SUMMARY

These guidelines define the principles of APQP including the founding elements (the team, the timing and the support required), the core constituent items and the supporting documentation.

The APQP model described into this document is covering both internal developments and production and sub-contracted Ones additionally, this document explains how to define the best adapted model for each site. Division and Business Units and how to deploy it for one programme.

1. CONTENTS

FOREWORD

a) The company's quality vision will move from reactive firefighting to proactive improvement and prevention.

b) Our company recognizes that the Aerospace industry is different from other industries and is developing an **Advanced Product Quality Planning (APQP)** aerospace standard which is tailored to suit its specific needs:
   - Low volumes
   - Long life cycles
   - High levels of regulation

c) Compliance to these guidelines will provide the following benefits:
   - Reduced complexity at the time of developing the quality plan for all products for any programme.
   - Thoroughly detailed communication reports and paths intended to provide early warnings about programme status at all levels, including the Extended Enterprise.
   - Planning upfront to satisfy the customer expectations and deliver products on-quality, on-time and on-cost.
   - Increased confidence in capturing the customer requirements at the launch of the programme.
   - Clearly identify any deviations as early as possible in the programme to avoid last minute changes associated traditionally with the learning curve on new programmes.
   - Focus on programme status rather than managing tools definition and reporting.
   - Drive continuous improvement by providing a structured frame to analyse the lessons learned from one programme to the next.

d) APQP drives the deployment of the Quality Core Tools as they are all included into the APQP models. The APQP model provides a holistic view of the product development cycle; to be able to run the APQP methodology effectively it is necessary to concentrate on the related Work Packages of a Programme/Project that deliver a physical product.

e) The intent of APQP is not to replace the Product Development Process (PDP), but to complement PDP and enforce it. APQP could be fully embedded in the related programme / project Quality Plan, depending on the business needs.

f) APQP implementation will drive continuous improvement of company business processes by calling for quality core tools and pushing company processes to highlight the most important activities for delivering a product on-quality, on-time, on-cost.

g) In the perspective of Supply Chain the Cost of Non-Quality (CNQ) in our company will be reduced and supplier's product delivery quality will be improved by:
   - Enabling a shift from correction to prevention;
   - Implementing Supply Chain Quality Management industry best practice processes and tools.

h) These company Guidelines has been developed within the frame of **QUEST project**.

i) The company **Business Improvement & Quality** is in charge of the approval, release and integration within the Company Management System (CMS), checking consistency with other company Policies and Guidelines.

1. SCOPE OF THE DOCUMENT

a) These company Guidelines for Advanced Product Quality Planning are defined to ensure that:
- Our company is complying with the recommended IAQG best practices described into the Supply Chain Management Handbook (SCMH).
- Our company will comply to the next edition of the EN 9100 – 2017 edition and to the specific upcoming standard for APQP due in 2017.
- All company business units are able to define and deploy APQP in a standardized manner and will benefit of the knowledge in this topic in order to gain the maximum efficiency into the deployment process.

b) The APQP model to be applied in all company Divisions is described within this document. The intent is to provide a unique, fully replicable, standard model that can be applied through the Work Breakdown Structure (WBS) of the Programme/Project and to any Work Package (WP) regardless of its product development layer level (component, subcomponent, element) neither its domain (Structure, Systems…).

c) APQP could be fully embedded in the related programme / project Quality Plan, depending on the business needs.

d) This document does not define:
- The specific tools and documents specific to each Division/Business Unit such as the key deliverables used to monitor APQP elements.
- The definition and deployment scope and related roll out for each company Division/Business Unit.

2. APPLICABILITY OF THE DOCUMENT

a) These company guidelines apply to all company Divisions/Business Units.
b) Whilst the principles of this document are mandatory, its application in each Division will be tailored to meet the specific needs of the related business. For each constituent item of the APQP standard, this document will highlight what has to be implemented as is and what can be tailored.
c) Each company Division/Business Unit will have to define on which Programme/Project and related products and/or perimeter APQP applies. Each Division/Business Unit shall adapt APQP depending on its business and Critical to Quality (CTQ) deliverables.
d) The APQP model:
   1. Applies to hardware product (physical product) but does not apply to software. For software products APQP is covered by specific software development standards defined by the business. Integration needs are covered by the next higher system level where APQP shall apply.
   2. Can be deployed for new programme, modifications in legacy programmes, new supplier contracts or amendments.
   3. Can be applied on product when:
      - There is a new design or design modification;
      - There is a new process or a process modification.

3. REFERENCE DOCUMENTS AND ABBREVIATIONS

3.1 APPLICABLE DOCUMENTS

None.

3.2 REFERENCE DOCUMENTS

The publications listed below were used in the preparation of this document, and contain background information related to the subjects addressed:

[R1] Quality Policy
[R2] Supply Chain Handbook

3.3 DEFINITIONS AND ABBREVIATIONS

3.3.1 DEFINITIONS

For the purposes of this document, the following definitions apply.

Advanced Product Quality Planning
A process to assure that new and modified products satisfy customer needs and wants. This is accomplished by executing the necessary steps at the appropriate time throughout the product lifecycle.

Note: The project management approach of APQP provides effective early warning signals to drive on-time and on-quality delivery of products by monitoring key deliverables Critical to Quality (CTQ). Its success relies on a cross functional approach, avoiding functional silos that often propagate miscommunications. APQP drives a proactive and preventative mind-set.

Customer
Refers to the customer of the product delivered by the organization. It can be internal customer or external ones.

Supplier
Refers to the supplier of the product delivered to the organization. It can be internal suppliers or external ones.

Statement of Work
Contractual document prepared during project initiation and planning that describes what the project shall deliver and outlines all work required to complete the project (Adapted from ISO 10795:2011, 1.216).

Note: in this document it is considered that SOW contains the work breakdown structure, the product breakdown structure, the organization breakdown structure, resource breakdown structure (depending on the organization this information may be contained into other documents) and the project key objectives. When SOW is not containing the above, please replace SOW by the listed information set.

3.3.2 ABBREVIATIONS

The following abbreviations are used in this document:

- APQP Advanced Product Quality Planning
- CTI Critical Items
- CTQ Critical to Quality
- FAI First Article Inspection
- FMEA Failure Mode Effects Analysis
- GRAMS General Requirements for Aerostructure and Material Suppliers
- GRESS General Requirements for Equipment and System Suppliers
- IAQG International Aerospace Quality
- KC Key Characteristic
- PBS Product Breakdown Structure
- PDP Product Development Plan
- QMS Quality Management System
- QPT Quality Plan Timing
- WBS Work Breakdown Structure
- WP Work Package

4. APQP FUNDAMENTALS

4.1 PURPOSE OF APQP AND DEFINITON

a. APQP is a structured method which ensures the necessary steps are taken to assure that new products satisfy customer needs and wants and Divisions/Business Units standards.

b. APQP, as part of project management, provides effective early warning to support on-quality and on- time and delivery of the product by monitoring key deliverables critical to quality (CTQ).

c. APQP drives a cross functional approach to product development avoiding the creation of functional silos, and it drives a proactive and preventative mind-set.

d. APQP is not only about implementing the quality core tools (elements such as FMEA, Control Plan, KC…), as described in **Figure 1** APQP consist of planning activities, implementing them and continuously monitoring them to ensure their on-quality and on-time delivery.

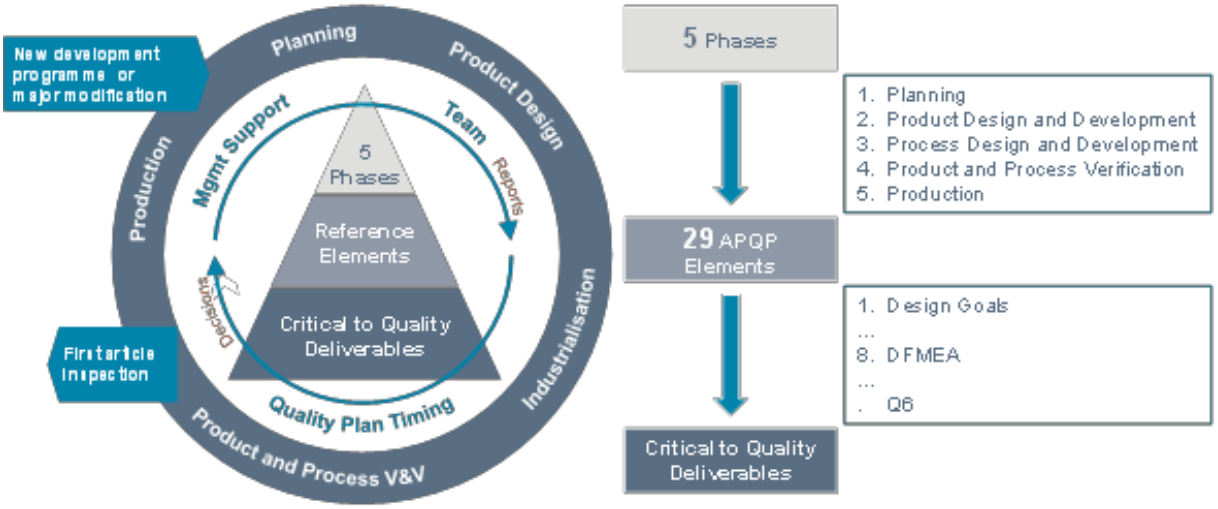


Figure 1: Advanced Product Quality Planning

4.2 APQP AND THE QUALITY CORE TOOLS

a) APQP drives the deployment of the Quality Core Tools as they are elements of the APQP models (Make and Buy).
b) However APQP is not limited to the monitoring of the Quality Core tools: in each of the **five APQP phases** key deliverables are defined to monitor product lifecycle processes/activities like project execution, engineering, process engineering, procurement, production and delivery activities. The goal is to provide a global view of what has been done and what are the issues to resolve in order to deliver the product on-time and at the required level of quality.
c) Development and production APQP activities are part of the Product Development and Production Quality System as presented in **Figure 2** and in our company's Quality Policy [R1].

Note: APQP should be extended to the whole product lifecycle.

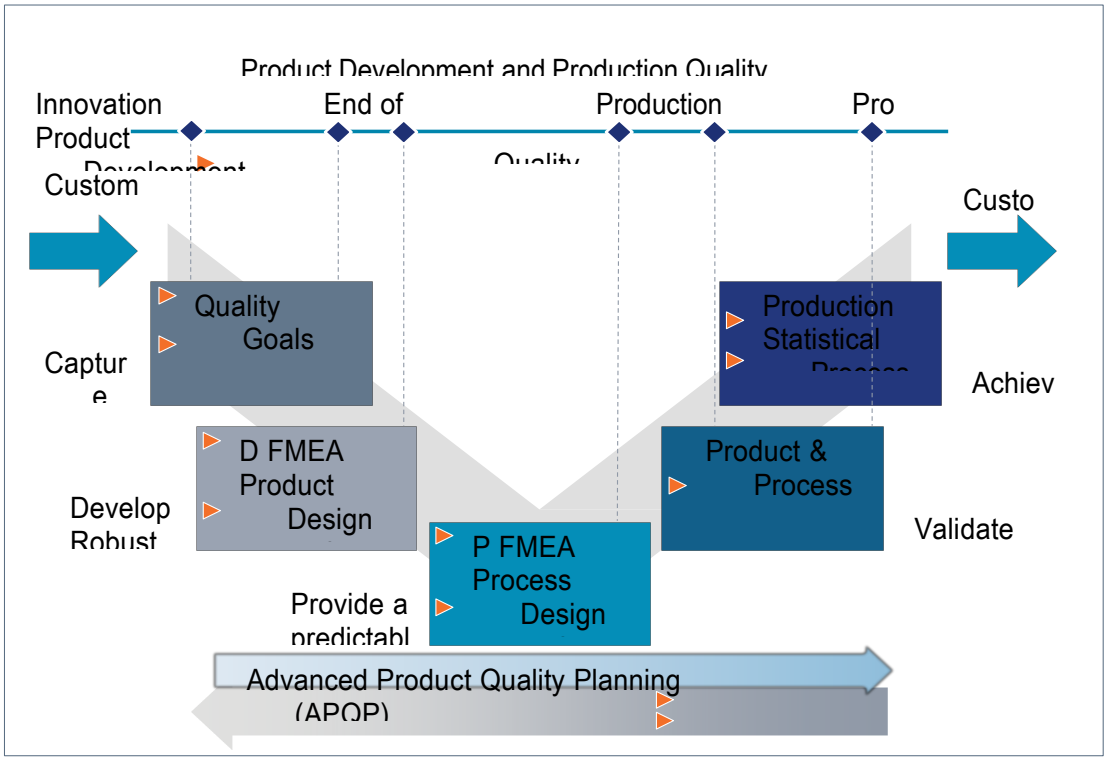


Figure 2: APQP in Product Development and Production Quality System

5. APQP STRUCTURE AND COMPANY MODEL

5.1 APQP MAIN PILLARS

5.1.1 ORGANIZATIONAL COMMITMENT AND MANAGEMENT

a) Each company Division must get full engagement and commitment of Top management (Head of Programmes, Head of Quality) from project launch.
b) Top management demonstrates commitment through:
- Completing specific APQP awarenesses
- Allocating appropriate resources;
- Leading periodic reviews and steering committees;
- Standardizing APQP practices;
- Removing roadblocks.

c) Each company Division/Business Unit shall implement an effective APQP reporting infrastructure in order to support management decisions.

5.2 MULTI FUNCTIONAL TEAMS

a) The company Division/Business Unit shall establish a multi-functional team to support each project. It consists of representatives all domains including: Programme, Engineering, Procurement, Manufacturing, Quality, Sales, Field Service, and suppliers when applicable.

b) APQP defines 3 roles in the team:
- WP leader (project management function) who determines the team membership, guides, assigns tasks, reports progresses and escalates issues to management;
- Deliverable owners who complete the required tasks and deliverables (internal or suppliers);
- The APQP leader who plans the assessments meetings, ensures on-time and on-quality of deliverables, documents and records.

c) For each Programme/Project, company Division/Business Unit shall formally nominate the team members, assign them a clear role, and cascade clear target dates to reach programme goals.

5.3 QUALITY PLAN TIMING

a) Each company Division/Business Unit shall create for each product an APQP Quality Plan Timing to schedule the key tasks to be accomplished and monitored in order to deliver a product conforming to quality, cost and delivery targets. The requirements to define and set up this Quality Plan Timing will depend on the related business.

b) The APQP Quality Plan Timing cascades programme/project key targets throughout the value stream; driven from final customer through internal operations and all sub-tiers.

c) It should contain:
- The customer key dates;
- The programme/project key dates including a final product delivery date;
- The scheduling of the APQP elements and deliverables with a clear beginning date and end date;
- The key dates to be cascaded to all the suppliers of the product sub-components.

Note: the product delivery date should be understood as the date when the product is ready for final customer acceptance (when applicable, this includes that the manufacturing process used for full production is in place and capable to produce at the required production rate).

d) The Quality Plan timing establishes a customer/supplier relationship throughout the value stream and should be understood as the base for their commitment.

5.4 APQP PHASES

APQP is composed of five phases as described in **Figure 3**. There are the logical steps from concept to production that any project should follow to deliver a product. Their time schedule should reflects concurrent engineering approach.

Figure 3: APQP phases

5.4.1 PLANNING

PHASE Activities:

- Collects all the technical and non-technical requirements applicable to the project/product;
- Defines the product and project quality goals;
- Ensures that the organization has decided what will be made in house and what will be purchased;
- Provides an agreed Quality Plan Timing for deliverables attached to each APQP element.

Outputs:

- The product concept is frozen and a pre-design is available; Concurrent product design and process design can start.

5.4.2 PRODUCT DESIGN & DEVELOPMENT Activities:

- Turns product specifications into a robust product definition;
- Provides a validated and verified product design;
- Team review and agree that the product can be manufactured and tested.

Outputs:

- Specified prototype testing (e.g. simulation & functional testing) have been completed;
- The product design is verified and validated by the design organization. Note: Any design changes after this phase requires change management.

5.4.3 PROCESS DESIGN & DEVELOPMENT Activities:

- Creates a robust manufacturing system that meets requirements in terms of quantity and quality of product;
- Defines the means to control the manufacturing system and its outputs.

Outputs:

- The process is ready for final verification;
- A production readiness review is conducted prior to initiating the significant production run.

5.4.4 PRODUCT & PROCESS VERIFICATION Activities:

- Launches the significant production run
- Performs the First Article Inspection (FAI)
- Collects data to demonstrate the manufacturing, test and assembly processes can produce conforming product
- at the required rate
- Management determines process readiness for entry into serial production by reviewing the results of:
    - Production readiness evaluation
    - Corrective actions taken for any issues identified to date

Outputs:

- Product made using all full production means conforms to all specified requirements
- FAI report is compiled and submitted to the customer

5.4.5 PRODUCTION Activities:

- Records Lessons Learned for continuous improvement
- Ensures robust product realization processes are in place
- Implements actions to reduce product and process variation

Outputs:

- Improved customer satisfaction
- On-time, on-quality, on-cost production and service

5.5 APQP ELEMENTS

a) Each company Division/Business Unit should confirm the key activities to be accomplished for each APQP phase. See **Annex 1** providing typical APQP element descriptions.
b) Key activities should be understood as the one which are sufficient to be monitored in order to guarantee the programme/project health.
c) The company's encourages a standardized approach by defining single sets of elements.
d) For each programme/project the applicability of the element of the model will have to be evaluated.
e) A standard model (29 elements) is defined in 2 parts:
   - Make part (22 common and 7 exclusively make)
   - Buy part (22 common and 7 exclusively buy).

