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Pierce, Mickey E. ***The Introduction to a successful product launch for new products using Advanced Product Quality Planning.***

Abstract

Currently, there is a very high demand to cut costs in the injection molding industry and customers are looking at every stage of a product launch to cut costs. APQP is a method that is utilized in launching a successful product that will reduce overall delays and costs to the customer.

Acknowledgments

First, I would like to thank my advisor, Dr. James Keyes, for all his support, expert advice, and ability to drive with such a positive attitude.

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Chapter I: Introduction

The need to communicate efficiently the effects and costs of not safely launching a new product for a customer is crucial. Phillips Plastics currently has customers that expect nothing but a fully implemented quality control plan when launching a new product for them: even with the added time and cost. However, there are other customers who do not see the benefits and long term paybacks of launching a new product using a systematic quality approach called Advanced Product Quality Planning. Medical, Consumer, and Military customers of all sizes understand the effects of successfully utilizing the Advanced Product Quality Planning process. One constraint that presents itself when presenting an APQP plan is the process has time and costs associated with it up front and there are customers that are not willing to utilize this plan upfront due to the time and cost. Many of today's most important management system standards- such as ISO 9001, ISO/TS 16949, AS9100, TL 900, are based on a process approach. These processes flow from one to another in a giant loop that includes customer requirements and feedback (Peterson, 2003). The research plan initiative to produce a quality cost proposal that will effectively show them first, what APQP is at Phillips Plastics, and second, why they should utilize it and the paybacks it will have. APQP is needed in today's market to satisfy the customer's need. APQP needs to be implemented at the earliest stages of a new product launch to identify and assure that the customer's needs, expectations, and requirements are met on time and in most cases launched early and with a lower cost to the customer. The foundation of the planning strategy is the improvement of quality. Stamatis, (1998) Quality and customer satisfaction is in very high demand in today's competitive market. The need to conceive, prepare, and implement a successful advanced product quality plan will be essential in safely launching a new product with success for the customer. The foundation of quality as a strategy

that provides the focus of matching products and services to a real need, which a customer approves and is satisfied with, requires advanced planning. Stamatis, (1998) the need for APQP is essential in the military, consumer, medical and industrial manufacturing settings.

Statement of the Problem

Phillips Plastics Corporation did not have a structured APQP program to provide a safe launch for new business opportunities. This practice prohibited new product launches to meet the customer's expectations at the lowest cost while providing the highest quality outcome.

Purpose of the Study

This study analyzed the need to implement an APQP plan and the principles it represents, and to align Phillips Plastics with their customers' expectations. It is crucial at the conceptual and developmental stages of a new product for a customer that the APQP plan is utilized. This will avoid confusion and misinterpretations of the requirements that the customer is requesting. This requirement could be their own companies' requirements or that of the affiliated organizations such as ISO, automotive, medical, or military requirements. It is crucial that the customer and Phillips Plastics align each other to work together to achieve these requirements and provide a complete successful, on time product launch.

APQP is not only viewed as a quality function, it also forms a foundation for new development project management safe launch programs. The structured method of defining and establishing the steps necessary to assure that a new product is safely launched and satisfies the customer is crucial. The key factor of the APQP safe launch implementation plan is to facilitate communication between everyone involved to assure all the required functions and steps are followed on time and in order resulting in customer satisfaction and future business opportunities.

Advanced product quality planning is a detailed, structured method of defining and establishing the proper steps necessary to assure that a new product launch satisfies what the customer is expecting. The whole idea around product quality planning is to facilitate communication with everyone involved in the launch of a new product to assure the product is launched on time. Advanced product quality planning requires the complete buy in by everybody in the company including top management and stock holders to assure customer satisfaction is met. Advanced product quality planning will assist and guide the team to launch a product on time, at the lowest cost and allow the team to adjust to changes as the customer requires with no delays to the production launch date. The customer's voice is what drives the product quality planning plan and will allow a close relationship with no surprises between the customer and the supplier.

Assumptions of the Study

1. Data provided by the company are accurate.
2. Data obtained throughout the study is reliable.
3. APQP model can be applicable to different industries, not only for the big three automotive companies for which it was developed.
4. The APQP model accomplishes the adapted goals and achievements of increasing product quality, improved manufacturing standards, lower product costs to the customer, and shorter lead times on deliverables.

Definition of Terms

AIAG. "The Automotive Industry Action Group is a globally recognized organization founded in 1982 by a group of visionary managers from Daimler Chrysler, Ford Motor Company, and General Motors. The purpose: To provide an open forum where members

cooperate in developing and promoting solutions that enhances the prosperity of the automotive industry. AIAG's focus is to continuously improve business processes and practices involving trading partners throughout the supply chain" APQP, (2006).

Voice of Customer. "The voice of customer is the process for capturing stated, unstated, and anticipated customer requirements, needs, and desires" Munro, Maio, Nawaz, Ramu, &Zrymiak, (2007, p. 18).

cGMP. Current Good Manufacturing practices refer to the current good manufacturing practice regulations enforced by the US Food and Drug Administration. FDA, (2005)

CFR. Code of Federal Regulations is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government. FDA, (2005)

Continuous Improvement. The relentless challenge of the status quo with the regard to the elimination of waste and customer satisfaction, which is also known as Kaizen process Rubrich & Watson, (2004).

Phillips Custom. Custom and Assembly operations facility owned by Phillips Plastics Corporation located in Phillips, WI.

Value Stream Mapping. The methodology of examining and creating a picture of all the contributing processes that occur in a company beginning with a customer order to when the customer receives the product Rubrich & Watson, (2004).

ISO 9001- An internationally recognized standard. The standard is intended for use in any organization which designs, develops, manufacturers, installs and/or services any product or provides any form of service. It provides a number of requirements which an organization needs to fulfill if it is to achieve customer satisfaction through consistent products and services which

meet customer expectations. It includes a requirement for the continual (i.e. planned) improvement of the Quality Management System Powerway Suite, (2009).

Limitations of the Study

This study was limited to Phillips Plastics Custom division. This project had a time frame of implementation of 6 months and was limited to the business situation during this time. The intention of the study was to develop an APQP process that can be a model for all project launches and future business opportunities.

Methodology

A literature review was used to define the characteristics of an APQP plan. Phillips Plastics Corporation has hundreds of different customers that develop a wide array of components. Each one of these customers' requirements vary based on the scope, location, and size of the product. This creates confusion when trying to standardize or develop a production launch system within a company with so many variables. Phillips Plastics Corporation has a modeled Automotive launch program but relies heavily on the customers qualification or launch process (if they have one) to meet customers' expectations. The need to research past and present projects from a wide array of industries was needed to come to the conclusion that a base APQP model was needed for all new business opportunities. This research was performed with the help of the Engineering Coordinator who prepares the APQP documentation for the Engineers on all new product launches. The research consisted of gathering current and past data from product launches that were successful or needed to be modified along the way. One thing that stood out was time and cost as key driving factors in the product launch programs. Launch data was compiled to analyze what data was pertinent to the customer during each phases of the launch. An implementation safe launch plan was developed to be utilized on all new product

launches within the project engineering department. The new plan was developed and has followed the Deming, Plan-Do-Check-Act (PDCA) cycle. This cycle was utilized in new product launches from conception to part submission for approval. The project team will utilize the PDCA process as a model to launch new products in all areas of the business. The team will utilize all of the pre-launch tools to provide their data and metrics to the team, and then follow the PDCA cycle to successfully submit the plan to the customer.

An APQP quality control plan as well as a new product safe launch implementation was developed and implemented to launch new business opportunities. The newly created APQP plan was developed, detailed, and presented to the launch team at Phillips Custom. The plan consists of a newly established gate review process that involves all engineering disciplines to work as a cross functional team as well as be present during the operational team buy-in of the new product. Newly developed documentation in this research was established to show pre-product launch improvements and in depth involvement from all members of the launch team.

Summary

This chapter provided an introduction to Phillips Plastics Corporation new product launch issues and the need to be more efficient at launching new products in all markets. This chapter also developed the foundation and set the precedent for the rest of this research on how important an Advanced Product Quality Planning process is in achieving market share and continued customer satisfaction. The next chapter will review literature related to new products, APQP fundamentals, and the product qualification tools.

Chapter II: Literature Review

The purpose of this literature review was to provide insight into product quality planning and how it can be applied to new product launches within a manufacturing environment. The chapter has been divided into two sections; the fundamentals of APQP, its tools and the five phases in implementing APQP to stay ahead of the competition with complete customer satisfaction. The second section of this literature review is the introduction and discussion of the product qualification process, which includes all of the attributes that have been taken from the APQP process and instilling it into a qualification process for the customer. Tools such as production part approval process (PPAP), control plans and a gate review safe launch system completes the quality planning process of safely launching a new product.

Fundamentals of APQP

APQP is a process developed in the late 1980's by a commission of experts gathered from the "Big Three" US Automotive manufacturers: Ford, GM, and Chrysler. The "Big Three" auto makers worked on a harmonized quality system to improve overall quality, and initiate cost reduction activities Reid, (2008).

APQP is a structured method of defining and creating the proper steps necessary to adequately launch a new product that satisfies the customer's needs or expectations. APQP is a disciplined process using a detailed plan of steps to ensure that the activities are completed in order. Following these detailed steps and completing each task thoroughly will provide the customer with a quality product that is on time and at a lower cost. The primary goal of advanced product quality planning is to effectively communicate with everybody involved in the project to assure that every step of the method is properly facilitated and completed on time.

APQP can only achieve complete customer satisfaction with the company's top management committing to this methodology with full support.

APQP's new product development process is designed to assure the product fulfills its design, reliability and quality expectations. Some of the benefits of Product Quality Planning are to direct resources to satisfy the customer, promote early identification of required changes, avoid late changes, and provide a quality product on time at the lowest cost APQP, (2008 p.3).

The first and most important step in establishing an APQP plan is to assign a process owner as well as a cross functional team. The team should have representatives from each function of the business, such as operations, purchasing, engineering, sales force, people services, logistics, component suppliers, and most importantly the customer APQP, (2008). Juran (1988), states "the best method to achieve optimum in quality designs is through participation of suppliers and customers". The team will then define a scope and determine customers' expectations and requirements.

The team's first objective or task is to then develop a product quality timing plan, Figure 1. The type of product, complexity and customer expectations should be considered in selecting the timing elements that must be planned and charted. A well-organized timing chart should list tasks, assignments and other events APQP, (2008 p.5).

There are five outlined phases of implementing an advanced product quality plan. Each of these phases is oriented to meet the customer's expectations. Each phase has a detailed list of inputs and outputs that that will determine what the customer's requirements are under each disciplined phase APQP, (2006, pg9).

