Operating System Procedure

Advanced Product Quality Planning (APQP)

Revision Number	Revision Descriptions	Revision Date

1. **Objective** *(Required)*

   Advanced Product Quality Planning (APQP) is a structured method of defining and establishing the steps necessary to assure that a product satisfies the customer. APQP is used when a new and/or significantly changed product or process could lead to a failure that would expose The Company to customer dissatisfaction, safety concerns, or unplanned increase of cost to produce.

2. **Scope** *(Required)*

   2.1. The APQP process is aligned to support the Company's design and development process goals and provides technical clarity for the activities required to complete product design and development milestones.Applies to (Specify applicable locations).

   2.2. The APQP tools separate the vital items (high risk) which require special effort to ensure success, from the trivial many items (low risk) which require little or no special effort.

   2.3. APQP tools are used throughout the design and development process and represent three primary categories: Predict, Prevent, Protect. APQP ***predicts*** future failures through efficient use of current practices and data. APQP ***prevents*** failures through calculation of and mitigation of risk. APQP ***protects*** against non-mitigated and/or not fully mitigated risks through quality control and evaluation techniques.

   2.3.1. **APQP *Predict* Tools:**

   - Failure Mode Avoidance (i.e., historical issues, Product Integrity concerns and manufacturing issues, etc.)
   - APQP Planning Matrix

   2.3.2. **APQP *Prevent* Tools:**

   - Design for Manufacturability and Assembly (DFMA)
   - Design Failure Mode and Effects Analysis (DFMEA)
   - Process Failure Mode and Effects Analysis (PFMEA)
   - Mold Qualification Pre Tool Let
   - Key Dimensions / Characteristics
   - Process Flowchart / Diagram (PFC)
   - Packaging Standards and Specifications

   2.3.3. **APQP *Protect* tools:**

   - Mold Qualification Post First Shot
   - Process Instructions
   - Product/Process Qualification and Validation activities

   2.4. APQP discovers opportunities for product and process improvement resulting in:

   - Safe and reliable products
   - Superior product quality and durability
   - Increased "velocity to market"
   - Lower cost

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3. **Procedure**

3.1. **APQP Inputs**

APQP begins with inputs. Each input is reviewed for potential risk. The tools within APQP convert or cascade the inputs into product and process requirements. The inputs are as follows:

- The Marketing strategy
- Voice of the Customer from multiple channels
- Past failures
- APQP Library, design/engineering standards and team experiences
- Product complexity level
- A new and/or significantly changed product design concept

3.2 **APQP Plan and Define**

3.2.1 Design and Product Development create initial D&D goals 2 weeks after Initial Concept Review (ICR) or by Design Start Package (DSP). All D&D goals shall be completed at Concept Review (CR).

3.2.1.1 Design collaborates with Product Development with support from Marketing, Product Integrity and Packaging to develop the D&D goals.

3.2.1.2 D&D goals shall be categorized into "Must Have", "Should Have" and "Could Have" in the Product Description template.

Must Have:

- The magic of the product - major features, actions, and aesthetics or storytelling moments which are vital to deliver a product that supports the Voice of the Customer.
- Removal of any of the Must Haves would result in a non-viable product.

Should Have:

- The supporting features of the product.
- All features that enhance the play, giving depth and play value.

Could Have:

- Any feature that provide additional play value beyond the Must Have and Should Have goals.
- Features which are not a necessity to deliver the intended play value supporting the D&D goals.
- Features that might require investigation to know whether they can be included based on cost or technical challenges.

3.2.1.3 For Turn Key project, the Design and Development Engineering team shall review and provide feedback on the initial D&D goals within 2 weeks of DSP. Based on the feedback, the US team will revise D&D goals in Product Description as necessary.

3.2.2 Product Development sets up APQP Toolkit anytime between 2 weeks after ICR and no later than 1 week after CR based on request from the downstream Development Engineering team. For Complexity 4-5 and key driver products, the Toolkit shall be

set up by the Development team where the D&D goals are originated; for any other products, the downstream Development Engineering team can initiate the Toolkit.

3.2.2.1 The Product Number, Name and the Date when APQP is started are entered into the Step 1 box on the "APQP Intro" page.

3.2.2.2 The Product Complexity Level is entered into the toolkit on Step 2 of the "APQP Intro" page.

3.2.2.3 Product Development copies and pastes the D&D goals from the Product Description into the *APQP Toolkit Planning Matrix* and rank the development type for each D&D Goal per the Development Type Ranking definition.

3.2.2.4 Product Development will upload the APQP Toolkit into xxx (to-be-determined) in Agile and notify the appropriate downstream Development engineering team.

3.2.2.5 The clarity of the metrics improves as the design evolves from ICR to CR and under special circumstances Final Product Review (FPR). All D&D goals shall be completed at CR. However if any design changes which are made between CR and FPR requiring D&D goals to be adjusted, the appropriate downstream Development engineering team (i.e., Asia, East Aurora, etc.) will adjust the D&D goals in APQP Toolkit in Agile.