Both are composed of 29 Elements as described in **Figure 4**. Each element is described into a dedicated id card (refer to **Annex 1**)

APQP	For MAKE	For BUY
Planning	**1.** Design Goals **2.** Quality Goals **3.** WP identification Make or Buy Decision **4.** Process flow Preliminary infos **5.** Critical items Preliminary infos **6.** Quality Plan Timing	**1.** Sourcing Decision **2.** Requirement transfer to suppliers **3.** Quality goals **4.** Requirement confirmation **5.** Quality Plan Timing **6.** Sub-Tier Supplier Selection
Product Design & Development	**7.** Engineering information **8.** Design Failure Mode and Effect Analysis **9.** Design critical items and Key Characteristics **10.** Design Validation and Verification (V&V **11.** Feasibility commitment	**7.** Engineering information **8.** Design Failure Mode and Effect Analysis **9.** Design critical items and Key Characteristics **10.** Design Validation and Verification (V&V) **11.** Sample Part Provision **12.** Feasibility commitment
Process Design & Development	**12.** Manufacturing process flow **13.** Plant lay out **14.** Process Failure Mode and Effects Analysis **15.** Process critical items and Key Characteristics **16.** Manufacturing & test equipment, tools, fixtures & jigs specified **17.** Development control plan **18.** Measurement System Analysis plan **19.** SOI/routings **20.** Prebuilt assessment (action plan) **21.** Management review (Production readiness)	**13.** Manufacturing process flow **14.** Plant lay out **15.** Process Failure Mode and Effects Analysis **16.** Process critical items and Key Characteristics **17.** Manufacturing & test equipment, tools, fixtures & jigs specified **18.** Development control plan **19.** Measurement system analysis plan **20.** SOI/routings **21.** Production readiness
Product & Process Verification	**22.** Measurement System Analysis **23.** Final Critical items/KC Product and process **24.** Production control plan **25.** First production run **26.** First Article Inspection	**22.** Measurement System Analysis **23.** Final Critical items/KC Product and process **24.** Production control plan **25.** First production run **26.** First Article Inspection
Production	**27.** Statistical Process Control **28.** Process capability indexes **29.** Q6(loops/PPS/KPIs/Standardize/Competence/Field Management)	**27.** Statistical Process Control **28.** Process capability indexes **29.** Root cause analysis

Figure 4: Advanced Product Quality Planning (APQP) Elements

5.6 CRITICAL TO QUALITY - CTQ

a) These are the key deliverables used to monitor the activities defined by the APQP element. These deliverables will be referenced as Critical To Quality (CTQ).
b) For each element, the Division/Business Unit shall define the set of deliverables they want to monitor. This set will become the base content of the APQP model.
c) These deliverables are selected by the expert of each related processes and should provide means to detect the main potential concerns/risks of each process.
d) For one project, each applicable CTQ deliverable will be assessed in a continuous manner, all along their completion (not only at delivery time). This allows the early warning to be efficient.
e) In order to do this assessment each Division/Business Unit shall build a checklist in order to check the adequacy of the deliverable to the expectations/requirements set to it.
f) For creating the checklists the process expert will review the deliverable and by applying his/her knowledge on the matter, will assess its quality. The knowledge application can be summarized into a set of certain parameters, or questions that the expert will seek to be answered during his/her review of the deliverable. By capturing this set of parameters into a checklist we achieve the following:
    - The release of the expert to perform other tasks, but without giving up on their assessment as they are captured in the checklist.
    - Enabling the application of expertise by a broader team of people who can be easily trained to apply the checklist; without the associated cost and time that requires bringing somebody to an expert level.

Note: As an example, a CTQ Checklist template is provided in **Annex 2**.

5.7 RED, AMBER, GREEN (RAG) RATING

a) The RAG status applies at work package level delivering products and is established for each CTQ deliverable applicable to the WP.
b) As mentioned, when describing the main founding elements of APQP, Management Support & Early Warning become a cornerstone. Hence, it is key to develop a reporting system that is simple, streamlined, clear and meaningful in an effort to provide Management with the right level of information to assess issues and take effective decisions.
c) The goal of the RAG rating is to communicate the same meaning for everyone involved without the need for additional explanations to interpret it.
d) The RAG rating looks into two key aspects of the deliverables:
    - Quality: The deliverable meets the quality criteria as described in the CTQ checklist.
    - Time: The deliverable is in accordance with the WP timing targets.
    - It is noted that both aspects are clearly interrelated (quality concerns if not properly managed will drive to a timing concern).
e) The RAG status should be established during CTQ assessments for each question. The APQP manager establishes the RAG status at CTQ level, element level and product level by compiling the base information considering worse case. It is finally agreed and reported to the customer by the work package leader.
f) The RAG rating principle should be as follows:
    - Red: Whenever a question cannot be answered with a clear yes, the deliverable owner should provide an action to recover on-time and on-quality. When an action plan cannot be provided or is not able to recover initial product timing, a red status should be raised: IMPACT TO THE FINAL WP PRODUCT DELIVERY SCHEDULE.
    - Yellow: Yellows are highlighted when the answer to the question is no, but there is a robust action plan to recover situation: THERE IS NO IMPACT TO THE WP PRODUCT DELIVERY SCHEDULE.
    - Green: All questions have a positive answer (Y) and are ongoing as planned.

6. APQP REPORTS

a) Each Division/Business Unit should implement a reporting method based on the quality assessment performed on each CTQ deliverable and their compilation for each product managed by APQP.
b) The reporting principle should contain the following levels:

1. CTQ level: CTQ checklist

They are used to check the on-quality of the deliverables associated to the APQP elements by the APQP leader and the Deliverable Owner. The evidences presented at the time of assessing the various criteria (questions) are recorded as well as the actions, along with owner and timing, upon the detection of any deviations/risks.
The outcome is a RAG rating for one CTQ deliverable considering the worst case of each question RAG status and the on-time of the deliverable.

2. Element level: element rating checklist

RAG evaluations of the CTQ set related to one element provide the base for compilation into the APQP Element Rating Checklist. The compilation rule is to consider the worst case (one red CTQ deliverable will make the element status red).

3. Product level: Work Package Summary Sheet

It summarizes the information related to the WP, including the RAG rating for each of the elements as well as the rating for the sub-WP. It provides a view on which phase issues are arising, and which are the contributing elements.
Additionally a summary of lower sub-WP provides the view on how the enabling products are performing.
These reports are the first level of information used during Management reviews and are used to report out the WP RAG rating.

4. Final product layer: Work package summary sheet

The work package summary sheet is used at any layer. It gives both the visibility of what is happening for a given work package and the summarised status of each sub work packages (managed by APQP methodology). The final product WP summary sheet compiles the whole project status.
APQP reporting shall be integrated into the WP-Project & Division/Business Unit Management reporting system and is reviewed on a regular base by management. The typical frequency is one month. This frequency can be adapted considering risks and issues arising during the APQP time frame. An isolated APQP reporting will not add value.

6.1 APQP IMPLEMENTATION IN THE COMPANY DIVISIONS/BUSINESS UNITS

a) The implementation roll-out plan for APQP for both external and internal WP shall be conducted in logical sequence usually starting from the Make side and then Buy one. It is mandatory that APQP model stay consistent in both cases (for the *buy* and for the *make* WP).
b) Some APQP definition activities are common to 'APQP for *make* WP' & to 'APQP for *buy* WP'. These activities are clearly identified in the following sections.
c) The heart of the APQP roll out consists for each BU in adapting the cpmpany's APQP model to the specific requirements of the related business. It will be done through:
   - Checking applicability of APQP Elements from the APQP company Model (Make & Buy).
   - Identification of potential APQP Elements missing from the APQP company Model (Make & Buy)
   - Definition of the APQP Element missing according to business specificities.
   - Identification of the CTQ deliverables for each applicable APQP element.
   - Definition of the CTQ checklists for each of the deliverables.
d) APQP requirements integration in the Divisional Quality Management system, Statement Of Work and contracts for suppliers is an important part of the implementation and success of the deployment, it shall be aligned with the overall roll out plan.

6.2 PROJECT ORGANIZATION FOR APQP IMPLEMENTATION

a) APQP implementation within company Divisions/Business units consists in an important change in the way to monitor the product development. It will impact the whole Multi-functional team members as well as the supplier in case of *buy* Work Package.

b) To succeed in implementing APQP, the implementation should be considered as a project itself. As any project it should be supported by management, scope & objectives and planning should be clear and agreed by all key stakeholders. In the different company Business units, a team should be nominated in order to define APQP models. In order to support the implementation phase, it is recommended to set up APQP steering committee with all the stakeholders.

c) The team should be composed of representatives from different departments including Programmes, Procurement, Quality, Engineering, and Manufacturing Engineering.

d) The steering committee should be made of representative from the same departments with Management representatives from the highest level. This is a best practice that was identified within company commercial A/C during initial APQP implementation.

e) The planning for APQP implementation will be specific for the different company Business units.

Note: The target date for the first APQP deployment should match with a new development programme or a major modification (product or process) in legacy programme.

6.3 IDENTIFY POTENTIAL MISSING ELEMENTS FOR THE SPECIFIC APQP BUSINESS UNIT MODEL

a) The APQP company model is made of 29 elements common for all Business units (See **section 5.3**). In order to adapt this standard to the specific requirements of the business, each of the Business units will have to ensure these 29 elements cover all the activities performed in the frame of an internally built or a supplied product.
b) During the implementation phase, company APQP Elements should be fine-tuned by each Business Unit to tailor the APQP model to their business.
c) When APQP is deployed on a specific product (Make or Buy), it is the responsibility of the multi- functional team during the kick off meeting to agree on the APQP elements and CTQ deliverables to be monitored from the APQP Business Unit model.
d) The selection of the Elements and CTQs should be driven by:
   - WP criticality;
   - Serial VS. Project-oriented;
   - Trigger for APQP (NPI, Major Modification (change in Design), Transfer of work (change of supplier), Re-industrialization (new plant, re-start of a production line).

6.4 CTQ DELIVERABLES IDENTIFICATION WITH PROCESS EXPERTS

a) Critical to Quality (CTQ) are the key deliverables used to monitor the activities defined by the APQP element.
b) These CTQ deliverables are generic: for one given element and for one given family of Work Package, the CTQ deliverables (there may be one or more per element) will be always the same regardless of the product level into the product breakdown structure. This will ensure a standardized report for the programme.
c) The CTQ deliverables shall be defined by each company Business unit in order to fit with their product specific requirements and their processes.
d) As the CTQ deliverables will be used to monitor the on-quality, on-time (cf. CTQ Assessment meeting) and on-cost (as a consequence).
e) Identification of CTQ has to be done by the Business and Process Experts.

Phase	Elements	Responsible for defining associated CTQ
Planning	01.Sourcing Decision	Supply Chain
	02.Requirement transfer to suppliers	Engineering
	03.Quality Goals	Engineering
	04.Requirement confirmation	Engineering
	05.Quality Plan Timing	Quality
	06.Sub tier Supplier Selection	Supply Chain
Product Design & Development	07.Engineering Info (DMU, BOM, 2D Dwgs, ECN…)	Engineering
	08.DFMEA	Engineering
	09.Design Critical Items (KCs)	Engineering
	10.Design Verification (V&V)	Engineering
	11.Sample Part Provision	Engineering
	12.Feasibility Commitment	Engineering
Process Design & Development	13.Manufacturing Process Flow	Manufacturing / ME
	14.Plant Lay Out (Facilities)	Manufacturing / ME
	15.PFMEA	Manufacturing / ME
	16.Process Critical Items / KC	Manufacturing / ME
	17.Manufacturing & Test Equipment, Tools, Fixturing & Jigs	Manufacturing / ME
	18.Control Plan (Preproduction)	Manufacturing / ME / Q
	19.MSA Plan	Quality / ME
	20.Manufacturing Process SOIs / Routing	Manufacturing / ME
	21.Production Readiness (Industrial Process Control Assessment)	Supply Chain / Quality/ ME
Product Process Verification	22.MSA	Quality / ME
	23.Final Critical Items / KC Product & Process	Quality / ME
	24.Production Control Plan	Manufacturing / ME
	25.First Production Run	Quality / ME
	26.FAI	Quality / ME
Serial Production	27.SPC	Quality / ME
	28.Cp / Cpk (Process Capability Indexes)	Quality / ME
	29.Root Cause Analysis	Engineering / Quality / ME

Note: There may be several set of CTQ deliverables depending on the type of the Work Package (Internal Parts, Systems & Equipment, Structure, propulsion Systems …), this has to be determined during the APQP Business Unit models definition.

f) In case of deployment to suppliers CTQ deliverable owners shall be nominated for all CTQs identified as relevant for the WP. CTQ deliverable owners may be on Customer or on Supplier side and may be from different business organizations. Finally it will under the responsibility of the multi-functional team to agree on the CTQ deliverables / elements responsibilities for the product they are responsible for.

6.5 CTQ CHECKLISTS DEFINITION WITH PROCESS EXPERTS

a) In order to assess the maturity of the CTQ deliverables, a set of question has to be answered during the CTQ assessment meetings. In order to support this assessment and to implement standardized methods through each Business Unit, CTQ checklists shall be defined for each of the CTQ deliverable. (See **section 5.3**).
b) CTQ checklists have to be defined by the Business and Process Experts in charge of those deliverables.

Note: Questions inside the CTQ checklist shall be closed questions.

c) The CTQ checklists have to be produced in a standardized template in order to allow their aggregation to create the APQP report.

6.6 RUN PILOT CASE

An important step during APQP implementation consists of organizing pilot case(s). The objective is to collect operational feedbacks in order to:

- Assess efficiency of the APQP model and CTQ checklist created;
- Ensure that early warning detection using CTQ assessment is working and provide the expected results;
- Identify new CTQ deliverables;
- Refine, improve CTQ checklists;
- Adapt the APQP report.

Note: The pilots shall be aligned with the overall roll out plan and it is recommended to launch pilots internally on make parts before to launch pilot case with some suppliers.

6.7 APQP INTEGRATION IN THE QUALITY MANAGEMENT SYSTEM

Each of the company Divisionshall ensure that APQP is integrated in their Quality Management System with the relevant procedural documentation for the whole product lifecycle, this includes:

- APQP requirements are cascaded into Business unit processes.
- APQP is integrated into the Product Development Plan (PDP)

6.8 APQP INTEGRATED INTO THE PRODUCT DEVELOPMENT PLAN

a) The intent of APQP is not to replace the Product Development Process (PDP) but APQP to complement and enforce it (see **Figure 5**).

b) PDP follows a cross layers approach through the various review points. It describes the requirements to be met across the various product development layers for each review point (e.g.: For civil aircraft, synchronization points are called Maturity Gates - MGs). It follows the WBS / PBS top – down approach.

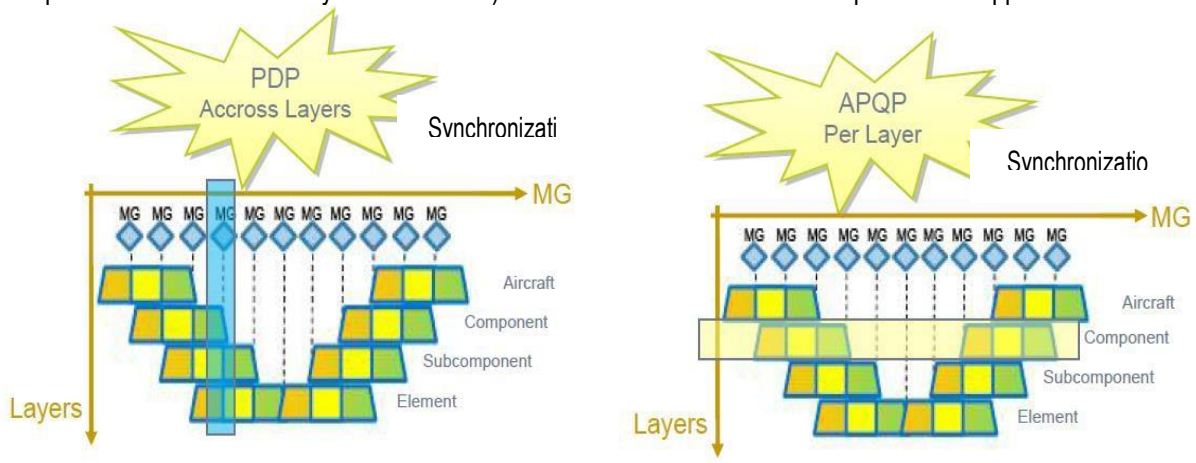


Figure 5: PDP & APQP Synchronization

c) APQP provides the means to assure, per layer and building block, that the product satisfies requirements. Its goal is to insure that for a specific product all steps are completed on time and on quality according Quality Plan Timing.

d) For each product layer, the APQP status will be reported at each PDP review in order to facilitate cross layer synchronisation.

e) This synchronisation has to be defined generally by the business Units and in detail in each project through the QPT.

6.9 CONSISTENCY BETWEEN PDP, BUSINESS PROCESSES AND APQP

APQP identifies a subset of key deliverables (CTQ) in order to assess the on-quality of the APQP elements. As described in the sketch bellow and in order to succeed for APQP deployment in the Business units, it's important to ensure as described in **Figure 6** that:

- APQP Elements and CTQ are integrated and part of the PDP;
- CTQ deliverables are the outcome of Business Processes.

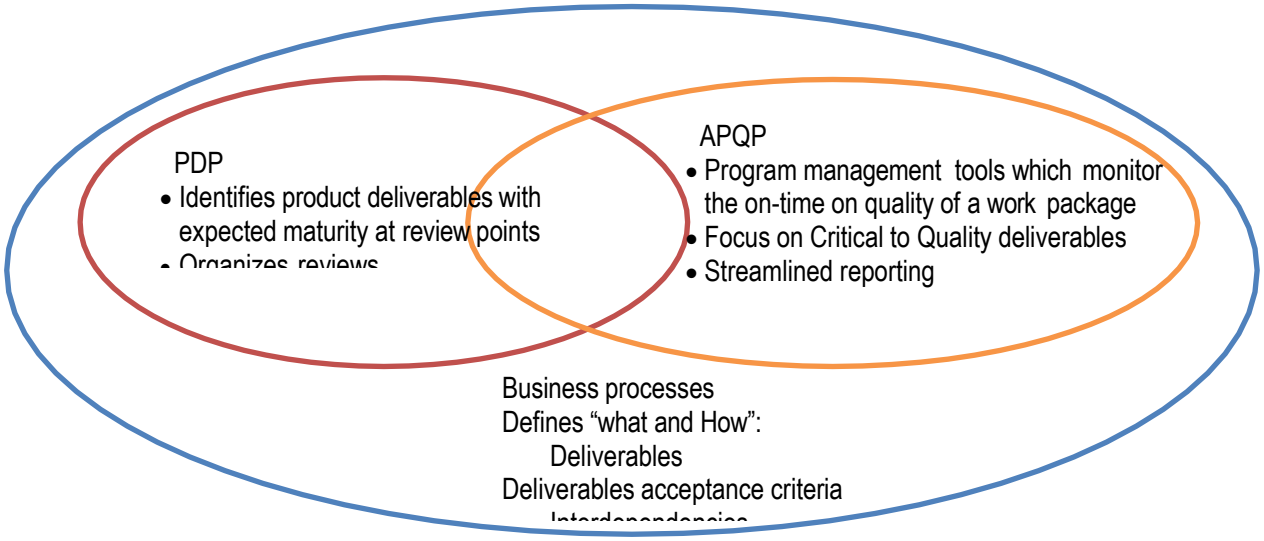


Figure 6: Consistency between PDP, Business Processes and APQP

6.10 APQP TRAINING CREATION

a) Business unit APQP experts should be trained on company level APQP model.
b) All company Divisions/Business units shall develop specific training according to their APQP Model.
c) APQP key actors when running the methodology shall have been trained. The training will have to bring two objectives regarding trainees:
   - Make them mastery with all APQP elements and CTQ deliverables;
   - Make them mastery with APQP as a methodology and process (use of specific APQP It tools, escalation process …).

Note: Training can be also developed and opened to suppliers.

