# Advanced Product Quality Planning **(APQP)** and Production Part Approval Process **(PPAP).**

Detailed Training Material.

# What is APQP?

**Advanced Product Quality Planning Cycle**


- Advanced Product Quality Planning method *to assure that a product satisfies the customer* (both internal and external)
- The goal of APQP is to:
  - ***Plan*** before acting
  - ***Anticipate*** and ***prevent*** issues
  - ***Validate*** before moving forward
  - Facilitate ***communication***

- Each Advanced Product Quality Plan is unique and is a ***living document***

- Particular emphasis should be placed on identifying ***critical path activities*** and ensuring those are ***fully resourced***

# APQP WHAT IS IT?

A structured methodology for the design and development of new and modified products from concept through to production

It provides a set of detailed requirements to be undertaken at each stage in the APQP system

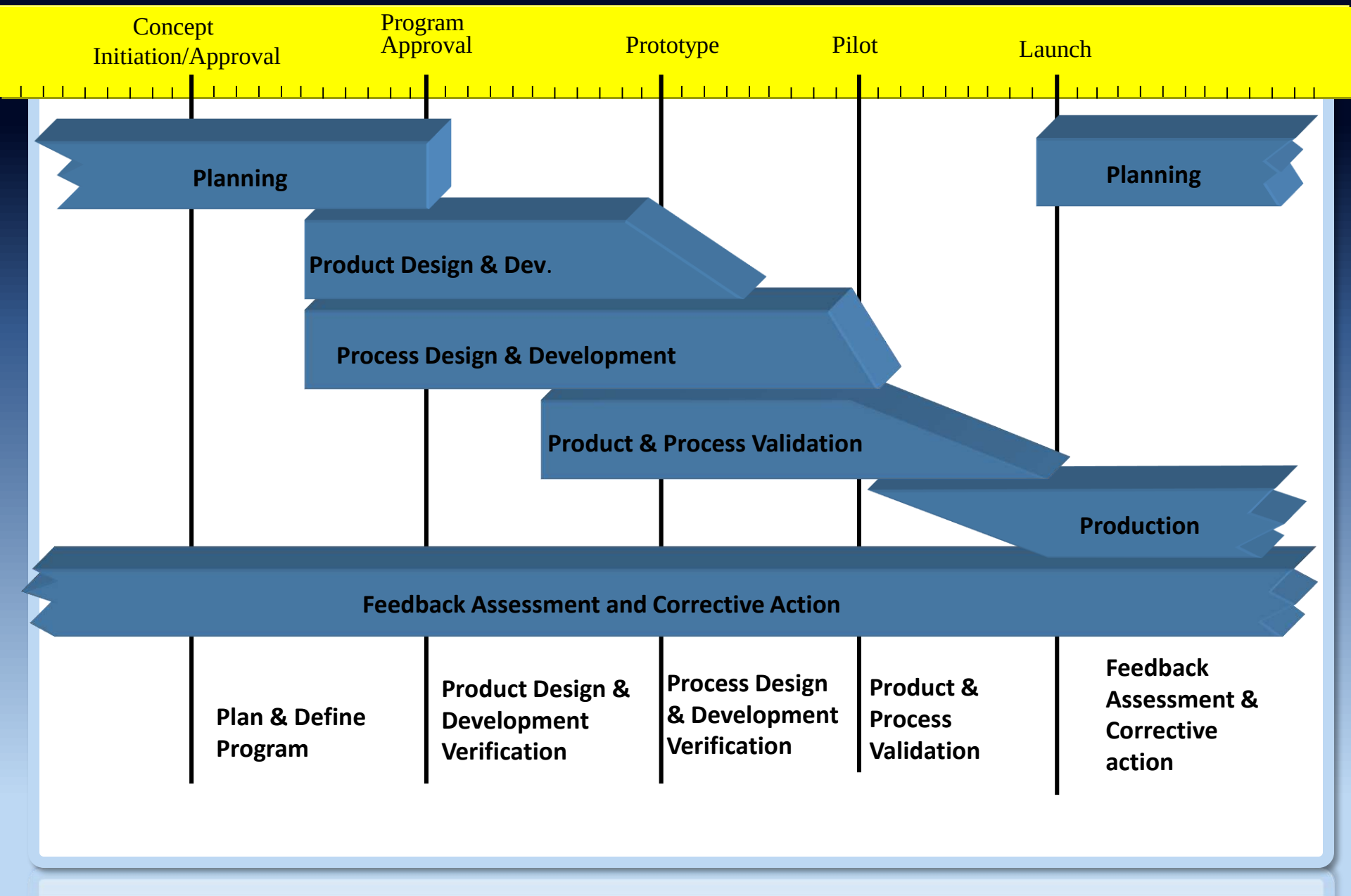
It involves the utilization of various techniques to be employed to identify and resolve problems before going into full production

# APQP WHAT IS IT?

The goal is to facilitate communication with everyone involved to assure that all required steps are completed on time.

Effective planning depends on a company's top management commitment to achieving customer satisfaction.

# APQP Timing Chart



# APQP

PHASE 1

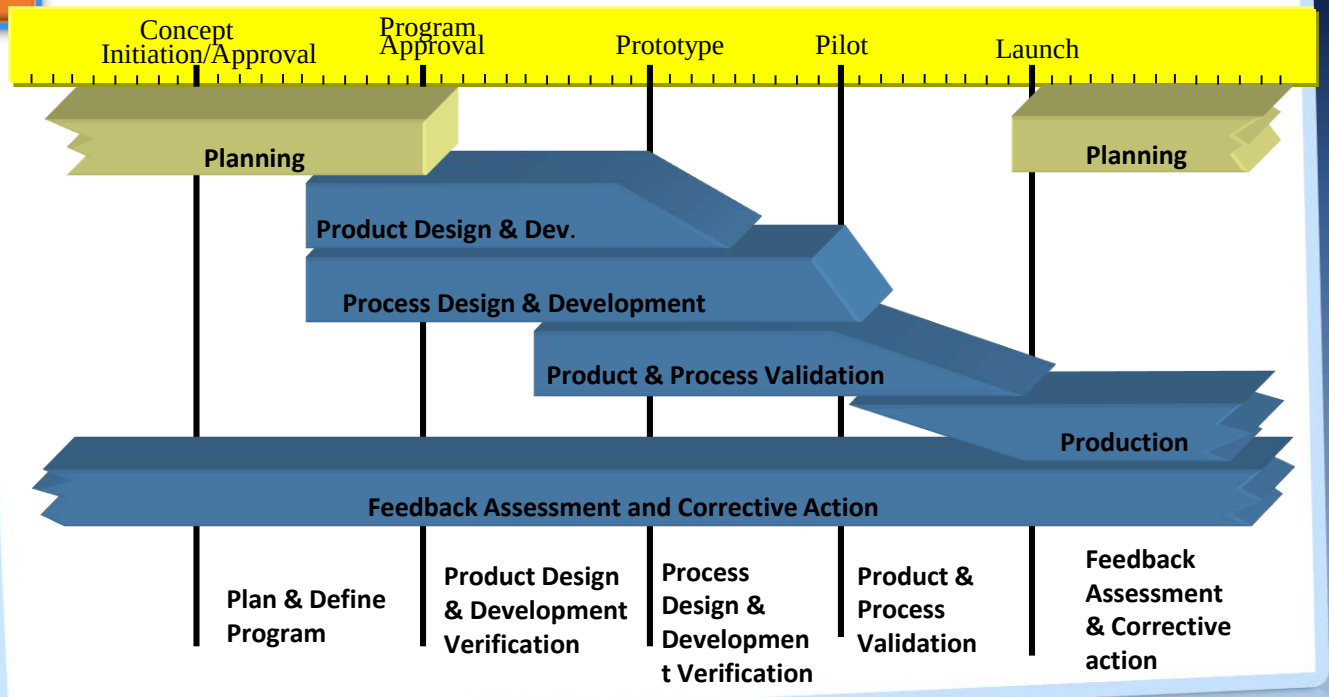
PHASE 2

PHASE 3

PHASE 4

PHASE 5

## PLANNING



# PHASE 1 | PLANNING

## Phase 1 Inputs

- Voice of the costumer
  - Market Research
  - Historical Warranty and Quality Information
  - Team Experience
- Business Plan/MKT Strategy
- Product/process Assumptions
- Product Reliability Studies
- Cuctomer Inputs

PLANNING

## Phase 1 Outputs

- Design Goals
- Reliability & Quality Goals
- Preliminary Process Flow Chart
- Preliminary Listing of special Product & Process Characteristics
- Product Assurance Plan
- Management Support

# APQP

PHASE 1

PHASE 2

PHASE 3

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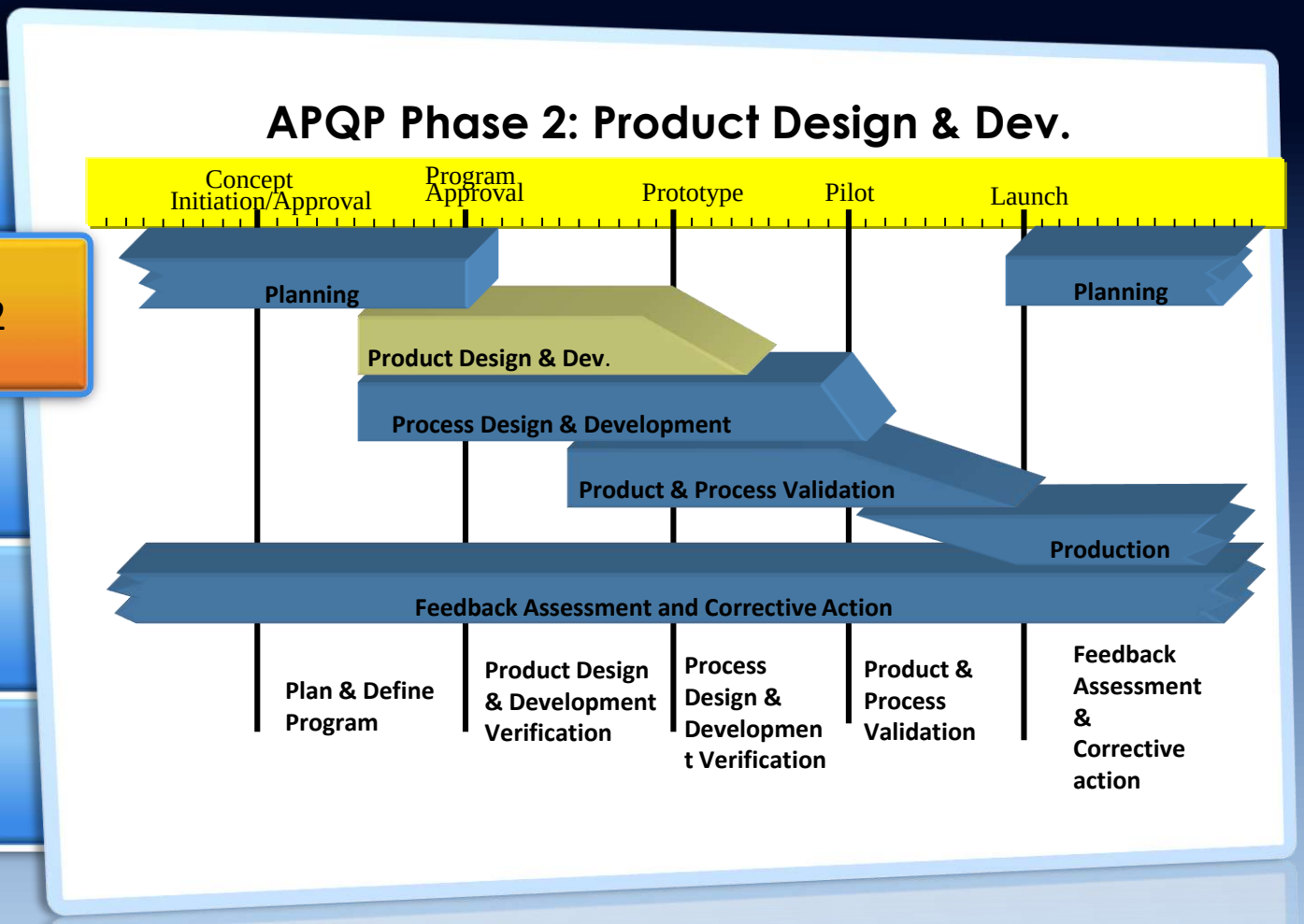
PHASE 5



# PHASE 2 | PRODUCT DESIGN & DEVELOPMENT

## Phase 2 Inputs

- Design Goals
- Reliability & Quality Goals
- Preliminary Bill of Material
- Preliminary Listing of Special Product & Process Characteristic
- Product Assurance Plan
- Management Support

PRODUCT & DESIGN DEVELOPMENT

## Phase 2 Outputs

- Design FMEA
- Design for Manufactturability and assembly
- Design Verification
- Design Reviews
- Prototype CP
- Engineering Drawings
- Engineering Spesifications
- Material Spesifications
- Drawing & Spec. Changes

# PHASE 2 | PROCESS DESIGN & DEVELOPMENT

## Phase 2 Inputs

- Design Goals
- Reliability & Quality Goals
- Preliminary Bill of Material
- Preliminary Listing of Special Product & Process Characteristic
- Product Assurance Plan
- Management Support

PROCESS DESIGN & DEVELOPMENT

## Phase 2 Outputs

- New equipment, Tooling and Facilities Requirement
- Special Product and Process Characterictics
- Gages/Testing Equipment Requirements
- Team Feasibility Commitment and Management Support

# APQP

PHASE 1

PHASE 2

PHASE 3

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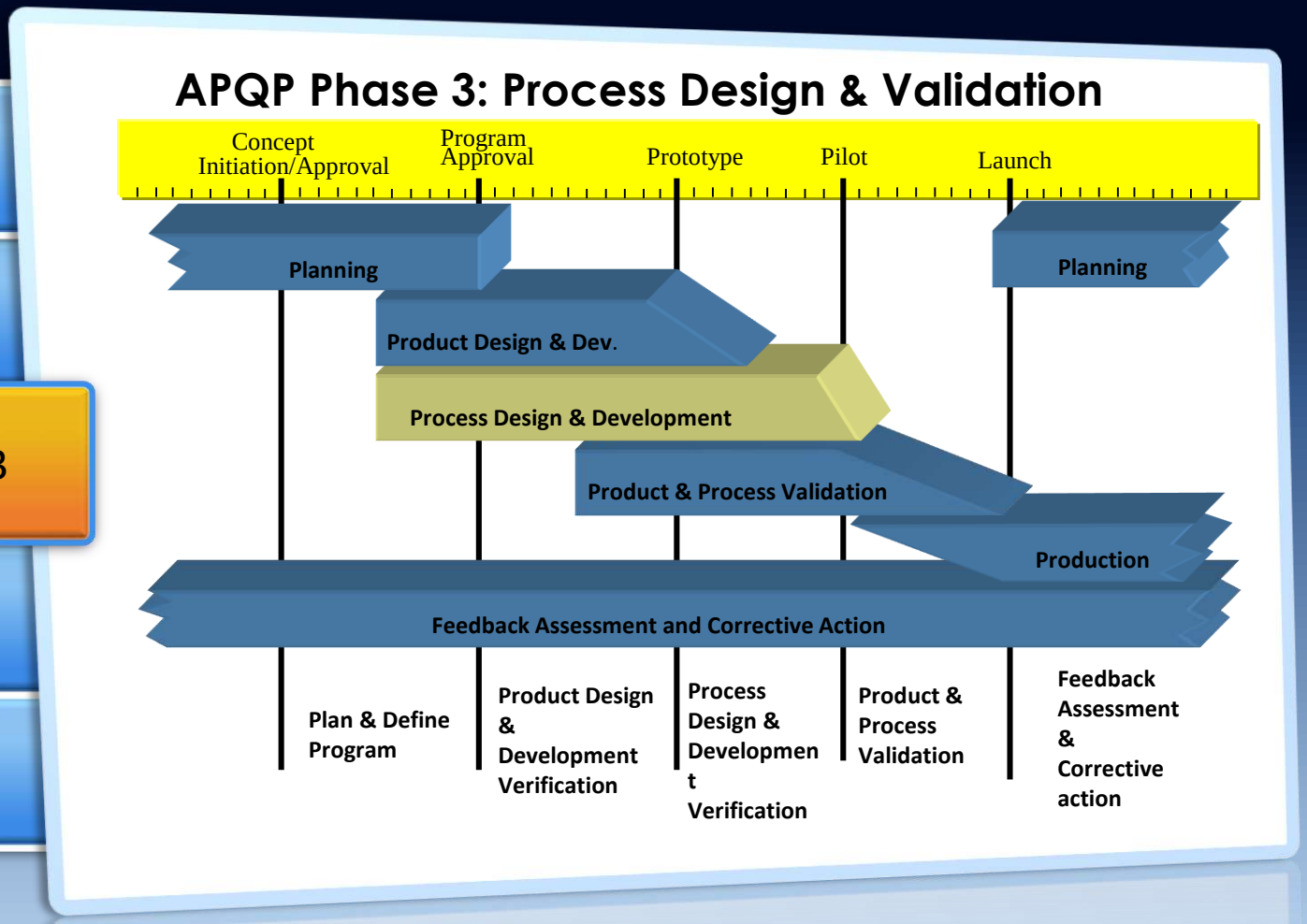
PHASE 5



# PHASE 3 | PROCESS DESIGN & DEVELOPMENT

## Phase 3 Inputs

Phase 2 Design Outputs

Phase 2 APQP Outputs

Process Design & Development

## Phase 3 Outputs

- Packaging Standards & Specs.
- Prod/Proc. Quality System Review
- Process Flow Chart
- Floor Plan Layout
- Characteristics Matrix
- PFMEA
- Pre-launch CP
- Process Instructions
- MSA Plan
- Preliminary Process Capability Study Plan
- Management Support (including operator staffing & training plan)

# APQP

PHASE 1

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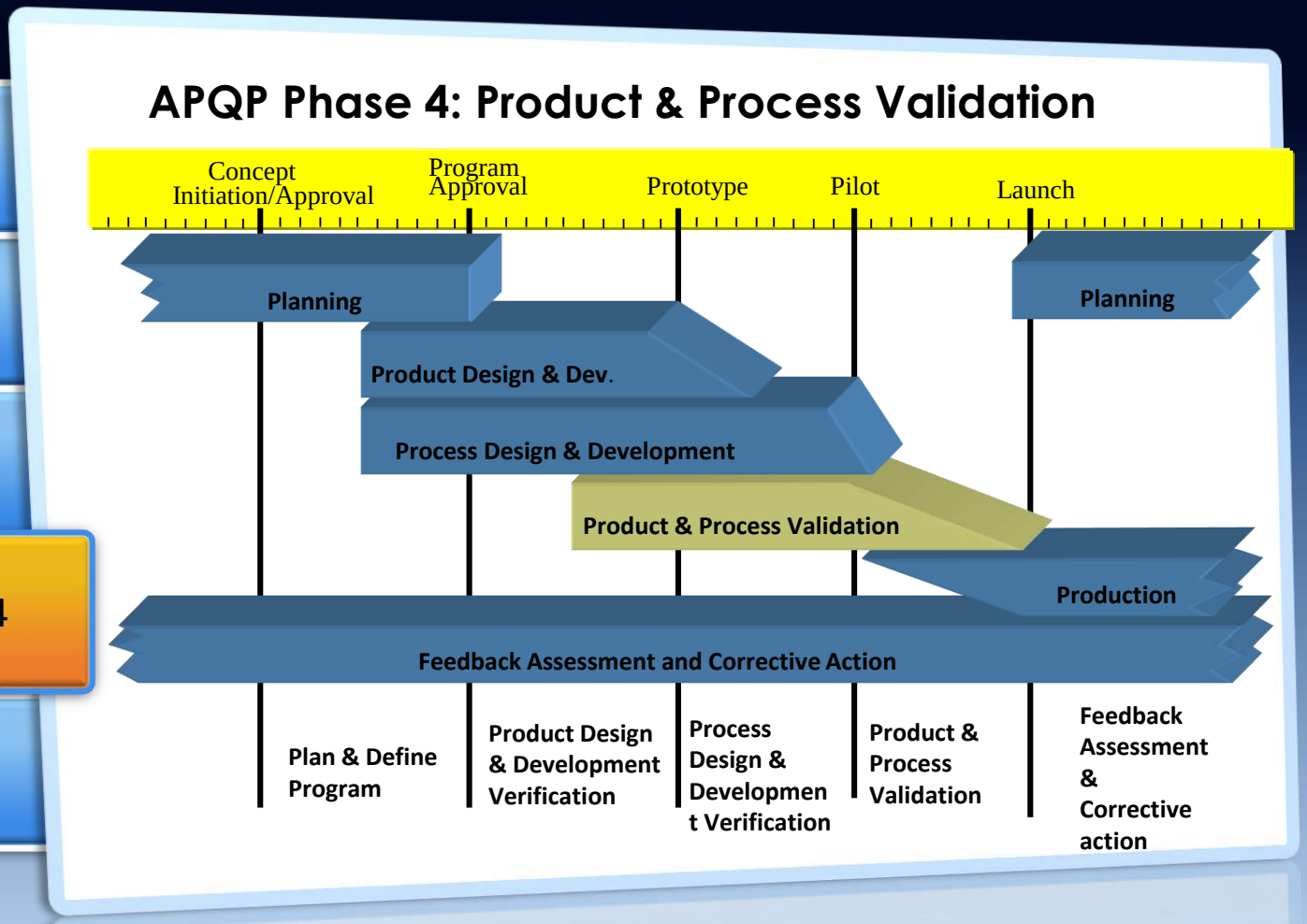
PHASE 5



# PHASE 4 | Product & Process Validation

## Phase 4 Inputs

- Packaging Standards & Specs.
- Prod/Proc. Quality System Review
- Process Flow Chart
- Floor Plan Layout
- Characterictics Matrix
- PFMeA
- Pre –Launch CP
- Process Instructions
- MSA Plan
- Preliminary process Capability Study Plan
- Management support (including operator staffing & training plan)

Product and Process Validation

## Phase 4 Outputs

- Significant production Run
- Measurement Systems Evaluations
- Preliminary Process Capability Study
- PPAP
- Production Validation
- Testing
- Packaging Evaluation
- Production CP
- Quality Planning Sign off and management Support

# APQP

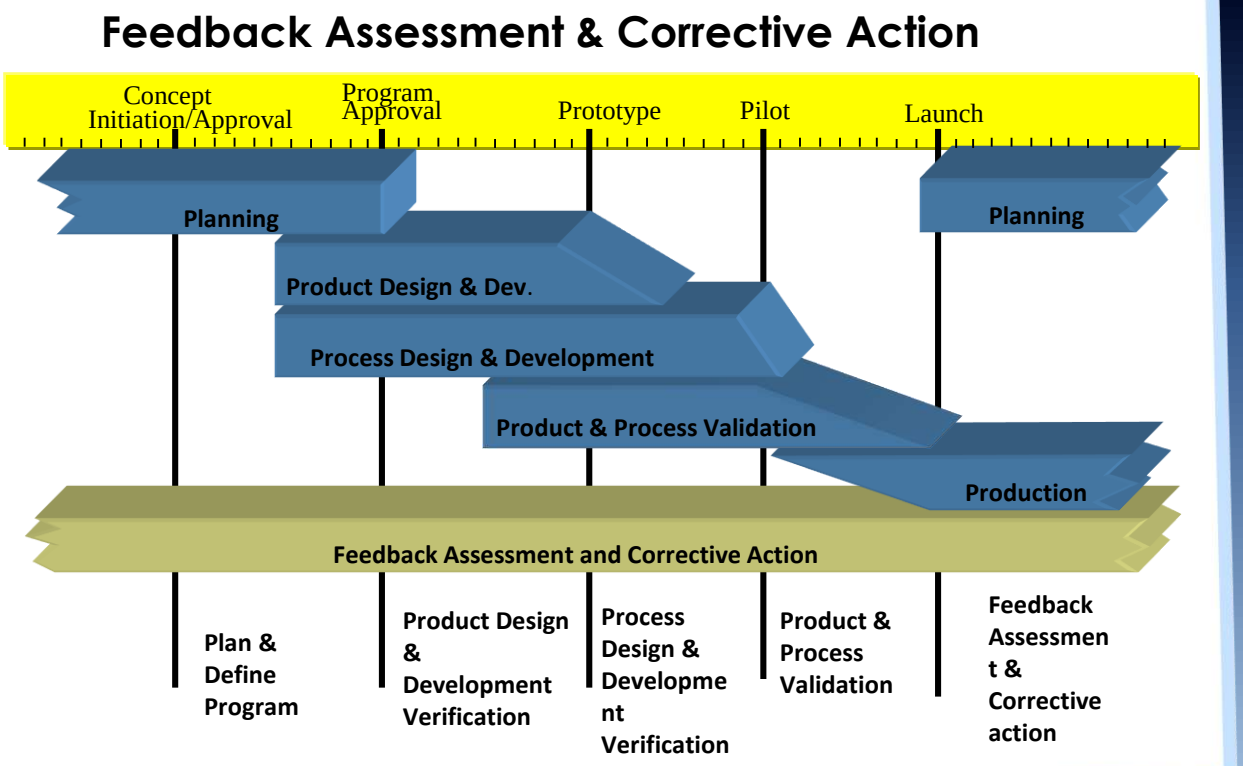
PHASE 1

PHASE 2

PHASE 3

PHASE 4

PHASE 5



# APQP Background

- Automotive industry challenges:
  - Innovation, more complex product
  - Reduce NPD times
  - Complicated Supply chain
  - Increasing customer and quality requirements
- Solution:
  - Ford, GM, Chrysler APQP Task Force jointly developed in the late 80's to standardize their respective supplier quality systems.
- Continuous Improvement:
  - Many industries outside the Automotive industry have embraced the AIAG APQP process to achieve similar benefits

# Objectives

Advanced product quality planning (APQP) is a system used for designing a quality product that meets the customers needs.

APQP can be applied to any industry.

Its purpose is to produce a quality plan which supports the development of a product or service that will satisfy the customer.

# Why use APQP?

The APQP assists with:

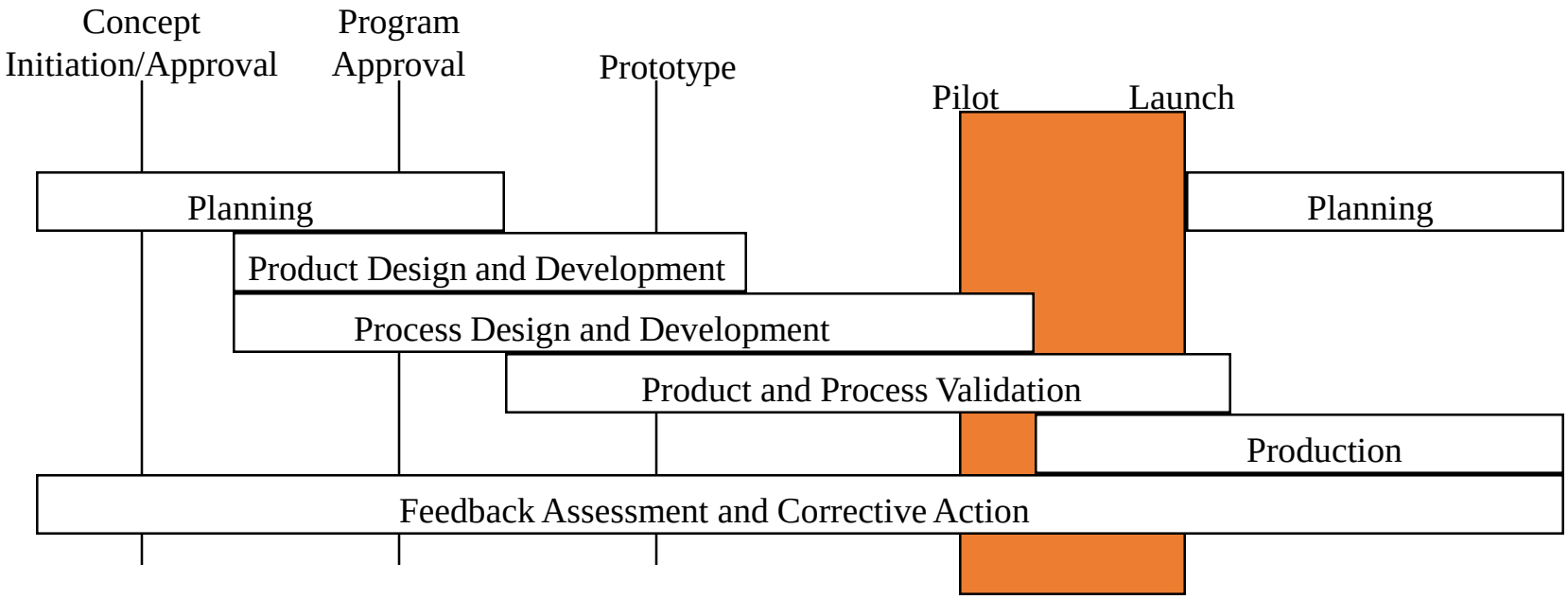
- Understanding the customer needs
  - Determine customer needs and translate into product characteristics and requirements.
- Proactive feedback and corrective action
  - Provides other feedback for similar projects with the objective of developing solutions for potential failures.
- Ensuring that the design is within your process capabilities
  - This brings the processes under statistical control and ensures that your manufacturing process can meet customer requirements and quantities.

