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Improving purchased material quality in a new product development project in medical device manufacturing

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TEKNILLINEN KORKEAKOULU DIPLOMITYÖN TIIVISTELMÄ

Informaatio- ja luonnontieteiden tiedekunta

Tuotantotalouden tutkinto-ohjelma

<table>
<tr><td colspan="3">Tekijä: Hannu Laakso</td></tr>
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<tr><td colspan="3">Työn ohjaajat: Tekniikan tohtori Karin Mårtenson
Insinööri (AMK) Jarno Vairimaa</td></tr>
<tr><td colspan="3">Ostetun materiaalin laatu lääketieteellisiä laitteita valmistavassa kohdeyrityksen Helsingin tehtaalla ei ole ollut tyydyttävällä tasolla, mikä aiheuttaa paljon turhaa työtä ja kuluja sekä pahimmassa tapauksessa voi vaarantaa potilasturvallisuutta. Uuden laitteen kehitysprojektissa ostettavien osien laatu haluttiin varmistaa jo suunnittelupöydällä. Tämän diplomityön tavoitteena oli tutkia mitä laatutyökaluja kannattaa käyttää tämän yrityksen tuotekehitysprojekteissa alihankkijoiden kanssa sekä auttaa laatutyökalujen käyttöönotossa. Käyttöönotetut työkalut olivat alihankkijan laatutoimenpiteiden hyväksyntäprosessi sekä raportti, jonka avulla pyrittiin parantamaan tiedonkulkua prototyyppien valmistuksessa ja käytössä esiintyneistä vioista. Näiden lisäksi aloitettiin yleisten tarkastusohjeiden ja mallikappaleiden valmistelu visuaalisten laatuongelmien vähentämiseksi.

Tulokset ja kokemukset prototyypeistä tukevat ajatusta, että projektin alkuvaiheessa on tärkeää käydä osien vaatimukset perusteellisesti läpi alihankkijoiden kanssa ja ottaa heidän kommenttinsa huomioon suunnittelussa mahdollisimman hyvin. Uudet laatutyökalut vaikuttivat käyttökelpoisilta monissa tapauksissa, mutta niiden käytön hyödyllisyys ja perusteellisuus riippuu paljon siitä minkä tyyppinen osa ja sen valmistusprosessi ovat. Kokeiltuja työkaluja voidaan käyttää kohdeyrityksessä tehokkaammin jatkossa, kun niiden käyttöönotosta on nyt enemmän kokemusta.</td></tr>
<tr><td colspan="2">Asiasanat: laatu, alihankkija, tuotekehitys, lääketieteellinen laite</td><td>Julkaisukieli: Englanti</td></tr>
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HELSINKI UNIVERSITY OF TECHNOLOGY

ABSTRACT OF THE MASTER´S THESIS

Faculty of Information and Natural Sciences

Industrial Engineering and Management

<table>
<tr><td colspan="3">Author: Hannu Laakso</td></tr>
<tr><td colspan="3">Subject of the thesis: Improving purchased material quality in a new product development project in medical device manufacturing</td></tr>
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<tr><td colspan="3">Instructors: Ph.D. Karin Mårtenson, BSc. Jarno Vairimaa</td></tr>
<tr><td colspan="3">The study has been conducted at the case company’s Helsinki site, where medical devices are manufactured. The quality of the purchased material has not been satisfactory. Quality problems cause a lot of extra work, costs, and even patient safety risks. A new product development project was initiated with the aim to ensure the quality of purchased items already at the design stage, involving suppliers. The target of this master’s thesis was to investigate which quality management tools should be used in this project, and to help implement them. The implemented tools were the Supplier Quality Controls Approval Process and the Proto build feedback report. The purpose of the feedback report was to improve the prototype communication. In addition, preparation of visual inspection instructions and visual samples were started.

The results and experiences from the prototype series support the notion that it is important to analyze the part specifications thoroughly with the suppliers in the beginning of the project and let the suppliers affect the design as much as possible. The new quality tools were mostly considered useful, but the applicability depends much on the nature of the item and its manufacturing process. After applying these tools initially in this project they can be implemented more efficiently with the suppliers in the future.</td></tr>
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I want to thank first of all the case company sourcing managers who provided me the opportunity to make this interesting study. The company's Helsinki site's sourcing, supplier quality, the project team leader, and the project designers gave really significant input to this study and helped me to implement the new quality management tools in this project. In addition, this study could not have been done without the case suppliers, who made remarkable effort to practice the quality tools with us and gave good feedback about the implementation process of the tools.

Special thanks to my instructors Karin Mårtenson and Jarno Vairimaa and to Professor Paul Lillrank, who was the supervisor of this study.

I'm very grateful to my family and friends, who supported me during this long project.

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Abbreviations

AOI	Automatic Optical Inspection
AQL	Acceptable Quality Level
COPQ	Cost Of Poor Quality
CSF	Critical Success Factor
CTQ	Critical To Quality
DFM	Design For Manufacturing
DFMEA	Design Failure Mode and Effect Analysis
DFT	Design For Testability
DMAIC	Define-Measure-Analyze-Improve-Control
DPMO	Defects Per Million Opportunities
DPPM	Defected Parts Per Million
FAI	First Article Inspection
FCT	Functional Circuit Tester
FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis
FPY	First Pass Yield
FTA	Fault Tree Analysis
Gage R& R	Gage Repeatability and Reproducibility, validation and verification of a measurement system
ICT	In-Circuit Tester
LSL	Lower Specification Limit – the minimum acceptable value of a variable
MAEP	Manufacturing Assisted Engineering Prototype
MVP	Manufacturing Verification Process
NB	Notified Body
OCAP	Out-of-Control Action Plan
OQC	Outgoing Quality Control
PCP	Process Control Plan
PFMEA	Process Failure Mode and Effect Analysis

PLR	Part Layout Report
PPL	Part Prioritization Log
PWA	Printed Wire Assembly
R&D	Research And Development
RR	Requirements Review – a part of Q-CAP
RoHS	Restriction of Hazardous Substances
SCR	Supplier Change Request
SQE	Supplier Quality Engineer
SPC	Statistical Process Control
Q-CAP	Quality Controls Approval Process
QM	Quality Management
TQM	Total Quality Management
USL	Upper Specification Limit – the maximum acceptable value of a variable

"The mould supplier's expertise is on the mould manufacturing – not playing with Excel"

– Designer's comment about the prototype feedback form

1 Introduction

1.1 Background and Motivation

This study was done in a global medical device company that has one manufacturing site in Helsinki, Finland. Research, product development and supportive engineering departments are also working in the same building. The plant in Finland assembles several different medical devices that are designed in the company. In addition the company distributes patient monitoring supplies and accessories that are made by many different suppliers. In this study the company is called Potmor for privacy protection.

The level of defects in purchased material has not been acceptable with many of the company's suppliers. Poor quality of purchased material causes a lot of time-consuming efforts for employees throughout the organization, customer dissatisfaction and disloyalty, and finally costs. It has been estimated that in some industries the Cost Of Poor Quality (COPQ) could exceed 10-30% of sales but still managers do not always realize that the portion could be so high (Juran et al. 1998). COPQ consists of, for example, defect prevention and appraisal and from internal and external failures (Gryna 2001).

This product development project is about developing a new model of one current product of the company. Let's call this new product 'Mede'. In this project quality and reliability of the product are considered to be very important parameters that affect the purchase decision. The term 'Quality' has many explanations. Gryna (2001) describes it to be "fitness for use" and "customer satisfaction and loyalty". In this study the word 'Quality' implies above all freedom from deficiencies and conformance to specifications.

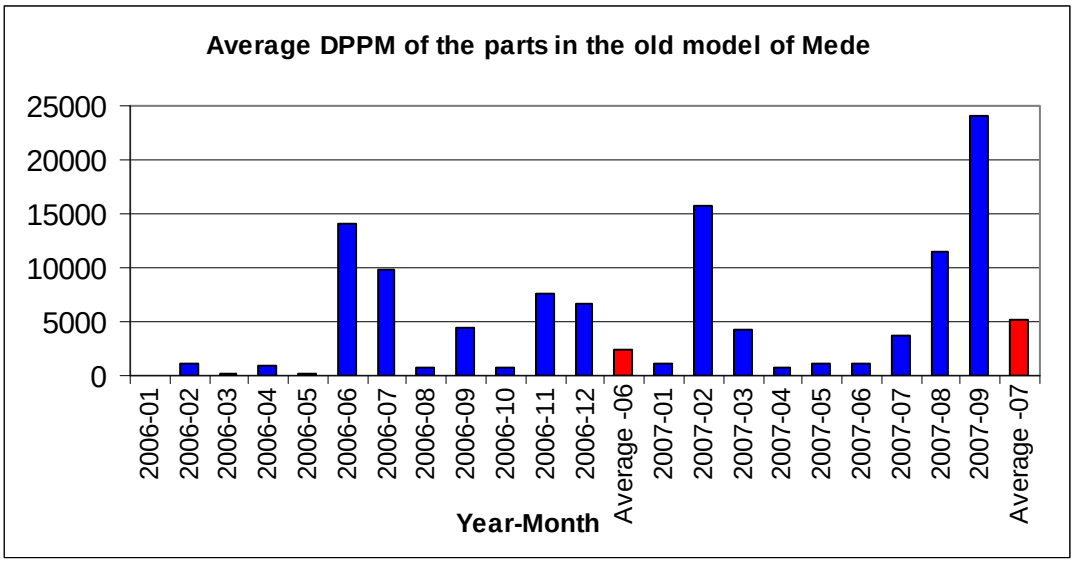

Figure 1.1. Average DPPM of the purchased parts in the old model of Mede during January 2006-September 2007.

A useful approach to estimate the quality of purchased material is to use the Defective Parts Per Million (DPPM) level for purchased items. Figure 1.1 shows average DPPM-levels for the parts in the old model of the Mede during 2006-2007. The values are based on the defective items found in incoming inspection, assembly and by customers. According to the figure, the average DPPM-level has been around 2500-5000 DPPM, which is not satisfactory. The volumes being low, even few defected batches of parts raise the average DPPM-level remarkably, which causes a lot of variation to the DPPM-level.

Timing of the Study

A reason for the relatively high levels of purchased material related defects in Potmor is the lack of experience in supplier quality management (QM) tools at the Helsinki site. Although more organized and stricter procedures for supplier qualification and auditing have been implemented during the last few years, the current supplier quality engineers would like to develop the supplier quality management actions from a reactive approach to a more proactive. This applies especially to using the quality tools in co-operation with suppliers. All in all there was a need and opportunity to improve the understanding about quality management tools inside the company and its suppliers.

In the Helsinki site there are now good resources in the sourcing function with experience from mass production industry to implement the use of quality management tools. One of the existing global quality management procedures in Potmor is called Quality Controls Approval Process (Q-CAP) which had been introduced in Potmor but was not yet really utilized in this site.

One product development project (PDP) in Potmor was in such a stage that it could be used as a base for this study and some pilot experiments could be performed by it. In that project, the business plan, concept development, and system-level design had been mainly done before beginning of this study. The detailed design was in process and prototyping of some components had begun as well.

1.1.1 Literature

No articles related specifically to medical device component suppliers or supplier quality management in medical device manufacturing company could be found. Many of the available studies and publications regarding the supplier quality management were related to automobile component or manufacturer companies (e.g. Gonzáles-Benito et al. 2001, Noviyarsi 2005). Especially Japanese automobile manufacturers have put lot of emphasis to supplier management and development (Sako 2005). Particularly Toyota Company is known for its initiatives for supplier performance development. The results of those articles regarding quality management on those higher volume businesses were considered to give useful reference to this study. Quality management dependence on the context has been studied as well (e.g. Benson et al. 1991, Sousa 2000).

Many articles emphasize the importance of co-operation with the supplier (Seppälä 2001), within the supply-chain (Fynes et al. 2005), and trust and stability (e.g. Lai et al. 2005) in a supplier relationship. There are several articles on implementing (Total) Quality Management (TQM) activities in the company (e.g. Dale et al., Gonzáles-Benito et al. 2001), and in the supply chain (e.g. Sila et al. 2007, Kaynak et al. 2007). Supply chain quality management that combines quality management and

supply chain management is one of the current research topics (e.g. Sila et al. 2006, Kaynak et al. 2008).

1.2 The Research Problems

The research problem behind this study is as follows:

- Which quality management tools and techniques could be used in product development projects to improve the quality of purchased material in the Helsinki site

Better quality of purchased components would decrease assembly problems and failures in manufacturing and therefore finally increase the yield of the end product. Better and more reliable medical device improves patient safety and thus customer satisfaction. The study focused on minimizing the defects that occur because of suppliers' incapability to manufacture good quality components. A major reason for the poor quality was the insufficient communication about the requirements for the components between the designers and the suppliers. In addition there were some cases where the expectations for components in Potmor exceeded the supplier's specifications. Also the prototypes had many times been of better quality than the actual production series.

The issues described above gave more detailed focus to this study. The target of this study was, through a case study, to search answers to the problems stated above. The following additional questions were stated to help with focusing the work, and to more concretely answer the research problem.

- How to get and give more accurate feedback from the design and the prototypes in early stages

- How to prepare the quality control activities for mass production with the suppliers

An additional goal of the study was to investigate how the quality management tools used in high volume manufacturing suited our medical device production.

The aim is to transfer the results from this case study into Good Design and Manufacturing Practices in Potmor, and also to the key suppliers, and to create training material to be used in PDPs in the future. The key suppliers were encouraged to change their working culture and processes from reactive repairing of problems one by one to continuous improvement and preventive process development.

1.3 Limitation of the Study Scope

As this study was made from the sourcing point of view, it did not include the quality of the product design, but focused on improving the suppliers' capability to implement the engineering design into a defect free product.

This study did not cover supplier selection and consolidation very deeply. Neither did it concentrate on decreasing the defects that originate from the assembly in manufacturing.

This study was done for one particular product development project in Potmor's Helsinki site. The results are fully applicable to other PDPs at this site and to a smaller degree throughout the company.

1.4 Research Material and Methods

1.4.1 Study Methods and Research Material Selection

This study was experimental and educative for different functions in Potmor and for some important suppliers. An essential part of the study was to assist Potmor's supplier quality engineers to implement the new supplier quality management tools described in chapter 5. It included teaching the suppliers and the company's design engineers to use those tools, which were chosen together with the company's supplier quality engineers.

A qualitative analysis was done about the problems and challenges that were faced during implementation of the quality tools with the case suppliers. The analysis was based on the author's experiences during the study, questionnaires and interviews with designers, supplier representatives and the company's supplier quality engineers. In addition an estimate was done about the time the implementation of the tools required from each of the parties. The suppliers in this study were Finnish, which made it easy to communicate and arrange face-to-face visits with them.

A quantitative analysis was done about the defects of the parts produced by the case suppliers for the few Manufacturing Assisted Engineering Prototype (MAEP)-series. The purpose of the analysis was to estimate how the implemented new quality management tools affected the part quality. Due to the delay in the PDP schedule, the Manufacturing Verification Process (MVP) series, which was to be used for product and supplier process validation before the mass production begins, could not be included in this study. The quality level data of the parts is mainly based on proto build feedback reports and measurement reports that were requested from the suppliers and the designers.

Finally, based on the experiments from this study, suggestions were stated about how to proceed with supplier quality management in this and in the following projects.

1.4.2 Reliability of the Research Material

One of the desirable outcomes of this study was to take advantage of QM tools in an appropriate extent with the suppliers. Because of the delay in the PDP schedule, the capability studies could not be included to this study, but they are essential part of Q-CAP. Those will give much more information about the quality of the parts and about the supplier's capability, than the MAEP series. Therefore the usefulness of the Q-CAP was difficult to estimate, and the main focus was to describe the implementation process of the quality tools.

The MAEP series were relatively small, and the quality of some of those could not be analyzed very systematically, because the designers did not always have much time for that. In addition, the plastic parts for the three MAEP series were mainly done at the mould supplier and thus the advantages of Q-CAPs with the plastic supplier cannot be seen before the MVP. Therefore special carefulness was needed when making conclusions from the quality data. The actual improvement of the quality of the components can be estimated in later studies after mass production is up and running.

Estimating the results of this work focused on how the questions in section 1.2 were answered. The estimates were based on the experiences from the MAEP1-3 prototype series of the purchased parts.

1.5 Performing this Study

1.5.1 Plan-Do-Check-Act – Cycle

The actions for this study will be made roughly in three main phases. Those could be named according to Plan-Do-Check-Act (PDCA)-cycle, also known as Deming wheel steps (Juran et al. 1998), but the Act-step was left outside of this thesis.

In the first phase – Plan, the study scope and targets were defined, and made known within the PDP. In addition the quality management tools and literature were studied, and implementation plans developed with the instructors. Quality history of the current products and suppliers were investigated to get reference data to understand the current situation and what items had shown most defects in the past.

The second step - Do - included teaching the designers and suppliers' representatives the new tools and helping them to implement those with the company's supplier quality engineers. Preparation for the mass production began during that step and plans for it were created.

In the Check – phase the achieved results were analyzed and answers to the research questions that were stated in section 1.2 were presented. The Act-step would be the implementation of the QM tools in the next PDPs in the future based on the results of this study.

1.5.2 The Sections of this Thesis

The eight chapters of this master's thesis are briefly described below:

This first chapter, Introduction, describes the background, motivation, purposes and limitations of this study. The chapter states the questions this study was searching answers for, and the study methods that were used.

The environment where this study was applied, the medical device manufacturing industry and this company, is described in chapter two. Chapter three discusses purchased material quality in product development projects.

Chapter four discusses the investigated problems and chapter five the quality tools that were used to find answers to the study questions. The results are presented in chapter six, and chapter seven discusses the results. Chapter eight summarizes and concludes the study.

2 Development of a Medical Device at the Case Company

This chapter introduces the medical device industry, some of the regulations that apply to this industry, the company and the Helsinki site, the product development project, and the sourcing function to which this study is related.

2.1 Medical Device Markets

A few big multinational companies divide the global markets of this kind of devices while some local companies have their shares in limited market areas. The corporation, where this study is done, is one of the biggest on the market.

According to the project plan, the biggest markets for this kind of products are in North America and Europe covering together ca. 75% of the global market. Economical drivers affect sales generally around the world. At the time this study was done there were severe problems in the global economy, which reflected to the sales of Potmor's products. All in all it is important to purchase reliable and cost-effective medical devices that can manage the treatment of large quantity of patients, although the importance of the measurement parameters varies around the world.

In a survey of medical device professionals (Dixon et al. 2006) the product quality was considered to be the most important internal factor that affected the product's success on the market. Poor quality causes costs to the company in many ways. Therefore, reducing that portion of costs, while improving the reliability and reputation of the product and the company at the same time, is expected to help this company to survive in the severe competition.

2.2 Regulations in the Medical Device Industry

The medical device industry is a regulated industry, because medical devices affect patient safety. Strict regulations have forced the company to create standard

operating procedures that are followed in the company worldwide. The Food and Drug Administration (FDA) in the United States and the competent authorities in European Union countries are some of the most important authorities related to this company that require medical device manufacturers to control their operations and product development procedures. In addition the markets in Japan and China are increasingly regulated. There have been pressures to restrict the regulations in US due to some severe accidents happened to patients during last decades (Maisel 2004).

The company must be FDA registered to be able to operate and sell its medical devices in the US. Also FDA requires a clearance for each medical device, before it can be marketed in the US (FDA 2007). Access to the US markets is important, because the market share of this product is remarkable. The way of documenting product development has lately changed in Potmor. Potmor's designers feel that the recently changed design controls procedures that originate partially from the FDA regulations slow down the product development projects in the company, including this project. On the other hand, according to a survey (Dixon et al. 2006) the regulations on this business would not have strong impact on the product development time. The change in work methods naturally raises resistance in the beginning but the resistance can be expected to decrease after people get used to following the new procedures.

The European Union has its Medical Device Directive 93/42/EEC, which is most easily fulfilled by adherence to harmonized standards, e.g. EN ISO 13485. If the company's quality management system is ISO13485-certified, it sets up certain requirements to the company. In Europe the market approvals for the devices are mainly based on the quality system certifications. Certifications and CE marks can be granted by notified bodies (NB) which are independent organizations that are monitored by national authorities of the EU member countries. The approval criteria vary between FDA and European authorities, and sometimes it occurs that a device approved in EU will not get approval from FDA. Biggest differences of the approval processes between the US and EU are that in Europe it is required to prove that the product is safe to the user and the patient, whereas in the US, in addition to the safety and other requirements, the evidence of the efficacy of the product is required.

Because of the differences in the regulations, introduction of new devices into use vary significantly between the US and Europe. (Kaplan et. al 2004, European Commission 2007)

FDA and EU both use a few different classifications for medical devices, which depend on how major and probable risk to patient safety the device could pose (Maisel 2004). This new product, Mede, is categorized as a class 2 device in the US (FDA 2004), and class II b in EU, which means that general controls are not considered to guarantee the safety of the device, but special controls are needed. As the reliability of use is important for patient safety, FDA also tracks safety troubles that occur in hospitals because of defected devices (Maisel 2004).

One part of the requirements of both mentioned authorities is Purchasing Controls, which includes controlling the suppliers. Its one major purpose is to guarantee that the components that are purchased are reliable and of good quality in order to avoid patient safety risks. Good quality means not only that the device works well without breakdowns but also that it has a good variety of characteristics and that it fulfills user's requirements (Gryna 2001). Potmor's site in Finland is known to have strong background regarding usability of its devices.

To ensure the high quality of its products and fulfillment of the regulations, Potmor has developed and emphasized the importance of its quality policies and procedures in its activities during the last years. Potmor has tightened its purchasing controls to improve compliance with the regulations and quality of the purchased items. For instance 'Lean six sigma' is the newest strategy used to decrease expenses in manufacturing and to bring quality culture into Potmor and its suppliers.

2.3 This Product Development Project at the Case Company

The Helsinki site has been manufacturing different kind of medical devices for a couple of decades, although there have been some ownership changes during the years. The site in Finland is part of a global entity which has sister sites in many

other countries. The Helsinki site's business is nowadays tightly connected to other sites in the corporation; although there is a local plant manager, many of the operations are controlled from higher levels that are physically located abroad.

This product development project was one of the biggest carried out at the Helsinki site at the time of the study. The new Mede will be an important part of the global product portfolio that will replace the old, fragmented portfolio of Potmor. The Mede is a mid-segment product. Thus the replacement of some of the old products is strongly related to the schedule of this project. The PDP schedule slipped slightly, which gave even more pressure to avoid time consuming efforts.

Most of the project team members were executing also the previous project, which developed the old model of Mede. Thus there were good background and experience in the PDP team. The supplier quality engineers (SQEs) were new in Potmor and eager to improve the awareness about quality management in projects among project teams and suppliers. As there are many product development teams at the Helsinki site, these new practices have to be teached repeatedly in many projects to the designers, project leaders and also to new key suppliers. Therefore it was also important to make good instructions for the project participants.