6.11 INTEGRATE APQP REQUIREMENTS INTO SUPPLIER CONTRACTS

This activity is specific to implement APQP for "buy" Work packages: APQP Quality Plan Timing, Elements and CTQ deliverables within APQP Business Unit Model shall be flown down and deployed to the suppliers. This step is a complex one as some APQP elements and CTQ deliverables may be seen by suppliers as new requirements and as additional workload & costs. The more robust solution consists in adding all applicable APQP elements and CTQ deliverables on contract with suppliers.

Note 1: as an example, our company accomplished this through the creation of an amendment of GRAMS & GRESS (requirement contractually applicable to suppliers) where all APQP deliverables are listed. This new amendment is applicable for all new contracts.

Note 2: When all or some APQP elements are not on supplier contract, three levers can be used:
- present it to the supplier as a win-win approach (way to improve its efficiency);
- in case of bad performance, ask him to apply it as corrective action;
- intermediate situation with tough negotiations (e.g. case where something is already in place but not sufficient).

7. APQP IMPLEMENTATION ON ONE PRODUCT

This section of the APQP CDS is to provide details & best practices on steps to be followed in order to manage WP through APQP as described in **Figure 7**:

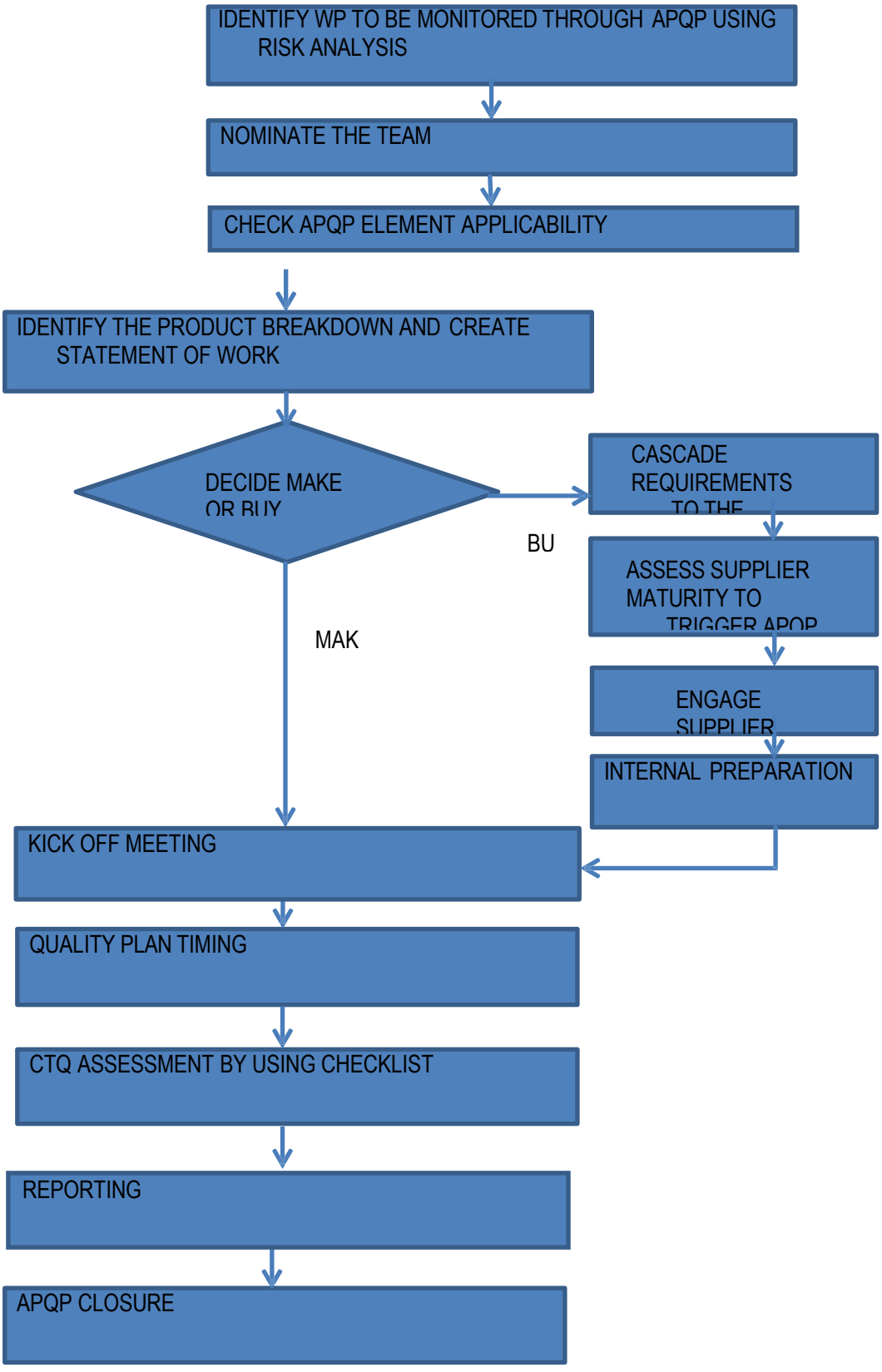


Figure 7: APQP Deployment steps

7

7.1 IDENTIFY WP TO BE MONITORED THROUGH APQP USING RISK ANALYSIS

a) APQP is applicable to manage all type of hardware products (no matter their complexity). It requires an increased monitoring effort; as a consequence each company Business units should define where to put this effort in agreement with customer requirements.
b) The APQP scope definition should be based on risk evaluated for each product.
c) An APQP risk analysis shall be performed for every WP/sub WP identified in the PBS/WBS, before project launch.
d) Head of Programme/Project Quality shall be accountable for the APQP risk analysis and ensure it is performed.

Note: The APQP risk analysis is performed involving all contributing functions in MFT (Engineering, Procurement for buy products, manufacturing engineering…). Based on the result of the risk analysis, the scope of APQP is agreed and recorded.

e) The APQP risk analysis shall consider at least the following items:
- Risks associated to the design;
- Risks associated to the Industrialization;
- Risks based on the Lessons Learned (on the supplier performance);
- Risk associated to the WP safety impacts.
- Other risk specific to the business unit such as customer risks, political.

7.2 NOMINATE THE TEAM

All project team members have to be formally identified. Their nomination should include their role inside the team. Main roles are project leader, deliverable owners, APQP leader.

- The team should consist of representatives from all stakeholders (including supplier in case of deployment to supplier and customer if contracted).
- An APQP leader expected to provide the support and expertize to the team in the application of the APQP methodology (e.g. perform CTQ assessment meetings). The APQP leader shall be independent from the WP Leader and the deliverable owner (see §7.5) to ensure an effective escalation process.
- WP leader is to provide the support and drumbeat within the WP team.
- Deliverable owners complete the required tasks and deliverables

7.3 CHECK APQP ELEMENT APPLICABILITY

a) Based on product specific attribute, some of the key activities may not be applicable (e.g.: design activities not applicable when only process is changed). For each APQP element and CTQ deliverables, the owner shall be identified and nominated. The identification of the work package APQP CTQ deliverables and associated owner shall be recorded and stored.
b) The APQP Critical to Quality (CTQ) deliverables monitoring efforts for the WP shall be established according to the risk analysis outcome.

Note 1: The level of monitoring can be increased and changed if any issues are detected during the APQP deployment.

7.4 IDENTIFY THE PRODUCT BREAKDOWN AND CREATE STATEMENT OF WORK

Break the final product down into manageable sub-components and formalize in a Statement of Work (SOW). For simple products, it may not be needed to break them down into sub-components.
The SOW also defines the key project milestones which are the input to create the Quality Plan Timing (QPT).

7.5 DECIDE MAKE OR BUY

In the planning phase, it has to be decided if the final product and the sub-components (if any) will be designed and made in-house or fully/partially subcontracted.

7.6 CASCADE REQUIREMENTS TO THE SUPPLIER

For each subcontracted product and sub-components, requirements have to be cascaded. Technical requirements are formalized in a specification and non-technical requirements (e.g.: APQP way of working, contracted quality requirements…) in a SOW. They are the base for customer/supplier agreement.

7.6.1 ASSESS SUPPLIER MATURITY TO TRIGGER APQP DEPLOYMENT

a) The gaps between supplier processes and the APQP expectations should be evaluated. This assessment may be done through capability assessments (TDCA, PMCA, IPCA …) especially for new suppliers or through analysis of existing data for already known suppliers.

a) The assessment should allow in particular the identification of the APQP elements not already managed by the supplier / not deployed at the supplier. This step consists in developing the plan to cover these gaps and will be shared during the preparation session and agreed with the supplier during the formal kick off. This plan may imply training sessions to be provided by the Business units to its supplier or specific support on activities that may be new for the supplier.

7.6.2 ENGAGE SUPPLIER

a) Engagement of the supplier is vital to the success of APQP deployment to a buy WP. An Internal preparation session has to be organized in order to prepare pre-analysis that will be presented to the supplier during Kick OFF meeting.

b) The preparation session with the supplier has two objectives:

- Engage the supplier;
- Prepare the Kick Off meeting.

7.6.3 INTERNAL PREPARATION SESSION

During this preparation session some deliverables are expected to be produced:

- Pre-risk analysis (based on sub-WP);
- Propose the APQP scope based on the previous steps (7.6.1, 7.6.2) and the risks evaluated in 7.1
- Contract status analysis.

7.7 APQP KICK OFF MEETING

a) Once the team has been nominated, a kick off session shall be completed, including the supplier (if the WP is purchased) and the customer if contracted. The expected outcomes are:

- Agreed final APQP scope formalized into the SOW;
- Agreed final APQP Element Applicability Matrix;
- Assignment for each of the APQP tasks (CTQ deliverables).

Note 1: as a best practice it is recommended to have WP leader & APQP leader counterparts on supplier side who will help ensure synchronization between CTQ deliverable owners.

- Confirm team member roles

Note 2: As an output of the session it is expected that both supplier & customer agree on APQP scope. For this it is recommended to:

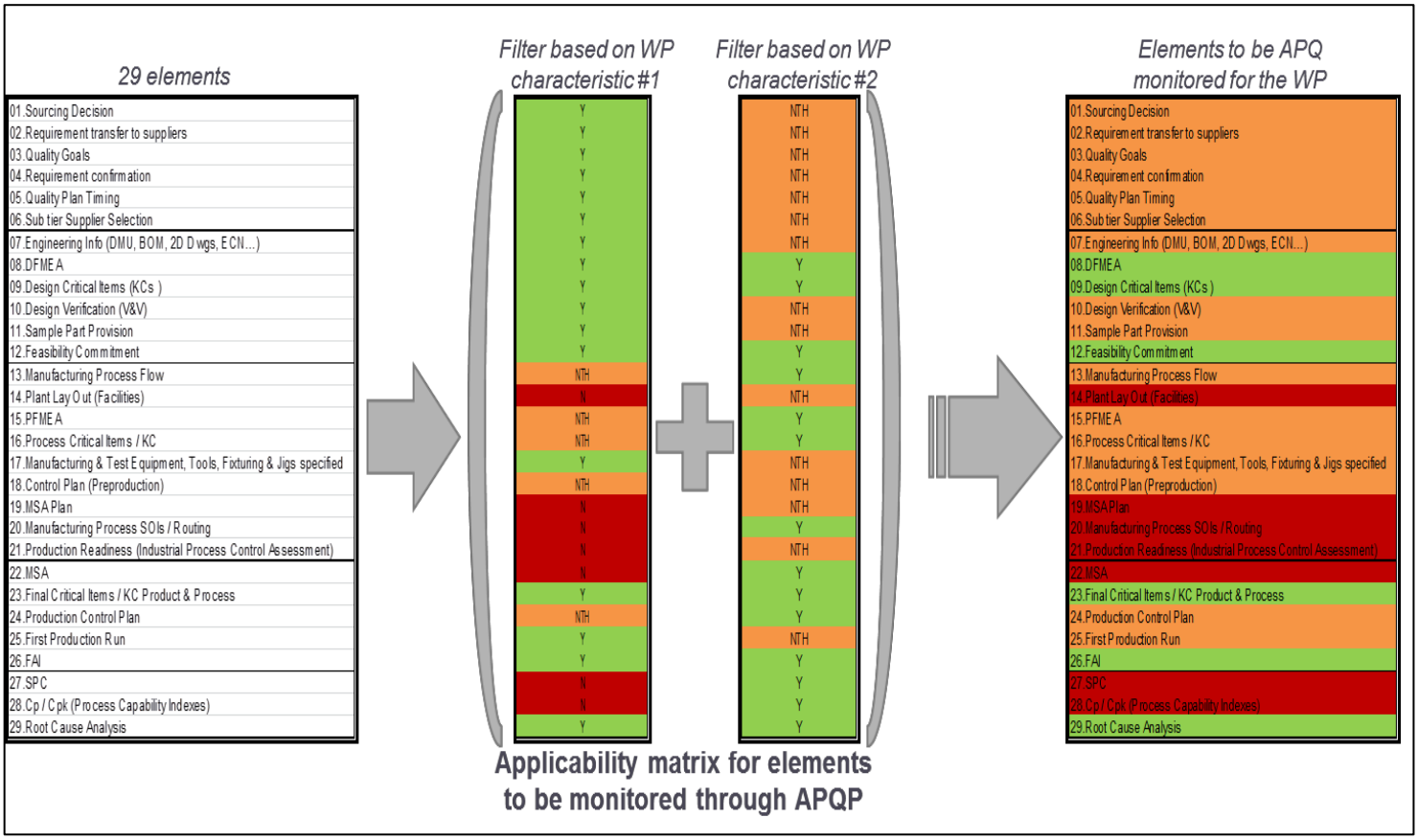
- Provide awareness to Team Members on the APQP methodology and expectations;
- Bring the members into a Team mind-set and Goal Sharing;
- Communicate WP objectives;

Note 3: Example of an APQP Element Applicability Matrix and Ownership Assignment. Below is an illustration on how this matrix should work:

One of key success factors for APQP is the appropriation of the methodology by the APQP key actors. APQP model should stay flexible meaning that each business should define its own matrix. For each product it is under the responsibility of the multi-functional team to agree on the elements to be monitored through the APQP methodology by applying this predefined applicability matrix and considering the product characteristics (e.g.: if the product design is not modified phase 2 can be skipped).

Three status of applicability per element for a dedicated WP:

- Y = element mandatory to be monitored through APQP
- N = element not mandatory to be monitored through APQP
- NTH (Nice to Have) = element applicability to be confirmed by the WP MFT team during the kick off meeting;
- Consolidation rules (Y + N = No; Y + NTH = NTH; NTH + N = No)



Applicability matrix for elements to be monitored through APQP

7.7 CREATE APQP TIMELINE: QUALITY PLAN TIMING

a) Once it is agreed what has to be done (refer to §8.7), the APQP leader shall create the APQP Quality Plan Timing(QTP).
b) The QPT shall be divided in three planning levels:
c) Customer planning level;
d) WP APQP tasks planning level (APQP Elements and CTQ timing);
e) Sub WP planning level.
f) The customer planning level shall contain the key project milestone to the end of project. These key project milestones include the WP target date, requirement documents, demonstrators, test specimens and milestone reviews.
g) The WP APQP tasks planning level shall contain the APQP phases: (Planning, Product Design & Development, Industrialization Design & Development, and Production Process Verification & Serial Production). The timing of each of the APQP phases shall be the result of summarizing the timing of the various APQP elements contributing to it. The WP APQP tasks planning level shall contain the applicable APQP elements timing. The timing of each of the APQP elements shall be the result of summarizing the timing of the various CTQs contributing to it.
h) The sub WP planning level shall contain all the key sub WP milestones to be cascaded to the supplier.

Note 1: An example of QPT is displayed in Annex 2.

Note 2: The commitment of the project team company Business unit and its supplier) to the APQP Quality Plan Timing is key to the project success.

7.8 APQP EXECUTION ACCORDING TO THE QPT

The following action starts in phase 1 of the APQP which includes the creation of the QTP (previous step).

7.8.1 PERFORM ASSESSMENT BASED ON DELIVERABLE CHECKLISTS

i) The APQP leader shall be the accountable for performing APQP CTQ deliverable assessments meetings within his / her Work package in accordance with the Quality Plan Timing schedule. The deliverable owner (potentially the supplier if buy parts) participation is mandatory.
j) The CTQ deliverable checklists are used as support document of the assessment meeting and clear evidences are expected to be delivered by the CTQ owner.
k) Each deviation found during an APQP CTQ deliverable assessment shall have a corrective action.
l) The frequency of the CTQ deliverables assessment meetings shall be agreed by the MFT in the QPT. This frequency can be continuously adapted to the risk / issues identified during the CTQ deliverable assessments.

7.8.2 ESCALATE ISSUES AND GET MANAGEMENT FEEDBACK AND SUPPORT

Based on assessments results, a report is provided to management on a regular base. The reporting structure has to be defined by each business units aligned with §7 APQP REPORTS. Typically, each checklist provides a deliverable status (Red/Amber/Green) compiled for each element and for one product. Sub-components status is compiled through product layers (as per the product breakdown). Cross layer compilation is based on a customer/supplier relationship (a Red status for a subcomponent may not endanger the customer product timing and consequently will not be escalated as Red).

See an example in **Figure 8**.

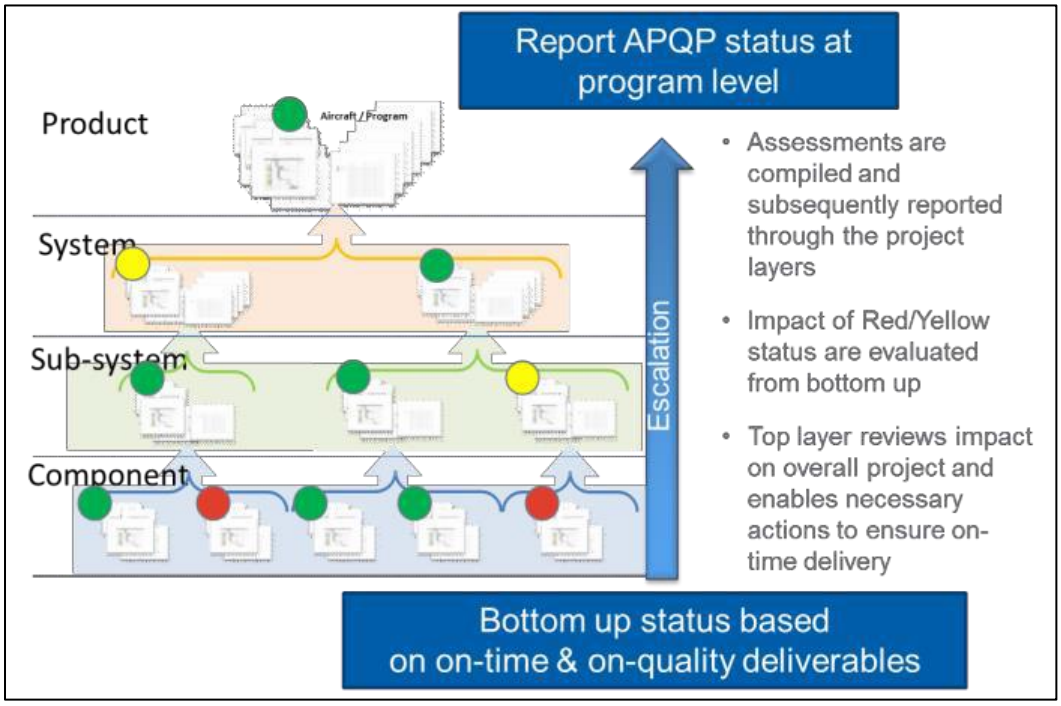


Figure 8: Principles on APQP Report status at Programme level.

