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**ENNAKOIVAN TUOTELAATUSUUNNITTELUPROSESSIN
TEHOKKUUDEN KEHITTÄMINEN PKC WIRING
SYSTEMS:LLÄ**

Opinnäytetyö

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TIIVISTELMÄ OPINNÄYTETYÖSTÄ

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Työn nimi ENNAKOIVAN TUOTELAATUSUUNNITTELUPROSESSIN TEHOKKUUDEN KEHITTÄMINEN PKC WIRING SYSTEMS:LLÄ		
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<p>Uusien tuotteiden valmistaminen onnistuneesti ja tehokkaasti ovat tärkeimpiä yritysten kilpailukykyyn ja taloudelliseen menestykseen vaikuttavia toimenpiteitä. Tämän vuoksi yrityksen tuotelaatusuunnittelun on oltava hyvin suunniteltu ja toteutettu.</p> <p>Tämän opinnäytetyön päätavoite on tunnistaa heikkoudet PKC Wiring Systems:n (kohdeyritys) nykyisessä tuotelaatusuunnittelussa ja parantaa mallia, jotta tuotteen laatutavoitteet ja vaatimukset voidaan viedä systemaattisesti ja dokumentoidusti tuotteeseen ja prosesseihin riittävin resurssein. Kun tuotannon ylösajon aikana on voitu minimoida potentiaaliset riskit, tuotteen laatu voidaan taata. Työssä selvitetään toimintatutkimuksen metodeilla, millaisella mallilla heikkouksia voidaan parantaa. Ongelmiin haetaan vastauksia kirjallisuustutkimuksen sekä työryhmän avulla.</p> <p>Työn tuloksista havaittiin epävarmuuksien olevan peräisin puutteellisesta ennakoivan tuotelaatusuunnitteluprosessin (APQP) tuntemisesta, toimintatavoista sekä dokumentaatiosta. Epäselvyyksiä oli myös kyseisen prosessin toteuttamislajisuuden määrittämisessä, eikä vastuita oltu määritelty riittävällä tasolla. Varsinaista uutta ja erillistä APQP mallia ei kehitetty, vaan jo olemassa olevia toimintatapoja ja prosesseja parannettiin ja selkeytettiin tehostamaan nykyistä toimintaa ja vastaamaan paremmin vaatimuksiin. Tuotteen toteuttamisen suunnittelu ja ennakoivan laadun suunnittelun prosessit suunniteltiin uudelleen, dokumentoitiin, tarkasteltiin ja implementoitiin organisaatiossa.</p>		
Asiasanat APQP (ennakoiva laatusuunnittelu), autoteollisuus, laadunvarmistus, PPAP (tuotanto-osan hyväksymisprosessi), projektinhallinta, SOP (tuotannon aloitus) ja tuotekehitysprojekti		

ABSTRACT

CENTRAL OSTROBOTHNIA UNIVERSITY OF APPLIED SCIENCES	Date March 2010	Author Hanna Leskinen
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Name of thesis IMPROVING THE EFFICIENCY OF ADVANCED PRODUCT QUALITY PLANNING PROCESS AT PKC WIRING SYSTEMS		
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<p>The successful launching of new products to the market has proven to be one of the most important factors when defining procedures which influence the competitiveness and financial success of businesses. Therefore company's product quality planning must be well planned and implemented.</p> <p>The main research area of this master's thesis was to identify weaknesses of the current product quality planning at PKC Wiring Systems. The purpose was to improve the model so that product quality requirements can be addressed to products and processes systematically with needed documentation and resources. The product quality can be ensured when the potential risks are minimized during the production ramp-up. This thesis uses empirical research to investigate what kind of a process model can be created to address these problems. Literature reviews and workshop group were applied in finding the solution to problems.</p> <p>The results indicated that uncertainty is caused by lack of awareness in the product quality planning procedure, operations and documentation. The definition of scope in advanced product quality planning process was unclear. Furthermore, responsibilities were not defined in the sufficient level. New separated APQP model was not developed, instead the current procedures and processes were improved and simplified to make current operations more effective and to correspond to the requirements. Product implementation planning and advanced product quality planning processes were re-planned, documented, reviewed and implemented in the organization.</p>		
Key words APQP (advanced product quality planning), automotive industry, quality assurance, PPAP (production part approval process), project management, SOP (start of production) and product development project		

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This thesis has been made for Central Ostrobothnia University of Applied Sciences, Master's Degree for Technology Competence Management. The thesis has been made for the case company, and the study has been conducted during years 2009 and 2010.

The target of this thesis was to create a more effective APQP model for the case company PKC. This way product quality deviations can be eliminated in the beginning of production launch. It can be also assumed that product quality, delivery precision and cost level will be improved.

I would like to thank my instructors and supervisors. Especially I would like to express my gratitude to M.Sc. Ulla Sipilä for instruction and guidance during research. Also special thanks to my friend M.Sc. Mari Jauhola for correction of the language of this thesis.

Finally, warm thanks to my husband Jussi, my daughter Veera and all my friends.

Tupos

April 25th, 2010

Hanna Leskinen

ABBREVIATIONS

APQP	Advanced Product Quality Planning
BOM	Bill of material
CP	Control plan
DFMEA	Design Failure Mode and Effect Analysis
ERP	Enterprise resource planning
FMEA	Failure Mode and Effect Analysis
PFMEA	Process Failure Mode and Effect Analysis
PPAP	Production Part Approval Process
PSW	Part Submission Warrant
RFQ	Request for quotation
RTS	Review of technical specification
RPN	Risk Priority Number
R&D	Research and development
SFMEA	System Failure Mode and Effect Analysis
SOP	Start of production
SPC	Statistical process control
TQM	Total Quality Management

TIIVISTELMÄ OPINNÄYTETYÖSTÄ

ABSTRACT

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ABBREVIATIONS

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1 INTRODUCTION

1.1 Background of the study

Elements of advanced product quality planning (APQP) are implemented to the company under research but the elements are not transparently connected to the daily operational procedure. The concept of APQP and its terms are not known in the organisation to the extent they should be for an effective APQP execution. Also, the responsibilities are not defined clearly enough. The company's present project management model has been built according to stage gate method, on which APQP is also based. Automotive industry's advanced APQP requirements are not taken into account in a sufficient level in the company's current project management model.

In early 2008, a thesis was made for the company regarding quality assurance in production technology transfer projects (Quality Assurance in Production Technology Transfer Projects). One of the further questions of the thesis was to do research on the organization's working methods and functionality of the quality system. (Lievonon 2008.) The thesis on APQP considers the organization's operations comprehensively from the voice of customer to production launch. APQP is part of the automotive industry specific ISO/TS 16949 quality system requirement.

1.2 Company presentation

PKC Group offers and supplies design and contract manufacturing services for wiring harnesses, electronics and cabling. The group has production facilities in Finland, Russia, Estonia, Poland, Brazil, Mexico and China. PKC Group has almost 5000 employees worldwide and approximately 500 employees in Finland. The group's net sales in 2009 was EUR 201.8 million. PKC Group Oyj is listed in NASDAQ OMX Helsinki Ltd. The group's head office is located in Kempele.

PKC Group is the mother company of two distinct business groups: PKC Electronics and PKC Wiring Systems. PKC Electronics provides design and contract manufacturing

services for electronics industry. This thesis is made from the wiring harnesses business point of view of and it concentrates on PKC Wiring Systems (later PKC). PKC Wiring Systems is a manufacturer and product developer for demanding and tailored solutions, from design to the end product. Main proportion of products is delivered for the automotive industry and they are used in trucks and industrial machines. Also cable assemblies are produced mainly to telecommunication industry by wiring of electronics. Quality is an important factor, since majority of the products go to the automotive industry.

1.3 Research questions and methods

Effective product and process design and start of production are a necessity for success in the business today and even more so in the future. It means that a company's APQP process needs to be well-designed and implemented in accordance with the requirements of the customers. Product quality, delivery precision and cost level are vital factors because of competitive advantage. In addition, fast response time and individual tailoring are important.

There are three research questions that will be answered in this thesis:

Q1: How APQP process can be made more effective at PKC Wiring Systems?

Q2: What are the factors when something goes wrong and/or is successful? Why?

Q3: What critical factors should be developed?

This thesis doesn't take into account cases where the product is designed by PKC; only cases where PKC is a manufacturer of the product are considered. R&D part of APQP is not within the scope of the thesis.

Case study methods have been applied in this thesis. According to Yini (2003), case study is empiric research which explores modern occurrence in its actual context especially when limit between occurrence and context is not clearly visible. Eriksson and Koistinen (2005) define the context as follows: Those elements and operations, where the case is connected closely form context. The context is made up of historical background of the case or from wider environment. This wider area can compose from cultural environment, function environment or political situation in which target area the case is.

Especially research strategy or approach is under consideration in this case study realization. Generally, case study is a multiform and iterative process, which does not necessarily proceed straightforward. During the research, the researcher goes through many phases, which can be executed and presented in undefined order. These phases are:

- specification of research questions, analysis of research frame
- definition and selection of cases
- definition of used theoretical viewpoint and concept
- logic of dialogue definition between materials and research questions
- determination of analysis means and interpretation regulation and
- determination of reporting method. (Eriksson & Koistinen 2005.)

Operations analytical research approach has been used in this case study thesis. The methodology consists of techniques used to analyze and gather research data along with techniques used to answer the research questions. The research approach of this study is constructive. The constructive approach means problem solving through the construction of diagrams, models, plans and organizations. Constructive approach is widely used in operations research. (Kasanen & Lukha. & Siitonen 1993.)

First, problem is defined in constructive studies. The solution is based on an empirical findings and relevant theoretical framework. The quality of research results is evaluated by studying the scope of applicability of the solution. The research approach provides that the constructed solution increases general knowledge and theory about the specific problem. (Olkkonen 1993.)

This thesis, which emphasizes the targets, follows the order:

1. Diagnosing (identification and definition of the problem)
2. Planning (examination of alternatives to solving the problem)
3. Implementation (selecting of one alternative and its implementation)
4. Evaluation (studying the effect of made actions)
5. Learning (identification of general findings)

Researcher acts in solid co-operation with all those parties whom the problem affects. (Järvinen & Järvinen 2000; Olkkonen 1993.)

The purpose is to understand activities and features of APQP to help evaluate its functionality and improvement potential.

1.4 Objectives and scope

The meaning of this thesis is to rationalize and standardize Request for quotation (RFQ) process, Research and development (R&D) projects, Start of production (SOP) and Production Part Approval Process (PPAP) to create complete APQP model, which is also suitable for the current project management model. The Research and development is not in the scope of this thesis.

The main goal of this thesis is to improve the efficiency of PKC's current APQP process and to create an effective APQP model. After the creation of improved model, needed changes will be easier to implemented and product quality defects can be eliminated as early as possible in the product and process planning phases. Customer requirements can be implemented to final product with needed control and documentation. When the risks are minimized during quality planning, defect free, capable and effective product manufacture process can be ensured. Also information flow is ensured inside of PKC and with customers. The purpose is also to get a tool for operational planning and for internal and external assessment.

1.5 Structure

Below is a short description of the thesis.

Chapter 1. Introduction to the thesis research. The research environment and organization are presented in the beginning of this chapter. Research questions, methods, objective and scope are also in this chapter.

Chapter 2. Theoretical part. Chapter begins with depicting the "Big picture" – the Advanced Product Quality Planning and its' characteristics in an integrated environment. The theory of Advanced Product Quality Planning forms a

frame of automotive industry's quality, quality assurances and project management.

- Chapter 3. Empirical analysis. Diagnosing, planning, implementation, evaluating and learning of the study are presented in this chapter. Conduction of the study is illustrated by research and timing chart figures. After that the analysis of current performance of Advanced Product Quality Planning follows. The required Advanced Product Quality Planning elements are implemented as quality management system requires, but the risk points were seen in communication and documentation during the product quality planning.
- Chapter 4. Results. The means to improve performance and to reach the aspired level are demonstrated. The definition of process scope is identified and implemented in this chapter. The implemented main and sub processes and procedures, outputs and process owners of Advanced Product Quality Planning are presented in this chapter.
- Chapter 5. Conclusion of the thesis. The research results are evaluated in the light of validity and reliability. Further areas of research and investigation are suggested.

2 THEORETICAL CONTEXT

Next figure illustrates the theoretical context of this thesis.