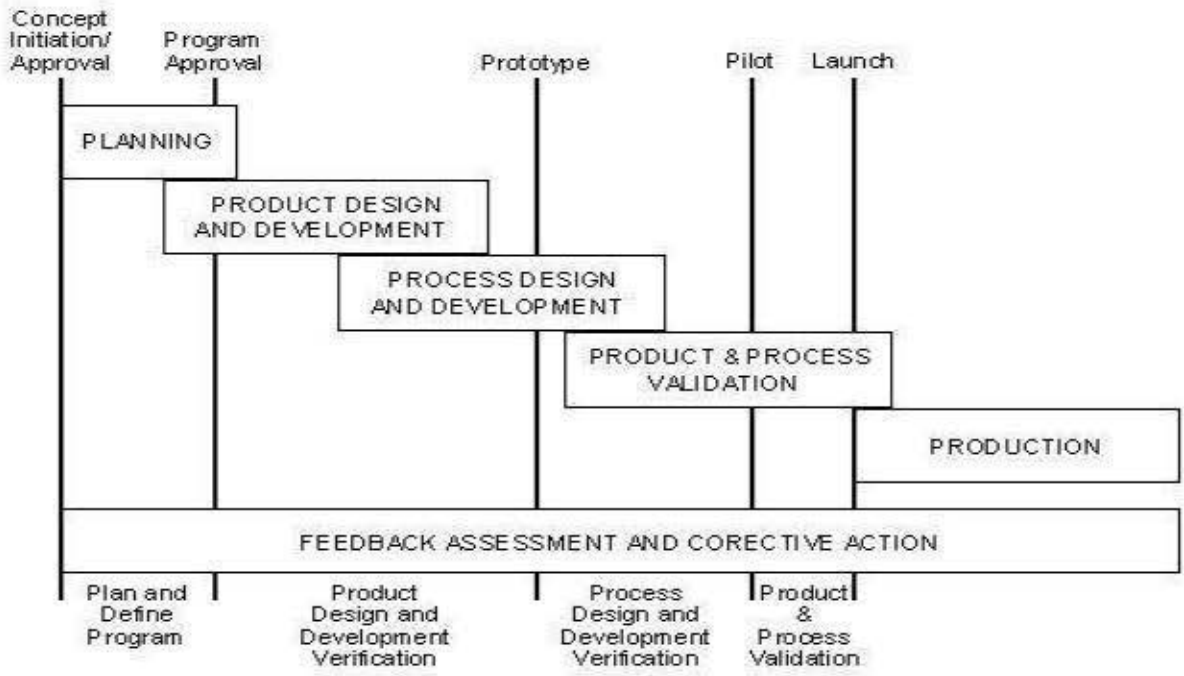

Figure 1 Product Quality Timing Chart APQP, (2008, p.6)

The five phases of implementing an advanced product quality plan are:

Plan and define the program

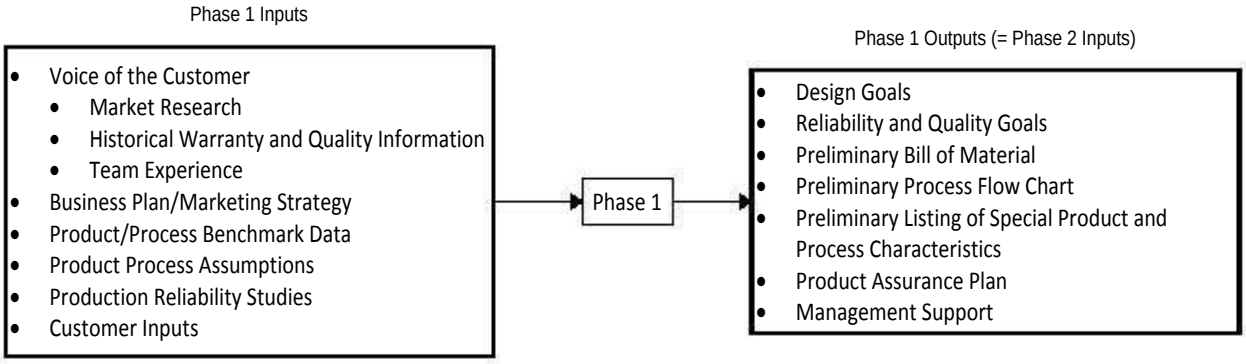

Figure 2 Phase 1 Inputs-Output PPC Quality Manual, (2011)

Plan and Define the Program Phase. This is a critical area in understanding what the customer's needs and expectations are. The voice of the customer is the key attribute in this phase. The voice of the customer information can be obtained in several ways, such as market

research, historical warranty data or quality data, and previous team knowledge or experience. The team will then translate this voice of the customer data into measurable design objectives, or design goals. Items such as regulatory requirements, special composite requirements, quality standards, and preliminary Bills of Material's (BOM) are established at this time. This data is then compiled by the team and establishes a product assurance plan. The product assurance plan can have different functions or determining inputs, but at minimum should include:

- Outline of the program requirements, through quotes, and redline procedures
- The identification of reliability, durability, and apportionment/allocation goals and/or requirements.
- Assessment of new technology, complexity, materials, application, environment, packaging, service, and manufacturing requirements, or any other factor that may place the program at risk.
- Use of Failure Mode and Effect Analysis(FMEA)
- Development of preliminary engineering requirements.APQP, (2008, pg13)

This phase also allows the supplier to be aware of what the customer's goals of the program are. Each customer is unique to their requirements. APQP, (2006)

Product design and development

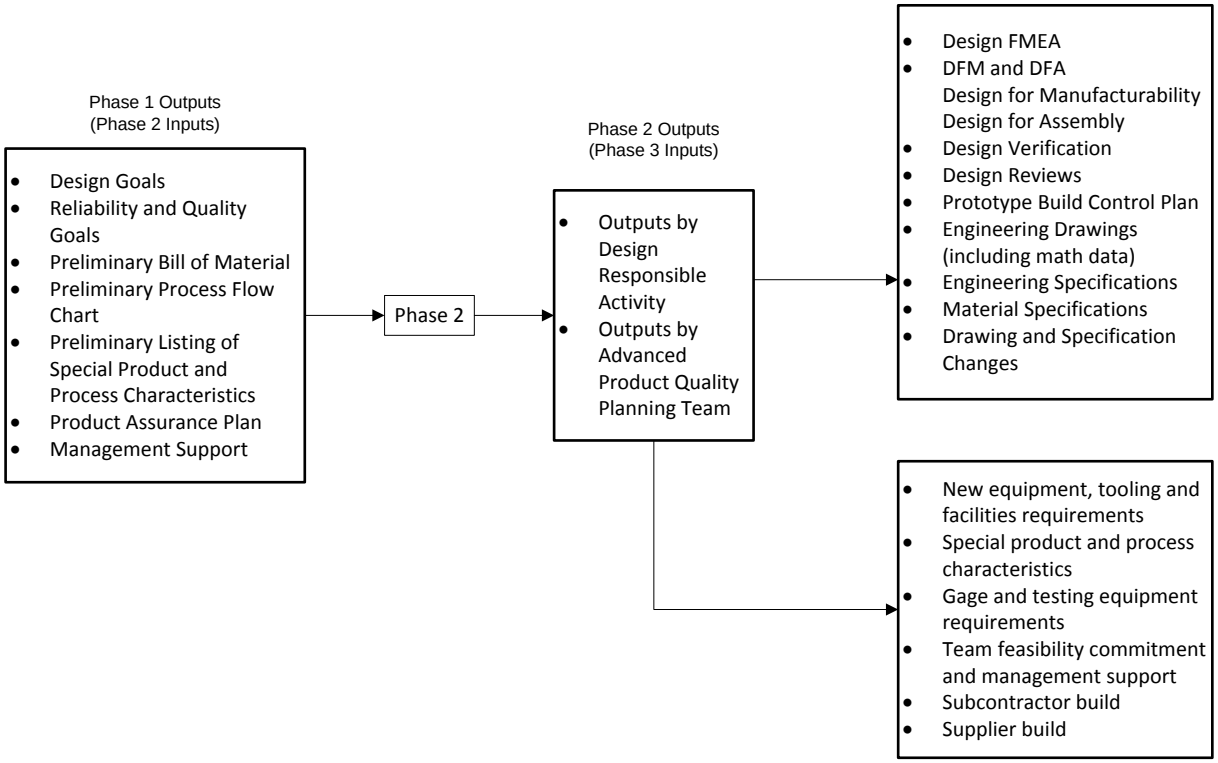

Figure 3 Phase 2 Inputs-Outputs PPC Quality Manual, (2011)

Product Design and Development Phase. In this stage, design reviews are conducted to monitor the progress of the project relative to customer requirements, drawings engineering specifications and material specifications are also approved. Scangas, (2007) a robust design must permit meeting quoted production rates and schedules, have the confidence level of meeting the engineering requirements and specifications, and meet all the pertinent quality information that was conveyed by the inputs "voice of the customer" in the plan and define stage. "Sethi, (2000, pg 1) states "that product quality is showing to have market success and profitability advantages when implementing a new product. Measuring or Inspection methods as well as any other test equipment will need to be added to the overall plan and will need to be closely tracked as the project moves forward. A comfort level will also need to be reached

amongst the supplier team that they can meet the design requirements and customers' expectations.

The team must also determine the outputs at this stage to set the precedent for the inputs into phase three. Critical design reviews, Design Failure Mode and Effect Analysis (DFMEA), Design of Experiments, and Design for Manufacturability and Assembly (DFM), must also be completed in this phase. All of these tools are critical in the design analysis so the team will have an effective method to prevent problems or misunderstandings. The team must also be critical of the engineering specifications and have a good detailed understanding of the controlling specifications to identify the functionality, aesthetic, or even molding or assembly issues. The team must be assured that the submitted designs, requirements, and regulations can be repeatable in manufacturing, assembly, and shipping.

Process design and development

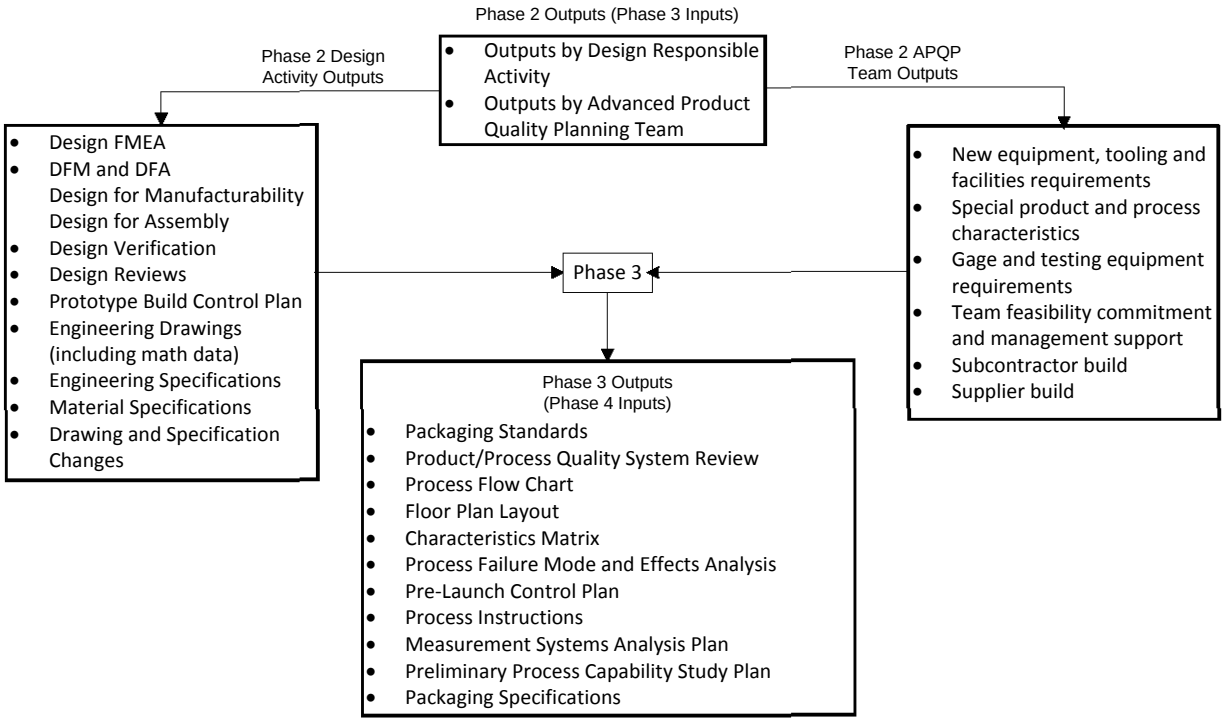

Figure 4. Phase 3 Input-Outputs PPC Quality Manual, (2011)

Process Design and Development Phase. During this stage, a collaborative relationship must be forged between the supplier and the customer to develop a manufacturing process that will produce quality parts. Accomplishing this task requires the input from phases one and two. International, (2001) During this stage it is important to determine if the process or product is not capable and that design imperfections are identified and re-designed to meet specifications, Juran, (1988). This task is very important as it takes all the design concepts and established paper processes and applies them to the manufacturing floor. This assures the manufacturing system is robust and capable of meeting all customer requirements and expectations.