# Why use APQP?

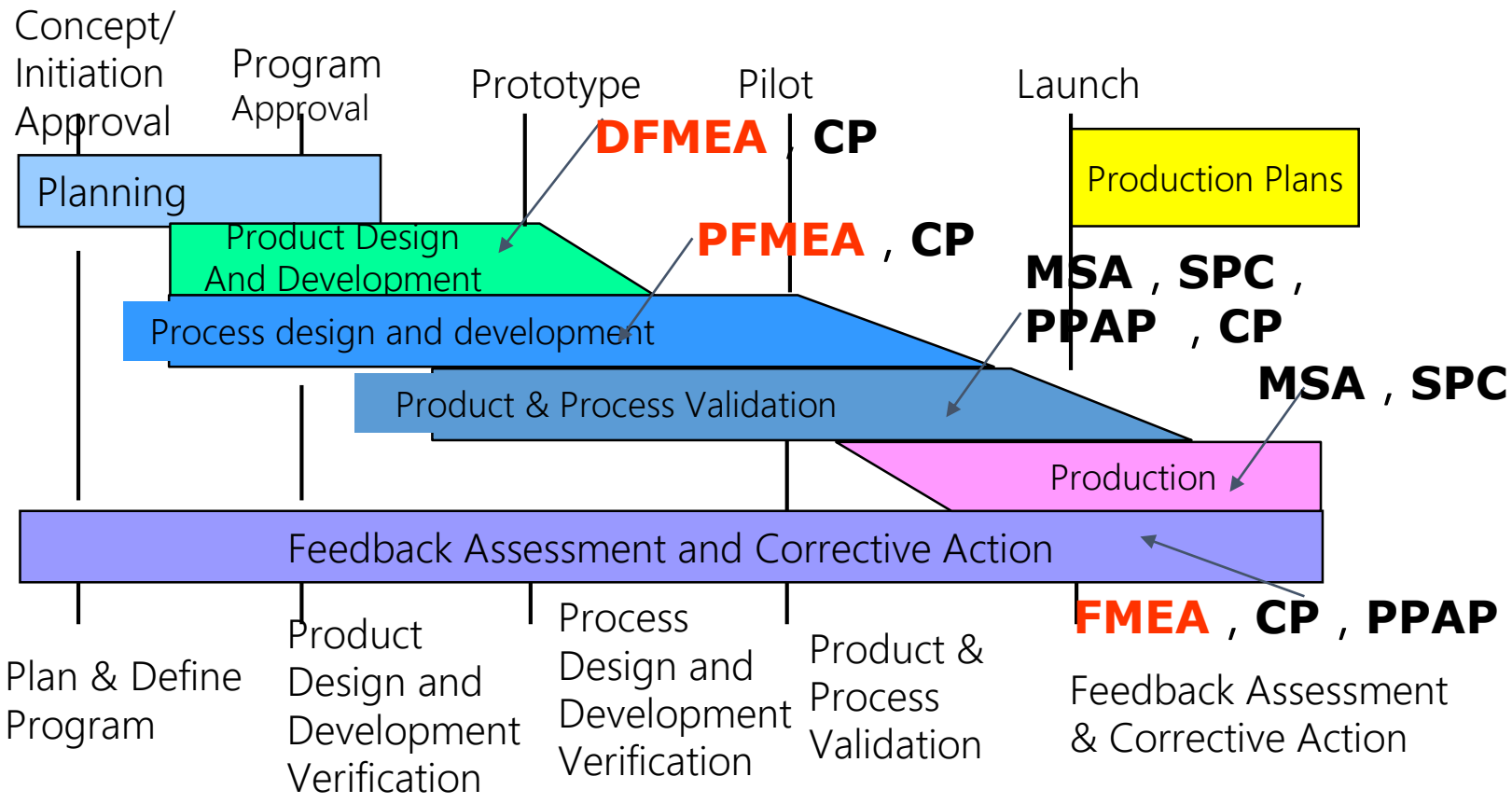
The APQP assists with:

- Conduct reviews
  - These are formal reviews carried during the development of a product to assure it meets the specified requirements.
- Control special or critical characteristics
  - Special/critical characteristics are identified and the process is assessed to assure it can meet the requirements. A control plan is prepared to indicate how this will be achieved.

# APQP Five Phase Process



# APQP Process



# Phases 2 and 3

- Phase 2 - Design
  - Objectives
    - Develop design features and characteristics
    - Critically review engineering requirements
    - Assess potential manufacturing problems
  - Outputs by Design Responsibility Activity
  - Outputs by Advanced Product Quality Planning Team
- Phase 3 - Process
  - Objectives
    - Develop a comprehensive and effective manufacturing system
    - Ensure that the manufacturing systems meet customer requirements
  - Outputs

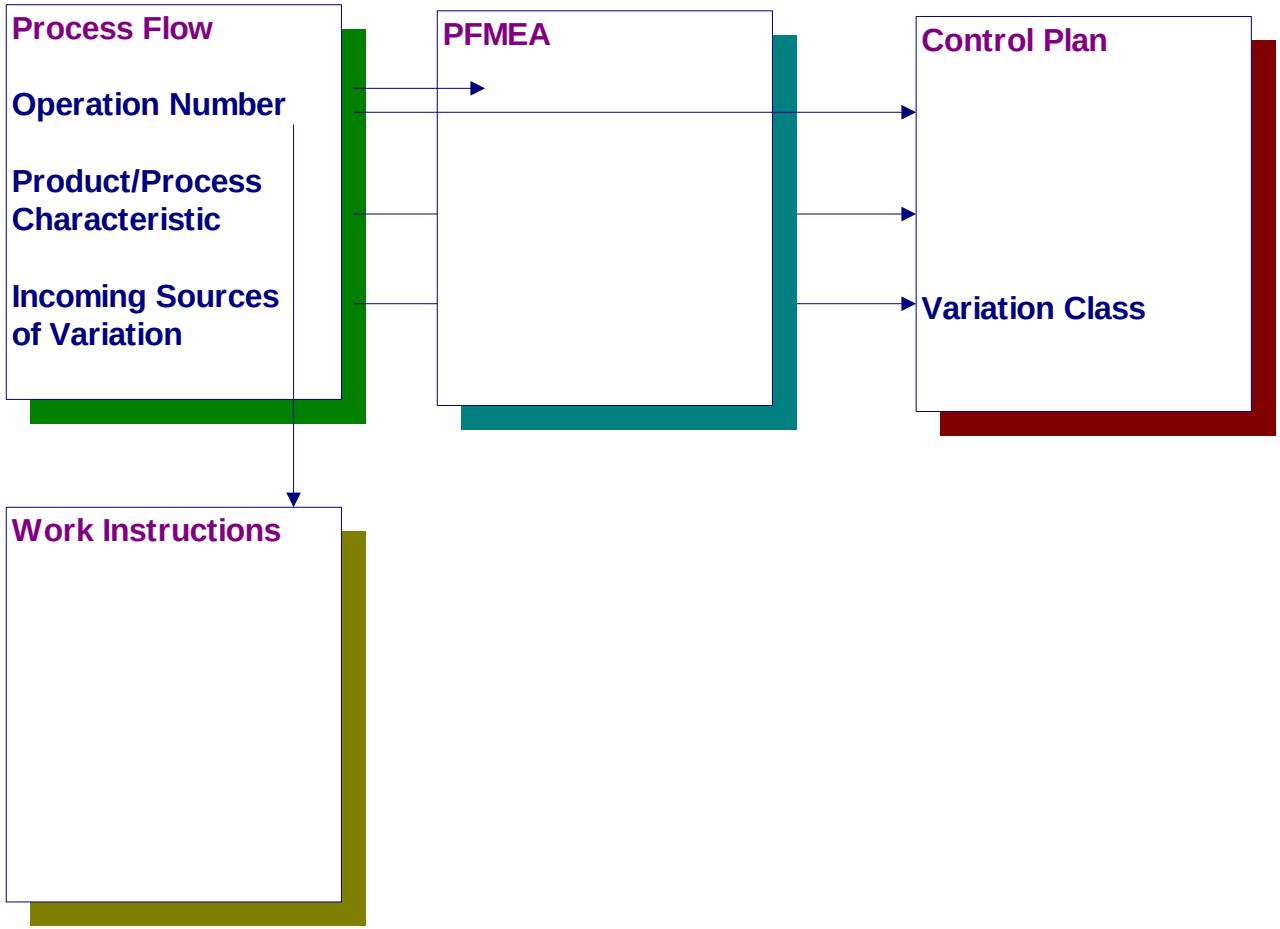
# Links Between the Tools

| | | |
|---|---|---|
| Contract Review Program Plan | Determine Customer Expectations and Plan for Quality | Phase I |
| DFMEA | Identify Key Characteristics | Phase II |
| DVP&R and Team Feasibility Commitment | Determine Risk and Feasibility | Phase II |
| Produce Process Flow Diagrams | Associate Characteristics with Process Steps and Identify Key Characteristics | Phase III |
| Conduct Process FMEA | Expose Sources of Variation and Finalize Key Characteristics | Phase III |
| Develop Control Plan | Determine Methods to Improve Process and Control Variation | Phase III |
| Work Instruction Development | Implement Control Plan and Standardize the Process | Phase III |
| Product and Process Validation | Ensure Customer Expectations are Met | Phase IV |
| Ensure Continuous Improvement | Exercise Management Oversight | Phase V |

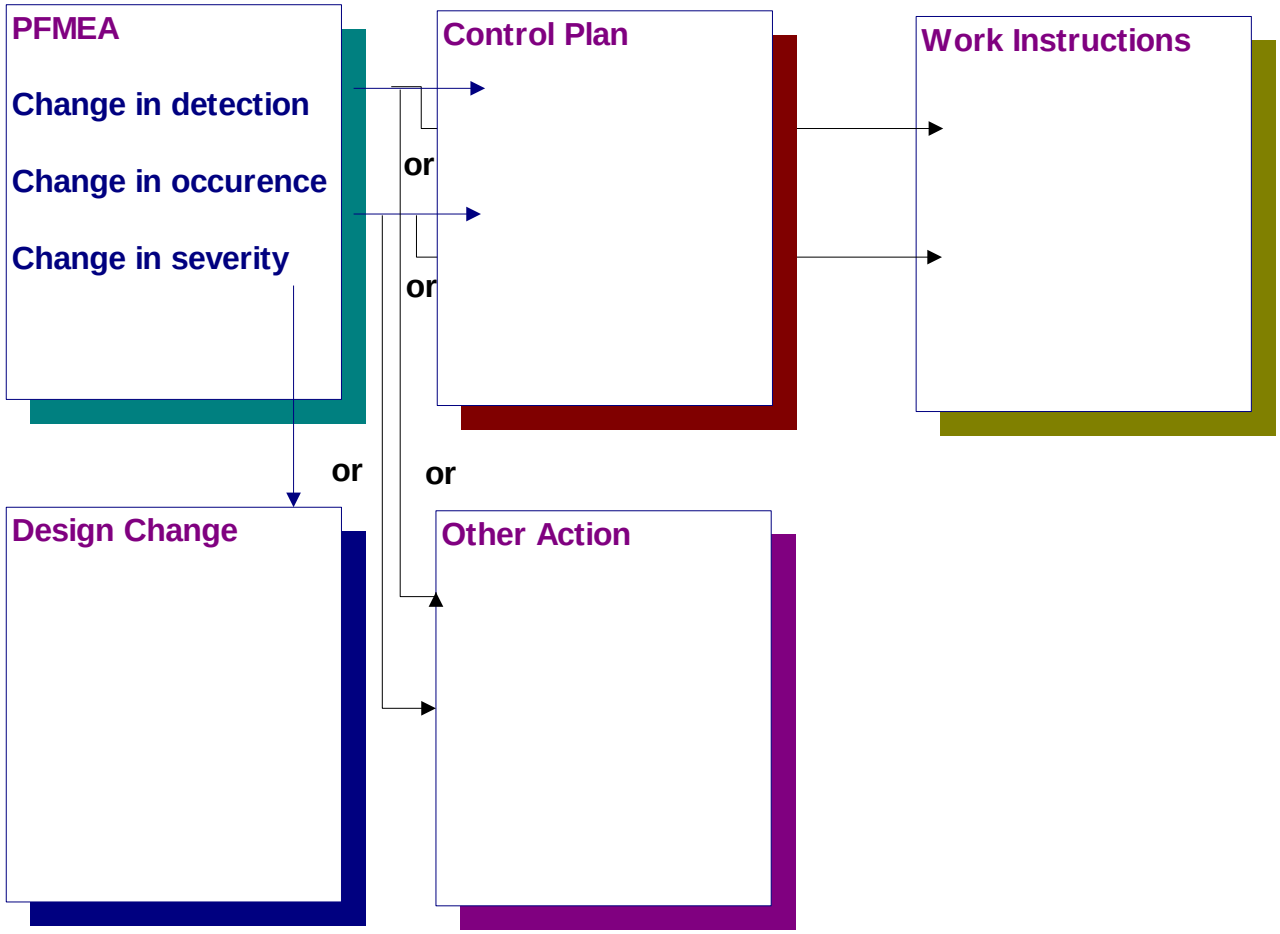
# How a PFMEA Works

- Where does the data for the PFMEA come from?
- What types of people are a part of the PFMEA team?
- What types of activities should we spend a lot of time on?

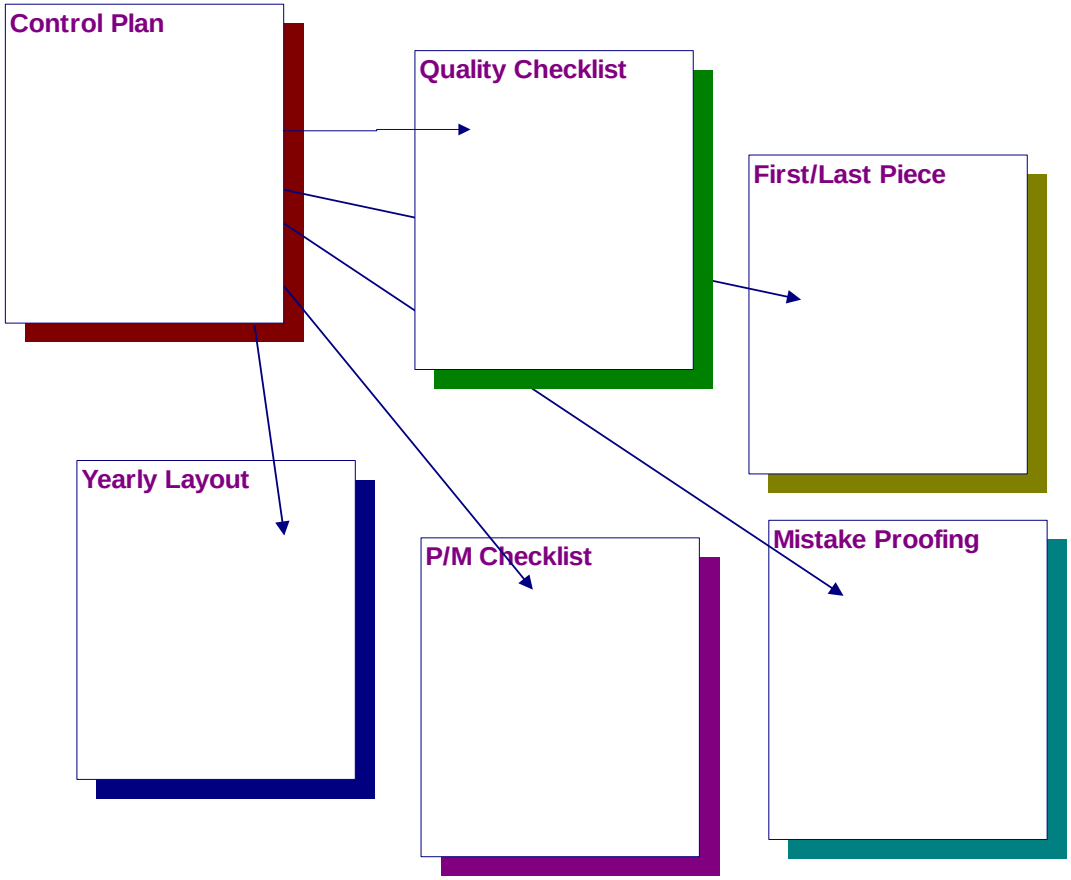
# Link Between the Documents



# APQP Links to PFMEA



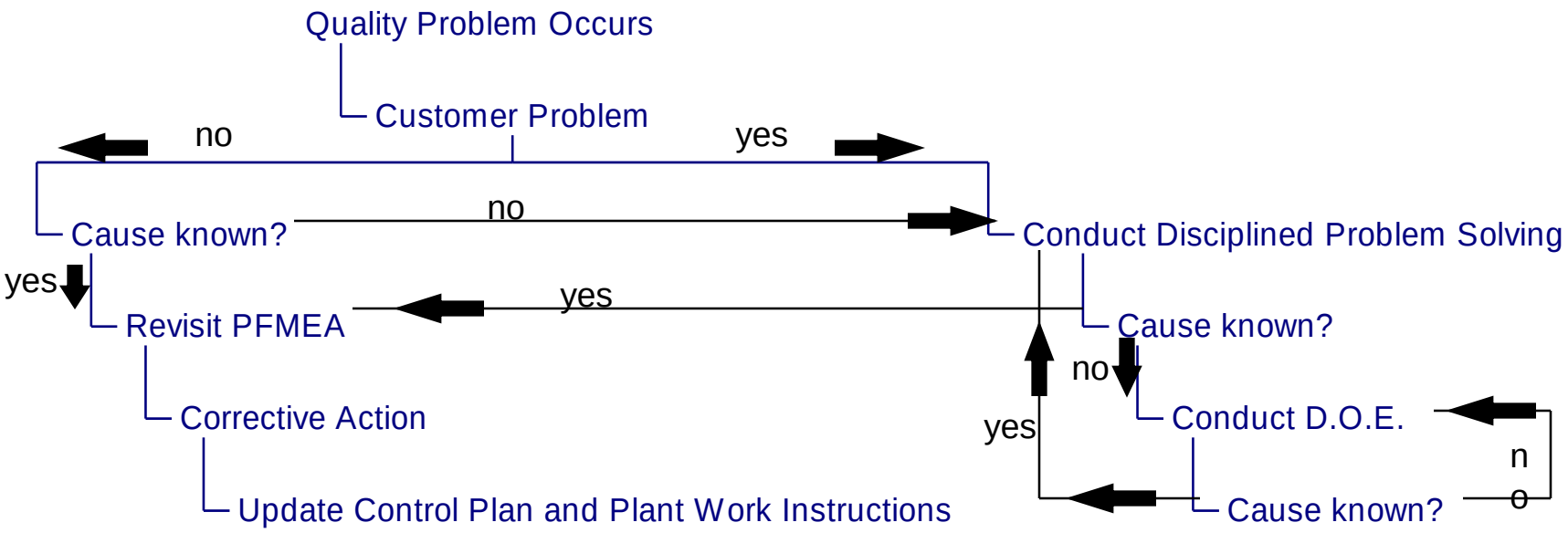
# APQP Links to Control Plan



# PFMEAs/Control Plans and 8-Ds During APQP

- PFMEAs should be driven by real data, including 8-Ds (internal and external), warranty and returned pat analysis
- PFMEAs should be completed by process experts and should be a driver of the control plans and work instructions
- Work instructions (Post control log, process parameter logs, preventive maintenance, etc.) implement the control plan in the process
- When there is a quality problem there is an opportunity to improve the control plan and the work instructions

# Quality Problems



# Cause unknown

- Use PFMEA

Note: When a customer problem occurs, follow customer prescribed methodology

# When to use 8-D

- When the cause is unknown
- When you need to get input from several parties
- When customers dictate use

Note: We use voting techniques, X to Y variable testing, and IS/IS Not to determine the root cause. However, you still may not know what the root cause is?

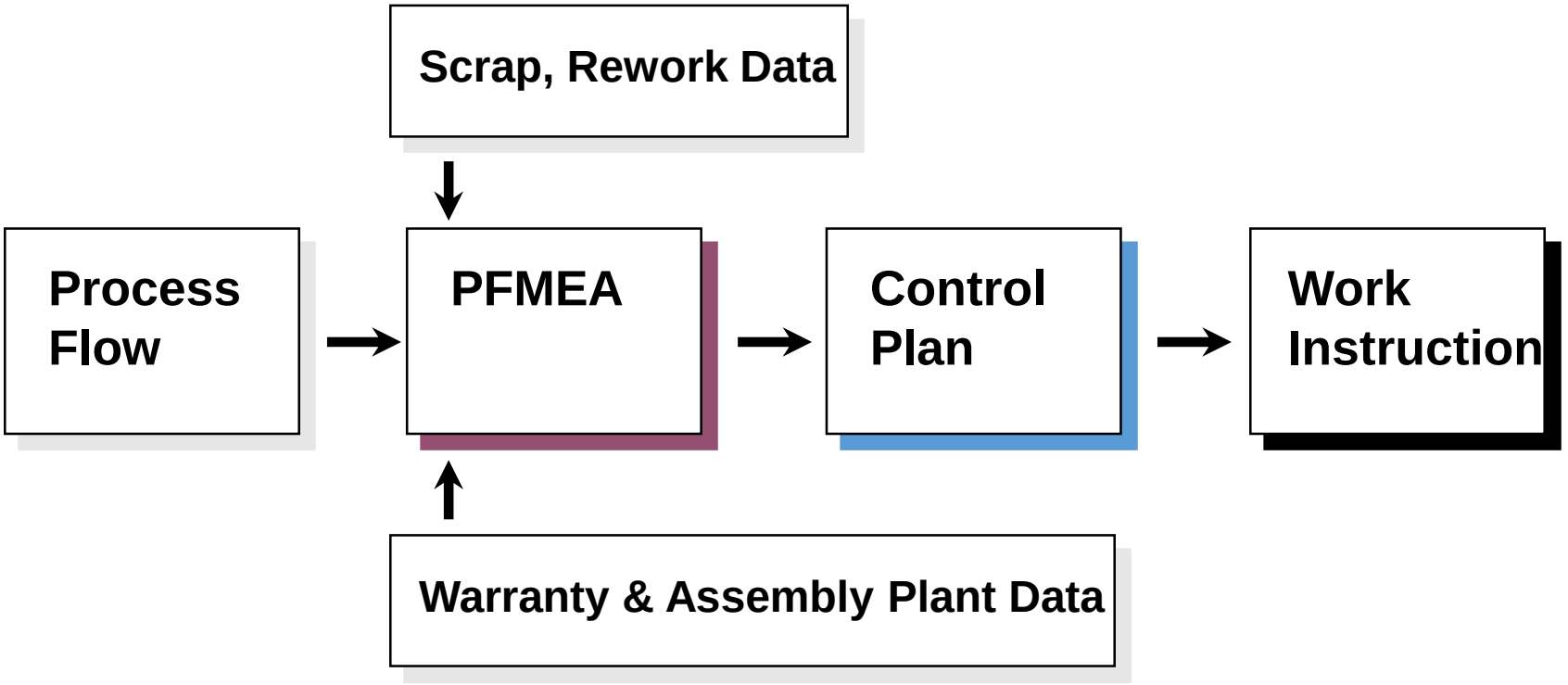
# When to use Designed Experiments or Regression

- After using 8-D, the cause is still unknown
- Designed experiments between cause and effect voted by team could identify the vital few root causes
- Semi-conductor companies collect product and process information that could be used to identify root cause using regression

# QS-9000 Semi-Conductor Supplement

- Conduct containment in 24 hours, electrical verification in 48 hours and root cause and corrective identification in ten days
- Complete returned product analysis
- Analyze the product in a qualified laboratory
- Make sure the corrective actions are effective
- Use the knowledge gained in similar processes and products

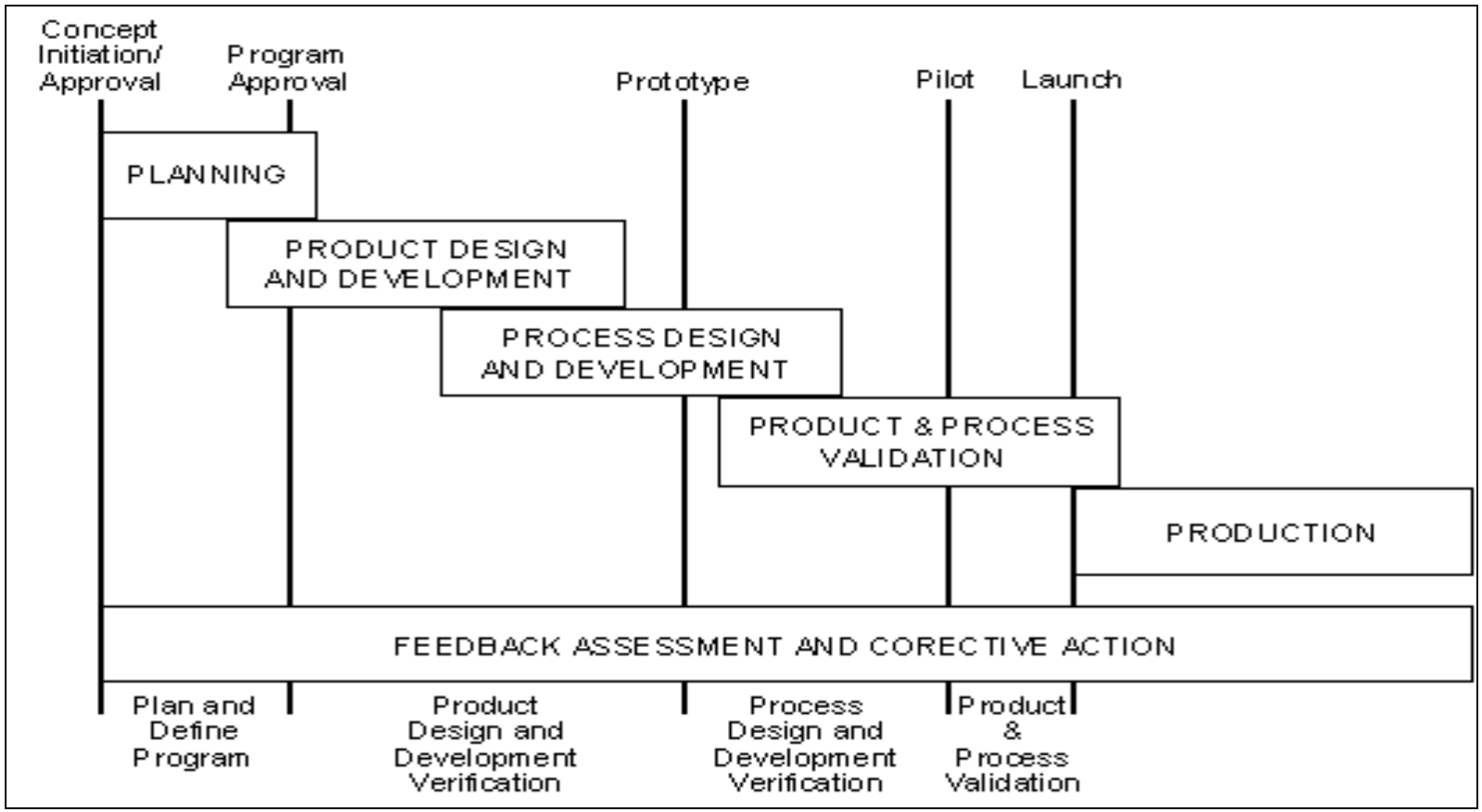
# Update the PFMEA & Control Plans



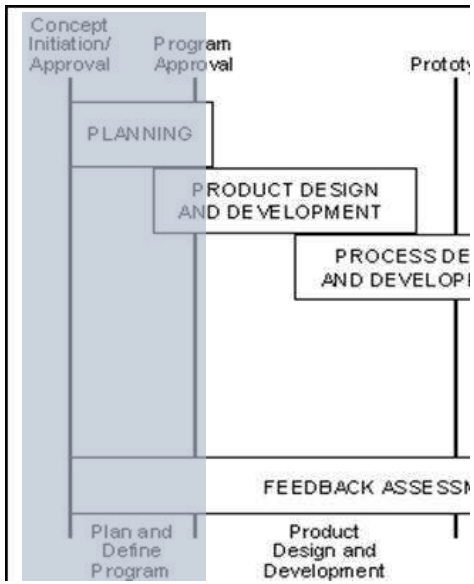

After the 8-D is completed, the PMEA and the control plan should be revised and updated as applicable

# APQP – timing chart and phases - AIAG

The Advanced Product Quality Planning process consists of **four** phases and **five** major activities and has some 20+ supporting tools (e.g. DFMEA, PFMEA, CTQ, Special Characteristics, Control Plan, SPC) along with ongoing feedback assessment and corrective action.



