# Understanding AIAG-VDA System/Design FMEA

## For Design and Project Team Members


OMNEX

315 Eisenhower Parkway Suite 214
Ann Arbor, Michigan 48108
USA
734-761-4940
Fax: 734-761-4966

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Omnex provides training, consulting and software solutions to the international market with offices in the USA, Canada, Mexico, China (PRC), Germany, India, the Middle East, and SE Asia. Omnex offers over 400 standard and customized training courses in business, quality, environmental, food safety, laboratory and health & safety management systems worldwide.

**Email: info@omnex.com**

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# Course Objectives

- Explain the difference between DFMEA and SFMEA.
  - Demonstrate an ability to properly construct a Boundary (Block) Diagram.
- Demonstrate an ability to properly and effectively complete all steps in the DFMEA process.
  - Identify Functions, Requirements, Failure Modes, Causes and Controls and properly enter the information in a DFMEA.
- Explain how a DFMEA can help identify effects and severity for a process failure mode.
- Explain how to prioritize continual improvements.

# Agenda

- Course Overview and Introductions
- Chapter 1 – Introduction to Failure Modes and Effects Analysis (FMEA)
- Chapter 2 – Developing an FMEA
- Chapter 3 – Design FMEA Prerequisites
- Chapter 4 – Developing the Design FMEA
- Summary

# Course Overview

- Focus of the course is on the AIAG-VDA FMEA Handbook 1st Edition method for the development of Failure Modes and Effects Analysis.
  - Published by AIAG and VDA.
- All learning objectives relate to the AIAG-VDA FMEA method.

# 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.

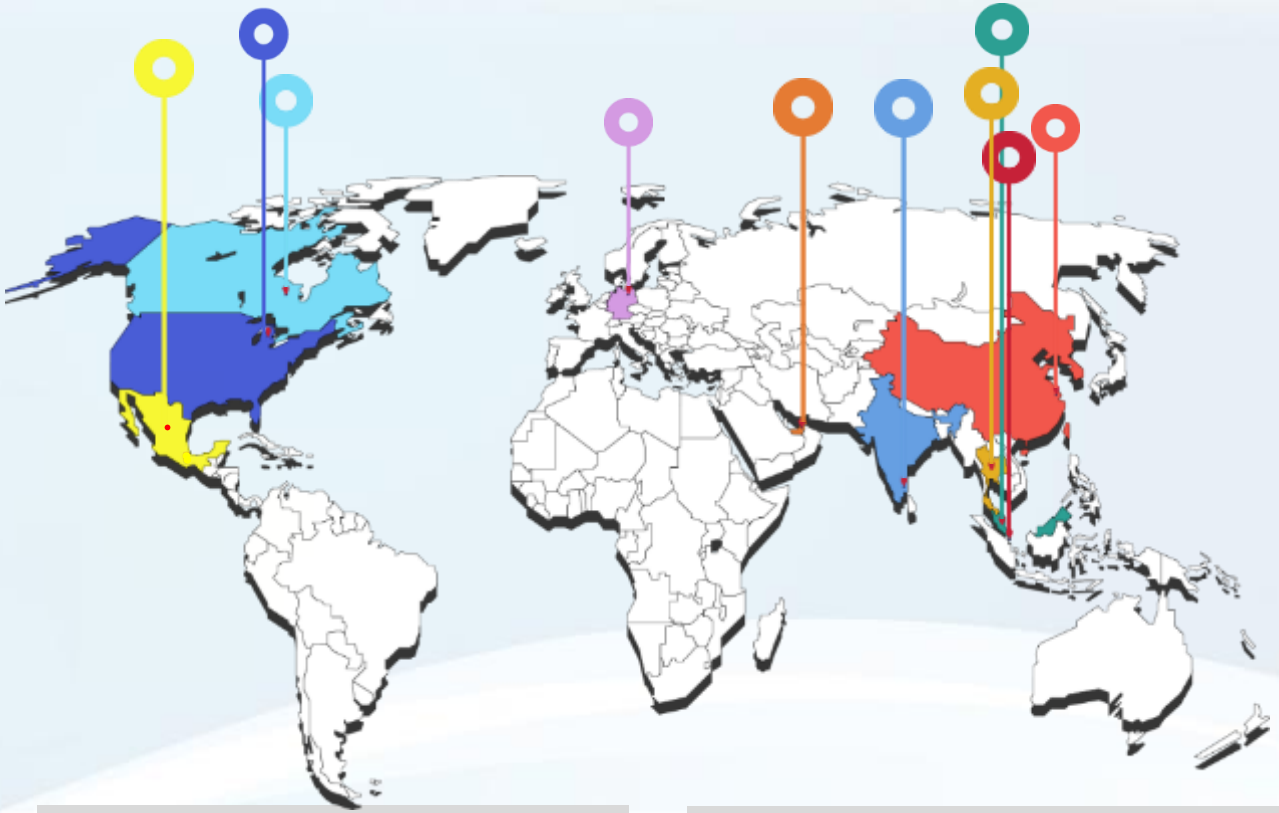
# About Omnex

- 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 ISO/TS 16949.
- Served on committees that wrote QOS, ISO 9001, QS-9000, ISO/TS 16949 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Former member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).

**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.**


www.omnex.com
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
  - What is your involvement in the new product development process?
  - What are your experiences with DFMEA?
  - What are your expectations of this course?
  - Please share something unique and/or interesting about yourself.

# Chapter 1

## Introduction to Failure Mode and Effects Analysis

# Chapter 1: Introduction to FMEA – What We Will Cover

## Learning Objectives

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

- Describe an FMEA
- Describe the benefits of an FMEA
- Describe the types of FMEAs
- Compare a System FMEA to a Design FMEA

## Chapter Agenda

- What is an FMEA?
- Maintaining FMEAs
- System vs Design FMEAs
- Types of FMEAs

# WHAT IS AN 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.

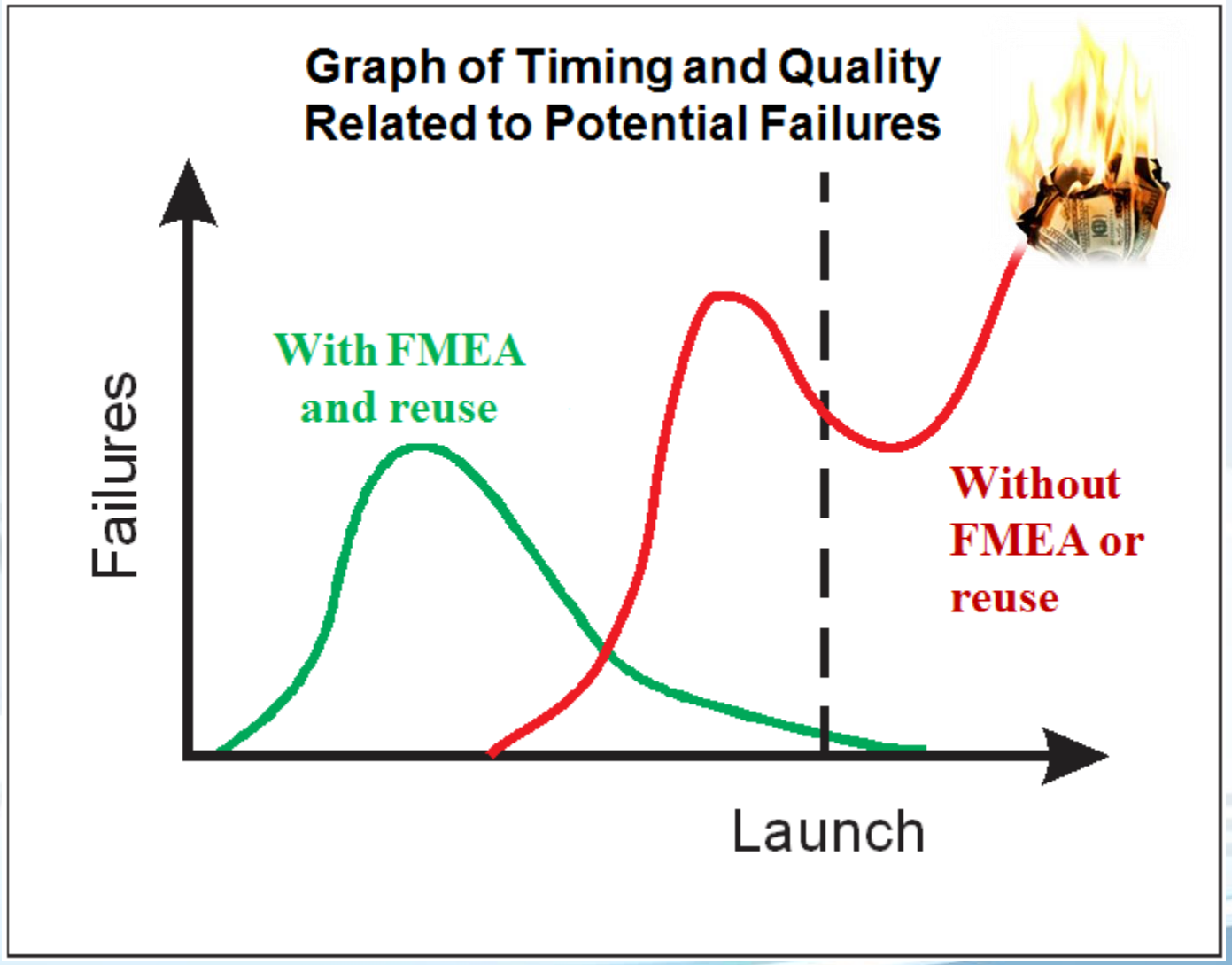
**Risk Assessment and Knowledge Management**

# 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**

# FMEA Advantage



# TYPES OF FMEAS

# Primary Types of FMEAs

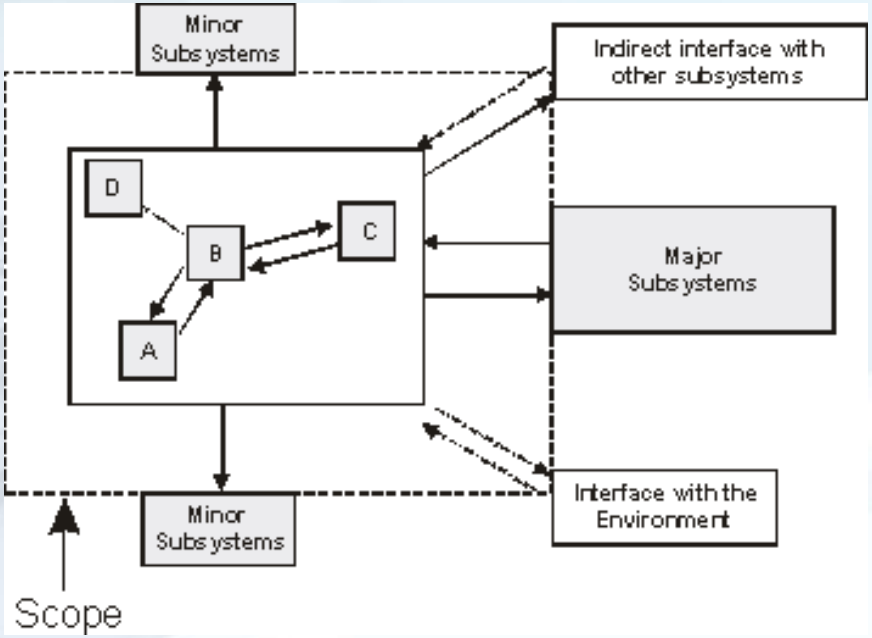
- **System FMEA:** Used to analyze systems and subsystems in the early concept and design stages.
  - Focuses on potential failure modes associated with the **functions and interfaces** of a system inherent in the **design**.
- **Design FMEA:** Used to analyze products before they are released to production.
  - Focuses on potential failure modes associated with the **functions** of a product inherent in the **design**.
  - NOTE: VDA uses the term **Product FMEA** instead of 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

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.

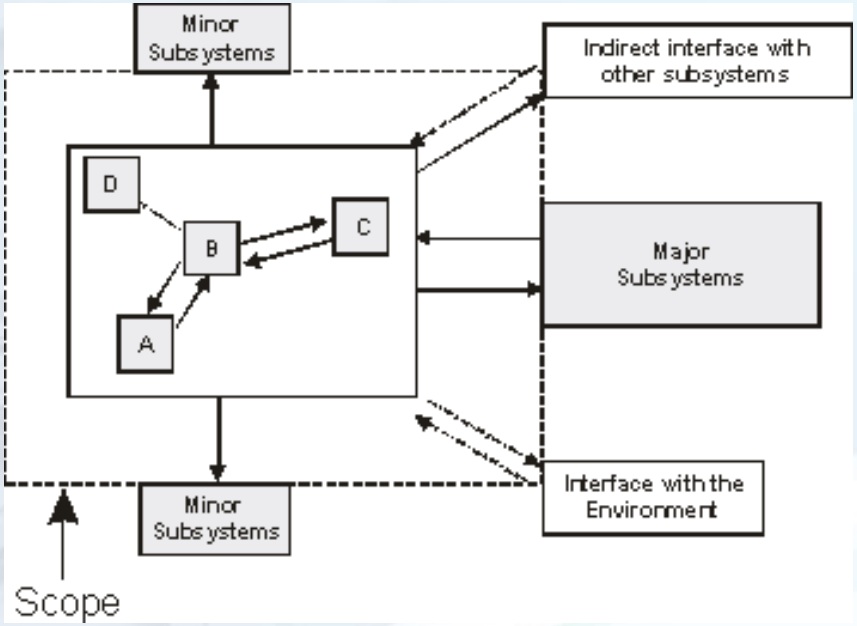
# SFMEA vs. DFMEA




## Interfaces

- Interfaces within the product are shown by solid and dashed lines.
- The Environment also touches each of the subsystems which requires the "**Environmental Interfaces**" to be considered when completing the FMEA.
- Also, the interfaces to major and minor subsystems, whether direct or indirect, should be included.
- The interfaces which are identified in the System FMEA should be included in the respective Subsystem DFMEA.

# SFMEA vs. DFMEA




## Interactions

- Interactions between subsystems and components can occur among any of the interfacing systems; i.e. a change in one subsystem or component may cause a change in another subsystem or component.

Example 1: Subsystem A heats up, resulting in Subsystem B and D gaining heat through their respective interfaces, as well as Subsystem A giving off heat to the environment.

Example 2: if the environment is composed of high humidity and Subsystems A and C are dissimilar metals separated by a non-metal composing Subsystem B, Subsystem A and C can still have an electrolytic reaction due to the moisture from the environment. Thus, interactions among non-contacting subsystems can be relatively difficult to predict but may be important.

# Other Scopes of FMEAs

**Design and Process FMEA may take on different names depending on the application**

- **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.

# Chapter 1: Introduction to FMEA – What We Covered

## Learning Objectives

You should now be able to:

- Describe an FMEA
- Describe the benefits of an FMEA
- Describe the types of FMEAs
- Compare a System FMEA to a Design FMEA
- Describe the different cases for when to use an FMEA

## Chapter Agenda

- What is an FMEA?
- Maintaining FMEAs
- System vs Design FMEAs
- Types of FMEAs

# Chapter 2

## Developing an FMEA

**Process Applicable to Any Type of FMEA**

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# Chapter 2: Developing an FMEA – What We Will Cover

## Learning Objectives

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

- Describe the structure of an FMEA
- Describe the steps to conduct an FMEA

## Chapter Agenda

- Conducting an FMEA
- Basic Structure of an FMEA

# CONDUCTING AN FMEA



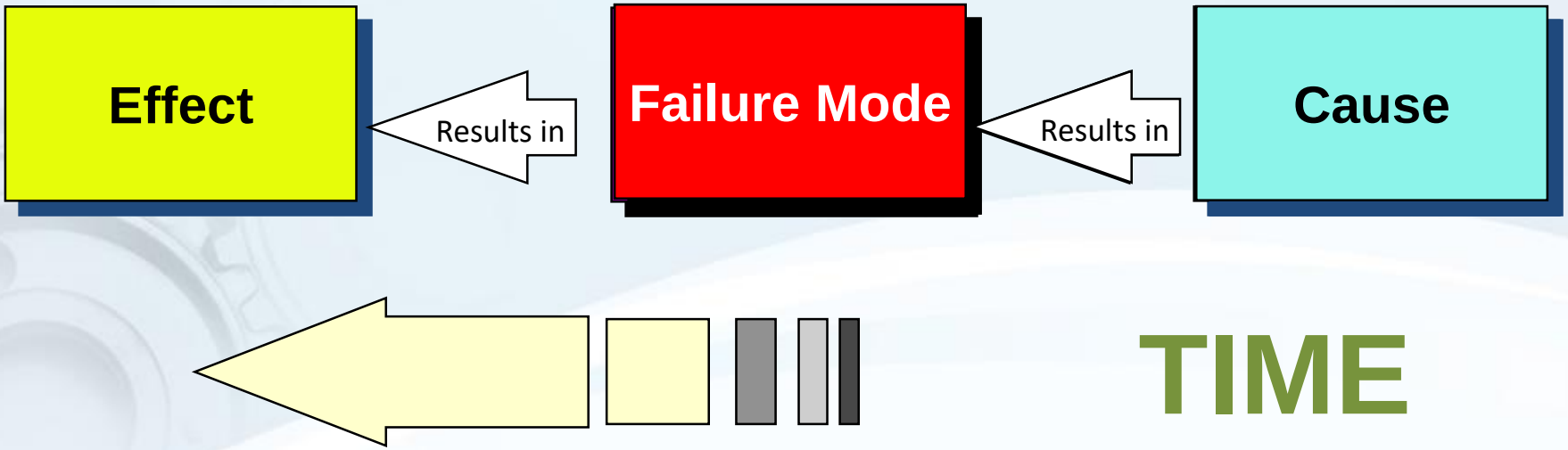

**The intent is to provide a common foundation for FMEA across the sectors of the automotive industry represented by these organizations.**

# Not a "Blue Book"

- The VDA-AIAG Handbook is not part of the "Core Tools" set, but may be required by the major OEMs as per their CSRs.
- The core tools belong to GM-Ford-FCA….
  the "Handbook" is co-owned by VDA and AIAG.


# FMEA Model – AIAG-VDA FMEA Handbook

**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

# Omnex 7-Step DFMEA Process

1. **PLANNING & PREPARATION**
   - 5Ts
2. **STRUCTURE ANALYSIS**
   - Boundary/Block Diagram
   - Structure Development
   - *P-Diagram*
   - *Interface Diagram* (optional)
3. **FUNCTION ANALYSIS**
   - Functions *and Requirements*
4. **FAILURE ANALYSIS**
   - *Causes in Focus Level before* causes in Lower Levels
5. **RISK ANALYSIS**

5b. **Link Special Characteristics to Functions/Requirements**

6. **OPTIMIZATION**
7. **RESULTS DOCUMENTATION**

7b. **Link to DVP&R**

**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

***Italic font*** = Omnex-specific changes to the AIAG-VDA DFMEA process

# 7-Step Process – AIAG-VDA FMEA Handbook

Seven Step Approach

| System Analysis | | | Failure Analysis and Risk Mitigation | | | Risk Communication |
|---|---|---|---|---|---|---|
| 1st Step<br>Planning & Preparation | 2nd Step<br>Structure Analysis | 3rd Step<br>Function Analysis | 4th Step<br>Failure Analysis | 5th Step<br>Risk Analysis | 6th Step<br>Optimization | 7th Step<br>Results Documentation |
|  |  |  |  |  |  |  |
| Project identification | 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 |
| Project plan: InTent, Timing, Team, Tasks, Tools (5T) | **DFMEA:**<br>Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts<br><br>**PFMEA:**<br>Structure tree or equivalent: process flow diagram | **DFMEA:**<br>Function tree/net, function matrix parameter diagram (P-diagram)<br><br>**PFMEA:**<br>Function tree/net or equivalent process flow diagram | **DFMEA:**<br>Potential Failure Effects, Failure Modes, Failure Causes for each product function<br><br>**PFMEA:**<br>Potential Failure Effects, Failure Modes, Failure Causes for each process function | **DFMEA & PFMEA:**<br>Assignment of Prevention Controls to the Failure Causes<br><br>**DFMEA & PFMEA:**<br>Assignment of Detection Controls to the Failure Causes and/or Failure Modes<br><br>**FMEA-MSR:**<br>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:<br>• Executive summary<br>• Scope of the FMEA<br>• A reference to the specific S/O/D Rating Tables used in the analysis<br>• Action Priority<br>• Results and conclusions of the analysis |
| Analysis boundaries: What is included and excluded from the analysis | **DFMEA:**<br>Identification of design interfaces, interactions, close clearances<br><br>**PFMEA:**<br>Identification of process steps and sub-steps | **DFMEA:**<br>Cascade of customer (external and internal) functions with associated requirements<br><br>**DFMEA & PFMEA:**<br>Association of requirements or characteristics to functions | **DFMEA:**<br>Identification of product failure causes using a parameter diagram or failure network<br><br>**PFMEA:**<br>Identification of process failure causes using a fishbone diagram (4M) or failure network | **DFMEA & PFMEA:**<br>Rating of Severity, Occurrence and Detection for each failure chain<br><br>**FMEA-MSR:**<br>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. |

# Transition Strategy

- Existing FMEAs conducted with an earlier version of the FMEA handbook may remain in their original form for subsequent revisions.
- When practical, existing FMEAs used as a starting point for new programs should be converted to comply with the new 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 can follow the FMEA method presented in this guidebook **unless company procedure defines 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 any customer specific requirements and standards.**

***AIAG-VDA FMEA Handbook 1st Edition***

# Optimizing the FMEA Process

- Communicate effectively
- Utilize / build upon existing product information
  - Requires an acceptable DFMEA 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 and process segments
- Acquire and deploy needed information before meetings
  - Historical information on the same or surrogate products; this can impact effects, causes, occurrence, etc.