The tools that are utilized to assure customer specifications are met are:

- Packaging standards and specifications
- Product/Process quality review
- Process flow chart
- Floor plan layout
- Characteristics matrix
- Process Failure Mode and Effect Analysis
- Pre-Launch control plan
- Process instructions
- Measurement Systems Analysis Plan
- Preliminary Process Capability Plan
- Management support APQP, (2008, Pg 26-29)

Product and process validation

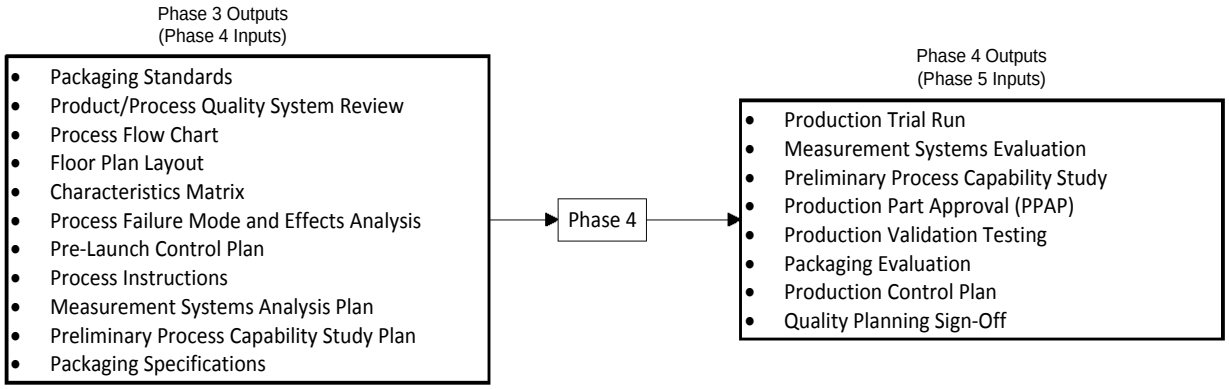

Figure 5. Phase 4 Inputs-Outputs PPC Quality Manual, (2011)

Product and Process Validation. This phase deals with the necessary requirements for validating the manufacturing process and product design. A preliminary production run is performed to validate that the production process is capable of meeting the customers' needs. The goal in this phase is to have a process capable and that parts are manufactured to the customer's design International, (2001). The APQP team must validate that the manufacturing personnel are following the control plans as well as the process flow charts as documented in the APQP plan. The validation run/runs must be qualified using the pre-determined, production equipment, manufacturing parameters, and all other attributes that have been identified as customer requirements. The validation runs are pre-determined in the pre-production approval process and is usually customer specific and detailed in customer formats such as protocols. The outputs of these validation runs are critical in creating a repeatable manufacturing process. These outputs are represented throughout the whole process and call out for certain checks and balances along the way. Some of these checks contain run at rate demonstrations, preliminary process capability testing and process reviews. The testing methods are also performed and will contain production validating testing, and measurement system analysis and qualification testing

methods. The outcome of these measurements will yield master samples (or retain samples for future references), production part approvals and finally a quality planning sign off of parts. This also allows the production run to be balanced against the control plan to assure the attributes are feasible. Packaging evaluations are then performed to assure the final product shipping to the customer, meets their packaging expectations. APQP (2008, pg 34)

Feedback, assessment, and corrective action

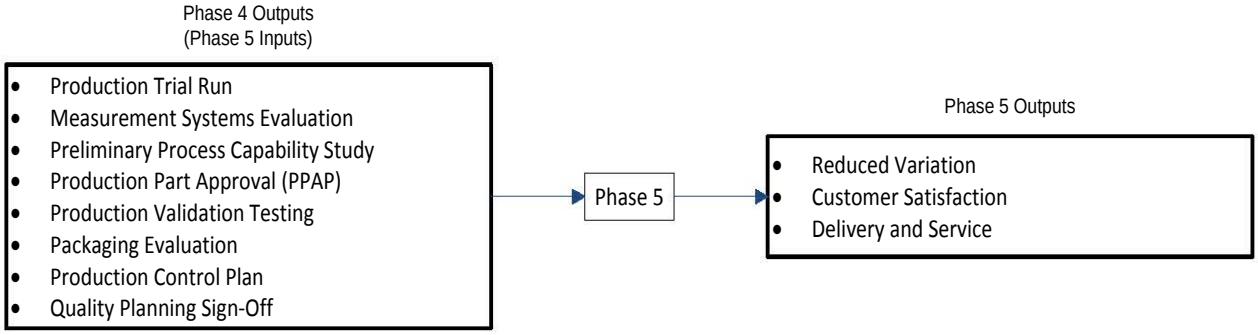

Figure 6. Phase 5 Inputs-Outputs PPC Quality Manual, (2011)

Feedback, Assessment and Corrective Action Phase. The importance of this phase is to determine the program's success and transition into production. The phase also has a lessons learned document with a corrective action and continuous improvement plan. Both of these plans are crucial and become inputs into the planning phase of the next program thereby completing the plan-do-check-act cycle. International, (2001) This is also the time the teams can evaluate all of the documents that have been developed and validate their effectiveness. It also evaluates if there is any variation concerns or common repeatable causes. The reduction of variance tools, corrective action plans, and statistical tools, such as statistical process control charts should be utilized to reduce or eliminate these variations. These eliminations are a direct

result of cost savings to the company and the customer. Continuous improvement and a lessons learned/best practice study should be the last step that does not stop.

Product Qualification

Product Qualification is the process of certifying that a certain product or process complies with the customers set of requirements or expectations. Product qualification has a very broad definition with a wide range of customers. APQP was established in the automotive industry for this reason and relied heavily on the PPAP process for their part qualification, or validation process. However, as more industries are adapting to qualification processes, they start to expect the same attention or details as an automotive PPAP process. This assures their parts or processes meet their expectations and requirements. Industries outside of automotive use validation processes, protocol processes or self-created qualification processes. These processes vary greatly depending on the size or scope of the project. This becomes hard for the supplier to analyze and establish really what the customer wants. PPAPs, control plans, and gate reviews are a great collaboration of qualification tools that help in safely launching a product that can be repeatable and comply with customers' regulations and requirements. This study is based upon the detailed APQP process with a detailed list of part qualification tools.

Production Part Approval Process (PPAP)

Chrysler, Ford and General Motors, (2006) state that the purpose of production part approval process is to determine if all customer engineering design record and specification requirements are properly understood by the organization and that he manufacturing process has the potential to produce product consistently meeting these requirements during an actual production run at the quoted production rate.

Production part approval process is a documented copy and agreement that the supplier is well aware of the customers' expectations. The general purpose of the agreement is to make the supplier aware of all design records and specifications, to ensure that the requirements are clearly understood, and that the supplier has a process that is capable of meeting the customers' expectations. It gathers all of the information that was collected and documented in the advanced product quality planning method, and documents it in the supplier's production part approval process format. This is then presented to the customer for approval. Nine categories make up the production part approval process. They consist of:

- PPAP process and requirements
- Scope and limitations of approval
- Evaluation of evidence submitted
- Customer phased PPAP requirements
- Levels of submission and evidence required
- Parts submission warrant
- Supporting evidence
- Materials Data and use of International Material Data System
- Process capability Leong, Thomas (2008)

A number of reasons drive the need for an organization to gain approval from the customer. Those reasons are:

- A new part or product is being produced.
- There is a correction or discrepancy on a part that has been previously submitted.
- A product that is/ or will be manufactured as engineering changes to the design, specifications, or materials.

- If the supplying organization announces any changes internally to the design of the product or process, site.

An important element when working with the customer on PPAP's, the level of submission warrant the customer is requiring is critical. There are five levels of evidence or submissions to choose from. Organizations tend to use a level three submission level as a default unless specified by the customer. The five levels of submission are:

- Level 1 – Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to the customer.
- Level 2 – Warrant with product samples and limited supporting data submitted to the customer.
- Level 3 – Warrant with product samples and complete supporting data submitted to the customer.
- Level 4 – Warrant and other requirements as defined by the customer.
- Level 5 – Warrant with product samples and complete supporting data reviewed at the organization's manufacturing location. PPAP, (2006)

Control Plans

The purpose of the control plan methodology is to aid in the manufacture of quality products according to customer requirements. It does this by providing a structured approach for the design, selection, and implementation of value-added control methods for the total system Stamatis, (1998). Systematically, all control plans are generally labeled as a "controlled document" to assure it is a locked process and cannot be altered unless approved by the customer and re-validated. Control plans are written descriptions of the systems for controlling parts and processes APQP, (2008). Separate control plans cover three areas, they are:

- Prototype – A description of the dimensional measurements and material and performance tests that will occur during prototype building.
- Pre-Launch – A description of the dimensional measurements and material and performance tests that will occur after prototype and before full production.
- Production – A comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems that will occur during mass production.

The control plan is a very key and informative tool for the manufacturing floor, it is imperative that it stays controlled and operators have access to the tool at all times. It should stay within range of the process it controls. Since processes are expected to be continually updated and improved, the control plan reflects a strategy that is responsive to these changing process conditions and, as consequence, the control plan is a continual improvement tool as well as a controlled document Stamatis, (1998).

Gate Reviews

Gate reviews are a project management tool that provides a check and balance between the project leader and the team that a project is ready for the next phase. It was found in past engineering launches that it wasn't uncommon to gain a commitment to start a project and never look back. It is now realized that there is a need to establish check points or gates along the way to assure the project is on track and should continue and the associated risks are manageable. The best approach in creating gate review is through a gate review board. These boards will create a checklist of milestones or objectives that need to be checked and the time that is associated with the review. The project team would come to the meeting presenting each objective to the board for full approval. The gate review board's job is then to analyze and

comment on the proposed tasks so it complies with company or customer regulations or expectations. The idea is there should not be much of a discussion if the project team was thorough in their research and presentation. It is important that the gate review board stays consistent on projects and has no variances form project to project. This will allow the board to establish a standard which leads to a quick identification of a successful project versus a troubled project. Mochal, (2008)

If the project is accepted by the gate review board, is it then passed through the gate and advances to the next milestone. If the task is not passed through the gate review board, it will have to be corrected and then re-apply to the gate review board for a second review.
Gate reviews allow an audit of the project team and keeps the customer or project from running at risk. Extreme discipline needs to be established to keep a standard in the gate review process so no suspect milestones or tasks get through to the next stage which would be very costly to the company and customer, and detrimental to future business opportunities. PPC Quality Manual, (2011)

Summary

Advanced production quality planning and production qualification principles are needed to ensure that an organization's marketing brand image stays ahead of its competition. They are the foundation for any continual improvement effort to achieve faster, better and cheaper cycles for the organization Munro, (2003). The literary review has provided an outline of the steps needed to implement a cost savings production launch plan for Phillips and its customers. These plans must be properly followed through and communicated in order for this plan to work.

Chapter III: Methodology

Introduction

Phillips Plastics Corporation is continuing to advance its business opportunities in the medical, industrial, defense and consumer markets. One area of growth that continues to present itself to Phillips Custom is the medical field. These medical programs are a prime candidate for a detail oriented APQP plan. However, these plans are not always accepted by Phillips' customers, not realizing the importance or the value. These reasons have caused a lot of deadline issues and costly problems for both Phillips and their customers including increased costs, missed shipments, non-conforming products, and dissatisfied customers. The need to implement an APQP plan that would support all industries in the same fashion, as well as standardize quality planning and product qualification to meet customer expectations was needed. This study analyzed the existing APQP plan and customers that it represents, as well as medical customer validation protocols or self-created APQP plans. A newly developed APQP plan was developed and implemented to support a model for all industries.