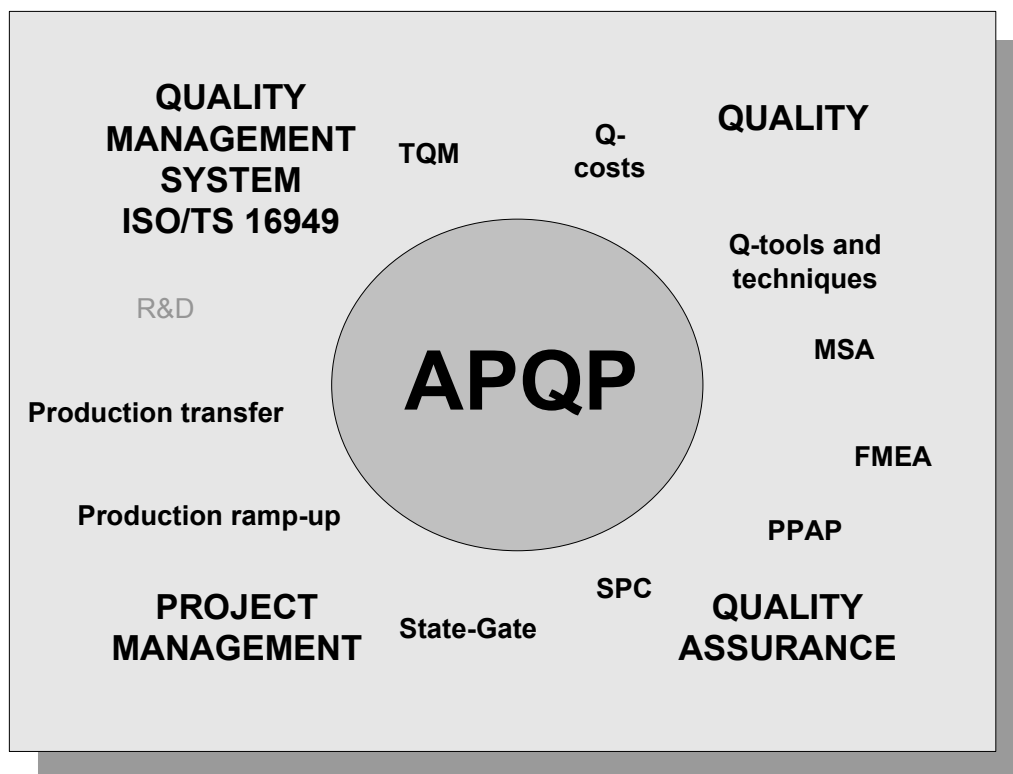


FIGURE 1. *Theoretical context of the thesis.*

ISO/TS 16949 is international automotive industry's own technical specification. Advanced product quality planning (APQP) is one of the specification's structured methods. (Hoyle 2005.) It is used to define and establish the steps necessary to ensure that product satisfies the customer. APQP process assures that product quality objectives and requirements are implemented systematically to the product and processes with adequate resources and documentation. (Chrysler, Ford and General Motors 2008.)

Quality can be defined as a wide business improvement where the target is profitability, customer satisfaction and durable and growing competitiveness. Quality development demands a lot of work in every level of company. The customer assesses the company's true quality. Analytical techniques and quality tools are used to achieve the benefits in the product quality, lead-time and costs. (Lahti 2002.)

Quality assurance is a systematic process, where organization's management processes are defined, planned, implemented and evaluated. (Burke 2001.) According to Kerzner (2003) project management is organization's resource planning, organization, control and monitoring. Stage-gate model is broadly used in the real world to control the projects. The stage-gate is a systematic method in which a new product idea is conducted through various stages to product launch. (Cooper 2001.)

2.1 Quality and advanced product quality planning in automotive industry

When talking about manufacturing company, the customer needs to assure the quality of their suppliers. Product quality can be inspected when product is received or used. Customer can also assure the quality at supplier's facility and make sure that the used methods and equipment are in good condition and products are produced according to requirements. If volumes of received materials are high, it makes no sense to check all received materials or batches. Quality standards are created to solve this problem. According to Lecklin, it is reasonable to establish the objectives and to standardize the processes necessary to deliver results by organization. Control and inspection duties can be given to external party, therefore allowing companies using their resources to development work. (Lecklin 1999.)

ISO/TS 16949 is international automotives industry's own technical specification for quality. Customers demand the certification from practically all suppliers which deliver products to automotive industry. Without the certification it is not easy to get to automotive market. ISO/TS 16949 has been prepared together with key automotive manufacturers. The main idea of the standard is to delegate tasks to supplier. Supplier has to take more responsibility regarding quality, delivery accuracy and cost management. The purpose of ISO/TS is to develop quality systems, which ensure continuous improvement of

the supply chain. The focus is on preventing defects and reducing variation and waste. (Hoyle 2005.)

ISO/TS 16949 helps company for example to improve the supply chain of product and process quality. It provides general and uniform international quality management system requirements and strengthens confidence of the global supplier quality. It also helps to create uniform practices and procedures to the general third-party registration. It offers model for process audits which focuses on customer satisfaction. ISO/TS 16949 seeks to strengthen global standards approval instead of national standards. (Hoyle 2005.)

APQP is a part of the ISO/TS 16949 requirements. APQP is a structured method that must be used in ISO/TS certified automotive industry companies to define and establish the steps necessary to ensure that product satisfies the customer. APQP is originally developed for the major auto manufacturers and their cooperation between the suppliers. The goal of APQP is to facilitate communication with everyone involved to ensure that all required steps are completed on time. APQP:

- directs resources to meet the needs of the customer
- helps to identify the need for changes at an earlier stage
- avoids late changes and
- allows the manufacture of high-quality product on time at the lowest possible cost. (Chrysler et al. 2008.)

During the APQP process it is assured that product quality objectives and requirements are implemented systematically to the product and processes. Adequate resources and the needed documentation are also ensured. Needed verification, rating, monitoring, measuring, inspection and testing operation are carried out with the requisite techniques and proper customer requirements. Also recordings for approval of the product are implemented. Each APQP is unique. (Chrysler et al. 2008.)

In organization's product quality planning each APQP project must be defined by the process owner. After internal or external customer contact, the cross-functional team must be formed. The team includes technical experts and representatives from production, production planning, purchasing, quality, sales and other necessary operations and partners, such as subcontracting. Composition of the group and representatives of different

functions are defined according to the scope of project or APQP case. (Chrysler et al. 2008.)

The scope and content of APQP project are determined, responsible project leader is selected, roles and responsibilities as well as internal and external customers are identified. Customer requirements are also defined. All parties (including subcontractors) are part of the team and its task is to understand customer expectations, to assess the feasibility of the proposed design. Team also needs to notice performance requirements, the manufacturing process, identify costs, schedules, and any plans for the restrictions and / or edge conditions. In addition, team determines the necessary assistance resources and identifies a documented process and procedures. (Chrysler et al. 2008.)

The selected project team leader gathers regular meetings of the cross functional team. If necessary, other partners such as customers and suppliers participate. Team leader is responsible for the APQP process, scheduling and execution. He ensures that the necessary training plan, quality control plans and other required documentation is prepared. Project team leader also ensures that the APQP project in different phases (transition from one stage to another) is controlled and responsible persons of different phases are identified. In addition, he ensures that audits, scheduling and documentation are conducted when necessary. Project leader determines appropriate problem-solving methods to be used. Suitable problem-solving methods are for example cause and effect diagram and FMEA. (Chrysler et al. 2008.)

According to product quality planning timing chart (figure 2.), the required input data is defined in the “Define the Scope” -chapter. Chapters “1 Plan and Define” and “2 Product Design and Development” are performed only in cases the organization has any design responsibility of the product design. Chapter 3 covers the Process Design and Development and Chapter “4 Product and Process validation”. Chapter “5 Feedback Assessment and Corrective Action” is continuous improvement and it covers life cycle of the product. (Chrysler et al. 2008.)

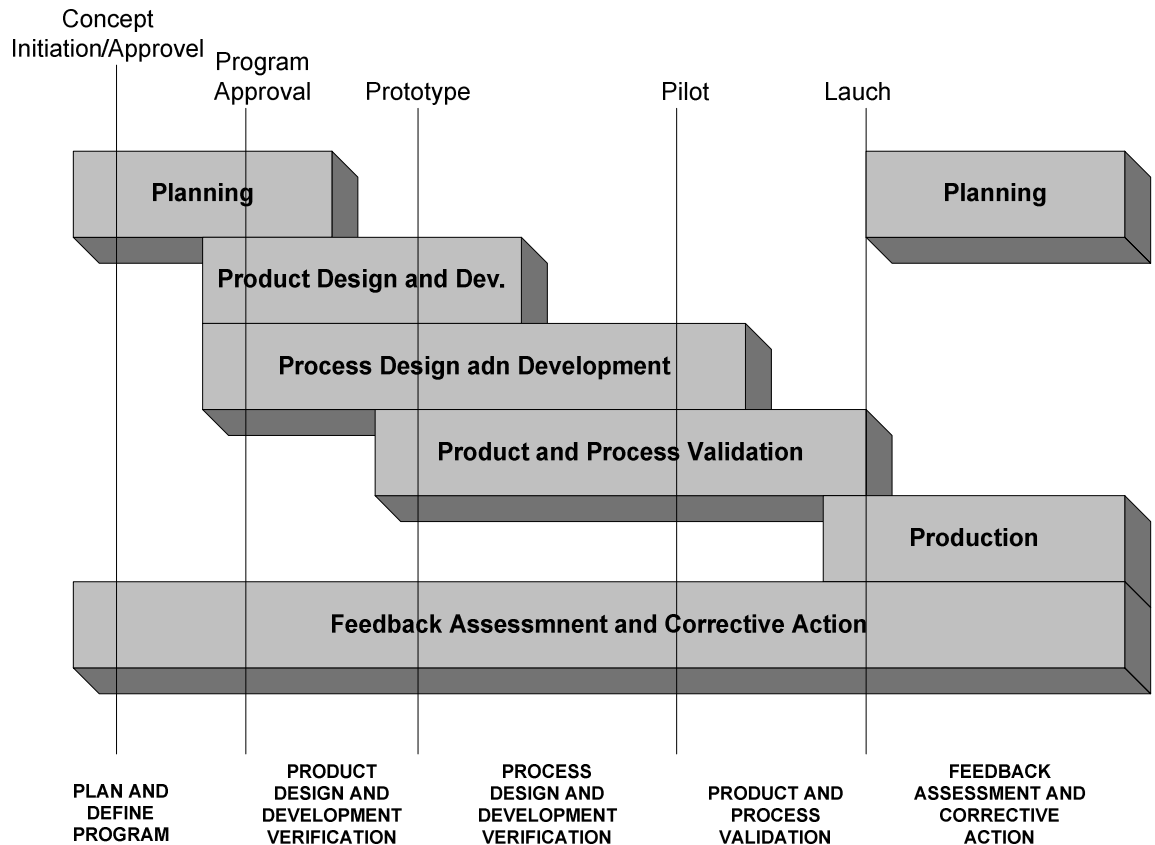


FIGURE 2. A rough APQP timing and chapter chart. (Chrysler et al. 2008.)

Customer needs and expectations are processed, identified and understood in the **plan and define phase**. Design, reliability and quality targets are set. The preliminary bill of materials and the flow chart are prepared. The initial specific product and process characteristics are identified in this phase. The product quality control plans is also defined. (Chrysler et al. 2008.)

All design factors are identified and technical requirements are reviewed in the **product design and development phase**. At this phase, a prototype is also manufactured to ensure that the product reaches the targets. Output from this phase includes the design failure mode and effect analysis (DFMEA), technical drawings and the specifications. (Chrysler et al. 2008.)

Process design and development is the implementation phase for the previous phases of the plans. This phase includes, for example, definition of the package, preparing of the process flow chart, process failure mode and effect analysis (PFMEA), process quality control plan (CP), work instructions, measurement system analysis (MSA), and a preliminary process capability study. At this stage, the production line is planned with mistake proofing methods utilised where possible. The physical construction of a production line is started when it is possible. (Chrysler et al. 2008.)

Product and process validation is a phase to ensure the quality control plan (CP) and the designed process flow are followed. Product and process validation confirms that the final product reaches the customer requirements. Production part approval process (PPAP) is a part of this phase to provide evidence that all requirements are fulfilled. (Chrysler et al. 2008.)

Feedback, assessment and corrective action phase ensures the process stability and customer satisfaction. Best practices can be also identified. This is continuous activity throughout the product life cycle (figure 3.). Feedback is provided for example by internal control results, audits and customer feedback. (Chrysler et al. 2008.)

