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NEW TECHNOLOGY SUPPLIER DEVELOPMENT IN REGULATED CONTRACT MANUFACTURING

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New Technology Supplier Development in Regulated Contract Manufacturing

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Abstract
The purpose of this study was to investigate working on a project with a new technology supplier in a regulated environment. The aim was to identify the effects related to a triangular relationship, success criteria and success factors. The improvement needs identified during the study were converted into suggestions for improvements.

The study was qualitative by nature and used observation, case study and interviews/questionnaires as research methods. The literature review and observation part was carried out from 2013 until 2015. The case study, interviews and questionnaires and data analysis were made in 2016. The personnel to be interviewed and cases to be studied were taken as discretionary samples.

These results suggest that the new technology supplier projects are following the same principles as other projects. The main finding during the study was that the new supplier relationship will need more time and focus to be able to succeed and this should be taken into account in the schedule and resourcing. There is also a need for improving internal project processes around the technology projects to be more efficient especially when working with a new team.

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Technology, Supplier, Regulated, Contract, Manufacturing

CONTENTS

1 INTRODUCTION

The subject of this thesis is developing methods for improving the co-operation, understanding and responses to the needs of customers with the newly selected technology suppliers. The subject was agreed together with my employer, a Medisize Oy representative. The main aim was to find the most beneficial development work for the company, which would have close connection to my current duties as an employee. The thesis will benefit the sister companies to develop their co-operation with new automated technology suppliers with more tailored assembly technology. This thesis gives guidance for the co-operation creation from the supplier selection process until the supplier acceptance trial for the assembly machine.

As the author of the thesis, I got the opportunity to work in a close relationship with the project team to industrialize sub-assembly manufacturing for a product with one pharmaceutical customer and two new assembly technology suppliers (Supplier 1 and Supplier 2). The subject was current as the project was on going at the same time as the thesis was written. The supervisor on behalf of Medisize Oy was Plant Manager (MSc) Keijo Riuttala.

The thesis was seeking information on how the three parties view the technology acquisition project and success factors. The main focus was in the responsibilities of the sub-contractor that is leading the new technology supplier relationship and acquisition project. The technology suppliers were limited into automation and printing suppliers. The work was based on qualitative methods. This thesis presents some improvement opportunities concerning the relationship and co-operation to achieve the best possible project outcome.

Phillips-Medisize Corporation designs and contracts manufactures of both components and finished products into drug delivery markets. The main customers in the drug delivery segment are so-called “Big Pharma” companies. (Phillips-Medisize 2013.) The Medisize Oy Kontiolahti Plant is focusing on multicomponent drug delivery devices with high volumes.

The Drug Delivery Devices life cycle is rather long compared to consumer products. The decision point, when a concept, supplier and co-operation model for Drug Delivery Device assembly line production is selected, will determine the success in production for the following decade. The supplier-customer relationship has to be well established to ensure good co-operation for the life cycle of the assembly machine. The assembly lines are owned by the pharmaceutical company, delivered by the technology supplier, and run by contract manufacturer. Medisize is the contract manufacturer in this case. This triangle, shown in Figure 1, has to have the same goals and the common understanding of how to meet these goals. The performance has to be well built in to the assembly process. The line has to be robust, and the robustness must meet the compliance towards standards. Regulations have to be proven in several steps prior to production starting. This relationship creation, co-operation and the technical solutions are built during the assembly technology project. This project is a temporary endeavour undertaken to create a unique result. The project also has a beginning and an end.

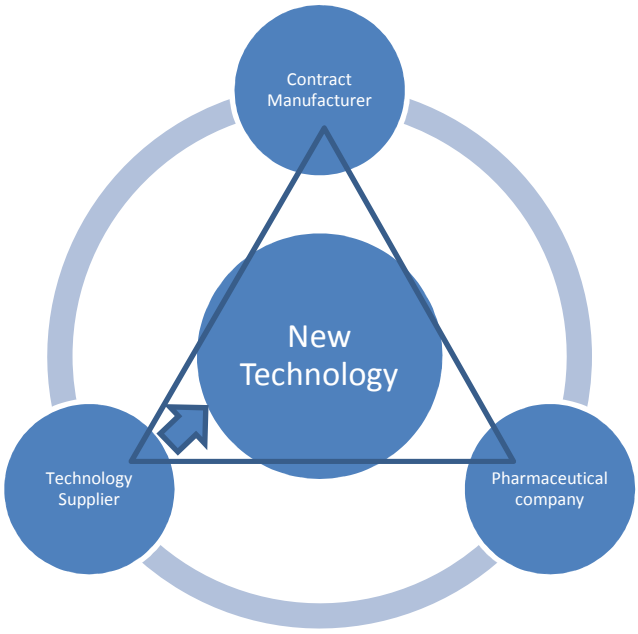

Figure 1. Relations of the three participants and the outcome.

The process of acquiring new technology for the production plant will start from customers' needs and will end after removing the technology from use. This thesis is limited to the process after the supplier selection until the production starts. The production phase is only used for measuring the success of these previous phases.

The areas related to the thesis work are supplier management, supplier knowledge, project management including resourcing, co-operation between the parties and information transfer between the parties.

The literature regards project management, supplier management, information transfer and for manufacturing technology acquisition, but in the literature the context has been missing some of the elements or aspects used in this thesis work. The aspects to be taken into account more are a regulated environment and the triangle of owner (pharmaceutical company), supplier (technology supplier) and user (contract manufacturer) of the assembly technology.

2 LITERATURE REVIEW

2.1 Success factors and failures

When evaluating the success and customer satisfaction in cases of production technology the same rules apply as for other customer relationships. Particular missing features will cause clear dissatisfaction. Some features, even though a customer has not been able to define them beforehand, will cause customer satisfaction when available. The product in this case includes the whole supplier development project including the production technology operating in the final destination as an end product. This entire chain needs to be taken into account when evaluating the quality and the customer satisfaction.

The project objectives are appropriate criteria for success. There are several more objectives for the project than just cost, time and quality especially when considering all stakeholders in a project. The objectives are not the same throughout the project

lifecycle. (Wit 1988, 164.) The success criteria can be also expanded to a wider perspective. This would have two types of success criteria. The first criterion is goal achievement, including the successful handover of the direct deliverables in an agreed timeline, budget and according to the specification. The second criteria would be mission achievement of the project, meaning how much the project supports the execution of the company strategy and achieving the goals of the strategy. (Andersen 2008, 93.)

The success factors are the enabler for the success criteria in a project. There are several different lists of success factors presented in the literature for general projects, e.g. by Pinto and Slavin (1988), Grude, Turner and Wateridge (1996), Morris and Hough (1997), Turner (1999), Cooke-Davis (2001), Hartman and Ashrafi (2002). (Basu 2012, 61, 64.)

The literature identifies project management success and failure factors for the projects. An example of the list is presented below.

Success factors for the project management:

- clear outlining for the project work
- project manager concentrating on the project
- clear assignment
- motivated employees
- common goal
- clear anticipation, roles and human resource allocation
- appreciation of participants' values
- good planning
- objectives split in milestones
- shaping of the goals
- continuous communication and introductory training for team members
- decision making is based on information with good quality
- follow-up of the results and milestones

(Lööw 2002, 18-19.)

Most common failure factors:

- inadequate planning
- inadequate togetherness
- confused project
- no follow-up against the project plan
- inadequate motivating
- inadequate framing of the project
- the project manager is not able to say no
- the project group is too homogeneous
- too big of a project

(Lööw 2002, 18-19.)

For the project there can be set for different type of success criteria:

- time criterion
- monetary criterion
- effectiveness criterion
- client satisfaction criterion

(Pinto & Slevin 1988, 169-170).

Less information can be found for specific technology related projects and even fewer for the GMP (Good Manufacturing Practice) regulated environment. The GMP regulation is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product and used for ensuring that products are consistently produced and controlled according to quality standards.

An automation project has to support the company strategy to get the needed justification for the implementation of a changed production process. It is also important to get early involvement from the personnel that will work with the installed system. Knowledge will spread and the users will be more motivated. The lifetime of the system has to be included as one element when considering the possible solutions for the automation. (Sandberg 1992, 25.)

Mallon collected success factors for the manufacturing technology acquisition from relevant interviews and literature in his thesis. Mallon identified 75 success/failure factors (see Appendix 1) and 38 measures (see Appendix 2). The factors were grouped in 9 categories and measures in 7. In his study 51% of the success and failure factors were unique to an individual project, and 47% of the measures were unique to the project. Production output, quality and downtime were the three most frequently used measurements. Manufacturing performance measures presented the largest group of the measurements, followed by economic and financial. (Mallon 2002, 111-116, 123, 304.)

Mallon also suggested using the factors and measures to create checklist questions for different phases of the project. These help to evaluate the success of technology acquisition (Mallon 2002, 304).

Especially for automation application projects in a bio-pharmaceutical environment, it is mentioned that clear organisation can make the project succeed or fail. A systematic manner established for handling and storing the project related data in the beginning of the project will help. (Buckbee & Alford 2008, 161.) Based on the study made by Pinto and Covin, the critical success factors are dependent on the type of the project and the stage of the project life cycle (Pinto & Covin 1989, 59).

Evaluating the three different aspects of the project outcome to assess the success or failure of the project has been suggested. The first one is the implementation process and its efficiency and performance of the project team taking into account: staying on schedule, on budget, meeting the technical goals and a good working relationship within a team and parent organisation. The second is the perceived value of the project assessed by the project team emphasizing the value and usefulness of the project's deliverables and potential impact of the users. The third aspect is an external measure by the client to measure the project performance from client satisfaction point of view. (Pinto & Mantel 1990, 270.) Wit (1988, 165) has defined the project success as follows

> **"The project is considered an overall success if the project meets the technical performance specification and/or mission to be performed, and if there is a high level of satisfaction concerning the project outcome among key people in the parent organization, key people in the project team and key users or clientele of the project effort".**

2.2 Human resources and relationship

Part of project management is organising, managing and leading the personnel working on a project. Different skills in the project team will be needed to be utilized and it is suggested to involve the team members to planning to get their better commitment to the project. Project team member involvement can vary during the project life cycle; some may be full time for the whole project, while some may be only involved part time in a certain phase of the project. To be able to utilize the resources in the best way the human resources need to be planned as a part of the project planning. (PMI 2013, 255; Hyppänen 2009, 85.) One person may be involved in several projects at the same time. There might be several project managers involved.