# 1. Plan and Define Program




**Assure that customer needs and expectations are clearly understood.**

**INPUTS:**

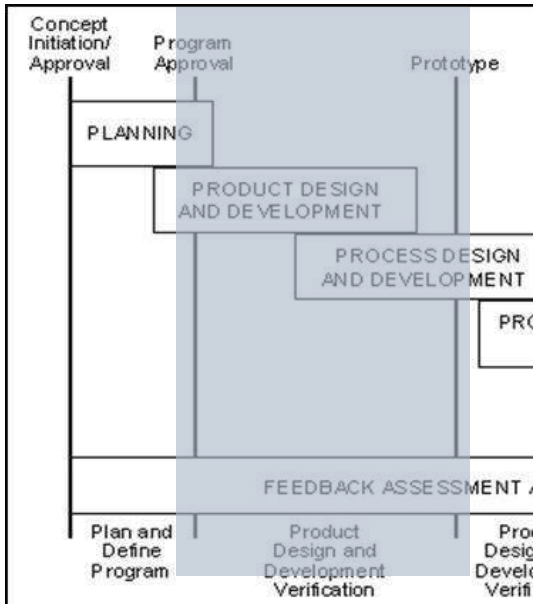
- Voice of the Customer
  - Market Research
  - Historical Warranty and Quality Information
  - Team Experience
- Business Plan/Marketing Strategy
- Product/Process Benchmark Data
- Product/Process Assumptions
- Product Reliability Studies
- Customer Inputs

**OUTPUTS:**

- Design Goals
- Reliability & Quality goals
- CONC targets
- Preliminary Bill of Materials
- Preliminary Process Flow Chart
- Preliminary list of Special Product and Process Characteristics
- Product Assurance Plan
- Management Support

* The inputs and outputs applicable to the process may vary according to the product process and customer needs and expectations.

# 2. Product Design and Development - 1




**Develop design into a near final form. Prototype and feasibility studies – volumes, schedule, manufacturing.**

**INPUTS:**

- Design Goals
- Reliability & Quality goals
- Preliminary Bill of Materials
- Preliminary Process Flow Chart
- Preliminary list of Special Product and Process Characteristics
- Product Assurance Plan

**OUTPUTS:**

- Design Failure Mode and Effects Analysis (DFMEA)
- Design For Manufacturability and Assembly
- Design Verification
- Design Reviews
- Prototype Build – Control plan
- Engineering Drawings (Including Math Data)
- Engineering Specifications
- Material Specifications
- Drawing and Specification Changes

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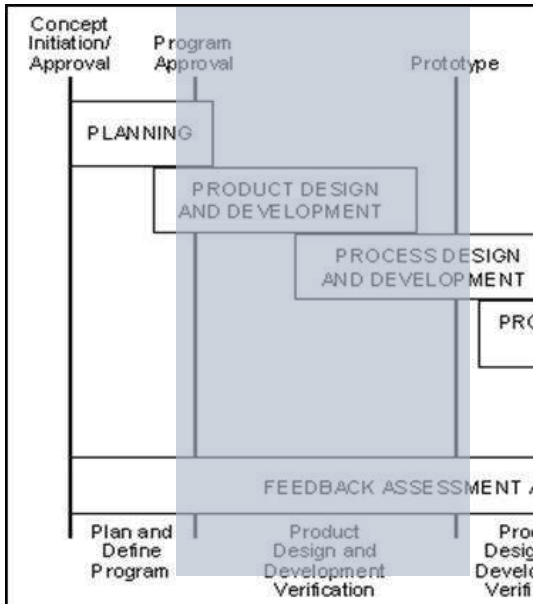
# 2. Product Design and Development - 2




**Develop design into a near final form. Prototype and feasibility studies – volumes, schedule, manufacturing.**

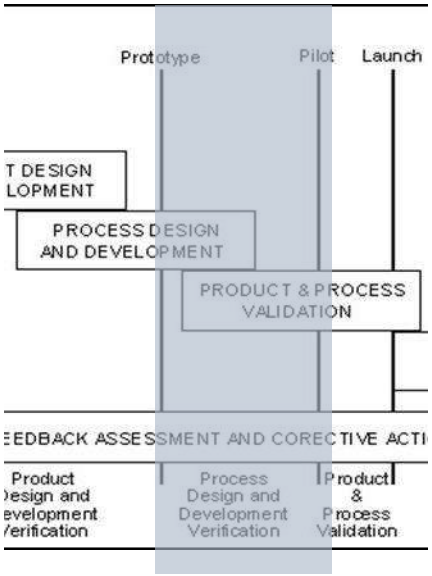
**INPUTS:**

- Design Goals
- Reliability & Quality goals
- Preliminary Bill of Materials
- Preliminary Process Flow Chart
- Preliminary list of Special Product and Process Characteristics
- Product Assurance Plan

**OUTPUTS:**

- New Equipment, Tooling and Facilities Requirements
- Special Product and Process Characteristics
- Gages/Testing Equipment Requirements
- Team Feasibility Commitment
- Management Support

# 3. Process Design and Development




**Develop a manufacturing system and its related control plans to achieve quality products.**

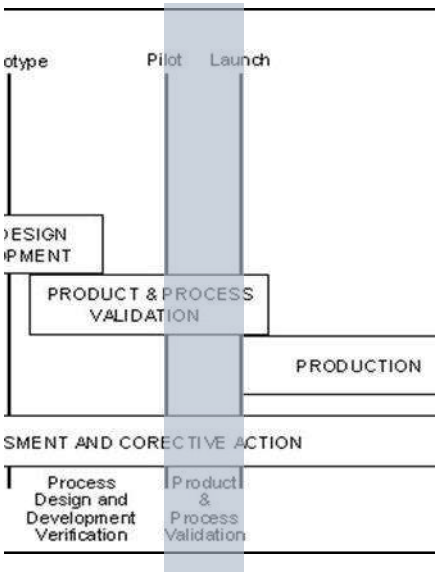
## INPUTS:

- Design Failure Mode and Effects Analysis (DFMEA)
- Design For Manufacturability and Assembly
- Design Verification
- Design Reviews
- Prototype Build – Control Plan
- Engineering Drawings (Including Math Data)
- Engineering Specifications
- Material Specifications
- Drawing and Specification Changes
- New Equipment, Tooling and Facilities Requirements
- Special Product and Process Characteristics
- Gages/Testing Equipment Requirements
- Team Feasibility Commitment
- Management Support

## OUTPUTS:

- Packaging Standards
- Product/Process Quality System Review
- Process Flow Chart
- Floor Plan Layout
- Characteristics Matrix
- Process Failure Mode and Effects Analysis (PFMEA)
- Pre-Launch Control Plan
- Process Instructions
- Measurement Systems Analysis Plan
- Preliminary Process Capability Study Plan
- Packaging Specifications
- Management Support

# 4. Product and Process Validation




**Validate manufacturing process through production trial run.**
**Validate that the control plan and process flow chart are effective and that the product meets customer expectation.**

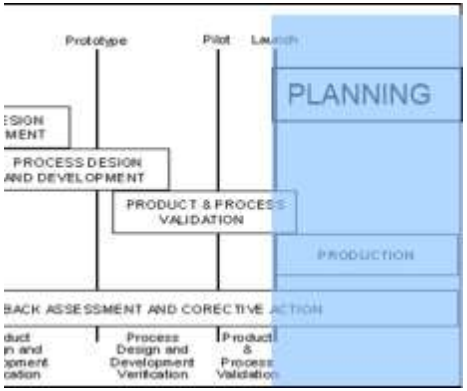
**INPUTS:**

- Packaging Standards
- Product/Process Quality System Review
- Process Flow Chart
- Floor Plan Layout
- Characteristics Matrix
- Process Failure Mode and Effects Analysis (PFMEA)
- Pre-Launch Control Plan
- Process Instructions
- Measurement Systems Analysis Plan
- Preliminary Process Capability Study Plan
- Packaging Specifications
- Management Support

**OUTPUTS:**

- Measurement Systems Evaluation
- Significant Production Run
- Preliminary Process Capability Study
- Production Part Approval
- Production Validation Testing
- Packaging Evaluation
- Production Control Plan
- Quality Planning Sign-Off - formal
- Management Support

# Feedback, Assessment, Corrective actions




**Evaluate outputs, effectiveness of the product quality planning efforts.**

**INPUTS:**

- Production Trial Run
- Measurement Systems Evaluation
- Preliminary Process Capability Study
- Production Part Approval
- Production Validation Testing
- Packaging Evaluation
- Production Control Plan
- Quality Planning Sign-Off and Management Support

**OUTPUTS:**

- Reduced Variation
- Improved Customer Satisfaction
- Improved Delivery and Service
- Effective use of best practice, lessons learned
- Maximum ROI
- Minimum Waste
- Minimum CONC

# Application to Different Mfg. Environments

- High Volume
  - APQP plans and activities are organized by part number and are very specific to the part
- Low Volume
  - APQP plans may be specific to part families with activities focused on the parent part
  - More limited validation would be done on child parts
  - Family part differences should be understood and higher risk differences incorporated into APQP plans
- Engineer to Order (ETO)
  - APQP plans may use a part family approach for standardized elements
  - Consider a manufacturing process focus for non-standard elements
    - Create FMEAs and Control Plans for manufacturing processes rather than parts

# APQP Summary:

**What we do:**

- Design Quality
  - DFMEA / PFMEA / DFM/A
- Manufacturing Quality
  - Control Plans
  - Process Flows
  - Measurement System Analysis
  - Capability Analysis
  - Process Validation
  - Run at rate
- Supplier Qualification & Quality Requirements
- Product Qualification
  - 1st Article Inspection
  - PPAP
  - Tooling & Gauges
  - Testing

**How we do it:**

APQP

UP

FRONT

DETAILED

QUALITY

PLANNING

**What we get:**

- Defect Free Launches
- Reduced Warranty Claims
- Zero Spills
- Customer Satisfaction
- Robust Products
- Greater Supplier Control
- Reduced supplier cost

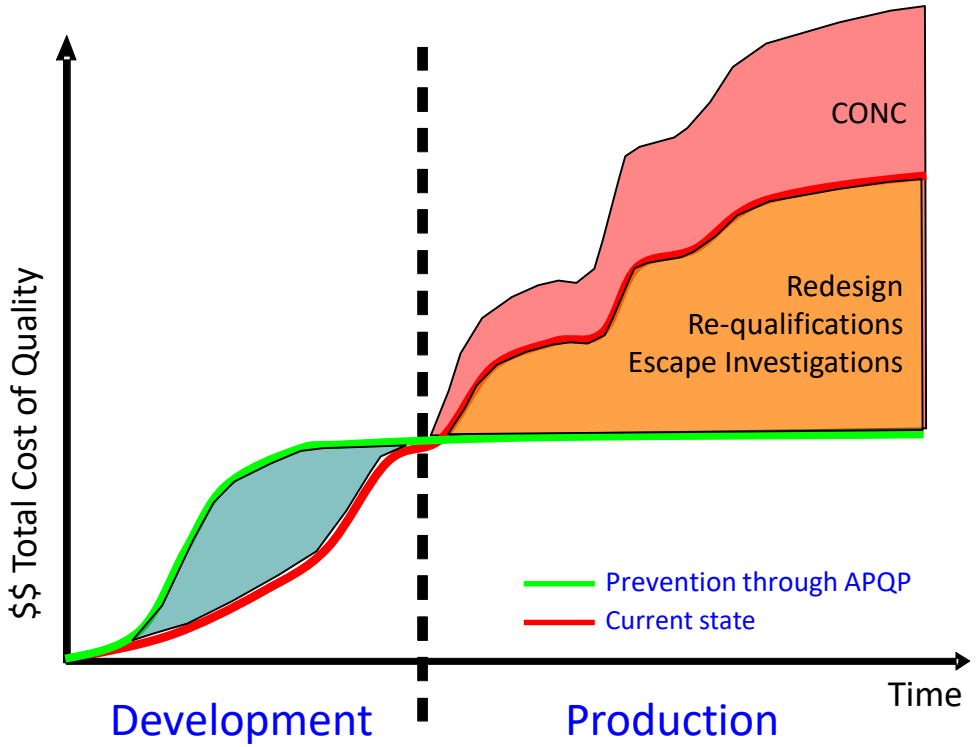
**Leadership Engagement is Critical**


Hamed Ali Mohamed2@gmail.com

# APQP Benefits:

Manufacturing process functions that are clearly planned, validated, documented and communicated that result in:

- Robust and reliable designs
- Reduced process variation
- Enhanced confidence in supplier's capabilities
- Better controlled process changes
- Defect free launches
- Improved Customer satisfaction
- Improved Delivery and Service
- Maximum ROI
- Minimum Waste
- Minimum Cost of Non-conformance



# Key Take Aways:

- APQP is cross-functional planning and execution to produce product that fully meets the customer's expectations ***the first time***
- AIAG APQP phases are Planning, Product Design, Process Design, Validation, Production
- Phase approach ensures activities are completed in the appropriate order
- Can be applied to different manufacturing environments – High Volume, Low Volume, ETO
- It's cross-functional – Marketing/Design/Manufacturing/SCM/Quality

# Approval Process (PPAP)

# What is a First Article Inspection?

- A First Article Inspection (FAI) requires that all dimensions for a part be checked and verified prior to full production and receipt of part into the customer facility.
- All dimensions, (except reference dimensions), characteristics, and specifications, as noted on the design record and process control plan, are to be listed on the FAI Report with the actual dimension results recorded.

# What is PPAP?

- Production Part Approval Process
- Standard used to formally reduce risks prior to product or service release, in a team oriented manner using well established tools and techniques
- Initially developed by AIAG (Auto Industry Action Group) in 1993 with input from the Big 3 - Ford, Chrysler, and GM
- AIAG's 4th edition effective June 1, 2006 is the most recent version
- PPAP has now spread to many different industries beyond automotive

# Production Run

- PPAP data must be submitted from a production run using:
  - Production equipment and tooling
  - Production employees
  - Production rate
  - Production process

**All data shall reflect the actual production process that will be used at start-up!**

# Purpose of PPAP

- Provide evidence that all customer engineering design record and specification requirements are properly understood by the organization
- To demonstrate that the manufacturing process has the potential to produce product that consistently meets all requirements during an actual production run at the quoted production rate

# What's the Difference in PPAP vs. FAI?

- FAI gives confidence regarding the sample.
- In addition, PPAP gives confidence in future product.

# When is PPAP Required?

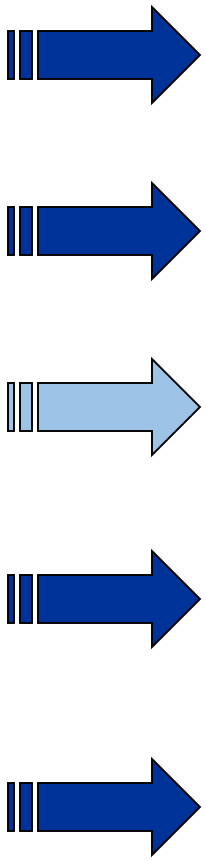
- New part
- Engineering change(s)
- Durable Tooling: transfer, replacement, refurbishment, or additional
  - Tooling inactive > one year
- Correction of discrepancy
- Change to optional construction or material
- Sub-supplier or material source change
- Change in part processing
- Parts produced at a new or additional location

**PPAP is required with any significant change to product or process!**

# Benefits of PPAP Submissions

- Helps to maintain design integrity
- Identifies issues early for resolution
- Reduces warranty charges and prevents cost of poor quality
- Assists with managing supplier changes
- Prevents use of unapproved and nonconforming parts
- Identifies suppliers that need more development
- Improves the overall quality of the product & customer satisfaction

# PPAP Submission Levels



| | |
|---|---|
| Level 1 | Production Warrant and Appearance Approval Report (if applicable) submitted to Eaton |
| Level 2 | Production Warrant, product samples, and dimensional results submitted to Eaton |
| Level 3 | Production Warrant, product samples, and complete supporting data submitted to Eaton |
| Level 4 | Production Warrant and other requirements as defined by Eaton |
| Level 5 | Production Warrant, product samples and complete supporting data (a review will be conducted at the supplier's manufacturing location) |

# PPAP Submission Requirements

| Requirement | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| 1.Design Record | R | S | S | * | R |
| 2.Engineering Change Documents, if any | R | S | S | * | R |
| 3.Customer Engineering approval, if required | R | R | S | * | R |
| 4.Design FMEA | | | | | |
| 5.Process Flow Diagrams | | | | | |
| 6.Process FMEA | | | | | |
| 7.Control Plan | | | | | |
| 8.Measurement System Analysis studies | | | | | |
| 9.Dimensional Results | | | | | |
| 10.Material, Performance Test Results | | | | | |
| 11.Initial Process Studies | | | | | |
| 12.Qualified Laboratory Documentation | | | | | |
| 13.Appearance Approval Report (AAR), if applicable | S | S | S | * | R |
| 14.Sample Product | R | S | S | * | R |
| 15.Master Sample | R | R | R | * | R |
| 16.Checking Aids | R | R | R | * | R |
| 17.Records of Compliance With Customer Specific Requirements | R | R | S | * | R |
| 18.Part Submission Warrant | S | S | S | S | R |
| [illegible] | S | S | S | S | R |

Note: For each level, full APQP is required. The PPAP level simply indicates which elements you submit, and which you retain at your site.

Any customer specific requests fall under Element # 17

customer and retain a copy of records or documentation items at appropriate

R = The organization shall retain at appropriate locations and make available to the customer upon request

* = The organization shall retain at the appropriate location and submit to the customer upon request

# PPAP Element 17: Eaton Requirements

- Depending on the specific Eaton business, Eaton may require:
  - APQP Kickoff - team
  - APQP Timeline Template
  - Action Item Log
  - Production Feasibility Agreement (PFA)
  - Gage Plan
  - Dimensional Correlation Matrix
  - Pass Through Characteristics (PTC)
  - Safe Launch Control Plan
  - AS 9102 Forms (Aerospace Industry)
  - Ramp Up & Down Plan
  - Packaging Specification Data Sheet
  - Submit Bar Code Label Packaging Approval
  - PPAP Interim Recovery Worksheet
  - Capacity R@R Worksheet
  - Production Readiness Review (PRR)

# PPAP Status

- Approved
  - The part meets all Eaton requirements
  - Supplier is authorized to ship production quantities of the part
- Interim Approval
  - Permits shipment of part on a limited time or piece quantity basis
- Rejected
  - The part does not meet Eaton requirements, based on the production lot from which it was taken and/or accompanying documentation

**Production quantities shall not be shipped before Eaton Approval**

# Eaton PPAP Process

- Eaton determines PPAP level based on component risk
  - Submission requirements are increased for higher risk components
- Eaton communicates requirements to supplier (RFQ, APQP Kick-off Meeting, and/or PPAP request – PPAP Workbook, etc.)
- Eaton provides a standard PPAP workbook with all necessary tools
  - Supplier can use their own templates and tools if they meet the AIAG requirements
- Supplier conducts APQP per AIAG requirements (Use PPAP workbook forms as necessary)

# Adapting PPAP for High Mix/Low Volume and Engineer to Order Manufacturing

- Group parts into part families
  - Which parts use the same manufacturing process flow?
  - Which parts have 90%+ features in common?
- Design and validate processes based on part families
- Look at individual processes – use planning and prevention tools such as PFMEA, Control Plan by process

# PPAP Element #1: Design Record

- Includes:
  - Component drawings
  - Assembly drawings
  - Bill of Materials
  - Referenced engineering specifications
  - Material specifications
  - Performance or test specifications
- Ensures manufacturer has the complete design record at the correct revision levels
- This requirement may be satisfied by attaching the “ballooned” design record to the Production Feasibility Agreement (PFA) – located in the PPAP Workbook
  - Some Eaton businesses may use an alternate approach

# PPAP Element #2: Authorized Engineering Change Documents

- The supplier shall provide authorized change documents for those changes not yet recorded in the design record, but incorporated in the product, part or tooling, such as:
  - ECNs (must be approved, not pending)
  - Specification changes
  - Supplier change requests
  - Sub-assembly drawings
  - Life or reliability testing requirements

# PPAP Element #3: Customer Engineering Approval

- Written statement from Customer Engineering approving the parts
  - Example: supplier designed components in which we require additional information for validation of designs…for structural integrity
  - The engineering design requires approval
  - Other elements of the PPAP validate the manufacturing process

# PPAP Element #4: Design Failure Mode and Effects Analysis (DFMEA)

- Provide potential cause and effect relationships for the basic design of the product
- Helps to plan design needs for:
  - Materials selection
  - Tolerance stack-up
  - Software
  - Interfaces
  - DVP&R  (life cycle tests)
- Employs R.P.N rating system
  - High R.P.N's and Severity> 8 need recommended Corrective Actions (CA)
- PROLaunch element
  - Initial DFMEA in Phase 2
  - Complete DFMEA in Phase 3
- May be "Family" based

# Difference between DFMEA and PFMEA

- DFMEA ***does not*** reference manufacturing controls
  - Design controls include:
    - Tolerance stack-up analysis
    - Simulation
    - Finite Element Analysis
    - Testing
- Recommended actions should be ***Design*** actions
  - Re-design
  - Testing
  - Analysis

# DFMEA Common Pitfalls

- One time document
  - Must be continuously reviewed and updated
  - What if the latest change or revision has a significant impact?
- Not submitted or reviewed with supplier
- The After Thought
  - Completed after drawing and production release
  - Doesn't help to direct the design effort
- Does not consider all potential failure modes
- Critical and/or Special Characteristics not identified
- Only considers full assembly
  - Not completed to correct level – component, sub assembly, assembly, product
- Family based DFMEA not all inclusive
  - Not reviewed for specific/ custom application/ designs

# “Good” DFMEA Example

| Potential Failure Mode(s) | Potential Failure Effects | Class | SEV | Potential Causes | OCC | Current Controls Prevent | Current Controls Detect | DET | RPN |
|---|---|---|---|---|---|---|---|---|---|
| Impeller Failure | Low Flow at High Speeds & High Flows | | 8 | Impeller Fracture | 2 | | Impeller stress analysis, thermal limits, vibration analysis | 6 | 96 |
| Relief Valve Open | Reduced Overall Efficiency due to Internal Leakage | | 8 | Relief Valve Stuck due to Contamination | 3 | | Relief valve force margin, relief valve clearances, sharp edges | 5 | 120 |
| Housing Fracture | Reduced Overall Efficiency due to Internal Leakage | | 4 | Housing Fracture due to Vibration | 3 | | Analyze housing vibration modes in conjunction with vibration requirements | 6 | 72 |

| Actions Recommended | Action Owner | Target Date | Actions Taken | New SEV | New OCC | New DET | New RPN |
|---|---|---|---|---|---|---|---|
| Perform Stack Up Analysis with Transient / Steady State Thermal Effects | Joe Smith | 11-May-14 | Stackups complete | 8 | 2 | 2 | 32 |
| Perform Cartridge Static Load & Deflection Analysis | Jan Doe | 11-Aug-14 | Analysis complete | 8 | 2 | 2 | 32 |
| Perform Thermal Stack Analysis and Thermal Shock Test | Joe Smith | 12-Sep-14 | Thermal analysis complete | 4 | 3 | 3 | 36 |

# Progress Check: DFMEA

- In which APQP phase would you first create a DFMEA?
  - APQP: Phase 2 – Product Design
- Which of the following activities should be done before the DFMEA?
  - Create PFMEA
  - Customer CTQs identified
  - Suppliers Selected
  - Gage Plan Created


- Which FMEA risks need recommended actions?
  - Any over 100 RPN
  - Higher risks - by RPN, Severity or Occurrence
- What is the impact of creating a PFMEA without a DFMEA?
  - May not properly understand the severity of failure effects

# PPAP Element #5: Process Flow Diagram(s)

- Step by Step designation of the process flow required to produce the referenced product which meets all customer requirements
  - Provide linkage to PFMEA and Control Plan
  - Traditional block diagram
  - May employ “Family” based diagrams
  - Should cover all steps from Receiving to Shipping

(for additional details reference Advance Product Quality Planning and Control Plan AIAG Manual)

# Process Flow Diagrams

**PROCESS / INSPECTION FLOWCHART**

| | | | | | |
|---|---|---|---|---|---|
| Product Program | | | Issue Date | ECL | **ECL** |
| Supplier Name | **ORGANIZATION** | | Part Name | **NAME** | |
| Supplier Location | **CITY** | **STATE** | Part Number | **NUMBER** | |

Legend:

○ Operation ⇨ Transportation □ Inspection D Delay ▽ Storage

| STEP | Operation or Event ○ ⇨ □ D ▽ | Description of Operation or Event | Evaluation and Analysis Methods |
|---|---|---|---|
| | | | |

**The process flow diagram utilizes these symbols to clearly identify each step in the process**

# Preparing the Process Map

- Team Effort:
  - Engineers
  - Operators
  - Supervisors
  - Maintenance
  - Supply Chain
- Possible Inputs to Mapping:
  - Engineering specifications
  - Lead time requirements
  - Target manufacturing costs
  - Operator experience
  - Observation
  - Brainstorming