2.4 Sourcing at the Case Company

Potmor's Helsinki site being part of a global entity, the sourcing function in Finland is also one part of the global sourcing organization, which follows Potmor's global procedures. The sourcing function in Potmor consists of sourcing leaders, who are responsible for the business relationship with the suppliers, and supplier quality engineers, who are responsible for the quality of the suppliers' purchased material.

2.4.1 Sourcing and Supplier Quality Functions

The sourcing team in Finland's site has experienced a lot of changes during the last years. Some sourcing leaders and supplier quality engineers have left their positions and some of those have been replaced, but the number of sourcing leaders has been

reduced. Now the team consists of some experienced sourcing leaders who have long history in Potmor and some new ones.

In contrast, the number of supplier quality engineers has increased during the last years in Potmor's Helsinki site. The new SQEs have brought experience from high volume mass production industry, and on the other hand from other divisions and functions of Potmor. Thus there are better possibilities to move towards a more preventive supplier quality problem solving-strategy than the old way, which has been mainly 'fire-fighting' due to lack of resources in sourcing and supplier quality management skills, and the big number of suppliers.

2.4.2 Supplier Base at the Case Company's Helsinki site

At present the amount of suppliers for Potmor's Helsinki site is counted in hundreds. There are at least three reasons for the large number of suppliers for the site. The manufacturing plant location has changed a couple of times, some of the old products, which have a lot of suppliers are still in production, and Potmor has not earlier focused on reducing the number of the suppliers. The large supplier base causes big efforts to improve the quality of all the suppliers, and also to be compliant with respect to FDA's requirements and Potmor's own procedures.

Sourcing leaders' contacts with some of the less important suppliers are so weak, that the sourcing leaders say that they do not have a real understanding what is the situation at the suppliers' manufacturing and their future. Also the travel restrictions for cost savings during last years have decreased possibilities for visiting the suppliers, and building better contacts with them.

In recent years, the global sourcing strategy has changed, which have reflected to the Finland's site sourcing as well. Now the target is to consolidate the supplier base to fewer suppliers, and to create more true partnerships than before with the strategic suppliers. Due to the current fragmented supplier base in Potmor's Helsinki site, the volumes of the purchased components are not very large with most of the suppliers. Therefore the negotiating power has not been very effective, and it has been difficult

to get real involvement from some suppliers. Poor interest from supplier side has been noticed in Potmor's sourcing function to be a real problem with some of the old products.

One concrete reason for the need of a better level of co-operation with suppliers and better quality components is because Lean-manufacturing approach has been introduced in Potmor. Lean sets requirements to the suppliers to provide the material without defects lot after lot, or otherwise the production could stop in Potmor. In 'traditional' production the quality problems could be more easily hidden into the storages (Gryna 2001).

In the past it has been unusual to let Potmor's suppliers help with designing the items that will be manufactured. But during the last few years, the advantages of the supplier's better integration into a PDP have been noticed also at a higher level in Potmor, and the supplier's early involvement is part of the customer-supplier partnership development strategy.

3 Improvement of Purchased Material Quality in Product Development Projects

3.1 Introduction

In this chapter the following topics are discussed: Implementation of quality management tools and techniques, co-operation with suppliers, purchased material quality management in different functions of the company and in the different phases of the project.

The use of proper quality management tools and techniques during every step of a product development project can be expected to affect the amount of quality problems in the mass production stage. The quality of the end product is dependent on many factors. This study concentrates on how to reduce quality problems that are caused by the purchased material.

The problems that originate from possible design failures are not in the actual focus of this study, although those can have an impact to the quality of the purchased material. Some of the quality management tools described in the later chapters influence partially the design of the purchased components, so the importance of the design is not totally left out of the scope; attention is given to the communication about the design, tolerances and specifications between suppliers and designers.

In a PDP the risk that supplier's products are not of high quality, originates from the nature of PDPs. Usually the project is dealing with something new: new technology, new manufacturing machines or tools, or for example new regulations. One remarkable new regulation that affects many types of items and manufacturing processes is called the Restriction of Hazardous Substances (RoHS) Directive, which is "the restriction of the use of certain hazardous substances in electrical and electronic equipment" (NWML 2008). For example the concentrations of lead in the components is limited in all new products from 1st of July 2006 in EU, but presently

medical devices are excluded from the RoHS regulations (NWML 2008). Many countries outside EU have or will have similar kind of legislation. The restriction will affect many parameters and processes in printed wire assembly manufacturing and create risks if the new manufacturing processes appear to be unstable or unreliable.

This Mede is the first big product in the Helsinki site that was designed to be RoHS-compliant already from the beginning. In Potmor there is not yet much quality history available from manufacturability and functionality of RoHS-compliant materials and components in circuit boards. Thus being aware of the risks and problems that are related to new technology in the products is necessary to avoid unexpected problems.

As discussed in section 1.1 - Background and Motivation, this study is done to decrease the defect levels of purchased material. Purchased material quality reflects to the first pass yield (FPY) of the assembled product. FPY is usually the percentage of items that passes the manufacturing process successfully, without any repair during the process flow. Figure 3.1 illustrates roughly the flow steps, and some parameters that affect the final yield of a finished product. Clearly, the better the design and the communication between the designers and the suppliers, the better is the suppliers' manufacturing process in the upstream of the process, and the better yields can be expected at the end of the flow.

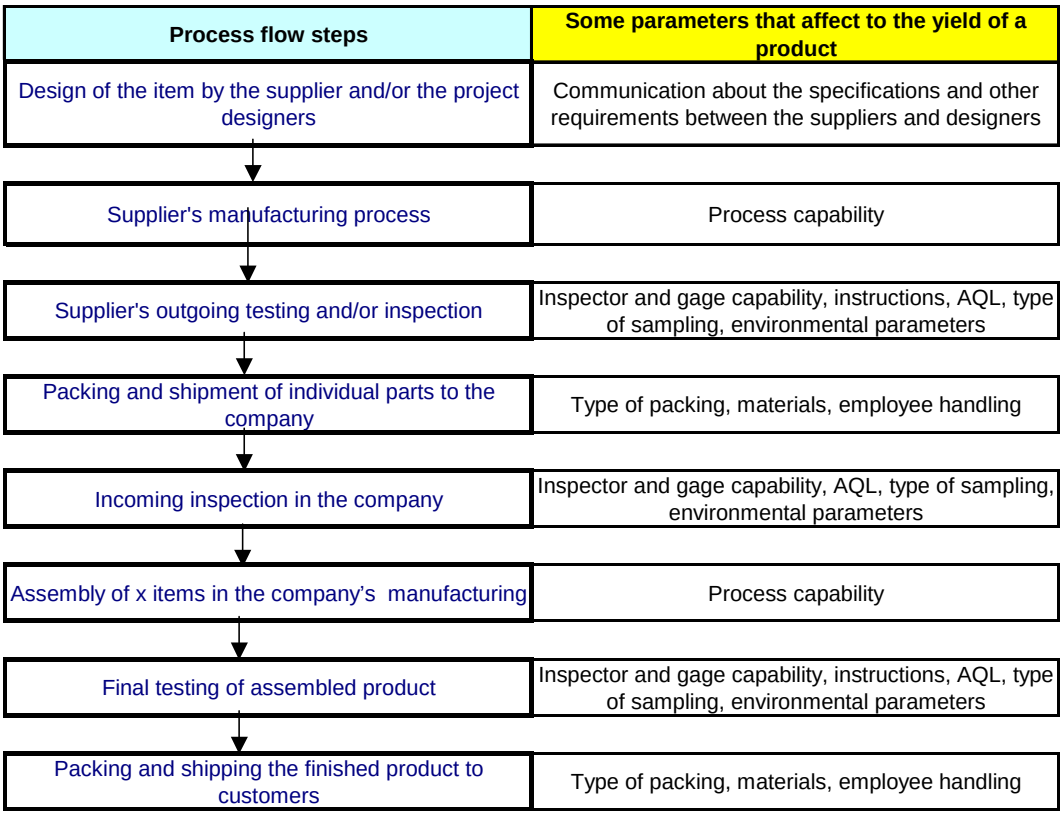

Figure 3.1. Steps that affect the quality of the finished product.

3.2 Introducing Change in Quality Culture

Good quality of the products cannot be bought from a consultant, who creates the 'quality culture' to the organization in short time (Lamprecht 2000). Many guidebooks emphasize that creating the 'quality culture' in the company and at suppliers' will take its time, whether the consultant is talented or not, and that should be accepted by all participants.

Some rules of the road for introducing change in quality culture have been listed (Juran et al. 1998) and e.g. the following advices were followed during this project: "Provide participation", "Provide enough time", and "Keep the proposals free of excess baggage". Providing enough time includes e.g. that small tryouts of change would be made to provide smooth transition to the new culture.

A study (Bunney et al. 1997) that was made about implementation of quality management tools and techniques in a non-mass production environment, a speciality

chemicals manufacturer, stated some findings regarding the implementation. Many studies were associated to training of the techniques; its timing, objectives, providing good examples that are related to the everyday processes, and the right persons to be teached, including management. It was pointed out that a single tool or technique should not be expected to solve all issues, and that it is important to teach how a particular tool can help the persons that would be using it and which other tools could be utilized with it to improve the effectiveness. Especially managements' understanding about the limits and possibilities of the tools is important. Root causes to failures with using quality tools were (Kwok et al. 1998) when, where and how to apply those.

An additional problem with using the tools was (Kwok et al. 1998) how the tools are related to each other and how they could be used more successfully together. A model is proposed that integrates different quality tools that are regularly available in manufacturing and service industries. In the model the quality management methods and tools are classified to three levels to ease the understanding and use. Figure 3.2 shows the enhanced model of Total Control Methodology prepared by Kwok et al. (1998).

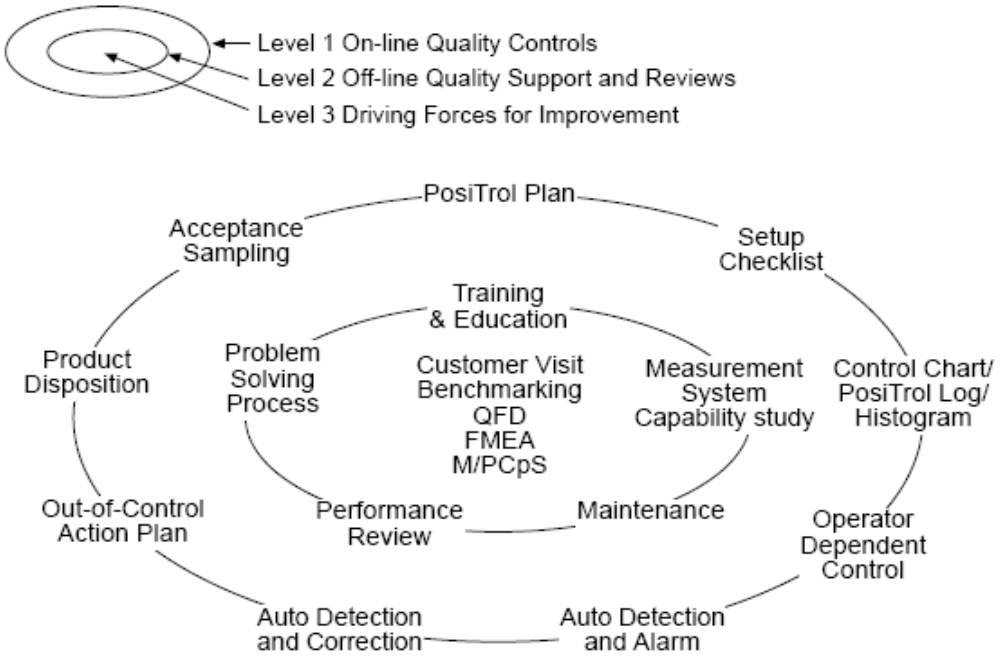

Figure 3.2. Enhanced Total Control Methodology in a case study made by Kwok et al. (1998). QFD stands for Quality Function Deployment, FMEA for Failure Mode and Effects Analysis, and M/PCpS for Machine/process capability study.

Antony et al. (2002) compared CSFs for Total Quality Management (TQM)'s implementation in Hong Kong organizations with the results from two earlier studies done to Indian and US organizations. In addition to the sufficient training and the education of the tools, the role of the quality department, quality data reporting, and supplier-customer relationship were stated to be CSFs in all the three environments.

Gryna (2001) mentions some obstacles to achieve quality goals, and one of his seven points is "Failure to understand the skepticism about the 'new quality program'". The project team members and suppliers probably have many reasons for refusing to implement quality tools in their area of work. Their comments are valuable and are to be listened and learned from. They have undeniable experience about their working environment and have their opinions on what kind of quality controlling tools and methods would be reasonable specifically for them.

3.3 Implementation of QM Tools with the Suppliers

Quality management has been shown (e.g. Sousa 2000) to have some dependence on the context to which it is applied. The following section briefly reviews the literature about contextual factors affecting quality management in companies. Sections 3.3.2 and 3.3.3 discuss the impact of manufacturing volume on supplier quality management from the purchasing company point of view. The two sections are partially based on interviews with the supplier quality engineers, who have experience from supplier quality management in different kind of companies. Section 3.3.4 presents some challenges that might be faced when quality improvement actions are done with suppliers.

3.3.1 General Factors Affecting Quality Management in a Company

Manufacturing strategy, corporate and management support are examples of the parameters that affect quality management in companies. On the other hand, managers' perception about the ideal quality management was shown (Benson et al. 1991) not to systematically vary among different contextual variables.

Cua et al. (2001) supposed that conformance quality was lower in plants having low volume and high variety of products, in contrast to plants where the manufacturing is more process-based. According to him a low volume-high variety manufacturing company does not have such good opportunities to utilize long-term defect data for process improvement.

Sousa (2000) studied the differences in QM practices between some companies, which varied mainly in their manufacturing strategy. On one extreme were 'cost leaders' and on the other side 'niche differentiators'. Cost leaders had high volume and low level of customization and product variety, resulting in lower prices. Niche differentiators had low volume, but high customization, product variety, design capabilities and delivery speed, with low new product introduction times. In between was a 'broad differentiator', with characteristics in between the extremes. The medical device resulting from the PDP falls somewhere in between the extremes as well. There are several customization options for the Mede, but on the other hand the time to market is long and manufacturing has to be process oriented due to the strict regulations.

The studied niche differentiators used Real Time-In-Process Feedback and In-Process Off-Line Feedback tools to react quickly to the troubles with new products, which are common in that kind of production. In addition they used many Zero Defects-mechanisms to prevent failures from occurring, which suites well to a complex process environment. High volume cost leaders on the other hand relied more on Overall-Process Off-Line Feedback tools which do not give that detailed level information as In-Process Off-Line Feedback tools and used more Formalized New Product Introduction Processes. (Sousa 2000)

3.3.2 Supplier Quality Management in Very High Volume Production

The volume of the production, which corresponds to the manufacturing strategy, has its effects to supplier quality management in practice. For example in mobile phone manufacturing, where the volumes are very high, there are more prototype builds of

the components, and the builds are also bigger. It gives more statistically valid information about the quality development between the proto builds and about the yields that can be expected in mass production.

The sections of Production Part Approval Process (PPAP) are generally used especially in car manufacturing companies and their suppliers. PPAP includes partially the same tools and methods as the Q-CAP, which is described in section 5.2. Additionally PPAP includes material performance test results records, appearance approval report, use of Statistical Process Control (SPC) and Out-going Quality Control (OQC) practices in volume production. For example according to Noviyarsi's study (2005) about quality engineering in Malaysian automotive suppliers the most commonly used quality techniques in those companies were parts of PPAP; Failure Mode and Effect Analysis (FMEA), Process Capability Analysis, SPC, benchmarking and cost of quality, and some basic methods such as mind mapping, brainstorming etc. Although PPAP was not mentioned in that study, it appears that if any tools are used, mainly the same tools and techniques are used in different companies and countries.

3.3.3 Supplier Quality Management in Smaller Volume Production

Some of the typical tools in the small volume production are certificates of conformity, supplier audits, supplier corrective action requests for defected material, prototype build reporting, product change management between different series, setup checklists and out-of-control plan.

When the volumes are low, it may be economical for the supplier to produce big lots at a time. Especially if they do not follow Lean-manufacturing principles the big stock decreases slowly. If there are defected items in that big stock, it can produce quality problems for long time, although the root cause has been corrected.

With small series it is difficult to get very good estimate about the quality of the purchased parts. One isolated defect can cause big DPPM-numbers and thus make the situation with a supplier appear worse than it actually is. On the contrary, one

large purchased lot of simple good quality items, e.g. screws improve the average DPPM-metrics at the manufacturing site level.

Many quality tools exist, but using all of those is not very reasonable with low volumes, because the implementation may be time consuming and expensive, but still not adequate to reduce the number of defects.

The relatively low volumes of the full production series may also have impact to the supplier's attitude. It might decrease some suppliers' willingness to begin to use any quality tools or start quality improvement programs that require documentation or special arrangements for one customer.

3.3.4 Challenges with Improving the Supplier's Quality Performance

One part of this study was to get some important suppliers to better understand the general importance of good quality of supplied items. Implementing Total Quality Management should be the long-term target for the case suppliers. TQM emphasizes the importance of every worker's efforts in every branch and at every level in the organization for continuous improvement and paying attention to quality improvement activities instead of only quality organization taking care of those (Dale et al. 1999, Gonzáles-Benito et al. 2001).

The supplier's willingness to improve the quality of its products can be expected to have a major effect on how well it implements the quality tools and how useful those appear. The willingness can originate from inside the supplier's organization. In that case the supplier probably sees that there is a possibility to improve their processes systematically with long-term improvement programs which are expected to create savings in its own manufacturing. The motivator could also be external, for example keeping the customer happy by fulfilling their requirements, but without real commitment and trust to preventive quality management and hence continue carrying out the high level of inspections (Gonzáles-Benito et al. 2001).

Some smaller companies may have so light organization that they do not have skilled personnel or otherwise resources to start using quality tools that may require much more time from the workers and quality managers than they are used to. That in turn would reflect to the purchasing prices of the items and the small company could lose its advantage on the market. To prevent that, efforts would be needed to help them recognize the benefits of the implementation.

A desirable win-win situation occurs if the customer can share its experience about process and quality management with the supplier who can provide knowledge to the customer about the materials and technology in the area of its expertise. Fynes et al. (2004) conclude learning from each other to even deeper level: "— both buyers and suppliers may learn new ways of learning from each other." In contrary, pushing a distant supplier to use time consuming quality management tools can even do harm to the relationship if the supplier feels that it does not get any advantage from using those tools. Although it is said that the customer is the king in business, "— one should recognize that not all kingdoms are of equal importance or influence." (Lamprecht 2000). This can happen if the customer has treated the supplier improperly in the past or the customer's business is small to the supplier.

On the other hand the use of the tools should not be the main purpose. The easier the tools are to use the easier is the implementation of the tools and the cheaper it is to the parties. Usually people get used to following certain procedures, computer programs, and tools after using those a few times. Nowadays the amount of documentation required has grown so much, especially in the medical device industry that all the 'extra' work should require as little time as possible. The training to use the tools is also important to guarantee good results for both the company and its vendor (Lamprecht 2000).

If the supplier does not see the advantages of the quality tools and wants to increase the price of the purchased parts, then the following methods can be tried: Showing quality statistics from previous products, Cost Of Poor Quality (COPQ)-calculations, benefit sharing (González-Benito 2001) and giving opportunities for long-term partnership and bigger business, if quality and co-operation has been satisfactory.

One study (Lai et al. 2005) states that relationship stability is positively linked to supplier's commitment to quality improvement. Furthermore, if the supplier understands the requirements of the final product that are related to patient safety, it can motivate them.

3.4 Co-operation

The following sections discusses co-operation in purchased material quality management between supplier and buyer companies and also between the organizations in the buyer company.

3.4.1 Co-operation with the Suppliers

Increased interdependence between buyers and vendors has created needs to develop supplier-customer partnerships in today's manufacturing business, whereas the old way, where the customer commanded and the supplier obeyed, is losing its popularity (Trent et al. 1999, Gryna 2001). It can be supposed that good relations with suppliers increase the possibilities to prevent and correct many problems during a PDP and later when the product is released to the markets. The suppliers that have highly critical items, and which cause high total expenditure to the customer, should be in a focus of sourcing functions strategic improvements, and collaboration with them should be arranged (Juran et al. 1998).

The term relationship can be divided into several components. Trust, communication and information exchange, co-operation, risk/reward sharing, commitment, power/dependence and adaptation are dimensions of a relationship that could be developed with the supplier (Seppälä 2001, Fynes et al. 2005).

3.4.2 Co-operation between Sourcing, Supplier Quality, and R&D

To really make the implementation and the use of quality management tools convenient and productive, good relationships and open communication channels between different functions inside the company are essential. Management's support is considered important for successful quality program (Noviyarsi 2005). Therefore

when there is more than one function affecting the PDP, only the sourcing manager's support is not enough.

In addition a few good prototypes might be a result of careful fine-tuning at the supplier's side and thus poorly represent a mass production component. The PDP team and Sourcing leaders respectively may resist very heavy quality efforts made by the supplier, because it could raise prototype and purchasing prices. Good knowledge of the supplier's processes is therefore useful, and sourcing and R&D functions in the company do not necessarily share a common understanding about the supplier's processes with the SQEs.

Therefore it can be expected that resistance to change will be faced in most of the quality improvement projects from both the R&D function and suppliers. Especially the PDP team's designer's enthusiasm to use resource requiring QM tools may not always be so high as sourcing quality engineers would like it to be. The designers easily feel that it slows down the product development process too much or it does not add any value to the project.

3.5 Purchased Material Quality Management during the Project

Most of the decisions made during the design and prototyping stage of the project will affect the quality of the product during its lifetime. After the prototyping is finished, first test and pilot series are done. Pilot series give some understanding about the problems that may occur at the suppliers manufacturing processes in mass production. The transition from pilot to mass production includes agreeing how quality controls will be continued after the pilot builds.

3.5.1 Design and Prototyping Phases

In the design phase many major decisions related to the success of the product are made. The costs related to the lifecycle of the product, it's ability to meet the specifications and the time needed for product ramp up are highly dependent on the

design phase decisions (Gryna 2001). From quality perspective, the supplier's ability to produce exactly such parts as the designers have planned is important. Supplier's early involvement in the project can help to get better understanding about the properties of different materials and technologies of the supplied components. Competent suppliers know probably very well what is possible to do in their area of expertise and can help to design the part most reliable, easiest and cheapest way (Gryna 2001, Petersen et al. 2005). Giving responsibility to the design for the supplier was shown (Petersen et al. 2005) to affect positively to product development team's effectiveness 'with the right suppliers'. Primo's and Amundson's research (2002) indicated that supplier involvement in to new product development brought remarkable benefits in product quality, because the supplier is then able to affect many design aspects.

Tracking the improvement of the quality of the prototypes already from the first series to the actual production series gives good possibilities to investigate and prevent problems early enough, before repairing of those becomes very difficult and expensive.

