

# Production Part Approval Process (PPAP)

QUALITY



# Course Objectives

- Explain the importance of Quality
- Understanding the difference between Traditional product development approach and PPAP
- Explain all items listed as PPAP requirements.
- Explain the purpose of PPAP levels.
- Explain when the customer should be notified of changes.
- Identify all aspects of an initial production run.
- Be able to use the PPAP checklist in evaluating a PPAP.

# Agenda

- Chapter 1 – Introduction to Quality
  - Quality
  - Evolution of Quality
  - Quality Control
  - Quality Assurance
  - Comparison of QC and QA
  - Traditional Product Development approach
- Chapter 2 – Introduction to PPAP
  - What is PPAP?
  - Why PPAP?
  - Evolution of PPAP
  - Comparison between Traditional approach and PPAP
  - Definitions

# Agenda

- PPAP in a QMS
- Managing Changes and Submissions
- Submission Levels
- Record Retention
- Significant Production Run
- Chapter 3 – PPAP Submission Elements
  - Requirements and Deliverables
  - **Breakout Exercise 1**
  - Product Design Elements
  - Manufacturing Process Elements
  - General Elements
  - Part Submission Warrant and Status
- Chapter 4 – Assessing a PPAP Package
  - **Breakout Exercise 2**

# A BRIEF INTRODUCTION TO OMNEX

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# Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
  - Integrated management system solutions.
  - Elevating the performance of client organizations.
  - Consulting and training services in:
    - Quality Management Systems, e.g. ISO 9001, IATF 16949, AS9100, QOS
    - Environmental Management Systems, e.g. ISO 14001
    - Health and Safety Management Systems, e.g. OHSAS 18001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
  - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.



# About Omnex

- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 400 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS 16949.
- Served on committees that wrote QOS, ISO 9001:2000, QS-9000, ISO/TS 16949 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).



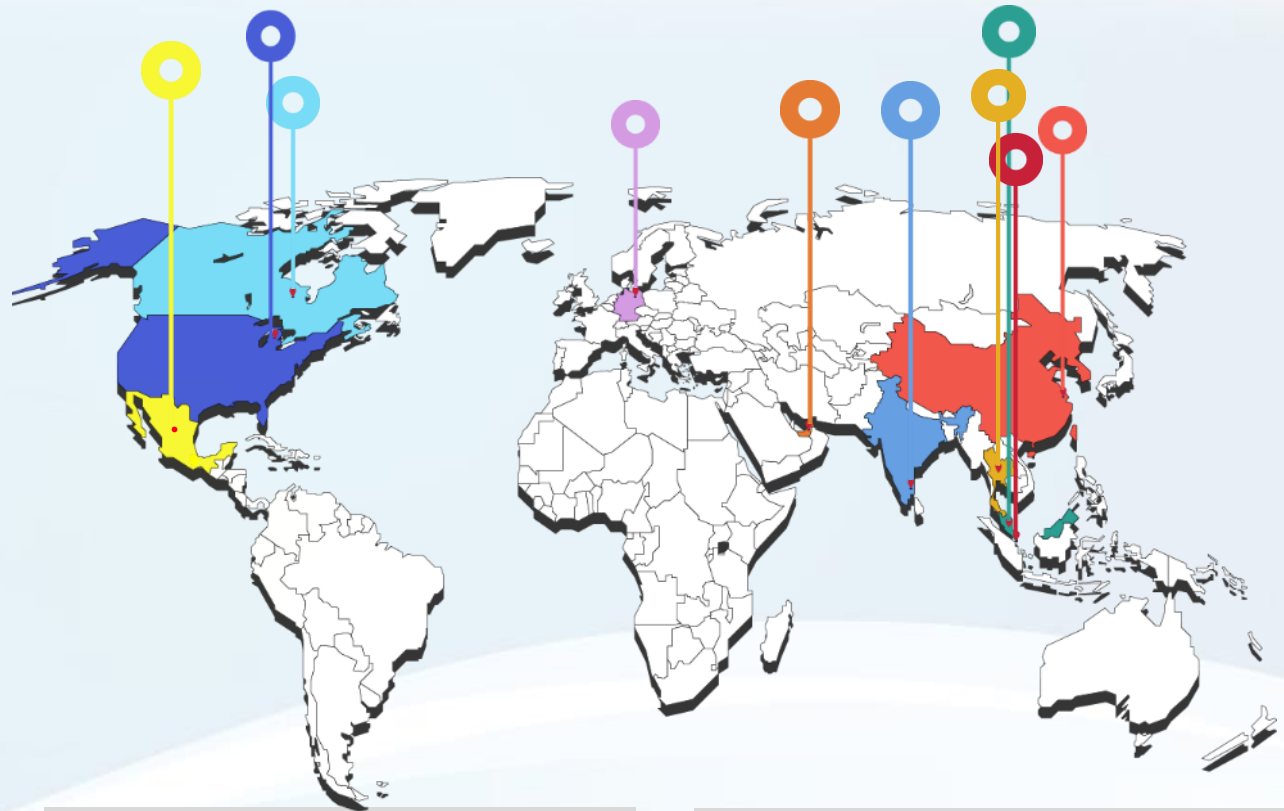




Omnex is headquartered and operates from the United States through offices in Michigan.

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

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● Omnex Global Head Quarters (Michigan, USA)  
West Coast Operations (San Jose, CA)

● Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)

● China (Shanghai, Guangzhou, Wuhan, Chengdu)

● Canada (Mississauga)

● Europe (Berlin, Germany)

● Middle East (Dubai, Saudi Arabia, Bahrain)

● Thailand (Bangkok)

● Mexico (Monterrey)

● Singapore

● Malaysia (Kuala Lumpur)



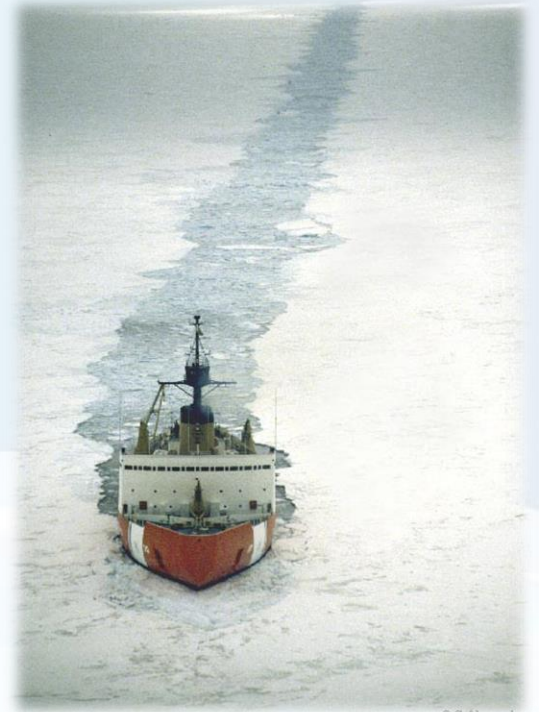


# Rules of the Classroom

- ✓ Start and end on time
- ✓ Return from breaks and lunch on time
- ✓ All questions welcome
- ✓ Your input is valuable and is encouraged
- ✓ Don't interrupt others
- ✓ One meeting at a time
- ✓ Listen – and respect others' ideas
- ✓ No “buts” – keep an open mind
- ✓ Cell phones & pagers off or silent mode
- ✓ No e-mails, texting or tweeting during class
- ✓ If you must take a phone call or answer a text please leave the room for as short a period as possible

# Icebreaker

- Instructor Information:
  - Name
  - Background
- Student Introductions:
  - Name
  - Position / Responsibilities
  - What is your involvement in the new product development process?
  - What are your experiences with PPAP?
  - Please share something unique and/or interesting about yourself.



# Chapter 1

## Introduction of Quality

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# Chapter 1: Introduction of Quality– What We Will Cover

## Learning Objectives

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

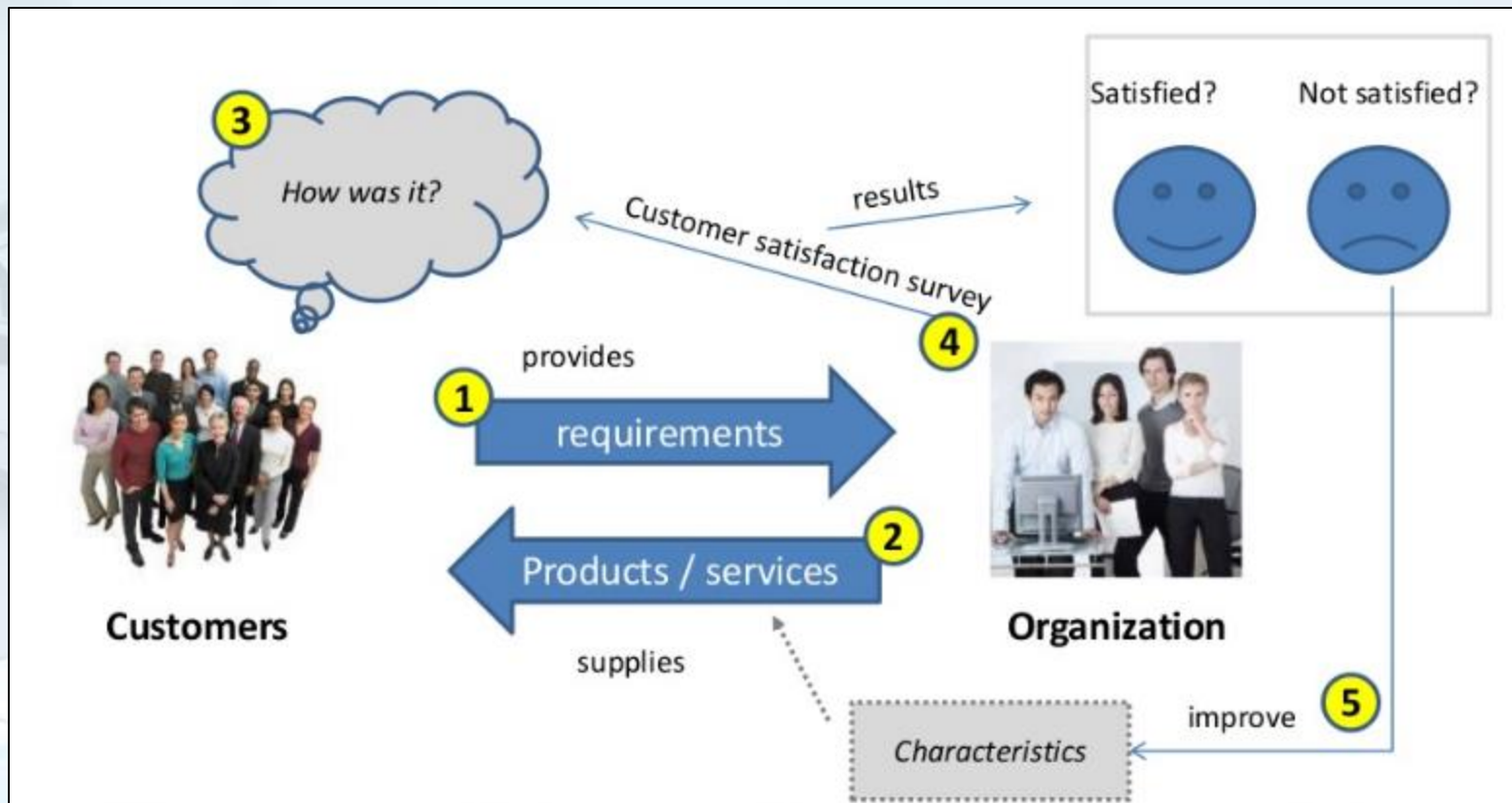
- Understand the importance of Quality
- Describe the evolution of Quality
- Understand the concept of QA and QC
- Understand the Juran's Trilogy
- Understand the difference between Quality control and Quality Assurance
- Understanding the Traditional product development approach

## Chapter Agenda

- Quality
- Evolution of Quality
- Quality Control
- Quality Assurance
- Comparison of QA and QC
- Traditional Product Development Approach

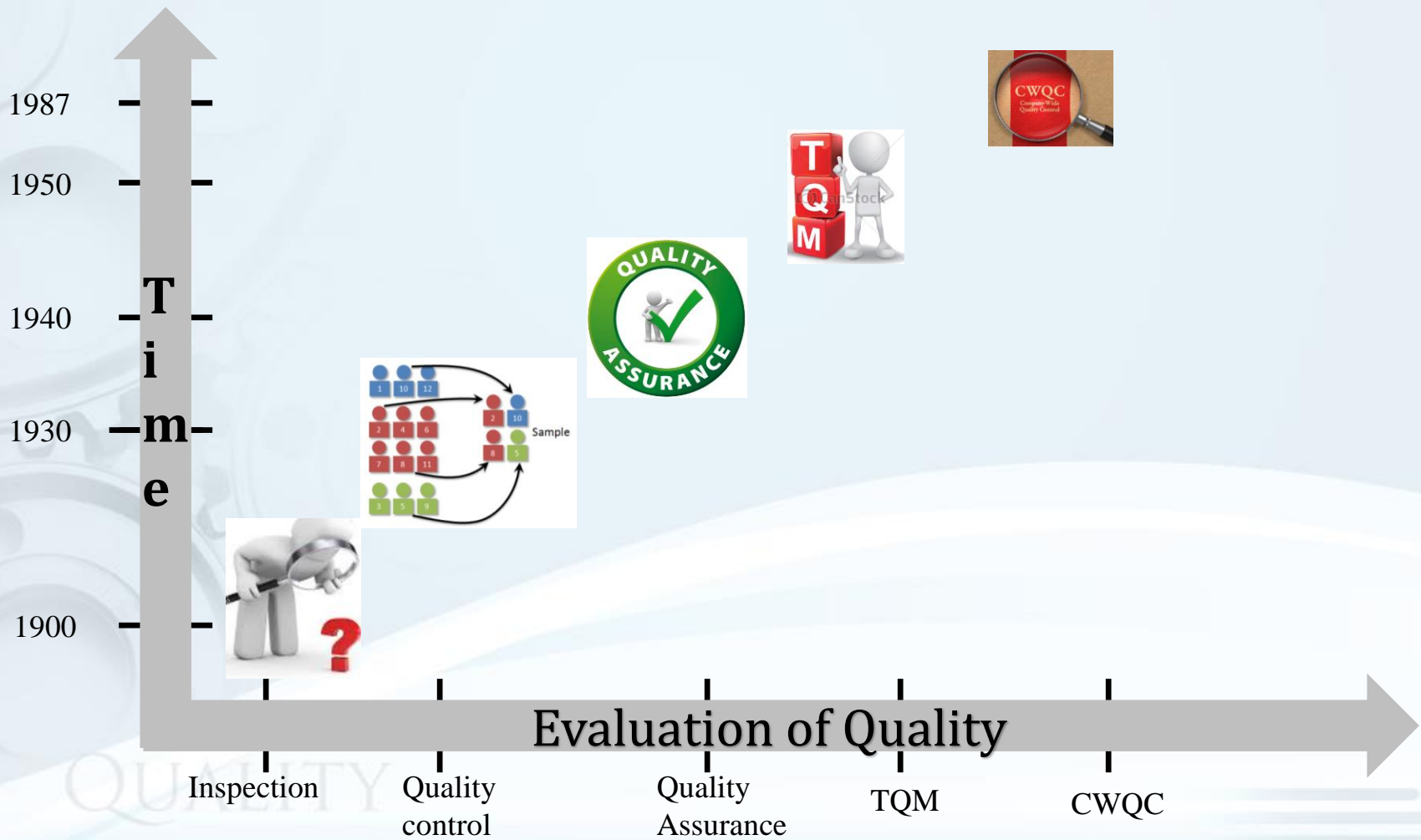
# What is Quality?

- **Quality:** degree to which a set of inherent characteristics of an object fulfils requirements.





