Setting up a Quality Management System for MR Production & Service

Final report

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GROUP D

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avans hogeschool

Glossary

EPS = European Project Semester

DMAIC = Cycle method used for improving, optimizing and stabilizing business processes and procedures. Comes from words: Define, Measure, Analyze, Improve and Control.

QM = Quality Manager

QMS = Quality Management System

ISO = International Organization for Standardization

POA = Plan of Approach

WBS = Work Breakdown Structure

MRI = Magnetic Resonance Imaging

ESD = Electro Static Discharge

Management summary

This report aims to give a comprehensive impression of the project conducted by European Project Semester group D. The purpose of this report is to give an overview about the goals, content and results of the project. The project of the EPS group D is carried out at the company MR Coils. MR Coils is a company that makes prototypes for MRI scanners and components of MRI scanners. MR Coils is part of MR Holding. MR Holding is divided in five daughter companies. One of the companies is MR Production & Service. MR Production & Service is a new started company and a quality management system needed to be implemented. The quality management system consists of the quality manual and different external documents as working instructions, forms, policies and procedures.

The project is done according to the DMAIC method. The DMAIC method consists of five different phases, for each part in the assignment the DMAIC method is used. The quality manual is divided in different chapters and paragraphs, these are also used to make the planning in the Gantt Chart. The plan of approach states information about the project and shows the planning, the requirements and the work breakdown structure of the project. Information used in the project is obtained from interviewing employees and desk researching. During the desk research the quality manual and external document of MR Coils are used. Furthermore, the guidelines of the ISO 13485:2012, ISO 9001:2015, and ISO 14971:2007 are used as a source of information.

The written quality manual has references to external documents, which are part of the quality management system. Every guideline of the ISO 13485:2012, except from the product realization part, is taken into account and imbedded into the quality management system. In order to ensure that the implementation of the QMS is efficient, it is crucial that the employees are familiar with the QMS and engaged to work according to its content. Therefore, once the CEO and/or the quality manager approve policies, procedures or processes, these are implemented in the company by giving trainings.

The result of this project is an effective and integrated quality management system. The quality manual and the regarding external document are familiar to the employee. The policies and procedures are there to guide employees in their working activities. The effectiveness evaluation is conducted in an audit, the internal audit and the external audit, carried out by an official certificated company.

The recommendations concerning the QMS to the quality manager are that he should look at what the project team has already accomplished for the product realization chapter, and adjust as well as add information where necessary. The recommendations for the implementation of the QMS are that the company prepares and schedules every training for each employee, who requires the knowledge about a specific part of the QMS. Another recommendation on this subject is, to look at other companies within MR Holding, to see whether there are more employees, for who the training would be useful. The recommendations for maintaining the QMS are to carry out a management review once a year. The management review is an assessment in which all the processes and procedures of the QMS are evaluated.

Table of contents

Preface

EPS group D consists of four engineering students from different countries: Jesse van den Brink from The Netherlands, Sonja Repo from Finland, Christoph Fetzer from Germany and Paula Alonso González from Spain. Working in a real-life project within the frame of the EPS is a great and unique opportunity to enhance professional competences of the members of EPS group D. Therefore, we would hereby like to express our gratitude to all the people that are involved in making this possible. Special thanks go to Michel Italiaander (CEO, MR Coils) and Schelte Post (Quality Manager, MR Coils) for giving us the opportunity to perform a project for MR Coils. Besides, special thanks also to our tutor Johan Wouters for giving advices and assistance whenever needed, and to Frans van Seggelen for helping the project team to find an appropriate company and a project. We would also like to thank all involved persons at the AVANS and the employees of MR Coils for putting time and effort into the project and the European Project Semester.

1. Introduction

In this chapter the project carried out for MR Coils is presented. The chapter includes information about the company and the main causes for the project. In addition, project goals and the program of requirements are introduced. The planning of the project is also included to this chapter.

1.1 Introduction of the company

The project is carried out in the company MR Coils which is providing specialized and innovative Magnetic Resonance Coils for MRI systems. However, the project results are primarily used in the company MR Production and Service. MR Production and Service is a company, which is based on a close collaboration with the companies which belong to MR Holding. Figure 1 presents the existing companies within the MR Holding, and the connection between them.

MR Production and Service is a company focused on producing and repairing coils, and other components for MRI systems. In order to answer the customer requirements, and to produce and repair medical products, MR Production and Service needs ISO 13485:2012 quality certificate for medical products. Therefore, a quality management system that corresponds with the requirements of ISO 13485:2012, must be implemented in the company. The figure 2 shows the first MRI scanner which enables MR Production and Service to test the functioning of their own products.

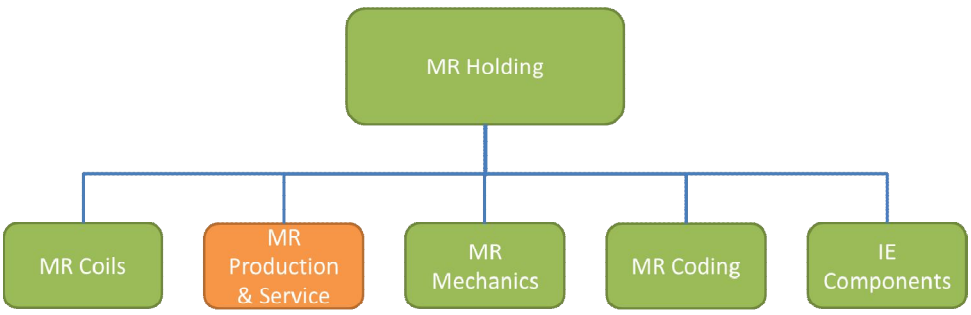

Figure 1: Structure diagram

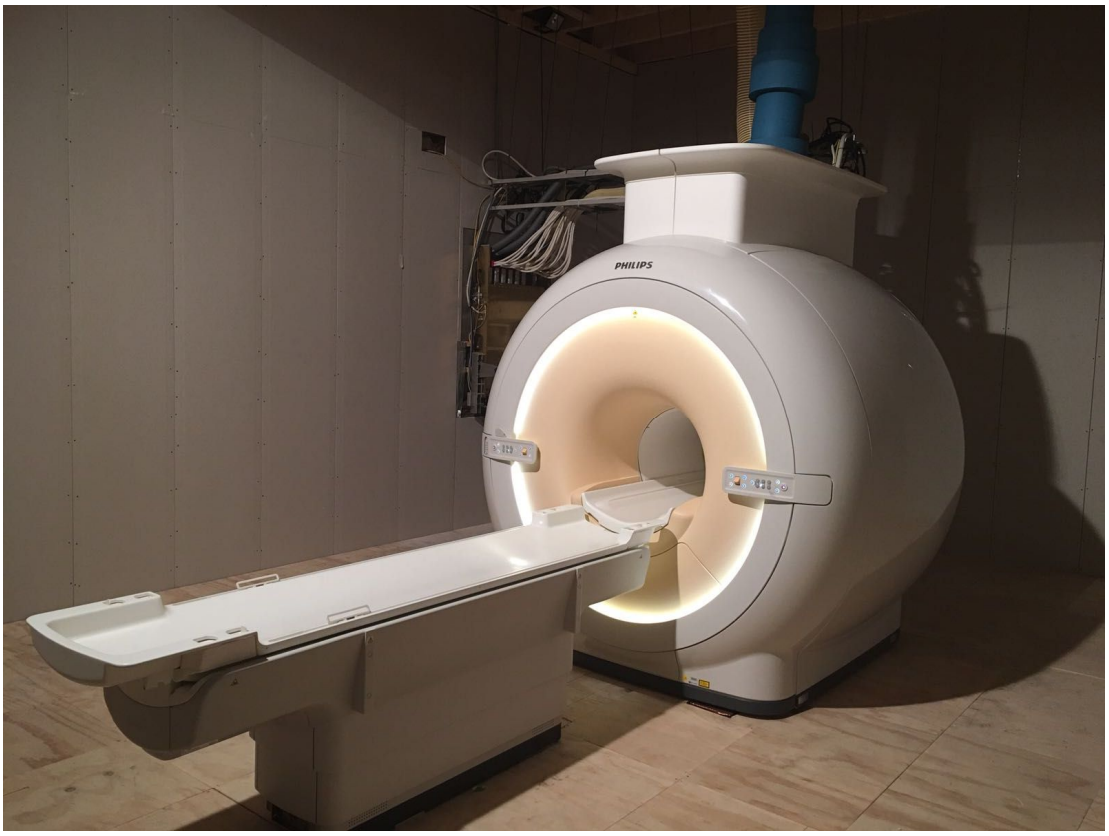

Figure 2: The first MRI scanner

1.2 Project goals

Consequently, the main goal of the project is to create an effective quality management system based on requirements of ISO 13485:2012 for MR Production and Service. To ensure that the project team reaches the goal, DMAIC method (see Attachment 2, DMAIC) is used in the process of creating the QMS. The phases of the DMAIC method are carried out for every topic of the QMS. The topics included to the QMS are presented in the ISO 13485:2012 breakdown (see Attachment 1, ISO 13485 content).

In addition, an internal audit is included in the project to confirm that the QMS allows MR Production and Service to get the ISO 13485:2012 quality certificate for medical devices. Besides the ISO 13485:2012 requirements, it is necessary that the QMS corresponds with the requirements of other quality certificates. As a result, the QMS is created to cover the requirements of ISO 13485:2012, ISO 9001:2015, and ISO 14971:2007 quality certificates.

1.3 Secondary goals

In addition, secondary goals have been set by the project team members. In short, these goals are defined personally and aim to develop team members' professional skills, and personal growth. Secondary goals set by the team members include goals such as: gaining work experience, improving English language skills, improving project management, and enhancing knowledge in different business areas.

Since these requirements are set individually, the achievement level of them is not monitored or measured during the project. In brief, all team members are accountable for their own personal goals. More information about team member's personal goals can be found in chapter 6.3 Overall experience.

1.4 Program of requirements

The project's POA is set up with the goal of giving information about several aspects and boundaries of the project, as not only project objectives, planning and necessary sources are included, but also the program of requirements (see Attachment 4, POA). These requirements are defined by the quality manager and the group members.

However, the main requirements set for the project are set by the International Organization for Standardization. These requirements are listed in: ISO 13485:2012, ISO 9001:2015, and ISO 14971:2007 quality certificates.

In addition, other requirements for the QMS are provided by the company MR Coils. These contain requirements like documentation templates, terminology, and language. Every document created within the project should follow specific guidelines and a format that the company provides to the project team. Specific terminology of the background is used in some documents, but explained if needed. As other companies, MR Production and Service decides to have and keep its documents written in "Business English" which provides all the information as clearly and concisely as possible.

AVANS Hogeschool has set also requirements for the project groups of EPS program. These requirements are operational and define, how each group should work within

the project. On behalf of AVANS it is demanded that the project team reports its results and progress at regular intervals to the project tutor. This is done by participating in a tutor meeting every other week. Moreover, the tutor has been responsible for giving advices and guidance for the team, when needed. In addition to the tutor meetings, the team has been required to give a presentation of the progress and the results at the midterm and at the end of the project.

1.5 Planning

The planning of the project is made in accordance with the time, which is given for the project on behalf of AVANS. The planning of the project is made with program MS Project. The exact project plan is included in WBS (see Attachment 3, WBS). It not only contains all the milestones of the project, but also the steps that are taken to achieve these milestones. Consequently, the timeframe and division of the tasks is included.

In addition to the project plan, other plans have been drawn up. Other parts of the planning are in the Plan of Approach (see Attachment 4, POA) as already described in previous chapters. The plan of approach includes information about the risk management, as well as the roles and responsibilities of the project team members. It also presents the communication methods and the costs of the project. In a word, POA contains all the information related to the planning of the project.

2. Modelling based on existing knowledge

In this chapter the information sources used in the project are informed. The sources used in the project are mainly documents provided by ISO. Moreover, the steps in define phase of DMAIC method are explained.