The objectives of this study were to:

1. Create a well-defined Advanced Product Quality Plan for the use of customer presentations as well as best practice technology within the Philips Project Engineering team.
2. Create a well-defined Advanced Product Quality Plan tool that proactively directs resources, promotes early identification of customer required changes, and provides the customer a quality product on time and at the lowest cost.

3. Create a pre-production planning tool that is useful in the presentation of new product opportunities to Phillips Engineering and is a cost savings implementation given to the customer at new quote or conceptual talks of a new product.

An improved APQP safe launch process was needed to ensure that new business launches are performed and launched to meet customer and business needs. This chapter describes in detail the methodology and procedures utilized to achieve the above mentioned objectives.

Data Required

In order to better understand the needs and expectations of customers when relating to APQP, it was important to understand what APQP plans were being utilized and for what customers. Phillips Plastics Corporation's engineering coordinator provided adequate qualitative data on past practices when launching new business. Data was also obtained from Phillips Plastics Corporations Tool Log, see Appendix H. The tool log is a tracking tool on where the project is in its progression, costs and resources associated with the project, as well as the type of business it is. This information was key in developing opportunities for a successful APQP project launch program. Analyzing current customers' product launches and validation expectations and the automotive model that was currently being used, provided a good foundation to better define what requirements are expected from the customer and helped identify a model that adequately provided all customers the ideal (future state) APQP safe launch plan. Current team members provided benchmarking history on what requirements and expectations have been met or not met on previous launches. Brainstorming sessions with these production launch teams and monitoring current state flow charts provided insight and opportunities to map out the requirements for a future state plan.

Methods

Project management methodology was utilized for this project. A product quality planning cycle, known as the Plan, Do, Check, Act (PDCA) cycle was used in this research to conceive, design, implement and follow the APQP system. The PDCA cycle was first introduced by Dr. Deming and was known as the staple of the product planning process Walton, (1986). Continuous improvement and customer satisfaction can only happen by taking lessons learned from existing programs and apply them systematically to new programs. The PDCA cycle is a well-defined program that can help achieve this.

In the "Plan" phase, the planning and defining of customer expectations were determined; the action plan will be developed. A new business award gate review and approval document was reviewed and gone through with the project management team, see Appendix A. Phillips Custom utilized an APQP flow chart with a series of work instructions and standard operating procedures to initiate a new APQP product launch, see Appendix B. It is important that determined personnel and resources are identified by the management team during this phase.

Process and product design and development took place during the "Do" stage. The opportunities agreed upon amongst Phillips and the customer will be implemented. Two tools are utilized for both internal and external tracking, as well as developing responsibilities and necessary gate reviews. The first is a gannt chart, which is shared with the customer to keep track of the project launch tracking. The second tool Phillips Plastics utilizes is a project launch process map to identify key milestones, develop each stage of the "Do's" and identify team members, see Appendix G. The do stage was where the work, design, and procedures and agreements will now take place between the customer and Phillips Plastics Corporation.

During the "Check" stage Phillips tested its product and process validations. All of the verifying of data is done at this stage; all of the capability requirements were identified. This information is gathered by taking sample sizes from the pre-production runs and measuring critical characteristic features to identify if the process is stable or out of control. The control plans, failure mode and effect analysis, pre-production approval processes, and engineering gate reviews are developed and presented. See Appendix C for the Quality Engineering gate review, a detailed checklist that supplier and customer requirements are or will be met. Appendix D shows the Project engineering gate reviews, which also require meeting customer's expectations. The project engineering gate review checklist performs more tooling and sampling efforts to assure that the project is preparing production for success. In Appendix E the Manufacturing Engineering gate review checklist concentrates on jigs, fixtures, devices and all secondary equipment. Ergonomics and people skills are also monitored at this time. This list verifies that all production tools are also production ready for reproducing and repeatability. The final action of this stage is to approve and go through in detail the final gate review checklist (see Appendix F) before the next stage. Capability studies, metrology work and data analysis is monitored here to assure the process is stable and ready for production. This gate review is the last check before work orders are released.

The "Act" stage is where the necessary adjustments to solutions that were identified take place. This is also the stage where corrective actions and identifying future steps took place. The management of the PDCA program is critical to implement a successful APQP process. A current state and future state of the PDCA/APQP relationship was developed and documented for future growth and opportunities.

Summary

An Advanced Product Quality Plan was utilized to properly identify cost savings opportunities for Phillips customers. The PDCA methodology plan was utilized to meet the three objectives of the study. This methodology was developed and put in place as a tool for customer satisfaction as well as a continuous improvement tool for the Phillips new product launch team. The PPC project launch team has developed a model that will be consistent across all industries. This will be a project launch model that is utilized in every new business launch regardless of the size of the customer or size or scope of the project.

Chapter IV: Results

Phillips Plastics Corporation did not have a structured APQP program to provide a safe launch for new business opportunities. This practice prohibited new product launches to meet the customer's expectations at the lowest cost while providing the highest quality outcome. The framework of Phillips Plastics Corporation's new APQP project launch plan depicts a combination of good practices or synergies, as well as critical success elements. A structured plan guides the process along a path of common developments and ideas. The structured plan makes a more robust launch system that is easy to follow, fosters communication amongst the whole team and creates a team environment. The APQP plan also provides the use of a cross functional team that determines the phases of the project by breaking it down into smaller manageable tasks that are monitored by gate reviews to assure the plan is complete, on-time and meeting the customer's expectations.

The implementation plan was broken down into sections and then compared from current state to future state. The plan was developed using such tools as vision creation, statistical data analysis, and simultaneous engineering and reengineering, and was all monitored by the use of gate reviews. The newly created plan followed the five project steps of the automotive based APQP quality timing chart.

Current State

A key opportunity in developing the future state of the Phillips Plastics project launch team was to define what the current state was. In the process of developing this process, strengths and weaknesses were uncovered. Weaknesses being identified allowed for the redefining of the project launch program and the focus Phillips Plastics Corporation needed in the future to better meet customers' expectations. There was evidence of successful traits and

processes that met Philips and customers' project launch expectations, but there were also gaps in the process that failed to meet certain customers' expectations. Overall the greatest opportunity that was identified was the need for a complete project launch program that would exceed project requirements, be a cost savings tool, and most importantly drive continuous improvement methodologies so Phillips can continue to grow its market share.

Future State (Vision State)

A standard procedure needed to be developed in order to assure there is commonality amongst the project launch team. This procedure consisted of a four step flow chart. The first step included the project launch, which established project objectives, setting up a cross functional team, gathered design and customer criteria's and expectations as well any research documentation that is needed. The second step included a strength, weakness, opportunities, and threats (SWOT) analysis to identify any issues that were pertinent from the beginning. The third step was to set up the measurement standards and definitions and what metrics or key performance indicators the project will be measured against. The fourth step included a process/production implementation plan which would release the project to a go live state into production. The key elements in this step are adequate training, and an open continuous improvement forum that results in the feedback and communication amongst all involved in the launch. The completed Gannt chart/project tracking tool is also utilized, see Appendix I.

Statistical Data Analysis

Benchmarking is a systematic approach to identifying standards for comparison. It provides input to the establishment of measurable performance targets, as well as ideas for product design and process design. It also provides ideas for improving business processes and standard work procedures. Product and process benchmarking by gap analysis should include

the world class or best in class based on customer and internal objective performance measures and research into how the performance was achieved. APQP, (2008)

Data collection was utilized to gain historical information on previous launches in certain market segments. Some of the information tools that were performed to gain valuable statistical data analysis on prior launches were monitoring, benchmarking, data analysis, and predictions, see Appendix J. The Launch Summary tool is utilized as a scorecard for analysis of how the project performed.

Monitoring was performed through techniques such as market conditions, organization performance and competitor actions and performances. Launch processes were monitored to assure that statistical control of common cause variations was present and system improvements were not necessary. The business strategy was also monitored to find out what key performance indicators were being met and if the process was on track in achieving the set goals. Benchmarking was also monitored to help better understand the current performance of project launches. This tool was looked at in comparison to other competitors and "best in class" synergies. One key element here was to measure the effects on multiple key performance indicators. Studying the interrelationships from one area to the other was critical. Another key area that was monitored in data analysis was the cost impact. Studies were performed to assure the project launches returned maximum benefits to the company, see Appendix K. A medical project summary tool was utilized to track costing variances and key performance cost measures. This was performed on a comparison cost situation with similar market launches at different times. Prediction was the last tool monitored. This tool was utilized through members of the team that have historical knowledge of cyclical concerns or benefits. It was clearly identified that the prediction models are only as good as the data that is input into the system. Design of

Experiments was also monitored in the prediction study to look at cross functional studies for repeating or replication past practices.

Simultaneous Engineering and Reengineering

Simultaneous Engineering is a process where cross functional teams strive for a common goal. It replaces the sequential series of phases where results are transmitted to the next area for execution. The purpose is to expedite the introduction of quality products sooner. The organization's product quality planning team assures that other areas and teams plan and execute activities that support the common goal APQP, (2008).

A key to success with developing new products and implementing project launches at Phillips Plastics Corporation is the cross functional team Phillips utilizes. Phillips' Plastics has a Design Development Center with complete capabilities from design to low production product launches. This aids in all of Phillips' plans' success. The development team uses a tool called "Design for Manufacturability". This tool, with collaboration from the customer and suppliers, identifies up front that the design is robust; this means that the products is designed at the most effective cost to the customer, and can be produced efficiently in the manufacturing plant.

Summary

Data was observed and analyzed from both previous and current practices by gathering data, analyzing the data and then creating gap analysis of the data, see Appendix L. The gap analysis assessment represented data in each of the critical categories. Data was then converted from the statistical data into useful information that we could turn into tools to help create the APQP plan. Having a clear and coordinated methodology lifecycle has been highlighted as one of the success factors for introducing new products Carbone, (2005). The APQP plan that PPC Custom currently uses is tailored around the TS 16949 automotive requirement and left a lot of

uncertainty when launching a project in another industry type. Phillips Plastics Corporation could not as a division, assess the caliber of project launches to be successful or not. A simplified project launch module was not in place and left holes unfilled when the project went through its phases.

Chapter V: Discussion

Phillips Plastics Corporation is a rapidly growing company that produces injection molded parts and assemblies for a wide array of customers, including, military, consumer, automotive, industrial, and medical. With the continuous growth it is imperative that new business products and launches continuously improve to ensure customer satisfaction and continued growth. Effective APQP and safe launches are the two key components to successful business launches. Without a successful APQP safe launch program, the focus of new product launches kicking off successfully and satisfying customers becomes a challenge. An analysis was performed on the current APQP process and how it performed at another Phillips Plastics Corporation facility on medical project launches. The intention was to understand the impact APQP had on product launches and to successfully benchmark an APQP process that will be adapted and applied to all new, safe product launches. The end goal was to implement an APQP safe launch program that will be utilized in every market sector of Customs' business to ensure customer satisfaction and continuous growth.

The main objectives of this study were to provide a detailed APQP safe launch process that will be utilized in all new product launches regardless of the market sector to improve product quality, shorten the time to the market, and eliminate post launch product issues. The plan was implemented and due to time constraints results were not completely captured. The implementation plan lays a foundation for successful new product launches, customer satisfaction, and continued growth for the business.

Limitations

The primary limitations for the plan were timing and customer base launch data. Currently, the project management group covers all market sectors, but was not all present at the time of this study. Phillips Plastics Custom facility currently does have an APQP process in place, such as control plans, pre-production approval process, failure mode and effect analysis, or a production launch system, but these will be integrated into a complete APQP safe launch program in the future. The time and resources needed to fully implement these all into one system fall outside of the time frame of this study. The goal of the study was to provide the implementation structure for a complete APQP safe launch program that can be executed on all new business opportunities and support the project management team to safely launch new product.

