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Improving the flow of production materials at Company X

Bachelor of Science in Industrial Engineering & Management

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Preface

In front of you lies my bachelor thesis *"Improving the flow of production materials".* This study has been performed at company X. This report is the last step in order to complete the Bachelor of Industrial Engineering and Management (IEM) at the University of Twente.

First of all, I would like to thank company X, both supervisors of company X and all the other employees participating in the research. They gave me a good input in terms of information and familiarize me with the several processes.

Secondly, I would like to thank Marco Schutten, who was the first supervisor of the university. His contribution in my research in terms of quick feedback and other support was very useful. Besides that, I would even like to thank Leo van der Wegen who performed as the second reader of my thesis.

Enjoy Reading!

Twan ter Laak

Heino, September 2021

Management summary

This thesis focusses on the improvement of the flow of production materials at company X. Company X fills tubes with liquid products by means of several filling machines. During this filling process, several materials are used.

Introduction

During the set-up of a batch for the production of the tubes at several filling lines, wrong materials show up. These materials are used to fill the tubes and are reusable. The work preparation department is responsible to clean and prepare and control these materials between the batches. However, these materials damage somewhere and withstand the quality controls at the work preparation department. Company X wants to decrease the number of those wrong materials during the set-up since they result into problems. The goal is to decrease the current percentage of wrong materials during the set-up.

Approach

To solve the problem, we first familiarised ourselves with all the current processes. We take a look at the process of filling the tubes, the process at the work preparation department to clean and prepare the materials, the several protocols for the production of pharmaceuticals. We perform Gemba walks and interviews to understand the processes. The next step is to identify several causes that results into the action problem of the damaged materials during the set-up. We conduct interviews with people from several functions to investigate the problem. The next step is to create solutions for the several causes of the problem.

Conclusion and recommendations

The current visual quality check of the materials has an acceptable margin of error. Company X should accept that there is a certain error rate in these quality checks. This is caused by the fact that these quality checks are performed by humans. To decrease the core problem, company X should focus on the prevention of damaging the materials.

It turns out that it is most beneficial to improve the material flow for machine 1 and 2. This process is more complex than of machine 3 and 4. The way in which the materials of machine 1 and 2 are transported and loaded in the ultrasonic baths results into damage of the materials. The most fragile materials are the insertion pipes and the filling needles.

We recommend company X to implement new boxes for the transportation from the machine 1 and 2 to the WVB. By implementing 2 new boxes with compartments and divide the materials over the compartments, the degree of freedom for the materials is limited.

The second recommendation is to implement 2 types of racks for the most fragile materials. These materials are the filling needles and insertion pipes. After the materials come from the line, they can be put in those racks until they are ready to be stored again. This decreases the chance of damage during the process, since the materials cannot come into contact with other materials anymore.

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List of Abbreviations

Abbreviation	Description
Autoclave	Machine that is used to sterilize the materials before use them at the filling lines.
CHT	Clean Hold Time. Materials should be used within a limited amount of time.
DHT	Dirty Hold Time. Materials should be cleaned within a limited amount of time.
QE	Quality Engineer. Job function that is responsible for the quality of the product.
Product contact material	Material that touches the liquid product.
Non-product contact material	Material that does not touches the liquid product.
IDC	An IDC-bag fits on an IDC-gate. This is the only way to bring materials in machines 1 or 2 without influencing the sterile environment.
WVB	The work preparation department, where the materials are cleaned.

1. Introduction

This report describes the research done in order to complete the Bachelor Industrial Engineering and Management at the University of Twente. To goal of this research is to prevent that reusable materials, used during the production, end up damaged at the filling line of company X. Section 1.1 introduces the company. We provide a general description about the process of filling the tubes in Section 1.2. Section 1.3 introduces the locations of the department where the assignment is performed. The problem context is provided in Section 1.4. Lastly, Section 1.5 and 1.6 discusses the main research question and the other research questions respectively.

1.1 Company

Company X is a worldwide company operating in the healthcare sector. The company fills tubes containing a liquid. In total, the company fills 3 different liquid products in the tubes: product 1, product 2 and product 3.

1.2 Filling process of tubes

The filling process of the tubes happens by means of 4 filling machines: machine 1, machine 2, machine 3 and machine 4. Each product goes into their own specific tube. The machines transfer the liquid product from large containers (the bulk), into the tubes.

- Machine 1 and 2: product 1
- Machine 3: product 2
- Machine 4: product 3

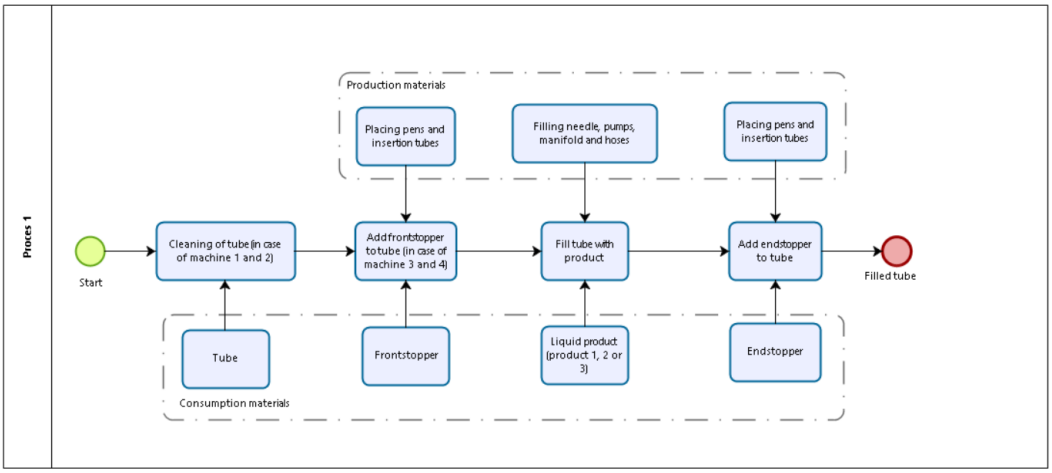

Figure 1 General filling process

Figure 1 contains a visual explanation of the general process of filling the tubes. This visualizes the steps from an empty tube towards a filled one. We distinguish consumption materials and production materials. Consumption materials are materials that are included in the final product. Production materials are materials that are used to fill the tubes. The production materials can be divided into the product contact materials and the non-product contact materials. Product contact materials are the materials that touch the liquid product. The non-product contact materials do not touch the liquid product.

The consumption materials included in the end-product are:

- The tube (1)
- The liquid product (2)

This is either product 1, product 2 or product 3

- Frontstopper and/or endstopper (3)

Prevents the liquid from leaking out of the tube

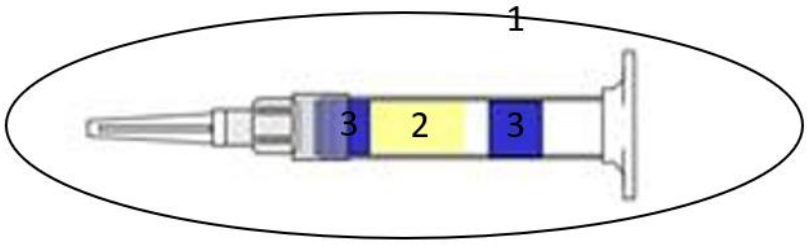

Figure 2 Filled tube

Most of the production materials are reusable. Between the production of 2 batches a series of actives takes place. This is called the change-over between batches. The change-over consists of 3 steps: control, cleaning and set-up.

- During the control step, the operators check if the line was clean during the production.
- Afterwards, the cleaning takes place. During this step operators remove all the production materials from the line and send them to the WerkVoorBereiding (WVB, which is Dutch for work preparation department). At the WVB, the production materials are cleaned and prepared for a new batch. During cleaning, the line is cleaned with water and ethanol and sanitated in the end.
- The last step of the change-over is the set-up. During the set-up, the line is prepared to produce a new batch. Operators install the production materials and connect the bulk to the line.

1.3 Machines and locations at the sterile department

As mentioned before, at the sterile department there are 4 filling lines and the WVB located.

Machine 1 and 2
Machine 1 and 2 are similar to each other. Both machines are in a separate room.

Machine 3 and 4
The machine 3 and machine 4 are comparable as well. These 2 machines are in the same room.

WVB
The reusable production materials removed from the line during cleaning will be transferred to the WVB. The goal of the WVB is to clean, prepare, control and sterilize both the producing materials for

their use in a new batch at the filling lines. Sterilization of materials is done by the autoclave. The autoclave is a machine that processes materials with dry steam.

1.4 Problem identification

This section describes the problem by visualizing the problem cluster, describing the core problems, describing the norm and reality and defining the research scope.

1.4.1 Problem cluster

By means of interview with people we derive the problem cluster.