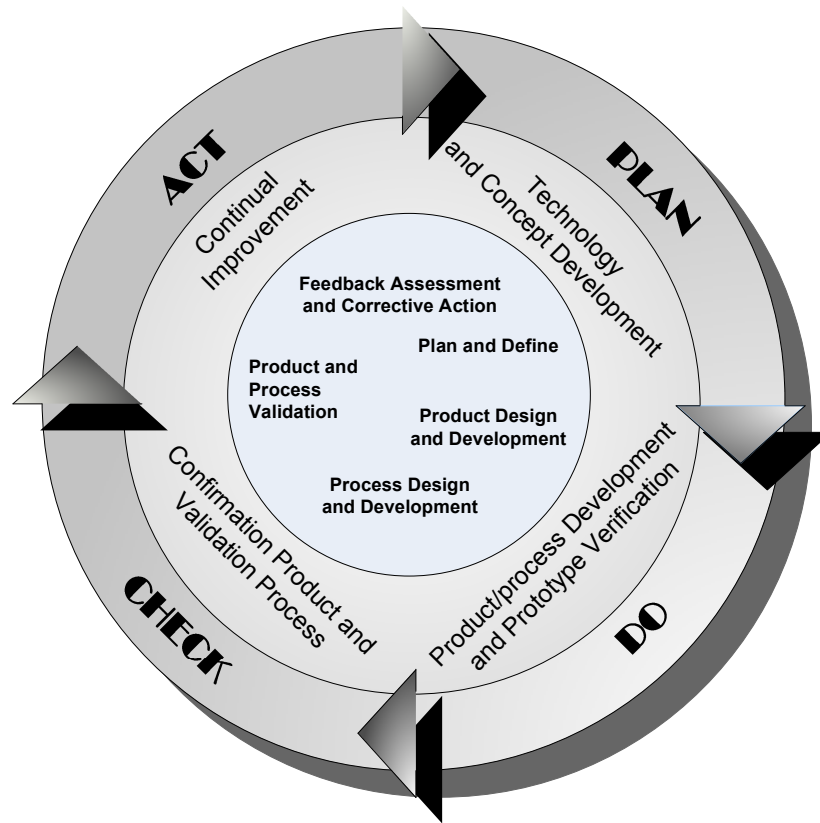


FIGURE 3. APQP cycle takes into account the principles of continuous improvement. (Chrysler et al. 2008.)

2.2 Quality

Quality improvement is possible when personnel are committed to quality work. Every employee has to get the needed information and understand basics of quality and process thinking. Quality can be defined to be wide improvement, where target is profitability, customer satisfaction and maintaining and growing of competitiveness. Because of quality, many advantages can be achieved. Quality is not an absolute value. Quality development demands a lot of work in every level from the workers to the top management. Quality work and development cannot stop to any target. The quality work is continuous improvement. (Lahti 2002.)

Quality is defined as a capability to fulfil customer's expectations and requirements. Quality level can be improved by using prevention. Presupposition of quality improvement is that problems can be identified and solved by organization. Quality tools are used in the problem solving. Processes can be evaluated using different kind of indicators and by setting targets operations can be directed to the direction organization wants. Supposition to this is that employees know about the process thinking and statistical quality control. (Lahti 2002.)

Process thinking is vital demand of successful quality work. Because of process thinking, organization's operations can be understood better and all connected matters and dependences can be seen. It is also easy to evaluate operation's correctness and successfulness. If product quality and manufacturing process improvement is wanted, the actual process data is needed from the present state. After that statistical process control (SPC) can be used. Detailed and reliable measurement results need to be collected from the manufacturing process that SPC can be utilized. (Hoerl 2002.)

Earlier quality has been understood as defect free products. Since then quality has become organization's comprehensive business concept. It covers all operations in company. Defining quality has become more difficult because of the development of quality thinking and growing importance of quality. The quality has no comprehensive definition. Quality concept largely depends on the situation which varies case by case. (Lahti 2002.)

2.2.1 Total Quality Management, TQM

From the manufacturing point of view, an effective means of Total Quality Management can be divided into eight categories:

1. The role of top management and quality policy
2. The role of quality department
3. Training
4. Product/service design
5. Supplier's quality control
6. Process management/operational procedures
7. Quality data and reporting

8. Employees attitude (Jokinen 2004.)

In Total Quality Management company's top management commits to the quality on early stage (Silén 2001.). TQM philosophy focuses on falling costs, mistake proofing, process, perseverance, understanding and learning, cooperation, to the development of top teams, customer satisfaction and business success.

2.2.2 Quality in business

The company has to establish quality system which makes quality work possible. With the help of quality system the requirements and views of the management and customer requirements are systematically reported to organization. The quality system includes operating specific game rules of management system. However, the customer assesses the company's true quality. (Salomäki 2003.)

For a company to succeed in today's market, it is to manage the quality of its three main dimensions: product quality, time and costs both internally and externally. Internal product quality means that the product has been manufactured as it is designed and it is ready to enter the next step of the production. The work is completed at once and the processes are capable. External product quality means that the final product corresponds to customer specification and requirements. Then the product complains can be avoided and that can be company's competitive advantage. If the internal product quality is well managed, the external product quality is easy to achieve. (Lahti 2002; Salomäki 2003.)

Internal time management aims to shorten lead times in all processes. External time management means that the product can be delivered to the customer within the agreed timeframe. When the internal time management is working well, also an external time management can be achieved. Internal cost management in business means the manufacturing cost minimization, rationalization, and ensuring an adequate profit. When the manufactured product can be competitively priced, external costs are managed. (Lahti 2002; Salomäki 2003.)

If problems can be identified and resolved by organization, a good quality level can be achieved. The problem here means the difference between what is happening and what should happen. A chaotic condition in solving problems is not normally possible: problems can be identified and restricted, so that they can be addressed systematically using quality tools. Production problems often arise from the production system weaknesses. For example, the following factors may lead to problems: negligent product design, weaknesses in material incoming inspection, and failure of quality capability measurement, the lack of workers' training, gauge not calibrated, or inadequate production conditions. (Lahti 2002.)

2.2.3 Quality costs

According to Philip B. Crosby, quality costs are the result when things are not done correctly the first time. Crosby thinks that quality is free and quality economy does not exist, but bad quality costs. The only performance index is the cost of quality. In Crosby's quality cost model, acceptable costs of bad quality are shared:

1. with costs of ideal process and
2. non-acceptable process variation and error costs.

(Silén 2001; Loukkola 2001; Silén 1998.)

Company's quality costs must be public information so that quality costs can be measured and development of quality level can be monitored. Quality cost details can be used for a number of the company's assessments, for example presenting problems to business management, identifying development targets and monitoring the development of quality level. (Crosby 1979; Silén 1998.)

The target of the processes is to bring benefits for the company. One of the process factors that lower efficiency of the company is the loss caused by quality problems. Additional costs become for example from reworking products. Quality costs are formed due to bad quality and they consist of the defects and prevention of them.

Different types of defects:

- Internal: rejects, reworks, re-inspections, error analysis, sorting, overproduction and depreciations

- External: complaints, guarantee works, returns of rejected materials and price reductions
- Lost businesses: bad quality costs and bad image

The costs of preventive actions:

- Inspection cost: all kind of inspections
- Training
- Audits and assessments (internal and sub-suppliers)
- Quality management system development

It is impossible to weed out all of the company's quality costs. However each company has optimum situation in which quality costs are minimum. (Lahti 2002; Salomäki 2003.)

2.2.4 Analytical techniques and quality tools

This chapter presents the best known quality tools and analytical techniques. These tools and techniques are also applied in APQP.

Benchmarking. Informal benchmarking works in practice by visiting other companies. From visitations company can get ideas how it can develop its own organization. Formal benchmarking is development method, which is element of continuous improvement. Formal benchmarking is divided into three main types:

1. Internal benchmarking
2. Competitive benchmarking and
3. Functional/generic benchmarking. (Jokinen 2004.)

Cause and effect diagram. The cause-and-effect diagram is also called “fishbone diagram” or “Ishikawa diagram”. The effect is considered to be the head, and the sub-causes and potential causes of the problem or quality condition/characteristic to be the bone structure of the fish. It is an analytical tool to find the relationship between effect and all influenced causes. Cause-and-effect diagrams are typically used by quality circles, quality improvement teams, problem-solving teams, etc., as part of brainstorming to find out ideas and opinions about the possible major causes of the problem. Results are then used to offer recommendations and to resolve or counteract the problem. Primary

groupings of diagram are materials, equipment, people, environment, method and system, and customer requirements (figure 4). (Chrysler et al. 2008.)

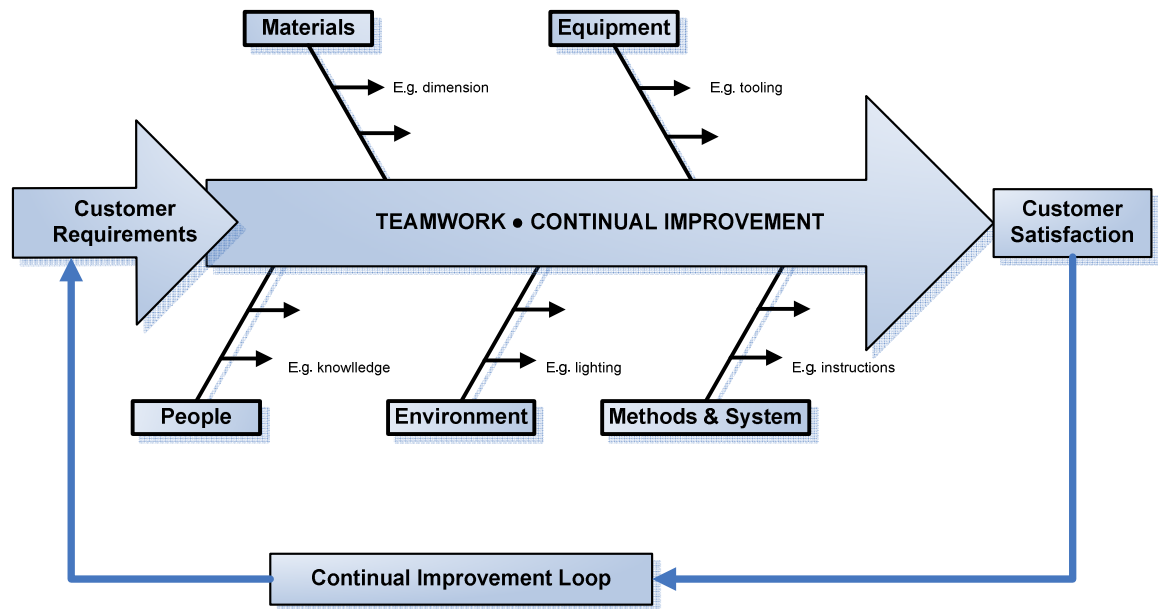


FIGURE 4. Cause and effect diagram. (Chrysler et al. 2008.)

Mistake proofing is a technique to identify errors after they occur. Mistake proofing should be used as a technique to control repeated tasks or actions and prevent non-conformances from being passed on to the sequential operation and eventually to the customer. Error-proofing is used to identify potential process errors and design them out of the product or process to eliminate the possibility that the error could produce a non-conformance. The name of one mistake proofing method is Poka-Yoke. (Chrysler et al. 2008.)

Process flow charting is a visual approach to describing and developing related or subsequent work activities. It provides analysis for planning, development activities, and manufacturing process and a means of communication. Process flow chart is used to identify improvements and to locate critical or significant product and process

characteristics that will be addressed in control plans to be developed later. (Chrysler et al. 2008.)

Measurement system analysis (MSA) is specified for monitoring and measuring devices and methods. It is used to check the identified characteristics against the specification. Measurement data, or some statistic calculated from them, are compared with statistical control limits of the process. If the comparison indicates that the process is out of statistical control, then an adjustment of some kind is made. Otherwise, the process is allowed to run without adjustment. (DaimlerChrysler, Ford and General Motors 2002.)

Failure Mode and Effect Analysis (FMEA) is method, which examines the potential defects in the product/design (DFMEA), process (PFMEA) or organization/system (SFMEA). It can be used to assess the potential risks and to prioritize the risk level. With a help of FMEA the corrective actions can be focused to right topics and areas. FMEA approaches the risk analysis from view points of severity, occurrence and detection probability. Each of these factors are scored and their outcome is RPN = Risk Priority Number. (Jokinen 2004)

Production Part Approval Process (PPAP) defines generic requirements for production part approval, including bulk materials and production processes. These main components of PPAP are:

- design records,
- authorized engineering change documents,
- customer engineering approval,
- FMEA,
- process flow diagrams,
- CP,
- MSA,
- dimensional results,
- records of material,
- initial process studies,
- qualified laboratory documentation,
- appearance approval report,
- sample production parts,

- master sample,
- checking aids,
- customer-specific requirements and
- part-submission warrant (PSW)

The purpose of PPAP is to determine if all customer engineering design record and specification requirements are properly understood by the organization. It also determines that the manufacturing process has the potential to produce product consistently meeting the requirements during actual production run at the quoted production rate. PPAP is applied to organizations supplying production parts, production materials, service parts, or bulk materials to automotive industry. (DaimlerChrysler, Ford and General Motors 2006.)