3.2.2.6 Changes to the D&D goals will require agreement with the originator of the D&D goals.

3.2.3 The Product Integrity Engineer of the Core Team collects and enters the PI concerns for the planned product and any PI past issues into the "APQP Intro" Page "PI Concerns/Past Manufacturing Issues". Refer to attached Severity Ranking table for the severity ranking.

3.2.4 The Manufacturing Engineer of the Core Team collects and enters issues on processes similar or identical to the planned product into the APQP Intro Page PI Concerns/Past Manufacturing Issues". Refer to attached Severity Ranking table for the severity ranking.

3.2.5 A Core Team member enters the CFT contact details into the "APQP Intro" Page

3.2.6 The "APQP Flow" in APQP Toolkit is available for the Core Team to review and time the APQP working sessions.

3.2.7 The "APQP Planning Matrix" is completed by the Core Team. The previously entered rankings for D&D goals "Development Difficulty" are reviewed and discussed by the Core Team. If a disagreement on the ranking occurs, the Core team must communicate with the Product Development team who originally selected the ranking (as soon as possible). The ranking must be reconciled to assure everyone is working from the same product assumptions. The Development Difficulty rankings drive consideration for further product engineering tools such as DFMA, DFMEA, etc.

3.2.8 The Core Team selects the "Manufacturing Difficulty" rankings based on the guidelines in the APQP Toolkit. The rankings drive consideration for further process engineering tools such as Process Flow, PFMEA etc.

3.2.9 The "Sort" button orders the D&D goals based on risks which provides the Core Team with ideas on how much APQP will be valuable for the project.

3.2.10 The Tools indicated by red are required and shall be scheduled in accordance with the product development milestone dates. The tools indicated by yellow should be reviewed for lessons learned and could be performed (but not required) if there is a perceived risk based on the Core Team's experience.

3.2.11 The transfer of the D&D Goals to the DFMEA Worksheet tab occurs when the "Transfer D&D Goals" button is selected.

3.3 **APQP Product Design and Development**

3.3.1 **DFMA:** The Product Development Engineer leads the DFMA activity per the timing and product maturity. DFMA should be conducted as early as possible in the development cycle to achieve the maximum benefit. DFMA activities are described in greater detail in the (DFMA Standard Operating Procedure (SOP). Actions derived from the DFMA are collected in the "Actions List" tab for follow up and closure.

3.3.2 **DFMEA:** The Product Development Engineer also leads the DFMEA. DFMEA should be conducted as soon as inputs from DFMA are available. DFMEA activities are described in greater detail in the (DFMEA SOP). Actions derived from the DFMEA are collected in the "Actions List" tab for follow up and closure. In addition, nominated key dimensions/characteristics may be created in DFMEA as a result of the discovered risk. The key dimensions/characteristics are determined using 2 criteria: 1) direct impact on safety, regulatory and/or D&D performance goals and 2) unacceptable risk per Criticality Zone (red and orange areas on the attached Criticality Matrix).

3.3.3 **Key Dimensions/Characteristics** are transferred to the following APQP tools:

- Mold Qualification (for tool maker input prior to Tool Let)
- Process Flow Chart (selection of SPECIAL processes)
- PFMEA (as Failure Modes on the processes that create the characteristic)

3.4 **APQP Process Design and Development**

3.4.1 **The Process Flow Chart /Diagram (PFC):** PFC should be started before DFMA and completed after PFMEA. PFC is determined when SPECIAL processes are required to deliver the product performance. The PFC and SPECIAL processes in the PFC are reviewed and updated when one or more of the following information is known:

- New technology for manufacturing is used
- PI concerns linked to manufacturing processes
- Manufacturing issues ("APQP Intro")
- Key dimensions/characteristics are nominated

PFC activities are described in greater detail in the (Process Flow Chart SOP).

3.4.2 **PFMEA:** PFMEA should be started after DFMEA and completed by FPR. However the closure of PFMEA actions can be done by either Tool Let (for process design related actions) or Final Engineering Pilot (FEP) (for process development

related actions). The Manufacturing/Process/Industrial Engineer leads the PFMEA based on DFMA inputs that may change the planned manufacturing approach and result in manufacturing issues and/or key dimensions/characteristics. Only SPECIAL processes will be required for APQP, but the CFT of PFMEA can choose to expand their scope on processes not deemed SPECIAL. PFMEA activities are described in greater detail in the (PFMEA SOP).

3.4.3 **Process Instructions:** Process Instructions shall be started at PFMEA and completed by Production Pilot. The Process Engineer/Industrial Engineer/Manufacturing Engineer determines the need to create instructions on SPECIAL processes which are high risk and have not been mitigated to an acceptable level. The Process Instructions are focused on the key dimensions/characteristics and process parameters required for capable process operations, and/or operations linked to product safety and regulatory compliance and operator safety. The Process Instructions shall be developed and available shortly after PFMEA. They are an extension of the Current Process Controls columns of PFMEA. Details on Process Instructions can be found in the (Process Instruction SOP).