A supervisor is responsible for ensuring the well-being of the employee when the project manager is responsible for the success of the project. The project manager and the supervisor need to work in deep co-operation and they need to have good negotiation, interpersonal and organising skills. (Hyppänen 2009, 85.) The success of the organisation is dependent on how the individuals and groups are going to work actively towards to the common goals, and the commitment to work towards the goals is more important than the structure of the organisation. Conflict management is one of the challenges. (Hokkanen & Strömberg 2003, 59.)

Authoritarian management is not the way to manage a professional organisation working in a project. The team needs to work effectively to meet the goals. A project team needs to be planned. The plan should take into account not only the competences and skills but also the capability to work as a team. Conflicts between the team members will be reflected in the functionality of the whole team. (Ruuska 2005, 43.) A human resource plan should include defined roles, responsibilities, organisation charts, plan when, and how personnel will be acquired and how long they are needed and needs for training (PMI 2013, 263-267).

Project success depends on the management and leadership skills, functionality of the organisation and decision-making processes and the communication skills and relation management skills. Project management is still too often thought to be only managing technical items and leadership as well as relationship management are forgotten.

(Ruuska 2005, 30-31.) The project manager has key role in leading the project. His/her role is additionally to manage and lead in order to minimize disturbing factures around the team. Leading the team will be based on teamwork and co-operation between professionals. Hierarchy should have less weight. The project manager is an operative leader that has the responsibility of daily activities. He/she will delegate the tasks to the team members and concentrate on the control processes. (Ruuska 2005, 123-126.)

Stakeholders will have their own agenda that they want from a project. The expectations from the stakeholders need to be exposed to be able to define and agree the scope and objectives of the project. The project sponsor and the customer are the two main defined stakeholders. Poor stakeholder control can lead to confusion and frustration in the project team through perceived interference. One individual would present the customer by who has the necessary authority to make the decisions in the ideal situation. (Young 2006, 72.)

This type of relationship is according to the agency's theory. Agency theory is directed at studying a relationship in which one party called the principal delegates work to another called the agent. The agent is performing the work. The agency theory is especially addressing the question of how to achieve the optimal solution for the principal. One area that requires attention in a project is communication (Eisenhardt 1989, 58-63; Young 2006, 79.) A bridge over different parties to define common goals and working methods can be created with well-organised communication. The knowledge about the work and behaviour of an agent is transferred to the principal and risk of the different approaches is getting lower. This can also be achieved with longer relationships when the principal knows the agent better. (Eisenhardt 1989, 58-63.) The project manager will also control different interest groups via communication (Ruuska 2005, 123-126).

Communication during the project supports the basic functions of the projects to support achieving the goals. Communication ensures the understanding between the parties and creating basis for co-operation and dialogue. Motivating, coaching and encouraging the team members are all parts of the communication. It also summarizes the steps taken and identifies the next steps. The project environment requires a quick response to the required changes with shared knowledge and learning. (Kauppinen,

Nummi & Savola 2010, 306; PMI 2013, 288.) The project manager holds most of the communication responsibility. The project manager's work includes communication with team members and other project stakeholders internally in the different organisation levels and to external parties. Project communication has several aspects to be taken into account: planning, collection, creation, distribution, storage, retrieval, management, control monitoring and disposition. Communication in the project management environment and general management requires the same skills. (PMI 2013, 288.) Effective communication will influence the project outcome (PMI 2013 288; Wellman 2011, 283; Kauppinen et al. 2010, 306).

The communication plan should be part of the project planning (PMI 2013 288; Wellman 2011, 298). It has been repeatedly identified in post-project assessments that communication needs improvement. Project teams are built up from individuals from different geographical or specialist areas and may include cross-functional or inter-organisational teams. This means that communication networks have to be planned separately to particularly suit individual projects. If the project team is small and has already worked together, setting up the communication system is rather straightforward. When the project is complex, large and includes multiple new persons working for the first time together, setting up the communication will be much more demanding.

The project communication must be able to facilitate a large amount of information and highlight the important items from the big volume of information. The communication has to flow in two directions. There are both formal and informal elements in the project communication. Formal communication includes e.g. plans, monitoring, reports, reviews and informal communication includes e.g. personal relationships and discussions. Cultural differences and interpretation have to be taken into account in the communication. The communication need to be open, robust and honest internally and towards the external stakeholders. (Wellman 2011, 283-295, 300.)

Successful project communication can be summarized as follows:

- Project goals, including the result, schedule and resources have been clarified and are clear for all parties
- Team members know their responsibilities and tasks and understand the relation to the overall project

- Reporting is efficient and adequate
- Enough correct information is given promptly to those needing it
- Documenting and archiving supports the project work
- Appropriate tools are used for producing and distributing the information
- Meetings are planned, structured, interactive and the made decisions are clear

(Kauppinen et al. 2010, 313.)

2.3 Project management

Project management is identified as a way to organise group of people to function to meet the goals of the project and complete the defined tasks. It is mostly managing the people. (Ruuska 2005, 29.) Project management, if well done, can support the achievement of success in a project. Good project management however does not quarantine success, and despite poor management the project can be a success. (Wit 1988, 165.)

The project may be led from the task perspective where the main focus is on the tasks to be done and how to optimize the work to do the defined tasks (Andersen 2008, 5). This is a widely used perspective reflected by the project management standard PMBOK® (2013) and also by Ruuska (2005). The project owner naturally needs to control the project. It is a fact that the project owner, here the customer, and the agency, here the project team and supplier, delivering the project does not have exactly the same attitudes, knowledge, information and interests causing the need of controlling of the project progress. Controlling the project depends on the project characteristics. If the project has a high outcome of measurability and work processes of the project are well known then controlling the project can be based on the outcome. (Andersen 2008, 14-16.) Based on this classification controlling the machine delivery project can be based on the outcome.

Even though the outcome control can give the formal structure for the project the socialization covering the whole project team will support achieving the common goals

by formatting of an understanding of the ambitions of the project owner (Andersen 2008, 17).

Different life cycle models and phases are presented for the projects. For example there is the six model with six phases and phase gates presented by Young, the three phase model by Ruuska and an unlimited number of phases presented by PMI (Young 2006, 34-35, PMI 2013, 41-43, Ruuska 2005, 32). The model by Ruuska is used in this thesis.

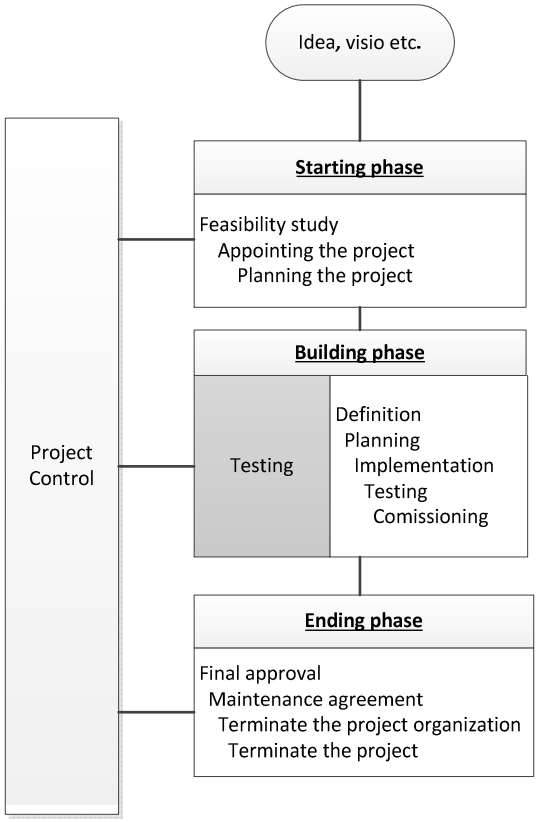

Figure 2. Project life cycle and phases (Ruuska 2005, 32).

The **starting phase** of the project will include the feasibility study, setting the project and creating a project plan (Ruuska 2005, 33-34). The correlation between the planning of the project and the project success has been shown. The challenge with traditional project planning is that the key decisions are made when we have the least information. The project manager tends to follow the original plans and goals to achieve deadlines and budget even sacrifice the project relevance. Changing the plan in a project may harm the project success. A minimum of two levels of planning needs to be prepared.

The high level plan is more impervious to the changes and the detailed plan with higher details and more flexibility is tied to the high level plan. (Andersen 2008, 123-127.) The high level plan should have milestones as basic building blocks.

The **building phase** includes the following phases: product definition, design, realization, testing and implementation phase (Ruuska 2005, 36). The main challenges in project work are rarely technical issues but mainly related to lack of control and missing methods. A project may have been prepared poorly. It could be that the scope of the project is unclear or changing or the commitment and support is missing, causing resourcing issues. Resources are part time, causing commitment problems and increasing the amount of personnel involved. There might be issues of goals and different views between the project- and line organisations. Personnel conflicts reflect the whole project group. Unrealistic goals result in no possibility of achieving them.

There might be project planning mistakes such as: over optimistic schedules and work evaluations, the availability of resources being over-evaluated, competence and experience of the personnel involved are not taken into account and the surrounding links to other tasks. There can be poor scheduling: not enough details in the schedule, the timelines do not correspond to the work itself, tasks are missing, no safety margins are used, and schedules are not up-to-date or not readable. Lost time might be compensated by taking time away from the next project phases. A clear starting and end points are missing. It is important that the starting of the project is launching the project work immediately. Defining the milestones and deadlines are important for follow-up and to be able to set goals more frequently during the project. (Ruuska 2005, 38-48.)

Effective communication during this project phase is essential due to a project being managed with communication (Ruuska 2005, 75). The operative communication required to carry out the tasks in a working environment is emphasized in project communication. Weak signals need to be followed to detect the changes that can affect the project performance quickly enough. (Ruuska 2005, 79.) Effective project work requires that the project manager is on a daily basis in contact with the project group. Communication to receive advice and instructions from other project team members is also important. Meetings are one of the characteristics of project work. Unofficial communication and networking between project team members are needed.

Communication has been identified as a part of the critical path. Project work will easily slow down if important information is not transferred to the persons requiring it. (Ruuska 2005, 80-81.) It is commonly known that a message can be misunderstood easily or does not reach the target. The message will change more when there are more persons between the sender and receiver. (Pelin 2009, 296.)