Statistical Process Control (SPC). Quality development is based on process thinking and process management. When statistical process control (SPC) and SPC development are considered to be applied the first requirement is process thinking. Process is series of events or operations carried out. Therein inputs are changed to outputs. According to process thinking all target-oriented doing happens in the processes. Because processes operate interactively, together they create bigger entity, system. (Hoerl 2002.)

Quality development aims at improving the systems. The system consists of sub-processes. In practice the development work is focused also to small details. Work process consists of part factors which affect to the outputs. The part factors are environment, man, message (data), machine, method and material. If some of these factors change, it can reflect to quality of the process output. Each of these factors causes natural or normal variability. These variation components can increase or decrease each other's affect. The varying combination of these part factors causes normal total variation of process. (Hoerl 2002.)

Measurements should not be taken as part factors of work processes because the measuring doesn't affect to the process output. Measuring gives data. According to the data processes are adjusted to desired direction. The starting point of process development is knowledge of the process. Next step is to define and describe the process. One illustrating and graphical method for process description is flow chart technique. After defining and

describing of the process the capability of the process can be measured. This is basis for process control and process development. (Hoerl 2002.)

Control plan (CP) is used and maintained throughout the product life cycle. Early in the product life cycle its primary purpose is to communicate and document the initial plan for process control. Later, it guides manufacturing in how to control the process and ensure product quality. Eventually, the CP remains as a living document, reflecting the current methods of control, and measurement system used. The CP is updated as measurement systems and control methods are improved and evaluated. (Chrysler et al. 2008.)

2.3 Quality assurance

Quality assurance is a planned and systematic prevention which ensures that the quality criterias are met within the project or process. Quality assurance objective is that the desired quality level is achieved. For this reason, it is important to follow monitoring, evaluating and preventions according to product quality planning. (Artto 2006.)

Burke (2001) defines that quality assurance is systematic process, where organization's management processes are defined, planned, implemented and evaluated. Because of these reasons appropriate reliability is secured and the product is manufactured consistently by demanded requirements. (Figure 5.)



FIGURE 5. *Quality assurance umbrella.* (Burke 2001.)

According to Kerzner (2003), quality assurance is common term to the general operations and administrative processes which try to assure that products and services achieve the required quality level. Quality assurance is the area where project manager has the biggest influence to project quality. Good quality assurance system identifies targets and standards, is multi-functional and preventive-oriented. The system plans data collection and its use from continuous improvement point of view. Good quality assurance system also plans capability measurement implementation and maintenance including quality inspections. (Kerzner 2003.)

2.4 Project management

Kerzner (2003) defines that project management is organization's resource planning, project organization, project control and project monitoring in the relatively short-term period that is created by a specific goal and objectives. Time, costs and capability are constraints of the project. Additionally good customer relations are considered as a constraining factor, if the project is made outside the client. (Kerzner 2003.)

Project management means unifying the actions in a project and its management areas. According to the actions it is possible to implement the project as a whole accordance with the objectives. Its task is to guide the implementation of project management, interdependence of tasks, and the regions of the different information management. Definition and refinement of the objectives during the project are also related to realization of project management. (Artto 2006.)

The total project planning initially focuses on managing the whole project planning and preparation of feasibility. In this case, suitable tools can be a project description, project presentation and project plan. In a project implementation and control stage total project planning consists of balancing different parts of project and management work. In this case, suitable tools can be used in the project plan in addition to reporting and change management methods. The purpose of total project management is to ensure that the right things are made during the project. In practice, total project management belongs primarily to project manager's job description. (Artto 2006.)

With good project management it is possible to achieve a wide range of benefits. It helps to identify the responsibilities of operations to ensure that all tasks have been taken into account regardless of turnover of individuals. In addition, it is possible to minimize the need for continuous reporting and to identify the time constraints for the scheduling, and to identify a methodology for cost analysis. Successful project management allows also the measurement of actual success in relation to the planned and identify problems at an early stage, when performing corrective actions is possible. In addition, it provides a better assessment of the capability of future plans and the knowledge of when the goals can not be achieved or when it will be successful. (Kerzner 2003.)

In the first instance various obstacles must be solved that the chances of project management could be utilized. These obstacles include for example the complexity of the project, the client specific requirements, purpose of the changes and restructuring of the organization. The project risks, changes in technology or advance planning and costs may be an obstacle to the success of the project. (Kerzner 2003.)

Extensive project management includes a number of complex factors, functions and their relations with the planning, organization and control. These factors and functions and the management of their relationships is practically possible at the same time. Success is likely by focusing on key elements. (Clarke 1999.)

The stage-gate model (figure 6.) is broadly used in the real world to have control over the projects. The model is used to manage, control and make the development process more effective, which is generally a new product development.

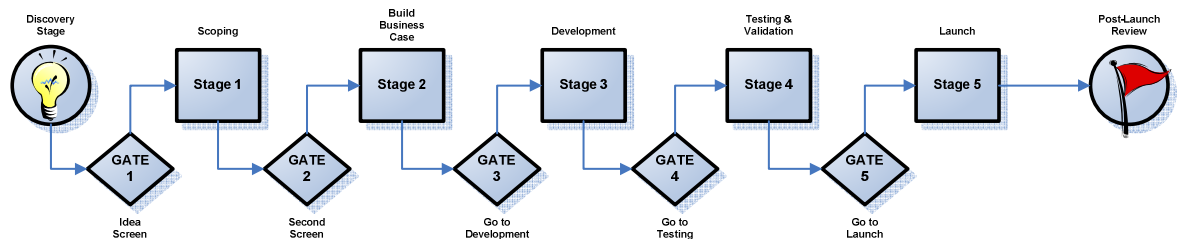


FIGURE 6. Cooper's Stage-Gate model (Cooper 2001.)

The stage-gate is a systematic method in which product development project is led through the various stages from the product idea up to market. Stage-gate has usually from four to six phases which each consists of a set of defined, horizontal and parallel operations. It is possible to proceed to the next stage through a gate. The gates are controlled processes, quality assurance points and decision points to decide whether to continue or reject to previous stage. Of these stages and gates comes the name of the model: Stage-Gate. (Cooper 2001.)

3 ANALYSIS OF THE PRESENT STATE

Diagnosing and planning of APQP improvements are presented in this chapter.

3.1 Background

The problems in PKC's quality planning can be seen from the first customer contact to production launch. For example, the needed product quality requirements with needed documentation are not implemented and prepared during the production ramp-up and production transfer projects in a sufficient level. Problems have also appeared in communication inside PKC.

According to the thesis (Quality Assurance in Production Technology Transfer Projects) made earlier, the company has good procedures and practises, but they are not used by employees. It is recognized that it will be necessary to investigate why the current tools are not utilized enough. One of the further questions of the thesis was to do research on the organization's working methods and functionality of the quality system. (Lievonen 2008.) The thesis on APQP considers the organization's operations comprehensively from the voice of customer to production launch by investigating the current tools, procedures and practises. This APQP is part of automotive industry specific ISO/TS 16949 quality system requirement.

Research questions in this thesis were defined as follows: how APQP process can be made more effective, what deviations the current APQP process has, and what kind of procedure should the company have for APQP. Methods of the study were selected to be workshop of experts, and the current APQP procedure. (Figure 7.)

Next figure illustrates the research process of this thesis.

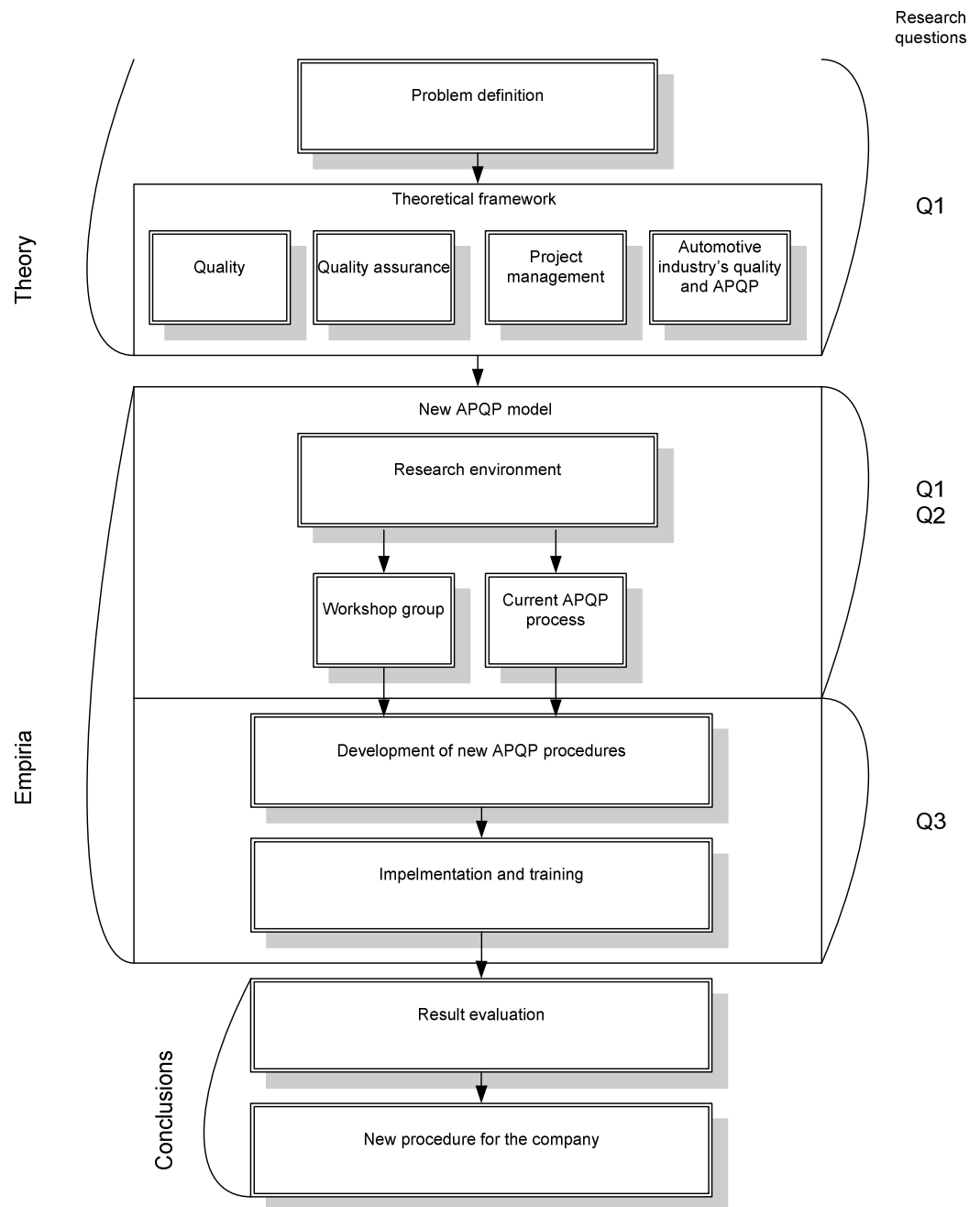


FIGURE 7. Research process.

It was defined that the current status of APQP should be examined and specified on each site of the company, and a work shop group to evaluate and to audit the current APQP should be founded. Experts from different operations were agreed to convene to solve the problems. The team would consist of the company's key persons from sales, product development, production and quality.

3.2 Current practices

Request for quotation (RFQ) process, Research and development (R&D) projects, Start of production (SOP) and Production Part Approval Process (PPAP) create a complete APQP at PKC. RFQ, R&D, SOP and PPAP processes include the documented procedures which cover routines in the different operations. These operations are sales, product development, pre-production, production and quality.

PKC project management model has been built according to the principles of Stage-Gate method (figure 8). It consists of five stages and four gates. All the defined requirements must be fulfilled and a decision must be made before proceeding to the next stage. The decisions are made together with the project client, project group and project leader. This general project management model can be applied in different types of projects. (Kujala 2006.) The APQP is also suitable for the current project management model.

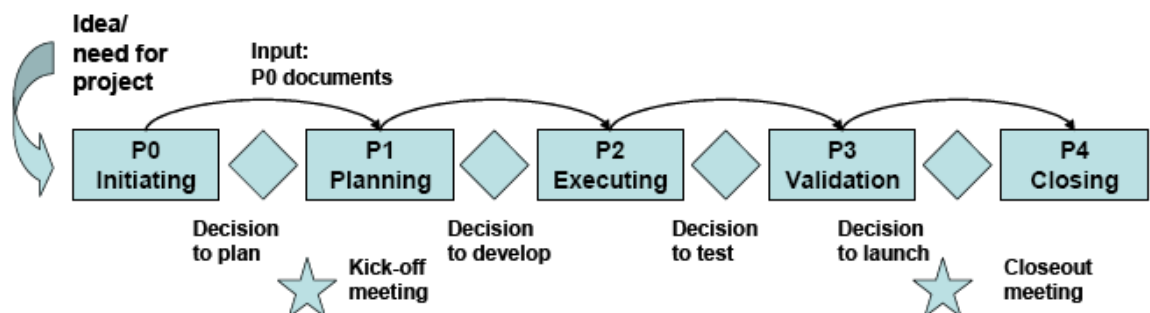


FIGURE 8. PKC's project management model.

