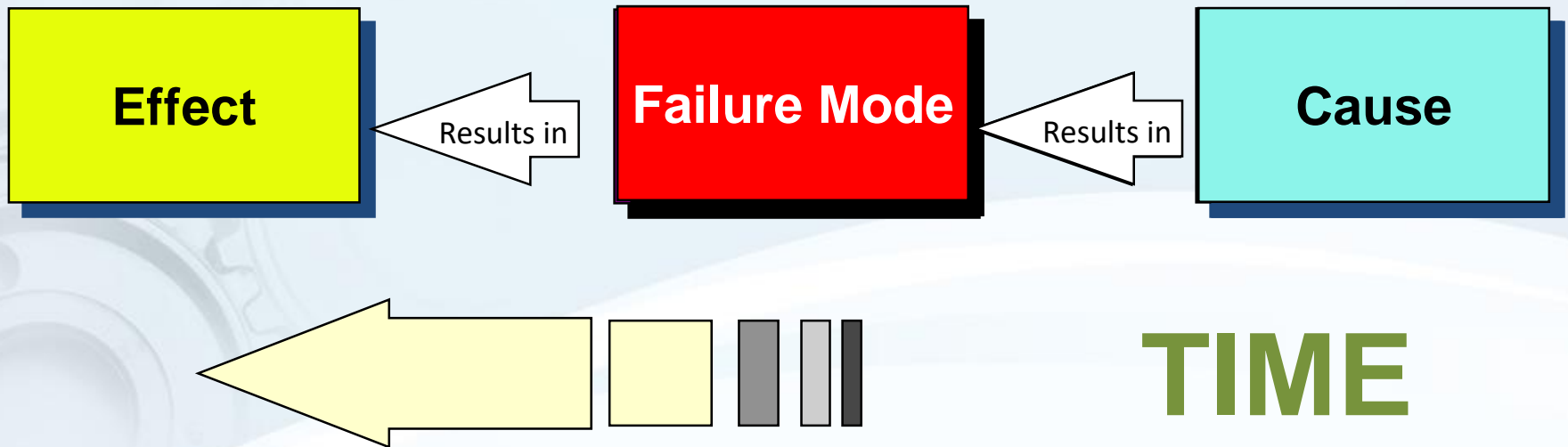
*AIAG-VDA FMEA 1<sup>st</sup> Edition*

# CONDUCTING AN FMEA

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# FMEA Model

## Linking Failure Mode to Cause and Effect



We must understand the risks involved in these linkages

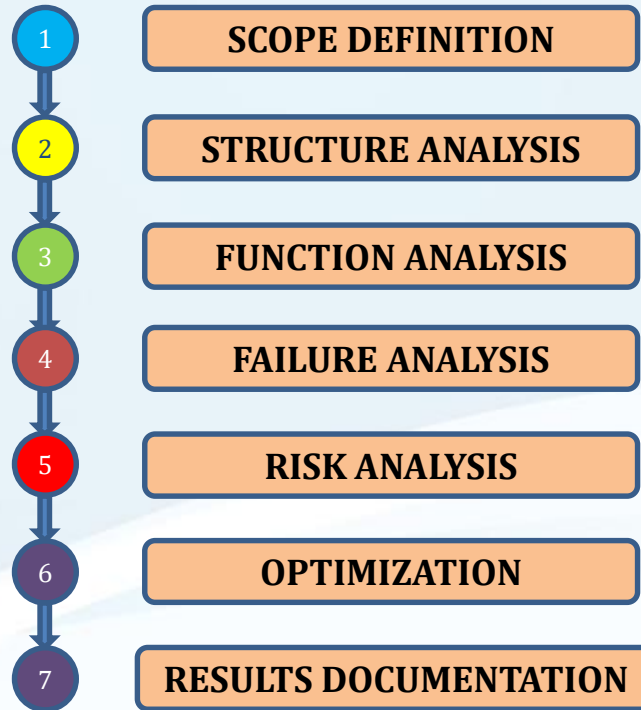
# Conducting an FMEA – General Approach

- Complete necessary prerequisites
  - Define the scope of the analysis
  - Identify and list all the requirements
- For each requirement
  - Identify potential failure modes
- For each failure mode
  - Assess potential effects of failures
  - Identify the cause(s)
- For each cause
  - Identify what control(s) are/will be in place to prevent or detect the cause or failure mode
  - Identify and implement continual improvement actions