2.1 Research sources

The main source of quality management system's requirements is in the external document *"NEN-EN-ISO 13485:2012"* (Brinker, 2012). In other words, this ISO document gives requirements for the quality management system of the company. However, it does not give solutions or examples on how to fulfil these requirements. It only gives the guidelines, for the contents of the QMS, for instance what procedures and processes must be implemented within the company. Therefore, the project team members have been given an opportunity to use their creativity to search and produce potential solutions for answering these requirements. This has been done by writing new policies, working instructions, and procedures, but also by creating new registries and instruments to improve and maintain the effectiveness of the QMS. Similarly, other ISO documents have been used on creation of the quality management system. These documents are: *"NEN-EN-ISO 14971:2007"* (Brinker, NEN-EN-ISO 14971:2007, 2007)and*"93/42/EEG"* (Council Directive 93/42/EEG, 2007).

Besides the above-mentioned ISO documents, the quality manual of MR Coils is used to evaluate the current situation and the contents of the work of companies within MR Holding. The quality manual of MR Coils includes information about the policies, procedures and processes that are already implemented in the companies of MR Holding. In addition, it includes the references to the documents, registrations, and working instructions that are used to carry out the tasks which are included to the quality management system of MR Coils. It is noted, that some policies, procedures, processes, and/or documents of MR Coils are also applicable to MR Production & Service. Therefore, it is necessary to define to what extend existing parts of MR Coils' QMS can be used on creating the QMS for MR Production and Service.

2.2 Define phase

The define phase of DMAIC method(see Attachment 2, DMAIC) includes several steps. The first step of the define phase is to determine who of the team members is responsible for working on a specific subject of the quality management system and the deadline to finish it. The deadlines and person responsible for every task are included to the Work Breakdown Structure (see Attachment 3, WBS). This step of define helps to make sure that every team member knows its responsibilities and timetable of the project. At the same time, it is ensured that the team members have gone through all the parts of the new QMS of MR Production and Service.

The next step of the define phase is to outline the requirements of the ISO 13485:2012 that are applicable for the scope of MR Production and Service. In other words, this step ensures that the contents of the requirements are understood and essential for the QMS of MR Production and Service.

The last step of the define phase is to evaluate the functionality and usability of the procedures, policies, processes, and documents that are included in quality manual of MR Coils and used in companies of MR Holding. In this step, it is stated, which parts of QMS already exist. It is also answered whether are these effective or not, if they fulfil the requirements, as well as what is still missing.

3. Research methods

In this chapter, the methods and the tools to create the QMS are described. The methods that are used help to ensure that the requirements of the QMS are met. In addition, the tools that are utilized make the work as efficient as possible.

3.1 Methods

The research methods that are used to create the QMS for MR Production and Service are utilized in the measurement phase (see Attachment 2, DMAIC). This phase starts with the step in which the problems and improvement opportunities of the existing procedures, policies, and/or processes are detected.

The most important research method which is used in this step is interviews. By conducting interviews, different perspectives and opinions are gathered. This method is significantly important when considering the implementation of the QMS. With interviews, it is noted what serves the purpose of the MR Production and Service, how the employees are willing to work, but also what is possible to implement within the MR Production and Service.

Every interview that is conducted, has been made to follow the same pattern: preparation, performance, and evaluation. The phase contains tasks as: creation of the questions, reservation of the space, and coordination of the people involved. The next phase of the interview is the actual performance. This is usually done by two project team members. The other team member is responsible for asking the questions, due to responsibility of the QMS subject, and the other one has the responsibility for making the notes. The last phase is to evaluate the information which was received in the interview.

In addition, other research methods can be used to find and define improvement opportunities from QMS. For example, an important approach of gathering background information is online research. By doing online research, it is possible to find new and creative ideas to answer to the ISO 13485:2012 requirements.

After information from the interviews and the online research has been processed in the measurement phase, the amount of work to be done is amplified. After this, the missing parts of the QMS can be produced. In other words, in this phase the work itself is also carried out. The time needed for creating new documents is hard to estimate, since many factors are affected to it. For example, in some cases more interviews are needed. Besides that, processes and contents of the QMS subject can change during the creation process.

3.2 Tools

Different kinds of tools have been used to ease the team work within the group. These tools have been provided by MR Coils. The figure 3 shows an example of the tools that the project team has been using. The tools shown in the figure 3 are: smartboard, meeting room, and wallpaper.

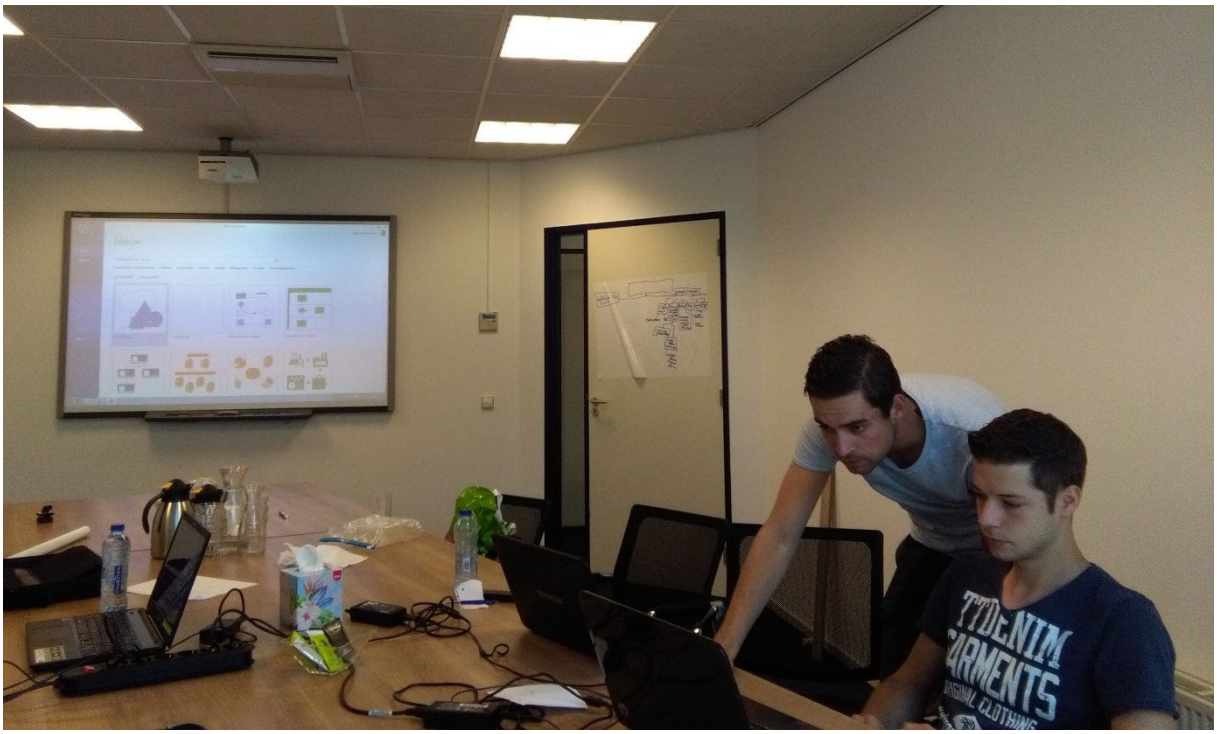

Figure 3: Teamwork

In order to make it easier to obtain, analyse and visualise the information, different tools are used. The project group has working with the following methods and its tools:

Plan of approach

The plan of approach is a method used to get a clear view of the content of the project. The plan of approach is used to properly map the project so that all stakeholders have sufficient information about the project. The plan of approach consists of several different parts like the planning and the content of the project. In addition, the risk management and costs of the project are included. In short, the plan of approach is a combination of different tools and methods used in project management which are explained further in this chapter. (Types research approaches, 2016)

Program of requirements

The program of requirements is used make sure every requirement is taken into account. It is a list of requirements like statutory requirements, requirements from stakeholders and other requirements.(De Heij, 2008)

Work Breakdown Structure

The work breakdown structure (WBS) is a technique used to get a clear overview of all that needs to be done. The WBS is used for getting overview of the ISO 13485; every chapter of the ISO 13485 is separated and divided in even smaller steps. This way the workload of the QMS becomes clearer. Moreover, the planning of the resources and the time becomes easier and more concrete. (workbreakdownstructure.com, 2014)

Gantt chart

The Gantt chart is a chart that is used for planning. After the Work Breakdown Structure is made, this can be used to make a Gantt chart planning. For every step of the WBS, actions are assigned. These actions are combined and after these bundled actions are carried out, a milestone is completed. When the Gantt chart is created, the result is a timeline with milestones, previous activities and follow-up actions. In other words, the Gantt chart is a visual tool to present the project plan. (What is a Gantt Chart, 2016)

Excel

Excel, developed by Microsoft, can be used for calculating, graphing and visualising information. Excel is used for creating a clear overview of information such as lists of resources that need to be maintained.

MS Project

Microsoft Project is a software program which can be used for project planning. MS Project has the ability to link duration, manpower, budget, previous activities and many other aspects to activities. For this project, MS Project is used to plan the activities of the Work Breakdown Structure in a Gantt chart planning. (Rouse, 2015)

4. Implementation research

In the analysis phase of the DMAIC method, it is estimated whether the content created in the measurement phase can be implemented in MR Production and Service. Before transferring to the analysis phase, the content for the QMS is already created to correspond with the requirements. In other words, in the analysis phase the equivalency between the QMS and ISO 13485:2012 requirements is ensured. This step is done by going through the ISO document *"NEN-EN-ISO 13485:2012",* and by making sure that the requirements are met.

After the part of the QMS is completed, it is presented to the CEO and the QM of MR Production and Service. The CEO and the QM are responsible for accepting the new policies, procedures, and/or processes to the usage of the company. While presenting the new contents of the QMS, the ISO requirements are discussed. Furthermore, feedback is received to improve the policy, procedure, and/or process. According to the feedback the policy, procedure, and/or process is fixed.

5. Results

This chapter presents the results of the MR Coils project. The main result of the project has been the QMS for the company MR Production and Service. In addition, concrete results such as the quality manual and implementation of the QMS are exposed in this chapter.

5.1 Quality management system

The QMS created by the project team has been made to correspond with the requirements of: ISO 13485:2012, ISO 9001:2015, and ISO 14971:2007. It has been produced to make certification possible for the company MR Production and Service. Moreover, it helps the company to maintain and improve the quality of its products and processes. The QMS consists of several subjects which are presented in the ISO breakdown (see Attachment 1, ISO 13485 content).

5.2 Implementation

The goal of the improvement and control phase of DMAIC method, is to implement the policies, procedures, and/or processes into the practise. The success of the implementation depends on the approval of the CEO and the QM. Moreover, it is also crucial that the employees are familiar with the QMS and engaged to work according to its content. Consequently, this is ensured by providing training sessions for the employees related to the subject.

The trainings have been held after the policy, procedure and/or process has received approval of the QM and the CEO. Before the trainings can be conducted, a few preparations are made. These preparations consist of activities such as: scheduling both time and place, and presentation making. Furthermore, the presentations have been held by following the policy training of employees which was also created by the project team for the QMS of MR Production and Service. The training of the employees' policy includes the method according to what each training in MR

Production and Service is done. For example, after the trainings it must be registered that the employees have understood the matter and are committed to work according to the information given in the training. In addition, the record “Overview of trainings” is updated. This registration has been made to give an overview of the training that the employee has participated. By following this policy, it has been made sure that the ISO requirements for the human resources are met. The figure 4 presents the presentation room, in which the training has been held.