3.5.2 From Pilot Phase to Mass Production

Usually it's estimated that the long-term capability of a process is noticeably worse than the short-term capability (iSixSigma 2008). This is because the supplier's pilot production lot represents the supplier's capability on short-time view, or even the capability of one single work shift at supplier's factory. When the operator changes or the machine setups are fine-tuned, it most probably has at least a small effect to the process capability. Therefore the long-term, actual capability can be estimated only roughly based on the pilot series.

3.5.3 Testing and Inspection as Part of Quality Control

Defect detection methods like testing and inspection, are not ways to improve product quality, but to highlight when poor quality is present. It should be noted that testing and inspection might fail to identify poor quality (Dale et al.1999). However detection methods are still used to decrease customer dissatisfaction.

To improve cost-effectiveness, inspection, testing, or measurement of a particular item should be done as few times as possible, as every check costs. Different parts have different criticality, and it is not cost-effective or useful to inspect all simple standard components. If sampling is used, there is always risk of accepting a defected lot or rejecting good lots (Juran et al. 1998).

To make the process simpler for the customer, the suppliers should make the inspections totally, and incoming inspection at the customer should be minimized, or at least be based on sampling.

4 Problems

The quality levels of the current items and suppliers are presented in section 4.1 to give a view about the purchased material quality and section 4.2 describes the quality management methods in use before the study was started. Section 4.3 discusses the problems of poor communication about the prototypes with the suppliers, and the unclear requirements for the visual quality.

4.1 Background Quality Data

Reference statistics for this study were taken from all purchased components in the site, and in addition from one previous model of the product. First pass yield (FPY), contributors to FPY, and defect levels of the purchased components of the current model were investigated to help focusing the scope of the study.

4.1.1 First Pass Yield of the Current Model of the Product

FPY in the final testing of the current model of the product has been mainly less than 90% after the product launch in summer 2004, as shown in the figure 4.1. The target for FPY of this new product was set to be >90% in the pilot series, and >95% for full production. The FPY data does not take into account the component defects that are noticed in the incoming inspection and during the assembly process, it only shows the FPY of final testing.

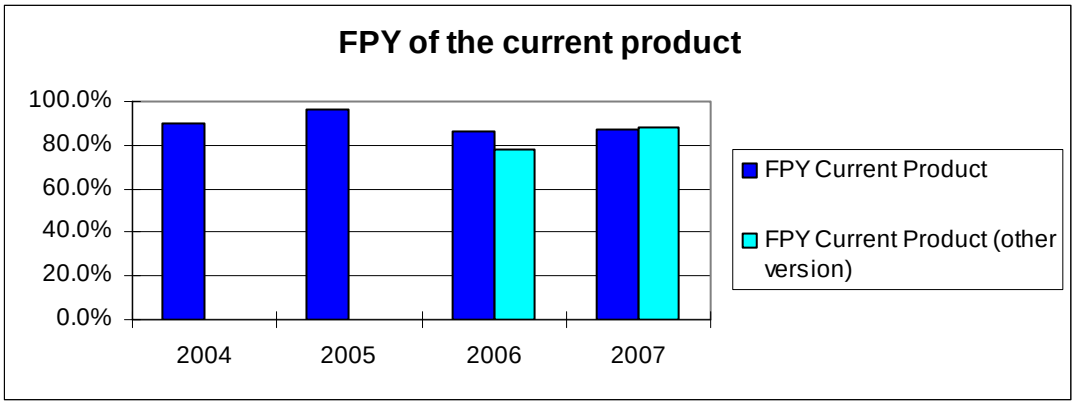

Figure 4.1. First Pass Yield and manufacturing quantities of the current model of the product, and its version having special options.

Purchased material quality of the old product was estimated in section 1.1 based on the DPPM levels of the components. As shown in figure 3.1, the quality of purchased material affects finally the first pass yield of the whole product. For the current model of the product, approximately 35-40 % of the defects found in the final testing during 2006-2007 were based on different failures with the purchased material as shown in figure 4.2. This means that part of the components has not been caught in either incoming inspection or assembly, but they are caught in the final testing.

Based on that 35-40% of component related problems in final testing, and the high DPPM of the purchased components shown in figure 1.1, it can be concluded that the purchased material is one of the most important sources of the quality problems in the manufacturing of the old product in Potmor's Helsinki site.

Because there are many factors affecting FPY of the product, FPY is not a sufficiently reliable metric to measure suppliers' quality performance. Therefore this study focuses only to inspect the improvement of the quality of the purchased material, and assembly and testing in Potmor are excluded from this study. Thus DPPM values of the components are better background data for this study than FPY information.

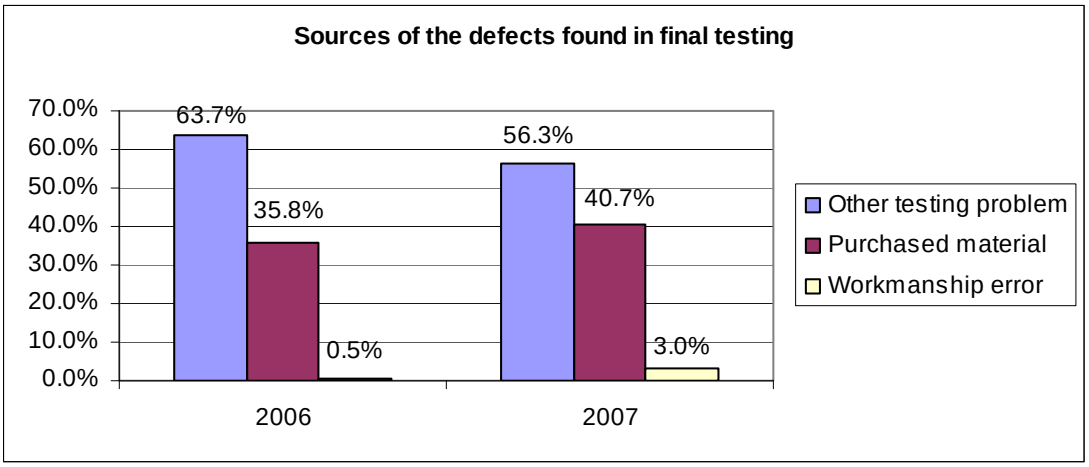

Figure 4.2. Sources of the defects that have been found in the final testing of the current model of the product.

4.1.2 Defective Parts Per Million in the Old products

DPPM statistics on the supplier level and the item code level give better view to supplier related problems than FPY, which is affected by many other factors. A target for supplier defect levels in Potmor's sourcing function in mass production is currently 5 on the sigma scale, which corresponds to ca. 232 DPPM or yield 99.97674%. That value includes defects found in incoming inspection, manufacturing, and field. During last years the average DPPM value for all products in Potmor have been much above that, as shown in figure 4.3. In August 2006 there was one very big defective lot of items, which raised the DPPM so high. Also for the current model of the product, the DPPM values were clearly over 232 during January 2006 – September 2007 as was shown in figure 1.1.

Figure 4.4 shows the DPPM statistics in supplier level in the old product. Nearly all of the defects are caused by six of the suppliers of the old model during 2006-2007. Earlier data was not available, because the reporting process started in the current form in autumn 2005. The DPPM values above consist of the defects in purchased items found in incoming inspection, manufacturing, and at customers.

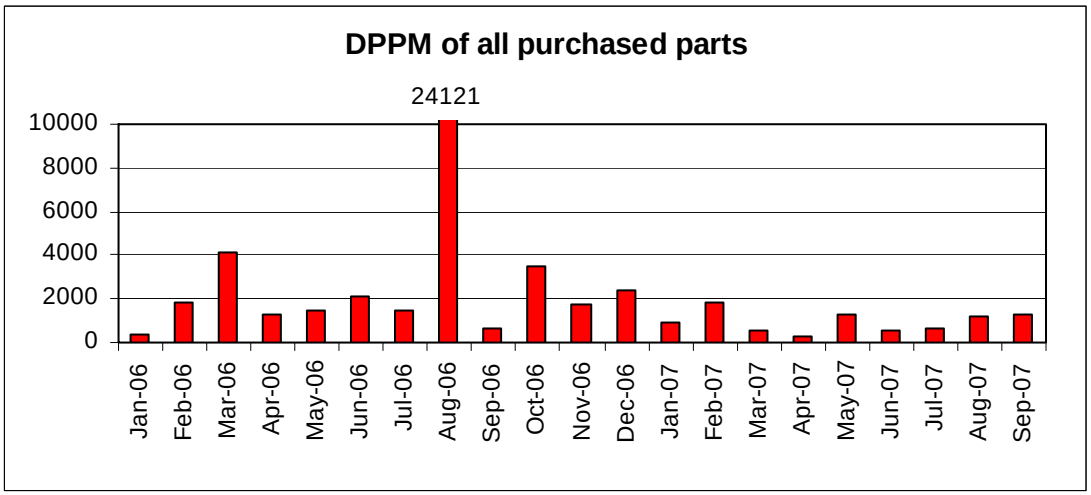

Figure 4.3. Average DPPM for all purchased parts during January 2006-September 2007.

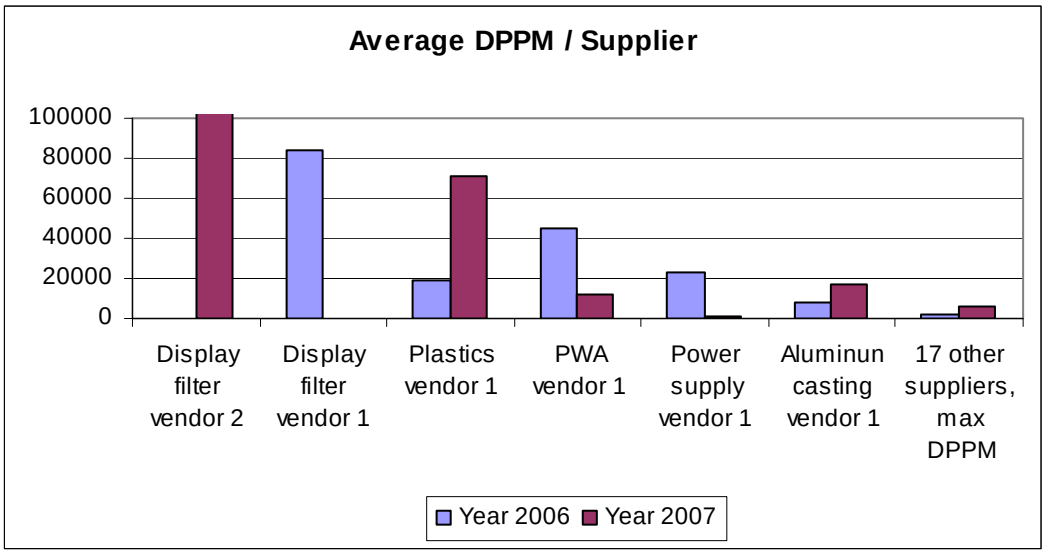

Figure 4.4. Worst suppliers in the old form of Mede during January 2006 - September 2007.

Based on figure 4.4 it can also be stated that there is no need to make heavy quality control actions with all the suppliers of the product, but effective actions with the worst ones. Figure 4.5 shows the components that have been the most defective during 2006-2007. According to that figure, the biggest quality problems of the components of the old product have been with Printed Wire Assemblies (PWAs), custom mechanical parts, display filter and power supplies.

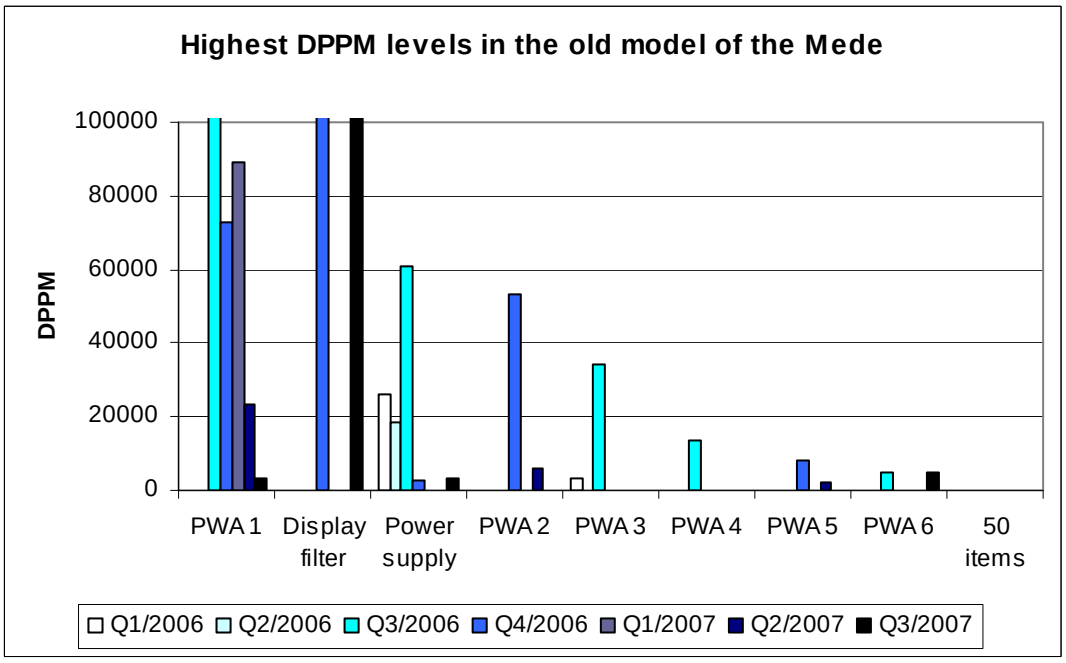

Figure 4.5. Highest DPPM values for the old form of Mede during 2006-2007 for the most defective components of the product.

The complaint analysis that the project has done for the previous products showed that especially power supply units had many failures during the use of the products, but defected units had not been caught in the testing of the whole product, before shipping to the customers. That makes the problem difficult to remove by only inspecting. For any other components there have not been any remarkable quality problems in the old product.

The DPPM values and defected material reports shown only by themselves do not present the real quality level of the components of the product, because some of the defects were actually by Potmor's own mistakes, for instance with the product documentations. However, this data were investigated in depth, and documentation related problems did not have remarkable effect on the data with the problematic items. Hence, there are quality problems with those items in the old product, which may appear in this new product as well.

4.2 Supplier Quality Management Practices used earlier an this Site

According to previous project managers and sourcing personnel, the Helsinki site had not previously used many tools systematically with suppliers previously in PDPs, and neither had the suppliers been very actively suggesting using such tools. An essential part of this study was to find rationales for using and to start using such quality assurance methods during PDPs that would help lowering the defect ratios later in the mass production stage.

There are many kinds of quality management tools and procedures that are commonly used in companies worldwide. Usually all of those cannot be used or there is no need or resources to use all tools with many suppliers in a particular product development project. Using heavy QM tools are not necessarily the best way to control the quality of some low volume parts that are not critical to the functionality of the device and thus do not affect patient safety, if the time and effort needed are considered higher than the few defects during the lifetime of the product would cause.

4.2.1 In Design and Prototyping

As mentioned earlier, there had not been well-documented and organized quality control procedures of methods in use with the suppliers earlier; the suppliers rather trust their professional workers, who are said to know what they are doing. Only some accessory suppliers have been requested to provide process control plan describing their manufacturing process.

With the Printed Wire Assembly supplier that is used in this project, the prototype feedback communication had been earlier mainly verbal or through e-mails and the supplier had filled simple feedback reports. The supplier had filled a simple feedback form and listed, if some failures or notifications had been made during the manufacturing process and sent it to the electronics designers of the PDP team. The supplier had not reported all the problems they had faced during the prototype manufacturing, only the major ones. On the other side, the electronics designers had been calling or emailing their notes about the received proto builds to the supplier representative. Sourcing leaders or supplier quality engineers had not been much informed about the challenges during the prototype manufacturing either. The designers were not required to formally document their responses to supplier's feedback. Therefore some of the feedback may have been forgotten. The reports had not been gathered anywhere except on the individual designers computers.

Although the form was quick to fill and that kind of communication does not need much efforts, the feedback did not always include all the necessary information. Objective history data about the proto builds was very difficult to find, and no formal evidence about corrective actions or quality improvement between the proto builds existed. Some years ago the PDP-teams were not even very interested in how well the prototype manufacturing succeeded at this particular PWA supplier.

Mechanics designers had not documented their findings on test run parts to any database earlier, only to simple files that has been sent to the supplier. Based on those files the suppliers were requested to make corrections to the moulds or tools and to their manufacturing processes. There had often been need for repairing the

mould although the defects in the test parts had been clearly shown to the mould supplier. After the mould was ready, a new mould approval review template was completed. Its purpose had been to confirm that the parts have met the requirements.

In mechanical parts drawings there have been marked normal dimensions, specifically tolerated dimensions, and the dimensions that were followed with a special attention, when the designers had inspected the lots from the test moldings. Measurements or dimensions specifically related to suppliers' process monitoring had not been marked to the specifications.

4.2.2 In the Beginning of Mass Production

Currently all the new or somehow changed items are verified in Potmor based on a small sample lot to confirm that they meet the specifications, but based on it, the long-term capability of the supplier's manufacturing process cannot be estimated reliably.

Qualification audits are sometimes done to specific kinds of suppliers when the production of new part is planned to ramp up or the part has been transferred to another manufacturing site. However, in those audits no systematical capability studies had been done to the supplier's manufacturing process.

4.2.3 During the Mass Production

One part of everyday supplier quality management in Potmor is reporting about defected material to the suppliers. The defects may appear in incoming inspection, manufacturing or as complaints from customers. If the defect is considered to be enough severe or to be a repeating problem, then corrective actions are required for the suppliers, otherwise only notification of the defect is sent and a credit note is requested from the supplier. At the time of this study, Potmor's SQEs had started to request responses for the severest reclamations on so called eight disciplines (8D)-form. 8D is a problem solving method consisting of 8 steps, which focuses on both short-term firefighting and long-term correction (ASQ 2007).

In addition, the suppliers are tracked based on the DPPM level of their parts. The supplier quality engineer will study if the supplier's DPPM hits a predefined trigger level to evaluate, if a root cause investigation has to be started. The quality problems that endanger production cause many actions from supplier and SQE. The procedures and work instructions include also other actions tasks, including auditing supplier, and confirming that certain types of suppliers have particular ISO-certifications. Surveillance audits are done for certain types of suppliers, but those do not apply the suppliers of this project.

There had not been organized quality reviews regularly with the Helsinki site's key suppliers for a few years before the start of this study, but the quality reviews were started again during this study.

4.3 The Need for Feedback from Prototyping

4.3.1 Background to the Problem

Getting precise feedback from and to the suppliers regarding the manufacturability of the items was seen as an essential area of improvement in Potmor and the suppliers. That feedback in turn should reflect the design of the components.

One problem with some older products that had been noticed in Potmor was that the quality of the prototypes had been better than the actual products. It was said to be one origin for long lasting quality problems later in Potmor's manufacturing. The consequences have not been totally solvable and have caused lots of costs during the years. Making changes to the purchased parts requires nowadays a lot of documentation and other work, and sometimes the changes are not done because of that, especially in the old products. Also giving feedback to supplier is important in order for them to develop their manufacturing processes. Long-term development action needs with the suppliers can be more easily focused, if there is good data about the issues during the prototyping.

One obvious reason for the serial manufacturing parts being sometimes worse than the prototypes is that the prototypes do not necessarily pass the normal manufacturing process at the supplier's plant. The prototypes can sometimes be manufactured with different machines than the actual series. The supplier can also make more careful inspection to those and pick up the best parts of the lot it has produced to be sent to the PDP team. In addition the supplier may make some special repairing and processing to the prototype parts. These are methods the supplier might use to give Potmor a perception of good quality. The purpose of the "prototype enhancement" may be to keep the position as the supplier of those particular parts for the project, avoid heavy improvement processes in suppliers manufacturing site, or normal custom at the plant.

In the end, making the prototypes seem better than the actual mass production lots as described above, creates costs and troubles to both parties and therefore should be avoided. Establishing common, clear rules already at the beginning of the proto build manufacturing between the parties can be used to avoid problems later.

4.3.2 The Suppliers in the Scope of the Problem

Prototyping plays a big role when it comes down to circuit board or Printed Wire Assemblies (PWAs) and designed mechanical part suppliers. In this Potmor's medical device production both have been typically design items, not standard parts. Most of the mechanical prototypes are made at first with some kind of rapid proto manufacturers, not by the actual supplier. In comparison, the circuit boards are mainly made from the beginning in the supplier's plant and thus the collaboration begins early with those suppliers.

PWAs have a major role in the functionality of such a medical device as the one that will be the outcome of this PDP. Therefore PWA was one of the two major component categories that were considered very important to get good feedback from the prototype series manufacturing. Purchasing prices of PWAs are also remarkably high and thus affect greatly the total price of the product.

Customized mechanical parts affect the visual quality, the durability and the assembly of the device. Those parts were therefore selected to be the second component category that was focused on in this study.

5 Methods

Improving the quality of the purchased material effectively requires various methods, tools and co-operation with the project participants in different phases of a product development project, depending on the type of purchased component.

Section 5.1 discusses ways to divide the variety of the purchased parts in this project to a couple of categories that would require different levels of quality actions, in order to optimize the use of the available resources to focus on the most important components. The following sections discuss and describe some QM-tools that could be used in different stages of this project and states arguments for their usage. The most important of those tools is the Quality Controls Approvals Process (Q-CAP), which is introduced in section 5.2. The prototype feedback report-tool is introduced in section 5.3, and the mass production tools in section 5.4.

5.1 Prioritization of the Quality Management Efforts

The author and the SQEs saw a need for some kind of prioritization tool to assist choosing proper QM-tools to be used with each particular item. A Part Prioritization Log (PPL) is an example of a tool for such purposes. The PPL is used to analyze what the risks or risk levels are related to technology, manufacturing process and sourcing of each part. The outcome of the PPL is the action plan for quality management efforts for all the components of the product. The PPL should be done together with some of the PDP designers, lead designers, sourcing quality engineer(s) and sourcing leader(s). At first the team's task is to evaluate and justify briefly three different risk levels for each part: technology, manufacturing process, and sourcing risk levels.

All the three risks levels mentioned above are estimated for all the parts on a scale 1-4 to avoid extra complexity. By multiplying those three different risk level values, a Risk Priority Number (RPN) is calculated for each part. Depending on the RPN, appropriate actions are planned to all the items. Based on the Pareto principle, also known as the 80/20-rule, approximately 20% of the contributors usually cause 80%

of the problems. The most time requiring quality management actions in the project should concentrate on the worst 20% contributors.

5.2 Quality Controls Approval Process (Q-CAP)

The Quality Controls Approval Process (Q-CAP) is introduced in this section. First, the purpose and the structure of Q-CAP are presented, and then the elements of Q-CAP. It is a relatively new, global process in Potmor, which has not really been used in Potmor's Helsinki site before this project. One of the most important tasks in this study was to analyze the applicability of different sections of Q-CAP to this product development project, its suppliers, and learn about its implementation, in order to optimize its implementation in the following projects.