7.9 APQP CLOSURE

The APQP project is closed when the product is fully qualified, the process capability under control and the monitoring of product and process performance is done by the normal production monitoring processes (e.g.: customer services, non-conformity management…).

Lessons learnt shall be captured and fed back to the APQP process and product/process documentation.

ANNEX 1: APQP ELEMENT DESCRIPTION

NOTE: This set of element description is provided as an example of what has been defined in the commercial Aircraft Division and IAQG SCMH
Further improvements will be done to adapt it for the overall company businesses.

Phase 1 Planning	**Introduction**

Phase Definition:
The goal of phase 1 is to put in place the framework of the project. All inputs should be identified and captured, these inputs come from the customer, regulatory requirements, benchmark data, lessons learned, company know-how and strategy. This will allow the building of the technical, quality and manufacturing requirements, identifying the parts to be outsourced, the building of the sourcing plan, and finally the building of the APQP Quality Plan Timing which describes all APQP activities and the schedule aligned with the project needs. At this stage the project team is in place, every stakeholder understand what he must do and by when. There is a product and a process concept available, Phase 2 and 3 can now build a product and a process upon this robust base plan.

Phase 1 Planning (Make)

Phase 1 Planning (Buy)

ELEMENT CARDS SPECIFIC TO THE MAKE MODEL

Element 1.01 Make	**Design Goals**

Element Owner:

Customer and Supplier engineering (when supplier participates in the early stage of the design).

Element Definition

The technical design requirements take customer wants and needs, along with any other regulatory requirements and convert these into clearly defined design objectives. These design requirements should cover items such as:

- Functional performance
- Architecture constraints (e.g.: space, interfaces, external envelope…)
- Type of material
- Special processing constraints
- Weight
- Any specific acceptance criteria based on attribute information (appearance, color, odor, noise, …)
- Regulatory requirements (safety environment and trade compliance, …)
- In-house best practices & lessons learned
- Reliability

The goal of the technical requirements is to define and prioritize the constraints and expectations. These requirements should be reviewed and mutually agreed with the customer.

Deliverables:

Agreed technical requirement documents between supplier and customer with configuration control

Inputs:	**Source of input:**
Benchmark	Sales and Marketing, Engineering
Lessons Learned	Previous Programs (cross-functional activity)
Know How	Cross Functional Input
Customer Requirements	Sales and Marketing, Engineering

Resources:

Design and Manufacturing Engineering, Sales and Marketing, Program

Methodology:

- Analyze data from previous programs, applicable standards, and information obtained from customer/market, product/process design guidelines in order to create the list of technical requirements which should be captured in a formal document with changes tracked as appropriate.
- Concurrent engineering is the best practice that helps guarantee both customer needs and wants and supplier knowledge are considered as early as possible.
- There should be a design review process in place to monitor the creation of the technical requirements.
- Quality Function Deployment (QFD) is a tool which can be used to conduct this exercise.

Reference document

None

Element 1.03 Make	**WP – Definition/Make or Buy**

Element Owner:
Programme

Element Definition:

- The identification of the work to be done (work package) will allow the breakdown of the project into its constituent components enabling an effective and efficient management of the project by nomination of the work package leaders.
- Once the breakdown of the project into manageable work package is done this will drive supplier identification and selection early in advance to enable the launch of the design process on those identified long lead time, or critical, items. The criticality of the items can be defined around new technology, complexity of technology, supplier maturity…

Deliverables:

Work Break Down Structure:
A deliverable-oriented, organised ing of project elements which organises and defines the total scope of a project. Each descending level element represents an increasingly detailed definition of project components; which may be either products or services.

SOW:
A narrative description of products, components, services, works and also possibly subsidiary tasks to be supplied or done to reach the specified result of the Project, Subproject or Work Package.

Make or Buy Decision:
Identification of which WP will remain make and which ones will be buy

Necessary Inputs:	**Source of input**
Design requirements	Design engineering
High level program requirements	Program
Supplier Know How and Lessons Learned evaluation	Cross functional team Supplier benchmarking and capability
Industrial strategy Purchasing strategy	Manufacturing engineering manager Procurement manager

Resources:
Led by program with inputs from Manufacturing Process Engineering, Procurement/Contract, Suppliers and Quality.

Methodology:

1. Multi-functional team reviews design and program requirements
2. A WBS and a SOW is discussed and agreed within the teams
3. From the 2 above mentioned documents, a Product Breakdown Structure is issued considering Business unit industrial, purchasing strategies
4. Each element of the PBS is reviewed by MFT to decide Make or Buy
5. Feedback loops are organized to mature WBS,SOW and PBS considering all identified constraints

Reference document
None

Element 1.04 Make	**Process Flow – preliminary information**

Element Owner:
Manufacturing Engineering

lement definition

- The Preliminary Process Flow is the definition of the Industrial System to manufacture the complete product from receiving to shipment to the customer. The preliminary process flow provides an anticipated overview of the manufacturing process flow in order to allow the detailed process design to begin. This should highlight the most critical process steps that require longer lead times or additional qualification.
- It should provide definition for the following typical items:
- ME Resource estimations, Ind. Feedback for Technology selection, Level of Criticality classification for new concepts, Test Reports, Industrial trade-offs, A/C Split, Ind. System Concept Breakdown structure, Interface Responsibilities, Long Lead Items roadmap, A/C manufacturing / assembly sequence, Impact of customization guidelines over the Ind. System, Harmonization trade-offs for jigs, tools and machines, Global specification of performance and conceptual characteristics for machines, jigs & tools, Required dates of availability for machines, jigs & tools, List of main production operations, Workload estimation, Cycle time estimation, Critical path estimation, Conceptual plants lay-out and CapEx estimation.

Deliverables:
Preliminary manufacturing process flow chart signed off by manufacturing engineering, engineering, production and quality.

Necessary Inputs:	**Source of input:**
Technical requirements	Design Engineering
Quality requirements	Quality and Design Engineering Manufacturing process expertise
Manufacturing Engineering	
Key Characteristics and critical items	Design and Manufacturing Engineering and Quality Lesson learned
from similar products	Design and Manufacturing Engineering and Quality Competitor
benchmark	Cross functional input

Resources: Manufacturing Engineering Quality Engineer Procurement
Design engineering

Methodology:

1. Cross Functional (Engineering, Manufacturing Engineering, Procurement, Quality) team reviews the inputs from product specification, quality goals, preliminary process CTIs/ KCs, Preliminary BOM and other project inputs
2. Manufacturing Engineering makes a proposal which considers all identified constraints.
3. Cross functional team reach agreement, preliminary and consistency with the Bill Of Material is verified.

Element 1.05 Make	**Preliminary Listing of Critical Items**

Element Owner:
Design Engineering and Manufacturing Engineering

Element Definition

- Critical items (CTI) are the items which will have a significant impact on product realization and subsequently its use. Key Characteristics (KCs) are an attribute or a feature whose variation has a significant impact on the Critical Item. The impact includes safety, performance, fit, form and function, manufacturability, service life, etc…These items require specific actions to ensure they are adequately managed through the design and manufacturing processes.
- The determination of preliminary product and process CTI/KC is done by a cross functional team including Design and Manufacturing Engineering supported by Quality. It is a best practice to use Quality Function Deployment (QFD) and previous DFMEA/PFMEA on similar product/processes.
- The list of CTIs/KCs becomes part of the technical requirements.

Deliverables:
Agreed preliminary list of key characteristics and critical items between supplier and customer

Inputs:	**Source of Inputs**
Lessons Learned and Know How	Cross Functional Team
DFMEA/PFMEA on similar product Program Requirements	Design and Manufacturing Engineering
Technical (design and process) Requirements	Project Leader
	Design and Manufacturing Engineering

Resources:
Quality, Program Management, Design Engineering, Manufacturing Engineering experts (as required)

Methodology:
1. Each involved function (Quality, Program Management, Design Engineering, and Manufacturing Engineering) should review the technical requirements and data inputs and create their CTIs/KCs proposal.
2. The team meets and agrees on the preliminary CTIs/KCs.
3. Flow this list into product and process design and to supply chain when necessary.

Quality Function Deployment (QFD) can contribute to this activity. CTIs/KCs are the result.

Reference Document

Element 1.01 Buy	**Sourcing Decision**

Element Owner:
Procurement

Element definition
In order to start the APQP process it is needed to make sure:

- The potential suppliers have received all the necessary requirements (APQP requirements must be included) to understand the work to be done. This is the list of all applicable documentation
- The technical offers have been reviewed by all relevant functions in order to evaluate their relevancy
- All stake holders have formally participated and accepted the selection of the supplier

The supplier should be informed of the sourcing decision including actions to be taken in order to start the APQP process.

Deliverables:
Signed purchasing contract
Compliance matrix showing all deviation to customer requirements and actions to recover

Necessary Inputs:	**Source of Inputs:** Customer Reliability and Quality targets
for	Cross functional team product and program
Preliminary BOM	Design Engineering
Preliminary Process Flow	Manufacturing Engineering and Quality
Technical requirements	Design Engineering
Product and process CTI/KCs	Design and Manufacturing Engineering Commercial and
project timing requirements	Customer and Program Manager Applicable procedural and
standard	Customer
documentation	

Resources:
Quality, Design and Manufacturing Process Engineering, Sales, Program Management, Customer

Methodology:

1. Customer formalized its requirements in a Request For Quotation (RFQ) including APQP requirements
2. Buyer send RFQ to pre-selected list of suppliers
3. Each function evaluates compliance to each item that it is responsible for
4. Multi-functional team selects supplier and raises possible recovery actions for non-compliant items.
5. Supplier contract is awarded accordingly. APQP can be planned

Reference document
None

Element 1.02 Buy	**Requirement transfer to supplier**

Element Owner:

Customer

Element Definition

The customer will prepare a Design specification which will convert customer wants and needs, along with any other regulatory requirements into clearly defined design objectives. These design requirements should cover items such as:

- Functional performance;
- Architecture constraints (e.g.: space, interfaces, external envelope…)
- Type of material;
- Special processing constraints;
- Weight;
- Any specific acceptance criteria based on attribute information (appearance, color, odor, noise, …)
- Regulatory requirements (safety environment and trade compliance, …)
- In-house best practices & lessons learned;
- Reliability;
- Production process requirements (e.g.: process specifications, special processes…).

In addition the customer will formalize into a document (Statement Of Work) the work to be done, this includes a description of products, components, services, works and also possibly subsidiary tasks to be supplied or done to reach the specified result of the Project, Subproject or Work Package.

Deliverables:

Agreed Design specification agreed between supplier and customer with configuration control SOW agreed between supplier and customer with configuration control

Inputs:	**Source of input**
Design requirements	Design Engineering
Process requirements	Manufacturing engineering
High level program requirements	Sales and Marketing, Engineering
Benchmark	Previous Programs (cross-functional activity)
Lessons Learned	Cross Functional Input

Resources:

Design and Manufacturing Engineering, Sales and Marketing, Program, Purchasing

Methodology:

1. Multi-functional team reviews design and program requirements. Concurrent engineering is the best practice that helps guarantee both customer needs and wants and supplier knowledge are considered as early as possible.
2. A Design specification and a SOW is discussed and agreed within the teams.

There should be a design review process in place to monitor the creation of the technical requirements. Quality Function Deployment (QFD) is a tool which can be used to conduct this exercise.

Reference document

None

Element 1.04 Buy **Requirement Confirmation**

Element Owner:
Design Engineering

Element Definition

- The Design Organization is able to demonstrate in a clear product specification that it understands and is able to support the customer's technical, process, reliability and quality requirements. In this specification, the Design Organization will also take into account its own best practices and consider constraints in defining product requirements.
- Techniques such as Design for x (DFx) (six sigma, manufacturability, assembly, cost, test, maintainability…) can help focus the design by considering the specific constraints highlighted and prioritized in the technical design requirements (see 1.02), quality goals, reliability goals, & process requirements.

The production organization is able to demonstrate that the proposed production system will be able to sustainably manufacture the product considering technical specification including quality, process, supply chain requirements and constraints

Deliverables:
Design Specification issued by the design organization and approved by the competent person in the organization holding Design Authority (customer)
Process specification agreed between the manufacturing organization and customer

Necessary Inputs:	**Source of Input**
Customer Reliability and Quality targets for	Quality and Design Engineering product and program
Suppliers' own reliability and quality targets for	Quality and Design Engineering product and program
Product KCs	Design Engineering
Technical requirements	Design Engineering Supplier design guidelines and know-how
Environmental and Regulatory Requirements	Quality
Process requirement	Manufacturing Engineering

Resources:
Quality, Design and Manufacturing Process Engineering from the design and manufacturing organization(s)

Methodology:
1. The designer collects all relevant information to support the creation of the design specification this will include: Customer technical, reliability and Quality requirements, preliminary CTIs/KCs for product /program/process, supplier design guidelines, supplier technical know-how and Supplier industrial constraints.
2. The designer creates a design specification which captures all these requirements considering the identified DFx constraints.
3. The design specification is reviewed internally at the supplier with the relevant functions
4. The specification is then passed onto the authorized person(s) for release
5. In parallel the manufacturing engineering team will issue a process specification considering all project inputs (industrial strategy, make or buy decision, manufacturer know how, regulatory and environmental requirements).
6. The process specification has to be agreed by the customer

Reference document: None

Element 1.06 Buy	**Sub-tier Supplier Selection**

Element Owner:

Procurement

Element Definition

- Items of the preliminary BOM that are to be made in-house or outsourced should be identified as early as possible. A plan must be developed for the identification and selection of sub-tier suppliers to support the development and part production for the items to be outsourced. The plan must consider the overall program timing deadlines and the components identified in the preliminary BOM and any subsequent update to the BOM. The timing plan is synchronized with Engineering and other functions to ensure availability of necessary inputs for timely sub-tier selection.
- Requirements which will be flowed down to sub-tier suppliers should be identified and a plan put in place to

Deliverables:

Timing plan for selection of suppliers

Definition of requirement to be flowed down to sub-tier suppliers

Agreed approach to managing and controlling these flow-down requirements.

Necessary Inputs:	**Source of inputs:** Customer reliability and Quality targets
for product	Cross-Functional team and program
Preliminary BOM	Design Engineering
High level specification	Design Engineering
Preliminary Process Flow	Manufacturing Engineering
Commercial and project timing requirements	Program Management / Contract Manager Statement of
work	Project Leader
List of approved suppliers and their capabilities	Procurement

Resources:

Procurement, Quality, Design and Manufacturing Engineering, Program/Contract Management.

Methodology:

1. Perform make or buy analysis
2. Program Manager/Contract Manager provides to procurement all requirements to be flowed down to suppliers.
3. Procurement develops their approach to flow down requirements to suppliers (including deliverables, monitoring KPIs…)
4. Procurement gathers key information (program timing, preliminary BOM)
5. Procurement builds a sourcing plan considering the above
6. Plan to be agreed with by Program/Contract Manager and Design (last date for delivery of technical documentation)
7. Procurement to implement and monitor the plan

Reference document

None

ELEMENT CARDS COMMON TO THE MAKE AND BUY MODEL

Element 1.02 Make /1.03 Buy	**Reliability and Quality Goals**
Element Owner: Customer, Engineering and Quality	
Element Definition • Reliability and quality goals are defined based on regulatory requirements, customer expectations and program targets. In terms of reliability, objectives are likely to include Mean Time Between Failure / Mean Time Between Repair / Mean Time Between Unplanned Repair, and Operational Reliability. Quality goals should be based on metrics which cover the complete product lifecycle (development, series production, in service performance). Quality metrics are likely to include: parts per million rejects (through the complete supply chain), right the first time yields (First Pass Yield, RFTY…) for first articles and production, recurrent problems, on-quality approval of PPV, FAI, Defect Per Million Opportunities (DPMO). These metrics should be specific, measurable, agreed, actionable, reportable, challenging and time bound.	
Deliverables: Agreed list of KPIs (Key Performance Indicators) covering quality and reliability performance for the complete product lifecycle	
Necessary Inputs: Customer Reliability and Quality targets for program Suppliers (internal/external) Capability	**Source of inputs** Sales & Marketing , Engineering, Quality and product and manufacturing engineering Quality and Procurement
Resources: Quality, design and manufacturing engineering, procurement, marketing & sales approved by Quality and Program managers	
Methodology: 1. Collect Customer Reliability and Quality targets for product and program 2. Determine the appropriate Reliability and Quality targets in order to meet the above 3. Determine the associated KPIs and get approval from Quality and Program Managers 4. Flow these goals into product and process design and to the supply chain 5. The goals achievement validation occurs in phase 2 thru 5	
Reference Document None	

Element 1.05 Buy/ 1.06 Make	Quality Plan Timing (QPT)

Element Owner:

Project leader

Element Definition

- Advanced Product Quality Planning is intended to provide products that meet customer needs and expectations, on time and at the lowest cost. The intent of the QPT is to ensure that each activity is completed in line with overall project timing requirements. Each activity identified should be recorded in a timing chart identifying the planned start and end date, with a designated responsible person. Progress against the plan should be monitored regularly and delays escalated through the defined reporting process. Frequency of reviews should be defined in the QPT
- The QPT is built for the product, it will cascade the need for key deliverables on the sub- assemblies and components that make this product.
- The creation of this timing plan is a one-time exercise which is built with concurrence of each task owner. It is the best feasible timing plan considering everybody's constraints in regards to customer expectations. The plan is created during phase 1 and will only be modified if the overall project timing changes. Monitoring the APQP process and the adherence to the timeline is key to successful implementation. The QPT is the base for the team commitment and should ensure program timing success.

Deliverables:

Agreed QPT

Necessary Inputs:	Source of input
APQP applicable task lists	APQP Team
Project timing requirements	Project Leader and Customer

Resources:

Procurement, Quality, Sales and Customer Support, Production, Design and Manufacturing Engineering, Program Management, Human Resources and others as required.

Methodology:

1. Program leader provides the project timing requirement to the team.
2. The project team reviews which APQP elements are applicable.
3. Each task owner proposes their preliminary timing plan to the Project leader
4. Team reviews clashes and agrees to acceptable timing plan which achieves program targets
5. Project leader validates timing and communicates it.
6. Team provides their deliverables as agreed.
7. APQP manager monitors and reports on progress.
8. Project leader escalates major issues to upper management.
9. As sub-tier suppliers are selected, they should develop their own QPT consistent with their customer's requirements.