Conclusions

Once the new APQP plan is implemented, the potential biggest impact will be to ensure that the new product completely meets the requirements of the customer. The current APQP processes is utilized to the fullest and has been successful, but with the APQP implementation plan that is evident in this study, new product launches will be a better tool. For the team members using the tool, it will be a valuable benefit for the company, and most importantly, it will be a sizable benefit for the customer.

Recommendations

It is recommended that Phillips Plastics Custom facility organize a cross functional team from the new project launch side and work on fully implementing the proposed plan. A complete APQP safe launch project is detailed and will need to be determined on the timing of the layout, with resources and time being the limitations. The system should also be implemented electronically in the computer operating system to assure it is controlled and accessible to everyone. The need to successfully launch a safe product and meet customer requirements is crucial in every industry. This plan was proposed for the Phillips Plastics Custom division, but could be implemented in other divisions in the corporation or could be utilized in any similar organization that have the same goals that Philips does, to continue to exceed customer satisfaction and also continue to gain market share in the industry.

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Appendix A: APQP Gate Review and Approval.

Phillips
PHILLIPS PLASTICS CORPORATION™

Gate Review Meeting #____

AQP Gate Review & Approval

Project Part # (s): _____
Program Name: _____
Customer: _____
Date: _____

Molding ☐
Assembly ☐
Molding & Assembly ☐

Has the project team addressed the following:

Project Engineering (should give a quick explanation of the program)

1. Project Overview / Description
2. Project Time Line (key milestones)
3. Project Financial Review
4. - Material, Overhead, Labor (any surprises)
5. Forecast (Production Planning)
6. Documentation (prints, IPLR, MIF, spec's, customer requirements)
7. Customer Relationship

Manufacturing

1. System Life Cycle Requirements (If applicable)
2. Required Manufacturing Space and Equipment Layout
3. Process Value Steam Map
4. Personnel Resources Requirements – compared to current quotation
5. WI, SOP and Validation Plan
6. Part and runner weight accurate
7. Sample packet filled out and complete
8. **Work order attachments**

Quality

1. Results of IQ, OQ Inspection
   a. **Cpk, Ppk, Cpm for inspection dimensions.**
2. IPLR's / MIF (overall impact on the lab ~ # of dimensions)
3. Receiving Inspection
4. Part / Supplier Qualification (Are they capable? Any capacity constraints)
5. Validation Plan (Protocol)
6. Batch Record/DHR if required

Notes: If additional items are required to be completed prior to approval, Project Team will generate Gate Review Open Issues List (F7.1029). Once this list has been completed, Gate Review Approval Form can be re-circulated for management approval.

Management Team Approval & Date (Two signatures required. Operations Manager required)

_____ _____ ☐ Approved
_____ _____ ☐ Rejected

Project Team

Signature _____ Signature _____ Signature _____ Signature _____

F7.1026, Revision: x/xx/xx

Appendix B: APQP Product Launch process.

Phillips PHILLIPS PLASTICS CORPORATION	Title: Advanced Quality Planning Process		
	WI7.1003	Revision Date: x/xx/xx	Page 1 of 4

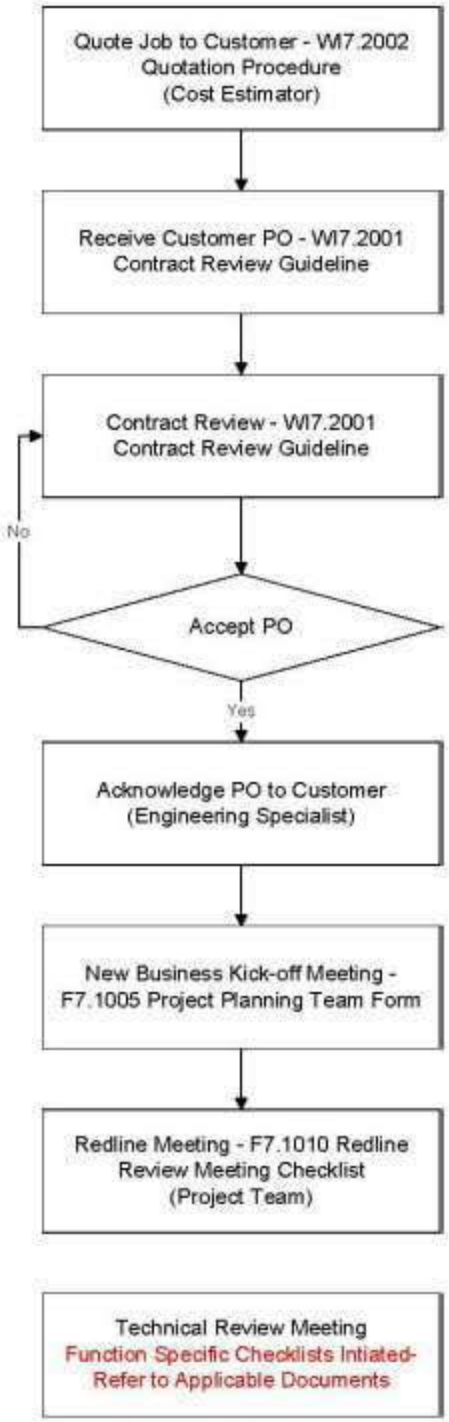
1. Purpose/Scope:
   1.1 To detail the process used by Phillips Custom for defining, documenting and implementing project team deliverables related to new and transferred product from quote through production readiness for the purpose of meeting regulatory and customer requirements.

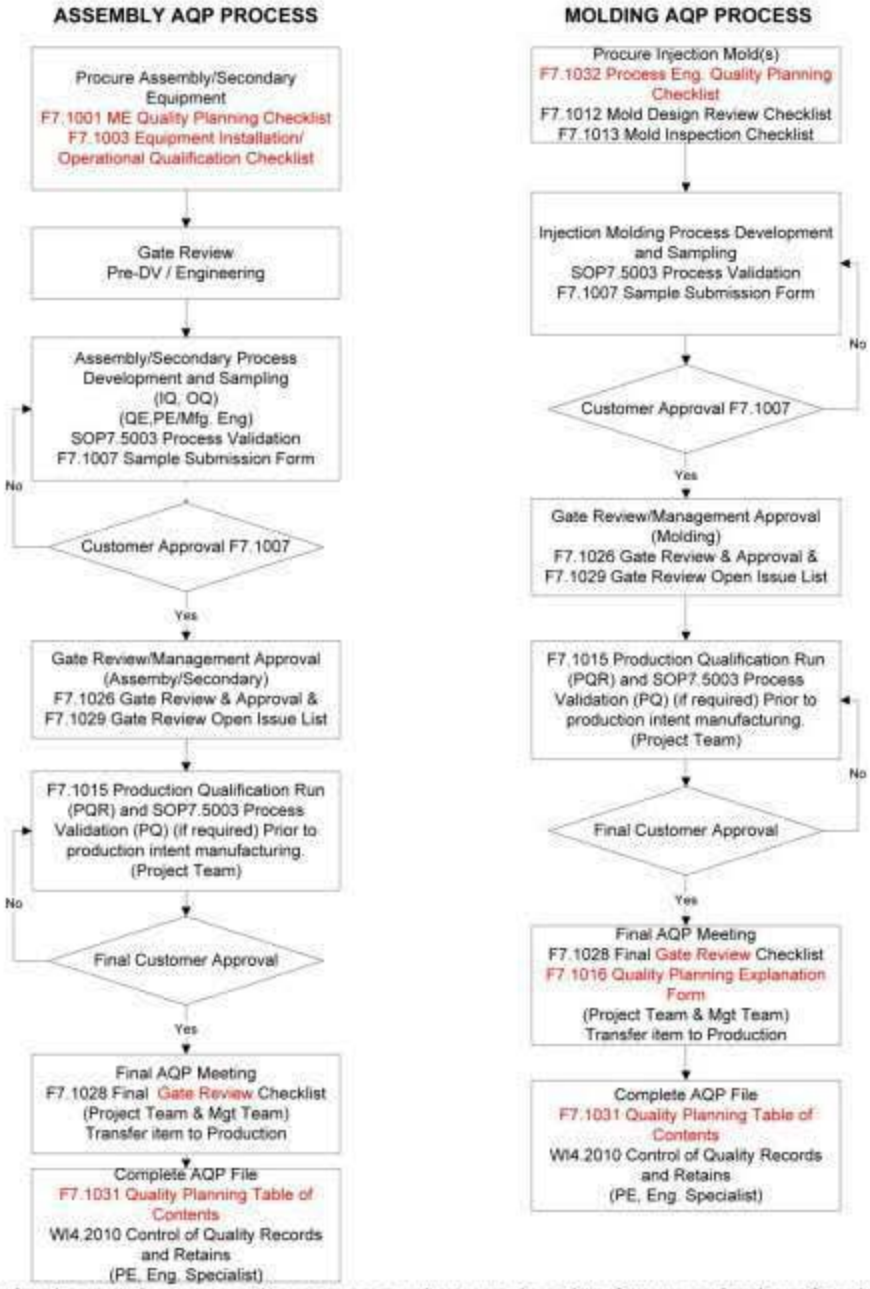
2. Definitions:
   2.1 **Quality Plan:** A document or group of documents whose purpose is to insure all areas affecting the end quality of the product/process are addressed, ensuring that Medical Molding & Assembly can meet or exceed any quality requirements of our customers.
   2.2 **Take-Over Tool:** A tool that was not designed by PPC and was run at another injection molder or PPC facility.
   2.3 **AQP:** Advance Quality Planning
   2.4 **Gate Review**: A Management review meeting with the project team whereas the project team is seeking approval to move into the validation stage of a said program. By receiving this approval, the project team may initiate the final phase of the validation known as the PQ runs
   2.5 **Advanced Quality Planning (AQP)**: The process used by Phillips Custom to coordinate resources and actions to bring a product from business award to production approval.

3. Applicable Documents:
   3.1 SOP7.5003 Process Validation
   3.2 WI7.2001 Contract Review Guideline
   3.3 WI7.2002 Quotation Procedure
   3.4 WI4.2010, Control of Quality Records and Retains
   3.5 F7.1001 Manufacturing Engineering Quality Planning Checklist
   3.6 F7.1002 Jig and Fixture Quality Planning Checklist
   3.7 F7.1003 Equipment Installation/Operational Qualification Checklist
   3.8 F7.1004 Project Engineering Quality Planning Checklist
   3.9 F7.1005 Project Planning Team Form
   3.10 F7.1007 Sample Submission Form
   3.11 F7.1010 Redline Review Meeting Checklist
   3.12 F7.1012 Mold Design Review Checklist
   3.13 F7.1013 Mold Inspection Checklist
   3.14 F7.1015 Production Qualification Run
   3.15 F7.1016 Quality Planning Explanation Form
   3.16 F7.1026, Quality Planning Gate Review & Approval
   3.17 F7.1028, Final Gate Review Checklist
   3.18 F7.1029, Gate Review Meeting Open Issue List
   3.19 F7.1030 Quality Engineering Quality Planning Checklist
   3.20 F7.1031 Quality Planning Table of Contents
   3.21 F7.1032 Process Engineering Quality Planning Checklist
   3.22 F7.1033 Packaging Quality Planning Checklist
   3.23 F7.5008 Inspection Request

4. Tasks:
   4.1 See below process flow chart

Phillips PHILLIPS PLASTICS CORPORATION	Title: Advanced Quality Planning Process		
	WI7.1003	Revision Date: x/xx/xx	Page 2 of 4





* Please note that due to project scope and/or customer requirements, the order of events on the above flowchart may need to be modified.