# FMEA STRUCTURE

# AIAG-VDA FMEA Handbook Form

This process requires the identification / analysis for at least three levels of product flow-down

| STRUCTURE ANALYSIS | | | FUNCTION ANALYSIS | | | FAILURE ANALYSIS | | | | RISK 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) | 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 |
| | | | | | | | | | | |

# AIAG-VDA FMEA Handbook Form

This process requires the identification / analysis for at least three levels of product flow-down

| STRUCTURE ANALYSIS | | | FUNCTION ANALYSIS | | | FAILURE ANALYSIS | | | | RISK 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) | 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) |
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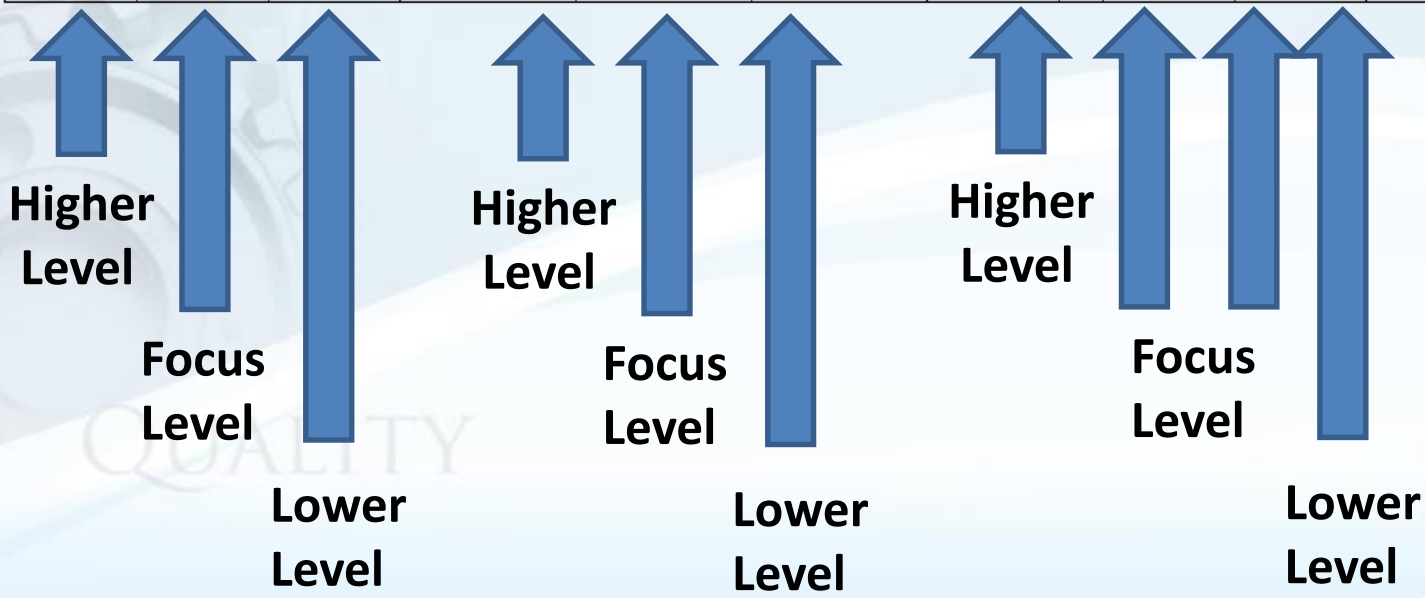


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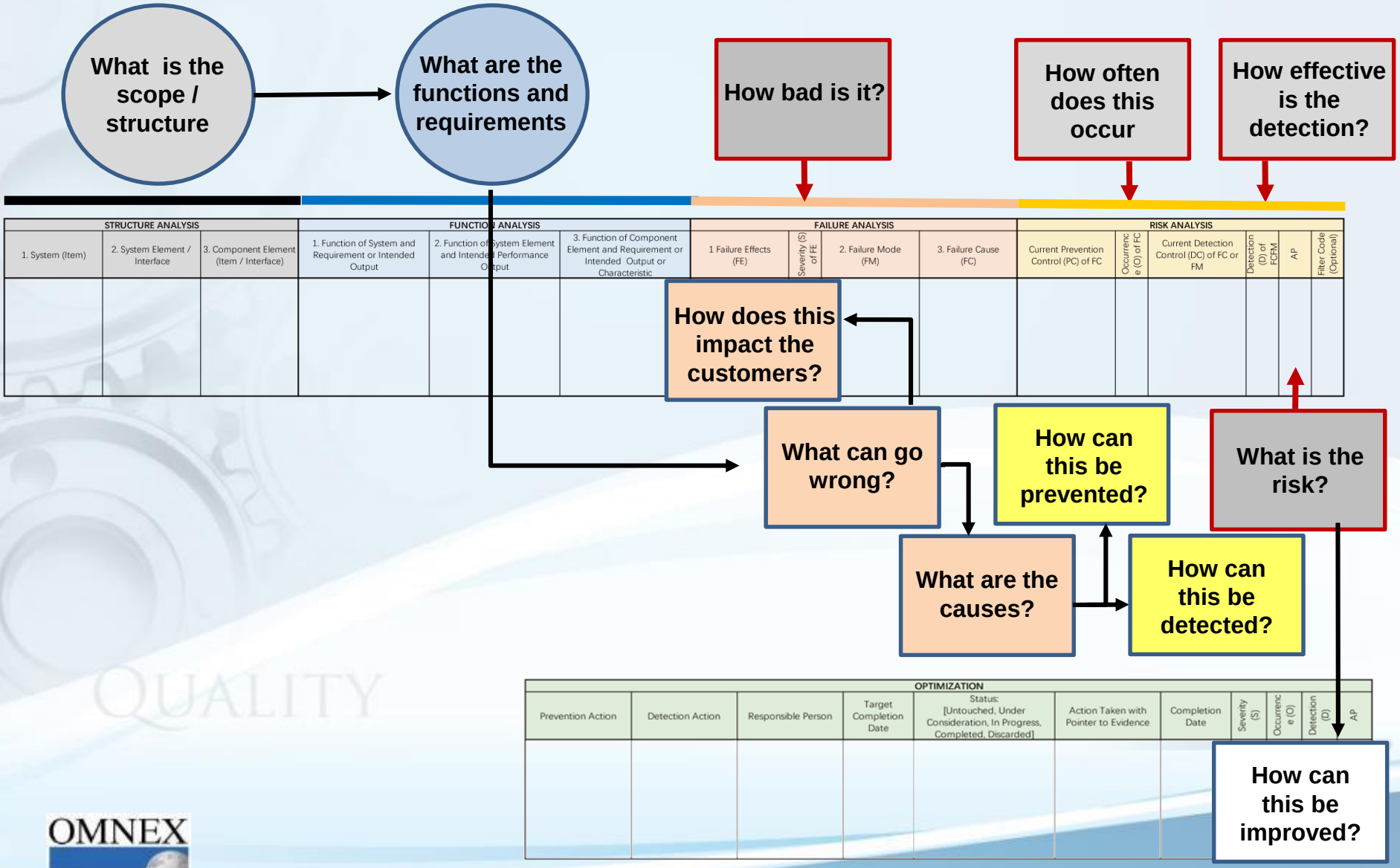
# Sequence – AIAG-VDA FMEA Handbook

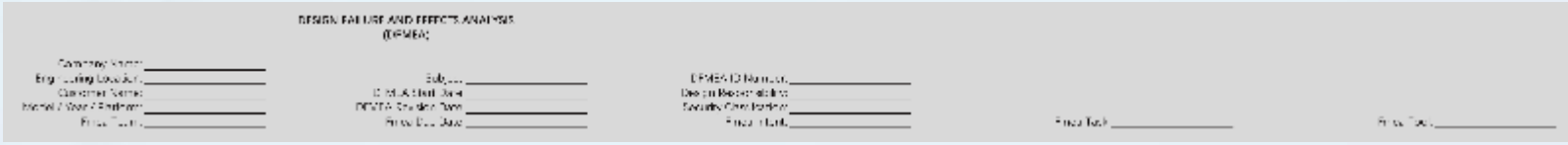



| STRUCTURE ANALYSIS | | | FUNCTION ANALYSIS | | | FAILURE ANALYSIS | | | | RISK ANALYSIS | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. System (Item) | 2. System Element / Interface | 3. Component Element (Item / Interface) | 1. Function of System and Requirement 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) | Current Prevention Control (PC) of FC | Occurrence (O) of FC | Current Detection Control (DC) of FC or FM | Detection (D) of FC/FM | 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 |
| | | | | | | | | | | |

# 7-Steps and the Form

**1st Step**
**Planning and Preparation**




## System Analysis and Risk Mitigation

**2nd Step**
**Structure Analysis**

**3rd Step**
**Function 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 |

**4th Step**
**Failure Analysis**

**5th Step**
**Risk Analysis**

| 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 FC/FM | AP | Filter Code (Optional) |

**6th 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 |

**7th Step**
**Results Documentation**

Layout of document may be company-specific

# Chapter 2: Developing an FMEA – What We Covered

## Learning Objectives

You should now be able to:

- Describe the structure of an FMEA
- Describe the steps to conduct an FMEA

## Chapter Agenda

- Conducting an FMEA
- Basic Structure of an FMEA

# Chapter 3

## Design FMEA Prerequisites

| System Analysis (Prerequisites) | | |
|---|---|---|
| 1st Step<br>Preparation | 2nd Step<br>Structure Analysis | 3rd Step<br>Function Analysis |
|  |  |  |
| Project Identification | Visualization of the Analysis Scope | Visualization of Product or Process Functions |

*"If I had six hours to cut down a tree, I would spend four hours sharpening the axe."*

**– Abraham Lincoln**

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# Chapter 3: Design FMEA Prerequisites – What We Will Cover

## Learning Objectives

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

- Describe who the customer is for FMEAs
- Explain design functions
- Complete a Function Analysis
- Describe Planning and Preparation
- Describe the scope of analysis
- Complete a Boundary Diagram
- Describe the purpose of a P-Diagram and Interface Matrix

## Chapter Agenda

- Step 1: Planning and Preparation
  - Scope of Analysis
- Step 2: Structure Analysis
  - Boundary Diagrams
  - P-Diagram
  - Interface Matrix
- Step 3: Function Analysis – Product Design

# PROJECT PLANNING

1st Step Planning and Preparation

Project Identification

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

Boundary/Block Diagram
Structure Development
*P-Diagram*
*Interface Diagram* (optional)

3 **FUNCTION ANALYSIS**

Functions *and Requirements*

4 **FAILURE ANALYSIS**

*Causes in Focus Level before*
causes in Lower Levels

5 **RISK ANALYSIS**

5b Link Special Characteristics to Functions/Requirements

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b Link to DVP&R

**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

***Italic font*** = Omnex-specific changes to the AIAG-VDA DFMEA process

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# Step 1: Project Planning and Preparation

The purpose of the Design FMEA Preparation Step is to define what is included and excluded in the FMEA based on the type of analysis being developed, i.e. system, subsystem or component.

**The main objectives of Design FMEA Preparation are:**

- Project identification and boundaries
- Project plan: InTent, Timing, Team, Tasks, Tools (5T)
- Analysis boundaries: What is included and excluded from the analysis
- Identification of baseline FMEA with lessons learned
- Basis for the Structure Analysis step

# Understanding the Scope of the Analysis

## 1st Step: Planning and Preparation

**5Ts**

- FMEA inTent
  - Why are we here?
- FMEA Team
  - Who needs to be on the team?
- FMEA Timing
  - When is this due?
- FMEA Task
  - What work needs to be done?
- FMEA Tool
  - How do we conduct the analysis?

**Key Aspects:**

- What to include and what to exclude in FMEA
- FMEA project plan including important dates, responsible persons, potential team members, timelines...
- Boundaries of the analysis

# 5Ts — 1. FMEA InTent

- It is recommended that members of the FMEA team are competent in the method, based on their role on the team.
- When members of the team understand the purpose and intent of the FMEA, they will be more prepared to contribute to the goals and objectives of the project.

# 5Ts — 2. FMEA Timing

- One of the most important factors for the successful implementation of an FMEA program is timeliness.
- Up-front time spent properly completing an FMEA, when product/process changes can be most easily and inexpensively implemented, will minimize late change crises.
- The FMEA should be carried out according to the project plan (APQP) and be evaluated at the project milestones according to the state of the analysis.
- The FMEA as a method for system analysis and failure prevention is best initiated at an early stage of the product development process.

# 5Ts — 2. FMEA Timing

**Senior Management Commitment to Timing:**

- The FMEA workshop needs to start on time and should be part of the Design Timing Schedule.
- Companies have more success with FMEAs when allotted time is built into the schedule.
- Engineers need to have FMEA activities built into the schedule and have interest shown by senior management.
- Senior Management interest is shown by:
  - Regular FMEA gate reviews
  - Being educated in FMEA
  - Supporting FMEA education
  - Supplying any resources required

# 5Ts — 3. FMEA Team

- The FMEA team consists of multi-disciplinary (cross-functional) members who encompass the necessary subject matter knowledge.
- This should include facilitation expertise and knowledge of the FMEA process.
- The success of the FMEA depends on active participation of the cross-functional team as necessary to focus on the topics of discussion.

# 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.

***This, in itself, is sufficient justification for using the FMEA process.***

***FMEA 4th Edition***

*Without a team, very little analysis is likely to occur and the associated risks may be either underestimated or missed entirely*

# FMEA Team

**The Core Team may consist of the following people:**

- Facilitator
- Design Engineer
- System Engineer
- Component Engineers
- Test Engineer
- Quality/Reliability Engineer
- Others responsible for the development of the product

**The Extended Team may consist of** others that may have specialized knowledge that will help the core team analyze specific aspects of the product.

# 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

# Keys to FMEA Team Success

## Support by Management

- Ensure competency of team members
- Team sized for the task
- Scope not too large
- Objectives well-defined
- Follow a well-defined process
- Objectives considered relevant and significant
- A measurable for success identified
- Time is allotted for analysis and improvement
- Activity integrated with organization's development process
- Input information and data are available

# Management Responsibility

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

***FMEA 4th 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 Handbook 1st Edition***

# Senior Management Commitment

The FMEA process can take considerable time to complete! Important to FMEA development are the active participation of the product and process owners and commitment from senior management. Senior Management carries the responsibility for the application of FMEA:

- Ultimately, senior management is responsible for acceptance of the risks and risk minimization actions identified in the FMEA.
- Senior management needs to make FMEAs a critical topic during Design Reviews.
- Senior management needs to take an active interest in the results of an FMEA and support the mitigation of the risk, whatever time and resources are required.

- Senior management is responsible for the “FMEA” culture in the company.

# Senior Management Commitment

- Senior Management interest is shown by:
  - Regular FMEA reviews
  - Being educated in FMEA
  - Supporting FMEA education
  - Supplying any resources required
- Companies have more success with FMEAs when allotted time is built into the schedule.
- Engineers need to have built FMEA activities into the schedule and have interest shown by senior management.

# 5Ts — 4. FMEA Tasks

- The 7-Step Overview provides the framework for the tasks and deliverables of the FMEA. In addition, the FMEA team should be prepared to review the results of their analysis with management and the customer, upon request.
- The FMEA may also be audited by an internal auditor, customer auditor, or third-party registrar to ensure each task has been fulfilled.

# 5Ts — 4. FMEA Tasks

Seven Step Approach

| System Analysis | | | Failure Analysis and Risk Mitigation | | | Risk Communication |
|---|---|---|---|---|---|---|
| 1st Step<br>Planning & Preparation | 2nd Step<br>Structure Analysis | 3rd Step<br>Function Analysis | 4th Step<br>Failure Analysis | 5th Step<br>Risk Analysis | 6th Step<br>Optimization | 7th Step<br>Results Documentation |
|  |  |  |  |  |  |  |
| Project identification | 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 |
| Project plan: InTent, Timing, Team, Tasks, Tools (5T) | **DFMEA:**<br>Structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts<br><br>**PFMEA:**<br>Structure tree or equivalent: process flow diagram | **DFMEA:**<br>Function tree/net, function matrix parameter diagram (P-diagram)<br><br>**PFMEA:**<br>Function tree/net or equivalent process flow diagram | **DFMEA:**<br>Potential Failure Effects, Failure Modes, Failure Causes for each product function<br><br>**PFMEA:**<br>Potential Failure Effects, Failure Modes, Failure Causes for each process function | **DFMEA & PFMEA:**<br>Assignment of Prevention Controls to the Failure Causes<br><br>**DFMEA & PFMEA:**<br>Assignment of Detection Controls to the Failure Causes and/or Failure Modes<br><br>**FMEA-MSR:**<br>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:<br>• Executive summary<br>• Scope of the FMEA<br>• A reference to the specific S/O/D Rating Tables used in the analysis<br>• Action Priority<br>• Results and conclusions of the analysis |
| Analysis boundaries: What is included and excluded from the analysis | **DFMEA:**<br>Identification of design interfaces, interactions, close clearances<br><br>**PFMEA:**<br>Identification of process steps and sub-steps | **DFMEA:**<br>Cascade of customer (external and internal) functions with associated requirements<br><br>**DFMEA & PFMEA:**<br>Association of requirements or characteristics to functions | **DFMEA:**<br>Identification of product failure causes using a parameter diagram or failure network<br><br>**PFMEA:**<br>Identification of process failure causes using a fishbone diagram (4M) or failure network | **DFMEA & PFMEA:**<br>Rating of Severity, Occurrence and Detection for each failure chain<br><br>**FMEA-MSR:**<br>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. |

# 5Ts — 5. FMEA Tools

- There are numerous FMEA software packages that can be used to develop a DFMEA and PFMEA as well as follow up on actions.
- This software ranges from dedicated FMEA software to standard spreadsheets customized to develop the FMEA.
- Companies may develop their own in-house database solution or purchase commercial software.

# 5Ts — 5. FMEA Tools

- In any case, the FMEA team needs to have knowledge of how to use the FMEA software selected for their project as required by the company.
- There are two views of FMEA examples shown in the manual.
- The Software View depicts what the user sees when developing a FMEA using specialized software that utilized e.g. system element structure, function net, failure net, etc.
- The Form (or Matrix) View depicts what the user sees when developing a FMEA in a spreadsheet.

**Note:** The development of the steps will be shown using the "Form" (manual) approach with Excel and the software approach using the web-based software from OnmexSystems EwQIMS.

# Project Plan

**The Project Plan is the output from the 5T process.**

- The DFMEA Project Plan (subset of the APQP Plan) should be developed once the DFMEA project is known.
- The DFMEA activities (The 7-Step Process) should be incorporated into the plan.

# Identification of the Baseline or Foundation FMEA

**Part of the preparation for conducting the DFMEA is knowing what information is already available.**

- This includes the use of a baseline (foundation) DFMEA or product family DFMEA which allows for variances based on different customers buying similar product or systems.
- Like brake systems, in general they basically are the same, but have variances based on the customer.

# Identification of the Baseline or Foundation FMEA

A Family DFMEA is a specialized foundation design FMEA for products:

- Common Boundaries
- Related Functions
- A “New Product” in the family, the new specific components and functions would be added to the family

**Note: This requires a subject matter expert design engineer to decide if the variance is unique or may drive a change to fundamental system.**

# DFMEA HEADER INFORMATION

# Header Information

During Scope Definition, the header of the DFMEA document should be completed. The header includes some of the basic DFMEA scope information, as follows ➔

- The FMEA header should clearly identify the focus of the FMEA as well as information related to the document development and control process.
- This may include an FMEA number, identification of the scope, design responsibility, completion dates, etc.
- Needs to be consistent with the other Design and Process documentation information.

# Header Information

- **Company Name:** Name of company of the DFMEA
- **Engineering Location:** Geographical Location
- **Customer Name:** Name of customer(s) for this document and System / Subsystem / Component / Part
- **Model Year / Platform:** Starting vehicle model year and/or vehicle program as applicable
- **Subject:** Name of DFMEA project
- **DFMEA Start Date:** The date the team initiates the DFMEA
- **DFMEA Revision Date:** The revision of the specific unique DFMEA document (latest date it was changed)
- **Cross-Functional Team:** DFMEA development team members
- **DFMEA ID Number:** A unique identification number for the DFMEA document
- **Design Responsibility:** Name of person who is responsible for the design; this person also accepts ownership of the content and findings of the DFMEA
- **Confidentiality Level:** The level of confidentiality determined by the DFMEA owner, e.g. Internal Business Use, Proprietary, Confidential

# AIAG VDA

## Interactive Example using EwQIMS Software

# STRUCTURE ANALYSIS

2nd Step
Structure Analysis

Visualization of the Analysis Scope

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

Boundary/Block Diagram
Structure Development
*P-Diagram*
*Interface Diagram* (optional)

3 **FUNCTION ANALYSIS**

Functions *and Requirements*

4 **FAILURE ANALYSIS**

*Causes in Focus Level before*
causes in Lower Levels

5 **RISK ANALYSIS**

5b Link Special Characteristics to Functions/Requirements

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b Link to DVP&R

**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

***Italic font*** = Omnex-specific changes to the AIAG-VDA DFMEA process

OMNEX

# Step 2: Structure Analysis

## Boundary or Extent of the DFMEA

### Defines what is included and excluded from the analysis

**Need to know:**

- What is included
- What is not included
  - That is, what is the scope of the analysis?
    - Component
    - Assembly
    - Subsystem
    - System
- Common Tools Used
  - Boundary (Block) Diagram
  - Step 2 Activities
    - Structural (Tree) Analysis
    - Interface Matrix
    - Parameter (P) Diagram

# BOUNDARY DIAGRAMS

# Boundary Diagram

Graphical illustration of the relationships between the subsystems, assemblies, subassemblies, and components within the object as well as the interfaces with the neighboring systems and environments.