Reference document

QPT template

Element 2.07	Engineering info Make and Buy

Element Owner:

Design Engineering

Element Definition

- The engineering information is the set of document resulting of the design process. The engineering information is anything used to describe the product including drawings, interface drawings, digital mock ups, finite element models, math data, system and equipment specifications, supplementary specifications and material specifications.
- In addition to the customer requirements the design process have to consider all constraint that may affect the product such as manufacturing (preliminary process flow), maintainability (customer design requirements), low process variability constraints (CIs KCs).
- If a supplier, such as a build to print supplier, has not been involved in the on-going Design Review process, a review of the design record with the supplier shall be performed to ensure that using design record documents, parts can be produced to the requirements and their conformity can be verified with proper testing or inspection methods.
- The means of verification have to be included within the specification and/or drawings (common datum, target points, reference planes etc.). This information is cascaded into the Validation and Verification Plan (V&V) and ultimately into the control plan and appropriate shop floor documentations.

Deliverables:

Set of documents needed to uniquely specify fit, form and function of the product

Necessary Inputs:	Source of Input:	
Product Specification	Design Engineer	
Preliminary list of Key Charac	teristics	Design Engineering Manufacturing Engineering
Preliminary process flow	Quality Engineering	

Resources:

Product Design Engineers, Manufacturing Engineers, Inspection specialists, Drafting standards specialists

Methodology:

1) Review historical quality information for characteristics with quality issues that need key characteristic control and add the requirements to the drawings or manufacturing requirements.
2) Key Characteristics workshop is performed using a structured process (such as DFMEA).
3) GD&T review is performed: drawings use standard GD&T practices i.e. datum, gage points etc. to support inspection activity.
4) Inspection Reviews are performed: Special inspection methodologies are called out on the drawings or the special processes for manufacturing requirements.
5) Any recommendations to design improvements are made after the reviews indicated above.
6) For subcomponents, the same process is used to determine lead responsibility in conducting these reviews.
7) For the Complex System/Sub-assembly all involved participate as necessary in the reviews.

Reference document

None

Element 2.08 Make and Buy	**Design Failure Mode and Effects Analysis (DFMEA)**

Element Owner:

Design Engineer and his/her team

Element Definition

- A Design Failure Mode and Effects Analysis (DFMEA) is an analytical technique undertaken by a cross functional team to identify all potential failure modes, their associated causes/mechanisms and to make sure that they have been considered and addressed by the design of the product. All designs related to system, subassembly and component should be evaluated. A DFMEA is a living document that is updated as the design is developed and evolves based on customer needs, latest performance information, manufacturability, etc. Risk of any one design issue is scaled based on the impact to the design failure, expected occurrence and ability to detect/control the event. One FMEA standard that can be referenced is the SAE J1739.
- There is a close link between the DFMEA and the PFMEA (Process Failure Mode and Effects Analysis). Updates to either may impact on the other and should be taken into account.

Deliverables:

A Design Failure Mode and Effects Analysis (DFMEA) that identifies all the probable causes and effects of failure due to design.

Necessary Inputs:	**Source of Input:**
Technical Specification	Design Engineer
Lessons Learned	Cross functional team
Best Practice	Cross functional team

Resources:

Customer, Quality Engineer, Design Engineer, Manufacturing Engineer

Methodology:

1. Determine the function, features or requirements of design.
2. Document what can fail/go wrong.
3. List the effects of the failure.
4. Rank the severity of the failure.
5. List the potential causes of the failure.
6. List the preventions taken so the cause cannot occur.
7. Rank the frequency of each specific cause occurring.
8. List the detection methodology(s).
9. Rank effectiveness of the detection methodology(s).
10. Determine the Risk Priority Number (RPN), calculated as follows: Severity of the risk

    X Likelihood of occurrence X Ease of detection

    The higher the number, the higher the risk and the need to undertake an action to remove/reduce/detect the root cause(s) which generates the risk.
11. Select the corrective actions to be implemented.
12. After implementation of the corrective actions re-rank Severity, Occurrence, Detection based on evidence of the effectiveness of the actions.
13. Any high risk items should generate a Key Characteristic in order to detect and control the risk.These will be considered during the Process FMEA

Reference document

None

Element 2.09 Make and Buy	Design Critical Items and Key Characteristics

Element Owner:

Design Engineering

Element Definition

- Preliminary critical items and key characteristics are identified during the planning phase by identifying the customer "must have". During the design process and the DFMEA analysis the initial list should be reviewed. Additions to the list will be made when any new risks that cannot be eliminated by design need to be controlled by key characteristics or critical items. Where appropriate they will be indicated on the design. The finalization of critical items and key characteristics should be completed after the PFMEA, and the product and process verification (phase 4)
- The selection of the critical items and the key characteristics is done by evaluating the risk "an item" or a characteristic has not to meet customer expectations with a high impact from the customer perspective. Key characteristics are a sub set of the critical items and are features used to control the variability of one critical item.
- It is recommended to use formal methods to select CtI and KC such as Quality Function Deployment and FMEA (KC and Cti in this case are both inputs and outputs)

EN9100 are as follows:

Critical items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

Key Characteristics

An attribute or feature whose variation has a significant effect on product form, fit, function, performance, service life or produceability, that requires specific actions for the purpose of controlling variation.

Deliverables:

An updated list of the CIs and KCs.

Necessary Inputs:	**Source of Input:** Voice of the Customer Design Engineering Process Engineering
Product Design Customer Specifications DFMEA, PFMEA, Preliminary CIs and KCs	List Quality Engineering

Resources:

Product Design Engineering, Manufacturing Engineers

Methodology:

1) Consult the list of CIs and KCs determined phase1.
2) Conduct the design identifying high manufacturing risk areas that cannot be designed out.
3) Conduct the DFMEA identifying high risk areas that cannot be designed out.
4) From any preliminary PFMEA(s) identify high manufacturing risk areas that cannot be removed by process changes.
5) During phase 2, 3 and 4, identify CIs and KCs that, when in control, reduce the risks to an acceptable level.
6) Update the preliminary CIs and KCs list with the new information.

Reference document

None

Element 2.10 Make and Buy	**Design Verification & Validation**

Element Owner:

Product Development Team

Element Definition

- Activities to be performed to verify conformance to design intent and to validate conformance to customer requirements as spelled out in the Design specification of phase 1.
- These activities comprise:
  - Simulation test
  - Mock-ups
  - Expert reviews
- The tests and inspections to be performed on each component or assembly and their related success criteria.
- Any test specifically requested by the customer.
- A detailed schedule showing hardware availability, and testing, inspection and reporting activities.
- Etc.

Deliverables:

A Plan comprising the elements described above.
Formal reports documenting with objective evidence that the Technical Design Requirements have been fulfilled

Necessary Inputs:	**Source of Input:**
Product Design Inputs Customer Specifications Proto parts meeting design intent Preliminary Statement of Work	Design Engineering

Resources: Design engineers

Methodology:

1) Ensure that the design specification is updated with all additional requirements that emerge from the design process.
2) Include any activities/tests/inspections needed to validate new or novel features.
3) Include any test needed or requested by the customer for their own product validation needs.
4) Identify the resources product hardware and test or inspection facilities needed to validate the Design. Include the necessary level of maturity of the product hardware suitable for each validation event.
5) Use the build plan which defines the timeline and resources for every validation event. The generation of formal reports of each activity has to be included in the plan. The plan has to take into account the impact of progressive release of design information.
6) Each validation element closes when the formal reporting is completed and noted discrepancies are resolved.
7) Validation closes when all elements are closed per 7 above.

Reference document

None

Element 2.11 Make and Buy	**Team Feasibility Commitment**

Element Owner:
Project leader

Element Definition

- At this stage, the design has been made robust against the risk identified during the DFMEA, all remaining risks have generated Key characteristics and all validation and verifications have been performed to confirm that the design meets customer expectations. Phase 3 is started as the manufacturing process is being concurrently developed. The team can formally state that the product can be manufactured to the defined requirements and specifications, qualified & tested all in the quantity desired and within the budget/ timing guidelines. Commitment is based on the analysis of the design and a consensus of a team of representatives from, but not limited to, the following disciplines: design, production, quality from both customer and supplier when applicable
- The record of this commitment should be in a report that scores each element under consideration, as being favorable or unfavorable, with the duly noted recommendation to proceed. The report should identify the impact or proposed changes to meet standards for those elements identified as unfavorable.
- At this stage, phase 3 can proceed to the freeze of the manufacturing process definition.

Deliverables: A Team Feasibility Commitment Report which:

1) lists any unfavourable issues with their impact and a plan to mitigate/eliminate the issues
2) documents the organization's commitment to produce the product

Necessary Inputs: Any and all inputs gathered from the activities identified to this point of the APQP process. Those being but not limited to:	**Source of Input:**
Customer wants	Marketing and sales
Design input requirements	Design team; Product Quality Tooling, equipment capability,
facility needs	Manufacturing Engineering Material estimates, labour cost
estimates	Operations
Demand profile	
Budget constraints	Management

Resources: Design, Production, Quality, Manufacturing Maintenance and supplier when applicable.

Methodology:

1) Team develops a report evaluating design maturity (V&V results) and any issue foreseen after the process evaluation (PMEA outcome, process specification review, CIs and KC reviews…)
2) Management is advised of the findings of the report.
3) Unfavourable elements are highlighted and potential resolutions are proposed.
4) Resolutions that require discussion with the customer are shared with the customer and may defer the decision until the customer agrees to the resolution.
5) Resolutions that can be controlled by the supplier are laid out in a closure plan.
5) If management, after balancing the demands of the product under consideration, including its unfavourable elements, their resolutions and all other organizational commitments, agrees to produce the product, the

Reference document None

Element 2.11 Buy	**Sample part provision**

Element Owner:

Product Development Team

Element Definition

- A Development Product/Part Build Plan defines product manufacturing requirements, inspections and assembly sequences to be performed to support the verification and validation testing.
- The plan should define:
  - The source of the material for build
  - The minimum level of maturity for each product/part
  - The manufacturing process that will be used to produce those parts
  - The quantity of parts required
- A detailed schedule for the manufacturing, and inspection and reporting activities.
- The execution of this plan is monitored through the APQP process.
- Discrepancies noted during the manufacture/build process may signal the need for design changes or the need for CIs or KCs.

Deliverables:

A Plan comprising the elements described above agreed between supplier and customer

Formal reports documenting the outcome of the manufacture/build process and clearly documenting discrepancies that arise along with their proposed solutions.

Necessary Inputs:

Product specification (engineering info.)

V&V plan

Design requirements

Source of Input:

Design Engineering

Resources: Product Development Engineers, Certification Specialist Engineers

Methodology:

1) Ensure that the product specification is updated with all additional requirements that emerge from the design process.
2) Consult standard work to identify all tests/inspections known to validate the product.
3) Align the build plan with the verification and validation needs.
4) Include any inspections needed to validate new or novel features.
5) Identify the resources; product hardware, inspection facilities, assembly tooling needed to meet the build plan intent. Include the necessary level of maturity of the product hardware suitable for each build defined.
6) Create a master build plan which defines the timeline and resources for every validation event. The generation of formal reports of each build activity has to be included in the plan. The plan has to take into account the impact of progressive release of design information.Plan has to be agreed between supplier and customer
8) Where necessary, update the design through design revision or the addition of KCs to the drawing, based on discrepancies uncovered by the build plan activity.

Reference document

None

Phase 3 Process Design & Development	Introduction

Phase Definition:

During phase 3 the process which will be used to manufacture the product is designed and developed. This activity covers both internal production and the external supply chain. Phases 1 & 2 provide the necessary inputs to ensure that the team developing the process understands the customer's requirements, the design requirements and the manufacturing organization's requirements. The manufacturing process is then designed and developed to ensure that all of these requirements can be met consistently both within internal manufacturing operations and by the suppliers. The production readiness review at the end of this phase, held at the intended manufacturing site, provides the team and the customer with confidence that the process is capable of producing the product consistently and in line with the customer and the manufacturer's requirements.

For Buy

For Make

3.12 make/ 3.13 Buy	Process Flow Element

Element Owner:
Manufacturing Engineering

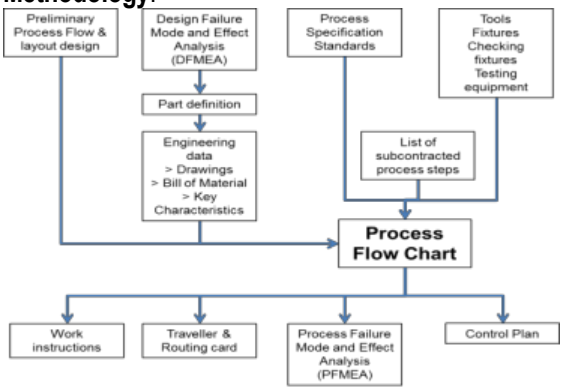
Element Definition
The Process Flow describes the sequence of operations required in order to manufacture the complete product from goods receiving to shipment to the customer. It should also take account of the transfer operations from one step to the next. It is unique to the product and is sufficiently detailed in order to clearly and completely define the process required to make the product.
The activity should start once the preliminary design is complete. The activity should build upon the preliminary process flow created in Phase I. The activity is complete when the work instructions and control plan have been finalized.
It should take account of the inputs from the 4Ms (Man, Method, Machinery and Materials).

Deliverables:
Formal Process Flow Chart signed off by Manufacturing Engineering, Production and Quality.

Necessary Inputs:	Source of inputs:
Preliminary Design	Design Engineering Drawings
Bill of Material	Design Engineering
Preliminary Process Flow	Production Engineering
Key Characteristics	Design Engineering, Quality & Manufacturing Engineering

Resources: Manufacturing Engineering, Quality Engineer, Production Control & Procurement as required.

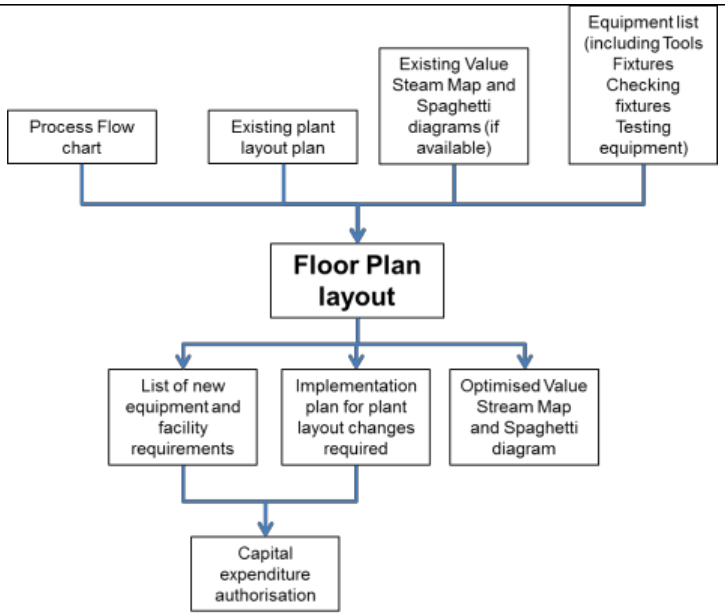
Methodology:



1. Manufacturing Engineering update the Preliminary Process flow chart to reflect the latest design, BOM and process details.
2. A Cross functional team comprised of manufacturing engineers, quality specialists, and production engineers reviews the proposed process flow chart and agrees or amends as appropriate considering their own constraints.

Reference document
Process Flow Chart template example

Element 3.13 Make/3.14 Buy	**Floor Plan Layout**
Element Owner: Manufacturing Engineer	
Element Definition The floor plant layout should be developed to clearly show the position and layout for all processes used to manufacture and test product. Quality control location points should be identified on the layout. Synchronous material flow and floor usage optimization should be taken into account when performing the layout in an effort to economize space usage increasing the value added of floor space and minimizing the travel and handling of materials, parts and assemblies. Lean Principles such as Value Stream Mapping (VSM) and Spaghetti diagram techniques can be used in support of this.	
Deliverables: Plant layout plan approved by the Production Manager and the Quality Manager.	
Necessary Inputs: Process flow chart Equipment list Existing plant layout plan Value Steam Map & Spaghetti Diagrams (if available) Building Layout	**Source of inputs:** Manufacturing Engineering Manufacturing Engineering/Facility Mgmt Manufacturing Engineering Manufacturing Engineering/Lean Experts Facility Management
Resources: Manufacturing Engineer; Production Manager; Quality Engineer; Quality Manager; Facility Management; Lean Experts; Health Safety & Environment Representative	



Methodology:

1. Manufacturing Engineer develops a draft layout plan to map a physical flow which is appropriate to produce the product including Quality Control locations.
2. Cross functional review with Production, Quality, Facilities and Maintenance in order to optimize the draft plan using relevant experience, lessons learned and best practice benchmarking.
3. Equipment relocated/placed (when it becomes available) as planned.
4. Process Engineer updates the layout plan in line with the inputs and obtains formal agreement from Production Manager and Quality Manager.

Reference document None

Element 3.14 Make/ 3.15 Buy	Process Failure Mode and Effect Analysis (PFMEA)

Element Owner:
Manufacturing Engineering & Quality

Element Definition
A Process Failure Mode and Effect Analysis (PFMEA) is an analytical tool used to identify possible risks of creating non-conforming product and create action plans to mitigate those risks.

It is a living document which is updated as non-conformances arise and risks are addressed. It is the basis for continuous improvement which can also serve as a "lessons learned" repository. A PFMEA is a critical step in the development of processes and can have a large impact on the success of a program.

The PFMEA should be developed in parallel to the design/development of the manufacturing process and it should be continuously updated as the process is refined.

The PFMEA should be started early in the development of the manufacturing process.

The team should focus on aggressive reduction in the total system risk, as indicated by the Risk Priority Numbers (RPN) derived in the FMEA process.

Special attention is paid to Key Characteristics that are flowed from the DFMEA or customers.