# Seven Step Process

## AIAG VDA FMEA 1<sup>st</sup> Edition



**Design/Process FMEA**

# Seven Step Process – Based on AIAG VDA FMEA 1<sup>st</sup> Edition

System Analysis			Seven Step Approach			Risk Communication
1st Step Planning & Preparation	2nd Step Structure Analysis	3rd Step Function Analysis	4th Step Failure Analysis	5th Step Risk Analysis	6th Step Optimization	7th Step Results Documentation
						
<b>Project Identification</b>	Visualization of the analysis scope	Visualization of product or process functions	Establishment of the failure chain	Assignment of existing and/or planned controls and rating of failures	Identification of the actions necessary to reduce risks	Communication of actions taken to reduce risks
<b>Project plan:</b> Intent, Timing, Team, Tasks, Tools (5T)	<b>DFMEA:</b> Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts  <b>PFMEA:</b> Structure tree or equivalent: process flow diagram	<b>DFMEA:</b> Function tree/net, function matrix parameter diagram (P-diagram)  <b>PFMEA:</b> Function tree/net or equivalent process flow diagram	<b>DFMEA:</b> Potential Failure Effects, Failure Modes, Failure Causes for each product function  <b>PFMEA:</b> Potential Failure Effects, Failure Modes, Failure Causes for each process function	<b>DFMEA &amp; PFMEA:</b> Assignment of Prevention Controls to the Failure Causes  <b>DFMEA &amp; PFMEA:</b> Assignment of Detection Controls to the Failure Causes and/or Failure Modes  <b>FMEA-MSR:</b> Analysis of provisions for functional safety and regulatory compliance	Assignment of responsibilities and deadlines for action implementation	The layout of the document may be company specific. The content may include the following: • Executive summary • Scope of the FMEA • A reference to the specific S/O/D Rating Tables used in the analysis • Action Priority • Results and conclusions of the analysis
<b>Analysis boundaries:</b> What is included and excluded from the analysis	<b>DFMEA:</b> Identification of design interfaces, interactions, close clearances  <b>PFMEA:</b> Identification of process steps and sub-steps	<b>DFMEA:</b> Cascade of customer (external and internal) functions with associated requirements  <b>DFMEA &amp; PFMEA:</b> Association of requirements or characteristics to functions	<b>DFMEA:</b> Identification of product failure causes using a parameter diagram or failure network  <b>PFMEA:</b> Identification of process failure causes using a fishbone diagram (4M) or failure network	<b>DFMEA &amp; PFMEA:</b> Rating of Severity, Occurrence and Detection for each failure chain  <b>FMEA-MSR:</b> Rating of Severity, Frequency and Monitoring for each failure chain	Implementation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken	Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
Identification of baseline FMEA with lessons learned	Collaboration between customer and supplier engineer teams (interface responsibilities)	Collaboration between engineering teams (systems, safety, and components)	Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity)	Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures	The content of the documentation fulfills the requirements of the organization, the intended reader, and relevant stakeholders, and details may be agreed between the relevant parties.
Basis for the Structure Analysis step	Basis for the Function Analysis step	Basis for the Failure Analysis step	Basis for the documentation of failures in the FMEA form and the Risk Analysis step	Basis for the product or process Optimization step	Basis for refinement of the product and/or process requirements and prevention and detection controls	Record of risk analysis and reduction to acceptable levels.