- Early in the design program, a Boundary Diagram may be no more than a few blocks representing major functions and their interrelationships at the system level.
- As the design matures, Boundary Diagrams may be revised, or additional ones developed to illustrate lower levels of detail – all the way down to the component level.

# Boundary Diagram

The Boundary or Block Diagram indicates the flow of information, energy, force, fluid, etc. within the scope of the design.

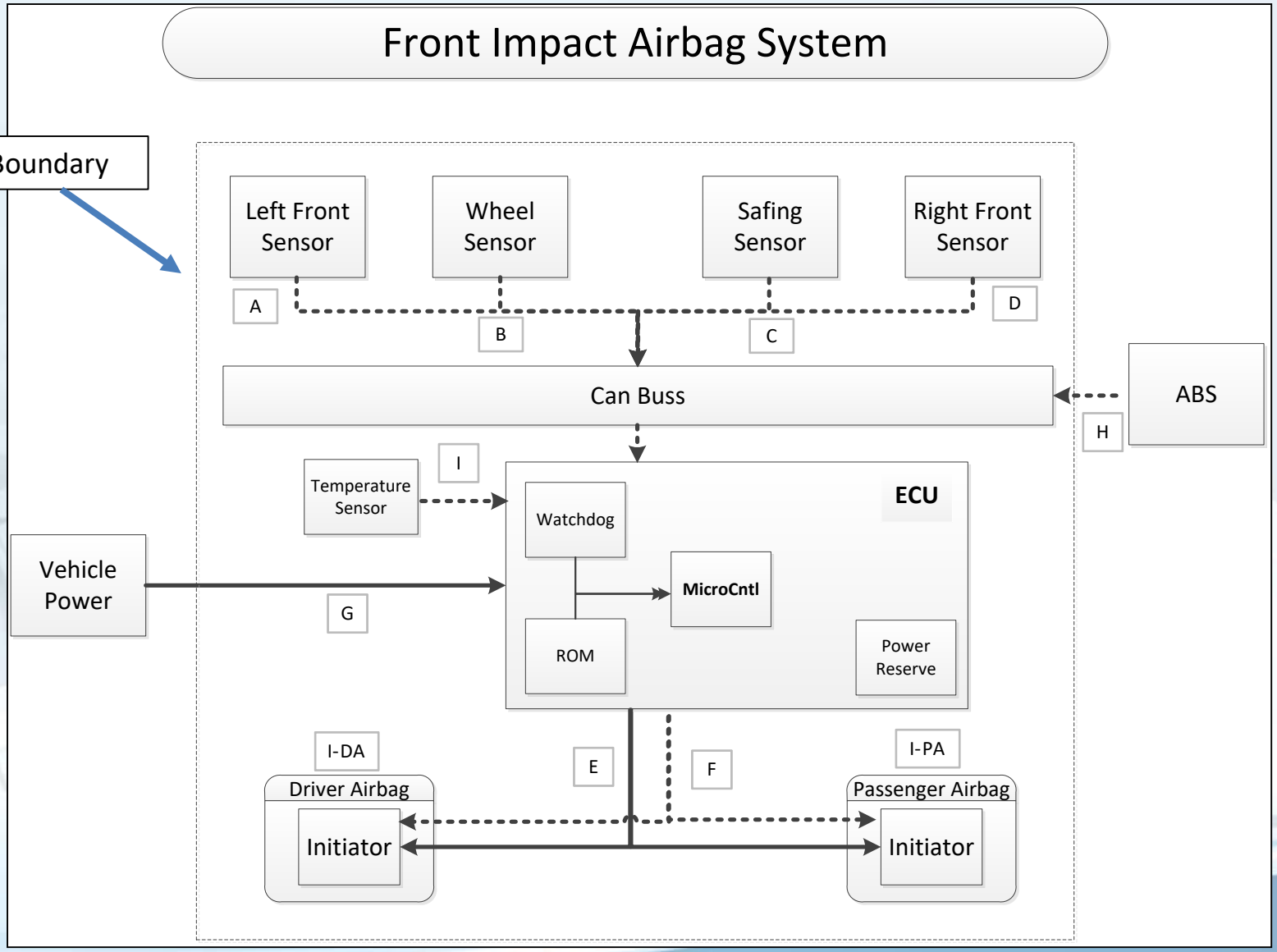
- The objective is to understand the deliverables (input) to the block, the process (function) performed in the block, and the deliverables (output) from the block.
- The Block Diagram of the product shows the physical and logical relationships between the components of the product.
- There are different approaches / formats to the construction of a Block Diagram.

# Boundary Diagram – Airbag

An airbag is a vehicle safety device. It is an occupant restraint consisting of a flexible envelope designed to inflate rapidly in an automobile frontal collision in excess of 14 mph (solid barrier) to prevent vehicle occupants (driver and front passenger) from striking interior objects such as the steering wheel, dashboard or window.

- The design is conceptually simple; a central "**Airbag Control Unit**" (ACU) (a specific type of ECU) monitors an impact sensor.
- When the requisite 'threshold' has been reached or exceeded by the collision detecting sensor, the Airbag Control Unit will trigger the ignition of a gas generator propellant to rapidly inflate a nylon fabric bag.

# Boundary Diagram – Airbag System




Class Case Study

# Item Boundaries

| *Reference* | *Name* | *Type* | *In Scope of item?* | *Relationship to the item* |
|---|---|---|---|---|
| *<ID referring to the boundary diagram>* | *<name>* | *<ECU\|Bus\|Sensor\|Actuator>* | *YES/NO* | *<describe the relationship to the item>* |
| FS | front sensor | Sensor | yes | senses front collision |
| ECU | control unit | ECU | yes | control unit |
| I-DA | initiator - driver airbag | Actuator | yes | provides sufficient volume of gas to deploy airbag |
| I-PA | initiator - passenger airbag | Actuator | yes | provides sufficient volume of gas to deploy airbag |
| VS | Vehicle speed | Sensor | no | provides speed information to the system |
| VP | vehicle power | Power Source | no | Provides vehicle power to the system |

# AIAG VDA

## Interactive Example using EwQIMS Software

# Appreciation of a System

**Dr. W. Edwards Deming includes Appreciation of a System within his System of Profound Knowledge**

- Synthesis – Explains the reason for the system and how the ***system*** works.
  - Take the thing you want to understand as part of a larger whole.
  - Explain the behavior of the containing whole.
  - Disaggregate the understanding of the containing whole into the role or function of the parts.
- Understanding of a system never lies inside the system; it always lies outside the system.
  - To manage a system effectively, focus on the interactions.
  - Improve the performance of a part only if it improves the performance of the whole.

# Step 2: Structure Analysis

Information gathered in the Planning step is transferred to visualize the relationships and interactions between the design or process elements.


- **Goal of Structure Analysis**
  - An overview of the system structure of the product
  - Definition of the system boundaries/interface description
  - Allows for the reuse of system elements

Note: the AIAG-VDA requires at least 3 levels in the structure:

Higher Level > Focus Level > Lower Level

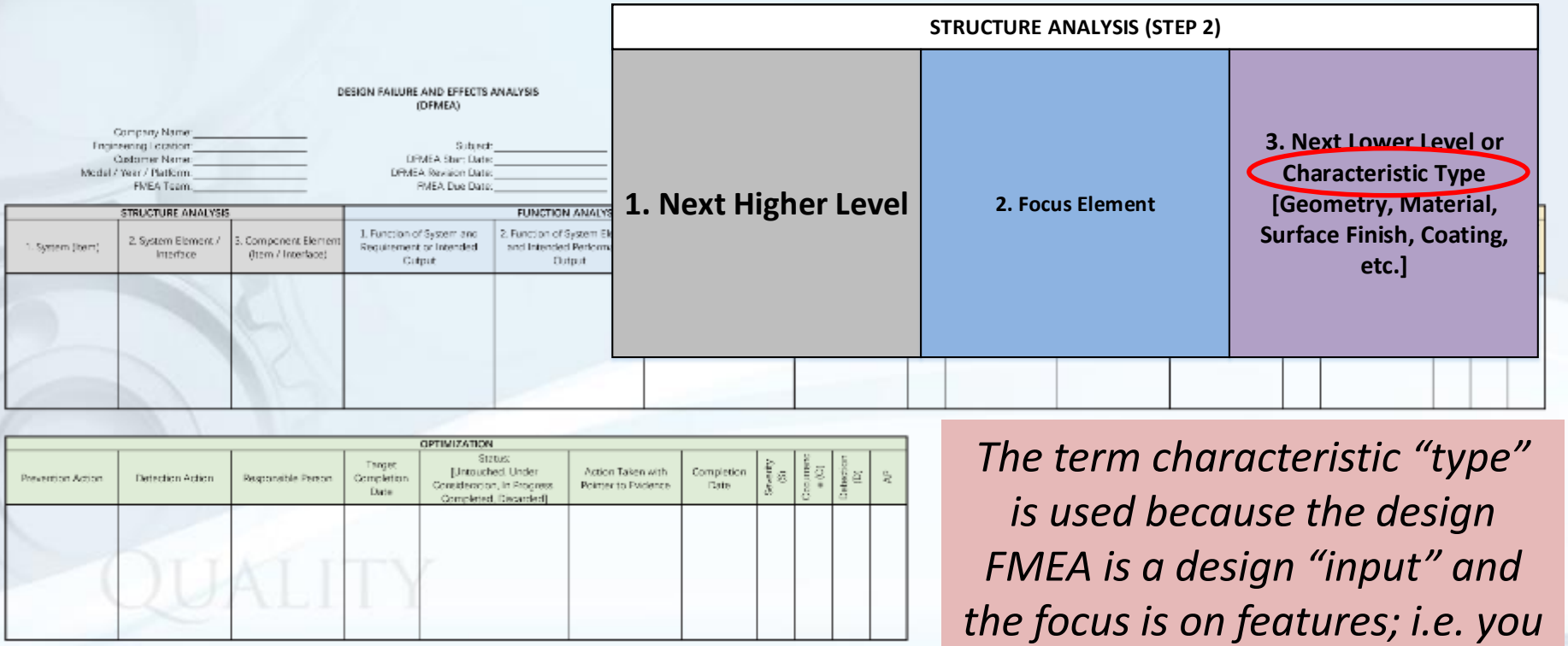
# Structure Analysis: Structure Trees

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections.

- A clearly structured illustration of the complete system is guaranteed to prevent redundancy by the fact that each system element exists only once.
- The interactions between System Elements may be described later as functions and represented by function nets (see Step 3 Function Analysis).
- There **IS** always a system element present, even if it **IS** only derived from the function and cannot yet be specified more clearly.

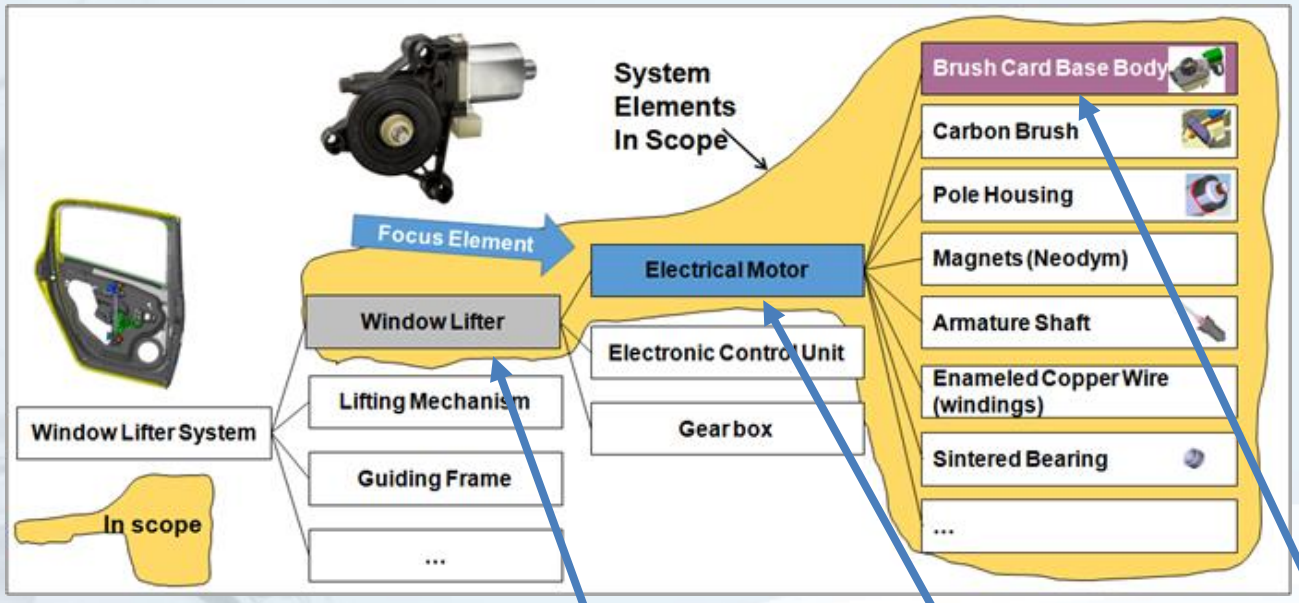
# Structure Analysis: System Structure in Excel

The system structure can be created in the Structure Analysis section of the Spreadsheet:




*The term characteristic "type" is used because the design FMEA is a design "input" and the focus is on features; i.e. you do not have the characteristics yet!*

# Example of Structure




**Software Version**

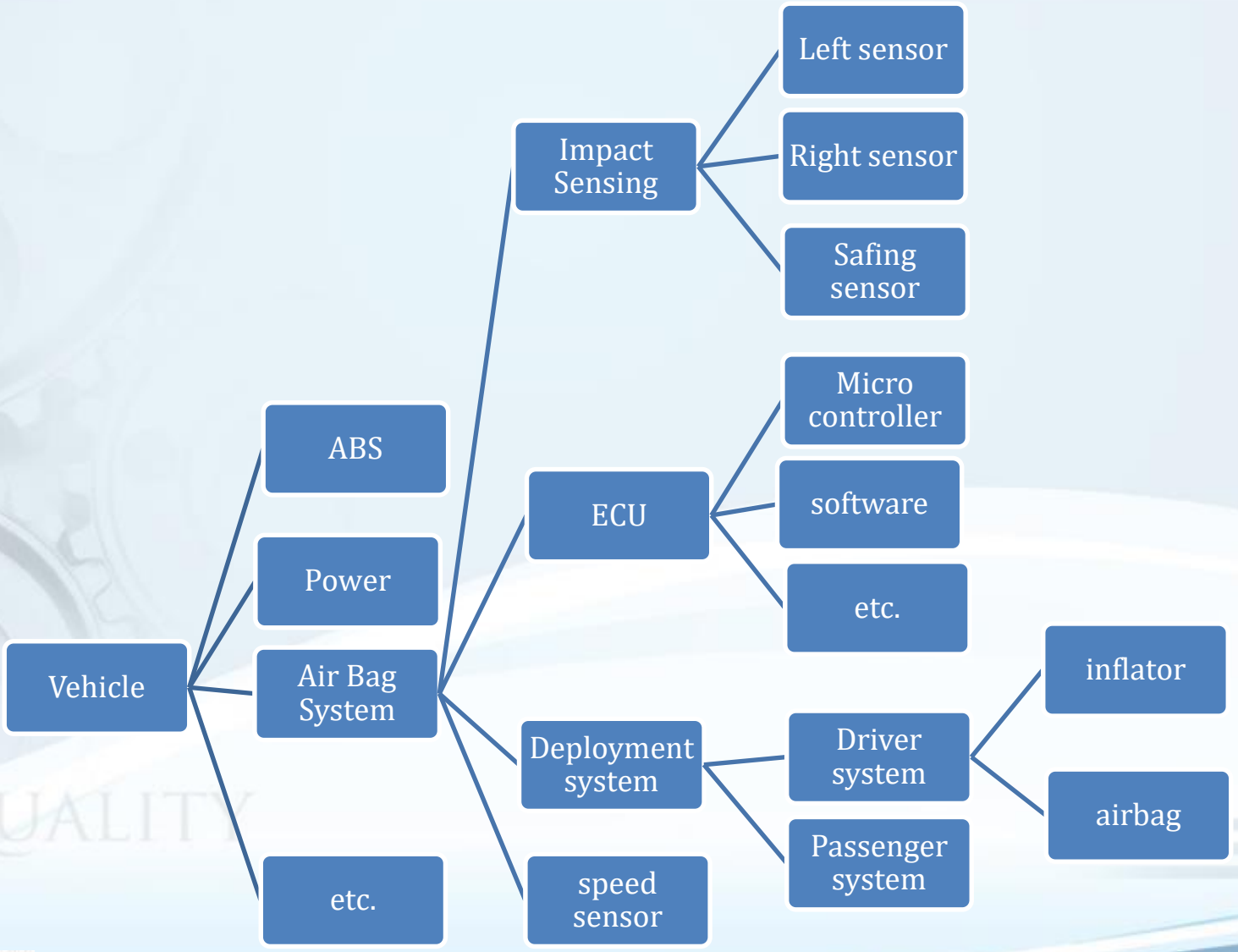
**Form or Matrix Version**

| STRUCTURE ANALYSIS (STEP 2) | | |
|---|---|---|
| 1. Next Higher Level | 2. Focus Element | 3. Next Lower Level or Characteristic Type |
| Window Lifter | Electrical Motor | Brush Card Base Body |
| | | Carbon Brush |
| | | Pole Housing |
| | | Etc. |

*Adapted from: AIAG-VDA FMEA Handbook 1st Edition*

Class Case Study

# System Structure



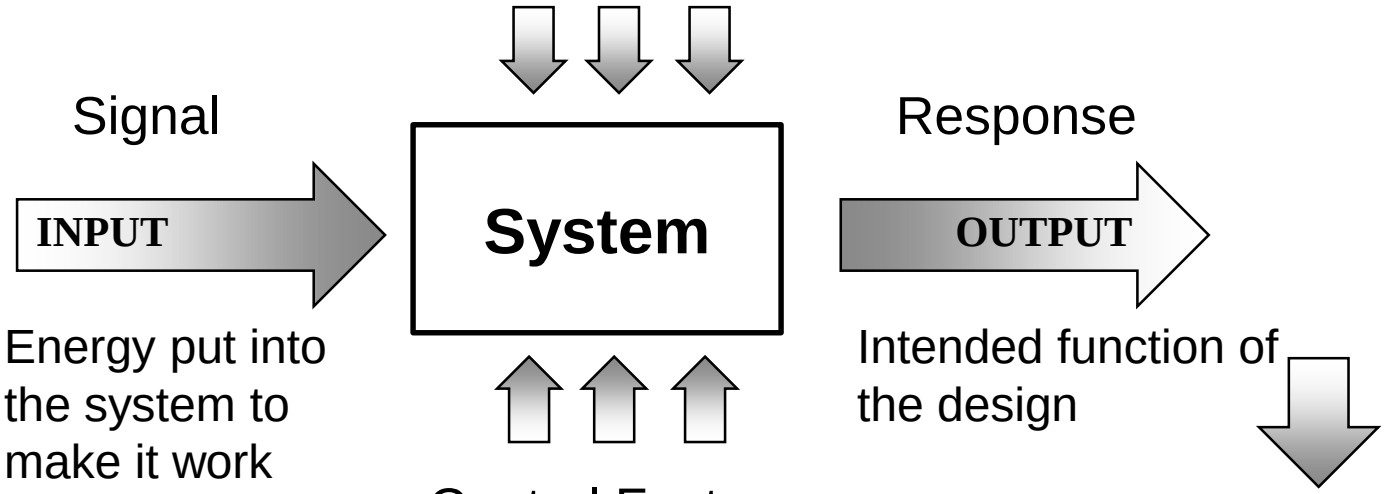
# Parameter (P) – Diagram

- A structured tool to help the team understand the physics related to the function(s) of the design.
  - The team analyzes the intended inputs (**Signals**) and outputs (**Functions**) for the design as well as those controlled and uncontrolled factors which can impact performance.
- Once the inputs and outputs are identified, error states, noise factors, and control factors are then established.