5.2.1 Purpose and Structure of Q-CAP

The purpose of the Quality Controls Approval Process is to communicate and develop the methods that a supplier would use to manufacture, control and evaluate the parts it will supply to the company, in order to ensure the quality of the components and thus the whole product. As the name says, it's the process, which Potmor uses to approve the quality controls that the supplier will do to ensure the quality of the components provided to Potmor. Q-CAP has many similar components as the Production Part Approval Process (PPAP) that is commonly used in the car industry (Dale 1999). Potmor provides the supplier excel templates with calculation macros for all the Q-CAP elements.

Potmor uses the term Q-CAP for a collection of seven commonly known elements tied together, which are described in more detail in the next sections: Requirements Review, Process Failure Modes and Effects Analysis (PFMEA), Process Control Plan, Gage Repeatability And Reproducibility Evaluation And Validation (Gage R&R), Part Layout Report, Capability Study and Packaging Plan. In Q-CAP the previous element always gives input to the following element.

A well-executed Q-CAP should not only reduce defect rates through development of control plans and measurement, but also increase the supplier's understanding of

product requirements. On the other hand, the designers should learn from the supplier about the manufacturability of the items, and possibly make changes to design according to the suppliers' suggestions. In addition, Q-CAP should improve the supplier's ability to evaluate and fine-tune its own measurement and test systems before the actual production begins. Finally, it should enhance relationship with the suppliers, as identifying and solving problems together requires active and open communication between the parties.

5.2.2 Elements of the Q-CAP

Requirements Review

Q-CAP begins with Requirements Review (RR), which is executed by a cross-functional team that consists of supplier quality engineer, designer(s) and the supplier's representative(s). The team reviews the specifications and the requirements to ensure that there is a common understanding of those. Concerns and potential improvements relative to design, specifications, tolerances, producibility, testing, measurement, or inspection are discussed. Requirements review also includes determining the relevancy of the Q-CAP elements with respect to components and assemblies under review.

As a part of Requirements Review, it's recommended that the supplier would make some kind of Design For Manufacturing (DFM) analysis. DFM is a detailed and structured evaluation of supplier's capabilities to manufacture the item according to the specifications. After the actions that were identified in the review are finished, the manufacturing process can be determined, which is the input for the Process Failure Modes and Effects Analysis (Process FMEA).

Failure Mode and Effect Analysis (FMEA)

There are different kinds of FMEAs that are used generally. In Q-CAP, the Process FMEA (PFMEA) is done after Requirements Review. FMEA can be made for also for the design of the whole product or for an individual component (Design FMEA or DFMEA).

Failure Mode and Effect Analysis (FMEA), also known as Failure Mode, Effect and Criticality Analysis (FMECA), is a systematical method used to examine a product for possible failures that may occur, for instance, in the manufacturing process, or in the design of the product. The examination is done starting from a sub-system level moving up to the system level; e.g what happens if this component or part of the process fails. Then the effects and probabilities of the causes onto the product or system are estimated and the seriousness of the effects are analyzed. After each possible failure is determined, the causes of the possible failure are investigated. Based on those, corrective and preventive actions or controls are planned to minimize the probability and effect of a failure. (Sower et al. 1998, Gryna 2001)

FMEAs should be living documents that are updated whenever new information is available. It's also important to have a capable team containing members from different organizations, when making the FMEA. The FMEA itself does not prevent anything if no control plan and actions are perfomed based on it. One other mistake that can be made is to overestimate the ability of the detection controls. (Resource Engineering, Inc 2008)

Process FMEA in Q-CAP

PFMEA focuses on uncovering failures in the manufacturing process that could impact product quality, reduce process reliability and create environmental or safety problems. In a well-made Q-CAP the supplier starts the Process FMEA to quantify possible failure modes that may happen in its manufacturing process of the part. The PDP designers then estimate what would be the effects and the severity of the failure to the product. After that, the supplier estimates the cause(s) and the frequencies of the failure, and describes current controls to prevent the failure from occurring.

The supplier plans actions against the most probable, severe failures that are not easily detected in the process. Priorities on the actions should be based on the Risk Priority Number (RPN) that consists of the probability, seriousness and probability to detect the failure. For example Pareto Analysis that uses the '80/20 rule' (Juran et al. 1998) could be made to create an action plan for the most important actions. After

the action plan is made and some of the biggest risks mitigated, new RPNs can be estimated, based on how effective the actions are considered to be. After completion, the customer company's supplier quality engineer should review the PFMEA before the supplier should start creating the process control plan.

Control Plan

In the (Process) Control Plan (PCP) the supplier documents how it controls its manufacturing process and reacts to abnormal conditions. The control plan is based on PFMEA findings. It includes all the process steps that PFMEA included, the equipments used at each step, the important quality characteristic, the specifications, the control methods and the control equipments, and the reaction plans if the process is out of control, or if the parts are out of specifications. Supplier quality engineer reviews the Process Control Plan before the evaluation of the supplier's measurement tools and system for repeatability and reproducibility.

Gage Repeatability and Reproducibility (Gage R&R) Evaluation and Validation

Gage R&R evaluation and validation are done to test and validate that the operators, testing and measurement tools at the supplier are capable and effective to be used in quality control. Repeatability means the variation of the measurement tool, when it's used to measure the parameters in the product. Reproducibility describes how much there is variation on the operator's performance.

The parameters that are measured are divided to attribute, i.e. discrete and continuous parameters. Attribute parameters are considered as either acceptable or unacceptable. Continuous parameters are usually used to measure dimensional measures that have some specific tolerances around the target value.

In practice, two or more operators' use the gage to measure or inspect some acceptable, and some unacceptable example items. The measured values are documented on the excel-sheet. The measurement or inspection is repeated at least once to get more information about the repeatability and reproducibility of the

measurement. The different gages and operators should get as similar results as possible related to each other. The results should remain the same also when the measurement or the inspection is repeated.

If the results are not acceptable, i.e. there is too much variation in the total measurement and test process, then gauging improvements, e.g. calibration of the tool, or specification adjustments have to be considered together with the supplier and the project team's supplier quality engineer.

As a side effect, the supplier is hoped to improve its measuring process, if it's not yet on a satisfactory level, and to understand more about the effects of the measuring or inspection process. Good example of a difficult measurement is a visual inspection of scratches on a mechanical part. If it's done by human eye, all the appraisers have their own impression of what kind of scratch is unacceptable and what is acceptable.

After the inspectors and the gauges have been validated for use, Part Layout Report and Capability Studies can be done reliably. It is advisable to perform Gage R&R at periodic intervals during the volume production to guarantee that the measurement system stays reliable. That applies especially when the gauges are maintained, calibrated, or the operators change.

Part Layout Report

The Part Layout Report (PLR) is a first article inspection report used to verify that a five-piece sample conforms to all the specifications that are marked in the drawings. All the measurable parameters are measured and documented for each sample. In other words, PLR verifies that the supplier has understood the requirements for the part, and that the manufacturing process produces such items that had been designed.

The specifications under inspection include notes, material type, regulatory labels, part markings, connector gender and poor fit with mating assemblies. The expectation is that the supplier should give feedback about the specifications. Supplier quality engineer and designer of the project team review the report, communicate the results to the supplier and plan further actions.

As the five-piece sample does not give statistically significant information, PLR is not actually measuring the capability of the manufacturing process. It is estimated in the next element of the Q-CAP, Capability Study.

Capability study

A capability study (cpk-study) is conducted to assure that the variation in the manufacturing process stays within the specification limits. A process capability metric C_{pk} is measured at the capability study. A high C_{pk} indicates that the manufacturing process will consistently produce acceptable items consistently in the mass production stage. It can be used to help the personnel to understand how capable the manufacturing process is, and to determine critical parameters on the control chart (Kwok et al. 1998) if such will be used in the mass production.

If the measured parameters are continuous by nature (Continuous Variable Capability Study), then a minimum of 25-30 samples is recommended. If the parameters are either acceptable or not acceptable (Attribute Variable Capability Study), then a minimum of 30 samples should be measured to get a statistically more significant sample. It's also recommended to have samples from different production lots to address the variation that is present in the manufacturing process.

Continuous Variable Capability Study

If the critical characteristics are measurable on a numerical scale, the supplier carries out a Continuous Variable Capability Study. The C_{pk} is affected by how far the process mean is from the target value and how much there is variation in the process.

$$C_{pk} = \min\{\frac{USL - \mu}{3\sigma}, \frac{\mu - LSL}{3\sigma}\} \qquad (5.1)$$

Where USL and LSL are Upper and Lower Specification Limits, μ is process mean and σ (sigma) is the standard deviation of the process, calculated as follows:

$$\sigma = \sqrt{\frac{\sum_{i=1}^{N}(X_i - \mu)^2}{N}} \qquad (5.2)$$

According to eq. (5.1), C_{pk} represents the scaled distance related to three standard deviations (3σ) between the process mean and the specification limit that is closest to the mean. The process spread is 6σ, which is the expected distance between the highest and lowest values of a characteristic, if normality is assumed. According to the normality assumption about 99,74% of the items will stay in ±3σ around the mean of the process. (Mitra 1998)

The excel sheet also provides the Z-score, which in practice is C_{pk} * 3. Figure 5.1 describes the process capability. The curve in the figure is constructed of individual measurements of the chosen process parameter. The narrower the distribution and closer to the target value is the peak of the curve, the bigger and better are the C_{pk} and the Z-score, and the more capable is the process.

Attribute Variable Capability Study

If the critical variable under investigation cannot be described by a numerical value, but is either acceptable or non-acceptable, then Attribute Variable Capability Study is executed. For example the outcomes of visual inspections are usually approved or rejected by nature. Also if an on/off-jig is used to determine, if the measured parameter is inside the specs, then Attribute Variable Capability Study is carried out.

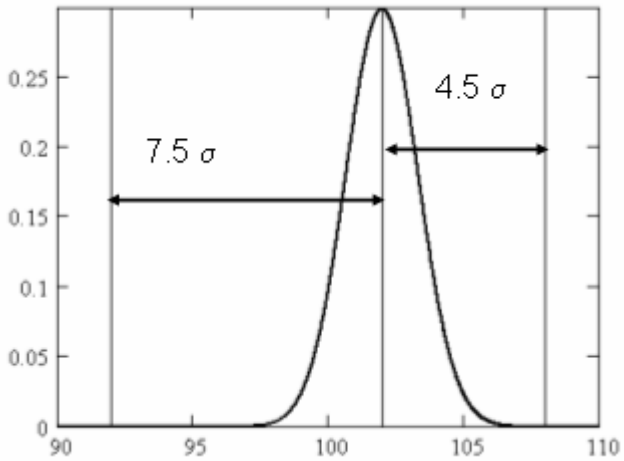

Figure 5.1. A process with a Cpk value 1.5. (USL-μ) = 4.5σ. (Levinson 2008)

The supplier measures the characteristic for the samples and marks on the excel-sheet how many units in the sample were defected, total number of units and number of opportunities for defects in one unit. The excel-form then calculates total number of opportunities, defects per units, defects per opportunities and defects per million opportunities. Based on those values, the excel-form gives the Z bench-score similarly as in Continuous Variable Capability Study. The requirement for Z bench-score is that the measured values can be expected to follow a two-sided normal deviation.

Actions Based on the Capability Study Score

If the Z-score (and thus the C_{pk}-value) in the continuous capability study is lower than the target value, the data have to be investigated with the supplier and the necessary actions agreed to prevent problems in the future. This applies as well, if the measured variable is discrete by its nature, like in the attribute variable capability study.

The first task is to estimate the severity of the defect; in other words how well the specifications and tolerances are met, and what the consequences are for mass production. The reliability of the measurements can be analyzed with a Gage R&R study, which is done before the Cpk-study.

When the severity and consequences of the defect is estimated, the root cause and the origin for the results are investigated. The problem can be for instance in the manufacturing devices, mould, tools, surface treatment, handling, packaging tolerances of the specification etc., or in the combination of some of those. If the root cause cannot be removed, and the results are acceptable, then at least the specifications have to be changed to meet the process capability. Otherwise the company's incoming inspection or manufacturing will return acceptable parts to the supplier.

If the parameter having poor cpk-value is under Statistical Process Control, or will otherwise be detected early enough in the process, further actions may be ignored. However that kind of approach is not representing preventive quality management.

If the root cause is found and the defects are fixed, a new capability study should be executed to confirm its effectiveness. If the results are still unacceptable then the analysis is started again.

Packaging Plan

A packaging plan is required to ensure that the protection of the product is appropriate during the transportation from the supplier to the customer and accepted by both parties. In other words, the packaging must not cause any defects to the product. Potmor has specific packaging guidelines and requirements that have to be fulfilled.

5.2.3 Process Audits as Part of Capability Studies

Supplier quality engineer makes process audits to supplier's manufacturing process, when the capability studies are executed at the supplier. In most of the cases it's done during manufacturing the pilot series of the product. During the process audit, the suppliers manufacturing process is run through beginning from incoming inspection until packing and shipment to the customer.

The purpose is to estimate how capable the supplier's process is to produce good quality components in mass production, and on the other hand to help the supplier to find the areas needing most urgent improvement in their manufacturing process. The audit can be done as a formal audit or as a "free-form" assessment.

5.3 Proto Build Feedback Report

Proto build feedback report forms are meant to track and communicate the issues faced during the prototyping for the PDP. The report tool is based on excel templates, and each purchased item has its own report-file, and the information from

the old builds of the item remains in the file. The purpose and the conclusion of the proto build are documented and the supplier is asked to fill in e.g. the process steps, the process cycle times, the process quality step-by-step, the incoming inspection results, and to list the documentation related to the proto build and any additional comments. The supplier is requested to bring up all the problems they had faced and the defects they had noticed during their prototype production. In addition they can include pictures of the defects for PDP team's approval and comments. The designer has to comment whether the defect can be accepted or not.

The PDP team should also communicate to the supplier about the noticed defects in their inspection and testing of the prototypes on that form. Each defect shall be documented to include the suggestions for corrective actions to prevent the defect to reoccur. It's very important that also the information about defects noticed during the designers' prototyping process goes back to the supplier. The corrective action taker can be the supplier, the PDP team member(s) or both. Using this form should not necessarily replace the communication via phone or emails, but the conclusions of those conversations should be marked down to the report form to ensure that all required information is shared with all the desired members and can be found easily afterwards.

This particular Proto Build Feedback Report-tool had not been used before in Potmor, neither was it part of Q-CAP. The Finnish supplier quality team wished to make its use an optional part of Q-CAP.

5.4 Mass Production Tools

5.4.1 Tools to Ease the Inspections

Some general quality management tools to be prepared before mass production starts are described below: Use of reference samples, appropriate work instructions for the operators, and inspection parameters, devices, and gauges.

Samples

One way to avoid unnecessary rejections in the supply chain is to get common inspection approval criteria accepted between the suppliers, customers design engineers, and incoming inspection before mass production starts. Visual quality control made by humans is challenging to control and requires systematic monitoring (Vesikallio 2006). Therefore inspection environments have to be similar inside the supply chain and use common visual quality criteria in all checkpoints. In addition, samples of the visually critical items have to be submitted to the supplier and to the surface treatment sub-contractor and all of the parties have to accept those. One option is to have one 'golden sample', which is non-defected, one slightly defected, but acceptable, and one defected, which is not acceptable. The samples should be stored in such a place that they will not get damaged, dirty, nor shall the color of the sample change, to remain as valid reference items.

Work Instructions

For critical-to-quality components there should also be written inspection work instructions, with drawings or pictures included, available for all the inspectors in the supply chain. Also a picture of the final product could be used to give the inspectors better understanding about the quality requirements of the single component. Supplier quality engineer's task is to check that the instructions correspondents to the process control plan, which has been done during Q-CAP.

Inspection Parameters, Devices, and Measurement Jigs

Harmonization of the inspection environment at the facilities in the supply chain could help to reduce different opinions about acceptable visual defects. The topics to be checked are e.g. the amount of light, color of the light, possible windows close to the inspection station, and the inspection distance, angles, and time.

For the components that are functionally important, e.g. printed wire assemblies, there have to be calibration and maintenance plans in the control plan for all the testers, inspection devices, and jigs.

Furthermore, all jigs for assembly and inspections have to be created, evaluated, and approved for the use in mass production by SQE, while the supplier's manufacturing process are validated during manufacturing the pilot series.

5.4.2 Statistical Process Control and Inspections

Statistical Process Control (SPC) is commonly used to denote that a process is managed through the use of statistical methods (Dale et al.1999). SPC can be used to estimate statistically how the chosen process variables change from lot to lot with help of control charts (Juran et al. 1998) and to give management information to help with decision making (Dale et al.1999). In practice, certain parameters of the component are measured from a lot to see how well the process stays in within the limits. Based on the control charts it can be estimated, what kind of factors are causing variation in the process, and actions could be planned and performed, if the variation is too high. Thus an Out-of-Control Action Plan (OCAP) should be connected to the control chart, so that the operator would know what to do, if the process is out of control (Kwok et al. 1998). OCAP is actually one part of Q-CAP's control plan, but unless emphasized to the supplier, it may not be utilized well enough.

It's important to point out that SPC does not solve the problems; rather it helps to identify them (Dale et al. 1999). Bunney et al. showed (1997) that management's poor understanding about SPC usage raised high expectations for using only control charts and the impression that SPC itself would create major savings. However the cost savings come from the actions based on the information SPC.

Most of the important suppliers in this project use some kind of Outgoing Quality Control (OQC) to check that the item meets customer's specifications. For some custom mechanical items there will be 100% visual check by the operator, who makes the last action to the item. The supplier determines their incoming and outgoing inspections for mass production in the control plan, which the SQE approves. When there is quality statistics available about the parts, the SQE, the designers, and the supplier can make adjustments to the inspection levels. For some

items there will be sampling based inspection, which can also be connected to SPC. It is more reliable if the inspector is different person than the operator, who has finished the item. The operator may become blind to his/her own mistakes that cause visual defects after making hundreds of similar items. The drawings of the mechanical parts have to include the dimensions that need to be followed with the SPC.

5.4.3 Testing as Part of the Quality Control

Testing in the case companies of this study applies mainly to the Printed Wire Assembly supplier. The supplier has an X-ray inspection machine, In-Circuit-Tester, functional testers and an automatic optical inspection (AOI) machine. Testing of the PWAs is in fact the supplier's measurement method for SPC.

All the PWAs will not go through all those testers and inspections. It has not been considered needed for some of the simpler PWAs, which are not difficult to manufacture nor so critical to patient's safety. Testing naturally increases the price of the PWA. Even though the PWAs have been tested at the supplier in the old model of the product, failures are found all the time in the final testing of the assembled product.

5.4.4 Mass Production Actions

If defect levels at the supplier or at Potmor are perceived to be unacceptable high, then preventive and corrective actions are needed to bring the process back under control. The need for actions can originate for instance on the supplier's SPC charts, on Potmor's supplier DPPM-tracking, or on some other detection method. The root cause for the poor yield has to be found before continuing supply of the parts. Kwok et al. (1998) suggest many different problem-solving methods, including Ishikawa cause-and-effect diagram, Pareto analysis, Design of experiments etc. Changes in the inspection instructions or levels at each party could be considered and if the problems are severe, long-term quality improvement programs with the supplier can be started.

If Q-CAP is executed for a part having high defect level, then Process FMEA and control plans can be a good basis to start problem solving to improve the process. As mentioned earlier, PFMEAs and control plans should be living documents that could be updated when new information about the process has been achieved. To help the quality problem solving in complex supply chains, a supply chain diagram can be done for the most important items.

6 Results

Section 6.1 describes what kind of prototype series were made in this PDP. Section 6.2 presents the quality management tools that were implemented in the PDP. Section 6.3 introduces how the QM tools appeared to affect the quality of the prototype series items. Section 6.4 presents how Potmor and its suppliers prepared their quality management practices for the mass production stage.

6.1 Description of the Proto Series in the Project

The prototypes that were done during this study were different kinds of rapid prototypes for mechanical parts and many small prototype series with the Printed Wire Assembly supplier. After those, all suppliers made some parts for a few manufacturing assisted engineering prototypes (MAEP) series called MAEP1, MAEP2a, MAEP2b, and MAEP3. The manufacturing verification process (MVP) series was not included in this thesis. The lot sizes of the prototype series were counted in tens or in few hundreds.

For plastic parts, the first series that was affected by this study was the first batch from the moulds and that lot was also used in the MAEP prototypes. After that the mould supplier modified the moulds based on the feedback from Potmor. The mould supplier is a sub-supplier for Potmor. After MAEP3 the biggest modifications had been made, the moulds were moved to the plastic part supplier, who started to improve the quality of the parts by adjusting the molding parameters. Thus there will not be very many test series with the mass production equipment before the actual production series, except for some special parts.

The light-metal casting, sheet metal and PWA suppliers manufactured the MAEP series with the mass production equipments except the mould supplier die-casted the light-metal parts for MAEP1.

The parts for the MAEP Builds of the new product were functionally tested by manufacturing and/or engineering depending on the build. The builds were used for

product development, product verification, manufacturing process development, and marketing purposes. For some parts, like printed wire assemblies some proto builds were made before MAEP series. MAEP3 builds were fully functionally tested by manufacturing and used for manufacturing validation. The MVP, which is not included to this thesis, will simulate full production, and all the suppliers are supposed to manufacture, inspect, and test the MVP series with the final machines and techniques.

6.2 Quality Management Tools Implementation in the Project

The applicability of the different quality tools depends on the volumes and the type of manufacturing (batch, line, process manufacturing etc.) and the industry. The manufacturing at the Helsinki site is relatively low volume and supplier quality management differs from 'real high volume production', where the SQEs had most experience. It was noticed during this project that the case suppliers were not so familiar with the QM tools as the high volume production suppliers had been.

The following tools and techniques were implemented during the Product Development Project before the end of this study: Part Prioritization Log (PPL), Quality Controls Approval Process (Q-CAP), and proto build feedback report. The use of those is presented in this section.

6.2.1 Part Prioritization Log

With the help of Part Prioritization Log (PPL), Quality tools were focused to the critical to quality parts. PPL helped to understand which quality tools should be used with which assembly and wit the individual parts that belong to that assembly. Later the PPL was used to track the progress of the quality tools implementation, which took considerable effort due to great quantity of the components and the long intervals between the proto builds.

For quality tool usage, the parts were divided to three different categories. The lowest category was the standard-category. It included all simple screws, off-the-self-components, items that the supplier has totally designed according to PDP team's specifications, and items that are considered very easy to manufacture. The second category was called Part Layout Report (PLR), according to the one component of Q-CAP. For the PLR parts the supplier measured or confirmed most of the specifications of the drawings for five items, and requested feedback from the PDP team. The strictest category was Q-CAP + build report, which meant that Q-CAP would be executed, and Proto Build Feedback form used.