PKC's projects produce different kinds of documents to fulfil the need of reporting and documentation. The required documents are standardized. Templates and instructions for the documents that are required in the stage-gate model can be found in a common database. (Kujala 2006.)

At PKC, cross functional team work is based on the work of the relevant business account. Each account has its own defined team which consists of representatives from different operations. Most of the team members are working in the customer interface.

3.3 Analysis of the problems

It was observed by workshop group that elements of APQP are implemented in PKC but the elements are not transparently connected to the daily operational procedures. The concept of APQP and its terms are not known by the organisation to the extent they should be for an effective APQP execution. Also, responsibilities have not been defined clearly enough. Company's present project management model is built according to the stage gate method, on which APQP is also based. During the APQP process, the stage gate model has not been systematically used. Automotive industry's APQP requirements are not taken into account in the sufficient level in the company's cross functional team and current project management model.

3.4 Aspired level of performance

The aspired level of performance analysis is based on PKC quality management and the researcher's own experience. In order to reach the aspired level of performance, the meaning of APQP and its exact requirements at PKC must be defined. It is also important to know the scope of APQP in the different types of projects or processes. APQP process owners must be identified and defined. The identified process improvements must also be implemented. Figure 9 illustrates the timing plan for achieving the aspired level.

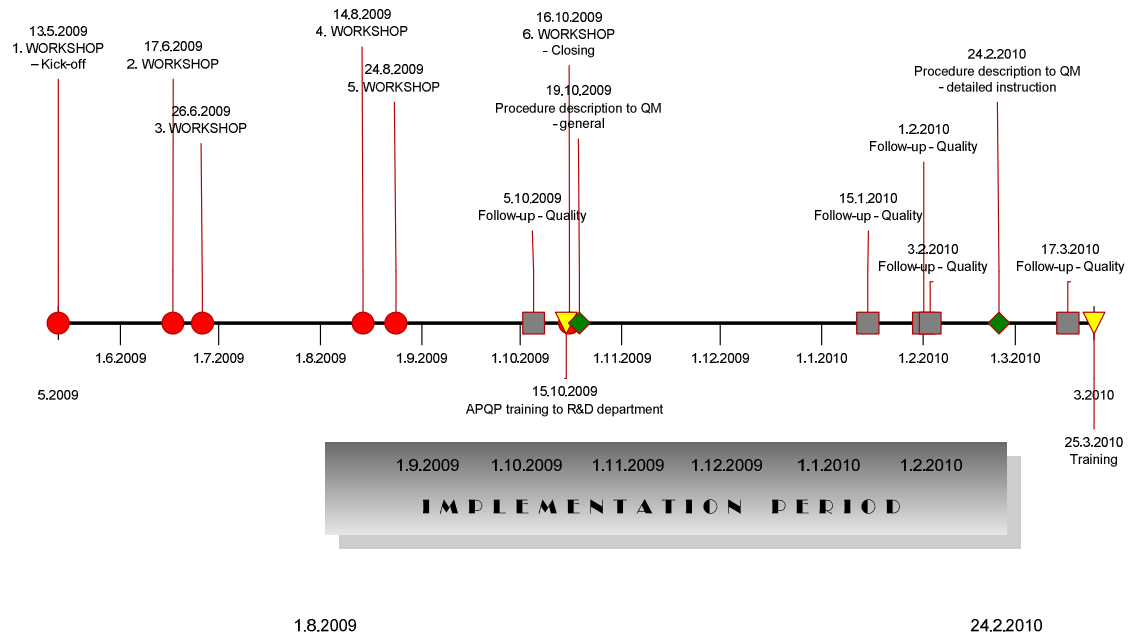


FIGURE 9. Conduction the study: timing chart plan.

The thesis focuses on the company's continuous development model's phases between customer contact and production launch. The company focuses on constant development of its quality, in order to be able to serve customers in the future with the right solution at the right time. APQP process was decided to be improved by workshop group.

4 SOLUTIONS FOR THE RESEARCH QUESTIONS

Research questions in this thesis are how APQP process can be made more effective, what deviations the current APQP process has, and what kind of procedure the company should have for APQP. Methods of the study are workshop of experts and current APQP procedure. The implementation, evaluation, and learning of the new APQP improvements are presented in this chapter.

4.1 Development of new APQP model

The first task in the research process of creating the new APQP procedure was to survey the research environment to find out the current procedures in the different sites of the company. This was carried out by studying the company's public information and employing the researcher's own experience (6 years in the company). The APQP process descriptions of all PKC's sites were sent to the researcher for reviewing.

The work shop group was founded to evaluate and audit the current status of APQP at PKC. The experts from different operations and from two different sites were convened to solve the problems. The group consisted of the company's key persons from sales, product development, production and quality. The group members work in different processes and they have the needed knowledge concerning current operative environment and procedures. The kick-off meeting took place in May 2009. The work shop team convened six times (figure 10).

According to APQP manual, APQP topics and requirements were examined by the workshop group. The sub processes were identified; what they really mean in PKC. According to the manual, sub processes were evaluated and compared to actual operation; what they really should mean and are they in the sufficient level at PKC.

Scheduled corrective actions with responsible persons were defined for the sub processes that were not in the sufficient level or needed to be improved. The biggest changes and

actions were focused on R&D operations. Procedure improvements and definitions were also needed in other operations.

APQP starts from a customer contact. The first contact which is based on the manufacturing product and/or process is a quote. PKC quotes have been divided into 13 different types (presented in four groups in this thesis). Production transfer also starts APQP. The performed APQP sub processes were defined to all possible quote types and to production transfer. Tables 1 and 2 are the outputs of the workshop group.

Quotation groups

A. The quotations contain typically very limited number of part numbers and concerns known, supplemental and/or products already in serial production e.g. technical change
B. The quotations for component sales, re-quotes, prototypes or initial sample order
C. The quotations are typically quotes made for potential new customers, quotes for complete new product families and/or new product model generations or quotes that require product design (R&D) work being performed.
D. The quotations for spare parts or labour (rework)

TABLE 1. PKC's quotation groups. The scope of APQP depends on quotation type.

	Quotation group				Production transfer
	A	B	C	D	
APQP					
0 Define the scope					
Design review	X	X	X	X	
Preliminary BOM	X	X	X	X	
Preliminary process flow chart	X	X	X	X	X
New equipment, tooling and facilities Requirements	X	X	X	X	X
Special Product and Process Characteristics	X	X	X	X	X
Gages/Testing Equipment Requirements	X	X	X	X	X
Management support			X		
Prototype Build - Control Plan		X	X		
Drawing and Specification Changes	X		X	X	
1 Plan and define program					
1.1 Voice of the customer			X		
1.2 Business plan and marketing strategy			X		
1.3 Product/Process benchmark data			X		
1.4 Product/Process assumptions			X		
1.5 Product reliability studies			X		
1.6 Customer inputs			X		
1.7 Design Goals			X		
1.8 Reliability and Quality Goals			X		
1.9 Preliminary Bill of Material			X		
1.10 Preliminary Process Flow Chart			X		
1.11 Preliminary Identification of Special Product and Process Characteristics			X		
1.12 Product Assurance Plan			X		
1.13 Management Support			X		
2 Product design and development					
2.1 Design Failure Mode and Effects Analysis (DFMEA)			X		
2.2 Design for Manufacturability and Assembly			X		
2.3 Design Verification			X		
2.4 Design Reviews			X		
2.5 Prototype Build - Control Plan			X		
2.6 Engineering Drawings (Including Math Data)			X		
2.7 Engineering Specifications			X		
2.8 Material Specifications			X		
2.9 Drawing and Specification Changes			X		
2.10 New Equipment, Tooling and Facilities Requirements			X		
2.11 Special Product and Process Characteristics			X		
2.12 Gages/Testing Equipment Requirements			X		
2.13 Team Feasibility Commitment and Management Support			X		X
3 Process Design and development					
3.1 Packaging Standards and specifications			X		X
3.2 Product/Process Quality System Review			X		X
3.3 Process Flow Chart			X		X
3.4 Floor Plan Layout			X		X
3.5 Characteristics Matrix			X		X
3.6 Process Failure Mode and Effects Analysis (PFMEA)			X		X
3.7 Pre-Launch Control Plan			X		X
3.8 Process Instructions	X		X	X	X
3.9 Measurement System Analysis Plan			X		X
3.10 Preliminary Process Capability Study Plan			X		X
3.11 Management Support			X		X
4 Product and Process Validation					
4.1 Significant Production Run			X		X
4.2 Measurement System Analysis			X		X
4.3 Preliminary Process Capability Study			X		X
4.4 Production Part Approval	X	X	X	X	X
4.5 Production Validation Testing	X	X	X	X	X
4.6 Packaging Evaluation	X	X	X	X	X
4.7 Production Control Plan			X		X
4.8 Quality Planning Sign-Off and Management Support			X		X
5 Feedback, assessment and corrective action					
5.1 Reduced Variation					
5.2 Improved Customer Satisfaction					
5.3 Improved Delivery and Service					
5.4 Effective Use of Lessons Learned/Best Practices					

TABLE 2. Implemented APQP sub-processes according to quotation groups. Besides the scope is defined for production transfer.

Next, APQP process owners were defined to every topic. The defined APQP process owners were sales, R&D, business development, pre-production, production and quality. APQP topics were focused on processes. These processes were identified to be RFQ, R&D, SOP (ramp-up, production transfer) and PPAP. A separated matrix was created by workshop group (table 3).

APQP	Processes				Outputs/document	Process owners
	RFQ	R&D	SOP	PPAP		
0 Define the scope						
Design review	x				RTS (internal or external)	Pre-production
Preliminary BOM	x				BOM to ERP	Pre-production
Preliminary process flow chart	x				BOL to ERP	Pre-production
New equipment, tooling and facilities Requirements	x				Tooling plan	Pre-production
Special Product and Process Characteristics	x				Offer review	Pre-production
Gages/Testing Equipment Requirements	x				Tooling plan	Pre-production
Management support	x				RFQ Management Review form	Sales
Prototype Build - Control Plan			x		Prototype control plan	Production
Drawing and Specification Changes			x		Engineering Change Order document	Pre-production
1 Plan and define program						
1.1 Voice of the customer		x				Sales
1.2 Business plan and marketing strategy		x				Business development
1.3 Product/Process benchmark data		x				R&D
1.4 Product/Process assumptions		x				R&D
1.5 Product reliability studies		x				R&D
1.6 Customer inputs		x				R&D
1.7 Design Goals		x				R&D
1.8 Reliability and Quality Goals		x				R&D
1.9 Preliminary Bill of Material		x				R&D
1.10 Preliminary Process Flow Chart		x				R&D
1.11 Preliminary Identification of Special Product and Process Characteristics		x				R&D
1.12 Product Assurance Plan		x				R&D
1.13 Management Support		x				Sales
2 Product design and development						
2.1 Design Failure Mode and Effects Analysis (DFMEA)		x				R&D
2.2 Design for Manufacturability and Assembly		x				R&D
2.3 Design Verification		x				R&D
2.4 Design Reviews		x				R&D
2.5 Prototype Build - Control Plan		x				R&D
2.6 Engineering Drawings (Including Math Data)		x				R&D
2.7 Engineering Specifications		x				R&D
2.8 Material Specifications		x				R&D
2.9 Drawing and Specification Changes		x				R&D
2.10 New Equipment, Tooling and Facilities Requirements		x				R&D
2.11 Special Product and Process Characteristics		x				R&D
2.12 Gages/Testing Equipment Requirements		x				R&D
2.13 Team Feasibility Commitment and Management Support		x	x		Ramp-up or production transfer plan, feasibility study	Sales
3 Process Design and development						
3.1 Packaging Standards and specifications	x				Packing specification to ERP	Pre-production
3.2 Product/Process Quality System Review			x		Process audit sheet and action plan	Quality
3.3 Process Flow Chart			x	x	Process flow chart	Pre-production
3.4 Floor Plan Layout			x		Production layout, department layout, work place layout	Production
3.5 Characteristics Matrix			x	x	(part of) PFMEA	Quality
3.6 Process Failure Mode and Effects Analysis (PFMEA)			x	x	PFMEA	Production
3.7 Pre-Launch Control Plan			x	x	Control Plan	Production
3.8 Process Instructions		x	x	x	Work instructions	Pre-production
3.9 Measurement System Analysis Plan				x	MSA plan	Quality
3.10 Preliminary Process Capability Study Plan			x		Manufacture of initial sample - Failure analysis audit	Production
3.11 Management Support			x		Detailed Ramp-up or production transfer plan, capacity plan with management sign	Production
4 Product and Process Validation						
4.1 Significant Production Run			x		PTR results	Production
4.2 Measurement System Analysis				x	MSA	Quality
4.3 Preliminary Process Capability Study			x		Manufacture of initial sample - Failure analysis audit	Production
4.4 Production Part Approval				x	PPAP documentation	Quality
4.5 Production Validation Testing			x	x	PPAP documentation	Production
4.6 Packaging Evaluation			x	x	Packing instruction	Production
4.7 Production Control Plan			x	x	Control Plan	Production
4.8 Quality Planning Sign-Off and Management Support			x	x	Process audit sheet and action plan with management sign	Production
5 Feedback, assessment and corrective action						
5.1 Reduced Variation					Corrected actions	Production
5.2 Improved Customer Satisfaction					Corrected actions	Sales
5.3 Improved Delivery and Service					Corrected actions	Sales
5.4 Effective Use of Lessons Learned/Best Practices					Quality planning reports and documents	Sales

executed only in R&D projects
continuous work

TABLE 3. APQP sub-processes, grouping of main processes, outputs of sub-processes and process owners.