The criticality of the communication is highlighted also by the study made by PMI. Based on the study it was confirmed that

> **The project success is dependent upon communicating the right information to the appropriate stakeholders using clear and relevant language that resonates with the audience. Ultimately, more effective communications leads to improved project and program management, more successful projects, high performance, and fewer dollars at risk. (PMI 2013b.)**

Using a common set of processes, procedures and standard documentation formats will make sharing the information easier. This can be supported by using common computer software for data recording and scheduling. (Yong 2006, 33.)

Introduction training for project team members are essential to get the commitment to the project goals and understand the working methods and tools used in the project. The experience in and capabilities of project work has to be evaluated and strengthened. A kick-off meeting is one part of the introductory training including the introduction to project goals, project organisation, communication and meeting methods, documentation and reporting principles and the working methods and standards to be used in project. (Ruuska 2005, 86-88.)

Each member of the project group will know the reason for the project, the deliverables of the project, the customers of the project, which part of the project his/her tasks are related to and what are the expectations for him/her. Participation in defining the schedules and work plans will improve the commitment. The unofficial norms inside of the project group need to be known by the project manager. When creating the project group personal networks need to be taken into account when organising the project. (Ruuska 2005, 88-89.)

The **ending phase** is the most neglected phase of the project. There has to be a clear closing point for the project. Project documents have to be reviewed to make certain

they are up-to-date. (Watt 2014.) The project related documentation and materials are combined into a project file. Arrangements related to the after project situation for the system is agreed. (Ruuska 2005, 37.) The closing meeting is also an important step for the project work where a full report of the project is presented and discussed (Mallon 2002, 323).

Project documentation is one reason for the long closing time of a project. Documentation is created to verify that the project is fulfilling customer expectations. The documentation is also a tool for transferring the know-how to the organisation from the project team. The need to deliver the documents as a part of the project is understood but they are not finalized in detailed manner. (Leppälä 2011, 49.) The lessons-learned from the project is created to evaluate the possible points to be improved upon and good ways of working can then be transferred to the next projects. This is also a part of the quality management system evaluation regarding how well the project process has functioned. (Watt 2014.)

2.4 Quality in Technology

Quality means the capability to fulfil needs and expectations. When a company measures the quality of a product they compare the product to the specified product definition. (Haverila, Uusi-Rauva, Kouri & Miettinen 2009, 372.) In order to be able to meet the needs and expectations and fulfil the criteria it is needed to define the features and quality level required for the technology manufactured. The following contributory factors are to be considered when defining the system's quality aspects: functionality, flexibility, delivery time and cost (Figure 3). (Suomen automaatioseura ry 2001, 5.)

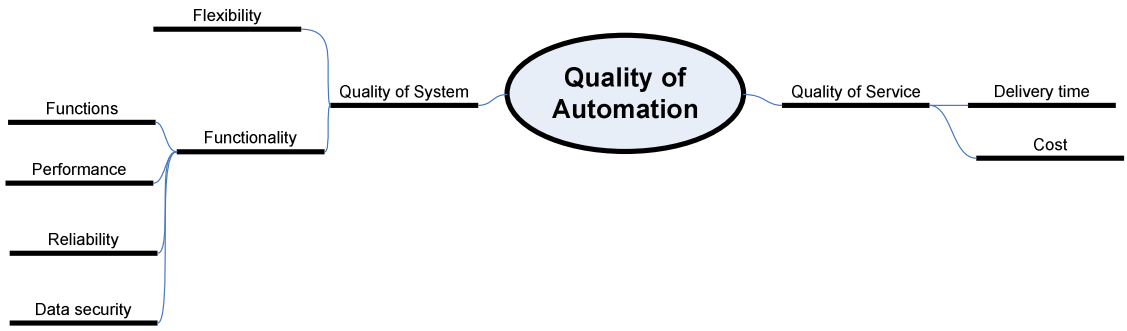

Figure 3. Contributory factors in automation quality (Suomen Automaatioseura 2001, 5.)

The automation system lifecycle begins from the need for an automation system, will continue until production and finally will end to the ramp down of the line (Figure 4) (Suomen Automaatioseura 2001, 17).

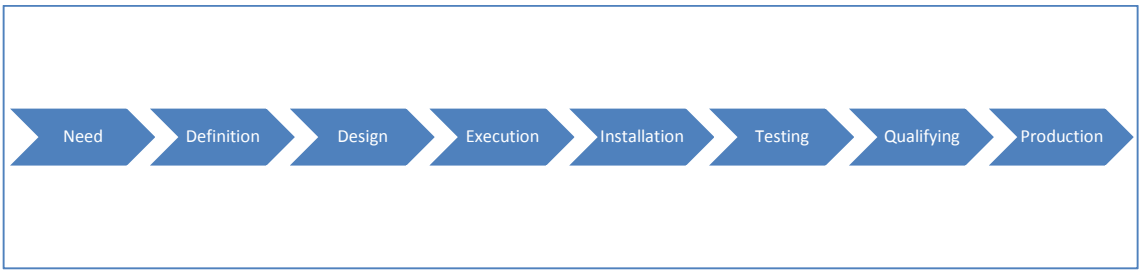

Figure 4. Automation system lifecycle (modified from Suomen Automaatioseura 2001, 17).

There is a standardized approach for automation manufacturing and testing called GAMP (Good Automated Manufacturing Practice). It is a system for producing quality equipment using the concept of prospective validation following a life cycle model. This guidance is specifically designed to aid suppliers and users in the pharmaceutical industry. The GAMP guidance has a life cycle approach to meet the regulatory requirements. The GAMP V-model (Figure 5) illustrates the typical steps, deliverables and connection between the requirements and the verification of the requirements. The V-model is illustrated in Figure 5. (ISPE 2008, 13, 55.)

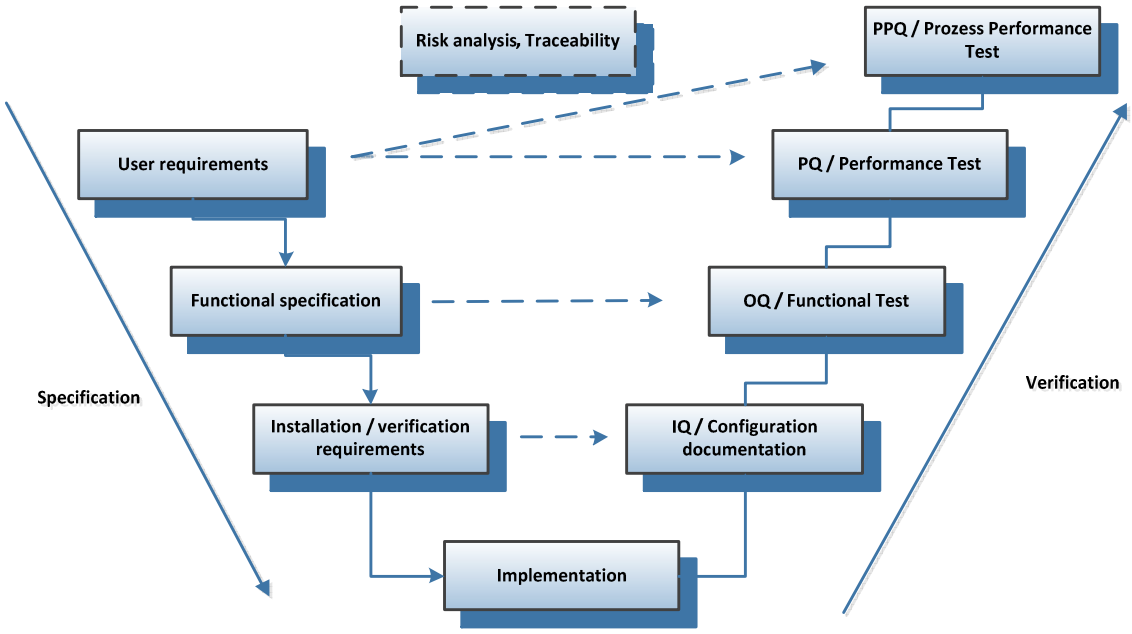

Figure 5. Modified GAMP V-Model (ISPE 2008, 13, 55).

After the need for automation system has been identified the definition phase begins. The V-Model steps Process Requirements, Equipment and Control System URS (User Requirement Specification) are part of the definition phase where the quality and functionality requirements for the equipment are described for the information transfer.
User Requirement Specification is a requirement specification that describes what the equipment or system is supposed to do, thus containing at least a set of criteria or conditions that have to be met.
The data needed for information transfer to suppliers are described. It is also important that all the parties have the same interpretation of the requirements.

Already in offer phase the following points need to be considered:

- Has the quotation request been understood?
- Does the offer correspond the quotation request?
- Have there been additional suggestions that have not been thought about in the quotation request?
- What benefits does the quotation give?
- Is the price in the same frame as other quotations?
- What risks are involved with the quotation and supplier?
- What position in the company do customers have?

- Does the company know the supplier and their way of working?
- Does the supplier have all the preconditions needed from the knowledge and skill point of view?

(Iloranta & Pajunen-Muhonen 2008, 265-266.)

There are requirements for the realization of an automation project in a GMP regulated environment. Management is responsible for establishing the adequate organisation with adequate competences to ensure that the devices are designed and produced according the requirements. The responsibilities and authorities are to be defined. There is also a requirement to validate the manufacturing processes due to the fact that not all the properties of the manufactured devices produced can be 100% tested. (FDA 820.20 & 75.) Relevant sections of the regulation:

> Sec. 820.20 Management responsibility.
> (a)Quality policy. Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.
> (b)Organization. Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.
> (1)Responsibility and authority. Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.
> (2)Resources. Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.
>
> Sec. 820.75 Process validation.
> Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented. (FDA 21CFR part 820.)

Validation and qualification are parts of successful and regulatory compliance assembly technology acquisition. The technology produced is tested against the design specifications in a documented manner. (Buckbee & Alford 2008, 5.) The reason for requiring validation is the belief that quality cannot be tested in a product, but must be built into the product (Buckbee & Alford 2008, 184). It is essential to make sure that the

supplier company is aware of the need to fulfil the regulatory compliance. The expertise and needed resources have to be verified prior to a contract being made. This can be done with a proper vendor evaluation, e.g. an audit.