## 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

### Error States

Undesirable output or Failure Modes

- Compliance
- Functional
- Annoyance

# Interface Analysis

**An interface analysis describes the interactions between elements of a system.**

- There are five primary types of interaction:
  - Physical Connection (Brackets, Bolts, Clamps, Adhesive, etc.)
  - Material Exchange (Air, Hydraulic Fluid, Fuel, etc.)
  - Energy Transfer (Heat, Friction, High Voltage, or Motion)
  - Data Exchange (Inputs, Outputs, Carriers, information exchange, cyber security items)
  - Human-Machine (Controls, switches, mirrors, glass reflection, displays, seating)
  - Clearances
  - Interfaces between subsystem and components
- The interface analysis document is the boundary diagram and also the P-Diagram.

# Interface Matrix

- Illustrates relationships between the subsystems, assemblies, subassemblies, and components within the object as well as the interfaces with the neighboring systems and environments.
- Documents the details, such as types of interfaces, strength/importance of interface, potential effect of interface, etc.

# Interface Matrix – Airbag

Class Case Study

| P | E |
|---|---|
| I | M |

P: Physically touching E: Energy transfer
I: Information exchange M: Material exchange

Numbers in each corner represent the above interface types, with values denoting the following:

+2 Interaction is necessary for function

+1 Interaction is beneficial, but not absolutely necessary for functionality

0 Interaction does not affect functionality

-1 Interaction causes negative effects but does not prevent functionality

-2 Interaction must be prevented to achieve functionality

| | Front Sensor | Control Unit | Initiator – Driver | Initiator – Passenger | Driver Airbag | Passenger Airbag | 0 |
|---|---|---|---|---|---|---|---|
| **Front Sensor** | | 0 2<br>0 0 | 0 -2<br>0 0 | 0 -2<br>0 0 | 0 0<br>0 0 | 0 0<br>0 0 | 0 0<br>0 0 |
| **Control Unit** | 2 | | 0 2<br>0 0 | 0 2<br>0 0 | 0 0<br>0 0 | 0 0<br>0 0 | 0 0<br>0 0 |
| **Initiator – Driver** | -2 | 2 | | 0 -2<br>-2 0 | 0 0<br>2 0 | 0 0<br>-2 0 | 0 0<br>0 0 |
| **Initiator – Passenger** | -2 | 2 | -2 | | 0 0<br>-2 0 | 0 0<br>2 0 | 0 0<br>0 0 |
| **Driver Airbag** | | | 2 | -2 | | 0 0<br>0 0 | 0 0<br>0 0 |
| **Passenger Airbag** | | | -2 | 2 | | | 0 0<br>0 0 |
| | | | | | | | |

# AIAG VDA

## Interactive Example using EwQIMS Software

# FUNCTION ANALYSIS

3rd Step
Function Analysis

Visualization of Product or Process Functions

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

**Boundary/Block Diagram**
**Structure Development**
***P-Diagram***
***Interface Diagram* (optional)**

3 **FUNCTION ANALYSIS**

**Functions *and Requirements***

4 **FAILURE ANALYSIS**

***Causes in Focus Level before***
**causes in Lower Levels**

5 **RISK ANALYSIS**

5b **Link Special Characteristics to Functions/Requirements**

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b **Link to DVP&R**

**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

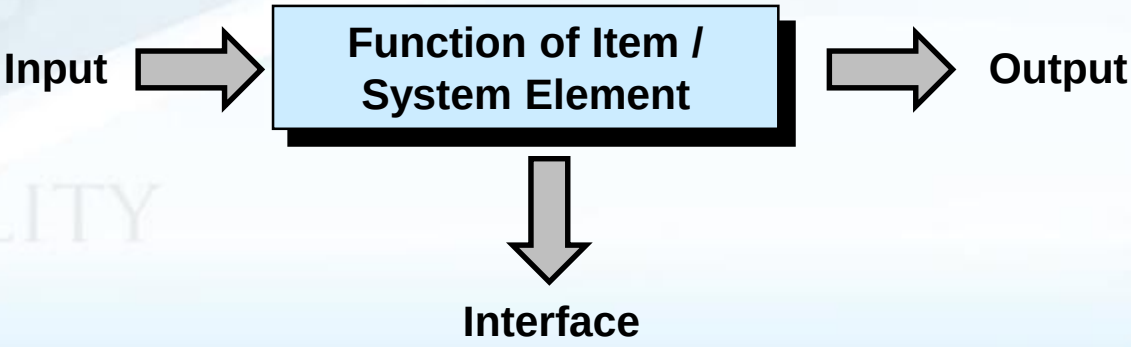
***Italic font*** = Omnex-specific changes to the AIAG-VDA DFMEA process

# Goal of Function Analysis

- Overview of the product functionality and the flow of the functional requirements through the structure
- Verification against the customer requirements / specifications
- Function tree/net, or equivalent function matrix parameter diagram (P-diagram)
- Association of requirements or characteristics to functions
- Overview of cause and effect relationships
- Creating the basis for the failure analysis

# Design Functions

- What **SHOULD** the product/service (structural elements) be doing?
  - What are the Functional Deliverables?
- The description of a function needs to be clear.
- Functions describe the relationship between the input and output of an item system element with the aim of fulfilling a task.



# Design Functions

**Caution:**

- Clearly distinguish between the basic functions of a product, its detailed requirements and design constraints and assumptions.
- For example, a disk brake system has the basic function of stopping a vehicle on demand but it could also have…
  - A specific requirement that the vehicle stops within 200 feet of demand on dry pavement.
  - Design constraints: e.g. size, weight, environment, etc.
- A single function can have multiple requirements.

**Note:** some organizations combine the functions with their requirements. This can lead to confusion in subsequent analyses. It is recommended to record the requirements separate from the base functions.

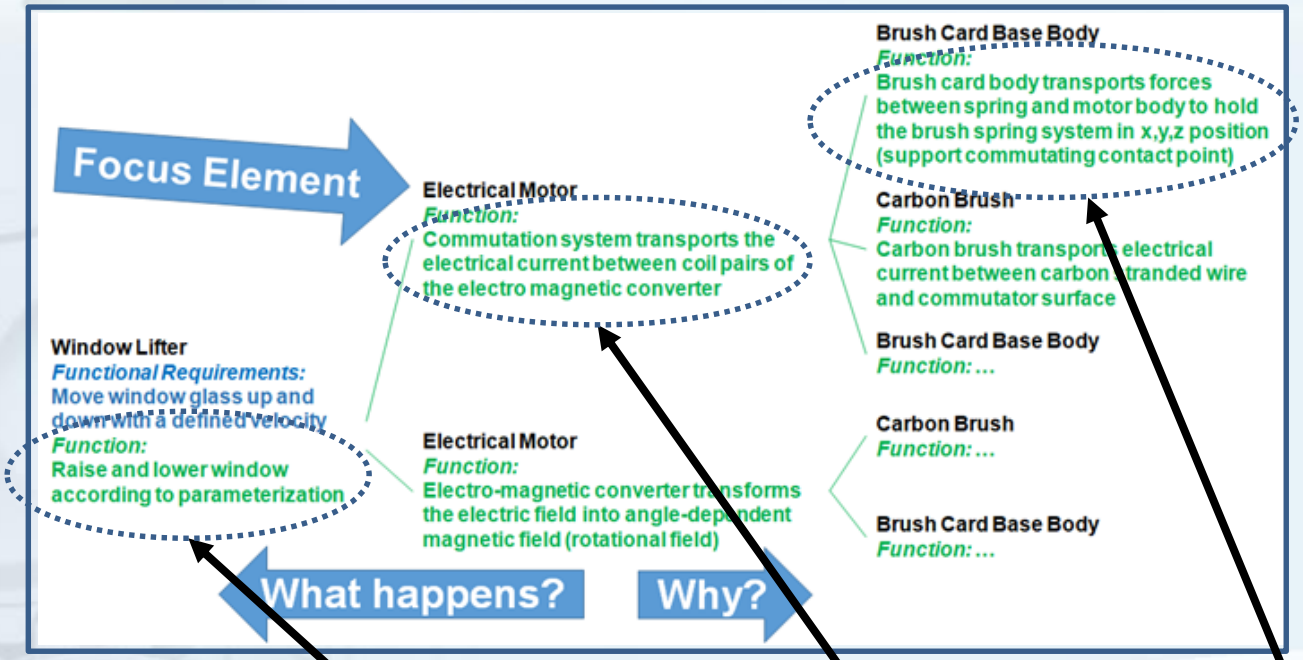
# Requirements

**List all the requirements/deliverables for each function.**

- List each requirement separately.
  - **Recommended:** Provide a name and number for each deliverable to be evaluated.
  - Show design level per engineering drawing.
- The recommended phrase format is to use an "action verb“ followed by a "noun" to describe a measurable function.
- When the product/material must function under certain conditions, document those conditions.

# Function Analysis

- Allocates the identified functional requirements to the system structural elements
- Flows down the functional requirements of the item to the lower level elements
- Answers the question *"What is the purpose of the specific level (system) element?"*




# Example of Functional Analysis to Form

| FUNCTION ANALYSIS (STEP 3) | | |
|---|---|---|
| **1. Next Higher Level Function and Requirement** | 2. Focus Element Function and Requirement | 3. Next Lower Level Function and Requirement or Characteristic |
| **Raise and lower window according to parameterization.** | Commutation system transports the electrical current between coil pairs of the electromagnetic converter | Brush card body trans-ports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point) |

***source: AIAG-VDA FMEA Handbook 1st Edition***

# Matrix Function Analysis

When using a spreadsheet approach, the following three templates should be used (see handout)

**Higher Level**

| STRUCTURE ANALYSIS | FUNCTION ANALYSIS | FAILURE ANALYSIS |
|---|---|---|
| 1. System (Item) | 1. Function of System and Requirement or Intended Output | Higher Level Failure Mode 1 Failure Effects (FE) |

ID

**Focus Level**

| STRUCTURE ANALYSIS | FUNCTION ANALYSIS | FAILURE ANALYSIS |
|---|---|---|
| 2. Focus Element | 2. Function of the Focus Element | Focus Level Failure Mode 2. Failure Mode (FM) |

ID

**Lower Level**

| STRUCTURE ANALYSIS | FUNCTION ANALYSIS | FAILURE ANALYSIS |
|---|---|---|
| 3. Component Element (Item / Interface) | 3. Function of Component Element and Requirement or Intended Output or Characteristic type | Next Lower Level Failure Mode; 3. Failure cause |

ID

# AIAG VDA

## Interactive Example using EwQIMS Software

# Chapter 3: Design FMEA Prerequisites – What We Covered

## Learning Objectives

You should now be able to:

- Describe who the customer is for FMEAs
- Explain design functions
- Complete a Function Analysis
- Describe Planning and Preparation
- Describe the scope of analysis
- Complete a Boundary Diagram
- Describe the purpose of a P-Diagram and Interface Matrix

## Chapter Agenda

- Step 1: Planning and Preparation
  - Scope of Analysis
- Step 2: Structure Analysis
  - Boundary Diagrams
  - P-Diagram
  - Interface Matrix
- Step 3: Function Analysis – Product Design

# Chapter 4

## Developing the Design FMEA

| Failure Analysis and Risk Mitigation | | |
|---|---|---|
| 4th Step<br>Failure Analysis | 5th Step<br>Risk Analysis | 6th Step<br>Optimization |
|  |  |  |
| Establishment of the Failure Chain | Assignment of Existing and/or Planned Controls and Rating of Failures | Identification of the Actions Necessary to Reduce Risks |

OMNEX

# Chapter 4: Developing the Design FMEA – What We Will Cover

## Learning Objectives

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

- Explain design failure modes
- Identify failure modes from requirements
- Explain causes of failure modes
- Explain design controls
- Distinguish between prevention and detection controls
- Explain the key elements of the risk analysis
- Define requirements for Results Documentation and Communication

## Chapter Agenda

- Design Failure Modes
- Step 4: Failure Analysis
  - Potential Effects of Failure
  - Potential Causes of Failure
- Step 5: Design Controls and Risk Analysis
  - Evaluation: Indices and Action Plans
- Step 6: Optimization
- Step 7: Results Documentation

# FAILURE ANALYSIS

4th Step
Failure Analysis

Establishment of the Failure Chain

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

**Boundary/Block Diagram**
**Structure Development**
***P-Diagram***
***Interface Diagram* (optional)**

3 **FUNCTION ANALYSIS**

**Functions *and Requirements***

4 **FAILURE ANALYSIS**

***Causes in Focus Level before***
**causes in Lower Levels**

5 **RISK ANALYSIS**

5b **Link Special Characteristics to Functions/Requirements**

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b **Link to DVP&R**

**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

***Italic font*** = Omnex-specific changes to the AIAG-VDA DFMEA process

OMNEX

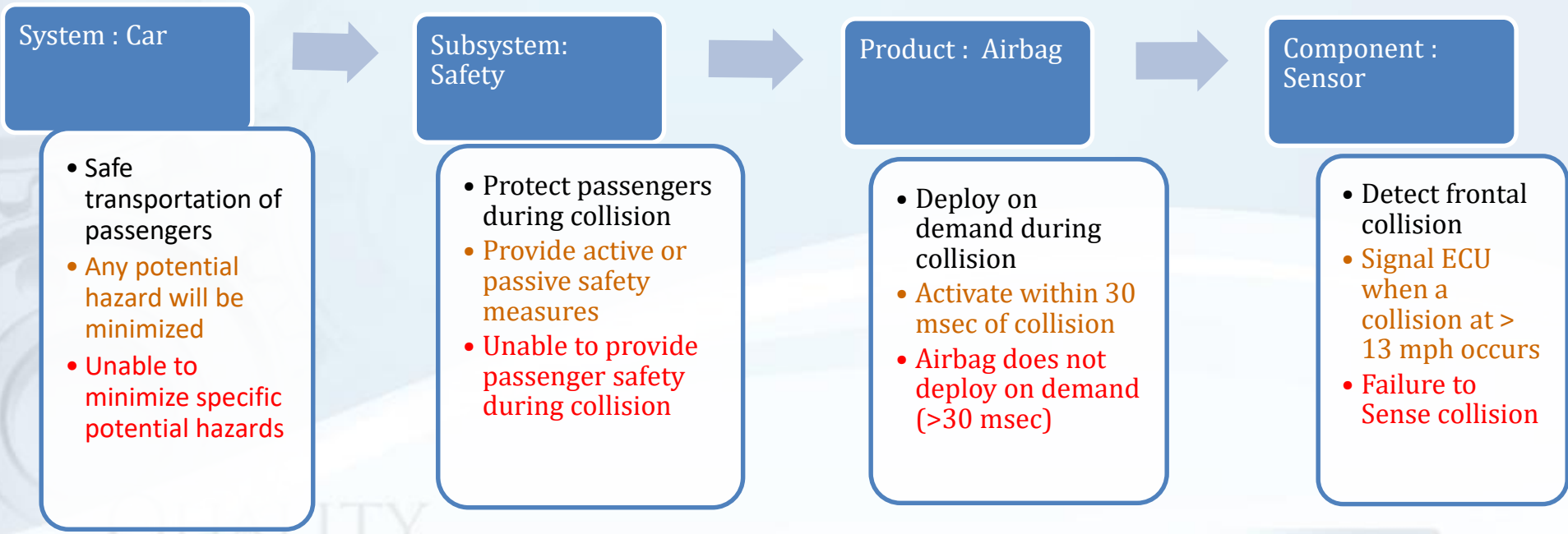
# Potential *Design* Failure Mode

1. Identify and List All the Requirements
2. *For Each Requirement*
   - *Identify Potential Design Related Failure Modes*

How the design could potentially fail to provide a defined function to a customer

# Failure Analysis

Failures of functions are deduced from the functions already identified in Step #3 and in this step (#4)



# 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?

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

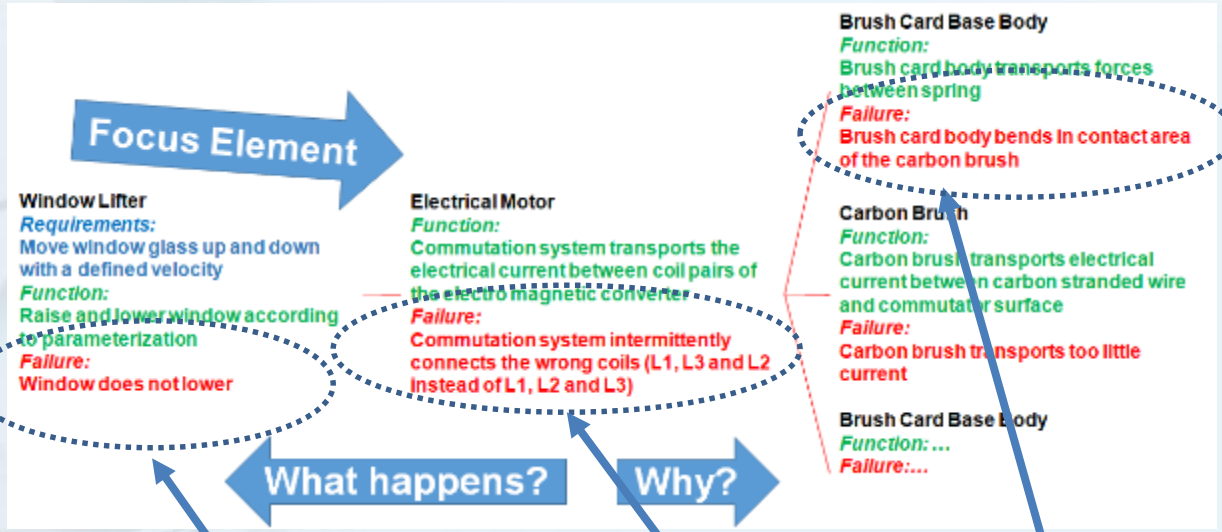
Related Malfunctions

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

# Example

| Item | Function | Requirement | Failure Mode |
|---|---|---|---|
| Disk Brake system | Stop vehicle on demand | Stop vehicle traveling on dry pavement demand within 70 meters from 100 km/hr | Vehicle does not stop |
| | | | Vehicle stops in excess of 70 meters |
| | | | 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 Analysis as Structure Tree and Form




| FAILURE ANALYSIS (STEP 4) | | |
|---|---|---|
| **1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User** | 2. Failure Mode (FM) of the Focus Element | 3. Failure Cause (FC) of the Next Lower Element or Characteristic |
| **Window does not lower** | Commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3) | Brush card body bends in contact area of the carbon brush |

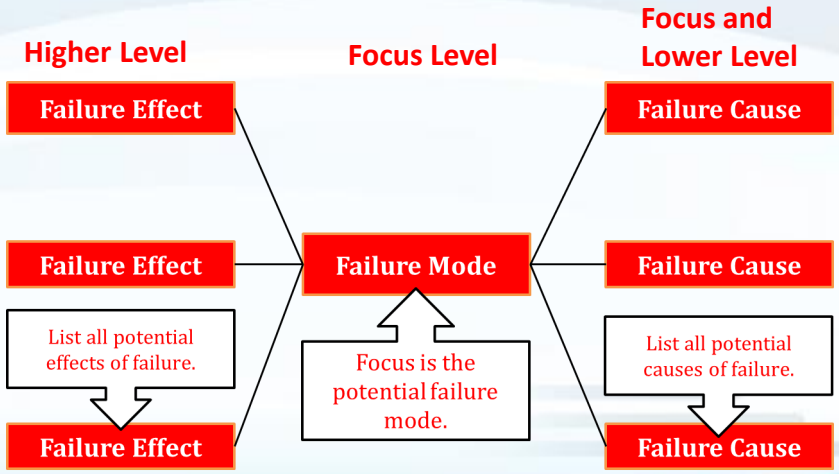
***source: AIAG-VDA FMEA Handbook 1st Edition***

# POTENTIAL EFFECTS OF FAILURE

# FMEA Process

1. Identify and List All the Requirements
2. For Each Requirement
   - Identify Potential Design Related Failure Modes
3. *For Each Failure Mode*
   - *Assess Potential Effects of Failures*
   - Identify the Cause(s)

Failure Net Analysis



# Effect of a Failure Mode

"Potential effects of failure are defined as the effects of the failure mode on the function, as perceived by the customer."

"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."

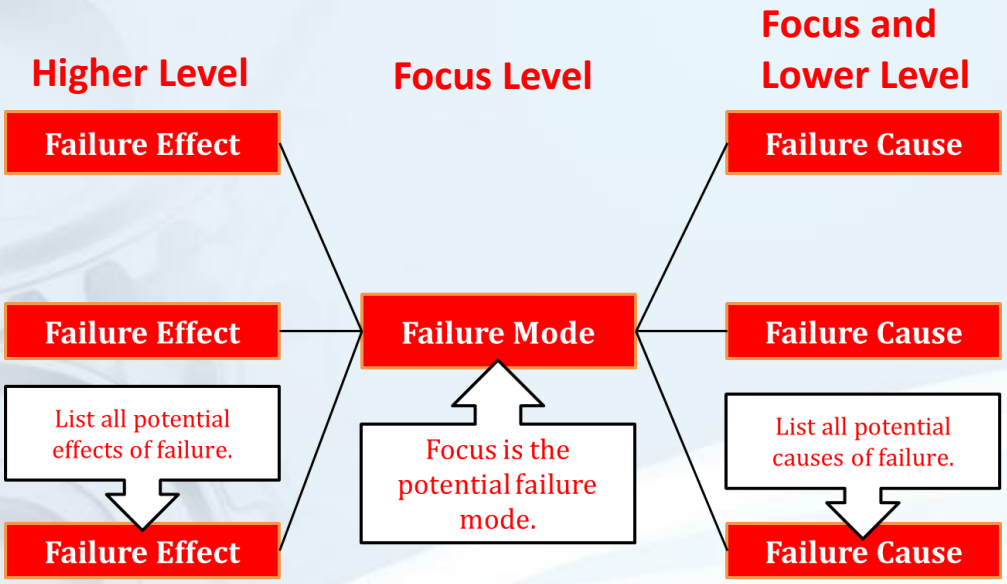
**Source: FMEA Fourth Edition, 2008**

- Customer includes:
  - Manufacturing and Assembly processes of the Product
  - Next higher assembly
  - System
  - Vehicle
  - End-User
  - Government Regulation

The "*so what*" factor – what will be the symptoms?