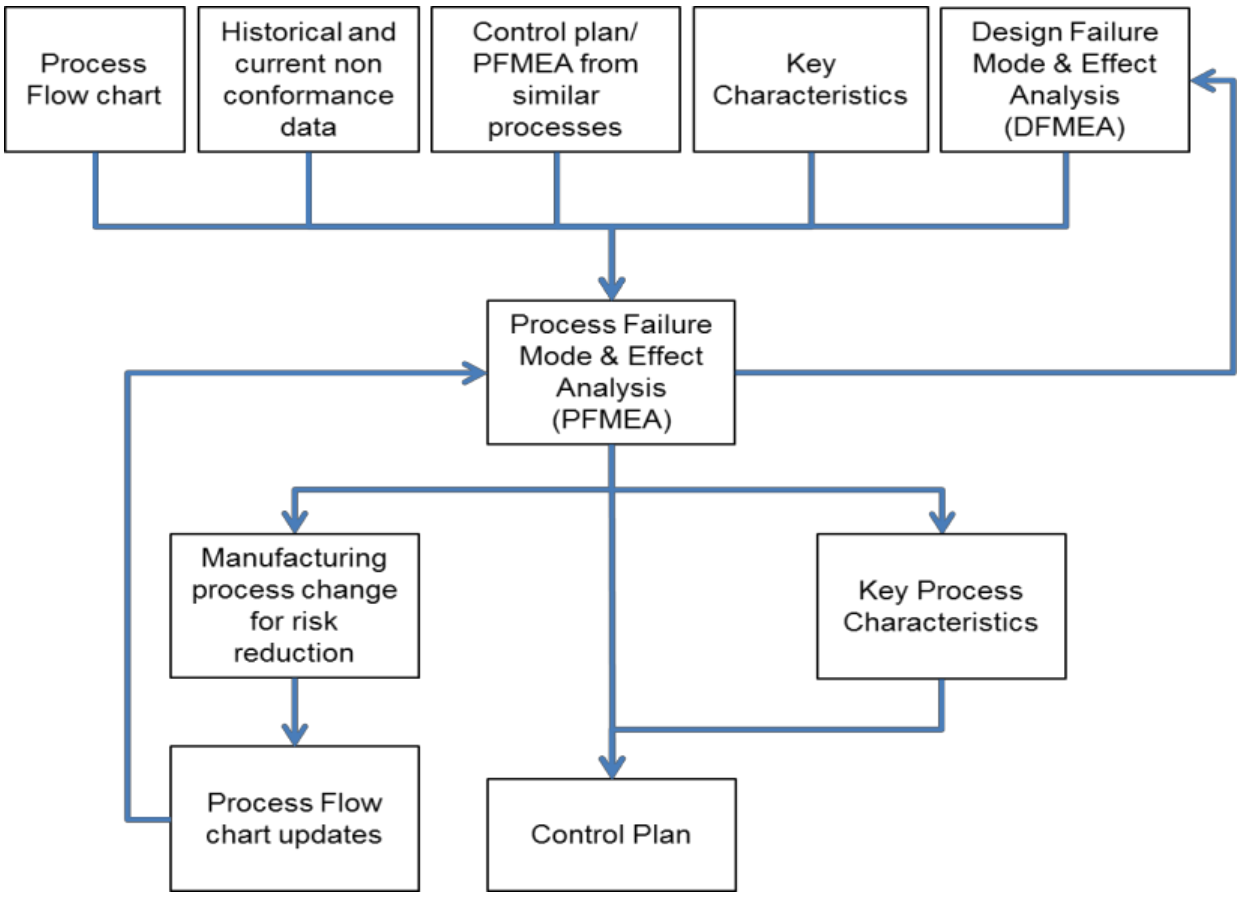
There is a close link between the PFMEA and the DFMEA (Design Failure Mode and Effect Analysis). Updates to either may impact on the other and should be taken into account.

Deliverables:
Completed signed off PFMEA and an agreed plan to reduce the highest priority risks.

Necessary Inputs:	Source of inputs:
Process flow chart	Manufacturing Engineering
Historical and current non conformance data for similar parts and processes	Quality
DFMEA	Design Engineering (internal or customer)
Key Characteristics	Design Engineering & Quality
Control Plan (from similar processes)	Quality

Resources:
Manufacturing Engineering (including technical experts as required) Quality Engineer
Production representative Design Engineering Maintenance
Health, Safety & Environment (HS&E) Representative

Methodology:



1. A Cross functional team meets to undertake the PFMEA activity. This is likely to be a series of meetings which will be focused around the process steps as defined in the Process Flow chart. Meetings will be documented on the PFMEA grid.
2. All high RPN items need to have actions. The actions need to be assigned to an owner and there must be an agreed reporting and escalation process to ensure successful implementation of the risk mitigation activities.
3. There is a close link between the DFMEA and the PFMEA. Where it is not possible to remove risk from the process then this must be reconsidered as part of the DFMEA (and vice versa) and removed by design activity.
4. High risk items may be mitigated by the assignment of and control of Process Key Characteristics
   Reference document

Reference documents:

PFMEA template

Element **Process Key Characteristics**

3.15 Make/3.16 Buy

Element Owner:

Manufacturing Engineer and Quality Engineer

Element Definition

Process Key Characteristics can be inputs to or outputs from the process, they are the most important ones impacting the product quality. When these parameters are under control the product quality is guaranteed. Key Process Inputs are the process parameters which, if measured and controlled to be within prescribed limits, will guarantee the capability of the production process. Key Process Outputs are the product or process attributes which, when measured and compared to prescribed limits, validate the capability of the process. In other words, these are the key parameters which will identify process variation that could impact product quality.

Recording of these process key characteristics, via SPC charts or other means, enables a preventive approach to quality. Process drift can be recognized and addressed before it leads to non-conformity.

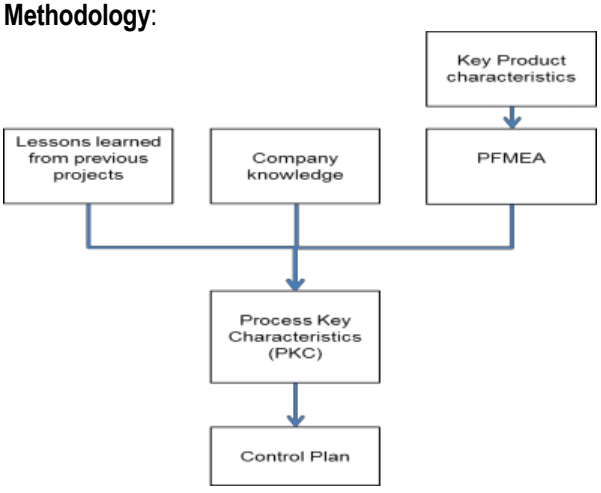
Deliverables:

List of Process Key Characteristics identified.

Necessary Inputs:	**Source for inputs:**
Key product Characteristic s PFMEA	Design Engineering/Customer Manufacturing Engineering/Quality

Resources: Manufacturing Engineer Quality Engineer Operations

Methodology:



1. Highlight high risk items from PFMEA where the RPN cannot be reduced by reducing the occurrence or severity through design action. This provides the initial list of process steps requiring Process Key Characteristics.
2. Review the process steps and identify potential Process Key Characteristics. Measure and evaluate the variability each one provides. If a proposed characteristic provides no variability or it cannot be reliably detected, it is not a Process Key Characteristic. Alternatively where it provides high variability correlated to Quality issues, it is finalized as a Process Key Characteristics.
3. Finalize the list of Process Key Characteristics and review with the Quality Engineer. These Process Key Characteristics must be monitored as designated through the control plan by either 100% checking or SPC (Statistical Process Control).

Reference document None

Element 3.16 Make/3.17 Buy	**Manufacturing & test Equipment, tools, fixtures & jigs specified**

Element Owner:
Manufacturing Engineer

Element definition
In order for a successful product launch it is essential to have a proper definition of, and planning for, all equipment, tooling, fixtures, jigs required to produce and qualify the product. This activity will cover the following:

- Checking the need for additional capacity on existing equipment and/or the refurbishment or modification of any existing equipment, tooling, jigs or fixtures and testing equipment. This evaluation will also consider human resources
- Planning the implementation of additional means and resources required to meet planned capacity and to cover all process steps defined into the manufacturing flow
- Commissioning of new equipment, tooling and facilities for new processes. To finally validate the plan the human resources have to be available and trained.

The supplier must track the progress against their plans on a regular basis in order to promptly identify and react to delays or problems. The customer should be given regular progress reports in a form agreed to by the customer.

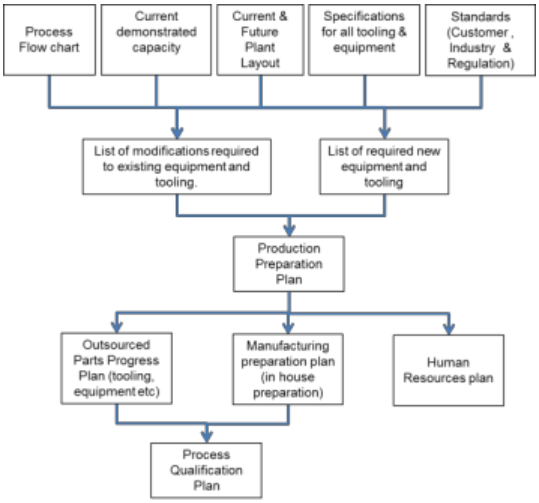
Deliverables:

- Capacity evaluation for all existing equipment.
- Approved and agreed implementation plan for equipment, tooling and facilities covering additional equipment for capacity increase and new equipment for new processes (the plan includes qualification procedure)
- Production Preparation Plan covering all aspects of human resources, tooling and equipment procurement, preparation, commissioning and validation.

Necessary Inputs:	**Source of inputs:**
Process Flow Chart	Manufacturing Engineering
Current and Future Plant layout	Manufacturing Engineering
Current demonstrated capacity	Production Planning
Specifications for all tooling and equipment	Manufacturing Engineering & Quality Standards (customer and
industry specific)	Manufacturing Engineering & Quality

Resources: Manufacturing Engineer; Quality; Procurement (for outsourced equipment/tooling); Project Leader; Production; Maintenance; Human Resources

Methodology:



1. Establish a cross functional team and regular reviews which enables the plans to be established and agreed and progress to be monitored.
2. Define escalation criteria and method for how to react to delays or problems with the project
3. progression.

Reference document: None

Element 3.17 Make/ 3.18 Buy	**Pre-Production Control Plan**

Element Owner: Manufacturing Engineer and Quality.

Element Definition:

The purpose of the control plan is to document all quality controls to be imposed on the product including: Features to be monitored, the measurement methods, the sampling size and frequency and the control limits to respect. The control plan covers the product from incoming raw material until dispatch of the finished good to the customer. It may also reach out to shop assist suppliers.

The control plan details how quality is, controlled and confirmed at each stage of the manufacturing process, including, when necessary, the actions to be taken when deviations are found (reaction plans). It should be sufficiently detailed in order to clearly define who is responsible for undertaking the quality check at each stage of the process. The control plan must be agreed by the supplier's quality and production departments and by the final customer.

The control plan should be prepared and applied from the prototype/preproduction phase onwards. It should be revised and updated throughout the life of the product in response to any new quality issues or changes.

During the preproduction phase the number of controls is generally much higher than during series production because the producer has not yet identified and removed all sources of variation. As these variations are removed the number/frequency of controls can be reduced.

Deliverables:

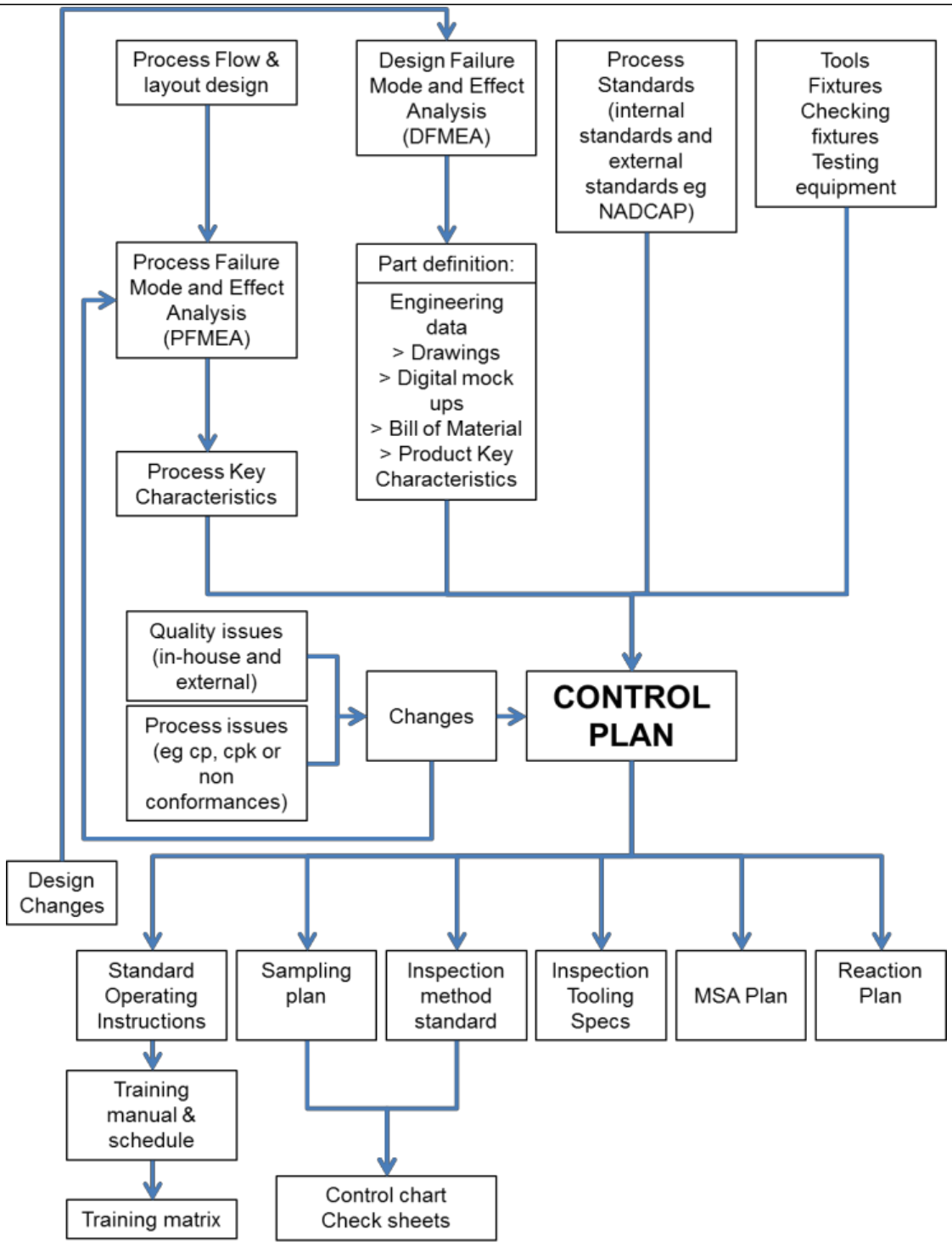
Control plan signed and approved by: Quality and production and the Customer upon request.

Necessary Inputs:	**Source of inputs:**
P-FMEA, D-FMEA	Manufacturing Engineering & Quality
Product Key Characteristics	Design Engineering
Process Key Characteristics	Manufacturing Engineering & Quality
Process flow chart	Manufacturing Engineering
Inspection standards	Quality
Drawings	Design Engineering
Historical quality concerns	Quality
Process capabilities (similar processes)	Manufacturing Engineering Change requests (to update the control plan)
	Various sources

Resources:

Quality (Accountable for Control Plan)
Manufacturing Engineering (Responsible for defining the process characteristics) Design Engineering (Responsible for defining the product characteristics) Additional input as required from:
Operations (Support) Supply Chain (Support)
Facilities Maintenance (Support)

Methodology:



1. Establish a series of cross functional reviews to define the necessary controls in order to guarantee the quality of the finished product.

Reference document:

Element 3.18 Make/3.19 Buy	Measurements Systems Analysis (MSA) Plan

Element Owner: Quality Engineer

Element Definition:

Measurement Systems Analysis (MSA) is a structured approach based on statistical tools to evaluate and measure the error in a reading from the measurement system due to the measurement system.

Excessive errors in the readings have to be corrected. The purpose of MSA is to identify: The nature of the variation introduced by the measurement system, where the variation is introduced, the root cause of the variation and how the variation can be removed.

Measurement systems need to be validated as capable for the measurements they are required to perform, as outlined in the Control Plan. A plan should be developed for completing MSA activity on those systems.

The key variables to be assessed are:

- Precision
- Repeatability – variation due to a single operator or piece of equipment
- Reproducibility – variation between operators
- Accuracy
- Resolution – ability to measure small changes based on defined tolerance Bias – a consistent difference in the measurement vs known standard
- Stability– bias over time
- Linearity– bias throughout the measurement range

The evaluation should consider the Inspector, Inspection Method, Component, Measuring Equipment and Environmental conditions. Gage R&R is a common methodology for conducting measurement system analysis for precision but it is not sufficient for analyzing all variables (it does not cover resolution, bias, stability or linearity).

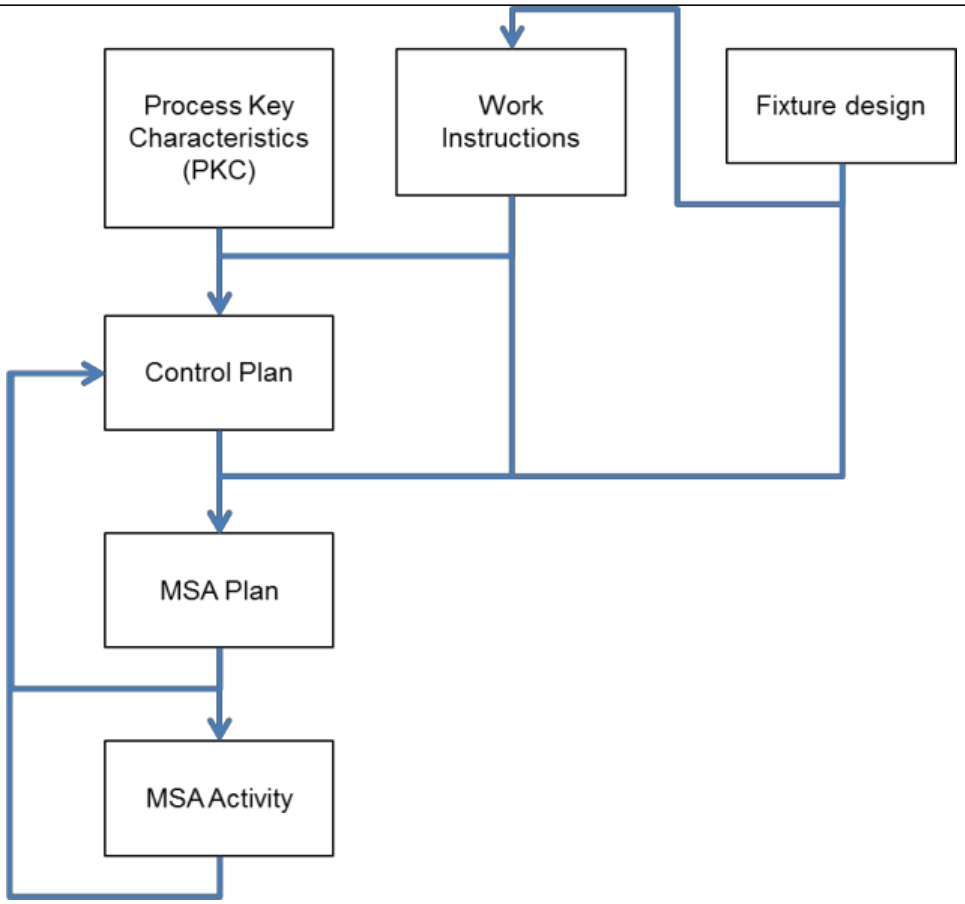
During this phase the activity will start to assess the components of accuracy (resolution, bias, stability, and linearity) using prototype parts, measuring equipment and calibration data. Precision is assessed during the MSA activity in Phase 4 when actual parts and final measuring equipment is available.