Approvals:					
Quality Manager	Engineering Manager	Operations Manager	Mfg. Engineering Manager	QA/Regulatory Manager	Assembly Operations Manager
Date:					

Appendix C: Quality Engineering Gate Review.

Phillips	Phillips Custom - Quality Engineering Quality Planning Checklist				
Customer:		**Part/Program Name:**		**Part /Assembly Number:**	

	ACTION	STATUS	COMMENTS
1.	Are the Customer Validation Requirements understood? • Does the Customer or product require Design of Experiments? • Enter Appropriate Protocol Number	☐Yes ☐No ☐N/A ☐Yes ☐No ☐N/A	
2.	Has a Device Master Record (DMR) been established?	☐Yes ☐No ☐N/A	
3.	If a DMR has been generated, is it for Drug or Device assembly?	☐Drug ☐ Device	
4.	**If a drug product, both a PST and a Quality sign off required on the work order. Contact Engineering Specialist to put "GMP" in Item Description.**	☐Yes ☐No ☐N/A	
5.	Are the Suppliers on the Approved Suppliers List??	☐Yes ☐No ☐N/A	
6.	Are suppliers aware that a validation or First Article is required or material certifications? Reference PCQA process: WI7.4013	☐Yes ☐No ☐N/A	
7.	Is incoming quality criteria and incoming inspection plan defined for components and external secondary operations?	☐Yes ☐No ☐N/A	
8.	Have quality criteria been identified and agreed to for FAIR, Start-up, In Process and Capability?	☐Yes ☐No ☐N/A	
9.	Have IPLRs been established and prioritized?	☐Yes ☐No ☐N/A	
10.	Have MIFs been established for metrology with proven capability through Gage R&R for applicable SPC dimensions?	☐Yes ☐No ☐N/A	
11.	Has Applied Stats been set-up to record variables data from both the In process lab and Set-up technicians as applicable?	☐Yes ☐No ☐N/A	
12.	Have assembly Test Methods been established for set-up technicians with proven capability through Gage R&R?	☐Yes ☐No ☐N/A	
13.	Has the impact on the Inprocess lab and set-up technicians been considered based on the number and frequency of measurements?	☐Yes ☐No ☐N/A	
14.	Is a Batch Record or Device History Record Required?	☐Yes ☐No ☐N/A	
15.	Have the following documents been created and controlled: • Batch Record • Bill of Materials document • Label/part/product reconciliation • Reject Sheets	 ☐Yes ☐No ☐N/A ☐Yes ☐No ☐N/A ☐Yes ☐No ☐N/A	
16.	Have product labeling requirements been determined?	☐Yes ☐No ☐N/A	
17.	Have prints been controlled/created for all applicable components, including labels and packaging?	☐Yes ☐No ☐N/A	
18.	Is label reconciliation required?	☐Yes ☐No ☐N/A	
19.	Have the documents listed above been reviewed and controlled prior to Gate Review?	☐Yes ☐No ☐N/A	

#	ACTION ITEMS/Comments	RESPONSIBILITY

Signature _____ **Date**_____

Quality Engineer

Appendix D: Project Engineering Gate Review.

Phillips

Phillips Custom - Project Engineering
Advanced Quality Planning Checklist

Customer: **Part/Program Name:** **Part /Assembly Number:**

	GENERAL	STATUS	COMMENTS	OWNER
1.	Is F7.1030 Quality Engineering Quality Planning Checklist been initiated / completed?	☐Yes ☐No ☐N/A		QE
2.	Is F7.1001 Manufacturing Engineering Quality Planning Checklist initiated / completed?	☐Yes ☐No ☐N/A		ME
3.	Is the F7.1032 Process Engineering Quality Planning Checklist initiated / completed?	☐Yes ☐No ☐N/A		ProcE
4.	Is the F7.1002 Jig and Fixture Quality Planning Checklist initiated / completed?	☐Yes ☐No ☐N/A		Jig/Fix
5.	Is the F7.1033 Packaging Quality Planning Checklist initiated / completed?	☐Yes ☐No ☐N/A		PackEng
6.	Was the First Right of Refusal process adhered to? If the tool was not placed internally at Phillips, explain why.	☐Yes ☐No ☐N/A		PE
7.	Was offshore tooling considered? If the tool was not placed offshore, explain why.	☐Yes ☐No ☐N/A		PE
8.	If a new customer, has IT set up a customer label?	☐Yes ☐No ☐N/A		Eng Spec
9.	Is the customer Shipping Instruction updated in IQMS?	☐Yes ☐No ☐N/A		Eng Spec
10.	Has an updated print been proposed /controlled for parts and purchased components if applicable?	☐Yes ☐No ☐N/A		PE, Eng Spec
11.	Have customized BOM, with appropriate items lot controlled, and work order attachments been initiated for molding and secondary operations including packaging?	☐Yes ☐No ☐N/A		PE, Eng Spec
12.	Have all materials and purchased components been identified and ordered?	☐Yes ☐N/A		PE
13.	Is a copy of the print red line drawing signed and approved by customer? • Has it been filed? • Is the Redline Meeting Checklist (F7.1010) complete?	☐Yes ☐N/A ☐Yes ☐N/A ☐Yes ☐N/A		PE
14.	Is Mold Design Review Checklist (F7.1012) complete and in Engineering File?	☐Yes ☐No ☐N/A		PE
15.	Is the customer performing biocompatibility on the parts? If so, tool coatings should be applied prior to testing. Any change to surface coatings post testing need to be re-evaluated by the customer.	☐Yes ☐No ☐N/A		PE
16.	Are materials purchase lead time understood and clearly communication with purchasing?	☐Yes ☐No ☐N/A		PE
17.	Is the Cash Conversion Cycle break even or Phillips favorable? CCC= (Days inventory outstanding + Days Receivables Outstanding)-Days Payable Outstanding	☐Yes ☐No ☐N/A		PE / Mat Mgr
18.	Have packaged goods been evaluated for storage allocation and shipping and information shared with Materials Manager?	☐Yes ☐No ☐N/A		PE
19.	Preparation and control of production documents: • Has the Sample Packet been completed accurately and completely? • Has the Production Packet been completed? • Have the Operator Work Instructions been completed? • Have the Limit Sample Boards been completed?	☐Yes ☐No ☐N/A ☐Yes ☐No ☐N/A ☐Yes ☐No ☐N/A ☐Yes ☐No ☐N/A		Eng Spec, Proc Eng, Mfg Eng

Signature _____ **Date**_____

Project Engineer

Appendix E: Manufacturing Engineering Gate Review.

Phillips

Phillips Custom - Manufacturing Engineering

Quality Planning Checklist

Customer:	**Part/Program Name:**	**Part / Assembly Number:**
Mfg Engineer	**Project Engineer**	

	Project Timeline and Production Requirements	*STATUS*	*COMMENTS*
1.	Identify sample dates and production start dates based on customer program timeline.	Dates:	
2.	Determine equipment needs based on production ramp up, forecast volume requirements, tooling and fixture cavitation and molding cycle time forecast	Volumes:	
	Planning, Secondary Equipment and Automation	*STATUS*	*COMMENTS*
3.	Has a User Requirements Specification (URS) been created for all NEW secondary equipment as appropriate?	☐Yes ☐No ☐N/A	
4.	Has an F7.1003 Equipment Installation/Operational Qualification Checklist been initiated for all new equipment?	☐Yes ☐No ☐N/A	
5.	Where equipment purchases may be required, have corporate idle assets been reviewed? Are equipment available internally?	☐Yes ☐No ☐N/A	
6.	Are packaging stands, special lighting, static reduction, contamination control requirements understood and available?	☐Yes ☐No ☐N/A	
7.	Have equipment and fixture accuracy been considered against final product specification?	☐Yes ☐No ☐N/A	
8.	Have equipment set-up jigs or devices been considered to ease machine set-up and reduce changeover downtime?	☐Yes ☐No ☐N/A	
9.	Has the Standing and Seated Ergonomic worksheets/BRIEF survey been reviewed during cell layout?	☐Yes ☐No ☐N/A	
10.	Have regular design and status reviews been established with the equipment/process providers or suppliers?	☐Yes ☐No ☐N/A	
11.	Has a FMEA been performed to identify equipment or assembly factors that negatively impact product quality?	☐Yes ☐No ☐N/A	
12.	Has the equipment been designed to meet the customer take time with the quoted number of operators?	☐Yes ☐No ☐N/A	
	Secondary Processes	*STATUS*	*COMMENTS*
13.	Has calibration of critical devices that impact quality or could impact "special processes", like welding, been reviewed and completed? (F7.1003)	☐Yes ☐No ☐N/A	
14.	Are customer abrasion resistance requirements understood for secondary operations?	☐Yes ☐No ☐N/A	
15.	Is the molded material compatible with secondary operations: treatments, special inks or coatings required?	☐Yes ☐No ☐N/A	
16.	Has a print review or redline process taken place to ensure capability and criticality of key dimensions are considered?	☐Yes ☐No ☐N/A	
17.	Process factors/window (worse case, hi/lo) that impact product quality are identified to test during the (OQ) Operation Qualification?	☐Yes ☐No ☐N/A	
18.	Have design of experiments been considered to optimize secondary processes?	☐Yes ☐No ☐N/A	
19.	Visual samples have been retained from experiments and saved to add to the visual sample board contained in the production packet?	☐Yes ☐No ☐N/A	

	Purchased Materials	*STATUS*	*COMMENTS*
20.	Have raw material needs (adhesives, inks, films, catalysts, thinners) been identified?	☐Yes ☐No ☐N/A	
21.	Have shelf life and expiry date of raw materials been considered when ordering and managing future inventory?	☐Yes ☐No ☐N/A	
22.	Inventory of spare process components or consumables (horns, pads, etc) have been considered?	☐Yes ☐No ☐N/A	
23.	Have purchased component interactions been considered for tolerances, accuracy, fixture design and assembly processes?	☐Yes ☐No ☐N/A	
24.	Materials Manager is aware of the upcoming program and inventory needs?	☐Yes ☐No ☐N/A	
25.	Have we considered the most cost effective and risk minimizing inventory sizes and lot/run sizes with the Quality team?	☐Yes ☐No ☐N/A	
	Value Stream Verification	*STATUS*	*COMMENTS*
26.	Have we considered storage requirements (space, location, temperature control) for the purchased and molded incoming materials?	☐Yes ☐No ☐N/A	
27.	Have we considered storage requirements (space, location, temperature control) for the outgoing materials?	☐Yes ☐No ☐N/A	
28.	Have we considered WIP storage locations on the production floor for incoming and outgoing materials?	☐Yes ☐No ☐N/A	
29.	Have members of the Ergonomics/Safety Committee been involved with cell design?	☐Yes ☐No ☐N/A	
30.	Product flow is efficient: incoming and outgoing materials flow into and out of the line cleanly.	☐Yes ☐No ☐N/A	
	Requirements before Assy Pre-Gate Review	*STATUS*	*COMMENTS*
31.	Work cell design and location has been identified and approved by area Production Manager?	☐Yes ☐No ☐N/A	
32.	Number of operators required is understood and shared with Production Manager?	☐Yes ☐No ☐N/A	
33.	Pre-production runs (design verification and practice builds) are planned and shared with the Scheduler and Production Manager?	☐Yes ☐No ☐N/A	
34.	Storage locations, both warehouse and WIP, is understood and shared with Materials and Production Manager?	☐Yes ☐No ☐N/A	
	Requirements before Assy Gate Review	*STATUS*	*COMMENTS*
35.	Work cell design is in place and has been verified from a safety and ergonomics perspective?	☐Yes ☐No ☐N/A	
36.	Equipment and assembly protocols are approved and ready to be executed?	☐Yes ☐No ☐N/A	
37.	Operator level production packet or work instructions have been generated?	☐Yes ☐No ☐N/A	
38.	Set-up instructions have been provided for processes and equipment in the production packet?	☐Yes ☐No ☐N/A	
39.	Have Golden Samples for vision systems been considered? If so, generate a CALWI on how the samples were created.	☐Yes ☐No ☐N/A	
40.	Operator, set-up, maintenance and engineering training have been considered in the timeline?	☐Yes ☐No ☐N/A	

	ACTION ITEMS/Comments	*RESPONSIBILITY*	*COMPLETE*

Signature _____ **Date**_____

Manufacturing Engineer

BRIEF™ Survey – BASELINE RISK IDENTIFICATION OF ERGONOMIC FACTORS Version 3.0

Step 1 Complete Job Information

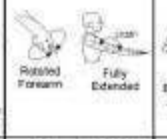
Job Name: _____ Site: _____ Station: _____

Date: _____ Dept: _____ Shift: _____ Product: _____

Step 2 Identify Risks

2a. Mark Posture and Force boxes when risk factors are observed.