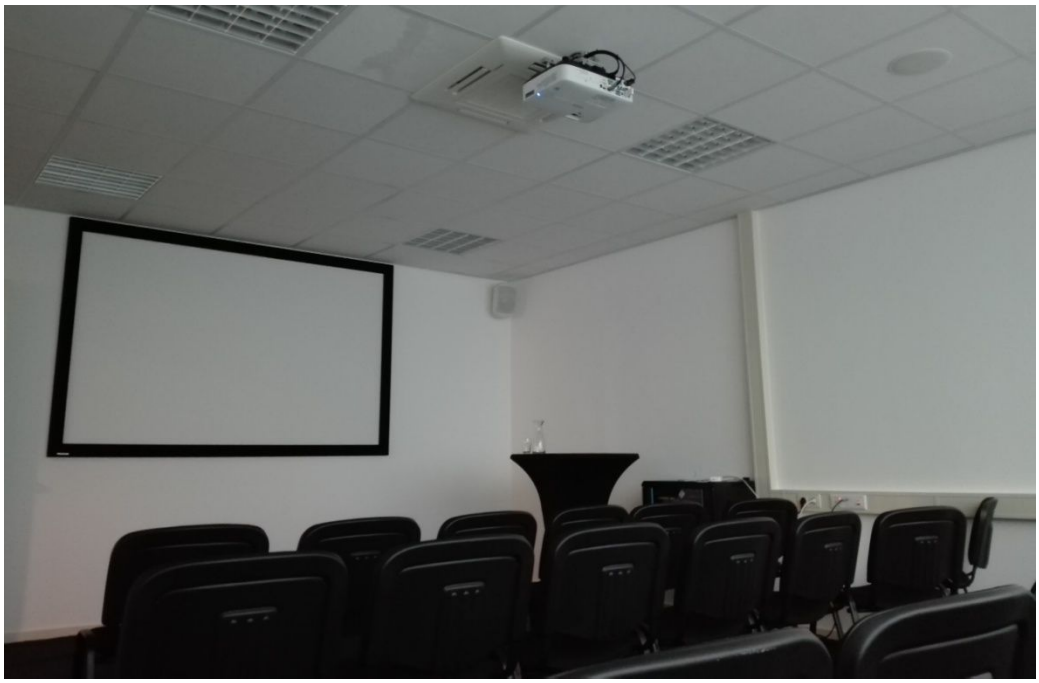

Figure 4: Presentation room

The project team has also been given a chance to participate on unofficial audit, conducted by main customer Philips. It gives the project team an opportunity to see, in what extend they have succeeded on creating a functioning QMS. Since the audit will be conducted in the end of January, the results of the audit are not included in this report. However, arrangements for the audit have been made. The project team has made preparations for the audit, such as: made sure that all the documents are in the ERP system EXACT, and that every document follows the same template and format. In

addition, the project team has oriented to the most common audit questions and procedures.

5.3 Quality manual

The quality manual for the MR Production and service represents our major goal. The purpose of a quality manual in general is to show how the quality management system operates. It includes the quality goals, policies, staff and function roles as well as procedures. In our case, the team excluded individual chapters from the quality manual itself. This means, that the quality manual refers to external documents such as policies, procedures and processes of the QMS. The main advantage of this approach is to keep the quality manual and all of its chapters easily updateable. If a policy or a procedure has to be updated, it can be implemented without changing the version number of the whole quality manual. Another reason for excluding several chapters and referring to them is to keep the quality manual easily readable.

Due to the official nature of all the documents created within this project such as the Quality Manual itself and each and every document involved, only some of them are attached in this report. Attachments 5-11 show a little part of the project group during these 5 months. It is also attached a general overview about how is the structure where all the created documents that have been already approved in the QMS are saved in the server. (Attachment 12)

6. Conclusion and recommendations

Conclusions and recommendations are formed based on the results of the project (see chapter 6. Results). This chapter has been written to give information about the challenges and experiences encountered during the project. In addition, achievement level of the project goals is estimated. Additional recommendations related to the project are also given.

6.1 Challenges

Due to this project, the project team members have come across with both successful and challenging situations. The fact of working with unknown people from different cultures may not be that easy as expected. Even though it could have affected in a negative way because of possible culture shock, the differences of culture have helped to learn and combine new aspects during the project.

The figure 5 includes the pictures of each project team member. In the first row of the figure 5: Christoph Fetzer and Paula Alonso González, second row: Sonja Repo and Jesse van den Brink.

Figure 5: Project team members

As mentioned in chapter 1. Preface, the project team members are also coming from different educational backgrounds. This has been also something that was taken into account and used when combining the knowledge and working together.

In addition, the responsibility of setting up the main guidelines and documents for a new company as MR Production & Service seemed to be too much at the beginning of the project. However, once the POA and WBS were established and all the unknown and needed information about the company was discovered, the project began more efficiently and even faster than expected from the QM. While receiving pleasant comments from the QM, the project teams' motivation increased and the team kept working on the same way.

6.2 Recommendations

The recommendations for MR Production & Service are split up in three different parts: recommendations for the quality manual, recommendations for the implementation of the QMS, and recommendations for maintaining the effectiveness of the QMS.

Recommendations for the QMS

When starting this assignment, it was told that this would be a very big assignment, and that it would be challenging to finish it. The reason for this is that the project group started a few weeks later due to problems with other companies, and because MR Coils never had a group of interns before. As the weeks passed by, it seemed that the project group could finish the project in time, and create the whole QMS for MR Production and Service. Yet it seemed that the product realization chapter (see Attachment 1, ISO 13485 content) was far bigger than imagined and some information had to be supplied by the stakeholder. As a result of this it was not possible to finish the entire product realization chapter. Due to this, we recommend that the Quality Manager should look at what the project team has already accomplished for the product realization chapter, and adjust as well as add information where necessary.

Recommendations for the implementation of the QMS

The quality manual is a bundle of policies, procedures, records, registrations and lots of other external documents. All these documents need to be known and acknowledged by the regarding employees. The employees learn to work according to the policies and other documents after trainings, provided by the project team or the management. Due to the short time window, not all trainings can be given. If MR Coils want the quality manual of MR Production & Service to be fully implemented, it is recommended that the company prepares and schedules every training for each employee, who requires the knowledge about a specific part of the QMS. Another recommendation on this subject is, to look at other companies within MR Holding, to see whether there are more employees, for who the training would be useful. These

employees would then join the training; for example, subjects like documentation, control of records, and other general topics.

Recommendations for maintaining the QMS

The most important thing to maintain the QMS is the management review. The management review is an assessment in which all the processes and procedures of the QMS are evaluated. In this review the internal- and external audits are also reviewed. The audits are a display of the efficiency of the QMS of the company. The result of each audit shows points in which the QMS does not cooperate with the reality. If something needs to be changed, it has to be done in the correct way.

6.3 Overall experience

MR Coils has been excellent company to do a project. The main reason for this is that the project assignment has been pleasing, and the reason for the project and its goals have been stated clearly. The project team has also been very grateful for the performance of the management team of MR Coils. The management team has been giving a lot of trust and support to the project team which has helped the team members to accomplish their personal goals. Moreover, the management of MR Coils has been giving constructive feedback and motivation to the team during the project which has helped to improve the performance of the team members. In short, all the employees of MR Coils have been welcoming and pleasant, and supported to carry out the project. The figure 6 shows, the atmosphere in the team outing of MR Coils.

Figure 6: Team outing of MR Coils

Working in a small company has been a great opportunity for each project team member to get a lot of responsibility to produce and plan their own work. In other words, it has been the team members' responsibility to decide how they will work to achieve the project goals, but also personal goals. Moreover, it has enabled team members to improve their social skills, due to the fact that the employees within MR

Holding are from various cultures and age groups. Moreover, it has provided more fundamental knowledge and experience from different business areas, since each team member has had overall responsibility of some of the subjects in the QMS. The figure 7 demonstrates how the employees have fun in lunch breaks.

Figure 7: Lunch break activities

During the EPS, the project team members have been gaining plenty of useful experience and knowledge. In addition to this, the members have received valuable work experience related to their studies, while working with the project. In short, the whole EPS has added an enormous value for each team member in a different way. More about the team member's personal experiences is included in Overall experiences of EPS (see Attachment 13, Overall experiences of EPS).

6.4 Achievement of the goals

The quality manual as a guideline for the QMS was successfully completed. All external Documents related to the QMS have been linked in the quality manual and to regarding processes. The core- and sub-core processes were defined, set up, and approved by all involved functions inside the company. By providing trainings to the employees in order to present the policies and guidelines, the implementation of the QMS was initiated. The project goals have been achieved.

In addition, risk-related policies according to the ISO 14971 were set up and approved. Furthermore, an extensive list of requirements for the QMS and the risk management according to the 93/42/EEC was created in order to initiate a future CE-certification. An initial audit by Philips was planned for the second week of January. It has been rescheduled by Philips and will take place at the end of January. Therefore, the results of the audit are not included in this report.

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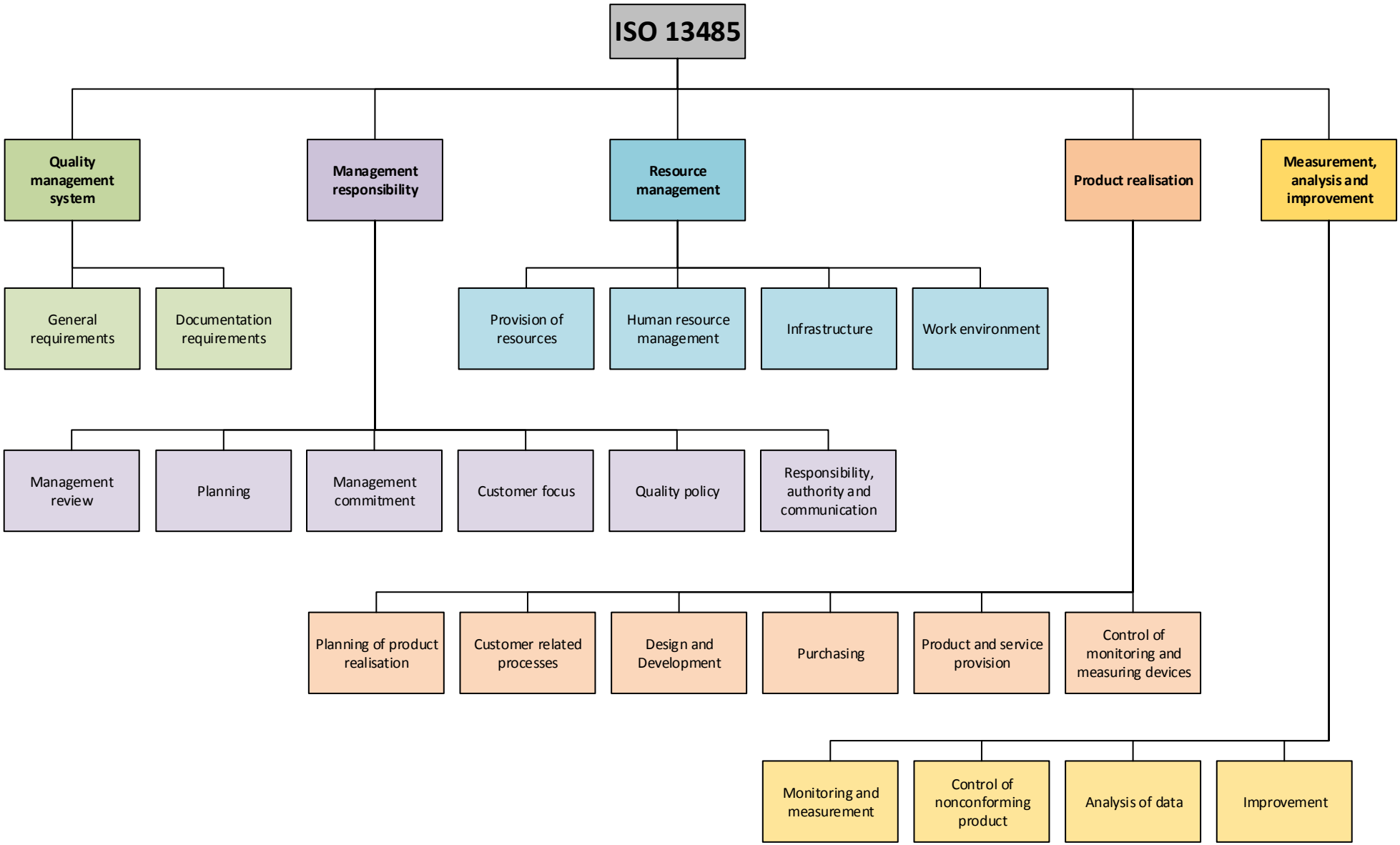
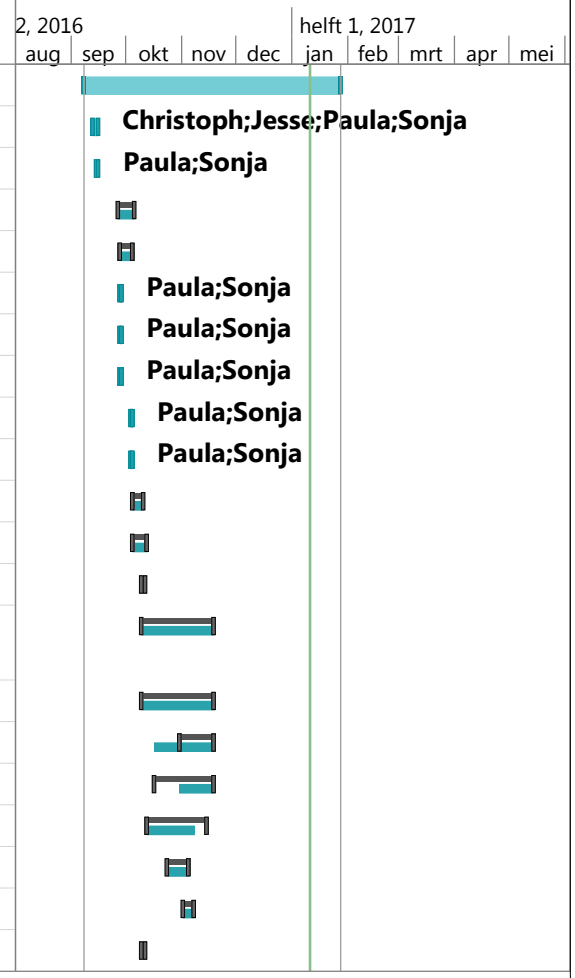
8. Attachments and appendices