Deliverables:

Plan which identifies all measurement systems to be evaluated including who is responsible for evaluating them and the timing for doing this. The plan must be aligned with overall program needs.

Necessary Inputs:	Source of inputs: DFMEA/Customer PFMEA
Key Product Characteristics Key Process Characteristics Control Plan Work Instructions Fixture Design	Quality Engineer & Manufacturing Engineer Manufacturing Engineer Manufacturing Engineer Customer

Methodology:



1. Review Control plan and identify all items which need to be measured.
2. Review the measurements and the appropriateness of the selected measurement tool and measurement method i.e. work instructions (does the measurement achieve what you need it to achieve). Where the measurement tools or methods are not appropriate, investigate and update control plan as appropriate.
3. Identify which of the measurement items need full MSA. Criteria to consider for appropriateness of MSA include:
   > Criticality of the measurements (as a minimum anything linked to a key characteristic)
   > Past experience of using the measurement system and evidence of its capability
   > KCs
4. Create a plan for when each of the measurements need to be validated. The plan should consider tooling, measurement equipment and part availability as well as operator training and the overall program plans. The plan must clearly state who is responsible for each activity and the due date.
5. As further controls are added to the control plan the MSA Plan must be updated to reflect these changes (Step #2).
6. Where possible start to check the components of accuracy through using similar to or actual parts,
7. measuring equipment and calibration data.

Reference document: None

Element 3.19 Make/ 3.20 Buy	**SOI / Routings**

Element Owner:
Manufacturing Engineer

Element definition
This step covers the creation of all Manufacturing Process Documentation which includes travelers, work instructions, inspection instructions and other documents held at the work station including maintenance schedules and instructions, SPC charts, data collection check sheets, visual management templates and documentation associated with the product.

The manufacturing process documentation provides sufficient definition and detail for those responsible for operating the process.

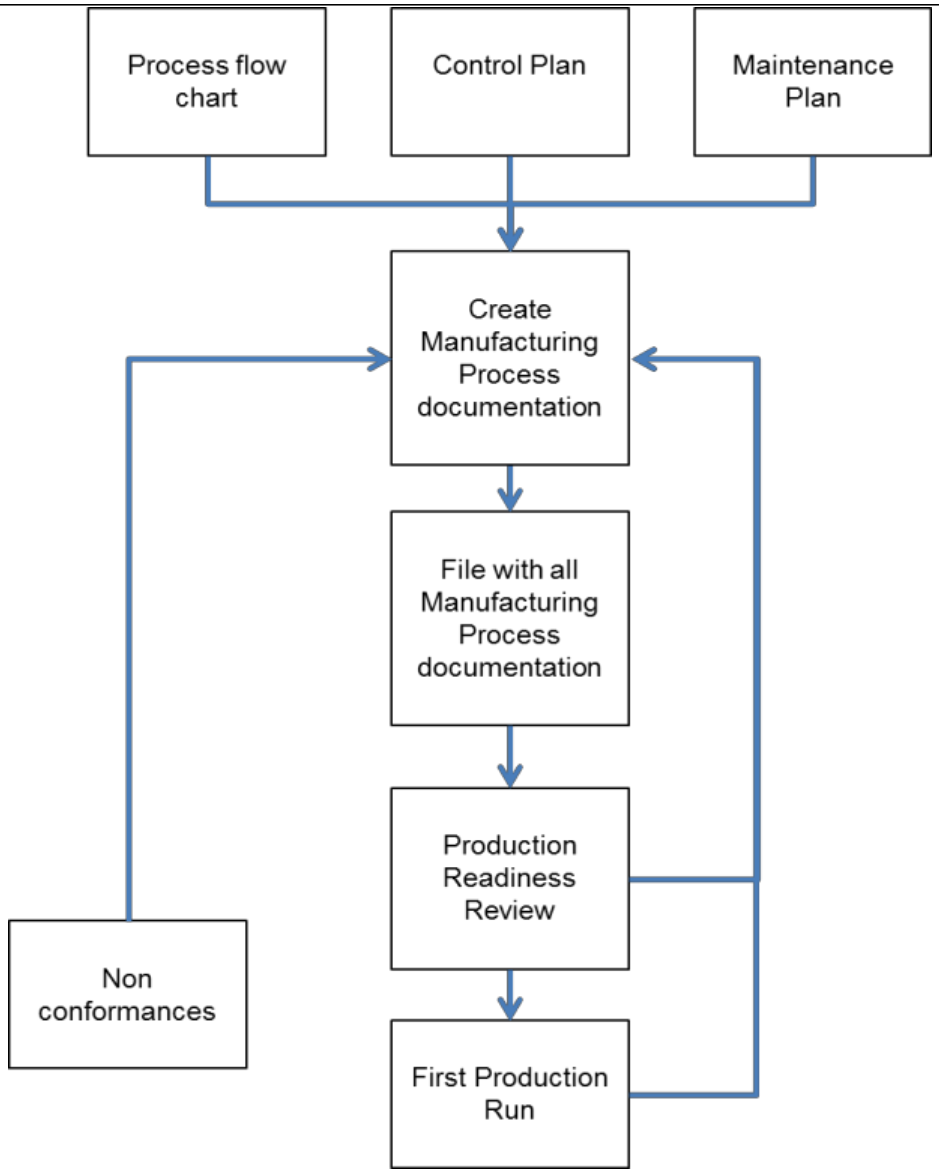
This activity is applicable for every part produced (development prototypes through to full production).

Deliverables:
File containing all applicable work station documentation.

Necessary Inputs:	**Source of inputs:**
Process Flow Chart	Manufacturing Engineer
Control Plan	Quality Engineer & Manufacturing Engineer
Maintenance Plan	Facility Maintenance
Best Practice	Manufacturing Engineer & Quality
Operator Experience	Operators & Quality

Resources: Manufacturing Engineer Quality Engineer Facility Maintenance Operators

Methodology:



1. Manufacturing Engineer to review process flow chart and define detailed product routing.
2. Configure MRP system to reflect the defined product routing.
3. Determine all process steps which require detailed production documentation.
4. Create required detailed production documentation.
5. Validate production documentation with operators and quality.
6. Issue documentation and make available at workstation.
7. Manage any changes through configuration control.

Reference document: None

Element 3.20	**Pre-built assessment Make**

Element Owner: Production Manager

Element definition

An assessment is held in the shop floor to confirm the readiness of the production process to deliver a product which meets the customer's requirements. The review will cover all aspects of the manufacturing process including equipment, process, operator training, manufacturing documentation, control plan and associated measurement tools.

The plant will demonstrate that all aspects of the production preparation have been completed.

Where the production process is not ready, an action plan will be established to close all outstanding issues. At the next step Management should confirm that all outstanding actions are satisfactorily closed before the significant production run can be started.

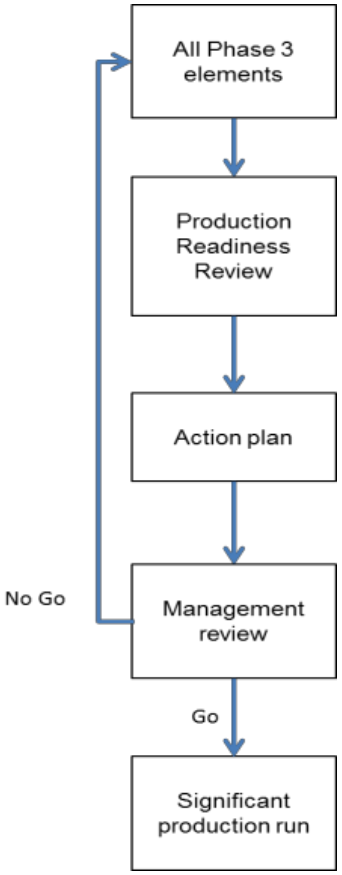
Deliverables:

Finalized and agreed upon production process with all appropriate documentation, equipment, and information systems in place to support the production of the product.
Action plan for outstanding items.

Necessary Inputs:	**Source of inputs:** Manufacturing process, equipment,
tooling	Manufacturing Engineering and fixtures.
Work station documentation (including	Manufacturing Engineering routing and WIS)
Trained operators and training matrix	Production & Human Resources ERP configured to support
the ordering and	Production Planning
production planning processes.	
Subcontracted material availability confirmed	Procurement

Resources: Manufacturing Engineer Production Manager

Methodology:



1. A Cross functional team reviews all production preparation activities and confirms they are completed satisfactorily
2. A Shop floor assessment is conducted to confirm that production preparation activities have been completed effectively and that the process has been implemented consistently with all documentation and planning.
3. An Action plan developed to close any identified gaps

Reference document None

Element 3.21 Make	**Management review**

Element Owner: Project leader

Element definition

Once the production process has been assessed and all gaps have been identified, it is the responsibility of the management team (engineering, production, manufacturing engineering, procurement and quality) to decide the launch of production in final conditions.

The goal of this formal review is to make sure that process and product maturity are meeting customer expectations. Any remaining issues and risks are accepted including their consequences. At this stage it is considered that they are mitigated by actions identified and in place and no impact on the EIS is foreseen.

The production process is finalized ready for initial production, the product design meets the specification and there are no significant changes foreseen. The production process includes all inputs such as supplied parts.
Any process changes beyond this review should go through the change management process.

Deliverables:

Go/no Go decision

Necessary Inputs:	**Source of inputs:**
Pre-built assessment	Production/plant manager
V&V results from phase 2	Engineering
Product changes status	Engineering

Resources:

Head of Manufacturing Engineering Head of plant/production
Head of quality
Head of procurement Head of program Head of engineering

Methodology:

A Formal review is held at the management level with attendance from key team members able to demonstrate that the process is able to produce a product that meets the customer's expectations as defined in the quality & reliability goals and technical specifications.

Reference document None

Element 3.21 Buy	**Production Readiness Review**

Element Owner:
Supply chain manager

Element definition
A review is held at the producer to confirm the readiness of the production process to deliver product which meets the customer's requirements. The review is supported by an assessment which covers all aspects of the manufacturing and test process including equipment, process, operator training, manufacturing documentation, control plan and associated measurement tools, supplied parts status, production planning (refer to IPCA+).

Where the production process is not ready, an action plan will be established to close all outstanding issues. Customer supply chain manager and supplier should agree and confirm that all outstanding actions are satisfactorily closed before the significant production run can be started.
The production process is finalized at this stage and ready for initial production.
Any process changes beyond this review should be submitted to the customer for approval (as per contractual agreement)

Deliverables:
Expected IPCA+ level achieved
Action plan to cover gaps agreed and implemented

Necessary Inputs:	**Source of inputs:** Manufacturing process, equipment,
tooling	Manufacturing Engineering and fixtures.
Work station documentation (including routing	Manufacturing Engineering and WIS)
Trained operators and training matrix	Production & Human Resources ERP configured to support
the ordering and	Production Planning
production planning processes.	
Subcontracted material availability confirmed	Procurement

Resources:
Customer supply chain manager Supplier Manufacturing Engineer Supplier Production Manager Supplier Quality Engineer & Manager Supplier Procurement
Supplier Production Planning

Methodology:
1. A Cross functional team reviews all production preparation activities and confirms they are completed satisfactorily
2. Shop floor assessment (IPCA+) is conducted to confirm that production preparation activities have been completed effectively and that the process has been implemented consistently with all documentation and planning.
3. An Action plan developed and agreed with customer to close any identified gaps considering project Key dates

Reference document
None

Phase 4 Product and Process Validation	Introduction

Phase Definition:

The goal of this phase is to demonstrate that the manufacturing and assembly processes can produce conforming product at the required rate. Upon successful completion of the previous phases, the first step in Phase 4 is the Significant Production Run in which parts are made at with production equipment and processes. This is done to gain knowledge of production readiness as well as product conformity. Of particular interest are measurement systems, control plans, capacity verification and First Article Inspection (FAI). After FAI approval by customer, parts may be shipped as interim-approved parts.

Make and Buy

Element: 4.22 Make and Buy	**Measurement Systems Analysis (MSA)**

Element Owner:
Quality / Manufacturing Engineering

Element Definition:
The purpose of the Measurement Systems Analysis is to implement the MSA Plan (Element 18) and assess variation introduced by measurement systems. The key variables to be assessed are stability, repeatability and reproducibility. Variation is introduced by the measurement device, fixtures, operators and shop floor environmental conditions.
Stability and gage R&R activities will be performed for each of the measurements that need to be validated as identified in the MSA plan.
Where the target level of error due to the measurement system (as defined in the MSA Plan) is not achieved, action should be taken to reduce the error to below the targeted value.
Recognized benchmark data shows the measurement system error threshold to be less than 10% for both precision to tolerance as well as precision to total variation.

Deliverables:
- MSA report including Gage R&R charts
- Action plan for those that are not within requirements

Necessary Inputs:	**Source of Inputs:**
MSA Plan	Manufacturing Engineering
Key Characteristics Control Plan	Design and Manufacturing Engineering Manufacturing
Work Instructions Measurement Devices Design Tooling	Engineering Manufacturing Engineering Manufacturing
Trained Inspector	Engineering Manufacturing Engineering
	Quality

Resources:
Quality Engineer; Manufacturing Engineer; Production Engineer; Production Operators or Inspection Technicians

Gage R&R Methodology:
1. Review the MSA Plan.
2. Collect the appropriate number of parts from the Significant Production Run and subsequent builds as required.
3. Undertake data collection in accordance with the MSA Plan.
4. Analyze data and compute gage error (precision to tolerance and precision to total variation).
5. Take actions for improvement if necessary.

Stability Methodology:
1. Check parts for the first five production runs to verify that the results are within the required MSA percent (see 9103).

Reference document None

Element: 4.23 Make and Buy	**Final Critical Items/KC Product & Process**

Element Owner:
Engineering / Manufacturing Engineering / Quality

Element Definition:
The quality team has to review the data captured during the first production in order to:

- identify which KC is capturing variability (product and process)
- evaluate if the set of KC identified in phase 2 and 3 is sufficient to measure product quality

From these data quality,engineering and manufacturing engineering team must agree which will be the final Critical Items / Key characteristics (considering the product and the process) to be considered during the production phase of the program from the initial identified listings. All relevant documentation must be updated accordingly (e.g.: control plan, drawings, process specification)

During the exercise an effort will be made to translate as many Product KC/ CTI as possible into Process KC/CTI to gain from the benefits of a preventive approach, as the process will be advising of potential concerns even before non-conforming product is actually produced.

Deliverables:

- Final List of Critical Items / Key characteristics
- Updated product and process definition documentation

Necessary Inputs:	**Source of Inputs:**
Preliminary list of Key Characteri Control Plan	stics / CTI Manufacturing Engineering / Engineering Design and Manufacturing Engineering

Resources:
Quality Engineer; Manufacturing Engineer; Production Engineer; Production Operators or Inspection Technicians

Methodology:

- Analyse data captured during first production run
- Review and agree the final Critical Items / Key characteristics list
- For each Product KC/ CTI identify the related process KC/CTI
- Update Control Plan accordingly.

Reference document None

Element 4.24 Make and Buy	**Production Control Plan**

Element Owner:
Manufacturing Engineer and Quality.

Element Definition:
The Production Control Plan is a logical extension of the Pre-launch Control Plan. The Significant Production Run provides opportunity to evaluate the output, review the control plan and make appropriate changes.

The Control Plan is a living document which should be updated throughout the life of the program/project to reflect the controls in place in the production process at any point in time. Where Control Plans are a customer approved document, each change should be reported to the customer and approved.

The purpose of the Control Plan is to document all the controls to be performed on the features identified on the component (including the measurement methods and means) and the sampling frequency from incoming raw material to the dispatch of finished goods to the customer.

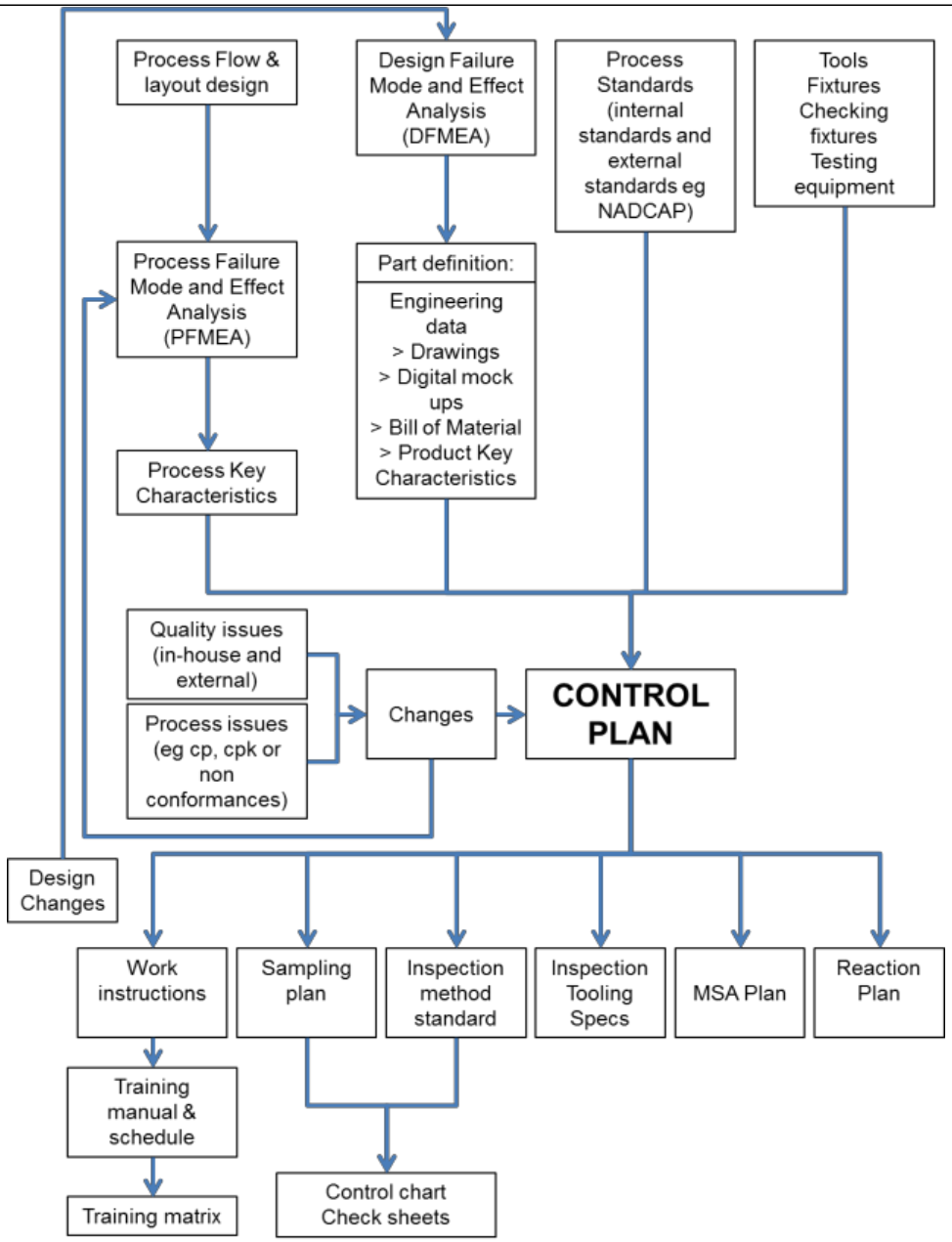
The Control Plan details how quality is controlled and confirmed at each stage of the manufacturing process, including, when necessary, the actions to be taken when deviations are found (reaction plans). All characteristics to be controlled shall be listed on the Control Plan.