# Optimizing the FMEA Process

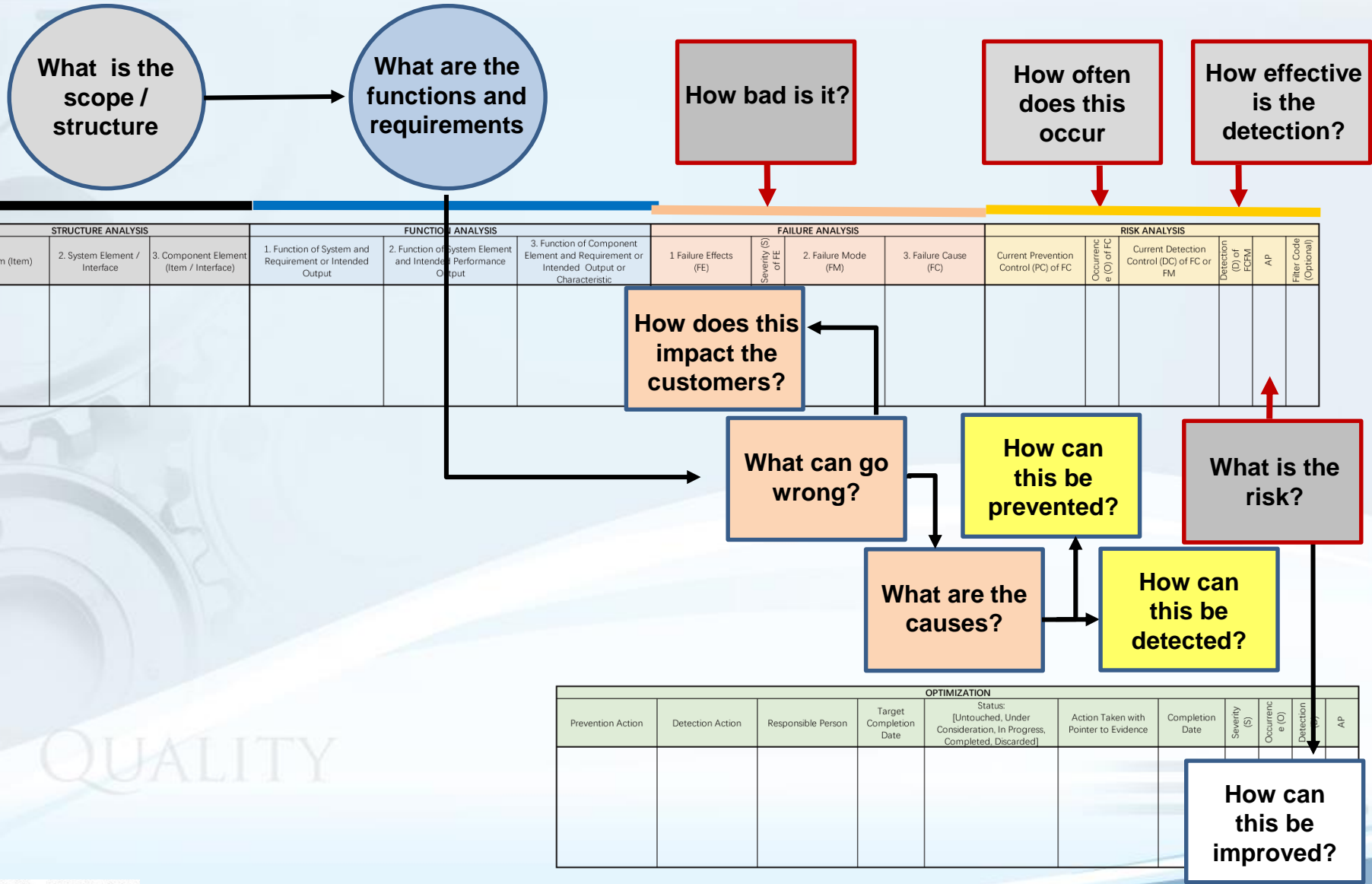
- Communicate effectively
- Utilize / build upon existing product information
  - Requires an acceptable DFMEA and DVP&R Plan of the referenced product
  - Focus is on the “new” stuff in the product; i.e., differences and changes in the product requirements and use
  - Can utilize design segments
- Acquire and deploy needed information before meetings
  - Historical information on the same or surrogate products; this can impact effects, causes, occurrence, etc.