The supplier of the automation technology has to have knowledge in Good Automation Practices. GAMP guidance gives practical guidance aimed at assisting pharmaceutical manufacturing companies to achieve computerized systems that are demonstrated to be fit for the intended use in fulfilling the current regulatory requirements. (ISPE 2008, 13, 55.) Technology and practices improve. Current regulatory expectations and industry practices are changing. It is important that project team members, especially validation and quality assurance personnel, stay up to date in order to be able to fulfil the expectations. (Buckbee & Alford 2008, 145.)

2.5 Summary

Based on the literature individual success or failure factors that would apply to all projects cannot be identified. They vary among the evaluated projects and are mostly unique to the project. The success criteria are not as project specific, but certain common criteria can be identified, such as: time, money, quality, and client satisfaction. There are also criteria where the positive effect on the company strategy is evaluated. The criteria can vary depending on the project at hand. Also, the overall evaluation of the project is not directly dependent on meeting criteria. It is also suggested that the criteria change during the project life cycle. There are general aspects that are identified to increase the probability of project success; e.g good project management and leadership, resourcing and communication as key elements.

There is a large amount of project literature available. The project approach in literature is generally the same. There are different models of the project phases available. The planning of the project has been shown to correlate with success. The structured way of communication with supporting templates and tools are highlighted to support the project work. It is also mentioned that flexibility and the ability to handle changes is required. The need for competent resources and well set organisation is part of a well-

managed project. The project manager is in the key role to orchestrate the project and the team. Automation projects will fit in to the general project approach.

Specialities in the regulated environment are documented in a few found documents. Regulation is written in the form of general statements that will suite all types of production. This will give lot of room for interpretation. Even though the GAMP guideline is especially written for automation, there is still a lot of room for individual details to be defined in a project specific way. The interpretation of the requirements and the industry practise is changing over time even though the regulation itself has stayed the same. It is also highlighted that awareness of the requirements is essential.

3 PURPOSE AND METHODS

3.1 Purpose

The goal of this thesis is to identify the success factors of establishing co-operation and developing a new technology supplier to meet customer expectations in a highly regulated environment and answer the following questions:

1. How should a relationship with a new technology supplier be established in order to enable success?

The automation technology projects are not mainly copy projects. It is possible that the supplier delivers only one assembly line during the supplier relationship. The new technology projects will require new technologies to be used. This will also mean that new technology suppliers are to be taken in to the acceptable supplier pool. The technology projects carry a high financial burden and will have a major effect on customer satisfaction. It has been identified in the literature that working with the new project team and with different cultures carries a risk regarding project efficiency. It is important to identify the means of achieving success with a new technology supplier.

2. What are the main measures identifying the success of new technology supplier development?

It is important to measure processes. The items to be measured need to be defined so they can be measured. It is important to ensure that all parties have the same understanding of the project goals and commitment to achieving the goals.

3. How does a triangle relationship affect the project management?

The project literature mentions stakeholders. The effect of the three party relationship on project management is not addressed. Technology projects are run with three party involvement, and improving the understanding of the effects will enable the improvement of the processes related to it.

4. What are the main improvement areas in the new technology supplier development?

The projects are important for the company success in the future. It is important to identify the improvement areas for future development.

The thesis will describe the current status of company approach to new technology supplier development. The project identifies the improvement needs for the approach. As a result of the thesis work there is a set of guidelines identifying the key success factors for developing the new supplier and co-operation combining information from the literature, expectations and gained experience.

This thesis will benefit Medisize as a contract manufacturer by creating a company level standard with tools to select, evaluate and develop the supplier. Schedule and total cost benefit will be gained. The project management will be improved. New customers will be assured that the contract manufacturer is capable of operating with new technology suppliers. Customers will benefit by getting better control on project risks in cost, time schedule, performance and compliance. New technology suppliers will benefit by getting a clearer picture of the requirements and needs. Better life cycle management of the assembly technology will be achieved.

3.2 Methods

This thesis used three qualitative research methods:

- observation,
- interviews and
- case study.

The personnel group was too narrow to be able to analyse the information based on the quantitative methods. The main aim was to make the study for Medisize Oy and not to make general interpretations. The personnel to be interviewed were taken as a discretionary sample from the whole group based on their knowledge and research ability using current customer and supplier contacts.

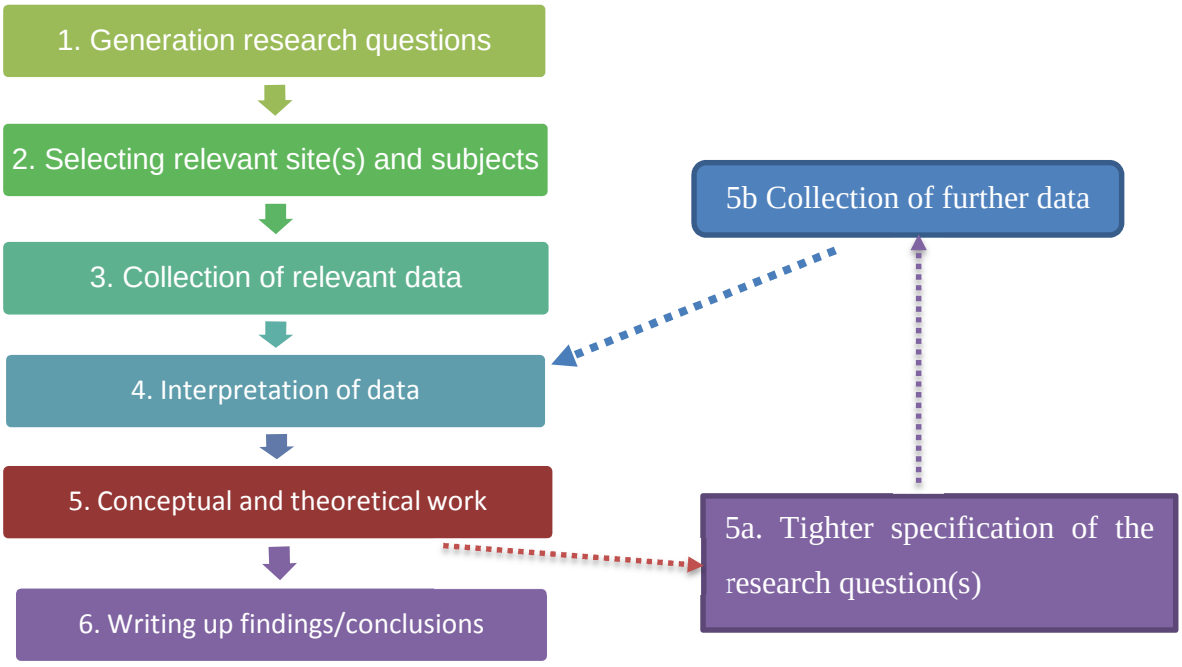

Figure 6. An outline of the main steps of qualitative research (Bryman & Bell 2011, 390).

Observation as participant-as-observer was used to collect information of the projects from the inside. The project team members were aware of the thesis work going on. I was part of the project team and collected the information by taking part in the actual project work in my work role of quality representative in the project team of contract manufacturer.

I collected the information from existing projects with methods such as conversations and observations. During the thesis work I closely observed one project, including two automated machines from two different suppliers. They were sub-projects for one larger industrialization project. The internal project group included the program manager, two project managers, one for each line, me as a project manager of quality, validation engineer, production quality support, and several technical or production specialists from different expertise areas e.g maintenance, production technician, vision system. There was only one project manager and production quality support in the internal team that had not worked with the team members in previous projects. The customer was existing, but some of the customer team members were new to the project team. The areas that were causing or identified as probable reasons for future challenges to fluent project work are described.

I used **Interviews** for identifying the expectations and also bottlenecks of the current practices. I used the case study for data collection of the current methods and processes. I interviewed supplier, Medisize and pharmaceutical industry representatives. I used these interviews to define the expectations for the new technology supplier development that will in the end as an assembly line. The interviews also included an analysis of previous cases.

Selected personnel in Phillips-Medisize organisation took part to open theme interviews or answered to open questionnaire. The focus group included project managers, production managers and development engineer who all went through three themes, GMP, Three party involvement and Project success factors and measures during the discussions or questionnaire. Supplier representatives and customer representatives answered the same thematic questions during the interviews or via questionnaire. Phillips-Medisize higher management and a procurement representative received a question regarding the measurables of the project.

There were thirteen Phillips-Medisize personnel and two suppliers interviewed. There were open theme questions sent by e-mail to three customer representatives and three supplier representatives. Responses from two suppliers were received. There were limited open theme questions sent by e-mail to two Phillips-Medisize representatives.

The content of the interview invitation is in Appendix 3 and content of the e-mail is in Appendix 4.

Medisize representatives from other plants took part in interviews personally or with a thematic questionnaire. Medisize Kontiolahti Plant project managers and production managers took part in semi-structured interviews individually. The aim was to identify their expectations, experience, possible downfalls and success factors for the triangle relationship and the implementation of the new technology supplier and the new technology to the production. The aim was also to identify the measures that characterize the successful implementation of new a technology supplier.

Suppliers and customers participated in semi-structured interviews personally or answered a thematic questionnaire, depending on accessibility. The aim for these interviews was to receive information from an angle different to the triangle parties and identify their expectations, experience, downfalls and success factors. They also identified the characteristics describing successful implementation of a new technology supplier and in case of a supplier, identify the characteristics of a successful relationship with a new customer or user.

The five themes were:

- How does GMP regulation affecting the line project (positive and negative items)?
- How does three party (1st Line Owner (pharmaceutical company), 2nd Project Manager (contract manufacturer), 3rd Line Supplier (technology supplier) involvement affecting the line project (positive and negative items)?
- What are the measures used to evaluate the project's success?
- What are the success factors in the project?
- What improvement areas can be identified from the project management and project work in Phillips-Medisize?

I analysed the collected data for their content by identifying the same themes from the data collected. The relevance for the research questions of thesis work was basis for selecting the themes. The relevant data was identified and marked. The collected data

was classified and typed and finally summarized. There was information from feedback and a lessons learned questionnaire included as a part of the case-study.

A **case study** was used for identifying the best practices and industry standards. There will be GAMP (Good Automated Manufacturing Practise) guidelines analysed. GAMP gives guidelines how to ensure that computerized automated systems are fit to the intended use and compliant with applicable requirements (ISPE 2008, 14). Related standards like ISO 13485:2003 and PS9001 were studied. Data from technology transfer studies were reviewed. The time line of the project, the time line for implementing the technology to production and achieved OEE was analysed from previous new technology supplier development projects.