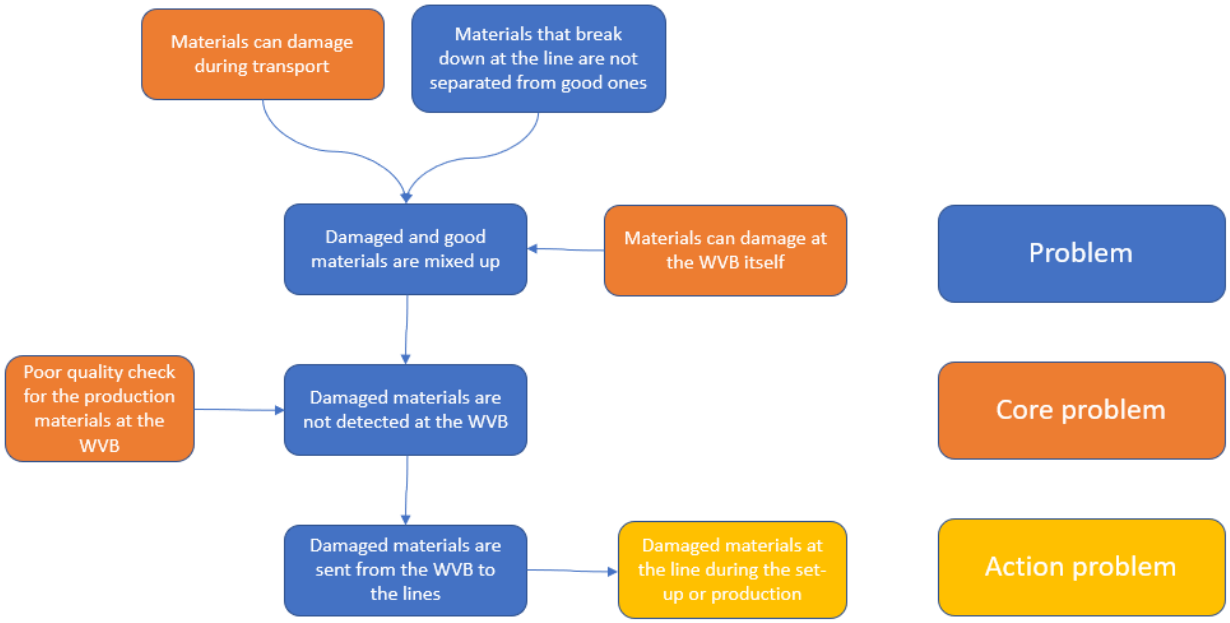

Figure 3 Problem cluster

1.4.2 The action problem

The action problem in our project is that production materials turn out to be damaged during the set-up for a new batch. It is possible to replace these damaged production materials, but it causes problems for operators at the line. Operators must add reserve materials to the line. This takes extra time, extra materials and results in confusion about the use and attendance of reserve materials at the line.

1.4.3 The core problem

It occurs that materials damage during transport or that materials that damage during production are not separated from the good ones. Additionally, the production materials damage at the WVB itself. This all results in the fact that damaged and good production materials are mixed up. This results in damaged production materials that are not detected. The core problems we derive is the poor quality check for the production materials at the WVB, and the damage of the materials both during the transport and at the WVB itself.

1.4.4 Measurement of norm and reality

Currently, it is estimated that in 5% of the set-ups there are damaged production materials. According to company X, a realistic goal is to reduce the percentage of damaged production materials during the set-up to 4%.

1.4.5 Research scope

The focus of the project is on the flow of production materials from the filling lines (machine 1, machine 2, machine 3 and machine 4) to the WVB and the process at the WVB itself. We include both production materials coming from the line after a batch ends, as well as the production materials coming from the line during the set-up phase or by means of an intervention. The only focus is on the production materials that are replaceable during the production of a batch. This is called an intervention.

The process of sending production materials and consumption materials from the WVB to the filling lines is out of scope. This is already optimized by company X a few years ago. We assume that production materials are in stock at the intern warehouse.

1.5 Main research question

The goal of the research is to prevent damaged materials of ending up at the line during the set-up. The research question we will focus on is:

- ***How can company X improve the process in which materials are sent to and processed at the work preparation department?***

1.6 Research questions

To answer the main research question, we answer several research questions. The first research question focuses on the analysis of the current situation. The second research question focus on the literature available to support. The third research question focus on improving the current situation. Each research question consists out of sub-research questions. We answer those research question in chapters 2 to 4.

1.6.1 Analyse

Chapter 2 involves the analysis of the current situation. The research question we focus on is:

- ***What is the current situation at company X regarding the use and process of production materials?***

We divide the research question in several sub-research questions. The sub-research questions we compute are:

- ***How does the actual process flow of production materials for machine 1 and 2 look like?***
- ***How does the actual process flow of production materials for the machine 3 and machine 4 look like?***
- ***Which condition of the production materials does not result in an intervention?***
- ***How is the visual quality check performed?***
- ***What is the throughput and inventory level of the production materials?***

To answer the sub-research questions, we will perform interviews and observations at the sterile filling department.

1.6.2 Literature

The research question we answer in chapter 3 is:

- ***What literature is available to improve the process to and at the WVB?***

To work towards the solutions, we perform a literature review. Chapter 3 describes the theoretical background we use during our research.

The goal is to prevent damaged materials of ending up at the filling lines. Hicks and Matthews (2010) provide an overview of several paradigms for manufacturing system improvements. Within each paradigm there are several tools and methods available to use. The 2 paradigms linked to our project of prevent damaged materials of ending up at the filling line are: process control and quality control.

The first method we will focus on is Six Sigma since it is linked to the process control paradigm. Secondly, we focus on Total Quality Management. This is related to the quality control paradigm.

There are several causes that results into our core problem. The framework should support in tackling the most relevant causes. The sub-research questions are:

- ***How can the Six Sigma method be used within our project?***
- ***How can Total Quality Management be used within our project?***

1.6.3 Improve

Chapter 4 focusses on the improvement plan of the problem. The research question in this chapter is:

- ***How can we improve the process flow of production materials to and at the WVB?***

The sub-research questions are:

- ***What causes should we tackle to solve the main problem?***
- ***Which solutions are available for the identified causes of the problem?***

2. Analysis of the current situation

This chapter involves the analysis of the current situation. Each section focusses on one research question. Section 2.1 focusses on the process flow of production materials for machine 1 and machine 2. Section 2.2 describes the process flow of production materials for machine 3 and machine 4. Section 2.3 provides a description of several kinds of damage and their context. Section 2.4 focusses on the visual quality checks. Section 2.5 provides a description of the inventory levels and throughput of the production materials for machine 1 and machine 2.

2.1 Process flow from machine 1 and machine 2

The start of the process flow is the moment when the production material leave machine 1 and machine 2. The end event is the moment when the production material is ready to be used at machine 1 and machine 2.

In Section 2.1.1 we provide general information about machine 1 and machine 2. Section 2.1.2 provides the process flow from machine 1 and machine 2 to the WVB and the process flow for preparing the new batch. Section 2.1.3 includes the list of production materials. The reasons why the materials are disassembled are stated in Section 2.1.4. In Section 2.1.5 we elaborate on the transportation from machine 1 and machine 2 to the WVB. Section 2.1.6 discusses the cleaning methods and Section 2.1.7 gives an introduction of the visual quality checks. Section 2.18 gives an explanation about the storing the materials. In the end, we discuss the way how materials are transported from the WVB to machine 1 and 2 in Section 2.1.9.

2.1.1 General information machine 1 and machine 2

The filling process at machine 1 and machine 2 happens under aseptic circumstances. This is needed because the product cannot be sterilized afterwards. The hygienic level within machine 1 and 2 is of level A, the highest grade. The level outside machine 1 and 2 is level D. Access to the area inside machine 1 and 2, during production, is possible by gloves. So that there is no direct contact of the operator with the product.

The tubes are situated in tubs of 16x10 pieces. The tubs are transported through the machine by means of an assembly line. The line processes 10 tubes per cycle. Per cycle, there are 10 filling needles that fills the tubes. In the same cycle, 10 stopper are pushed in the tube by means of insertion pipes and placing pens. The only stoppers added in these machines is the endstopper.

2.1.2 Process flow charts machine 1 and machine 2

We visualize the process of the materials from machine 1 and machine 2 by means of 2 flow charts. Figure 5 contains the flow chart from production materials after using them until storing them. Figure 6 contains the visualization of receiving a new order for a set of production materials under the materials can be send to the line.