# Process Flow Diagrams

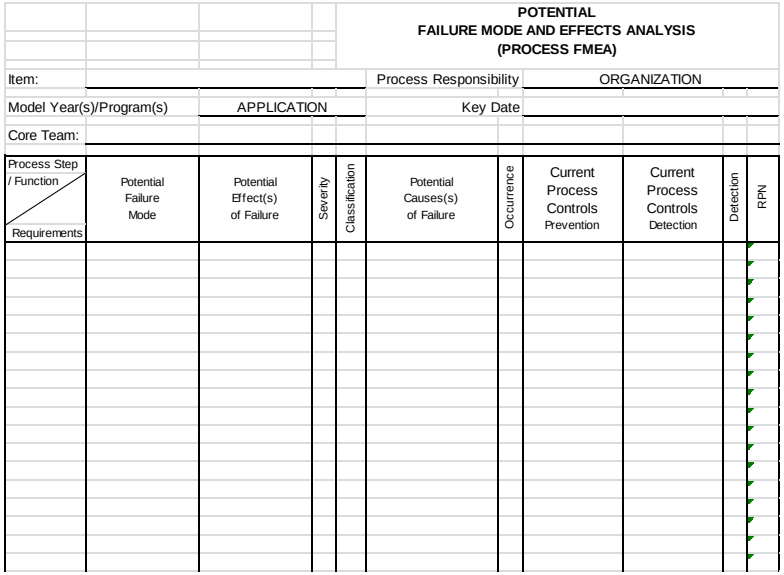
- Reviewers Checklist
  - ✓Process Flow must include all phases of the process
    - Receiving
    - Storage/ material handling
    - Manufacturing
    - Offline inspections and checks
    - Assembly
    - Testing
    - Shipping
  - ✓Should include abnormal handling processes
    - Scrap
    - Rework
    - Extended Life Testing
  - ✓May also include Transportation

# Process Map and APQP

- During which APQP phase would you first create a process map?
  - ✓APQP: Phase 1 – Planning
- Why not wait until later in the process?
  - A basic understanding of the process assists in cost estimating/ quoting
  - Need to know process steps to understand what equipment/tooling/gages may be required
- Why would volumes and lead-times be important to know?
  - Volumes and lead-times might influence the manufacturing processes you select (i.e. automated processes for high volume)

# PPAP Element #6: Process FMEA (PFMEA)

- What is It?
  - A tool used to identify and prioritize risk areas and their mitigation plans.
- Objective or Purpose
  - Identifies potential failure modes, causes, and effects. Inputs come from the process flow diagram.
  - Identifies key inputs which affect quality, reliability and safety of a product or process.
- When to Use It
  - New product launches
    - After completion of the process flow diagram.
    - Prior to tooling for production
  - When troubleshooting production issues
  - When planning and closing preventive and corrective actions



POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

Item: | Process Responsibility | ORGANIZATION

Model Year(s)/Program(s) | APPLICATION | Key Date

Core Team:

| Process Step / Function / Requirements | Potential Failure Mode | Potential Effect(s) of Failure | Severity | Classification | Potential Causes(s) of Failure | Occurrence | Current Process Controls Prevention | Current Process Controls Detection | Detection | RPN |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |

**IMPORTANT!**

**The PFMEA should be completed using a *cross-functional* team!**

# FMEA Origins

- Initially developed by the US Military as Failure Mode Effects and Criticality Analysis (FMECA)
- Widely adopted by NASA during the 1960s to prevent errors on the Apollo program
- Brought over to the automotive industry by Ford after issues with Pinto fuel tanks


Apollo 1 Failure


Ford Pinto

# PFMEA - Step 1

| Process Step | Potential Failure Mode | Pot | | C | | O C C | Current Controls: Prevent | Current Controls: Detect | D E T |
|---|---|---|---|---|---|---|---|---|---|
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specificed requirements? Consider: (A) No Function (B) Partial/Over/Degraded Function (C) Intermittent Function (D) Unintended Function. | Wh … vari … r … re … What are the effects of the failure on the function as perceived by internal and external customers? | How severe is the eff… See SEV table. | Classify any special p… characteristics needin… controls. | …uses … input …? … se the … s of … can be …ntrolled? | How often does the cause of the failure mode occur? See OCC table. | What are the existing process controls to **prevent** the cause of failure or failure mode from occurring or reduce the rate of occurrence? **Should include an SOP number.** | What are the existing process controls to **detect** the cause of failure or failure mode and lead to corrective action(s)? **Should include an SOP number.** | How well can you detect the cause of failure mode? See DET table. |
| Assemble Hardware Kit | Wrong and/or missing parts/labeling (B) | Customer unable to install product | 8 | | Operator places wrong hardware and/or label with kit | 3 | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 |
| Assemble Hardware Kit | Bad seal (B) | Customer unable to install product, due to missing hardware. | 8 | | Bagger error | 2 | Work Instructions | Visual Inspection | 8 |

**Failure Modes**
**For each Process Input, determine the ways in which the input can go wrong.**

**Using the completed Process Flow Diagram, enter the process step.**

**TIP**

- **There should be at least one failure mode for each input.**

# Potential Failure Mode

- List all credible failure modes or ways the process/operation can fail in the PFMEA document before addressing failure effects and failure causes
- In each instance, the assumption is made that the failure could occur, but will not necessarily occur
- The failure mode:
  - "… is the manner in which the process could potentially fail to meet the process requirements and/or design intent."
  - Is a description of nonconformance
  - Assumes incoming parts are correct
  - Considers subsequent operations
- Typical failure modes could be, but are not limited to:
  - Bent
  - Open circuited
  - Dirty
  - Binding
  - Cracked
  - Improper setup
  - Burred
  - Deformed
  - Tool worn
  - Handling Damage

# Example Failure Modes by Activity

| *Placement* | *Bend* | *Test* | *Insert* | *Remove / Unload* | *Index* | *Measure* |
|---|---|---|---|---|---|---|
| Missing Component | X Orientation | Accept Non-Conforming Part | No Insertion | Fails to Remove Non-Conforming Part | X-Y Orientation | Accept Non-Conforming Part |
| Wrong Component | Z Orientation | Reject Conforming Part | Partial Insertion | Removes Conforming Part | No index | Reject Conforming Part |
| Multiple Components | Y Orientation | No test | Over Insertion | Miscategorization | | No measure |
| X Location | Radial Orientation | | | No remove | | Inaccurate Gaging |
| Y Location | Dirt Contamination | | | Missed op | | |
| Z Location | Damage | | | Damage | | |
| Radial Orientation | Flattened | | | Contamination | | |
| Dirt Contamination | Cracked | | | | | |
| Damage | Folded | | | | | |
| Upside down | Broken fold | | | | | |
| Backwards | Scratch | | | | | |
| | Dents | | | | | |
| | Chips | | | | | |
| | Deformed | | | | | |
| | No bend | | | | | |
| | | | | | | |

# Example Failure Modes by Activity (cont.)

| *Stake* | *Dip* | *Package* | *Initialize* | *Synchronize* | *Setup* | *Pump-Up* |
|---|---|---|---|---|---|---|
| No Stake | Missed Operation | Incorrect Qty | Fail to Clear Registers | Fail to Recognize Station | Incorrect Setup | Does not Pump-Up |
| Under Stake | Partial Dip | Incorrect Label | Write Incorrect Value to Register During Clearing | No Synchronize | Incomplete Setup | |
| Over Stake | | Incorrect Box | | | No Setup | |
| | | Mixed Parts | | | | |
| | | Damage | | | | |
| | | | | | | |
| | | | | | | |

| *Feed-Out* | *Wind* | *Cut-Off* | *Press* | *Load* | *Fill / Oil* | *Torque* |
|---|---|---|---|---|---|---|
| Wrong Wire | Too Few Coils | No Cut-Off | High force | Wrong part | Wrong fluid | Damaged component |
| No Feed | Too Many Coils | | Low force | Mix part | Too much fluid | No torque |
| Feed Too Short | Free Length Short | | Tooling alignment | Dirty part | Too little fluid | Over torque |
| Feed Too Long | Free Length Long | | Too Fast Speed | Wrong lane | | |
| | | | Too slow speed | Wrong orientation | | |
| | | | Short stroke | Damage | | |
| | | | Over stroke | | | |
| | | | | | | |

# Example Failure Modes by Activity (cont.)

| ***Rotate*** | ***Mark*** | ***Grease*** | ***Mold*** |
|---|---|---|---|
| Partial Rotation | Incomplete | Wrong Grease | Density variation |
| Over Rotation | Illegible | no grease | Dimension variation |
| No rotation | Wrong Mark | X-Y Orientation | Sink |
| Rotate to wrong side | Missing Mark | Z Orientation | Flowlines |
| Damaged component | Wrong location | Damage | Shorts |
| | Contamination | Too much | Warp |
| | | Too little | Molded contamination |
| | | Contamination | Weldlines |
| | | Incorrect number of greasing points | color variation |
| | | | brittleness |
| | | | scratches |
| | | | drag marks |
| | | | gate stubs |
| | | | burns |
| | | | flash |
| | | | mixed parts |
| | | | part count incorrect |
| | | | bubbles |
| | | | sirface contamination |
| | | | voids |
| | | | splay |
| | | | damaged part |
| | | | wrong part |

# PFMEA - Step 2

| Process Step | Potential Failure Mode | Potential Failure Effects | SEV | CLASS | Potential | Occ | Current Process Controls | Detect | DET |
|---|---|---|---|---|---|---|---|---|---|
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specificed requirements? Consider: (A) No Function (B) Partial/Over/Degraded Function (C) Intermittent Function (D) Unintended Function. | What is the impact on the output variables (customer requirements) or internal requirements? What are the effects of the failure on the function as perceived by internal and external customers? | How severe is the effect to the customer? See SEV table. | Classify any special product or process characteristics needing additional controls. | What cause to go w… What could failure, in something tha… corrected or controlled? | How often does the cau… mode occur? See OCC | …occurrence? **Should include an SOP number.** | …are the existing …ss controls to …t the cause of …or failure mode …ad to corrective …action(s)? **Should include an SOP number.** | How well can you detect the cause of failure mode? See DET table. |
| Assemble Hardware Kit | Wrong and/or missing parts/labeling (B) | Customer unable to install product | 8 | | Operator places wrong hardware and/or label with kit | 3 | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 |
| Assemble Hardware Kit | Bad seal (B) | Customer unable to install product, due to missing hardware. | 8 | | Bagger error | 2 | Work Instructions | Visual Inspection | 8 |

**Potential Failure Effects**
**For each Failure Mode, determine what effect the specific failure could have on the process output.**

**TIPS**

- **There should be at least one failure effect for each failure mode.**
- **Effects should be specific, clear, and leave no doubt to the uninformed reviewer.**

# Potential Effect(s) of Failure

- Effect of failure mode based on what customer might notice/experience
- Includes subsequent process operations
- Typical effects may include, but are not limited to:
  - No Function
  - Partial/Over Function/Degraded over time
  - Intermittent Function
  - Unintended Function
  - Erratic operation

# PFMEA – Step 3

| Process Step | Potential Failure Mode | Potential Failure Effects | SEV | CLASS | Potential Causes | OCC | Current Controls: Prevent | Current Controls: Detect | DET |
|---|---|---|---|---|---|---|---|---|---|
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specificed requirements? Consider: (A) No Function (B) Partial/Over/Degraded Function (C) Intermittent | What is the impact on the output variables (customer requirements) or internal requirements? What are the effects of the failure on the function as perceived by internal and external customers? | How severe is the effect to the customer? See SEV table. | Classify any special product or process characteristics needing additional controls. | What causes the input to go wrong? What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | What are the existing process controls to **prevent** the cause of failure or failure mode from occurring or reduce the rate of occurrence? **Should include an SOP number.** | What are the existing process controls to **detect** the cause of failure or failure mode and lead to corrective action(s)? **Should include an SOP number.** | How well can you detect the cause of failure mode? See DET table. |
| | sing | Customer unable to install product | 8 | | Operator places wrong hardware and/or label with kit | 3 | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 |
| Assemble Hardware Kit | Bad seal (B) | Customer unable to install product, due to missing hardware. | 8 | | Bagger error | 2 | Work Instructions | Visual Inspection | 8 |

**Class**
Identify special product or process characteristics

# PFMEA - Step 4

| Process Step | Potential Failure Mode | Potential Failure Effects | SEV | CLASS | Potential Causes | OCC | Current Controls: Prevent | Current Controls: Detect | DET |
|---|---|---|---|---|---|---|---|---|---|
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specificed requirements? Consider: | What is the impact on the output variables (customer requirements) or internal | How severe is the effect to the customer? See SEV table. | Classify any special product or process characteristics needing additional controls. | What causes the input to go wrong?<br><br>What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | What are the existing process controls to **prevent** the cause of failure or failure mode from occurring or reduce the rate of occurrence? **Should include an SOP number.** | What are the existing process controls to **detect** the cause of failure or failure mode and lead to corrective action(s)? **Should include an SOP number.** | How well can you detect the cause of failure mode? See DET table. |
| Assemble Hardware Kit | Wrong and/or missing parts/labeling (B) | Customer unable to install product | 8 | | Operator places wrong hardware and/or label with kit | 3 | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 |
| Assemble Hardware Kit | Bad seal (B) | Customer unable to install product, due to missing hardware. | 8 | | Bagger error | 2 | Work Instructions | Visual Inspection | 8 |

**Potential Causes**
**For each Failure Mode, determine the possible cause of the failure.**

**TIP**

- **There should be at least one potential cause for each failure mode.**

# Potential Cause(s) of Failure

- "…how the failure could occur."
- Described in terms of something that can be corrected/controlled
- Requires determination of root cause
- Sources of process variation that cause the failure mode to occur
- Typical failure causes may include, but are not limited to:
  - Improper torque – over, under
  - Improper weld – current, time, pressure
  - Inaccurate gauging
  - Improper heat treat – time, temperature
  - Inadequate gating/venting
  - Part missing or installed incorrectly
  - Thermocouple broken
  - Typographical error

# PFMEA - Step 5

| Process Step | Potential Failure Mode | Potential Failure Effects | SEV | CLASS | Potential Causes | OCC | Current Controls | | DET |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Prevent | Detect | |
| What is the process step or input being evaluated? | In what way(s) could the step or input fail to meet the specified req (A) Partial (C) (D) | What is the impact on the output variables (customer? | ess | | What causes the input to go wrong? What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | What are the existing process controls to **prevent** the cause of failure or failure mode from occurring or reduce the rate of occurrence? **Should include an SOP number.** | What are the existing process controls to **detect** the cause of failure or failure mode and lead to corrective action(s)? **Should include an SOP number.** | How well can you detect the cause of failure mode? See DET table. |
| Assemble Hardware Kit | Wrong and/or missing parts/labeling (B) | Customer unable to install product | 8 | | Operator places wrong hardware and/or label with kit | 3 | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 |
| Assemble Hardware Kit | Bad seal (B) | Customer unable to install product, due to missing hardware. | 8 | | Bagger error | 2 | Work Instructions | Visual Inspection | 8 |

Current Controls
For each potential cause, list the current method used for preventing and/or detecting failure.

**TIPS**

- **This step in the FMEA begins to identify initial shortcomings or gaps in the current control plan.**
- **If a procedure exists, enter the document number.**
- **If no current control exists, list as "none." There may not be both preventive and detection controls.**

# PFMEA - Step 6

| Process Step | Potential Failure Mode | Potential Failure Effects | SEV | CLASS | Potential Causes | OCC | Current Controls | | DET |
|---|---|---|---|---|---|---|---|---|---|
| W… s… | …(B) Partial/Over/Degraded Function (C) Intermittent Function (D) Unintended Function. | What is the impact on the output variables (customer requirements) or internal requirements? What are the effects of the failure on the function as perceived by internal and external customers? | How severe is the effect to the customer? See SEV table. | Classify any special product or process characteristics needing additional controls. | What causes the input to go wrong? What could cause the failure, in terms of something that can be corrected or controlled? | How often does the cause of the failure mode occur? See OCC table. | …ng …o …of …de …ve occurrence? **Should include an SOP number.** | **Should include an SOP number.** | How well can you detect the cause of failure mode? See DET table. |
| Assemble Hardware Kit | Wrong and/or missing parts/labeling (B) | Customer unable to install product | 8 | | | 3 | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 |
| Assemble Hardware Kit | Bad seal (B) | Customer unable to install product, due to missing hardware. | 8 | | | 2 | Work Instructions | Visual Inspection | 8 |

**Assign Severity (How serious is the effect if it fails?)**

**Assign Occurrence (How likely is the cause to occur?)**

**Assign Detection (How easily can the cause or failure mode be detected?)**

# PFMEA - Definition of Terms

- **Severity (of Effect)** - severity of the effect on the Customer and other stakeholders (Higher Value = Higher Severity)
- **Occurrence (of Cause)** - frequency with which a given Cause occurs and creates Failure Mode. (Higher Value = Higher Probability of Occurrence)
- **Detection (Capability of Current Controls)** - ability of current control scheme to detect the cause before creating the failure mode and/or the failure mode before suffering the effect (Higher Value = Lower Ability to Detect)

**Caution: Notice the scale difference for Detection**

# Example: Severity Rating Definitions

| Suggested PFMEA Severity Evaluation Criteria | | | | |
|---|---|---|---|---|
| **Rank** | **Effect** | **Criteria: Severity of Effect on Product (Customer Effect)** | **Effect** | **Criteria: Severity of Effect on Process (Manufacturing / Assembly Effect)** |
| 10 | Failure to Meet Safety and/or Regulatory Requirements | Potential failure mode affects safe Product operation and/or involves noncompliance with government regulation without warning | Failure to Meet Safety and/or Regulatory Requirements | May Endanger Operator (machine or assembly) without warning |
| 9 | | Potential failure mode affects safe Product operation and/or involves noncompliance with government regulation with warning | | May Endanger Operator (machine or assembly) with warning |
| 8 | Loss or Degradation of Primary Function | Loss of primary function (Product inoperable, does not affect safe Product operation) | Major Disruption | 100% of product may have to be scrapped. Line shutdown or stop ship. |
| 7 | | Degradation of primary function (Product operable, but at reduced level of performance) | Significant Disruption | A portion of the production run may have to be scrapped. Deviation from primary process including decrease line speed or added manpower. |
| 6 | Loss or Degradation of Secondary Function | Loss of secondary function (Product operable, but comfort / convenience functions inoperable) | High Disruption | 100% of production run may have to be reworked off line and accepted |
| 5 | | Degradation of secondary function (Product operable, but comfort / convenience functions at reduced level of performance) | | A portion of production run may have to be reworked off line and accepted |
| 4 | Annoyance | Appearance or audible Noise, Product operable, item does not conform and noticed by most customers (>75%) | Moderate Disruption | 100% of production run may have to be reworked in station before it is processed. |
| 3 | | Appearance or audible Noise, Product operable, item does not conform and noticed by most customers (50%) | | A portion of production run may have to be reworked in station before it is processed. |
| 2 | | Appearance or audible Noise, Product operable, item does not conform and noticed by most customers (<25%) | Minor Disruption | Slight inconvenience to process operation or operator. |
| 1 | No Effect | No discernible effect | No Effect | No discernible effect |

# Example: Occurrence Rating Definitions

| Suggested PFMEA Occurrence Evaluation Criteria | | |
|---|---|---|
| **Rank** | **Likelihood of Failure** | **Criteria: Occurrence of Cause - DFMEA (Incidents per Item / Products)** |
| 10 | Very High | => 100 per Thousand |
| | | => 1 in 10 |
| 9 | High | 50 per Thousand |
| | | 1 in 20 |
| 8 | | 20 per Thousand |
| | | 1 in 50 |
| 7 | | 10 per Thousand |
| | | 1 in 100 |
| 6 | Moderate | 2 per Thousand |
| | | 1 in 500 |
| 5 | | 0.5 per Thousand |
| | | 1 in 2,000 |
| 4 | | 0.1 per Thousand |
| | | 1 in 10,000 |
| 3 | Low | 0.01 per Thousand |
| | | 1 in 100,000 |
| 2 | | =< 0.001 per Thousand |
| | | 1 in 1,000,000 |
| 1 | Very Low | Failure is eliminated through preventive control |

# Example: Detection Rating Definitions

| Suggested PFMEA Prevention / Detection Evaluation Criteria | | | | | | |
|---|---|---|---|---|---|---|
| **Rank** | **Likelihood of Detection** | **Opportunity for Detection** | **Inspection Types** | | | **Criteria: Likelihood of Detection by Design Control** |
| | | | **A - Error Proofed** | **B - Gauged** | **C - Manual** | |
| 10 | Almost Impossible | No Detection Opportunity | | | X | No Current Process Control; Cannot Detect or is not Analyzed |
| 9 | Very Remote | Not Likely to Detect at any Stage | | | X | Failure Mode and/or Error (Cause) is not easily detected (eg random audits) |
| 8 | Remote | Controls will probably not detect. Problem detection post processing. | | | X | Failure Mode detection post processing by operator through visual tactile audible means |
| 7 | Very Low | Controls have poor chance of detection Problem detection at source. | | X | X | Failure Mode detection in-station by operator through visual tactile audible means or post processing through use of attribute gauging (go/no go, manual torque check / clicker wrench etc.) |
| 6 | Low | Controls might detect. Problem detection post processing. | | X | X | Failure Mode detection post processing by operator through variable gauging or in-station by operator through the use of attribute gauging (go/no go, manual torque check / clicker wrench etc.) |
| 5 | Moderate | Controls might detect. Problem detection at source. | X | X | | Failure Mode or Error (Cause) detection in-station by operator through the use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light buzzer etc.). Gauging performed on set-up and first piece check (for set-up causes only) |
| 4 | Moderately High | Controls may detect. Problem detection post processing. | X | X | | Failure Mode detection post processing by automated controls that will detect discrepant part and lock part to prevent further processing. |
| 3 | High | Controls have a good chance to detect. Problem detection at source. | X | | | Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing. |
| 2 | Very High | Controls almost certain to detect. Error detection and or problem prevention. | X | | | Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made. |
| 1 | Almost Certain | Detection not applicable, error prevention. | X | | | Error (Cause) prevention as a result of fixture design, machine design or part design. discrepant parts cannot be made because item has been error proofed by process/product design. |

# PFMEA - Step 7

| Process Step | Potential Failure Mode | Potential Failure Effects | SEV | CLASS | Potential Causes | OCC | Current Controls | | DET | RPN |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Prevent | Detect | | |
| Assemble Hardware Kit | Wrong and/or missing parts/labeling (B) | Customer unable to install product | 8 | | Operator places wrong hardware and/or label with kit | 3 | Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 | 192 |
| Assemble Hardware Kit | Bad seal (B) | Customer unable to install product, due to missing hardware. | 8 | | Bagger error | 2 | Work Instructions | Visual Inspection | 8 | 128 |

**Calculate the Risk Priority Number**
**RPN = Severity x Occurrence x Detection**

## TIPS

- **The RPN is used to prioritize the most critical risks**
- **Higher RPNs are flags to take effort to reduce the calculated risk**
  - **Continually work to improve highest risk items - don't set an RPN threshold**
- **In addition to RPN, examine top Severity and Occurrence risks**

# PFMEA – Remediation Guidelines

- **Severity** – can only be improved by a design change to the product or process
- **Occurrence** – can only be reduced by a change which removes or controls a cause. Examples are redundancy, substituting a more reliable component or function or mistake-proofing.
- **Detection** – can be improved by deploying better controls. Examples are mistake-proofing, simplification and statistically sound monitoring.

**In general, reducing the Occurrence is preferable to improving the Detection**

# FMEA – Step 8

| Current Controls | | DET | RPN | Actions Recommended | Responsible | Actions Taken | SEV | OCC | DET | RPN |
|---|---|---|---|---|---|---|---|---|---|---|
| Prevent | Detect | | | | | | | | | |
| Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 | 192 | Implement scale to weigh hardware kits | Kolumban | 7/11/11 - Scale implmented to weigh kits. SK.- *Complete* | 8 | 3 | 5 | 120 |
| Work Instructions | Visual Inspection | 8 | 128 | Repair/replace worn bagger | Zindler | 2010 Capital Plan - New HM Autobagger. Follow status on HM 2010 VSM implementation plan. 7/11/11 - New Bagger implemented 3Q 2010. APZ - *Complete* | 8 | 1 | 8 | 64 |

For the high risk items, determine the recommended actions.

