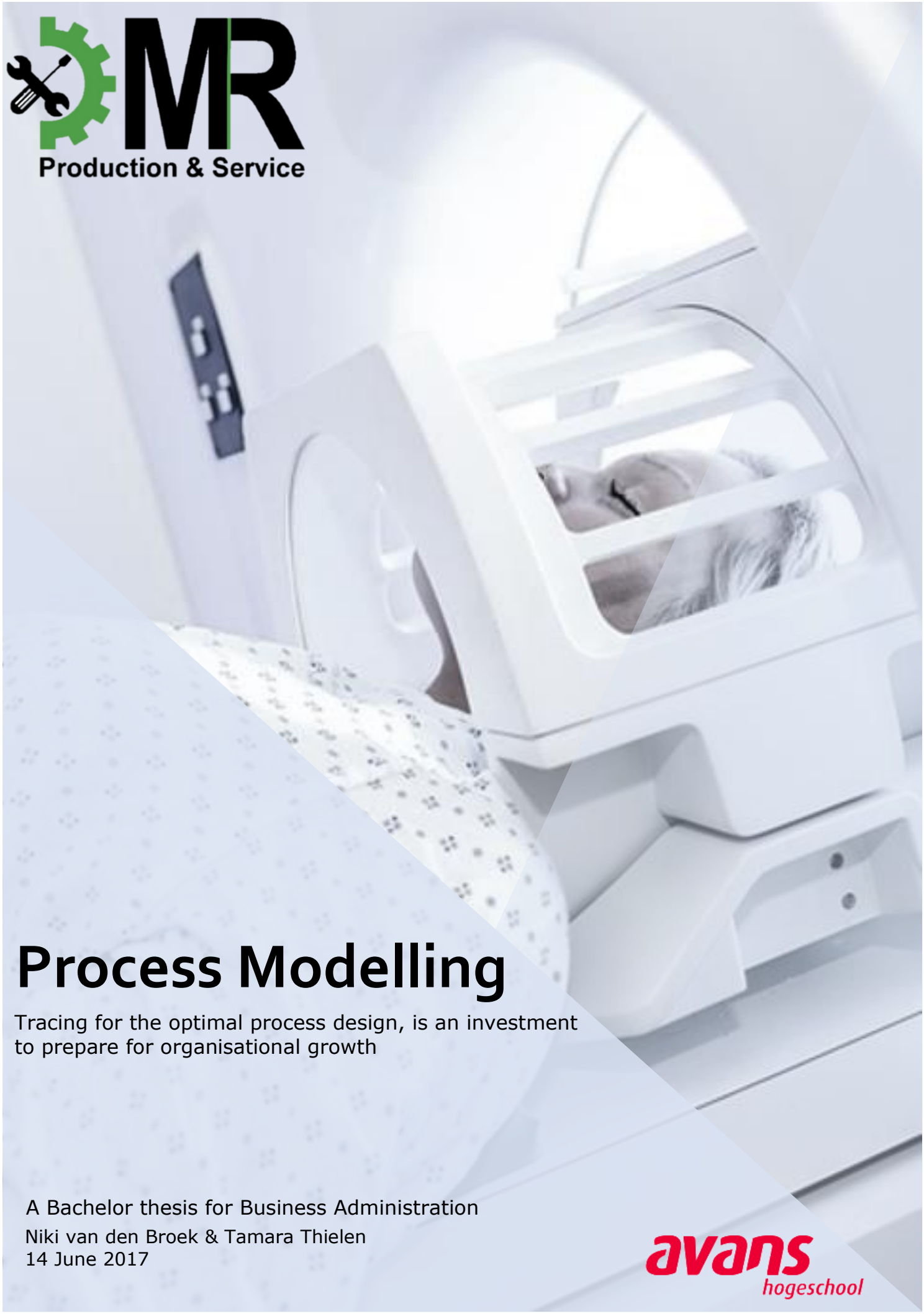

Process Modelling

Tracing for the optimal process design, is an investment to prepare for organisational growth

A Bachelor thesis for Business Administration

Niki van den Broek & Tamara Thielen

14 June 2017

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Company overview

Organisation	MR Production & Service
Address	Schimmink 18 5301 KR Zaltbommel
Telephone	+316 115 053 93
Business coach	Schelte Post Quality Manager Email: SPost@mrcoils.com Telephone: +316 115 356 62

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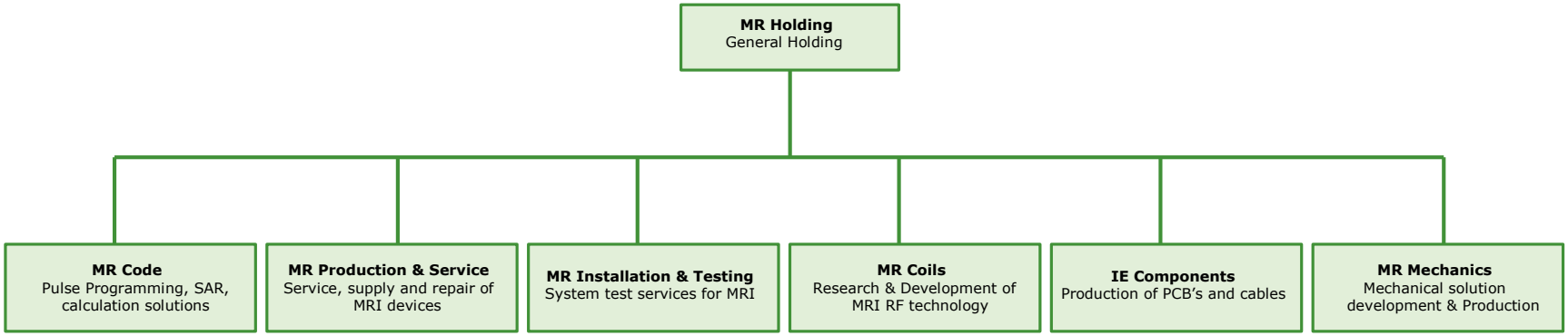
Business context & Identify

1. Business context - Organogram

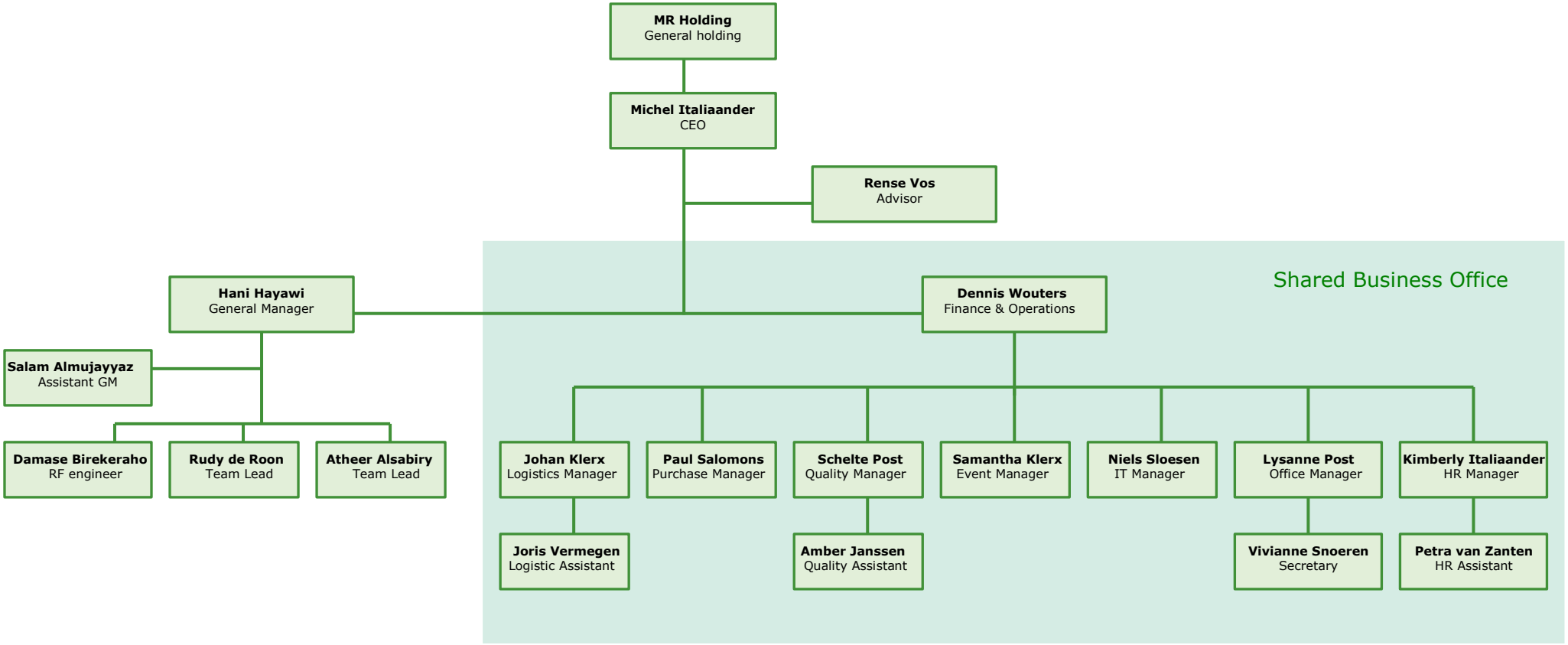
A. Organogram MR Holding

The following figure represents the organogram of MR Holding. All organisations share a Business Office, which is not included in this organogram. As shown, MR Production & Service is one of the subsidiaries of MR Holding. An organogram of MR P&S is included in appendix 1B.



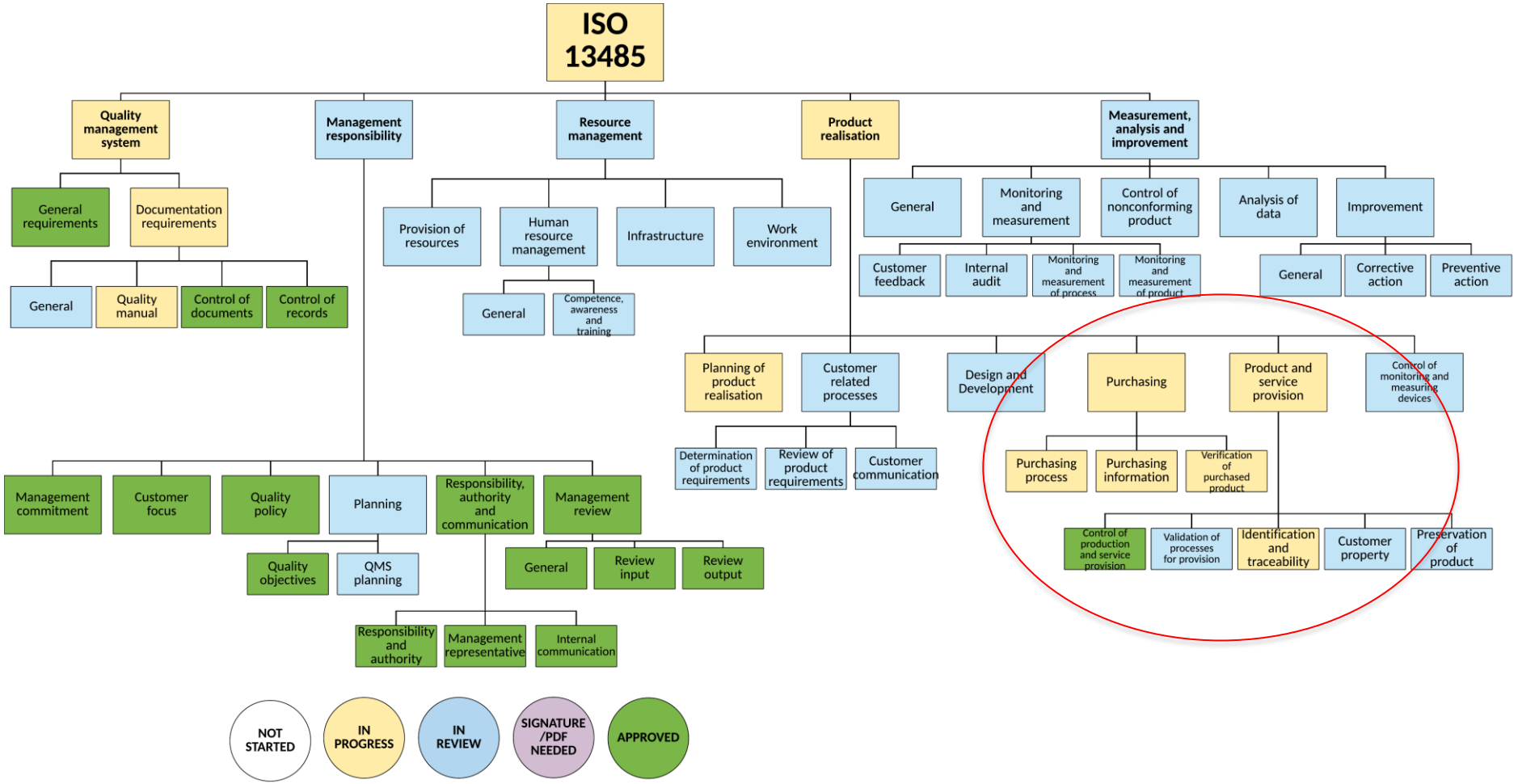
B. Organogram MR Production & Service

The following organogram shows the organisation structure of MR P&S and its connection to the holding and shared Business Office.



2. Business context – ISO 13485

The following figure shows the requirements of ISO 13485 and the progress of MR P&S concerning these requirements at the starting date of this research. This research is focussing on the purchasing and traceability process which are highlighted.



3. Business context - Sub-questions

This appendix shows all sub-questions that are answered during this research:

IDENTIFY:

1. **Which elements of the Quality Management System should be designed or improved to have a good Quality Management System?**
   - 1.1 How are the current processes of MR P&S set up?
     - 1.1.1 How is the current traceability process set up?
     - 1.1.2 How is the current purchasing process set up?
   - 1.2 Which requirements should MR P&S meet to let its processes flow optimal?
     - 1.2.1 What are the requirements stated by ISO 13485?
     - 1.2.2 How would the processes flow in an optimal situation from the perspective of MR P&S?
   - 1.3 What causes the differences between the current and the optimal situation?
     - 1.3.1 What are the differences between the current and the optimal situation?
     - 1.3.2 What are the problems caused by these differences?
     - 1.3.3 Which steps should be taken to tackle these problems?

DESIGN:

2. **How can these elements be documented in the Quality Management System?**
   - 2.1 How can MR P&S meet all the requirements concerning traceability?
     - 2.1.1 What should be documented in the policies?
     - 2.1.2 What should be documented in the processes?
     - 2.1.3 What should be documented in the records and registrations?
   - 2.2 How can MR P&S meet all the requirements concerning purchasing?
     - 2.2.1 What should be documented in the policies?
     - 2.2.2 What should be documented in the processes?
     - 2.2.3 What should be documented in the records and registrations?

OPTMIZE:

3. **Is the documentation for the Quality Management System optimal to implement?**
   - 3.1 What are the potential risks in the designed documentation for the Quality Management System?
     - 3.1.1 What are the potential risks in the traceability process?
       - a. What is the occurrence of every risk?
       - b. What is the severity of every risk?
       - c. What is the detection rate of every risk?
     - 3.1.2 What are the potential risks in the purchasing process?
       - a. What is the occurrence of every risk?
       - b. What is the severity of every risk?
       - c. What is the detection rate of every risk?
   - 3.2 How can the discovered potential risks be eliminated?
   - 3.3 Are all discovered potential risks eliminated?
     - 3.3.1 What elements of the designed processes should be tested in a pilot study?
     - 3.3.2 Which questions should be answered by the pilot studies?
     - 3.3.3 How will the pilot studies be executed?
     - 3.3.4 Do the pilot studies reveal new potential risks?
     - 3.3.5 How should the new potential risks be eliminated?

VERIFY:

4. **Are the final documents for the Quality Management System set up in a way that they are suitable, feasible and acceptable for MR P&S?**
   - 4.1 What are the legal consequences of implementing the Quality Management System?
   - 4.2 How should MR P&S involve everyone in the changing process that comes with implementing the Quality Management System?
     - 4.2.1 How can MR P&S communicate what is going to change?
     - 4.2.2 How can MR P&S create all participants are aware of the changes?
     - 4.2.3 How can MR P&S manage that all participants adapt to the changes?
     - 4.2.4 How can MR P&S make sure all participants keep adapting to the changes?
   - 4.3 What are the financial consequences of implementing the Quality Management System?
     - 4.3.1 What are the one-off investment costs?
     - 4.3.2 What are the yearly costs after implementing the new designs?
     - 4.3.3 What are the benefits and/or savings after implementing the new designs?

4. Business context - List of stakeholders

A list of the stakeholders and the interview topics that are held during this research:

CEO MR Holding: Michel Italiaander
- The mission, vision and objectives of MR P&S
- The desirable purchasing process
- The desirable traceability process
- Feedback on designed processes
- Approval optimised documentation

General Manager & assistant General Manager MR P&S: Hani Hayawi and Salam Almujayyaz
- The current and desirable traceability process
- The current and desirable purchasing process
- The involvement of employees of MR P&S
- Feedback on designed processes
- Approval optimised documentation

Quality Manager: Schelte Post
- The costs of implementing a QMS
- The way of setting up documents for a QMS
- The current and desirable purchasing process
- The current and desirable traceability process
- The involvement of employees in the changes
- The purchasing terms and conditions
- Feedback on designed processes

Finance & Operations Manager: Dennis Wouters
- The current and desirable traceability process
- The current and desirable purchasing process
- The cashflow of MR P&S and the costs of ISO 13485

Logistic manager: Johan Klerx
- The current inbound process
- The current outbound process
- The usability of the documented material

Purchasing Manager: Paul Salomons
- The current and desirable Purchasing process
- The usability of the documented material
- The purchasing terms and conditions

Purchase assistant: Joris Vermeegen
- The current measures taken in Exact
- The possibilities of Exact

Engineer: Rudy de Roon
- The current inventory system
- The current repair and production process (used test and registrations)
- The usability of the documented material

Business advisor: Rense Vos
- The purchasing terms and conditions
- Legalisation concerning purchasing

Philips consultant: Frank Rosbak
- The purchase and supplier evaluation process of Philips
- The supplier selection methods used by Philips and recommended by NEVI

5. Identify - Current traceability policy

This appendix displays the traceability policy which was set up by the organisation before the start of this research:

Policy: Traceability

Purpose of this document:

This document has been set up to describe the traceability policy for MR Production & Service. This document contains information about the rules and regulations concerning the traceability process.

Responsibilities:

- The **purchase manager** is responsible for purchasing components from suppliers, who provide the right product information.
- The **RF engineers** are responsible for the execution of the Kanban system and updating the database when a bin is empty.
- The **general manager** is responsible for the execution of the process.
- The **logistic manager** is responsible for maintaining and executing the Kanban system.
- The **quality manager** is responsible for reviewing the purchasing process.
- The **CEO** accountable for the process.

Traceability incoming products

The traceability of incoming products can only be done in cooperation with the suppliers. The suppliers need to record the product information in their system (article numbers, their suppliers, batch numbers). When MR Production & Service receives a product, the product information must be traceable by the serial number given by the supplier. The logistic manager checks in the serial number in the database of MR Production & Service. The supplier is responsible for the availability of the correct product information.

Traceability of products in production

Traceability can be done on different levels, which depend on the costs and usefulness. The traceability on cheap and high quantity products is less than on expensive low quantity
To trace which product out of stock is assembled in which product, MR Production & Service uses a two-bin Kanban system. The two-bin Kanban is a system to control the stock value and can be used to trace back products. In the warehouse, for every article there are two-bins. Both bins are filled with a different batch of products. The logistic manager registers which batch is in which bin, this is done using the batch numbers. The engineers take products out of the stock till the first bin is empty. When the first bin is empty, the engineer takes out the bin and places it next to the shelve (see figure 1: Kanban two-bin shelve). When the employee takes out the second bin roles automatically forward. After that the engineer updates the database by entering that the first bin is empty. This way the system knows the first batch is out of stock. The purchase manager receives a notification that one bin is empty, so he knows he have to order a new batch. When the new batch of products arrives, the logistic manager books in the products in the database. This way every component in the final product can be traced back to its batch.

Figure 1: Kanban two-bin shelve

Traceability outgoing products

To trace outgoing products the system needs specific information about the product (product information, article number, batch number, serial number). MR Production & Service only sells products to customers and to distributors (Philips), who will sell them to customers. When products are directly sold to the customer traceability is done by updating the database. To trace which products are at which customers, MR Production & Service needs cooperation from the distributors. The products sold to the distributors will be provided with a serial number, specific to that product. When the distributors sell a product to a customer they update their database with the information which product from which batch is send to which customer.

Chain of Custody

The Chain of Custody (CoC) is a concept which regards the entire supply chain. Traceability of the product can be handled through the CoC. The outcome of this concept is a paper trail of documented information from the raw materials to the final product which is delivered to the customer. The chain of custody is not necessary for every product. The depth of the traceability depends on the kind of products. The A products are traced back to the raw material suppliers. The B products are traced back to the suppliers' suppliers. The C products are just traced back to their suppliers, further information is not necessary. (see figure 2: Chain of Custody)

Note: The gradations (A, B or C products) of traceability are different from the gradations in cycle count and purchasing.

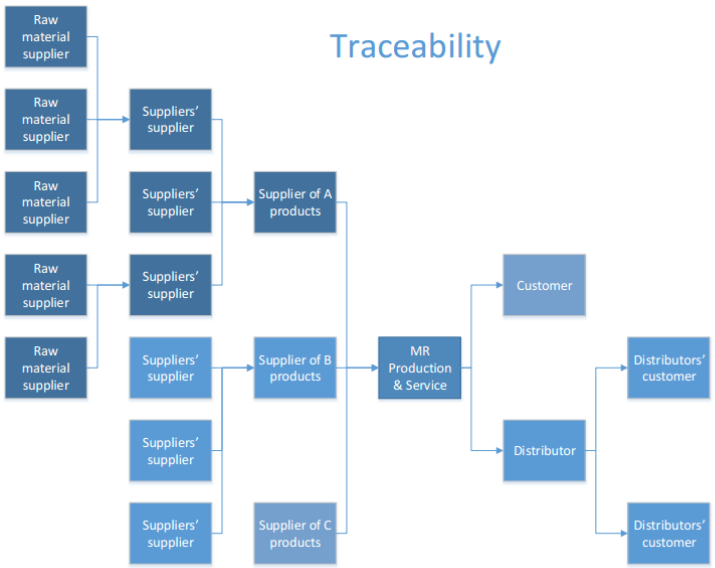


Figure 2: Chain of Custody

6. Identify - Current inbound process RACI

This appendix displays the inbound process which was set up by the organisation before the start of this research:

Inbound logistics

Introduction

This document has been set up to describe the inbound logistics process of MR P&S. Each separate activity has been described, including who is responsible and what documentation / systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who has final responsibility and can be held accountable if the product and/or process does not work according to a plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person is responsible for giving advices concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. This is one way communication.
	(NL: geïnformeerd)	

Start of the process

The process starts whenever a product is delivered to MR P&S.

Assess the required amount of storage			
Description:	The logistics assistant assesses according to the size of the delivered product whether extra storage is needed or not. If extra storage is needed, storage preparations are set up. If not, the part can be received.	R:	RFE
		A:	PL
		C:	
		I:	PL
Documentation:			

Transport of product			
Description:	Parallel to the assessment of the required storage place and the regarding preparation, the transport company ships the part to MR P&S.	R:	Transp. Company
		A:	Transp. Company
		C:	
		I:	
Documentation:			

Receive and check product			
Description:	The logistics assistant receives the delivery and checks it on completeness, accuracy and condition according to the transport documents and the purchase order. If the delivery is correct, it is stored.	R:	PL
		A:	PL
		C:	RFE
		I:	Purchasing
Documentation:	Purchase order		

Store product			
Description:	The delivery is stored at its prepared place. The function which the delivery relates to is informed. These could be for example the project lead or the purchasing.	R:	Logistics
		A:	Logistics
		C:	
		I:	PL, Purchasing, ..
Documentation:			

Update logistics database			
Description:	The logistics assistant updates the logistics database in EXACT. The inbound logistics process ends here.	R:	Logistics
		A:	Logistics
		C:	
		I:	MGR
Documentation:			

7. Identify - Current repair registration form

This appendix displays the repair registration form that engineers of MR P&S filled in during a reparation before the starting date of this research:

	receive_interfacebox_453567513901-113					
date	16-feb-16					
	Problem		**Status**			**Remarks**
1	preamp ch1 amplify 25.5 dB		not repaired			preamp ch1 is not the same preamp of the another channels
2	ch15 aka ch31		repaired (point 4)			amplify 25.5dB but it is the same brand as the other good preamps (not like ch1 aka ch17)
3	connectors ch9 aka ch25 not tight / not good fixed to the PCB		not repaired			good soldering requierd
4	L25 and L27 chock coils bad soldering (pic)		repaired			seems to be like short circuit due to too much solder (repaired from 25.5dB to 28.4dB)
5	checked					All receive channels are checked
						Detune lines are checked
						MalFun is OK
						ID codes is 191 (37k and 16k)
6	black knob missing on the bottom		repaired			have to be ordered
	Box 113		**Input impedance without preamp power**			
	Channel:	Amplification	R	J		
	1	26,6	-1,5	30,6		Replaced the Wantcomm preamp for a new preamp
	2	27,9	-0,8	25,9		
	3	27,9	-1	28,3		
	4	28,5	-0,7	25,4		
	5	28,4	-0,6	25,9		
	6	28,1	-0,9	28,5		
	7	28,2	-1,1	31,8		
	8	27,4	-0,7	29,5		
	9	28	-1,2	30,5		
	10	28,3	-1	26,3		
	11	28	-1	28,4		
	12	28,5	-0,6	25,2		
	13	28,3	-0,8	27,6		
	14	28,1	-0,8	25,5		
	15	29,3	-0,8	30,3		
	16	28,3	-1,2	32,3		
date	3-may-2016					
	Channel:	Amplification				
	1	27,5				odu pin broken + changed from 117R white preamp
	2	27,1				
	3	27,9				
	4	27,7				
	5	27,8				
	6	27,5				
	7	27,5				
	8	26,6				
	9	27,4				
	10	27,7				
	11	27,4				
	12	27,8				
	13	28,3				changed from 117R white preamp
	14	27,4				
	15	27,6				changed from 117R white preamp
	16	28,3				changed from 117R white preamp
date	27-mei-16					
	3x pins refGnd, Detune/MalFun and spaire pin are repaired					
date	1-aug-16					
	2N7002 mosfet replaced because id code wont change before					

8. Identify - Current reparation process RACI

This appendix displays the reparation process which was set up by the organisation before the start of this research:

Production part repair process

Introduction

This document has been set up to describe the repair process of a production part. Each separate activity has been described, including who is responsible and what documentation / system is used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
A	Accountable	The person who has final responsibility and can be held accountable if the product and/or process does not work according to a plan. There is only one person accountable in a process.
C	Consulted	This person is responsible for giving advices concerning either content or process, depending on what is needed.
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. This is one way communication.

Start of the process

The process starts either as soon as a broken production part arrives at MR P&S or when a newly produced part failed the system test.

Store in cabinet “to be repaired”			
Description:	The broken part is stored in the cabinet “to be repaired”. The storage place and the status of the part are registered in *EXACT*.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

Fill in bench test report			
Description:	The bench test report is filled in.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:	Bench test report		

Draw up repair plan			
Description:	The project lead sets up a repair plan. All required components are determined and the stock is checked. If all required components are available, the repair can take place now. If components are missing, the purchase manager is informed	R:	PL
		A:	CEO
		C:	MGR
		I:	PM
Documentation:			

Purchasing process			
Description:	Depending on the previous step, all required components are ordered according to the purchasing process.	R:	PM
		A:	CEO
		C:	PL
		I:	MGR
Documentation:	HOL_PUR_PRO_Purchasing		

Repair broken part			
Description:	The RF Engineer repairs the broken part and fills in the bench test report.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

Execute product test			
Description:	The product functionality is tested by the RF Engineer. If the part passes the test without any problems, it is stored in the cabinet “ready for system test”. If it doesn’t pass, a new repair plan has to be drawn up by the project lead.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

Store in cabinet "ready for system test"			
Description:	The repaired part is stored in the cabinet "ready for system test". The storage place and the status of the part are registered in *EXACT*.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

Execute system test			
Description:	The system test is executed to check whether the part works in its environmental conditions. If the part passes the test without any problems, it stored in the warehouse. If it doesn't pass, a new repair plan has to be drawn up by the project lead. The RF Engineer fills in the bench test report.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:	System test report		

Store part in warehouse			
Description:	The repaired part is stored in the warehouse. The storage place is registered in EXACT. The invoice for working hours and overhead costs is prepared now, which takes place in the debtor management process. The "production part repair process" ends here.	R:	RFE
		A:	CEO
		C:	PL
		I:	CEO
Documentation:	HOL_LOG_POL_Storaging HOL_FIN_PRR_Debtor management		

9. Identify - Current outbound process RACI

This appendix displays the outbound process which was set up by the organisation before the start of this research:

Outbound logistics

Introduction

This document has been set up to describe the outbound logistics process of MR P&S. Each separate activity has been described, including who is responsible and what documentation / systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who has final responsibility and can be held accountable if the product and/or process does not work according to a plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person is responsible for giving advices concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. This is one way communication.
	(NL: geïnformeerd)	

Start of the process

The process starts whenever outbound logistics are needed.

Contact logistics			
Description:	The project lead gives the logistics assistant the order to ship the product and forwards all required information.	R:	PL
		A:	PL
		C:	Logistics
		I:	Logistics
Documentation:			

Setup transport of product			
Description:	The Logistics assistant prepares the paperwork. The Transportation checklist has to be considered. Detailed information can be found in the “Policy transportation”.	R:	Transp. Company
		A:	Transp. Company
		C:	
		I:	PL
Documentation:	Transportation checklist, Policy transportation		

Prepare package			
Description:	Logistics assistant packs the product appropriately and ensures that its ready for dispatch. Detailed information can be found in the “Packing instruction”. The Packing slip is added according to the “Policy transportation”.	R:	Logistics
		A:	Logistics
		C:	
		I:	
Documentation:	Packing instruction, Packing slip		

Send product			
Description:	The Logistic assistant sends the product to customer.	R:	Logistics
		A:	Logistics
		C:	
		I:	PL
Documentation:			

Update logistics database			
Description:	The logistics assistant records: - Date of shipment - Article number - Name customer	R:	Logistics
		A:	Logistics
		C:	
		I:	PL
Documentation:			

Contact project lead			
Description:	The logistics assistant contacts the project lead that the product is sent. The outbound logistics process ends here.	R:	Logistics
		A:	Logistics
		C:	
		I:	PL
Documentation:			

10. Identify - Current packaging policy

This following packaging guidelines are applied at MR P&S:

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.

11. Identify - Current purchasing policy

This appendix displays the purchasing policy which was set up by the organisation before the start of this research:

Policy: Purchasing

Purpose of this document:

This document has been set up to describe the purchasing policy of MR Production & Service. This document contains information about the rules and regulations concerning the purchasing process.

Responsibilities:

- The **purchase manager** is responsible for purchasing products and/or components, according to this policy. The purchase manager is also responsible for giving guidance to the purchase assistants and executing the supplier evaluation at least once a year.
- The **purchase assistant** is responsible for assisting the purchase manager.
- The **logistics manager** is responsible for checking the incoming products and/or components.
- The **quality manager** is responsible for updating this policy when needed.
- The **CEO** is accountable for the compliance of this policy.

Purchasing process

MR Production & Service´s purchasing process can be found in external documents (see "PAS_PUR_PRO_Purchasing" and "PAS_QMG_PRO_Purchasing process overview"). The suppliers are selected by stated criteria:

- Price
- Delivery time
- Relationship with supplier

Based on these criteria, either the supplier relation is maintained, or a new supplier is contacted. Quality isn't criteria because MR Production & Service demands a stated quality. To make sure that suppliers maintain the demanded level of quality, MR Production & Service sends the supplier assessment form (see "PAS_PUR_FOR_Supplier assessment") for new suppliers. This form can be used as a tool to evaluate, whether the supplier serves the needs of the company.

In addition, MR Production & Service does the supplier evaluation at least once a year. Records of supplier evaluations are held. The supplier evaluation policy includes all the information related to the procedure (see "PAS_PUR_PRC_Supplier evaluation").