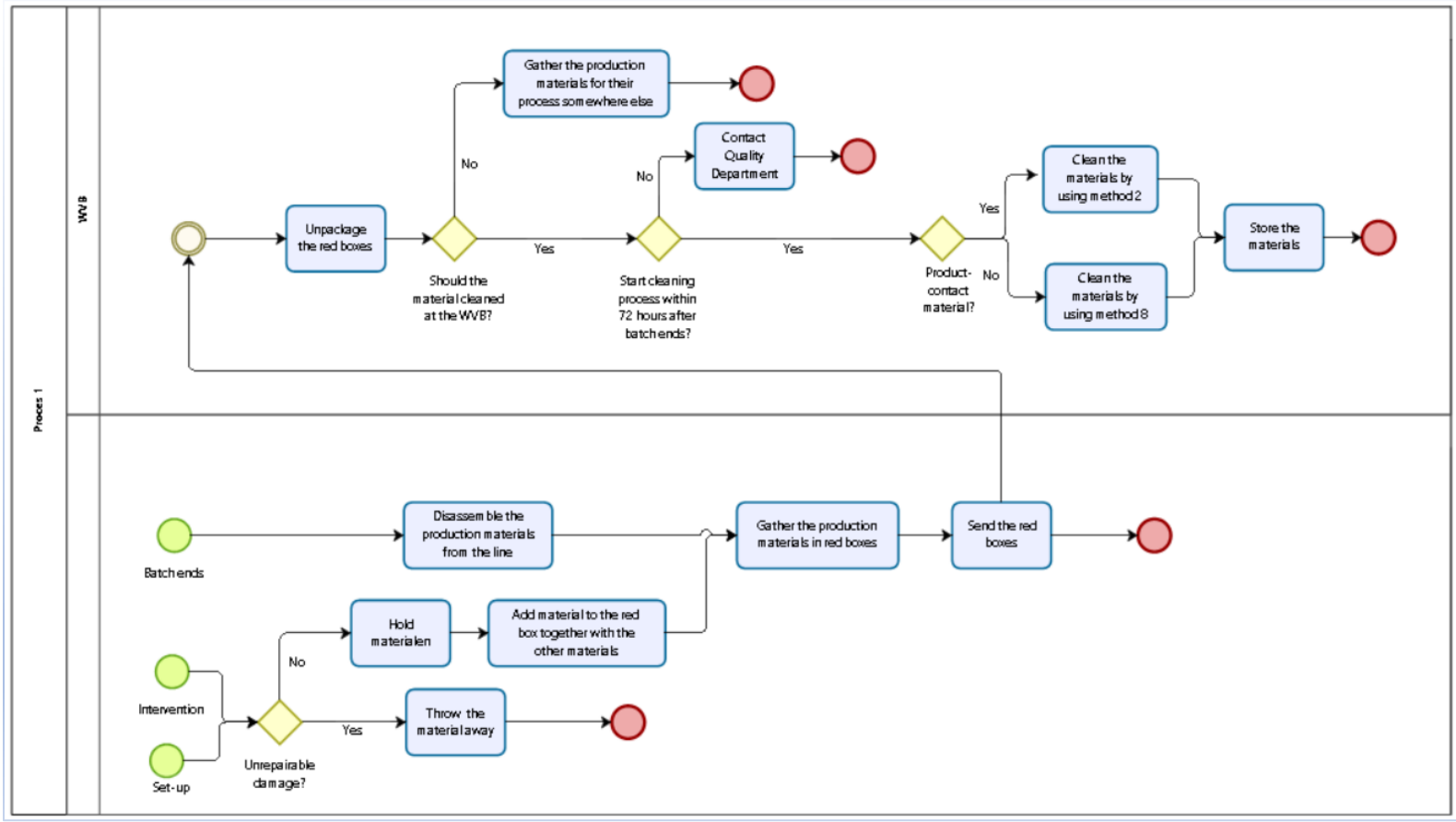

Figure 4 Process from machine 1 and 2 to WVB

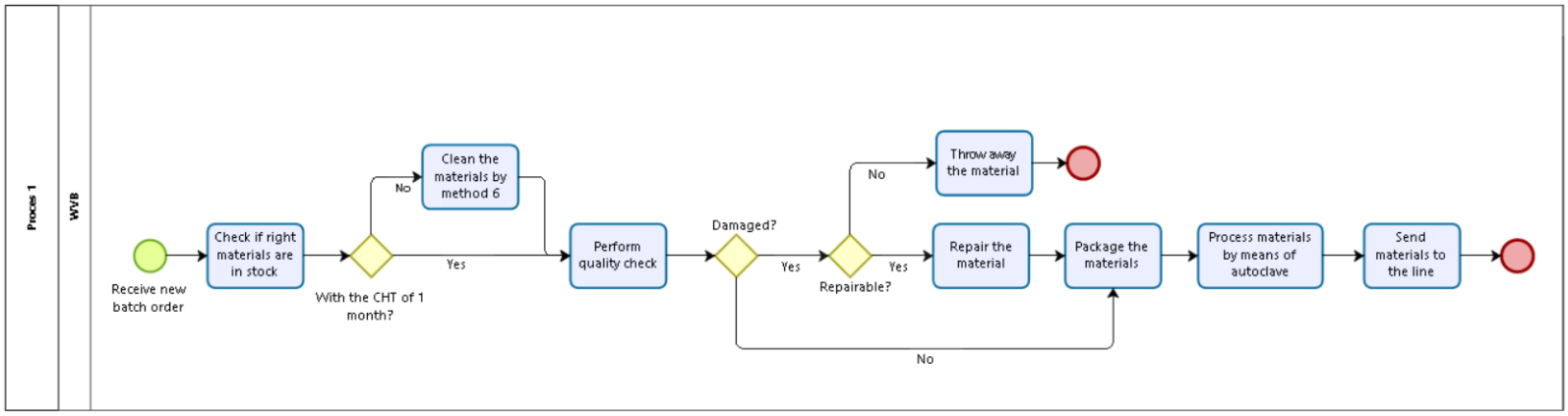

Figure 5 Prepare materials for a new batch

2.1.3 List of the production materials

Machine 1 and 2 both processes 10 tubes per cycle. This influences the number of materials on the line. The relevant materials are filling needles, insertion pipes, placing pens, pumps and manifold.

Material	Amount
Pump	10
Manifold	1
Filling needle	10
Insertion pipe	10
Placing pens	10

Table 1 Relevant materials on machine 1 and 2

2.1.4 Causes for disassembling the production materials

There are 3 reasons why materials are disassembled from the line: the batch ends, the material turns out to be damaged during the set-up or the material is changed by means of an intervention.

Batch ends

After a batch ends, operators disassemble the materials from the machines. This activity is performed by 1 or 2 operators. Besides the production materials in table 2**,** there are other materials that leave machine 1 or 2 as well, such as hoses and tools. The end of a batch is the most common way in which the materials leave machine 1 or 2. After a batch ends, there is no need for an aseptic work environment anymore. The doors of the machine is allowed to open to disassemble the materials, making it easier for the operators.

It differs between operators when they stop processing the batch. Some operators stop with the production as soon as the desired number of tubes is achieved. Others continue until no bulk is left over. Stopping as soon as the number of tubes is met results in liquid that is still in the filling needles, hoses, pumps and manifold. Continuing until all the bulk is used makes sure there is limited liquid left in filling needles, hoses, pumps and the manifold.

It is desired to have as little ‘disassembling’ from the materials that contains liquid near the machines as possible. This prevents unnecessary dirtiness in and around the machines. Disassemble the materials at the WVB has the preference. Even if the production is stopped after no bulk is left, there can be small rests of liquid in materials. Liquid might drop out of these materials, when disassembling it. The more liquid is spilled at the machines, the more must be cleaned. The order of disassembling the materials differs per operator.

Damaged production material in set-up phase

During the set-up, the production materials enter machine 1 and machine 2 in special cases. The operators take the respective production material out of the case by using gloves and pincers. The operators perform a short, last visual check of the materials. If the operators doubts whether the materials are indeed useable or not, he decides to not use it. During the set-up there is a new set of filling needles, insertion pipes and placing pens available.

Damaged production materials during batch

Sometimes a material damages during the batch. This can be solved by means of an intervention, in which the respective material is changed. Damaged production materials are either detected visibly or by means of In Process Control (IPC). IPC inspects the tubes, afterwards and outside the machines and looks for deviations within the tubes (height of the stopper, small components in the liquid, etc.). Deviations indicate for possible damages of the production materials.

Table 2 represents the materials, the amount of materials changed in total and the amount of interventions that is caused by the damage of the specific material. This gives insight in the frequencies of interventions of each material. During an intervention, multiple materials can be changed. When an insertion pipe is damaged and must be replaced, the placing pen must be replaced as well. This prescript explains the high number of placing pens replaced compared to the intervention linked to this material.

Material	**# Materials changed**	**# Interventions linked to material**
Filling needle	20	6
Insertion pipe	90	52
Placing pen	91	1
Pumps	0	0
Manifold	0	0

Table 2 Interventions of production materials (multiplied by a known factor)

2.1.5 Transportation from machine 1 and machine 2 to WVB

For both machine 1 and machine 2 there are 2 red boxes to transport the used production materials from these machines to the WVB. These red boxes are only used for the transport from the machines to the WVB and not vice versa. The red boxes include a few smaller open boxes. The purpose of these smaller open boxes is to keep the smaller production materials (insertion pipes, filling needles, pins) together and prevent the production materials from damage is this way. It is still possible that pumps are on top of the open boxes.