New APQP procedure was specified. It was decided that APQP should be separated into two different procedures:

- 1) Product is designed by customer and PKC is a manufacturer.
- 2) Product is designed by PKC.

Because R&D procedures needed so many corrections and changes, they were decided to be left outside of APQP improving. This topic will be one of the further development needs.

The general APQP procedure description was improved and updated to the quality manual according to ISO/TS requirements. APQP definition and purpose were described and the progress of APQP project and process was also documented. It was defined that the selected project leader or business account manager would be responsible for overseeing of the APQP implementation. The APQP chapters were defined and documented also to the quality manual according to APQP chart (figure 2).

It was specified that sub-processes also needed detailed process descriptions and defined outputs (table 3). After this the procedure would be consistent. Also the contents and purpose of APQP sub processes would be known by the organization. The following sub processes were documented into the quality manual according to the APQP manual:

0 Define the scope

Design review

Preliminary BOM

Preliminary process flow chart

New equipment, tooling and facilities Requirements

Special Product and Process Characteristics

Gages/Testing Equipment Requirements

Management support

Prototype Build - Control Plan

Drawing and Specification Changes

2.13 Team Feasibility Commitment and Management Support

3 Process Design and development

3.1 Packaging Standards and specifications

3.2 Product/Process Quality System Review

3.3 Process Flow Chart

- 3.4 Floor Plan Layout
- 3.5 Characteristics Matrix
- 3.6 Process Failure Mode and Effects Analysis (PFMEA)
- 3.7 Pre-Launch Control Plan
- 3.8 Process Instructions
- 3.9 Measurement System Analysis Plan
- 3.10 Preliminary Process Capability Study Plan
- 3.11 Management Support
- 4 Product and Process Validation
 - 4.1 Significant Production Run
 - 4.2 Measurement System Analysis
 - 4.3 Preliminary Process Capability Study
 - 4.4 Production Part Approval
 - 4.5 Production Validation Testing
 - 4.6 Packaging Evaluation
 - 4.7 Production Control Plan
 - 4.8 Quality Planning Sign-Off and Management Support
- 5 Feedback, assessment and corrective action
 - 5.1 Reduced Variation
 - 5.2 Improved Customer Satisfaction
 - 5.3 Improved Delivery and Service
 - 5.4 Effective Use of Lessons Learned/Best Practices.

APQP manual is reference for the prepared process descriptions above.

The most significant operational changes were creation of new RTS procedure, updating of offer review, implementation of prototype failure analysis audit, improved ramp-up and production transfer plan and process audit sheet for APQP. These procedural improvements are presented in the next chapters.

RTS procedure. Old product review procedure had a weakness. It was removed and it was replaced with a new Review of Technical Specification (RTS) procedure. New RTS procedure is based on existing model used in automotive industry. It was planned and implemented for the purpose of making wider review of manufacturability and product structure. The product review procedure was a tool only for pre-production contrary to

RTS which is a tool and a check list for R&D, pre-production and production. The RTS procedure covers product structure, manufacturability and process planning elements. The RTS checklist will be for internal and external use. In RTS, critical requirements and deviations are identified as early as possible. (Appendix 1.)

Offer review. A logical place to identify Special product & process characteristics is during the RFQ phase. They were defined to be identified during the offer review. Offer review procedure and the offer review form were updated. (Appendix 2.)

Prototype failure analysis audit. PKC did not previously have a procedure or internal requirements for prototype quality planning without a separate customer requirement, which is why prototype control was not prepared, and process planning was not systematic enough. A new procedure was planned and implemented. Procedure was named “Manufacture of prototype I and II – Failure analysis audit”. The procedure has two types: type I for products which do not end up in actual production and type II for products which go to production. Potential failure risks are identified and listed in both types, but Failure analysis is prepared only for type II. (Appendix 3.)

Ramp-up and production transfer plan. All APQP requirements were not listed in the ramp-up and production transfer plan form used previously. APQP requirements were added on the form. The body of plan was also changed: formal management reviews and quality planning sign-off are monitored by using the plan. The plan is a living document and tool during the ramp-up and it is closed at the end of the ramp-up by sign-off. (Appendix 4.)

Process audit sheet. The current process audit check list was evaluated and it needed a different approach. A new checklist was prepared to verify that product, manufacturing process with process flow and layout are designed and implemented properly. (Appendix 5.) The new checklist was attached to the process audit form. Procedure was documented into the quality manual.

APQP training. Because APQP procedure and terminology were not well-known within the organization, a training was planned. The first training was arranged for 15 participants in Estonia. The participants came from different functions such as sales, logistics,

purchasing, production planning, pre-production, production and quality. These people are working in cross functional teams in the RFQ, R&D and SOP projects. Similar training will also be arranged in other PKC sites in the near future.

The contents of APQP training was roughly as follows:

1. General presentation of APQP. Definition of APQP was presented; the timing chart (figure 2) and the meaning of APQP were thoroughly illustrated.
2. Scope of PKC's APQP. The defining of APQP scope according to quote type was presented. The scope and requirements were presented according to the selected quote type. All steps that need to be done in practice to achieve APQP's requirements were studied. Also new and improved procedures were introduced.
3. APQP processes at PKC. Processes, outputs and process owners were presented.
4. Conduction of PKC's APQP – project management. Projects of different size and their required APQP elements, responsibilities of project leader, and the meaning of cross functional teams were presented.
5. Group exercise. The participants were divided into three groups: “supply chain”, “product and process design”, and “quality” groups. The task was to identify APQP elements from daily routines and to present them to other groups.
6. Summary. The training was concluded with a short summary of new improved APQP model. The benefits and “risk points” were gone through.

4.2 Conduction the study

Conclusion meeting was held on October 2009. After that APQP's details were specified in smaller groups. The final specifications were made in the middle of February 2010. Implementation of the improved APQP model was decided by workshop group. The updated procedures were built in such a way that other processes support the complete APQP approach. The organization was trained for general awareness of APQP and new updated procedures were also presented. The main topics of APQP improvements are illustrated in the figure 10.

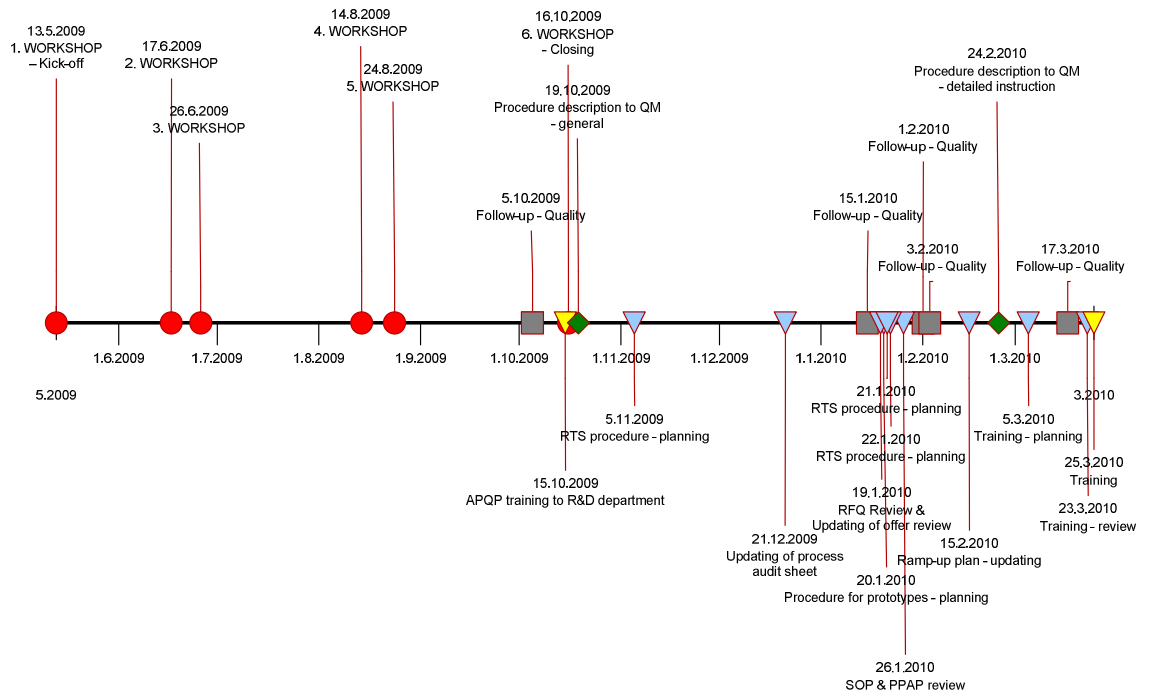


FIGURE 10. Conduction of the study: timing chart

4.3 Evaluation and learning of new APQP model

It can be supposed that new product and process implementation operations will improve because of the thoroughly documented procedures with clear instructions. Everybody knows their own responsibilities, because they are now clearly defined and implemented. Also, awareness of the APQP terminology and procedure-related requirements has been improved thanks to the workshops and training. According to the feedback regarding the training, the participants were satisfied: they got a clear picture of APQP.

The importance of cross-functional team was also emphasized during the improvement of APQP. The procedures are aimed to be kept as light as possible and appropriate, so that the operations with requirements can be performed effectively. A separate APQP process was avoided because it would make the procedure too heavy and there could be a risk of ignoring the required quality requirements. Furthermore, the link to daily routines could have been lost. This is why the requirements were linked to current procedures.

It can also be assumed that product quality, delivery precision and cost level will be improved. Product quality objectives and requirements are now being led more systematically and documented to the product and processes with adequate resources. Also necessary verification, rating, monitoring, measuring, inspection and testing operations, as well as recordings for approval of the product can be implemented better according to requisite techniques and proper customer requirements.

Problems can arise if the instructions are not followed. Today, project management is also challenging because cross-functional team members are sitting in several sites. The project leader is responsible for ensuring that the customer specific requirements are taken into consideration in the APQP projects. The project control is a key task of the project leader in order to achieve required results.

A method for evaluating the new procedures for APQP is the expert evaluation in groups. In this method, new suggested procedures are viewed and discussed with company's process owners and quality management. Suggested procedures are sent to quality management for reviewing and commenting before an evaluation meeting. By reviewing the suggested procedures it is ensured that new selected procedures fit the set requirements and needs. It can also be used in strategy process. The selected procedures were implemented into the company. New APQP model will be assessed during an internal audit in April 2010. (Figure 10.)

5 CONCLUSION

5.1 Answering the research problems

The research problems in this thesis focused on finding a structured procedure for APQP. The investigated issue is a vital component in the company's continuous improvement. Three different research questions were set to this thesis.

Q1: How can APQP process be made more effective at PKC Wiring Systems?

First question concerned the factors which affect the improvement efficiency of APQP. The solution to this research problem was found from the literature and partially from empirical study. Each topic was thoroughly investigated and issues were reflected to the company's current procedures. Also the new means for APQP were investigated. Especially systematic progression of the project, selecting of the suitable quality tools and project management are affecting the improvement of APQP.

Q2: What are the factors when something goes wrong and/or is successful? Why?

The second research question (what goes wrong, what is successful) was related to the current situation of APQP. This was investigated by the workshop group. The workshop group gave information on the current situation but also about the future needs. Based on the present state information it was possible to define the processes and develop new procedures. Currently, the company is lacking controlled procedures regarding the identification of customer and quality system needs. Documented process descriptions and defined process owners were also missing. Scope of the APQP was not clear in different-size projects. These lacks caused uncertainty about the APQP within the company. Generally bases of APQP were found in organization and because of this it was easy to start developing APQP processes. Especially the current PPAP processes were one of the identified success factors.