QUALITY

# AIAG VDA FMEA STRUCTURE

QUALITY

# New AIAG and VDA FMEA – 1<sup>st</sup> edition



# 7-Step Process Form – Proposed AIAG-VDA 1<sup>st</sup> Edition

1<sup>st</sup> Step

Scope Definition



**DESIGN FAILURE AND EFFECTS ANALYSIS (DFMEA)**

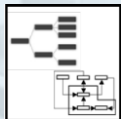
Company Name: _____	Subject: _____	DFMEA ID Number: _____
Engineering Location: _____	DFMEA Start Date: _____	Design Responsibility: _____
Customer Name: _____	DFMEA Revision Date: _____	Security Classification: _____
Model / Year / Platform: _____	Fmea Due Date: _____	Fmea Intent: _____
Fmea Team: _____		Fmea Task: _____
		Fmea Tool: _____

## System Analysis

## and Risk Mitigation

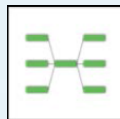
2<sup>nd</sup> Step

Structure Analysis



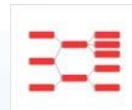
3<sup>rd</sup> Step

Function Analysis



4<sup>th</sup> Step

Failure Analysis



5<sup>th</sup> Step

Risk Analysis



STRUCTURE ANALYSIS			FUNCTION ANALYSIS		
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic

FAILURE ANALYSIS			RISK ANALYSIS						
1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM	Detection (D) of FCFM	AP	Filter Code (Optional)

6<sup>th</sup> Step  
Optimization



OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP



# 7-Step Process and Spreadsheet

## The FMEA Spreadsheet

### DESIGN FAILURE AND EFFECTS ANALYSIS (DFMEA)

Company Name: \_\_\_\_\_  
 Engineering Location: \_\_\_\_\_  
 Customer Name: \_\_\_\_\_  
 Model / Year / Platform: \_\_\_\_\_

Subject: \_\_\_\_\_  
 DFMEA Start Date: \_\_\_\_\_  
 DFMEA Revision Date: \_\_\_\_\_

DFMEA ID Number: \_\_\_\_\_  
 Design Responsibility: \_\_\_\_\_  
 Security Classification: \_\_\_\_\_

STRUCTURE ANALYSIS			FUNCTION ANALYSIS			FAILURE ANALYSIS			
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)	1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic	1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)
			→						
			→						
			→						

Higher Level

Focused Level

Lower Level



# Comparison of 4<sup>th</sup> Edition AIAG FMEA and AIAG VDA, 1<sup>st</sup> Edition FMEA

STRUCTURE ANALYSIS		
1. System (Item)	2. System Element / Interface	3. Component Element (Item / Interface)

FUNCTION ANALYSIS		
1. Function of System and Requirement or Intended Output	2. Function of System Element and Intended Performance Output	3. Function of Component Element and Requirement or Intended Output or Characteristic

FAILURE ANALYSIS			
1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM)	3. Failure Cause (FC)

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

RISK ANALYSIS					
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Control (DC) of FC or FM	Detection (D) of FCFM	AP	Filter Code (Optional)

OPTIMIZATION										
Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Untouched, Under Consideration, In Progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	AP





# Chapter 4

## Transition Strategy to AIAG VDA FMEA

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# Transition Strategy

- Existing FMEAs developed using the previous AIAG 4th Edition FMEA "Product and Process FMEA" of VDA Edition, may remain in their original form for subsequent revisions.
- The organization should thoughtfully plan the transition from their current FMEA process(es) and methods to the new AIAG & VDA FMEA process and tools.
- When practical, existing FMEAs used as a starting point for new programs should be converted to reflect the new rating scales, analytical methods, and format. However, if the team determines that the new program is considered a minor change to the existing product, they may decide to leave the FMEA in the existing format.
- New projects should follow the FMEA method presented in this Handbook unless company leadership and Customer Specific Requirements (CSRs) mandate a different approach.
- The transition date and project milestone after which new projects follow this method should be defined by the company taking into consideration Customer Specific Requirements.