# FMEA – Steps 9 and 10

| Current Controls | | DET | RPN | Actions Recommended | Responsible | Actions Taken | SEV | OCC | DET | RPN |
|---|---|---|---|---|---|---|---|---|---|---|
| Prevent | Detect | | | | | | | | | |
| Work Instructions, Pack Positive | Visual Inspection; Scale to weigh kits | 8 | 192 | Implement scale to weigh hardware kits | Kolumban | 7/11/11 - Scale implmented to weigh kits. SK.- *Complete* | 8 | 3 | 5 | 120 |
| | | | 128 | Repair/replace worn bagger | Zindler | 2010 Capital Plan - New HM Autobagger. Follow status on HM 2010 VSM implementation plan. 7/11/11 - New Bagger implemented 3Q 2010. APZ - *Complete* | 8 | 1 | 8 | 64 |

**Resp (responsibility)**
**Assign a specific person who will be responsible for recommended actions.**

**Actions Taken**
**As actions are identified and completed, document in the "Actions Taken" column.**

**SEV, OCC, DET, RPN**
**As actions are complete reassess Severity, Occurrence, and Detection and recalculate RPN.**

# Summary Steps To Complete a FMEA

1. For each Process Input, determine the ways in which the Process Step can go wrong (these are Failure Modes)
2. For each Failure Mode associated with the inputs, determine Effects on the outputs
3. Mark special characteristics (product and process)
4. Identify potential Causes of each Failure Mode
5. List the Current Controls for each Cause
6. Assign Severity, Occurrence and Detection ratings after creating a ratings key appropriate for your project
7. Calculate RPN
8. Determine Recommended Actions to reduce high risks
9. Take appropriate Actions and Document
10. Recalculate RPNs
11. Revisit steps 7 and 8 to continually reduce risks

# Example: “Good” PFMEA

PROCESS OR PRODUCT TEAM: Product Family XYZ
RESPONSIBLE TEAM LEADER: Jane Doe
DATE (Orig) 3/1/2002 (REV) 3/1/2011
MEMBERS: John Smith, Jane Doe, Sun Tzu, Szent István, John of Gaunt

| Process step/Input | Potential Failure Mode | Potential Failure Effects | SEV | Class | Potential Causes(s) of Failure | OCC | Current PROCESS Controls - Prevention - | Current PROCESS Controls - Detection - | DET | RPN | Actions Recommended | Resp. | Actions Taken | SEV | OCC | DET | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Op 35. Test and grease | No grease in bearing sleeve | Sleeve/bearing wears out - warranty claim | 7 | | Operator turns off grease, grease not pumping, or barrel empty | 5 | | Visual inspection | 8 | 280 | Add message to prompt the operator that the grease is off. Add sensor to grease valve to sense that it is firing. | BPB. October 2004 Completed | New prompt and sensor | 8 | 3 | 5 | 120 |
| | | | | | | | | | | | Add new sensors to detect pumping of air | PT. October 2010 Completed | New sensors added | 8 | 3 | 4 | 96 |
| | | | 7 | | Impropoer grease volume block used | 2 | | Visual inspection | 8 | 112 | Add sensors to confirm correct voume block is used | PT. October 2010 Completed | Modified equipment and changed program to look at sensors | 8 | 2 | 4 | 64 |
| | No grease in bearing (Product Z only) | Premature bearing/sleeve failure - warranty claim | 7 | | Grease not pumping or barrel empty | 2 | | Visual inspection | 8 | 112 | Add new sensors to detect pumping of air | PT. October 2010 Completed | New sensors added | 8 | 2 | 4 | 64 |
| | | | 7 | | Impropoer grease volume block used | 2 | | Visual inspection | 8 | 112 | Add sensors to confirm correct voume block is used | PT. October 2010 Completed | Modified equipment and changed program to look at sensors | 8 | 2 | 4 | 64 |
| | Wrong bearing housing | Customer will not be able to install | 6 | TP-12 | Wrong set-up | 2 | | 100% inspection of housing in tester | 4 | 48 | | | | | | | 0 |
| | Damage to mounting holes | cosmetic issue and potential effect on bolt torque | 5 | | Part mislocated in tester fixture | 3 | | 100% visual check | 8 | 120 | Modify program to prompt operator to check orientation | PT. December 2010 Completed | Modified program | 5 | 3 | 7 | 105 |
| | | | | | | | | | | | Change design of fixture and locators | PT. February 2011 Completed | Installed March 2011 | 5 | 2 | 7 | 70 |

# Process FMEA (PFMEA)

- Reviewers Checklist
  - ✓Verify risks are prioritized and high risk items have identified improvement actions
  - ✓Make sure that high risk process concerns are carried over into the control plan
  - ✓Make sure that all critical failure modes are addressed
    - Safety
    - Form, fit, function
    - Material concerns
- See PPAP Workbook for detailed PFMEA chec

# Progress Check: PFMEA and APQP

- In which APQP phase would you first create a PFMEA?
  - APQP: Phase 3 – Process Design
- Which of the following activities should be done before the PFMEA?
  - Purchase capital equipment
  - Create the DFMEA
  - Purchase End of Line Testers
  - Make Tools/Molds


- Which FMEA risks need recommended actions?
  - All
  - Any over 100 RPN
  - Higher risks - by RPN, Severity or Occurrence
- How would you utilize PFMEA in an ETO environment?
  - By part families or by manufacturing processes

# PPAP Element #7: Control Plan

- What is It?
  - A document that describes how to control the critical inputs (FMEA) to continue to meet customer expectations
- Objective? - Planning
  - Needed gaging, testing, error proofing
  - Sampling and frequencies
  - How to react when something fails a test or inspection
- When to Use It
  - Implementing a new process
  - Implementing a process change

CONTROL PLAN

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|---|---|---|---|---|---|
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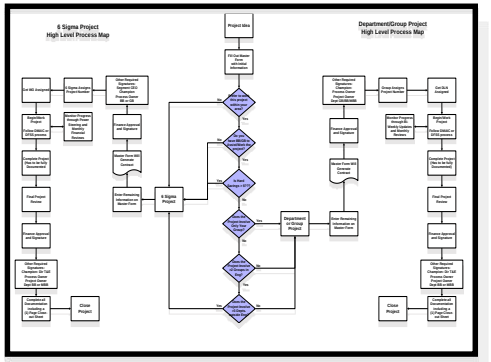
| PART/ PROCESS NUMBER | PROCESS NAME/ OPERATION DESCRIPTION | MACHINE, DEVICE JIG, TOOLS FOR MFG. | CHARACTERISTICS | | | SPECIAL CHAR. CLASS | METHODS | | | | | REACTION PLAN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | NO. | PRODUCT | PROCESS | | PRODUCT/PROCESS SPECIFICATION/ TOLERANCE | EVALUATION/ MEASUREMENT TECHNIQUE | SAMPLE SIZE | SAMPLE FREQ. | CONTROL METHOD | |

**Since processes are expected to be continuously updated and improved, the control plan is a living document!**

# Control Plan

## Tool Interaction




**Process Flowchart**

**Process Steps**

**New/Revised Process Steps**

| Process Step | Key Process Input | Potential Failure Mode | Potential Failure Effects | S E V | Potential Causes | O C C | Current Controls | D E T | R P N | E O C |
|---|---|---|---|---|---|---|---|---|---|---|
| Receive Payment | Checks | Delay internal mail | AR balance does not go down | 7 | Inadequate staffing in mail room | 7 | None | 10 | 490 | |
| Identify Customer | Wire Transfer reference line | Information not supplied | AR balance is past due | 10 | Customer or bank did not include name and/or account info on wire transfer | 5 | Acct identifies problem when trying to apply payment | 5 | 250 | |
| Identify Invoice | Checks | Incorrect invoice supplied | Invoice shows outstanding (AR balance does go down) | 5 | Customer error | 5 | Customer might catch it when reviewing the next statement | 10 | 250 | |
| Identify Invoice | Checks | Invoice number not supplied | Invoice shows outstanding (AR balance does go down) | 5 | Customer error | 10 | Acct identifies problem when trying to apply payment | 5 | 250 | |

**Process FMEA**

**Process Steps**

**New/Revised Process Steps**


**Control Plan**

**Risk Prioritized Process Steps**

**Improved Controls**

# The Control Plan Form

**CONTROL PLAN**

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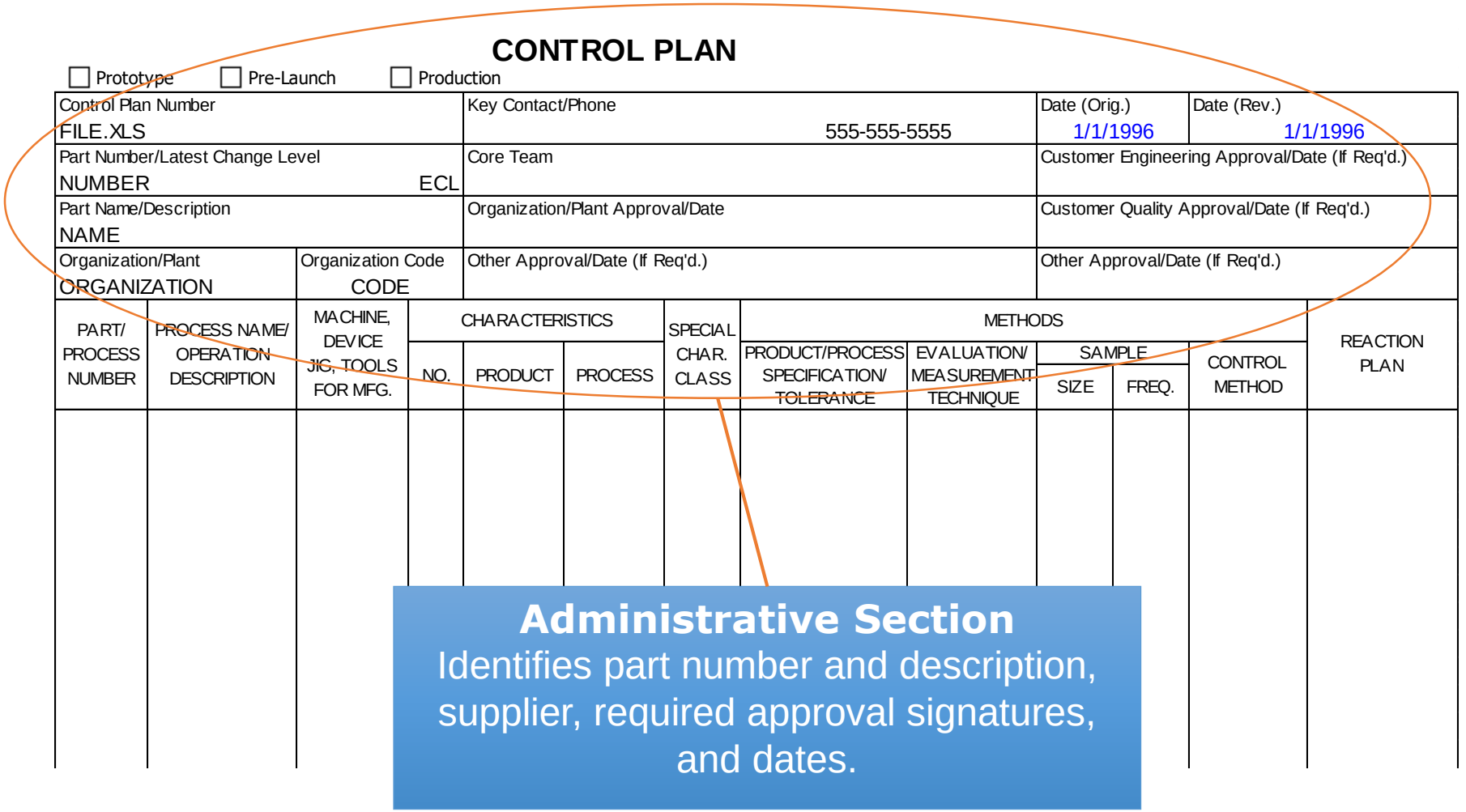
# The Control Plan Form



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| | | | | | | | | | | | | |

**Administrative Section**

Identifies part number and description, supplier, required approval signatures, and dates.

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## 3 Distinct Phases

1. **Prototype** – a description of the dimensional measurements and material and performance tests that will occur during Prototype build.
2. **Pre-Launch** – a description of the dimensional measurements and material and performance tests that will occur after Prototype and before full Production.
3. **Production** – a comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems that will occur during mass production

# The Control Plan Form

**CONTROL PLAN**

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| PART/ PROCESS NUMBER | PROCESS NAME/ OPERATION DESCRIPTION | MACHINE DEVICE JIG, TOOLS FOR MFG. | CHARACTERISTICS NO. | CHARACTERISTICS PRODUCT | CHARACTERISTICS PROCESS | SPECIAL CHAR. CLASS | METHODS PRODUCT/PROCESS SPECIFICATION/ TOLERANCE | METHODS EVALUATION/ MEASUREMENT TECHNIQUE | METHODS SAMPLE SIZE | METHODS SAMPLE FREQ. | METHODS CONTROL METHOD | REACTION PLAN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | |

**Each stage of *production and testing*. Can be:**

- **Each operation indicated by the process flow**
- **Each workstation**
- **Each machine**

**Include testing and audits**

**"Process Number" should cross reference with PFMEA and Process Map**

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| | | | | | | | | | | | | |

***Product characteristics*** **that are important. These can be determined by referencing:**

- **ST Dimensions on the drawing**
- **Customer critical characteristics**
- **Process critical characteristics**

**There may be several for each operation**

**Can be dimensional, performance or visual criteria**

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| | | | | | | | | | | | | |

***Process parameters*** **that are important. A process parameter is a setting made within a process that effects the variation within the operation. Examples include:**

- **Temperature (molding, heat treat, etc.)**
- **Pressure**
- **Fixture settings**
- **Speed**
- **Torque**

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| | | | | | | | | | | | | |

***Class*** **refers to special characteristics – product or process. Should align with FMEA**

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| | | | | | | | | | | | | |

**This is a specification from the Design Record or a key process parameter**

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| | | | | | | | | | | | | |

**How is the characteristic or parameter going to measured? Examples include:**

- **Caliper**
- **Attribute gage**
- **Visual**
- **Fixture**
- **Test equipment**

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| | | | | | | | | | | | | |

**How many parts will be measured and how often.**
**Examples:**
- **Final testing, visual criteria**
  - **100%**
- **SPC, Audit,**
  - **The sample size and frequency**

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| NAME | | | | | |
| Organization/Plant | Organization Code | Other Approval/Date (If Req'd.) | | Other Approval/Date (If Req'd.) | |
| ORGANIZATION | CODE | | | | |

| PART/ PROCESS NUMBER | PROCESS NAME/ OPERATION DESCRIPTION | MACHINE, DEVICE JIG, TOOLS FOR MFG. | CHARACTERISTICS | | | SPECIAL CHAR. CLASS | METHODS | | | | CONTROL METHOD | REACTION PLAN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | NO. | PRODUCT | PROCESS | | PRODUCT/PROCESS SPECIFICATION/ TOLERANCE | EVALUATION/ MEASUREMENT TECHNIQUE | SAMPLE SIZE | SAMPLE FREQ. | | |
| | | | | | | | | | | | | |

**How the characteristic or parameter will be controlled (this is the record) Examples include:**

- Xbar/R Chart
- NP Chart
- Pre-control Chart
- Checklist
- Log sheet
- Mistake proofing
- 1st piece inspection
- Lab report

# The Control Plan Form

**CONTROL PLAN**

☐ Prototype ☐ Pre-Launch ☐ Production

| Control Plan Number | | Key Contact/Phone | | Date (Orig.) | Date (Rev.) |
|---|---|---|---|---|---|
| FILE.XLS | | | 555-555-5555 | 1/1/1996 | 1/1/1996 |
| Part Number/Latest Change Level | | Core Team | | Customer Engineering Approval/Date (If Req'd.) | |
| NUMBER | ECL | | | | |
| Part Name/Description | | Organization/Plant Approval/Date | | Customer Quality Approval/Date (If Req'd.) | |
| NAME | | | | | |
| Organization/Plant | Organization Code | Other Approval/Date (If Req'd.) | | Other Approval/Date (If Req'd.) | |
| ORGANIZATION | CODE | | | | |

| PART/ PROCESS NUMBER | PROCESS NAME/ OPERATION DESCRIPTION | MACHINE, DEVICE JIG, TOOLS FOR MFG. | CHARACTERISTICS | | | SPECIAL CHAR. CLASS | METHODS | | | | REACTION PLAN |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | NO. | PRODUCT | PROCESS | | PRODUCT/PROCESS SPECIFICATION/ TOLERANCE | EVALUATION/ MEASUREMENT TECHNIQUE | SAMPLE SIZE | SAMPLE FREQ. | CONTROL METHOD | |
| | | | | | | | | | | | | |

**What happens when the characteristic or parameter is found to be out of control. Must include:**

- **Segregation of nonconforming product**
- **Correction method**

**May include (as appropriate):**

- **Sorting**
- **Rework/Repair**
- **Customer notification**

# Control Plan – Example

**A supplier manufactures a circuit board with electronic components soldered on the board. Properly soldered connections are the major product characteristics. Two major process characteristics for the wave solder machine are solder level and flux concentration. An automated feeder controls the solder level by sensing the level of solder and feeding in additional solder as the level is reduced. This characteristic is measured 100% by checking electrically for continuity. The flux must be sampled and tested for the concentration level.**

## CONTROL PLAN

| ☐ Prototype | ☐ Pre-Launch | ☑ Production | | |
|---|---|---|---|---|
| Control Plan Number<br>002 | | Key Contact/Phone<br>T. Smith / 313-555-5555 | Date:(Org.)<br>11/29/2009 | Date (Rev.)<br>2/20/2010 |
| Part Number/Latest Change Level<br>54321231 / D | | Core Team<br>Erin Hope, Alan Burt, Ken Light | Customer Engineering Approval/Date (If Req'd.) | |
| Part Name/Description<br>Electronic Circuit Board | | Supplier/Plant Approval/Date | Customer Quality Approval/Date(If Req'd.) | |
| Supplier/Plant<br>ACR Control | Supplier Code<br>439412 | Other Approval/Date (If Req'd.) | Other Approval/Date (If Req'd.) | |

| Part / Process Number | Process Name / Operation Description | Machine, Device, Jig, Tools, for MFG. | Characteristics | | | Special Char. Class | Methods | | | | | Reaction Plan |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | No. | Product | Process | | Product/Process Specification/ Tolerance | Evaluation / Measurement Technique | Sample Size | Sample Freq. | Control Method | |
| 2 | Soldering Connections | Wave solder machine | | Wave solder height | | | 2.0 +/- .25 mc | Sensor continuity check | 100% | Continuous | Automated inspection (error proofing) | Adjust and retest |
| | | | | | Flux concen - tration | | Standard #302B | Test sampling lab environment | 1 pc | 4 hours | x-MR chart | Segregate and retest |

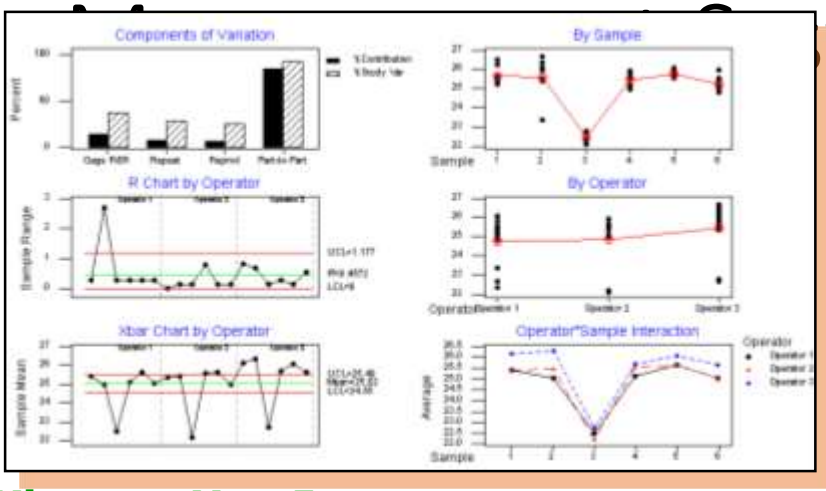
# Control Plan: Reviewer's Checklist

- ✓ Remember the Control Plan is a planning tool –
  - Use it to decide what you should be doing
  - The AIAG format will help make sure the plan makes sense and is complete
- ✓ Use process flow diagram and PFMEA to build the control plan; keep them aligned
- ✓ Controls should be effective. Keep it simple.
- ✓ Ensure that the control plan is in your document control system
- ✓ Good control plans address:
  - All testing requirements - dimensional, material, and performance
  - All product and process characteristics at every step throughout the process
- ✓ The control method should be based on an effective analysis of the process
- ✓ Control plans should reference other documentation
  - Specifications, tooling, etc.

# Control Plan and APQP

- In what APQP Phase would you first create a control plan?
  - ✓Prototype CP in Phase 2: Product Design
  - ✓Pre-production CP in Phase 3: Process Design
  - ✓Production CP in Phase 4: Validation
- How does the reaction plan help with process design?
  - ✓Identify rework needs, quarantine product location needs, etc.

# PPAP Element #8:
# Measurement System Analysis (MSA)




## What is It?

An MSA is a statistical tool used to determine if a measurement system is capable of precise measurement.

## Objective or Purpose

- To determine how much error is in the measurement due to the measurement process itself.
- Quantifies the variability added by the measurement system.
- Applicable to attribute data and variable data.

## When to Use It

- On systems measuring critical inputs and outputs prior to collecting data for analysis.
- For any new or modified process in order to ensure the quality of the data.

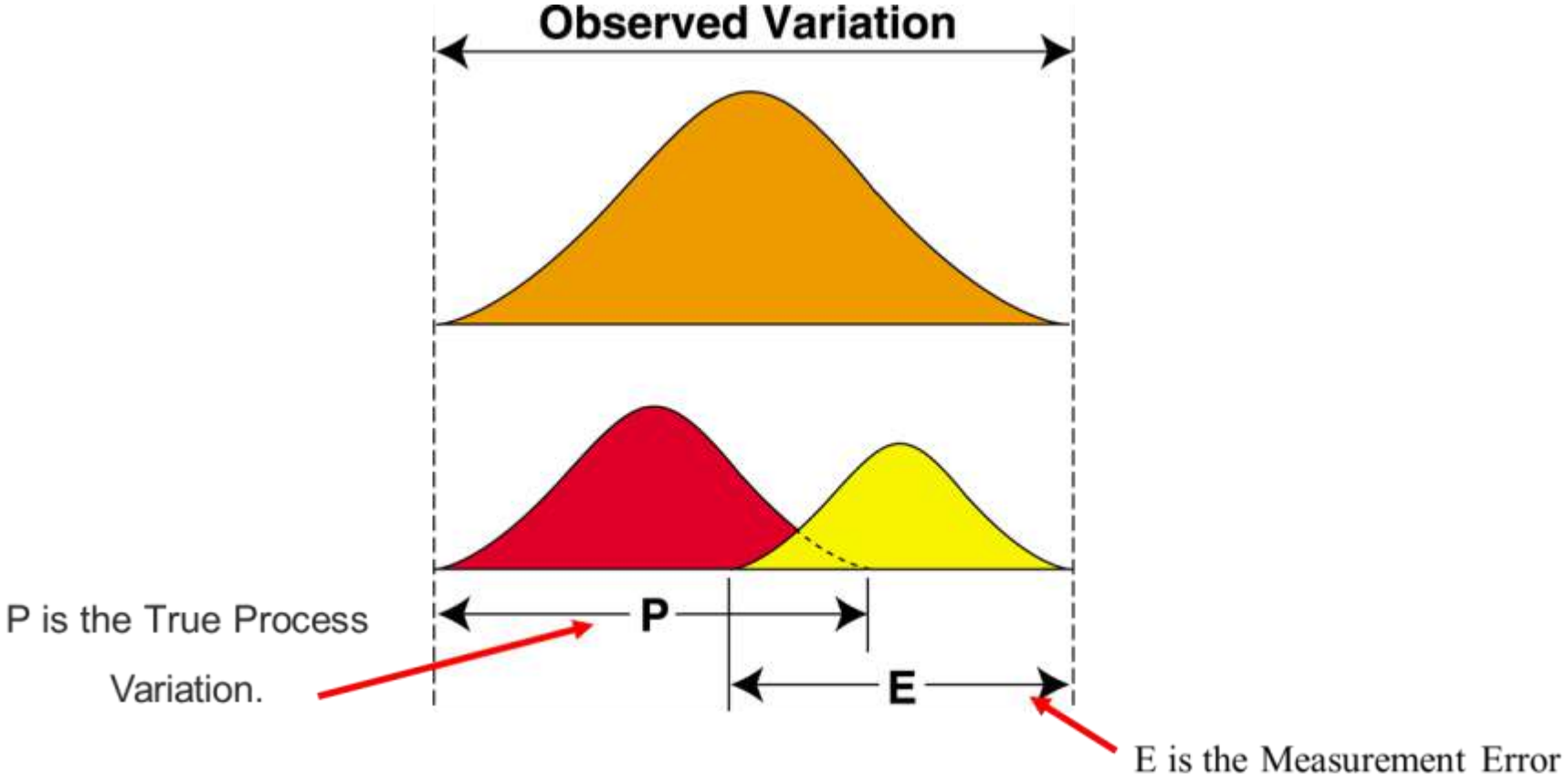
## Who Should be Involved

Everyone that measures and makes decisions about these measurements should be involved in the MSA.

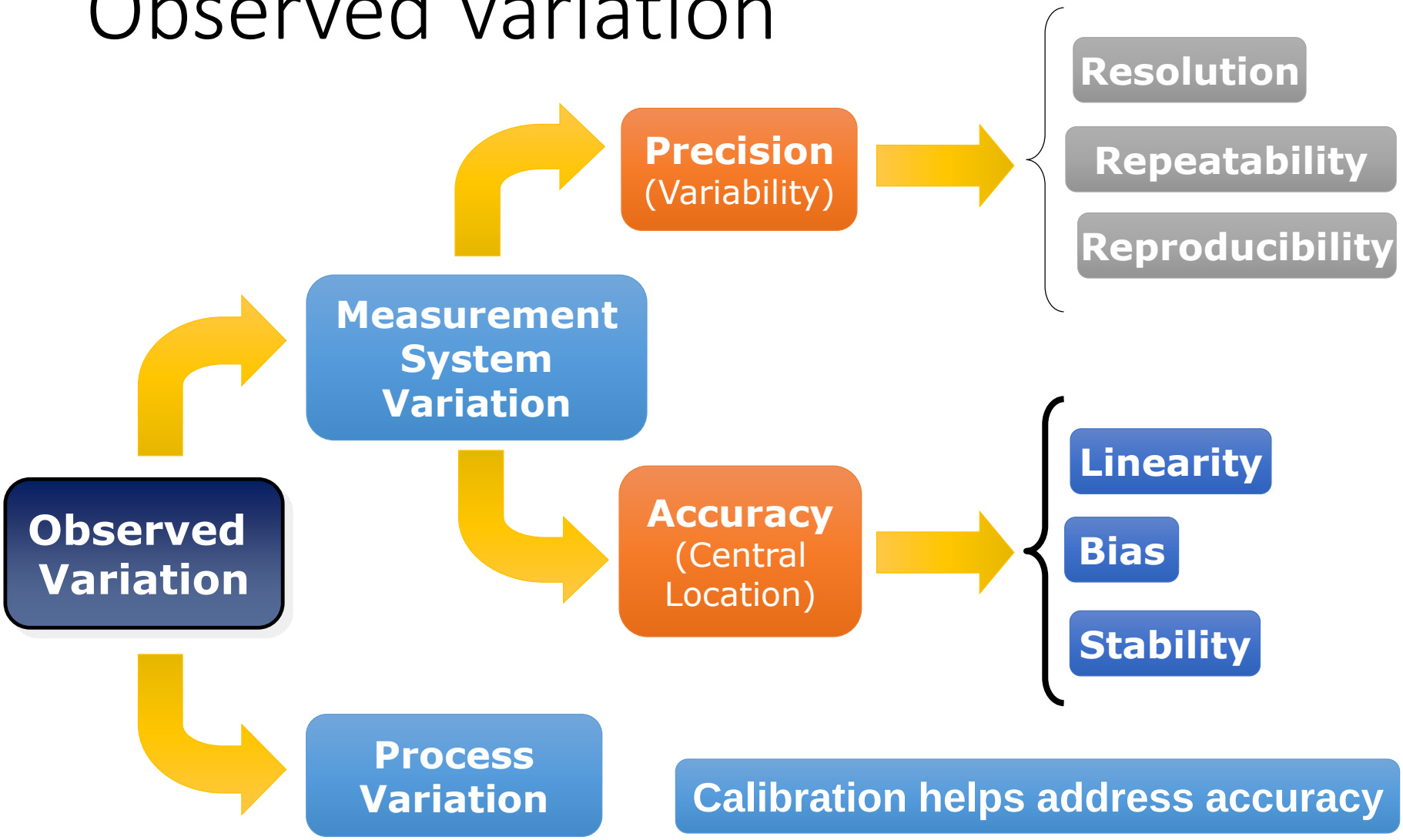
**IMPORTANT!**

**Measurement System Analysis is an analysis of the measurement process, *not* an analysis of the people!!**

# Inspection – what do you really see?



# Observed Variation



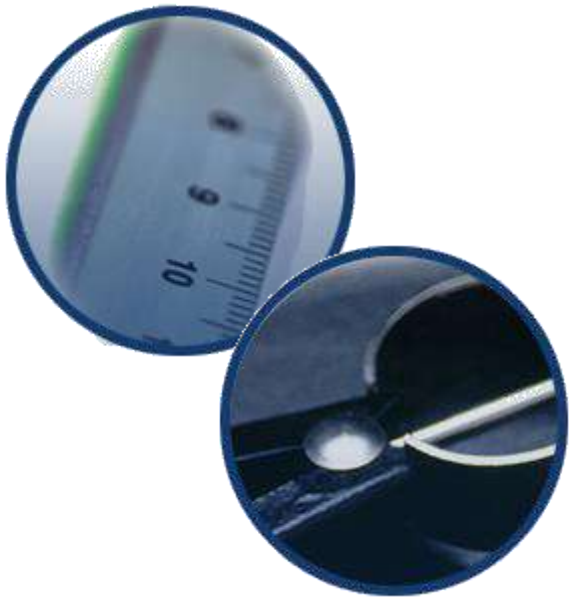
## Resolution

**Error in Resolution**

**The inability to detect small changes.**

**Possible Cause**

**Wrong measurement device selected - divisions on scale not fine enough to detect changes.**



# Measurement System Analysis (MSA)

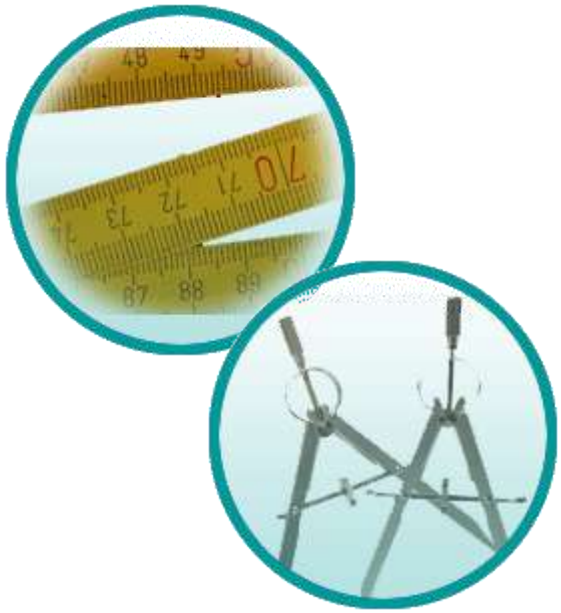
## Repeatability

**Error in Repeatability**

**The inability to get the same answer from repeated measurements made of the same item under absolutely identical conditions.**

**Possible Cause**

**Lack of standard operating procedures (SOP), lack of training, measuring system variablilty.**



**Equipment Variation**

# Measurement System Analysis (MSA)

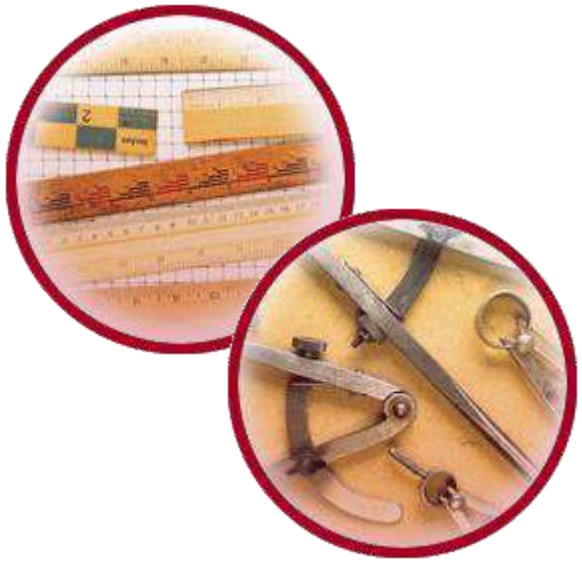
## Reproducibility

**Error in Reproducibility**

**The inability to get the same answer from repeated measurements made under various conditions from different inspectors.**

**Possible Cause**

**Lack of SOP, lack of training.**



**Appraiser Variation**

# Variable MSA – Gage R&R Study

- **Gage R&R is the combined estimate of measurement system Repeatability and Reproducibility**
- **Typically, a 3-person study is performed**
  - **Each person randomly measures 10 marked parts per trial**
  - **Each person can perform up to 3 trials**
- **There are 3 key indicators**
  - **% P/T or measurement variation compared to tolerance**
  - **% R&R or measurement variation compared to process variation**
  - **Number of distinct categories (ndc)** or measure of resolution

# Variable MSA – AIAG GR&R VAR(Tol)

**GAGE REPEATABILITY AND REPRODUCIBILITY DATA SHEET**
**VARIABLE DATA RESULTS**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Part Number NUMBER | | Gage Name | | Appraiser A | | Part Number NUMBER | | Gage Name | | Appraiser A | | |
| Part Name NAME | | Gage Number | | Appraiser B | | Part Name NAME | | Gage Number | | Appraiser B | | |
| Characteristic | Specification Lower Upper | Gage Type | | Appraiser C | | Characteristic | | Gage Type | | Appraiser C | | |
| Characteristic Classification | | Trials | Parts | Appraisers | Date Performed | Characteristic Classification | | Trials | Parts | Appraisers | Date Performed | |

**Included in PPAP Workbook**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4. | AVE | | | | | | | | | | | $X_a$= |
| 5. | R | | | | | | | | | | | $r_a$= |
| 6. | B 1 | | | | | | | | | | | |
| 7. | 2 | | | | | | | | | | | |
| 8. | | | | | | | | | | | | |
| 9. | | | | | | | | | | | | |
| 10. | | | | | | | | | | | | |
| 11. | C | | | | | | | | | | | |
| 12. | 2 | | | | | | | | | | | |
| 13. | 3 | | | | | | | | | | | |
| 14. | AVE | | | | | | | | | | | $X_c$= |
| 15. | R | | | | | | | | | | | $r_c$= |
| 16. | PART AVERAGE | | | | | | | | | | | X= $R_p$= |
| 17. | $(r_a + r_b + r_c)$ / (# OF APPRAISERS) = | | | | | | | | | | | R= |
| 18. | $x_{DIFF}$ = (Max X - Min X) = | | | | | | | | | | | $X_{DIFF}$= |
| 19. | * $UCL_R = R \times D_4$ = | | | | | | | | | | | $UCL_R$= |

**Automatically calculates %GRR, %PV, ndc**

* $D_4$ =3.27 for 2 trials and 2.58 for 3 trials. $UCL_R$ represents the limit of individual R's. Circle those that are beyond this limit. Identify the cause and correct. Repeat these readings using the same appraiser and unit as originally used or discard values and re-average and recompute R and the limiting value from the remaining observations.