The case study included success evaluation of previous projects and a study from existing technology projects. Previous projects were analysed based on the project data and the presently used assembly technology. Six projects were analysed. The lessons learned if available from the projects were analysed to identify the success and downfall factors.

The interpretation of the data was made by reflecting information on the data from the literature. If the conclusions from the collected data can be used also for other similar projects in the company was investigated. The improvement needs were listed based on the data collected, and suggestions were made. There is a concept draft created based on the data. The concept handbook draft includes guidelines for the new technology supplier development and co-operation.

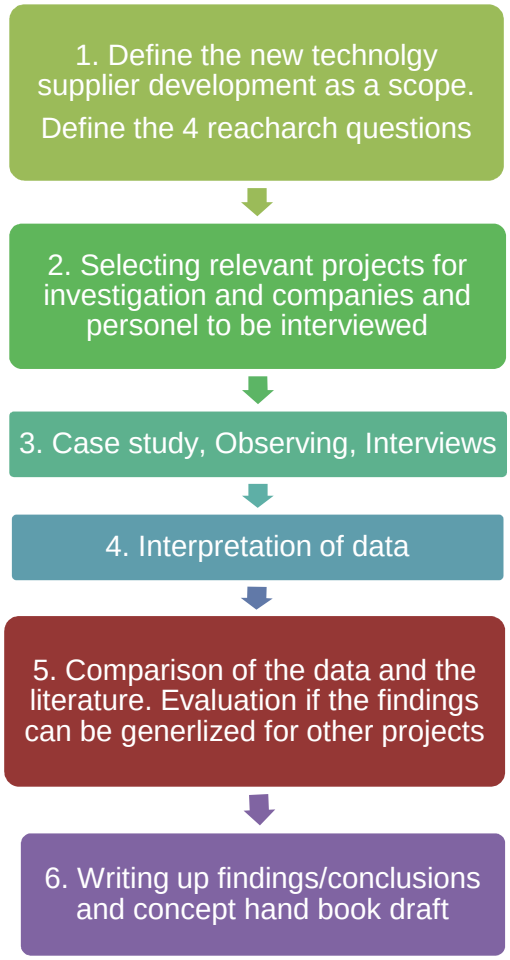

Figure 7. An outline of the main steps of the thesis established into Bryman Bell model.

4 RESULTS

4.1 Observing the project work

It was recognisable that internal project tools including communication were not standardised but were depending on the Project Managers way of working. This was not visible to most of the suppliers due to they dealt only with one project manager nor was it visible to the customer representative due to communication in their direction being more harmonized by the program manager. The effect of this for the project was not highlighted significantly due to the fact that the project group was located next to each, other enabling non-formal communication and follow-up and also weekly structured internal meetings. The positive effect of team's long experience in project

work cannot be underestimated. Even with the experienced team and locating the team members it took some time and effort to be in track regarding the status of the project and tasks to be done. The information was not available in a systematic way in a shared location. Information was distributed with e-mails and telephone conversations. Meeting minutes were not always made and if they were they were not always shared. The document status lists, internal and supplier, were not up-to-date all the time making the follow-up of the workload difficult. The document status list was lacking a link to real project steps, making critical path analysis difficult.

The teamwork was stressed during the pressurised time. The workload is not evenly distributed in different responsibility areas during the project. Several tasks are linked together and cannot progress prior to a previous task being completed. There are simultaneous tasks to be carried out with a limited amount of resources. The delayed tasks can cause recognizable bottlenecks during the project phases. The project schedule or task list does not recognisably highlight these points of difficulty or hubs. The snowball effect caused by delayed input e.g. URS approval, product specification or product design freeze cannot be evaluated from the schedule either. There are some periods from the documentation point of view during the project that the work load is much higher than in other points. These locations are related to documentation reviews and creation e.g supplier FDS, SDS, HDS, Design Reviews, FMEA, Customer Product Specifications and their implementation, validation plan review/approvals and internal procedures for the production. It is a fact that the amount of the documentation in this type of GMP regulated project is higher than in a regular project. This increases the importance of the coordination of the activities in relation to documents such as review comments, follow-up implementation of the comments and circulation of the documents for approval. Coordinating the documentation is as important as coordinating the physical activities during the project. The next phase cannot start prior to the documentation from the previous phase being complete. Clear identification, easy availability and structured locations for archiving the documentation is essential for the easy retrieving of the documentation. This will make the status checks easy and reduce the time used for searching the information.

There are some quiet times between the high activity periods when the other team members are highly occupied with the physical line building actions. During line

building the project manager or his/her representative is in the key role of following up on the progress of the physical line building work. When the line starts to be rather ready the supplier validation starts. This changes the pressure point of the activities again. The readiness for the next step can be achieved with the awareness of the coming tasks and being on top of the status of the project.

This was investigated also by evaluating the procedures from the company quality system. Procedures and guidelines for managing the project were written at a very general level. This will give the possibility to adjust the approach based on the customer and supplier systems, but on the other hand, it does not give guidance for different project managers to have the same systematic approach to lead the project. This lack of guiding procedures would not be an issue if the internal training program would provide the tools for the project managers.

The job descriptions for project manager and project manager automation were reviewed. It is the responsibility of the project manager to ensure that all project related documents are created and well-managed. They also have to have GMP-knowledge. Introductory training was partly discussed during the interviews, and the personnel evaluated that there are possibilities to improve the system. The requirements and specialities coming from regulated environment and GAMP 5 were found especially not to be sufficiently elaborated to the new project managers. The introductory training programs of three project managers were reviewed. The program includes the project management procedures, ISO13485 and MDD93/42/EEC, but based on the interviews the program does not give enough knowledge to project managers independently ensure that all the project related quality documents are prepared and all the regulatory requirements are taken into account during the project. These items are also the responsibility of the quality representative of the project, but if the requirements are not taken into account during the commercial negotiations and project scheduling it might be rather impossible to get them without project delays and cost impacts.

The lessons learned made together with the customer. The successes identified were that the equipment was delivered on time with one exception. The deliveries to the markets were made on time. The professionalism of the team members was recognized. Co-operation, communication and overall atmosphere were identified as good.

The following recognized improvement opportunities from both the customer's and Phillips-Medisize's sides were identified: delay of the one machine delivery, better updating of sub-groups needed with face to face meetings, more pro-active risk communication, and communication in case of issues. The terminology used during the communication was seen as a risk for misunderstandings. It was also noted that the hand over to production has to be improved. The supplier follow-up needs to be more effective. More pro-active proposals with rational and more data based decisions were expected. Schedules have to be realistic and detailed enough.

4.2 Case study

There were different projects evaluated based on the plan and the outcome. All the projects evaluated were Phillips-Medisize assembly or printing line projects for different customers where Phillips-Medisize was holding the Project Management responsibility. The projects were carried out between 2000 and 2016 and made for different customers and with different suppliers.

Project 1 was an assembly line project for a new development version of the product. There was a new supplier (supplier 1) for the line. The project manager and the team members from Phillips-Medisize also from the customer (customer 1) and supplier side were experienced. The supplier already had experience in supply assembly technology in the pharmaceutical or medical device sectors. A time schedule was a part of the offer. The full schedule from project kick off to production was 20 months. When the project was completed the delay of the validation approval to the original schedule was 2½ months. The costs were over budget by 7.4%. The line performance indicators capacity fulfilled the criteria; the reject rate did not meet the criteria, and the quality of the product fulfilled the criteria. The project was still considered as successful.

Project 2 was an assembly line project also for a development version of the product. There was also a new supplier (Supplier 2) for the line. The project manager and the team members from Phillips-Medisize as also from the customer and supplier side were

experienced. The supplier had already experience to supply assembly technology to pharmaceutical or medical device sectors.
The costs exceeded the budgeted by nearly 38%. The time went over schedule remarkably. The line performance indicators fulfilled the criteria. The project was still considered as successful.

Project 3 was a copy line project for the existing product with a supplier (supplier 3) that had delivered an almost identical assembly line set up once before. It was shown that the budget and time schedule were squeezed from the totally new line. The time line of nine months and the budget were kept without remarkable downfalls. The line performance indicators fulfilled the criteria. The project was considered as a real success.

Project 4 was a line project for new product with a supplier (supplier 4) Phillips-Medisize had worked with earlier. The project was discontinued due to the decision of the customer.

Project 5 was a line project for existing product with an updated assembly concept from an existing supplier (supplier 4) that did not know the product before. The project exceeded the time line by 6 months. The line performance indicators fulfilled the criteria. The project was considered a success.

Project 6 was a line project for new development version of the product from a new supplier (supplier 5) that did not know the product before. The project was exceeding the time line remarkably. Optional line capacity had to be taken into use to minimize the effect of the dely. The project did achieve the end goal and was not evaluated as a failure.

Five of the six projects analyzed did exceed the schedule. There was good information regarding the financial aspects available for analyzing two of the projects. Both of them exceeded the budget. Line performance criteria were the most often achieved.

4.3 Interviews and questionnaire

The first theme was the GMP and how it affects the equipment projects. The results of the interviews and questions are summarized in Table 1.

Table 1. Effects of the GMP on the Projects

Item	No of participants identifying the item / all	Only Positive	Only Negative	Both positive and negative
Documentation	17/20	6	2	8
Bureaucracy /approval processes	6/20	0	6	0
Requirements defined for the project/ equipment (URS)	6/20	6	0	0
Interpretation of standard	6/20	1	5	0
Common requirements from standard	5/20	5	0	0
Effect on the time line	5/20	5	0	0
Effect on the manufacturing processes of the device	4/20	4	0	0
Effect on supplier selection	4/20	4	0	0
Effect on the resourcing	4/20	4	0	0
Effect on product safety	2/20	2	0	0
Effect on the cost	1/20	1	0	0

It was clearly stated and understood by all that it is essential to the business segment to follow the regulations related to the GMP, but only two (2) stated clearly that this is mandatory for this business segment. The main downfall was seen in the area that even though there are written requirements of the regulations each supplier and customer has made its own interpretation of the requirements. The interpretations and demands can vary also inside the organisation and between the project and project groups. This interpretation concerns especially regarding the depth of the testing required and details of documentation. The GMP requirements and documentation requirements should be taken into account already in supplier selection.