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# Chapter 5

## Omnex Workshops on AIAG VDA FMEA

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# Omnex Workshops on AIAG VDA FMEA

## AIAG-VDA FMEA Understanding, Implications, and Strategy - Executive Overview

Duration: 1 Day

### Seminar Content

Join Omnex for this important industry approach integrating AIAG and VDA FMEAs. Omnex FMEA experts many who are writers of the FMEA standards have worked extensively with both AIAG and VDA FMEAs formats. They will show you how to manage your existing AIAG or VDA FMEAs and the steps to transition to the AIAG-VDA FMEA approach.

This half-day or 1 day seminar will provide a high-level review of the changes in the new AIAG-VDA FMEA and the requirements and recommendations for top management.

The approaches discussed and employed in this course are consistent with the intent and guidelines in the AIAG-VDA FMEA Handbook (1st edition, 2019) issued by AIAG and VDA.

### Who Should Attend

Top Management and their direct reports including Quality Leadership and AIAG-VDA FMEA Implementation Leader.

## Understanding AIAG-VDA DFMEA (SFMEA and DFMEA) for Design and Project Team Members

Duration: 1 Day

### Seminar Content

Join Omnex for this important industry approach integrating AIAG and VDA FMEAs. Omnex FMEA experts many who are writers of the FMEA standards have worked extensively with both AIAG and VDA FMEAs formats. They will show you how to manage your existing AIAG or VDA FMEAs and the steps to transition to the AIAG-VDA FMEA approach.

Omnex will share best in class practices to get the most of the AIAG-VDA DFMEA including managing requirements, working with the supply chain, integrating PPMs and also creating a product and process architecture for managing FMEAs. Get the greatest savings by employing Design Reuse and also linking PPM history with AIAG-VDA FMEA. Most of all, get hands on real world experience working with AIAG-VDA DFMEA at our Open Enrollment or on your product onsite.

This 1 day seminar addresses all of the elements of the Design Failure Mode Effects Analysis (DFMEA) and Design Verification Planning process, and defines it as a process within your organization.

The training is an introduction and an overview to understanding the seven steps of the AIAG-VDA FMEA process. This course has similar content to the Practitioner course but without the case study.

The approaches discussed and employed in this course are consistent with the intent and guidelines in the AIAG-VDA FMEA Handbook (1st edition, 2019) issued by AIAG and VDA, APQP Second Edition, and IATF 16949:2016.

### Who Should Attend

Those who have direct responsibility for introducing new products and/or a new manufacturing processes and systems would benefit from this seminar. This includes: program/product managers, quality managers, design engineers, manufacturing engineers, APQP team members and others who have direct responsibility for new product development and improvement.





# Omnex Workshops on AIAG VDA FMEA

## Understanding AIAG-VDA Process FMEA and Control Plans for Process and Project Team Members

Duration: 1 Day

### Seminar Content

Join Omnex for this important industry approach integrating AIAG and VDA FMEAs. Omnex FMEA experts many who are writers of the FMEA standards have worked extensively with both AIAG and VDA FMEAs formats. They will show you how to manage your existing AIAG or VDA FMEAs and the steps to transition to the AIAG-VDA FMEA approach.

Omnex will share best in class practices to get the most of the AIAG-VDA PFMEA including managing requirements, integrating PPMs and Warranty history and creating a product and process architecture for managing FMEAs. Get the greatest savings by employing Process Reuse and also linking PPM and Warranty history with AIAG-VDA PFMEA. Most of all, get hands on real world experience working with AIAG-VDA PFMEA, Process Flow (Structure Analysts), and Control Plan at our Open Enrollment or at your product onsite.