# Development of Quality approach



# What is Quality Control?

Operational techniques and activities that are used to fulfil the requirements for quality



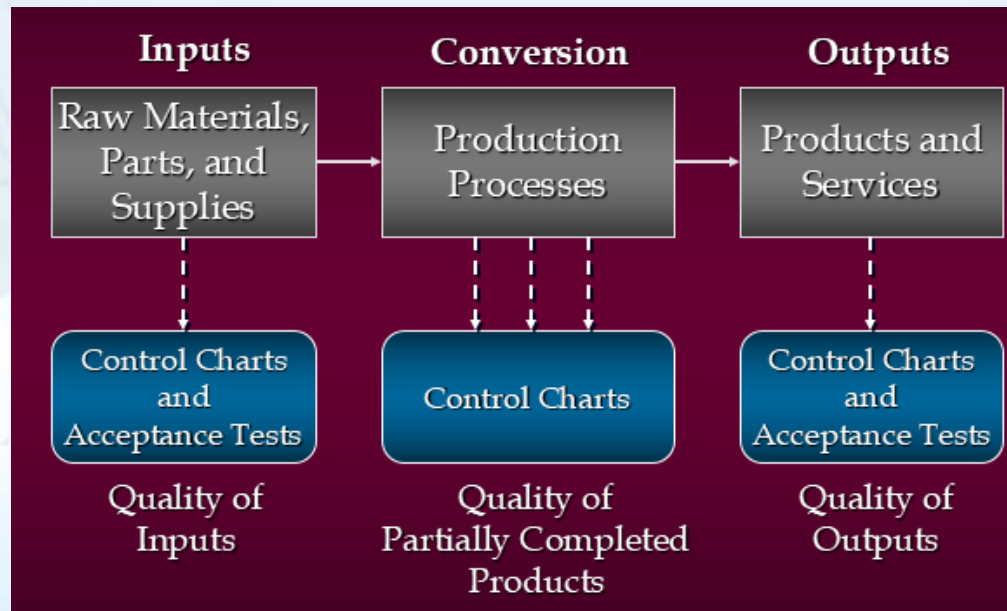
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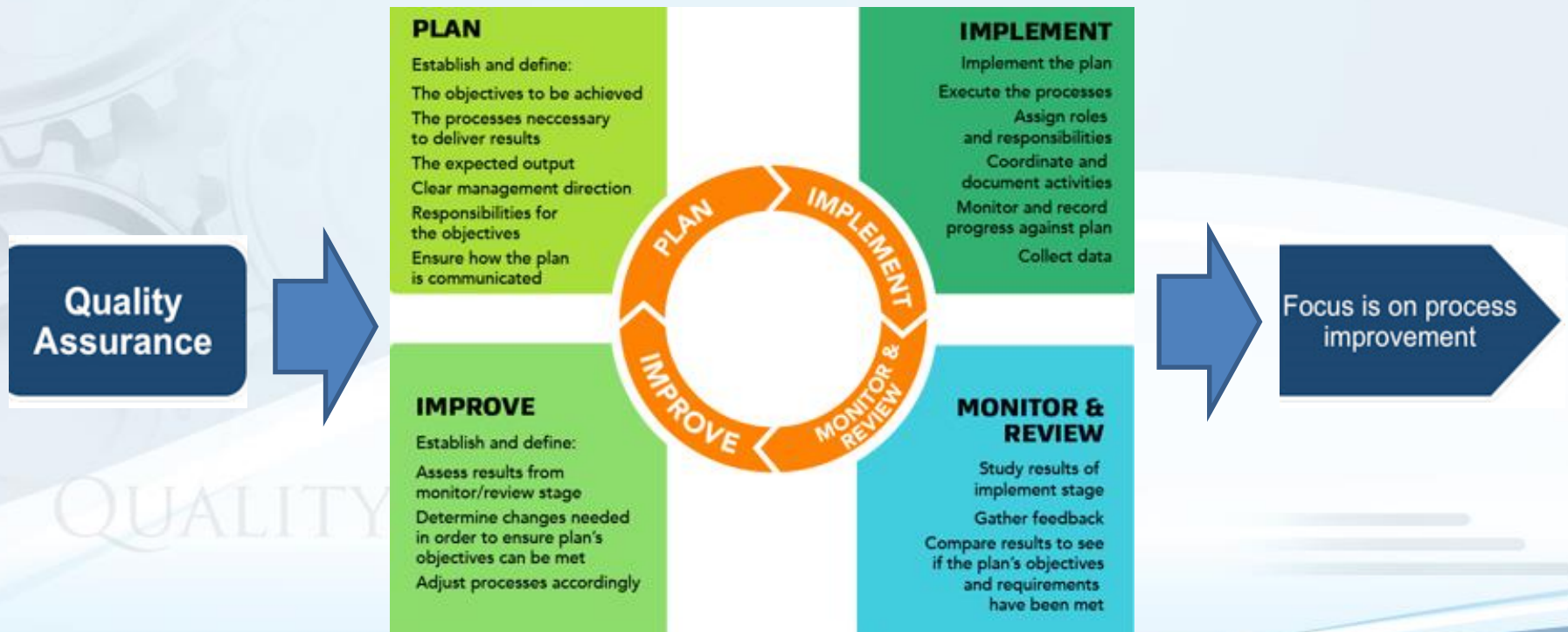
# What is Quality Control?

- Quality control (QC) includes the activities from the suppliers, through production, and to the customers.
- Incoming materials are examined by Incoming inspection.
- In process production are controlled through SPC, Inspection.
- Finished goods are studied to determine if they meet customer expectations.



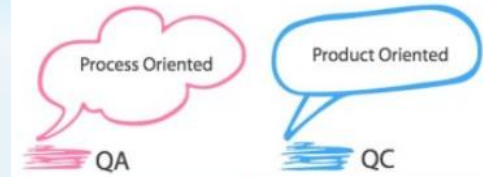
# What is Quality Assurance?

Part of quality management, focused on providing confidence that quality requirements will be fulfilled.



# Comparison of QA and QC

Quality Assurance Vs Quality Control



| <i>Quality Control</i>  | <i>Quality Assurance</i>  |
|---|---|
|  |  |
| <i>Focused on Product</i>   | <i>Focused on Process</i>   |
| <i>Reactive</i>   | <i>Pro-active</i>   |
| <i>Line Function</i>  | <i>Staff Function</i>   |
| <i>Finds Defects</i>  | <i>Prevent Defects</i>  |
| <i>Testing</i>  | <i>Quality Audits</i>   |

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# Traditional approach

- There was no process of getting approval from the customer
- There was no structured way to communicate the development of product between manufacturer and customer.
- There were no prescribed design records and formats that to be maintained.
- Change controls were not documented.

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# Chapter 1: Introduction of Quality – What We Covered

## Learning Objectives

You should now be able to:

- Understand the importance of Quality
- Describe the evolution of Quality
- Understand the concept of QA and QC
- Understand the Juran's Trilogy
- Understand the difference between Quality control and Quality Assurance
- Understanding the Traditional product development approach

## Chapter Agenda

- Quality
- Evolution of Quality
- Quality Control
- Quality Assurance
- Comparison of QA and QC
- Traditional Product Development Approach

# Chapter 2

## PPAP Introduction

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# Chapter 2: PPAP Introduction – What We Will Cover

## Learning Objectives

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

- Understand the concept of PPAP
- Understand the difference between PPAP and Traditional Product development approach
- Describe how PPAP fits in a quality management system
- Identify the type of changes that must be reported to the customer
- Identify when and how submissions to the customer are conducted
- List the submissions levels for PPAP
- Describe the key elements of a significant production run

## Chapter Agenda

- Concept of PPAP
- Evolution of PPAP
- PPAP in a QMS
- Comparison of PPAP with traditional product development approach
- Managing Changes and Submissions
- Submission Levels
- Record Retention
- Significant Production Run





# PPAP

- **Definition:** PPAP is a customer product qualification process for approving new or revised purchased products, or production processes used **prior to** shipment of direct material products for production use.
- **Scope:** Applies to internal and external organization sites supplying Bulk and Production Materials, Production or Service Parts.
  - Standard catalog production or service parts shall comply *unless formally waived* by the authorized customer representative.

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# PPAP

- **Purpose:** To determine and provide evidence that all customer engineering design record and specification requirements are properly understood by the organization and that the manufacturing process has the potential to produce product consistently meeting these requirements during an actual production run at the quoted production rate.

**PPAP IS REQUIRED BEFORE QUANTITY SHIPMENT AND IS  
DEPENDENT ON REQUIREMENTS OF THE CUSTOMER**



# EVOLUTION OF PPAP

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# Origin of PPAP concept

- The PPAP evolved from a process that NASA engineers created to better predict equipment malfunctions after the launch-pad failure of the first Apollo mission.
- The goal of NASA's process was to prevent the kind of equipment malfunctions that caused the failure of Apollo 1.
- This process was further refined by the American automotive industry as a way to streamline and improve its component supply chain through AIAG.

# Approach in PPAP

- Provides understanding of information about product that to be developed.
- Predetermined methods to obtain approval of product/product and changes.
- Ensures part submissions are submitted with proper information and enough data to sustain product conformance
- Provides a record of part conformance at launch
- Details pertinent design records to ensure traceability of part design status at origin
- Controls product and process change process

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# Comparison of PPAP with Traditional Product development approach

| S. No | Traditional Approach   | PPAP  |
|-------|--|---|
| 1     | No process to ensure understanding of customer requirements.                                   | Provides understanding of information about product that to be developed.                                     |
| 2     | No structured way to communicate the development of product between manufacturer and customer. | Predetermined methods to obtain approval of product/product and changes.                                      |
| 3     | There were no prescribed design records and formats that to be maintained.                     | Ensures part submissions are submitted with proper information and enough data to sustain product conformance |
| 4     | Change controls were not documented.   | Controls product and process change and documented.   |

# DEFINITION

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# Definitions

- **Marked print** is an engineering drawing modified, signed and dated by the customer engineer (the engineering change number must be included)
- **Checked print** is a released engineering drawing with actual measurement results recorded by the organization adjacent to each drawing dimension and other requirements.
- **Design record** is the part drawing, specifications and/or electronic (CAD) data used to convey information necessary to produce a product.

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# Definitions

- **Bulk material** is a substance such as adhesives, sealants, chemicals, coatings, fabrics, lubricants, etc. A bulk material may become production material if issued a customer production part number.
- **Production material** is material which has been issued a production part number by the customer and is shipped directly to the customer.
- **Appearance item** is a product that is visible once the vehicle is completed. Certain customers will identify appearance items on the engineering drawings. In these cases, special approval for appearance (colour, grain, texture, etc.) is required prior to production part submission.

# Definitions

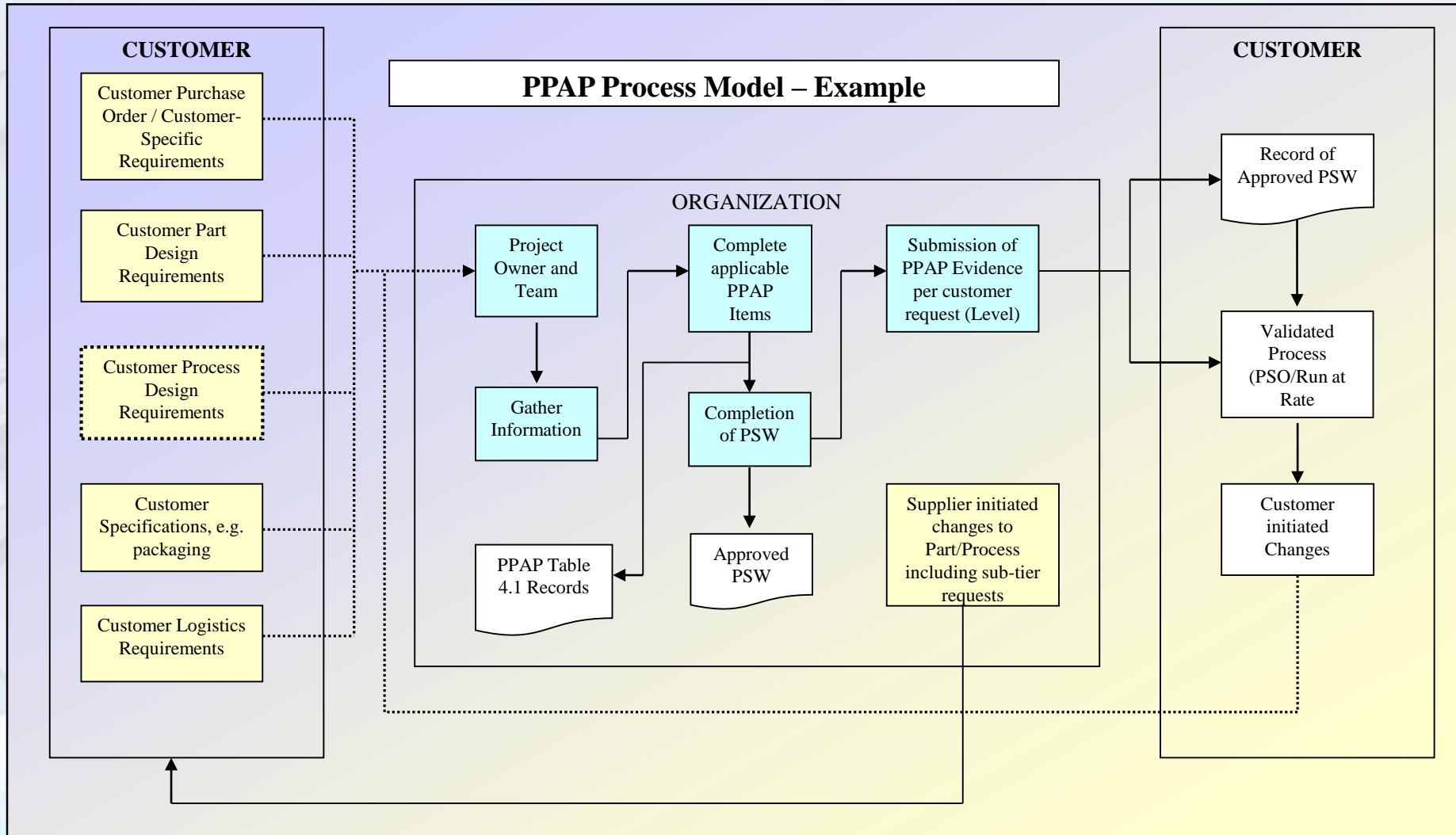
- **Percent Inspection points that Satisfy Tolerance (PIST):**  
Percent of Inspection Points that Satisfy the Tolerances indicated on the design drawing
- **Percent Indices which are Process Capable (PIPC):**  
Percent of Inspection points (Critical/Significant Characteristics) that are Process Capable with Cpk indexes greater than or equal to 1.33 for the production phase

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# PPAP IN A QMS

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# PPAP Aligned With Automotive Process Approach



# As a Part of the Quality Management System

## IATF 16949:2016, clause 8.3.4.4 states

*“The organization shall establish, implement and maintain a product and manufacturing approval process conforming to requirements defined by the customer(s).*

*The organization shall approve externally provided products and services...prior to submission of their part approval to the customer.”*

- PPAP is a COP (Customer Oriented Process)
- PPAP can be modified by Customer Specific Requirements

# Document and Forms Issues

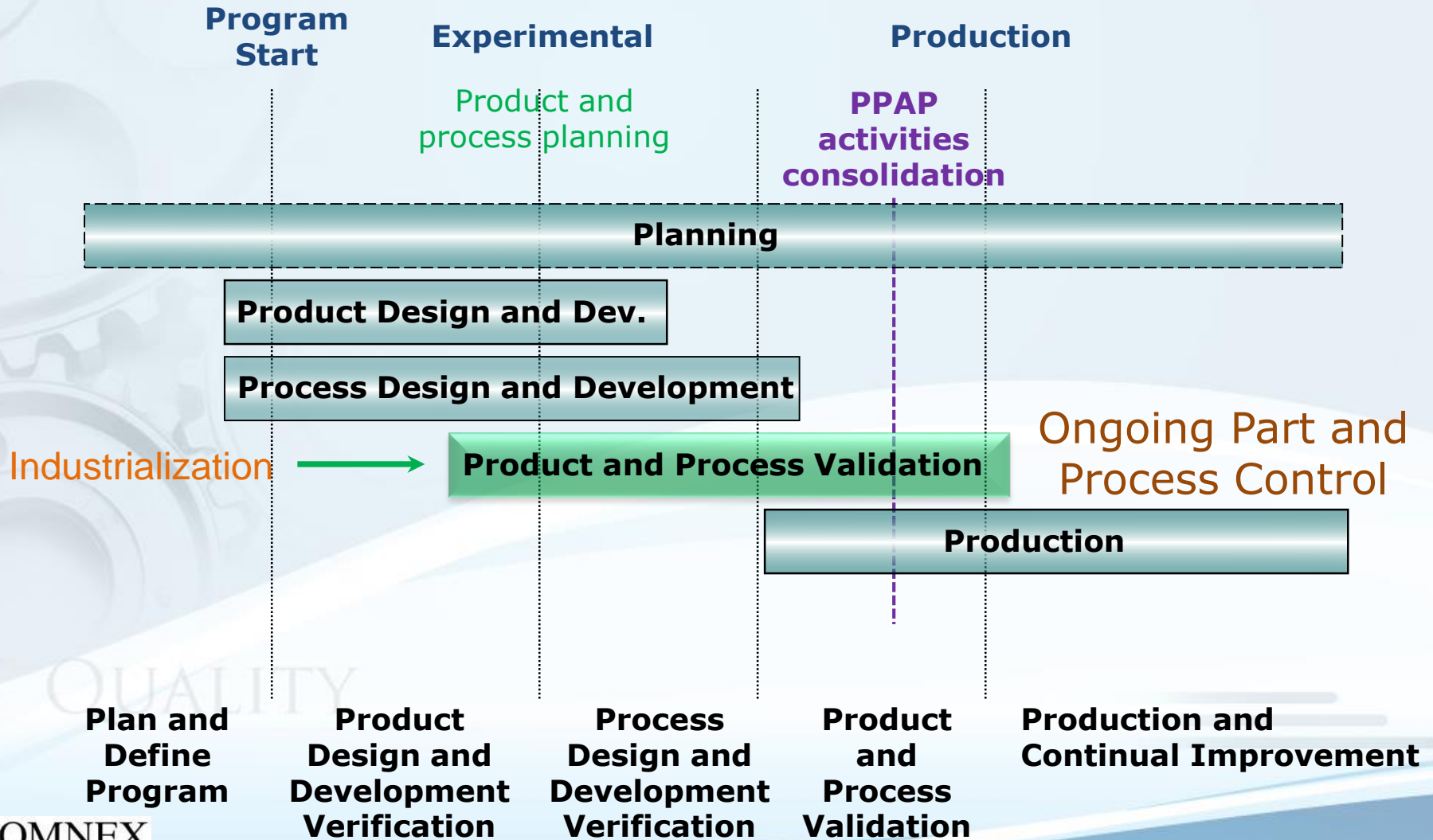
- All forms referenced in the PPAP document may be replaced by computer-generated exact facsimiles.
- Facsimiles must be approved by the authorized customer representative prior to first submission.
- Retention and submission requirements for various levels are in table 4.2, found on page 18 of the PPAP manual.