From the moment the materials leave the line, they are collected in the red boxes. There is no sequence how to fill the boxes.

2.1.6 Cleaning the materials

At the WVB, the materials are cleaned during several steps. For machine 1 and machine 2, there are two ultrasonic baths. One is dedicated for the non-product contact materials and the other for product contact materials. The ultrasonic baths contain baskets. These baskets are used during most steps of the cleaning. During these processes, the materials are free to move within the baskets; materials can come into contact with each other. According to interviews with operators, it turns out that the use of these baskets damages the materials.

There are several methods for different kind of materials.

- Cleaning method 2

This method is used to clean the product contact materials. Figure 6 visualizes the steps of cleaning method 2.

- Cleaning method 6

This method is used to clean the materials when the Clean Hold Time (CHT) is exceeded. Figure 7 visualizes the steps of cleaning method 6.

- Cleaning method 8

This method is used to clean the non-product contact materials. Figure 8 visualizes the steps of cleaning method 8.

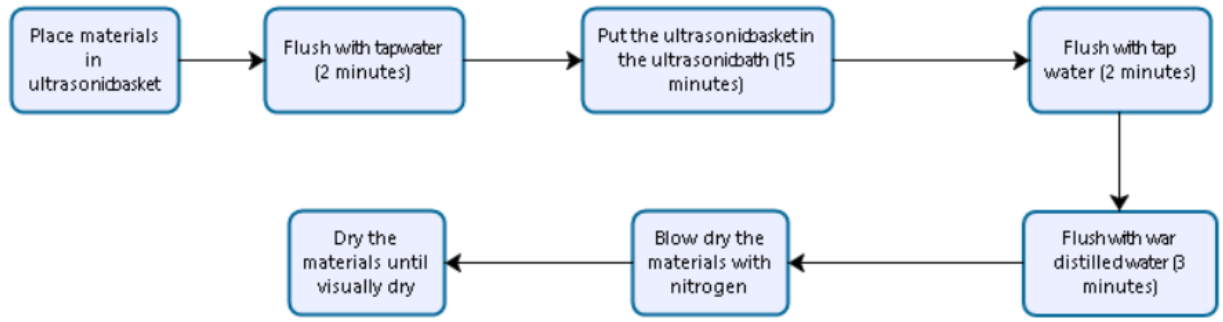

Figure 6 Cleaning method 2

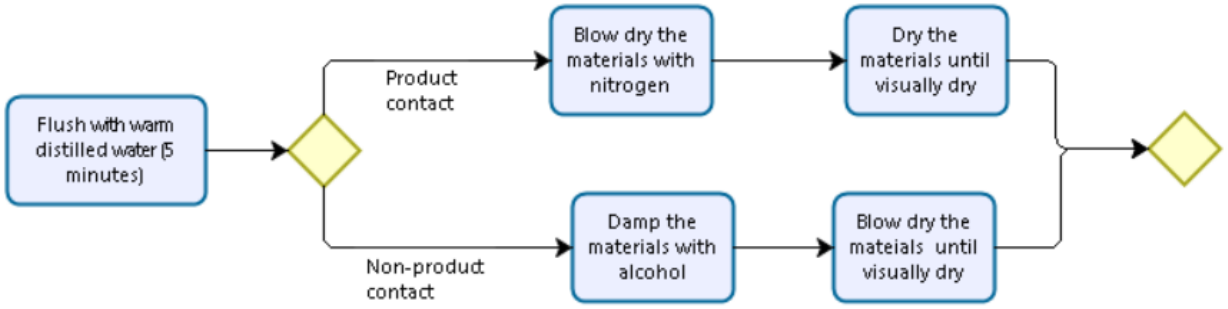

Figure 7 Cleaning method 6

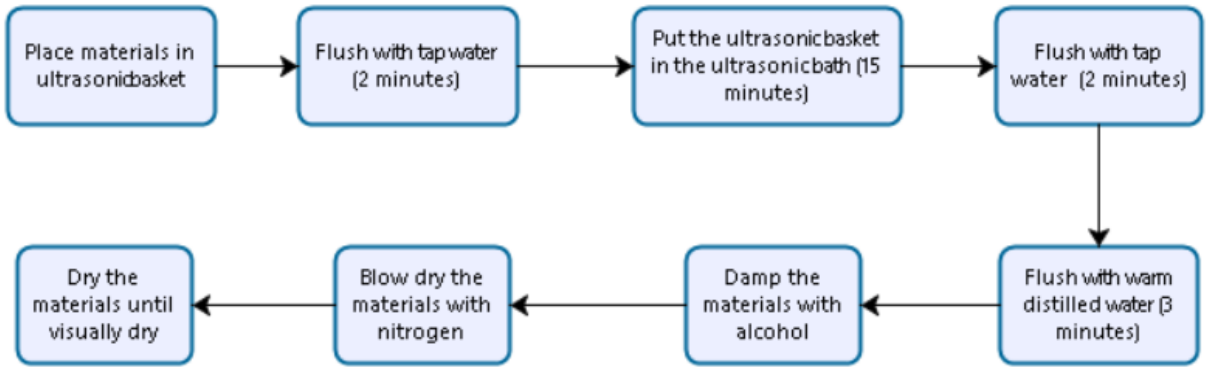

Figure 8 Cleaning method 8

2.1.7 Quality checks

Within the process flow there are 3 moments when the production materials are checked on quality.

- Quality check before storage
- Quality check before sending the materials to the filling lines
- Quality check during set-up

2.1.8 Storage

The production materials of machine 1 and 2 are stored at a separate room within the WVB. In this room there are cabinets containing several drawers with specials trays. The filling needles, insertion pipes and placing pens are situated in these trays. They are grouped per type of material and per expiration date.

2.1.9 Transport from the WVB to machine 1 or 2

The transport of the filling needles, insertion pipes, placing pens and pumps from the WVB to machine 1 or 2 happens in special cases. These cases are designed particularly for these production materials. It prevents the production materials from damage. The production materials are locked in the cases and do not have any degree of free movement. There are 3 types of cases:

- Case type 1: contains 10 insertion pipes and 10 placing pens.
- Case type 2: contains 10 filling needles.
- Case type 3: contains 2 pumps.

In general, operators prepare 2 sets of case 1 and case 2 before a batch. For case 3, containing the pumps, there are 5 to 6 cases. The full cases are enclosed in a IDC-bag that fits on the IDC-gate of machine 1 and 2. These are special bags that guarantee that the materials stay clean. Another advantage of the cases is that the production materials cannot damage the IDC-bags. Sharp parts can result in rips in the IDC-bag. This happens accidentally in case of the manifold, that is not transported in a special case (Interview). From interviews, we can say that the filling needles, insertion pipes, pumps and placing pens indeed do not damage during the process in the autoclave and the transport to machine 1 or 2 (Interviews). It turned out that operators are satisfied about these cases.

After the materials are packed in the right way, they are processed by means of the autoclave. The materials leave the autoclave from the WVB side. By means of special trolleys, the boxes with materials are transported to the gate of machine 1 or 2 again.

2.2 Process flow from machine 3 and 4

We start when the materials leave machine 3 or 4 and end when the materials are ready to be used again. We also mention the current detection measures. Figure 9 provides a visualization of the process.

In Section 2.2.1 we give some general information about machine 3 and 4. Section 2.2.2 includes a visualization of the process from the materials leaving the line until storing them. Section 2.2.3 includes the list of production materials. The start event for the process of sending the materials to the WVB is discussed in Section 2.2.4. In Section 2.2.5 we discuss the transportation of the materials from machine 3 and 4 line to the WVB. The cleaning, quality checks and storage of the materials is discussed in Section 2.2.6, 2.2.7 and 2.2.8 respectively. Lastly, we discuss the method of transport the materials from the WVB to machines 3 and 4 lines in Section 2.2.9.

2.2.1 General information about the machine 3 and 4

A big difference between machine 1 and 2 on the one hand and machine 3 and 4 on the other is that the air within machine 3 and 4 is not separated from the air outside the lines. In addition, there is direct contact of the operator with the product. The area around machine 3 and 4 is of level B. In the autoclave, the materials are sterilized. Within machine 3 and 4, the hygienic level is of level A. Product 2 and product 3 can be sterilized afterwards which is the reason that these materials can be sterilized afterwards.

Machine 3 and 4 adds both a frontstopper and endstopper to the tube. Machine 3 fills 1 tube per cycle. Machine 4 fills 2 tubes per cycle.

2.2.2 Process flow charts machine 3 and 4

By means of 2 flow charts we visualize the process flow of the production materials from machine 3 and 4. Figure 9 visualizes the process after the materials leave the line until they are stored at the WVB. The preparation of the materials before a new batch can be found in figure 5.