The workshop group was unanimous on how to improve the company's functions concerning APQP. Main issues concerning the improvement of processes concerned the improvement of APQP procedure and APQP documentation. Based on the information received during this research, some improvements in the company must be made to create thorough instructions and tools for providing a quality product in time, at the lowest costs.

Q3: What critical factors should be developed?

The third research question set to the thesis was about identifying critical factors of APQP which needed to be developed. To do this, information on current procedures, as well as an assessment of what is good and what issues need to be improved, was needed (research question 2). The current procedures of APQP were illustrated. The illustration of the current procedure was based on the information received from experts of the workshop group and evaluation of the actual APQP procedures. The critical factors were identified throughout APQP. Weaknesses were identified in RFQ, R&D and SOP processes. One of the critical factors was ignorance of APQP requirements and terminology at the company. The following procedures were decided to be improved: RTS, offer review, prototype process, ramp-up and production ramp-up plan and process audit sheet. The organization was also trained for APQP. Other critical factors which were left outside of this thesis were R&D procedures, improving of MSA and tooling plan. They are identified as further development needs.

The new procedure reached the set targets and was seen as a suitable procedure for the company. The new APQP includes documented and improved procedures. It is a comprehensive procedure, which can be implemented in each of the company locations.

5.2 Validity and reliability of the study

According to Yin (2003), a researcher must maximize four aspects of quality in case studies. These are constructive, internal and external validity, and reliability. In constructive validity, the correct operational measures will be established for the concepts being studied. This constructive validity concerns data collection and composition phases. Internal validity establishes the causal relationships and it is usually used in experimental

and quasi-experimental research. Internal validity concerns the data analysis phase. External validity establishes the domain to which findings of the study can be generalised. This concerns the research design phase. Reliability demonstrates that the operation made in the study can be repeated with the same results. Reliability concerns the data collection phase.

According to Heikkilä (2001), the validity of the research means that the research measures what it is meant to measure. Validity will be ensured with thorough pre-planning and deliberate information gathering. Reliability is the ability to produce non-random results. It can be divided into internal and external reliability. Internal reliability can be measured so that the same statistical unit is measured several times. External reliability means that the measure can be repeated in some other circumstances.

Constructive validity. When looking at the constructive validity of this study, theoretical discourse included information from several secondary sources. The used sources included many different books and researches both from abroad and Finland. From thorough and clear theory base it was easy to formulate the suggested methods, due to the fact that the person writing the thesis has good outlook on the issues concerned. When this information and knowledge are added to the knowledge of the workshop group, constructive validity in this thesis can be considered comprehensive.

Internal validity. Based on research material, a conclusion can be made and therefore theory can be created. Research material was collected from theory, gathering information from experts and using existing data. Data collection was carried out by several different experts. For example, the workshop group had representatives from two different production sites.

External validity of the study relates to whether results are applicable to other automotive industry companies. In this thesis, new procedure is tailored for the case company and for its functions and culture. There are certainly general methods and means used in the procedure, but shifting the procedure to another company without any modification or review might not work. Each company has its own procedures and culture so it is likely the new model would not fit exactly to another company's procedures.

Reliability. The characteristics of the environment and a need for creativity lead to the conclusion that the solutions and recommendations would not be exactly the same if given by another researcher. A different time for the research would also change the output of the research. Despite the reliability of the research, it cannot be proved conclusively that the research is completed with the best possible understanding and it is likely that another researcher would have the same principles of solution.

5.3 Further development needs

Further development needs concern mainly the parts that were identified during the study, but were decided to be left outside of this thesis. The biggest and most important process to develop is “Product Design and Development” phase of APQP. This phase covers PKC’s R&D procedures. After this, the APQP model will be complete.

Regarding the APQP’s sub-processes and its tasks, more investigation will be needed on MSA of pull force test, tooling plan and ramp-up procedures. A practical way to proceed in measure system analysis (MSA) plan for pull force tests cannot be clearly defined. The test equipment is mostly manual and the test results depend on the operator and other environmental factors. Also, it was identified that two different types of tooling plans are used in the organization. It would be good to standardize these plans and make one effective tooling plan procedure with needed instructions. The ramp-up plan was improved, but it is recommended that the procedure was developed further and proper description for project management improvement was created.

After all the issues thoroughly explained and defined, the implementation of this procedure should be carried out globally. It is important that the same procedure is in use in all locations and the procedures are carried out the same way. Then also effective benchmarking can be fulfilled.

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APPENDIX 1



REVIEW OF TECHNICAL SPECIFICATIONS (RTS)

Customer	
Part Name	
Part No. & Rev. Level	
Drawing No. & Rev. Level	
Project	
Resp. Engineer	
Resp. SQA Engineer	
RTS Team	
RTS Date	
<input type="checkbox"/> RTS Open with Actions (Pending RTS's) <input type="checkbox"/> RTS Closed (Completed RTS's)	



REVIEW OF TECHNICAL SPECIFICATIONS (RTS)

CHECKLIST

	Non-Applicable	Supplier Approved (Yes or No)	Action Required	Action Description or Comments		Action Item and Responsibility	Completion Date
				PART NO.			
1. PRE-PRODUCTION DRAWING AND SPECIFICATIONS REVIEW							
1.1 (1)					Are all required drawings to the correct revision levels according to the RFQ (request for quote), and is all documentation available?		
1.2 (2)					Are all needed assembly instructions, manufacturing standards etc. available?		
1.3					Found errors/questions in customer documents or drawings?		
1.4 (3)					Are general dimensions understood?		
1.5 (4)					Are tolerances and geometrical tolerances acceptable?		
1.6 (17)					Are all components approved, by customer or PKC?		
1.7 (8)					Are the KCC's (Key Component Characteristics), consequence class and special characteristics considered in the development of the production process?		
1.8 (9)					Is identification of material requirements understood?		
1.9 (11)					Are the text (Company Logo) markings understood?		
1.10 (12)					Are the geometrical description specifications available, if applicable (Digital Shape Model)?		
1.11 (13)					Are all standards available (General Specifications (GS), ANSI, SAE, etc.)?		
1.12 (22)					Is installation approval (components) required?		
1.13 (16)					Is checking equipment required for special applications?		

1.13 (16)	Is checking equipment required for special applications?						
1.14 (19)	Are there special requirements for packaging/handling/storage considered?						
1.15 (24)	Are material specification composition/properties/special requirements understood?						
1.16 (21)	Is there any special part identifying markings for in-process gauging or test verification planned?						
1.17 (15)	Are any preservatives used for product?						
1.18 (10)	Is there any special requirement regarding to traceability?						
1.19 (5)	Are the datum systems/master location points/inspection checkpoints understood?						
1.20 (6)	Is there (on documentation) master sample requirements? If no, then N/A. If yes, contact to quality responsible.						
1.21 (31)	Production and/or Preproduction?						
1.22 (34)	Miscellaneous						
2.PRODUCTION PLANNING							
2.1 (20)	Is capacity planning available/done?						
2.2 (32)	Remaining open questions concerning the concept of the part						
3. PKC DESIGN, R&D							
3.1 (33)	Advice on material choice for the part						
3.2 (25)	Has the reliability of the material (environmental, resistance, life cycle) been considered?						
3.3 (26)	Has comfort (noise, smell, feel)						
3.4 (27)	Are strength of materials considered? (e.g. joining, welding, impact strength)						
3.5 (28)	Have the requirements for surface treatment been considered?						
3.6 (29)	Have color, embossing, gloss requirements been considered?						
3.7 (30)	Have apperance requirements been considered?						
3.8 (7)	Is etching or sandblasting of the tool required?						
3.9 (18)	Are additional environmental activities considered? (e.g. Life Cycle Assessment)						
3.10 (23)	Is the part/system subject to legislative requirements?						
3.11 (14)	Are the cleanliness requirements understood?						



GUIDELINE FOR RTS CHECKLIST

PURPOSE

This Checklist is used in order to avoid the need for Design Change after the tooling and sample ordering, caused by the inability to meet the Technical Specifications required on the documents. It is used to collect, document, and handle the production comments, remarks, and product advice on the Technical Specification of that part(s).

ABOUT THE CHECKLIST

The checklist is created in Microsoft Excel and exists out of 1 workbook with 3 data sheets.

Cocer Sheet

In this section it is vital to give exact information about the drawing on which the RTS is based. State very clearly:

- Part Number and Issue
- Drawing Number and Issue
- Date when the RTS is performed

Checklist

The Checklist is built up as a list of questions.

For each question, the checker has to consider whether the technical requirements are complete, feasible, measurable, and understandable.

Comments and action items are to be given in the appropriate text block.

Each question **must** be answered with "X" in the checkbox. You have three (3) possibilities:

Supplier Approved (must be a Yes or No response). If you concur that you satisfy the requirements shown in the element description, answer with a "Yes". If changes are necessary to meet the requirements shown in the description, answer "No", and detail the actions needed to fulfill the requirements for the element.

Action Required

Non- Applicable (Non-Applicable responses will be reviewed by customer to ensure this is an appropriate response)

The answers to the checker questions or remarks are recorded in the text block, as well as all actions agreed upon during the meeting.

Instructions for Review:

1. PRE-PRODUCTION - DRAWING AND SPECIFICATION REVIEW
1.1 - Are all required drawings to the correct revision levels according to the RFQ (request for quote), and is all documentation available? Ensure that all approved engineering drawings, assembly drawings, mounting instructions, etc. are available and at your disposal. Confirm that the revisions on the documents correlate to the revision levels as shown on the quotation. Review any pending design changes.
1.2 - Are all needed assembly instructions, manufacturing standards etc. available? If a Technical Regulation is identified on the drawing or Part Version Report , develop a plan and indicate who will be responsible and when the required testing will be performed. All tests need to be performed and fulfilled prior to Initial Sample Approval at the latest.
1.3 - Found errors/questions in customer documents or drawings? Found error or question in the customer documents that need to be fixed by customer.
1.4 - Are general dimensions understood? Ensure there are no questions about the general dimensions or notations on the drawing. Understand the purpose of the feature if necessary. Review the tolerances associated with each feature and obtain comfort in the manufacturability of the feature as specified on the drawing.
1.5 - Are tolerances and geometrical tolerances acceptable? Ensure you understand the purpose of the geometric symbols and how the dimension relates to the datums. Review the allowable tolerance given and obtain comfort in the manufacturability of the feature as specified on the drawing.
1.6 - Are all components approved, by customer and/or PKC? Confirm that the components can be produced according to PKC and/or customer approval.
1.7 - Are the KCC's (Key Component Characteristics), consequence class and special characteristics considered in the development of the production process? Check carefully the KCC's, consequence classes and special characteristics indicated and review how these will be controlled in your production process (e.g. Manufacture of initial sample - Failure analysis audit FMEA-CP, SPC, Capability Studies, etc...).
1.8 - Is identification of material requirements understood? If the components material (type, grade, or specification reference number) is to be marked directly onto the part, ensure you understand the requirements for the marking, you understand the identifiers required, and the location of the marking is understood.
1.9 - Are the text (customer/supplier Company Logo) markings understood? Ensure you understand the requirements for marking the parts with customer/supplier company logos as identified on the drawings. Understand the location requirements, and specify the process utilized to mark the components.
1.10 - Are the geometrical description specifications available, if applicable (Digital Shape Model)? Verify that you have the appropriate Digital Shape Models (also known as a CAD model or NUFO) and that the file is of the correct revision.
1.11 - Are all standards available (General Specifications (GS), ANSI, SAE, etc.)? Ensure you have copies of the General Specification, or any industry specifications that are referenced on the component drawing. Ensure you understand the expectations as identified in the specification focusing on key points and lessons learned from previous experiences with the requirements. Be sure this specification is referenced during the quotation phase for the component.
1.12 - Is installation approval required? For some parts an official installation approval is required before product can be delivered. Ensure this has been discussed with the appropriate contact persons at the customer, and this activity has been planned.
1.13 - Is checking equipment required for special applications? Review if any special gages or fixtures are needed to evaluate master location points. Review if there is a need for special fixtures as required by Design Engineering.
1.14 - Are there special requirements for packaging/handling/storage considered? Ensure you understand the requirements for packaging/handling/storage of the components, and specify if any special requirements are needed.
1.15 - Are material specification composition/properties/special requirements understood? Ensure you understand the material specifications referenced on the drawing. If specific material testing or functional requirements are referenced in the specification, review the verification method to the test requirements.
1.16 - Is there any special part identifying markings for in-process gauging or test verification planned? How will the part be identified to indicate that testing, measurements, or verification has been completed?
1.17 - Are any preservatives used for product? Ensure you understand the GS specification regarding preservation of the component. How will the components be processed to ensure the preservation of the components as specified in the GS specification?