Purchasing information

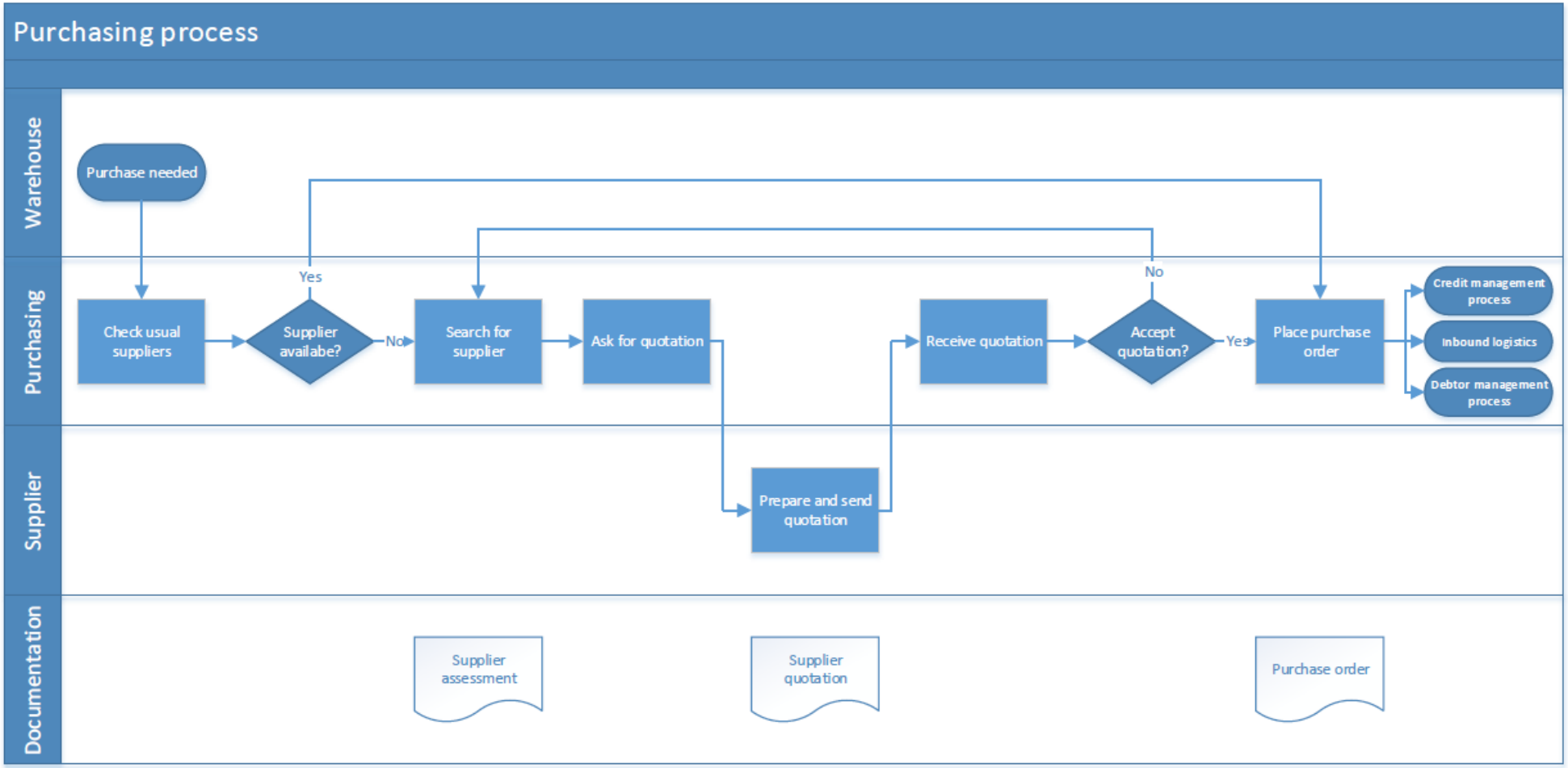
Records of purchasing information can be found in the database of EXACT, ERP-system.

Verification of purchased product

The logistics manager is responsible for the process inbound logistics, and for the verification of the purchased product. After the product/components has been received the logistics manager checks that the item number, product description and the quantity in packing slip corresponds with the purchase order. The logistics manager counts randomly whether the actual quantity of products and/or components is the same as in packing slip. Other test procedures or inspections are not necessary, since MR Production & Service orders mainly products and components which are known and qualified in advance.

12. Identify - Current Purchasing Process

At the starting date of this research there was no RACI available concerning the purchasing process. The following flowchart represents the purchasing process as was documented:



13. Identify - Current supplier assessment form

This appendix displays the supplier assessment form which was set up, but not used by the organisation before the start of this research:

Supplier assessment form

MR Production and Service strives to work with suppliers, that support the needs of the company.

For this we ask you, as a supplier to fill in this self-assessment form, which will take a few minutes. The answers will be used to further improve the collaboration with our suppliers. It's also part of our MR Production and service quality management system, which is setup according to ISO 13485 and ISO 9001 guidelines.

Please respond to the question presented below.

Name of the person filling this form	
Title of the person filling this form	
Date	
Name of the company	
Address of the company	
Telephone number	
E-mail	
Website	
Name of Chief Executive	
Name of Sales Representative	
Name of Quality Manager	
Number of employees in total	
Do you have any certificates? If yes, please attach a copy! If no, please answer to questions below!	
NOTE: answer to following question, if you don't have any certificates!	
Would you allow us or a third party to inspect your facilities?	☐ **YES** ☐ **NO**
Has any other company or third party audited you?	☐ **YES** ☐ **NO**
Would you provide us a copy of third party audit report?	☐ **YES** ☐ **NO**
Do you have any plans to get certified?	☐ **YES** ☐ **NO**
If yes, when is your first inspection expected?	
Does your company have Quality Manual? If yes, please attach it!	☐ **YES** ☐ **NO**
Do you carry out self-inspections of your facilities and systems?	☐ **YES** ☐ **NO**
If yes, how often?	

If yes, how do you monitor effectiveness and closure of corrective actions?	
How is the senior management kept aware of the quality improvement program?	
How are your suppliers approved, and by whom?	
Do you maintain a list of certified, and acceptable supplier categorized accordingly?	☐ **YES** ☐ **NO**
Does your system allow you to use products of unapproved suppliers?	☐ **YES** ☐ **NO**
Do you purchase against agreed specifications only?	☐ **YES** ☐ **NO**
Are storage conditions monitored/controlled in warehouse?	☐ **YES** ☐ **NO**
What checks are carried out on incoming materials?	
Do you have a status labelling system?	☐ **YES** ☐ **NO**
What system do you use to maintain the traceability of materials?	
How are rejected materials separated?	
Do you have a formal system for reviewing and updating specifications and manufacturing instructions?	☐ **YES** ☐ **NO**
Do you have a change control system?	☐ **YES** ☐ **NO**
Are you willing to sign a change control agreement?	☐ **YES** ☐ **NO**
Do you have a deviation management system?	☐ **YES** ☐ **NO**
When and how do you inform your customers about deviations?	
Do you have QA compliant training system?	☐ **YES** ☐ **NO**
Do you have a formal complaint procedure?	☐ **YES** ☐ **NO**
Do you report findings of the complaints to customers?	☐ **YES** ☐ **NO**
Do you have a recall policy?	☐ **YES** ☐ **NO**
Is your QM department independent from production?	☐ **YES** ☐ **NO**
Do you maintain a calibration schedule for your machines and equipment?	☐ **YES** ☐ **NO**
Do you have written instructions for the tests performed?	☐ **YES** ☐ **NO**

14. Identify - Current supplier evaluation procedure

This appendix displays the supplier evaluation procedure which was set up, but not used by the organisation before the start of this research:

Procedure: Supplier evaluation

Purpose of the document:

This document has been set up to describe, how suppliers are evaluated in MR Production & Service. It includes information about the methods and the tools, that are used in the supplier evaluation.

Responsibilities:

- The **purchasing manager** is responsible for carrying out the supplier evaluation at least once a year. It is also purchasing manager's responsibility to gather and review information about the suppliers. And, to use the methods and tools mentioned in this policy. The purchase manager also has to inform the QM about the possible changes, which might affect to this policy.
- The **CEO** is accountable for the compliance of the supplier evaluation.
- The **QM** is responsible for updating this policy.

Steps of the supplier evaluation:

1. Define suppliers

Every supplier of MR Production & Service is not evaluated. The first step of the supplier evaluation is to define, which suppliers are considered in the evaluation. These suppliers are usually the suppliers, whose revenue is highest and are used the most. The revenues of each supplier can be found in EXACT database.

2. Evaluate suppliers

After defining the suppliers, that are evaluated, the purchase manager executes the supplier evaluation. The performance indicators, that are used to evaluate the suppliers are:

a) pricing,
b) delivery time,
c) reliability,
d) quality,
e) communication,
f) agreements, and
g) environment.

In order to measure these indicators, the purchase manager reviews the performance of the suppliers among the daily tasks. In addition, the document "PAS_PUR_REC_Purchase rating" can be used as a tool to evaluate the inputs like: delivery time, reliability, and agreements. The document "PAS_PUR_REC_Purchase rating" is filled with the help of the purchasing information, which can be found in EXACT database.

When, the purchase manager has gathered enough information about the suppliers, the suppliers are evaluated according to the above-mentioned performance indicators. These indicators are rated from 1 to 5, and registered in document "PAS_PUR_REC_Supplier rating". After the overall rating is done, the purchase manager defines, whether the supplier is approved or not. There are no guidelines, for approving the suppliers, since it's noted that some supplier must be used even though they are performing poorly. However, the follow-up actions are defined for each supplier, in order to improve the relationship with the supplier.

15. Identify - Current supplier evaluation form

This appendix displays the supplier evaluation form which was set up, but not used by the organisation before the start of this research:

Cred.N	Name	Revenue 201	Supplier type	Pricing	Delivery time	Reliability	Quality / ISO	Communication	Agreements	Enviroment	Overall Rate	Approved ?	Follow-up Action	Self-assessment	ISO (9001:2015)	K/Download	Enviroment (ISO 14001:2004) / Safe	K/Download	Safety / Corporate Social Responsibility	K/Download	Legenda 1 = Poor 2 = Inadequate 3 = Adequate / needs attention 4 = Good 5 = Excelle
1111111	Name		General	5	5	5	5	5	5	5	5					D		D		L	
				3	3	3	3	3	3	3	3										
				1	1	1	1	1	1	1	1										
											0										

16. Identify - ISO requirements checklist

The following tables shows the requirements of ISO 13485 concerning traceability (A) and purchasing (B). It reveals if these are reached in the current and desired situation, and shows if there is a gap:

A. Traceability

Requirements	Current situation	Desired situation	GAP
7.5.9.1 General			
Procedures to trace products/materials in accordance with applicable regulatory requirements		X	X
Define the extend of traceability	-	X	X
Records to trace all incoming and outgoing products/materials	-	X	X
Maintain all records concerning traceability		X	X
Implement all measures documented to ensure traceability		X	X
7.5.9.2 Particular requirements for implantable medical devices			
Records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.			
Require suppliers of distribution services to have distribution records			
Records of the name and address of the shipping package consignee			
7.5.10 Customer property			
Identify customer property under control of the organisation	-	X	X
Verify customer property under control of the organisation	X	X	
Protect customer property under control of the organisation	-	X	X
Safeguard customer property under control of the organisation	-	X	X
Records of customer property that is lost, damaged, or unsuitable		X	X
Report lost, damaged, or unsuitable customer property to customers		X	X
7.5.11 Preservation of product			
Procedures to preserve the conformity of products during processing, storage, handling, and distribution	X	X	
Prevent medical device damage, alteration, and contamination	X	X	
Design and construct suitable packaging and shipping containers	X	X	
Document requirements for special conditions needed if packaging alone cannot provide preservation	?	X	?
Protect products when exposed to hazards and expected conditions	X	X	

B. Purchasing

Requirements	Current situation	Desired situation	GAP
7.4.1 Purchasing Process			
Procedures to control purchased products conforms to purchasing information (7.4.2)	-	X	X
Supplier evaluation and selection criteria are based on: • the supplier's ability to provide products that meet the organisation's requirements • the performance of the supplier • the effect of the purchased product on the quality of the medical device		X	X
Supplier evaluation and selection criteria are proportionate to the risk associated with the medical device.		X	X
Plans to monitor suppliers	-	X	X
Plans to (re-)evaluate suppliers	-	X	X
Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements		X	X
Records of supplier selection		X	X
Records of supplier monitoring	-	X	X
Records of supplier evaluation	-	X	X
Records of necessary follow-up actions arising from these activities.	-	X	X
Maintain all records concerning purchasing		X	X
Implement all measures documented concerning purchasing		X	X
7.4.2 Purchasing information			
Purchasing information shall include, as appropriate: • product specifications • requirements for product acceptance, procedures, processes and equipment • requirements for qualification of supplier personnel • quality management system requirements	-	X	X
Review purchasing requirements prior to their communication to the supplier		X	X
Agreement that suppliers agree to notify the manufacturer of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements		X	X
Document relevant purchasing information related to traceability (see 7.5.9)		X	X
7.4.3 Verification of purchased product			
Verification activities to ensure that purchased products meet the specified purchasing requirements		X	X
The extent verification activities shall be based on the supplier evaluation results and proportionate to the risk associated with the purchased product		X	X
Determine whether a product not meeting the specified purchased requirements, affects the product realisation process of the medical device		X	X
State intended verification activities and method of product release in the purchasing information, when the organisation of its customers intends to perform verification at the supplier's premises			
Records of verification of purchased products		X	X
Maintain all records concerning purchasing		X	X
Implement all measures documented concerning purchasing		X	X

Section

II

Design

17. Design/Optimise – Traceability policy

This appendix displays the new traceability policy which is set up by the authors during this research:

Purpose of this document

This document has been set up to describe the traceability policy for MR Production & Service. This document contains information about the rules and regulations concerning traceability.

Responsibilities

- The **purchase manager** is responsible to record all purchased products.
- The **logistics manager** is responsible for monitoring all incoming and outgoing products.
- The **engineers** are responsible to record all materials used.
- The **quality manager** is responsible for reviewing the traceability process.
- The **CEO** accountable for the compliance of this policy.

Why traceability

- To create insight of the location of products.
- To reduce the amount of recalls when a defect is detected.
- To reduce the affected costs of recalls.
- To show customers their safety is a priority.

Scope

MR Production & Service is able to trace all products from supplier to customer as shown in figure 1:

Figure 2: Scope traceability

This scope ensures:

- Failing components can be allocated to a specific batch.
- MR Production & Service can trace which batches are used in every FRU.
- Specific FRUs can be recalled.
- MR Production & Service can check if a problem with a specific FRU occurred before.

Measures

Measures to ensure the scope of traceability are included in several processes of the organisation as is shown in figure 2 and explained in table 1:

Figure 2: Traceability measures

Table 1:

Nr	Process	Step in process	Action	Documentation
1.	Purchasing	Purchase component	Supplier information is recorded to ensure the supplier of every purchased product is traceable.	HOL_QMG_PRR_Purchasing process overview
2.	Inbound	Label component	All incoming components are assigned and labelled with a batch code.	HOL_LOG_PRR_Inbound logistics
3.	Inbound	Store component	Components are stored at an allocated location. This is registered to ensure all components can be traced within the organisation.	PAS_LOG_POL_Storage
4.	Production and Repair	Produce or repair FRU	Every FRU is labelled with an article and serial code. The combination ensures every FRU has a unique code.	PAS_QMG_PRR_R&R_04_Production part repair
4.	Production and Repair	Produce or repair FRU	All used components to repair or produce an FRU are recorded, including their batch numbers and the article and serial number of the produced or repaired FRU.	PAS_QMG_PRR_R&R_04_Production part repair PAS_SER_REG_Repair form
5.	Production and Repair	Store FRU	FRU is stored at an allocated location in the warehouse. This is registered to ensure all components can be traced within the organisation.	PAS_QMG_PRR_R&R_04_Production part repair PAS_LOG_POL_Storage
6.	Outbound	Send FRU to customer	When an FRU is sent, customer information is recorded including serial and article number of FRU. This number is linked to the records made in the purchasing, inbound a production and repair process.	HOL_LOG_PRR_Outbound logistics

18. Design/Optimise – Storage policy

This appendix displays the new storage policy which is set up by the authors during this research:

Policy: Storage

Purpose of this document

This document has been set up to describe the storage policy of MR Production & Service. This document contains information about the rules and regulations concerning the storage of products.

Responsibilities

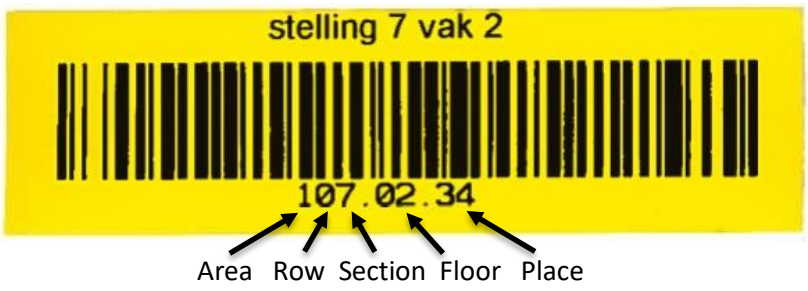
- The **logistic manager** is responsible for the inventory control. The logistic manager is responsible for executing storage management, and customer property and product preservation.
- The **RF engineers** are responsible for supporting the inventory control.
- The **general manager** is responsible to control the accuracy of the stock levels.
- The **quality manager** is responsible for reviewing the storage policy.
- The **CEO** is accountable for the compliance of this policy.

Storage conditions:

In order to slow down the aging process of the products and components in inventory, MR Production & Service has defined requirements for the conditions of storage. Since MR P&S has property of customers under its supervision, these requirements will ensure all customer properties are safeguarded. The storage conditions of production space shall correspond to the **conditions of overall working environment (PAS_PRO_POL_Control of work environment).** For other storage spaces, there are no requirements. Although, it is desirable to avoid moisture and contamination in the storage places. Safety measures are also taken during the shipment of products. This is documented in the **Outbound Logistics (HOL_LOG_PRR_Outbound logistics)**.

Storage management

MR Production & Service maintains an effective storing system. The storing system defines specific storage places for every component and FRU in inventory, which ensures employees are able to find components and FRUs quickly. Every storage place has its own barcode (see picture below). The barcode gives, when scanned, information about the component/FRU and its storage place.



The first numbers in the barcode indicates the storage area, and the row, in which the component belongs to. The second numbers tell the section. And the last numbers specify the floor and the place of the component in it. If the floor is 0, the component is stored on the ground.

Inventory control

Control of component inventory

To control the components inventory, MR Production & Service uses a two-bin Kanban system. The two-bin Kanban is a system to control the stock value. MR Production & Service uses two bins for components in the warehouse as explained in the **Kanban procedure (PAS_PUR_PRC_Kanban)**. Every bin is registered with related product information for traceability purpose. This is documented in the **Inbound Logistics process (HOL_LOG_PRR_Inbound logistics).**

Control of end products under repair

MR Production & Service stores products based on their repair status. The repair status of the products is either: waiting for repair, ready for system test, or repaired and tested. All the products are stored in cabinets according to this. In the cabinet, it is marked, which kind of products are stored in it.

Control of end product inventory

The amount of end products stored is registered. Every end product is related to a level of safety stock. When the stock of end products reaches below safety stock, the logistic manager informs the purchase manager to start the **purchasing process (HOL_QMG_PRO_Purchasing process overview)**. The control of the registry is included in the **cycle count policy (PAS_PRO_POL_Cycle count)**

19. Design – Kanban procedure

This appendix displays the new Kanban process which is set up by the authors during the Design phase of this research. An optimised version of the Kanban procedure is included in appendix 38.

Procedure: Kanban

Purpose of the document:

This document has been set up to describe, the responsibilities of employees to maintain the Kanban system. It includes information about the methods, the tools, and the responsibilities of the employees.

Responsibilities in the Kanban:

Logistic manager

- The logistic manager is responsible to store all components in Kanban units. A reorder card with information of every product is stored with every Kanban unit.
- At a fixed time a day, the logistic manager collects the to-order cards and hands these over to the purchase manager. He records in Exact which batches are out of stock and which new batches are used.
- When new material arrives, the logistic manager places the items in the empty unit which is placed on the re-order shelve by the engineers. The to-order cards are taken from the waiting for arrival bin and stored with the Kanban unit. The unit is placed on its original place, behind or underneath the Kanban unit used.

Engineers

- During production and reparations only components from the first or most accessible Kanban units are used by the engineers.
- When the first unit is empty, it is replaced by the second unit. The reorder card is placed in a to-order bin. The empty unit is stored on the to-order shelve.
- Engineers use the material from the second Kanban unit, while waiting for the receipt of the material in order.

Purchase manager

- When the logistic managers hands over the to-order cards to the purchase manager, the purchase process starts. After re-ordering, the re-order cards are placed in a wait-for-arrival-bin. This ensures all employees can see what products are expected to be delivered.

General manager

- The general manager is accountable to ensure all engineers follow the instructions to maintain the Kanban system.

20. Design/Optimise – Document to safeguard property

This appendix displays the control of work environment policy. The authors of this research included measures to safeguard (customer) property within this policy:

Policy: Control of work environment

Purpose of the document:

This document has been set up to give information about, maintaining safe work environment in production space of MR Production & Service. It includes information about, how to monitor the safety of work environment and avoid electrostatic discharge. Also, needed equipment and clothes are introduced.

Responsibilities

- **Employees in production space** are responsible for daily monitoring and controlling of the work environment conditions. It is also every employee's responsibility to use ESD equipment while working in production space.
- The **general managers** are responsible for ensuring that monitoring and controlling of work environment is done according to this policy. General managers are also responsible for maintaining the security in production space of MR Production & Service.
- The **CEO** is responsible for communicating changes to the rules and verbal / non-verbal support of the current policy. CEO is also responsible to provide needed ESD equipment for employees of MR Production & Service.
- The **quality manager** is responsible for updating this policy.

Work environment requirements

Work environment in production space of MR Production & Service is considered an ESD space. This way, electrostatic discharge in production space can be avoided, which means that breaking of products and components is prevented. The requirement that MR Production & Service has for ESD space, is that equipment and employees of production space is adjusted to same voltage level. This ensures that electrostatic discharge is not created in the production space of MR Production & Service. In other words, every table, chair, cabinet and the floor of production space has same voltage level as the employees working in it. This is assured with help of below-mentioned requirements, and regular control and monitoring of work environment conditions.

Resource requirements

In order to meet the work environment requirements, all employees are given certain resources at the beginning of the **employment "PAS_HRE_POL_Training of employees".** These are included in **"PAS_HRE_REC_Resource checklist".** These resources will prevent electrostatic discharge in production space. For visitor in ESD room MR Production & Service has overcoats to wear.

Specific health or cleanliness requirements are not necessary, because MR Production & Service doesn't work with products, which quality could be affected by these.

Training requirements

MR Production & Service assures that its personnel are appropriately trained, to work in above-mentioned work environment conditions. This is ensured by either hiring employees that have certain competences, see **“PAS_HRE_REC_Skills and requirements”**, or arranging trainings for employees, see **“PAS_HRE_POL_Training of employees”.**

Monitoring and controlling

In order to maintain the quality of products, it is important that work environment conditions are monitored and controlled regularly. In MR Production & Service this is done daily with help of ESD Test equipment. It makes sure that the voltage level of person stepping in, is the same like in ESD room. This prevents the formation of electrical discharge. The working instruction for working safely in ESD space are in external document **“PAS_PRO_WOI_Working ESD safe**”.

The conditions of the whole work environment and its equipment, are checked frequently (at least once a year). This is done by a resistance measurement. When executing the resistance measurement every equipment in production space is adapted to same voltage level. The measuring device that is used to do the resistance measurement is Multimeter (see LIST OF MACHINES). The resistance measurement is done by trained RF engineer, with minimum bachelor degree of electrical engineering (see “**PAS_HRE_REC_Skills and requirements”).** The resistance measurements are documented to register **“PAS_QMG_REC_Resistance measurement**”. In the register, the person executing the resistance measurement writes down in the comments:

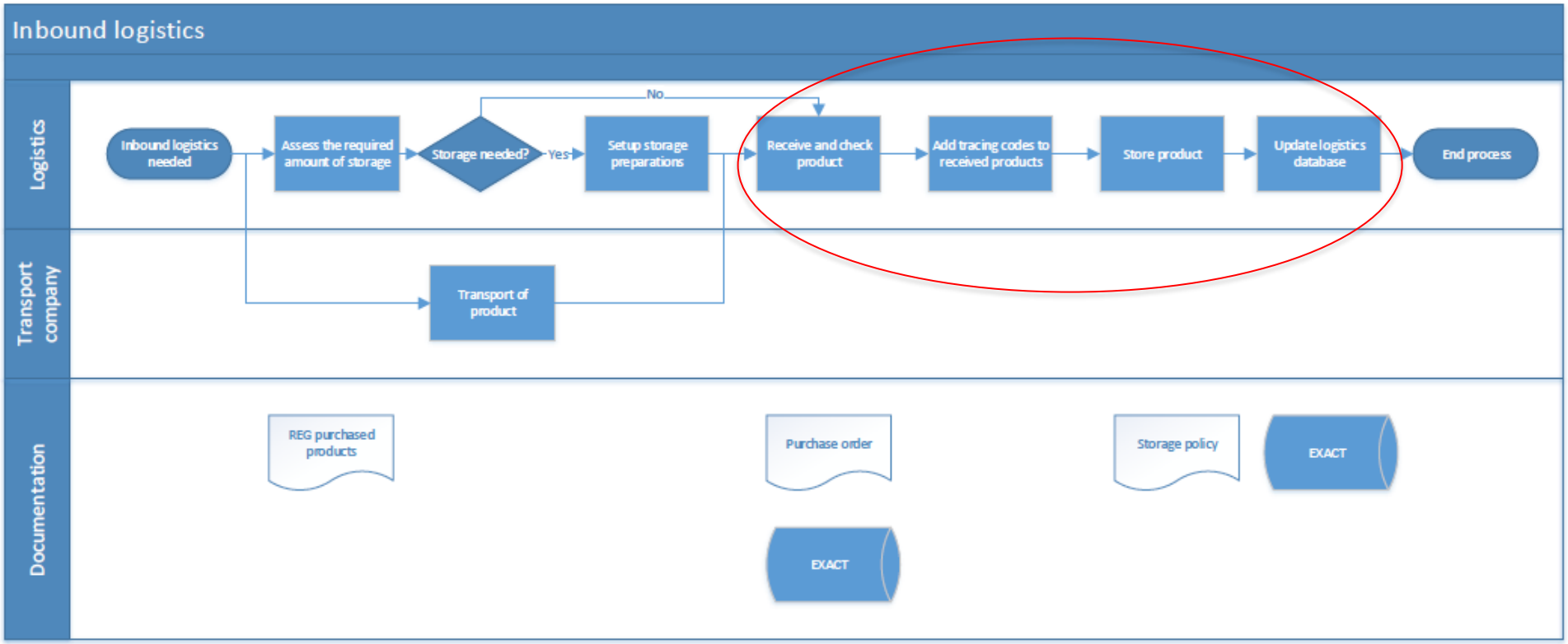
- results of the first measurement,
- if needed, follow-up actions taken (new measurements, adjustments etc.).

After the resistance measurement is executed, and the results of measurements correspond with the work environment requirements, the employee signs registration “**PAS_QMG_REC_Resistance measurement”.**

The general manager is responsible for ensuring that this is done at least once a year. When placing new tables, chairs, or cabinets the resistance measurement is also carried through for the new equipment.

21. Design/Optimise – Inbound process

This following flowchart presents the new recommended inbound process. The steps which are added to ensure traceability are highlighted:



22. Design/Optimise – Inbound process RACI

Since the inbound process was already approved, only steps to ensure traceability are added to the current inbound process. The steps which are added to this process are highlighted in green.

Inbound logistics

Introduction

This document has been set up to describe the inbound logistics process of MR P&S. Each separate activity has been described, including who is responsible and what documentation / systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who has final responsibility and can be held accountable if the product and/or process does not work according to a plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person is responsible for giving advices concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. This is one way communication.
	(NL: geïnformeerd)	

Start of the process

The process starts whenever a product is purchased by MR Production & Service.

Assess the required amount of storage			
Description:	The logistics assistant assesses according to the size of the delivered product whether extra storage is needed or not. If extra storage is needed, storage preparations are set up. If not, the part can be received.	R:	RFE
		A:	PL
		C:	
		I:	PL
Documentation:			

Transport of product			
Description:	Parallel to the assessment of the required storage place and the regarding preparation, the transport company ships the part to MR Production & Service.	R:	Transp. Company
		A:	Transp. Company
		C:	
		I:	
Documentation:			

Receive and check product			
Description:	The logistics assistant receives the delivery and checks it on completeness, accuracy and condition according to the transport documents and the purchase order and updates the database in Exact with this information.	R:	LM
		A:	FOM
		C:	PM
		I:	GM, PL
Documentation:	Purchase order, Monitor form, Database in Exact.		

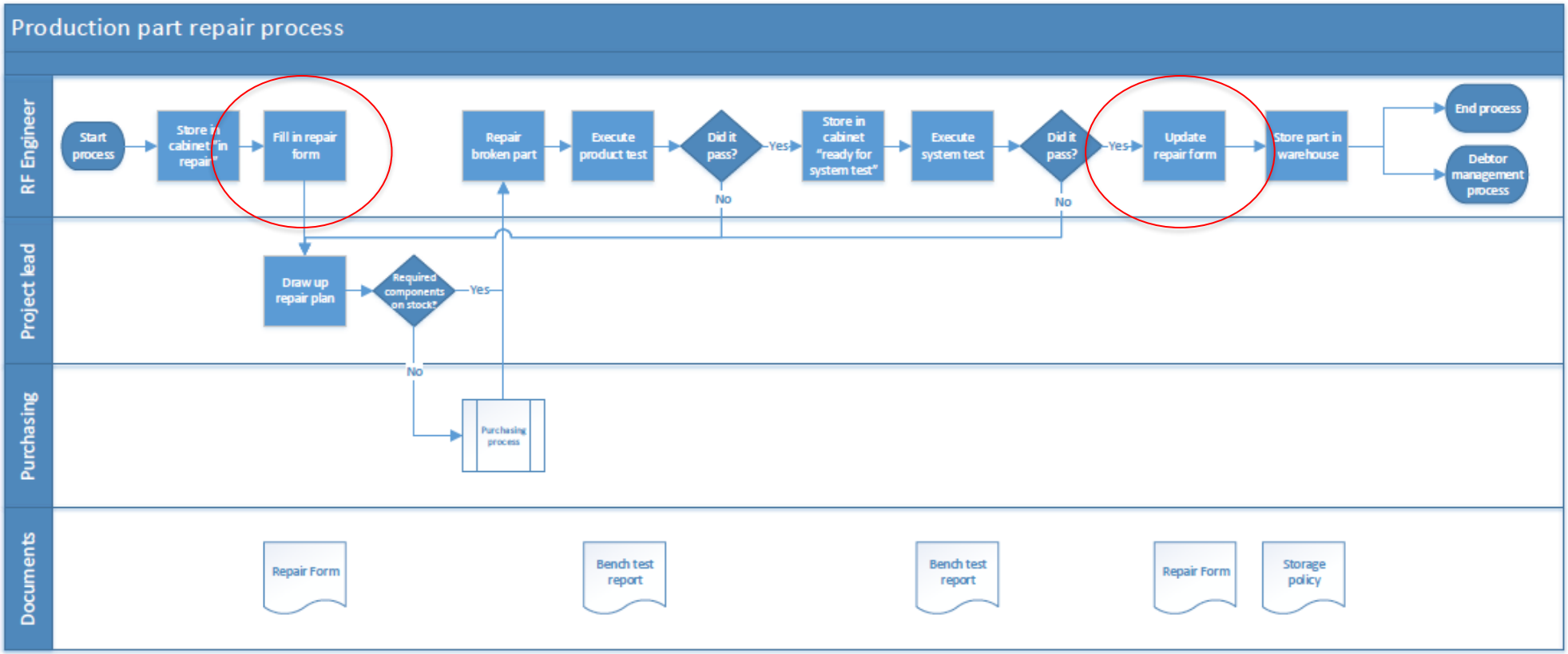
Add tracing codes to received products			
Description:	The logistics assistant provides every batch of components with a unique batch numbers and the FRUs with an article and unique serial number. These numbers are used for traceability purposes.	R:	LM
		A:	FOM
		C:	
		I:	PL
Documentation:			

Store product			
Description:	The delivery is stored at its allocated place as is shown in the storage policy. The function which the delivery relates to is informed. These could be for example the project lead or the purchasing.	R:	LM
		A:	LM
		C:	
		I:	PL, PM, ..
Documentation:	PAS_QMG_POL_Storage		

Update logistics database			
Description:	The logistics assistant updates the logistics database in Exact with the new stock amount and their product, serial and batch numbers. The inbound logistics process ends here.	R:	LM
		A:	FOM
		C:	PM
		I:	
Documentation:	Database in Exact		

23. Design/Optimise - Repair process

This following flowchart presents the new recommended repair process. The steps which are added to ensure traceability are highlighted:



24. Design/Optimise – Repair process RACI

Since the repair process was already approved, only steps to ensure traceability are added to the current repair process. The steps which are added to this process are highlighted in green.