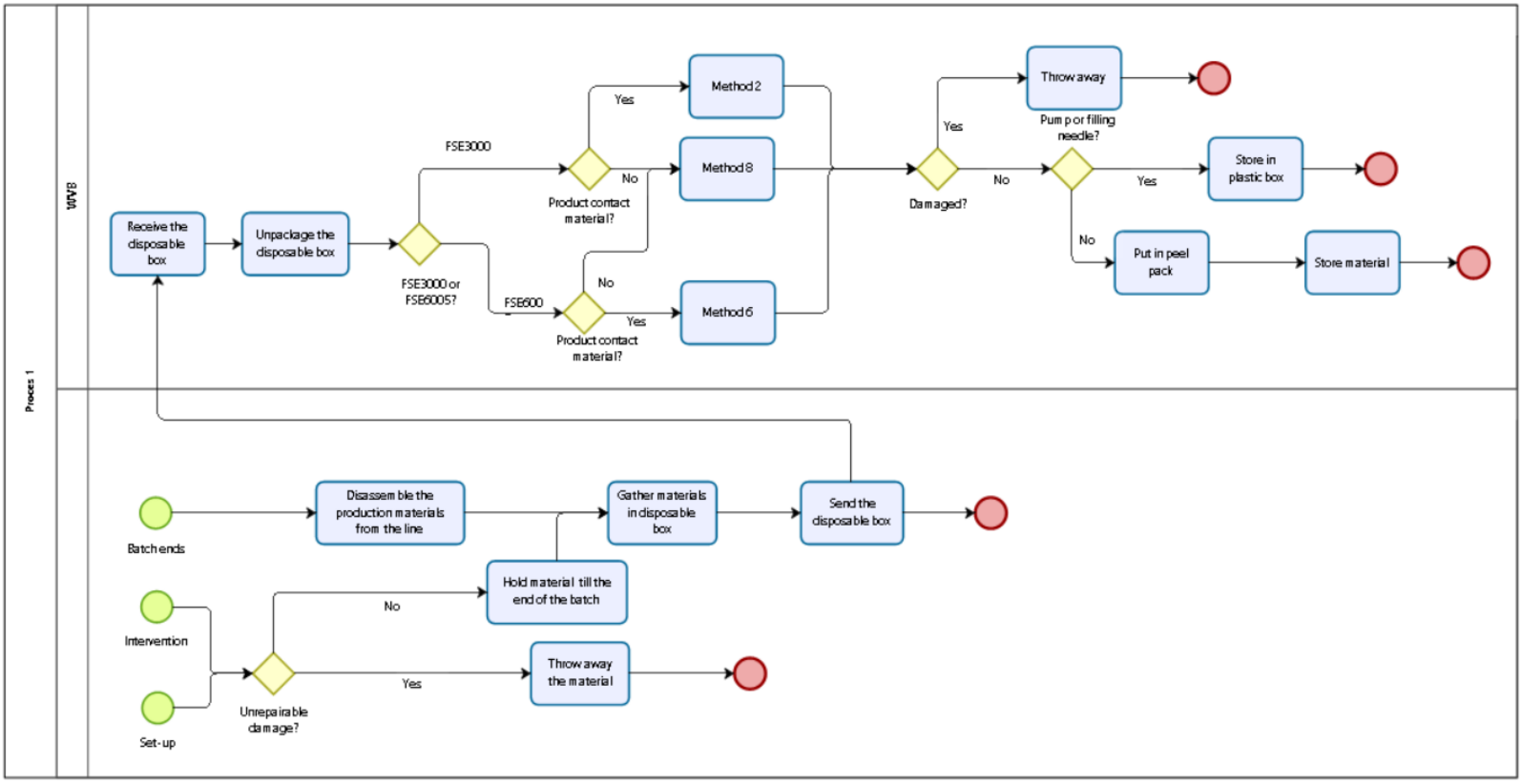

Figure 9 Process flow of machine 3 and 4

2.2.3 List of the production materials

The machine 3 processes 1 tube per cycle and the machine 4 processes 2 tubes per cycle. Table 3 involves the relevant materials.

	Number of materials for machine 3	Number of materials for machine 4
Pump	1	2
Frontstopper insertion pipe	1	2
Placing pen (frontstopper)	1	2
Endstopper insertion pipe	1	2
Placing pen (endstopper)	1	2
Filling needle	1	2

Table 3 Relevant materials on machine 3 and 4

2.2.4 Start event for the process

The 3 start events are similar as for machine 1 and 2: after a batch ends, during the set-up or during the production.

Batch ends:

At machine 3 and 4, there is in most cases some liquid in the product contact materials left. In most cases, the machines do not run until all the bulk is used but until the right number of tubes is produced.

Damaged production materials during set-up

Per batch there are 4 to 6 materials (filling needles, placing pens) available in total, depending on the operator at the WVB. The capacity of the autoclave is validated on a maximum of 6 pieces, but it turned out that 4 pieces are even sufficient (interview). Therefore, some operators decide to prepare 4 pieces. Every single production material is packed in a peel-pack.

Damaged production materials during the batch

Materials can even damage during the production. Replacing the materials during production at machine 3 or 4 is easier than at machine 1 or 2.

2.2.5 Transportation from machine 3 and 4 to the WVB

Access to the WVB, from the Level B department, is possible by passing 2 gates. The distance between the WVB and the level B department is much shorter than the distance between the WVB and machine 1 and 2. The total amount of materials that leave machine 3 and 4 is way less compared to the machine 1 and 2. The materials are gathered in disposable boxes. The tubes are delivered in these boxes and stay in the boxes just before they enter the filling line. After the tubes are out of the boxes, they are not used again.

There are 2 options for the unused materials at machine 3 and 4. The unused materials are still clean and packed in peel packs. Firstly, the materials can stay in the level B area. Since the materials are already clean and sterilized, they still can be used. The only condition is that the production material should meet the expiration date of the Clean Hold Time. Using the production materials in this way results in some additional administrative work. The sterilization run of the specific production material should be linked to the new batch.

The second option is to transfer the unused materials back to the WVB. The materials are still clean, so it is not needed to clean them again. The materials must be packed in a new peel pack since the peel packs are not allowed to be process in the autoclave twice. The original Clean Hold Time, which is the date till when the materials are usable if they are clean, does not change and the description will be transferred to the new peel pack. Of course, the materials are processed again by means of the autoclave.

2.2.6 Cleaning the materials

The steps of cleaning the materials at the WVB can be found in figure 6, figure 6 and figure 8. In total, there are three ultrasonic baths used for the materials of machine 3 and 4. One is dedicated for the non-product contact materials of both lines; one is dedicated for the product contact materials of machine 3 and the other for the product contact materials of machine 4.

2.2.7 Quality checks

For both the materials of machine 3 and 4 there are no tools available. The quality check is only performed in a visual way. Just after the production materials are clean and before the materials are packed in peel packs, there is a quick visual check. Afterwards, inspecting the materials become way more difficult.

2.2.8 Storage

The production materials are stored at the WVB. The total amount of production materials that is in circulation is way less as the materials for machine 1 and 2. For either machine 3 or 4, there should be 2 sets of 6 production materials (filling needle, placing pen, insertion pipes) abroad. The placing pens, insertion pipes are stored in 1 peel pack each. After the materials are cleaned, they are put into the peel packs. Each peel pack contains a sticker with the expiration date of the Clean Hold Time. The Clean Hold Time is 1 month for all the materials.

2.2.9 Transport from the WVB to machine 3 and 4

The peel packs with materials such as the insertion pipes and placing pens are placed in baskets. Between 4 to 6 materials each are available.

The pumps are connected to the hoses and the filling needles already. This results in less work during the set-up. The pump, hoses and filling needle are transported in a closable case.

2.3 Damage of the materials

In this Section we provide a description about the characteristics of the materials. Section 2.3.1 provides some information about the grey area there exists regarding the damage. Section 2.3.2 and 2.3.3 explains how placing pens, insertion pipes and filling needles work respectively. Section 2.3.4, Section 2.3.5 and Section 2.3.6 explains the different kinds of damage on placing pens, insertion pipes and filling needles. We explain the repairability of materials in Section 2.3.7. The frequency of damage on insertion pipes and filling needles is explained in Section 2.3.8 and 2.3.9.

2.3.1 Gray area of damage

Damage of the production materials and the acceptance of it turns out to be very subjective. There exists a grey area about the damage of these materials. It is desirable to have no damage on the materials at all. Throw away each material that contains a small damage is not realistic according to operators: *"If I must throw away these materials because of this small scratch, I have to throw away most of the materials since they even contain such small scratches."* This opinion is supported by other employees specialized in quality as well: *"Ideally, the production line runs with materials containing no damages at all. But up to a certain level these damages are allowed".*

2.3.2 Working of placing pen and insertion pipe

The green part represents the insertion pipe, red the placing pen and blue the stopper.