It was highlighted that the documented URS make it much easier to discuss and clarify the expectations to the supplier; however, it was also said that it is important to go thoroughly through the requirements together to ensure that there is the same understanding of the written text. The URS requirements have to be measurable and verifiable.

Documented decisions can be reviewed later if they are documented properly. This can be used for evaluating the project decisions and have a good traceability to change control during the project.

The bureaucracy related to the review, modification and approval process was seen as delaying the processes. The documents need to be scanned and sent to all parties. The authority to sign is with defined functions, and the deputy system does not always work as it should. It is also sometimes hard to get in touch with the needed persons.

Mainly the GMP requirements were connected to documentation requirements, machine material selection and clean room suitability. The connection of GMP to the patient safety was only mentioned by one supplier and one customer representative. The connection to improved reliable production processes was highlighted by two customers, one supplier and one Phillips-Medisize representative.

The second theme was how the three parties involved in the project are affecting the equipment projects. The summary of the interview and question results are in Table 2.

Table 2. Effects of the three party relationships on the projects.

Item	No of participants identifying the item /all	Only Positive	Only Negative	Both positive and negative
Know-how	10/20	9	0	1
Communication	8/20	2	5	1
Common Goal	8/20	4	4	0
Costs and financial risk	7/20	3	4	0
Decision making	6/20	1	5	0
Responsibilities	5/20	0	3	2

The different parties will have their own areas of expertise and will give possibilities to learn new aspects and also identify possible problems in the project. This was mentioned as a positive aspect in nine (9) interviews.

Three party involvement was seen to have a more negative than positive effect on the communication. Communication was seen harder to be kept efficient when three parties are involved. Reasons given were that the reporting was needed to be adjusted specifically to each receiving party. It was also identified that the speed of the responses are slower when several parties are involved.

Each participant has their own interests. The focus on the main goal needs to be kept, but with several parties involved this is hard to achieve. The focus on the goals is not easy to maintain and there are easily sidetracks due to the involvement of several parties. It was anyhow stated that three party involvement can also assure that the goals are not missed. The involvement of the customer was seen as positive by the fact that the end result will not be a surprise causing correction rounds in the last meters of the project.

A positive effect seen from the financial side was that the risk was divided between several parties. The negative effect was seen for the project cost through more personnel and travelling costs being created because a representative from each company took part in to the meetings, review rounds and decision making. Also additional requirements coming up from customer requests, when the requirements for product specification and deliveries during the project are clarified, increase the costs.

The decision making is not as efficient when three parties are involved and large organisations have to process the item to be decided. When there are several organisations involved also the work load can be divided between the parties.

The third theme was what measures project success. The results of the interviews and questionnaires are summarized in Table 3.

Table 3. Measures to evaluate project success.

Item	No of participants identifying the item / all
Line performance -Output (3) -Capacity (4) -Efficiency (3) -Quality (7) -Scrap rate (5)	22/22
Schedule	17/22
Budget/costs	11/22
Successful trial runs	5/22
Long term function in production	4/22
Ramp-up speed	4/22
Co-operation/feeling after project	4/22
Customer satisfaction	4/22
Usability	3/22
Items closed	1/22

The results showed that clearly that the line performance was seen by all participants somehow as a criterion to evaluate success. They mentioned different items but clearly they can be grouped under one header named line performance. Schedule and budget were also mentioned by most of the participants. The identified criteria also included results during the post-project grouped here under long-term function in production. The end user of the equipment was taken into account by some of the personnel with usability. Soft values like “feeling” for project success were only mentioned a few times. Clearly the schedule, budget and the line performance were the main project measurables that were mentioned.

The fourth theme concerned the success factors in equipment projects. The results of the interviews and questionnaires are summarized in Table 4.

Table 4. Success factors for the project success

Item	No of participants identifying the item /all
Clear requirements	8/20
Communication	8/20
Follow-up / control	7/20
Planning/pro activity	6/20
Co-operation/good relationship	6/20
Realistic expectations	4/20
Commitment	4/20
Competences in the team	4/20
Prompt decision making	3/20
Information availability in the project start up	3/20
Clear Responsibilities	2/20
Training	2/20
Right supplier selection	2/20

There were 13 items identified as success factors.

Both clear requirements and communication were mentioned in eight (8) interviews. Seven (7) interviews mentioned good follow-up and controlling of the project activities as success factors. Planning beforehand and reacting pro-actively to seen issues or bottlenecks were mentioned by six (6) persons.

The plans have to be realistic. It was stated during interviews that there is a risk to make unrealistic project plans to win the project from the customer. The project schedule expectations are high and sometimes linked to the already defined product launch schedule. This will place high pressure on the projects that realistically can take one and a half years if they proceed without an extremely accelerated speed. Unrealistic plans can also be caused by poor the communication of the requirements at the beginning of the project. Currently the process causes that the budgeting may be done without enough data to make the line offer. It was seen by the personnel that the proposal process would need to have a good basis to be able to set realistic goals for both schedule and budget. This will also require that the product design and product requirements are available in time. If there are changes to the design, test requirements or other requirements, it will have a big impact on both schedule and price when the assembly concept is already defined.

The communication matrix, responsibilities and decision making capabilities were mentioned to have a big impact on the schedule. There are always items coming up during the project that require decisions to be made. These decisions need to be made in a timely manner to keep the project time lines. This will require that the authority who makes the decision is already defined at the beginning of the project and the way of contact is clear.

The **fifth theme** was what improvement areas can be identified from the project management and project work in Phillips-Medisize. The information gathered during the interviews is summarized in Table 5.

Table 5. Identified improvement areas.

Item	No of participants identifying the item/all
Documentation requirements and handling	8/20
Process approach and concept	6/20
Communication	4/20
Project group	4/20
Training	3/20
Active approach/ suggestions	3/20
Know-how transfer between the project and production teams	1/20
Cost-awareness and follow-up	3/20
Planning	2/20

The interviews identified that currently the company is relying to supplier and customer documentation as well as process requirements and suggestions. The documentation requirements were not presented to suppliers or customers as existing models, and it was seen that due to this there is no clearly defined model, and there is too much time and effort needed to finalize the documentation that can be approved by all parties.

It was identified that Phillips-Medisize should take a more active role in creating package for the automation supplier validation documents that can be used as a starting point for discussions. The interviewed personnel stated that the review and approval processes are inefficient. The rules for the review process and project document review should over rule all other activities. The individual persons should make the review

privately first and the comments should be summarized in a meeting. The project schedule should also have the documentation clearly linked to it. Storing and distributing the documents were not seen as very effective processes.

Communication, both internal and external, was identified as one main area for improvement. Communication inside the Phillips-Medisize team needs some improvement. The physical locations of the team members limit the silent information transfer. Customers and suppliers stated that communication could be quicker and more pro-active. The information transfer during the handover from pre-production to production and during the personnel change was a weak point.

Training, especially for the new project team members and new employees, could be more effective and task specific. There is no standardized way of working by the project managers. This would also include a clearly defined process and concept for this type of project. The setting up the project group needs more focus. The end users for the line are to be involved early enough. The group needs to have a small enough core-team with the needed know how and stability.

Phillips-Medisize should take more active role starting already from the offer phase, give new ideas for technology, process improvements, component and assembly processes and also for the improvements to lower costs in long run. The experience from the earlier projects should be used actively to challenge the offers from suppliers and requests from customer to achieve realistic time schedules, budgets and resourcing.

Planning is an improvement area that all the sub-projects, infrastructure projects and logistic activities have to take into account when creating and updating the detailed project plan and schedules. It is difficult to make an assembly if one purchased component is missing or the power to the line is not connected.

4.4 Summary

Based on the study the project manager has an influence on keeping track of the schedule and budget. He/she will also influence the team spirit and the working atmosphere in the project, but the project manager cannot influence if the bases for the project are not healthy, e.g. the design is not ready or working or the schedule and budget have been unrealistic from the beginning. Phillips-Medisize did not make decisions to discontinue the project and the decision was not due to project work itself.

Stress and confusion during the project reduces by setting up a good communication structure and process plan for the project, including clear responsibilities and clear goals for different phases of the project. This is especially important when working with three party projects and for the project groups that are working with new colleagues and new partners.

Following the GMP requirement is a necessity just as any other. The supplier needs the knowledge regarding it, and the project team is responsible for verifying that this is a deliverable and proper documentation is a goal.
The collected data will be evaluated based on the original research questions.

First the relationship building with a new technology supplier was evaluated to enable success. With a new supplier more attention is to be paid to agree on the procedures for effective communication. The supplier quotes and schedules have to be evaluated with critical eyes to see if they are realistic based on Phillips-Medisize experience. More attention is to be paid to make sure that the messages, requirements and the way of working is understood. When the supplier selection is done the capabilities for the required work are evaluated not only from a technical point of view but also from GMP and GDP points of view. More time and resources are required for this phase of the project when a new supplier is used. The quality resource should be available from Phillips-Medisize's side to support and answer the questions. It is even more important for a new supplier that the project group stays the same throughout the project without remarkable changes. More control from the Phillips-Medisize group towards to the supplier is required to avoid misunderstandings and unexpected delays due to reworking

the physical devices or documentation. It will require a more active role from all participants in the communication to establish the good co-operation.

Secondly, the main measures to identify the success of a new technology supplier were considered. The main measures do not differ if the supplier is old or new. The line performance, schedule and costs are the main items to be followed. Due to the fact that the line performance can be seen only in the latest phases of the project, it is not the best tool to follow the supplier development during the project. With the new supplier the follow-up for the schedule and related deliverables like documents need to be given more attention. The project team could evaluate more actively the co-operation, feeling inside the project group and closing the items like changes, updates and actions during the project phase and used as measures for new supplier.

Thirdly, the effect of the triangle relationship in project management was looked at. The communication is more complex than with in a two partner relationship. The communication structure, methods, locations for data transfer and clear responsibilities need to be well established. The route of communication needs to be defined so that no one who needs the information is out of the loop. The risk of delays in communication is also bigger when there are several steps in the communication process. Project group has to agree the most effective way of distributing the information. The time required for the communication needs to be in the project or program Manager's schedule. The project schedule has to include the decision points and review and approval deadlines for the documentation.