Production part repair process

Introduction

This document has been set up to describe the repair process of a production part. Each separate activity has been described, including who is responsible and what documentation / system is used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
A	Accountable	The person who has final responsibility and can be held accountable if the product and/or process does not work according to a plan. There is only one person accountable in a process.
C	Consulted	This person is responsible for giving advices concerning either content or process, depending on what is needed.
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. This is one way communication.

Start of the process

The process starts either as soon as a broken production part arrives at MR P&S or when a newly produced part failed the system test.

Store in cabinet “to be repaired”			
Description:	The broken part is stored in the cabinet “to be repaired”. The storage place and the status of the part are registered in EXACT.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

Fill in repair form			
Description:	The RF engineer fills in the repair form. This form includes records of the article and serial number of the FRU.	R:	RFE
		A:	GM
		C:	PL
		I:	PL
Documentation:	Repair Form PAS_QMG_FOR_R&R_Reparation registration form		

Draw up repair plan			
Description:	The project lead sets up a repair plan. All required components are determined and the stock is checked. If all required components are available, the repair can take place now. If components are missing, the purchase manager is informed	R:	PL
		A:	CEO
		C:	MGR
		I:	PM
Documentation:			

Purchasing process			
Description:	Depending on the previous step, all required components are ordered according to the purchasing process.	R:	PM
		A:	CEO
		C:	PL
		I:	MGR
Documentation:	HOL_PUR_PRO_Purchasing		

Repair broken part			
Description:	The RF Engineer repairs the broken part and fills in the bench test report.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

Execute product test			
Description:	The product functionality is tested by the RF Engineer. If the part passes the test without any problems, it is stored in the cabinet “ready for system test”. If it does not pass, a new repair plan has to be drawn up by the project lead.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

Store in cabinet "ready for system test"			
Description:	The repaired part is stored in the cabinet "ready for system test". The storage place and the status of the part are registered in *EXACT*.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:			

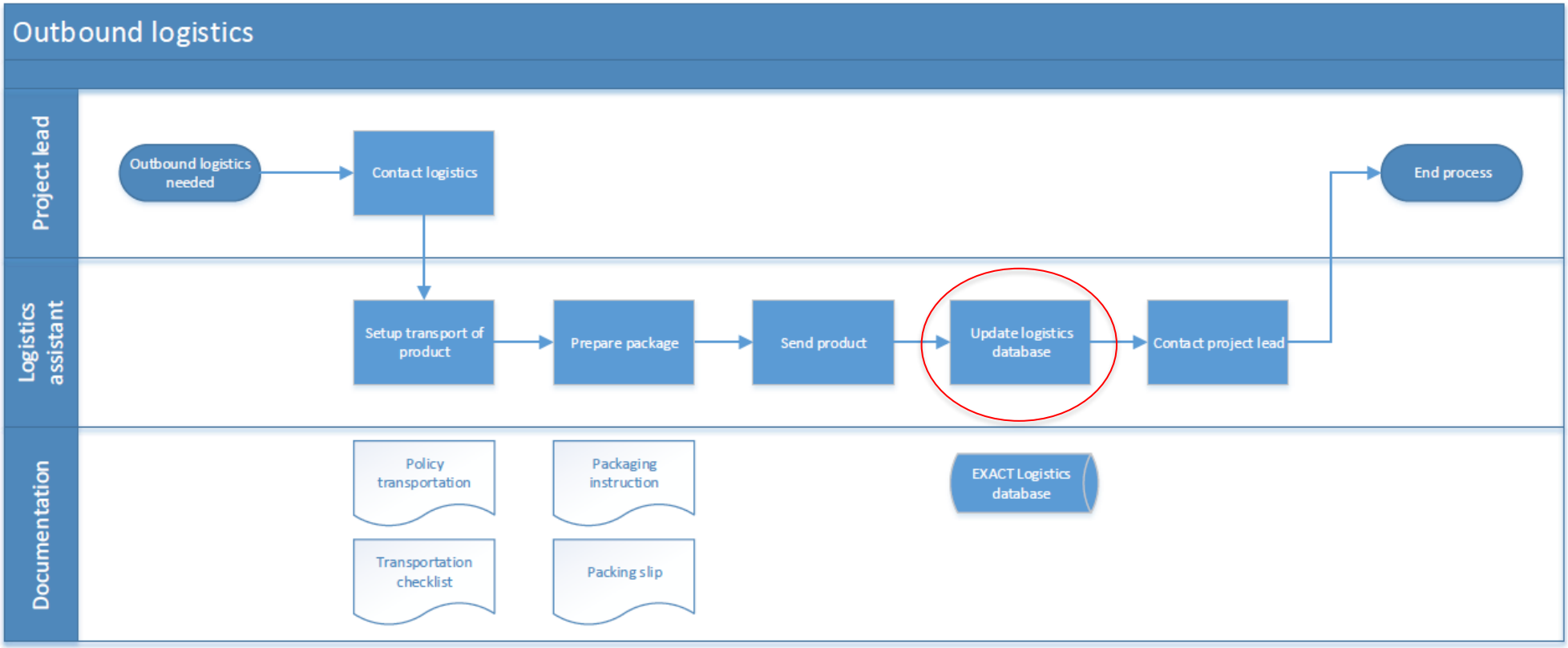
Execute system test			
Description:	The system test is executed to check whether the part works in its environmental conditions. If the part passes the test without any problems, it stored in the warehouse. If it does not pass, a new repair plan has to be drawn up by the project lead. The RF Engineer fills in the bench test report.	R:	RFE
		A:	CEO
		C:	PL
		I:	MGR
Documentation:	System test report		

Update repair form			
Description:	The RF engineer updates the repair form and take measures if needed. This form includes records of the components used and their specific batch numbers.	R:	RFE
		A:	GM
		C:	PL
		I:	PL
Documentation:	Repair Form		

Store part in warehouse			
Description:	The repaired part is stored in the warehouse. The storage place is registered in EXACT. The invoice for working hours and overhead costs is prepared now, which takes place in the debtor management process. The “production part repair process” ends here.	R:	RFE
		A:	CEO
		C:	PL
		I:	CEO
Documentation:	HOL_LOG_POL_Storaging HOL_FIN_PRR_Debtor management		

25. Design/Optimise – Outbound process

This following flowchart presents the new recommended outbound process. The steps which are added to ensure traceability are highlighted:



26. Design/Optimise – Outbound process RACI

Since the outbound process was already approved, only steps to ensure traceability are added to the current outbound process. The steps which are added to this process are highlighted in green.

Outbound logistics

Introduction

This document has been set up to describe the outbound logistics process of MR P&S. Each separate activity has been described, including who is responsible and what documentation / systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who has final responsibility and can be held accountable if the product and/or process does not work according to a plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person is responsible for giving advices concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. This is one way communication.
	(NL: geïnformeerd)	

Start of the process

The process starts whenever outbound logistics are needed.

Contact logistics			
Description:	The project lead gives the logistics assistant the order to ship the product and forwards all required information.	R:	PL
		A:	PL
		C:	LM
		I:	LM
Documentation:			

Setup transport of product			
Description:	The Logistics assistant prepares the paperwork. The Transportation checklist has to be considered. Detailed information can be found in the “Policy transportation”.	R:	Transp. Company
		A:	Transp. Company
		C:	
		I:	PL
Documentation:	Transportation checklist, Policy transportation		

Prepare package			
Description:	Logistics assistant packs the product appropriately and ensures that its ready for dispatch. Detailed information can be found in the “Packing instruction”. The Packing slip is added according to the “Policy transportation”.	R:	LM
		A:	LM
		C:	
		I:	
Documentation:	Packing instruction, Packing slip		

Send product			
Description:	The Logistic assistant sends the product to customer.	R:	LM
		A:	LM
		C:	
		I:	PL
Documentation:			

Update logistics database			
Description:	The logistics assistant updates the logistics database in EXACT with the new amount of stock and the customer information. This is done for traceability purposes.	R:	LM
		A:	FOM
		C:	PL
		I:	PL, PM
Documentation:			

Contact project lead			
Description:	The logistics assistant contacts the project lead that the product is sent. The outbound logistics process ends here.	R:	LM
		A:	LM
		C:	
		I:	PL
Documentation:			

27. Design/Optimise - Purchasing policy

This appendix displays the new purchasing policy which is set up during this research by the authors:

Policy: Purchasing

Purpose of this document

This document has been set up to describe the purchasing policy of MR Holding and each of its subsidiaries. This document contains information about the rules and regulations concerning the purchasing process.

Responsibilities

- The **purchase manager** is responsible for purchasing products and components, according to this policy. The purchase manager is responsible for the supplier selection and supplier evaluation and is also responsible for giving guidance to the purchase assistants.
- The **purchase assistant** is responsible for assisting the purchase manager.
- The **logistic manager** is responsible for monitoring incoming products.
- The **quality manager** is responsible for updating this policy when needed.
- The **CEO** is accountable for the compliance of this policy.

Purchasing goal

- If applicable, select suppliers which meet supplier requirements as stated in the **purchase terms and conditions (HOL_QMG_PRO_Terms and Conditions)**.
- Purchase material and services which comply to the quality standards of MR Holding by defining product specifications.
- Treat all suppliers fairly and ethically.
- Support and encourage suppliers to improve their performance on quality, delivery, cost, and service.
- The overall purchasing process can be found in **Purchasing process overview (HOL_QMG_PRO_Purchasing process overview)**.

Authorization

Authorisation information is documented in the **Autorisation form (HOL_QMG_PRO_Autorisation Form)**. This documentation creates clarity amongst separation of authorities and improves efficiency within the purchasing process. The separation of functions spread risks and protects from financial difficulties.

Selecting a vendor

A list of preferred suppliers for each type of goods and services based on past performance and prerequisites of customers shall be maintained. The purchaser is strongly encouraged to order at these preferred suppliers to keep the list of suppliers to a minimum. Suppliers shall be selected on: quality, price, delivery time and service.

Evaluate vendors

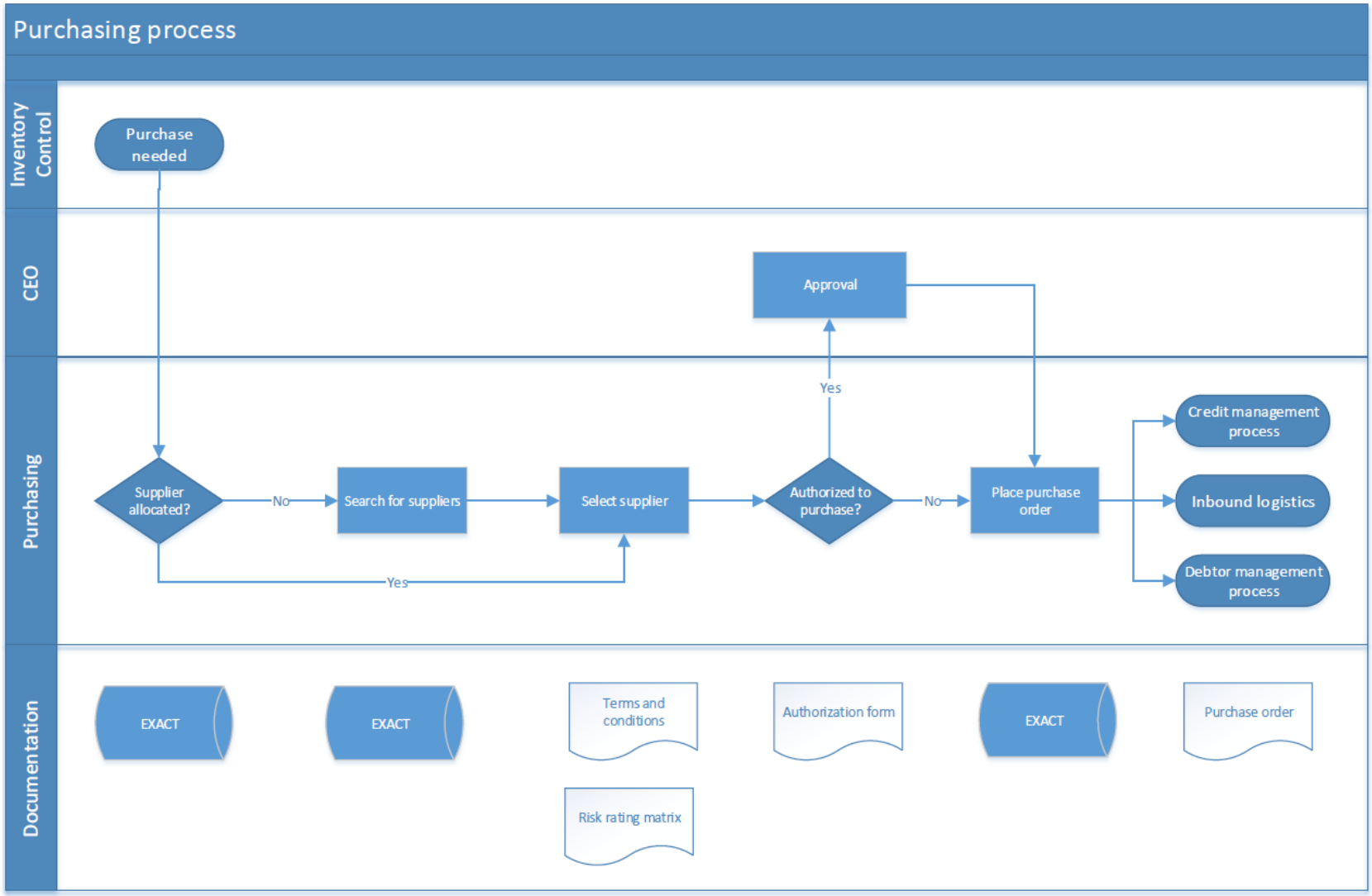
MR Holding evaluates suppliers to guarantee product quality and continuous improvement. The evaluation process of MR Holding is represented in the **Supplier Evaluation Process (HOL_QMG_PRO_Supplier Evaluation process)**. The questions in the vendor rating system are based on the supplier's performance to meet the company's strategy.

Verification of purchased product

To ensure that purchased products meets specified purchasing requirements, an inspection of incoming purchases is done as is recorded in the **inbound process (HOL_LOG_PRR_Inbound logistics).**

28. Design/Optimise – Purchasing process

The following flowchart presents the new recommended purchasing process, which is created by the authors during this research:



29. Design – Purchasing process RACI

This appendix displays the new purchasing process which is set up by the authors during the Design phase of this research. An optimised version of the purchasing process RACI is included in appendix 39.

Process: Purchasing

Introduction

This document has been set up to describe the purchasing process within MR Holding and each of its subsidiaries. Each separate activity has been described, including who is responsible and what documentation / systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who is in the end responsible and can be held accountable if the product does not work according to plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person gets involved for advice concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. One way communication.
	(NL: geïnformeerd)	

Start of the process

This process starts when there is a need for a purchase order. This need can be caused by the following triggers: when the inventory is underneath safety stock level, or when an article, not on inventory, should be purchased.

Supplier allocated?			
Description:	The purchase manager checks the database to see whether there is a supplier is allocated by an external partner or if the product is purchased before. YES -Proceed to step: select supplier. NO - Proceed to step: start searching for a new supplier.	R A C I	PM FOM Database
Documentation:	Exact		

Search for suppliers			
Description:	The purchase manager checks if the product can be purchased at a preferred supplier. If this is possible, the supplier will be selected. If the product cannot be purchased at a preferred supplier, the purchase manager searches for new suppliers who meet the product requirements.	R A C I	PM FOM Database PL
Documentation:	Exact		

Select supplier			
Description:	When only one supplier is allocated or found, it will be selected. When more than one supplier is allocated or found, the purchase manager selects a supplier in negotiation with the general manager based on the following criteria: Quality, Cost, Service, Delivery. When selecting a new supplier, the purchase manager identifies the risk rating and registers this in Exact. Selecting a supplier also means the sending of Purchase terms and conditions, Supplier assessment form and a Non-disclosure agreement, when necessary. The purchase manager keeps records of this selection process.	R A C I	PM FOM MGR PL
Documentation:	HOL_QMG_PRO_Terms and Conditions HOL_QMG_PRO_Supplier assessment form HOL_QMG_PRO_Non-disclosure agreement HOL_QMG_PRO_Risk rating matrix		

Authorized to purchase?			
	When a supplier is selected, the purchase manager checks in the authorization form whether he is authorized to place the order. YES - Proceed to step: place purchase order. No: - Proceed to step: Approval Note: When the purchase is executed for an external partner, approval by the external party must be given before proceeding the purchasing process.	R	PM
		A	CEO
		C	FOM
		I	PL
Documentation:	HOL_QMG_PRO_Autorisation Form		

Approval			
Description:	The CEO needs to give approval before a purchase order can be placed.	R	PM
		A	FOM
		C	CEO
		I	PL
Documentation:			

Place purchase order			
Description:	The purchase manager places the order in Exact. The purchasing process ends here.	R	PM
		A	FOM
		C	
		I	PL, LM
Documentation:	Exact		

30. Design/Optimise – Supplier Selection tool

This appendix displays the new supplier selection tool which is set up during this research by the authors:

Supplier selection tool

	Supplier 1		Supplier 2		Supplier 3	
Delivery	Answer	Score:	Answer	Score:	Answer	Score:
Is the supplier able to send the order within a desired timescale?						
Is the desired quantity available?						
Is there a minimum order quantity?						
Cost	Answer	Score:	Answer	Score:	Answer	Score:
Does the supplier apply reasonable prices?						
Quality	Answer	Score:	Answer	Score:	Answer	Score:
Does the supplier use a reasonable guarantee period?						
Is the supplier taking his responsability towards the environment?						
Is the supplier using a proper quality management system?						
Service	Answer	Score:	Answer	Score:	Answer	Score:
Is there a helpdesk available?						
Is the website easy in usage?						
Does the supplier use reasonable payment deadlines?						
Do products come with a track and trace code?						
Is the supplier able to do emergency deliveries?						
Total						

31. Design – Purchasing Terms and Conditions

This appendix displays the new purchasing terms and conditions which are designed by the authors during the Design phase of this research. An optimised version of the purchasing terms and conditions is included in appendix 40.

Purchase Terms and Conditions

Article 1. Definitions

The following terms shall have the indicated definitions:

- *Buyer(client):* the entity issuing the order
- *Seller(supplier):*the person, firm or company to whom the order is addressed.
- *Agreement*: the negotiated and legally enforceable understanding between the seller and buyer.
- *Delivery:* the manner of delivering the materials from seller to buyer under the order.
- *Order:* the purchase order issued by buyer for the use of materials, which may be an oral communication or a written or electronic document, and may also include particular shipping instructions and/or other specifications required by the buyer for the materials.
- *Materials:* all the products and/or services to be supplied by seller under the order.
- *Parties:* The buyer and the seller, and possible third parties.

Article 2. Relevance

a. In case of conflict, agreed specific commitments prevail these terms and conditions.
b. These purchasing terms and conditions apply to all requests, offers and commands relating to the delivery of materials by the seller to the buyer, rejecting the terms and conditions of the seller.

Article 3. Alterations

a. At all times, the buyer is authorized to alter the quantity and/or quality of the order in consultation with the seller. These alterations are to be agreed on in writing.
b. If, in the opinion of the seller, an alteration will have consequences for the agreed fixed price and/or the delivery date of the ordered materials, he is obligated to inform the buyer as soon as possible, at least within 8 working days after the notification of the desired alterations to the order, before accepting the alterations.

Article 4. Transfer of liabilities

a. It is only possible for the seller to assign liabilities regarding the agreement to a third party if this has been approved of on paper in advance. Reasonable conditions can be attached to this permission.
b. In cases of transfer of (a portion of) the obligations under the agreement of the seller to a third party, seller is obliged to inform buyer of the securities that have been established for the payment of VAT, income tax and social contributions which are prescribed for employers.

Article 5. Prices and price review

a. The prices in the agreement do not include VAT, and include all costs in connection with the fulfilling of the sellers obligations.
b. The prices are fixed, unless the agreement states the circumstances that lead to an adjustment in price, as well as determining the manner in which the adjustment takes place.

Article 6. Invoicing and payment

a. Payment of the invoice, including VAT, should take place within 90 (nighty) days after receiving the invoice and the approval of the materials and any possible installation/editing needed by the buyer.
b. The buyer is entitled to suspend payment if he should notice any shortcomings within the order of the materials and any possible installation/editing needed.
c. The buyer has the right to reduce the price of the invoice with amounts indebted by the seller.
d. It is not possible for the buyer to waive the rights of payment.

Article 7. Delivery date

a. The agreed date of delivery is essential. In case of a late delivery the seller is in default, without further notice.
b. In case of an imminent delivery failure, seller should immediately inform buyer in writing. This is without prejudice to any consequences as a result to the encroachment under the agreement or statutory provisions.

Article 8. Delivery

a. The delivery shall take place at the agreed address and at the agreed date and time, according to current valid Incoterm DDP (Delivered Duty Paid).
b. Buyer has the right to postpone the delivery. In this case the seller should pack the materials appropriately, store them separately, securely and properly, and clearly label and identify the delivery) and identifiably and separately store them, conserved securely and properly.

Article 9. Shortcomings/breach of contract

a. In case of an accountable shortcomings of the seller, he is in default without further notice.
b. Notwithstanding the right to compensation and other statutory rights arising from a breach of contract, the buyer is entitled to claim a fine up to 20 % per day from the day of the default, with a maximum of 100 % of the amount to be paid by the buyer.
c. The statutory interest on amounts that the buyer has paid in advance will be deducted from invoices to be paid over the period of the default.
d. In case of non-attributable shortcomings the obligations of both parties will be postponed for a period up to 10 (ten) weeks.
e. Parties may only appeal towards each other on non-attributable shortcomings if the party concerned notifies the other party of these actions on paper. However, this must be done as soon as possible, within 5 (five) days after the non-attributable shortcomings are made clear, and submission of the necessary evidence.
f. If the seller states that one or more of his shortcomings are not attributable to him and the buyer accepts this argument, the buyer has the right to terminate the order agreement. In such situations the parties will not charge each other.

Article 10. Warranty

a. Seller guarantees that the materials and any possible installation/editing thereof meet the expectations of what has been previously agreed.
b. Seller guarantees that the goods are fully complete and ready for use. He ensures that all parts including auxiliary materials, accessories/attachments, equipment, spare parts and instruction manuals, which are necessary for realizing the written purpose of the buyer, are supplied, even if these have not been specifically named.
c. Seller guarantees that the delivery complies with all relevant legal provisions regarding quality, environment, safety and health.

d. If the buyer finds that the delivery does not (fully or partially) meet with what the seller has guaranteed in accordance with paragraphs *a. to c. Inclusive* of this article, the seller is in default, unless the latter can prove the defects cannot be attributed to him.

Article 11. Intellectual and industrial property rights

a. The seller guarantees the free and undisturbed use by the buyer of the delivered materials. He indemnifies the buyer against the financial consequences of third party claims due to infringement of their intellectual and industrial property rights.
b. The seller is entitled to use the information which has been provided by the buyer, but only in connection with the contract. This information is and remains the property of the buyer.

Article 12. Documentation

a. The seller is obliged to provide the corresponding documentation to the buyer prior to or simultaneously with the delivery of the materials.
b. The buyer is free to use this documentation, including reproducing it for personal use.

Article 13. Liability

a. The seller is liable for all damages that may arise in connection with the fulfilling of the obligations under the agreement.
b. The seller indemnifies the buyer against all financial consequences of claims of third parties in any connection with the fulfillment of his obligations under the agreement.
c. Buyer has the right to request seller to take out insurance, to cover the risks. Upon this request the seller is required to grant the buyer permission to inspect the relevant policy.

Article 14. Transfer of risk and ownership

a. The ownership of the materials passes to the buyer after they have been delivered and assembled, and, if necessary installed.
b. If the buyer provides the seller with materials made available for the benefit of the fulfillment of the obligations under the agreement, such as auxiliary materials, equipment, drawings, specifications and software, these remain the property of the buyer. Seller shall keep these separate from objects belonging to himself or to others, and shall mark them as property of the buyer.
c. The moment the materials, including raw materials, auxiliary materials and software have been processed into materials of the seller, the materials are henceforth referred to as property of the buyer. This is without prejudice to *article 14d*.
d. The risks surrounding the materials pass to the buyer the moment the delivery and subsequent approval of the materials have occurred in accordance with *article 16* of these purchasing terms and conditions.

Article 15. Secrecy and prohibition of disclosure

a. Supplier shall keep the existence, the nature and content of the agreement and any other business information, and anything related from being made public without the written consent of the client.
b. If buyer considers necessary, supplier shall sign a Non-Disclosure Agreement.
c. In case of violation of the provisions in this paragraph of the Non-Disclosure Agreement, the buyer will impose a penalty up to €200.000 for each violation. The amount of the fine is paid directly by the seller after the aforementioned determination and communication to the seller.

Article 16. Inspection

a. At all times buyer has the right to examine the materials, during production, processing and storage, as well as after the delivery.
b. At first request the seller will provide access to the principal or his representative to the place of production, processing of storage. Seller shall lend its cooperation to the inspection.
c. If an inspection as referred to in this article cannot take place at the agreed time by means of the seller, or if an inspection must be repeated, the resulting costs for the buyer go to the seller.
d. In case of rejection of the delivered materials, the seller is required to take care of the repair or replacement of the materials within 5 (five) working days. If the seller should not comply with his obligations within this deadline, the buyer has the right to purchase the required materials from a third party, or to take certain measures or actions to have a third party at the expense or risk of the seller.
e. If the seller does not collect the rejected materials within 7 (seven) days, the buyer has the right to return the materials at the seller's expense.

Article 17. Packaging

a. At all times buyer has the right to return the (transport)packaging to the seller, who will bear these costs.
b. Processing or destruction of (transport)packaging is the responsibility of the seller. If processed or destroyed at the request of seller, this is done at the risk and expense of the seller.

Article 18. Disbandment

a. In case of failure by the seller to fulfil its obligations under the agreement or other agreements arising therefrom, as well as including in the event of closure, withdrawal of any permits, seizure of (a part of) business assets or materials intended for the execution of the agreement, liquidation or takeover or any comparable situation of the supplier's company, he is legally in default.
b. Without prejudice to any other rights the customer may terminate the contract in whole or in part if the seller or any of its employees or representatives any benefit or service is offered or provided to a person who is part of the client's business section or to one of his employees or representatives.
c. In the cases stated above the client has the right to terminate the contract without notice and unilaterally, without judicial intervention in whole or in part.
d. Dissolution takes place by means of a registered letter or judicial writ to the supplier

Article 19. Order, safety and environment

a. Seller and its employees as well as any third parties engaged by him are to consider and observe the safety, health and environmental regulations.
b. Any company rules and regulations in the field of safety, health and environment of the buyer must be followed. A copy of these rules and regulations are available to seller on request, and are free of charge.

Article 20. Disputes

a. Disputes between the parties, this meaning only one of the parties considering it as such, shall as far as possible be put through consultation to find a proper solution.
b. If the parties do not reach a solution, the dispute will be settled by the competent court in the district in which the client's business is secured.

Article 21. Applicable law

On the agreement, including these purchase terms and conditions, only the Dutch law is applicable. Foreign laws and conventions such as the Vienna Sales Convention are excluded.

4. Additional terms concerning orders and accepting work from the buyer

Article 22. Supplementary definitions

- *Materials:* Issues as defined in *14b*, which are processed into the materials or are used in the execution of the work, with the exception of the equipment to be used.
- *Equipment:* All vehicles, accessories, cranes, scaffolding and included parts, consumables and such that seller uses to fulfil its obligations under the agreement, excluding the materials to be processed into the materials objects.

Article 23. Relevance

a. These additional conditions apply to all requests, offers and contracts relating to the execution of orders and / or the acceptance of work by the supplier.
b. In addition to the additional terms, the terms and conditions of purchase (these apply to the aforementioned requests) offers and agreements, unless these are waived by the nature of the items in the supplementary conditions.
c. For the purposes of these conditions, third parties who are involved in fulfilling obligations under the agreement(s) shall also be understood as employees.

Article 24. Employees, equipment and materials

a. Personnel involved by the seller to execute the agreement shall meet the buyers special requirements, and in the absence thereof, the general requirements of competence and expertise.
b. If in the opinion of the client there is not underqualified staff, the buyer is required to demand removal of such personnel and the seller is obliged to replace, subject to the provisions of paragraph *a* of this article.
c. Buyer has the authority to inspect and test all materials and equipment used for fulfilling the obligations of the agreement, and to identify the personnel involved by the seller in performance of the contract.

Article 25. Grounds and buildings of the buyer

a. Seller should be informed of the circumstances on the grounds and in the buildings where work is to be performed before the execution of the agreement is initiated.
b. Costs of delay in the execution of the agreement caused by circumstances as are referred to above are for the expense and risk of the seller.

Article 26. Work activities on the grounds/in the buildings of the buyer

a. The seller shall ensure that his presence and the presence of his staff on the grounds and buildings of buyer will not hinder the undisturbed progress of the buyer and third parties of the client.
b. Before the execution of the agreement is initiated, seller and his staff must familiarize themselves with the rules and regulations applicable to the grounds and buildings of buyer, including safety, health and environment, and will behave accordingly.
c. A copy of the said rules and regulations will be provided by the buyer at request of seller.

Article 27. Payment

a. The buyer will only pay once the work is completed by the seller to the satisfaction of the buyer and / or the assignment has been carried out satisfactorily by the seller and after, at first request of the buyer, seller has demonstrated that he has paid the personnel and contributors involved.
b. Buyer has the right to pay seller for the social contributions, VAT and income tax including national insurance in relation to the work performed, which he as owner under the Sequential Liability Act may be liable for, by depositing onto his blocked account within meaning of the Sequential Liability Act.
c. Notwithstanding the preceding paragraph, buyer is always authorized to deduct the social premiums referred to in the previous paragraph, VAT and income tax including national insurance from the building sum and to pay directly to the relevant business association or the receiver of direct taxes on behalf of seller.
d. In the case referred to in paragraphs *b and c inclusive* of this article, by payment thereof the buyer is discharged toward the seller, as far as these amounts are concerned.

Article 28. Obligations of the seller

a. The seller is responsible for independently, and under his own responsibility, bringing a good result of the work, in accordance with the applicable rules and regulations regarding safety and the environment.
b. Work and/or the assignment(s) are to be performed well and properly, and to the provisions of the agreement.
c. In principle, representatives of the seller are available during working hours, their absence, replacement and accessibility being arranged in consultation with the buyer.
d. Seller must have a valid registration with the business association with which he is registered and to have a residence permit, insofar as it is required. At the first request of the seller, buyer must show the aforementioned documents.
e. At first request of the buyer, seller must hand over a record containing the full name(s), address, date and place of birth, social security number and conditions of employment of all staff, that have been set to work from week to week by the seller.
f. Upon request of the buyer, seller must provide pay slips or the man-hours accountability of all personnel employed, for inspection in accordance with a model drawn up by the buyer.
g. Seller has to strictly fulfil all its obligations towards the staff put into work by him.
h. At first request of the buyer, seller must always provide a copy of the statements regarding payment to the business association and the collector of direct taxes.
i. Supplier shall indemnify buyer from liability against third parties for failure to comply with the supplier’s obligations under the agreement or under the law.
j. Supplier will perform the agreement independently to the latest technical standards and is responsible for this.
k. Waste and packaging material must be disposed of by the supplier after fulfilment of his obligations.