The stopper will be placed in the upper section of the insertion pipe. This section has the same diameter as the stopper. Both the insertion pipe and placing pen move downwards. The stopper is pushed through the insertion pipe since the speed of the placing pen is higher compared to the insertion pipe. The lower section of the insertion pipe has a smaller diameter, pressing the stopper a bit together. The placing pen pushes the stopper to the end of the insertion pipe. As soon as the stopper reached the right height, the insertion pipe moves up. The placing pen holds his position and the stopper is forced out of the insertion pipe. Since there is no friction between the tube and the stopper, there is no change in air pressure within the tube itself. In the end, both the placing pen and insertion pipe return to their original position to place the next stopper.

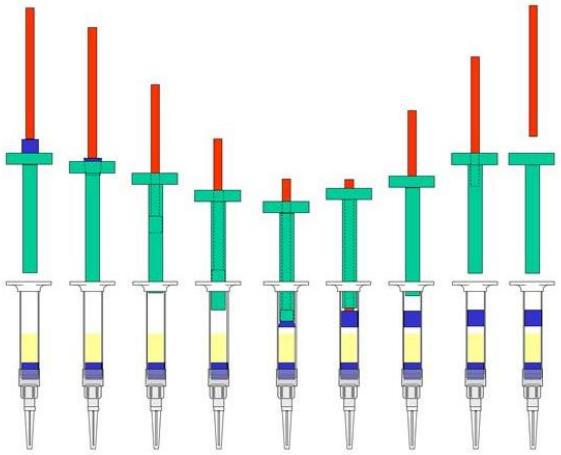

Figure 10 Placing a stopper by means of insertion pipe and placing pen

2.3.3 Working of filling needle

The tub with a row of 10 tubes is placed under the 10 filling needles. Ideally, the filling needles are centred in the middle of the tubes. As soon as the tub is in the right position, the filling needles move downwards into the tube and fill it in one cycle. Moving the needles downwards prevents liquid from ending on the flank of the tube. After they tubes are filled, the needles move upwards and the tub moves further.

2.3.4 Damage of insertion pipes

The insertion pipes are relatively fragile. Specifications of the insertion pipe become way more accurate than other materials. This is mainly caused by the distance the insertion pipe has against the stopper and the tube. Ideally, the insertion pipe is round without damage on the shaft. In general, there are 3 types of damage: the shaft of the insertion pipe is not fully round, there are dents on it or there are scratches on it.

A insertion pipe that is not fully round results in both problems with the stopper and the tube. An oval insertion pipe has a higher probability of touching the tube, which should be prevent as much as possible.

Dents on the insertion pipe cause problems with placing the stopper. A dent on the outside of the shaft results in a bump on the inside. This causes unnecessary friction if the stopper is forced through it. This friction might lead to heat (interview). These bumps might even lead to small particles coming from the stopper. These small particles might end up in the liquid, which will be detected by the Intern Product Control. Dents on the end of the shaft are more likely to position the stopper not fully right into the tube. If the dents are more upwards, there is more length in the shaft to position them right (operator).

Additionally, the shaft is slightly out of position when there are dents. A dent that is situated higher on the shaft results logically in a higher deviation of the shaft.

2.3.5 Damage of the placing pens

The placing pen is, in contrast to the filling needle and the insertion pipe, not hollow. This makes it less sensitive for damage. The only damage that occurs on the placing pen is that the small part at the end breaks off. In general, this only happens during production.

2.3.6 Damage of filling needles

The curvature of the needle itself is a common problem. Ideally, the needle itself should be completely straight. In this way, the needle ends up in the centre of the tube to fill it. If the filling needle is not centred, it is likely that small drops of liquid end up at the flank of the tube. After placing the stopper, some liquid will be between the ribs of the stopper, which is not ideally. In the past, company X had quite some problems with liquid between the ribs of the stopper.

2.3.7 Repairability of the materials

Damaged production materials are not useless anymore per definition. Some damage can be repaired. It is questionable whether this is desirable or not according to Quality Engineers. There are no guidelines regarding of repairing the materials.

Up to a certain amount it is possible to repair a curved filling needle by pressing it into the right direction manually. The decision whether it is useful or not depends per operator.

This is both possible on the line as well as on the WVB. On the WVB there is a tool available that supports in centering the needle. The needle is clamped in the tool and contains a marking. Repairing the material on the filling line itself is done based on a good sense. There are no tools available in supporting the right centre of the needle. By means of a pair of pincers, operators can bend filling needles into the right direction.

There is limited insight in the amount in which filling needles are repairable (interview). According to operators, it is arguable that there is a limit for it due to metal fatigue.

It depends per operator whether they repair the insertion pipes or not. Dents and scratches are not repairable. Regarding the oval insertion pipes, some operators decide to press them into the right direction. Others decide not to and throw them away.

2.3.8 Frequency of damage insertion pipe

By means of a sample, we gather data about the frequencies of the damage. We only measure the insertion pipes and filling needles, since it turns out that these materials result into the most problems. From interviews we determine the several kinds of damage. Figure 11 contains an indication about the frequency of each kind of damage.

The 3 types of damage are roundness of the shaft, dents on the shaft and scratches on the shaft. Each type is classified into 4 levels. By means of visual inspection we measure the damage.

Roundness of the shaft:

1. Completely round
2. Doubtable whether the shaft might be round or not
3. Shaft is not round
4. Shaft is clearly not round

Dents on the shaft:

1. No dents on the shaft
2. Very small dents on the shaft
3. Greater dents on the shaft
4. Big dents on the shaft

Scratches on the shaft:

1. No scratches on the shaft
2. Small scratches on the surface
3. Scratches into the surface
4. Big scratches into the surface

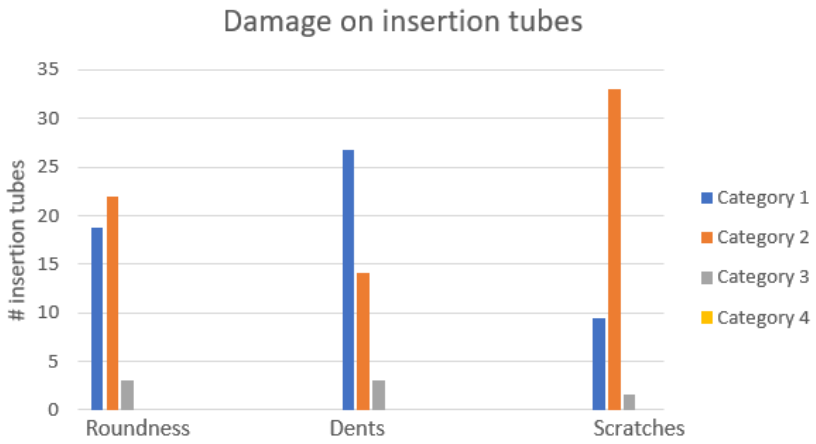

Figure 11 Damage on insertion pipes (multiplied by a known factor)

2.3.9 Frequency of damage for filling needles

The main damage of the filling needles is a curvature of the needle. By means of the tool, we identified 4 classes of damage. Figure 12 contains an indication about the frequency of the damage.

Curvature:

1. Completely right
2. Middle of needle does not pass the outer reference point
3. Outside of the needle does not pass the outer reference point
4. Outside of needle passes the outer reference point

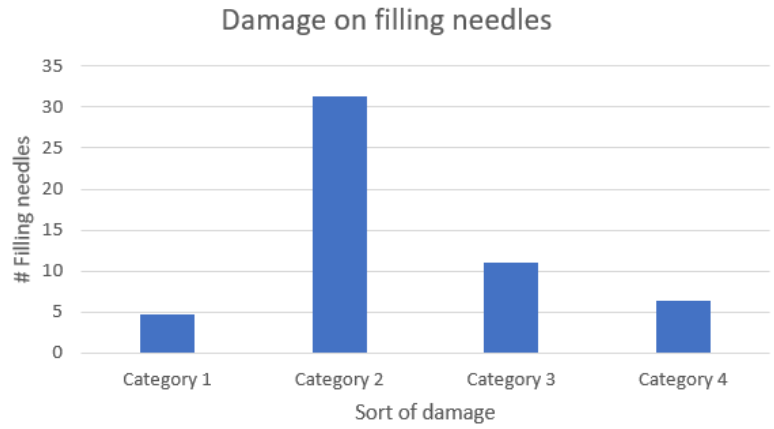

Figure 12 Damage on filling needles (multiplied by a known factor)

2.4 Performing the visual quality check

This section provides information about the visual quality check. In Section 2.4.1 we provide the instruction about the visual quality check. Section 2.4.2 explains the different interpretations there might be about damage on the materials. The moments when the quality check happens is explained in Section 2.4.3. In the end, the tools to support the visual quality check are discussed in Section 2.4.4.

2.4.1 Visual check instructions

The goal of the visual control of the production materials is to check if the production materials are damaged or not.