# Effect in AIAG-VDA FMEA Handbook

In the AIAG-VDA FMEA approach, an effect is the failure mode of the higher level structural element.



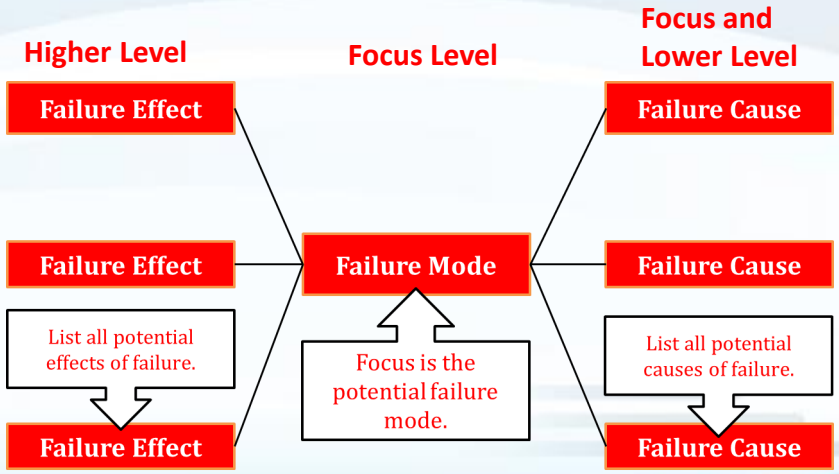

| FAILURE ANALYSIS (STEP 4) | | |
|---|---|---|
| 1. Failure Effects (FE) to the Next Higher Level Element and/ or Vehicle End User | **2. Failure Mode (FM) of the Focus Element** | **3. Failure Cause (FC) at the Focus Level and Next Lower Element or Characteristic** |

# POTENTIAL CAUSES OF FAILURE

# Potential Cause(s) of Failure

1. Identify and List All the Requirements
2. For Each Requirement
   - Identify Potential Design Related Failure Modes
3. *For Each Failure Mode*
   - Assess Potential Effects of Failures
   - *Identify the Cause(s)*

Failure Net Analysis



# Potential Cause(s) of Failure

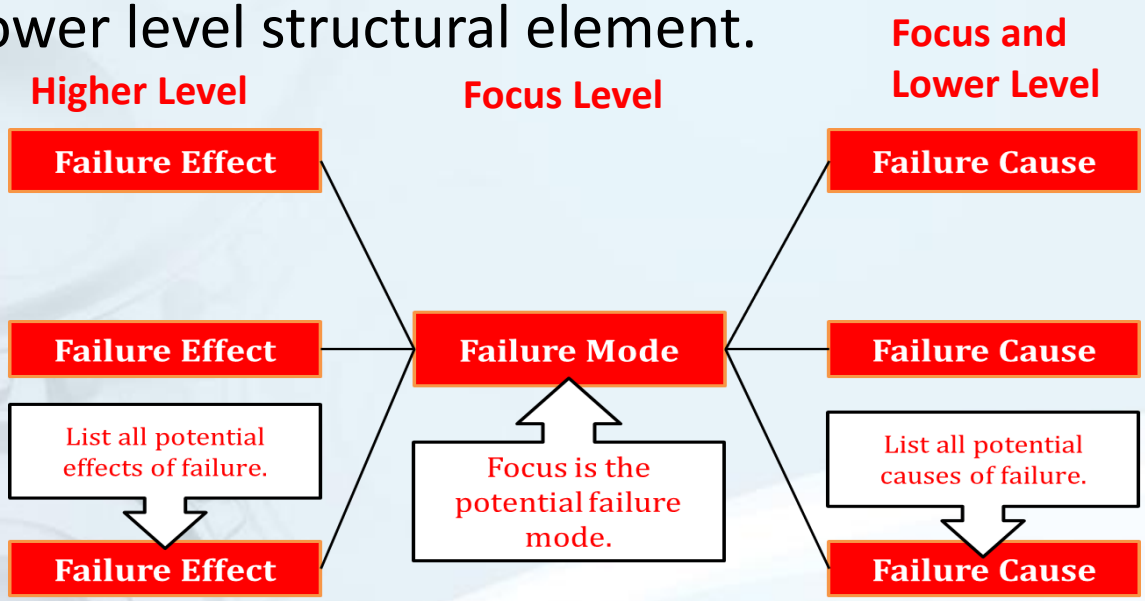
Potential cause of failure is defined as an indication of *how the design process could allow* the failure to occur, described in terms of something that can be corrected or can be controlled.

**Source: FMEA Fourth Edition, 2008**

- Potential cause of failure may be an indication of a design weakness, the consequence of which is the failure mode.
- Causes are the circumstances that induce or activate a failure mechanism.

# Cause in AIAG-VDA FMEA Handbook

In the AIAG-VDA FMEA approach, a cause is the failure mode of the lower level structural element.




| FAILURE ANALYSIS (STEP 4) | | |
|---|---|---|
| 1. Failure Effects (FE) to the Next Higher Level Element and/ or Vehicle End User | **2. Failure Mode (FM) of the Focus Element** | **3. Failure Cause (FC) at the Focus Level and Next Lower Element or Characteristic** |

# Causes

## Causes of Design Failure Modes can stem from

A. Lack of understanding of the actual customer needs

B. Lack of understanding of all functional, safety and reliability requirements

C. Lack of understanding of the specific failure mechanisms
   - Especially related to interfaces
   - Including environmental impacts, expected abuses, etc.

D. Lack of understanding of variation and its propagation

**and**

E. Lack of communication of A – D to lower design levels

# Potential Cause(s) of Failure

Potential cause of failure is defined as how the failure mode could occur, described in terms of something that can be corrected or controlled.

- Each cause assignable to a failure mode should be listed and considered separately.

- In the development of the FMEA, the identification of all potential causes of the failure mode is key to subsequent analysis.
  - Although varied techniques (such as brainstorming) can be used to determine the potential cause(s) of the failure mode, it is recommended that the team should focus on an understanding of the failure mechanism for each failure mode.

# Potential Cause(s) of Failure

- Investigation of causes needs to focus on the failure mode and ***not*** on the effect(s).
- In determining the cause(s), the team should assume the existence of the cause under discussion will result in the failure mode.
  - i.e. assume the failure mode does not require multiple causes to occur.
    - FMEAs assume Single Point Failures (SPF); i.e. the cause will produce the failure mode.
    - Fault Tree Analysis (FTA) allows for analysis of Multiple Point Failures (MPF) (i.e. redundancies).
- If there are several causes for a failure mode, this should result in multiple lines (cause branches) for the failure mode.

Assume the product / service is produced correctly

# Example

| Failure Mode | Mechanism | Cause |
|---|---|---|
| Vehicle does not stop | No transfer of force from pedal to pads | Mechanical linkage break due to design allowing environmental corrosion |
| | | Master cylinder vacuum lock due to seal design |
| | | Loss of hydraulic fluid due to incorrect connector torque specifications |
| | | Loss of hydraulic fluid due to hydraulic lines crimped/compressed, inappropriate tube material specified |
| Vehicle stops in excess of yy feet | Reduced transfer of force from pedal to pads | Mechanical linkage joints stiff due to inappropriate lubrication specification |
| | | Mechanical linkage joints corroded due to inadequate corrosion protection |
| | | Partial loss of hydraulic fluid due to hydraulic lines crimped, inappropriate tube material specified |

# Failure Net Analysis

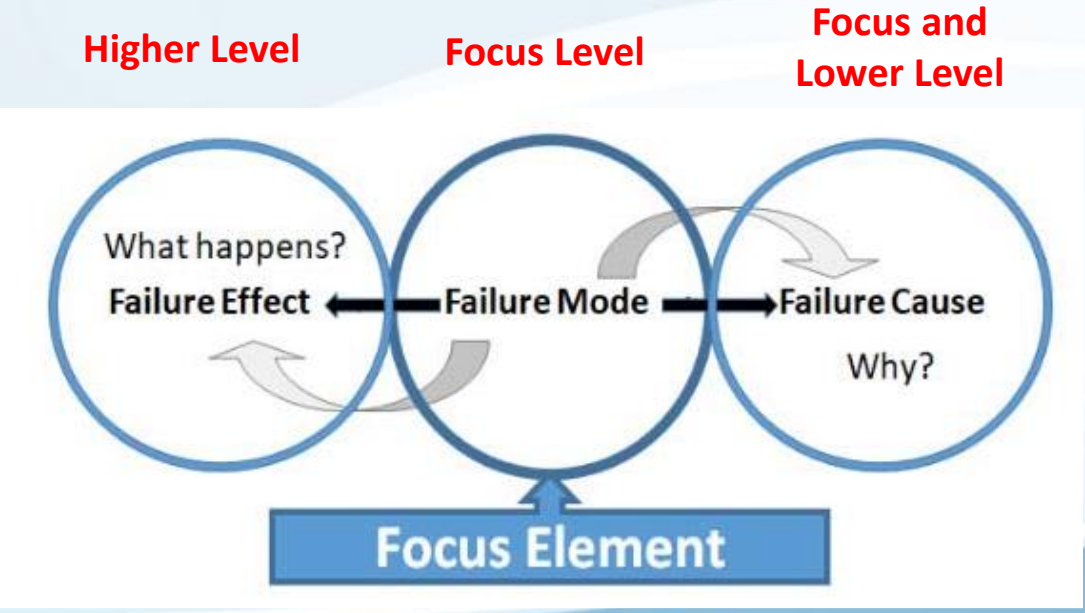
- At this point in the analysis, the functions and requirements and their relayed failure modes have been determined for all levels.
- To determine the causes and effects for each failure mode in each step, Failure Chains need to be developed.

# The Failure Chain

There are three different aspects of failures analyzed in an FMEA:

- **Failure Effect (FE)** the consequences of a failure mode
- **Failure Mode (FM)** manner in which an item could fail to meet or deliver the intended function
- **Failure Cause (FC)** indication of why the failure mode could occur

***Note: these are all failure modes at different levels***



# Failure Analysis as a Matrix

By inspecting the items in the Function Analysis, begin building the Failure Chain.

- **Failure Effects (FE):**
  The effect of failure associated with the “Function of System or System Element” in the Function Analysis.
- **Failure Mode (FM):**
  The mode (or type) of failure associated with the “Function of System Element” in the Function Analysis.
- **Failure Cause (FC):**
  The cause of failure associated with the “Function of Component Element and Output or Characteristic” in the Function Analysis.

# Example Using Spreadsheet Form

| 1. Next Higher Level | 1. Next Higher Level Function and Requirement | 1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User |
|---|---|---|
| Window Lifter Motor | Raise and lower window according to parameterization | Torque and rotating velocity of the window lifter motor too low |

| 2. Focus Element | 2. Focus Element Function and Requirement | 2. Failure Mode (FM) of the Focus Element |
|---|---|---|
| **Electrical Motor** | Commutation system transports the electrical current between coil pairs of the electromagnetic converter | Commutation system intermittently connects the wrong coils (L1, L3 and L2 instead of L1, L2 and L3) |

| 3. Next Lower Level or Characteristic Type | 3. Next Lower Level Function and Requirement or Characteristic | 3. Failure Cause (FC) at the Focus Level and Next Lower Element or Characteristic |
|---|---|---|
| **Brush Card Base Body** | Brush card body transports forces between spring | Brush card body bends in contact area of the carbon brush |

# AIAG VDA

## Interactive Example using EwQIMS Software

# RISK ANALYSIS

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

**Boundary/Block Diagram**
**Structure Development**
***P-Diagram***
***Interface Diagram* (optional)**

3 **FUNCTION ANALYSIS**

**Functions *and Requirements***

4 **FAILURE ANALYSIS**

***Causes in Focus Level before***
**causes in Lower Levels**

**5th Step**
**Risk Analysis**

**Assignment of Existing and/or Planned Controls and Rating of Failures**

5 **RISK ANALYSIS**

5b **Link Special Characteristics to Functions/Requirements**

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b **Link to DVP&R**

**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

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OMNEX

# Design Controls

1. Identify and List All the Requirements
2. For Each Requirement
   - Identify Potential Design Related Failure Modes
3. For Each Failure Mode
   - Assess Potential Effects of Failures
   - Identify the Cause(s)
4. *For Each Cause*
   - *Identify what control(s) 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**

**Types of Design Controls:**

**Prevention (P):**

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

**Detection (D):**

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

# Design Controls

- The preferred approach is to first use prevention controls, if possible.
- The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the design intent.

First consider how to prevent, then how to detect

# 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

# Design Controls

- Design Control columns in the DFMEA describe the methods that will be used to control the design process.
- The Test Plan (DVP&R) provides the details of those controls.

# RISK ANALYSIS

5th Step
Risk Analysis

Assignment of Existing and/or Planned Controls and Rating of Failures

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

**Boundary/Block Diagram Structure Development**
***P-Diagram***
***Interface Diagram* (optional)**

3 **FUNCTION ANALYSIS**

**Functions *and Requirements***

4 **FAILURE ANALYSIS**

***Causes in Focus Level before* causes in Lower Levels**

5 **RISK ANALYSIS**

5b **Link Special Characteristics to Functions/Requirements**

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7 **RESULTS DOCUMENTATION**

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# Special Characteristics

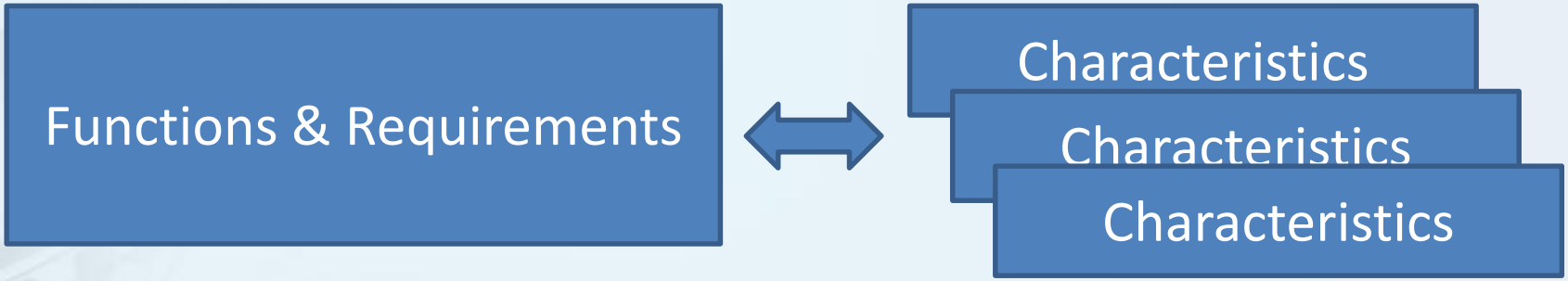
**Special Characteristics** are, as defined by IATF 16949, a **product characteristic or manufacturing process parameter** that can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.

- Some companies require that all characteristics on the print be part of the process review. That is, all characteristics need to be included in the FMEA and Control Plan, and need to be studied for capability in PPAP. All types of measurement systems need to be studied for MSA as well.
- Control of characteristics designated as safety critical, function critical, and customer interface need to follow the customer-specific requirements or organization requirements, whichever is most stringent.

# Linkage to Special Characteristics

- This step should be used to highlight high-priority failure modes and their associated causes.
- As a result of this analysis, the team may use this information to update the preliminary list of special characteristic by identifying those failure modes leading to special characteristics.
- 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.

# Characteristics and Requirements – Special Characteristics




**Link the Design to Manufacturing to Shop Floor Controls**

| Sample rules for Special Functions | |
|---|---|
| Severity = 9 or 10 | Safety Related |
| Severity = 5 to 8 with ***High*** Occurrence | Candidate |


# EVALUATIONS

## Indices and Action Plans

**NOTE : It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team, even if the product / process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e. the ratings are subjective).**

# Severity of Effect

Severity is the rank associated with the most serious effect of the failure mode on the customer:

- Assess the severity of each effect by team consensus using the ranking table, in the Effects column.
- Enter the ranking for the most serious effect in the “S” (Severity) column.

Recommendation: record the severity for each effect

# DFMEA Severity – AIAG-VDA FMEA Handbook

| SEV | Effect | Severity Criteria | Corporate or Product Line Examples |
|---|---|---|---|
| 10 | Very High | Affects safe operation of the vehicle and/or other vehicles, the health of operator or passenger(s) or road users or pedestrians | |
| 9 | | Noncompliance with regulations | |
| 8 | High | **Loss** of primary vehicle function necessary for normal driving during expected service life | |
| 7 | | **Degradation** of primary vehicle function necessary for normal driving during expected service life | |
| 6 | Moderate | Loss of secondary vehicle function | |
| 5 | | **Degradation** of secondary vehicle function | |
| 4 | | Very objectionable appearance, sound, vibration, harshness, or haptics | |
| 3 | Low | Moderately objectionable appearance, sound, vibration, harshness, or haptics | |
| 2 | | Slightly objectionable appearance, sound, vibration, harshness, or haptics | |
| 1 | Very Low | No discernible effect | |

The table may be augmented to include product specific examples.

OMNEX

Safety is 10 regardless of warning – Split rating of 10 and 9

# Occurrence (Probability of)

The Occurrence rating (O) is a measure of the effectiveness of the prevention control, taking into account the rating criteria.

- 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.

# Occurrence

- A consistent occurrence ranking system should be used to ensure continuity.
- The occurrence ranking number is a relative rating within the scope of the FMEA and may not reflect the actual likelihood of occurrence.

**Occurrence ranking will be affected by the Prevention Design Controls**

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| 10 | Extremely High | **First** application of new technology anywhere without operating experience and/or under uncontrolled operating conditions. No product verification and/or validation experience.<br><br>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist. | |
| 9 | Very High | **First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br><br>Prevention controls not targeted to identify performance to specific requirements. | |
| 8 | | **First** use of design with technical innovations or materials on a new application. New application or change in duty cycle / operating conditions. No product verification and/or validation experience.<br><br>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance. | |

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| 7 | High | **New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br><br>Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance. | |
| 6 | | **Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.<br><br>Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause. | |

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| 5 | Moderate | **Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.<br><br>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause, and provide some indication of performance. | |
| 4 | | **Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.<br><br>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance. | |

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| 3 | Low | **Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.<br><br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design. | |
| 2 | Very Low | **Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.<br><br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.<br>design conformance. | |
| 1 | Extremely Low | Failure eliminated through preventive control and failure cause is not possible by design | |

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

**Notes:**

- **Product Experience:** History of product usage within the company (novelty of design, application or use case). Results of already completed detection controls provide experience with design.
- **Prevention Control:** Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins
- A 10, 9, 8, 7 can drop based on product validation activities

# Detection

The Detection rating (D) is an estimated measure of the effectiveness of the detection control to reliably demonstrate the failure cause or failure mode before the item is released for production.

- Detection is the index associated with the best detection control shown in the Current Control (Detection) 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 – AIAG-VDA FMEA Handbook

| DET | Ability to Detect | Detection Maturity Method | Opportunity for Detection | Corporate or Product Line Examples |
|---|---|---|---|---|
| **10** | **Very Low** | Test procedure yet to be developed. | Test method not defined. | |
| **9** | | Test method not designed specifically to detect failure mode or cause. | Pass-Fail, Test-to-Fail, Degradation Testing | |
| **8** | **Low** | New test method, not proven. | Pass-Fail, Test-to-Fail, Degradation Testing | |
| **7** | | Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or retooling. | Pas-Fail Testing | |
| **6** | **Moderate** | | Test-to-Failure | |
| **5** | | | Degradation Testing | |

# DFMEA Detection – AIAG-VDA FMEA Handbook

| DET | Ability to Detect | Detection Maturity Method | Opportunity for Detection | Corporate or Product Line Examples |
|---|---|---|---|---|
| **4** | **High** | Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production. | Pass-Fail Testing | |
| **3** | | | Test-to-Failure | |
| **2** | | | Degradation Testing | |
| **1** | **Very High** | Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to **always** detect the failure mode or failure cause. | | |

# DFMEA Detection – AIAG-VDA FMEA Handbook

- Detection Controls shall be rated for each detection activity performed prior to delivery of the design for production.
- The timing of the detection control (before or after technical release) should also be considered as part of the detection rating.
  - Ratings 5 – 10: Post technical release and prior to production launch.
  - Ratings 1 – 4:  Prior to technical release.

Considers capability to detect and timing

# Action Priority

- At this point in the FMEA process, the team needs to decide if further efforts are needed to reduce any risks identified.

- Due to the inherent limitations on resources, time, technology, and other factors, the team needs to choose how to best prioritize these efforts.

# Action Priority

- The initial focus of the team should be oriented towards failure modes with the highest severity rankings.
  - When the severity is 9 or 10, it is imperative that the team needs to ensure that the risk is addressed through existing design controls or recommended actions (as documented in the FMEA).
- The priority of an action should be based on the discussions among the team considering the concerns and product/process knowledge as well as based on information captured by the FMEA process.