Notes:

**GAGE REPEATABILITY AND REPRODUCIBILITY DATA SHEET**
**VARIABLE DATA RESULTS**

| Part Number NUMBER | Gage Name | Appraiser A | | |
|---|---|---|---|---|
| Part Name NAME | Gage Number | Appraiser B | | |
| Characteristic | Gage Type | Appraiser C | | |
| Characteristic Classification | Trials | Parts | Appraisers | Date Performed |

| Measurement Unit Analysis | | | | % Tolerance (Tol) | | |
|---|---|---|---|---|---|---|
| **Repeatability - Equipment Variation (EV)** | | | | | | |
| EV = $R \times K_1$ | **Trials** | **$K_1$** | | % EV = | 100 (EV/Tol) | |
| = | 2 | 0.8862 | | = | | |
| = | 3 | 0.5908 | | = | | |
| **Reproducibility - Appraiser Variation (AV)** | | | | | | |
| AV = $\{(X_{DIFF} \times K_2)^2 - (EV^2/nr)\}^{1/2}$ | | | | % AV = | 100 (AV/Tol) | |
| = | | | | = | | |
| = | | | | = | | |
| | **Appraisers** | **2** | **3** | | | |
| n = parts r = trials | **$K_2$** | 0.7071 | 0.5231 | | | |
| **Repeatability & Reproducibility (GRR)** | | | | % GRR = | 100 (GRR/Tol) | |
| GRR = $\{(EV^2 + AV^2)\}^{1/2}$ | **Parts** | **$K_3$** | | = | | |
| = | 2 | 0.7071 | | = | | |
| = | 3 | 0.5231 | | | | |
| **Part Variation (PV)** | 4 | | | | | |
| PV = $R_P \times K_3$ | 5 | 0.4030 | | % PV = | 100 (PV/Tol) | |
| = | 6 | 0.3742 | | = | | |
| = | 7 | 0.3534 | | = | | |
| **Tolerance (Tol)** | 8 | 0.3375 | | | | |
| Tol = Upper - Lower / 6 | 9 | 0.3249 | | ndc = | 1.41(PV/GRR) | |
| = ( Upper - Lower ) / 6 | 10 | 0.3146 | | = | | |
| = | | | | = | | |

For information on the theory and constants used in the form see *MSA Reference Manual* , Fourth edition.

# Variable MSA – Gage R&R Steps


1. **Select 10 items that represent the full range of long-term process variation**
2. **Identify the appraisers – they should be operator who normally use the gage**
3. **If appropriate, calibrate the gage or verify that the last calibration date is valid**
4. **Open the GR&R VAR(Tol) worksheet in the AIAG Core Tools file to record data, or use MiniTab**
5. **Have <u>each</u> appraiser assess <u>each</u> part 3 times preferably in random order (Minitab can generate a random run order)**
6. **Input data into the GR&R VAR(Tol) worksheet or MiniTab**
7. **Enter the number of operators, trials, samples and specification limits**
8. **Analyze data and review GR&R and PV values**
9. **Take actions for improvement if necessary.**

# Measurements Systems Analysis MSA

## Tips and Lessons Learned

- ✓ **Important: An MSA is an analysis of the process, not an analysis of the people. If an MSA fails, the process failed.**
- ✓ **A Variable MSA provides more analysis capability than an Attribute MSA. For this and other reasons, always use variable data if possible.**
- ✓ **The involvement of people is the key to success.**
  - ✓ **Involve the people that actually work the process**
  - ✓ **Involve the supervision**
  - ✓ **Involve the suppliers and customers of the process**
- ✓ **An MSA primarily addresses precision with limited accuracy information.**

# MSA: Reviewer's Checklist

- ✓If the gage/inspection measures a special characteristic or other important feature, then conduct a Gage R&R
- ✓Make sure the study is recent - less than 1 year
- ✓Compare the control plan gages against the Gage R&Rs
- ✓% R&R and %P/T should be less than 10%
  - ✓Values greater than 10% should be reviewed with Eaton
- ✓Number of distinct categories should be >5
- ✓If you question that gage, then
  - Question the technique and part sampling
  - Ask for additional studies

# MSA Summary

- Measurement systems must be analyzed BEFORE embarking on process improvement activities
- MSA helps understand how much observed variation is from the measurement system
- MSA will tell you about the repeatability, reproducibility and discrimination
- Sample selection is very important – sample during normal production to capture total range of process variation
- MSA assessors should be operators that would normally use the measurement system
- MSA should be done on a regular basis

# PPAP Element #9: Dimensional Results

**Production Part Approval / Dimensional Test Results** — Corporate SCM Form-XX (Rev. A, 2014)

| | | | |
|---|---|---|---|
| Supplier | 0 | Part Number | 0 |
| Supplier / Vender Code | | Part Name | |
| Inspection Facility | | Design Record Change Level | 0 |
| | | Engineering Change Document | |

| Item | Dimension / Specification | Specification / Limits | Test Date | Qty. Tested | Measurement Method | Supplier Measurement Results (DATA) | OK | Not OK |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
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**What is It?**

Evidence that dimensional verifications have been completed and results indicate compliance with specified requirements

**Objective or Purpose**

- To show conformance to the customer part print on dimensions and all other noted requirements

**When to Use It**

- For each unique manufacturing process (e.g., cells or production lines and all molds, patterns, or dies

# Dimensional Results

- Reviewer's Checklist
  - ✓All design record specifications (notes, referenced specifications, etc.) shall be included in the Dimensional Results
    - Material and performance specifications results can be reported on the separate Material, Performance Test Results
  - ✓Results shall include samples from each tool cavity, manufacturing line, etc.
  - ✓Data points should come from PPAP samples included with PPAP submission
    - The agreed upon # of parts from the production run must be shipped to the customer for verification of form, fit, and function
    - Supplier must clearly identify PPAP samples used for dimensional results
  - ✓Results that do not meet the design specification shall be addressed prior to PPAP submission
    - "Not OK" results typically require changes to the manufacturing process prior to PPAP submission. In some cases the customer may agree to engineering changes.

# PPAP Element #10: Records of Material/Performance Test Results

- Material Test Results
  - The supplier shall perform tests for all parts and product materials when chemical, physical, or metallurgical requirements are specified by the design record or Control Plan
  - For products with Eaton-developed material specifications and/or an Eaton-approved supplier list, the supplier shall procure materials and/or services from suppliers on that list
- Performance Test Results
  - The supplier shall perform tests for all parts or product materials when performance or functional requirements are specified by the design record or Control Plan

# Material Results

**Production Part Approval**
**Material Test Results**

| ORGANIZATION:<br>SUPPLIER / VENDOR CODE: | | | PART NUMBER:<br>PART NAME:<br>DESIGN RECORD CHANGE LEVEL:<br>ENGINEERING CHANGE DOCUMENTS: | | | |
|---|---|---|---|---|---|---|
| MATERIAL SUPPLIER:<br>*CUSTOMER SPECIFIED SUPPLIER / VENDOR CODE:<br>*If source approval is req'd, include the Supplier (Source) & Customer assigned code. | | | NAME of LABORATORY: | | | |
| MATERIAL SPEC. NO. / REV / DATE | SPECIFICATION / LIMITS | TEST DATE | QTY. TESTED | SUPPLIER TEST RESULTS (DATA) | OK | NOT OK |
| | | | | | | |
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Material Results shall include:

- ✓ The name of the laboratory that conducted the test
- ✓ The type of test that was conducted
- ✓ The number, date, and specification to which the part was tested
- ✓ The actual test results

# Performance Test Results

| | |
|---|---|
| ORGANIZATION: ORGANIZATION<br>SUPPLIER / VENDOR CODE: CODE | PART NUMBER: NUMBER<br>PART NAME: NAME<br>DESIGN RECORD CHANGE LEVEL: ECL<br>ENGINEERING CHANGE DOCUMENTS: |
| NAME of LABORATORY:<br>*CUSTOMER SPECIFIED SUPPLIER / VENDOR CODE:<br>*If source approval is req'd, include the Supplier (Source) & Customer assigned code. | |

| TEST SPECIFICATION / REV / DATE | SPECIFICATION / LIMITS | TEST DATE | QTY. TESTED | SUPPLIER TEST RESULTS (DATA)/ TEST CONDITIONS | OK | NOT OK |
|---|---|---|---|---|---|---|
| | | | | | | |
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Performance Test Results shall include:

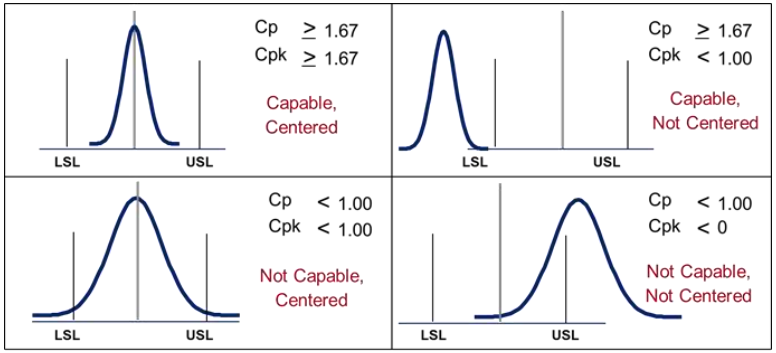
- ✓ The name of the laboratory that conducted the test
- ✓ The type of test that was conducted
- ✓ A description of the test
- ✓ The parameters tested
- ✓ The actual test results

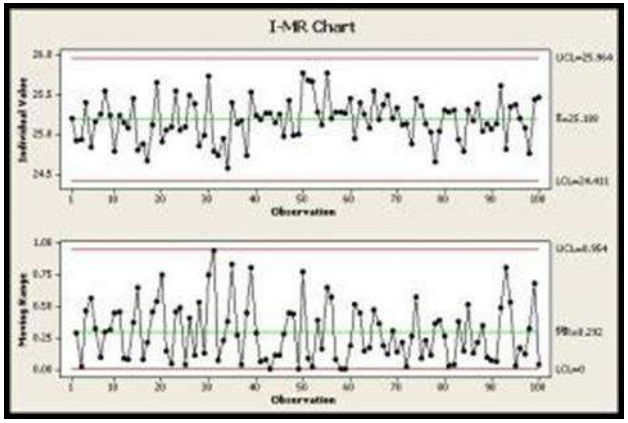
Blanket statements of conformance are unacceptable for any test results.

| SIGNATURE | TITLE | DATE |
|---|---|---|
| | | |

# PPAP Element #11: Initial Process Studies

- Capability studies are measures of how well the process is meeting the design requirements.
  - Is the process employed Stable and Capable?
- MSA before Cpk
  - MSA must be acceptable and should represent tools/process used for Initial Process Studies
- >1.67 Cpk for SCs, >1.33 for other characteristics
- Cpk & Ppk minimums are higher for initial release vs. ongoing

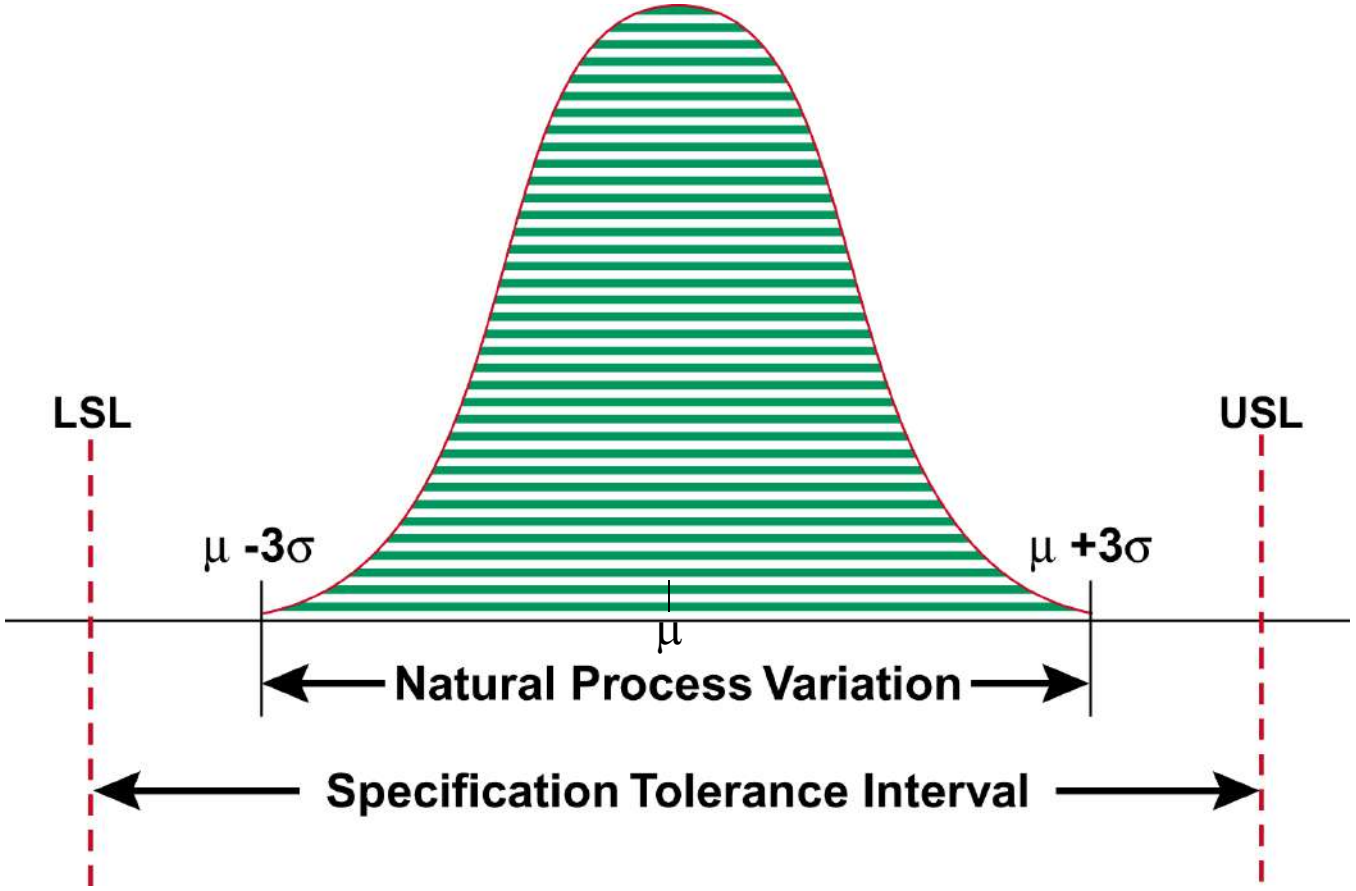


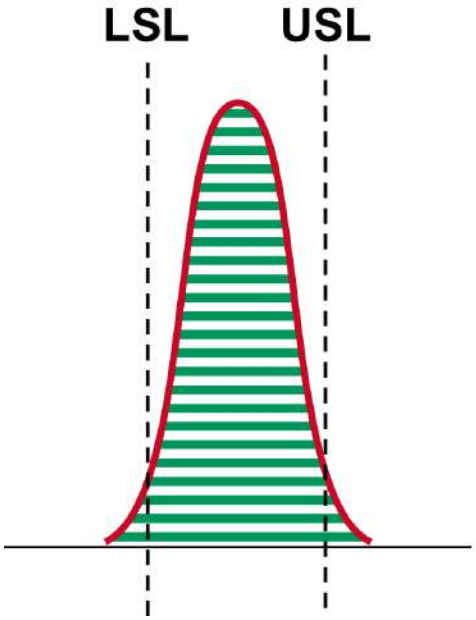
# PPAP Element #11: Initial Process Study
# Purposes of Initial Process Study

- To evaluate how well a process can produce product that meets specifications
- To provide guidance about how to improve capability
  - better process centering
  - reduced variation
- Capability studies can be used to identify a problem or to verify permanent corrective actions in the problem solving process.

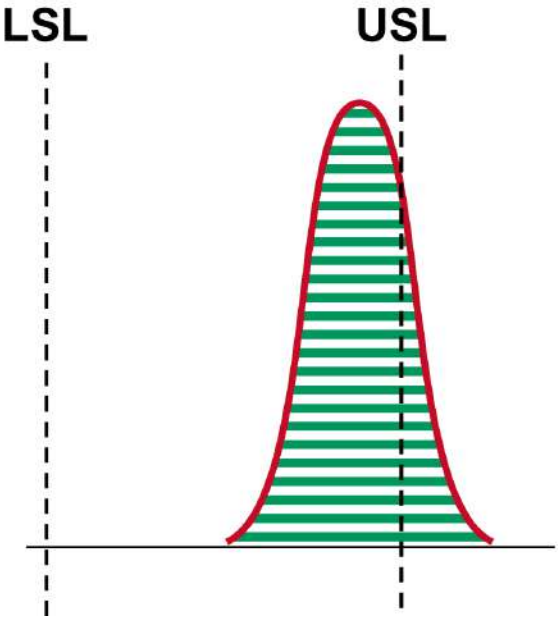
# Process Capability: The Two Voices



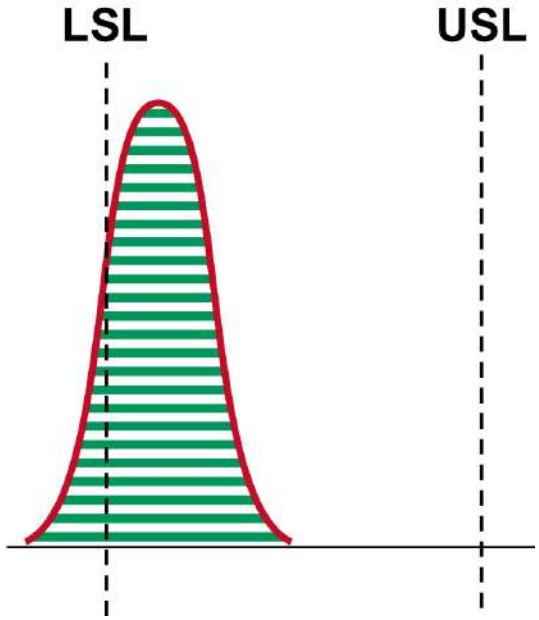
# Examples of *Non-Capable* Processes




**Product produced beyond both Upper and Lower Spec Limits.**

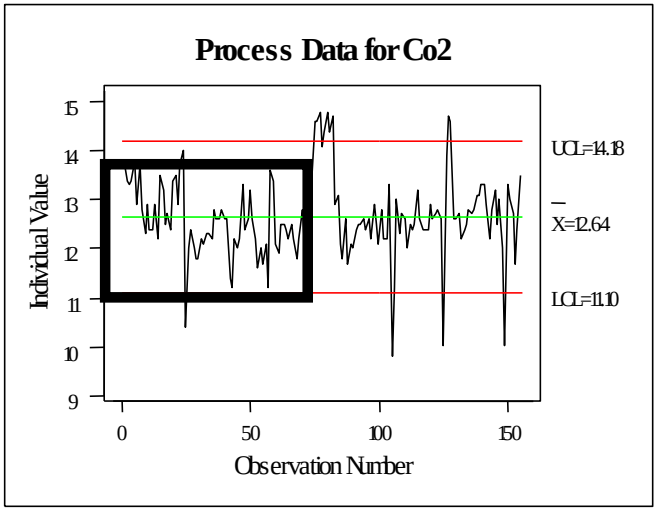



**Product produced above the Upper Spec Limit.**

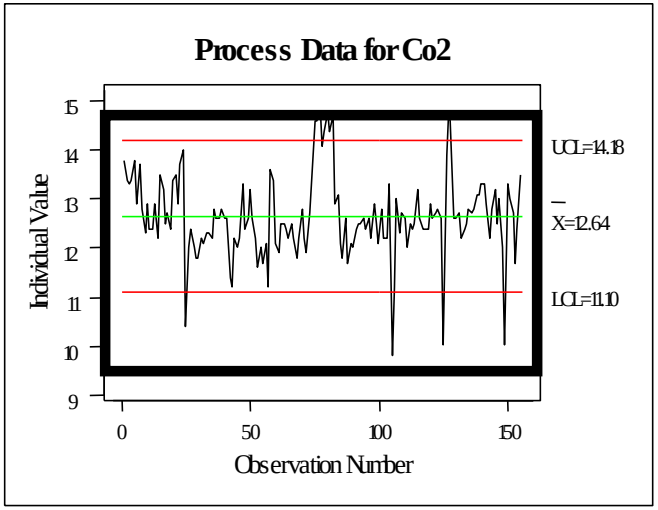



**Product produced below the Lower Spec Limit.**

# Capability Studies




A **short-term** capability study covers a relative short period of time during which extraneous sources of variation have been excluded. (Guideline: 30-50 data points.)




A **long-term** capability study covers a longer period of time in which there is more chance for a process shift. (Guideline: 100-200 data points.)

# Steps for Determining Process Capability


1. Decide on the product or process characteristic to be assessed
2. Verify the specification limits
3. Validate the measurement system
4. Collect data per sample size/frequency in Control Plan
5. Assess data characteristics
6. Assess process stability
7. Calculate process capability

Let's take a closer look at data characteristics and process capability

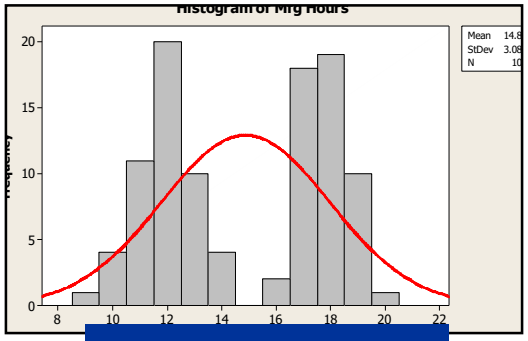
# Step 5: Data Characteristics

**Step 5**

## Assess data characteristics

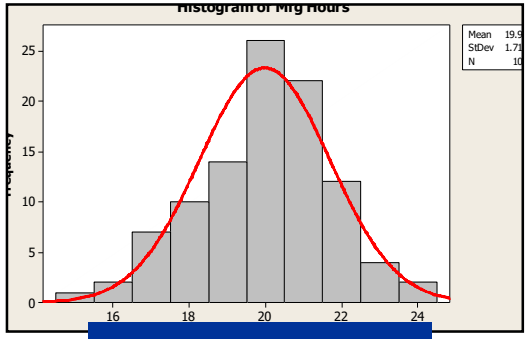
**Examine the shape of your data.**

- **Is it what you would expect? If not, investigate.**

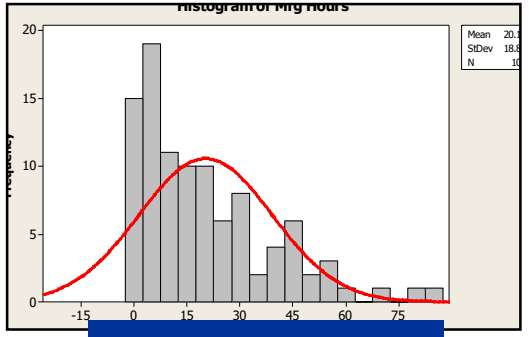



**Bimodal Data**

**The shape of your data is important for determining which type of Capability Analysis applies. If the data exhibits a non-normal shape, consult your statistics reference.**




**Normal Data**



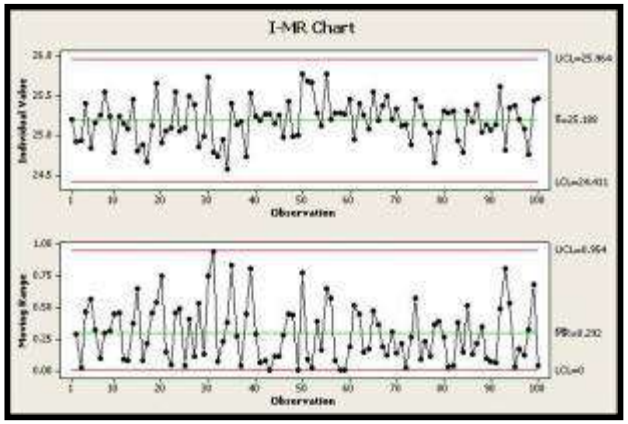

**Skewed Data**

# Step 6: Process Stability

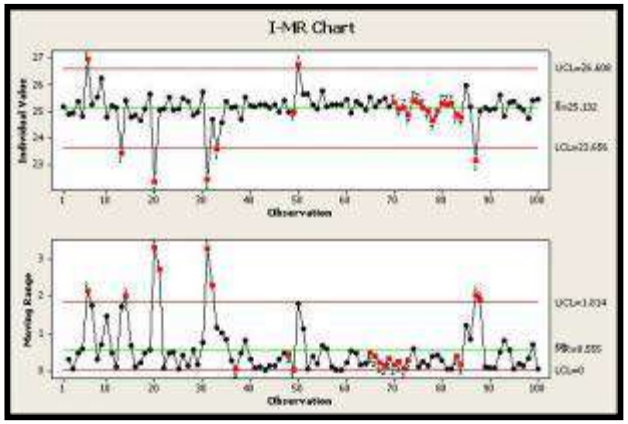
**Step 6**

Assess process stability in order to understand how your process behaves over time. Control charts are the recommended tool.