32. Design/Optimise – supplier assessment form

This appendix displays the new designed supplier assessment form:

Supplier assessment form

To guarantee the quality of all purchased products, MR Holding requires its suppliers of materials and services to answer the questions of this Supplier assessment form.

Company name

Name Company representative

Title company representative

Date

Has the organisation obtained any of the following certifications; ISO 9001, TL 9000, TS 16949, ISO 13485, or AS 9100?

- Yes, please attach a copy of the certificate to this form.
- No, please answer the questions below.

1. General Information

1.1.	Does the organisation have plans to achieve one of the abovementioned certifications? ▪ If yes, when is the first inspection expected?	Yes ☐ No ☐
1.2.	Are customer audits and/or inspections by MR Holding or its agencies permitted?	Yes ☐ No ☐
1.3.	Would you provide MR Holding or its agencies a copy of a third party audit report?	Yes ☐ No ☐
1.4.	Does the organisation have a Quality Manual? ▪ If yes, please attach a copy to this form.	Yes ☐ No ☐
1.5.	Does the organisation carry out self-inspections on the facilities and systems? ▪ If yes, how often?	Yes ☐ No ☐
1.6	Does the organisation apply procedures to guarantee traceability?	Yes ☐ No ☐

2. Supplier selection

2.1	Does the organisation select supplier based on specific criteria? ▪ If yes, what are these criteria?	Yes ☐ No ☐
2.2	Does the organisation maintain a list of certified, and/or acceptable suppliers?	Yes ☐ No ☐
2.3	Does your system allow you to use products of unapproved suppliers?	Yes ☐ No ☐
2.4	What checks are carried out on purchased products?	

3. Product quality		
3.1	Does the organisation control the condition of its warehouse?	Yes ☐ No ☐
3.2	Does the organisation apply procedures to guarantee all products are produced conform the requirements?	Yes ☐ No ☐
3.3	Does the organisation have a formal system for reviewing and updating specifications and manufacturing instructions?	Yes ☐ No ☐
3.4	Does the organisation have a recall policy?	Yes ☐ No ☐
3.5	Does the organisation have a complaint procedure?	Yes ☐ No ☐

33. Design/Optimise – Non-disclosure agreement

This appendix displays the new designed non-disclosure agreement:

Nondisclosure Agreement MR Production & Service

This Nondisclosure Agreement (the "Agreement") is entered into by and between _____ with its principal offices at _____ ("Disclosing Party") and _____, located at _____ ("Receiving Party") for the purpose of preventing the unauthorized disclosure of Confidential Information as defined below. The parties agree to enter into a confidential relationship with respect to the disclosure of certain proprietary and confidential information ("Confidential Information").

1. **Definition of Confidential Information.** For purposes of this Agreement, "Confidential Information" shall include all information or material that has or could have commercial value or other utility in the business in which Disclosing Party is engaged. If Confidential Information is in written form, the Disclosing Party shall label or stamp the materials with the word "Confidential" or some similar warning. If Confidential Information is transmitted orally, the Disclosing Party shall promptly provide a writing indicating that such oral communication constituted Confidential Information.

2. **Exclusions from Confidential Information.** Receiving Party's obligations under this Agreement do not extend to information that is: (a) publicly known at the time of disclosure or subsequently becomes publicly known through no fault of the Receiving Party; (b) discovered or created by the Receiving Party before disclosure by Disclosing Party; (c) learned by the Receiving Party through legitimate means other than from the Disclosing Party or Disclosing Party's representatives; or (d) is disclosed by Receiving Party with Disclosing Party's prior written approval.

3. **Obligations of Receiving Party.** Receiving Party shall hold and maintain the Confidential Information in strictest confidence for the sole and exclusive benefit of the Disclosing Party. Receiving Party shall carefully restrict access to Confidential Information to employees, contractors, and third parties as is reasonably required and shall require those persons to sign nondisclosure restrictions at least as protective as those in this Agreement. Receiving Party shall not, without prior written approval of Disclosing Party, use for Receiving Party's own benefit, publish, copy, or otherwise disclose to others, or permit the use by others for their benefit or to the detriment of Disclosing Party, any Confidential Information. Receiving Party shall return to Disclosing Party any and all records, notes, and other written, printed, or tangible materials in its possession pertaining to Confidential Information immediately if Disclosing Party requests it in writing.

4. **Time Periods.** The nondisclosure provisions of this Agreement shall survive the termination of this Agreement and Receiving Party's duty to hold Confidential Information in confidence shall remain in effect until the Confidential Information no longer qualifies as a trade secret or until Disclosing Party sends Receiving Party written notice releasing Receiving Party from this Agreement, whichever occurs first.

5. **Relationships.** Nothing contained in this Agreement shall be deemed to constitute either party a partner, joint venturer or employee of the other party for any purpose.

6. **Severability.** If a court finds any provision of this Agreement invalid or unenforceable, the remainder of this Agreement shall be interpreted so as best to effect the intent of the parties.

7. **Integration.** This Agreement expresses the complete understanding of the parties with respect to the subject matter and supersedes all prior proposals, agreements, representations, and understandings. This Agreement may not be amended except in a writing signed by both parties.

8. **Waiver.** The failure to exercise any right provided in this Agreement shall not be a waiver of prior or subsequent rights.

This Agreement and each party's obligations shall be binding on the representatives, assigns, and successors of such party. Each party has signed this Agreement through its authorized representative.

Disclosing Party	Receiving Party
By: _____	By: _____
Printed Name: _____	Printed Name: _____
Title: _____	Title: _____
Dated: _____	Dated: _____

34. Design – Supplier evaluation system

This appendix displays the new supplier evaluation system which is set up by the authors during the Design phase of this research. An optimised version of the supplier evaluation system is included in appendix 42.

This figure represents the overview of the supplier evaluation system. The purchase manager does not fill in this form. The form updates automatically when an evaluation is executed.

Supplier Evaluation System - Supplier 1

Supplier name:

Review frequency

Date of evaluation					
Criteria	**weight**	**score**	**score**	**score**	**score**
Delivery	25%	Delivery	Delivery	Delivery	Delivery
Timely	0,4				
Quantity	0,2				
Packaging	0,2				
Warning Signs	0,1				
Documentation	0,1				
Totaal	1				
Cost	25%	Cost	Cost	Cost	Cost
Competitive pricing	0,4				
Price stability	0,3				
Price accuracy	0,1				
Advance notice of price changes	0,2				
Totaal	1				
Quality	25%	Quality	Quality	Quality	Quality
Guarantee	0,45				
Broken items	0,4				
Quality Management System	0,1				
Corporate Social Responsibility	0,05				
Totaal	1				
Service	25%	Service	Service	Service	Service
Communication	0,35				
Payment deadlines	0,3				
Traceability	0,3				
Emergency delivery	0,05				
Totaal	1				
End score					

Satisfying rating	≥8	Supplier is performing well, no action required.
Medium satisfying rating	6 - 8	A decision needs to be made if the rating is satisfying based on the risks category the supplier and the progression since previous ratings. When the performance needs improvement on a natural time scale, set up an action plan.
Dissatisfying rating	≤6	Performance is not acceptable and immediate action plan is required. Frequency of supplier rating is increased to at least twice a year.

When an evaluation is held, the purchase manager answers the following questions by choosing one of the answers which are included in a drop down list.

Supplier Evaluation

Date of evaluation:
Evaluated by:
Review period:

Delivery		Rating	Delivery
Timely	Orders arrive at the date as is stated in the purchase order		
Quantity	Arrived articles are corresponding with the purchase order		
Packaging	Suitable packaging is used		
Warning Signs	Suitable warning signs are used on the packages		
Documentation	Proper documentation (packing slips, invoices, technical manual, etc.) attached to delivery		
Total			

Cost		Rating	Cost
Competitive pricing	On average, products are reasonably priced (compared to competitors)		
Price stability	The price of the products fluctuates		
Price accuracy	The price in the purchase order corresponds with the price on the billing		
Advance notice of price changes	The supplier provides timely notice of price changes		
Total			

Quality		Rating	Quality
Guarantee	Products come with a suitable guarantee period		
Broken items	Broken products identified right after delivery		
Quality Management System	The supplier uses of a proper quality management system		
Corporate Social Responsibility	The supplier takes corporate social responsibility towards her environment		
Total			

Service		Rating	Service
Communication	The suppliers responses are correct and timely		
Payment deadlines	The payment deadlines are benefical		
Traceability	Products are traceable during shipment		
Emergency delivery	The supplier handles quickly when an emergency delivery is needed		
Total			

The drop down lists show the following options to answer the questions of every evaluation:

Delivery	
Timely	100% of the time
	90% ≥ < 100% of the time
	80% ≥ < 90% of the time
	70% ≥ < 80% of the time
	< 70% of the time
Quantity	100% corresponding
	90% ≥ < 100% corresponding
	80% ≥ < 90% corresponding
	70% ≥ < 80% corresponding
	< 70% corresponding
Packaging	100% of the time
	90% ≥ < 100% of the time
	80% ≥ < 90% of the time
	70% ≥ < 80% of the time
	< 70% of the time
Warning Signs	100% of the time
	90% ≥ < 100% of the time
	80% ≥ < 90% of the time
	70% ≥ < 80% of the time
	< 70% of the time
Documentation	100% of the time
	95% ≥ < 100% of the time
	90% ≥ < 95% of the time
	85% ≥ < 90% of the time
	< 85% of the time

Cost	
Competitive pricing	Lowest price available
	Relatively low prices
	Average prices
	Relatively expensive
	Price is very high in compare to others
Price stability	Price does not fluctuate
	Price fluctuated once
	Price fluctuates yearly
	Price fluctuates monthly
	Price fluctuates weekly
Price accuracy	Always
	Sometimes
	Never
Advance notice of price changes	> 30 days before change
	14 ≥ < 30 days before change
	7 ≥ < 14 days before change
	<7 days before change
	No notice of price changes are given

Quality	
Guarantee	Always
	≥ 95% of the time
	75 ≥ < 95% of the time
	< 75% of the time
	Never
Broken items	0 broken items identified
	1 ≥ < 3 broken items identified
	3 ≥ < 5 broken items identified
	5 ≥ < 10 broken items identified
	≥ 10 broken items identified
Quality Management System	ISO certificated
	Other quality certificate
	Implementing a QMS
	No QMS
Corporate Social Responsibility	CSR certificated
	Good measures are taken
	Fair measures are taken
	Supplier takes no responsibility

Service	
Communication	Always
	Most of the time
	Sometimes
	Almost never
	Never
Payment deadlines	> 50 days
	21 ≥ < 50 days
	7 ≥ < 21 days
	< 7 days
	immediate payment
Traceability	Products come with track and trace code
	Supplier sends shipment confirmation
	Products are not traceabile during shipment
Emergency delivery	No emergency delivery needed
	Excellent response
	Good response
	Poor response
	No response

35. Design/Optimise – Risk rating Matrix

This appendix displays the new designed Risk rating Matrix. The next page shows the ratings applied by Philips per product category:

		Likelihood				
		Rare This risk may occur in exeptional circumstances	**Unlikely** This risk may occur at some time.	**Moderate** This risk will probably occur at some time.	**Likely** The risk will ocuur in most circumstances	**Certain** The risk is expected to occur in all cercumstances
		Less than once a year	At least once a year	At least once a 6 months	At least once per month	At least once per week
	Level	1	2	3	4	5
Negligible No injuries.	0	0	0	0	0	0
Minor Light injury. First-aid treatment is required.	1	1	2	3	4	5
Serious Serious injuries. Medical treatment is needed.	2	2	4	6	8	10
Major Long term injuries. Hospital admission is needed.	3	3	6	9	12	15
Fatality Single death	20	20	40	60	80	100

Impact of the risk in medical device

Result	Risk Rating	Interpretation
0-2	Z - Negligible	Supplier with risk rating Z will not be evaluated.
3-6	Y - Moderate	Supplier with risk rating Y will be evaluated in January.
8-12	X - Major	Supplier with risk rating X will be evaluated in January and July.
15-100	W - Critical	Supplier with risk rating W will be evaluated in January, April, July and October.

The form **"BOM_Explosion_Report"** shows the FRUs and components of Philips which MR P&S shall purchase. Philips marked 1.123 of these products with a product risk label. MR P&S is recommended the use the same product risk labels as Philips and link these to all the products in the database, since Exact also refers to the supplier of every product. This ensures the highest risk category per supplier can be determined.

For the remaining 10.303 products, the product risk category still needs to be determined. Technical knowledge is needed to assign all products to its risk categories. It is recommended to make the engineers responsible to assign all products to a risk by the use of the risk matrix. Since assigning all products with a risk category is a very time consuming process, it is recommended to only label a product when it is purchased.

Philips assigned the following product groups to a specific category:

W critical (15/1.123 producten):
- endplate, connector
- mn connector shield

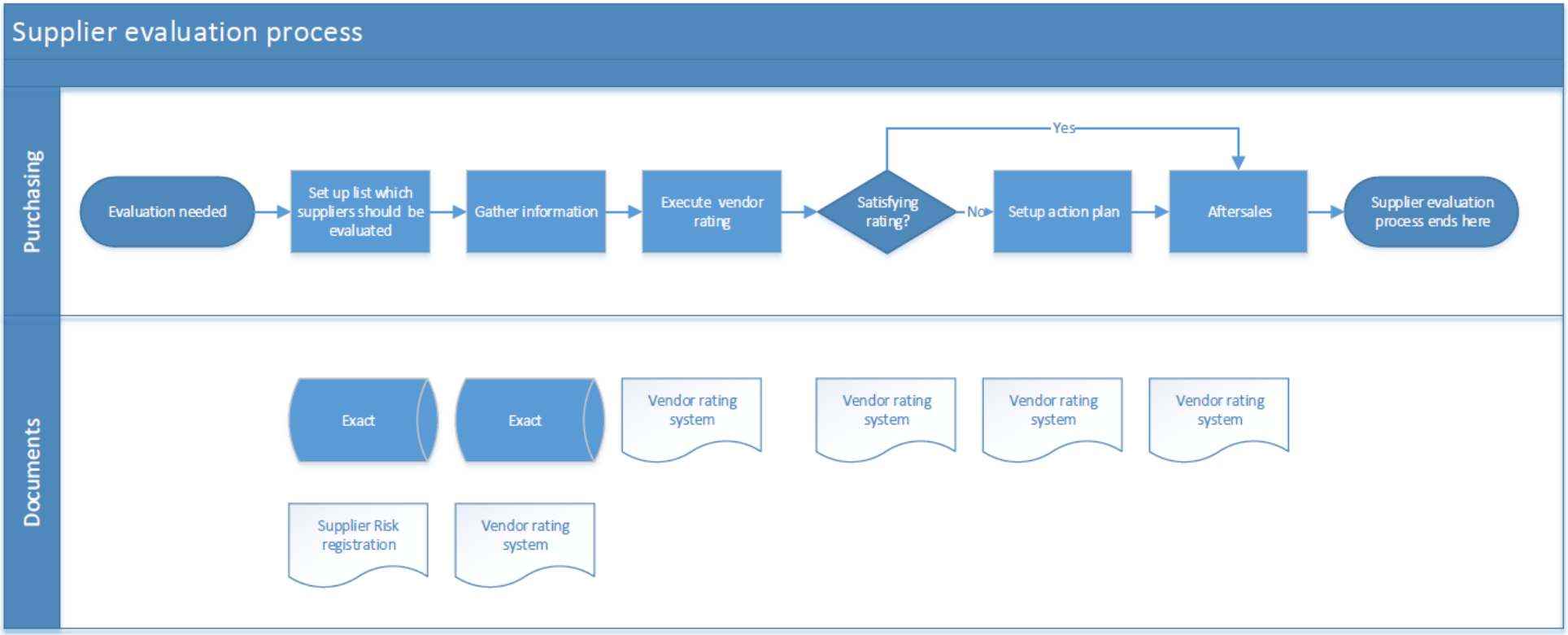
X major (83/1.123 producten):
- Assembly (7)
- Assy (9)
- Base (6)
- Cable (17) - cable 1h, 0 deg
- Cover (10)

Y moderate (121/1.123 producten):
- Assy (7) - assy, pcb rung
- CDAS (26) - cdas_clk
- PFEI (15)
- Washer (6)
- Wire (9) - wire,#14awg,wht,600v

Z negligible (904/1.123 producten):
- 7T (55) - 7t mn small loop coil pcb
- Assy (24) - assy, universal driver board
- Battery (6)
- Bracket (25) - bracket, driver pcb
- Cable (66) - cable 1h, pu 0 deg
- CDAS (25) - CDAS Tx1 TO FC Tx1
- Harness (17) - HARNESS, GG2-X04 GG2-X04-OUT
- Mainscable
- Drill-fab

36. Design/Optimise – Supplier evaluation process

The following flowchart shows the new designed supplier evaluation process:



37. Design/Optimise – Supplier evaluation process RACI

This appendix displays the new designed supplier evaluation process RACI:

Process: Supplier evaluation

Introduction

This document has been set up to describe the supplier evaluation process within MR Holding and each of its subsidiaries. Each separate activity has been described, including who is responsible and what documentation/systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who is in the end responsible and can be held accountable if the product does not work according to plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person gets involved for advice concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. One way communication.
	(NL: geïnformeerd)	

Start of the process

This process starts when the purchase manager gets a notification to evaluate the suppliers.

Set up list which suppliers should be evaluated			
Description:	The purchase manager sets up a list of the suppliers who need to be evaluated. The Supplier Risk Registration shows which suppliers needs to be evaluated and when.	R	PM
		A	FOM
		C	Database, LM
		I	
Documentation:	Exact Risk Registration		

Gather information			
Description:	For every supplier on the list, the purchase manager gathers monitored information from the database in Exact.	R	PM
		A	FOM
		C	Database, LM
		I	
Documentation:	Exact, HOL_QMG_REG_Supplier Evaluation System		

Execute Supplier Evaluation			
Description:	The purchase manager answers the questions in the Supplier Evaluation System, based on the gathered information.	R	PM
		A	FOM
		C	LM
		I	MGR
Documentation:	HOL_QMG_REG_Supplier Evaluation System		

Question: Satisfying rating?			
Description:	Based on the legend in the vendor rating system, it is clear if the rating is satisfying. YES - Proceed to step: provide feedback. NO - Proceed to step: setup action plan.	R	PM
		A	FOM
		C	
		I	MGR
Documentation:	HOL_QMG_REG_Supplier Evaluation System		

Set up action plan			
Description:	The purchase manager sets up an action plan.	R	PM
		A	CEO
		C	FOM, CEO
		I	MGR, LM,
Documentation:	HOL_QMG_REG_Supplier Evaluation System		

Aftersales			
Description:	The action plan is communicated to the supplier. The supplier evaluation process ends here.	R	PM
		A	FOM
		C	FOM, CEO
		I	
Documentation:			

Section

III

Optimise

38. Optimise – Kanban procedure

This appendix displays the new Kanban procedure which is improved by the authors during the Optimise phase of this research. The optimisation measures are highlighted:

Procedure: Kanban

Purpose of the document:

This document has been set up to describe, the responsibilities of employees to maintain the Kanban system. It includes information about the methods, the tools, and the responsibilities of the employees.

Responsibilities in the Kanban:

Logistic manager

- The logistic manager is responsible to store all components in Kanban units. A reorder card with information of every product is stored with every Kanban unit.
- At a fixed time a day, the logistic manager collects the to-order cards and hands these over to the purchase manager. He records in Exact which batches are out of stock and which new batches are used.
- When new material arrives, the logistic manager places the items in the empty unit which is placed on the re-order shelve by the engineers. The to-order cards is taken from the waiting for arrival bin and stored with the Kanban unit. The unit is placed on its original place, behind or underneath the Kanban unit used.
- The logistic manager reviews the Kanban units of risk-full suppliers at a monthly basis to ensure the inventory levels are optimal. At the end of the year the logistic manager reviews all Kanban units based on historic data.

Engineers

- During production and reparations only components from the first or most accessible Kanban units are used by the engineers.
- When the first unit is empty, it is replaced by the second unit. The reorder card is placed in a to-order bin. The empty unit is stored on the to-order shelve.
- Engineers use the material from the second Kanban unit, while waiting for the receipt of the material in order.

Purchase manager

- When the logistic managers hands over the to-order cards to the purchase manager, the purchase process starts. After re-ordering, the re-order cards are placed in a wait-for-arrival-bin. This ensures all employees can see what products are expected to be delivered.

General manager

- The general manager is accountable to ensure all engineers follow the instructions to maintain the Kanban system.
- The general manager reviews the Kanban units of risk-full suppliers at a monthly basis to ensure the inventory levels are optimal. At the end of the year the logistic manager reviews all Kanban units based on historic data.

39. Optimise – Purchasing process RACI

This appendix displays the new purchasing process RACI which is improved by the authors during the Optimise phase of this research. The optimisation measures are highlighted:

Process: Purchasing

Introduction

This document has been set up to describe the purchasing process within MR Holding and each of its subsidiaries. Each separate activity has been described, including who is responsible and what documentation / systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who is in the end responsible and can be held accountable if the product does not work according to plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person gets involved for advice concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. One way communication.
	(NL: geïnformeerd)	

Start of the process

This process starts when there is a need for a purchase order. This need can be caused by the following triggers: when the inventory is underneath safety stock level, or when an article, not on inventory, should be purchased.

Supplier allocated?			
Description:	The purchase manager checks the database to see whether there a supplier is allocated by an external partner or if the product is purchased before. YES -Proceed to step: select supplier. NO - Proceed to step: start searching for a new supplier.	R	PM
		A	FOM
		C	Database
		I	
Documentation:	Exact		

Search for suppliers			
Description:	The purchase manager checks if the product can be purchased at a preferred supplier. If this is possible, this supplier will be selected. If the product cannot be purchased at a preferred supplier, the purchase manager searches for new suppliers who meet the product requirements.	R	PM
		A	FOM
		C	Database
		I	PL
Documentation:	Exact		

Select supplier			
Description:	When only one supplier is allocated or found, it will be selected. When more than one supplier is allocated or found, the purchase manager selects a supplier in negotiation with the general manager based on the following criteria: Quality, Cost, Service, Delivery. When selecting a new supplier, the purchase manager identifies the risk rating and registers this in Exact. When a supplier is selected, the purchase manager decides if it is necessary to send a Supplier assessment form and a Non-disclosure agreement. The purchase manager keeps records of this selection process.	R	PM
		A	FOM
		C	MGR
		I	PL
Documentation:	HOL_QMG_PRO_Supplier assessment form HOL_QMG_PRO_Non-disclosure agreement HOL_QMG_PRO_Risk rating matrix		

Authorized to purchase?			
	When a supplier is selected, the purchase manager checks in the authorization form whether he is authorized to place the order. YES - Proceed to step: place purchase order. NO - Proceed to step: Approval Note: When the purchase is executed for an external partner, approval by the external party must be given before proceeding the purchasing process.	R	PM
		A	CEO
		C	FOM
		I	PL
Documentation:	HOL_QMG_PRO_Autorisation Form		

Approval			
Description:	The CEO needs to give approval before a purchase order can be placed.	R	PM
		A	FOM
		C	CEO
		I	PL
Documentation:			

Place purchase order			
Description:	The purchase manager places the order and registrants this in Exact. In addition, the purchase manager sends the Purchase Terms and Conditions to the supplier. When the supplier applies terms and conditions as well, the purchase manager collaborates with the supplier. When both parties do not come to an agreement, go back to step: search for supplier. When both parties come to an agreement, the order is placed. The purchasing process ends here.	R	PM
		A	FOM
		C	
		I	PL, LM
Documentation:	HOL_QMG_PRO_Purchase Terms and Conditions Exact		

40. Optimise – Purchase terms and conditions

This appendix displays the new purchasing terms and conditions which are improved during the Optimise phase by the authors of this research. The optimisation measures are highlighted:

Purchase Terms and Conditions

This document defines the terms and conditions relating to the quality of products and materials supplied to MR Holding and its subsidiaries. Supplier shall supply materials and/or services in compliance with the terms stated in this document. It is the responsibility of the supplier to review and fully understand the requirements, before accepting a purchase order.

Article 1. Definitions

The following terms shall have the indicated definitions:

- *Buyer(client):* the entity issuing the order
- *Seller(supplier):*the person, firm or company to whom the order is addressed.
- *Agreement*: the negotiated and legally enforceable understanding between the seller and buyer.
- *Delivery:* the manner of delivering the materials from seller to buyer under the order.
- *Order:* the purchase order issued by buyer for the use of materials, which may be an oral communication or a written or electronic document, and may also include particular shipping instructions and/or other specifications required by the buyer for the materials.
- *Materials:* all the products and/or services to be supplied by seller under the order.
- *Parties:* The buyer and the seller, and possible third parties.
- *Days:* official working days

Article 2. Relevance

c. In case of conflict, agreed specific commitments prevail these terms and conditions.
d. These purchasing terms and conditions apply to all requests, offers and commands relating to the delivery of materials by the seller to the buyer, rejecting the terms and conditions of the seller.

Article 3. Alterations

c. At all times, the buyer is authorized to alter the quantity and/or quality of the order in consultation with the seller. These alterations are to be agreed on in writing.
d. If, in the opinion of the seller, an alteration will have consequences for the agreed fixed price and/or the delivery date of the ordered materials, he is obligated to inform the buyer as soon as possible, at least within 8 working days after the notification of the desired alterations to the order, before accepting the alterations.

Article 4. Transfer of liabilities

c. It is only possible for the seller to assign liabilities regarding the agreement to a third party if this has been approved of on paper in advance. Reasonable conditions can be attached to this permission.
d. In cases of transfer of (a portion of) the obligations under the agreement of the seller to a third party, seller is obliged to inform buyer of the securities that have been established for the payment of VAT, income tax and social contributions which are prescribed for employers.

Article 5. Prices and price review

c. The prices in the agreement do not include VAT, and include all costs in connection with the fulfilling of the sellers obligations.
d. The prices are fixed, unless the agreement states the circumstances that lead to an adjustment in price, as well as determining the manner in which the adjustment takes place.

Article 6. Invoicing and payment

e. Payment of the invoice, including VAT, should take place within 90 (nighty) days after receiving the invoice and the approval of the materials and any possible installation/editing needed by the buyer.
f. The buyer is entitled to suspend payment if he should notice any shortcomings within the order of the materials and any possible installation/editing needed.
g. The buyer has the right to reduce the price of the invoice with amounts indebted by the seller.
h. It is not possible for the buyer to waive the rights of payment.

Article 7. Delivery date

c. The agreed date of delivery is essential. In case of a late delivery the seller is in default, without further notice.
d. In case of an imminent delivery failure, seller should immediately inform buyer in writing. This is without prejudice to any consequences as a result to the encroachment under the agreement or statutory provisions.

Article 8. Delivery

c. The delivery shall take place at the agreed address and at the agreed date and time, according to current valid Incoterm DDP (Delivered Duty Paid).
d. Buyer has the right to postpone the delivery. In this case the seller should pack the materials appropriately, store them separately, securely and properly, and clearly label and identify the delivery) and identifiably and separately store them, conserved securely and properly.

Article 9. Shortcomings/breach of contract

g. In case of an accountable shortcomings of the seller, he is in default without further notice.
h. Notwithstanding the right to compensation and other statutory rights arising from a breach of contract, the buyer is entitled to claim a fine up to 20 % per day from the day of the default, with a maximum of 100 % of the amount to be paid by the buyer.
i. The statutory interest on amounts that the buyer has paid in advance will be deducted from invoices to be paid over the period of the default.
j. In case of non-attributable shortcomings the obligations of both parties will be postponed for a period up to 10 (ten) weeks.
k. Parties may only appeal towards each other on non-attributable shortcomings if the party concerned notifies the other party of these actions on paper. However, this must be done as soon as possible, within 5 (five) days after the non-attributable shortcomings are made clear, and submission of the necessary evidence.
l. If the seller states that one or more of his shortcomings are not attributable to him and the buyer accepts this argument, the buyer has the right to terminate the order agreement. In such situations the parties will not charge each other.

Article 10. Warranty

e. Seller guarantees that the materials and any possible installation/editing thereof meet the expectations of what has been previously agreed.
f. Seller guarantees that the goods are fully complete and ready for use. He ensures that all parts including auxiliary materials, accessories/attachments, equipment, spare parts and instruction manuals, which are necessary for realizing the written purpose of the buyer, are supplied, even if these have not been specifically named.
g. Seller guarantees that the delivery complies with all relevant legal provisions regarding quality, environment, safety and health.
h. If the buyer finds that the delivery does not (fully or partially) meet with what the seller has guaranteed in accordance with paragraphs *a. to c. Inclusive* of this article, the seller is in default, unless the latter can prove the defects cannot be attributed to him.

Article 11. Intellectual and industrial property rights

c. The seller guarantees the free and undisturbed use by the buyer of the delivered materials. He indemnifies the buyer against the financial consequences of third party claims due to infringement of their intellectual and industrial property rights.
d. The seller is entitled to use the information which has been provided by the buyer, but only in connection with the contract. This information is and remains the property of the buyer.

Article 12. Documentation

c. The seller is obliged to provide the corresponding documentation to the buyer prior to or simultaneously with the delivery of the materials.
d. The buyer is free to use this documentation, including reproducing it for personal use.

Article 13. Liability

d. The seller is liable for all damages that may arise in connection with the fulfilling of the obligations under the agreement.
e. The seller indemnifies the buyer against all financial consequences of claims of third parties in any connection with the fulfillment of his obligations under the agreement.
f. Buyer has the right to request seller to take out insurance, to cover the risks. Upon this request the seller is required to grant the buyer permission to inspect the relevant policy.

Article 14. Transfer of risk and ownership

e. The ownership of the materials passes to the buyer after they have been delivered and assembled, and, if necessary installed.
f. If the buyer provides the seller with materials made available for the benefit of the fulfillment of the obligations under the agreement, such as auxiliary materials, equipment, drawings, specifications and software, these remain the property of the buyer. Seller shall keep these separate from objects belonging to himself or to others, and shall mark them as property of the buyer.
g. The moment the materials, including raw materials, auxiliary materials and software have been processed into materials of the seller, the materials are henceforth referred to as property of the buyer. This is without prejudice to *article 14d*.
h. The risks surrounding the materials pass to the buyer the moment the delivery and subsequent approval of the materials have occurred in accordance with *article 16* of these purchasing terms and conditions.

Article 15. Secrecy and prohibition of disclosure

d. Supplier shall keep the existence, the nature and content of the agreement and any other business information, and anything related from being made public without the written consent of the client.
e. If buyer considers necessary, supplier shall sign a Non-Disclosure Agreement.
f. In case of violation of the provisions in this paragraph of the Non-Disclosure Agreement, the buyer will impose a penalty up to €200.000 for each violation. The amount of the fine is paid directly by the seller after the aforementioned determination and communication to the seller.

Article 16. Inspection

f. At all times buyer has the right to examine the materials, during production, processing and storage, as well as after the delivery.
g. At first request the seller will provide access to the principal or his representative to the place of production, processing of storage. Seller shall lend its cooperation to the inspection.
h. If an inspection as referred to in this article cannot take place at the agreed time by means of the seller, or if an inspection must be repeated, the resulting costs for the buyer go to the seller.
i. In case of rejection of the delivered materials, the seller is required to take care of the repair or replacement of the materials within 5 (five) working days. If the seller should not comply with his obligations within this deadline, the buyer has the right to purchase the required materials from a third party, or to take certain measures or actions to have a third party at the expense or risk of the seller.
j. If the seller does not collect the rejected materials within 7 (seven) days, the buyer has the right to return the materials at the seller's expense.

Article 17. Packaging

c. At all times buyer has the right to return the (transport)packaging to the seller, who will bear these costs.
d. Processing or destruction of (transport)packaging is the responsibility of the seller. If processed or destroyed at the request of seller, this is done at the risk and expense of the seller.
e. All electro-static sensitive devices (ESD) shall be properly packaged to provide protection from electrostatic discharge. All ESD sensitive products shall be clearly identified with an ESD warning on each tray, tube, or tope and reel within the shipment.
f. Material packaging shall not negatively influence Material quality or include any impurities.
g. All products shall, where possible, be labelled with both human readable and bar code at the lowest level of packaging (reel, tube, bagged tray).
h. All product packing slips shall, if applicable, contain RoHS compliancy statement which shall be attached to the hardcopy as an attachment in accordance with RoHS-F004 specifications.