The actual logic to drive prioritization is left to each company and is not on the form

# Action Priority (AP) – AIAG 4th Edition

- Risk Priority Number (RPN)
  - RPN is calculated as:

RPN = Severity x Occurrence x Detection

  - RPN is used to rank relative risk associated with specific failure modes.
  - Corrective action is taken thereafter to reduce the RPN, as appropriate.

# Action Priority (AP) – AIAG-VDA FMEA Handbook

- **IF** the organization chooses to modify the S,O,D tables for specific products, processes, or projects, the AP table should also be carefully reviewed and modified if necessary.
- It is recommended that potential Severity 9-10 failure effects and Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

**Note — Interpretation:**

- **This is not a prioritization of High, Medium, or Low risk, it is the prioritization of the need for actions to reduce risk.**

# Action Priority (AP) – AIAG-VDA FMEA Handbook

- **Priority High (H): Highest priority for action**
  - The team ***needs to*** either identify an appropriate action to improve prevention and / or detection controls or justify and document why current controls are adequate.
- **Priority Medium (M): Medium priority for action**
  - The team ***should*** identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.
- **Priority Low (L): Low priority for action**
  - The team ***could*** identify actions to improve prevention or detection controls.

**At a minimum the statement: "No Further Action is Needed" must be included.**

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 9-10**

| O/D | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | M | M | H | H | H | H |
| 3 | L | L | L | L | M | M | H | H | H | H |
| 4 | M | H | H | H | H | H | H | H | H | H |
| 5 | M | H | H | H | H | H | H | H | H | H |
| 6 | H | H | H | H | H | H | H | H | H | H |
| 7 | H | H | H | H | H | H | H | H | H | H |
| 8 | H | H | H | H | H | H | H | H | H | H |
| 9 | H | H | H | H | H | H | H | H | H | H |
| 10 | H | H | H | H | H | H | H | H | H | H |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 7-8**

| O/D | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | M | M | H | H | H | H |
| 3 | L | L | L | L | M | M | H | H | H | H |
| 4 | M | M | M | M | M | M | H | H | H | H |
| 5 | M | M | M | M | M | M | H | H | H | H |
| 6 | M | H | H | H | H | H | H | H | H | H |
| 7 | M | H | H | H | H | H | H | H | H | H |
| 8 | H | H | H | H | H | H | H | H | H | H |
| 9 | H | H | H | H | H | H | H | H | H | H |
| 10 | H | H | H | H | H | H | H | H | H | H |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 4-6**

| O/D | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | L | L | L | L | L | L |
| 3 | L | L | L | L | L | L | L | L | L | L |
| 4 | L | L | L | L | L | L | M | M | M | M |
| 5 | L | L | L | L | L | L | M | M | M | M |
| 6 | L | M | M | M | M | M | M | M | M | M |
| 7 | L | M | M | M | M | M | M | M | M | M |
| 8 | M | M | M | M | H | H | H | H | H | H |
| 9 | M | M | M | M | H | H | H | H | H | H |
| 10 | M | M | M | M | H | H | H | H | H | H |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 2-3**

| O/D | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | L | L | L | L | L | L |
| 3 | L | L | L | L | L | L | L | L | L | L |
| 4 | L | L | L | L | L | L | L | L | L | L |
| 5 | L | L | L | L | L | L | L | L | L | L |
| 6 | L | L | L | L | L | L | L | L | L | L |
| 7 | L | L | L | L | L | L | L | L | L | L |
| 8 | L | L | L | L | M | M | M | M | M | M |
| 9 | L | L | L | L | M | M | M | M | M | M |
| 10 | L | L | L | L | M | M | M | M | M | M |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

| S 1 O/D | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | L | L | L | L | L | L |
| 3 | L | L | L | L | L | L | L | L | L | L |
| 4 | L | L | L | L | L | L | L | L | L | L |
| 5 | L | L | L | L | L | L | L | L | L | L |
| 6 | L | L | L | L | L | L | L | L | L | L |
| 7 | L | L | L | L | L | L | L | L | L | L |
| 8 | L | L | L | L | L | L | L | L | L | L |
| 9 | L | L | L | L | L | L | L | L | L | L |
| 10 | L | L | L | L | L | L | L | L | L | L |

# AIAG VDA

## Interactive Example using EwQIMS Software

# OPTIMIZATION

6th Step
Optimization

Identification of the Actions Necessary to Reduce Risks

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

Boundary/Block Diagram
Structure Development
*P-Diagram*
*Interface Diagram* (optional)

3 **FUNCTION ANALYSIS**

Functions *and Requirements*

4 **FAILURE ANALYSIS**

*Causes in Focus Level before*
causes in Lower Levels

5 **RISK ANALYSIS**

5b Link Special Characteristics to Functions/Requirements

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b Link to DVP&R

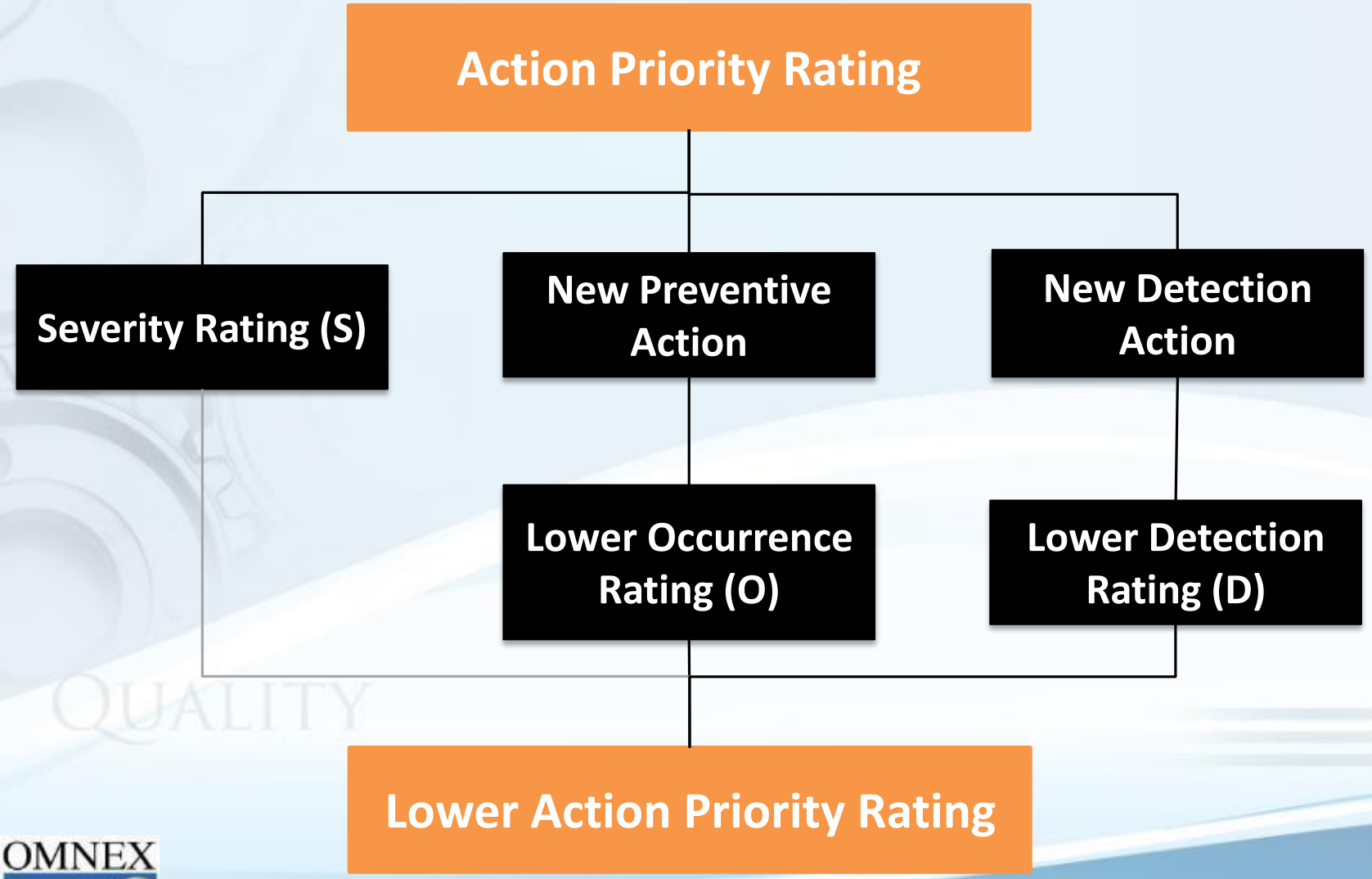
**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

***Italic font*** = Omnex-specific changes to the AIAG-VDA DFMEA process

OMNEX

# Step 6: Optimization



# Recommended Actions

Intent of any recommended action is to reduce any one or all of the occurrence, detection, and/or severity 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<br>• Error proofing | • Prevent the cause or failure and its effect from occurring |
| Detection | • Increase or change in the design validation / verification actions<br>• Design change to enhance detection likelihood<br>• Revised test plan | • Detect that the cause has occurred and take corrective action<br>• Detect that the failure mode has occurred and correct |

# Recommended Actions

**AIAG-VDA FMEA Handbook:** Recommended actions are split into prevention and detection actions.

| 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 |
| | | | | NEW! | | | | | | |

# Recommended Actions

## Suggested levels for Status of Actions:

- **Open**
  The action has neither been defined nor discussed.
- **Decision Pending (optional)**
  The action has been defined but has not yet been decided on. A decision paper is being created.
- **Implementation Pending (optional)**
  The action has been decided on but has not yet been implemented.
- **Completed**
  Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.
- **Discarded**
  Discarded status is assigned when a decision is made to not implement an action. This may occur when risks related to cost, implementation timing, or business strategy are greater than technical risks.

# Recommended Actions

**Status of the Actions**

- The FMEA is not considered “complete” until the team assesses each item’s Action Priority and either accepts the level of risk or documents closure of all actions.
- Closure of all actions should be documented before the FMEA is placed under revision control (or released) to Serial Production.

If no actions are recommended, at a minimum, the statement that “*No Further Action is Needed*” must be included

# Recommended Actions – Assessment of Action Effectiveness

- When an action has been completed, Occurrence and Detection values are reassessed as a prediction of effectiveness, and a new Action Priority may be determined.

- However, the status of the action remains "implementation pending" until the effectiveness has been verified. Only then should it be changed to "completed."

# Action Priority (AP) – AIAG-VDA FMEA Handbook

- **IF** the organization chooses to modify the S,O,D tables for specific products, processes, or projects, the AP table should also be carefully reviewed and modified if necessary.
- It is recommended that potential Severity 9-10 failure effects and Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

**Note — Interpretation:**

- **This is not a prioritization of High, Medium, or Low risk, it is the prioritization of the need for actions to reduce risk.**

# Continual Improvement

**The DFMEA serves as a historical record for the process.**

- Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers need to be visible or, at a minimum, available and accessible as part of version history.
- The completed analysis becomes a repository to capture the progression of process decisions and design refinements.
- However, original S, O, D ratings may be modified for foundation, family or generic DFMEAs because the information is used as a starting point for a process specific analysis.

# RESULTS DOCUMENTATION

7th Step
Results Documentation

Communication of Actions Taken to Reduce Risks

1 **PLANNING & PREPARATION**

**5Ts**

2 **STRUCTURE ANALYSIS**

**Boundary/Block Diagram**
**Structure Development**
***P-Diagram***
***Interface Diagram* (optional)**

3 **FUNCTION ANALYSIS**

**Functions *and Requirements***

4 **FAILURE ANALYSIS**

***Causes in Focus Level before***
**causes in Lower Levels**

5 **RISK ANALYSIS**

5b **Link Special Characteristics to Functions/Requirements**

6 **OPTIMIZATION**

7 **RESULTS DOCUMENTATION**

7b **Link to DVP&R**

**Legend:**

= Omnex improvements over the AIAG-VDA DFMEA process

***Italic font*** = Omnex-specific changes to the AIAG-VDA DFMEA process

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# FMEA Results Documentation

- The scope and results of an FMEA should be summarized in a report.
- This report can be used for communication purposes within a company, or between companies. In this way, it is also ensured that all details of the analysis and the intellectual property remain at the developing company.

**Note**

- **The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions.**
- **If "No Action Taken," then the Action Priority is not changed, and the risk of failure is carried forward into the product. Actions are open loops that need to be closed in writing.**

# FMEA Results Documentation

**The content of the documentation must fulfill the requirements of the intended reader and details may be agreed between the relevant parties.**

The layout of the document may be company specific. The content may include the following:

A. A statement of final status compared to original goals established in the Project Plan.
   a. **FMEA InTent:** Purpose of this FMEA?
   b. **FMEA Timing:** FMEA due date?
   c. **FMEA Team:** List of participants?
   d. **FMEA Task:** Scope of this FMEA?
   e. **FMEA Tool:** How do we conduct the analysis method used?

# FMEA Results Documentation

The layout of the document may be company specific. The content may include the following:

B. A summary of the scope of the analysis and identify what is new.

C. A summary of how the functions were developed.

D. A summary of at least the high-risk failures as determined by the team and provide a copy of the specific S/O/D rating tables and method of action prioritization (i.e. Action Priority table).

E. A summary of the actions taken and/or planned to address the high-risk failures including status of those actions.

# FMEA Results Documentation

The layout of the document may be company specific. The content may include the following:

F. A plan and commitment of timing for ongoing FMEA improvement actions.
   a. Commitment and timing to close open actions.
   b. Commitment to review and revise the DFMEA during mass production to ensure the accuracy and completeness of the analysis as compared with the production design (e.g. revisions triggered from design changes, corrective actions, etc., based on company procedures.)
   c. Commitment to capture "things gone wrong" in foundation DFMEAs for the benefit of future analysis reuse, when applicable.

# Linkage Between DFMEA and DVP&R

- The third step of the 7-Step Process, **Functional Analysis**, links the function-requirements.
- The fifth step, **Risk Analysis**, identifies "**preventive and detective controls**" linked to the function and the requirement.
- These controls are the same controls in the DVP&R or test plan.
  - Omnex recommends that DVP&R house both controls.
- The linkage between the requirements and the test plan in the "V" is provided by the DFMEA and DVPR linkages.

# Chapter 4: Developing the Design FMEA – What We Covered

## Learning Objectives

You should now be able to:

- Explain design failure modes
- Identify failure modes from requirements
- Explain causes of failure modes
- Explain design controls
- Distinguish between prevention and detection controls
- Explain the key elements of the risk analysis
- Define requirements for Results Documentation and Communication

## Chapter Agenda

- Design Failure Modes
- Step 4: Failure Analysis
  - Potential Effects of Failure
  - Potential Causes of Failure
- Step 5: Design Controls and Risk Analysis
  - Evaluation: Indices and Action Plans
- Step 6: Optimization
- Step 7: Results Documentation

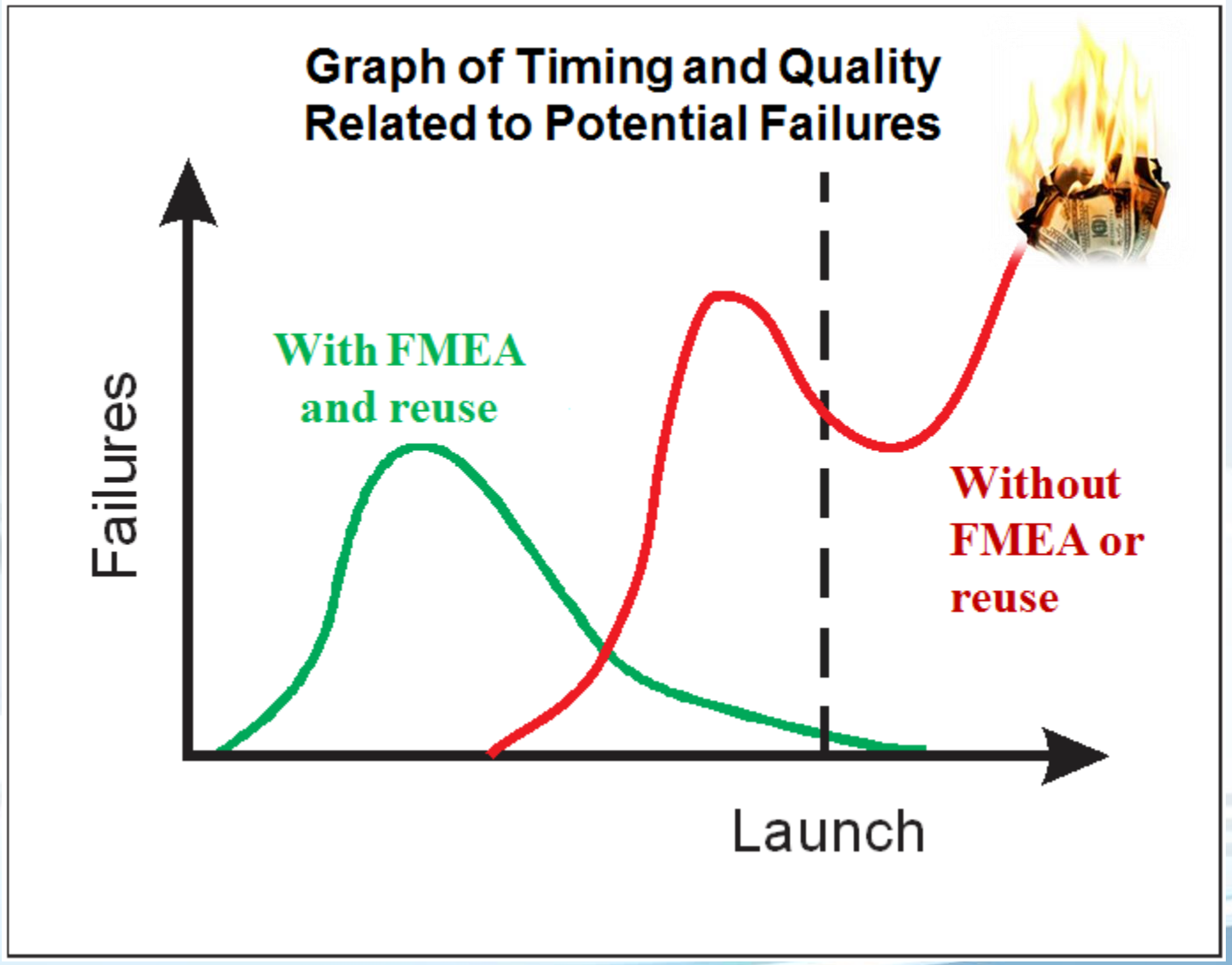
# FMEA Summary

# 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

# FMEA Advantage



# Key Changes to DFMEA (AIAG-VDA FMEA)

- 7-Step DFMEA Development Process
- More prescriptive Risk Analysis forms, which include a significant addition to the number of columns of data
- Introduction of three product levels:  Higher, Focus, and Lower Levels
  - Failures at the Focus Level, effects at the Higher Level and causes at the Focus and Lower Levels
  - Amounts to a 3-Dimensional analytical structure difficult to represent in spreadsheet formats
- New definitions of Severity, Occurrence and Detection indices for Design and Process FMEA analyses
- Use of a new composite index called “Action Priority” to categorize relative risk
- Introduction of a new, supplemental Design FMEA for the risk analysis of “Monitoring and System Response“ associated with a very specific type of electronic product (FMEA-MSR)

# Getting Started Checklist and Action Plan

- Conduct Executive Overview
- Train Facilitators and Team
- Procure AIAG-VDA Software that incorporates the 7 steps and provides linkages to DVP&R and Control Plans
- Incorporate AIAG-VDA FMEA into APQP Process
- Establish Customer and Supply Chain Linkages
- Update Purchasing
- Establish Requirements Management Process
- Procure Software and Establish Libraries and Reuse Strategy
- Develop strategy for pilot and launch program

# Maintaining FMEAs

The FMEA documents living information and should be reviewed whenever there is a product design change, and should be updated as required.

- To have value, FMEA updates must occur at these change points:
  - New design or process is planned
  - Modification to a component, system or process is planned
  - **Important** – Update FMEA to capture problem solving analyses and results
  - Component or system is used in a new environment, location or application

Knowledge Management

# FMEA Keys

- Manage Quantified Risk
  - Focus on Known Potential Risks First
- Act
  - Improvement Proposals
  - Responsibility, Timing, Tracking
  - Verification

The Design FMEA must **not** rely on the process controls to overcome potential design weaknesses, and must take into account the limitations of the manufacturing process (concurrent engineering).