2b. For body parts with Posture or Force marked, mark Duration and/or Frequency box(es) when limits are exceeded.

	Hands and Wrists		Elbows		Shoulders		Neck	Back	Legs
									
	Left	Right	Left	Right	Left	Right			
2a. Posture	☐	☐	☐	☐	☐	☐	☐	☐	☐
2a. Force	Pinch Grip or Finger Press ≥ 3 lb (1.9 kg), or Power Grip ≥ 10 lb (4.5 kg) ☐ ☐		≥ 10 lb (4.5 kg) ☐	≥ 10 lb (4.5 kg) ☐	≥ 10 lb (4.5 kg) ☐	≥ 10 lb (4.5 kg) ☐	≥ 2 lb (0.9 kg) ☐	≥ 25 lb (11.3 kg) ☐	Foot Pedal ≥ 10 lb (4.5 kg) ☐
2b. Duration	≥ 10 sec. ☐	≥ 10 sec. ☐	≥ 10 sec. ☐	≥ 10 sec. ☐	≥ 10 sec. ☐	≥ 10 sec. ☐	≥ 10 sec. ☐	≥ 10 sec. ☐	≥ 30% of day ☐
2b. Frequency	≥ 30/min. ☐	≥ 30/min. ☐	≥ 2/min. ☐	≥ 2/min. ☐	≥ 2/min. ☐	≥ 2/min. ☐	≥ 2/min. ☐	≥ 2/min. ☐	≥ 2/min. ☐
Score									
Risk Rating	H M L	H M L	H M L	H M L	H M L	H M L	H M L	H M L	H M L

Step 3 Determine Risk Rating

In the Score box, write the number of risk factor categories (0-4) checked for each body part. Using the table at right, circle the corresponding Risk Rating for each body part. ▶

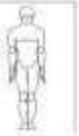
Score	Risk Rating
3 or 4	= High (H)
2	= Medium (M)
0 or 1	= Low (L)

Step 4 Identify Physical Stressors

Mark physical stressors observed:

- ☐ Vibration (V)
- ☐ Low Temperatures (L)
- ☐ Soft Tissue Compression (S)
- ☐ Impact Stress (I)
- ☐ Glove Issues (G)

▶ Use the corresponding letters to show location of stressors. ▶



Appendix F: Final Gate Review.

Phillips — Phillips Plastics Corporation

Phillips Custom – Project Engineering

Final Gate Review

Customer: | **Part/Program Name:** | **Part / Assembly Number:**

Project #(s)

1. Final Quality Planning Checklist

	STATUS	Res	COMMENTS
1. For Molding PQR runs, have the following people reviewed and signed off the PQR packet to ensure their feedback is provided? • Mold Technician • Production Support Technician • Operator • Team Leader	1st Shift ☐Yes ☐No ☐N/A 2nd Shift ☐Yes ☐No ☐N/A 3rd Shift ☐Yes ☐No ☐N/A	Ops Mgr	
2. Have tooling issues been resolved satisfactorily in regard to cosmetic and dimensional attributes?	☐Yes ☐No ☐N/A	PE	
3. Have manufacturing and assembly action items been satisfactorily addressed?	☐Yes ☐No ☐N/A	ME / PE	
4. Have all molding process issues been resolved as evidenced by the PQR run?	☐Yes ☐No ☐N/A	ProcE	
5. Have metrology, measurements or procedural issues satisfactorily completed as evidenced by the PQR run?	☐Yes ☐No ☐N/A	QE	
6. Are shipping instructions complete? Review form F-SR-Customer#	☐Yes ☐No ☐N/A	PE	
7. Review PQ Run SPC Dimension Data. ○ Cpk, Ppk, Cpm		QE	
8. Has component classification been updated to reflect capability of the PQ runs?	☐Yes ☐No ☐N/A	QE	
9. Have all Work Order Attachments, Work Instructions, Production Packets and Master parameters been updated and controlled as necessary?	☐Yes ☐No ☐N/A	PE, ME, QE	
10. Have the logistics for Purchasing, Inventory, Warehousing and secondary operations and or sterilization activities been reviewed and set-up correctly.	☐Yes ☐No ☐N/A	PE, Mat Mgr	
11. Review Financial Summary.	☐Yes ☐No ☐N/A	PE	
12. Review Tooling Report Card.	☐Yes ☐No ☐N/A	PE	
13. Are the auditable document files prepared?	☐Yes ☐No ☐N/A	PE	

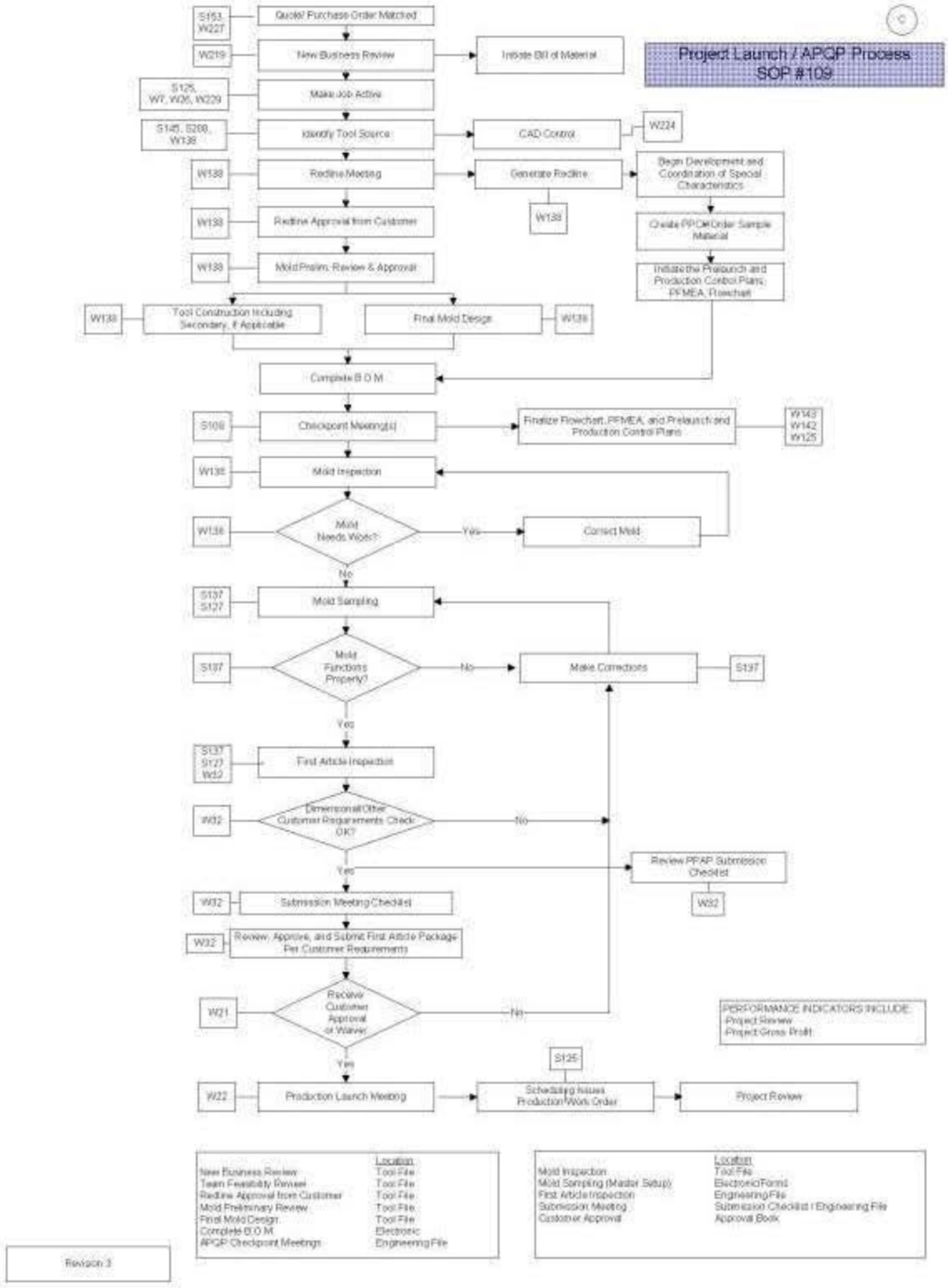
2. FOLLOW-UP ACTIVITIES

	Follow up meeting required for action item review (providing closure)	Engineering Spec.	☐Yes ☐No

3. REVIEW

Operations Mgr	Date	Materials Mgr	Date	Eng Mgr	Date
Quality Mgr	Date	Manufacturing Eng Mgr	Date	Other	Date

Appendix G: Project Launch



Appendix H: Project Tool Log

Project Log
CUSTOM
Sorted by: Project Manager

3/21/2012
11:55:46AM
Page Number:

Project#/ Work Order	Customer/Project Information	Customer Purch Info	
XXX -PIERCE	FOAM INSERTS; BUILD SINGLE CAVITY TOOL; *Tool ID:* - *Program:* *Market:* CONSUMER	PO#: xxxxx Sales Orders: xxxxx Quote #: xxxxxx Discount :	WO Start 3/7/2012 WO End 4/30/2012 Direct Cost to Date: $ Outstanding Purch: $ Total Cost: $ Total Est Cost: $ Project Sales: $ Invoiced to Date: $

Secondary Tooling

Task Name	Duration	% Complete	Task Start	Task End	Eng Hrs
1. SECONDARY BUILD/REISS INDUSTRIES	1 Day		3/7/2012		8.0
2. SAMPLE/TOOL TWEAKS					
3. CUSTOMER APPROVAL/INVOICE/CLOSE				4/30/2012	

Notes:

Project#/ Work Order	Customer/Project Information	Customer Purch Info	
XXXX -PIERCE	LH / RH WING; BUILD A 1+1 FAMILY TOOL; *Tool ID:* *Program:* *Market:* CONSUMER	PO#: xxxxx Sales Orders: xxxxx Quote #: xxxxx Discount :	WO Start 3/20/2012 WO End 10/31/2012 Direct Cost to Date: $0 Outstanding Purch: $0 Total Cost: $0 Total Est Cost: $ Project Sales: $ Invoiced to Date: $0

Tool Build - New Build (Domestic)

Task Name	Duration	% Complete	Task Start	Task End	Eng Hrs
1. TOOL BUILD/PLACED	1 Day	5	3/20/2012		
2. SAMPLE/TOOL TWEAKS					
3. LAYOUT/APQP/SUBMISSION					
4. CUSTOMER APPROVAL/INVOICE/CLOSE				10/31/2012	