- Attachment 1, ISO 13485 content
- Attachment 2, DMAIC
- Attachment 3, WBS
- Attachment 4, POA
- Attachment 5, Repair and replace process
- Attachment 6, Packaging guidelines
- Attachment 7, Working ESD safe
- Attachment 8, HR tasks
- Attachment 9, Control of documents
- Attachment 10, Control of nonconforming product process
- Attachment 11, Control of nonconforming product policy
- Attachment 12, Already approved documents in the QMS
- Attachment 12, Overall experiences of EPS


ISO 13485
Quality management system
Management responsibility
Resource management
Product realisation
Measurement, analysis and improvement
General requirements
Documentation requirements
Provision of resources
Human resource management
Infrastructure
Work environment
Management review
Planning
Management commitment
Customer focus
Quality policy
Responsibility, authority and communication
Planning of product realisation
Customer related processes
Design and Development
Purchasing
Product and service provision
Control of monitoring and measuring devices
Monitoring and measurement
Control of nonconforming product
Analysis of data
Improvement

D - Define	M - Measure	A - Analyze	I - Improve	C - Control
• Define person responsible and deadline for the subject • Define the requirements of ISO 13485 that are included in scope • Define the current state of the procedure, policy, and/or process	• Measure problems and improvement opportunities of the procedures, policies, and/or processes • Measure the amount of work and perform it	• Analyze the equivalency with ISO 13485 requirements • Present the procedure, policy and/or process to the QM and the CEO to improve it	• Finalize the procedure, policy, and/or process according to the feedback • Ask approval of the CEO and the QM	• Give training to the employees related to the procedure, policy and/or process

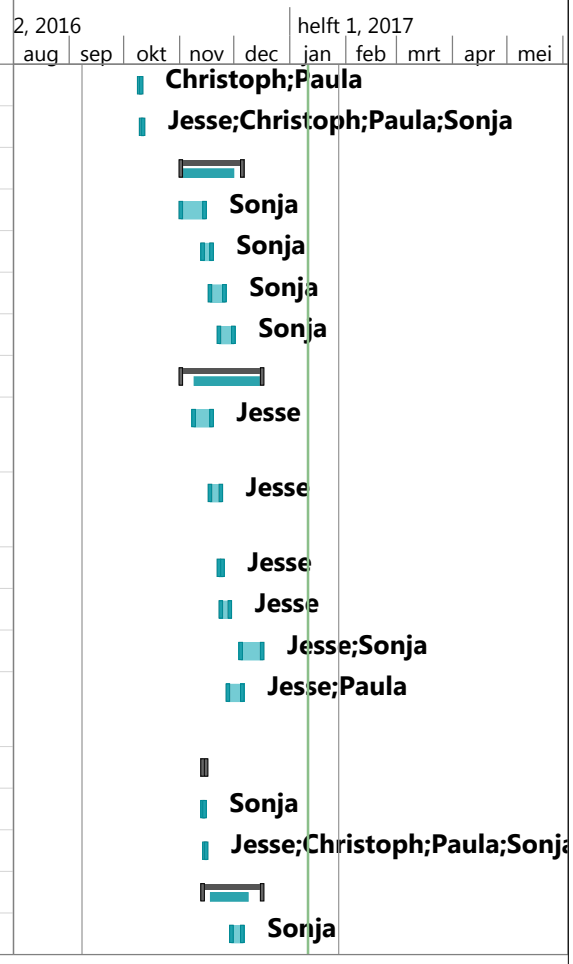
Id	Taal	Task Name	Duur	Begindatum	Einddatum	Resourcenamen
1		Project MR Coils	102 dager	don 8-9-16	vri 27-1-17	
2		**Plan of Approach**	**3 dagen**	**din 13-9-16**	**don 15-9-16**	**Christoph;Jesse;Paula;Sonja**
3		**Business prospect**	**1 dag**	**don 15-9-16**	**don 15-9-16**	**Paula;Sonja**
4		**Production process**	**7 dagen**	**din 27-9-16**	**woe 5-10-16**	**Christoph;Jesse**
10		**Purchasing process**	**5 dagen**	**woe 28-9-16**	**din 4-10-16**	**Paula;Sonja**
11		plan interview	1 dag	woe 28-9-16	woe 28-9-16	Paula;Sonja
12		execute interview	1 dag	woe 28-9-16	woe 28-9-16	Paula;Sonja
13		process overview	1 dag	woe 28-9-16	woe 28-9-16	Paula;Sonja
14		RACI	1 dag	din 4-10-16	din 4-10-16	Paula;Sonja
15		check/change/verify	1 dag	din 4-10-16	din 4-10-16	Paula;Sonja
16		**Communication process**	**4 dagen**	**woe 5-10-16**	**maa 10-10-16**	**Paula**
21		**Logistics**	**6 dagen**	**woe 5-10-16**	**woe 12-10-16**	**Jesse**
29		**Tutor meeting**	**2 dagen**	**maa 10-10-16**	**din 11-10-16**	**Christoph;Jesse;Paula;Sonja**
32		**Documentation requirements**	**30 dagen**	**maa 10-10-16**	**vri 18-11-16**	**Christoph;Paula**
33		**Control of documents**	**30 dagen**	**maa 10-10-16**	**vri 18-11-16**	**Christoph;Paula**
37		**Control of records**	**15 dagen**	**maa 31-10-16**	**vri 18-11-16**	**Christoph;Paula**
41		**Control of drawings**	**25 dagen**	**maa 17-10-16**	**vri 18-11-16**	**Christoph;Paula**
45		**Management responsibility**	**23 dagen**	**don 13-10-16**	**maa 14-11-16**	**Christoph;Jesse;Paula;Sonja**
68		**Customer feedback**	**10 dagen**	**maa 24-10-16**	**vri 4-11-16**	**Sonja**
73		**Midterm presentation**	**4 dagen**	**woe 2-11-16**	**maa 7-11-16**	**Christoph;Jesse;Paula;Sonja**
76		**Tutor meeting**	**2 dagen**	**maa 10-10-16**	**din 11-10-16**	**Christoph;Jesse;Paula;Sonja**



Project: WBS
Date: woe 11-1-17

Task		Inactive Summary		External Tasks	
Split		Manual Task		External Milestone	
Milestone		Duration-only		Deadline	
Summary		Manual Summary Rollup		Progress	
Project Summary		Manual Summary		Manual Progress	
Inactive Task		Start-only			
Inactive Milestone		Finish-only			

Id	Taal	Task Name	Duur	Begindatum	Einddatum	Resourcenamen
77		preparing	1 dag	maa 10-10-16	maa 10-10-16	Christoph;Paula
78		executing	1 dag	din 11-10-16	din 11-10-16	Jesse;Christoph;Paula;Sonja
79		**Resource management**	**24 dagen**	**woe 2-11-16**	**maa 5-12-16**	**Sonja**
80		Human resources	9 dagen	woe 2-11-16	maa 14-11-16	Sonja
81		Transportation	5 dagen	maa 14-11-16	vri 18-11-16	Sonja
82		Work environment	6 dagen	vri 18-11-16	vri 25-11-16	Sonja
83		Infrastructure	6 dagen	woe 23-11-16	woe 30-11-16	Sonja
84		**Product realization**	**33 dagen**	**woe 2-11-16**	**vri 16-12-16**	**Jesse**
85		Planning of product realization	8 dagen	woe 9-11-16	vri 18-11-16	Jesse
86		Customer-related policies	4 dagen	vri 18-11-16	woe 23-11-16	Jesse
87		Design and development	2 dagen	woe 23-11-16	don 24-11-16	Jesse
88		Purchasing	3 dagen	don 24-11-16	maa 28-11-16	Jesse
89		Product and service provision	10 dagen	maa 5-12-16	vri 16-12-16	Jesse;Sonja
90		Control of monitoring and measuring devices	6 dagen	maa 28-11-16	maa 5-12-16	Jesse;Paula
91		**Tutor meeting**	**2 dagen**	**maa 14-11-16**	**din 15-11-16**	**Christoph;Jesse;Paula;Sonja**
92		preparing	1 dag	maa 14-11-16	maa 14-11-16	Sonja
93		executing	1 dag	din 15-11-16	din 15-11-16	Jesse;Christoph;Paula;Sonja
94		**Measurement, analysis and improve**	**25 dagen**	**maa 14-11-16**	**vri 16-12-16**	**Christoph;Paula;Sonja**
95		Monitoring and measurement	4 dagen	woe 30-11-16	maa 5-12-16	Sonja



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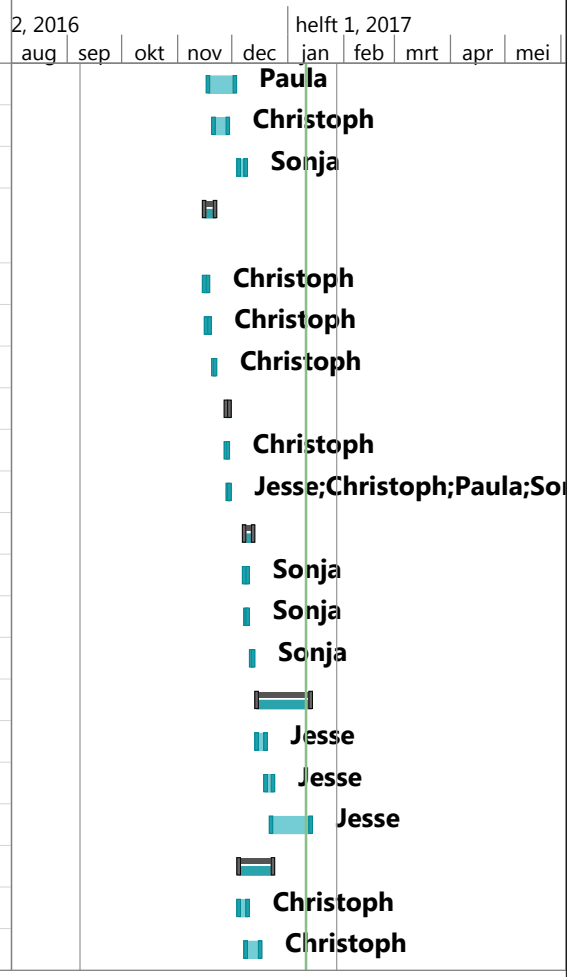
Task	Inactive Summary	External Tasks
Split	Manual Task	External Milestone
Milestone	Duration-only	Deadline
Summary	Manual Summary Rollup	Progress
Project Summary	Manual Summary	Manual Progress
Inactive Task	Start-only	
Inactive Milestone	Finish-only	