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# APQP Phases and PPAP



# MANAGING CHANGES AND SUBMISSIONS

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# Change Management

- Organizations shall obtain approval from the authorized customer representative for:
  - **ANY CHANGE!**
  - OEMs have stated there is essentially no reason to **NOT** notify your authorized customer representative, no matter how trivial or subtle the anticipated change.
  - This includes direct material product and production process changes including sub-tier suppliers.

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# Customer Notification and Submission Requirements

- The organization must notify the authorized customer representative of any planned changes to the design or production process supplier or sub-supplier sites.
- This notification must be made ***prior to implementation of the proposed change.***
- After notification and approval of the proposed change and the implementation of the change, PPAP is required unless formally waived (documented) by the authorized customer representative.

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# Customer Notification and Submission Requirements

- Some examples:
  - Different construction or material
  - New or modified tools, dies, molds (including additional or replacement tools, but not perishable tools)
  - Refurbishment or rearrangement of tools / equipment
  - Different plant or location
  - Supplier changes:
    - Parts/services
    - Non-equivalent materials
    - Ownership
  - Tooling has been inactive for 12 months or more
  - Changes to components
  - Change in test/inspection method

# When Submission is Always Required

- A new part or product
- Correction of a previously submitted part
- Product modified by an engineering change to design records, specifications, or materials
- New process technology for Bulk Materials

Unless waived in writing by authorized customer representative

# When Submission is Waived

- If the authorized customer representative waives a formal submission:
  - All applicable items in PPAP file must still be reviewed and updated as necessary.
  - PPAP file must contain the name of the authorized customer representative granting the waiver and the date.
  - Customer notification is required for any change.

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# Regardless of Submission or Not

- PPAP files shall contain evidence of completion of all applicable items from PPAP Table 4.2 Retention / Submission Requirements. *(see next slide)*
- At a minimum, PPAP records shall be maintained for the length of time that the part is active plus one calendar year.
  - Active includes production and service; see PPAP 4<sup>th</sup> Edition Glossary for more on “*active part*”.
- If the customer waives submission, the date and name of the grantor must be in the file.

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# Retention/Submission Requirements Table 4.2

| <u>Requirement</u>                                     | <u>Submission Level</u> |                |                |                |                |
|--|-------------------------|----------------|----------------|----------------|----------------|
|  | <u>Level 1</u>          | <u>Level 2</u> | <u>Level 3</u> | <u>Level 4</u> | <u>Level 5</u> |
| 1. Design Record                                       | R                       | S              | S              | *              | R              |
| - for proprietary components/details                   | R                       | R              | R              | *              | R              |
| - for all other components/details                     | 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   | R                       | R              | S              | *              | R              |
| 5. Process Flow Diagrams                               | R                       | R              | S              | *              | R              |
| 6. Process FMEA  | R                       | R              | S              | *              | R              |
| 7. Control Plan  | R                       | R              | S              | *              | R              |
| 8. Measurement System Analysis Studies                 | R                       | R              | S              | *              | R              |
| 9. Dimensional Results                                 | R                       | S              | S              | *              | R              |
| 10. Material, Performance Test Results                 | R                       | S              | S              | *              | R              |
| 11. Initial Process Studies                            | R                       | R              | S              | *              | R              |
| 12. Qualified Laboratory Documentation                 | R                       | S              | S              | *              | R              |
| 13. Appearance Approval Report (AAR),<br>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                              | R                       | R              | S              | *              | R              |
| With Customer-Specific Requirements                    |                         |                |                |                |                |
| 18. Part Submission Warrant (PSW)                      | S                       | S              | S              | S              | R              |
| Bulk Material Checklist (see 4.1 above)                | S                       | S              | S              | S              | R              |

(Normative)

*[NOTE: Table 4.2 lists submission and retention requirements. Mandatory and applicable requirements for a PPAP record are defined in the PPAP manual and by the customer.]*

# SUBMISSION LEVELS

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# Submission Levels

- The customer will identify submission level based on the following criteria:
  - Organization compliance to IATF 16949 requirements
  - Supplier quality recognition status
  - Part criticality
  - Customer's experience with prior submissions
  - Organization's expertise with the specific commodity

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# Submission Levels

- There are five (5) Submission Levels
  - **Level 1** – Warrant only
  - **Level 2** – Warrant, product samples, limited data
  - **Level 3** – **Warrant, product samples, complete data submitted\***
  - **Level 4** – Warrant, other requirements as defined by the customer
  - **Level 5** – Warrant, product samples, complete data reviewed at organization's manufacturing location

**\*Level 3 is Default Level for Part & Product Suppliers**

# Submission Levels

## For FCA:

- Organizations providing parts to Assembly plants shall follow guidelines for submission level 4.
- Organizations providing parts to component or powertrain plants shall follow guidelines for submission level 2.

## For Ford:

- Organizations shall submit PPAP per Ford's Phased PPAP.

## For GM:

- No Customer-Specific Requirement for this item.

***Always Verify Current CSRs;  
for 1<sup>st</sup> Tier Suppliers as well as OEMs***

# RECORD RETENTION

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# Record Retention

- The organization is required to complete and retain copies of all documentation identified in the “*Retention/Submission Requirements Table 4.2*” section of PPAP regardless of submission level for each submission.
- The organization shall ensure that PPAP records from a superseded part PPAP file are included or referenced in the new part PPAP file.
- These records shall be readily available for internal use, customer use and auditors.

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# Record Retention

- Records shall be maintained for the length of time the part is active, plus one year.
- **Active parts** are those currently being supplied to the customer for original equipment or service applications.
  - Part is active until tooling scrap authorization is given by the customer or until written confirmation from Customer Purchasing activity deactivates the part.

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# SIGNIFICANT PRODUCTION RUN

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# Significant Production Run

- Product for PPAP must be produced in a significant production run:
  - One (1) to eight (8) hours of production
  - Minimum 300 consecutive parts (unless otherwise agreed by Customer Representative)
  - At production site, at production rate, using production tooling, gaging, process, materials, and operators
  - Representative parts from each unique flow: lines, cells, cavities, molds, tools, patterns must be measured and tested

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# Significant Production Run

- Related Activities and Outputs
  - PPAP Submission Documents
  - Measurement Systems Evaluation
    - Qualify systems prior to use for PPAP
  - Preliminary Process Capability Studies
    - At initial production run or trended across stable, sequential runs
  - Production Part Layout and Dimensional Report (in PPAP Report)
  - Production Validation Testing (derived from the DVP)
  - Final Feasibility Analysis
    - Assessment of initial production run
  - Process Review (Process Flow Diagram and PFMEA)
  - Production Control Plan Established
  - **Process Readiness Assessment (optional)**

# Chapter 2: PPAP Introduction – What We Covered

## Learning Objectives

You should now be able to:

- Understand the concept of PPAP
- Understand the difference between PPAP and Traditional Product development approach
- Describe how PPAP fits in a quality management system
- Identify the type of changes that must be reported to the customer
- Identify when and how submissions to the customer are conducted
- List the submissions levels for PPAP
- Describe the key elements of a significant production run

## Chapter Agenda

- Concept of PPAP
- Evolution of PPAP
- PPAP in a QMS
- Comparison of PPAP with traditional product development approach
- Managing Changes and Submissions
- Submission Levels
- Record Retention
- Significant Production Run



# Chapter 3

## PPAP Submission Elements

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# Chapter 3: PPAP Submission Elements – What We Will Cover

## Learning Objectives

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

- Describe Product Design Elements
- PIST
- Describe Manufacturing Process Elements
- PIPC
- Describe General Elements
- Describe Part Submission Warrant and Status

## Chapter Agenda

- Requirements and Deliverables
  - **Breakout Exercise 1**
- Product Design Elements
- Determining PIST
- Manufacturing Process Elements
- Determining PIPC
- General Elements
- Part Submission Warrant and Status

# REQUIREMENTS AND DELIVERABLES

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# PPAP Process Requirements

- The organization shall meet **ALL** requirements on the design record and specifications.
- Any results that are outside specification are cause for the organization NOT to submit the PPAP.
  - Make every effort to correct **ALL** nonconformances.
  - Customer must be contacted if organization is unable to meet all requirements to determine appropriate corrective actions.
  - Blanket statements of conformance are unacceptable for inspection and test results.

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# PPAP Deliverables

## Evidence To Prove Requirements Are Met

### Product Definition

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

### PPAP Core Elements

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

### PPAP Core Elements

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

### PPAP Approval

- 19 PPAP Review and Sign-Off

# GENERAL CONSISTENCY REVIEW

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# Getting Started

- Before getting into the details of the individual documents / sections, it is recommended to review the consistency of the submission as a whole.
  - Identify the change (revision) level and dates of the documents to verify they are all the same.
  - Are all the material certs and lab test submitted?
  - Are all the dimensional tolerances consistent: print to analysis to report?

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**Overall** section of the PPAP checklist

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# PART SUBMISSION WARRANT AND STATUS

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## 2.2.18 Part Submission Warrant

- After satisfactory completion of all applicable PPAP requirements, the organization shall complete the information required on the Part Submission Warrant (PSW).
- A separate PSW shall be completed for each customer part number.
- **Part Weight** – Average of 10 measured parts to four decimal places (0.0000) in kilograms, unless otherwise specified by the customer.

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- Complete and verify part information, consistent with documents contained in submission
- Complete all boxes and fields
- Prepare a separate PSW for each part number
- Declaration must be signed by an authorized representative of organization's management

**FCA**   **Part Submission Warrant**

FIAT CHRYSLER AUTOMOBILES

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Part Name \_\_\_\_\_ Cust. Part Number \_\_\_\_\_ **1**

Shown on Drawing No. \_\_\_\_\_ 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 No. \_\_\_\_\_ Checking Aid Engineering Change Level \_\_\_\_\_ **2** Dated \_\_\_\_\_

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

Organization Name & Supplier/Vendor Code \_\_\_\_\_ **3** 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  n/a

Submitted by IMDS or other customer format: \_\_\_\_\_ **5**

Are polymeric parts identified with appropriate ISO marking codes?  Yes  No  n/a **6**

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

|   |  |
|---|--|
| <input type="checkbox"/> Initial Submission   | <input type="checkbox"/> Change to Optional Construction or Material |
| <input type="checkbox"/> Engineering Change(s)  | <input type="checkbox"/> Supplier or Material Source Change          |
| <input type="checkbox"/> Tooling: Transfer, Replacement, Refurbishment, or additional | <input type="checkbox"/> Change in Part Processing                   |
| <input type="checkbox"/> Correction of Discrepancy                                    | <input type="checkbox"/> Parts Produced at Additional Location       |
| <input type="checkbox"/> Tooling Inactive > than 1 year                               | <input type="checkbox"/> Other – please specify below _____ <b>7</b> |

**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 and other requirements as defined by customer.

Level 5 – Warrant with product samples and complete supporting data reviewed 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 \_\_\_\_\_ **8**

**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 review. I have noted any deviations from this declaration below.

EXPLANATION/COMMENTS: \_\_\_\_\_

Is each Customer Tool properly tagged and numbered?  Yes  No  n/a **9**

Organization Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Name \_\_\_\_\_ Phone No. \_\_\_\_\_ **10** FAX No. \_\_\_\_\_

Title \_\_\_\_\_ E-mail \_\_\_\_\_

**FOR CUSTOMER USE ONLY (IF APPLICABLE)**

PPAP Warrant Disposition:  Approved  Rejected  Other \_\_\_\_\_ **11**

Customer Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Name \_\_\_\_\_ Customer Tracking Number (optional) \_\_\_\_\_ **12**



# Data Requirements in PSW

1. Customer part number and organization part number
2. Checking aid engineering change level
3. Vendor code
4. International address format
5. IMDS applicability
6. Submission reason – “Other” explanation space provided
7. Submission results
8. Declaration Statement (from the process, affirm, production rate of \_\_\_/\_\_\_ hours, noted deviations)
9. Customer tooling identification (as applicable)
10. E-mail on signature block
11. Warrant disposition: Approved/Rejected/Other
12. Customer tracking number (optional)



# Parts Submission Warrant

- Production parts from more than one cavity, mold, tool, die pattern or production process, line or cell shall have a complete dimensional evaluation (see **2.2.9**).
- The specific cavities, molds etc. shall be identified on the PSW or in a PSW attachment and noted on the warrant in the **Mold/Cavity/Production Process** line.
- If a part is produced by multiple cavity molds, tools, dies and patterns, then a complete dimensional evaluation is required for each cavity, tool, etc.

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# Parts Submission Warrant

- The organization-authorized official shall sign the warrant and include date, title and phone number.
- PSWs may be submitted electronically.
- More than one change can be included on a single warrant.

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# Part Submission Status

- Organizations will be notified by customer of PPAP submission status.
- For “self-certifying” suppliers, submission of required documentation is considered as approved unless determined otherwise by the customer.
- Parts or product for use in normal processing at customer must never be shipped without customer approval of PPAP.

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# Part Submission Status

## (Submission Status Definitions)

- **Approved:** Parts meet all customer specifications and requirements. Organization is authorized to ship production quantities subject to releases from customer scheduling activity.
- **Interim Approval:** Permits shipment on a limited time or quantity basis. Interim approval is only granted when the organization has:
  - Clearly defined the non-compliances preventing approval, and
  - Prepared an action plan agreed upon by the customer.  
(Resubmission is required to obtain a status of Approved)
- **Rejected:** The submission of the production lot from which it was taken, and accompanying documentation, does not meet customer requirements.
  - No production quantities shall be shipped.
  - The Organization must correct the production process.
  - Customer's Purchasing activity must be advised of date for corrected parts.
  - Corrected product and documentation shall be submitted and approved.





# Part Submission Warrant

Part Name Washer Assy - LHM CLUTCH MACHINED COMPLETE Cust. Part Number P202115-2816  
 Shows on Drawing Number P202115-2816 Orig. Part Number \_\_\_\_\_  
 Engineering Change Level R Dated 16-May-13  
 Additional Engineering Changes \_\_\_\_\_ Dated \_\_\_\_\_  
 Safety and/or Government Regulation  Yes  No Purchase Order No. 20359 Weight (kg) 1.2070  
 Checking Aid Number \_\_\_\_\_ Checking Aid Eng. Change Level \_\_\_\_\_ Dated \_\_\_\_\_

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

City \_\_\_\_\_ Region \_\_\_\_\_ Postal Code \_\_\_\_\_ Country \_\_\_\_\_  
 MSN \_\_\_\_\_  
 Customer Name/Division \_\_\_\_\_  
 Super/layer Code \_\_\_\_\_  
 Transmission \_\_\_\_\_  
 Application \_\_\_\_\_

**MATERIALS REPORTING**

Has customer-required Substances of Concern information been reported?  Yes  No  
 Submitted by MDS or other customer format INDSN 1175188111

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 and other requirements as defined by customer.  
 Level 5 - Warrant with product samples and complete supporting data reviewed 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 New Revision Level - Hub seal groove notch implementation

**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 site of 10 pcs/1 hour. I also certify that documented evidence of such compliance is on file and available for your review. I have noted any deviations from this declaration below.

**EXPLANATION/COMMENTS:** AS PER CN # 062TE-TRN-NV.

Is each Customer Tool properly tagged and numbered?  Yes  No  N/A

Organization Authorized Signature [Signature] Date 30-Aug-13  
 Print Name \_\_\_\_\_ 805-542-9739  
 Title Qual

**FOR CUSTOMER USE ONLY (IF APPLICABLE)**

PPAP Warrant Disposition:  Approved  Rejected  Other Interim approval pending PER mem @ KIP  
 Customer Signature [Signature] Date Aug 9, 2013  
 Print Name MANISH SABHARWAL Customer Tracking Number (optional) CN # 062TE-TRN-NV.

Sample PSW:  
Interim Approval

# Assessing Part Submission Warrant

## 18) PSW

### Things to consider:

- a) Does part number and drawing revision number match with the drawing?
- b) Are all fields of the PSW filled out correctly? Information not applicable to any specific part must be identified as “N/A”.
- c) Is any exception to manufacturing process or PPAP run noted on the PSW?
- d) Is an action plan included to address any exception to drawing and process requirements?
- e) Is the IMDS number included, showing the latest revision submitted to the Material Data System with plant specific ID number?
- f) Does PSW specify molds / cavities / production processes pertaining to the PPAP?
- g) Has supplier noted production rate on PSW at which the PPAP samples were produced during significant production run?

# Assessing Part Submission Warrant

## 18) PSW

### Things to consider:

- h) Are checking aids used in everyday processing of a part identified on the PSW?
- i) Is the reason for submission clearly identified and confirmed?
- j) Does the PPAP level confirm to as required by Purchase Order?
- k) Is part weight expressed in kilograms to four significant decimal places (0.0000) using the average from three parts?

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# Breakout Exercise 1

Complete the PSW

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# Breakout Exercise 1: Complete the PSW

## Handouts

- Drawing of ABC company

## Instructions

- Read the Handout carefully
- Use the recommended format or the Excel workbook provided by the instructor.
- Be prepared to present your team's

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## 2.2.1.1 Reporting of Part Material Composition

- The organization shall provide evidence that the Material / Substance Composition is reported (data) as specified by the customer.
  - *Note: Follow IMDS (International Material Data System) or other customer-specific requirements.*
  - See <http://www.mdsystem.com/index.jsp>
    - Use “*Global Automotive Declarable Substance List*”
    - Added to the new PSW form

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## 2.2.1.2 Marking of Polymeric Parts

- Where applicable, the organization shall identify polymeric parts with the ISO symbols.
- Generic identification and marking of plastic and rubber.
- Information entered on Part Submission Warrant.