The designers and supplier quality engineers had some experience-based knowledge of suppliers and parts that had been problematic during the lifetime of the previous, similar devices. In addition to that, part yield statistics from the old product was used as a support data to determine the parts and suppliers that would cause most of the problems. That data is shown in figure 6.1. Unfortunately there was only two-year yield history for purchased parts available, so the quality problems that occurred earlier, immediately after the launch of the preceding product, cannot be learned from.

Table 6.2 shows DPPM data from years 2006 and 2007 for the suppliers that have Q-CAP-parts in this PDP. As the plastic parts are sourced from a new supplier in this project, another supplier for plastics is used as a reference. Light-metal casting and plastics suppliers had had so high general defect rates that actions were necessary. Although the PWA supplier's DPPM rates are not that high, the PWAs are very critical to the function of the whole device, thus the PWA supplier was chosen to be one case company in this study. Painting suppliers are sub-suppliers for plastics and light-metal suppliers and therefore their DPPM contributions could not be estimated for the old product.

Supplier	Item	Received	Defects	DPPM
Plastics supplier 1	Plastics part 1	41	69	1682927
Plastics supplier 1	Plastics part 2	600	300	500000
Display Filter supplier 2	Display Filter	2434	343	140920
Plastics supplier 1	Plastics part 3	3994	462	115674
Display Filter supplier 1	Display Filter	2000	168	84000
PWA supplier 1	PWA 1	3386	234	69108
Plastics supplier 1	Plastics part 4	240	15	62500
Fab&Mach supplier 1	Metal part 1	3980	124	31156
Fab&Mach supplier 1	Metal part 2	3532	54	15289
Fab&Mach supplier 2	Metal part 3	3831	29	7570
PWA supplier 2	PWA 2	3722	27	7254
Plastics Supplier 2	Plastics part 5	3402	17	4997
PWA supplier 2	PWA 3	3708	10	2697
Plastics supplier 2	Plastics part 5	4109	8	1947
Plastics supplier 2	Plastics part 5	4000	6	1500
PWA supplier 2	PWA 4	3456	4	1157
PWA supplier 2	PWA 5	3622	4	1104
PWA supplier 2	PWA 6	3688	4	1085
Display supplier	Display	4081	4	980
Power supply supplier 2	Battery	8100	5	617
Fab&Mach supplier 1	Metal part 4	3690	2	542
Plastics supplier 3	Plastics part 5	5700	3	526
Power supply supplier 1	Power	3865	2	517
Fab&Mach supplier 3	Metal part 5	3257	1	307
PWA supplier 1	PWA 7	3510	1	285
PWA supplier 2	PWA 8	3564	1	281
Many suppliers	Other parts	337004	0	0

Table 6.1. Average DPPM statistics from January 2006 to September 2007 used as a base for the Part Prioritization Log. Yellow color used to show the parts over 10000 DPPM.

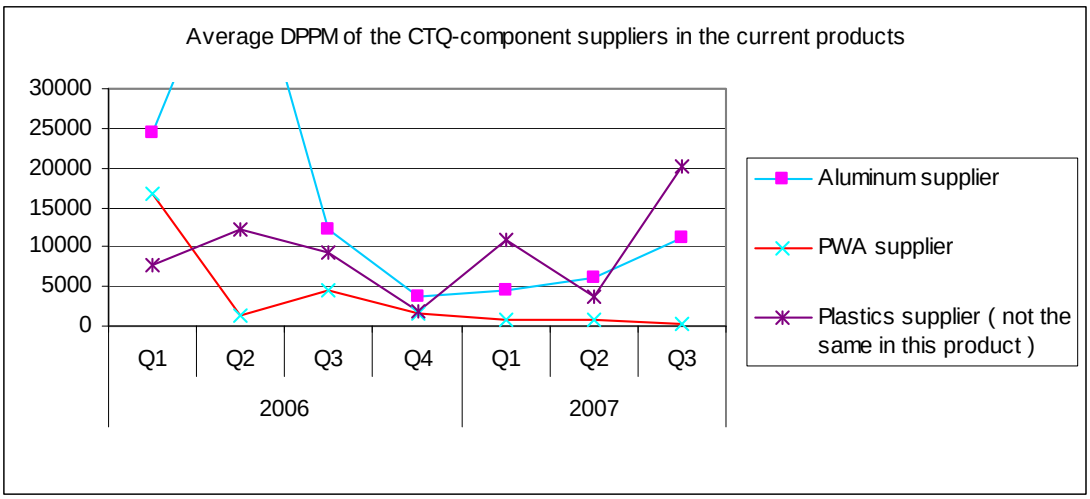

Figure 6.2. Average DPPM levels from January 2006 to September 2007 for the suppliers that have Q-CAP-parts in this PDP. As the plastic parts are sourced from a new supplier, another supplier for plastics is used as a reference.

Table 6.3 shows the applied quality tools and the part groups. The red fields were not finished this study was completed. Process audits, SPC, and VQII are here considered to affect all items of the supplier. The "*"-sign means that the Requirements reviews were not documented, but done more or less informally and verbally during the project. The suppliers assembled many individual plastic and light-metal parts to a sub-assembly, which they shipped to Potmor. Those are noted as "in assy" in table 6.3. All the individual parts were not included in the sub-assemblies, and are not noted in table 6.3.

The biggest challenge regarding the PPL was the application of the quality tools to the units assembled by a supplier. In some cases the assembler was different supplier than the manufacturer of the part, and with some parts the painting supplier gave their input to Q-CAPs and proto build feedback report. Because the number of the items was so large, a logistics diagram parts was created (Appendix I) for some suppliers to clarify the supply chain. It included also the quality action category for each part.

	Q-CAP												
Supplier / QM tool	**RR**	**PFC**	**PFMEA**	**CP**	**GR&R**	**PLR**	**A.Cpk**	**C.Cpk**	**PP**	**Proto report**	**PA**	**SPC**	**VQII**
PWA	4/10	4/10	4/10	4/10	4/10	4/10	4/10	1/10	-	10/10	yes	yes	-
Plastics assemblies	*	5/7	5/7	5/7	yes	7/7	?/7	5/7	7/7	7/7	yes	yes	yes
Plastics individual parts	*	in assy	in assy	in assy	yes	28/51	in assy	in assy	in assy	51/51	yes	yes	yes
Painting of plastics	*	-	5/5	5/5	later	-	?/5	-	-	5/5	-	-	yes
Aluminum assemblies	2/2	-	2/2	-	-	-	-	2/2	2/2	2/2	yes	yes	yes
Aluminum individual parts	6/7	6/7	-	6/7	later	7/7	-	-	-	7/7	yes	yes	yes
Painting of aluminum	*	-	1/1	1/1	-	-	-	-	-	1/1	-	-	yes
Sheet metal	-	-	-	-	-	8/8	-	-	-	3/8	yes	yes	yes

Table 6.3. Implementation of the quality tools in this PDP. RR stands for Requirements review, PFC for Process flow chart, CP for Control plan, GR&R for Gage R&R, A.Cpk for Attribute variable capability study, C.Cpk for Continuous variable capability study, PP for Packaging Plan, PA for Process audit, and VQII for general level Visual quality inspection instructions. The table data shows the total number of the parts in each group, and the number of parts in that group to which the each Q-CAP components and the proto build report was applied.

The quantities of components in each category were after manufacturing of MAEP3 series more than 70 in the standard-category, 36 in the Part Layout Report-category including 7 parts in PLR assemblies, and 37 in the Q-CAP-category including 24 parts that belonged to Q-CAP assemblies. However these quantities do not match exactly with the ones in figure 6.3, because of the different implementations of the Q-CAPs with the suppliers. A more detailed description is presented in the next section. Proto build report was used with all of the PWAs, plastic, and light-metal parts and with some of the sheet metal parts.

There were some minor changes to the PPL during the designing and prototyping process. One reason was that the designers did not fully understand the meaning of Part Layout Report in the beginning, and the supplier quality team did not have a clear vision how to implement PLR with some of the suppliers. Some of the PLR-parts did not have reasonable parameters to be measured. Additionally, some components turned out to be pure off-the-self or only slightly modified standard items for which no QM actions were carried out.

6.2.2 Quality Controls Approval Process

There was some challenge to agree with the two SQEs how and when to implement different sections of Q-CAP and the proto build feedback form in this project. Some reasons for the difficulties were that this was in practice the first PDP to use those tools in Potmor's Helsinki site. It had been used only once in a small transfer project of some injection molded plastic parts, and that particular supplier had used similar tools before. Most of the case suppliers in this PDP were not familiar with Q-CAP or prototype reporting. Also the practices that the SQEs had learned from very high volume production industry were not always reasonable to be implemented in this environment.

Q-CAP was finally carried out with three 1st-tier suppliers, and two of their sub-suppliers. The suppliers, with whom Q-CAPs were implemented for some of their items, were the PWA-, the custom plastics-, the custom light-metal-casting supplier, and the sub-supplier that provided painting for the plastics and light-metal suppliers'

parts. In addition to those Q-CAP-suppliers, the sheet metal supplier had Part Layout Report-items.

There were no major changes or cancellations to the plans for the supplier quality management created in the beginning of this study. With the case suppliers most of the actions were completed as planned. The following exceptions were based mainly on the focusing of the available resources.

A few critical-to-function components that were categorized as Q-CAP-components or part layout report components in the beginning were left out from the study scope. Those items were more or less standard components for the suppliers who made similar products with much higher volumes to their other customers. It was decided to rely on the supplier's normal quality management processes. No defects were found in the prototypes of these items, which supported leaving out further quality actions with those suppliers.

With one foreign supplier the Q-CAP was not implemented although it was started with them. Their product was challenging to manufacture, affected the visual appearance of Mede and therefore chosen as Q-CAP-part. Problems were noticed, when the MAEP series arrived and the quality of those parts was poorer than the previously sent prototype pieces. After the project's other SQE visited the sub-supplier in Asia, he decided to cancel the Q-CAP. The specifications were changed to meet the capabilities of the supplier to avoid low yield in volume production. Achieving the desired quality level according to the previous specifications would have needed too much effort from the SQEs. The quality level was satisfactory for the prototypes that were done based on the new specifications.

Q-CAPs with the Light-metal Casting Supplier

Situation at the Beginning of this Project

Potmor had a long history with this ISO 9001-certfied supplier. There had been some quality problems with this supplier during last years. Not all the quality problems were directly the supplier's or their sub-supplier's fault, but Potmor's specifications

for the items have sometimes been insufficient. The average DPPM-levels for this supplier are shown in figure 6.2. Based on that quality data, the light-metal casting supplier's quality had to be improved. The supplier agreed that there is need for identifying the problems early in the prototyping phase and was motivated to co-operate.

Their quality manager already knew process flow chart and to some extent PFMEA and control plan, although he had not used those much earlier. He was not familiar with Gage R&R, capability studies, and this kind of prototype report, but he showed a lot of interest in learning Q-CAP and proto build report and was willing to try those in this project. The supplier's team was not requested to make any actions yet in this stage, but to familiarize themselves with the Q-CAP learning material.

Q-CAP Implementation Process with the Light-metal Casting Supplier

Table 6.4 presents the timing of the Q-CAP activities with the light-metal supplier. All Q-CAP elements except Gage R&R and cpk-study were performed with the light-metal supplier during this study. Table 6.3 shows how the quality tools were applied to the individual parts and to the assemblies.

The supplier's factory was visited at the time of MAEP1 series and the Q-CAP implementation was discussed again with the supplier. MAEP1 parts were the first real light-metal parts and made with the suppliers own machines.

Q-CAP timing with Light-metal casting supplier												
Yellow: done or updated				Red: scheduled								
		MAEP1		MAEP2a		MAEP2b		MAEP3		MVP		
Requirements review												
PFMEA												
Control Plan												
Gage R&R												
Part Layout Report												
CPK-study												
Packaging Plan												

Table 6.4. Timing of the Q-CAP sections with the Light-metal supplier. The time between MAEP1 and MAEP3 was approximately 8-10 months.

The previous prototypes had been rapid prototypes from another supplier. The requirements review started officially with the supplier's technical specialist, Potmor's mechanics designer and SQE. The designers and the supplier's technical specialist had already earlier discussed about the design.

During that visit it was agreed that the supplier starts working with the PFMEAs and control plans. Those had been requested already a couple of months earlier, but the supplier had not started making those. Two main issues were presumed to cause the delay: the supplier had not done PFMEAs or control plans earlier, and the instructions were not clear enough. What made it complicated was that the supplier made two Q-CAP-assemblies in this PDP including parts also from other suppliers, and additionally the supplier made one individual part, which was not part of either of the assemblies. Additionally lack of 'extra' time for making these new 'exercises' postponed the completion. The proto feedback report was introduced to them at the same time, which probably made Potmor's requirements more confusing for the supplier. According to the supplier, the amount of new, difficult documents made the situation difficult to them, although the SQE and the author tried to present and teach them carefully and thoroughly. Additionally Potmor's SQE team faced at that time small personnel changes. The remaining SQE had not visited the supplier before MAEP3 and did not know very well what had been discussed and agreed with this supplier regarding these QM activities.

The supplier made PFMEAs for the assembly processes and the control plans for each individual items. The first versions of PFMEAs and control plans were quite simplified and not very detailed. It took several weeks to get the first versions ready from the face-to-face meeting. The experienced delay emphasizes the importance of giving hand-on help to the supplier, if they make it for the first time. This time the training and instructions were given before they started to make the PFMEAs and control plans, and later by phone after they had done the first versions.

The supplier considered that face-to-face meetings were necessary in the beginning and follow-up-meetings were needed to prevent possible misunderstandings. They also thought that there was too much repetition with making nearly the same control

plans for many items. That feedback was important to hear, and after that more attention was given to explain the utilization and advantages of the tools to them.

The supplier was requested to improve their PFMEAs and control plans. The new versions they made were more specific and considered acceptable and ready for MAEP2 series. The supplier quality manager said after MAEP3 that they would review the PFMEA based on the experiences got from the prototypes. He mentioned that the control plan showed the need to calibrate some measurement devices in their manufacturing.

As the painting supplier paints one light-metal part, their input for PFMEA and control plan was also needed. It was decided for simplicity that the painting supplier makes separate PFMEA and CP regarding their painting process. This appeared to be a good decision, as the suppliers had different templates for the documents and different styles to make those.

Part Layout Report was done for all light-metal parts from the MAEP1 by the mould supplier. Making that report did not appear to be a problem for any of the parties and it was sent to the designers. The reports were analyzed together with the supplier's technical specialist and Potmor's mechanics designers. The reports gave exact and reliable information how well the mould and supplier's process were able to produce the items that the designers had planned. It helped to analyze which moulds and sections in the moulds needed repair or adjustment. During that review some dimension specifications and tolerances were adjusted to meet the outcome of the process, if it did not have a negative effect on the whole product. On-off jigs were planned to verify some dimensions in the process capability studies and during the mass production according to SPC. Although it took one full workday to go through the seven items, the both parties were satisfied with the PLR review and its outcome. The supplier also commented afterwards that PLR gives good report about the changes made to the mould and tolerances.

As shown in table 6.4, part layout report was also planned for the MAEP3 series, but only for the sections and areas of the parts that had been changed after MAEP1. The reports were not yet available for review at the time of this study.

Gage R&R and process capability studies were scheduled at the time of the MVP, so they cannot be estimated in this study. However, an issue was noticed, when those studies were planned; the supplier prepared to use a third-party measurement provider for the capability studies, as the supplier does not have capacity for making such large quantity of measurements. The light-metal supplier will measure actual volume production series. The Gage R&R will probably be made for the light-metal supplier's measurement system later when there is a good variety of acceptable and unacceptable parts available. That implies that the capability study results have not been verified, at least according to this Gage R&R procedure.

Packaging was planned and first new packages used in early stage, during and after MAEP1, making it possible to enhance it during the later prototype series. However, no major changes were needed for the packaging at the time of MAEP3.

Table 6.5 shows roughly the time spent for the Q-CAP activities with the light-metal supplier. The supplier's hours are estimated based on the written questionnaire, the designers and SQEs hours on oral interviews and author's experiences. The requirements review was done in so many phases that it could not be estimated. However, the hours spent for the elements of the Q-CAP may increase later, as the PFMEAs and control plans should be updated whenever needed. The supplier ordered the part layout reports from the mould manufacturer, so the supplier did not need to spend time for the measurements and only the PLR review took time. The SQE's one hour for the attribute variable Gage R&R was spent on the discussions with the author how feasible it would be to execute it.

Q-CAP resource estimate for the two Q-CAPs with the light-metal supplier												
		Man hours needed for the activity										
	# of them	Q-CAP Introd.	RR	PFMEA	CP	C. GR&R	A. GR&R	PLR	C.Cpk	A.Cpk	PP	Total hours:
SQEs	1	4	*	3	3	0.5	0.5	4	-	-	0	**15**
Designers	3	2	*	0	0	-	-	8	-	-	1	**11**
Supplier's QM or equiv.	3	8	*	24	24	-	-	10	-	-	1	**67**
Supplier's workers	1	1	*	10	10	-	-	**	-	-	0	**21**
total for the company:	4	6	*	3	3	0.5	0.5	12	-	-	1	**26**
total for suppliers:	4	9	*	34	34	0	0	10	-	-	1	**88**
total:	8	15	*	37	37	0.5	0.5	22	-	-	2	**114**

Table 6.5. Estimation of the time used for the different Q-CAP elements with the light-metal supplier.

Q-CAPs with the Plastics Injection Molding Supplier

Situation at the Beginning of this Project

The plastics injection-molding supplier was a new supplier to Potmor, although some of their personnel were familiar to the project team from some of the earlier projects. The supplier had ISO/TS 16949-certification and experience from working in automobile business. Therefore some of the commonly used quality management methods were familiar to them.

Q-CAP Implementation Process with the Plastics Supplier

The supplier was providing over 50 plastic parts for this project, thus forcing to focus the Q-CAP efforts to the most difficult and critical parts and assemblies. Table 6.3 shows the quantities of plastic parts and assemblies that were under Q-CAP implementation. Table 6.6 presents the timing of the Q-CAP sections.

Q-CAP timing with Plastics supplier										
Yellow: done or updated				Red: scheduled						
		MAEP1		MAEP2a		MAEP2b		MAEP3		MVP
Requirements review										
PFMEA										
Control Plan										
Gage R&R										
Part Layout Report										
CPK-study										
Packaging Plan										

Table 6.6. Timing of the Q-CAP elements with the plastics supplier.

Requirements review was a very long process that actually began at the quoting phase and supplier selection. This study focuses mainly the activities after the supplier was selected. The drawings were analyzed many times together with the supplier, but that had not been documented to the Q-CAP templates due to the large number of items. After the first pieces from the moulds were ready, the dimensional and visual requirements were discussed many times in all day meetings with the mould supplier representative, the plastics supplier's project leader, and Potmor's designers. The Prototype feedback form was used to document the required actions. This topic is discussed in more detail in section 6.2.4.

The supplier could not start making the PFMEA and Control Plan before the first moldings, because the 2D-drawings containing tolerances and detailed specifications were not ready. After the first versions of the drawings were ready, the supplier provided the PFMEAs and control plans in a few weeks for the Q-CAP items. The documents were done well; only small improvement suggestions were given to the supplier, which made the requested modifications pretty quickly.

Gage R&R was done for the supplier's measuring device and the operator, and the supplier did not need any help doing it. However, at first they made the tests only for one operator, but when requested, they repeated the test for three operators. It took only three days to get the new results, which were acceptable. More Gage R&R's are to be done after the parts and jigs to measure them are ready.

Part Layout Reports were not done yet at the time of MAEP3, because the moulds were still modified at the mould suppliers. The supplier was supposed to make PLR for the first test run pieces they find acceptable. Verification measurements belong to the plastic supplier's normal processes.

Continuous variable capability studies will be done to the MVP series for the Q-CAP assemblies and the individual items that go to those assemblies. Attribute variable capability studies will not be done, if the visual quality seems to be good.

Neither remarkable communication problems were noticed nor motivating was needed for the supplier to execute the Q-CAP. Their experience with these quality tools was easy to notice, as they had also many suggestions how they will manage all the Q-CAP sections for the large quantity of parts. Some of the parts were sub-assembled at their site, some were sent to the light-metal supplier for sub-assembly, and the painting supplier painted a few of the parts.

The time estimates for Q-CAP activities with the plastic supplier are shown in table 6.7. It includes only the elements that were done at the time of MAEP3. The supplier's hours are based on the written questionnaire, the designers and SQEs hours on oral interviews and the author's experiences. As six Q-CAPs were started with the plastic supplier, it required a lot of time from their quality inspector and other project team members. But as the PFMEA and control plans were so good, the SQE did not need to use much time to inspect those. Requirements review (RR) was done during the mould modification process, thus the time needed for that cannot be estimated.

Q-CAP resource estimate for the six Q-CAPs with the plastic supplier												
		Man hours needed for the activity										
	# of them	Q-CAP Introd.	RR	PFMEA	CP	C. GR&R	A. GR&R	PLR	C.Cpk	A.Cpk	PP	Total hours:
SQEs	1	2	*	2	2	1	-	-	-	-	0	**7**
Designers	3	2	*	0	0	0	-	-	-	-	1	**3**
Supplier's QM or equiv.	2	1	*	24	12	5	-	-	-	-	1	**43**
Supplier's workers	1	1	*	12	0	5	-	-	-	-	0	**18**
total for the company:	4	4	*	2	2	1	-	-	-	-	1	**10**
total for suppliers:	3	2	*	36	12	10	-	-	-	-	1	**61**
total:	7	6	*	38	14	11	-	-	-	-	2	**71**

Table 6.7. Resource estimation for the different elements of the Q-CAP with the plastics supplier.

Q-CAPs with the Painting Suppliers

Situation at the Beginning of this Project

This supplier had two different sites painting parts for this project: one for plastics and one for light-metal. The light-metal-painting site provides painting for some of the old products casted by the light-metal supplier as well. The plastics painting site does not paint any parts for the old product, but the other SQE was familiar with that site. The plastic supplier currently does co-operation with the plastic painting site and actively took responsibility for the communication to that site.

The supplier's sales representative coordinated their activities at both sites related to this PDP, and he also worked as the quality manager for the light-metal-painting site. The organizations behind him differed between the two sites. The plastics painting site seemed to be more quality management system oriented than the light-metal painting site. The quality on the light-metal painting site before MAEP1 was based on operators and quality manager's activity and problem solving case by case without defect trending or defect documentation.

Q-CAP Implementation Process with the Painting Suppliers

Again, the requirements reviews had not been formally documented, but the drawings were analyzed many times together with the supplier in face-to-face meetings. As table 6.8 shows, the supplier prepared the PFMEA and control plan for plastic parts during MAEP1 and MAEP2a.