# *Thank You!*

## *Questions?*


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

# Appendix

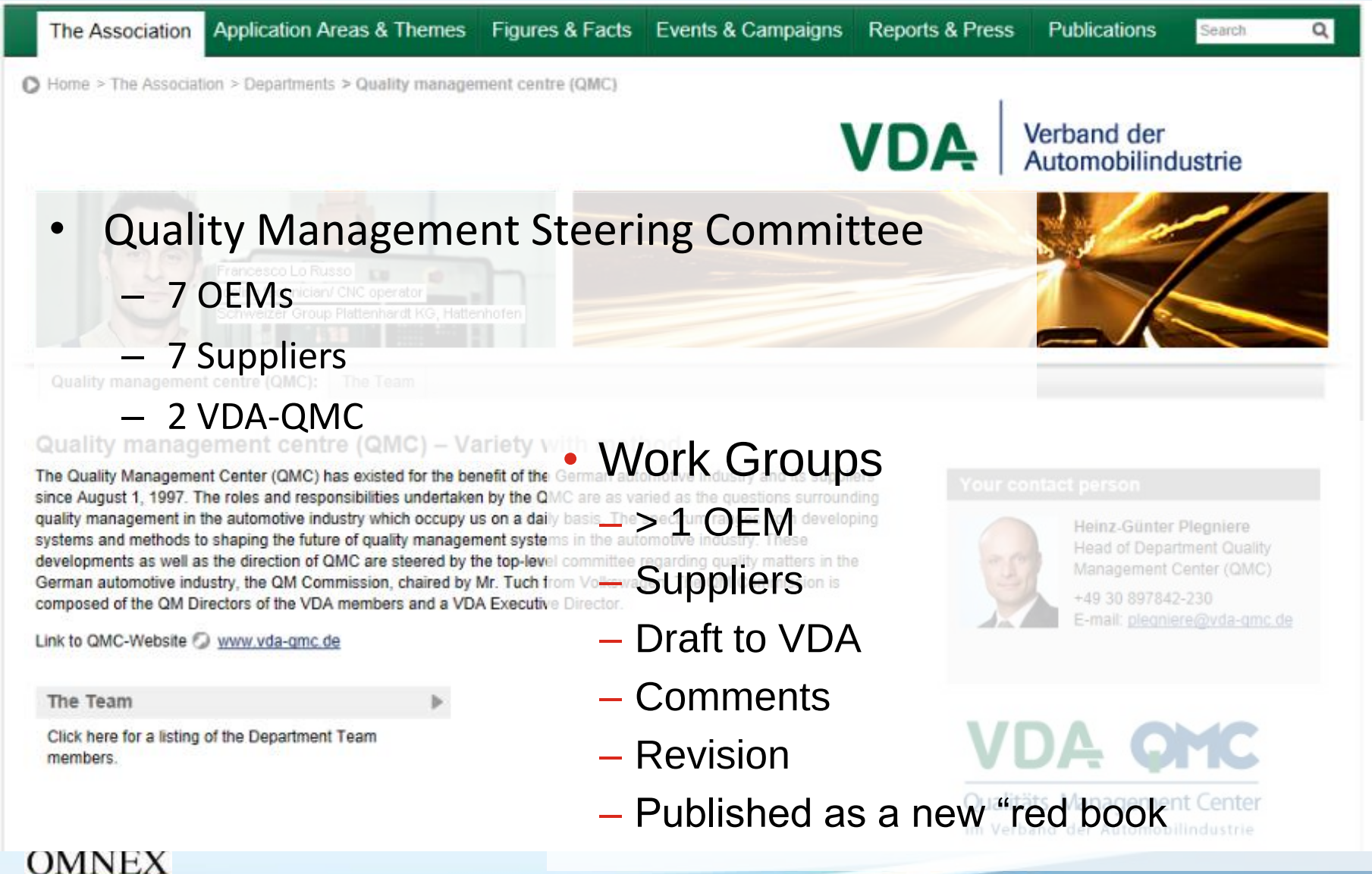
DFMEA Form Comparison

Team Information

IT Support

Tables

# VDA




- Quality Management Steering Committee
  - 7 OEMs
  - 7 Suppliers
  - 2 VDA-QMC
- Work Groups
  - > 1 OEM
  - Suppliers
  - Draft to VDA
  - Comments
  - Revision
  - Published as a new “red book

# VDA Publications

- A total of 30 Volumes available in the English language.
- VDA volumes which impact the APQP Training Initiative:
  - Vol 2: Quality Assurance for Suppliers: Production Process and Product Approval
  - Vol 4: Quality Assurance in the Process Landscape
    - Chapter 5: Product and Process FMEA
  - Vol 5: Capability of Measurement Processes (and Systems)
  - Vol 6: Quality Standard of the German Automotive Industry
    - Part 3: Process Audit

# EVALUATING DFMEAS

# Evaluating DFMEAs — Did the Supplier Use the Seven Steps?

## Step 1 – Planning and Preparation

- Is there evidence of the use of the 5Ts?
  Project Plan – inTent, Timing, Team, Tasks, Tools
- Has supplier defined the scope of the analysis (e.g. using a Boundary Diagram)?
- Does the scope of analysis include the interfaces and interactions necessary?
- Was this DFMEA event planned with a family DFMEA document for design reuse?
- Is failure history from Warranty, Customer, and internal plant data for surrogate parts available and considered for design improvement purposes?
- Are DFM and DFA being considered in functional requirements related to manufacturability.
- Is there a System DFMEA, Subsystem DFMEA, and Component DFMEA planned? What is the planning for linkages between the documents?

# Evaluating DFMEAs — Did the Supplier Use the Seven Steps?

## Step 2 – Structure Analysis:

- Was the Structure Analysis conducted? The structure should include the Focus Element, and the Higher and Lower Elements at the very least.
- Is there an interface diagram or P-Diagram included? Does it include all the Key Functions and its requirements including the following:
  - Noise Factors
  - Control Factors
  - Unintended Output?
  - Input/Output
  - Non-functional Requirements

## Step 3 – Function Analysis

- Does the Function Analysis include Functions and Requirements?
- Are the functions defined as “verb-noun” and do the requirements have the following characteristics – unambiguous; understandable; atomic (singular); achievable; verifiable?
- Are there interface functions for an assembly?

# Evaluating DFMEAs — Did the Supplier Use the Seven Steps?

## Step 4 – Failure Analysis

- Are the failure modes in terms of not achieving the requirement?
  - Are there failure modes for all requirements, as applicable?
- Is the effect a failure caused by the focus element failure?
- Is the cause focused on the "Focus Element" design and how the requirements or design at the Focus Element could cause the failure?

# Evaluating DFMEAs — Did the Supplier Use the Seven Steps?

## Step 5 – Risk Analysis

- Has the DFMEA applied the Severity, Occurrence and Detection correctly from the tables? Have a few been sampled for consistency?
  - The Severity should be based on the "highest" failure looking at the cause and effect linkage up to the customer.
  - The Occurrence is based on prevention controls. Is significant error-proofing applied?
  - Is the Detection control and rating based on the most effective detection control?
- Was the Action Priority (AP) logic correctly applied and sampled?
- Are the prevention and detection controls carefully transferred to the DVP&R or test plans and sampled?
- Are the Special Functions identified for Severity 9 & 10 Requirements / Functions and Severity 8 & 7 Requirements / Functions with **High** Occurrence?

# Evaluating DFMEAs — Did the Supplier Use the Seven Steps?

## Step 6 – Optimization

- Does the recommended action follow the logic of the AP tables:
  - Severity 9 & 10 with **High** and **Medium** AP rating?
  - Severity 8 & 7 with **High** Occurrence or **High** Detection?
  - Is "**none**" recorded when there are no recommended prevention and detection controls actions?
- Is collaboration between the customer or supplier (including internal supplier) considered for severity reduction?
- Are there opportunities for error-proofing or ability to move a detection control up earlier in the design cycle?
- Is there a responsible party, promised date, status, and action taken with evidence of actions taken, completion date, and a reassessment of Severity, Occurrence, and Detection?
- Are there promised dates which have been missed? Are promised dates too far out into the future? Are action taken dates and promised dates showing consistent discrepancies?

# Evaluating DFMEAs — Did the Supplier Use the Seven Steps?

## Step 7 – Results Documentation

- Is there evidence of risk communication? Did it go to the right parties?
- How is the organization communicating and linking to supplier DFMEAs? Customer DFMEAs?
- How much improvement was seen as a result of this AIAG-VDA DFMEA activity?
- How is this information captured for change management and lessons learned?

# Evaluating DFMEAs — DFMEA SR Checklist

## APQP – DFMEA Suitability Review Checklist

**Recommendation:**

**Product/Component:**
**Date of Review:**
**Prepared For:** **Supplier [ X ]** **Peer [ ]**
**Supplier/Peer Name:**
**Prepared By:** **FMEA Number:**

**Indicate Yes/No by Checking the appropriate box**

*Note: Items checked **No** indicate improvement is needed*

| Y | N | General |
|---|---|---|
| ☐ | ☐ | **1)** Are the Failure Modes, Effects, Causes and Design Controls properly distinguished? |
| ☐ | ☐ | **2)** Is there evidence that a cross-functional team was used to develop the FMEA? |
| ☐ | ☐ | **3)** Are applicable entries in the Header completed? |
| ☐ | ☐ | **4)** Does the DFMEA appear to drive Design Improvements as the ***primary*** objective? |
| ☐ | ☐ | **5)** Is the DFMEA document completely filled out, including header information, action plans and recalculated RPN? |
| ☐ | ☐ | **6)** Does the DFMEA address internal, customer and warranty issues and other Quality indicators |
| ☐ | ☐ | **7)** Is there a Block Diagram and does it include intefaces and interactions, as appropriate? |

# Evaluating DFMEAs — DFMEA SR Checklist

| Y | N | | |
|---|---|---|---|
| | | **Item / Function/Requirements** | |
| ☐ | ☐ | **8)** | Is the design intent, or purpose clear? Are Performance Requirements specified? |
| ☐ | ☐ | **9)** | Are functional requirements described clearly (verb-noun format)? |
| | | **Failure Modes** | |
| ☐ | ☐ | **10)** | Are the failure modes developed from the functional requirements and interface functions? |
| ☐ | ☐ | **11)** | Does the DFMEA address all failure modes identified as high risk with executable action plans? |
| | | **Effects of Failure** | |
| ☐ | ☐ | **12)** | Are effects on safe operation and government regulation considered? |
| ☐ | ☐ | **13)** | Are multiple effects higher element, system, customer (end user) considered? |
| | | **Cause(s)** | |
| ☐ | ☐ | **14)** | Are the Root Causes identified appropriate? |
| ☐ | ☐ | **15)** | Are design deficiencies considered that may result in manufacturing / assembly variation or misbuilds? |
| ☐ | ☐ | **16)** | Are manufacturing / assembly causes excluded? (addressed in PFMEA) |
| ☐ | ☐ | **17)** | Are all causes listed on a separate line? |
| ☐ | ☐ | **18)** | Are causes described in terms of the design and process development process and lower le\ |
| | | **Current Prevention Design Controls** | |
| ☐ | ☐ | **19)** | Can the Design Controls listed eliminate or ameliorate the Cause(s) of Failure Modes prior to engineering release? |
| ☐ | ☐ | **20)** | Are error proofing controls used for high risk failure modes? |
| ☐ | ☐ | **21)** | Do Design Controls stress Prevention and Analytical over Physical testing? |

# Evaluating DFMEAs — DFMEA SR Checklist

| Y | N | | |
|---|---|---|---|
| | | | **Current Detection Design Controls** |
| ☒ | ☐ | **22)** | Can the Design Controls listed detect the Cause(s) of Failure Modes, or detect the Failure Modes prior to engineering release? |
| ☐ | ☐ | **23)** | Are manufacturing / assembly Detection methods excluded? |
| ☒ | ☐ | **24)** | Is there a distinction between Prevention and Detection type design controls? |
| ☒ | ☐ | **25)** | Are the Detection Type Design Controls individually ranked? |
| | | | **Severity Rating** |
| ☒ | ☐ | **26)** | Are Severity ratings based on the most serious consequence of the Failure Mode? |
| | | | **Occurrence Rating** |
| ☒ | ☐ | **27)** | Is the Occurrence rating based on the AP Tables and based on the prevention control |
| | | | **Detection Rating** |
| ☒ | ☐ | **28)** | Are ratings based on the AP Tables? |
| | | | **Classification** |
| ☒ | ☐ | **29)** | Are Function Class for Safety and Special Functional **candidates** identified as appropriate |
| | | | **AP** |
| ☒ | ☐ | **30)** | Do the recommended actions focus on High and Medium Risks |
| | | | **Recommended Actions** |
| ☒ | ☐ | **31)** | Are Recommended Actions listed that reduce the Severity Occurrence and Detection for the hi |
| ☒ | ☐ | **32)** | Are responsibility and timing for Recommended Actions listed? |
| ☒ | ☐ | **33)** | Are preventive, instead of detection, actions listed? Do the Recommended Action exclude manufacturing / assembly controls? |
| ☒ | ☐ | **34)** | Are Severity, Occurrence, Detection, and the resulting Severity, Occurrence, and Detection numbers recalculated for the identified |
| ☒ | ☐ | **35)** | Are the Recommended Actions actionable and executable? |

# TEAM INFORMATION

# 5Ts — 3. FMEA Team

**The Core Team may consist of the following people:**

- Facilitator
- Design Engineer
- System Engineer
- Component Engineers
- Test Engineer
- Quality/Reliability Engineer
- Others responsible for the development of the product

# 5Ts — 3. FMEA Team

**The Extended Team may consist of the following people:**

- Technical Experts
- Process/Manufacturing Engineer
- Service Engineer
- Project Manager
- Functional Safety Engineer
- Purchasing
- Supplier
- Customer Representative
- Others that may have specialized knowledge which will help the core team analyze specific aspects of the product

# 5Ts — 3. FMEA Team

**Management, e.g. project manager:**

- Authority to make decisions about the acceptability of identified risks and the execution of actions
- Define the persons responsible for pre-work activities, FMEA facilitation, and the design/process engineer responsible for implementation of actions resulting from the analysis
- Management has the ultimate responsibility of selecting and applying resources and ensuring an effective risk management process is implemented within scheduled project timing
- Responsibility and ownership for development and maintenance of the FMEAs
- Management responsibility also includes providing direct support to the team(s) through on-going reviews and eliminating roadblocks
- Responsible for budget

# 5Ts — 3. FMEA Team

**Lead Design/Process Engineer (Technical Lead):**

- Technical responsibility for the FMEA contents
- Preparation of the Business Case for technical and/or financial decisions
- Definition of elements, functions, requirements, and interfaces
- Focusing on the topics
- Procurement of the necessary documents and information
- Incorporating lessons learned

# 5Ts — 3. FMEA Team

**FMEA Facilitator:**

- Coordination and organization of the workflows in the FMEA
- Mitigation of conflicts
- Participation in the team formation
- Participation in the preparation of the rough schedule
- Participation in the invitation to the first team meeting for the analysis phase
- Participation in the preparation of the decision guidelines/criteria
- Development of corporate or product line examples for rating tables (optional) with support from Design/Process Engineer

# 5Ts — 3. FMEA Team

**FMEA Facilitator (*cont'd*):**

- Method competence (FMEA) and familiarization of participants in the FMEA method
- FMEA Software documentation competence (as necessary)
- Social skills, able to work in a team
- Competent moderator, ability to convince, organization and presentation skills
- Managing execution of the 7 steps of FMEA method
- If necessary, preparation or wrap-up of FMEA meetings
- Moderation of the FMEA workgroup

**NOTE: Any team member with the relevant competence and training in the VDA FMEA Handbook, and software or spreadsheet method, may fulfill the role of facilitator. It's recommended the team member must have been actively involved in FMEAs using the AIAG-VDA FMEA Handbook methods to be able to facilitate or be certified.**

# 5Ts — 3. FMEA Team

**Core Team Members:**

- Contribute knowledge from relevant product and process experience
- Contribute necessary information about the product or process that is the focus of the FMEA
- Contribution of existing experiences from previous FMEAs already known
- Participation in the execution of the 7 steps of FMEA
- Involvement in the preparation of the Business Case
- Incorporating lessons learned

# 5Ts — 3. FMEA Team

**Extended Team Members / Experts:**

- Contribution of additional information about special topics
- Contribution of necessary information about the product or process that is the focus of the FMEA
- Involvement in the preparation of the Business Case

# ORGANIZATION OF THE DFMEA AND PFMEA LIBRARIES

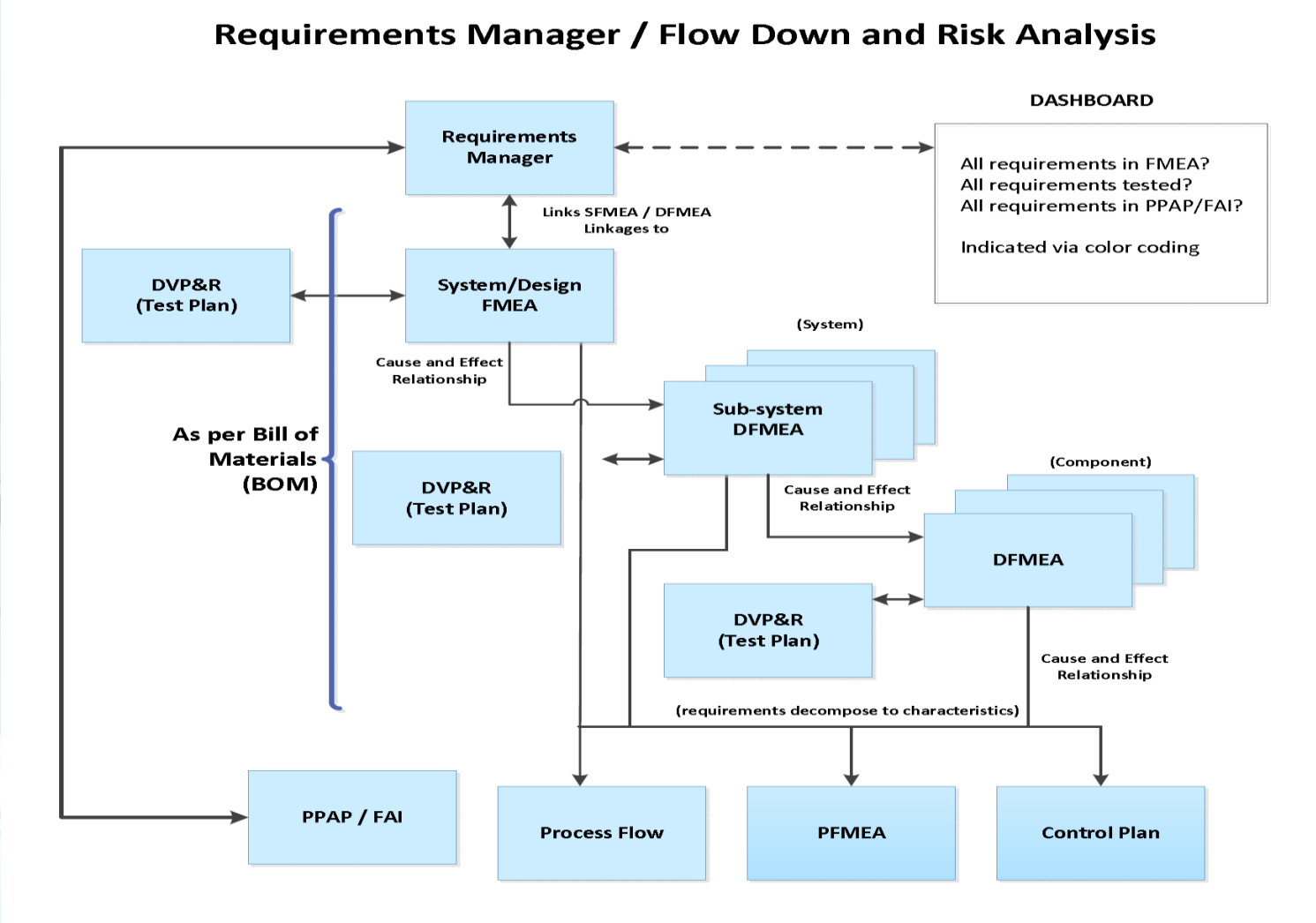
## Design and Process Reuse

# Linkage Between DFMEA and DVP&R

- The third step of the 7-Step Process, **Functional Analysis**, links the function-requirements.
- The fifth step, **Risk Analysis**, identifies "**preventive and detective controls**" linked to the function and the requirement.
- These controls are the same controls in the DVP&R or test plan.
  - Omnex recommends that DVP&R house both controls.
- The linkage between the requirements and the test plan in the "V" is provided by the DFMEA and DVPR linkages.*

***Not addressed in AIAG-VDA FMEA Handbook**

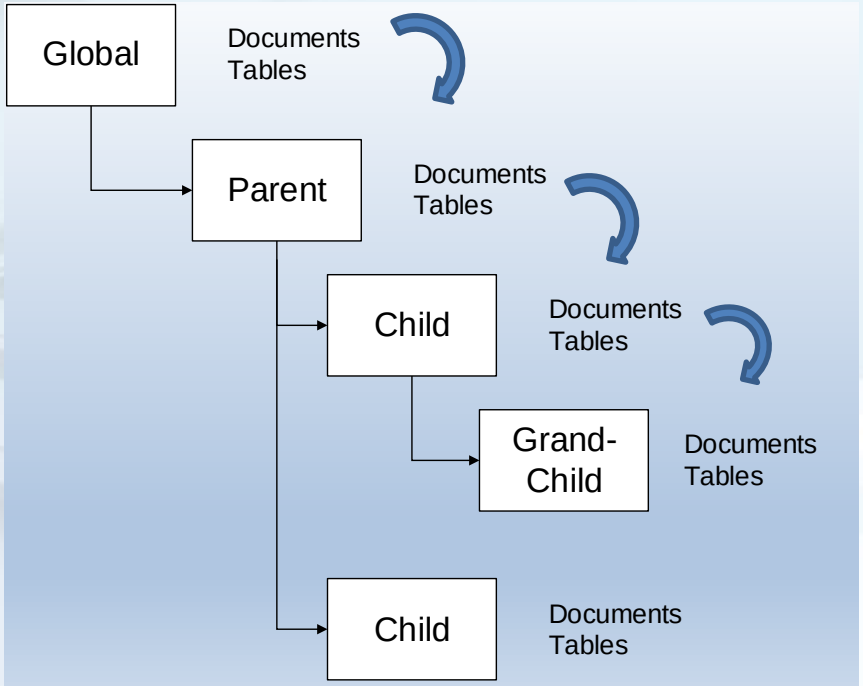
# Linkages Between DFMEA, PFMEA and the Shop Floor