Id	Taal	Task Name	Duur	Begindatum	Einddatum	Resourcenamen
96		Control of nonconforming product	11 dagen	vri 18-11-16	vri 2-12-16	Paula
97		Analysis of data	6 dagen	maa 21-11-16	maa 28-11-16	Christoph
98		Improvement	4 dagen	maa 5-12-16	don 8-12-16	Sonja
99		**Credit and debit management**	**4 dagen**	**woe 16-11-16**	**maa 21-11-16**	**Christoph**
100		Process overview	2 dagen	woe 16-11-16	don 17-11-16	Christoph
101		RACI	2 dagen	don 17-11-16	vri 18-11-16	Christoph
102		check/change/verify	1 dag	maa 21-11-16	maa 21-11-16	Christoph
103		**Tutor meeting**	**2 dagen**	**maa 28-11-16**	**din 29-11-16**	**Christoph;Jesse;Paula;Sonja**
104		preparing	1 dag	maa 28-11-16	maa 28-11-16	Christoph
105		executing	1 dag	din 29-11-16	din 29-11-16	Jesse;Christoph;Paula;Sonja
106		**Storage policy**	**3 dagen**	**don 8-12-16**	**maa 12-12-16**	**Sonja**
107		Interview	2 dagen	don 8-12-16	vri 9-12-16	Sonja
108		Documentation	1 dag	vri 9-12-16	vri 9-12-16	Sonja
109		Verify	1 dag	maa 12-12-16	maa 12-12-16	Sonja
110		**ISO 14971**	**22 dagen**	**don 15-12-16**	**vri 13-1-17**	**Jesse**
111		Research	3 dagen	don 15-12-16	maa 19-12-16	Jesse
112		Interviews	4 dagen	din 20-12-16	vri 23-12-16	Jesse
113		Documentation	16 dagen	vri 23-12-16	vri 13-1-17	Jesse
114		**ISO 93/42/EEG**	**15 dagen**	**maa 5-12-16**	**vri 23-12-16**	**Christoph**
115		Comparisor list	5 dagen	maa 5-12-16	vri 9-12-16	Christoph
116		Documentation requirements	6 dagen	vri 9-12-16	vri 16-12-16	Christoph



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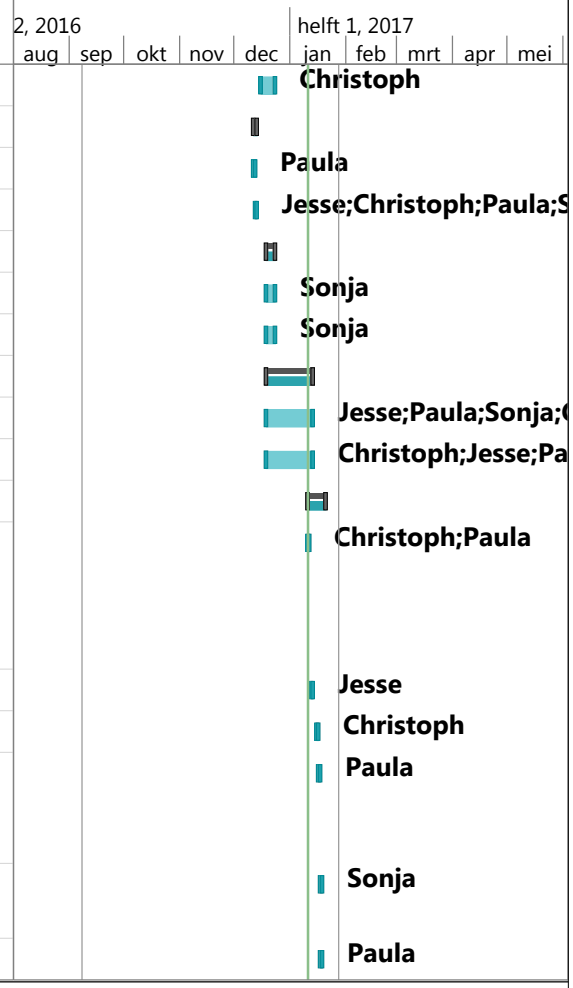
Inactive Milestone	Finish-only	

Id	Taal	Task Name	Duur	Begindatum	Einddatum	Resourcenamen
117		Finalizing	6 dagen	vri 16-12-16	vri 23-12-16	Christoph
118		**Tutor meeting**	**2 dagen**	**maa 12-12-16**	**din 13-12-16**	**Christoph;Jesse;Paula;Sonja**
119		preparing	1 dag	maa 12-12-16	maa 12-12-16	Paula
120		executing	1 dag	din 13-12-16	din 13-12-16	Jesse;Christoph;Paula;Sonja
121		**Finalization of the documents**	**5 dagen**	**maa 19-12-16**	**vri 23-12-16**	**Sonja**
122		Layout check	5 dagen	maa 19-12-16	vri 23-12-16	Sonja
123		Spelling check	5 dagen	maa 19-12-16	vri 23-12-16	Sonja
124		**Preparation for the trainings**	**20 dagen**	**maa 19-12-16**	**vri 13-1-17**	**Christoph;Jesse;Paula;Sonja**
125		Scheduling	20 dagen	maa 19-12-16	vri 13-1-17	Jesse;Paula;Sonja;Christoph
126		Making presentation	20 dagen	maa 19-12-16	vri 13-1-17	Christoph;Jesse;Paula;Sonja
127		**Trainings**	**8 dagen**	**woe 11-1-17**	**vri 20-1-17**	**Christoph;Jesse;Paula;Sonja**
128		Organigrama and mission, vision & goals, ISO, Control of documents, records and drawings	1 dag	woe 11-1-17	woe 11-1-17	Christoph;Paula
129		Management responsibility	1 dag	vri 13-1-17	vri 13-1-17	Jesse
130		Core process	1 dag	maa 16-1-17	maa 16-1-17	Christoph
131		Control of nonconforming product and transition procedure	1 dag	din 17-1-17	din 17-1-17	Paula
132		Transportation policy, storing policy, and packing quidelines	1 dag	woe 18-1-17	woe 18-1-17	Sonja
133		Communication policy	1 dag	woe 18-1-17	woe 18-1-17	Paula



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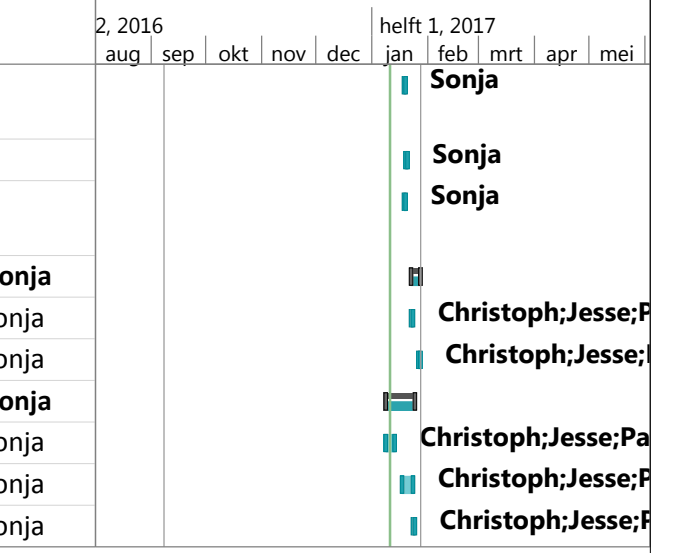
Project Summary		Manual Summary		Manual Progress	
Inactive Task		Start-only			
Inactive Milestone		Finish-only			

Id	Taal	Task Name	Duur	Begindatum	Einddatum	Resourcenamen
134		Work environment and infrastructure	1 dag	don 19-1-17	don 19-1-17	Sonja
135		Human resources	1 dag	vri 20-1-17	vri 20-1-17	Sonja
136		Customer feedback and Quality manual	1 dag	don 19-1-17	don 19-1-17	Sonja
137		**Non-official audit**	**5 dagen**	**maa 23-1-17**	**vri 27-1-17**	**Christoph;Jesse;Paula;Sonja**
138		Preparation	1 dag	maa 23-1-17	maa 23-1-17	Christoph;Jesse;Paula;Sonja
139		Execution	1 dag	vri 27-1-17	vri 27-1-17	Christoph;Jesse;Paula;Sonja
140		**Finalization of the project**	**12 dagen**	**maa 9-1-17**	**din 24-1-17**	**Christoph;Jesse;Paula;Sonja**
141		Writing the report	5 dagen	maa 9-1-17	vri 13-1-17	Christoph;Jesse;Paula;Sonja
142		Making the presentation	4 dagen	woe 18-1-17	maa 23-1-17	Christoph;Jesse;Paula;Sonja
143		Final presentation	1 dag	din 24-1-17	din 24-1-17	Christoph;Jesse;Paula;Sonja



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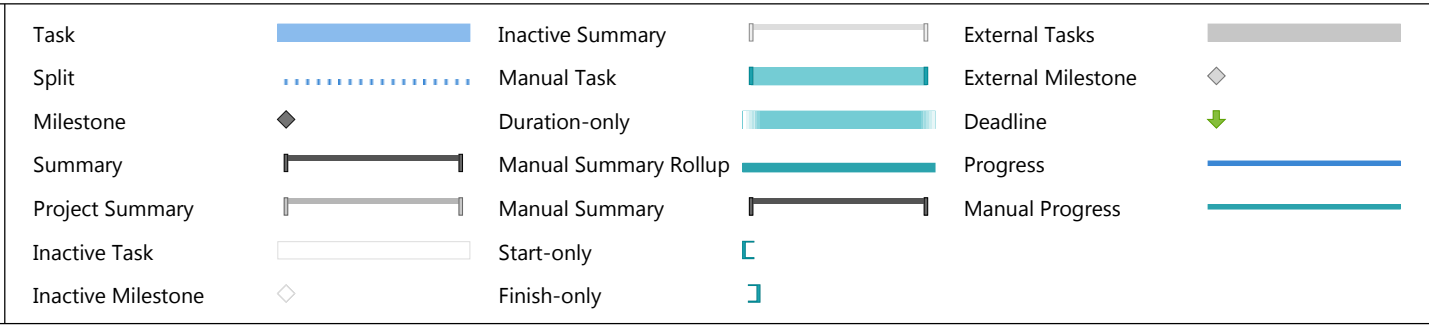


Plan of Approach

EPS

Sonja Repo, Paula Alonso González, Jesse van den Brink, Christoph Fetzer

Contents

1. Context of the project

The project will be performed to MR Coils BV which is a spinoff company of the University Medical Center Utrecht founded by Michel Italiaander. MR Coils BV is focused on making Magnetic Resonance Coil prototypes for MRI systems in Zaltbommel, Netherlands. The company is based on a close collaboration between the high field research group of the UMC Utrecht and close partnership with Philips. In the same domain in Zaltbommel will be put into operation several new companies to work together with the MR Coils BV in order to ease the collaboration with the stakeholders.

The project will be executed for one of the upcoming company MR Production and Services. MR Production and Services will be a company focused on selling and repairing the coils. In order to sell the coils as medical products MR Production and Service needs a quality management system which is made according to requirements of ISO 13485 certificate for medical devices. The project is about making new policies for the company in order to implement the new quality management system.

The end product of the project will be several different policies needed for the new quality management system of MR Production and Service in order to get ISO 13485 certificate. In order to make these policies several documents have to be created. These documents are process overviews, quality manual and work instructions.

2. Project Objectives

The objective of this project is to set up and write down different documents as policies or procedures for a quality management system of MR Production and Service, suitable for every employee and stakeholder involved in the specific process, accomplished within a timeframe of six months.