Article 18. Disbandment

e. In case of failure by the seller to fulfil its obligations under the agreement or other agreements arising therefrom, as well as including in the event of closure, withdrawal of any permits, seizure of (a part of) business assets or materials intended for the execution of the agreement, liquidation or takeover or any comparable situation of the supplier's company, he is legally in default.
f. Without prejudice to any other rights the customer may terminate the contract in whole or in part if the seller or any of its employees or representatives any benefit or service is offered or provided to a person who is part of the client's business section or to one of his employees or representatives.
g. In the cases stated above the client has the right to terminate the contract without notice and unilaterally, without judicial intervention in whole or in part.
h. Dissolution takes place by means of a registered letter or judicial writ to the supplier

Article 19. Order, safety and environment

c. Seller and its employees as well as any third parties engaged by him are to consider and observe the safety, health and environmental regulations.
d. Any company rules and regulations in the field of safety, health and environment of the buyer must be followed. A copy of these rules and regulations are available to seller on request, and are free of charge.

Article 20. Disputes

c. Disputes between the parties, this meaning only one of the parties considering it as such, shall as far as possible be put through consultation to find a proper solution.
d. If the parties do not reach a solution, the dispute will be settled by the competent court in the district in which the client's business is secured.

Article 21. Applicable law

On the agreement, including these purchase terms and conditions, only the Dutch law is applicable. Foreign laws and conventions such as the Vienna Sales Convention are excluded.

4. Additional terms concerning orders and accepting work from the buyer

Article 22. Supplementary definitions

- *Materials:* Issues as defined in *14b*, which are processed into the materials or are used in the execution of the work, with the exception of the equipment to be used.
- *Equipment:* All vehicles, accessories, cranes, scaffolding and included parts, consumables and such that seller uses to fulfil its obligations under the agreement, excluding the materials to be processed into the materials objects.

Article 23. Relevance

d. These additional conditions apply to all requests, offers and contracts relating to the execution of orders and / or the acceptance of work by the supplier.
e. In addition to the additional terms, the terms and conditions of purchase (these apply to the aforementioned requests) offers and agreements, unless these are waived by the nature of the items in the supplementary conditions.
f. For the purposes of these conditions, third parties who are involved in fulfilling obligations under the agreement(s) shall also be understood as employees.

Article 24. Employees, equipment and materials

d. Personnel involved by the seller to execute the agreement shall meet the buyers special requirements, and in the absence thereof, the general requirements of competence and expertise.
e. If in the opinion of the client there is not underqualified staff, the buyer is required to demand removal of such personnel and the seller is obliged to replace, subject to the provisions of paragraph *a* of this article.
f. Buyer has the authority to inspect and test all materials and equipment used for fulfilling the obligations of the agreement, and to identify the personnel involved by the seller in performance of the contract.
g. Supplier does not deal with discrimination, child labour and inadequate working conditions. Neither does the supplier purchase products from a supplier that deals with these matters.
h. Prior to the agreement the supplier must, in writing, state whether the offered and supplied materials contain environmentally hazardous substances that may be released during normal use as well as in case of malfunctions, repairs, maintenance or calamities, removal, storage, dumping, discharging or destroying at the end of the life of the relevant materials.
i. If the materials do contain environmentally hazardous substances, the supplier must provide a clear instruction with preventive measures on how to avoid release of these substances. In addition, he must state the measures that must be taken to ensure safety of personnel and employees in case of release of the hazardous substances.

Article 25. Grounds and buildings of the buyer

c. Seller should be informed of the circumstances on the grounds and in the buildings where work is to be performed before the execution of the agreement is initiated.
d. Costs of delay in the execution of the agreement caused by circumstances as are referred to above are for the expense and risk of the seller.

Article 26. Work activities on the grounds

d. The seller shall ensure that his presence and the presence of his staff on the grounds and buildings of buyer will not hinder the undisturbed progress of the buyer and third parties of the client.
e. Before the execution of the agreement is initiated, seller and his staff must familiarize themselves with the rules and regulations applicable to the grounds and buildings of buyer, including safety, health and environment, and will behave accordingly.
f. A copy of the said rules and regulations will be provided by the buyer at request of seller.

Article 27. Payment

e. The buyer will only pay once the work is completed by the seller to the satisfaction of the buyer and / or the assignment has been carried out satisfactorily by the seller and after, at first request of the buyer, seller has demonstrated that he has paid the personnel and contributors involved.
f. Buyer has the right to pay seller for the social contributions, VAT and income tax including national insurance in relation to the work performed, which he as owner under the Sequential Liability Act may be liable for, by depositing onto his blocked account within meaning of the Sequential Liability Act.
g. Notwithstanding the preceding paragraph, buyer is always authorized to deduct the social premiums referred to in the previous paragraph, VAT and income tax including national insurance from the building sum and to pay directly to the relevant business association or the receiver of direct taxes on behalf of seller.
h. In the case referred to in paragraphs *b and c inclusive* of this article, by payment thereof the buyer is discharged toward the seller, as far as these amounts are concerned.

Article 28. Obligations of the seller

l. The seller is responsible for independently, and under his own responsibility, bringing a good result of the work, in accordance with the applicable rules and regulations regarding safety and the environment.
m. Work and/or the assignment(s) are to be performed well and properly, and to the provisions of the agreement.
n. In principle, representatives of the seller are available during working hours, their absence, replacement and accessibility being arranged in consultation with the buyer.
o. Seller must have a valid registration with the business association with which he is registered and to have a residence permit, insofar as it is required. At the first request of the seller, buyer must show the aforementioned documents.
p. At first request of the buyer, seller must hand over a record containing the full name(s), address, date and place of birth, social security number and conditions of employment of all staff, that have been set to work from week to week by the seller.
q. Upon request of the buyer, seller must provide pay slips or the man-hours accountability of all personnel employed, for inspection in accordance with a model drawn up by the buyer.
r. Seller has to strictly fulfil all its obligations towards the staff put into work by him.
s. At first request of the buyer, seller must always provide a copy of the statements regarding payment to the business association and the collector of direct taxes.
t. Supplier shall indemnify buyer from liability against third parties for failure to comply with the supplier’s obligations under the agreement or under the law.
u. Supplier will perform the agreement independently to the latest technical standards and is responsible for this.
v. Waste and packaging material must be disposed of by the supplier after fulfilment of his obligations.

Article 29. Product change and discontinuance notification

a. Seller shall notify buyer of all proposed changes that impact the form, fit, function, quality, reliability or status of the material with regard to environmental legislation. Seller notifies the buyer by the use of a change notification on paper.
b. Changes affecting a significant amount of parts defined as greater than 5 (five) part numbers shall be accompanied with an Excel file listing those affected part numbers.
c. Seller shall notify buyer 30 (thirty) days prior to any change implementations by the use of a written notice.
d. Seller shall maintain internal documentation for all changes for a period of no less than 3 (three) years for commercially used products.
e. Buyer has the right to reject any and all intended changes required by the supplier.
f. Seller may be required to cover any re-qualification costs made by the buyer as a result of product changes or product obsolescence initiated by seller.

Article 30. Product Quality Notification

a. Where seller suspects that non-conforming product may have been shipped buyer, seller shall immediately provide written notification.
b. When seller identifies non-conforming product prior to shipment and wishes to obtain concession or deviation permission for its use, release or acceptance, seller shall immediately provide written request to buyer of the non-conforming product applicable to that purchase order.
c. If buyer rejects any goods as non-conforming, buyer may, at its option, (a) reduce the quantities of goods ordered under this document by the quantity of non-conforming goods, (b) require seller to replace the non-conforming goods, and/or (c) exercise any other applicable rights or remedies buyer may have.
d. Seller shall perform Failure Analysis on all returned non-conforming material and shall provide results to buyer when requested. Seller shall collect the data resulting from returned non-conforming material failure analyses and evaluate trends and recurrences for continuous improvement.

Article 31. Quality Assurance

a. Unless otherwise specified and approved by buyer, seller is required to have an applied Quality Management System in place that is operated in accordance with and accredited by a third party certification body to the current version of the standard such as ISO 9001, TL 9000, TS 16949, ISO 13485, or AS 9100. Accredited certification is to be furnished by request.
b. Upon request, seller shall provide all appropriate product certifications including all applicable safety, regulatory, and operating systems certifications at seller's sole cost and expense.
c. It is seller's responsibility to install any additional processes, tests, or methods in order to fulfil customer requirements.
d. Changes to seller's Quality Management System or any significant organizational changes shall be communicated to buyer immediately.

41. Optimise – Supplier evaluation process RACI

This appendix displays the new supplier evaluation RACI which is improved by the authors during the Optimise phase of this research. The optimisation measures are highlighted:

Process: Supplier evaluation

Introduction

This document has been set up to describe the supplier evaluation process within MR Holding and each of its subsidiaries. Each separate activity has been described, including who is responsible and what documentation/systems are used. This document has been set up for quality purposes. We strive for a way of working in which uniformity (if possible), creativity and continuous improvement of both content and process come together.

RACI

Each step of the process (activity) includes a RACI, as written below. This matrix has been set up to describe roles and responsibilities of each involved person within a project.

R	Responsible	The person responsible for this action. This person reports to the person accountable.
	(NL: Verantwoordelijk)	
A	Accountable	The person who is in the end responsible and can be held accountable if the product does not work according to plan. There is only one person accountable in a process.
	(NL: Eindverantwoordelijk)	
C	Consulted	This person gets involved for advice concerning either content or process, depending on what is needed.
	(NL: Geraadpleegd)	
I	Informed	A person who needs to be informed about progress of the project, important decisions which may influence other projects, etc. One way communication.
	(NL: geïnformeerd)	

Start of the process

This process starts when the purchase manager gets a notification to evaluate the suppliers.

Set up list which suppliers should be evaluated			
Description:	The purchase manager sets up a list of the suppliers who need to be evaluated. The Supplier Risk Registration shows which suppliers needs to be evaluated and when. In addition, the ten suppliers with the highest order amount in EUR are added to this list.	R	PM
		A	FOM
		C	Database, LM
		I	
Documentation:	Exact Risk Registration		

Gather information			
Description:	For every supplier on the list, the purchase manager gathers monitored information from the database in Exact.	R	PM
		A	FOM
		C	Database, LM
		I	
Documentation:	Exact, HOL_QMG_REG_Supplier Evaluation System		

Execute Supplier Evaluation			
Description:	The purchase manager answers the questions in the Supplier Evaluation System, based on the gathered information.	R	PM
		A	FOM
		C	LM
		I	MGR
Documentation:	HOL_QMG_REG_Supplier Evaluation System		

Question: Satisfying rating?			
Description:	Based on the legend in the vendor rating system, it is clear if the rating is satisfying. YES - Proceed to step: provide feedback. NO - Proceed to step: setup action plan.	R	PM
		A	FOM
		C	
		I	MGR
Documentation:	HOL_QMG_REG_Supplier Evaluation System		

Set up action plan			
Description:	In collaboration with the Finance and Operations Manager, the purchase manager sets up an action plan.	R	PM
		A	CEO
		C	FOM, CEO
		I	MGR, LM,
Documentation:	HOL_QMG_REG_Supplier Evaluation System		

Aftersales			
Description:	The purchase manager provides feedback to the supplier. The supplier evaluation process ends here.	R	PM
		A	FOM
		C	FOM, CEO
		I	
Documentation:			

42. Optimise – Supplier evaluation system

This appendix displays the new supplier evaluation system is improved by the authors during the Optimise phase of this research. The optimisation measures are highlighted:

This represents the overview of the supplier evaluation system. The purchase manager does not fill in this form. The form updates automatically when an evaluation is executed.

Supplier Evaluation System - Supplier 1

Supplier name:

Review frequency

Date of evaluation					
Criteria	**weight**	**score**	**score**	**score**	**score**
Quality of delivery	50%	Quality of delivery	Quality of delivery	Quality of delivery	Quality of delivery
On time	0,4				
Quantity	0,2				
Packaging	0,05				
Warning Signs	0,05				
Damaged items	0,25				
Documentation	0,05				
Totaal	1				
Cost	25%	Cost	Cost	Cost	Cost
Competitive pricing	0,4				
Price stability	0,1				
Price accuracy	0,1				
Advance notice of price changes	0,1				
Price negotiations	0,3				
Totaal	1				
Quality of service	25%	Quality of service	Quality of service	Quality of service	Quality of service
Communication	0,15				
Payment deadlines	0,15				
Traceability	0,15				
Emergency delivery	0,1				
After sales	0,25				
Quality Management System	0,15				
Corporate Social Responsibility	0,05				
Totaal	1				
End score					

Satisfying rating	≥8	Supplier is performing well, no need to fill in the action plan.
Medium satisfying rating	6 - 8	A decision needs to be made if the rating is satisfying based on the risks category the supplier and the progression since previous ratings. When the performance needs improvement on a natural time scale, set up an action plan.
Dissatisfying rating	≤6	Performance is not acceptable and immediate action plan is required. Frequency of supplier rating is increased to at least twice a year.

When an evaluation is held, the purchase manager answers the following question by choosing one of the answers which are included in a drop down list. Security measures are taken to ensure the formulas in the document cannot be changed without a password. Only the fields that should be filled in can be adjust.

Supplier Evaluation

Date of evaluation:

Evaluated by:

Review period:

Quality of delivery		Rating
On time	Orders arrive at the date as is stated in the purchase order	
Quantity	Arrived articles are corresponding with the purchase order	
Packaging	Suitable packaging is used	
Warning Signs	Suitable warning signs are used on the packages	
Damaged Items	Amount of products rejected right after delivery	
Documentation	Needed documentation (packing slips, … of conformity) attached to delivery	
Total		

Cost		Rating
Competitive pricing	On average, products are reasonably priced (compared to competitors)	
Price stability	The prices are relatively stable	
Price accuracy	The price in the purchase order corresponds with the price on the billing	
Advance notice of price changes	The supplier provides timely notice of price changes	
Price negotiations	The supplier provides the oppertunity to negotiate concerning price	
Total		

Quality of service		Rating
Communication	The suppliers responses are correct and timely	
Payment deadlines	The payment deadlines are benefical	
Traceability	Products are traceable during shipment	
Emergency delivery	The supplier handles quickly when an emergency delivery is needed	
After sales	Supplier is handling complaints properly	
Quality Management System	The supplier uses of a proper quality management system	
Corporate Social Responsibility	The supplier takes corporate social responsibility towards her environment	
Total		

The drop down lists show the following options to answer the questions of every evaluation:

Quality of delivery	
On time	100% of the time
	90% ≥ < 100% of the time
	80% ≥ < 90% of the time
	70% ≥ < 80% of the time
	< 70% of the time
Quantity	100% corresponding
	90% ≥ < 100% corresponding
	80% ≥ < 90% corresponding
	70% ≥ < 80% corresponding
	< 70% corresponding
Packaging	100% of the time
	90% ≥ < 100% of the time
	80% ≥ < 90% of the time
	70% ≥ < 80% of the time
	< 70% of the time
Warning Signs	100% of the time
	90% ≥ < 100% of the time
	80% ≥ < 90% of the time
	70% ≥ < 80% of the time
	< 70% of the time
Damaged items	0 damaged items identified
	1 ≥ < 3 damaged items identified
	3 ≥ < 5 damaged items identified
	5 ≥ < 10 damaged items identified
	≥ 10 damaged items identified
Documentation	100% of the time
	95% ≥ < 100% of the time
	90% ≥ < 95% of the time
	85% ≥ < 90% of the time
	< 85% of the time

Cost	
Competitive pricing	Lowest price available
	Relatively low prices
	Average prices
	Relatively expensive
	Price is very high in compare to others
Price stability	Price does not fluctuate
	Price fluctuates with inflation
	Price fluctuates yearly
	Price fluctuates monthly
	Price fluctuates weekly
Price accuracy	Always
	Sometimes
	Never
Advance notice of price changes	> 30 days before change
	14 ≥ < 30 days before change
	7 ≥ < 14 days before change
	<7 days before change
	No notice of price changes are given
Price negotiations	Price negotions are possible
	Price is set, but discounts are offered
	No negotiation possible

Quality of service	
Communication	Contact person available
	Help desk available
	Great contact with supplier
	Contact with supplier is proper
	Contact with supplier is poorly
Payment deadlines	± 90 days
	± 60 days
	± 30 days
	± 14 days
	± 7 days
	immediate payment
Traceability	Products come with track and trace code
	Supplier sends shipment confirmation
	Supplier sends trace information on request
	Products are not traceabile during shipment
Emergency delivery	No emergency delivery needed
	Excellent response
	Good response
	Poor response
	No response
After sales	Supplier searches in colaboration for solution
	Supplier handles complaints very well
	Supplier handles complaints properly
	Supplier handles complaints poorly
	No complaints occured
Quality Management System	ISO certificated
	Other quality certificate
	Implementing a QMS
	No QMS
Corporate Social Responsibility	CSR certificated
	Good measures are taken
	Fair measures are taken
	Supplier takes no responsibility

43. Optimise – Short-term monitor form

This appendix displays the monitor form used by the Logistic- Purchase manager and logistic assistant to execute the pilot in the Optimise phase. The purchase order information is linked to the inbound logistics information. MR PS is recommended to use this form as short-time solution, until Exact is equipped.

Purchase order					
Order number	Purchase product	Purchase quantity	Supplier	Purchase order date	Expected delivery date

Inbound logistics											
Actual delivery date	Actual product quantity	Products are in good condition	Explain:	Delivery is suitable packed	Explain:	Suitable warning signs used	Explain:	Proper documentation attached	Explain:	Conform to specifications?	Explain:

44. Optimise – Short-term repair registration form

This appendix displays the repair registration form used by the engineers to execute the pilot in the Optimise phase. MR PS is recommended to use this form as short-time solution, until Exact is equipped.

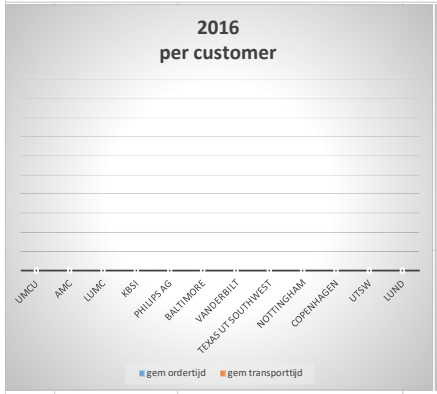
Repair no	Product Name	12 NC	SN	Start date	Finished date	Status	Time spent	Reported problem	Date benchtest	Benchtest performed by	Result benchtest	Implemented solution
Example	16Ch 1H Recieve IFB	4535-673-95031	107	20 March 2017	21 March 2017	Not repaired	2h30	Bad SNR suspected broken pre-amps	21 March 2017	Rudy de Roon	Found 3 broken pre-amps	Replaced broken pre-amps
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												

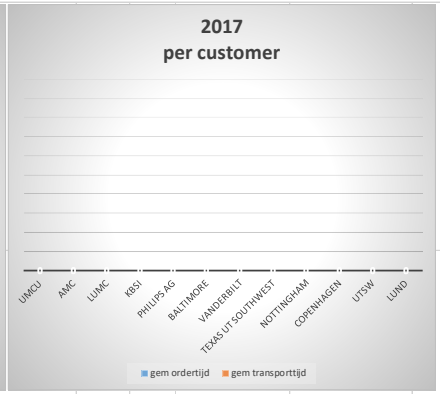
Implementation performed by	No of components replaced	12NC of used components	Date systemtest	Systemtest performed by	Result systemtest	Remarks	Structural change needed?	Follow up
Rudy de Roon	3		21 March 2017	Rudy de Roon	Passed systemtest	Advise for future problem solving	Yes	Fill in Change Request Form
								-
								-
								-
								-
								-
								-
								-
								-
								-
								-
								-
								-
								-
								-

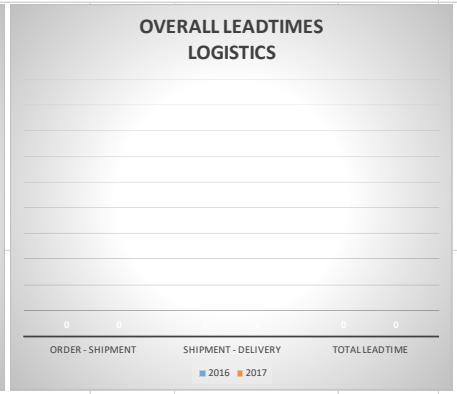
45. Optimise – Short-term shipment information form

This appendix displays shipment information form used by the logistic manager to execute the pilot in the Optimise phase. MR PS is recommended to use this form as short-time solution, until Exact is equipped.

Owner tab: Johan Klerx







Item	customer	Description	12NC	Qty	Seria	PO	Track and Trace nur	buy/make FRU	order dat	Shipment date	delivery dat	Jaar	Lead time order-shipment	Transport tim	Total lead time	Remarks

Section

IV

Verify + recommendations

46. Verify – Key note directive 93/42/ECC

The following Key note of directive 93/42/ECC gives inside in the direction the directive will go to in the future:

Key note: EU Medical Devices Directive (MDD 93/42/EEC) and the coming EU Medical Devices Regulation – similarities and expected differences

Dr. Matthias Neumann
German Federal Ministry of Health, Division 122 „Medical Devices Safety“,
Friedrichstraße 108 – 10117 Berlin, Germany

Summary
The Commission is considering a revision of the current regulatory framework for medical devices consisting of the three Directives:

- Directive 90/385/EEC: Active Implantable Medical Devices
- Directive 93/42/EEC: Medical Devices
- Directive 98/79/EC: In-vitro-Diagnostic Medical Devices

The Commission is developing two Regulations:

- Aproposal for a Medical Devices Regulation combining and superseding the existing Directives 90/385/EEC and 93/42/EEC. An official proposal is envisaged for end of September 2012.
- A proposal for an In-vitro-Diagnostic Medical Devices Regulation.

Based on the New Approach, rules relating to the safety and performance of medical devices were harmonised in the EU in the 1990s. The proposal of the new Medical Devices Regulation is also based on the New Approach with different modules for the conformity assessment procedures and a high level of responsibility required from the manufacturer. Manufacturers and Notified Bodies will be mainly responsible in the pre-market phase and for market access. Competent Authorities will be responsible for market surveillance, vigilance and clinical investigations. Compared with the 25 articles of the Directive 93/42/EEC the forthcoming Regulation is expected to have more than 90 articles. Some new proposals of the planned

Regulation are expected in the following fields:

1. Scope

- The scope will be extended: devices manufactured utilising non-viable tissues and cells of human origin will be included; certain invasive or implantable devices for aesthetic purposes will be included.
- The term “medical purpose” will be included in the definition.
- The issue of reprocessing of single-use medical devices will be included.

2. Economic operators

- Minimum requirements on distributors, importers, authorised representatives will be defined.
- Manufacturers must appoint a person for regulatory compliance.
- Concept of importer will be re-introduced with the consequence that importer must often become a manufacturer.

3. Traceability

- The marking of the medical device with its UDI (Unique Device Identification) shall be an additional labelling requirement – UDI is not an alternative to existing labelling requirements.
- UDI allows the unambiguous identification of a specific medical device on the market.
- Specific requirements for an UDI system will be part of the Regulation.
- Manufacturers have to mark their devices with a unique “barcode” allowing the automatic (machine readable) identification of the specific device.
- In parallel manufacturers have to feed a UDI Database with essential information about the marketed devices.
- Step-wise approach (starting with implants and class III devices).
- Requirements will be probably very similar to the FDA UDI Regulation which is based on a concept developed by GHTF (Global Harmonization Task Force) and IMDRF (International Medical Device Regulators Forum).

4. EUDAMED

EUDAMED shall become the central European Database for Medical Devices on:

- Clinical investigations
- registered products (in the future all devices have to be registered – except
- custom-made devices)
- Incident reports and field safety actions and trend reports, SAE (Serious
- Adverse Event) reports
- UDI

5. Notified Bodies

- Requirements on Designating Authorities
- Requirements on Notified Bodies
- New Designation process with involvement of a European Assessment
- Team. The Commission intends to become responsible for these
- assessments.

6. Conformity assessment

- Integrated in the Regulation is a mechanism for the scrutiny of certain
- conformity assessments: Notified Bodies shall inform the Commission and the
- MDEG (Medical Devices Expert Group or something similar) about new
- applications for conformity assessments for devices that fall into class III.
- Upon duly justified request of the MDEG, the Notified Body shall submit a
- summary of the preliminary conformity assessment prior issuing a certificate.
- The MDEG or the Commission may submit comments on the preliminary
- conformity assessment within 90 days after submission of the summary
- referred in the first sentence of this paragraph; the MDEG may agree on
- shortening the time period.
- The Notified Body shall give due consideration to any comments received in
- accordance with paragraph xx. It shall convey to the MDEG and the
- Commission an explanation as regards this consideration, including any due
- justification not to take account of the comment received, and its final decision
- regarding the conformity assessment in question.

7. Clinical investigations

- For the purpose of this Regulation "clinical investigation" means any
- systematic investigation in one or more human subjects undertaken to assess
- the safety and/or performance of the device.
- Only for "Approval studies" the Regulation provides concrete requirements
- for others – research or prototype testing studies not.
- EUDAMED will become (besides others) a central IT-platform for the
- application for clinical investigations.
- SAE reporting will be regulated.
- Centralised procedure for multinational studies.
- Sponsor may start a coordinated approval procedure.
- One application which will be transferred (via EUDAMED) to all concerned
- Competent Authorities.
- Sponsor may indicate the leading Competent Authority.

8. Better cooperation

Mandating a body at EU level with tasks such as:

- To ensure consistent application of the regulatory framework for medical devices;
- To improve the cooperation between national Competent Authorities and between them and the Commission;
- To ensure a better functioning of the internal market;
- To pool expertise.

47. Verify – Financial analysis

This appendix gives inside and further explanation on the financial consequences of implementing all given recommendations. Since MR P&S only exists since 2016, no historical financial data is available (Wouters, 2017). Therefore, information is based on interviews, observations, literature study and best practises. First of all the main assumptions are stated. After that, the financial analysis of implementing and working towards the recommended Quality Management design are divided in two. First of all, the one-off investment costs are described. These are the costs that are paid once and do not repeat. Thereafter the yearly costs and savings are described.

A. Assumptions

Hourly wages

For confidentiality purpose, the hourly wages per employee are generalised in negotiation with the quality manager of MR P&S:

- CEO € 50 hourly wage
- Managers, advisors and consultants € 25 hourly wage
- Assistants and engineers € 15 hourly wage

Working days:

Furthermore, it is estimated a year contains 52 weeks of 5 days = 260 days a week. Minus (public) holidays or illness, it is assumed a total working year contains 200 working days.

Yearly purchases

The exact yearly spending of MR P&S is not clarified (Wouters, 2017)(Salomons, 2017). Based on observation, the total expenditures for MR P&S are assumed to be approximately €300.000 a year.

Yearly revenue

The exact yearly revenue of MR P&S is not clarified (Wouters, 2017)(Salomons, 2017). MR Holding had an estimated consolidated revenue of €3.000.000 in 2016 (Wouters, 2017). The Holding has five subsidiaries besides MR P&S. For this reason, the estimated yearly revenue of the Holing can be divided by six to compute the revenue of all individual subsidiaries. This is not completely reliable since all companies have different revenue models, and fluctuate in revenue since they exist for less than a year. Nevertheless, the yearly revenue of MR P&S is estimated on: €3.000.000 / 6 = €500.000 a year.

ISO certification

For this financial analysis it is assumed that the recommendations will be fully implemented and integrated, and the complete ISO certificate is obtained by MR P&S.

B. One-off investment costs

Costs of conducting QMS material

Invested hours in developing strategy, processes and work instructions

The direct costs of hiring the authors to fulfil and implement the documentation of this research are approximately:

→ 2 interns x 4 months x €250 montly wage = €2.000

Hours invested by employees who were involved in conducting the Quality Management System

Interviews:

▪ CEO, Michel Italiaander	7 hours x €50 hourly wage	= € 350
▪ General manager, Hani Hayawi	9 hours x €25 hourly wage	= € 225
▪ Assistant manager, Salam Almujayyaz	4 hours x €25 hourly wage	= € 100
▪ Financial manager, Dennis Wouters	3 hours x €25 hourly wage	= € 75
▪ Quality manager, Schelte Post	15 hours x €25 hourly wage	= € 375
▪ Purchase manager, Paul Salomons	6 hours x €25 hourly wage	= € 150
▪ Logistic manager, Johan Klerx	3 hours x €25 hourly wage	= € 75
▪ Logistic assistant, Joris Vermeegen	3 hours x €15 hourly wage	= € 45
▪ RF engineer, Rudi de Roon	2 hours x €15 hourly wage	= € 30
▪ Business advisor, Rense Vos	2 hours x €25 hourly wage	= € 50
▪ Philips consultant, Frans Rosbak	1 hour x €25 hourly wage	= € 25
	→ Total costs	= €1.500

Consultations:

▪ CEO, Michel Italiaander	4 hours x €50 hourly wage	= €200
▪ General manager, Hani Hayawi	4 hours x €25 hourly wage	= €100
▪ Quality manager, Schelte Post	22 hours x €25 hourly wage	= €550
	→ Total costs	= €750

Pilots:

▪ Purchase manager, Paul Salomons	4 hours x €50 hourly wage	= €200
▪ Logistic manager, Johan Klerx	1 hour x €25 hourly wage	= € 25
	→ Total costs	= €225

Total cost of conducting QMS material investment costs	
Invested hours in developing strategy, processes and work instructions	€2.000
Hours of employees involved in conducting Quality Management System:	
- Interviews	€ 1.500
- Consolations	€ 750
- Pilot	€ 225
Total cost of conducting QMS	€ 3.975

Costs of implementing all measures in Exact

Hours equipping and filling fields within Exact

Based on interviews it is recommended that the logistic assistant is responsible to equip and filling in the recommended field within Exacts. He will take this responsibility, since he already has experience in equipping Exact (Vermeegen, 2017)(Italiaander, 2017)(Post, 2017). In the opinion of the logistic assistant, it would take approximately two months (Vermeegen, 2017). Therefore is assumed uit will take 8 hours a day x 5 days a week x 8 weeks = 320 hours.

A list of all measures that should be taken to equip Exact is included in the Exact Action Plan in appendix 48. When the logistic assistant needs support, it is recommended to contact The Computer Company, since MR P&S has an agreement with this organisation for supporting activities regarding Exact. Therefore, this activity does not include extra costs (Wouters, 2017).
→ Logistic assistant, Joris Vermeegen 320 hours x €15 hourly wage = €4.800

Hours equipping the Barcode scanner to connect with Exact

Since MR P&S already has a barcode scanner, no purchase costs are involved to order the scanner. The IT-manager already equipped the barcode scanner with information in Exact for the cycle counting process (Salomons, 2017). For this reason, the assumption is made that he is able to link the Barcode scanner to Exact, for efficiency of the recommended measures within the inbound and outbound process.
→ IT manager, Niels Sloesen 8 hours x €25 hourly wage = €200

Total costs of implementing all measures in Exact	
Hours equipping and filling fields within Exact	€4.800
Hours equipping the Barcode scanner to connect with Exact	€ 200
Total cost of implementing Exact	€5.000

Costs of implementing the recommended Kanban system

Hours equipping inventory with Kanban units and visual controls

To implement Kanban, a lot of actions are required as visually represented in appendix 49. It is assumed these actions will take approximately:

▪ General manager, Hani Hayawi	16 hours x €25 hourly wage	= € 400
▪ Assistant manager, Salam Almujayyaz	16 hours x €25 hourly wage	= € 400
▪ Logistic manager, Johan Klerx	16 hours x €25 hourly wage	= € 400
▪ Purchase manager, Paul Salomons	30 hours x €25 hourly wage	= € 750
▪ Logistic assistant, Joris Vermeegen	36 hours x €15 hourly wage	= € 540
	→ Total costs	= €2.490

Costs Kanban units & visual controls

It is assumed the direct costs of purchasing Kanban units and visual controls will cost €0,20 per batch of component. Therefore, the total costs are assumed as:
→ 20.000 components x 2 Kanban bins x cost per visual control (€0,20) = €8.000

Total costs of implementing Kanban	
Hours equipping inventory with Kanban units and visual controls	€ 2.490
Costs Kanban units & visual controls	€ 8.000
Total cost of implementing Kanban	€10.490

Costs Tablet

Purchase Tablet

In chapter 5 it is recommended to use a tablet to register the monitor information in Exact during the inbound process. Based on consulting different service providers (Bol.com, Kieskeurig, Apple, Coolblue) the costs of a tablet vary between €22,99 and €3.649. Since the costs of purchasing a tablet vary enormously, the "Consumentenbond" is consulted. This is an independent comparison website which states the 5 best tablets vary in price between €649 and €769 (Consumentenbond, 2017).