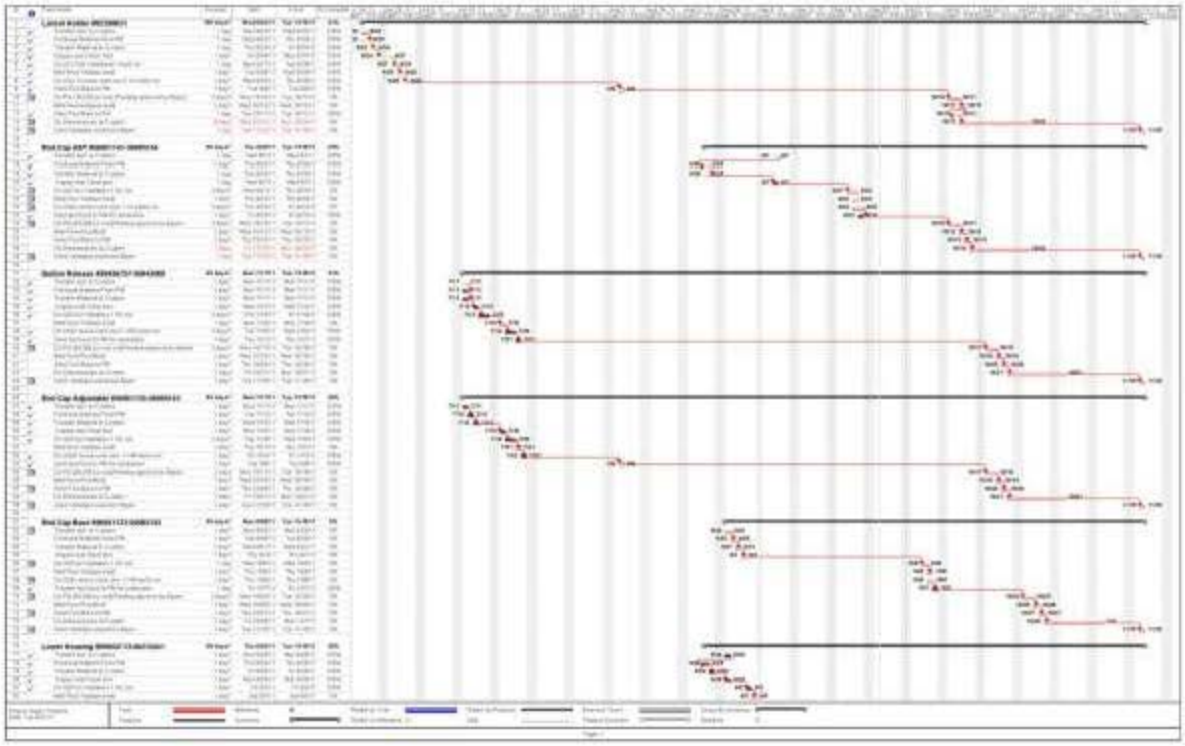
Notes:
TERMS: 1/3 UPON PO RECEIPT, 1/3 UPON PPAP SUBMISSION, 1/3 UPON APPROVAL

Act 10-Tool Build,Tool Procurement: 5%-Release / 10%-Prelim Tool / 15%-Final Tool / 100%-Tool Delivered 1st Time
Act 20-Sample,Tool Tweak,Secondary Operations: 50%-Sampling / 100%-Approval

Act 30-Layout,APQP,Submit: 50%-Work Begun / 100%-Submission
Act 40-Cust Approval,Invoice,Close: 50%-Invoiced / 100%-Closed

Yellow = No PO Issued / Red = No PO and project over 6 mos old /

Appendix I: Project Timeline



Appendix J: Launch Summary

Green Launches

	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Plan %	75	75	75	75	75	75	75	75	75	75	75	75
Act %	0%	50%	50%	66	100	100						

Appendix K: Medical Project

Closed Project Summary & Type

CUSTOM

Reporting against April 2012

4/18/2012 12:53:13AM
Page Number: 2

Project Number	Customer Project Name	Close Date Market	Purch Cost	Labor Cost	Final Direct Cost	Estimated Direct Cost	Discount	Sales $	Gross Profit

Sales Summary by Project Type - CUSTOM

Reporting against April 2012

	Sales	Purch Cost	VAS	Discount	Project Count	Ave Sales	Ave VAS
Validation - Mold	0	0	0		1	0	0
Total April 2012	$ 0	$ 0	$ 0		1	$ 0	$ 0

Financial Summary - Actual vs Forecast	Actual	Forecast	
Sales	**$ 0**	**$ 88,208**	
Value Added Sales (Sales less Purch Costs)	**$ 0**	**$ 23,643**	
Fixed ($69,300) & Misc Var Costs ($4,000)	73,300	73,300	
Sample Costs	0	731	
Corporate Allocations (6% of Sales)	0	5,292	
Interest	500	500	*
Projected NIBT - April 2012	**$(73,800)**	**$(56,180)**	
Depreciation *(Included in Fixed costs)*	530	530	*
Projected EBITDA - April 2012	**$(72,770)**	**$(55,150)**	

*less * items*

_PPC_ClosedSummaryByType_v12 REV 01/31/2012

High-lighted sections indicate that invoiced amt is less than sales order amt

Appendix L: Gap Analysis Assessment

Medical Components Gap Assessment, January 9, 2012: Internal Recommendations						
Area	**Summary Recommendation**	**Item**	**Specific Recommendation**	**Value**	**Effort**	**Time**
Facility	The facility needs to be much cleaner than it currently is. Understanding that numerous presses have recently been relocated into the facility, leading to a recent level of disorganization, the amount of dust, oil, resin and cardboard debris is significant. The facility is in need of improved housekeeping practices for all departments. After an improvement plan is developed and expectations are clearly understood, the team should start with frequent housekeeping audits (see attached form) and follow up with a formal 5S initiative	1	Start with basic deep cleaning leading to regular housekeeping audits.	High	Low	1 to 3 months
		2	Consider bringing in ServiceMaster, for example, to do a deep clean on individual presses and other pieces of equipment.	High	Low	1 to 3 months
		3	Once a baseline of cleaning has been implemented, start an extensive 5S program to improve the organization and general look of the facility.	Mod	High	6 to 12 months
		4	Consider getting rid of 5-10 older presses to reduce the congestion on the floor.	Low	Low	3 to 6 months
		5	Get rid of individual mold tech tool boxes and implement community tool boxes shared by shifts. Reduced clutter and tribal knowledge.	Mod	Mod	3 to 6 months
		6	Get cleaning supplies, brooms, mops etc. off the production floor. Use cleaning cart(s)	Mod	Low	1 to 3 months
		7	Be prepared to know exactly what is in cleaning chemicals used on the production floor, and potentially eliminate some that may not be used in a medical device environment. Develop a WI that specifies what chemicals are approved and what the process is if new chemical are added	Low	Low	3 to 6 months
		8	Consider repairing and re-painting the concrete walls below the windows around the perimeter of the building (inside)	Low	Low	3 to 6 months
		9	Windows are in need of a professional cleaning	Low	Low	3 to 6 months
		10	Implement formal control over pest control program (SOP, documentation)	Mod	Low	1 to 3 months
		11	Eliminate food and drink from production floor.	Low	Low	3 to 6 months
Material Flow	Consider making the Custom II a stand-alone molding facility.	12	Move jig and fixture group and equipment to Custom I tool repair area.	Mod	High	6 to 12 months

Medical Components Gap Assessment, January 9, 2012: Internal Recommendations						
Area	**Summary Recommendation**	**Item**	**Specific Recommendation**	**Value**	**Effort**	**Time**
		13	Turn existing jig and fixture area into functioning receiving area for resins and possibly an inspection area for quality coaches.	Mod	High	6 to 12 months
		14	Get quality coaches/in-process inspection out of the office area into a dedicated area with space, lighting and suitable environment facilitate inspection. If under-utilized presses are decommissioned additional space would be available to place this on the production floor.	High	High	3 to 6 months
Traceability	Raw materials need to be traceable forward to individual lots. Lots need to be traceable back to raw materials.	15	IQMS can facilitate this. You need to be able to take any lot from the floor or inventory and know exactly what materials, by lot, have been used to produce it.	High	Mod	1 to 3 months
Validation and Quality Systems	The facility needs a comprehensive validation program and scalable quality system to meet the requirements of a medical facility and the products manufactured	16	Create a validation master plan that defines what needs to be validated, and to what extent. Provide guidance to establish what needs to be re-qualified when equipment is repaired, moved or modified.	Mod	Mod	3 to 6 months
		17	Develop a qualification assessment process for tooling and equipment.	Mod	Low	1 to 3 months
		18	Implement a calibration program for presses. Define what needs to be calibrated, checked or verified based on critical outputs (e.g. process outputs/measurements that are identified as validation acceptance criteria).	High	High	3 to 6 months
		19	IQ/OQ, and if applicable, PQ presses as a baseline regardless of short-term planned use.	Mod	High	6 to 12 months
		20	Validate individual tools to family of like presses.	Low	Mod	6 to 12 months
		21	Validate the sorting mechanism/robot for each press.	Mod	Mod	3 to 6 months
		22	Validate facility controls (e.g. Compressed air, HVAC, temperature monitoring, lighting).	Low	Mod	6 to 12 months

Medical Components Gap Assessment, January 9, 2012: Internal Recommendations						
Area	**Summary Recommendation**	**Item**	**Specific Recommendation**	**Value**	**Effort**	**Time**
Preventing Mix-ups/ Cross-Contamination	Implement a line clearance program.	23	Prior to starting a new run, ensure that all materials and documentation from the prior run have been removed.	High	Low	1 to 3 months
		24	Document line clearance in real-time and file documentation as part of the batch record/CHR for the run immediately following the clearance.	High	Low	1 to 3 months
		25	Make it the responsibility of operators and mold techs to own the line clearance process and keep the presses/secondary equipment clean.	Mod	Mod	3 to 6 months
Production Controls	Streamline operations on the production floor.	26	Eliminate retains/sample boards on the floor in favor of digital views in IQMS.	Low	High	6 to 12 months
		27	Stop using process setup sheets with +/-10% ranges. Focuses instead on verifying that process outputs fall within validated ranges. Control process setup inputs by controlling parameter disks.	Mod	Mod	3 to 6 months
		28	Verify that short runs are sampled frequently enough to ensure that statistical significance is achieved in Cpk. One subgroup is insufficient.	Low	Low	3 to 6 months
Change Control	Implement a comprehensive change control program with procedure(s) to ensure that changes to facilities, equipment, processes and the quality management system do not adversely impact product quality or patient safety.	29	Document all changes.	High	Mod	1 to 3 months
		30	Review and approve all changes prior to implementation. Review should include risk assessment.	High	Mod	1 to 3 months
		31	Assess the impact of changes on the validated state of facility, equipment and process, and ensure that all is returned to the validated state prior to using for production.	Mod	Low	1 to 3 months
GMP Audits	Implement routine good manufacturing practice (GMP) audits throughout the facility.	32	Audits should be conducted jointly between quality management and management of the area being audited. Audits should be documented, and corrective actions made on the spot if possible.	High	Low	1 to 3 months

Medical Components Gap Assessment, January 9, 2012: Internal Recommendations						
Area	**Summary Recommendation**	**Item**	**Specific Recommendation**	**Value**	**Effort**	**Time**
Production Launch Gate Reviews	Implement gate review process with joint functional ownership as part of AQP process.	33	Hold gate review meetings prior to PQ. Have stakeholders (e.g. Project Engineering, Manufacturing Engineering, Quality Engineering) present to Production management to justify why the product is ready to go into production. Hold people accountable.	High	Low	1 to 3 months
Lot Release	Implement formal production lot release process.	34	Review each batch record/CHR for completeness, accuracy and good documentation practice (GDP). Nothing gets shipped that isn't stamped released. Nothing gets released without 100% QAP. Trend QAP as 'on-right-the-first-time'. Lots that have gone through MRB require higher level of authority for disposition.	High	Low	1 to 3 months