The instruction provides the following description about the visual check at the WVB: *"Inspect all insertion pipes, placing pens, pumps, filling needles and other materials for the set-up during the preparation for an order on deviations (dents and damages) by means of visual control. Make use of the tools/calibers. Hand the materials in at the production manager and pick new materials from the intern warehouse."* After performing the tasks, the operator must even sign a document to prove it.

2.4.2 Different kind of interpretations

The own perception of right and wrong materials is of big influence within the quality control. There can be different kinds of judgements about the same damage. As told in Section 2.3.1 there exists a gray area about the decision what is wrong or not.

We found out that there is no difference in knowledge about damage on the production materials between operators at the WVB and operators at the lines. When we performed interviews, both kinds of operators were able to explain the damage of materials and consequences very precisely.

2.4.3 Several quality checks

As told before, in theory there should be 3 moments when the quality of materials should be checked.

- **Quality check before store the materials (at the WVB)**

Right after the materials are clean and dry, the operators at the WVB should inspect each material according to the instruction. However, from the 3 quality checks, this one turns out to be the least important.

- **Quality check before package the materials (at the WVB)**

The second moment when the materials are visually checked is before the materials are prepared for a new batch. The operators at the WVB perform this check. After receiving the order of a new batch, the WVB prepares the production materials for using them. The operator at the WVB gathers all the production materials needed in the right quantities. Before the operator installs the materials in the case, he inspects the production materials. The inspection of the material happens mostly in a visual way. There are tools available to support the check. The operator can inspect the materials from a close perspective.

According to operators, a lot of damaged materials are already detected at the WVB. The detected materials do not end up at the filling line. However, there remains a small percentage that passes the quality check at the WVB.

- **Quality check during the set-up (at the line)**

In the set-up phase, the last quality check of the materials is performed by the operators at the line. The set-up is performed by 2 operators. At the line there are no tools available to support the check.

In case of machine 1 or 2, the cases enter the machine via the IDC-gates. The operator take the materials piece by piece out of the cases, and inspects them before installing them. If the operators judge the material as good, he installs the material on the line. If the operators doubts whether the material is good or not, he decides to not install it. A case with new materials is available to use.

2.4.4 Tools to support

At the WVB there are 2 tools available to support the quality check for the production materials of machine 1 and 2. The first tool supports the quality check of the filling needles. It includes a holder where the filling needle can be placed in. The purpose of the tool is to check if the needle itself is vertical. If the filling needle is not vertical, the operator can bend the needle into the right position.

The second tool can be used to check if the filling needles, insertion pipes and placing pens can be clamped in machine 1 and 2 in the right way. The tool checks if there are no metal burrs on the production material that withholds the materials to be in the right position on the line. The materials should get in the tool smoothly. From a sample size of 30 pieces for the filling needles, insertion pipe and placing pen it turns out that all materials fit in the tool.

2.5 What is the throughput, inventory level and consumption of the production materials?

This section focusses on the inventory and throughput of the production materials for machine 1 and 2. We describe them respectively in Section 2.5.1 and Section 2.5.2. In Section 2.5.3 we discuss the average consumption per year.

2.5.1 Inventory level of production materials for machine 1 and 2

The current inventory levels of the materials are included in Table 4. We measured the level at the begin of a production season. During the 2 production sessions, the inventory does not have a constant level. At the begin of each season, a new set of materials is added to the current inventory.

Material	Inventory levels
Filling needles	141
Insertion pipes	140
Placing pens	145
Pumps	47
Manifold	9

Table 4 Inventory level production materials of machine 1 and 2 (multiplied by a known factor)

2.5.2 Throughput of production materials for machine 1 and 2

The throughput is related to the production volume at machine 1 and 2. There are multiple scenarios about the use of these 2 lines; 0 lines are running, 1 line is running and 2 lines are running.

0 lines are running

In general, when machine 3 or 4 is running, machine 1 or 2 are not. In this case, the materials are all at the WVB in the cabinets.

1 line is running

Production at machine 1 or 2 runs mostly by using either machine 1 or 2 at the same time. The available operators switch between the 2 machines. While one line is in production, 2 other operators go to the other to perform the sanitization and the set-up. During the set-up the number of materials from table 5 are available. The materials stay at the line during the production of the batch. While one line is running, the set-up at the other will be performed. The same set materials of table 5 is available at the line. If the first line ends production, production moves to the second line. At the first line, the line clearance is performed and the materials go the WVB. In general, the materials are clean within a few hours. This is in time, before the set-up at the first line starts again.

2 lines are running

Sometimes both machine 1 and 2 run at the same time. Basically, this only happens if production runs behind schedule. Only two batches will be produced simultaneously, otherwise the intern inventory becomes too high. The available operators are divided over machine 1 and 2. Due to capacity problems, the line does not run during the pauses. When a production batch ends, the operators dedicated to that line make sure the line clearance is done, start the sanitization and perform the set-up.

The current inventory level is high compared to the actual throughput. The Clean Hold Time (CHT) influences the actual throughput of all the materials. In general, operators decide to take the materials with the longest CHT. These are always the material that came in last. Therefore, this system can be seen as a Last In First Out system. This results into the fact that not all materials are used an equal amount of times.

Material	Materials used for running machine 1 or 2
Filling needles	20
Insertion pipes	20
Placing pens	20
Pumps	10
Manifold	1

Table 5 Materials during set-up

2.5.3 Consumption of filling needles, insertion pipes and placing pens

The transactions of the production materials in the intern warehouse are traceable. This makes it able to dive into the amount of production materials that is consumed. We only have the information for the filling needles, insertion pipes and placing pens. The average consumption can be found in the Table 6.

Material	Average consumption (pieces/year)
Filling needle	68.3
Insertion pipe	187.1
Placing pen	79.0

Table 6 Consumption of materials (Multiplied by a known factor)

2.6 Conclusion

Company X fills the tubes by means of several filling lines: machine 1, 2, 3 and 4.

A relative large amount of materials flows between machine 1 and 2 and the WVB. The materials are transported from machine 1 and 2 to the WVB in red boxes. When the materials are at the WVB, they are cleaned during several steps. The exact route materials follow differs between the non-product contact materials and the product contact materials. When the materials are clean, they are stored in cabinets at the WVB. Before using the materials again at the line, the materials are sterilized by the autoclave. Most of the materials are transported from the WVB to machine 1 and 2 in special cases.

The number of materials leaving machine 3 or 4 is less compared to machine 1 or 2. Transport the materials from machine 3 and 4 to the WVB happens in disposable boxes. The materials are cleaned at the WVB to reuse them again. The cleaning method differs between product 2 and product 3. Additionally, there is a difference in the cleaning method between the product contact and non-product contact materials as well. Each individual material is stored in a peel pack.

It turns out that the most critical materials are the filling needles and the insertion pipes. Regarding the insertion pipes, the materials damage quickly and the performance on the line is narrow. The filling needles damage easily. Less problems occurs with pumps, placing pens and the manifold. These materials can be identified as robust and less sensible for damage. The frequency in which insertion pipes and filling needles turn out to be damaged at the line much higher as the other materials.

The visual quality control of the materials happens at 3 points: before storing them, before preparing them for use and at the line itself. For the materials of machine 1 and 2 there are a few tools to support. For the materials of machine 3 and 4 there are no tools available. It turns out that there is some grey area about the damage of the materials.

In most of the times machine 1 or 2 is running. In general, there is 1 machine running at the time during the season. It remains difficult to predict the exact throughput for the materials since there is no structure regarding the use of the inventory.

3. Theoretical framework

This chapter provides 2 theoretical methods that might be useful within our project. As mentioned before, we found 2 theoretical frameworks that might assist in the process control and quality control. The framework should support in tackling the relevant causes of our problem. Section 2.1 describes the Six Sigma theory. Section 2.2 focusses on Total Quality Management.

3.1 Six Sigma

The Six Sigma management focusses on a constant quality of a process. A process can be defined as collection of interacting components that transform inputs into outputs toward a common aim (Gitlow et al, 2012, p.7). In manufacturing, services and administrative processes it improves both the defect reduction as well as cycle times (Gitlow et al, 2012)**.** Six Sigma strives for a maximum of 3.4 failures per 1 million opportunities. Focusing on a constant quality is a continuous process, including several steps of improvement (Bergman et al., 2018)**.** We elaborate on the First Time Right method in the section below.

3.1.1 Theory of First Time Right (FTR)

First Time Right is both a concept and a KPI used within Six Sigma. It focusses on carrying out activities right in the first time and every time. Each mistake in the process results in rework, which is a type of waste. The goal is to prevent mistakes in the process. It is important to produce without failures and damages instead of repair and inspect the materials.

Within processes that involves human factors, mistakes might occur. The management cannot expect from employees to be flawless all the time. “It is the responsibility of employees to work orderly and dedicated, but is the responsibility of the management to minimize the chance of potential failures” (Theissens, 2019, P.192).