On average, a top five tablet costs: (649+660+749+769+720)/5 = €709,40.
→ Therefore can be assumed a reliable tablet can be bought for ≈ €709

Hours equipping Tablet to connect with Exact

Observations and interviews show, Exact is an online program where you can log in to with Internet connection (Post, 2017).
→ Therefore, no costs are included to equip the tablet to link with Exact.

Total costs of tablet	
Purchase Tablet	€ 709
Hours equipping Tablet to connect with Exact	€ 0
Total cost of implementing Tablet	€ 709

Costs of security cameras

Purchase security cameras

Based on consulting different service providers (Bol.com, Kieskeurig, Coolblue) the costs of a security camera vary between €4,95 and €6.260,89. Since this varies enormously, the website "Kieskeuring.nl", an independent comparison website, is consulted to indicate the price of the 5 best-tested security cameras. According to Kieskeuring, these security cameras vary in price between €19,99 and €115 (Kieskeuring, 2017).

The highest price of these 5 security cameras is assumed to be a reasonable price for MR P&S, since it has to protect a lot of (customer) property. On the other hand, it only has to film a relatively small amount of surface: the workplace (96 m^2) and the inventory (484 m^2).
→ Therefore can be assumed the security cameras will approximately cost 2 x €115 = €230

Hours installing security cameras

According to the specifications of the five best-tested security cameras, they are all easily installed within the room and viewable when you login to the only software (Kieskeuring, 2017). It can be assumed this would be the case for MR P&S as well. For this reason, it is estimated the installing of the security cameras would cost approximately one hour.
→ Logistic manager, Johan Klerx 1 hours x €25 hourly wage = €25

Hours to write a protocol of "cameras at work"

As recommended in paragraph 6.1, MR P&S is obligated to write a protocol "cameras at work" to describe the rights of employees concerning the recorded data (Hendriks & Jameas Legal Translations, 2015). It is recommended to give the quality assistant, Amber Janssen, this responsibility since she has experience in technical writing and legal regulations (Post, 2017). It is assumed this will take approximately 8 hours of work.
→ Quality assistant, Amber Janssen 8 hours x €15 hourly wage = €120

Total costs of security camera	
Purchase security camera	€ 230
Hours installing security camera	€ 25
Hours to write a protocol of "cameras at work"	€ 120
Total cost of security cameras	€ 375

Setup of a non-disclosure agreement

In chapter 4 it is recommended to send a non-disclosure agreement. This is not required by ISO but a preference of MR P&S and its customer (Post, 2017)(Rosbak, 2017). The juridical analysis revealed it is important that an NDA is set up properly to avoid information is transmitted to third parties (Brownell, n.a.). Therefore, it is recommended to hire a professional jurist to set up the NDA, instead of sending the one established in the Design phase of this research. It is assumed the CEO, quality manager and purchase manager are included within a first consultation meeting with the jurist. Literature study revealed the hourly fee of a jurist is in general between €80 and €150 an hour (De HBO Jurist, 2015) (Nationale Advies Balie, 2017). Therefore, the hourly fee is assumed to be approximately (80+150)/2= €115 for one hour discussion and two hours to conduct the non-disclosure agreement.

▪ CEO, Michel Italiaander	1 hours x €50 hourly wages	= € 50
▪ Quality Manager, Schelte Post	1 hours x €25 hourly wages	= € 25
▪ Purchase manager, Paul Salomons	1 hours x €25 hourly wages	= € 25
▪ Jurist	3 hours x €115 hourly fee	= €345
	→ Total costs	= €445

Costs of ISO certificate

ISO certification

MR P&S started with the setup of a Quality Management System according to ISO 13485 (Post, 2017). The shared Business Office already made a lot of documentation, but this is partly incomplete and out-dated due to organisation growth. Optimising all policies, processes and records is very time-consuming. As described in the Business context, due to the limited timescale of this research, this Bachelor thesis only focuses on the optimisation and implementation of the purchasing and traceability processes. As visually represented in the ISO progress diagram in appendix 2, purchasing and traceability are two topics of the in total 23 topics of the ISO 13485 requirements. Therefore, the costs of the certification are divided. MR P&S plans to get ISO certificated by the Notified body Lloyd's Register RQA. This will cost €10.000 in total (Post, 2017). Therefore, the total costs of ISO concerning traceability and purchasing are assumed as:
→ €10.000 / 23 topics x 2 topics = €434,78 ≈ €435

Hours spend during official ISO audit

Observation showed that during the official ISO audit, several employees are involved to guide de visit, discuss, and answer questions:

▪ CEO, Michel Italiaander	1 hours x €50 hourly wage	= €50
▪ General manager, Hani Hayawi	1 hours x €25 hourly wage	= €25
▪ Quality manager, Schelte Post	8 hours x €25 hourly wage	= €200
▪ Quality assistant, Amber Janssen	8 hours x €15 hourly wage	= €120
	Total costs	= €395

→ Therefore, the total costs the official ISO audit concerning traceability and purchasing are assumed as: €395 / 23 topics x 2 topics = €34,35 ≈ €35

Total of ISO certificate	
ISO certification	€435
Hours spend during official ISO audit	€ 35
Total cost of ISO certificate	€470

Costs marketing communication

Setting up strategic marketing plan

Currently, the shared Business Office of MR P&S does not include a marketing manager. Therefore, another manager should take the responsibility to set up a strategic marketing plan, or the organisation should hire a marketing manager. As described, the costs to find and train new employees are disregarded within this thesis.

However, the setup of a strategic marketing plan is included within the analysis, since it is an important recommendation to answer the central research question. It is an extensive research and therefore assumed that it will take approximately a time-period of the same length as the time invested to write this Bachelor thesis. Therefore, 15 working weeks of 40 hours are assumed as the costs to set up a strategic marketing plan. It is assumed the manager would inform and discuss with the CEO and General manager, as much as the authors of this research did with the CEO en Quality manager.

▪ CEO, Michel Italiaander	11 hours x €50 hourly wages	= € 550
▪ General manager, Hani Hayawi	37 hours x €25 hourly wages	= € 925
▪ Marketing Manager	600 hours x €25 hourly wages	= €15.000
	→ Total costs	= €16.475

Executing the strategic marketing plan

The executing of a strategic marketing plan will include costs as well, but since it is not an action to answer the central research question of this Bachelor thesis, the costs are out of scope. Besides, the costs of executing an internal and external strategic marketing plan varies largely depending on the chosen marketing and communication materials (Alsem, 2017). It would therefore not be reliable to take this into account within this Bachelor thesis, without actually setting up the marketing plan.

Total cost marketing communication	
Setting up strategic marketing plan	€16.475
Executing strategic marketing plan	Out of scope
Total cost of Marketing communication	€16.475

Total one-off investment costs

To conclude, the total of all one-off investment costs are included in the following table:

Total one-off investment costs	
Costs to conduct QMS material	€ 3.975
Costs of implementing Exact	€ 5.000
Costs of implementing Kanban	€10.490
Costs of tablet	€ 709
Costs of security cameras	€ 375
Costs to conduct non-disclosure agreement	€ 470
Costs of ISO certificate	€ 830
Costs marking communication plan	€16.475
Total	€38.324

B. Yearly cost

This paragraph describes the extra costs MR P&S will approximately make on a yearly base, after implementing the recommended designs.

Extra measures within purchase processes

Purchase with Exact

The recommended measures concerning the purchase process include extra activities such as a deliberate supplier selection, recording of measures and sending documents to the supplier (Supplier assessment, purchase terms and conditions, and an NDA). This takes extra time per day. On the other hand, the purchase manager only has to register the purchase information in one database, instead of several locations. In addition, with the implementation of Kanban, there is no confusion about the trigger to start purchasing anymore. Both Exact as the Kanban inventory create a trigger to start purchasing. The purchase manager does not need to search for the specific product to purchase, and the date and quantity the order needs to be placed. Therefore can be

assumed it takes approximately 10 minutes longer a day to execute the new designed purchasing process. Therefore the total extra hours a year concerning the purchase process are estimated as:
10 minutes / 60 minutes * 200 working days a year = 10 hours a year.
→ Purchase manager, Paul Salomons 10 hours x €25 hourly wage = €250

Purchase without Exact
When the recommended measures in the purchase process are executed without Exact, the purchasing manager should share information to several employees; CEO, general manager, logistic manager, engineers. There is no hard drive where every shareholder can see the information placed during a purchase order. To share information, the purchase manager needs to register all information in several different hard drive folders, print it and save it in multiple archive ring binders. However, with the implementation of Kanban, there is no confusion about the trigger to start purchasing anymore. The purchase manager does not need to search for the specific product to purchase, and the date and quantity the order needs to be placed. It can be assumed it takes approximately 1 hour longer a day to execute the new designed purchasing process without Exact (Salomons, 2017).

Therefore the total yearly hours of the measures within the purchasing process are estimated as:
1 hour * 200 working days a year = 200 hours a year.
→ Purchase manager, Paul Salomons 200 hours x €25 hourly wage = €5.000

Saving implementing Exact purchasing process:
→ Therefore can be concluded: The difference between the purchase process when Exact is fully integrated differs approximately €5.000 – €250 = €4.750 a year.

Extra measures within inbound processes
Monitoring with Exact
According to the pilot it took approximately 3 minutes a day extra to execute the inbound process measures for purchasing and traceability purpose: check the arrived orders with the stated monitor information and record in Excel. In addition to the activities of the pilot, the logistic manager also needs to update the inventory levels and attach batch numbers to the components. Therefore, the assumed time is extended in comparison to the pilot. However, it is recommended to record the information on a tablet in Exact instead of on paper, and using a barcode scanner to increase the registered levels of inventory. This will speed up the process. For this reason can be assumed it would still take approximately 3 minutes longer a day to execute the new designed inbound process. Therefore the total yearly hours of the measures within the inbound process are estimated as 3 minutes / 60 minutes * 200 working days a year = 10 hours a year extra for the logistic manager.

In addition, it recommended within paragraph 4.2, to carry out random inspections to check if the quality of delivered products match the specific product specifications. It is recommended to let engineers perform this test, since they have the best knowledge of components and FRUs (Post, 2017). It is estimated this will take approximately 2 hours a year for an engineer.

▪ Logistic manager, Johan Klerx	10 hours x €25 hourly wage	= €250
▪ Engineer	2 hours x €15 hourly wages	= € 30
	→ Total costs	= €280

Monitoring without Exact
According to the pilot it took approximately 3 extra minutes a day to execute the inbound process measures for purchasing and traceability purpose: check the arrived orders with the stated monitor information and record in Excel. Besides, batch numbers need to be attached to the components and the inventory levels need to be updated manually. For this reason can be assumed it would take approximately 3 extra minutes a day to execute the new designed inbound process without Exact. Therefore the total yearly hours of the measures within the inbound process are estimated as: (3 + 3 minutes) / 60 minutes x 200 working days a year = 20 hours a year

The extra costs to carry out random inspections to check if the quality of delivered products match the specific product specifications are estimated as equal to in time than with Exact. For this reason, it is estimated this will take approximately 2 hours a year for an engineer.

▪ Logistic manager, Johan Klerx	20 hours x €25 hourly wage	= €500
▪ Engineer	2 hours x €15 hourly wages	= € 30
	→ Total costs	= €530

Saving implementing Exact inbound process
→ Therefore can be concluded: The difference between the inbound process with or without Exact differs approximately €530 – €280 = €250 a year.

Extra measures within repair and production processes
Registration step
According to the pilot it took approximately 3 minutes extra a day to execute the repair process measures for traceability purpose. The pilot is executed without Exact, but it is expected it would take an equally amount of time. For this reason, the total yearly hours of the measures within the repair process are estimated as: 3 minutes / 60 minutes x 200 working days a year = 10 hours a year. Currently, MR P&S has three engineers employed. When the organisation grows tenfold, these costs will grow, but this is out of scope and therefore excluded from this report.

▪ Engineer, Damase Birekeraho	10 hours x €15 hourly wages	= €150
▪ Engineer, Rudy van Roon	10 hours x €15 hourly wages	= €150
▪ Engineer, Athreer Alsabiry	10 hours x €15 hourly wages	= €150
	→ Total costs	= €450

Use Kanban
When the first Kanban unit is empty, the second one will be used. As explained in the Kanban manual in appendix 49, the engineers use the components from the fist bin. When the first bin is empty, it is exchanged with the second bin. The engineer will place the reorder card in the to-order bin. The purchase manager collects the to-order bin with all reorder cards and starts the purchasing process. These cards are a visual check moment of the triggers Exact generates to start purchasing. It is assumed that working with a Kanban system does not cause extra time for the employees. In the current situation, the bins also have to be changed and filled.

Extra registration measures within outbound processes
Outbound with Exact
According to the pilot it took approximately 3 minutes extra a day to execute the outbound process measures for traceability. Within the pilot, the logistic manager used an Excel format to record the unique article code of the FRU, recording the sending date, location and track-and-trace code and updating the stock levels. When Exact is implemented and the logistic manager can use a barcode scanner, therefore it is assumed it will only cost 2 minutes extra a day.

Therefore the total yearly hours of the measures within the outbound process are estimated as: 2 minutes / 60 minutes * 200 working days a year = 6,67 hours a year. For this reason, a total yearly cost of:
→ Logistic manager, Johan Klerx 6,67 hours x €25 hourly wage = €166,67 ≈ €167

Outbound without Exact
According to the pilot it took approximately 3 minutes extra a day to execute the outbound process measures for traceability. This was without Exact and scanner. Therefore the total yearly hours of the measures within the outbound process are estimated as: 3 minutes / 60 minutes * 200 working days a year = 10 hours a year. For this reason, a total yearly cost of:
→ Logistic manager, Johan Klerx 10 hours x €25 hourly wage = €250

Saving implementing Exact outbound process:
→ Therefore can be concluded: The difference between an evaluation when Exact is fully integrated differs approximately €250 – €167 = €83 a year.

Extra cost made to evaluate suppliers
The total list of suppliers consists out of more than 150 suppliers (Salomons, 2017). For this analysis it is assumed the list includes 160 suppliers. As recommended in chapter 4, not every supplier needs to be evaluated. For this financial analysis is assumed the total quantity of suppliers per risk rating will be:

▪ Z:	160 suppliers x 25% x 0 evaluations a year	= 0 evaluations
▪ Y:	160 suppliers x 25% x 1 evaluations a year	= 40 evaluations
▪ X:	160 suppliers x 25% x 2 evaluations a year	= 80 evaluations
▪ W:	160 suppliers x 25% x 4 evaluations a year	= 160 evaluations
	Total	= 280 evaluations

With Exact
When Exact is implemented, it will take approximately 1 minute to reveal the monitor results per supplier. In addition, the pilot revealed it took approximately 5 minutes per supplier to fill in the supplier evaluation system. 6 minutes is 10% of an hour, therefore the following costs are assumed:
→ Purchase manager, Paul Salomons 280 evaluations x €25 hourly wages x 10% = €700

Without Exact
The pilot resulted it took approximately 45 minutes to reveal the monitor information of one supplier recorded over a time aspect of one month. It depends on the quantity of the deliveries and the period since the last evaluation how long it will take to connect purchase with inbound information. Nevertheless, an average time period of 45 minutes is taken into account.
In addition, the pilot revealed it took approximately 5 minutes per supplier to fill in the supplier evaluation system.
There is decided the total time per evaluation is assumed as 45+5 = 50 minutes.
→ Purchase manager, Paul Salomons 280 evaluations x €25 hourly wages / 60 x 50 = €5.833,33
→ Therefore, the total evaluation costs are stated at ≈ €5.833

Saving implementing Exact supplier evaluation process:
→ Therefore can be concluded: The difference between an evaluation when Exact is fully integrated differs approximately €5.833 – €700 = €5.133 a year.

Extra costs to review quantity of Kanban units and Safety Stock levels
As recommended in the Kanban manual in appendix 49, the quantity per Kanban unit should be reviewed regularly. Also the Safety stock levels need to be reviewed periodically. It is recommended to review all products at least ones a year and products from risk-full suppliers monthly. A risk-full supplier delivers a product, which will soon be taken out of production or where the supplier is unreliable.

It is recommended to review the critical levels of these components and FRUs monthly. It is assumed this will take approximately one hour a month. It is assumed the yearly discussion will take 16 hours. As represented in the Kanban procedure, see in appendix 38, it is recommended to make the general and logistic manager responsible for these monthly and yearly activities.

▪ General manager, Hani Hayawi	1 hours x 11 months x €25 hourly wage	= €	275
▪ General manager, Hani Hayawi	16 hours x €25 hourly wage	= €	400
▪ Purchase manager, Paul Salomons	1 hours x 11 months x €25 hourly wage	= €	275
▪ Purchase manager, Paul Salomons	16 hours x €25 hourly wage	= €	400
	→ Total costs	= €1.350	

Extra cost made to train all employees
As recommended in paragraph 6.2, it is essential to involve and train everyone in the implementing of a new process design, during all phases of change: unfreeze, move and freeze. Besides, the Refreeze phase is temporary in a continually improving environment. However, it is recommended to freeze before moving on to the next phase of unfreezing. Freezing ensures employees are not confused of the tasks they should do, since the tasks became standard procedures (Barron, 2015). Therefore, the training of employees by presentations, meetings, master classes and workshops are assumed as a yearly costs for the organisation. The costs for the activities are stated as at least 10 hours per employee for (providing) trainings.

▪ CEO	1 employee x 10 hours x €50 hourly wage	= € 500
▪ Managers, advisors and consultants	11 employees x 10 hours x €25 hourly wage	= €2.750
▪ Assistants and engineers	7 employees x 10 hours x €15 hourly wage	= €1.050
	→ Total costs	= €4.300

Internal audits
As described in paragraph 6.2, ISO states that the organisation shall implement internal audits (NEN & ISO, 2016). It is recommended to introduce these internal audits as a safeguarding method to check if employees are working as they should be working, and as a method to stimulate continual improvement of the processes. It is recommended to give the quality manager and his assistant the responsibilities to execute the internal audits. It is assumed this will take approximately 30 hours a year. There are no extra costs involved for the other employees since the audits are based on their way of working. Feedback will be provided during the trainings.

▪ Quality manager, Schelte Post	30 hours x €25 hourly wage	= € 750
▪ Quality assistant, Amber Janssen	30 hours x €15 hourly wage	= € 450
	→ Total costs	= €1.200

ISO audits
When MR P&S achieves the ISO 13485 certificate, every year an external audit will take place by the Notified body to evaluate the performance of MR P&S (Post, 2017). For the first three years, the costs of visitations are already included in the bundle of €10.000, which is included in the one-off investment costs (Post, 2017). However, it is assumed the same employees will attend the audits to guide, discuss, and answer questions:

▪ CEO, Michel Italiaander	1 hours x €50 hourly wage	= €50
▪ General manager, Hani Hayawi	1 hours x €25 hourly wage	= €25
▪ Quality manager, Schelte Post	8 hours x €25 hourly wage	= €200
▪ Quality assistant, Amber Janssen	8 hours x €15 hourly wage	= €120
	Total costs	= €395

As described before, purchasing and traceability are two topics of the in total 23 topics of the ISO 13485 requirements. Therefore, the costs of the attending are divided as well.
→ Therefore, the total costs the official ISO audit are assumed as: €395 / 23 x 2 = €34,35 ≈ €35

Total yearly costs
To conclude, the total yearly costs are included in the following table:

Total yearly costs	With Exact	Without Exact	Difference
Measures purchase processes	€ 250	€ 5.000	€ 4.750
Measures inbound processes	€ 280	€ 530	€ 250
Measures repair and production processes	€ 450	€ 450	-
Measures outbound processes	€ 167	€ 250	€ 83
Extra cost made to evaluate suppliers	€ 700	€ 5.833	€ 5.133
Extra costs to review quantity critical stock levels	€ 1.350	€ 1.350	-
Extra cost made to train all employees	€ 4.300	€ 4.300	-
Internal audits	€ 1.200	€ 1.200	-
ISO audits	€ 35	€ 35	-
Total	€ 8.732	€ 18.948	€10.216

When implementing the recommendations it is a priority to implement Exact on a short time-period, since it approximately saves €10.216 in comparison of working with the interim recommendations.

C. Yearly revenues/savings
This paragraph describes the extra revenues and savings MR P&S will approximately make on a yearly base, after implementing the recommended designs.

Overall
As described in paragraph 6.3 not all revenues and savings are concrete amounts, these are called social investments. It is impossible to calculate the benefits of social investments, even though they are definitely there. The possibility to attract more customers is an opportunity when implementing the strategic marketing plan. Since this plan is not conducted within this research, the extra revenue of new customers is out of scope.

When the recommendations concerning Kanban and Safety Stock are implemented properly, the inventory levels will be accurate. The most important yearly revenue of an optimal inventory is that MR P&S is able to reach its core business to deliver within 24 hours. This will increase customer satisfaction. This is crucial when initiating to grow (Hayawi & Almujayyaz, 2017). Besides, a proper inventory control also improves the cash flow of MR P&S. When inventory is send to the customer, it eventually turns back into cash. When MR P&S delivers in a shorter time-period, the customer will pay in a shorter time-period as well (Thacker, n.a.) (Wouters, 2017) (Schoeren, 2017)

Negotiation discounts
When the organisation implements the recommendations in the purchase process, the total list of suppliers will shrink. Therefore, it is very likely the purchase manager is more able to negotiate with its suppliers (Salomons, 2017). A decrease in costs can be achieved by volume discount. This is the discount given to a customer who buys a large quantity of goods. Based on literature study and interviews can be assumed the discount due to a strong negotiation position varies between 15 and 20 percent of the total spending (Sonotel, n.a.) (Business Link UK, 2009) (Bean, 2017) (Salomons, 2017). Since it is a time-consuming process to shrink the list of suppliers, it is assumed MR P&S cannot reach the negotiation goal of 20 percent immediately. Therefore, the average volume discount is assumed to be approximately 5 per cent compared to current expenditures. The exact yearly spending of MR P&S is not clarified, since the organisation exists for less than a year. Based on observation, the total expenditures for MR P&S are assumed to be approximately €300.000 a year. Therefore, the total negotiation discount can be assumed as:
→ €300.000 expensed x 5% discount = €15.000 a year.

Besides, negotiating with suppliers does not necessarily mean getting the product for the cheapest possible price. It is also possible to achieve benefits by means of social investments, such as the possibility to negotiate other factors such as delivery times, payment terms, or the quality of the goods (Gelderman & Albronda, 2013) (Italiaander, 2017). These benefits are included in the social investments.

Timesaving
The pilot revealed some recommendations take longer than in the current situation, but they are necessary to achieve the ISO certificate. For other activities the time involved breaks even. When the extra time of a particular activity, is completely or partly reduced by a time saving, it is already deducted in the previous paragraph, yearly costs. Other activities result in timesaving.

For the purchase manager and engineers this is a social investment. It creates efficiency; an order can be placed earlier. Currently, receiving an internal approval takes approximately three days (Salomons, 2017). This does not mean that the purchase manager has to halt his activities for three days, till he gets the approval to order. Instead, he can complete other activities. This also applies to the engineers. At the moment, 47 components are out of stock. This results in a waiting queue: 16 make-FRUs are waiting to be produced, because the required components are out of stock (Weekly meeting, 2017). However, this does not mean that the employees are literally waiting till the components are back in stock again. They can complete other activities or repair and produce other FRUs.

<u>Budgets</u>
In contrast, for the CEO it literally saves times. When implementing the recommendation to work with budgets, the management layer does not have to give its approval for every purchase order. The time needed to consider and finally give the internal approval after implementation can be spend on strategic activities instead. In the current situation, it is assumed it takes the CEO approximately 1 hour a week to give internal approval to every order. When the organisation works with budgets this will reduce the time spend by the CEO to give approval with approximately 90%. Therefore; 90% x 1 hour a week / 5 work days a week x 200 days a year = 36 hours timesaving. This can also be expressed in savings:
→ CEO, Michel Italiaander 36 hours x €50 hourly wage = €1.800

<u>Automatic inventory levels in Exact</u>
It does not seem to create a time saving for the engineers to keep records within Exact, but it definitely is a time saving for the logistic manager. When Exact is fully integrated, the logistic manager does not need to update the inventory stock levels manually anymore, because the levels will decrease automatically when scanning the products during the inbound and outbound process. When the engineers record the used components during a reparation or production it will also automatically decrease the stock level of components and finally increase the levels of FRUs in stock.

When Exact is not integrated, the logistic manager needs to updated Excel documents of the levels of inventory every day, based on the inbound registrations, reparation and production forms and the outbound registrations. Observations and interviews reveal this takes approximately half an hour a day. For this reason, a total yearly saving of: 0,5 hours x 200 working days a year = 100 hours a year is assumed.
→ Logistic manager, Johan Klerx 100 hours x €25 hourly wage = €2.500

Total yearly revenues/savings:
To conclude, the total yearly revenues/savings are included in the following table:

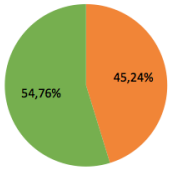
Total cost of conducting QMS material investment costs	
Negotiation discounts	€15.00
Time savings:	
- Budgets	€1.800
- Automatic inventory levels in Exact	€2.500
Total cost of conducting QMS	€19.300

D. Return on investment

The Return on investment (ROI) is calculated:
→ (€19.300 saving – €8.732 costs) / €8.732 costs x 100% = 121, 026% ≈ 121%

ROI is 121%

Revenues/sav	€	19.300,00	100,00%
Cost	€	8.732,00	45,24%
Profit	€	10.568,00	54,76%



Cost

Discription		Value in €
Measures purchase processes	€	250,00
Measures inbound processes	€	280,00
Measures repair and production processes	€	450,00
Measures outbound processes	€	167,00
Extra cost made to evaluate suppliers	€	700,00
Extra costs to review quantity critical stock	€	1.350,00
Extra cost made to train all employees	€	4.300,00
Internal audits	€	1.200,00
ISO audits	€	35,00
Total yearly costs	€	8.732,00

Revenues/savings

Discription		Value in €
Negotiation discounts	€	15.000,00
Timesaving: budgets	€	1.800,00
Timesaving: automatic inventory levels Exact	€	2.500,00
Total yearly revenues/savings	€	19.300,00

E. Return time

To calculate the return time of the one-off investment costs when all recommendations are implemented properly, the following formula is used:
→ Total one-off investment costs €38.324 / yearly profit €10.568 = 3,626 years ≈ 4 years.

48. Recommendations – Action plan Exact

This appendix reveals all actions MR P&S should take to equip Exact. During the Optimise phase several recommendations concerning the implementation revealed, these are included in this action plan.

Exact Registraties (P&S)	Al in Exact?	Complexiteit/prioriteit
EENMALIG		
Per FRU + Component dient de volgende statische informatie afleesbaar te zijn:		
Voorraadlevels van alle FRUs + componenten	Ja	
Risicocategorisering	Nee, vrij makkelijk mogelijk d.m.v. vrije velden	
Locatie in het magazijn	Ja	
Per Leverancier dient de volgende statische informatie afleesbaar te zijn:		
Risicocategorisering (gebaseerd op de hoogste product risico categorie)	Nee, zou wel mogelijk moeten zijn verwacht Joris	
PURCHASING		
Inkoop manager dient tijdens het inkoopproces het volgende in te kunnen vullen:		
Het ordernummer	Ja, want Exact stelt deze zelf samen	
Wie heeft deze order geplaatst	Ja, wordt geregistreerd vanuit de inlognaam	
Bij welke leverancier is deze order geplaatst? (nieuwe leverancier, gaat leverancierslijst omhoog)	Ja	
Welke componenten/Buy-FRUs (12NCs) er gekocht zijn en hoeveel	Ja	
Houdt rekening met de technische specs, die zijn te zien in de voorraadregistratie	nee, deze staan er nog niet in. Is wel mogelijk om ze toe te voegen	
Voor wie je het koopt, wie de eigenaar is	Wel voor welk bedrijf d.m.v. ordernummer, maar niet voor welke eigenaar (philips of MR P&S) Zou mogelijk moeten zijn doc	
De verwachte leverdatum	Ja	
De bevestigde leverdatum	Nee, zou wel moeten kunnen	
INBOUND		
De volgende informatie dient vast te hangen aan het ordernummer, zodat de inkoopinformatie hieraan gekoppeld is. Achteraf hoor je dan naast het bovenstaande, ook het volgende te kunnen zien per ordernummer:		
Welke producten en hoeveel er binnen zijn gekomen (voorraadlevel omhoog)	Ja	
De artikelcode (FRU) of batchcode (componenten)	Optie is er wel, maar niet in gebruik	
Wie deze order in ontvangst heeft genomen en checkt	Het is ergens terug te halen, maar zou handiger moeten kunnen	
Wanneer er problemen zijn omtrent de werkelijke leverdatum	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Wanneer er problemen zijn omtrent packing	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Wanneer er problemen zijn omtrent warning signs	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Of er damaged items ontvangen zijn	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Wanneer er problemen zijn omtrent needed information (packaging slip etc.)	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Legt ze op de goede locatie (weet je omdat dit in de voorraadregistratie staat)	ja	
REPAIR		
Eenmalig per batch componenten:		
Startdatum batch componenten: Bij begin van nieuwe batch	Geen idee	
Einddatum batch componenten: Na het gebruik van de laatste component van een bepaalde batch	Geen idee	
Momenteel vullen de engineers tijdens de reparatie vul je per 12NC + artikelcode van de FRU vul je het volgende in, in een Excel bestaand. Er wordt aangeraden om op wat langer termijn dit alles in Exact te registreren om achteraf te kunnen zien wat er aan dit soort FRU of deze specifieke FRU al eerder gerepareerd is:		
De startdatum van reparatie FRU	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
De einddatum van reparatie FRU	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Status	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Time spent	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Reported problem	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Date benchtest	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Benchtest performed by	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Results benchtest	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Implemented solution	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
12 NC used components + number of used components (voorraadlevel gaat omlaag)	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
12 NC broken components + number of broken components (voorraadlevel gaat omlaag)	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Repaired by?	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Date systemtest	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Systemtest performed by	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Results systemtest	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Remarks	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	
Structural change needed	Lijkt Joris wel, zou nog goed uitgezocht moeten worden	

OUTBOUND		
Bij verzending dient het volgende te worden ingevuld:		
Welke producten (12NC) verzend je er? (voorraadlevel gaat omlaag)	Ja	
Welke artikelcode? (Zo weet je de Repair informatie van de verzonden FRU)	Zou moeten kunnen	
Wie verzend het?	Zou moeten kunnen	
Waarheen	Zou moeten kunnen	
Welke datum	Zou moeten kunnen	
Met welke vervoerder?	Zou moeten kunnen	
Ontvangstbevestiging?	Zou moeten kunnen	
SUPPLIER EVALUATION		
De risicocategorisering per leverancier (gebaseerd op de hoogste product risico categorie) staat in Exact en creëert de trigger naar de inkoper om desbetreffende leveranciers te gaan beoordelen. Naast dat je alle bovenstaande informatie kunt zien per order, dien je dit ook te kunnen filteren, om het voor één bepaalde leverancier kunt aflezen. Zodat je een periode kunt aanklikken om de volgende informatie over alle orders in deze periode van deze leverancier af te lezen:		
Of er een verschil is tussen de bevestigde verwachte + werkelijke leverdatum	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Hoeveel in getal?		
Hoeveel in percentage van totale periode?		
Of er er een verschil zit tussen de bestelde en geleverde hoeveelheid	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Hoeveel in getal?		
Hoeveel in percentage van totale periode?		
Of problemen zijn geweest bij orders omtrent packaging	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Hoeveel in getal?		
Hoeveel in percentage van totale periode?		
Of problemen zijn geweest bij orders omtrent warning signs	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Hoeveel in getal?		
Hoeveel in percentage van totale periode?		
Of problemen zijn geweest bij orders omtrent damaged items	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Hoeveel in getal?		
Hoeveel in percentage van totale periode?		
Of problemen zijn geweest bij orders omtrent needed information	Zou moeten kunnen over periode bij bepaalde leverancier. Orderhistorie, statistiek	
Hoeveel in getal?		
Hoeveel in percentage van totale periode?		
Vervolgens invullen van supplier evaluation. Optie 1:		
Excel uploaden gekoppeld aan de leverancier, zodat je achteraf alle beoordelingen kunt bekijken van één leverancier	Ja	
Vervolgens invullen van supplier evaluation. Optie 2:		
Naam van de beoordelaar	Weet Joris niet, hij verwacht dat dit niet handig toe te voegen is	
Welke leverancier je beoordeeld, zodat je achteraf alle beoordelingen kunt bekijken van één leverancier.	Weet Joris niet, hij verwacht dat dit niet handig toe te voegen is	
Periode van de beoordeling (over welke periode van monitoren gaat het)	Weet Joris niet, hij verwacht dat dit niet handig toe te voegen is	
Objectieve PIs worden automatisch ingevuld door de informatie hierboven	Weet Joris niet, hij verwacht dat dit niet handig toe te voegen is	
Antwoorden op de subjectieve PIs nog invullen	Weet Joris niet, hij verwacht dat dit niet handig toe te voegen is	
Eindoordeel aflezen	Weet Joris niet, hij verwacht dat dit niet handig toe te voegen is	
Follow-up noteren	Ja	

49. Recommendations – Action plan Kanban

Kanban – The implementation manual

Author: Niki van den Broek & Tamara Thielen
Published: 26-5-2017

Action plan

Strategy	Action	Responsible	Paragraph
Collect data	Decide how to make visual controls for every product	Logistic manager	1
Setting up two-bin system	Calculate the bin quantity of every product	Logistic manager + general manager	2
	Calculate the size of the storage space needed	Logistic manager	
	Equip the warehouse to store all products	Logistic assistant	
Cards	Make laminated cards to go into every bin	Logistic assistant	3
Using the Kanban	A reorder card is placed on the bottom of each bin.	Logistic assistant	
	Material is drawn from the first (or most accessible) bin only.	Engineers	
	When the first bin is empty, it is exchanged with the second bin.	Engineers	
	The reorder card is placed in a to-order bin	Engineers	
	At the end of the day the purchase manager collects the to-order bins	Purchase manager	
	The purchase procedure starts	Purchase manager	
	The reorder card is placed in a wait-for-arrival bin	Purchase manager	
	Material is then drawn from the second bin while waiting for receipt of the material on order.	Engineers	
	When the new material arrives, it is placed in the empty bin, and the reorder card is returned to its proper place in the bin.	Logistic manager/ assistant	
Updating	Updating the order quantity regularly	Logistic manager	4
	Updating the risk full-products weekly	Logistic manager + general manager	4

1. How to use visual controls:

Several visual controls can be used to separate different batches. The visual control depends on the product stored and the storage space. The following visual controls can be taken into consideration:

Two – bin:
Divide batches over different bins. Place the bins behind or above each other to ensure only the components in the first bin are used until it is empty. When a bin is empty, the Kanban card is placed in the "to-order-bin".