**Refer to ISO 11469 and ISO 1629 for specific material and part weight**

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# Material Composition

## MDS Report

### Substances of assemblies and materials

**Materials which are subject to legal prohibitions must not be included!**  
**Dangerous substances formed or released during use must also be declared**  
**Please note: GADSL list for substances that require declaration**

### 3. Characterization of the Component

Part/Item No.: **12627211**  
 Article Name: **LGE PUMP ASM-OIL**

Report No.: -  
 IMDS ID / Version: **159207970 / 1**  
 Node ID: **159207970**

| Tree Level | Article Name<br>Article Name<br>Name<br>Substance name | Part/Item No.<br>Item- /Mat.-No.<br>Material-No.<br>CA S No. | IMDS ID / Version | Quantity | Weight<br>[g] | Portion<br>[%] | Portion<br>(from - to)<br>[%] | Classif.<br>GADSL,<br>SVHC | Parts Marking<br>Recyclate<br>(Indust./Consumer)<br>Application |
|------------|--|--|-------------------|----------|---------------|----------------|-------------------------------|----------------------------|---|
| 1          | LGE PUMP ASM-OIL                                       | 12627211   | 159207970 / 1     |          | 1187          |                |                               |                            |   |
| └2         | COVER-O/PMP (MCHG)                                     | 12627019   | 158447824 / 1     | 1        | 300           |                |                               |                            |   |
| └3         | ADC14  | ADC14  | (not available)   |          | 300           |                |                               | 2.1                        | No  |
| └4         | Aluminium (metal)                                      | 7429-90-5  |                   |          |               | 74.15          |                               |                            |   |
| └4         | Copper   | 7440-50-8  |                   |          |               | 4.5            | 4 - 5                         | D                          |   |
| └4         | Silicon  | 7440-21-3  |                   |          |               | 17             | 16 - 18                       |                            |   |

Hewlett-Packard GmbH

**Partial Example**

# Q100 Certification of Design, Construction and Qualification

## Automotive Electronics Council Component Technical Committee

|  |  |
|--|--|
| 11. Die Metallization:<br>a. Die metallization material(s):<br>b. Number of layers:<br>c. Thickness (per layer):<br>d. % of alloys (if present): | Ti/AICu/TiNARC- Ti/TiN/TiAICu/TinArc-Ti/AICu/TiNARC<br>3<br>M1 0.286um, M2 0.459um, M3 0.695 um                            |
| 12. Die Passivation:<br>a. Number of passivation layers:<br>b. Die passivation material(s):<br>c. Thickness(es) & tolerances:                    | 2<br>USG+NitUV (HFP USG+UV Nitride)  |
| 13. Die Overcoat Material (e.g., Polyimide):   | No   |
| 14. Die Cross-Section Photo/Drawing:   | See attached <input type="checkbox"/> Not available <input checked="" type="checkbox"/>                                    |
| 15. Die Prep Backside:<br>a. Die prep method:<br>b. Die metallization:<br>c. Thickness(es) & tolerances:   | LAPPED SILICON   |
| 16. Die Separation Method:<br>a. Kerf width ( $\mu\text{m}$ ):<br>b. Kerf depth (if not 100% saw):<br>c. Saw method:                             | 100% sawing<br><br>Single <input checked="" type="checkbox"/> Dual <input type="checkbox"/>                                |
| 17. Die Attach:<br>a. Die attach material ID:<br>b. Die attach method:<br>c. Die placement diagram:  | HITACHI DBP free EN4900<br>GLUE<br>See attached <input checked="" type="checkbox"/> Not available <input type="checkbox"/> |
| 18. Package:<br>a. Type of package (e.g., plastic, ceramic, unpackaged):   | plasticTFBGA   |

Partial Example

# Assessing IMDS Submittal and Approval

## Things to consider:

- a) Has supplier submitted IMDS data to the specific (receiving) plant ID number?
- b) Are part number and drawing numbers matching the part number as shown in Purchase Order and drawing number?
- c) Does weight and basic material composition match engineering drawing requirements?
- d) Does data submitted comply to Material Data System / ELV Directive requirements?
- e) Where applicable, are all polymeric parts identified with the appropriate ISO symbols and in the PSW?

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**PSW** section of the PPAP checklist

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# PRODUCT DESIGN ELEMENTS

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## 2.2.1 Design Records

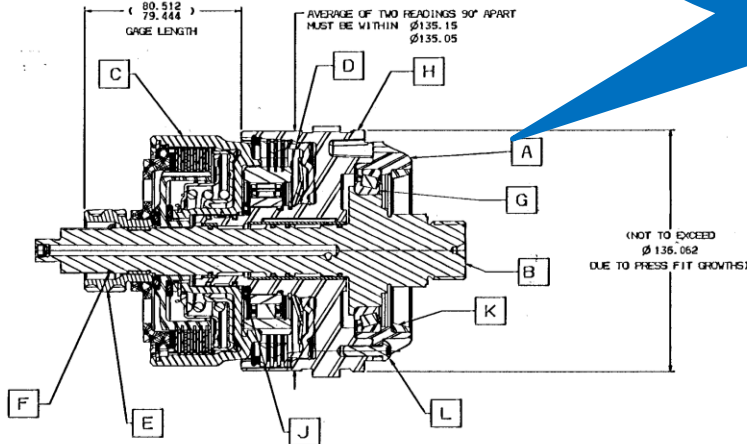
- The organization shall have all design records for saleable product, including components or details.
- If the record is in electronic form, a hard copy (“ballooned” print recommended) shall be made to identify measurements taken.
- There will only be one design record for any saleable part, component or product – it may refer to other documents, making them part of the design record.

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# Ballooned Characteristics



CONTROLLED DOCUMENT

LATEST ENGINEERING CHANGE LEVEL  
 DATE RECEIVED August 27, 2013  
 DATE APPROVED Aug. 16, 2013

Ensure that all items are ballooned. Materials, notes, tests

| CODE | PART NO. | PART NAME                              | NO. REQ'D |
|------|----------|--|-----------|
| (D)  | A        | RETAINER TRANS TRANSFER GEAR BEARING   | 1         |
| B    | B        | SHAFT ASSY - TRANSFER GEAR TO ANNULUS  | 1         |
| C    | C        | RETAINER ASSY - DIRECT CLUTCH          | 1         |
| (E)  | D        | CLUTCH ASSY - TRANSMISSION OVERRUNNING | 1         |
| F    | E        | GEAR SUN MACHINED                      | 1         |
| F    | F        | SNIP RING - EXTERNAL                   | 1         |
| G    | G        | CONE-BEARING TAPERED ROLLER            | 1         |
| H    | H        | RETAINER ASSY - LOW CLUTCH             | 1         |
| (F)  | J        | BEARING ASSY - DIRECT CLUTCH RETAINER  | 1         |
| K    | K        | CUP - BEARING TAPERED ROLLER           | 2         |
| L    | L        | SC/PAW HD - HEADER.P16 - LOBE.REC      | 8         |

|     |     |      |    |      |       |
|-----|-----|------|----|------|-------|
| AGE | REV | DATE | BY | CHKD | APP'D |
| -   | -   | -    | A  | -    | -     |

SEE PIP / CONSOLE PAGE FOR DIMENSIONAL DIMENSIONS REVISION HISTORY COMPLETE MODEL INFORMATION THIS IS A 3D DATA ORIENTED PART. THE DATA IDENTIFICATION DATA IS THE MASTER FOR THIS PART. FOR ADDITIONAL INFORMATION NOT SHOWN ON THIS DRAWING ANALYZE THE DATA MODEL.

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN (MM) TOLERANCES: LENGTH: ±0.25 ANGLE: ±0.5°

3D MODEL PRODUCTION UNLESS OTHERWISE SPECIFIED BY VIEW OR DIRECTION ARROW

VIEW: UNDERDRIVE ASSY - CASE TRANS

SCALE: FULL

DATE: 6/21/12

FILE: 621E (CATIA V5) D



# Assessing Design Record

## 1) Design Record

### Things to consider:

- a) Has the latest drawing released by the organization been included in PPAP package as is required?
  - Is this consistent with the customer's released drawing (if applicable)?
- b) Have all dimensions as well as any material specifications and drawing notes been ballooned / numbered as is required?  
Where a single callout references more than one feature, are the individual features ballooned?
- c) Note the engineering level of the drawing. We will use this to check against all other submission documents to ensure they have been updated.

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

## 1) **Design Record** section of the PPAP checklist

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## 2.2.2 Authorized Engineering Change Documents

- The organization shall have any authorized engineering change documents not yet recorded in the design record but incorporated in the part, product or tooling.

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# Assessing Engineering Change Documents

## 2) Engineering Change Documents (if PPAP is being submitted due to any type of change)

### Things to consider:

- a) Is a change request included for approval of any exceptions in meeting drawing or production process (this includes any exception to equipment, tooling, process, material, gauging, packaging)?
- b) Is an Engineering Change Document included, detailing the changes not yet recorded in the design record but already incorporated in the part, product or tooling at the time of PPAP submission?

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

## 2) **Engineering Change Documents** section of the PPAP checklist

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## 2.2.3 Customer Engineering Approval

- Where specified by the customer, the organization shall have evidence of customer engineering approval.

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# Assessing Engineering Review and Approval

## 3) Customer Engineering Approval

### Things to consider:

- a) Is the supplier responsible for design, product validation and testing (as notified in Purchase Order)?
- b) Has the supplier included evidence of customer engineering approval? (Ford SREA, GM3660, FCA Forever Requirement, DVP&R, etc.)
- c) Has engineering reviewed and approved relevant design and product validation and testing documents? (dimensional results, testing results and capability results) (Must be Yes for PPAP approval)

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

## **3) Customer Engineering Approval** section of the PPAP checklist

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## 2.2.4 DFMEA

- Design Failure Mode & Effects Analysis shall be developed in accordance with, and compliant to, Customer-Specific Requirements.
- When design-responsible:
  - Use – Ford, GM, FCA, *Potential Failure Modes & Effect Analysis, 4<sup>th</sup> Edition Reference Manual*, AIAG as a guideline for development
  - *Note: DFMEA may be applied to a family of similar parts or materials.*

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# Sample Form

\_\_\_\_\_ System  
 \_\_\_\_\_ Subsystem  
 \_\_\_\_\_ Component: **B**  
 \_\_\_\_\_ Model Year(s)/Program(s) **D**  
 \_\_\_\_\_ Core Team **G**

**POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (DESIGN FMEA)**  
 Design Responsibility **C**  
 Key Date **E**

FMEA Number **A**  
 Page \_\_\_\_\_ of \_\_\_\_\_  
 Prepared By: **H**  
 FMEA Date (Orig.) **F**

| Item                        | Function                               | Requirements                                   | Potential Failure Mode                                      | Potential Effect(s) of Failure  | Severity | Classification | Potential Cause(s) of Failure   | Current Design Controls Prevention                       | Occurrence | Controls Detection   | Detection | RPN | Recommended Action   | Responsibility                             | Target Completion Date | Action Results   |                |          |            |       |       |
|-----------------------------|--|--|---|---|----------|----------------|---|--|------------|--|-----------|-----|--|--|------------------------|--|----------------|----------|------------|-------|-------|
|                             |  |  |   |   |          |                |   |  |            |  |           |     |  |  |                        | Actions Taken  | Effective Date | Severity | Occurrence | RPN   |       |
| Front Door L.H. H8HX-0000-A | Maintain integrity of inner door panel | Prevent environment access to inner door panel | Integrity breach allows environ. access of inner door panel | Corroded interior lower door panels<br>Deteriorated life of door leading to:<br>• Unsatisfactory appearance due to rust through paint over time.<br>• Impaired function of interior door hardware | 5        |                | Upper edge of protective wax application specified for inner door panels is too low | Design requirements (#31268) and best practice (BP 3455) | 3          | Vehicle durability test. T-118 (7)   | 7         | 105 | Laboratory accelerated corrosion test                              | A. Tate<br>Body Engineer                   | 0X 09 03               | Based on test results (test no 1481) edge spec raised to 125                     | 0X 09 30       | 5        | 2          | 3     | 30    |
|                             |  |  |   |   |          |                | Insufficient wax thickness specified  | Design requirements (#31268) and best practice (BP 3455) | 3          | Vehicle durability test. T-118 (7)   | 7         | 105 | Laboratory accelerated corrosion test                              | A. Tate<br>Body Engineer                   | 0X 09 30               | Test results (No. 1481) show spec thickness is adequate.                         | 0X 09 30       | 5        | 2          | 4     | 40    |
|                             |  |  |   |   |          |                |   |  |            |  |           |     | Design of Experiments (DOE) on Wax Thickness                       | J. Smythe<br>Body Engineer                 | 0X 10 18               | DOE shows 25% variation in specified thickness is acceptable                     | 0X 10 25       | 5        | 2          | 3     | 30    |
|                             |  |  |   |   |          |                | Inappropriate wax formulation specified   | Industry standard MS-1893                                | 2          | Physical and Chemical Lab test - Report No. 1265 (5)<br>Vehicle durability test. T-118 (7) | 5         | 50  | None   |  |                        |  |                |          |            |       |       |
|                             |  |  |   |   |          |                | Corner design prevents spray equip from reaching all areas                          |  | 5          | Design aid with non-functioning spray head (8)<br>Vehicle durability test. T-118 (7)       | 7         | 175 | Team evaluation using production spray equipment and specified wax | T. Edward<br>Body Engineer and<br>Assy Ops | 0X 11 15               | Based on test 3 additional vent holes provided in affected areas (error-proofed) | 0X 12 15       | 5        | 1          | 1     | 5     |
|                             |  |  |   |   |          |                | Insufficient room between panels for spray head access                              |  | 4          | Drawing evaluation of spray head access (4)<br>Vehicle durability test. T-118 (7)          | 4         | 80  | Team evaluation using design aid buck and spray head               | T. Edward<br>Body Engineer and<br>Assy Ops | 0X 11 15               | Evaluation showed adequate access  | 0X 12 15       | 5        | 2          | 4     | 40    |
| a1                          | a2                                     | a3   | b   | c   | d        | e              | f   | g  | h          | i  | j         | k   | ----- l  | -----                                      | -----                  | m  | -----          | n        | -----      | ----- | ----- |

Generic Example



# Assessing Design FMEA

## 4) Design FMEA (if Supplier is Design Responsible)

### Things to consider:

- a) Is the supplier responsible for design (as notified in nomination letter/PO)?
- b) Has supplier defined the scope of the analysis? (e.g., using a boundary diagram)
- c) Is there a DFMEA for every component? (may be referenced)
- d) Does DFMEA list failure modes in physical, technical and measurable terms?
- e) Does effects of failures listed in DFMEA address the impact on each part, next higher assembly, system, vehicle, customer wants and government regulations?

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# Assessing Design FMEA

## 4) Design FMEA (if Supplier is Design Responsible)

### Things to consider:

- f) Does DFMEA identify potential design causes for all failure modes?
- g) Are the controls related causes or failure modes, and part of the design process activities?
- h) Are corrective actions, responsibilities and completion dates assigned to high severity numbers (8 and over) and high risk priority numbers?
- i) Does DFMEA identify potential special product functionality which will lead to special characteristics (e.g. critical, key, significant, etc.)?
- j) In case of no recommended actions, does DFMEA state “None” in the **Recommended Actions** column?

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

## 4) **Design FMEA** section of the PPAP checklist

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# MANUFACTURING PROCESS ELEMENTS

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## 2.2.5 Process Flow Diagrams

- Process Flow Diagrams or descriptions shall clearly describe the production process steps and sequence and meet the specified customer requirements.
- May use your organization-specified format.
  - e.g. See the Ford, GM, FCA – *APQP & Control Plan Reference Manual 2<sup>nd</sup> Edition Reference Manual*, AIAG

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# Manufacturing Process Flow Example

| Step |                            | Experienced Sources of Variations                                      | Process Flow Diagram | Function | Requirement |         |         |    |
|------|----------------------------|--|----------------------|----------|-------------|---------|---------|----|
| Num  | Description                |  |                      |          | ID.         | Product | Process | SC |
| 00   | Supplier                   |  |                      |          |             |         |         |    |
| 05   | Receive Hot Bars           | delivery timing variation  |                      |          |             |         |         |    |
| 10A  | store bars inside          | storage time; rack protection; humidity                                |                      |          |             |         |         |    |
| 10B  | store bars outside         | storage time; humidity   |                      |          |             |         |         |    |
| 20   | Screw Machine              | machine capability; operator training; tool variation; setup variation |                      |          |             |         |         |    |
| 30   | Wash                       | Variation in solution; solution life                                   |                      |          |             |         |         |    |
| 35   | Inspect -- inside diameter | operator skill; gaging   |                      |          |             |         |         |    |
| 40   | Grind - outside diameter   | tool wear variation; setup variation                                   |                      |          |             |         |         |    |
|      |                            |  |                      |          |             |         |         |    |
|      |                            |  |                      |          |             |         |         |    |

**Example  
No Specified  
Format is  
Required**

However, "a process flow diagram describes the flow of the product through the process – from incoming to outgoing. This should include each step in a manufacturing or assembly process as well as their related outputs (product characteristics, requirements, deliverables, etc.) and inputs (process characteristics, sources of variation, etc.)".