**Control Chart Examples**




**Process is stable and in control**

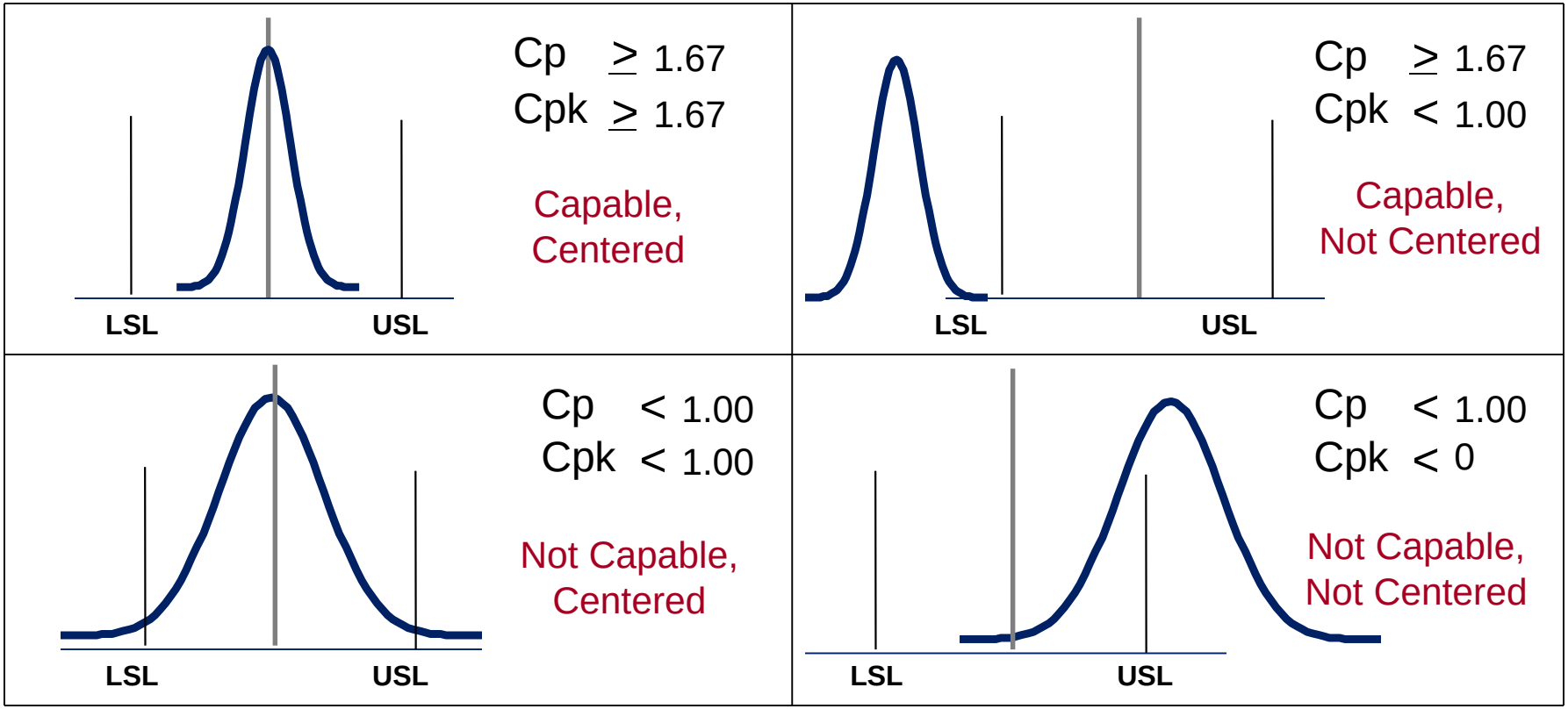



**Process is not stable and therefore not in control**

**Capability is only valid when the process being studied is stable!**

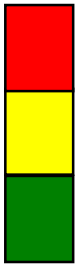
# Difference between Cp & Cpk

- **Cp** – determines capability of producing to specification
- **Cpk** – same as Cp, but also measures how *centered* the process is
- It is important to look at both!



# Acceptance Criteria

***Acceptance criteria for critical vs. non-critical characteristics***

| | Short-term | Long-term | Decision |
|---|---|---|---|
| **Red (Bad)** | <1.33 | <1.00 |  |
| **Yellow (Marginal)** | 1.33-1.67 | 1.00-1.33 | |
| **Green (Good)** | >1.67 | >1.33 | |

**Cpk must be greater than or equal to 1.67 for *critical* processes**

**Cpk must be greater than or equal to 1.33 for *non-critical* processes**

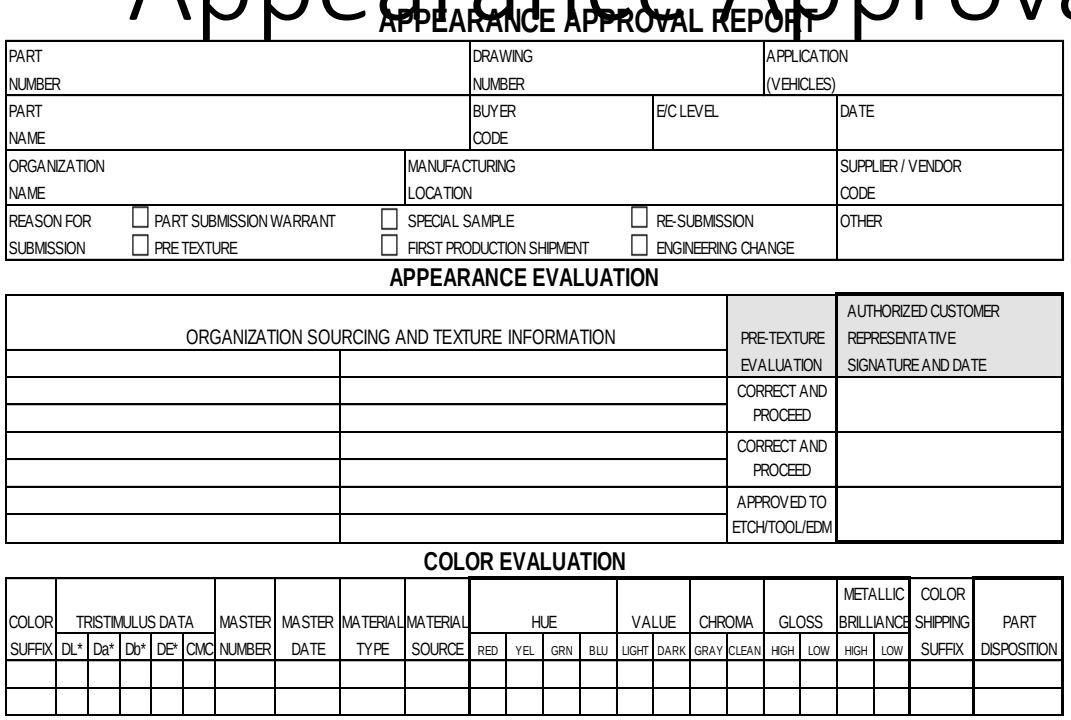
# Initial Process Study: Reviewer's Checklist

- ✓Check to see if the data demonstrates a stable process and exhibits a normal distribution
  - Note: source data/ charts to understand stability may not always be provided. If you have concerns, ask for the data.
- ✓PPAPs should only be approved if the capability is greater than 1.67 for critical dimensions and greater than 1.33 for non-critical dimensions
- ✓Capability template is in the PPAP Workbook

# PPAP Element #12: Qualified Laboratory Documentation

- Inspection and testing for PPAP shall be performed by a qualified laboratory (e.g., an accredited laboratory).
- The qualified laboratory (internal or external to the supplier) shall have a laboratory scope and documentation showing that the laboratory is qualified for the type of measurements or tests conducted
  - When an external laboratory is used, the supplier shall submit the test results on the laboratory letterhead or the normal laboratory report format
  - The name of the laboratory that performed the tests, the date(s) of the tests, and the standards used to run the tests shall be identified.
  - Eaton to validate results to specifications.

# PPAP Element #13: Appearance Approval Report



**APPEARANCE APPROVAL REPORT**

| PART NUMBER | DRAWING NUMBER | APPLICATION (VEHICLES) | |
|---|---|---|---|
| PART NAME | BUYER CODE | E/C LEVEL | DATE |
| ORGANIZATION NAME | MANUFACTURING LOCATION | | SUPPLIER / VENDOR CODE |
| REASON FOR SUBMISSION ☐ PART SUBMISSION WARRANT ☐ PRE TEXTURE | ☐ SPECIAL SAMPLE ☐ FIRST PRODUCTION SHIPMENT | ☐ RE-SUBMISSION ☐ ENGINEERING CHANGE | OTHER |

**APPEARANCE EVALUATION**

| ORGANIZATION SOURCING AND TEXTURE INFORMATION | | PRE-TEXTURE EVALUATION | AUTHORIZED CUSTOMER REPRESENTATIVE SIGNATURE AND DATE |
|---|---|---|---|
| | | CORRECT AND PROCEED | |
| | | CORRECT AND PROCEED | |
| | | APPROVED TO ETCH/TOOL/EDM | |

**COLOR EVALUATION**

| COLOR SUFFIX | TRISTIMULUS DATA DL* | Da* | Db* | DE* | CMC | MASTER NUMBER | MASTER DATE | MATERIAL TYPE | MATERIAL SOURCE | HUE RED | YEL | GRN | BLU | VALUE LIGHT | DARK | CHROMA GRAY | CLEAN | GLOSS HIGH | LOW | METALLIC BRILLIANCE HIGH | LOW | COLOR SHIPPING SUFFIX | PART DISPOSITION |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | |

## What is It?

- A report completed by the supplier containing appearance and color criteria

## Objective or Purpose

- To demonstrate that the part has met the appearance requirements on the design record

## When to Use It

- Prior to tooling for production

**IMPORTANT!**

**Only applies for parts with color, grain, or surface appearance requirements**

# Appearance Approval Report

## APPEARANCE APPROVAL REPORT

| | | | |
|---|---|---|---|
| PART NUMBER | DRAWING NUMBER | APPLICATION (VEHICLES) | |
| PART NAME | BUYER CODE | E/C LEVEL | DATE |
| ORGANIZATION NAME | MANUFACTURING LOCATION | | SUPPLIER / VENDOR CODE |
| REASON FOR SUBMISSION ☐ PART SUBMISSION WARRANT ☐ PRE TEXTURE | ☐ SPECIAL SAMPLE ☐ FIRST PRODUCTION SHIPMENT | ☐ RE-SUBMISSION ☐ ENGINEERING CHANGE | OTHER |

## APPEARANCE EVALUATION

| ORGANIZATION SOURCING AND TEXTURE INFORMATION | | PRE-TEXTURE EVALUATION | AUTHORIZED CUSTOMER REPRESENTATIVE SIGNATURE AND DATE |
|---|---|---|---|
| | | CORRECT AND PROCEED | |
| | | CORRECT AND PROCEED | |
| | | APPROVED TO ETCH/TOOL/EDM | |

## COLOR EVALUATION

| COLOR SUFFIX | TRISTIMULUS DATA DL* | Da* | Db* | DE* | CMC | MASTER NUMBER | … | METALLIC BRILLIANCE HIGH | LOW | COLOR SHIPPING SUFFIX | PART DISPOSITION |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | | | | | | | | | |

Administrative Section

Identifies part number and description, supplier, required approval signatures, and dates.

# Appearance Approval Report

## APPEARANCE APPROVAL REPORT

| | | | |
|---|---|---|---|
| PART NUMBER NUMBER | DRAWING NUMBER | APPLICATION (VEHICLES) APPLICATION | |
| PART NAME NAME | BUYER CODE | E/C LEVEL ECL | DATE |
| ORGANIZATION NAME ORGANIZATION | MANUFACTURING LOCATION ADDRESS CITY STATE ZIP | | SUPPLIER / VENDOR CODE CODE |
| REASON FOR SUBMISSION ☐ PART SUBMISSION WARRANT ☐ PRE TEXTURE | ☐ SPECIAL SAMPLE ☐ FIRST PRODUCTION SHIPMENT | ☐ RE-SUBMISSION ☐ ENGINEERING CHANGE | OTHER |

## APPEARANCE EVALUATION

| ORGANIZATION SOURCING AND TEXTURE INFORMATION | | PRE-TEXTURE EVALUATION | AUTHORIZED CUSTOMER REPRESENTATIVE SIGNATURE AND DATE |
|---|---|---|---|
| | | CORRECT AND PROCEED | |
| | | CORRECT AND PROCEED | |
| | | APPROVED TO ETCH/TOOL/EDM | |

Appearance Evaluation Details

Identifies supplier sourcing, texture information and submission customer signature.

# Appearance Approval Report

**COLOR EVALUATION**

| COLOR SUFFIX | TRISTIMULUS DATA | | | | | MASTER NUMBER | MASTER DATE | MATERIAL TYPE | MATERIAL SOURCE | HUE | | | | VALUE | | CHROMA | | GLOSS | | METALLIC BRILLIANCE | | COLOR SHIPPING SUFFIX | PART DISPOSITION |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | DL* | Da* | Db* | DE* | CMC | | | | | RED | YEL | GRN | BLU | LIGHT | DARK | GRAY | CLEAN | HIGH | LOW | HIGH | LOW | | |
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| COMMENTS | | | | | | | | | | | | | | | | | | | | | | | |
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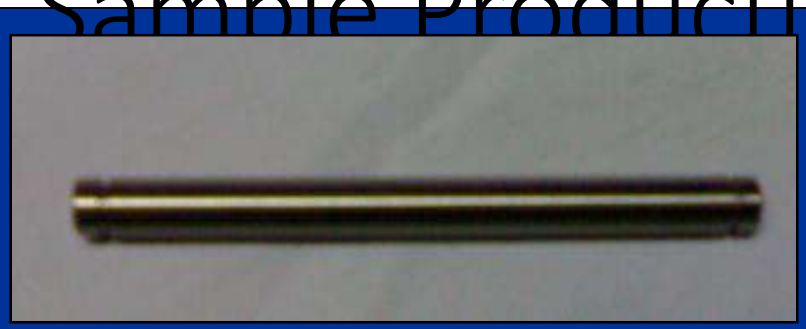
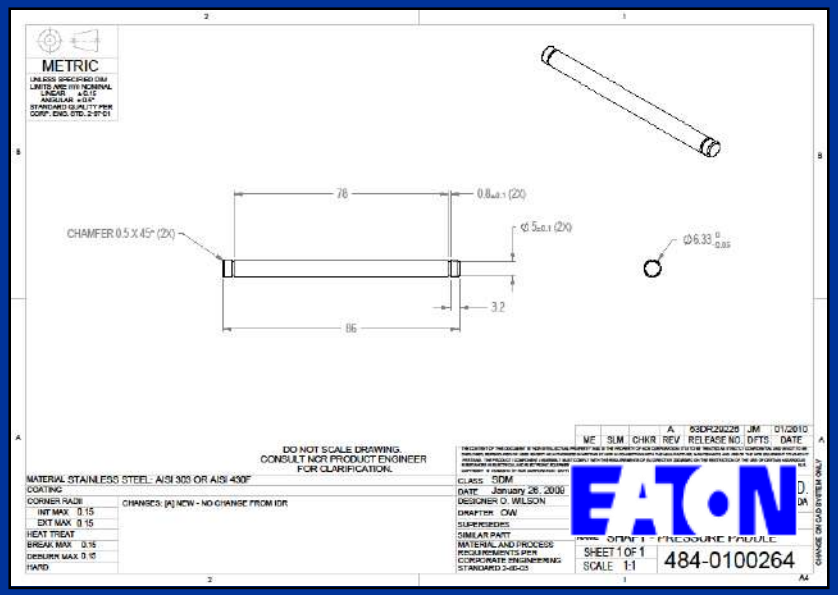
| | | | | | | | | | | | | | | | | | | | | | | | |
| ORGANIZATION SIGNATURE | | | | | | | PHONE NO. | | DATE | | | | | AUTHORIZED CUSTOMER REPRESENTATIVE SIGNATURE | | | | | | | | DATE | |

Color Evaluation Details

- Identifies supplier part color dimensions, use of color spectrometer or RAL charts to determine finish information
- Requires supplier and customer to sign

# PPAP Element #14: Sample Production Parts






**What is It?**

Actual samples that reflect the parts documented in the PPAP.

**Objective or Purpose**

- Confirm cosmetic or functional part approval.

**When to Use It**

- Sample parts should be delivered WITH the PPAP submission

# Sample Production Parts

- The sample parts provided should be the same parts measured for the dimensional results
- PPAP sample quantity is based on needs from Eaton Engineering, Manufacturing and Quality

# Sample Production Parts

Sample production parts MUST be properly identified

Include the following information on the part label:

- Date parts were packed
- Eaton part number
- Quantity
- Serial number
- Supplier part number (optional)
- Part description
- Country of origin
- Indication of regulatory compliance where applicable (RoHS, REACH, Conflict Minerals, etc.)
- Approval markings (UL, CE, etc.) where applicable

# PPAP Element #15: Master Samples
# PPAP Element #16: Checking Aids

- Master Sample (PPAP Element #15)
  - The “perfect” or “golden” sample that subsequent parts can be compared against
  - Often the first good part off a new tool for injection molding or stamping
  - Is sometimes used to verify testing equipment and measurement systems
  - Master samples are not normal for every product or manufacturing process
- Checking aid (PPAP Element #16)
  - Tools, gages, or test equipment, used to inspect production parts
  - Examples include:
    - Visual standards for color or appearance
    - Shadow boards or templates used to verify general shape or presence of required features
    - Custom gages

# PPAP Element #17: Eaton Requirements

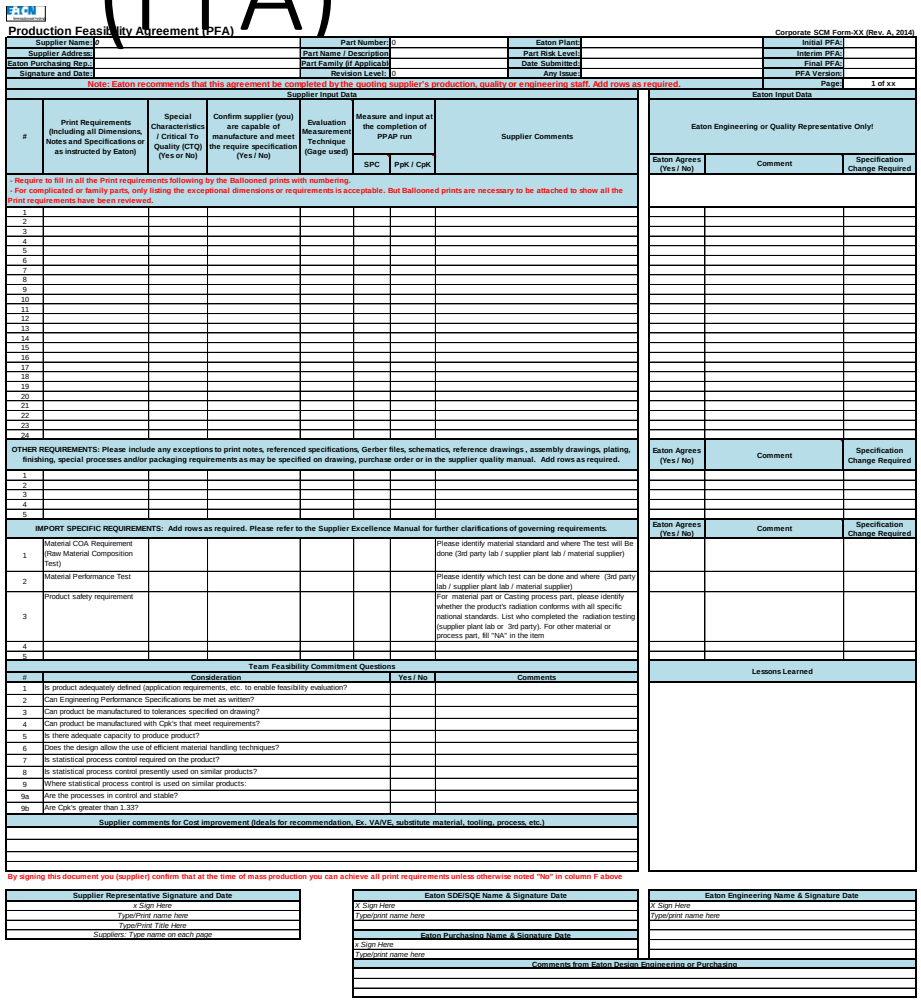
- APQP Kickoff - team
- APQP Timeline Template
- Action Item Log
- Production Feasibility Agreement (PFA)
- Gage Plan
- Dimensional Correlation Matrix
- Pass Through Characteristics (PTC)
- Safe Launch Control Plan
- AS 9102 Forms (Aerospace Industry)
- Ramp Up & Down Plan
- Packaging Specification Data Sheet
- Submit Bar Code Label Packaging Approval
- PPAP Interim Recovery Worksheet
- Capacity R@R Worksheet
- Production Readiness Review (PRR)

These items all have templates in the PPAP Workbook – many of which are self-explanatory

Items in blue have additional instructions embedded in the PPAP Workbook

Let's take a closer look at the items in red…

# Production Feasibility Agreement (PFA)



Production Feasibility Agreement (PFA)

Corporate SCM Form-XX (Rev. A, 2014)

| | | | | | |
|---|---|---|---|---|---|
| Supplier Name: | 0 | Part Number: | 0 | Eaton Plant: | Initial PFA: |
| Supplier Address: | | Part Name / Description: | | Part Risk Level: | Interim PFA: |
| Eaton Purchasing Rep.: | | Part Family (if Applicable): | | Date Submitted: | Final PFA: |
| Signature and Date: | | Revision Level: | 0 | Any Issue: | PFA Version: |
| | | | | | Page: 1 of xx |

Note: Eaton recommends that this agreement be completed by the quoting supplier's production, quality or engineering staff. Add rows as required.

| Supplier Input Data | | | | | | | | Eaton Input Data | | |
|---|---|---|---|---|---|---|---|---|---|---|
| # | Print Requirements (Including all Dimensions, Notes and Specifications or as instructed by Eaton) | Special Characteristics / Critical To Quality (CTQ) (Yes or No) | Confirm supplier (you) are capable of manufacture and meet the require specification (Yes / No) | Evaluation Measurement Technique (Gage used) | Measure and input at the completion of PPAP run | | Supplier Comments | Eaton Engineering or Quality Representative Only! | | |
| | | | | | SPC | PpK / CpK | | Eaton Agrees (Yes / No) | Comment | Specification Change Required |
| - Require to fill in all the Print requirements following by the Ballooned prints with numbering.<br>- For complicated or family parts, only listing the exceptional dimensions or requirements is acceptable. But Ballooned prints are necessary to be attached to show all the Print requirements have been reviewed. | | | | | | | | | | |
| 1 | | | | | | | | | | |
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| 23 | | | | | | | | | | |
| 24 | | | | | | | | | | |
| OTHER REQUIREMENTS: Please include any exceptions to print notes, referenced specifications, Gerber files, schematics, reference drawings , assembly drawings, plating, finishing, special processes and/or packaging requirements as may be specified on drawing, purchase order or in the supplier quality manual. Add rows as required. | | | | | | | | Eaton Agrees (Yes / No) | Comment | Specification Change Required |
| 1 | | | | | | | | | | |
| 2 | | | | | | | | | | |
| 3 | | | | | | | | | | |
| 4 | | | | | | | | | | |
| 5 | | | | | | | | | | |
| IMPORT SPECIFIC REQUIREMENTS: Add rows as required. Please refer to the Supplier Excellence Manual for further clarifications of governing requirements. | | | | | | | | Eaton Agrees (Yes / No) | Comment | Specification Change Required |
| 1 | Material COA Requirement (Raw Material Composition Test) | | | | | | Please identify material standard and where The test will Be done (3rd party lab / supplier plant lab / material supplier) | | | |
| 2 | Material Performance Test | | | | | | Please identify which test can be done and where (3rd party lab / supplier plant lab / material supplier) | | | |
| 3 | Product safety requirement | | | | | | For material part or Casting process part, please identify whether the product's radiation conforms with all specific national standards. List who completed the radiation testing (supplier plant lab or 3rd party). For other material or process part, fill "NA" in the item | | | |
| 4 | | | | | | | | | | |
| 5 | | | | | | | | | | |

| Team Feasibility Commitment Questions | | | |
|---|---|---|---|
| # | Consideration | Yes / No | Comments |
| 1 | Is product adequately defined (application requirements, etc. to enable feasibility evaluation? | | |
| 2 | Can Engineering Performance Specifications be met as written? | | |
| 3 | Can product be manufactured to tolerances specified on drawing? | | |
| 4 | Can product be manufactured with Cpk's that meet requirements? | | |
| 5 | Is there adequate capacity to produce product? | | |
| 6 | Does the design allow the use of efficient material handling techniques? | | |
| 7 | Is statistical process control required on the product? | | |
| 8 | Is statistical process control presently used on similar products? | | |
| 9 | Where statistical process control is used on similar products: | | |
| 9a | Are the processes in control and stable? | | |
| 9b | Are Cpk's greater than 1.33? | | |

Supplier comments for Cost improvement (Ideals for recommendation, Ex. VA/VE, substitute material, tooling, process, etc.)