One – bin:
Put several batches together in one bin, but separate them by the use of a little wand as shown in the picture. When the first part of the bin is empty, the Kanban card should be placed in the "to-order-bin".

Levels:
Mark a certain level on a shelf by the use of tape or paint. When the pile of components reaches beneath this level, the Kanban card should be placed in the "to-order-bin".

Numbering:
Count the number of components. When the number of components reach below a certain amount, the Kanban card should be placed in the "to-order-bin". This is only possible with components which are stored in small amounts to ensure they are visually and quickly countable.

Pin:
Mark the pin with several levels. When the products around the pin reach below the determined level, the Kanban card should be placed in the "to-order-bin".

Racking:
Colour the racking. Store components on the rack and let them roll forward when the first product is used. When a red colour becomes visible, the Kanban card should be placed in the "to-order-bin".

Spots:
Colour several spots in the warehouse and store the components on these specific spots. When a component is used and a red spot is visible, the Kanban cards should be placed in the "to-order-bin".

Label:
Label the cable on the re-order point. When the cable is used past this label, the Kanban card should be placed in the "to-order-bin".

2. Calculate the bin quantity:

The "bin" quantity can be calculated by the use of several different formulas. The following is recommended:

$$\text{Amount per bin} = (\text{ADU} \times \text{LT}) \times (1 + \text{SS\%})$$

ADU = average (daily) use
LT = supplier lead time (in days)
SS% = desired safety stock percentage, expressed as a decimal (e.g. 30% =0.30)
Usually the SS is set on 30 to 50%

When calculating the bin quantity the following should be taken into account:

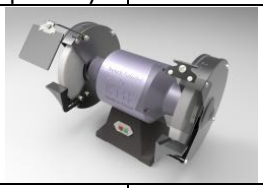
- Total budget to purchase and hold stock
- Time a product is still used in production
- Reliability of the supplier and his ability to deliver this component

3. Make laminated Kanban cards:

A Kanban card should be made to go into every bin. The Kanban cards should include the following information:

- Product name + 12NC code
- Supplier name
- Re-order quantity
- Lead time
- Location

Example 1:

MR P&S	
KANBAN CARD 1 of 2	
Part number	14613
Part Description	Smoke-shifter, left handed
Supplier	Acme Smoke-Shifter, LLC
Supplier ID	
Lead time	5 days
Reorder quantity	2
	
Location	Rack 1B3
Barcode	

MR Coils	
KANBAN CARD 1 of 2	
Part number	16790
Part Description	Connector
Supplier	Farnell
Supplier ID	
Lead time	7 days
Reorder quantity	7
	
Location	Rack 3A9
Barcode	

Template:

(organisation name)	
KANBAN CARD ___ of ___	
Part number	
Part Description	
Supplier	
Supplier ID	
Lead time	
Reorder quantity	
Location	
Barcode	

A Kanban card moves through the workflow. The team members can use the back of the card to record applicable metrics (e.g., start date, end date). This rich "card history" provides valuable information about the overall flow of work, a key health indicator of any Kanban system. Understanding the workflow not only identifies key bottlenecks before they significantly impact the system but also provides opportunities for continuous improvement. Accurately recording card metrics helps teams realize the full value of their Kanban system.

4. Updating the Kanban system:

The order quantities of all Kanban units should be recalculated at least once a year. A report of lead times of all components can be created by Exact. This report gives inside in the amount of products used over a period of time. The Kanban unit quantity should be updated at least once a year and new Visual Control Cards should be made.

Monthly a separate list with products, which are purchases at risk-full suppliers, is made. A risk-full supplier delivers a product which will probably soon be taken out of production or where the supplier is unreliable due to cash flow problems. The re-order quantities of these products are calculated monthly, and the safety stock levels are increased to cover for potential risks.

The "bin" quantity can be reviewed based on personal experience in combination with several different formulas. The following is recommended:

$$\text{Amount per bin} = (ADU \times LT) \times (1 + SS\%)$$

ADU = average (daily) use
LT = supplier lead time (in days)
SS% = desired safety stock percentage, expressed as a decimal (e.g. 30% =0.30)

Based on experience it can be decided to increase or decrease the SS% due to (un)forseen circumstances of the supplier, market, or planned repair or production projects.

Section

V

Practical framework

50. Practical framework - Interviews

During the research several interviews are held. Summaries of these interviews are included in the following appendix and are referred to by APA notations:

A. Hani Hayawi and Salam Almujayyaz (1 March 2017)

Interviewee: General manager and assistant general manager
Interviewer: Niki van den Broek and Tamara Thielen
Date: 1 March 2017
Time: 10.00-11.00
Interview Style: Structured interview

Hoofdproces MR P&S

Hani en Salam hebben tijdens het interview een generiek beeld geschetst van MR P&S. Volgens hen start het hoofdproces met een vraag vanuit Philips, wat leidt tot een reparatie of vervanging. Hani laadt ons de flowchart van het hoofdproces. Ze beschrijven het hoofdproces als volgt: Een klant van Philips ondervindt problemen met haar Philips MRI scan. Philips stuurt vervolgens een verzoek naar MR P&S om binnen 24 uur een FRU uit de voorraad naar haar klant te sturen, zodat de MRI weer volgens behoren functioneert. Vervolgens stuurt de klant de defecte FRU naar MR P&S. De logistiek manager neemt de FRU in ontvangst en de engineers repareren de FRU. Wanneer deze gemaakt is, wordt het in de FRU-voorraad gestald, totdat er een nieuw verzoek binnenkomt.

Volgens Hani en Salam is er een onderscheid in FRUs op het gebied van buy en make. Om een buy-FRU zelf te maken zouden ontzettend veel personeelskosten gepaard zijn. Er is daarom voor gekozen om deze FRUs (als assembly) in te kopen en vervolgens te stallen in de FRU-voorraad. In het geval van een make-FRU is het goedkoper om het te repareren of zelf te produceren. Volgens Salam is de meerderheid van de make-FRUs zelfs nergens ter wereld te koop en kan dit dus ook niet besteld worden. In dit geval zullen de engineers onderdeeltjes gebruiken uit de componentenvoorraad, om vervolgens een FRU te repareren of produceren om deze vervolgens in de FRU-voorraad te stallen. Het onderscheid tussen buy- en make-FRUs is bepaald in de tijd van Philips Cleveland en staat per FRU benoemd in de voorraadlijst.

De ondersteuning van het hoofdproces wordt volgens Hani en Salam uitgevoerd door de Business Office. Zij ondersteunen op het gebied van inkoop, logistiek, financiën, HRM en kwaliteit.

Samenwerking Philips

Hani en Salam geven aan dat MR P&S een transitie is van Philips Cleveland en daardoor in een unieke marktpositie terecht is gekomen. Philips is momenteel de enige klant van MR P&S, maar hetzelfde geldt andersom. Volgens Hani is MR P&S ook de enige leverancier voor Philips wat betreft het repareren en vervangen van Philips MRI randapparatuur. Uit het interview blijkt dat beiden tweemaal per week met Philips spreken. Op vrijdag vindt een weekly meeting plaats via een conference call en op dinsdag brengt een vaste consultant van Philips, Frans Rosbak, een bezoek aan MR P&S. Hani en Salam beschrijven deze klantrelatie als een uniek samenwerkingsverband. Uit het interview blijkt dat beiden ook grote kansen zien om hetzelfde werk voor MR Coils te gaan verrichten in de toekomst.

Strategie

Volgens Hani en Salam zijn gegevens als de missie, visie, strategie en kernwaarden nergens specifiek bepaald of gedocumenteerd. Ze vinden beiden dat kwaliteit een belangrijke voorwaarde vormt. Volgens Hani en Salam worden de FRUs met dezelfde componenten gerepareerd als ze in origine geproduceerd zijn. Daarnaast worden de producten meerdere malen getest, voordat ze in de FRU-voorraad worden geplaatst of naar de klant worden verzonden. Op deze manier wordt de originele kwaliteit gewaarborgd. Daarnaast zien Hani en Salam snelheid en flexibiliteit als belangrijke kernwaarden. MR P&S heeft namelijk een afspraak om binnen vierentwintig uur de bestellingen naar de klant te versturen.

B. Johan Klerx (20 March 2017)

Interviewee: logistic manager
Interviewer: Niki van den Broek and Tamara Thielen
Date: 20 March 2017
Time: 15.00-15.30
Interview Style: Structured interview

IST:
Tijdens het interview heeft Johan Klerx aangegeven dat hij alle pakketjes die binnenkomen controleert op zichtbare schade. Aan de hand van de pakbon controleert Johan of het aantal binnen gekomen producten overeenkomt met de bestelling. Hij noteert op de pakbon of de bestelling in goede staat is ontvangen en legt deze op het bureau van Paul. Daarnaast zet Johan bij alle bestellingen van MR P&S in EXACT hoeveel producten er zijn binnen gekomen. Hij doet dit momenteel alleen voor bestellingen van MR P&S en niet voor de bestellingen voor de andere ondernemingen. Voor MR P&S wordt dit gedaan, omdat Philips graag wil bijhouden hoeveel FRUs er in het magazijn liggen. Johan geeft aan dat er momenteel nog niet gecontroleerd wordt of bestellingen op de afgesproken data binnen komen. Ook worden er nog geen testen gedaan om de product specificaties te controleren. Voor een FRU is gemaakt en wordt verstuurd door MR P&S, wordt deze wel nog gecheckt. Bij deze controle blijkt ooit dat een bepaald onderdeeltje niet goed functioneert. Fouten in ontvangen producten, worden dus pas achterhaald wanneer het fout gaat voor verzending van een gerepareerde FRU. Wanneer een product gecontroleerd is, wordt gekeken voor welke bedrijf het pakketje is en dit bepaald hoe het verder afgehandeld moet worden. De producten voor de voorraad van MR P&S krijgen een code/sticker en gaan op de juiste bestemming in de schappen. Momenteel doet Johan het werk nog alleen. Hij is verantwoordelijk voor de controle.

SOLL:
Johan geeft aan dat in de ideale situatie, alle pakketjes nog steeds altijd geteld moeten worden. Dit om een beeld te hebben van de voorraad en deze op pijl te houden. Ook geeft hij aan dat het verstandig is om te gaan noteren op welk momenten bestellingen binnen komen. Dit om te controleren of leveranciers bezorgen volgens afspraak. Ook wordt het in de toekomst mogelijk verstandig om steekproeven te houden om te testen of gearriveerde producten voldoen aan de product specificaties. Dit kan bijvoorbeeld ook gedaan worden door te kijken naar de testrapporten. Om dit te blijven doen zal er meer personeel nodig zijn, en zullen taken verdeeld moeten gaan worden.

C. Paul Salomons (20 March 2017)

Interviewee: purchase manager
Interviewer: Niki van den Broek and Tamara Thielen
Date: 20 March 2017
Time: 13.00-14.00
Interview Style: Structured interview

1. Beleid
1.1 IST
Uit het interview is naar voren gekomen dat Paul ervan op de hoogte is dat er het afgelopen jaar een Inkoopbeleid is opgesteld. Hij is echter niet op de hoogte gesteld omtrent de inhoud of de plek waarop deze documentatie is vastgelegd. Paul geeft tijdens het gesprek aan dat hij in samenwerkingen met de engineers beslissingen maakt en hij meerdere malen een mailtje krijgt met een linkje "Ik wil dit specifieke product, wil je dat bij deze leverancier bestellen?" In de meeste gevallen volgt hij dit advies op, omdat de engineers het meeste productkennis hebben, hij geeft echter ook aan dat dit niet zo zou moeten in zijn ogen. Op deze manier krijgt MR P&S steeds meer leveranciers en dat is volgens Paul niet te bedoeling. Het is voor hem ook nog onduidelijk is waar de focus van het bedrijf op ligt: prijs, kwaliteit of levertijd.

1.2 SOLL
Wanneer Tamara het huidige inkoopbeleid laat inzien, geeft Paul aan dat hij dit nog redelijk oppervlakkig vindt en hij het prettig zou vinden als hier meer diepgang aan gegeven wordt. Tijdens het gesprek geeft Paul ook meerdere malen aan dat hij graag een reductie in het aantal leveranciers ziet. Paul is van mening dat de engineers het beste beeld hebben van het specifieke

product, maar dat het belangrijk is om zoveel mogelijk bij eenzelfde leverancier te bestellen. Volgens Paul zouden de engineers hier ook het belang van moeten gaan inzien. Paul geeft aan dat het daardoor mogelijk wordt om grotere volumes af te nemen, wat de onderhandelingspositie vergemakkelijkt.

2. Selectie

2.1 IST
Uit het interview is duidelijk geworden dat Paul geen eenduidige manier van leveranciersselectie hanteert. Enerzijds vindt hij snelle levertijd erg belangrijk, maar wanneer het voor eigen voorraad is, geeft hij aan dat dit minder belangrijk is. Ook geeft hij aan dat het voor P&S erg belangrijk is om bij ISO gecertificeerde bedrijven in te kopen. Tijdens het interview geeft Paul al aan dat hij niet goed weet wat de overkoepelende visie van de organisatie is. Hij koopt producten in vanuit de visie die hij op dat moment belangrijk vindt, omdat hij niet goed weet wat de overkoepelende visie van de organisatie is. Momenteel is het vaak zo dat hij productspecifiek een terugkoppeling vraagt aan de engineer "Heb je dit product heel snel nodig? Of is het prima dat je het pas over zes weken ontvangt? In dat geval kan ik het namelijk veel goedkoper inkopen."

De aanwezigheid van een ISO certificatie of een deugdelijk Quality Management System is volgens Paul momenteel opgenomen in het Supplier Assessment Formulier, maar hij geeft aan dat dit formulier nog niet in gebruik is.

2.2 SOLL
In de ogen van Paul zou dit formulier echter wel gebruikt moeten worden in de toekomst. Hij raadt aan om dit in de toekomst naar alle nieuwe leveranciers te sturen en voor de eerste stand van zaken vast een top 10/25 van de huidige leveranciers vast mee te nemen, om te bekijken of zij aan de selectiecriteria voldoen volgens het Supplier Assessment Form. Volgens hem heeft het formulier echter wel een professionaliseringsslag nodig en dient er vervolgens ook duidelijk te zijn wat de follow-up dient te zijn.

3. Beoordeling

3.1 IST
Uit het interview met Paul is gebleken dat de leveranciers momenteel nog niet op hun prestaties worden beoordeeld. Volgens Paul worden er wel prestaties opgenomen in het ERP systeem: Exact. Volgens Paul zou de logistiek manager, Johan, hierin de leverdatum noteren en wordt hierin gedocumenteerd of er bij levering beschadigingen aan het product zitten.

3.2 SOLL
In de ogen van Paul zou de inkoopafdeling deze leveranciers dienen te beoordelen door informatie die uit Exact wordt gehaald en hier vervolgens nog subjectieve aspecten aan toe te voegen.

Uit het gesprek met Paul is naar voren gekomen dat hij nog geen duidelijk beeld heeft van de criteria waarop de leveranciers zouden moeten worden beoordeeld. Hij geeft aspecten aan als prijs, levertijd, verpakking, communicatie en compleetheid. In zijn ogen is het belangrijk om dit kort te sluiten met Michel en Hani.

Paul zou graag zien gebeuren dat de top vijfentwintig leveranciers, gebaseerd op omzet, worden meegenomen in het beoordelingstraject, waarin ze één of tweemaal per jaar worden geanalyseerd. Deze beoordeling dient volgens Paul altijd teruggekoppeld te worden, in zowel positieve als negatieve vorm. Paul heeft geen duidelijk beeld hoe deze terugkoppeling gehouden dient te worden, maar hij verwacht dat dit prima telefonisch kan of via de mail.

D. Dennis Wouters (24 March 2017)

Interviewee: Operations and finance manager
Interviewer: Niki van den Broek and Tamara Thielen
Date: 24 March 2017
Time: 09.00-10.00
Interview Style: Structured interview

De functie als financial and operational manager
Dennis is verantwoordelijk voor operations en finance. Uit zijn woorden blijkt dat dit duidt op inkoop, logistiek en financiën. Hij begeleidt de logistiek manager (Johan Klerx) en inkoop manager (Paul Salomons) in het inkoopproces. Hij is medeverantwoordelijk voor het op pijl houden van de voorraad. Dennis controleert of er genoeg financiële middelen zijn en of er niet teveel voorraad ligt. Tijdens het interview geeft Dennis aan dat hij momenteel nog als manager boven Johan en Paul staat, maar hij in de toekomst meer verantwoordelijkheden aan hen wil overdragen.

Voorraadbeheer
Momenteel zijn alle componenten van Philips, maar op korte termijn zal P&S deze zelf gaan inkopen en financieren. Volgens Dennis is mogelijk om daarvoor twee magazijnen te maken in Exact. Als het op naam van MR P&S wordt ingekocht dan moet het ingeboekt worden in het magazijn van MR P&S, wordt het door MR P7S ingekocht voor Philips, dient het hierin te worden ingeboekt.

Volgens Dennis is MR P&S economisch eigenaar en Philips juridisch eigenaar van zowel componenten als FRUs. De voorraden staan dus op de balans van Philips, maar MR P&S heeft ze in bruikleen en is verantwoordelijk voor het in bewaring nemen. MR P&S heeft zich daarom goed verzekerd tegen diefstal, brand en schade. Daarnaast geeft Dennis aan dat ze daarom werken met goede sloten, sterke verpakkingsmaterialen en gecertificeerd personeel (opgeleid en getraind om bijvoorbeeld een heftruck te rijden). Volgens Dennis is het verstandig om camera's te plaatsen om diefstal tegen te gaan.

Inkoopbeleid
In de ogen van Dennis is het belangrijk om de lijnen van het inkoopbeleid zo kort mogelijk te houden. Dennis geeft aan dat de voorraad FRUs ook in de toekomst eigendom van Philips zullen blijven en er daarom altijd goedkeuring gevraagd zal moeten worden voor het bestellen van buy-FRUs. Voor het inkopen van componenten zal dit volgens Dennis veranderen. Momenteel is alle voorraad nog van Philips, maar zodra de eerste bestelling plaatsvind, zullen deze nieuwe componenten eigendom worden van MR P&S. Hierdoor zal de voorraad van componenten dus langzaam voor een steeds groter gedeelte eigendom worden van MR P&S. Dennis verwacht dat dit binnen een tijdsaspect van ongeveer één/twee maanden zal plaatsvinden. Dennis geeft aan dat voor de inkoop van componenten daarom geen goedkeuring gevraagd hoeft te worden aan Philips.

Uit het interview met Dennis blijkt wederom dat iedere inkoop wordt goedgekeurd door de CEO. Volgens Dennis zou dit op korte termijn moeten veranderen. In zijn ogen dient de inkoopmanager meer verantwoordelijkheid te krijgen om zelf in te schatten of inkoop mogelijk is of niet. Als een FRU op korte termijn af dient te zijn, kun je in de BOM-lijst kijken welke componenten er al zijn en welke besteld dienen te worden. Volgens Dennis is het wellicht een mogelijkheid om daarvoor autorisatie in te stellen, zodat Paul direct kan bestellen en het proces zo snel mogelijk door kan.

Volgens Dennis dient daarvoor wel de voorraadregistratie goed gecontroleerd te worden. Het is momenteel onduidelijk wie deze verantwoordelijkheid draagt. Volgens Dennis is het aan de CEO (Michel) en de general manager (Hani) om hier uitspraak over te doen.

Als de logistiek manager FRUs verzend naar de klant, kan de FRU voorraad onder safety stock komen en dient er een nieuwe te worden gekocht of gemaakt. Volgens Dennis draagt de logistiek manager de verantwoordelijkheid dit door te zetten naar de inkoopmanager. Vervolgens controleert de inkoopmanager of het onder stock is en weet hij vervolgens of hij een buy-FRUs moet inkopen.

Uit het interview blijkt dat Dennis het als een kans ziet om ditzelfde voor componenten door te voeren. Hiervoor geldt momenteel geen safetystock. De inkoopmanager dient een signaal te gaan krijgen dat een component onder safetystock is, zodat hij deze bij kan kopen.

E. Michel Italiaander (20 March 2017)

Interviewee: CEO
Interviewer: Niki van den Broek and Tamara Thielen
Date: 20 March 2017
Time: 10.00-11.00
Interview Style: Semi-Structured interview

Strategie
Over tien jaar hoopt Michel Italiaander dat MR P&S 150 tot 200 onderdelen kan maken voor de klinische markt. Hiermee worden klanten als Philips, Siemens en GE bedoeld, maar ook ziekenhuizen. De werkzaamheden zullen nog steeds voornamelijk gericht zijn op het bouwen van spoelen.

Klanten zullen kiezen om reparatie/productie werkzaamheden te laten verrichten door MR P&S, niet alleen omdat ze goed zijn in hun werk, maar ook omdat ze een totaalplaatje kunnen aanbieden door de nauwe samenwerking met haar zusterorganisaties. Michel Italiaander geeft aan dat het belangrijk is dat MR P&S vooral steeds efficiënter en sneller gaat werken maar hierbij altijd de hoge kwaliteit gewaarborgd dient te blijven.

Inkoop
Michel Italiaander geeft aan dat er centraal op één punt bestellingen gedaan moeten gaan worden. Bepaald hiervoor bevoegde mensen moeten dit doen via Exact, zodat op het einde van de maand een duidelijk beeld is wat er is besteld en door wie. Als er via Exact besteld wordt, is het belangrijk dat bij de producten in de database minimaal twee leveranciers beschikbaar zijn. Zodat er een goedkope leveranciers beschikbaar is, maar ook een leverancier die ingeschakeld kan worden bij spoedgevallen. Als blijkt dat er teveel inkopen gaan komen door een organisatie groei, zou dit inhouden dat er extra inkoop personeel aangesteld moet worden.

Als er op grotere schaal ingekocht moet gaan worden, zullen er tevens betere planningen moeten komen zodat de cashflow gespreid kan worden. Een forecastplanning zou gemaakt moeten worden door de engineers, niet door de inkoper. Om de cashflow nu op pijl te krijgen is het belangrijk dat MR P&S zo snel mogelijk op de ASL van Philips komt. Hiervoor moeten ze voldoen aan ISO 13485 en een milieu en kwaliteits-agreement tekenen. Michel Italiaander geeft aan dat onze leveranciers niet aan deze strenge eisen hoeven te voldoen, omdat wij ons alleen nog maar bezig houden met prototypen. Hij geeft ook aan dat er geen specifieke eisen gesteld worden vanuit ons aan leveranciers. Een leverancier hoeft dus niet aan een ISO norm te voldoen etc. Wel moeten ze kwaliteit leveren, zeggen wat ze doen en aangeven als er dingen veranderen of niet goed zijn.

<u>Goedkeuring aankopen:</u>
In het huidige inkoopproces worden alle bestellingen nog goedgekeurd door Michel Italiaander. Hij geeft aan dat dit erg onhandig is, zeker met het oog op organisatie groei. Michel Italiaander denkt dat dit opgelost kan worden door met budgets te gaan werken. Deze budgets zouden vast hangen aan een project. Op deze manier hoeft de CEO alleen dat budget goed te keuren en zolang de inkopen voor een project binnen dat project vallen, is de inkoper gemachtigd om de inkopen door te zetten. Voor MR P&S zouden de budgets vastgesteld moeten worden per FRU. Als de organisatie groeit en honderd keer dezelfde FRUs moet repareren, zou er namelijk een bepaald budget moeten worden vastgelegd waarvoor ze een reparatie moeten kunnen doen. De inkoper en of de projectleider zou verantwoordelijk moeten zijn voor de bewaking van het budget.

<u>Leveranciersbeoordeling:</u>
Michel Italiaander geeft aan dat het belangrijk wordt dat in principe uiteindelijk steeds dezelfde componenten ingekocht gaan worden. Kwaliteit staat hierbij voorop. Daarnaast moeten de producten voldoen aan de eisen van de engineers. Hierna is prijs belangrijk. Als het in het tijdsframe van de engineer past, dat er goedkoper ingekocht wordt heeft dit namelijk vaak gevolgen in een langere leverduur. Mocht dit te lang duren, dan zou een duurdere variant overwogen moeten worden. De engineer zou hierin de doorslag moeten geven. Michel Italiaander geeft verder aan dat het belangrijk is om te blijven kijken naar de beste en goedkoopste leveranciers. Als je een product kan kopen bij een huidige leverancier, maar het kan ergens goedkoper dan moet je de overweging maken of je met onderhandelen mogelijk een zelfde prijs bij de huidige leverancier kan krijgen. Is dit niet mogelijk, zou hij toch kiezen voor de goedkopere leverancier.

Traceerbaarheid
<u>Inbound</u>
Op gebied van traceerbaarheid geeft Michel Italiaander aan dat wij een tussenleverancier zijn. Als er bijvoorbeeld een product van Farnell binnenkomt dan zouden we batchnummers kunnen noteren, maar het nummeren of labelen van alle individuele componenten is niet mogelijk. De batches zou je echter wel kunnen registeren. Als we een halffabricaat inkopen (FRU) dan krijgen we hier een apart serienummer voor. Dit serienummer is makkelijk traceerbaar.

Voorraad
De voorraad van FRUs zal altijd van Philips blijven. De voorraden van componenten zijn nu ook nog van Philips, maar zodra er nieuwe componenten ingekocht worden, zal dit gedaan worden door MR P&S. Er moet goed worden omgesprongen met de inkopen van voorraad. Hoeveel er op voorraad moet komen te liggen hangt af van het component. Het houden van voorraad kost veel geld. Toch is het bij sommige producten wel belangrijk, omdat ze een levertijd van 16 of 20 weken hebben en als we hierop moeten wachten, kost het ons veel meer geld. Als een product de volgende dag geleverd kan worden, dan zijn dit soort maatregelen echter minder belangrijk. Michel Italiaander geeft aan dat het voor goedkopere componenten slim is om een Kanban Systeem te gaan gebruiken.

Voor de voorraad van FRUs moet de safety stock van Philips aangehouden worden. Ook voor componenten kan dit mogelijk gedaan gaan worden. Michel Italiaander geeft aan dat de lijst wel herzien moet worden. Sommige componenten gebruiken we namelijk maar eens in de zoveel jaar. Hier hoeft niet veel voorraad van te zijn. Wel moet er rekening gehouden worden, met het feit dat sommige componenten anders niet meer geleverd kunnen worden. Hiervan moet dus wel voorraad aanwezig zijn, anders levert dit later problemen op. De voorraad van MR P&S moet wel dezelfde 12NC nummers aanhouden, want dit staat in de BOM.

Om de voorraad van Philips en MR P&S overzichtelijk te houden, worden er in Exact twee magazijnen aangemaakt. In de schappen maakt het niet uit of er voorraad van Philips of MR P&S is, maar als Philips uiteindelijk niet langer meer klant van MR P&S wil zijn en zijn voorraad terugeist, is het wel belangrijk om te weten hoeveel voorraad nog van Philips is.

Outbound
Als we een FRU verzenden naar de klant kunnen we hier informatie van bijhouden. Wanneer we ze echter versturen via Philips, heeft Philips ervoor gekozen om hierover geen verdere informatie te verschaffen. Philips houdt dit zelf bij en Michel Italiaander geeft aan dat hij dit alleen maar prettig vindt. Zolang Philips het zo wil doen, kunnen wij dus allen maar traceren tot en met Philips. Als een product terugkomt, weten we van welke klant dit komt aan de hand van het artikel- en serienummer. We kunnen nu echter niet zien waar al onze gerepareerde FRUs zijn, omdat het traceren van FRUs via Philips niet verder gaat dan daar.

Cashflow
Philips betaald ongeveer na 90 dagen. Omdat MR P&S nog niet op de ASL staat, duurt het nu vaak nog langer. Als we dadelijk op de ASL staan, dan zouden bestellingen gemakkelijker betaald moeten kunnen worden, zodat er minder discussie nodig is. Als Philips ons sneller betaald, verbetert onze cashflow. Momenteel kopen we van alles voor Philips in, maar komt het geld pas veel later binnen. Philips kan dit doen door de grote naam die de organisatie heeft. Het is belangrijk dat de afspraken beter worden, want als we sneller geld ontvangen, kunnen we ook weer makkelijker producten op voorraad leggen, wat uiteindelijk ook weer gunstiger is voor Philips.

F. Hani Hayawi and Salam Almujayyaz (6 April 2017)

Interviewee: General manager and assistant general manager
Interviewer: Niki van den Broek and Tamara Thielen
Date: 6 April 2017
Time: 15.00-16.00
Interview Style: Semi-Structured interview

Traceability
Hani en Salam zijn niet bekend met de eisen omtrent traceability, maar ze zijn ervan bewust dat hier iets mee gedaan moet worden. Ze vinden het belangrijk om de ISO norm te behalen en begrijpen dan ook dat ze aan de eisen van traceability zullen moeten voldoen.

Uit het interview komt naar voren dat ze niet bekend zijn met het begrip “Kanban”. Na een korte uitleg lijken ze beide enthousiast en geven ze aan dat dit mogelijk zou moeten zijn voor de voorraad van componenten. Ze geven aan het goed onderzocht dient te worden hoe de batches van elkaar te onderscheiden zijn. Het lijkt hen het meest gebruiksvriendelijk dat een bakje gescand kan worden wanneer deze op is, zodat er automatisch in het systeem komt te staan dat dit de

einddatum is van deze batch, een volgende batch in werking treedt en hiermee automatisch een melding naar de inkoper gaat.

In de nabije toekomst zal dit laatste lastig worden, volgens Hani en Salam. Ze zijn enorme voorstanders van een safety stock level voor zowel FRUs als componenten, zodat MR P&S altijd binnen 24 uur kan leveren en projecten niet onnodig stil staan. Ze geven echter aan dat het op korte termijn niet mogelijk is een melding voor inkoop te geven, zodra producten onder safety stock komen.