# Best-in-Class Process Flow Diagram

| Step |                            | Experienced Sources of Variations                                      | Process Flow Diagram | Function | Requirement            |                           |         |    |
|------|----------------------------|--|----------------------|----------|------------------------|---------------------------|---------|----|
| Num  | Description                |  |                      |          | ID.                    | Product                   | Process | SC |
| 00   | Supplier                   |  |                      |          |                        |                           |         |    |
| 05   | Receive Hot Bars           | delivery time; factory location; humidity                              |                      | 05       |                        | correct decision          |         |    |
| 10B  |                            | storage time; humidity   |                      | 10B      |                        | inventory protocol        |         |    |
| 20   | Saw Machine                | machine capability; operator training; tool variation; setup variation |                      | 20       |                        | inventory protocol        |         |    |
| 30   | Wash                       |  | 30                   |          | tube inside diameter   |                           | CS      |    |
| 35   | Inspect -- inside diameter | operator   | 35                   |          |                        |                           |         |    |
| 40   | Grind - outside diameter   | tool wear variation; setup variation                                   | 40                   |          |                        |                           |         |    |
| 05   |                            |  |                      | 05       | OAL                    |                           |         |    |
| 06   |                            |  |                      | 06       | Chamfer degree         |                           |         |    |
| 07   |                            |  |                      | 07       | Chamfer length         |                           |         |    |
| 12   |                            |  |                      | 12       | Spacer inside diameter |                           | PC      |    |
| ND03 |                            |  |                      | ND03     |                        | tool replacement          |         |    |
| 14   |                            |  |                      | 14       | free of machine oil    |                           |         |    |
| ND04 |                            |  |                      | ND04     |                        | Washer Acid concentration |         |    |
| ND01 |                            |  |                      | ND01     |                        | correct decision          |         |    |
| 08   |                            |  |                      | 08       |                        |                           |         |    |
| 10   |                            |  |                      | 10       |                        |                           |         |    |
| ND05 |                            |  |                      | ND05     |                        | wheel speed               |         |    |
| ND06 |                            |  |                      | ND06     |                        | wheel feed rate           |         |    |

Operation # & Description

Sources of Variation

Process Characteristics

Product Characteristics

Flow Diagram

Best-In-Class Approach

# Assessing Process Flow Diagrams

## 5) Process Flow Diagrams

### Things to consider:

- a) Make sure PFD format is correct.
  - Does Process Flow clearly define complete sequence of production operations including: receiving, transportation, storage, subcontracted services, alternate paths (rework, repair and backup), labeling and shipping?
- b) Does Process Flow clearly identify any outsourced process with name of sub-supplier?
- c) Does Process Flow clearly include alternate paths i.e. rework, repair or back-up?

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# Assessing Process Flow Diagrams

## 5) Process Flow Diagrams

### Things to consider:

- d) Are details listed on Process Flow carried over consistently into the Control Plan and PFMEA (i.e., Part/Process Numbers and Process Name/Operations descriptions, Special Characteristic designation, etc. match on all three documents)?
- e) Does the title on Process Flow list correct part name, part number, engineering change level, document release and revision date?
- f) Does the Process Flow include all balloon features and where these features are made in the process?

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**5) Process Flow Chart** section of the PPAP checklist

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## 2.2.6 PFMEA

- Process Failure Mode & Effects Analysis shall be developed in accordance with, and compliant to, Customer-Specific Requirements.
- PFMEA is required for all manufacturing processes used to manufacture the product.
  - Use – Ford, GM, FCA, *Potential Failure Modes & Effect Analysis 4<sup>th</sup> Edition Reference Manual*, AIAG as a guideline for development.
  - *Note: PFMEA may be applied to a family of similar parts or materials.*

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# Sample Form

## POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PROCESS FMEA)

Item: B  
 Model Year(s)/Program(s) D  
 Core Team G

Process Responsibility C  
 Key Date E

FMEA Number A  
 Page \_\_\_\_\_ of \_\_\_\_\_  
 Prepared By: H  
 FMEA Date (Orig.) F

| Process Step |   | Requirements |  |         | Potential Failure Mode                           | Potential Effect(s) of Failure   | Severity | Classification | Potential Cause(s) of Failure   | Current Process Controls Prevention   | Occurrence | Current Process Controls Detection   | Detection | RPN | Recommended Action  | Responsibility      | Target Completion Date | Action Results   |                |          |            |           |     |
|--------------|---|--------------|--|---------|--|--|----------|----------------|---|---|------------|--|-----------|-----|---|---------------------|------------------------|--|----------------|----------|------------|-----------|-----|
| ID           | Description                                 | ID           | Product  | Process |  |  |          |                |   |   |            |  |           |     |   |                     |                        | Actions Taken  | Effective Date | Severity | Occurrence | Detection | RPN |
| Op 70:       | Manual application of wax inside door panel | LD 09        | Cover inner door, lower surfaces with wax to specification thickness |         | Insufficient wax coverage over specified surface | Allows integrity breach of inner door panel<br><br>Corroded interior lower door panels<br><br>Deteriorated life of door leading to:<br>• Unsatisfactory appearance due to rust through paint over time.<br>• Impaired function of interior door hardware | 7        |                | Manually inserted spray head not inserted far enough                                      | None  | 8          | Variables check for film thickness at start up<br>Visual check for coverage. | 5         | 280 | Add positive depth stop to sprayer  | Bob Tate<br>Mfg Eng | 0X 10 15               | Stop added sprayer checked online.   | 0X 10 15       | 7        | 2          | 5         | 70  |
|              |   |              |  |         |  |  |          |                | Spray head clogged<br>- Viscosity too high<br>- Temperature too low<br>- Pressure too low | Test spray at start-up and after idle periods and preventative maintenance program to clean heads | 5          | Variables check for film thickness at start up<br>Visual check for coverage. | 5         | 175 | Use Design of experiments (DOE) on viscosity vs. temperature vs. pressure | D Cherry<br>Mfg Eng | 0X 10 15               | Temp and Press Limits were determined<br>Control charts show process is in control<br>Cpk = 1.85 | 0X 11 15       | 7        | 1          | 5         | 35  |
|              |   |              |  |         |  |  |          |                | Spray head deformed due to impact   | Preventative maintenance programs to maintain heads   | 2          | Variables check for film thickness at start up<br>Visual check for coverage. | 5         | 70  | None  |                     |                        |  |                |          |            |           |     |
|              |   |              |  |         |  |  |          |                | Spray time insufficient   | None  | 5          | Lot sampling (visual) check coverage of critical areas                       | 7         | 245 | Install Spray timer.  | C Czymak<br>Maint   | 0X 11 15               | Automatic spray timer installed<br>Control charts show process is in control<br>Cpk = 2.05       | 0X 11 15       | 7        | 2          | 7         | 98  |
| a1           | a2  |              | a3   |         | b  | c  | d        | e              | f   | g   | h          | i  | j         | k   | ----- l   | -----               | -----                  | m  | -----          | n        | -----      | -----     |     |

**SAMPLE**



# Assessing Process FMEA

## 6) Process FMEA

\*Make sure the PFMEA format is correct.

### Things to consider:

- a) Are all operations from the Process Flow chart identified and listed sequentially on the Process FMEA?
- b) Are all ballooned / numbered features included on PFMEA?
- c) Are all balloon features failure modes listed in specific terms (e.g. separate line for over the upper limit, under the lower limit, and missing feature)?
- d) Are the effects of failures listed appropriately to address the impact on each part, next higher assembly, system, vehicle, customer wants, government regulations and operator safety? Are they consistent with the related DFMEA?
- e) Are all man-, method-, machine-, material-, measurement-related potential causes identified for all failure modes?
- f) Are listed causes described in terms of something that can be corrected or controlled? “Operator Error” as a potential failure should not be used; the failure must be rooted to a process or system.

# Assessing Process FMEA

## 6) Process FMEA

\*Make sure the PFMEA format is correct.

### Things to consider:

- g) Are corrective actions, responsibilities and completion dates assigned to high severity failure modes (Severity 9 or 10) and high risk priority numbers?
- h) In case of no recommended actions, does PFMEA state “None” in the **Recommended Actions** column?
- i) Are all special characteristics (e.g. critical, key, significant, etc.) identified and addressed on the PFMEA in the **Characteristic** column?
- j) Are severity, occurrence and detection rankings consistent with AIAG PFMEA Manual recommendations?
- k) Does the title on PFMEA list correct part name, part number, engineering change level, document release, revision date?
- l) Does the severity rating agree with DFMEA (if available)?
- m) Is PFMEA adequate to define all possible failure modes associated with product, process and manufacturing system?

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**6) Process FMEA** section of the PPAP checklist

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## 2.2.7 Control Plan

- Control Plans shall define ALL controls used for process control and comply with IATF 16949.
  - *(See IATF 16949 Appendix A)*
  - *(See APQP and Control Plan Reference Manual)*
- Control Plans for families of similar parts are acceptable if the new parts have been reviewed for commonality.
- Some customers require sign-offs on the Control Plans before PPAP submission.

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# Production Control Plan

## CONTROL PLAN

| <input type="checkbox"/> Prototype <input type="checkbox"/> Pre-Launch <input checked="" type="checkbox"/> Production |   | Key Contact / Phone                                |                 | Date (Orig) Jan-30-09   |  | Date (Rev) 28-Aug-13  |   |   |   |  |  |
|---|---|--|-----------------|---|--|---|---|---|---|--|--|
| Control Plan Number M S00203 (A150)   |   | Core Team  |                 | Customer Engineering Approval / Date (If Req'd)   |  |   |   |   |   |  |  |
| Part Number / Latest Change Lev   |   | Supplier / Plant Approval Date                     |                 | Customer Quality Approval Date (If Req'd)   |  |   |   |   |   |  |  |
| Part Name / Description<br>Retainer Assembly - Low Clutch machined complete   |   | Supplier Code                                      |                 | Other Approval Date (If Req'd)  |  |   |   |   |   |  |  |
| Supplier / Plant  |   | 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  | Freq.  |
| R10   | Receiving Inspection  | Molten Aluminum (Wabash Alloys) Ingots/Sows/T-Bars |                 | Chemical Composition  |  | A380 (DCX-MS-2410D)   | Spectrometer  | Every   | Batch   | Certificate from Supplier  | Quarantine<br>Material   |
| ST100   | Store Molten Metal (Hot pot only)                               |  |                 | Wabash Metal Temperature  | Maintain Temperature                       | 732 - 843° C ( 1350 - 1550°F)   | Wabash Alloys LLC Certified Analysis Report   | Every   | Hot Pot   | Record of temperature on metal receiving log   | Inform supervisor. Identify defective parts and remove from process. |
| C005  | Melting of Aluminium (Ingots/Sows/T-Bars/ In-house clean scrap) | Melters  |                 | Chemical Composition  | Metal Charge<br>Furnace temp - 750°F       | Add in-house scrap or T-bar/Sows/Ingots with green mark<br>750°F<br><br>A380 (DCX-MS-2410D), Sludge Factor-1.4<br><br>Green dot on each ingot/sow/t-bar<br>Clean dry scrap only (runners, gates, scrap castings without any assembled components) | PLC Controller on/off<br><br>Spectrometer<br><br>Visual                               | as required<br><br>100 %<br><br>once<br><br>Every | per production Monitoring<br><br>per shift<br><br>lot | Record on metal charge sheet<br>Automatic shut off by PLC<br>Store data in computer/<br>Hard copy/pre-control chart<br><br>Record in Melter Charge Sheet | Correct process.   |
| C010  | Inspect chemical composition                                    | Aluminum alloy                                     |                 | Chemical Composition  |  | A380 (DCX-MS-2410D)   | Spectrometer (PT)<br><br>Spectrometer (Acuren)  | Each<br><br>once<br><br>once                      | hot pot delivery<br>shift<br>(Melter)<br>Quarter      | Store data in computer   |  |
| C030  | De-gas/Flux Molten Metal  |  |                 | Flow meter settings<br><br>Pressure Gage<br>Rotation speed of impeller<br>Degassing time<br>Purge Meter Setting | De-Gas/Flux Molten Metal in Transfer Ladle | 50 - 80 SCFH<br><br>45 - 55 PSI<br>310 - 390 rpm<br>30 - 5.0 min<br>5 - 10 SCFH   | Flow meter gage<br><br>Pressure gage<br>PLC monitor<br>PLC monitor<br>Flow Meter gage | every<br><br>"<br>"<br>"<br>"                     | ladle<br><br>"<br>"<br>"<br>"                         | Record Degas yes/no on Melter/Hot pot tracking sheet   |  |



# Special Characteristics

- A **Special Characteristic** as defined by IATF 16949 (**3.1 Terms and Definitions for the Automotive Industry**) is a product characteristic or manufacturing process parameter that can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.
  - Demonstrated process capability or performance is required for Special Characteristics.
  - This is contrasted with a “Standard Characteristic”.
- All characteristics that need to be controlled are to be included in the FMEA and Control Plan.
- All types of measurement systems need to be studied for MSA as well.
- Additionally, customer-designated special characteristics need to follow the customer specific requirements and/or internal requirements, whichever is most stringent.

# Requirements of Control Plan

Control plan should be created in such a way that the below questions has to be satisfied.

- a) Does Control Plan accurately list flow chart operations (dock to dock) with all process characteristics / controls used for controlling process?
- b) Are all ballooned / numbered features included on the Control Plan?
- c) Are all significant characteristics included and identified on the Control Plan?
- d) Does Control Plan accurately list flow chart operations and their desired product characteristics and tolerance (with balloon numbers from prints) and all material and engineering specifications listed on drawing?
- e) Does Control Plan clearly list numbers / descriptions for production equipment, part specific gauges and test equipment to be used during production?
- f) Does Control Plan refer to documented measurement procedures and techniques?

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# Requirements of Control Plan

- g) Do reaction plans specify the containment and corrective actions (Reaction Plans) necessary to avoid producing nonconforming products or operating out of control process?
- h) Are all controls identified in the Control Plan consistent with all controls included in the PFMEA?
- i) Are sample sizes and frequencies documented appropriately on the Control Plan?
- j) Does the title on Control Plan list correct part name, part number, engineering change level, document release and revision date?
- k) Does Pre-launch Control Plan adequately list addition controls for program launch?
- l) Are control methods (check sheets/work instructions) reviewed to verify controls listed on Control Plan are accurately transferred to applicable control methods?

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**7) Control Plan** section of the PPAP checklist

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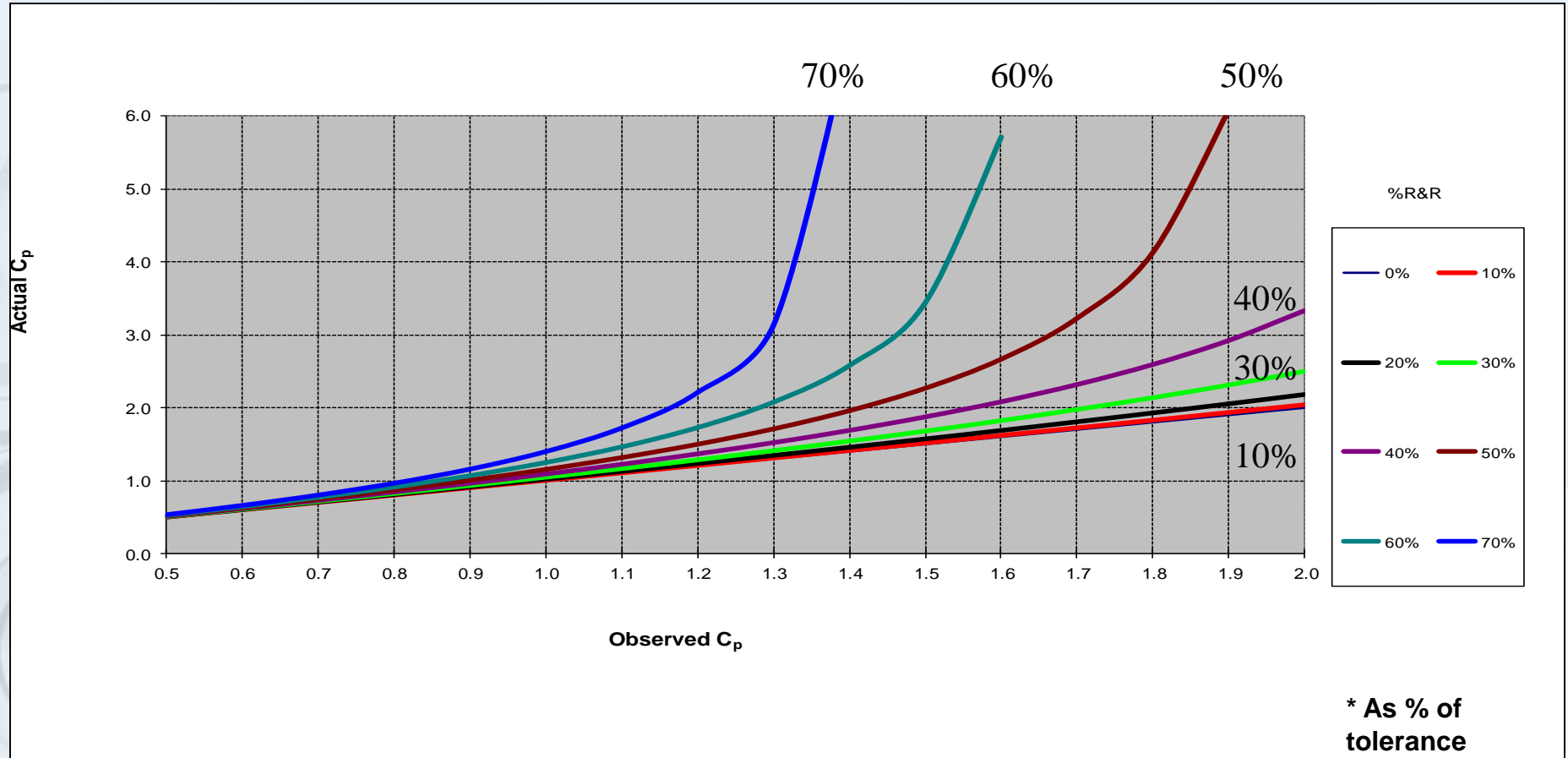
## 2.2.8 Measurement Systems Analysis Studies

- **MEASUREMENT SYSTEM ANALYSIS** shall include bias, linearity, stability and Gage R&R studies for **ALL** new or modified gages, test and measuring equipment

Refer to Ford, GM, FCA – *Measurement Systems Analysis*  
4<sup>th</sup> Edition Reference Manual, AIAG

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# R&R Effect on Capability



The greater the gauge variation, the lower the observed  $C_p$  value

# Assessing Measurement System Analysis Studies

## 8) Measurement System Analysis Studies

### Things to consider:

- a) IS GR&R included for all new or modified gauges, measurement and test equipment?
- b) Are the correct MSA analysis methods being used (consistent with MSA 4<sup>th</sup> Edition Reference Manual)?
- c) Is GR&R Acceptance criteria followed?
  - GR&R < 10% is Acceptable, GR&R from 10% to 30% is Marginal, GR&R > 30% Unacceptable
  - Is the GR&R compared to the process variation?
- d) Is corrective action plan submitted for all rejected items at the time of submission (action, responsible, due date)?