Q-CAP timing with Painting supplier for plastics (P) and light-metal parts (A)										
Yellow: done or updated				Red: scheduled						
		MAEP1		MAEP2a		MAEP2b		MAEP3		MVP
Requirements review	A&P	A&P	A&P	A&P	A&P	A&P	A&P			
PFMEA			P				A			
Control Plan		P	P				A			
Gage R&R		na								
Part Layout Report		na								
CPK-study		na								
Packaging Plan		na								

Table 6.8. Timing of the Q-CAP sections with the painting supplier.

The first versions of the PFMEA and control plan came in time; only the incompleteness of Potmor's specifications caused some delay. The PFMEA and CP were satisfactory and no major comments were suggested. Based on the plastic painting site's activity, communications, and the level of the documents it was clear that this was not the first time they made those documents for the plastics supplier.

Light-metal painting site on the other hand needed more than half a year to complete PFMEA and CP for this project. The main reason for the delay seemed to be lack of supplier's experience of using and implementing organized QM tools on that site. However, the supplier completed PFMEA and CP for light-metal painting after a few discussions on the phone and quick face-to-face meetings. The completed PFMEA and CP were based on the documents that were already done for plastics painting. Potmor's general level visual quality inspection instructions were not ready at MAEP3, thus the painting supplier's PFMEAs and control plans have to be updated, when the instructions are ready.

Attribute Gage R&R was first planned to be completed with the painting supplier, but due to small proto series and lack of good example pieces it was postponed. The Attribute Gage R&R will possibly be done after the MVP, when a variety of unacceptable parts are available. Instead of Gage R&R, a meeting between all the parties was held before MAEP3 to create a common understanding about the required visual quality level throughout the supply chain. This was seen extremely important, because the plastics supplier sends a few important painted parts to the light-metal supplier for sub-assembly. Another meeting with the participants mentioned above was scheduled after MAEP3 to continue the discussions. The rest of the Q-CAP elements were not requested for the painting supplier.

Table 6.9 shows the estimation of the SQE's and designer's working hours regarding the painting supplier Q-CAPs in this project. The estimation from the supplier was not received. Again the requirements review cannot be estimated. Attribute Gage R&R and cpk-study were not planned, but can be done with the supplier.

Q-CAP resource estimate for the two Q-CAPs with the painting supplier												
		Man hours needed for the activity										
	# of them	Q-CAP Introd.	RR	PFMEA	CP	C. GR&R	A. GR&R	PLR	C.Cpk	A.Cpk	PP	Total hours:
SQEs	1	3	*	4	4	na	-	na	na	-	0	**11**
Designers	3	0	*	0	0	na	-	na	na	-	1	**1**
Supplier's QM or equiv.	1	3	*	*	*	na	-	na	na	-	*	*
Supplier's workers	0	0	*	*	*	na	-	na	na	-	*	*
total for the company:	4	3	*	4	4	na	-	na	na	-	1	12
total for suppliers:	1	3	*	*	*	na	-	na	na	-	0	*
total:	5	6	*	*	*	na	-	na	na	-	1	*

Table 6.9. Resource estimation for the different elements of the Q-CAP with the painting supplier.

Q-CAPs with the Printed Wire Assembly Supplier

Situation at the Beginning of this Project

Potmor's relationship with the PWA supplier has been very open for many years and co-operation has been very good with them from both sourcing and engineering perspectives. Potmor is a very important customer for the supplier, and vice versa. The supplier was not very familiar with organized use of these QM tools before this study. The satisfactory part quality levels were presumably based on the skills of the supplier's employees, which made the manufacturing vulnerable to changes in personnel. Potmor's SQE and component engineer audited and helped the supplier to develop their quality management system at the time of this study.

Q-CAP Implementation Process with the Printed Wire Assembly Supplier

Many of the quality tools that Q-CAP includes were new to the supplier's representatives, but they said that they had understood the advantages of Q-CAP and supported its implementation. Because the Q-CAP elements were new to the supplier, a training Q-CAP was done for one PWA in a transfer project some months before the PDP. Table 6.10 shows the timing of the PWA Q-CAP sections.

Q-CAP timing with PWA supplier											
Yellow: done or updated						Red: scheduled					
Turquoise: Practice Q-CAP sections done. Related prototype series marked with "P"											
		MAEP P	MAEP1	MVP P	MAEP2a		MAEP2b		MAEP3		MVP
Requirements review											
PFMEA											
Control Plan											
Gage R&R	na	na	na	na	na	na	na	na	na	na	na
Part Layout Report											
CPK-study											
Packaging Plan	na	na	na	na	na	na	na	na	na	na	na

Table 6.10. Timing of the Q-CAP sections with the PWA supplier.

The Training Q-CAP Implementation with the PWA Supplier

On the requirements review of the training Q-CAP with the designer and SQE it turned out to be very difficult to determine good CTQ-parameters for that PWA. The only parameter needing additional measurements was finally left out, because its measurement was not feasible. The remaining parameters were measured with the Automatic Optical Inspection device during the prototyping, which was part of the supplier's normal process.

PFMEA and control plan for the training Q-CAP were done when the SQE carried out Q-CAP training for the supplier's quality manager at the their manufacturing plant. No Gage R&R was done because there were no parameters to measure. Only a verification document for the AOI device capability was requested from the supplier.

The part layout report was quite difficult to determine for this PWA. The PLR content was decided in a teleconference with the supplier's quality manager based on the advices received from other SQEs in Potmor. The PLR contained the checking that the CTQ-parameters were inside specifications on the MAEP series of the PWA. The automatic optical inspection (AOI)-device checked the soldering quality and connector positioning, so extra measurements were not needed. The functional circuit tester (FCT) and the in-circuit tester (ICT) were not ready at MAEP, thus they could not be confirmed at that time. As the parts would have been inspected at AOI anyway, the PLR did not introduce any additional part verification in this case.

Continuous variable cpk-study was not done for the training PWA, as no reasonable continuous CTQ-variables existed. Attribute variable capability study was completed based on MVP series of the practice PWA. The PWAs were first checked with the AOI on both sides of the PWA and after that the FCT tested the functionality of the PWAs. The ICT was not ready for use at that time. When the cpk-study was done, the PFMEA and the control plan were updated to improve readability. The packaging plan was not done for this supplier at all, as there are standardized packages in use with the supplier.

The Time Needed for the training Q-CAP completion with the PWA Supplier

The time-estimate for completing the training Q-CAP is shown in the table 6.11. This estimation does not include the traveling, which the SQE had to do to introduce and teach the Q-CAP implementation. The training time is included in the hours for the PFMEA and control plan. The very roughly estimated total cost of the training Q-CAP was 3000 € including the two visits to the supplier and the working hours listed below. The SQE's working hours includes the SQE-work performed by the author. The working hours for the training Q-CAP are a rough estimate and include some time spent on the PDP Q-CAP, as the Q-CAPs were partially overlapping in time. As the estimate shows, the SQE and the supplier's quality manager did most of the work with this Q-CAP.

Q-CAP resource estimate for the training Q-CAP with the PWA supplier												
		Man hours needed for the activity										
	# of them	Q-CAP Introd.	RR	PFMEA	CP	C. GR&R	A. GR&R	PLR	C.Cpk	A.Cpk	PP	Total hours:
SQEs	1	2	3	6	6	0	1	3	0	3	0	**24**
Designers	1	1	2	0	0	0	0	0	0	1	0	**4**
Supplier's QM or equiv.	1	1	1	6	6	0	1	3	0	4	0	**22**
Supplier's workers	1	1	1	3	2	0	0	1	0	1	0	**9**
total for the company:	2	3	5	6	6	0	1	3	0	4	0	**28**
total for suppliers:	2	2	2	9	8	0	1	4	0	5	0	**31**
total:	4	5	7	15	14	0	2	7	0	9	0	**59**

Table 6.11. Resource estimation for completing the different elements of the training Q-CAP with the PWA supplier.

The Q-CAP Implementation in the PDP with the PWA Supplier

Four PWAs were selected to be Q-CAP-parts and six to be Part Layout Report-parts with this supplier in this PDP. However the part layout reports were not done for the six parts, as the PLR was not feasible in the training Q-CAP. The elements of each of the four Q-CAPs were done approximately at the same time.

Prototypes for most of the PWAs had been done before beginning of the Q-CAPs and no fundamental design changes for the PWAs were made during this study. The requirements reviews for the four Q-CAP PWAs were made together with the responsible designers and the SQE after the MAEP1 series were already done. However, the requirements reviews were made mainly related to the Q-CAP, not to the manufacturability of the PWAs. However the requirements reviews for the Q-CAP-items should have been done before the MAEP1 series according to the supplier's quality manager to get the supplier's feedback to the design as early as is feasible.

The supplier made moderately quickly the PFMEAs and control plans in the PDPs four Q-CAPs based on the PFMEA and control plan for the training Q-CAP. The supplier did not need to make any additional actions except producing one assembly jig. The supplier's normal manufacturing and testing processes were expected to tackle all other CTQ-parameters.

The part layout report was done for two of the four Q-CAP PWA, but it was again quite useless without data from FCT and ICT, as the testers and AOI will inspect the CTQ-parameters on the Q-CAP PWAs. In addition, Potmor designs and constructs the FCTs and has access to the test database, so the test results are available for the PWA designers and the tester designers.

Continuous variable capability study was done already on the MAEP1 series for one PWA. It included measurement of one dimension at the PWA. The results showed that there should not be any concerns with that parameter, unless the flexible circuit board bends too much during the manufacturing process. However the bending is

easily detectable. Thus only AOI is used to monitor the parameter in mass production.

Plans for the MVP were to execute similar attribute variable capability study as for the one of the training Q-CAP. In practice the SQE and the designer will analyze the results from the AOI, FCT, and also from the ICT with the supplier's quality manager. In addition, results from the sampling based X-ray inspection for one PWA will be analyzed, and the effectiveness of the on/off-jig use related to positioning of the capacitor for another PWA will be confirmed.

Planned Process Audit Regarding PWA Supplier's MVP Series

The SQE will complete a PWA process audit at the PWA supplier's site related to the process capability studies and MVP series. The process audit was seen especially needed for this project, because a new manufacturing technique was taken into use for at least one of the PWAs in the project. The process audit focuses on one Q-CAP-item and the earlier made control plan for that item will be verified to be appropriate for mass production. That process audit and cpk-study results will be used to give a formal approval for the new manufacturing technique. The audit will follow a PWA specific checklist used in Potmor including all the major steps of the PWA manufacturing process.

Part Layout Report with the Sheet Metal Supplier

Situation at the Beginning of this Project

As the sheet metal parts were not considered very difficult to manufacture nor their dimensions so critical as some of the plastic or light-metal parts, only part layout report was done with the sheet metal supplier. The supplier provides a large variety of sheet metal parts to Potmor's old products and the supplier-customer relationship is open without bigger issues. The supplier was implementing a new manufacturing system to improve their manufacturing quality and willing to improve their quality together with Potmor during this study. Therefore the supplier had no objection to make the PLR for the prototype series.

The Part Layout Report Implementation with the Sheet Metal Supplier

The part layout report for these sheet metal parts is so simple that teaching the supplier to fill it did not require much time or efforts. At the first meeting it was agreed that the supplier would have made PLR for six parts of the MAEP1 series. However due to their internal communication mistakes they did it only for three. According to them it was a very time consuming operation and had taken two days for one operator, but all the marked dimensions including corner rounding were measured during that. One very time consuming part of the measuring was to calculate the tolerances for many measures that were noted to follow the general tolerances. Those tolerances were not thus marked on the 2D-drawings. After hearing that issue, it was decided that next time better instructions have to be given to the supplier to focus the measuring for the important dimensions only. It was not seen appropriate to include all the tolerances to the drawings, because those dimensions were not so important.

The received PLRs were gone through carefully with the designers and SQEs. The supplier had proposed some changes to target values, tolerances, and suggested that some dimensions would not be included to SPC. The designers implemented the changes or at least investigated those. Some inspections jigs were planned as well. After that the designers visited the supplier to discuss about the manufacturability of the parts. Based on that visit some design changes were done to ease the manufacturing and decrease the item price.

As some design changes were made before MAEP3 and to confirm the dimensions of the MAEP3 parts, PLR was requested for all eight sheet metal parts of that prototype series. It also lessened the designers' workload, as they did not need to use their time for measuring the parts. Lessons learned from the PLR at MAEP1 describe above, resulted in better instructions for the supplier to perform the PLR and a lower cost for performing it.

Designers' Input to Q-CAP

The Q-CAPs in this PDP did not require much additional work from the designers that they would not have done otherwise. The Q-CAP elements that require designer actions are requirements review, part layout report and capability study. Additionally, the designer should review the PFMEA and control plan made by the suppliers guided by the SQE and the author.

Requirement review would have been done in any case, but perhaps not in so great detail, especially for the PWAs. The requirements reviews were continuous processes particularly with the mechanical parts, where the moulds and tools were modified long time. The reviews were documented mainly to the prototype feedback forms.

The designers analyzed the part layout reports with the SQE and the author. The designers made many adjustments to the drawings based on the PLRs and gave instructions to the suppliers how to proceed with the moulds and tools.

The designers added pre-defined marks for the dimensions in the 2D-drawings that will be measured in capability studies and other marks that will be measured both in the capability studies and in the statistical process control during volume production. One designer said that the discussions about the markings clarified to him the meaning and purpose of the capability studies and the SPC.

6.2.3 Process Audits

Due to the delay in the PDP schedule, process audits could not be performed during this study. Therefore the applicability and usefulness of the audits could not be estimated in this study. The audits are considered very important to guarantee the success of the MVP series and the mass production and have to be done at the supplier's site with the designers. The plan was to perform the process audit with all of the case suppliers in this study in conjunction to the process capability studies.

6.2.4 Prototype Feedback Reporting

As mentioned earlier, this study was started when detailed design was in process. Decisions made during detailed design may have a significant impact on product quality and cost (Ulrich et al. 2008). Therefore good and early feedback about the design and prototypes from and to the supplier is very important. The experiences from this study support a predefined process using simple feedback forms. One form including a lot of information was not effective and efficient with different kind of suppliers and supply chains, but there should be two or three different templates available. The prototype feedback reporting affected the electronics and mechanics designers and the case suppliers in this study.

Implementing the Feedback Report with the Mechanics Suppliers

Two separate quality factors affected two mechanical parts suppliers in this study: the mould quality and the manufacturing process quality. The supplier purchased the moulds from a mould supplier instead of making those by themselves. This made it more challenging to improve feedback communication between Potmor, its supplier, and the supplier's mould supplier.

The mechanics designers who had their own customs to give their feedback to the mechanical part suppliers were now asked to change their habits. For the molded mechanics parts in this PDP the major part of the prototyping was the mould manufacturing and modification. In the earlier projects the mould enhancement has sometimes been difficult with some suppliers and they had not modified the mould well enough despite many requests. Thus the designers and SQEs felt that it was important to see the history of the defects in the prototype parts. Otherwise it would be difficult and time consuming to follow, if the mould manufacturer had repaired all the agreed defects or tried to avoid it. The report was filled many times in the beginning together with the designers to get experience about its use in practice.

Implementing the Feedback Report with the Light-metal-casting Supplier

The light-metal-casting supplier were not used to this kind of in-depth tool, but showed interest to use it. They were quite confused about how to fill it as they made

both assemblies and individual parts, including one painted part in the assembly. When seeing the whole situation from the supplier's perspective, their confusion was not a surprise. The use of the form was introduced a few times to them and detailed feedback was given from the first version they submitted. Especially the sub-assemblies the supplier made, were important for the whole product.

The part layout reports from the MAEP1 parts were added to the supplier's prototype feedback reports, so the visual, dimensional, and functional quality information was in one package. The defects were not always reported in time by the light-metal and the painting supplier for light-metal part, but the bigger challenge was to get the designer's feedback to the suppliers. The designers had not much time to look after the light-metal supplier's prototype feedback reports and probably expected that the supplier will act based on the reports. However the supplier had not modified the mould for one part before MAEP3, although it had been agreed with them.

Based on the experiences with all the case suppliers, a new version of the report that included the possible third party comments was done for the light-metal parts after MAEP2b. It would have helped the implementation of the form with the light-metal supplier, if the form had been simpler already from the beginning.

Implementing the Feedback Report with the Plastics Supplier

The biggest work regarding feedback communication was with the plastics supplier, their mould manufacturers and painting supplier. In the beginning also some of the mechanics designers and plastics supplier representative felt that the form is too heavy and confusing for the mould improvement purposes, especially as there were over 50 parts that had to be analyzed. For the MAEP2a, the report was simplified remarkably to improve the readability and lessen the time needed for giving and reading the feedback. Related to MAEP2b parts a mould acceptance review was included to the report. That review form had been a separate document to be filled after the mould was acceptable. Thus the feedback report eventually included both the mould repair history and the mould acceptance review information.

The biggest practical challenges with the new report that were not considered in the beginning, were how to fill and send the report for the assemblies or painted parts when there are two suppliers and the designers filling their comments to the form. Also the mould improvement process included three parties: the plastic supplier, mould supplier, and the designers. In addition, correcting the wrong printing setups on the form caused a lot of handwork. The supplier and mould maker did not like very much that the report was changed a couple of times during the prototyping. As the amount of plastic parts was so large, the form was not modified for third time for all the plastic parts to include the comments from the third party.

The mechanics designers were satisfied with the improvements made to the form, and so were the plastics supplier and mould manufacturer. Positive comments from the designers were that it helps the supplier to understand Potmor's real quality requirements, and also that it pushes the designers to check the parts more carefully. The designers usually agreed on the mould modification actions with the plastic and mould supplier representatives in many full day meetings.

The mould manufacturer had not understood well enough the purpose and use of the form nor the real quality requirements in the beginning. On the other hand, the requirements are difficult to determine for visual defects. In the beginning, regarding MAEP1 parts, the defects were just listed and a notice added, if the defect affected the functionality of the part. Later it was seen as ineffective feedback, as some of the mould manufacturers did not correct the defects in some parts at all, although the actions were agreed together with the mould manufacturers' representative and plastic supplier. For MAEP2a parts more specified instructions were given for each defect. During that process the designers had to decrease their quality requirements in some cases. The mould manufacturers opinion was that in some cases the designers had reported very minor defects that would not have been reasonable to fix. In the beginning the mould manufacturer had not considered that they would have needed to make the modifications according to the feedback report, and to document the actions they had taken to each defect.

Figure 6.15 shows the progress of the plastics prototype series from MAEP1 to MAEP3. After MAEP3 it was decided to include the severity of the defect to the form template to help prioritizing the mould modification in the future.

The assemblies that the plastic supplier made were so simple that the new, simpler version of the report was seen appropriate for communication about those. The prototype feedback form was used as well for the painted plastic parts. The comments regarding the painting quality were included to the part report, which was sent also to the painting supplier. The painting supplier for the plastic parts was asked to document the issues during their painting process, but the reports were not done. Thus the yield of their process was not available to Potmor in the prototypes. However the painting supplier representative explained the problems they had had in the meetings, as it has been done in the earlier projects. Their biggest problems were noted to the feedback form at the meetings.

Implementing the Feedback Report with the Sheet Metal Supplier

The prototype feedback form was introduced to the supplier at the same time as the part layout report. They agreed to use the form with Potmor when needed. As the quality of the parts was visually satisfactory, the designers filled prototype feedback forms for only three of the eight parts. Again the part layout reports were added to the prototype feedback report of the item.

Implementing the Feedback Report with the PWA Supplier

As mentioned in chapter 4 – Problems, there had been a prototype feedback form in use with the PWA supplier, but it was not considered good enough to ensure the communication about all the required information. The electronics designers were used to that form, and resistance to change was expected, when the new form was implemented. The PWA supplier were not used to this kind of thorough tool, but accepted to use it.

All the PWAs in this PDP were using the new form, but the other projects with the PWA supplier did not change to the new form yet, because it was not finalized. Some criticism was received from the electronics designers, based mainly on the

complexity of the new form. The author taught and helped the designers to give the their feedback to the supplier. As they felt the report somewhat difficult to read and had lots of other documentation to do, the designers considered the report filling to be time consuming. Some of the feedback was still given by phone and not documented, if the designer did not consider it to be the supplier's fault. As well the timing of sending the report to the supplier was unclear in the beginning.

Usually the supplier repairs the defects on the PWAs and sends the PWAs to Potmor and informs only, if they have had bigger problems with their manufacturing. Thus the yield Potmor saw had usually been 100%. After MAEP2a also the results from AOI were included to the report, if AOI was done. AOI showed better the true capability of the process and revealed better the supplier's challenges to the designers. After the MAEP3 the supplier was asked to document the quantities of the PWAs they had repaired after their visual inspections. Earlier they had not given that info, so a significant part of the advantage of the feedback form had not been utilized in this project with the PWA supplier.

6.3 Effects of the QM tools to the Quality of the Proto Series

6.3.1 Light-metal Die-casting Parts

The two Q-CAP assemblies included six light-metal parts, of which one included many parts from other suppliers as well. In addition to that the supplier made one PLR item. Figure 6.12 shows the progress of the light-metal items, and table 6.13 shows the yield of the two assemblies the light-metal supplier made. Figure 6.14 shows the background for the defects. The information from MAEP2 was based on discussions and notes, as the designers had not made proto build feedback reports for those, except for the PLR item. The individual parts for MAEP3 were not yet analyzed, but the supplier sent the feedback report regarding the two assemblies.

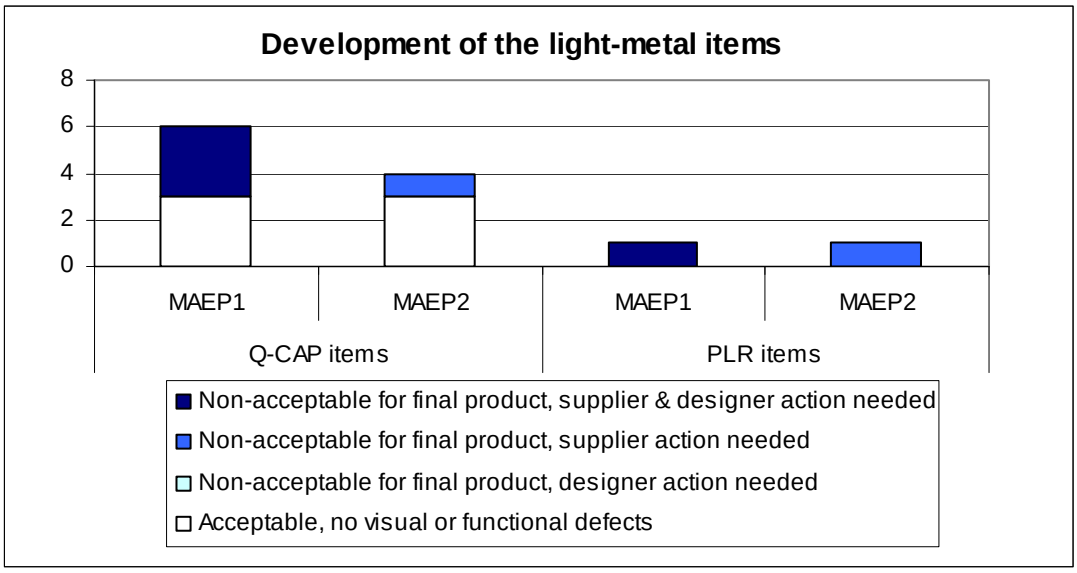

Figure 6.12. Progress of the prototype series of the light-metal parts. The items that required changes only to tolerances are included to the 'Acceptable, no visual or functional defects'-category.