MR P&S staat momenteel namelijk nog niet op de ASL lijst van Philips, mede omdat de organisatie geen ISO certificering heeft. Philips betaalt de organisatie daarom niet binnen de afgesproken negentig dagen. Gelijktijdig, is het voor MR P&S moeilijk om op de ASL lijst te komen, omdat ze zo laat betaald worden. Dit heeft namelijk een enorme uitwerking op de cashflow. Het is voor MR P&S momenteel nog niet mogelijk om de FRUs onder safety stock allemaal op peil te brengen, omdat de cashflow dit niet toelaat.

Desalniettemin zijn Hani en Salam enthousiast over het idee. Ze vinden het bepalen van de safety stock levels van componenten lastig en willen hier eigenlijk pas over een jaar mee beginnen. Ze zouden het echter wel erg op prijs stellen als we hier aanbevelingen van kunnen geven, zodat ze dit kunnen toepassen, wanneer de cashflow op orde is.

Purchasing

Zoals uit eerdere gesprekken naar voren is gekomen, staat kwaliteit altijd op nummer één voor Hani en Salam. Ze geven aan dat MR P&S levert aan de medische onderzoekmarkt en kwaliteit daarbij van levensbelang is. Dit dient daarom ook terug te komen in de leveranciersselectie en beoordelingscriteria.

Daarnaast zien Hani en Salam snelheid en flexibiliteit als belangrijke kernwaarden. MR P&S heeft namelijk een afspraak om binnen vierentwintig uur de bestellingen naar de klant te versturen. Levertijd is daarom ook een belangrijk criteria volgens Hani. Ze geven echter aan dat wanneer MR P&S een goed voorraadbeheerssysteem heeft, waarbij altijd iets op voorraad ligt, er niet meer streng hoeft te worden gekeken naar de levertijd. Op dit moment zal prijs de voorhand nemen, zolang dit niet ten koste gaan van de kwaliteit.

Conclusie: Wanneer traceability goed is ingericht geldt volgens Hani en Salam het volgende:
1. Kwaliteit
2. Levertijd
3. Prijs

51. Practical framework - Best practise

During this research Philips is used as best practice. The following appendix shows a summary of the interviews held with the consultant of Philips, Frans Rosbak:

Interviewee: Consultant Philips
Interviewer: Niki van den Broek and Tamara Thielen
Date: 21 March 2017
Time: 15.30-16.00
Interview Style: Semi structured interview

Selectie:
Tijdens het interview verteld Frans Rosbak dat bij Philips alle leveranciers goedgekeurd worden voor ze op de Approved Supplier List (ASL) komen. Om hier op te komen moeten ze voldoen aan de Quality agreement van Philips. Dit bestaat uit twee documenten: een kwaliteits- en een sustainability agreement. Aan beide agreements moet voldaan worden, om op de ASL te komen. De goedkeuring wordt gedaan door de afdeling Procurement, welke is opgesplitst in twee takken: de technische ontwikkelkant en de commerciële kant.

Product risico:
Uiteindelijk is er een andere afdeling binnen Philips, Supplier Quality, welke assessments doet om te kijken of de leveranciers ook voldoen aan de afspraken. Hoe vaak dit gedaan wordt, hangt af van de risico kwalificatie groep waarin de leverancier valt. Philips heeft vier risico kwalificatie groepen. In welke risicogroep een leverancier valt, hangt af van het risico en de impact op de kwaliteit van het eindproduct waarin het onderdeel gaat. Wanneer een leverancier tien verschillende producten levert en negen hiervan in de laagste categorie vallen, maar een in de hoogste, betekend dit dat de leverancier in de hoogste risico kwalificatie groep valt. Het product met de hoogste risico factor geeft de doorslag. De mate van risico van een product wordt bepaald door de R&D afdeling. De risico kwalificatiegroepen worden aangeduid met de letters W, X, Y en Z. Hierbij is W de hoogste risicogroep en Z de kleinste.

Omdat de wet en regelgeving omtrent Medical Devicises erg streng is, worden er hoge eisen gesteld. Philips zet hier nog extra vereisten boven op. Frans Rosbak geeft aan dat deze strenge eisen misschien te zwaar zijn voor een kleine speler als MR P&S. Wel geeft hij aan dat het slim is om dezelfde risk categorieën aan te houden als Philips. MR P&S repareert namelijk FRUs die vrij breed gebruikt worden in 7T scanners. Hier zitten onderdelen bij met een hoge risk-categorie. Als dit bijvoorbeeld 1W product en 15 X producten zijn, zou het belangrijk zijn dat MR P&S ook een strenge controle uitvoert op de toeleverancier van dat W product. Op de vraag bij wie de verantwoordelijkheid zou moeten liggen om de productcategorieën te bepalen, geeft Frans Rosbak aan dat hij aanraad dit door de ontwikkelafdeling (MR Coils) te laten doen.

Evaluatie:
Leveranciers die producten met een lage risk kwalificatie leveren, worden bij Philips ook minder vaak en minder streng beoordeeld als leveranciers met een hoge kwalificatie. De Supplier Quality afdeling, bestaande uit 35 man, doet audits bij de leveranciers afhankelijk van de risk categorieën. De beoordeling wordt gedaan aan de hand van een audit, bezoek of in lage risico gevallen aan de hand van deskresearch.

In de Vendor Rating System (VRS) van Philips wordt beoordeeld op: kwaliteit, proces, contact en timing aspecten. De uitkomst van de rating wordt ten alle tijden teruggekoppeld aan de leverancier. Binnen Philips kunnen leveranciers inloggen in het VRS. Zo kunnen ze zien hoe hoog ze scoren. Als de uitkomst heel slecht is, wordt een actieplan met de leverancier opgesteld. In de ergste gevallen wordt er een tijdelijke inkoopstop ingelast. Er worden dan afspraken gemaakt, dat er pas weer ingekocht wordt als er aspecten zijn verbeterd. Hieraan worden tijdsafspraken gekoppeld. Als een leverancier uiteindelijk nog niet voldoet, wordt gezocht naar een alternatief.

52. Practical framework - Consultation meeting

Since the CEO and general manager worked abroad for four weeks during this research, a collaboration meeting is held by mail communication. The mails give insight in the opinion of the involved employees towards the conducted supplier evaluation system and criteria:

Tamara Thielen
wo 12-4-2017 16:29

Markeren als ongelezen

Aan: Michel Italiaander; Hani Hayawi; Schelte Post; Paul Salomons;
CC: Niki van den Broek; Salam Almujayyaz;

1 bijlage

Vendor rati~.docx

Hi all,

Om de ISO-norm te behalen, zal een geselecteerd deel van jullie leveranciers beoordeeld moeten worden. Om dit mogelijk te maken, zijn wij bezig met het ontwikkelen van een beoordelingssysteem. Middels deze weg willen we graag toetsen of onze ideeën aansluiten bij jullie visies. In de bijlage hebben we een bestand toegevoegd met de door ons gekozen criteria en wegingsfactoren. We hebben deze gebaseerd op de gesprekken die we hebben gevoerd en onze eigen interpretatie.

Graag willen we jullie vragen het volgende aan te geven:

- Wat jullie van de wegingsfactoren vinden. (Wat is belangrijk aan een leverancier/wat is minder belangrijk?)
- Of we middels deze criteria op de juiste onderwerpen evalueren.
- Of de antwoordkeuzes in jullie ogen juist zijn.

Alle tips en op/aanmerkingen zijn welkom. We hopen dat jullie in de mogelijkheid zijn om dit uiterlijk woensdag 19 april te doen, zodat wij zo snel mogelijk kunnen beginnen met aanpassen en implementeren.

We horen graag van jullie. Alvast bedankt!

Met vriendelijke groet,
Niki en Tamara

Michel Italiaander
wo 12-4-2017 19:14

Markeren als ongelezen

Aan: Tamara Thielen; Hani Hayawi; Schelte Post; Paul Salomons;
CC: Niki van den Broek; Salam Almujayyaz;

U hebt geantwoord op 13-4-2017 08:23.

Hoi dames! Goed werk geleverd! Heb niet eens opmerkingen…!?

With kind regards, Met vriendelijke groeten,

Michel Italiaander

Confidential

Salam Almujayyaz

do 13-4-2017 10:16

Markeren als ongelezen

Aan: Tamara Thielen; Michel Italiaander; Hani Hayawi; Schelte Post; Paul Salomons;

CC: Niki van den Broek;

U hebt geantwoord op 13-4-2017 10:30.

Hallo Dames,

Ziet er goed uit qua inhoud. De vraag is of jullie hebben nagedacht hoe en wie dit zou moeten bijhouden?

Hoeft geen naam te zijn maar kan een functie zijn die dit moet bijhouden en evalueren.

Groeten Salam

Hani Hayawi

do 13-4-2017 20:11

Markeren als ongelezen

Aan: Salam Almujayyaz; Niki van den Broek;

CC: Tamara Thielen; Michel Italiaander; Schelte Post; Paul Salomons;

U hebt geantwoord op 14-4-2017 08:34.

Hoi Niki en Tamara,

Het ziet heel goed uit. In mei een keer voor zitten en bespreken lijkt mij de handigste.

Groeten,
Hani

53. FMEA – risk analysis traceability

This appendix includes the FMEA held to reveal the risks in the traceability process:

Function	Potential Failure mode	Severity (Potential effect of failure)		Occurrence (Potential cause of failure)		Detection (Potential detection of failure)		Total score	Action to take
Purchase components	Purchase MGR forgets to record supplier information	Impossible to trace the supplier of products	8	Human fault	5	Remote	8	320	Training to ensure all employees are aware to fill in the form.
Purchase components	Supplier information is not complete	Possibly unable to trace the supplier of products	6	Documentation fault	5	High	3	90	Exact should give a warning if the form is not completely filled in.
Purchase components	Supplier information gets lost	Impossible to trace the supplier of products	8	Maintain fault	1	Moderate	5	40	Authorise minimal amount of employees to be able to remove data from Exact.
Label components	The same batch number is used multiple times	Impossible to keep batches apart	2	Human fault	3	Moderate	5	30	Exact should give a warning if a batch number is used before.
Store components	Products are placed in the wrong container	Impossible to keep batches apart	2	Human fault	5	Moderate	5	50	Training to ensure the logistic manager is aware of storing products at its allocated place.
Produce or repair FRU	Engineer forgets to fill in repair form	Impossible to trace which components are used within an FRU	8	Human fault	5	Remote	8	320	Training to ensure all employees are aware to fill in the form.
Produce or repair FRU	Batch number of used components is not recorded	Impossible to trace which components are used within an FRU	6	Documentation fault	1	High	3	18	
Produce or repair FRU	The article and serial number of repaired/produced FRU is not written down	Impossible to trace which components are used within an FRU	8	Documentation fault	5	Moderate	5	200	Exact should give a warning if the form is not completely filled in.
Produce or Repair FRU	The wrong batch number is noted	The wrong FRUs are recalled when a defect occurs	6	Human fault	7	Very low	7	294	Training to ensure all employees are aware of the importance of writing down batch numbers.
Store FRU	FRU is not stored at allocated location	Impossible to trace FRUs within the organisation	4	Human fault	5	Moderate	5	100	Training to ensure the logistic manager is aware of storing products at allocated place.
Send FRU to customer	Logistic MGR forgets to record customer information	Impossible to contact correct customers when a defect occurs	8	Human fault	1	Moderate	5	40	Training to ensure the logistic manager is aware of the importance to record customer information.
Send FRU to customer	Customer information is not complete	Possibly unable to contact correct customers when a defect occurs	6	Documentation fault	5	Moderate	5	150	Exact should give a warning if for is not completely filled in.
Send FRU to customer	Sent FRU is broken	Customer complaints	9	Test fault	2	Almost certain	1	18	
Database in Exact	Exact is not functioning	Data cannot be recorded	5	System fault	1	Almost certain	1	5	

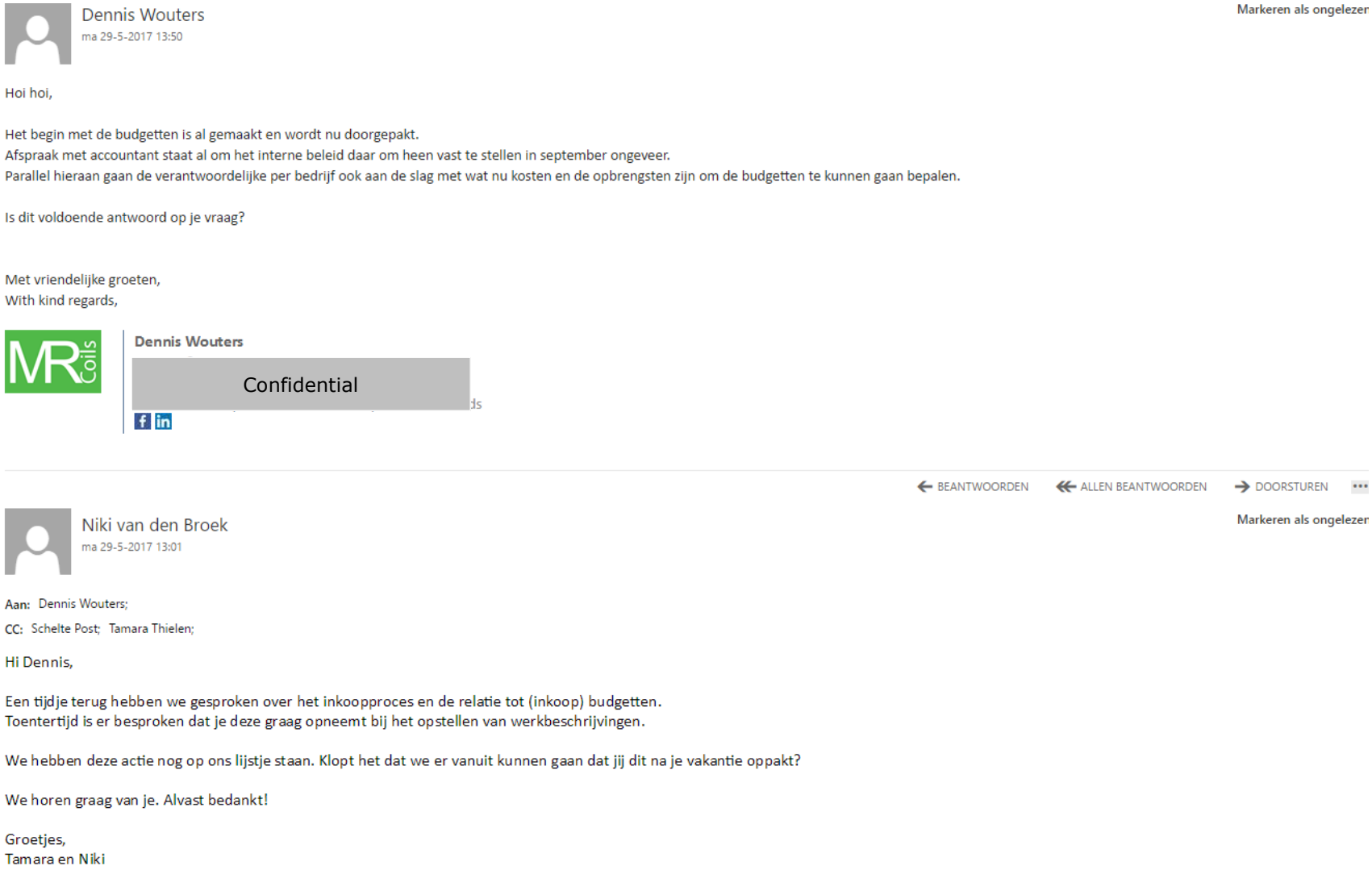
54. FMEA – risk analysis purchasing

This appendix includes the FMEA held to reveal the risks in the purchasing process:

Function	Potential Failure mode	Severity (Potential effect of failure)		Occurrence (Potential cause of failure)		Detection (Potential detection of failure)		Total score	Follow up needed?
Purchase needed	The purchase MGR receives no trigger from the inventory control to purchase	Inventory will be out of stock and this creates a delay in the core process.	10	System fault	1	Low	2	20	
Supplier allocated	Allocated supplier does not deliver product anymore	Purchase manager should search for new supplier.	5	External problem	5	Directly	1	25	Higher safety stock level before this occurs to have a buffer
Search for supplier	No supplier is available	Design should be changed. Change request.	10	External problem	5	Directly	1	50	Allocate more suppliers in the database who all deliver the same product
Select supplier	Only one supplier available who does not want to sign purchasing terms and conditions	Usual quality standards cannot be reached.	5	External problem	5	Directly	1	25	Start a discussion between both organisations
Select supplier	Minimal order quantity is very high	Costs turn out to be higher as calculated.	2	External problem	8	Very high	2	32	Search for different supplier. Allocate more suppliers in the database who all deliver the same product
Select supplier	Supplier has not read through the purchasing terms and conditions	Conflict with supplier over purchasing terms and conditions.	1	External problem	2	Very remote	9	18	
Approval	Takes long till approval is given	A delay in the core process occurs.	10	External problem or human problem	2	Directly	1	20	
Place purchase order	Purchase MGR forget to record purchase information	Company is unable to trace purchased products	5	Human fault	1	Moderately high	4	20	
Evaluation needed	Purchase MGR does not receive notification to evaluate	No evaluations will be held.	5	System fault	1	Very low	7	42	Ensure the purchase manager receives an automatic trigger from both the database and the mail.
Evaluation needed	A supplier who does not deliver products with a high product risk, but with a high financial risk is not evaluated.	Suppliers who deliver often are possibly not evaluated.	5	Documentation fault	5	Moderate	5	125	Add a financial element to the risk matrix
Evaluation needed	To many suppliers should be evaluated.	Suppliers evaluation is too time consuming. Will not be done.	5	Documentation fault	5	High	3	75	Higher the level in the product risk matrix to lower the amount of supplier to evaluate or hire a purchase assistant.
Monitor	Instructions unclear	No monitoring will be done, result - no evaluations can be done.	5	Human fault	2	Moderate	5	50	Execute pilot to train, give a presentation and give clear work instructions.
Monitor	Unclear which order is linked to which purchase	No evaluation possible	5	System fault or human fault	7	Moderate	5	175	Ensure both data is saved in Exact under the same purchase order.
Execute vendor rating	Purchase manager is influenced by previous scores	Unfair outcome. Unreliable	7	Human fault or system fault	7	Absolute uncertain	10	420	System does not show the outcome during evaluation.
Execute vendor rating	Purchase manager fills in columns whit formulas	No/ wrong score. Unreliable outcome.	7	Human fault or system fault	7	Moderate	5	245	Take security measures to ensure those columns cannot be changed.
Execute vendor rating	Purchase manager is influenced since he knows the supplier personally	Unfair outcome. Unreliable	7	Human fault	7	Uncertain	10	420	Us hard PIs instead of soft to ensure they are measurable.
Satisfying rating	Purchase manager is influenced and rates more satisfying	Unfair outcome. Unreliable	7	Human fault	7	Moderate	5	245	Ensure the follow-up of a certain score is stated.
Setup action plan	Not communicated to supplier	No continual improvement	2	Human fault	7	Moderate	5	70	Set up action plan with manager.
Aftersales	No control if actions on action plan are taken	No continual improvement	2	Human fault	7	Moderate	5	70	Ensure there is a feedback moment yearly.

55. Consultation concerning authorisation

Since the CEO and general manager worked abroad for four weeks during this research, a collaboration meeting is held by mail communication. The mails give insight in the opinion of the involved employees towards the conducted supplier evaluation system and criteria:



Dennis Wouters
ma 29-5-2017 13:50

Markeren als ongelezer

Hoi hoi,

Het begin met de budgetten is al gemaakt en wordt nu doorgepakt.
Afspraak met accountant staat al om het interne beleid daar om heen vast te stellen in september ongeveer.
Parallel hieraan gaan de verantwoordelijke per bedrijf ook aan de slag met wat nu kosten en de opbrengsten zijn om de budgetten te kunnen gaan bepalen.

Is dit voldoende antwoord op je vraag?

Met vriendelijke groeten,
With kind regards,

MR Coils
Dennis Wouters
Confidential

BEANTWOORDEN ALLEN BEANTWOORDEN DOORSTUREN

Niki van den Broek
ma 29-5-2017 13:01

Markeren als ongelezer

Aan: Dennis Wouters;
CC: Schelte Post; Tamara Thielen;

Hi Dennis,

Een tijdje terug hebben we gesproken over het inkoopproces en de relatie tot (inkoop) budgetten.
Toentertijd is er besproken dat je deze graag opneemt bij het opstellen van werkbeschrijvingen.

We hebben deze actie nog op ons lijstje staan. Klopt het dat we er vanuit kunnen gaan dat jij dit na je vakantie oppakt?

We horen graag van je. Alvast bedankt!

Groetjes,
Tamara en Niki

56. Notes traceability pilot

This appendix includes the notes of the traceability pilot:

Attending: Johan Klerx, Niki van den Broek and Tamara Thielen
Date: 2 June 2017
Time: 9.00 - 10.00

Hoeveel tijd was je kwijt om te monitoren?
- Het duurde 3 extra minuten per dag om het monitor formulier in te vullen.
- Het duurde 3 extra minuten per dag om het outbound formulier in te vullen.

Welke outbound informatie kun je achterhalen bij een verzonden FRU?
Antwoord:
- Wat is er verstuurd
- Wanneer is het verstuurd
- Wanneer is de aanvraag vanuit de klant verkregen
- Track en trace code
- Wanneer is de FRU aangekomen bij de klant (zoekt Johan zelf op met track en trace code)
- Naam van de klant
- Hoeveelheid verzonden FRUs
- 12NC van FRU
- Of het een buy-FRU of make-FRU betreft.

Welke purchasing informatie kun je achterhalen bij een FRU?
- Waar de FRU in het magazijn is opgeslagen.
- Welke bestelling de FRU was
- Omschrijving product
- Artikel code
- Leverancier
- Prijs

Is het mogelijk om te achterhalen waar een verzonden FRU gekocht/gemaakt is?
- Ja, dit kan Johan opzoeken. → Dat kan zowel in Exact als Excel. In Excel is het echter een andere lijst als de Excel lijst waarin te zien is waar FRUs naar verzonden zijn.
- Om te achterhalen waar een FRU gekocht/gemaakt is, wordt in exact of de Excel lijst gezocht op het 12NC van de FRU. Dit duurt ongeveer 1 minuut.

Is van de volgende 5 FRUs te achterhalen waar ze vandaan komen en waar ze momenteel zijn?
Johan heeft van een aantal recent verzonden FRUs opgezocht waar ze naar toe verstuurd zijn. Dit duurde ongeveer 1 minuut. Naderhand heeft hij de zelfde 12NCs ingevoerd in Exact om te achterhalen waar ze gemaakt zijn/vandaan kwamen. Dit duurde ongeveer 4 minuten.

Als je nu wilt achterhalen welke componenten er gebruikt zijn om een FRU te repareren, hoe zou je dat doen?
Johan zou opzoek gaan naar de general manager van MR P&S, Hani. Hani heeft inzicht in de reparatie formulieren waarop engineers bijhouden welke componenten er gebruikt zijn. Het duurde 3 extra minuten per dag om het repair registration formulier in te vullen. Omdat Johan zelf geen inzicht heeft in deze reparatie formulieren wegens autorisatie gronden, is het achterhalen van de specifieke componenten in een FRU een tijdrovend proces. Het duurde gemiddeld 30 minuten om te achterhalen welke componenten in een FRU gebruikt waren, de locatie, gerelateerde purchasing information.

Om te achterhalen in welke FRU een specifiek component gebruikt is, moesten alle reparatie formulieren een voor een geopend worden. Johan was gemiddeld 45 minuten per component bezig om te achterhalen in welke FRUs ze gebruikt waren.

57. Notes purchasing pilot 1

This appendix includes the notes of the first purchasing pilot:

Attending: Paul Salomons, Niki van den Broek and Tamara Thielen
Pilot supplier: based on monitoring from 2 May 2017 till 24 May 2017
Date: 24 May 2017
Time: 13.00-15.00

Overall

- Het duurde ongeveer 45 minuten om de inkoop en monitor informatie met elkaar te koppelen, per leverancier over het tijdsbestek van één maand.
- Het duurde één uur om een leverancier te beoordelen, vanwege het uitleggen en discussiëren tussendoor.
- Bij leveranciers die er toe doen wil je dit doen. Die componenten leveren die speciaal voor ons worden gemaakt. Volgens Paul heb je op "Supplier A" hebben wij helemaal geen invloed en zou je daar niet zo bovenop hoeven te zitten
- De percentages zorgen ervoor dat alles erg objectief is. In theorie is dat goed, maar volgens Paul moet je de menselijke factoren hier meer inhebben.
- Kopjes aanpassen: Nog maar 3 pijlers: Delivery Quality, Cost en Service Quality. Kwaliteit van de service en de kwaliteit van producten/delivery zijn verschillende dingen! Reactie Paul: Is het mogelijk dit systeem te gebruiken op alle Holdings, maar dan met andere percentages? Fijn dat dat zo handig kan omdat alles is doorgelinkt. Fijn! Voor productiebedrijf zijn kosten vast belangrijker, omdat je daar vooruit kan plannen. Bij MR Coils is een dag te laat leveren dodelijk.

Delivery

- Het is zo belangrijk dat er op tijd geleverd wordt, dit zou zwaarder mee moeten wegen!
- Dan maak je kopje met "rejected items" dan kijk je naar packaging, warning signs en damages:
- In plaats van proper veranderen naar "needed" information. Daarbij de voorbeelden veranderen naar packing slip en … of conformity. De andere voorbeelden die genoemd zijn, komen niet echt voor.
- Timely: Is on time niet een betere bewoording?
- Monitorbestand: Expected delivery date zou niet de datum zijn die wij verwachten, maar de datum die zij ons meegegeven "Bevestigde verwachte leverdatum". Momenteel wordt de orderbevestiging niet gecontroleerd en ingevoerd in Exact, dus dan kan dit niet goed ingevoerd te worden. Pas als "Supplier A" in hun orderbevesting zegt dat het een andere datum geleverd kan/zal worden, weet je dat je daar vanuit moet gaan. Momenteel wordt dit niet gecontroleerd.
  → Naast de inkoop en verwacht leverdatum, dan ook de bevestigde verwachte leverdatum invullen in Exact.
  → We hebben in de pilot de score van timely aangepast, zodat deze meer overeenkomt met de levering. De monitoring was niet representatief i.v.m. de datum orderbevesting.
- Voor "Supplier A" is optijd leveren geen probleem! Momenteel is dat nog geen probleem, kan wel in de toekomst veranderen, omdat je dan eerder moet leveren.
- Exact zou rekening moeten houden met weekend, dat doen ze nu niet.

Cost

- Price Stability: Reactie Paul; deze is lastiger. Als ik offertes aanvraag wordt de prijs lager, maar dat is geen fluctuatie van prijs toch? Je ziet geen verrassingen in prijzen, dus dan kan ik gewoon jaarlijks invullen neem ik aan.
- Price stability: Prijzen worden altijd aangepast om de inflatie. Lastig om deze in te vullen, fase tussenvoegen tussen sometimes en never, hardly never bijvoorbeeld?
- Samen met Paul tot de conclusie gekomen dat het wellicht slim is om mogelijkheid tot korting toe te voegen. Leverancier waar je bot "nee" krijgt, doe je niet prettig zaken mee.

Quality

- Kwaliteit is iets waar we naar willen streven, maar budget-technisch kan dit op het gebied van inkoop nog niet altijd gerealiseerd worden.
- Broken times: naar delivery verschuiven, dan wordt deze kop helemaal objectief en zijn de andere kopjes meer subjectief. Dan heb je alles logischer bij elkaar zitten.
- Broken items: De term "Broken items" is wel een beetje zwart-wit om zo te benoemen. Als er krasjes op zitten is het niet kapot, dan is het beschadigd → "Damaged".
- Guarantee: Garantie moet onder service i.p.v. kwaliteit. Ook nagaan of dit het goede woord is. Klanten krijgen garantie, bedrijven niet. Misschien veranderen naar: hoe gaan ze om met klachten? En dan opties als: nooit klacht gehad, we zoeken samen naar oplossing zoeken"
- Quality management system: Voor grote bedrijven is dit belangrijker dan voor kleinere.
- Corporate Social Responsibility: Goed dat je hier alleen pluspunten mee kan krijgen en geen minpunten.

Service

- Communication: Je hebt niet altijd meer contact met de medewerkers. Kunt offerte aanvragen en dan krijg je contact persoon, maar kan ook ooit digitaal. Extra optie aan toevoegen boven?
- Payment deadlines: opties die gebruikelijker zijn: 90, 60, 30, 14, 7 en vooruit betaling.
- Traceability: Bij verschillende krijg je het niet automatisch, maar wel als je een verzoek doet. Deze optie dus toevoegen: "Mogelijk op verzoek"

Risks

- Timely: Invoice: als wij niet betalen dan voldoen ze niet aan de leverdatum. Daardoor zou deze leverancier een slechte rating kunnen krijgen, terwijl het onze fout is.
- Price stability: Doordat de dollarkoers verandert, veranderen de prijzen in euro's. Op de site staat deze op dollars, maar uiteindelijk betalen we euro's. Zij zouden hier alleen niet slechter op beoordeeld moeten worden, het zou wel een "let op" momentje moeten zijn.
- Corporate Social Responsibility: Sommige bedrijven doen dit echt als verkooppraatje.

Eindscore + follow-up

- "No action required" misschien aanpassen "no need to fill in the action plan". Follow up actions kan je namelijk nog wel hebben. Goede evaluaties moet je ook delen!
- Reactie Paul: Eindscore is prima! Lijkt me representatief aan "Supplier A".

58. Notes purchasing pilot 2

This appendix includes the notes of the second purchasing pilot:

Attending: Paul Salomons, Niki van den Broek and Tamara Thielen
Pilot supplier: based on monitoring from 2 May 2017 till 24 May 2017
Date: 31 May 2017
Time: 13.00-15.00

Overall
- Het duurde ongeveer 45 minuten om de inkoop en monitor informatie met elkaar te koppelen, per leverancier over het tijdsbestek van één maand.
- Paul vult zelf de beoordeling in en vind het een mooi en duidelijk bestand en vind het een fijne basis om met leveranciers en collega's te delen.
- Het secuur invullen door Paul duurde minder dan 5 minuten, volgens Paul is dat prima behapbaar, niet te veel werk. hij vond het gemakkelijk om in te vullen.
- De punten die "supplier A" nu scoort vindt Paul representatief.
- Paul weet hoe hij procenten/keuze-opties aan kan passen, mocht dit in de toekomst nodig zijn voor MR P&S of voor de implementatie bij zusterondernemingen.

Cost
- Competitive prices = "Regular prices" krijgt maar 5 punten, dat lijkt me wel weinig.
  → Paul geeft ook aan dat je misschien moet kijken of de prijs ten opzichte van de kwaliteit en leverdatum zou het misschien meer moeten zijn.

Delivery
- Damaged items = in de opties staat nog steeds "broken" dat is iets te hard, ook aanpassen naar damaged.

Communication
- Communication = De optie "helpdesk" is 10 punten, maar die helpdesk kan ook slecht zijn. Als een bedrijf een vast aanspreekpunt heeft, dan zou dit 10 punten mogen hebben. Bij een helpdesk krijg je vaak steeds een andere medewerkers aan de telefoon of keuze opties.
  → Paul zou deze stelling liever zien als: "voldoende, matig, slecht"

End score
Paul zou de puntenscore iets veranderen:
- Rood = <5.9
- Oranje = 6 - 7 (Veranderen van kleur, zoals een stoplicht. Leveranciers die onder een 6 scoren zijn twijfelmatig. In pilot 1 kon je met een 7,9 nog een medium vallen, terwijl deze leveranciers prima scoren.)
- Groen = >7

Trigger om te beoordelen
- De trigger om te beoordelen is er nog niet. Paul zegt dat het hem handig lijkt om op korte termijn het Kraljic diagram te bepalen welke leveranciers beoordeeld dienen te worden. Zou volgens hem het fijnste zijn om zo af en toe wat te beoordelen in plaats van totaal. Je moet het niet op 1 dag zetten, maar in de eerste twee weken van januari, of de eerste weken voor of na de vakantie.

"Tell me, and I will forget. Show me, and I may remember. Train me and I will understand, but involve me, and I will learn"
- Philosopher Confucius.