3. Program of Requirements

In this section the requirements for the project are described. Requirements are defined by the company and the project team members.

3.1 Preconditions:

- The QM system has to correspond the requirements of ISO 13485 in order to prepare the company for the certification.
- The project has to be finished until 16th of January 2017.

3.2 Functional demands:

- The policies and their involved documents made for the quality management system have to fit for every employee in the company.

3.3 Operational requirements:

- The policies and process overviews need to be clearly laid out and in standard format, so that new employees can get into their job quickly.
- All policies, processes and procedures have to be documented in proper English. They should be adequate, easily readable and easily understandable.

3.4 Restrictions:

- All the documentation has to be done in a format that is defined specially for MR Production and Service.

3.5 Project boundaries:

- The setup documents in the project apply only to MR Production and Service. Other MR Holding companies are not being considered.

4. Work breakdown structure

Work breakdown structure of this project is represented in a different document, which is made by using MS Project. Work breakdown structure which is represented in this document is made for the first two months and it will be extended after all the activities in it are done. Final Work breakdown structure will be made after first two months, when the project team will get more information about the next steps of the project.

Last two weeks of the project are for finishing, which includes writing a final report of the project and finishing the documents.

5. Progress planning

The progress of the project will be informed to the supervisor of the project with weekly meetings. The project manager and the client are together responsible for verifying the results of the project team. Project team will also have every second week meeting with the project tutor. Project tutor will be responsible of controlling and helping the project team if needed.

The milestones of the project are represented on the Work breakdown structure as tasks. All the tasks in the Work breakdown structure have sub-tasks under it which can also be considered milestones. The deliverables after every milestone vary depending on the task that is performed. The deliverables are usually policies and related documents.

6. Roles and tasks of the project

6.1 Internal

The project team, PT, is the group responsible for planning and executing the project. It consists of a project manager and a variable number of project team members, who are brought in to deliver their tasks according to the project schedule.

The project team members are responsible for executing tasks and producing deliverables as outlined in the Project Plan and directed by the Project Manager. They are the employees who actively work with the project, at some stage during the lifetime of the project. Some may have a specific role in the team.

The PT is made up of 4 members, all of them international students of Avans Hogeschool.

- **Jesse van den Brink**is from Netherlands and studies Industrial Engineering. He is the project leader, who has the responsibility to check that each team member is doing its job and doing it with the best methods as possible.
- **Paula Alonso González** is from Spain and studies Chemical Engineering. She is the project administrator or coordinator of the PT. She is responsible for maintenance of the project plan, maintenance and updating of the project documentation. She provides administrative support to the project manager.
- **Christoph Fetzer** comes from Germany and he is studying Industrial Engineering. He is the communication manager. He is the communication manager of the PT whenever the team needs more information or assistance from the company. He is also responsible of documentation in the meetings.

- **Sonja Repo** is a Finnish student studying Industrial Management and Engineering. She is the final editor of the documents. She has the responsibility of completing and checking the reports before they are presented to the project manager or the tutor.

6.2 External

According the external relationships, there are three main advisors for the PT members.

6.2.1 Concerning Avans

- A tutor, **Johan Wouters** is the middleman between Avans Hogeschool and MR Coils. Project tutor will be responsible of controlling and helping the project team if needed.

6.2.2 Concerning MR Coils

- The quality manager of MR Coils, **Schelte Post** is the supervisor of the project. He is the person responsible for ensuring that the PT completes the project. The Project Manager develops the project plan with the team and ensures that the team is performing the project tasks. It is also the responsibility of the project manager to secure acceptance and approval of deliverables from the PT. The Project Manager is also responsible for delivering all the needed documents and information for the PT. He is also responsible of the communication, including status reporting, risk management, escalation of issues that cannot be resolved within the team. In other words, he is the guide for the assignments that the PT have to accomplish them. He is in the position to be responsible for providing the required feedback and for checking and assisting what has been achieve till the moment.

- **Michel Italiaander,** MR Coils BV is a client of the project. Therefore, he is the onewho identifies the project opportunity. His responsibility is to accurately represent his business units' needs to the PT, and to validate the deliverables that describe the product or service that the project will produce. He is also expected to bring information about the project back to the Customer community. Towards the end of the project, he will check the end product of the project and evaluate it while providing feedback to the PT.

7. Communication planning

7.1 External communication

The PT has weekly meetings with the project manager, Schelte Post. These meetings are destined to inform the guide of how they are developing tasks in the team, in terms of time and in terms of content as well. He is also responsible for giving the feedback to the PT. For instance, are they on the right track or have to rectify and/or change the working method.

Meetings of the PT with the tutor are already fixed beforehand. PT makes two updates of the project's progress per month. The purpose of the meetings is to keep the tutor informed about how the PT is working and about everything that is related with the entire project.

The PT will ask meetings to the project client when they see it is needed. For instance, when they feel it is necessary to have more information about the needs of the client or whether the improvements are made to suit what clients demand.

In addition of these three external members there are daily shortlines between the PT and the other employees in the company. These meetings have already been fixed at the beginning of every morning with the staff of MR Coils. This way every employee of the company can be up-to-date of what will the rest have to do in order to ask assistance of each other if it is necessary.

In addition to these above-mentioned meetings the project team will communicate via e-mail and WhatsApp with the external parties of the project. The communication manager is responsible for the external communication generally.

7.2 Internal communication

Every member of the project team is responsible of the internal communication of the project. This means that every member of the project team is responsible to inform other team members about the progress of the job and possible challenges.

The project team will perform 15-minute-long meeting every morning that they are working at the company.In the meeting the project team will talk about the tasks for the day and update the schedule of the day if needed. The general tools used for internal communication are Dropbox, where team members load all the documents concerning the project. They also use e-mail and WhatsApp for the internal communication between the team members.

8. Resource planning

The resources needed in the project are represented in the Work breakdown structure in the form of a Gantt chart. From the work breakdown structure, can be seen the schedule of each activity and the recourses needed for it.

9. The costs of the project

The cost of the project for the company MR Coils will be a monthly reward of 250 euros for the project team members. In order to get a reward of the work the project team members should work on times that are agreed together with the company's contact person, Schelte Post or Michel Italiaander. Company MR Coils will also be responsible of paying the travel costs of the team members that might occur.

10. Risk analysis

To make sure the project will succeed the risks have to be identified so the effects can be reduced. After identifying the risks, they are categorised by chance of occurrence and negative impact on the project. There are several ways to reduce the effects of the risks, for instance prevent the risk from happening or prepare yourself for when the risk occurs. The following risks may occur within the project:

- **A** The project team members do not co-assist well
  For all the students this is the first time they are working in a project group with students from other countries. Some students may have a hard time working together because every culture has his own habits and it's possible they clash. There is also a possibility that the personalities of the students clash, this would also have a negative effect on the project.
- **B** The vision of the students about the assignment is not similar to the vision of the company
  If the students achieve the goal of the project but due to a lack of communication the company had different expectations, on paper the project has been executed correctly but the company does not get the result they want.
- **C** The suggested policies are not accepted and used by the employees of the company
  The policies that are going to be written have to be useable and understandable for the employees. If the employees cannot adjust the policies to their daily activities the policies cannot be used.

- **D** The project team does not reach the final goal of the project in time
  There is a possibility the project team does not reach the final goal of the project in time due to the fact that the planning was unreliable or the project team could finish their work in time. If this occurs the project will stay unfinished and if necessary, another project team will take over the assignment.

The risks can be categorised by impact on the project and chance of occurrence. Both the categories are split up into five different levels. The impact on the project is split up from no impact to very large impact. The chance of occurrence is split up from almost no chance of occurrence to great chance of occurrence. In the chart below a visual display of the different risks and in which category they belong. In the green area low risks are placed, in the yellow area the mediocre risks are placed and in the red area the threatening risks are placed.

Risk reduction

To reduce the risks a couple of methods can be used: pro-action, prevention, preparation, repression and aftercare. Pro-action is a method to make sure the risks permanently disappears. Prevention is taking precautions to prevent or reduce the risk. Preparation is implementing certain regulations to reduce the impact of the risk. Repression is the knowledge how to react if the risk occurs. Aftercare is implementing regulations after the risk occurred to restore usual course of events.

- **A** The project team members do not co-assist well
  To reduce the risk that the team members do not co-assist well the students should be open to each other about how they feel about certain behaviour. Also different test will be made to see what kind of a person every member is and what the best way is to get along. This is an example of prevention.
- **B** The vision of the students about the assignment is not similar to the vision of the company
  To make sure the students and the clients are on the same page about the vision of the project there has to be clear and short-term communication. This is an example of prevention.
- **C** The suggested policies are not accepted and used by the employees of the company
  If the employees cannot use the policies, they can be adapted to a state the employees will be able to use the policies, this is an example of aftercare. To reduce the risk that employees

do not accept or use the policies there has to be lots of contact between the project team and the employees. This is an example of prevention.

- **D** The project team does not reach the final goal of the project in time
  To prevent that the project team will not reach the final goal in time, there will be made Gantt Chart from all the activities and milestones in the project so everyone has a clear view of what needs to be done when.

Production of new part process

Warehouse

Stock level on minimum

Manager / CEO

Assign project lead

Project lead

Initiate production of a new part

Review and approve documen-tation

Debtor mgmt. process

Logistics

Check if required components are on stock

Components on stock?

No

Purchasing process

RF Engineer

Yes

Build new part

Execute product test

Did it pass?

No

Yes

Store in cabinet "ready for system test"

Execute system test

Did it pass?

Yes

No

Store part in warehouse

End process

Production part repair process

Documentation

BOM

Picking order

Bench test report

System test report

Storage policy

Packaging guidelines

All the products are always packed safely, to prevent breaking of components. And as small and light package as possible.
Before closing the package, it must be assured that every product is included. This can be checked by using the "Packing slip".
If the customer has special requests for the package, they will be fulfilled if possible.

Category	Packing	Guidelines	Other information
Small products	Envelope	- Documents are put inside of the envelope - Address information is written to the envelope	Small products can be transported in envelope, if there is no risk of breaking the product.
Products that are transported outside Europe, or assembled by the customer	Bark free wooden box	- Warning sign sticker is attached outside of the box - Filled-air plastic, paper, and other packing materials are used to fill the empty space inside of the package - Documents are put to Documents encloser and attached to the box	Can contain any of the below-mentioned products Small karton boxes can be used inside of the package
Products that are transported inside Europe	Karton box	- Warning sign sticker is attached outside of the box - Filled-air plastic, paper, and other packing materials are used to fill the empty space inside of the package - Documents are put to Documents encloser and attached to the box	Can contain any of the below-mentioned products
Electronic components and PCBs	Highshield static shielding or Antistatic bubblefolie		It is recommended that package is wrapped to bubble plastic
Products that have protruding or vibrating parts	Foam package		If the product doesn't fit in foam package, other packages are used.

Document name:	PAS_QMG_WOI_Working ESD safe
Document content:	Working ESD safe
Approval date:	
Version:	1.00

Work instructions: Working ESD safe

Who is this instruction for?

This instruction is written for all employees of MR Production & Service who will be working in production space, which is an ESD safe environment.