# Family of Parts

AQuA pro product realization software

## Creating Design and Process Documents using Inheritance

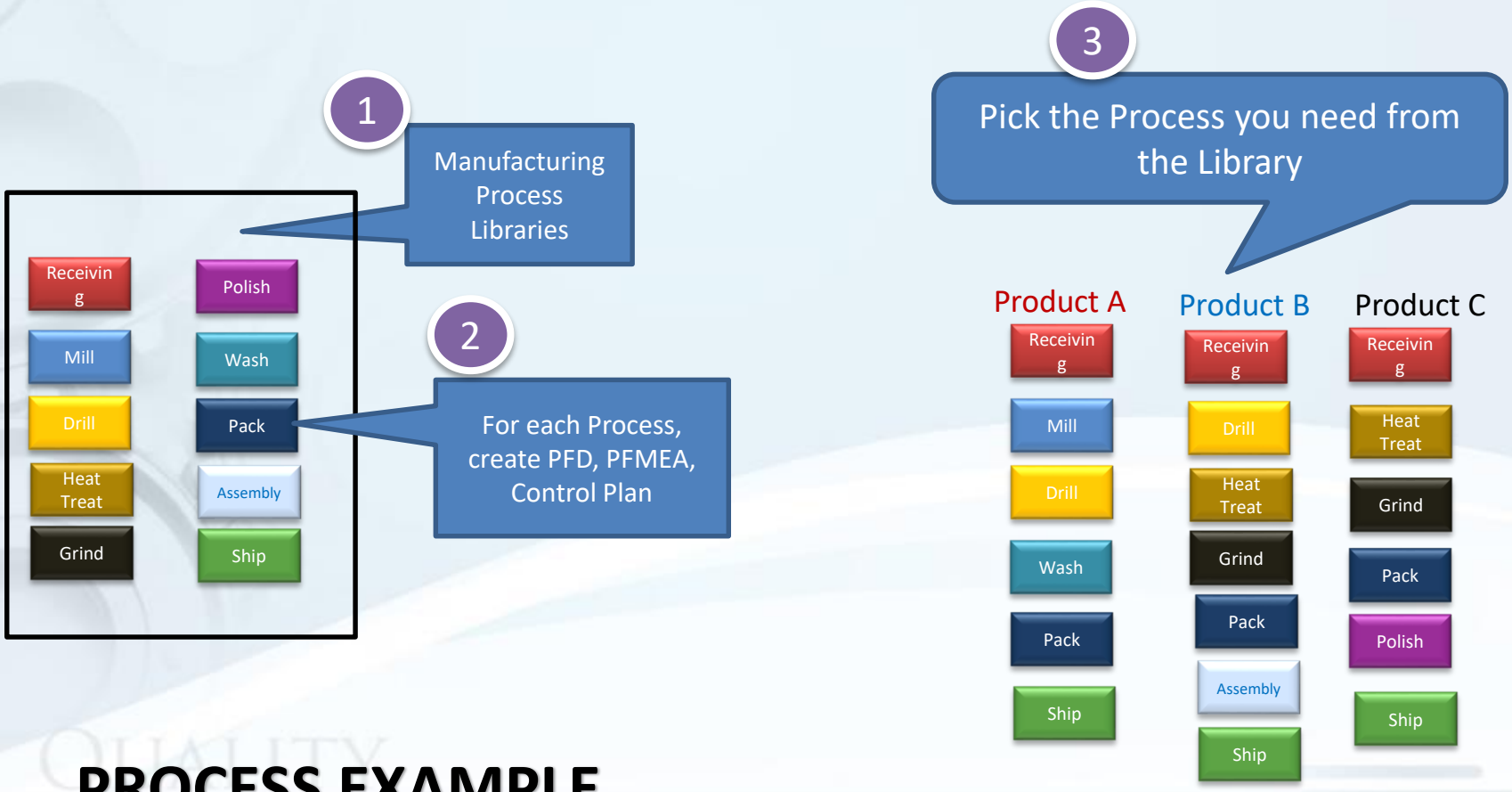




OMNEX SYSTEMS

OMNEX

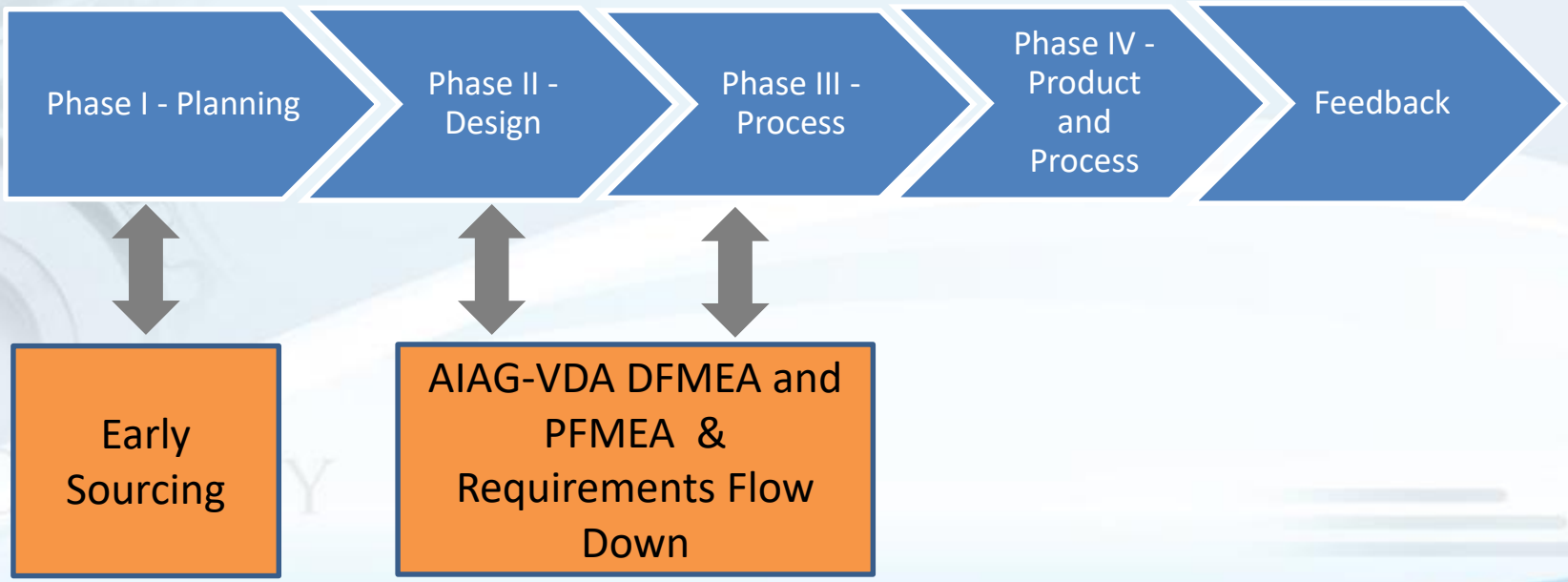
# Design and Process Reuse Libraries



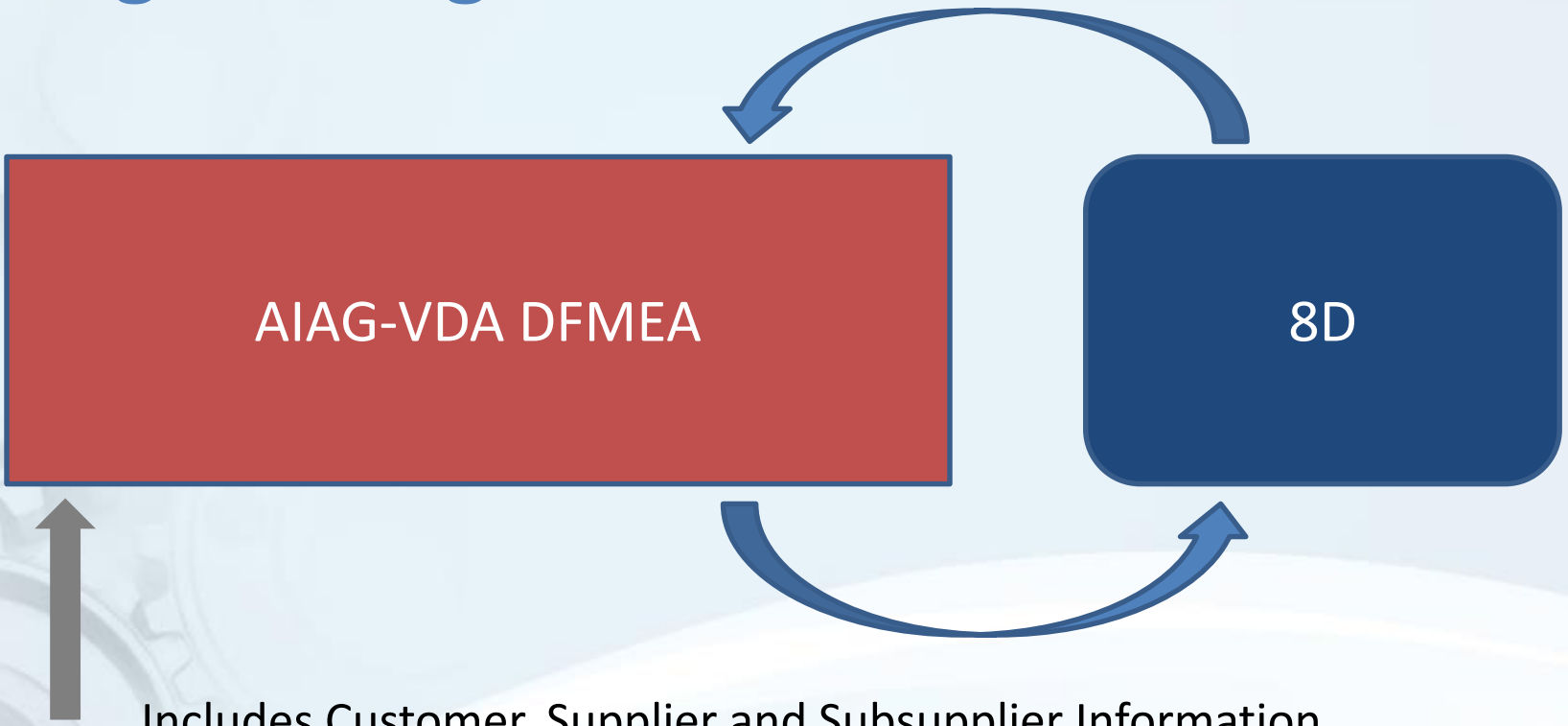

## PROCESS EXAMPLE

# APQP and Supply Chain Changes

Sales and Purchasing may need to have language on collaboration between customer, supplier and subsupplier



# Change Management and AIAG-VDA FMEA



# TABLES

# DFMEA Severity – AIAG-VDA FMEA Handbook

| SEV | Effect | Severity Criteria | Corporate or Product Line Examples |
|---|---|---|---|
| 10 | Very High | Affects safe operation of the vehicle and/or other vehicles, the health of operator or passenger(s) or road users or pedestrians | |
| 9 | | Noncompliance with regulations | |
| 8 | High | **Loss** of primary vehicle function necessary for normal driving during expected service life | |
| 7 | | **Degradation** of primary vehicle function necessary for normal driving during expected service life | |
| 6 | Moderate | Loss of secondary vehicle function | |
| 5 | | **Degradation** of secondary vehicle function | |
| 4 | | Very objectionable appearance, sound, vibration, harshness, or haptics | |
| 3 | Low | Moderately objectionable appearance, sound, vibration, harshness, or haptics | |
| 2 | | Slightly objectionable appearance, sound, vibration, harshness, or haptics | |
| 1 | Very Low | No discernible effect | |

The table may be augmented to include product specific examples.

Safety is 10 regardless of warning – Split rating of 10 and 9

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| **10** | **Extremely High** | **First** application of new technology anywhere without operating experience and/or under uncontrolled operating conditions. No product verification and/or validation experience.<br><br>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist. | |
| **9** | **Very High** | **First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br><br>Prevention controls not targeted to identify performance to specific requirements. | |
| **8** | | **First** use of design with technical innovations or materials on a new application. New application or change in duty cycle / operating conditions. No product verification and/or validation experience.<br><br>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance. | |

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| 7 | High | **New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br><br>Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance. | |
| 6 | | **Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.<br><br>Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause. | |

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| 5 | Moderate | **Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.<br><br>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause, and provide some indication of performance. | |
| 4 | | **Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.<br><br>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance. | |

# DFMEA Occurrence – AIAG-VDA FMEA Handbook

| OCC | Prediction of Failure Cause Occurring | Product Experience | Corporate or Product Line Examples |
|---|---|---|---|
| 3 | Low | **Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.<br><br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design. | |
| 2 | Very Low | **Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.<br><br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance.<br>design conformance. | |
| 1 | Extremely Low | Failure eliminated through preventive control and failure cause is not possible by design | |

# DFMEA Detection – AIAG-VDA FMEA Handbook

| DET | Ability to Detect | Detection Maturity Method | Opportunity for Detection | Corporate or Product Line Examples |
|---|---|---|---|---|
| **10** | **Very Low** | Test procedure yet to be developed. | Test method not defined. | |
| **9** | | Test method not designed specifically to detect failure mode or cause. | Pass-Fail, Test-to-Fail, Degradation Testing | |
| **8** | **Low** | New test method, not proven. | Pass-Fail, Test-to-Fail, Degradation Testing | |
| **7** | | Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or retooling. | Pas-Fail Testing | |
| **6** | **Moderate** | | Test-to-Failure | |
| **5** | | | Degradation Testing | |

# DFMEA Detection – AIAG-VDA FMEA Handbook

| DET | Ability to Detect | Detection Maturity Method | Opportunity for Detection | Corporate or Product Line Examples |
|---|---|---|---|---|
| **4** | **High** | Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production. | Pass-Fail Testing | |
| **3** | | | Test-to-Failure | |
| **2** | | | Degradation Testing | |
| **1** | **Very High** | Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to **always** detect the failure mode or failure cause. | | |

## C1.3.1 DFMEA OCCURRENCE (O): Incidents per Thousand Values

| Occurrence Potential (O) for the Product | | | |
|---|---|---|---|
| Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate | | | Blank until filled by user |
| **O** | **Incidents per 1000 items/vehicles** | **Occurrence criteria - DFMEA** | **Corporate or Product Line Examples** |
| **10** | **≥ 100 per thousand >/= 1 in 10** | **First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience.<br>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist. | |
| **9** | **50 per thousand, 1 in 20** | **First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br>Prevention controls not targeted to identify performance to specific requirements. | |
| **8** | **20 per thousand, 1 in 50** | **First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance. | |
| **7** | **10 per thousand 1 in 100** | **New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br>Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance. | |
| **6** | **2 per thousand 1 in 500** | **Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.<br>Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause. | |

| Occurrence Potential (O) for the Product | | | |
|---|---|---|---|
| Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate | | | Blank until filled by user |
| **O** | **Incidents per 1000 items/vehicles** | **Occurrence criteria - DFMEA** | **Corporate or Product Line Examples** |
| 5 | **.5 per thousand 1 in 2000** | **Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.<br>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance. | |
| 4 | **.1 per thousand 1 in 10,000** | **Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.<br>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance. | |
| 3 | **.01 per thousand 1 in 100,000** | **Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.<br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design. | |
| 2 | **≤ .001 per thousand 1 in 1,000,000** | **Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.<br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance. | |
| 1 | **Prevention controls eliminate failure** | Failure eliminated through prevention control and failure cause is not possible by design | |

**Product Experience:** History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.
**Prevention Controls:** Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins
**Note:** OCC 10, 9, 8, 7 can drop based on product validation activities.

***Table C1.3.1 - Alternate DFMEA Occurrence (O)***

## C1.3.2 DFMEA Occurrence (O) with Time Based Failure Prediction Values

| Occurrence Potential (O) for the Product | | | |
|---|---|---|---|
| Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating). | | | Blank until filled in by user |
| **O** | **Time Based Failure Cause Prediction** | **Occurrence criteria - DFMEA** | **Corporate or Product Line Examples** |
| **10** | **Every time** | **First** application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and/or validation experience.<br>Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist. | |
| **9** | **Almost every time** | **First** use of design with technical innovations or materials within the company. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br>Prevention controls not targeted to identify performance to specific requirements. | |
| **8** | **More than once per shift** | **First** use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br>Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance. | |
| **7** | **More than once per day** | **New** design based on similar technology and materials. New application, or change in duty cycle / operating conditions. No product verification and/or validation experience.<br>Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance. | |
| **6** | **More than once per week** | **Similar** to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.<br>Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause. | |
| **5** | **More than once per month** | **Detail** changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.<br>Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance. | |

| Occurrence Potential (O) for the Product | | | |
|---|---|---|---|
| Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating). | | | Blank until filled in by user |
| **O** | **Time Based Failure Cause Prediction** | **Occurrence criteria - DFMEA** | **Corporate or Product Line Examples** |
| **4** | **More than once per year** | **Almost identical** design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.<br><br>Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate likely design conformance. | |
| **3** | **Once per year** | **Detail** changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure.<br><br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause, and predict conformance of production design. | |
| **2** | **Less than once per year** | **Almost identical** mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.<br><br>Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause, and indicate confidence in design conformance. | |
| **1** | **Never** | Failure eliminated through prevention control and failure cause is not possible by design | |

**Product Experience:** History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design.

**Prevention Controls:** Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, Tolerance Stacks and Design Safety Margins

**Note:** OCC 10, 9, 8, 7 can drop based on product validation activities.

***Table C1.3.2 – Alternate DFMEA Occurrence (O)***

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 9-10**

| O/D | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | M | M | H | H | H | H |
| 3 | L | L | L | L | M | M | H | H | H | H |
| 4 | M | H | H | H | H | H | H | H | H | H |
| 5 | M | H | H | H | H | H | H | H | H | H |
| 6 | H | H | H | H | H | H | H | H | H | H |
| 7 | H | H | H | H | H | H | H | H | H | H |
| 8 | H | H | H | H | H | H | H | H | H | H |
| 9 | H | H | H | H | H | H | H | H | H | H |
| 10 | H | H | H | H | H | H | H | H | H | H |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 7-8**

| **O/D** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | M | M | H | H | H | H |
| 3 | L | L | L | L | M | M | H | H | H | H |
| 4 | M | M | M | M | M | M | H | H | H | H |
| 5 | M | M | M | M | M | M | H | H | H | H |
| 6 | M | H | H | H | H | H | H | H | H | H |
| 7 | M | H | H | H | H | H | H | H | H | H |
| 8 | H | H | H | H | H | H | H | H | H | H |
| 9 | H | H | H | H | H | H | H | H | H | H |
| 10 | H | H | H | H | H | H | H | H | H | H |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 4-6**

| **O/D** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | L | L | L | L | L | L |
| 3 | L | L | L | L | L | L | L | L | L | L |
| 4 | L | L | L | L | L | L | M | M | M | M |
| 5 | L | L | L | L | L | L | M | M | M | M |
| 6 | L | M | M | M | M | M | M | M | M | M |
| 7 | L | M | M | M | M | M | M | M | M | M |
| 8 | M | M | M | M | H | H | H | H | H | H |
| 9 | M | M | M | M | H | H | H | H | H | H |
| 10 | M | M | M | M | H | H | H | H | H | H |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

**S 2-3**

| **O/D** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | L | L | L | L | L | L |
| 3 | L | L | L | L | L | L | L | L | L | L |
| 4 | L | L | L | L | L | L | L | L | L | L |
| 5 | L | L | L | L | L | L | L | L | L | L |
| 6 | L | L | L | L | L | L | L | L | L | L |
| 7 | L | L | L | L | L | L | L | L | L | L |
| 8 | L | L | L | L | M | M | M | M | M | M |
| 9 | L | L | L | L | M | M | M | M | M | M |
| 10 | L | L | L | L | M | M | M | M | M | M |

# Action Priority (AP) – AIAG-VDA FMEA Handbook

## DFMEA

| S 1 / O/D | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | L | L | L | L | L | L | L | L | L | L |
| 2 | L | L | L | L | L | L | L | L | L | L |
| 3 | L | L | L | L | L | L | L | L | L | L |
| 4 | L | L | L | L | L | L | L | L | L | L |
| 5 | L | L | L | L | L | L | L | L | L | L |
| 6 | L | L | L | L | L | L | L | L | L | L |
| 7 | L | L | L | L | L | L | L | L | L | L |
| 8 | L | L | L | L | L | L | L | L | L | L |
| 9 | L | L | L | L | L | L | L | L | L | L |
| 10 | L | L | L | L | L | L | L | L | L | L |