Deliverables:
Updated Control Plan

Necessary Inputs:	**Source of Input:**
Pre-launch control plan	Quality
DFMEA	Design Engineering
PFMEA	Manufacturing Engineering
Process Flow Map	Manufacturing Engineering
Final List of Product and Process KC/CTI	Engineering / Manufacturing Engineering

Resources:
Quality (Accountable for Control Plan)
Manufacturing Engineering (Responsible for defining the process characteristics) Design Engineering (Responsible for defining the product characteristics) Additional input as required from:
Operations (Support) Supply Chain (Support)
Facilities Maintenance (Support)

Methodology:



1. Review all inputs into the Control Plan including DFMEA and PFMEA for identification of Key Characteristics and
2. Process Key Characteristics.
3. Evaluate completeness of the Control Plan's inclusion of Key Characteristics and Process Key Characteristics.
4. During the Significant Production Run walk the process with the Preliminary Control Plan to validate
5. implementation of controls.
6. Evaluate controls during the Significant Production Run for effectiveness.
7. If any non-conformances are observed during the run, update the Control Plan as needed.
8. List any issues with the Control Plan and resolve.
9. Publish the Production Control Plan when all issues are resolved and accepted by the customer.

Reference document None

Element 4.25 Make and Buy	First Production Run

Element Owner:
Manufacturing Engineer

Element definition

The Significant Production Run is conducted to verify that all production processes can achieve production quality and rate. In order to achieve this, the manufacturer should ensure that only final production processes are employed; specifically tooling, fixturing, gauging, and operators. Prior to the run the operators should be trained to the latest work instructions and during the run only these operators are allowed to build parts in the production line. Manufacturing support team members should be available to support them in order to solve any issues that may arise (Andon principles).

Attention should be placed on observing safety and ergonomic issues. In addition to producing parts, the production run should focus on verifying the manufacturing support system (component supply, preventative maintenance, tool and equipment changeover and the logistics system).

During the significant production run processes should be closely observed and data should be collected and problems recorded as they are found.
Collected data may include:

- Production performance (cycle time, equipment breakdowns, changeover time, actual run time, production line work balance, capacity data)
- Availability of all production documentation at work station
- Adherence to work instruction
- Quality data as per control plan
- Any risk or concerns observed
- Safety and ergonomic issues
- Effectiveness of fixtures

Parts that are produced from the Significant Production Run are used to provide data for FAI submission. Data will also be collected to calculate initial process capability. If non- conformances are generated during the run, action plans should be generated and root cause corrective action performed.
Problems identified during the significant production run should be used to correct/improve the production process and associated documentation in order to reduce risk and variation in series production.

Deliverables:

- Parts used from the First Production Run for the FAI.
- Report on performance of tooling, fixture, gauging, and operators work instruction and training to meet product requirements
- Identification of safety and ergonomic issues
- Action Plan

Necessary Inputs:	**Source of Inputs:**
Approved tooling, fixtures, gauging, and	Manufacturing Engineering
Manufacturing Engineering operators work instruction	
Production equipment Control Plan Maintenance plan	Manufacturing Engineering, Quality Facility Management
Design records	Design Engineering
Key Characteristics	Design and Manufacturing Engineering Manufacturing
Trained Operators	Engineering, Quality

Resources: Design Engineer Quality
Manufacturing Engineer
Production Operators or Inspection Technicians, as appropriate Production Manager

Methodology:

1. The manufacturer shall run parts using approved tooling, fixture, gauging, and operators work instruction. The quantity of parts to be produced will be the quantity required by the customer or the quantity of parts required in order to validate statistically that the process is capable (which ever quantity is higher).
2. Collect data as planned and segregate non-conforming products in order to identify the source and nature of defects.
3. Immediately involve the appropriate support functions (Engineering, Quality, Production Control, etc.) to track all problems found through to resolution and identify any process changes that are required.
4. Update all relevant documents (Manufacturing Process Documents, FMEA, Control Plan, etc.) after the problems are solved and/or the process changes implemented.

If the manufacturer is unable to achieve targeted quality levels after applying corrective actions to the process, it should be escalated to top management and the customer should be informed accordingly.

Reference document
None

Element 4.26 Make or Buy	**First Article Inspection (FAI)**

Element Owner: Quality

Element Definition:

The purpose of the First Article Inspection is to give objective evidence, based on an assessment of the first production article, that all engineering, design and specification requirements are correctly understood, accounted for, verified and complied with, and recorded. First Article Inspection is a complete, independent, and documented physical and functional inspection process to verify that prescribed production methods have produced an acceptable item as specified by engineering drawings, purchase order, engineering specifications, and/or other applicable design documents. (refer to 9102)

Deliverables:

Approved First Article Inspection Report

Necessary Inputs:	**Source of Input:**
Design Characteristics	Design Engineering
First Production Run Parts	Manufacturing
Pre-launch control plan	Manufacturing Engineer, Quality Engineering
Calibrated Measurement Devices	Quality
Functional Test Results	Design/Manufacturing Engineering
Material Certifications	Procurement / Quality
Lab Certifications	Quality
Test Requirements	Design Engineering
Design Record	Design Engineering
Process Documentation	Manufacturing Engineering
Non-Conformance Documentation	Quality
FAI report for any sub components	Procurement/Quality

Resources:

Quality with support from Manufacturing Engineering, Design Engineering and Procurement as required.

Methodology:

1. Review documentation for the manufacturing process (e.g., routing sheets, manufacturing/ quality plans, manufacturing work instructions, etc.) and make sure the manufacturing system is in place.
2. Collect and review for completeness and correctness all supporting FAI data which may include:
   > inspection data,
   > test data (including Acceptance Test Procedure)
   > nonconformance documentation and associated action plan). NOTE: International Aerospace Standard 9131 may be used as guidance.
   > Material certifications as applicable.
   > FAI reports from subcomponents
3. Verify that approved Special Process sources are used (as applicable).
4. Verify that Key Characteristic requirements have been met, as applicable (see International Aerospace Standard 9103 for guidance
5. Verify all production equipment including part specific gages and/or tooling are qualified and traceable, as applicable.
6. Verify that every design characteristic requirement is met and recorded within the FAI Report.
7. Record all results from these activities in the FAI Report.

Reference document: None

Phase 5 Production	Introduction

Phase Definition:

The goal of this phase is to put in place the key elements that will be used to monitor that the manufacturing process is continuously delivering product conform to the specification.

The key elements of this phase are the variation process and product variation evaluation and control tools (capability indexes and SPC) and the continuous improvement methods introduced by Q6 in our company and other standards at suppliers. The continuous improvement methods are all following the same logic: proper capture of issues, their analysis, their correction and the implementation of preventative actions to eradicate their recurrence.

Make

Buy

Element 5.27 Make and Buy	**Statisti cal Process Control**

Element Owner:
Quality Engineer, Manufacturing Engineer

Element Definition
Monitoring the production processes, with special attention given to Key Characteristics (KCs), should be conducted as an ongoing process to improve customer satisfaction and reduce cost thru variation reduction. Data analysis using statistical techniques (Cp and CpK) is the preferred method for identifying variation reduction opportunities. Appropriate actions should be implemented where improvement opportunities are identified. Statistical Process Control (SPC) is typically required for Key Characteristics and should be identified in the Control Plan.
It may be necessary to present planned improvement actions to the customer prior to implementation.
Product and process documentation (i.e. Process Flow Chart, PFMEA, Control Plan, etc.) should be updated as appropriate with the implementation of any improvement.

Deliverables:
On-going data analysis and planned improvement actions to reduce variation of the processes.

Necessary Inputs:	**Source of Inputs:**
Data from the Ongoing Production Runs	Quality Engineer, Manufacturing Engineer
Control Plan	Quality Engineer

Resources:
Quality Engineer, Manufacturing Engineer, Production Engineer, Design Engineer, Operators

Methodology:
1. Process Flowchart, Element, is used to identify production process outputs and inputs
2. Measure outputs to determine if they are in alignment with desired state and overall variability requirements
3. Determine the critical inputs for those outputs where variation reduction is desired
4. Analyze input parameters to determine impact on desired output
5. Establish action plan
6. Validate improvement (reduced variation)
7. Update and issue Standard Work and limits

Reference document
None

Element 5.28 Make and Buy	**Process capability indexes**

Element Owner: Quality / Manufacturing Engineering

Element definition

Preliminary process capability studies provide demonstration that the combination of people, machine, methods, material, and measurements will produce a product that will consistently meet the design requirements. Preliminary process capability studies should be performed on Key Characteristics identified in the control plan. Key Characteristics require special attention, because deviations in these characteristics can seriously affect product safety, product lifetime, assembly capability, product functionality, and/or quality of the subsequent manufacturing operations. The measurement of Key Characteristics will start being recorded during the Significant Production Run and will continue until sufficient data is collected to allow the calculation of process capability using Cp and Cpk indices. The minimum number of samples to be considered for a capability study shall be agreed upon with the Customer. A generally accepted standard is between 10 and 30 samples.

Deliverables:

Process capabilities indices (Cp, Cpk) completed (the minimum quantity of parts to allow calculation is defined by the customer).
Action plan to reach the expected level
Control plan update to adapt measurement frequency based on Cp and Cpk calculation

Necessary Inputs:	**Source of Inputs:**
Key Characteristics (KCs)	Design Engineer & Manufacturing Engineer,
Preliminary MSA results for Key	Quality /Manufacturing Engineer Characteristics
Significant Production Run Parts	Manufacturing Engineer

Resources:

Quality, Manufacturing Engineer

Methodology:

1. Preliminary Process capability study must be conducted on quantity of parts (as agreed upon with customer) for all Key Characteristic.
2. When performing Preliminary Process Capability Study, the same tooling and equipment intended for production must be used. Data collected from development or pre- production parts, can be considered.
3. The measurement of Key Characteristics will start being recorded (using a control chart) during the Significant Production Run and will continue until sufficient data is collected to allow the calculation of process capability using Cp and Cpk indices.
4. Process capability indices (Cp, Cpk) shall only be calculated after the process is determined to be stable. A process is not stable over time if special causes of variations are present. Those causes must be identified and removed.
5. If capability studies do not meet ≥1.33 then 100% inspection is expected until 1.33 is achieved.
6. When process capability reaches the expected level the inspection frequency can be adapted.

Note: Capability studies can be affected by Engineering Changes, Process Change Requests, Design Change Requests, or part tolerance changes and therefore must be re- submitted for characteristics affected by change.

Reference document: None

Element 5.29 Buy	**Root cause analysis**

Element Owner:
Production Operations, Customer Support

Element Definition
On-quality and on-time delivery of product must be maintained at or above the level desired by the customer throughout the life of the program. To ensure customers' delivery requirements are maintained, Quality and delivery performance and capacity should be monitored and
analyzed regularly. Actions should be taken to remediate quality and delivery issues before they arise.
When they arise, the supplier should take any suitable action to contain issue at the customer and within its premises. Further on, when the problem is contained, the supplier has to identify its true root cause to correct it and the preventative action that will prevent this problem to happen again within or outside the environment of the first occurrence. All this has to be formalized into the proper Practical Problem Solving (PPS) template.
The supplier shall seek for preventing problem to occur and build a continuous improvement plan. For this, in addition to process variation (quality) control it is expected that the supplier monitors its capacity (quantity). The capacity analysis should demonstrate the ability of the producer to meet the demand profile of the customer over the foreseeable time horizon.
Changes is in the demand profile should be identified and addressed as soon as they are communicated from the customer. The result of the gap analysis and associated actions should be presented into a Capacity Contingency Plan.

Deliverables:
PPS for any issue
Capacity Contingency Plan
Continuous improvement plan

Necessary Inputs:	**Source of Inputs:**
Quality metrics	Quality
Process variability	Manufacturing, Quality, Sales/Customer
Delivery metrics	Manufacturing, Quality, Sales/Customer
Cycle time at each step of the process including set-up time	Manufacturing
Yield at each step of the process	Quality
Forecasted demand for all parts that go thru the particular steps of the process	Sales/Customer

Resources:
Quality, Production Operations, Customer Support, Manufacturing, Sales and Marketing & Customer

Methodology:
- Collect on-quality, and on-time issues
- Provide to customer containment action
- Identify root cause
- Provide corrective and preventative actions
- Feedback on control plan and on product and process definition
- Monitor process variation vs customer targets and build improvement plan
- Monitor on-time performance vs customer target and build improvement plan
- Monitor capacity vs customer demand and build Capacity and Contingency Plan

Reference document:
None

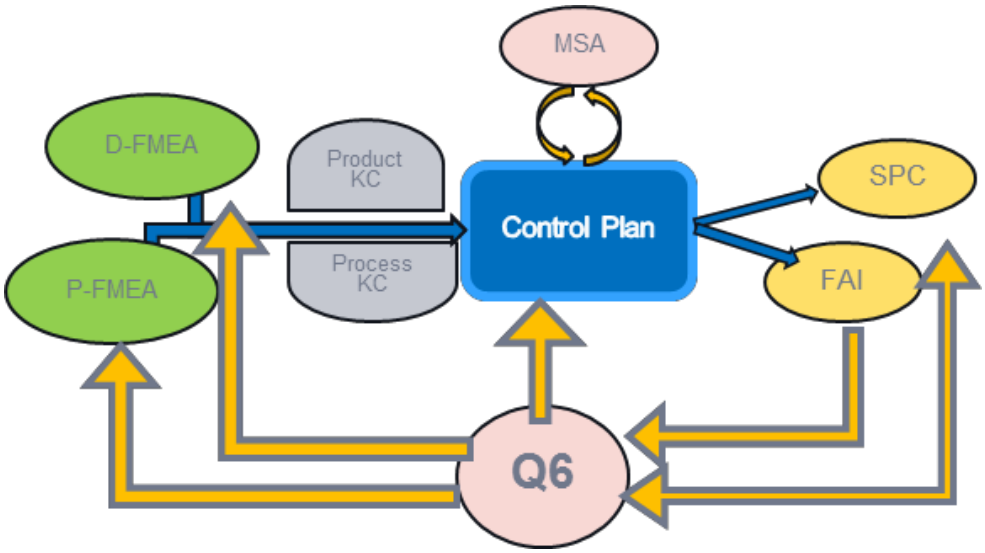
Element 5.29 Make	**Q6**

Element Owner:
Quality

Element definition

Q6 is a structured method to implement an efficient quality management system. It applies a set of robust quality and lean tools which manage the detection, visualisation communication and resolution of quality problems.

Based on the definition of the requirements for the six following elements: Q1 - Quality loops (feedback)
Q2 - Practical Problem Solving Q3 - KPI system
Q4 - Standardized work Q5 - Qualification
Q6 - Operational management



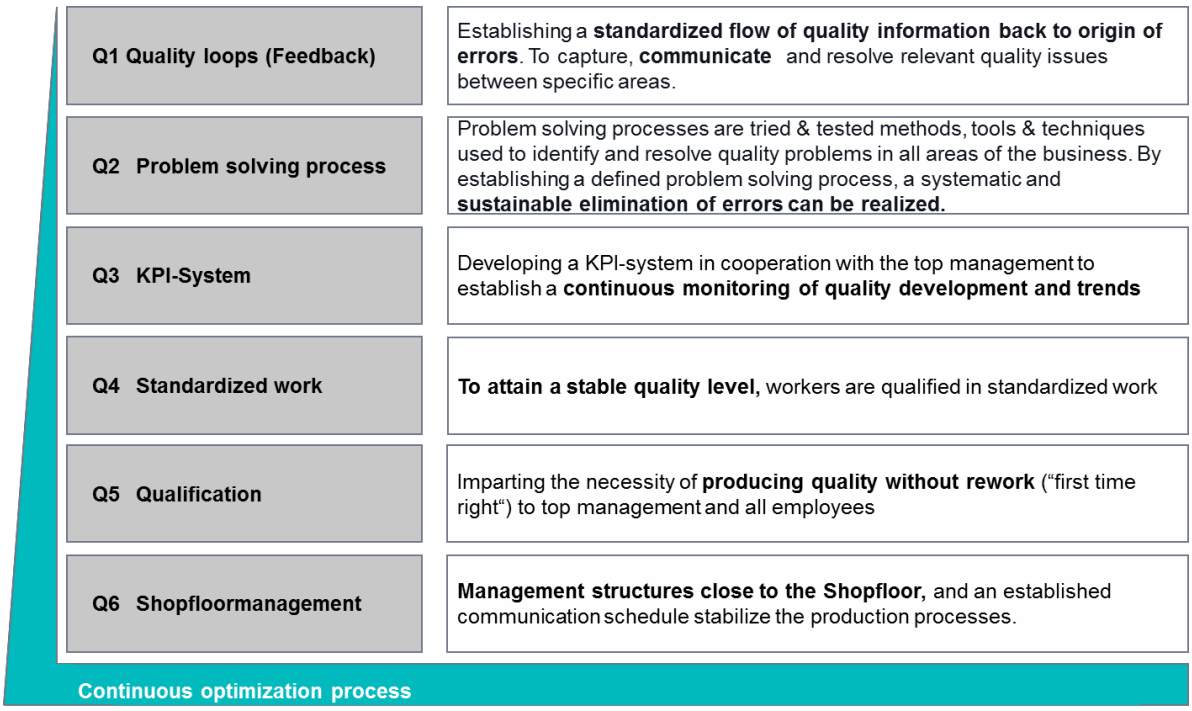
Deliverables:
Q6 project leader nominated
All Q6 elements in place at Shop floor level
Master List of all Problem solving done (open / ongoing / closed). Q6 maturity level achieved
Feedback loops from problem solving (PPS) to other Quality tools (Control Plan / PFMEA / DFMEA/ SPC…) defined and in place

Necessary Inputs:	**Source of Inputs:**
List of non-conformities	Quality /Manufacturing Engineer

Resources:
Plant/FAL Quality, Manufacturing, Manufacturing Engineering, Engineering, Lean. Specific support on request: Supply Chain.

Methodology:

Implementation of the Q6 elements:



ANNEX 2: EXAMPLES OF APQP TEMPLATE

QUALITY PLAN TIMING