Lessons Learned

By signing this document you (supplier) confirm that at the time of mass production you can achieve all print requirements unless otherwise noted "No" in column F above

| Supplier Representative Signature and Date |
|---|
| x Sign Here |
| Type/Print name here |
| Type/Print Title Here |
| Suppliers: Type name on each page |

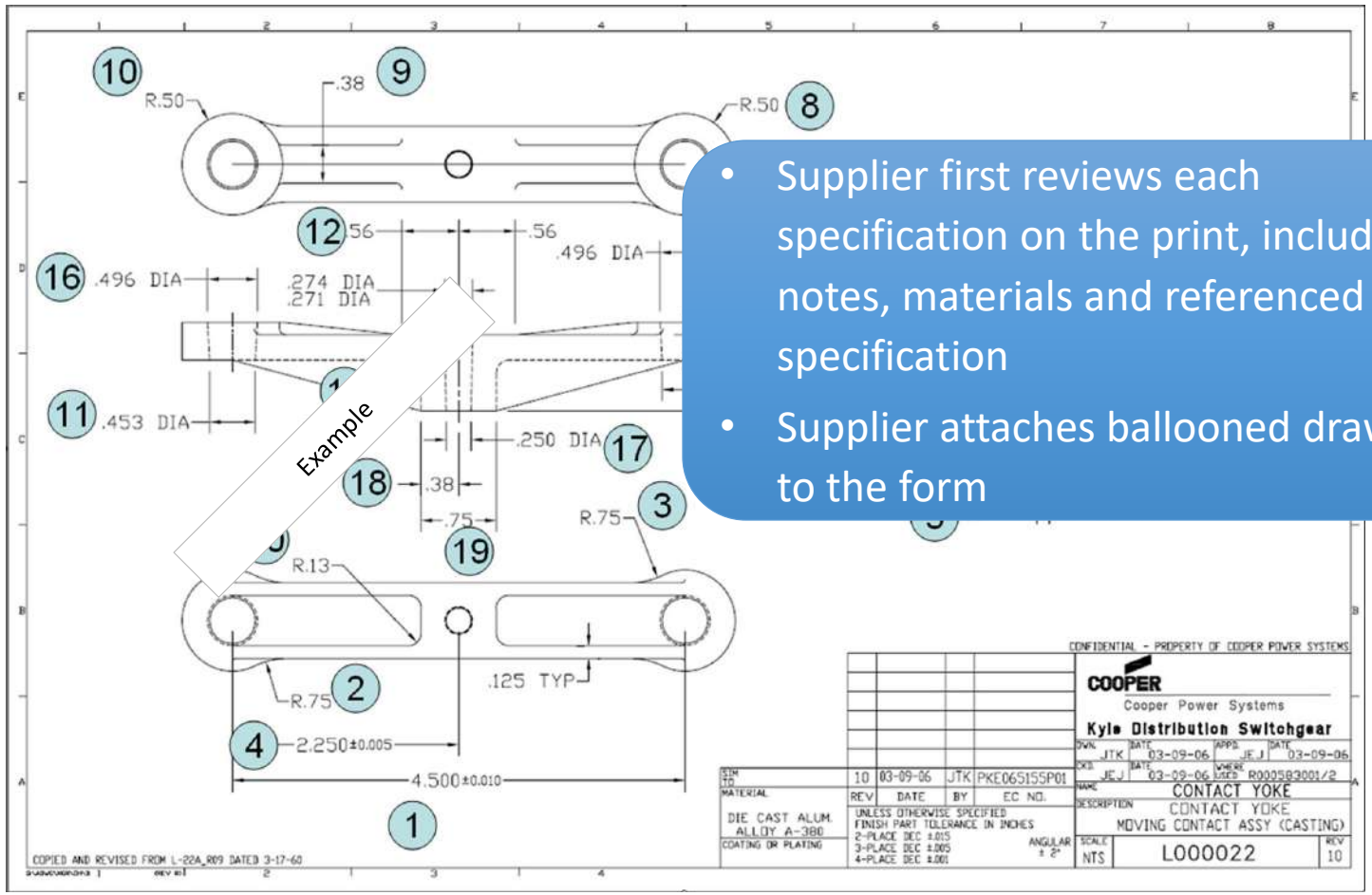
| Eaton SDE/SQE Name & Signature Date |
|---|
| X Sign Here |
| Type/print name here |
| **Eaton Purchasing Name & Signature Date** |
| x Sign Here |
| Type/print name here |

| Eaton Engineering Name & Signature Date |
|---|
| X Sign Here |
| Type/print name here |

Comments from Eaton Design Engineering or Purchasing

- The PFA is designed to ensure the supplier clearly understands and can meet all Eaton design requirements
- It also provides a formal way to solicit and track supplier design input

# PFA (cont.)




- Supplier first reviews each specification on the print, including notes, materials and referenced specification
- Supplier attaches ballooned drawing to the form

# PFA (cont.)

| Supplier Input Data | | | | | | | |
|---|---|---|---|---|---|---|---|
| # | Print Requirements (Including all Dimensions, Notes and Specifications or as instructed by Eaton) | Special Characteristics / Critical To Quality (CTQ) (Yes or No) | Confirm supplier (you) are capable of manufacture and meet the require specification (Yes / No) | Evaluation Measurement Technique (Gage used) | Measure and input at the completion of PPAP run | | Supplier Comments |
| | | | | | SPC | PpK / CpK | |
| - Require to fill in all the Print requirements following by the Ballooned prints with numbering.<br>- For complicated or family parts, only listing the exceptional dimensions or requirements is acceptable. But Ballooned prints are necessary to be attached to show all the Print requirements have been reviewed. | | | | | | | |
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- The supplier enters design specifications and indicates capability to manufacture
- For complex parts with many dimensions and features, the supplier may elect to focus on special characteristics and problem features/tolerances

# PFA (cont.)

| Eaton Input Data | | |
|---|---|---|
| Eaton Engineering or Quality Representative Only! | | |
| **Eaton Agrees (Yes / No)** | **Comment** | **Specification Change Required** |
| | | |
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When requested, Eaton indicates a design change to accommodate the supplier, or indicates the design must remain un-changed

# PFA (cont.)

| Team Feasibility Commitment Questions | | | |
|---|---|---|---|
| # | Consideration | Yes / No | Comments |
| 1 | Is product adequately defined (application requirements, etc. to enable feasibility evaluation? | | |
| 2 | Can Engineering Performance Specifications be met as written? | | |
| 3 | Can product be manufactured to tolerances specified on drawing? | | |
| 4 | Can product be manufactured with Cpk's that meet requirements? | | |
| 5 | Is there adequate capacity to produce product? | | |
| 6 | Does the design allow the use of efficient material handling techniques? | | |
| 7 | Is statistical process control required on the product? | | |
| 8 | Is statistical process control presently used on similar products? | | |
| 9 | Where statistical process control is used on similar products: | | |
| 9a | Are the processes in control and stable? | | |
| 9b | Are Cpk's greater than 1.33? | | |
| **Supplier comments for Cost improvement (Ideals for recommendation, Ex. VA/V** | | | |
| | | | |
| | | | |
| | | | |
| | | | |

- Supplier answers general feasibility questions and signs
- Supplier may also make cost improvement recommendations

**By signing this document you (supplier) confirm that at the time of mass production you can achieve all print requirements unless otherwise noted "No" in column F**

| Supplier Representative Signature and Date |
|---|
| *x Sign Here* |
| *Type/Print name here* |
| *Type/Print Title Here* |
| *Suppliers: Type name on each page* |

| Eaton SDE/SQE Name & Signature Date |
|---|
| *X Sign Here* |
| *Type/print name here* |
| |
| **Eaton Purchasing Name & Signature Date** |
| *x Sign Here* |
| *Type/print name here* |

# Gage Plan

**Gage Plan**

| | | | | | | |
|---|---|---|---|---|---|---|
| Supplier | | | | Part Revision | | |
| Manufacturing Location | | | | Document Revision | | |
| Part Name | | | | Eaton Plant | | |
| Part Number or Specification | | | | | | |
| Supplier | | | | Eaton Quality | Team | |
| Print Balloon No. | Characteristic (Dimension and tolerance) | Char. Type | Supplier's measurement method | Eaton User Plant Control Method | Is measurement method acceptable? | Issues / Comments / Next Steps |
| example | 999.999 +/- 0.9999 | Critical | CMM | CMM | Yes | Briefly describe planned actions. |
| | | | | | | |
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- Identify all gages to be utilized for product validation
- Include any clarification or additional set up required for accurate validation

# Gage Correlation Matrix

**Dimensional Correlation Matrix**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Supplier | 0 | | | | | Drawing Number: | | | | | Supplier Representative: | | |
| Manufacturing Location | | | | | | Part Revision and Date | 0 | | | | Phone number: | | |
| Part Name | | | | | | Document Revision | | | | | Correlation Date: | | |
| Part Number or Specification | 0 | | | | | Eaton Plant | | | | | | | |
| Eaton part/Assembly number | Print feature name | Sample Number | Upper Tolerance (+) | Lower Tolerance (-) | Total Tolerance | Nominal target | Bonus Tolerance Y/N | Eaton Measuring equipment type | Eaton reading | Supplier Measuring equipment type | Supplier reading | Delta | % of tolerance (if value is > or = to 25% or -25%, correlation improvement is recommended) |
| Example | Ball diameter | 1 | 0.0025 | 0.0025 | 0.005 | 5.556 | N | Beta laser mic | 5.5592 | Non contact laser | 5.5586 | 0.00063 | 13% |
| Example | Ball diameter | 5 | 0.0025 | 0.0025 | 0.005 | 5.556 | N | Beta laser mic | 5.5612 | Non contact laser | 5.5601 | 0.00113 | 23% |
| Example | Ball diameter | 2 | 0.0025 | 0.0025 | 0.005 | 5.556 | N | Beta laser mic | 5.5595 | Non contact laser | 5.5581 | 0.00142 | 28% |
| Example | Ball diameter | 4 | 0.0025 | 0.0025 | 0.005 | 5.556 | N | Beta laser mic | 5.5597 | Non contact laser | 5.5582 | 0.00151 | 30% |

- This template is for Suppliers to populate and compare their actual dimensions to Eaton measured values
- Only required for specific features as identified by Eaton

# Production Readiness Review (PRR)

**Supplier Production Readiness Review**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Supplier | 0 | | | | | Review Date | |
| Mfg. Location | | | | | | Commodity | |

| Element | Status G/Y/R | Intended for Use Prior to … | Readiness Criteria | Recovery Plan/Comments (if status is Red or Yellow) | Due Date | Responsible Person's Name | Comments |
|---|---|---|---|---|---|---|---|
| 1 | | PPAP / Production Run | Was an APQP project established and have required PPAP activities been completed in the APQP process? For those activates that remain open, are they planned to be completed in line with the APQP timeline? | | | | |

| | | | | Supplier Complete | Eaton Reviewed | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 2 | | Production Run | Did the supplier complete and did the plant / approving authority review the PPAP package in details and there are no outstanding issues pending? | | | | | | |
| 2.1 | | Production Run | a. Process Capability | | | | | | |

**Production Readiness Review (PRR) evaluates and verifies the readiness of a supplier to move from development to initial production**

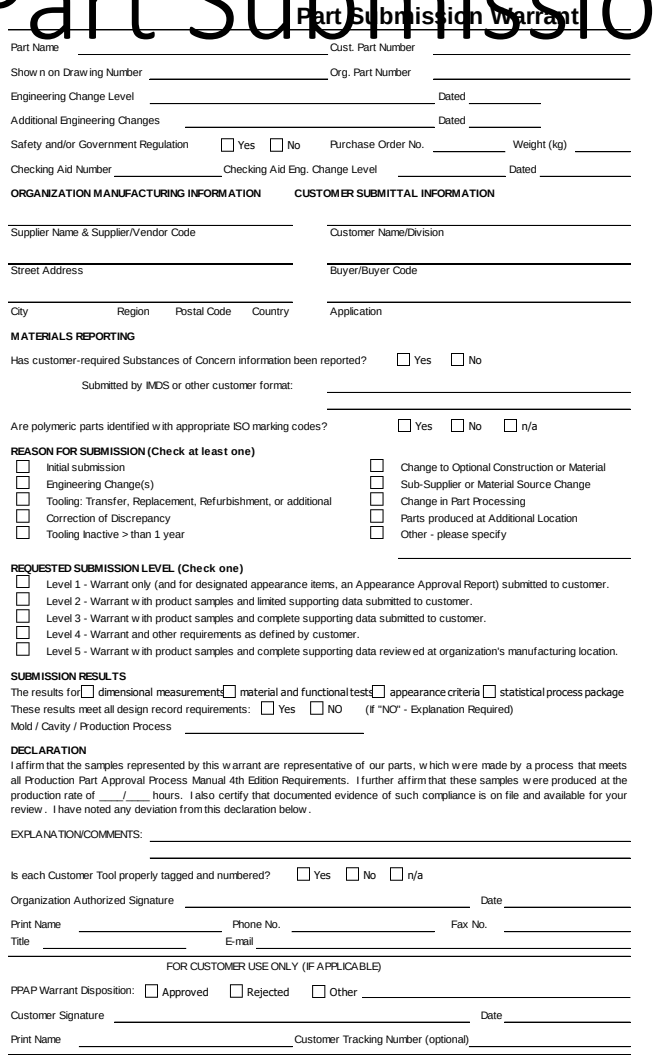
**Utilized as an assessment of risk identification/mitigation plan, not as a pass/fail audit**

**Conducted prior to the manufacturing build with time to mitigate risks**

**Completed on-site by Eaton personnel and/or by supplier as a self-assessment**

**Validates APQP Process was followed & checks other important factors for success**

# PPAP Element #18: Part Submission Warrant (PSW)



**Part Submission Warrant**

Part Name _____ Cust. Part Number _____

Show n on Draw ing Number _____ Org. Part Number _____

Engineering Change Level _____ Dated _____

Additional Engineering Changes _____ Dated _____

Safety and/or Government Regulation ☐ Yes ☐ No Purchase Order No. _____ Weight (kg) _____

Checking Aid Number _____ Checking Aid Eng. Change Level _____ Dated _____

**ORGANIZATION MANUFACTURING INFORMATION** **CUSTOMER SUBMITTAL INFORMATION**

Supplier Name & Supplier/Vendor Code — Customer Name/Division

Street Address — Buyer/Buyer Code

City Region Postal Code Country — Application

**MATERIALS REPORTING**

Has customer-required Substances of Concern information been reported? ☐ Yes ☐ No

Submitted by IMDS or other customer format: _____

Are polymeric parts identified w ith appropriate ISO marking codes? ☐ Yes ☐ No ☐ n/a

**REASON FOR SUBMISSION (Check at least one)**

- ☐ Initial submission
- ☐ Engineering Change(s)
- ☐ Tooling: Transfer, Replacement, Refurbishment, or additional
- ☐ Correction of Discrepancy
- ☐ Tooling Inactive > than 1 year
- ☐ Change to Optional Construction or Material
- ☐ Sub-Supplier or Material Source Change
- ☐ Change in Part Processing
- ☐ Parts produced at Additional Location
- ☐ Other - please specify _____

**REQUESTED SUBMISSION LEVEL (Check one)**

- ☐ Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.
- ☐ Level 2 - Warrant w ith product samples and limited supporting data submitted to customer.
- ☐ Level 3 - Warrant w ith product samples and complete supporting data submitted to customer.
- ☐ Level 4 - Warrant and other requirements as defined by customer.
- ☐ Level 5 - Warrant w ith product samples and complete supporting data review ed at organization's manufacturing location.

**SUBMISSION RESULTS**

The results for ☐ dimensional measurements ☐ material and functional tests ☐ appearance criteria ☐ statistical process package

These results meet all design record requirements: ☐ Yes ☐ NO (If "NO" - Explanation Required)

Mold / Cavity / Production Process _____

**DECLARATION**

I affirm that the samples represented by this w arrant are representative of our parts, w hich w ere made by a process that meets all Production Part Approval Process Manual 4th Edition Requirements. I further affirm that these samples w ere produced at the production rate of ____/____ hours. I also certify that documented evidence of such compliance is on file and available for your review . I have noted any deviation from this declaration below .

EXPLANATION/COMMENTS: _____

Is each Customer Tool properly tagged and numbered? ☐ Yes ☐ No ☐ n/a

Organization Authorized Signature _____ Date _____

Print Name _____ Phone No. _____ Fax No. _____

Title _____ E-mail _____

FOR CUSTOMER USE ONLY (IF APPLICABLE)

PPAP Warrant Disposition: ☐ Approved ☐ Rejected ☐ Other _____

Customer Signature _____ Date _____

Print Name _____ Customer Tracking Number (optional) _____

## What is It?

- Required document in which the supplier confirms the design and validation of manufacturing processes that will produce parts to specification at a specific rate

## Objective or Purpose

- Used to :
  - document part approval
  - provide key information
  - declare that the parts meet specification

## When to Use It

- Prior to shipping production parts

# Part Submission Warrant (PSW)

## Part Submission Warrant

Part Name _____ Cust. Part Number _____

Show n on Draw ing Number _____ Org. Part Number _____

Engineering Change Level _____ Dated _____

Additional Engineering Changes _____ Dated _____

Safety and/or Government Regulation ☐ Yes ☐ No Purchase Order No. _____ Weight (kg) _____

Checking Aid Number _____ Checking Aid Eng. Change Level _____ Dated _____

**ORGANIZATION MANUFACTURING INFORMATION** **CUSTOMER SUBMITTAL INFORMATION**

Supplier Name & Supplier/Vendor Code

Customer Name/Division

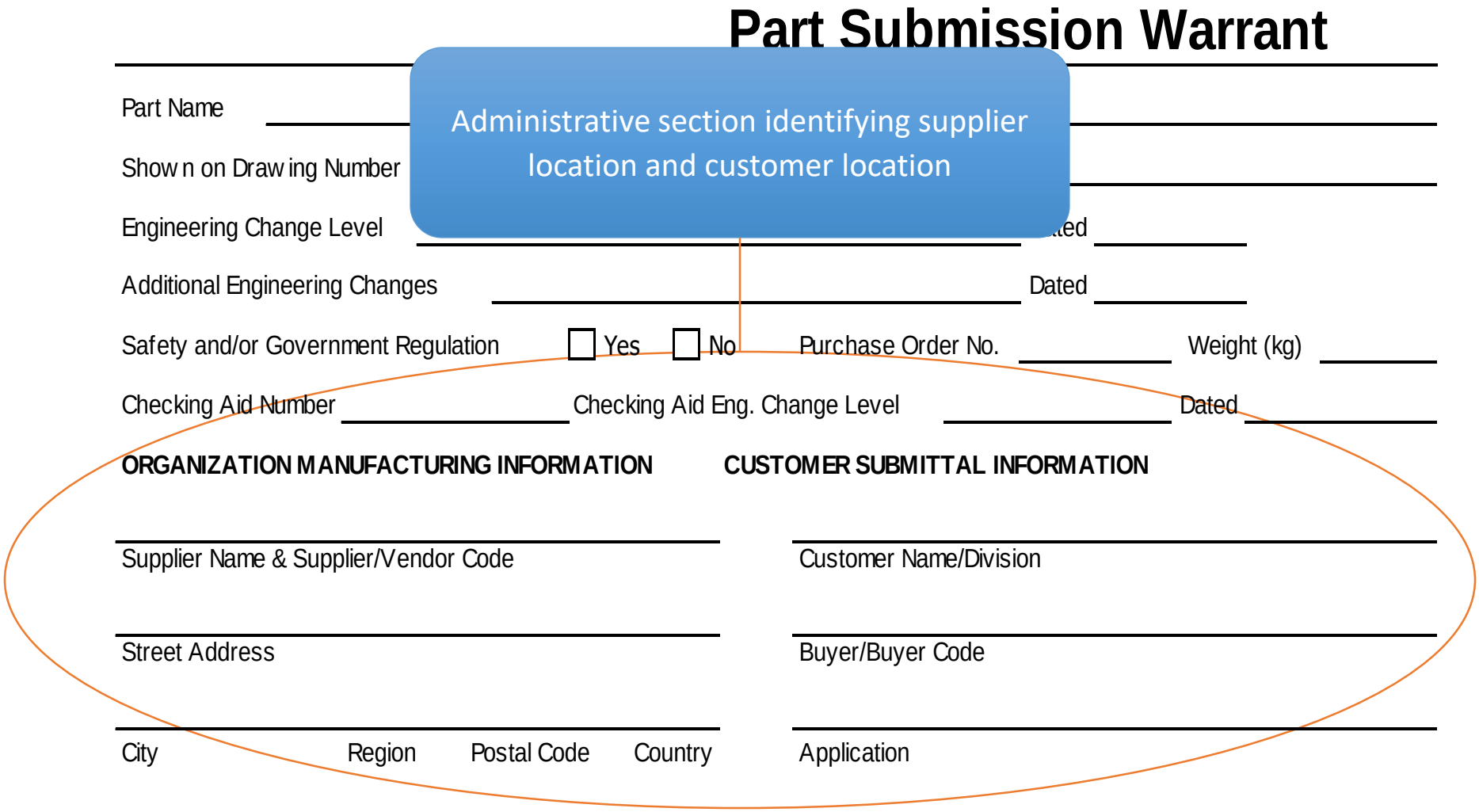
Street Address

Buyer/Buyer Code

City Region

Administrative section containing basic part information, including Part Number and Revision

# Part Submission Warrant (PSW)



# Part Submission Warrant (PSW)

**MATERIALS REPORTING**

Has customer-required Substances of Concern information been reported? ☐ Yes ☐ No

Submitted by IMDS or other customer format: _____

_____

Are polymeric parts identified w ith appropriate ISO marking codes? ☐ Yes ☐ No ☐ n/a

**REASON FOR SUBMISSION (Check at least one)**

- ☐ Initial submission
- ☐ Engineering Change(s)
- ☐ Tooling: Transfer, Replacement, Refurbishment, or additional
- ☐ Correction of Discrepancy
- ☐ Tooling Inactive > than 1 year
- ☐ Change to Optional Construction or Material
- ☐ Sub-Supplier or Material Source Change
- ☐ Change in Part Processing
- ☐ Parts produced at Additional Location
- ☐ Other - please specify

_____

**REQUESTED SUBMISSION LEVEL (Check one)**

- ☐ Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.
- ☐ Level 2 - Warra
- ☐ Level 3 - Warra …er.
- ☐ Level 4 - Warra
- ☐ Level 5 - Warra …ation's manufacturing location.

Here the supplier is required to identify how it has reported Substances of Concern:

- IMDS, RoHS, REACH, Conflict Minerals, etc.

**SUBMISSION RESULT**

The results for ☐ dimens… …ria ☐ statistical process package

These results meet all design record requirements: ☐ Yes ☐ NO (If "NO" - Explanation Required)

Mold / Cavity / Production Process _____

# Part Submission Warrant (PSW)

**MATERIALS REPORTING**

Has customer-required Substances of Concern information been reported? ☐ Yes ☐ No

Submitted by IMDS or other customer format: _____

Are polymeric parts identified with appropriate ISO marking codes? ☐ Yes ☐ No ☐ n/a

**REASON FOR SUBMISSION (Check at least one)**

- ☐ Initial submission
- ☐ Engineering Change(s)
- ☐ Tooling: Transfer, Replacement, Refurbishment, or additional
- ☐ Correction of Discrepancy
- ☐ Tooling Inactive > than 1 year
- ☐ Change to Optional Construction or Material
- ☐ Sub-Supplier or Material Source Change
- ☐ Change in Part Processing
- ☐ Parts produced at Additional Location
- ☐ Other - please specify _____

**REQUESTED SUBMISSION LEVEL (Check one)**

- ☐ Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.
- ☐ Level 2 - Warrant with product samples and limited supporting data submitted to customer.
- ☐ Level 3 - Warrant with product samples and complete supporting data submitted to customer.
- ☐ Level 4 - Warrant
- ☐ Level 5 - Warran ion's manufacturing location.

**SUBMISSION RESULTS**

The results for ☐ dimens ☐ statistical process package

These results meet all de quired)

Mold / Cavity / Productio

The supplier indicates the reason for the PPAP submission

# Part Submission Warrant (PSW)

**MATERIALS REPORTING**

Has customer-required S

Submitted

Are polymeric parts ident ☐ n/a

- The supplier indicates the PPAP level and certifies that the validation results meet all design specifications.
- This certification is by cavity, production line, etc.

**REASON FOR SUBMISSIO**

- ☐ Initial submission
- ☐ Engineering Change(s)
- ☐ Tooling: Transfer, Replacement, Refurbishment, or additional
- ☐ Correction of Discrepancy
- ☐ Tooling Inactive > than 1 year
- ☐ Change to Optional Construction or Material
- ☐ Sub-Supplier or Material Source Change
- ☐ Change in Part Processing
- ☐ Parts produced at Additional Location
- ☐ Other - please specify

**REQUESTED SUBMISSION LEVEL (Check one)**

- ☐ Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.
- ☐ Level 2 - Warrant w ith product samples and limited supporting data submitted to customer.
- ☐ Level 3 - Warrant w ith product samples and complete supporting data submitted to customer.
- ☐ Level 4 - Warrant and other requirements as defined by customer.
- ☐ Level 5 - Warrant w ith product samples and complete supporting data review ed at organization's manufacturing location.

**SUBMISSION RESULTS**

The results for ☐ dimensional measurements ☐ material and functional tests ☐ appearance criteria ☐ statistical process package

These results meet all design record requirements: ☐ Yes ☐ NO (If "NO" - Explanation Required)

Mold / Cavity / Production Process

# Part Submission Warrant (PSW)

**DECLARATION**

I affirm that the samples represented by this warrant are representative of our parts, which were made by a process that meets all Production Part Approval Process Manual 4th Edition Requirements. I further affirm that these samples were produced at the production rate of ____/____ hours. I also certify that documented evidence of such compliance is on file and available for your review. I have noted any deviation from this declaration below.

EXPLANATION/COMMENTS: _____

_____

Is each Customer Tool properly tagged and numbered? ☐ Yes ☐ No ☐ n/a

Organization Authorized Signature _____ Date _____

Print Name _____ Phone No. 555-555-5555 Fax No. _____

Title _____ E-mail _____

FOR CUSTOMER USE ONLY (IF APPLICABLE)

PPAP Warrant Disposition _____

Customer Signature _____

Print Name _____

- The supplier declares that the PPAP submission is based on production processes run at a normal or planned production rate.
- The supplier states the production rate.
- The supplier indicates that any customer owned tooling is properly identified

# Part Submission Warrant (PSW)

- Prior to submitting the PPAP, the supplier representative signs the warrant, indicating the part meets Eaton requirements
- The customer then approves or rejects the PPAP and signs to confirm the decision
- The customer approved PSW is a prerequisite for production shipments

**DECLARATION**

I affirm that the samples … by a process that meets all Production Part App… s were produced at the production rate of ____ … e and available for your review. I have noted a…

EXPLANATION/COMME… _____

_____

Is each Customer Tool properly tagged and numbered? ☐ Yes ☐ No ☐ n/a

Organization Authorized Signature _____ Date _____

Print Name _____ Phone No. 555-555-5555 Fax No. _____

Title _____ E-mail _____

FOR CUSTOMER USE ONLY (IF APPLICABLE)

PPAP Warrant Disposition: ☐ Approved ☐ Rejected ☐ Other _____

Customer Signature _____ Date _____

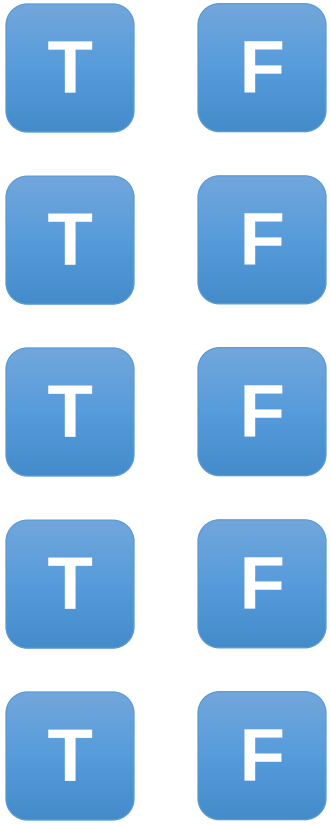
Print Name _____ Customer Tracking Number (optional) _____

# Part Submission Warrant (PSW)

- Reviewers Checklist
  - ✓Must be completely filled out
  - ✓Must be signed by the supplier
  - ✓P/N must match the PO
  - ✓Product family submissions allowed
  - ✓Submitted at the correct revision level
  - ✓Submitted at the correct submission level
  - ✓Specify the reason for submission
  - ✓Include IMDS, RoHS, etc. as required
  - ✓Clearly state the production rate used for validation

# PPAP Progress Check – Final (True/False)

- Eaton considers FAI to be better than PPAP
- FMEAs should have additional actions identified
- The supplier should complete the Control Plan prior to the production trial run
- The reaction plan part of Control Plan is optional
- The supplier should state the production rate used during the production trial run on the PSW



# PPAP Summary

- PPAP checks that any process changes have been properly designed and validated, and the resulting process is capable of repeatedly producing parts to specification
- The PPAP elements should be part of your Quality Management System. PPAP shouldn’t require much extra effort, because you’ve already done the work internally to manage your changes.
- Reacting to later issues with the product or process can be expensive and time-consuming!

# Thanks For Your Time