# Assessing Measurement System Analysis Studies

## 8) Measurement System Analysis Studies

### Things to consider:

- e) Are number of Distinct Categories (ndc) Index equal or higher than 5 on GR&R studies?
- f) Is Variable GR&R performed, preferably with three operators, ten parts, and three repetitions?
- g) Are Attribute Studies performed, preferably with 50 or more parts (including good, bad and marginal parts), with a minimum of two operators and two trials?
- h) If there is a dedicated fixture/gage, is there a layout verified by an approved (typically) third party inspection facility?
- i) Are work instructions included for use of dedicated fixture / gauge?
- j) Do measurement devices used have higher resolution than print? (print X.XX and measurement device is X.XXX)

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**8) MSA Studies** section of the PPAP checklist

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## 2.2.9 Dimensional Results

- Records of Dimensional Verifications required by the design record and the Control Plan shall provide evidence that specific requirements have been met for each unique manufacturing process.
- List all dimensions in a convenient format.
- All auxiliary documents shall contain the part number, change level, drawing date and organization name and accompany the dimensional results.
- Record actual results: all dimensions (except reference dimensions), characteristic, and specifications as noted on the Control Plan and design records.

# Dimensional Results

Methodically  
 check each  
 bubbled item  
 from the print

| Item | Dimension/Specification | Results (Data)                                       | OK | Not OK |
|------|-------------------------|--|----|--------|
|      |                         | Notes  |    |        |
| 323  | 17.580 Dim.             | Top Slot Depth                                       | *  |        |
|      |                         | Bottom Slot Depth                                    | *  |        |
| 324  | 80.650 Deg.             | 80.353 Angle Top Slot to F                           | *  |        |
|      |                         | 80.829 80.834 Angle Bottom Slot to F                 | *  |        |
| 325  |                         | 0.097 0.099 0.096 Top Slot to F                      | *  |        |
|      |                         | 0.053 0.058 0.059 Bottom Slot to F                   | *  |        |
| 326  | 1.500 Rad.              | 0.100 0.100 1.575 1.584 1.575 Radius Top Slot        | *  |        |
|      |                         | 1.579 1.587 1.586 Radius Bottom Slot                 | *  |        |
| 327  | 12.610 Dim.             | 0.250 0.250 12.607 12.630 12.599 Top Slot to Datum D | *  |        |
| 328  | 7.820 Dim.              | 0.250 0.250 7.794 7.790 7.786 Bottom Slot to Datum D | *  |        |
| 329  | 3.000 Dim.              | 0.150 0.000 3.108 3.111 3.106 Top Slot Width         | *  |        |
|      |                         | 3.109 3.111 3.108 Bottom Slot Width                  | *  |        |



# Assessing Dimensional Results

## 9) Dimensional Results

### Things to consider:

- a) Are all dimensional results submitted using the official PPAP format: CFG1003 forms?
- b) Do dimensional results reflect the PPAP production run?
- c) Are variable measurements provided for all characteristics? (Attribute results are allowed if variable measurements are not possible)
- d) Are ballooned dimensions on the latest released drawing linked to the Dimensional Results report?
- e) Has the organization shall provide evidence that dimensional verifications required by the design record and the Control Plan have been completed and results indicate compliance with specified requirements.
- f) If production parts will be produced from more than one cavity, mold, tool, die, pattern, or production process, e.g., line or cell, has the organization completed a dimensional evaluation on one part from each.
  - The specific cavities, molds, line, etc., shall then be identified in the "**Mold / Cavity / Production Process**" line on a PSW, or in a PSW attachment.



# Assessing Dimensional Results

## 9) Dimensional Results

### Things to consider:

- g) Are the dimensions measured and reported from the serialized PPAP layout samples?
- h) Is the Dimensional Report dated and signed?
- i) Has supplier submitted additional information as required by the customer to show compliance to CAD dimensions not referred on the Dimensional Report (e.g. 3D scanning, point cloud inspection, material thickness sectional analysis, etc.)?
- j) Were samples used for Dimensional Reports taken from the same run used for Process Capability Analysis?

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

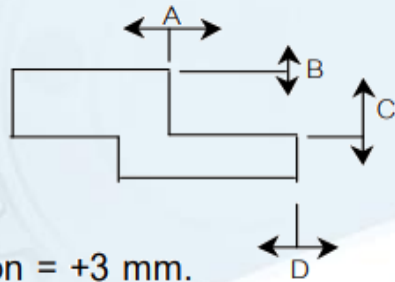
**9) Dimensional Results** section of the PPAP checklist

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# PIST

$$\text{P.I.S.T.} = \frac{\text{The number of inspection points that satisfy the tolerance}}{\text{The number of inspection points}} \times 100$$



| Inspection \ Samples | 1    | 2    | 3    | 4    | 5    |
|----------------------|------|------|------|------|------|
| A                    | (+4) | +2   | +3   | +1   | +1   |
| B                    | -1   | 0    | +1   | +2   | +2   |
| C                    | (+6) | (+5) | (+6) | (+4) | (+5) |
| D                    | +1   | 0    | -2   | -1   | 0    |

$$\text{P.I.S.T} = \frac{2}{4} \times 100 = 50\%$$

## 2.2.10 Material and Performance Test

- Organizations shall have records of Material and / or Performance tests specified on the Design Record (DR) or Control Plan (CP). Such tests shall be performed for all parts and product materials:
  - When chemical, physical or metallurgical requirements are specified by the DR or CP;
  - When performance or functional requirements are specified by the DR or CP.
- and reported in an understandable format including change levels, dates, ID numbers, specifications, quantity test, actual results, and any authorized engineering change documents not yet incorporated in the DR.

# Qualification Report

QRFL709025 - Qualification report

Table 2. TSOP48 12 x 20 mm - die / package related tests (Fab2 and Muar)

| Sub-group | Test Procedure      | MIL-STD-883 Procedure | Test Conditions                  | Results |       |      | Note |
|-----------|---------------------|-----------------------|----------------------------------|---------|-------|------|------|
|           |                     |                       |                                  | Lots    | Samp. | Fail |      |
| 1         | Operating Life Test | JESD22-A108           | 140 °C, V <sub>CC</sub> = 4.2 V  | 3       | 77    | 0    | (1)  |
|           |                     |                       | - 168 hrs                        | 3       | 77    | 0    |      |
|           |                     |                       | - 500 hrs                        | 3       | 77    | 0    |      |
| 2         | Operating Life Test | JESD22-A108           | - 40 °C, V <sub>CC</sub> = 4.2 V | 3       | 15    | 0    | (1)  |
|           |                     |                       | - 168 hrs                        | 3       | 15    | 0    |      |
|           |                     |                       | - 500 hrs                        | 3       | 15    | 0    |      |
| 3         | Retention Bake      | JESD22-A103           | 250 °C                           | 3       | 77    | 0    | (1)  |
|           |                     |                       | - 168 hrs                        | 3       | 77    | 0    |      |
|           |                     |                       | - 500 hrs                        | 3       | 77    | 0    |      |
| 4         | Write/Erase Cycling | AEC-Q100-005          | 25 °C                            | 3       | 77    | 0    |      |
|           |                     |                       | - 10 K, 50 K, 100 K cyc          | 3       | 77    | 0    |      |
|           |                     |                       | - 1000 bake, 150 °C              | 3       | 77    | 0    |      |
|           |                     |                       | - 1000 OLT, 140 °C, 4.2 V        |         |       |      |      |

**Sample Extract**

# Assessing Material, Performance Test Results

## 10) Material, Performance Test Results

### Things to consider:

- a) Are material and performance test results submitted using the official AIAG format: CFG-1004 & CFG-1005 forms?
- b) Are copies of the material certificates and lab test results included?
- c) Do the units of measurement for test results match with the units on applicable drawing and engineering specifications?
- d) Were the tests done at a certified lab?
- e) Has supplier provided a comparison of material specification limits to the material called out on the drawing specification in case supplier is procuring material equivalent to material listed on the drawing?
- f) For any and all changes to cavities on parts, have DVP&R testing results been submitted?

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**10) Material Performance Results** section of the PPAP checklist

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## 2.2.11 Initial Process Studies

- An acceptable level of initial process capability studies must be demonstrated prior to submission of **ALL** special characteristics designated by the customer or organization.
- Customer concurrence on index to be used is required.
- Variables data shall be used.
- Measurement System Analysis shall be performed prior to the studies.
- For variables data, it is important to collect and analyze data in the order produced using Xbar and R control charts.
  - 25 subgroups containing at least 100 readings from consecutive parts of the significant production run is the minimum acceptable

## 2.2.11 Initial Process Studies

- Process Study results are dependent on data normality, two-sided specifications, principles of stability from an average and range chart perspective.
- Refer to the Ford, GM, FCA *Statistical Process Control 2<sup>nd</sup> Edition Reference Manual*, AIAG.
- If acceptable process stability and capability cannot be achieved by submission, then the organization must provide the customer with an interim control plan and corrective action plan.
- The index for summarizing process capability or performance will be agreed upon – i.e.,  $(C_p, C_{pk})$ ,  $(P_p, P_{pk})$ , other metrics.



# Assessing Initial Process Capability Studies

## 11) Initial Process Capability Studies

### Things to consider:

- a) Has supplier submitted Initial Process Study for all customer interface characteristics (e.g. critical, key, significant, pass-through, etc.) that are called out on the drawing, Control Plan or requested by the customer?
- b) Are submitted studies representative of each unique production process, e.g., duplicate assembly line and/or work cell, each position of a multiple cavity die, mold, tool or pattern, etc.?
- c) Is capability / performance data submitted from significant production PPAP run (i.e. Production Trial Run or Run-at-Rate)?
- d) Does the Dimensional Report data fall within the distribution of the capability data?

# Assessing Initial Process Capability Studies

## 11) Initial Process Capability Studies

### Things to consider:

- e) Has supplier provided a corrective action plan including 100% inspection if process study results are not meeting requirements as stated on next slide?
- f) Capability results for normal distribution and stable processes must meet following criteria stated by the PPAP Reference Manual (*also see table next slide*)

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# Quality Indices (Process Capability Studies)

| Results                                    | Interpretation   |
|--|--|
| Index Value > 1.67                         | The process currently meets customer requirements. After approval, begin production and follow Control Plan.   |
| $1.33 \leq (\text{Index Value}) \leq 1.67$ | The process is currently acceptable but may require some improvement. Contact your customer and review results of the study. This will require changes to the Control Plan, if not improved prior to the start of volume production. |
| Index Value < 1.33                         | The process does not currently meet the acceptance criteria. Contact the appropriate customer representative for a review of the study results.  |

**Note: C and P indices can only be used with stable processes**

# Capability Studies

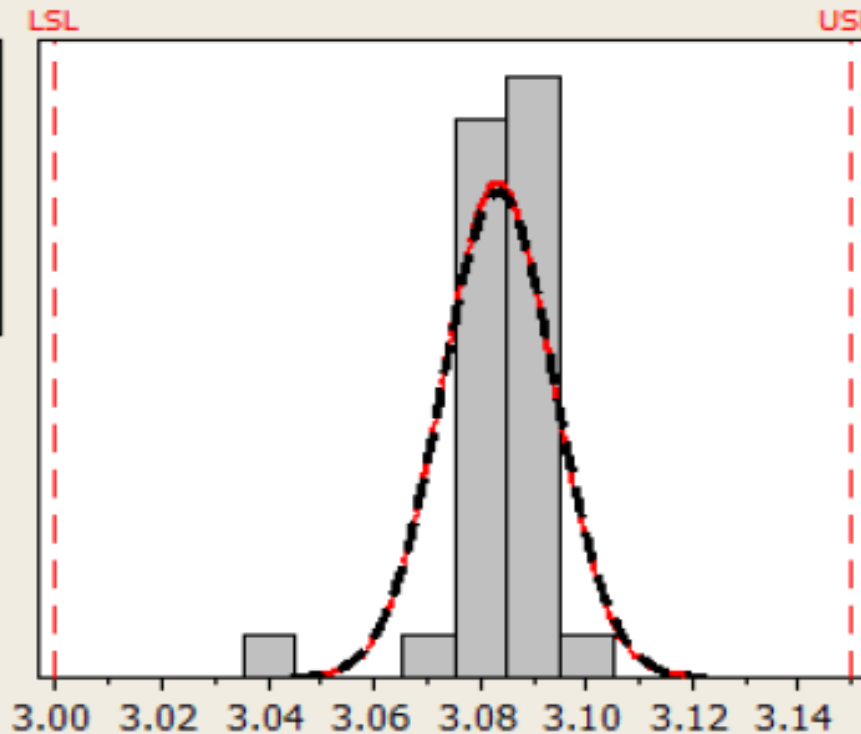
|    | Depth - Top Slot | Depth - Bottom Slot | Angularity - Top Slot | Angularity - Bottom Slot | Top Slot to Datum D | Bottom Slot to Datum D | Slot Width - Top | Slot Width-Bottom |
|----|------------------|---------------------|-----------------------|--------------------------|---------------------|------------------------|------------------|-------------------|
| 1  | 17.602           | 17.603              | 0.006                 | 0.071                    | 12.686              | 7.852                  | 3.1020           | 3.087             |
| 2  | 17.597           | 17.596              | 0.008                 | 0.083                    | 12.685              | 7.854                  | 3.0890           | 3.083             |
| 3  | 17.596           | 17.594              | 0.012                 | 0.079                    | 12.693              | 7.846                  | 3.0810           | 3.094             |
| 4  | 17.600           | 17.599              | 0.006                 | 0.074                    | 12.700              | 7.847                  | 3.1050           | 3.083             |
| 5  | 17.601           | 17.603              | 0.022                 | 0.054                    | 12.684              | 7.851                  | 3.0830           | 3.037             |
| 6  | 17.600           | 17.600              | 0.007                 | 0.086                    | 12.676              | 7.844                  | 3.0970           | 3.079             |
| 7  | 17.609           | 17.605              | 0.004                 | 0.061                    | 12.679              | 7.831                  | 3.1020           | 3.096             |
| 8  | 17.611           | 17.607              | 0.011                 | 0.058                    | 12.676              | 7.834                  | 3.0930           | 3.086             |
| 9  | 17.610           | 17.606              | 0.004                 | 0.071                    | 12.682              | 7.839                  | 3.0970           | 3.081             |
| 10 | 17.606           | 17.606              | 0.001                 | 0.069                    | 12.672              | 7.840                  | 3.0860           | 3.093             |
| 11 | 17.606           | 17.606              | 0.004                 | 0.069                    | 12.667              | 7.837                  | 3.0800           | 3.083             |
| 12 | 17.607           | 17.604              | 0.000                 | 0.065                    | 12.678              | 7.843                  | 3.0920           | 3.091             |
| 13 | 17.605           | 17.603              | 0.002                 | 0.065                    | 12.689              | 7.851                  | 3.0840           | 3.091             |
| 14 | 17.610           | 17.605              | 0.009                 | 0.060                    | 12.649              | 7.865                  | 3.0800           | 3.090             |
| 15 | 17.608           | 17.607              | 0.004                 | 0.069                    | 12.678              | 7.837                  | 3.1010           | 3.086             |
| 16 | 17.597           | 17.597              | 0.000                 | 0.077                    | 12.718              | 7.850                  | 3.1030           | 3.086             |
| 17 | 17.598           | 17.599              |                       |                          |                     |                        | 3.0800           | 3.084             |
| 18 | 17.598           | 17.598              |                       |                          |                     |                        | 3.0770           | 3.094             |
| 19 | 17.602           | 17.601              |                       |                          |                     |                        | 3.1090           | 3.082             |
| 20 | 17.598           | 17.598              | 0.006                 | 0.072                    | 12.692              | 7.866                  | 3.1100           | 3.089             |
| 21 | 17.599           | 17.598              | 0.000                 | 0.076                    | 12.677              | 7.852                  | 3.1078           | 3.085             |
| 22 | 17.597           | 17.597              | 0.002                 | 0.072                    | 12.704              | 7.854                  | 3.0900           | 3.089             |
| 23 | 17.600           | 17.599              | 0.001                 | 0.075                    | 12.682              | 7.856                  | 3.0950           | 3.085             |
| 24 | 17.597           | 17.596              | 0.011                 | 0.080                    | 12.688              | 7.860                  | 3.0820           | 3.078             |
| 25 | 17.602           | 17.602              | 0.001                 | 0.062                    | 12.705              | 7.855                  | 3.1070           | 3.083             |
| 26 | 17.605           | 17.602              | 0.003                 | 0.068                    | 12.687              | 7.848                  | 3.0940           | 3.076             |
| 27 | 17.605           | 17.603              | 0.006                 | 0.070                    | 12.706              | 7.850                  | 3.1090           | 3.080             |
| 28 | 17.598           | 17.599              | 0.008                 | 0.068                    | 12.689              | 7.849                  | 3.1030           | 3.073             |
| 29 | 17.604           | 17.602              | 0.001                 | 0.071                    | 12.680              | 7.847                  | 3.0900           | 3.083             |
| 30 | 17.601           | 17.597              | 0.007                 | 0.084                    | 12.691              | 7.855                  | 3.1080           | 3.075             |

Must be supported with data

# Capability Studies

## Process Capability of Slot Width-Bottom

| Process Data   |           |
|----------------|-----------|
| LSL            | 3         |
| Target         | *         |
| USL            | 3.15      |
| Sample Mean    | 3.0834    |
| Sample N       | 30        |
| StDev(Within)  | 0.0104091 |
| StDev(Overall) | 0.0105809 |



| Potential (Within) Capability |      |
|-------------------------------|------|
| Cp                            | 2.40 |
| CPL                           | 2.67 |
| CPU                           | 2.13 |
| Cpk                           | 2.13 |

---

| Overall Capability |      |
|--------------------|------|
| Pp                 | 2.36 |
| PPL                | 2.63 |
| PPU                | 2.10 |
| Ppk                | 2.10 |
| Cpm                | *    |

| Observed Performance |      |
|----------------------|------|
| PPM < LSL            | 0.00 |
| PPM > USL            | 0.00 |
| PPM Total            | 0.00 |

| Exp. Within Performance |      |
|-------------------------|------|
| PPM < LSL               | 0.00 |
| PPM > USL               | 0.00 |
| PPM Total               | 0.00 |

| Exp. Overall Performance |      |
|--------------------------|------|
| PPM < LSL                | 0.00 |
| PPM > USL                | 0.00 |
| PPM Total                | 0.00 |

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**11) Initial Process Capability Studies** section of the PPAP checklist

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## 2.2.11.4 Unstable Processes

- If the process does not behave consistently over time, then we say that the process is unstable.
- The causes that induce inconsistency are called as special causes.
- Depending on the nature of the instability, an unstable process may not meet customer requirements – **Notify the customer.**
- Identify, evaluate, and — where possible — eliminate special cause variation prior to PPAP.
- Submit corrective action plan to the customer prior to PPAP.