This 1 day seminar addresses all of the elements of the Process Failure Mode Effects Analysis (PFMEA) and Control Planning process, and defines it as a process within your organization. This is the same training as the Practitioner course but without the breakout case study or exam.

This seminar offers an insight to the linkages between various aspects of the PFMEA process. Specifically, the development and linkage of process flows/structure analysis and control plans are addressed. It shows how Process Flows/structure analysis, Control Plans and shop floor documentation can be used to achieve process standardization and improvement.

The approaches discussed and employed in this course are consistent with the intent and guidelines in the AIAG-VDA FMEA Handbook (1st edition, 2019) issued by AIAG and VDA, APQP Second Edition, and IATF 16949:2016.

### Who Should Attend

Those who have direct responsibility for introducing new manufacturing processes and systems would benefit from this seminar. This includes: program/product managers, quality managers, design engineers, manufacturing engineers, APQP team members and others who have direct responsibility for new process development and improvement.

## AIAG-VDA DFMEA (SFMEA and DFMEA) for Practitioners and Facilitators

Duration: 3 Days

### Seminar Content

Join Omnex for this important industry approach integrating AIAG and VDA FMEAs. Omnex FMEA experts many who are writers of the FMEA standards have worked extensively with both AIAG and VDA FMEAs formats. They will show you how to manage your existing AIAG or VDA FMEAs and the steps to transition to the AIAG-VDA FMEA approach.

Omnex will share best in class practices to get the most of the AIAG-VDA DFMEA including managing requirements, working with the supply chain, integrating PPMs and also creating a product and process architecture for managing FMEAs. Get the greatest savings by employing Design Reuse and also linking PPM history with AIAG-VDA FMEA. Most of all, get hands on real world experience working with AIAG-VDA DFMEA at our Open Enrollment or on your product onsite.

This 2.5 or 3 day seminar addresses all of the elements of the Design Failure Mode Effects Analysis (DFMEA) and Design Verification Planning process, and defines it as a process within your organization. This class was designed as a "how to" for practitioners and facilitators. This training offers an optional certification exam in addition to an optional one or two days of workshop to develop your own product using AIAG-VDA DFMEA (onsite training only).

The training is a hands on approach to understanding and using the seven steps of the AIAG-VDA FMEA process and to understand how it is managed as a process. This course is intended to be a dynamic, hands-on offering with approximately half the class time spent in workshops.

The approaches discussed and employed in this course are consistent with the intent and guidelines in the AIAG-VDA FMEA Handbook (1st edition, 2019) issued by AIAG and VDA, APQP Second Edition, and IATF 16949:2016.

### Who Should Attend

Those who have direct responsibility for introducing new products and/or a new manufacturing processes and systems would benefit from this seminar. This includes: program/product managers, quality managers, design engineers, manufacturing engineers, APQP team members and others who have direct responsibility for new product development and improvement.

Those directly responsible for DFMEA creation or facilitation should attend this course to upgrade their skills to the AIAG VDA DFMEA 1st Edition.

## AIAG-VDA Process FMEA and Control Plans for Practitioners and Facilitators

Duration: 3 Days

### Seminar Content

Join Omnex for this important industry approach integrating AIAG and VDA FMEAs. Omnex FMEA experts many who are writers of the FMEA standards have worked extensively with both AIAG and VDA FMEAs formats. They will show you how to manage your existing AIAG or VDA FMEAs and the steps to transition to the AIAG-VDA FMEA approach.

Omnex will share best in class practices to get the most of the AIAG-VDA PFMEA including managing requirements, integrating PPMs and Warranty history and creating a product and process architecture for managing FMEAs. Get the greatest savings by employing Process Reuse and also linking PPM and Warranty history with AIAG-VDA PFMEA. Most of all, get hands on real world experience working with AIAG-VDA PFMEA, Process Flow (Structure Analysts), and Control Plan at our Open Enrollment or at your product onsite.