Responsibilities

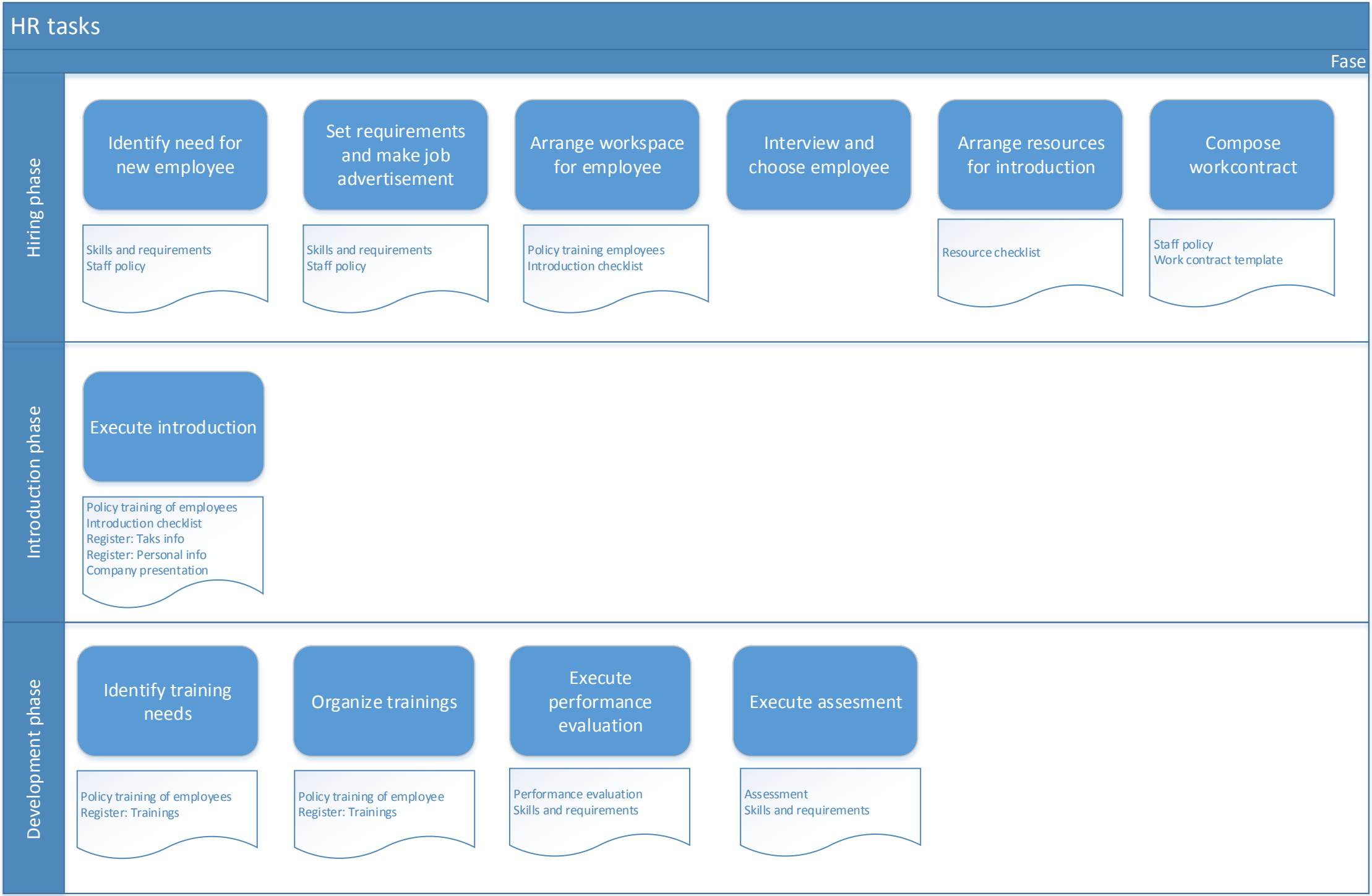
- The **employee** is responsible for working according to the rules and instructions given below.
- The **production manager** is responsible for evaluating whether the employees follow up the instructions.
- The **CEO** is accountable for the right execution of the instructions.

Risks of working in a ESD environment:

Failing to comply with these instructions can result in breaking of components.

Instructions:

Action	Details
***Before* entering ESD room:**	
1) Use ESD safe equipment	• Wristband • Heel grounder
2) Put on ESD safe clothes	• ESD overcoat (optional) • Electrostatic conductive clothes (cotton)
3) Test voltage	• Place your finger on the ESD Test equipment • This device shows, if you have the right voltage
4) Enter ESD room	• If you pass the voltage test you can enter the ESD room
5) Last Minute Risk Assessment	• The desk will have a sign, which shows a reminder to wear the wristband and heel grounder • The employee checks the ESD safe equipment and will start working


HR tasks
Fase
Hiring phase
Identify need for new employee
Skills and requirements
Staff policy
Set requirements and make job advertisement
Skills and requirements
Staff policy
Arrange workspace for employee
Policy training employees
Introduction checklist
Interview and choose employee
Arrange resources for introduction
Resource checklist
Compose workcontract
Staff policy
Work contract template
Introduction phase
Execute introduction
Policy training of employees
Introduction checklist
Register: Taks info
Register: Personal info
Company presentation
Development phase
Identify training needs
Policy training of employees
Register: Trainings
Organize trainings
Policy training of employee
Register: Trainings
Execute performance evaluation
Performance evaluation
Skills and requirements
Execute assesment
Assessment
Skills and requirements

Policy: Control of documents

Purpose of the document:

The purpose of this policy is to regularize the procedure of identification, creation, review and validation as well as the distribution and maintenance of documents in this company. It intends to ensure that all documents are constantly up to date and available to all appropriate employees at any time.

Responsibilities:

- The **CEO** is responsible for approving every document that requires certain approval. He is also responsible for spreading the policy, and making sure that every employee is following the policy.
- **Every department manager** is responsible for ensuring that the requirements of this policy are implemented within the involved area.
- **All employees** have specific access rights, depending on the department they belong to. Therefore, they are responsible for complying with the policy and making an appropriate use of the digital system chosen to storage documentation.

Detailed information about document responsibilities can be found in the **"Document responsibility matrix".**

Storage and backup:

Paper documents are scanned and if mandatory deposited in a central file cabinet. A detailed list of which documents have to be stored physically can be found in the document "**Disposition and retention times of documents".**

Electronic documents are saved on a server and registered in the document management system by the responsible employee. All documents are saved in an appropriate file format in order to ensure that they stay legible and identifiable. The naming of electronic documents is defined in "**File naming and folder structure instructions"**. A backup on external harddrives is being executed monthly. For documents that are stored both digitally and physically, the depository of the physical version is mentioned in "**Disposition and retention times of documents**".

The retention time of documents can be found in the work instruction **"Disposition and retention times of documents"**. The retention time of each document is also noted in the document management system. After the expiry of the retention time, the document is destroyed.

Document name:	PAS_QMG_POL_Control of documents
Document content:	Control of documents policy
Approval date:	
Version:	1.00

Constant actuality:

All policies are evaluated by the quality management at least once per year. This evaluation takes place in the first quarter of the business year. Outdated formulation is updated and changes are mentioned according to the version management. All changes have to be approved by the CEO.

Version management:

The version number of every document that requires versioning starts at 1.0 when created. This number changes when the document is updated according to the following scheme:

- **+ 0.1**. Minor risk-related change and functionality changes.
- **+ 1.0**. Major risk-related changes or functionality changes.

Revisions are mentioned in the version history table of every document that requires versioning. The initial version of the document has to be denoted as “old” at the beginning of the file name when it's archived.

Distribution:

The correct distribution of documents is warranted by a document management system, shared folders, and e-mails. The access permissions on shared folders are managed by the IT department. If there are new and updated documents, it will be informed by e-mail. Major document changes are also mentioned in the daily stand-up meeting of the regarding department. Documents determined for external parties have to be approved by the responsible department before sent out.

Documents of external origin:

The external origin of a document is mentioned in the document management system. The distribution of external documents is controlled by the administration according to the distribution policy.

Destruction of documents:

In order to ensure data protection, expired physical documents are shredded. Electronic documents are deleted.

Name:

Function:

Signature:

Document name:	PAS_QMG_POL_Control of nonconforming product
Document content:	Control of nonconforming product policy
Approval date:	
Version:	1.00

Policy: Control of nonconforming product

Purpose of the document:

This procedure defines the requirements and responsibilities for identification, documentation, control, disposition and actions to take in order to manage nonconforming items within MR Production & Service.

Responsibilities:

- **The CEO** is responsible for deciding how to act according to the process if any nonconformity shows up. He is also responsible for approving every change in already existing documents, as updates in policies or working instructions.
- **The project leader** is responsible for planning actions to take in order to correct the nonconformity.
- **The quality manager** is responsible for making sure that the non-compliance is properly registered, and also for informing the CEO on time, especially if there is a change request. He is also responsible for explaining and updating this process when necessary.
- **Every employee** who is involved in measuring the compliance of the product with the customer requirements, is responsible for identifying, analyzing and following this process.

Identification:

A nonconformity can be detected in many ways, by any person at any time. However, in order to sum up, only employee is going to be mentioned.
A nonconformity is found whenever a product/ process presents one or more of the following situations:

- It differs from the requirements, which are drawn up in the requirements specifications...
- Values are measured in the authentication/ integration test, and they are different from the standards of the verification specification and/or integration specification...
- …with as possible result of unintended side effects when using the product.

Therefore, it is necessary to address the nonconformity properly in the Change request form, identifying and describing the problem. This must include not only what is found, but what it was expected.

Analysis and disposition options:

The change is discussed and evaluated. Once it is approved, it is necessary to decide which disposition is going to be take. There are three different disposition options that can be chosen:

- **Eliminate the non-conformance**: the main goal is to return the product/process fully to the intended state.
- **Authorizing use**: if there is a concession from the requirements and the product or service is usable, although not fully compliant, then it is possible to accept the original use of that product or service.
- **Preclude original use**: either scrap the product or re-grade it.

Despite these 3 different options to deal with nonconforming products, MR Production & Service always tries to remove the nonconformity. Therefore, next steps are focused in this disposition option.

Actions to take

Depending on the type or grade of the nonconformity, two different ways to deal with it can be chosen:

- **Corrective actions**: actions that are decided to take once a problem is detected. They are meant to fix an already existing problem. They tend to solve and eliminate the problem's cause.
- **Preventive actions**: they are planned in order to avoid future potential problem to occur. They can be set up at any time, because they don't come from a real problem.

Required documentation

The following documents are used within MR Production & Service in order to have all the nonconformity's information documented:

- ***Change request form***: It can be found as "PAS_QMG_RFO_Change request form". This document is used to suggest a change. This adjustment can have the objective of dealing with already existing problems as nonconformities, or just improving process in terms of effectiveness. It includes identification and definition of the problem.
- ***Change order form***: it is an action list with the necessary activities to fix the nonconformity and functions responsible that are involved (see "PAS_QMG_RFO_Change order form").
- ***Change management registry***: it is a document where important steps of this process are recorded. For instance, when both change request and change order are approved (see "PAS_QMG_REC_Change management registry").
- ***Verification report***: this document is a proof where is described that the new product fulfills the requirements. It is important to remark that verification report is always product-related (see "PAS_QMG_RFO_Verification report".
- ***Integration report***: if necessary. It describes how the new product matches the system's requirements. It is important to remark that integration report is always product-related (see "PAS_QMG_RFO_Integration report").
- ***Declaration of conformity***: The release of the change can't be carried out without signing by CEO (see "PAS_QMG_RFO_Declaration of conformity").

Working method

The general overview of the process can be found in "PAS_QMG_PRO_Overview Control of nonconforming product". In addition, the description of the process also explains this process into more detail (see "PAS_QMG_PRO_ Control of nonconforming product").