## 2.2.11.5 Stable Processes

- A stable process produces Predictable results consistently. Process stability can be easily determined using control charts.
- Acceptance criteria:
  - All data should fall within the Upper and Lower control limits of Control chart.
  - 99.7% of all data points will fall between these two limits.

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# PIPC

$$\text{P.I.P.C} = \frac{\text{The number of process capability points that satisfy } C_{pk}}{\text{The number of process capability points}} \times 100$$

| c | Inspection Points | Samples |    |    |     |    | Cp  |
|---|-------------------|---------|----|----|-----|----|-----|
|   |                   | 1       | 2  | 3  | ... | 30 |     |
|   | A                 | +3      | +2 | +1 | ... | +2 | 1.4 |
|   | C                 | 0       | -3 | -2 | ... | -1 | 1.0 |

(The number of process capability points that satisfy  $C_{pk}$ , in this case, A and C dimensions are B rank, which require  $C_{pk} > 1.33$ )

$$\text{P.I.P.C} = \frac{1}{2} \times 100 = 50\%$$

(The number of process capability points)

# GENERAL ELEMENTS

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## 2.2.12 Qualified Lab Documentation

- Inspection and testing shall be performed by a qualified laboratory that has a laboratory scope and documentation showing that the laboratory is qualified.
- When a commercial/independent lab is used:
  - It shall be accredited.
  - The test results shall be on the Lab Letterhead or Report Form.
  - The name of the lab, date of the tests and standards used to run the tests shall be indicated.

**No Blanket Statements of Conformance!!**

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# Assessing Qualified Laboratory Documentation

## 12) Qualified Laboratory Documentation

### Things to consider:

- a) For measurement/tests performed at supplier internal labs, has supplier provided a lab scope?
- b) For measurements/tests performed at external labs, has supplier provided lab accreditation such as certification to ISO 17025, NIST or A2LA?
- c) Has supplier provided its quality management certificate, i.e., IATF 16949 or ISO 9001?

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

## **12) Qualified Lab Documentation** section of the PPAP checklist

QUALITY

## 2.2.13 Appearance Approval Report

- A separate appearance approval report (AAR) must be completed for each part or series of parts *that has appearance requirements* on the design report.
- AARs typically apply only for parts with color, grain or surface appearance requirements.
- AAR requirements vary by customer.

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# Generic Appearance 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 | <input type="checkbox"/> PART SUBMISSION WARRANT | <input type="checkbox"/> SPECIAL SAMPLE | <input type="checkbox"/> RE-SUBMISSION | <input type="checkbox"/> OTHER | <input type="checkbox"/> PRE TEXTURE | <input type="checkbox"/> FIRST PRODUCTION SHIPMENT | <input type="checkbox"/> ENGINEERING CHANGE |  |

### 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 |     |     |     |     | 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 |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |
|              |                  |     |     |     |     |               |             |               |                 |     |     |     |     |       |      |        |       |       |     |                     |     |                       |                  |

COMMENTS

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|                        |           |      |  |      |
|------------------------|-----------|------|--|------|
| ORGANIZATION SIGNATURE | PHONE NO. | DATE | AUTHORIZED CUSTOMER REPRESENTATIVE SIGNATURE | DATE |
|------------------------|-----------|------|--|------|

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2006

# Assessing Appearance Requirements

## 13) Appearance Requirements

### Things to consider:

- Has supplier submitted an Appearance Approval Report (if applicable)?
- For all cosmetic criteria, has supplier submitted pictures and/or samples showing acceptable conditions and unacceptable conditions?

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**13) Appearance Approval Report** section of the PPAP checklist

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## 2.2.14/15 Sample Product and Master Samples

- Sample Production Parts shall be requested by the customer and shall be defined by the submission request.
- Master Sample(s) shall be:
  - Retained for the same period as the PPAP record.
  - Identified as such and shows the customer approval date on the sample.
  - Retained for each mold, die, cavity, line, etc.
  - Replaced by a new approved master.

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# Master Sample and Retention

- One of the parts from the Significant Production Run that has undergone dimensional verification for PPAP shall be identified as the Master Sample.
- Organization and customer requirements generally are more likely to be of a larger amount due to the need and usefulness of this type of sample.
  - Each part in this case is identified and retained as a record of the PPAP event.

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# Assessing Sample Product and Retention of Master Samples

## 14) Sample Production Parts and 15) Master Sample

### Things to consider:

- a) Are the sample parts taken from a significant production run as outlined in the PPAP Manual?
- b) Has supplier submitted samples that clearly identify each unique cavity, mold, line, etc.?
- c) Has the supplier identified one of the parts measured as the master sample?
- d) Has supplier retained master samples at supplier end with unique identification for part number, cavity, revision, tool number, etc. and with a sample number that corresponds to the Dimensional Report?

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**14/15) Sample Production Parts and Master Samples** sections of the PPAP checklist

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## 2.2.16 Checking Aids

- Part specific inspection or test device shall be supplied with submission when requested.
- The gage shall be certified by the supplier to indicate that all aspects of it agree with part dimensional requirements.
- Documentation shall show that all released engineering design changes are incorporated into the gage design at time of PPAP submission.
- MSA shall be conducted in compliance with customer requirements.

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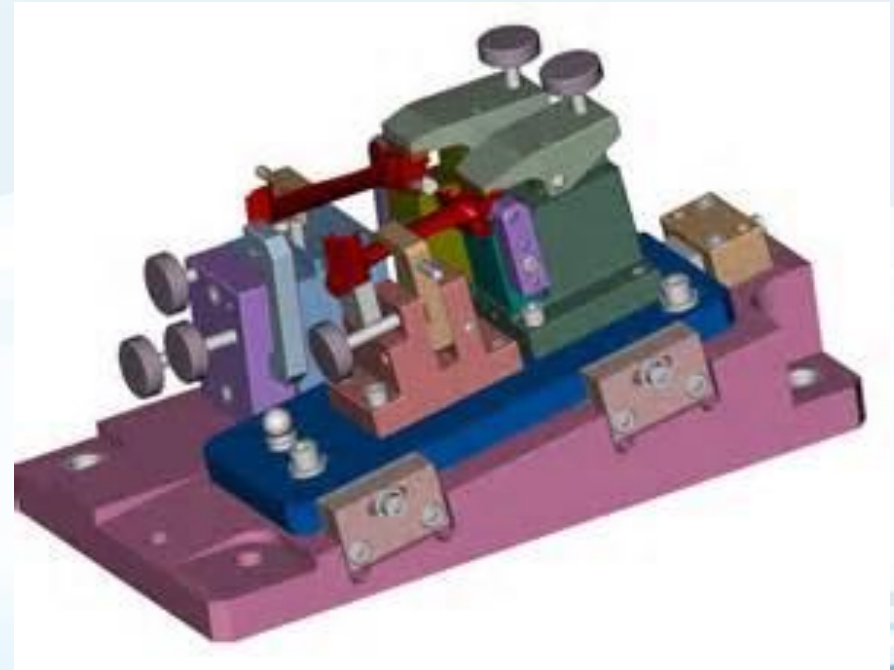
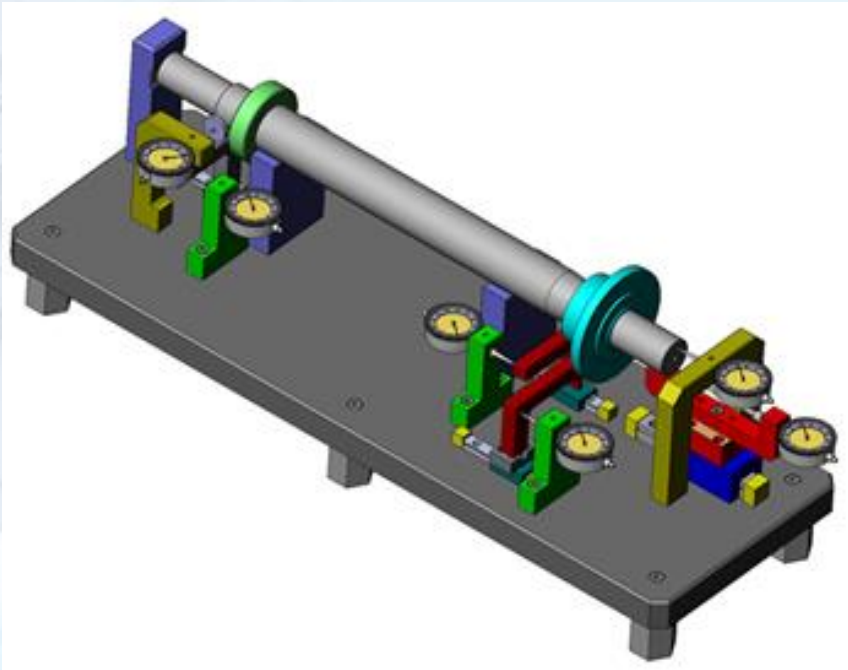
## 2.2.16 Checking Aids

- Checking aids subject to this requirement might include:
  - Part-specific Test technology (hardware)
  - Testing software with validation data
  - Part-specific measuring devices
  - Other?

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# Checking Aids

## Examples



# Assessing Checking Aids

## Also List of Gauges and CMM Fixtures

### 16) Checking Aids; also List of Gauges and CMM Fixtures

#### Things to consider:

- a) Has supplier submitted records of certification for all checking aids / part-specific gauging? This includes CMM measurements of the gauges.
- b) For inspection lab used for gauge certification, has supplier provided lab accreditation such as certification to ISO 17025, NIST or A2LA?
- c) Is identification of checking aid referred on PSW?
- d) Has supplier submitted gauge instructions on Control Plan for part-specific gauging?

# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**16) Checking Aids; also List of Gauges and CMM  
Fixtures** sections of the PPAP checklist

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## 2.2.17 Customer Specific Requirements

- Organizations shall determine Customer-Specific Requirements and shall have records of compliance to any that are applicable.
- When in doubt about the general or specific requirements:

**Contact your authorized customer representative!**

**Determine where additional CSR can be located!**

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**17) Customer Specific Requirements** section of the PPAP checklist

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# **OTHER RELATED INFORMATION**

## **Sub-Supplier Part Submission Warrant**

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# Sub-Supplier Part Submission Warrant

## (No PPAP Reference)

- Although PPAP does not specifically require sub-supplier PPAP / PSW **IATF 16949 8.4.2.3 Supplier Quality Management System Development** requires:
  - The organization shall require their suppliers of automotive products and services to develop, implement and improve a QMS certified to ISO 9001, unless otherwise authorized by the customer, with the ultimate objective of becoming certified to this Automotive QMS Standard.
- Some customers are requiring that a sub-supplier PPAP / PSW be part of the supplier's PPAP submission.

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# Sub-Supplier Part Submission Warrant

(No PPAP Reference)

## Things to consider:

- a) Is approved PSW included for sub-suppliers?
- b) Does part number and drawing revision number match with the drawing?
- c) Are all fields on the PSW filled out correctly? Information not applicable to any specific part must be identified as “N/A”.
- d) Has supplier marked “Yes” or “No” to meeting all drawing requirements? If “No”, explanation details and corrective action plan must be submitted.
- e) Is the IMDS number included, showing the latest revision submitted to the Material Data System, receiving plant specific ID number?

# Sub-Supplier Part Submission Warrant

(No PPAP Reference)

## Things to consider:

- f) Does PSW specify molds / cavities / production processes pertaining to the PPAP?
- g) Has supplier noted production rate on PSW at which the PPAP samples were produced during significant production run?
- h) Are checking aids used in the everyday processing of a part identified on the PSW?
- i) Is part weight expressed in kilograms to four significant decimal places (0.0000)?

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# Team Breakout Exercise

- Quickly review the PPAP submission (extract) from the class case study and complete:

**(xx) Sub-Supplier Part Submission Warrant (PSW)**  
section of the PPAP checklist

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# Chapter 3: PPAP Submission Elements – What We Covered

## Learning Objectives

You should now be able to:

- Describe Product Design Elements
- PIST
- Describe Manufacturing Process Elements
- PIPC
- Describe General Elements
- Describe Part Submission Warrant and Status

## Chapter Agenda

- Requirements and Deliverables
- Product Design Elements
- Determining PIST
- Manufacturing Process Elements
- Determining PIPC
- General Elements
- Part Submission Warrant and Status

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# Chapter 4

## Assessing a PPAP Package

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# Chapter 4: Assessing a PPAP Package – What We Will Cover

## Learning Objectives

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

- Assess a PPAP package to determine if it is acceptable

## Chapter Agenda

- Verifying the Initial Production Run
- Assess Overall Completeness
- **Break out Exercise 2**

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# Verifying Initial Production Run

- Review the documentation, etc. for the manufacturing process, including:
  - Engineering Drawings
  - DFMEA
  - Process Flows and Routing sheets
  - PFMEA
  - Control Plans
  - Work Instructions
  - Inspection plans
  - Gages, fixtures, etc. provided for measurement and test

**In other words, have they submitted all the required PPAP documents?**



# Verifying Initial Production Run

- Assess evidence that the manufacturing processes that produced the PPAP part(s) are those that will be used in serial production:
  - Production facilities
  - Personnel
  - Tooling
  - Equipment, cycle times
  - Gaging
  - Materials
  - Environment



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# Assess Overall Completeness

- Are all of the required components present?
- Based on quick sampling, do reports correlate with Product Definition Engineering Data:
  - Part Number?
  - Engineering Change Level/Date?
  - Engineering Data?
- Does all header information “match”?
- Relevant certs and approvals?
- Dimensional, Test reports complete?