3.4.4 APQP exists to drive actions that have a lasting improvement on the product and processes. Without the drive to take appropriate actions, a reactive find and fix outcome will prevail. Actions to reduce risk and improve the probability of success are derived from each of the activities and tools within APQP. Proper follow-up and closure with measured improvement is imperative to improve products, processes and methods.

3.5 **APQP Product and Process Validation**

3.5.1 The effectiveness of APQP shall be validated prior to Release to Manufacturing. Validation can include but not limited to:

- Qualification tests
- Acceptable dimensional results
- Acceptable performance measures
- Process stability evidence through Statistical Process Control (SPC)
- Process capability using Cp index and Cpk levels appropriate for the impact and volumes of the product
- First run throughput
- Quality Index

3.6 **Feedback, Corrective Action and Continual Improvement**

3.6.1 **APQP Library:** The Feedback and Continual Improvement efforts are captured and used in future APQP developments. The Feedback, sometimes referred to as "Lessons Learned" is submitted to the Library if the Core Team has determined the findings could benefit other products/processes, other product lines, Business Units and locations. The Submission and Approval of a Feedback item is loaded into the Engineering Standards Database, APQP Library, or other corporate database to be utilized in future projects.

3.6.2 **Corrective Action** is necessary when the uncontrolled circumstances of a product or process output result in an undesirable event. In order to learn from the experience and prevent similar problems in the future, it is necessary to collect and analyze certain failure data. The data may take the form of the following:

- The Problem Symptom, the issue in the words of the customer or signs of existing problems (visible problem).
- Problem Statement, a two-word OBJECT-DEFECT used as categories for future data collection and Library information.
- Problem Description, a complete description of the problem including What Where When and How Big the problem is. Used in selecting the most probable causes in problem solving.
- Root Cause, an identified reason for the presence of a defect or problem, it can reasonably be identified (cost beneficial), management has control to fix it, and effective recommendations for preventing its recurrence can be generated. A typical ***causal factor*** has multiple root causes.
- Actions taken to solve a problem, Permanent Corrective Action (PCA) which addresses the Root Cause to make the problem go-away and unlikely to return. Permanent Corrective Action is never how we inspect, test or sort for an issue.

This data is the basis of past failures, PI concerns, and manufacturing Issues that are entered into the APQP Toolkit "APQP Intro" page. This activity is sometimes referred to as Failure Mode Avoidance (FMA)

3.6.3 Never ending **Continual Improvement** is embedded within every process. The documentation of activities responsible for Continual Improvement must also be captured for input into future designs and processes. The Continual Improvement activities such as Lean, Experimental Design and Kaizen Events provide a valuable resource of information which can be transformed into:

- Standards/Standard Work
- Best Practices
- Reference documents which can be reused
- Etc.

3.6.4 Each source of Feedback, Legacy/Library, Failure History, and Continual Improvement are inputs in APQP Plan and Define on a new or significantly changed product or process. As the quality of feedback data increases and access to the data is maintained for simple acquisition, the APQP process will result in a higher velocity to market, fewer customer complaints and greater product development throughput

4. Definitions

4.1. Explanation of special terms.

5. Roles and Responsibility

5.1. **Design**, consulting with Marketing and the various Voice of the Customer sources and in support of the specific product category Marketing strategy, creates a vision of the product

and expresses the vision in a series of descriptive statements known as D&D Goals. D&D goals are further defined into three categories - Must Haves, Should Haves and Could Haves.

5.2. **Product Development**

- Consults with Design over the product vision and inputs engineering clarity with potential performance metrics.
- Sets up APQP Toolkit
- Leads APQP Planning Matrix, DFMA and DFMEA
- Facilitates APQP Working Sessions
- Manages the supplier who has product engineering responsibility. In other cases Product Development authors and produces the geometry and materials definitions required for the product to achieve the safety and regulatory requirements and performance requirements for D&D Goals.

5.3. The **Cross Functional Team (CFT)** is responsible for completing, verifying and closing action items determined by APQP tools. The CFT is comprised of a Core Team and a group of Subject Matter Experts (SMEs).

5.3.1 **The Core Team** plans the APQP effort, schedules and invites SMEs to various APQP working session events. The Core Team includes:

5.3.1.1 Product Development Engineer (or delegate). Refer to 2.2 above for primary responsibilities.

5.3.1.2 The Engineering function responsible for manufacturing and assembly (Process/Industrial/Manufacturing Engineer) provides preliminary process methods and past process performance issues on the selected process methods.

5.3.1.3 Product Integrity (PI) Engineer provides PI concerns, past safety and regulatory issues and quality requirements.

5.4 **SMEs** are periodically called upon due to their expertise and the APQP tools being used. SMEs come from multiple disciplines as indicated in the attached APQP Responsibility Matrix.

6. **Process Steps/Process Flowchart**

6.1. Clear description of each step in the process. Place Process Flowchart in this section.

7. **Accountability**

7.1. The process owner or department head from the process area with the largest stake in the procedure.

8. **Reference Documents**

8.1. Forms or other documents required for procedure compliance

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Approval:

Position Title

Position Title

Position Title

Position Title