Name:

Function:

Signature:

Control of nonconforming product

Phase

Employee

RF Engineer

Project leader

Quality manager

CEO

Documentation

Error is found

Unsuccessful

Implement change

End process

Set up change order

Test results

Set up change request

Successful

Set up transition

Release change

Set up change request

Set up change rorder

Set up change order

Validation report

Declaration of conformity

Policy training of employees

Quality assurance procedure

Set up transition policy

- MR Production and Service QMS — 12 januari 2017 19:57
  - Approved — 10 januari 2017 10:49
    - 2. Quality management system in general — 12 januari 2017 16:53
      - 2.3 Core processes — 12 januari 2017 16:53
        - Core processes — 12 januari 2017 16:53
          - Overview — 12 januari 2017 16:53
            - PAS_QMG_PRO_1 Starting conditions overview.pdf — 2 december 2016 10:28
            - PAS_QMG_PRO_2 Repair and replace process overview.pdf — 5 december 2016 10:13
            - PAS_QMG_PRO_3 Supplier RMA process overview.pdf — 16 december 2016 10:40
            - PAS_QMG_PRO_4 Production part repair process overview.pdf — 16 december 2016 09:59
            - PAS_QMG_PRO_5 Production of new part process overview.pdf — 16 december 2016 10:09
            - VISIO files — 10 januari 2017 13:00
          - RACI — 10 januari 2017 13:00
            - PAS_QMG_PRO_1 Starting conditions.docx — 9 januari 2017 10:08
            - PAS_QMG_PRO_2 Repair and replace process.docx — 9 januari 2017 10:09
            - PAS_QMG_PRO_3 Supplier RMA process.docx — 9 januari 2017 10:10
            - PAS_QMG_PRO_4 Production part repair process.docx — 9 januari 2017 10:11
            - PAS_QMG_PRO_5 Production of a new part.docx — 9 januari 2017 10:12
      - 2.3 Sub-core processes — Vandaag 16:57
        - Set up change order — 10 januari 2017 13:00
          - PAS_QMG_PRO_Set up change order overview v1.00.pdf — 9 januari 2017 12:52
          - PAS_QMG_PRO_Set up change order overview v1.00.vsdx — 9 januari 2017 12:51
          - PAS_QMG_PRO_Set up change order.docx — 9 januari 2017 10:23
        - Set up change request — 10 januari 2017 13:00
          - PAS_QMG_PRO_Set up change request overview v1.00.pdf — 9 januari 2017 12:42
          - PAS_QMG_PRO_Set up change request overview v1.00.vsdx — 9 januari 2017 12:42
          - PAS_QMG_PRO_Set up change request.docx — 9 januari 2017 10:24
      - 2.4 Quality objectives — 16 december 2016 12:36
      - 2.6 Control of documents — 12 januari 2017 16:51
        - PAS_QMG_POL_Control of documents.docx — 11 januari 2017 13:35
        - PAS_QMG_PRC_File naming and folder structure.docx — 11 januari 2017 13:38
        - PAS_QMG_REC_Disposition and retention times of document.xlsx — 10 november 2016 16:02
        - PAS_QMG_REC_Document responsibility matrix.xlsx — 21 november 2016 12:46
        - PAS_QMG_REC_Shortcuts.xlsx — 9 januari 2017 13:27
        - R016 Acceptance of Policy.docx — 21 april 2016 11:34
      - 2.6 Control of drawings — 12 januari 2017 16:51
        - PAS_QMG_PRC_Control of drawings.docx — 11 januari 2017 11:38
      - 2.7 Control of records — 22 december 2016 10:51
        - PAS_QMG_POL_Control of records.docx — 19 december 2016 11:16
    - 3. Management responsibility — 12 januari 2017 16:53
      - 3.6 Communication — 22 december 2016 10:51
        - PAS_QMG_POL_Communication.docx — 19 december 2016 11:12
      - 3.7 Management review — 22 december 2016 10:51
        - PAS_QMG_POL_Management review.docx — 21 december 2016 15:35
        - PAS_QMG_REC_Management review checklist.xlsx — 12 december 2016 13:56
      - PAS_GEN_ORG_Organigram.pdf — 10 november 2016 11:33
      - PAS_QMG_REC_Quality objectives.docx — 9 januari 2017 10:26
      - PAS_QMG_REC_Roles and responsibilities.xlsx — 21 december 2016 09:03
      - PAS_QMG_STA_Policy statement.docx — 21 december 2016 09:22
    - 4. Resource management — 10 januari 2017 10:49
      - 4.2 Human resource — 12 januari 2017 20:01
        - HR tasks.pdf — 21 november 2016 11:23
        - HR tasks.vsdx — 21 november 2016 11:23
        - PAS_HRE_POL_Staff policy.docx — 9 januari 2017 11:13
        - PAS_HRE_POL_Training of employees.docx — 9 januari 2017 10:11
        - PAS_HRE_REC_Assessment.docx — 24 november 2016 12:34
        - PAS_HRE_REC_Introduction checklist.docx — 10 januari 2017 10:51
        - PAS_HRE_REC_On-the-job training.docx — 10 januari 2017 10:48
        - PAS_HRE_REC_Overview of trainings.xlsx — 21 november 2016 14:50
        - PAS_HRE_REC_Performance evaluation.docx — 24 november 2016 12:34
        - PAS_HRE_REC_Resource checklist.docx — 3 januari 2017 19:37
        - PAS_HRE_REC_Skills and requirements.xlsx — 24 november 2016 11:42
      - 4.3 Infrastructure — 10 januari 2017 13:00
        - PAS_HRE_REC_Resource checklist.docx — 9 januari 2017 12:50
        - PAS_PRO_PRC_Maintenance of areas and resources.docx — 21 december 2016 15:36
        - PAS_QMG_REC_Persons responsible of areas.xlsx — 1 december 2016 12:08
      - 4.3 Transportation — 22 december 2016 10:51
        - PAS_LOG_POL_Storaging.docx — 21 december 2016 15:33
        - PAS_LOG_POL_Transportation.docx — 21 december 2016 15:33
        - PAS_LOG_WOI_Packaging guidelines.xlsx — 12 december 2016 13:39
      - 4.4 Work environment — 10 januari 2017 13:00
        - PAS_PRO_POL_Control of work environment.docx — 21 december 2016 15:33
        - PAS_PRO_WOI_Working ESD safe.docx — 3 januari 2017 19:31
        - PAS_QMG_REC_Resistance measurement.xlsx — 1 december 2016 12:49
    - 5. Product realization — 12 januari 2017 16:53
      - 5.4 Purchasing — 10 januari 2017 13:00
        - PAS_PUR_PRO_Purchasing process overview.pdf — 16 december 2016 10:23
        - PAS_PUR_PRO_Purchasing process overview.vsdx — 16 december 2016 10:22
        - PAS_PUR_PRO_Purchasing.docx — 9 januari 2017 10:14
    - 6. Measurement, analysis and improvement — Vandaag 16:56
      - 6.2 Monitoring and measurement — Vandaag 16:56
        - 6.2.1 Customer feedback — 10 januari 2017 13:00
          - PAS_QMG_ANA_Customer feedback.xlsx — 27 oktober 2016 09:30
          - PAS_QMG_FOR_Customer feedback.docx — 21 december 2016 08:33
          - PAS_QMG_POL_Customer feedback.docx — 21 december 2016 15:36
          - PAS_QMG_PRO_Complaints management overview.pdf — 28 november 2016 08:58
          - PAS_QMG_PRO_Complaints management overview.vsdx — 28 november 2016 08:57
          - PAS_QMG_PRO_Complaints management.docx — 9 januari 2017 10:29
          - PAS_QMG_REC_Complaint register.xlsx — 24 november 2016 14:21
        - 6.2.2 Internal audit — 10 januari 2017 14:01
      - 6.3 Control of nonconforming product — 10 januari 2017 13:00
        - PAS_QMG_POL_Control of nonconforming product.docx — 19 december 2016 12:02
        - PAS_QMG_PRD_Control of nonconforming product overview.pdf — 9 januari 2017 12:33
        - PAS_QMG_PRD_Control of nonconforming product overview.vsdx — 9 januari 2017 12:31
        - PAS_QMG_PRD_Control of nonconforming product.docx — 9 januari 2017 10:31
    - Different — 12 januari 2017 20:14
      - PAS_QMG_POL_Transition.docx — 19 december 2016 12:06
      - PAS_QMG_REC_Transition times.xlsx — 16 december 2016 14:59
  - In progress — 10 januari 2017 14:49

Overall experiences of EPS

Sonja Repo:

The European Project Semester has exceeded my expectations in many ways. First of all, the whole EPS program has been built wisely. The fact that the students have small courses before starting the project, gives an opportunity to rehearse lessons learned, but also to build team spirit. Moreover, the lessons helped the project teams to prepare for the project and this way to do better project management. In addition to the lessons, the project has added enormous value to me personally.

Working with a EPS project has given me a lot of knowledge and a great work experience, but also personal lessons. Working with people from different cultures has improved my communication and team working skills. Moreover, I have learned much about myself, for example: which kind of working way serves my development and keeps my motivation high. Furthermore, MR Coils has been a great example for me as a low-hierarchy company, in which I have not even seen as an option before. From this on I will try to find a similar company like MR Coils, in which the employees are committed to work towards shared goals.

Overall the EPS program has been a success. I have received a lot of knowledge and new experiences as well as memories and new friends. EPS also helped me to achieve my most important personal goals, such as personal growth and self-improvement. In short, I am really happy that I was able to take part in EPS.

Jesse van den Brink:

The EPS program has been a great experience for me, I have learned a lot. The project in during the EPS program was one of the best projects I have ever carried out. The creation and implementation of the quality management system for MR Production & Service was really interesting and it gave me the feeling our project actually helped the company. Writing a quality manual thought me a lot about quality management and other subjects.

One of the best things about the EPS program is the EPS group. The EPS group is so close, this because the foreign students not have anyone else in the Netherlands so they are assigned to each other. It is so great to see that everybody gets along so well, even though there are so many different cultures. I think it is a great experience to work with other students all over the world.

For me the classes we got were not that interesting, because I already attended 90 percent of the courses in Dutch. This was actually the only downside of the EPS program, but overall I had a great time!

My personal goals for this semester were improving my English, learning how to deal with other cultures in a professional environment and getting experience in working in a company. I think I did a really good job achieving my personal goals. My English has improved a lot since I started the EPS program. The last five months I have only spoken English at school and at the company, this resulted in improvement in fluently speaking English. My English writing has also improved, I notice that I can write without having to check a dictionary all the time. I think, also due to the cross-culture lessons from Brian Kayes, I learned a lot about other cultures, how to deal with the differences. Brian thought me a lot about the misunderstandings cultural differences can bring and how to avoid them. I think I also got experience working in a company, we have been working at the company for the last five months, working four days a week, almost the entire time. Working at MR Coils has been a great time, I learned a lot about the work environment in a company.

Christoph Fetzer:

For me, the EPS was a great experience. I'm glad that I chose the AVANS for my semester abroad. It was a unique opportunity to gain direct insight into a Dutch company and practical experience in an international environment. I never worked in the field of medical technology. Thanks to the real-life project at MR Coils, I consider the field of medical technology as something I would like to work on in the future. MR Coils gave us the opportunity to set up a quality management system from the beginning, which is a good basis for a professional specification on this topic.

The courses at the AVANS were useful and helpful. Though there were similarities to the courses I already had in Germany, it was interesting to see how business- and project related methods and tool are handled in the Netherlands. In addition, I really enjoyed getting to know international students from all over the world as well as the Dutch people and culture.

My personal goals for the EPS were to improve my written and spoken English as well as getting to know a different culture. Writing policies and procedures were an excellent practise of written business English. Due to the international environment in our project and at the AVANS, I also gained a good spoken command. Getting to know the Dutch culture, in particular the people, was very interesting. Compared to Germany, people are more open-minded and communicative. I can identify myself with those values and it is not unimaginably for me to come back to the Netherlands to live and work in here.

Paula Alonso González:

Personally, EPS has been a challenge. If I had to choose two words to sum up the experience would be learning and adaption. Learning, because during these 5 months I have not stopped learning. I know the country better, (I have also visited other countries as Germany, Belgium or Poland) and its culture. I have met many people from different places, with different customs and experiences. So, I can honestly say that I have learnt from everything new of that I have lived during these 5 months.

Therefore, I do not have anything bad to say about EPS. Having the feeling that time flies is just a prove that it has been a wonderful and completely positive experience.

After these five months that I can say that I have grown both personally and professionally. personally. I know myself better.

Professionally, I have not applied any knowledge of the degree that I am studying in my country (Chemical Engineering). However, I have learnt a lot about the quality management system within a company, and in this case, specifically the QMS of a new company like MR Production & Service Therefore, I can say that learning from experience working in a company for the first time has allowed me to grow professionally.

In addition, I can say that I know myself much better. I know which ones are my strengths. I also know where my weaknesses are and how I have to work to turn them into strengths My perspectives of how I currently see the world and life have also changed. And I guess that it is because I have achieved the goal of growing as a person.