The situation if the project would be carried out directly by the customer and supplier without Phillips-Medisize's involvement would be also challenging. Phillips-Medisize's responsibility is to make sure that the line can operate and is maintained in the operating environment. The possibility to be more prepared for the arrival of the line is given through the project management. Phillips-Medisize can ensure that the infrastructure and resources are ready to receive the production equipment. The operating personnel should get involved early to the project.

Each of the three parties has their own expertise area. The customer is responsible for the design of the product. They know the rationales behind the tolerances or defined

features. The line supplier is an expert in the line including feeding and assembling techniques. Phillips-Medisize is an expert in long-term production items and injection moulding of the components. The experience from the production and processes can be exported to the line design and solutions. When all this knowledge can be utilized during the development of the product and production processes, several risks can be mitigated so that they will not appear during the product life cycle. Without customer presence during the process the possibility to change the design and tolerances is not possible. Justifications for the features or tolerances that must exist are also available, making the decision making easier. If this can be utilized well in the project remarkable savings in time and also in the process can be made if a more stable process can be achieved with modifications. The improved production processes will benefit both Phillips-Medisize and customers with better reliability of the delivery performance.

The customer is the owner of the product, process and the manufacturing line. They approve the line and the quality of the product in the end, and early involvement will reduce the risk making wrong choices during the design of the line, testing of the line or documentation. The customers are responsible for taking the final product to the market and they are the first who will answer the questions coming from the markets or from the authorities. They also have the most experience of the current regulatory requirements and also current industry practices through their different suppliers.

The main improvement areas were identified as **fourth** theme**.** There is a need for a systematic process approach of automation project management. This would include process description, required templates for the project managers, training package for the new project managers and project team members and also a model package of the documentation required for the automation project. There needs to be centralised locations for data and documents created during the process. The systematic evaluation of the project performance with defined measurables is to be established not only in the end of the project but during the project connected to defined milestones. With these actions the way of working between persons could be harmonized. The work could be more efficient, and deputizing would be easier. The appearance of the external parties would be uniform. Process improvements could be identified. The risk of missing important items during the project causing costly correction moves could be reduced. The project group needs to be defined more precisely in the beginning of the project. It

should not only concentrate on the core team but should take into account all interest groups internally. This means also contact persons from production, logistics, maintenance, etc. need to be thought of. The clear responsibilities are to be defined for the members of the team. The importance of project group definition is increasing especially when the company is growing and new personnel are involved in the project. The core team should not have only new personnel from the company. The training package should have to be tailored for a specific job instead of giving a general overview suitable for training for all. A good example of this is the GMP requirements. General training can be similar but not all personnel needs to know about GAMP requirements and validation practices for automation, but for an automation project manager this is essential. The training program should cover also the leadership responsibilities and not only the managerial responsibilities.

Communication, internally and externally, should be planned. Internal communication methods should be harmonized. Meetings minutes as all other project documents should be easily retrievable for easy check-up of agreed or taken actions. This is especially important when deputizing, after absence or if changes in the personnel are made. Phillips-Medisize has the responsibility of assuring that minutes are made and actions are logged as well as archiving this information in to the company's own files to ensure that they are retrievable according the requirements.

When working with a new technology supplier there is a bigger risk to use unnecessary time for unclear responsibilities, communication and processes. There is also the risk of underestimating the requirements and the complexity of the project from the new supplier side. The basic project work has to be even more structured, planned and organised by the project leader. The project working methods and skills will help to overcome the challenges of communication with new partners. The well-structured working methods will give clarity to the work. A well working team will know its own responsibility areas and can support the new supplier by instructing and helping with their guidance. It has been demonstrated that in the beginning of the project face-to-face meetings will help to make relationships and reduce the possibilities of misunderstanding during the project. Documentation requirements will require more supervising with the new supplier and this need to be calculated in resourcing.

5 DISCUSSION

5.1 Comparison of theory and empirical results

The empirical data supported the items in the project management literature. No clear conflicts were identified. The basic project management elements that were defined in the literature were highlighted as important in the empirical data. The empiric data showed that the correct information and importance of communication starts already in offer phase. It is important to ensure that the supplier is capable to provide the required services. The project literature identified the same two areas also. Both literature and the empirical part identified the communication as an important and difficult part of the project process. The case study confirmed that good project management cannot save the project if there is no need to achieve the project goal.

GMP and GMAP requirements for planned and documented activities also reflect the interview results. The first three most mentioned items, Documentation,
Bureaucracy /approval processes and Requirements defined for the project/ equipment (URS) can be linked to the requirements in FDA 21 CFR part 820.20 and 75. Also the suitability of the GAMP and Regulation for all type of manufactured automation lines causes a challenge that even though the requirements are known for all parties the interpretation, depth of documentation and end result can vary widely.

The three party relationship was not highlighted from the literature. The agency theory of long term relationship and good communication will help also in this type of relationship. The project team can also be widened to cover both supplier and customer representatives working in the project. When comparing the results to the literature describing projects and project teams, they are in line with the literature.

The two types of success criteria described by Andersen can be identified from the interviews. The first criterion is goal achievement. This is strongest present. Supporting the production in long run as a part of achieving the strategy goals (the second criterion) in future can be found from the interviews. The line performance, schedule and budget

are widely mentioned in the literature as a measure to evaluate the success. The three criteria more often mentioned in the Mallon study were production output, quality and down time. These all were mentioned at least once in the interviews. There were nine (9) measures mentioned during the interview from 38 in Mallon's thesis: production output, quality, efficiency, capacity, schedule, within budget, meeting customer needs, customer returns and compliance. There were 20 success factors from Mallon's list mentioned during the interviews even though not all were identified during the theme success factors.

5.2 Improvements

There needs to be a tool pack for the new projects that includes the folder structure that can be copied and saved to project specific. The folder structure has to be established so that it is suitable for all automation projects and projects that have several sub-projects. The folders should include all the document templates for the project work. The mandatory documents required by Phillips-Medisize Quality System should be identified clearly. The folders should also include documents that are optional. Example of the folder structures presented in Figures 8-10.

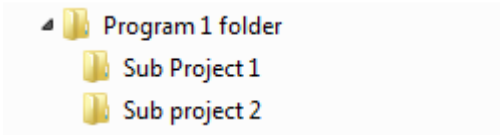

Figure 8. Program folder structure.

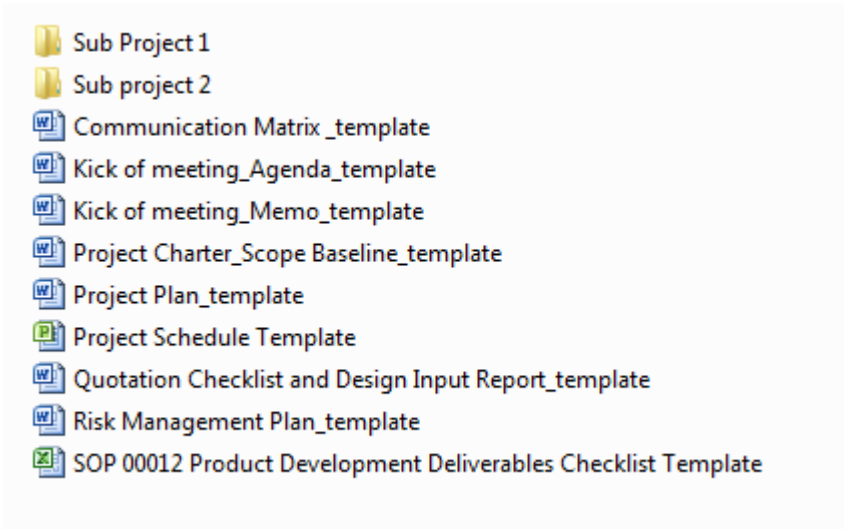

Figure 9. Program folder content.

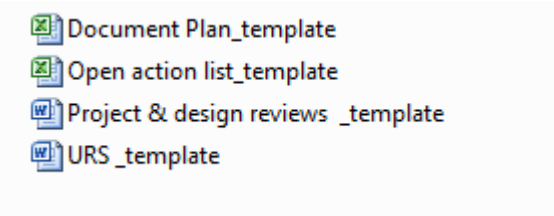

Figure 10. Sub project folder content.

Project team members need to have a clear understanding of their responsibilities and knowledge of the roles and responsibilities of the other team members. To clarify this in written format the use of an RACI matrix (Table 6) is suggested by literature to help in this task.

Table 6. RACI-matrix example

Names Activity	Name 1	Name 2	Name 3	Name 4
Task 1		R		
Task 2	R	A		
Task 3				

R=Responsible, A=Accountable, C=Consulted, I=Informed.

The communication map (Figure 11) that would include the procedures for the internal and external communication and suitable templates for the reporting is to be established. This would need to have the minimum requirements for the reporting taking into account the different project phases and required distribution and minimum participants for the meetings. The frequency of the meetings and reporting could be adjusted based on the project speed and amount of activities.

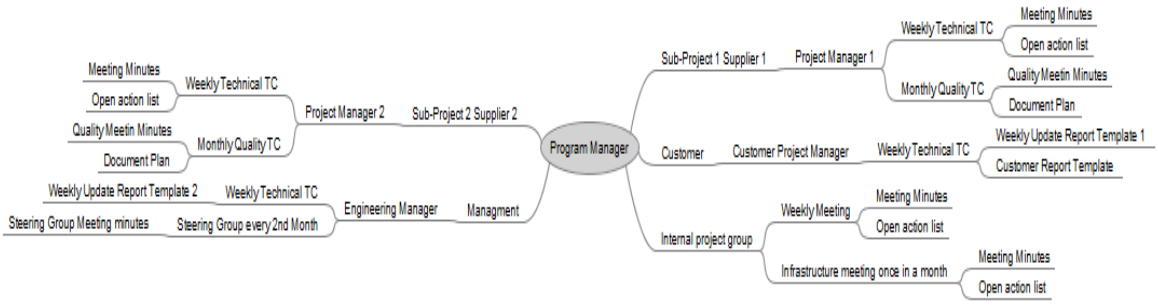

Figure 11. Communication mind map

The personnel coming to the projects need to be trained in the project environment. The project managers may have worked in different business segments in the same position, but it essential for the project group that the project manager understands the regulatory requirements. Fulfilling the regulatory requirements is one of the project goals. The project manager cannot make realistic plans if the requirements and efforts related to the task are not known. The GMP and GDP requirements need to be trained from the project point of view, not the production personnel point of view as has been included currently in the training plan. The good practices could be that there are new and old project group members working together in the project to enable the silent information to be transferred.