<p>1.18 - Is there any special requirement regarding to traceability? Ensure you understand the requirements for identification of the heat, lot, or batch number for the component. Identify the locations and requirements of the markings on the physical part. Communicate how the traceability information will be noted on the packaging and/or returnable containers. If extra requirements are necessary, please suggest these.</p>
<p>1.19 - Are the datum systems/master location points/inspection checkpoints understood? Determine if the datum system, master locations, and required inspection are adequate as reference for measuring. The related standards can be found on the drawing. Define with the Design Engineer and SOA the inspection check points needed for verification.</p>
<p>1.20 - Is there (on documentation) master sample requirements? Verify that you have all needed master samples available and they have been approved by customer engineering. Confirm that signatures have been obtained on the master samples. A reference number should be identified on the master as well. Master samples can be used when referencing color, gloss, grain, material, etc...Master samples are very important if color matching is required for surrounding parts.</p>
<p>1.21 - Preferable design, with respect to the supplier's production process concerning quality impact, economical impact, or assembly friendliness and serviceability. Quantify your quality and/or economical impact the suggestion will make to the part or system.</p>
<p>1.22 - Miscellaneous. Any open or other issues relating to the component.</p>
<p>2.PRODUCTION PLANNING</p>
<p>2.1 - Is the capacity planning available/done? Review your capacity planning regarding the part being quoted and be sure that any process constraints or bottlenecks have been identified and action taken to eliminate these constraints.</p>
<p>2.2 - Remaining open questions concerning the concept of the part. Perform different quotations if necessary.</p>
<p>3. PKC DESIGN, R&D</p>
<p>3.1 - Advice on material choice for the part. Suggest alternatives to material if there is a quality, economical or process advantage. Submit via separate quotation.</p>
<p>3.2 - Has the reliability of the material (environmental, resistance, life cycle) been considered? Review the requirements for reliability. Suggest if extra requirements may be needed based on historical field claim data for this part or similar parts. Suggest if part, process, or logistical changes can be made to optimize the components reliability.</p>
<p>3.3 - Comfort (noise, smell, feel). Consider and communicate any issues with comfort that may be experienced with this part. Suggest extra requirements if necessary.</p>
<p>3.4 - Are strength of materials considered? (e.g. joining, welding, impact strength). Consider the requirements for material strength after joining, gluing, riveting so components when developing the quotation.</p>
<p>3.5 - Have the requirements for surface treatment been considered? Verify the requirements for surface treatment of the part or component (full or partially painted, primed oily, etc...). Suggest if extra requirements may be needed. Verify that your suppliers process is approved by customer.</p>
<p>3.6 - Have color, embossing, gloss requirements been considered? Review the requirements for color, embossing, gloss, etc... Suggest if extra requirements may be needed. Ensure that approved master samples are available.</p>
<p>3.7 - Have appearance requirements been considered? Ensure you understand all requirements for appearance. Suggest if extra requirements may be needed.</p>
<p>3.8 - Is etching or sandblasting of the tool required? If grain or texture is required for this component, please be advised that the components must be approved with and without the surface texture. It is important that verification occurs of this part is to be matched with surrounding components. Identical texture is required in this case. Ensure you are able to manufacture to the specifications given. Review your measurement and evaluation techniques for these characteristics.</p>
<p>3.9 - Are additional environmental activities considered? (e.g. Life Cycle Assessment) Are additional environmental activities being considered where possible or needed? Consider small changes in packaging, processing, or transport which can have a positive environmental impact.</p>
<p>3.10 - Is the part/system subject to legislative requirements? Review if the part is subjected to legislative demands (T-Marking on the drawing or Part Version Report). If yes, review if approval certificates or special documentation is needed.</p>
<p>3.11 - Are the cleanliness requirements understood? Review the cleanliness requirements. Note if extra requirements may be needed and if any checking equipment will be necessary to control and verify the requirements. If the GS specification is referenced on the drawing, ensure you understand the requirements and can verify the components to these requirements.</p>

APPENDIX 3

Prototyypin I ja II valmistus - Virheriskikatselmointi
Manufacture of prototype I and II - Failure analysis audit



Tuotenumero / Part number:	
Prototyyppi / Prototype	
Versio / Revision:	
Tekopaikka / Production site:	

Pvm / Date	Kuittaus / Signature	Prosessivaihe / Process stage	NA / X / ok / ei ok / notok	Tulokset, Kommentit, Toimenpiteet / Results, Comments, Actions
		1.a Esivalmistelu 1.a Pre-production		
		Asiakkaan dokumentit, ok/ei ok Customer documents, ok/nok		
		PFMEA-CP katselmointi (uudet komponentit) / Jos uusia komponentteja löydetään heti ilmoitus "sourcingiin" PFMEA-CP audit (new components) IF new components are found, immediately information to sourcing.		
		Kaikki komponentit tunnettuja, ok/ ei ok All components known, ok/nok		
		Materiaalilista + COP BOM + COP		
		Pöytäkuva Table drawing		
		1.b Työntutkimus 1.b Work study		
		PFMEA-CP katselmointi (uudet komponentit ja työvaiheet)/ PFMEA-CP audit (new components and stage of operation)		
		Uusien komponenttien asennus, ok / ei ok Assembly of new componets, ok/nok		
		2 Tuotannosuunnittelu 2 Production planning		
		Tilaus vastaanotettu Received Order		
		Logistiikka: Jalostuslupa, jos tarvitaan (Tuotanto Kostamuksessa) Logistic: Refining license, If needed (Production in Kostamuksha)		
		Komponentit: toimittajat tiedossa, ok / ei ok Jos ei ok komponentteja, tarvitaan ehdotuksia/neuvottelua asiakkaan kanssa mitä tulisi käyttää. Components: Suppliers known, ok/nok IF not ok Components are found, need to propose/discuss with customer that what could be used instead		
		Toimitusaika ok / ei ok Lead times ok/nok		
		Tuotannon kapasiteetti saatavilla Production capacity available		
		Tuotantokapasiteetti sarjatuotantoon (prototyyppi II) Production capacity for serial production (prototype II)		
		3. Tuotanto, vastuullinen (työnjohtaja) / 3. Production, responsible (supervisor)		
		Työmenetelmien arviointi yhdessä työntutkimuksen kanssa, parhaiten menetelmien käyttöönotto mallisarja vaiheessa, P-versio. (prototyyppi II) During production Work methods estimation in cooperation with work study dept, best practices need to be found for P- release. (prototype II)		

P2.2 Implementation										
Worker training										
Installing machines, implementing tools, building lines										
Materials available for the test run, Preliminary Process Capability Study Plan										
Packing and delivery of test run products planned										
Test runs										
Significant Production Run										
Preliminary Process Capability Study										
MSA										
Buffer materials and products ensured										
Long lead time materials availability ensured for ramp-up										
Start of sample production										
Implementation approved, decision to verify										
P2.3 Process verifying										
Test run done										
Production validation testing										
PPAP										
Packaging Evaluation										
Production Control Plan										
Quality Planning Sign-Off and Mangement Support**										
Process audit from customer										
Product approved										
Process approved										
Corrective action plan approved										
Material availability for ramp-up ensured										
Resource for ramp-up ensured										
P2.4 Ramp-up										
Trained personnel available										
Volume production capacity and quality verified										
Start of serial production										
Transferring completed: no open action points										

***Mangement Support**

Confirmation of the planning and providing the resources and staffing to meet the required capacity

management representative / title / date

****Quality Planning Sign-Off and Mangement Support**

management representative / title / date

APPENDIX 5

PRODUCT/PROCESS QUALITY CHECK LIST

Customer or Internal Part No. _____

Revision Level _____

Question	Yes	No	N/A	Comment / Action required	Person responsible	Due Date
1 Is customer assistance or approval required for the development of the control plan?						
2 Has the organization identified who will be the quality liaison with the customer?						
3 Has the organization identified who will be the quality liaison with its suppliers?						
4 Has the quality management system been reviewed and approved per customer specific requirements?						
5 Are sufficient personnel identified to cover :						
a Control plan requirements?						
b Layout inspection?						
c Engineering performance testing?						
d Problem reaction and resolution analysis						
6 Is there a documented training program that:						
a Includes all employees?						
b Lists those who have been trained?						
c Provides a training schedule?						
7 Has training been completed for:						
a Statistical process control?						
b Capability studies?						
c Problem solving?						
d Mistake proofing?						
e Reaction Plans?						
f Other topics as identified?						
8 Is each operation provided with process instructions that are keyed to the control plan?						
9 Are standard operator instructions accessible at each work station?						
10 Do operator instructions include pictures and diagrams?						
11 Where operator/team leaders involved in developing standard operator instructions?						
12 Do inspection instructions include:						
a Easily understood engineering performance specifications?						
b Test frequencies?						
c Sample sizes?						
d Reaction Plans?						
e Documentation requirements?						
13 Are visual aids:						
a Appropriate, easily understood and legible?						
b Available?						
c Accessible?						
d Approved?						
e Dated and current?						
14 Is there a procedure to implement, maintain, and establish reaction plans, for issues such as out of control conditions based on statistical process control?						
15 Is there an identified problem solving process that includes root cause analysis?						
16 Are the latest drawings and specifications available for the operator, in particular at the points of the inspection?						
a Have engineering tests (dimensional, material, appearance, and performance) been completed and documented as required in accordance with customer requirements?						
17 Are the current forms/logs available for appropriate personnel to record inspection results?						
18 Are the following available and placed at the appropriate points of the operation?						
a Monitoring and measurement devices?						
b Gage instructions?						
c Reference samples						
d Inspection logs?						
19 Have provisions been made to certify and calibrate gages and test equipment at a defined frequency that is appropriate?						
20 Have required measurement system capability studies been:						
a Completed?						
b Accepted?						

21	Have initial process capability studies been conducted per customer requirements?						
22	Are layout inspection equipment and facilities adequate to provide initial and ongoing layout of all details and components in accordance with customer requirements?						
23	Is there a documented procedure for controlling incoming material that may include, for example, the following items:						
a	Characteristics to be inspected?						
b	Frequency of inspection?						
c	Sample sizes?						
d	Designated location for approved product?						
e	Disposition of nonconforming products?						
24	Have sample production parts been provided per customer requirements?						
25	Is there a procedure to identify, segregate, and control nonconforming products to prevent shipment?						
26	Are rework/repair procedures available to assure conforming product?						
27	Is there a procedure to requalify repaired/reworked material?						
28	Has a master sample, if required, been retained as part of the part approval process?						
29	Is there an appropriate lot traceability procedure?						
30	Are periodic audit of ongoing products planned and implemented?						
31	Are periodic assessments of the quality system planned and implemented?						
32	Has the customer approved the packaging and the packaging specification?						

Revision Date: _____

Prepared By: _____

FLOOR PLAN CHECKLIST

Customer or Internal Part No _____ Revision Level _____

Question	Yes	No	N/A	Comment / Action required	Person responsible	Due Date
1 Have lean concepts been applied in considering material flow?						
2 Does the floor plan identify all required process and inspection points?						
3 Have clearly marked areas for all material, tools, and equipment at each operation been considered?						
4 Has sufficient space been allocated for all equipment?						
5 Are process and inspection areas:						
a Of adequate size?						
b Properly lighted?						
6 Do inspection areas contain necessary equipment and record storage?						
7 Are there adequate:						
a Staging areas?						
b Impound areas?						
8 Are inspection points located to prevent shipment of nonconforming products?						
9 Are there controls for each process to eliminate contamination or inappropriate mixing of product?						
10 Is material protected from overhead or air handling systems contamination?						
11 Have facilities been provided for final product audit?						
12 Are facilities adequate to control movement of nonconforming incoming material?						

Revision Date: _____

Prepared By: _____

PROCESS FLOW CHART CHECKLIST

Customer or Internal Part No. _____ Revision Level _____

	Question	Yes	No	N/A	Comment / Action required	Person responsible	Due Date
1	Does the flow chart illustrate the entire process from receiving through shipping, including outside processes and services?						
2	In the development of the process flow chart, was the DFMEA used, if available, to identify specific characteristics that may be critical?						
3	Is the flow chart keyed to product and process checks in the control plan and PFMEA?						
4	Does the flow chart describe how the product will move i.e., roller conveyor, slide containers, etc.?						
5	Has the pull system/optimization been considered for this process?						
6	Have provisions been made to identify and inspect reworked product before being used?						
7	Are material controls for movement and staging of product including appropriate identification properly defined and implemented? The controls should address incoming supplier product as well as subcontracted processes.						

Revision Date: _____

Prepared By: _____