Yield	MAEP1	MAEP3
Q-CAP assebly 1 incl.painting	na	81%
Q-CAP assebly 2	87%	64%

Table 6.13. Yield of the assemblies for MAEP1 and MAEP3. MAEP2 products were assembled at Potmor using the parts done during MAEP1.

The most complex Q-CAP items required mould modification and designer's actions after MAEP1, but the simpler MAEP1 items met the tolerances, functional and visual quality requirements. Also the PLR part required actions from the mould manufacturer and the designers. The most severe quality problems with the light-metal casting parts were the screw holes. The problem affected the assemblies and the PLR item.

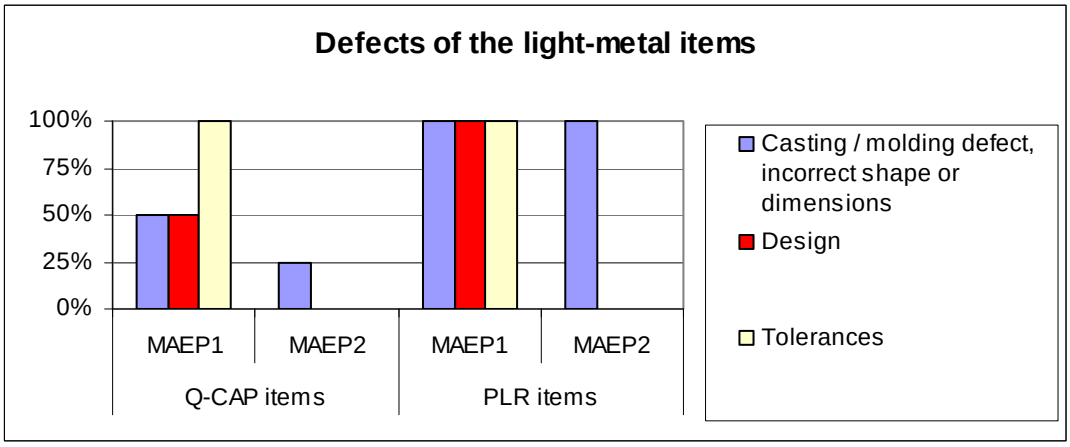

Figure 6.14. Origins for the noticed defect in the light-metal parts and assemblies.

The yields in table 6.13 are poor, but the defects were based on the mould incompleteness according to the feedback reports. The biggest concern was that a few parts required a lot of manual finishing in addition to the screw hole problems. Therefore the need for mould modification continues still after the MAEP3. The defects cannot easily be prevented with PFMEA and control plan, but the number of defects could have been reduced, if the requirements review would have been done better. It is important to react to the feedback properly, because in the mass production the changes are much more difficult.

6.3.2 Plastics Parts

Like the light-metal parts in this PDP, plastics parts quality development during MAEP1-3 series cannot be estimated based on DPPM levels. The MAEP1-3 parts were produced at the mould manufacturer, and all of the parts had nearly the same defects. The plastic supplier's manufacturing processes did not affect the part quality. The main focus in the mould modification was in the functional dimensions and the visual quality of the parts. Only the 2-component prototype parts were injection molded at the plastic supplier, but the mould has to be completed before the plastic supplier's process can be analyzed. All of the 2-component moulds were still under modification at the time of the MAEP3, so the same analysis was considered to be applicable for all the plastic parts from this supplier.

The 2-component parts caused the biggest problems for the supplier and the mould manufacturer. Better communication between the parties in the beginning of the project would have helped to choose better mould structure for some of the parts according to the designers. So the requirements review should have been done more precisely. All of the 2-component items were categorized as Q-CAP parts.

As the mould manufacturers did the 1-component plastic parts, the requirements review was the only element of the Q-CAP that affected the MAEP1-MAEP3 series. On the other hand the requirements review would have been done also if not completing the Q-CAP. Requirements review was started already during the quoting process. After the quoting, the usage of the Prototype report-tool affected the quality

of the parts. Although the designers measured some dimensions on the parts, the part layout reports that will be done before MVP will show how well the parts meet the specifications when made by the plastics supplier. Continuous variable capability study for the MVP parts will demonstrate the ability of the plastic supplier's process to manufacture identical parts inside tolerances.

Progress of the Plastics Parts Mould Modification

Figure 6.15 shows the development of the plastic parts during the MAEP series based on the prototype reports. The mould supplier had also made some series between the MAEPs to test the modifications to the moulds, but there was no time to make a prototype feedback report for all of those, especially if there were no progress. Thus the actual MAEP series were not as clear as the Figure 6.15 shows. For instance the MAEP2 consisted of the MAEP2a and the MAEP2b, but the data could not be easily separated for this analysis. Most of the moulds were ready after the MAEP3 and shipping of the moulds to the plastic supplier was started.

There were 8-10 months between the MAEP1 and MAEP3 series, so the progress of the moulds was expected to be faster than it was. Especially between the MAEP1 and MAEP2 there was not much progress, but the time between those series was short. The designers had not analyzed all of the parts so early that the mould maker could have modified all the moulds in time for MAEP2. Section 6.2.4 describes the challenges with the mould modifications in more detail.

According to figure 6.15 many of the Q-CAP and PLR items were difficult for the mould maker. The moulds for the standard items were modified without bigger challenges. In addition, designers' action was needed for many of the items. Many of the design changes were based on the test done for the assembled products at Potmor, but also on the mould manufacturer's and plastic supplier's feedback.

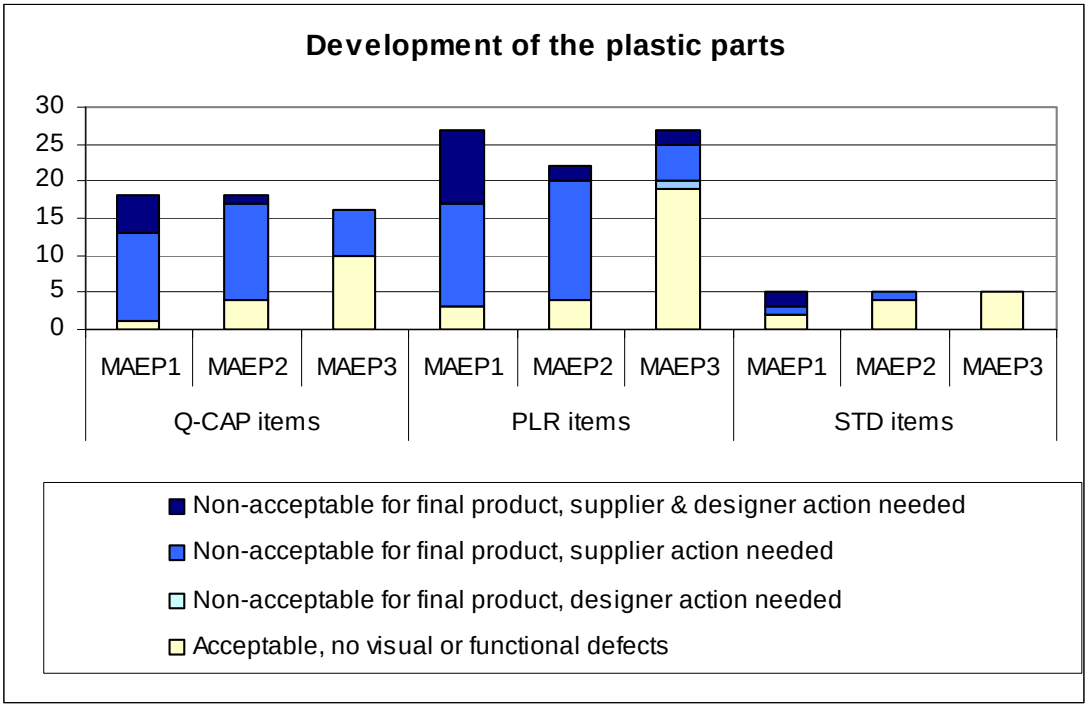

Figure 6.15. Progress of the prototype series manufactured at the mould manufacturers. The quantities of the parts vary because some of the earlier prototypes were used in the later series.

The proto build feedback report showed the amount of the defects that had not been corrected and the history of the agreed actions with the supplier and mould manufacturer. As the feedback forms contained defects of the all parts, defects have not been forgotten during the long process, which would have been possible in the project having over 50 plastic parts.

Figure 6.16 shows the most common defects on the plastic parts. Obviously the incomplete moulds caused most of the problems. Some painting quality problems existed in the beginning as well. Ultrasonic welding was the third defect category. As the incomplete mould causes most of the defects, it was not reasonable to compare the defects in the MAEP series to the old product defects.

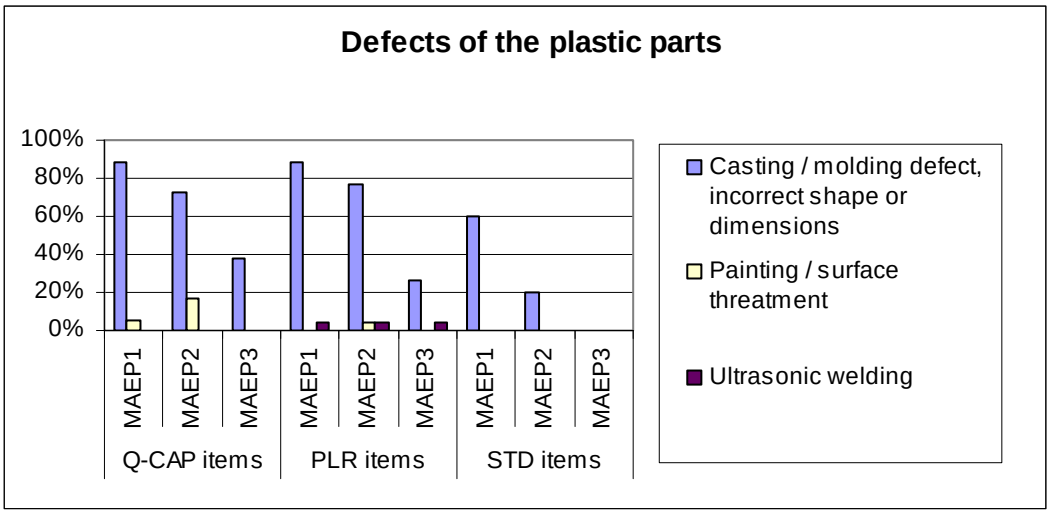

Figure 6.16. Origins for the noticed defect in the plastic parts and assemblies.

6.3.3 Painted Parts

As the figure 6.17 shows, the painting quality of the plastic parts was finally good in MAEP3, although one item was problematic due to the special manufacturing technique. As described in section 6.2.4, many meetings were held together with the painting supplier to agree on the methods to improve the painting quality. The painting supplier tested different paints and finally the quality was acceptable at MAEP3. However the true capability of the plastic painting site of the supplier can be estimated when the MVP series is made, as the MVP consists of over 200 pieces.

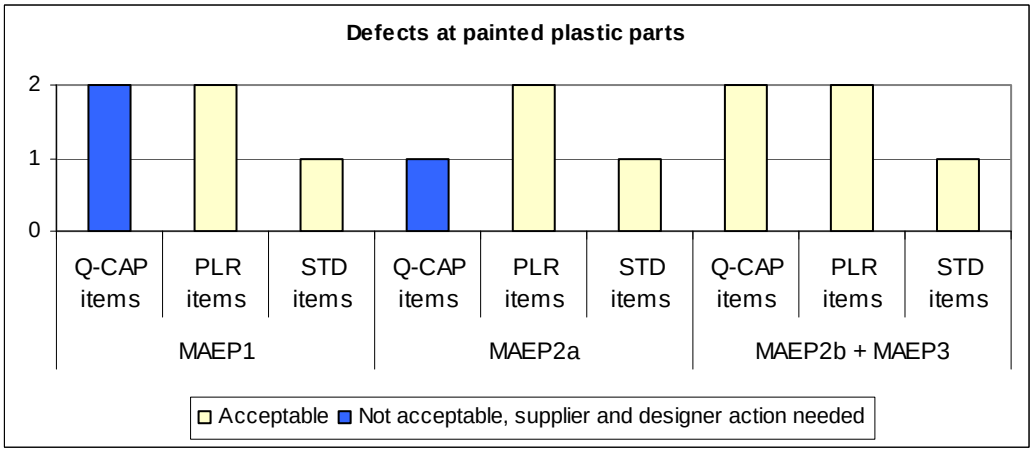

Figure 6.17. Progress of the painted plastic parts. The items are included to the quantities shown on figure 6.15.

Yield	MAEP1	MAEP2a	MAEP2b	MAEP3
Painting of the light-metal part	na	na	84%	86%

Table 6.18. Progress of the painted light-metal part. The MAEP1 and MAEP2a parts were not painted.

Table 6.18 shows the painting process yield for the last two series of the light-metal part. The first series were not painted so there was no information from those. The information of the last two MAEP series is based on the prototype feedback report the supplier provided after painting the parts. Although the yield was not very close to 100%, the PDP team was not concerned about it. The defects were due to special causes and partly the same in the both series. The painting supplier had identified the root causes after MAEP2b, but the preventive actions had not been effective enough. The supplier has to be requested to make better corrective and preventive actions before MVP.

6.3.4 Sheet Metal Parts

As the sheet metal parts were not Q-CAP parts, not much attention was given to their quality. The visual quality was not important, but the dimensions were. However the tolerances were not very tight. There were not major problems in the MAEP1 series of the sheet metal items. The part layout reports showed that most of the dimensions were inside the tolerances. After making the first MAEP, the supplier suggested a few modifications to the drawings to ease the manufacturability of the items. The designers were not aware of such small issues that could be problematic in the supplier's manufacturing and accepted the supplier's suggestions.

The designers requested some small modifications for a few parts during the prototyping. The changes were ready at MAEP3 and the parts were satisfactory, although the part layout reports for MAEP3 parts had not been analyzed yet.

6.3.5 Printed Wire Assemblies

Training Q-CAP PWA

The quality of the Training Q-CAP PWA is analyzed based on the attribute variable capability study. AOI and FCT were used to analyze the process capability as well as a part of the supplier's normal manufacturing process. AOI caught altogether six defected PWAs out of one hundred, which were reworked, and then FCT caught another six out of the one hundred, which included the reworked PWAs.

Defects found in AOI were not considered so major that actions from the supplier would have been requested. As shown in table 6.19, the Defects Per Million Opportunities (DPMO) was around 1.0, and Z.B value over 4.5 σ, which was acceptable for the prototype series. The defects found in the FCT were easily identified to one and the same component in each case. So the root cause was clearly seen as a special cause, a sub-supplier fault. There had been quality problems with the same component and sub-supplier earlier as well. The corrective action was to purchase those components from another sub-supplier. Other actions were not seen feasible.

Characteristic	Measurement Device	Defects	Units	Opportunities	DPMO	Z.B
Components / soldering	AOI, TOP SIDE	15	100	165400	0.91	4.77
Components / soldering	AOI, BOTTOM SIDE	24	100	152400	1.57	4.66
Function	Functional testing	6	100	20 (tests)	3,000	2.75
PWA level: Components / soldering	AOI, TOP SIDE	4	100	1 (PWAs)	40,000	1.75
PWA level: Components / soldering	AOI, BOTTOM SIDE	2	100	1 (PWAs)	20,000	2.05

Table 6.19. Attribute variable capability study for the practice Q-CAP.

PWAs in the PDP

As the size of the prototype series was low, from five to 120 pieces, one isolated defect caused big DPPM value. A better view about the supplier's problems will be got when the MVP series are produced. However the defects at the prototypes helps estimating whether executing the Q-CAP prevented the CTQ problems.

Overview of the PWA Quality

Figure 6.20 and figure 6.21 show the overview of the DPPM levels for the MAEP1 and MAEP3 based on the defect quantities found at Potmor. Only the supplier's manufacturing related defects are included in the values. The functional testers were under development in Potmor during MAEPs, so the supplier had not tested the boards. Potmor's test and design engineers found the defects in their tests and trial use at the assembled products. According to these figures the average DPPM for Q-CAP PWAs was many times higher than for PLR PWAs.

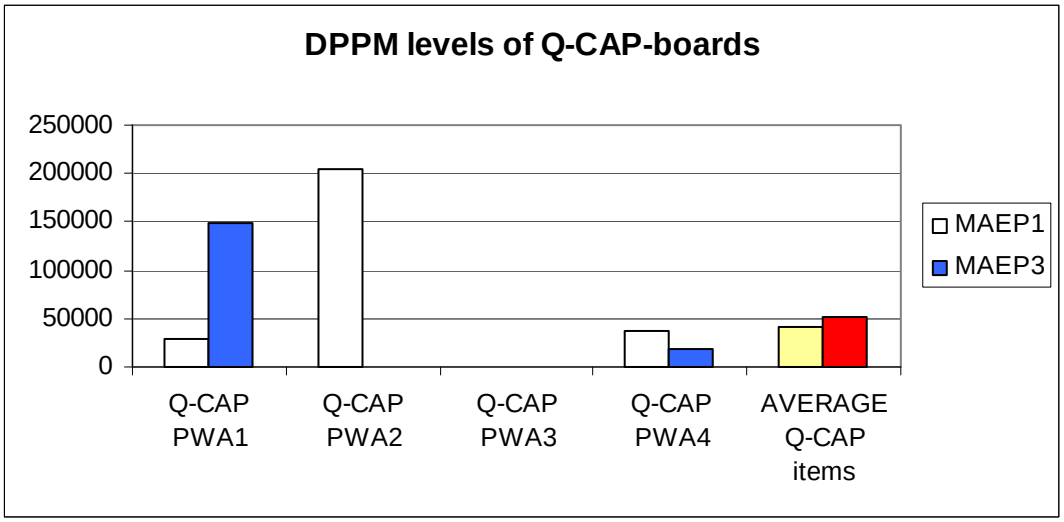

Figure 6.20. The perceived DPPM-levels of the Q-CAP PWAs at Potmor. The MAEP2 was done only for Q-CAP PWA2, but the DPPM was zero for that series.

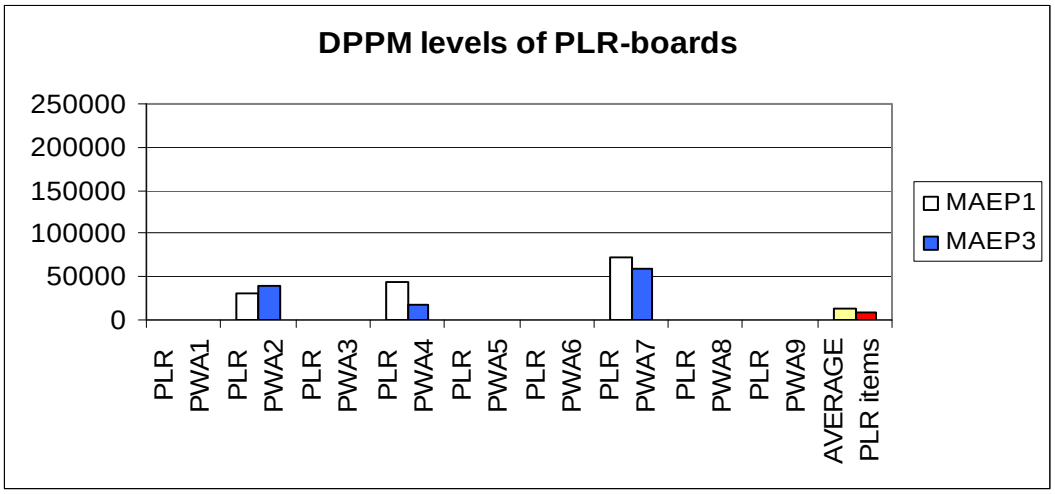

Figure 6.21. The perceived DPPM-levels of the Q-CAP PWAs at Potmor. The MAEP2 was done only for PLR PWA5 and 7, but the DPPM was zero for those series.

Figure 6.22 shows the defects per million opportunities found in the supplier's visual inspection. DPMO in this figure is the average of all the MAEPs, because the data did not separate clearly when the series were made. DPMO in this graph compares the number of the defects found to the number of possibilities for defect. The number of possibilities for defect is the number of soldering points and components multiplied by the quantity of PWAs in that lot. The figure shows that each Q-CAP PWA had some defects, and especially Q-CAP PWA3. Based on figure 6.20, figure 6.21 and figure 6.22 all the Q-CAP PWAs had problems, but the Q-CAP PWA3 defects were found and repaired at the supplier. Some of the PLR PWAs had quality problems as well and some of those were not caught at the supplier.

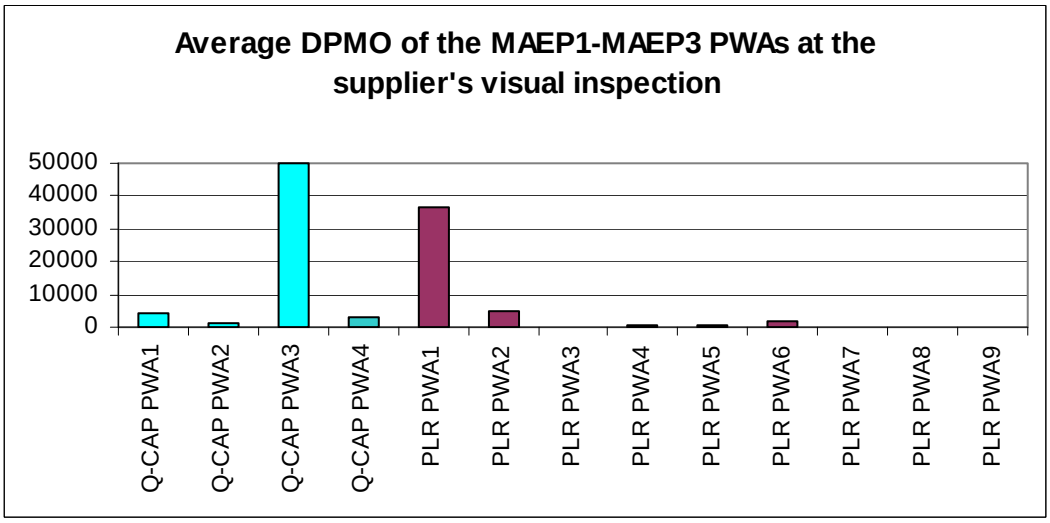

Figure 6.22. Average DPMO of the MAEP1-MAEP3 PWAs at the supplier's visual inspection.

The defect data from years 2008 and 2009 was received from the supplier after MAEP3 for the PWAs of the old product and for Mede's PWAs. Figure 6.23 summarizes the defect categories and figure 6.24 shows the most common defect types in more detail. According those figures, the most common defect categories in the old product PWAs have been different soldering and component defects. The same defect types were most common at the Q-CAP and PLR PWAs as well.