URS has to have clear measurable requirements. The involvement of the end users of the line from the beginning of the project for URS creation would enable the development of the production practices in long run. In the end the production uses the line much longer than the project team. Ramp-up time could be reduced with the increased involvement of the production personnel in the end of the project.

Process way of thinking would need to be incorporated in projects (Table 7). Checklists (Table 8) and milestones should be standardised between the projects. The process needs describing in more detailed for the quality system. This would make a backbone for the introductory training for new persons in the projects. The measures for a process need defining and implementing.

Phillips-Medisize's approach and requirements have to be clarified in documented way. Templates for project documentation and supplier documentation need to be available. The resources, time and milestones need to be included in the project plan for document deliverables.

Table 7. Project phases with documentation.

	Document name	ID (optional)	Version	Creator	Resp. Medisize	Not started (x)	Draft (x)	In approval (x)	Completed (ok)	Draf to approval (wk.no)	Notes
						30,2 %	7,9 %	25,4 %	74,6 %	138,1 %	
Before FAT can be started	**Validation**										
	Change Request (New printing line to MKL)								ok		
	Validation Master Plan								ok		
	Validation Plan								ok		
	User Requirement Specification (URS)								ok		
	Design Review								ok		
	SQ (answer to URS, like FS)								ok		
	Functional Desing Specification (FDS)								ok		
	Structural Software Desing Specification (SDS)								ok		
	Structural Hardware Desing Specification (HDS)								ok		
	Soft- and Hardware Component List								ok		
	Vistalink FS								ok		
	Visionsystem HDS								ok		
	Visionsystem FAT Protocol							x			
	Failure Mode and Effect Analysis (FMEA)								ok		
	Quality and Project Plan (QPP)								ok		
	Requirement Traceability Matrix (RTM)						x				
	Computerized System Classification								ok		
	Desing Qualification Summary (DQS)								ok		
	DQ Report (Medisize DQ report (appendix to Pro)							x			
	IQ Plan FAT								ok		

Table 8. Document status list.

Document status list

Document ID
Document Version
Page 1(2)

Updated (dd.mm.yyyy):
Circulation:

= approved
= under reviewing
= not started

Document	Document ID	Document owner	Version	Target date (Draft version available)	Sent for comments (to all)	Target date (comments available)	Target date (Final version	Supplier approval date	PM approval date	Customer approval date
Project Control Milestone check-list										
User Requirement Specification										
Validation Master Plan										
Quality and Project Plan										
Functional Specification										
Layout design										
Risk Assessment (FMEA)										
Safety risk analysis (CE)										
Requirement Traceability Matrix (RTM)										
DQ protocol										
IQ protocol with reports										
OQ protocol with reports										
CSV protocol with reports										
Design review										
List of materials										
Tolerance analysis for working stations										
Cycle time analysis										
DQ report										
IQ documents										
Compliance check of the installation with										
Check of machine readiness for OQ phase										
Verification of programmed fault and status messages										

5.3 Evaluation of the study

The thesis work has been extremely interesting even if also really challenging. The interviewed persons were selected based on their knowledge of the subject and their interest in replying to the questions. The amount of the interview results and questionnaires were rather low but gave a good overview from the Phillips-Medisize project perspective. The two languages, Finnish and English, created some challenges for comparing the information. The theme interviews gave challenges due to the persons not using exactly the same wording when describing the same issues. The challenge to stay objective when at the same time being an active team member was challenging. I could have made notes during the observing time of the project to collect also exact notes from the discussions made. Time keeping was much harder than expected. The time used for the thesis work from the literature review, typing the interviews and

writing itself was much more than what I was expecting. The suitable time slots were not easy to retrieve during the normal routines.

Some of the originally planned interviews did not take place due to time constraints, e.g. I did not make focus group interviews for Medisize technology users including assembly line setters, maintenance personnel and production supervisors as originally planned. I did not contact some of the suppliers due to missing connections.

The development work for improving the project procedures is not completed during this thesis work. The learnings have been taken already and put into use in the next project. Feedback from the customer has been positive but the end effect on the project cannot be seen yet.

I have learned a lot during the thesis work not only about the subject itself but also from the research techniques and the working methods. I have also learned a lot about myself and the difficulty of finalizing the work completely prior to a time line really causes pressure.

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List of success / failure factors identified by Mallon (Mallon 2002, 112-113).

No.	Category	Factor
1	Organisational	Need
2		Clearly defined objectives
3		Objectives Understood
4		Strategic aspect
5		Vision
6		Org/Dept. structure
7		Internal competition
8		Environment / change
9		Communication
10	Analytical	Proper analysis
11		Sufficient evaluation
12		Competitor analysis
13		Statistical analysis
14		Background analysis
15		Identify constraints
16		Documentation
17		Format of information
18		Customer needs / wants – survey
19	Technical	Design
20		Specification
21		Define functionality
22		Fit for purpose / application
23		Equipment age
24		Reliability
25		Sufficient Development
26		Computer controlled
27		Erase of re-set
28		Erase of maintenance
29		Set-up time
30		Understand technologies /science
31		Know technologies available / selection
32		Upgradable
33		Complexity
34		System
35	Management	Planning
36		Top management support
37		Team composition

38		Team cohesion
39		Team balance
40		Implementers
41		Sufficient time
42		On time
43		Knowledge of procedures
44		Hard work / long hours
45		Skill of project manager
46		Know people involved
47		Structured project management
48		Cross functional teams / integrated
49		Financial support
50		Control
51		Review
52		Project owner / champion
53		Human resources available
54	Human	Level of knowledge
55		Experience
56		Drive / motivation
57		Level of conviction / commitment
58		Perceptions
59		Negotiation skills
60	Operational	On-going production not affected
61		Trial run / pilot
62		Preventative Maintenance Programme
63		Slow build-up / ramp-up
64	Supplier	Supplier selection
65		Narrow down suppliers
66		Confidence in suppliers
67		Supplier relationships
68		Support
69		Frequency of contact
70		Co-ordination of Suppliers
71	Legal	Patenting
72		Patent Attorney skills
73	External Environment	Sales Levels
74		Miscellaneous Events
75		State of Industry

List of success / failure measures identified by Mallon (Mallon 2002, 114).

No.	Category	Measure
1	Manufacturing	Production output
2	Performance	Quality
3	Parameters	Downtime / uptime / reliability
4		Amount of maintenance
5		Efficiency / performance/ utilisation
6		Scrap / waste
7		Frequency of problems
8		Functionality
9		Throughput
10		Set-up / Changeover times
11		Capacity
12	Operational	Plant space
13		Ergonomic benefits
14		Training times
15		De-skill operations
16		Flexibility
17		Ease of implementation
18		Capability
19	Management	Management information
20		Management control
21		Data integrity
22	Time	Time taken
23		Schedule – start & finish on time
24	Economic / Financial	Operating costs
25		Cost – capital + other
26		Savings – labour / material
27		Within budget

28		Return on investment / payback
29		Profitability
30		Patent revenue
31	Business	Business objectives /strategy
32		Meeting customer needs
33		Additional / new business
34		Customer Returns (RTM's)
35		Marketing
36		Supply chain integration
37		New product derived
38	External	Compliance with regulatory bodies

Kutsu teemahaastatteluun

Hei,

Teen opinnäytetyötä Teknologiaosaamisen johtamisen koulutusohjelmassa (yamk) Karelia ammattikorkeakoulussa. Opinnäytetyön aihe on “New technology supplier development in regulated contract manufacturing”. Tarkoituksena tarkastella Phillips-Medisizelle uusien kokoonpano- ja painolinjatoimittajien kanssa tehtäviä projekteja ja miettiä mitä erityispiirteitä GMP ja sopimusvalmistus toimintaan tuo sekä mikä projektien onnistumista edesauttaa. Opinnäytetyössä esitetään myös mahdollisia kehitysehdotuksia joilla pystyttäisiin mahdollisesti lisäämään uusien laitetoimittajaprojektien onnistumista.

Tarkoituksena on tehdä teemahaastattelu joka nauhoitetaan ja litteroidaan. Teemat ovat: GMP, kolme toimijaa (linjan omistaja eli asiakas, linjan käyttäjä eli Phillips-Medisize ja linjan toimittaja) projektissa sekä projektin menestystekijät ja mittarit. Eri haastateltavien väliltä etsitään yhteneväisyyksiä ja eroavaisuuksia.
Haastattelut ovat luottamuksellisia ja niiden sisältöä ei tulla käyttämään muuhun kuin opinnäytetyöhön. Yksityisyyden suojaamiseksi henkilön tietoja ei opinnäytetyössä kerrota vaan haastattelut luokitellaan sen perusteella onko ne tehty Phillips-Medisizen henkilöstölle, asiakkaalle, vai toimittajalle.

Opinnäytetyön ohjaajana Phillips-Medisizellä on Keijo Riuttala ja Karelia ammattikorkeakoululla Mika Pasanen.

Ystävällisin terveisin Minna Kulmala

Dear Madam/Sir,

I am studying in Karelia University of Applied Science in Master's degree program of Technology Competence Management – Master of Engineering. Part of the studies is Master Thesis. Subject of my Thesis is
"New technology supplier development in regulated contract manufacturing". The object is to evaluate Phillips-Medisize projects for assembly – and printing lines. I will study what special features working in GMP environment and in business of contract manufacturing will give to the projects and what are the success factors. Possible improvement areas and suggestions are to be defined to improve the success in this type of projects.

As a part of the study I would like to ask you to answer by e-mail to the following questions:
-How GMP regulation is effecting to the line project (positive and negative items)?
-How the three party (1. Line Owner, 2. Project Manager and Contract Manufacturer, 3. Line Supplier) involvement is effecting to the line project (positive and negative items)?
-What are the measures used to evaluate the project success
-What are the success factors in the project?
-What improvement areas can be identified from the project management and project work in Phillips-Medisize?

The answers are classified to the categories of Medisize personnel, customer and supplier. The company or person answering are not shown in the thesis to secure the privacy.

The supervisors of the thesis are Mika Pasanen Principal Lecturer, PhD from Karelia University of Applied Science and Keijo Riuttala Plant Manager Phillips-Medisize Kontiolahti.

I would appreciate your reply to the questions before 24th of December 2015.
Looking forward to receive your reply.

Best Regards Minna Kulmala