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| PPAP Item                            | Description   | Inputs  | Outputs   | Key Items  | Review Notes  |
|--------------------------------------|---|---|---|--|---|
| <b>Design Records</b>                | Full definition of the product including <ul style="list-style-type: none"> <li>• Drawings</li> <li>• Math data</li> <li>• Material requirements</li> <li>• Performance requirements</li> <li>• Any other documentation required to fully define the product</li> </ul> | <ul style="list-style-type: none"> <li>• Customer requirements</li> <li>• Regulatory requirements</li> <li>• Design records from similar designs</li> <li>• Design standards</li> <li>• Functional requirements</li> <li>• Lessons learned</li> </ul> | <ul style="list-style-type: none"> <li>• Completed drawings and / math data</li> <li>• Completed material and performance requirements</li> <li>• Functional testing</li> </ul> | <ul style="list-style-type: none"> <li>• Design records cover all customer and regulatory requirements</li> <li>• Material and performance requirements are clearly written and reference standards where appropriate</li> <li>• All special characteristics are identified</li> </ul> | <ul style="list-style-type: none"> <li>• <b>If GD&amp;T is used, confirm proper use</b></li> <li>• <b>If standards are referenced, ensure there availability</b></li> </ul> |
| <b>Engineering Change Documents</b>  | Engineering changes that have been incorporated into the product but have not yet been recorded in the design record  | <ul style="list-style-type: none"> <li>• Customer requirements</li> <li>• Internal ECN documentation</li> <li>• ECN change control</li> </ul>   | <ul style="list-style-type: none"> <li>• Completed ECN documentation</li> </ul>   | <ul style="list-style-type: none"> <li>• All changes properly controlled</li> </ul>  |   |
| <b>Customer Engineering Approval</b> | <b>When required by the customer</b>  | <ul style="list-style-type: none"> <li>• <b>Customer requirements</b></li> </ul>  | <ul style="list-style-type: none"> <li>• <b>Customer approved engineering change documents</b></li> </ul>   | <ul style="list-style-type: none"> <li>• <b>Evidence of customer approval</b></li> </ul>   |   |

## DFMEA

Design Failure Mode and Effect Analysis (FMEA) is a method to analyze and discover:

- The potential failure modes of a system
- The effects these failures have on a system
- How to correct and/or mitigate the failures or the effect on a system

- Complete design record
- Functional worksheet
- Block diagram
- Customer Requirements
- Regulatory Requirements
- Interface Matrix
- Similar Design FMEA

Completed Design FMEA, including

- List of all the functions, and how the functions could fail
- Effects of failure
- Causes of failure
- Design Controls
- Detection – How good are the controls
- Prioritized list of actions to reduce risk and improve the design

- Cross Functional team
- Covers all Functions
- Clearly written requirements, not large groups
- Failure modes negative of Effects
- All customer effects
- Correlation of controls to failure modes
- Proper ID of key Characteristics
- Correct or control, one per cell

- Both types of controls used
- Proper use of prevention and detection
- Actions – are some implemented?
- Results of actions taken

## Process Flow Diagram (PFD)

Graphical depiction of the manufacturing process flow, including,

- Description of each product step
- Requirements of each process step

- Design outputs, (drawings, materials)
- Equipment & machines
- Budget & capacity
- Number of operators
- Production Qty

Completed PFD with descriptions and requirements clearly stated

- Requirements of process step
- Inputs & Outputs for each step
- Customers & Suppliers affected
- Sources of variation

- The majority of process steps add value to the product
- Movement, storage and decisions steps are minimized

## PFMEA

Process FMEA is a disciplined analytical process that allows the team to anticipate failures and prevent their occurrence. It is a method to analyze and discover:

- The potential failure modes of a process
- The effects these failures have on a process
- How to correct and/or mitigate the failures or the effect on a process

- Process Flow diagram
- DFMEA
- Characteristics matrix
- Similar PFMEAs

Completed Process FMEA that includes

- List of (all) Process Steps
- Focus on steps that are value added and make change to the product
- Requirements for each process step
- Failure Modes
- Effects on all customers considered
- Causes of the failure modes
- Controls in place to prevent or detect
- Prioritized list actions to reduce risk and improve the process

- All steps that add value or change the product are included
- Requirements are clearly & concisely written
- Key Char. included
- Failure mode the opp./neg. of requirements
- Review effects are for all customers
- Actionable, correctable, Controls – both types
- Prevention will stop from happening
- Detection will
- Actions listed. Will they improve?

- Consider a tool to evaluate risk assessment of all steps, but a low risk op. should be eliminated.
- Evaluate Actions taken to reduce the failure modes
- Too many requirements in a statement; break it up.
- Detection values may be ranked too low, i.e. Visual inspection is ranked 7, 8
- Some actions are implemented?
- Results for actions taken
- Safety review – Severity ranking 9, 10

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## Control Plan (CP)

A list of all the controls that will be used to control both product and process characteristics. The purpose of these controls are to ensure that the final product conforms to all customer requirements

- PFMEA Controls & Process steps
- Regulatory & Customer requirements
- Specifications & tolerances for product and process characteristics
- Purchased components / raw materials
- Machines, Gages, Fixtures, Tools
- Operator certification
- List of product & process characteristics and the controls put in place to ensure the process & product requirements are met
- Tools, Fixtures & Machines
- Reaction Plan
- Records & Control Method
- Measurement Techniques
- Frequency & Size
- Is there Linkage between PFD -> PFMEA -> CP
- Key Characteristics included
- Both Product & Process Characteristics included
- Clearly written (EMT) Evaluation Measurement Technique, not all visual
- Compare EMT frequency & size to dominant source of variation
- Receiving controls for components
- If process characteristics not listed, means may not understand intent.
- Controls require timely measurement

## MSA

Studies of the measurement system to determine the amount of variability that exists in the measurement system. These studies include

- Bias
- Linearity
- Stability
- Reproducibility
- Repeatability
- Product to be measured
- Characteristics to be measured
- Operators
- Environment
- Procedures / Work instructions
- Completed studies that show the amount of variability in the measurement system
- Who participated
- Where was the study done
- What was the equipment
- What part did you measure
- How was the study conducted
- Different Shifts
- Improvement actions
- Was the study done in the actual environment where production will be done

|  |  |  |  |  |
|--|--|--|--|--|
| <b>Dimensional Results</b>                     | Dimensional verification that the product meets all dimensional requirements of the design record  | <ul style="list-style-type: none"> <li>• Design record that defines dimensional requirements</li> <li>• Product from full production setting</li> </ul>  | <ul style="list-style-type: none"> <li>• Ballooned drawing</li> <li>• 100% dimensional layout</li> <li>• CFG1003</li> </ul>  | <ul style="list-style-type: none"> <li>• All items on drawing have been identified</li> <li>• Results available of all ballooned items</li> <li>• Product used for dimensional analysis</li> </ul>   |
| <b>Material &amp; Performance Test Results</b> | Tests results for all material and performance testing required by the design record   | <ul style="list-style-type: none"> <li>• Design record that defines material and performance tests</li> <li>• Equipment required to perform tests or an outside laboratory identified</li> <li>• Product from full production setting</li> </ul>                           | <ul style="list-style-type: none"> <li>• Completed reports for material and performance tests results</li> </ul>             | <ul style="list-style-type: none"> <li>• Tests results that show conformance for all required material and performance tests</li> <li>• Qualified laboratory documentation for internal or external laboratories</li> </ul>  |
| <b>Initial Process Studies</b>                 | <b>Statistical studies that demonstrate capability for, at a minimum, all Key Characteristics. In addition, demonstrated capability for items in the control plan where the control method is SPC.</b> | <ul style="list-style-type: none"> <li>• <b>Control Plan</b></li> <li>• <b>Key Characteristics</b></li> <li>• <b>Significant production run so that all causes of variation can impact the process</b></li> <li>• <b>Product from a full production setting</b></li> </ul> | <ul style="list-style-type: none"> <li>• <b>Cp, Cpk, Pp, Ppk, Control Charts provided for Key Characteristics</b></li> </ul> | <ul style="list-style-type: none"> <li>• <b>Is the process in Control?</b></li> <li>• <b>Control charts X-bar, R</b></li> <li>• <b>Cpk and Ppk close values</b></li> <li>• <b>Not stable, look at Ppk, Pp (history)</b></li> <li>• <b>Not stable, What actions are being taken to control the process</b></li> <li>• <b>Not Centered, Cp (≠) (not equal) Cpk, What actions are being taken to center the process.</b></li> </ul> |

**Qualified Laboratory**

For an internal laboratory, there must be a laboratory manual and scope. For an external laboratory, evidence of laboratory certification to a customer accepted standard and a copy of the scope.

- Any customer laboratory requirements
- Approved supplier list
- Evidence that external lab is certified to conduct requested inspections and tests
- Review the certificate and scope for external laboratories
- Review laboratory manual and scope for an internal laboratory

**Appearance Approval**

Evidence that a product with customer defined appearance requirements meets those appearance requirements

- Portion of the design record that defines appearance approval requirements
- Product from a full production setting
- Completed appearance approval report
- When color is part of the requirements, is there proper control of color standards and correct lighting for evaluation

**Sample Product**

Supply sample product to customer when required

- Customer requirements
- Product from a full production setting

**Master Sample**

A master sample is retained by the supplier when required by the customer

- One piece that was used for full dimensional layout
- One piece identified as the master sample and retained in a manner to properly protect the part

### Checking Aids

Any part specific assembly or component level inspection or testing equipment

- Customer requirements
- Fixtures or gages designed and made for part specific requirement

### Customer Specific Requirements

Any additional PPAP specific customer requirements

### Part Submission Warrant

A legal form that is completed once all PPAP items have been completed. It is the warrant to the customer and is signed by a responsible official of the organization

- All required PPAP items
- When a submission is required
  - New part or product
  - Correct a discrepancy
  - Engineering change
  - New process technology
  - Use of different construction or material
  - New or modified tools or equipment
  - Different plant site
  - Changed suppliers
  - Inactive tooling
  - Product and process changes
  - New inspection or test methods
- Completed Part Submission Warrant
- All information on form is correct
- Organization has followed the “When submission is required” items



# Breakout Exercise 2

## Review of PPAP document

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# Breakout Exercise 2: Review the PPAP documentation

## Handouts

- Drawing of ABC company

## Instructions

- Drawing has been revised to “B” level. Change content – Height changed from 20mm from 18mm with same tolerance.
- List the documents which requires modification
- List the reason for change

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# Chapter 4: Assessing a PPAP Package – What We Covered

## Learning Objectives

You should now be able to:

- Assess a PPAP package to determine if it is acceptable

## Chapter Agenda

- Verifying the Initial Production Run
- Assess Overall Completeness

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# DISCUSSION

As time allows, the instructor will review answers.



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*Thank You!*

*Questions?*



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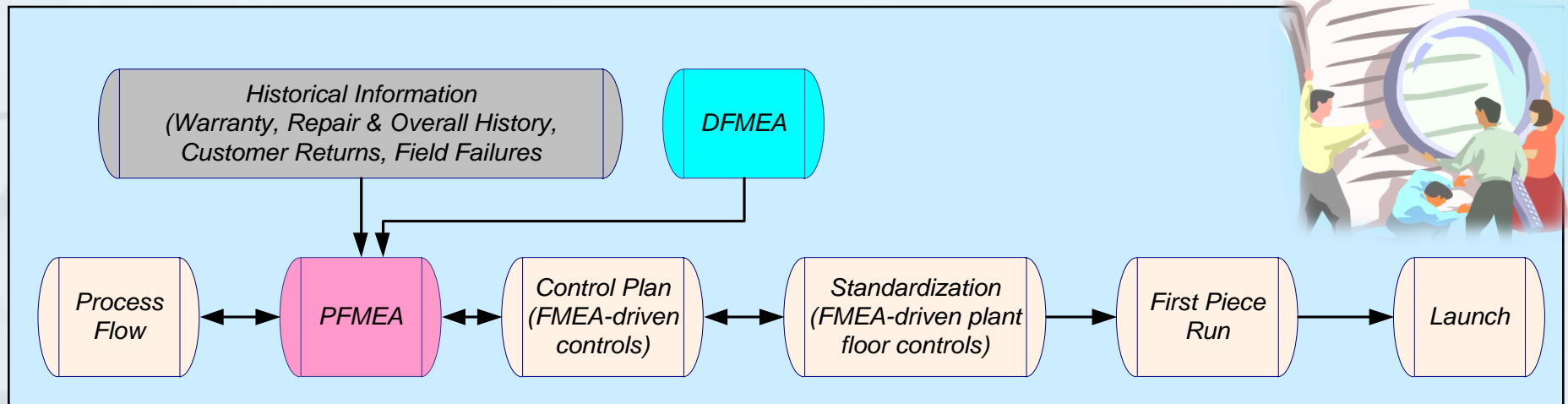
# Appendix

## Process Readiness Assessment

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# Process Readiness Assessment



- Use historical data on variation and NCs to focus assessment
- Examine and verify alignment:  
**PF → PFMEA → CP → WI → PPAP**
- Verify flow down of critical characteristics
- Assess standardized work
- Determine process capability
- Resolve process feasibility issues
- Verify instruction and training
- Confirm effective implementation of control strategy based on PFMEA

# The Readiness Assessment

## Implementation Assessment Checklist

| C Implemented |  |                                 |   |    |     |              |
|---------------|--|---------------------------------|---|----|-----|--------------|
|               | QUESTION:  | EVIDENCE REQUIRED               | LOOK FOR  | OK | N/C | OBSERVATIONS |
| 1             | Are controls in place to ensure only acceptable incoming material released for production?   | Receiving process               | <i>Incoming inspection data</i>                                       |    |     |              |
| 2             | Is the workplace properly configured and does it match the Process Flow Diagram?   | Process Flow Diagram & Process  | <i>Correlation between PFD &amp; actual process</i>                   |    |     |              |
| 3             | Are all tools and gages available and properly identified, calibrated and certified?   | gages / logs / certificates     | <i>ID on gages / calibration stickers / certificates, MSA Studies</i> |    |     |              |
| 4             | Are proper Work Instructions available for each operation? Are they sufficient to run the job properly, including handling of suspect & non-conforming part? Are boundary samples available to operators and in use? | Process & Operator Instructions | <i>Work Instructions available, Ask Operators, Boundary samples</i>   |    |     |              |
| 5             | Do all gages have operator instructions attached and clearly visible?  | gages & instructions            | <i>Instructions clearly posted &amp; operator knowledge</i>           |    |     |              |

# The Readiness Assessment

## Implementation Assessment Checklist

C Implemented

|    | QUESTION:   | EVIDENCE REQUIRED                              | LOOK FOR  | OK | N/C | OBSERVATIONS |
|----|---|--|---|----|-----|--------------|
| 6  | Do operators understand their instructions?   | instructions vs. operator performance          | <i>Ask the operators</i>  |    |     |              |
| 7  | Are operators actually performing as prescribed by their work instructions.                               | Operator instructions vs. operator performance | <i>Observe the operators</i>  |    |     |              |
| 8  | Is it possible to process the part in a fashion other than what is outlined in the quality documentation? | error proofing / Mistake Proofing              | <i>Possibility for use of wrong material, installed in process upside down.</i> |    |     |              |
| 9  | Do personnel responsible for quality have authority to stop production to correct quality problems?       | Process control documentation                  | <i>Ask the operators</i>  |    |     |              |
| 10 | Is there a plan for preventive maintenance on tools and equipment and is it followed?                     | Procedures / PM schedules / Maintenance logs   | <i>Maintenance records / Ask production staff</i>                               |    |     |              |
| 11 | Are described tests and inspections actually performed as stated? Do they detect bad parts?               | Process control documentation & records        | <i>Talk with Operators, review inspection records</i>                           |    |     |              |



# The Readiness Assessment

## Implementation Assessment Checklist

| C Implemented |   |   |  |    |     |              |
|---------------|---|---|--|----|-----|--------------|
|               | QUESTION:   | EVIDENCE REQUIRED                           | LOOK FOR   | OK | N/C | OBSERVATIONS |
| 12            | Are records maintained?   | Records                                     | <i>accuracy, current</i>                         |    |     |              |
| 13            | Are operators aware of Special Characteristics?   | Process control documentation               | <i>Ask the operators</i>                         |    |     |              |
| 14            | Are operators aware of Customer Complaints?   | Posted information, communications          | <i>Ask the operators</i>                         |    |     |              |
| 15            | Is there evidence of training and assessment of competency?   | Training matrix, records                    | <i>assessment method, results, ask operators</i> |    |     |              |
| 16            | Are scrap rates or other process metrics excessive?   | Process metrics                             | <i>posted, communicated</i>                      |    |     |              |
| 17            | Are there actions in place to correct unacceptable process metrics, RNC's?  | Action Plans                                | <i>results</i>                                   |    |     |              |
| 18            | Where the Control Plan calls for SPC is the data properly recorded? Does the data make sense and are reasonable control limits shown? | Process control documentation & SPC records | <i>Look at SPC records</i>                       |    |     |              |



# The Readiness Assessment

## Implementation Assessment Checklist

C Implemented

|    | QUESTION:   | EVIDENCE REQUIRED                              | LOOK FOR   | OK | N/C | OBSERVATIONS |
|----|---|--|--|----|-----|--------------|
| 19 | Are out of control points noted with the corrective action taken?                         | Procedures & SPC records                       | <i>SPC records &amp; corrective action log</i>     |    |     |              |
| 20 | Does the process demonstrate the required capability (Cpk)?                               | SPC & process control documentation            | <i>SPC records &amp; capability studies</i>        |    |     |              |
| 21 | Is Product status clearly identified  | material control procedures, tagging           | <i>product identification</i>                      |    |     |              |
| 22 | Is non-conforming product identified and controlled                                       | control of nonconforming product procedure     | <i>product control</i>                             |    |     |              |
| 23 | Does packaging and material handling protect parts from damage?                           | Packaging Instructions                         | <i>Review packaging &amp; Customer concern log</i> |    |     |              |
| 24 | What error-proofing is in place to ensure proper labels are placed on the part/packaging? | Process control documents & label instructions | <i>Label related Customer issues</i>               |    |     |              |

# The Readiness Assessment

## Implementation Assessment Checklist

| C Implemented |   |   |  |    |     |              |
|---------------|---|---|--|----|-----|--------------|
|               | QUESTION:   | EVIDENCE REQUIRED                               | LOOK FOR   | OK | N/C | OBSERVATIONS |
| 25            | Are customer commitments : In place? Are they effective? Are they part of the standard process? | Responses to customer issues                    | <i>Updated quality documents and verification of implementation.</i> |    |     |              |
| 26            | Is the process run @ quoted rate.   | line output.                                    | <i>Timing line output.<br/>Run at rate data.</i>                     |    |     |              |
| 27            | Do your work instructions support 8D and other corrective action items?                         | 8D's, Customer Concerns/ICA's                   | <i>Assigned containment and process related changes</i>              |    |     |              |
| 28            | Is the area maintained in a state of order and cleanliness?                                     | 5S program, housekeeping guidelines, procedures | <i>a place for everything and everything in its place</i>            |    |     |              |