Shortcuts, poor wetting, and incomplete soldering were the most frequent soldering defects. Most typical component defect was that the component or its foot did not touch the pad properly. However, the capability of the supplier's AOI improves during time, and the supplier had not any testers for the MAEP PWAs. The AOI and the testers will reduce at least the defect quantities that pass the supplier's manufacturing to Potmor. In addition the use of the devices helps adjusting the process parameters, which reduces the number of defects from the soldering process.

The quantities of the MAEP series were so small that the DPMU values are more approximates than good estimates of the process capability. Therefore a more detailed analysis is not feasible before the MVP series.

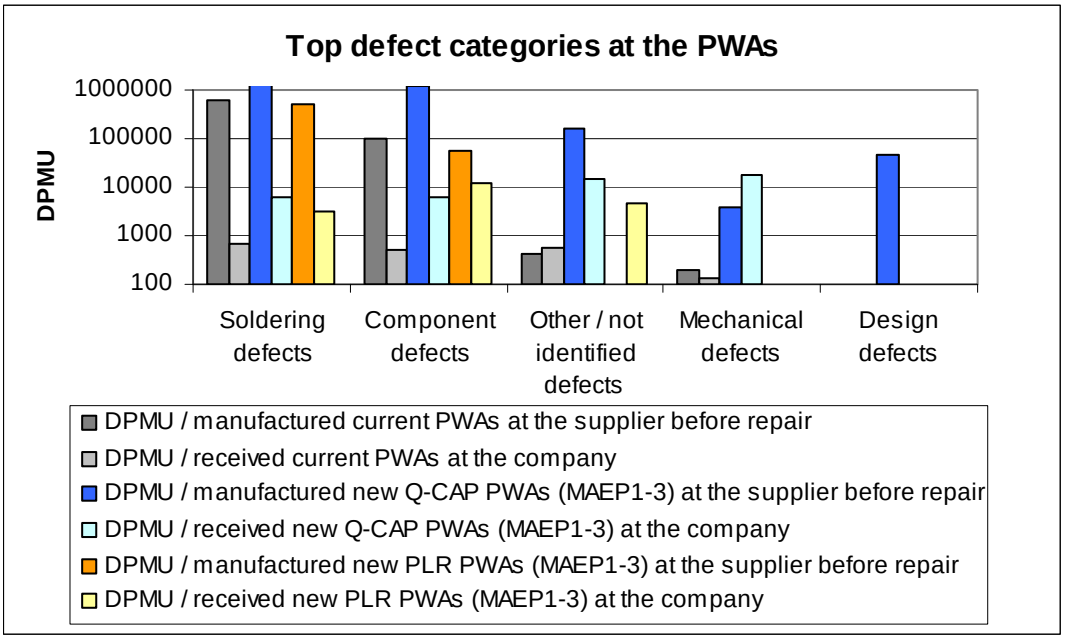

Figure 6.23. The most common defects categories found at supplier and at Potmor at the old and new PWAs.

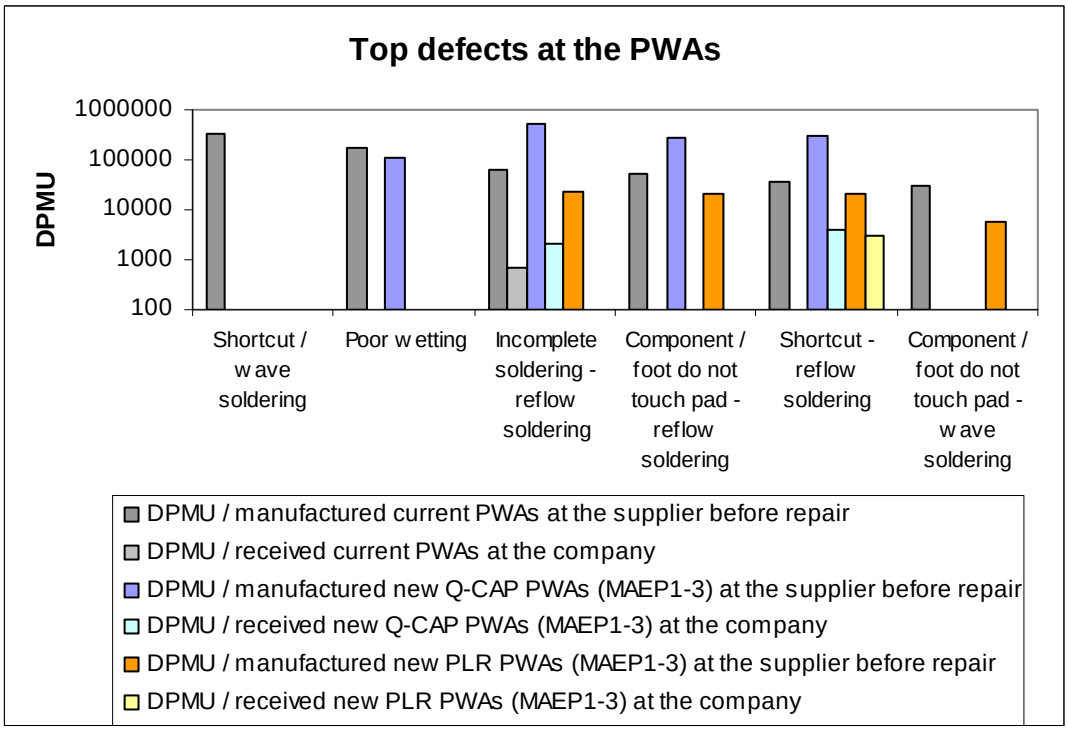

Figure 6.24. The most common defects found at supplier and at Potmor at the old and new PWAs.

Effect of the Quality tools on the PWA Quality

All the defects found at Potmor were informed to the supplier through the prototype feedback form. If the defect was considered severe enough, the supplier was requested to give a corrective action plan or suggest design changes. The supplier often had to request the designers to modify the specification documentation, which was misleading or incorrect.

Most of the defects found at the Q-CAP PWAs were not related to the CTQ-parameters, but to the soldering quality and placement of other components. Only exception was Q-CAP PWA3. The flexibility of the board caused soldering problems to wide connector on the Q-CAP PWA3 during the prototyping, because the rigid for the boards was bent. Its effect to the DPMO is shown in figure 6.22. The supplier informed Potmor about the problems through the prototype feedback form and meetings were held to solve the problem, which was noticed both at MAEP1 and MAEP3. A small prototype series before MVP will show if the actions were effective.

The part quality at this PWA supplier is based mainly on the supplier's basic process controls, adjustment of the process parameters and the tester quality. The PFMEAs and control plans did not cause remarkable changes to the supplier's processes; only small PWA specific inspections were added for the few Q-CAP PWAs. The soldering and component positioning related defect categories were the most common at both the Q-CAP and PLR PWAs. Soldering defect is a common cause by its nature; the soldering process is highly dependent on physical factors and the number of the defects decreases during prototyping process. The component positioning is highly dependent on the sub-supplier's manufacturing process quality. Thus there is some variation in the process, which is difficult to reduce, because it is not easy to affect the component manufacturers' processes. Inspecting 100% of the component packages is not very effective, thus it is usually better to trust the manufacturer and find possible defects at AOI.

6.4 Quality Control Preparation for Mass Production

The general visual quality inspection instructions were not finished at the time of MAEP3. It was waiting for detailed acceptance criteria for all possible types of surfaces, material, and defects. The criteria have to come from Potmor's designers, and has not been prioritized high on their work load. The visual quality requirements were discussed with the plastics, light-metal, and painting supplier before MAEP3 was done. That meeting gave guidelines to determine the acceptance criteria to be noted in the instructions.

6.4.1 Preparations Done with the Mechanics and Painting Suppliers

The suppliers had done preliminary work instructions for the operators regarding the parts of Mede. In addition to that, golden samples are manufactured when the design and moulds are complete. The inspection environments have to be harmonized before MVP so that the inspection situation simulates the volume production as well as possible.

SPC will be applied to the molded light-metal Q-CAP parts, probably both before and after the finishing. Hence it ensures that all the necessary information from the molding and finishing will be gathered. The items and dimensions in SPC can and should be changed if necessary.

Regular meetings to discuss business and quality topics have been preliminarily planned with the suppliers. In the meetings the monitored quality levels can be discussed and possible issues corrected.

6.4.2 Preparations Done with the PWA Supplier

Assembly and testing jigs were done to one Q-CAP item and to one PLR item. The one for Q-CAP item was related to the CTQ-parameter. The plans for MVP including the attribute variable capability study and the process audit were described in section 6.2.2. The quality topics are discussed in the monthly cross-functional meetings with the supplier, and the quality of the first few volume production series will get special attention from the supplier, Potmor's designers, operations, supplier quality engineer, and sourcing.

7 Discussion

This discussion focuses on the application processes of the tools with the suppliers, the designers, and the SQEs, as the small amount and size of prototype series made the measurable defect data small and not feasible for in-depth statistical analysis.

Most of the case suppliers have not been used to these quality management tools, because their customers' volumes are relatively low and they are not used to high quality requirements. Therefore the implementation with the suppliers would have required more support from the case company Potmor than it was possible to give. Although the SQE resources in Potmor are now much better than used to be a couple of years ago, Q-CAP is not the only responsibility for the SQEs. The limited time and the cost reductions affected SQE's and designer's possibilities to travel to the suppliers' sites during the prototyping process. It would have helped the suppliers not accustomed to quality management tools, if the process failure mode and effects analysis, the control plans and the prototype feedback forms had been done together with them for the first time.

Based on the experiences from this study, the Quality Controls Approval Process cannot be implemented with many suppliers in one PDP without increasing the SQE resources. On the other hand the time needed for the Q-CAP depends much on the supplier's previous experience about quality management and on the complexity of the supply chain. As the SQEs and designers now have more experience, it should be easier for them to use the quality tools in future projects with suppliers, and sub-suppliers.

The time between the series was long and therefore the supplier's manufacturing processes could have changed remarkably between the prototype series. In addition it was difficult for the Supplier Quality Engineers to follow the project progress, because they could not concentrate only on this Product Development Project.

The amount of documentation required by the updated design controls had decreased project electronics designers' willingness to do any documentation considered as extra, which affected the prototype feedback communication.

7.1 Use of the Tools with the Case Suppliers

The implementation of the quality management tools was planned to the Part Prioritization Log. The prioritization of the QM efforts was focused to the right items based on the experiences during the prototyping. The designers reported only one defect in the other parts than the ones supplied by the case suppliers. Among the case suppliers' parts the Q-CAP parts included most of the defects and the moulds for the Q-CAP parts were the most difficult to get completed. According to the designers, the tool manufacturing of the Q-CAP parts would have been faster if the co-operation with the suppliers during the quoting process had been better. The beginning of the tool manufacturing has a significant effect on the quality and the manufacturability of the molded mechanics parts.

The mechanics designers emphasized the importance of the supplier selection and the quoting process including the requirements review. After the supplier is selected, the orders should be given to the supplier to build trust and commitment to the project. Otherwise the supplier may not put enough efforts to analyze the manufacturability of the parts and the tools. The quoting for the tools should be documented carefully; in this project there were some misunderstandings about the agreed mould structures, which finally affected the mould manufacturing and modification process. The mould orders can have a long lead-time, and have to be done early in the project. When the supplier can be sure that the customer purchases the mould or other expensive tool, they can start designing and building such a tool they think is appropriate and give detailed feedback to the designers about the design. That would begin the requirements review properly.

7.1.1 Light-metal Supplier

The Q-CAP and the proto build report tool were new to both parties. Thus more visits to the supplier would have been needed to give the suppliers hands-on training

to utilize the tools effectively and efficiently. The supplier's understanding about the use and the advantages of the tools increased during the PDP. They said that they had started to give more attention to process monitoring and control. The supplier will implement some of the used quality management tools in their corporation's other sites as well.

Most of the challenges with the light-metal supplier concerned the sub-assembly that included a large part painted at a subcontractor. The PFMEA and control plan could not prevent all the defects at the sub-assembly and painting of the MAEP3 prototype series. The defects were partially due to the mould, partially due to the suppliers' processes. Therefore both suppliers' PFMEAs and control plans need to be reviewed and updated after the MAEP3.

The Part Layout Reports and the proto build feedback reports helped the designers to make the appropriate changes to the drawings, the target values, and the tolerances. The supplier got input from the reports to design the measurement jigs and to modify the moulds.

With the light metal supplier the PFMEAs were done for the assemblies, and control plans and PLRs for the individual casting parts that belong to the assemblies. After the capability studies it could be discussed whether to make control plans also for the assemblies. In that case only one control plan could cover all of the individual light-metal parts, if their manufacturing processes are very similar. As a result there would be two PFMEAs and control plans for the assemblies, and one PFMEA and control plan covering all the individual items. So the outcomes of the PFMEAs would be linked better to the control plans, ensuring better coverage and less repetition.

The designers and SQEs did not have much time for the prototype feedback process regarding the light-metal items and sub-assemblies, partly due to personnel changes in the designer and the SQE teams. More focus would have been needed, as the prototype feedback process was slightly complex in the beginning for the part that is painted and goes back to the supplier for sub-assembly. In addition the assembly is a very essential part of the product. The suppliers felt the used feedback form

confusing, so there was need for improvement both on the form and in its use. The reports from the last builds were finally informative and will initiate preventive and corrective actions from the suppliers or design changes.

7.1.2 Plastics Supplier

The execution of the first elements of the Q-CAP with the plastics supplier did not require much effort from the author or the SQE. The plastics supplier had a clear process in place to perform Q-CAP and using golden samples. The plastic supplier also ensured that the painting supplier made the PFMEA and the control plan. Thus Potmor can learn from their practices during this PDP. The advantages of performing the Q-CAP with the plastics supplier cannot be estimated yet, because the mould supplier molded nearly all of the parts. The PLRs, process capability studies, and process audits will be performed when the supplier receives the moulds from the mould manufacturer.

The challenges laid in the implementation of the prototype feedback process. The form itself and the process were improved during the PDP based on the supplier's and the mould manufacturers' feedback. Using the feedback form with over 50 plastic parts revealed the improvement opportunities on the feedback process and on the form. There were many people using the feedback information, and everyone had their own opinion about the required quality for the parts. Giving sufficiently clear instructions to modify the mould was difficult, but very important. The next version of the form will therefore include the prioritization for the defect corrections. The mould manufacturer did not always make the requested corrections, and did not give any reason for that. The mould modification became quicker, when the mould supplier was given permission to send the mould to the plastic supplier after all the requested modifications had been done. In this project no sanctions were used to speed up the mould modification process, but in the future clearer rules and processes must be agreed in the beginning of the project. Penalties have to be given according to predefined rules if the schedules cannot be met. In spite of the challenges faced, the mould modification was nearly finished at the time of MAEP3.

The prototype feedback from the plastic parts painting was not so well documented as expected, but the painting quality of the MAEP3 plastic items was satisfactory.

7.1.3 Sheet Metal Parts Supplier

In this PDP the part layout report was seen as an appropriate tool to be used with the sheet metal supplier, i.e. no Q-CAP was performed. The supplier got good data for themselves when doing the measurements and the quality requirements became more familiar to them. In addition, the designers' time was saved, as they did not need to measure the parts.

The visual quality was not important with those parts, and the tolerances for the dimensions were not too difficult for the supplier's manufacturing process. But if the specifications are tightened, a continuous variable Gage R&R and a capability study could be considered.

The prototype feedback form was sent only when the designers found defects. When the feedback form was connected to the PLR, the two reports supported each other. Linking the two reports together should be tried as well with the plastic parts in this PDP when the PLRs are done for those.

7.1.4 Printed Wire Assembly Supplier

It was noticed on both the practice Q-CAP and on the actual PDP's Q-CAPs that it's difficult to find reasonable critical-to-quality parameters to focus the Q-CAP efforts on the PWAs in this PDP. Where there are no critical dimensions to measure, the Gage R&R, the part layout report, and the continuous variable capability study are difficult to utilize for the PWAs. The Q-CAP could be more useful if the tolerances of the physical dimensions on the PWAs were stricter or the height of the soldering paste pile would be more critical and defined in more detail than in this PDP. Otherwise the most important is, in addition to the requirements review, to get the soldering process stabile and use the AOI and the testers appropriately to mitigate the quality risks.

In the future the PFMEAs and control plans for this supplier can be based on the ones that were completed for this PDP. The monthly meetings and open communication help to discuss about the Q-CAP implementation in this and future projects. The supplier's quality manager considered the Q-CAP to be reasonable, if appropriate parameters to measure are found.

The most common defects in the prototypes and in the old version of the Mede were the soldering and component defects. The component defects cannot be easily prevented with Q-CAP, but soldering problems could be decreased through better communication about the design in the beginning.

Although the feedback reporting was not very smooth with the PWA supplier in this PDP, most of the designers agreed that the feedback communication had not been good enough earlier and that improvements were needed. Also the supplier was grateful that the designers now had to react to all of the supplier's notifications or suggestions to change the design. Including the information from the visual inspection and the reworking to the feedback report should help the PDP team to better understand the manufacturability of the PWAs.

The proto build feedback form was too heavy for the designers and the suppliers, thus a simpler version of the form should be used in the future for PWAs. The prototype feedback reporting has to be started from the first prototypes as part of requirements review, and the prototype reports could be used to select the applicable Q-CAP elements with the supplier. The supplier wished that Potmor would ask their comments for the design and component selection before the first prototypes. They also wanted to know more about the function of the each PWA and on the other hand to advice the designers about better PWA-specifications and component selection. All in all, in the future the requirements reviews should be more thorough whether or not the Q-CAP is performed.

7.2 Preparing the Supplier Quality Management for the Mass Production

Because the completion of Potmor's general level visual quality inspection instructions was delayed, the suppliers could not yet finalize their working instructions. If the instructions are not completed in time, the suppliers might not have time to update their instructions before the MVP series. The instructions will serve also old products and all future projects.

All the parties agreed that the golden samples of mechanical parts have to be done and shared with the supplier chain members. The samples, testers, jigs, work instructions, and statistical process control in addition to the control plans are expected to help to identify and prevent quality problems during mass production.

In addition during this study light metal casting and sheet metal suppliers started to implement some long-term quality development projects to improve their quality. Their projects focused to basic quality management methods, like better process controls and regular quality focused meetings with production workers etc. The outcomes of the projects are hoped to help with the quality problems of the old products.

8 Summary and Conclusions

This study was made for a global medical device manufacturing company, called Potmor in this study, at the company's Helsinki site in Finland. In Potmor's Helsinki site there was a need to improve the purchased material quality. This study was made in the product development project of a new product that will have a major role in Potmor's product portfolio. The seven-element Quality Controls Approval Process (Q-CAP) and the Proto Build Feedback Report were implemented with five suppliers, Potmor's supplier quality engineers, and electronics and mechanics designers in this product development project. Preparation of the inspection instructions and criteria, the golden samples, and Statistical Process Control for most of the custom mechanical parts was started. The purpose of this study was to help the parties to implement the above mentioned quality management tools in a reasonable extent and analyze how to utilize the tools as well as possible. The implementation of the tools should finally result in better quality of the parts in the mass production. Some of the Q-CAP elements have not yet been performed due to the project schedule, but the plans for the execution have been done. The results of this study will be used in upcoming PDPs to optimize the quality tool implementation in Potmor.

All case suppliers were quite different from each other from the quality management point of view, which provided good learning material for this study and for future projects. The requirements review proved to be the most significant element of the Q-CAP with most of the case suppliers. The following conclusion by Dale et al. (1999) summarizes most of the lessons learned from this study: "Quality is created in the design stage and not in the control stage. The majority of the quality-related-problems are caused by poor or unsuitable designs of products and processes. Changing from detection to prevention requires not just the use of a set of tools and techniques, but the development of a new operating philosophy and approach, which requires a change in management style and way of thinking."

Many of the challenges faced with the plastic and light-metal suppliers could have been different if the requirements of the parts had been analyzed with them in detail in the beginning. A thorough review requires lots of time, good co-operation skills and commitment from the customer, supplier and sub-suppliers. Support from the sourcing function is also needed to create a productive requirements review.

This study showed that the other, more advanced, elements of the Q-CAP can be difficult for the suppliers to perform for the first time and they should be given hands-on training. The face-to-face trainings with some of the case suppliers proved to be very useful and more effective than giving advice by phone. Overestimating the suppliers ability to perform all Q-CAP elements by themselves may result e.g. in ineffective PFMEAs and control plans, and part layout reports that have taken many days to complete. All elements of the Q-CAP were not found to be suitable or necessary. E.g. for the PWAs of this PDP there were no reasonable dimensions or attributes to measure or inspect. For the most difficult custom mechanical parts all the Q-CAP elements were considered appropriate.

The importance of appropriate communication cannot be emphasized enough. Sometimes everything was not done in time or properly because there were misunderstandings or the supplier had not asked guidance for issues. The misunderstandings were not prevented although the suppliers were many times encouraged to contact Potmor if they had unclarities.

The author of this study did some of the tasks that the SQEs normally do with support from the SQEs. The SQEs worked as mentors and leaders in the background in this project. The author took care of most of the communication with the suppliers and the designers and coordinated the quality management tool implementation with them. The roles of the SQEs and the author might have confused the suppliers. The SQE is probably more capable to improve the implementation process, when (s)he is more in direct communication with the designers and the suppliers.

The SQEs and the designers have to arrange time to analyze and react to the prototype feedback, part layout reports and capability study results. Otherwise the

supplier might not make the necessary improvements to their processes or they can get the impression that their work has been useless. If the designers and the SQEs do not react in time, the same problems are faced again in the next build.

The prototype communication has to be effective and efficient, especially in a PDP having over 80 parts needing feedback communication. The study showed that the proto build feedback form has to be very easy and intuitive to use, otherwise the suppliers and designers may not take full advantage of it. The process how to use and send the form has to be smooth and accepted by the parties. A poor feedback process can cause delays to the whole project. Using only one type of feedback form for all kind of parts and assemblies was not optimal. The proper use and complexity of the form depends on the amount of information needed. Although the suppliers and designers were advised not to fill all the fields on the form, they were still confused how to use it. Finally after simplifying the report the feedback process began to function as it was expected with some of the suppliers, but still the process can be improved.

Suggestions for further studies

Although the case suppliers were all different from each other, it would be interesting to try these quality tools with suppliers that produce some other kind of parts. For instance one potential supplier group to study could be power supply vendors, because the power supplies are critical for the whole product and they have been problematic in the old products. Advice for the implementation could be asked from other Potmor SQEs with experiences quality management tool implementation with such suppliers.

Above all, a follow-up study should be made a couple of years after the mass production has been started when statistically reliable DPPM data is available to give answer to the research hypothesis; Does the quality management tools improve the purchased material quality in the product development project in medical device manufacturing.

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Appendices

Appendix I: Logistics Diagram for the Mechanical Parts