This 2.5 or 3 day seminar addresses all of the elements of the Process Failure Mode Effects Analysis (PFMEA) and Control Planning process, and defines it as a process within your organization. This class was designed as a "how to" for practitioners and facilitators. The training is a hands on approach to understanding and using the seven steps of the AIAG-VDA PFMEA process. This course is intended to be a dynamic, hands-on offering with approximately half the class time spent in workshops.

This seminar offers an insight to the linkages between various aspects of the PFMEA process. Specifically, the development and linkage of process flows/structure analysis and control plans are addressed. It shows how Process Flows/structure analysis, Control Plans and shop floor documentation can be used to achieve process standardization and improvement.

The approaches discussed and employed in this course are consistent with the intent and guidelines in the AIAG-VDA FMEA Handbook (1st edition, 2019) issued by AIAG and VDA, APQP Second Edition, and IATF 16949:2016.

### Who Should Attend

Those who have direct responsibility for introducing new manufacturing processes and systems would benefit from this seminar. This includes: program/product managers, quality managers, design engineers, manufacturing engineers, APQP team members and others who have direct responsibility for new process development and improvement.

Those directly responsible for PFMEA creation or facilitation should attend this course to upgrade their skills to the AIAG VDA PFMEA 1st Edition.

## AIAG-VDA FMEA for Managers and Implementers – Implementation Training

Duration: 2 Days

### Seminar Content

Join Omnex for this important automotive industry initiative integrating AIAG and VDA FMEAs. Omnex has worked with 1000s of organizations for over 50 years implementing FMEA in an APQP and New Product Development environment. AIAG-VDA FMEA needs to be understood in the context and its role in New Product Development and APQP. It is not a stand-alone tool but one that needs to be implemented with the New Product Development process with APQP and then afterwards as a part of a "manage the change" process. Let us not forget that DFMEAs, DVPR, Process Flow, PFMEA, and Control Plans are living documents that result in a control strategy in design and manufacturing environments. When we keep this in mind, then we understand the linkage between these control and risk prevention methodologies and the Cost of Quality including PPMs.

Omnex FMEA experts many who are writers of the FMEA and Core Tools standards have worked extensively with both AIAG and VDA FMEA formats. Also, Omnex has extensive background in implementing not only FMEAs but APQP, Core Tools and IATF 16949. So, number one, it is a part of an overall process of APQP, IATF 16949 and Core Tools, Second, it is important to understand AIAG-VDA FMEA as an approach that links the supply chain through the structure analysis, and failure analysis. Third, it is also the start of many standards that we will see as the industry transitions from Gas and Diesel vehicles to Electric Vehicles and Autonomous Cars. AIAG-VDA FMEA enhances and supports ISO 26262 with FMEAs and the MSR.

This 2 day seminar will share best in class practices to get the most of the AIAG-VDA FMEA including managing requirements, working with the supply chain, integrating PPMs and also creating a product and process architecture for managing FMEAs. This seminar will help you to get the greatest savings by employing Design and Process Reuse and also linking PPM and warranty history with AIAG-VDA FMEA.

The approaches discussed and employed in this course are consistent with the intent and guidelines in the AIAG-VDA FMEA Handbook (1st edition, 2019) issued by AIAG and VDA, APQP Second Edition, and IATF 16949:2016.

### Who Should Attend

Those who have direct responsibility for introducing new products and/or a new manufacturing processes and systems would benefit from this seminar. This includes: program/product managers, quality managers, and others who have direct responsibility for new product development and improvement.

Managers and those responsible for New Product Development processes and FMEAs in their organization or with the supply chain should attend this seminar to make the needed changes in the management system. Omnex recommends an implementation leader to drive AIAG VDA FMEA implementation within the organization. The training has been tailored for the Manager and Implementation leaders who need to drive the change within the organization.



*Thank You!*

*Questions?*



**info@omnex.com**  
**734.761.4940**