Within First Time Right, a structured risk analysis method called Process Failure Mode and Effect Analysis (Process-FMEA) is used. This method identifies potential failures in processes, products or services. The goal in the end is to prevent potential failures and create solutions for it.

To create a process-FMEA, 12 steps need to be considered (Bergman et al., 2018). These 12 steps are:

1. **Process:** It describes the process that is analyzed.
2. **Function:** It describes the function and goal of the process
3. **Requirements:** Involves the description or demands that should be met.
4. **Potential Failure Mode:** Describes the failures that can occur.
5. **Effects of failure:** Describes the impact to the processes if failures occur.
6. **Severity:** Describes the severeness of the impact on the problem
7. **Potential Causes:** Describes the causes of the failures. In order to identify the causes of the failures, this step includes an Ishikawa diagram. An Ishikawa diagram focusses on 6 different types of causes: measure, machine, material, method, man and environment.
8. **Controls:** Describes the current process control prevention to detect the failure mode.
9. **Occurrence:** Describes the likelihood that the failure occurs.

10. **Detection:** Describes the activities conducted to verify the product meets the specifications.
11. **Risk Priority Number (RPN):** The RPN-score indicates the risk. A higher number indicates for a higher risk.
12. **Actions:** Describes how to improve the process.

3.2 Total Quality Management (TQM)

According to Slack et al. (2016) Total Quality Management is: "An effective system for integrating the quality development, quality maintenance and quality improvement efforts of the various groups in an organization so as to enable production and service at the most economical levels which allow for full customer satisfaction". TQM is rather a management philosophy striving for continuous improvement in all functions of an organization. However, it turns out that the implementation of TQM is a complex and difficult process. (Mohammad Mosadegh Rad, 2006).

According to Kulenovic et al. (2020), there are 6 main factors important to take into account in TQM: top management leadership and commitment, customer focus, employees, suppliers, process management and information and analysis.

The most important factor for a successful implementation of TQM is the commitment of the top management. TQM is a management philosophy and the initiatives of improve quality comes from the management.

The customer satisfaction affects the success or failure of a company. A high level of customer satisfaction is crucial. Therefore, TQM should focus into the customer needs, wants, perceptions and preferences. The voice of the customer is critical within TQM.

Within an organization, each person has an influence on the quality. By offer trainings and educations, the employees can actively be involved.

The parts delivered by the suppliers form a main input in the process and in the final output of the process. Therefore a good supplier relationship is critical.

Organizations are systems of interconnected processes. Improving the process results into an improved performance of the organization (Deming, 1986).

Lastly, the information and analysis turns out to be a critical factor in TQM. Reliable information is needed to maintain and improve the quality. This data should be easily accessible for the employees.

3.3 Conclusion

Six Sigma focusses on a constant quality of a process. It strives for a maximum of 3.4 defects per 1 million opportunities. The First Time Right method is concept that focusses on carry out activities right in the first time and every time. The FMEA process helps to carry out the activities right in the first time.

In TQM the commitment of the top management is of great influence. In our case, the main focus of the top management is on the production process of filling the tubes. The process we focus on is important as well, but will never get a high priority. Additionally, TQM mainly focusses on a production aprocess,

where every step adds components or value to the product. This is not the case in our project. We cannot improve or develop the quality of the product.

The theory we use during the improvement part is the method of First Time Right. This method, coming from Six Sigma, focusses on the process rather than on quality. In the end, it is more logical to focus on a framework that focusses on maintaining the quality by preventing the materials from damage in the process. It is not the purpose to develop or improve the quality of materials. In theory, materials are of a good quality when leaving the line. Most damage occurs outside the machines. These reasons makes the TQM framework less applicable

4. Improving the current process

This chapter focusses on the improvement of the current process. To give structure towards a way of improving the current situation, we make use of the Process Failure Mode and Effect Analysis method from First Time Right. Section 4.1 combines the analysis phase and the FMEA. In Section 4.2 we provide the causes of the problem by means of an Ishikawa diagram. In Section 4.3, we elaborate on cause of materials breaking on the line. In Section 4.4, we focus on the fragile materials as a cause. In Section 4.5, we elaborate on the ultrasonic baths. Section 4.6 describes the solutions for the current red boxes. In Section 4.7 we describe the visual quality checks. Section 4.7 measures the possible solutions by means of a impact-effort matrix. Section 4.9 elaborates on the implementation of the solutions. Finally, Section 4.10 gives an indication about the effect the solutions have.

4.1 Process Failure Mode and Effect Analysis

The First Time Right method focuses on doing the job right in the first time. In our project, we make sure that only useable materials end up at the line again. In order to achieve this, we follow the steps of the Process Failure Mode and Effect Analysis method. In the end, step 12 is the most important step.

- The first step of the FMEA is the description of the process. During the whole project we focused on the process of sending the materials from the filling lines to the WVB and the way how materials are processed at the WVB.
- The second step, the function of each step in the process is explained in the Chapter 2.
- The third step involves the requirement that should be met. This is the ideal situation of having no damaged materials at the line during the set-up.
- The fourth step in the FMEA is the description of the potential failure mode. The potential failure mode is identical to the action problem of our research. This is the damaged materials that end up at the line during the set-up.
- Effects of the failure are explained in step 5. Damaged materials during the set-up results in extra work for the operators performing the set-up.
- Step 6 explains the severity of the failure mode. The effects of the failure more are not very serious. It has no influence on the quality of the end product. It only influences the time needed to perform the set-up itself.
- Step 7 includes the potential causes for the failure mode. Identify the causes and create solutions for the relevant causes is the first focus of this chapter. The Ishikawa diagram in section 4.2 identifies the relevant causes for the problem.
- Step 8 describes the current prevention method for the failure mode. In order to detect that damaged materials end up at the line the 2 visual quality checks at the WVB are performed. An elaborate description of the visual quality control can be found in section 2.4.
- The occurrence of having damaged materials on the line during the set-up is the current reality of the action problem. It turns out that the percentage of wrong materials during the set-up is around 5%.
- The likelihood to detect the actual damaged materials at the line is hard to predict.
- The Risk Priority Number (RPN), which indicates the risk for a problem, is not of influence within this research. Based on this Risk Priority Number, managers decide if the problem is urgent enough or not. However, in this research our goal is to solve the problem. This makes the

calculation of the RPN unnecessary. The possible solutions for the relevant causes in step 12 is the second main focus of this chapter.

4.2 Ishikawa diagram

We conduct various interviews and brainstorms with operators to find out the real problems behind the damage of materials. The Ishikawa diagram involves all causes that end up in the problem. The Ishikawa diagram mainly focusses on the problems of machine 1 and 2. From interviews, it turns out that it is most beneficial to focus on this machines. Not all causes mentioned in this Ishikawa diagram are easy to solve.

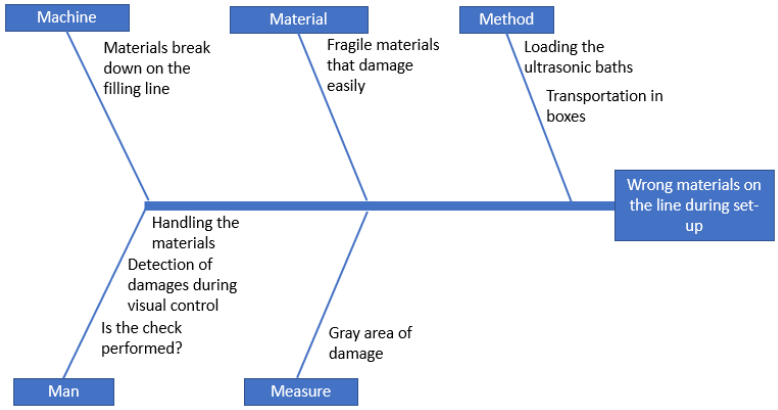

Figure 13 Ishikawa diagram

4.3 Materials break down on the filling line

This section is related to the machine cause of Figure 13. It is given that materials might break down on the filling line itself. In theory, there is a chance that the materials end up at the line again during the set-up. However, in according to operators it is not very likely that this happens.

4.4 Fragile materials

This section elaborates on the material cause of Figure 13. In Section 4.4.1 we discuss the relevance for taking the fragile materials into account for the solution. In Section 4.4.2 we elaborate on the prevention of damage.

4.4.1 Relevance for improvement

Fragile materials are another reason why the materials might damage. We have to deal with the current materials and create solutions to prevent them from damage. It turns out that the filling needles and insertion pipes are the most fragile materials. Prevent these materials from damage has a higher priority than the pumps, manifold and placing pens. The ability to change the materials itself is out of scope.

4.4.2 Prevention of damage

In the ideal situation we prevent each material from damage as good as possible. This is possible by lock each material during the transport. Since the materials are locked and cannot touch each other, the chance of damage is limited. However, at some point it probably takes more effort to lock the materials than it has benefits.

4.5 Loading the ultrasonic baths

This section elaborates on the method cause of Figure 13. In Section 4.5.1 we discuss the relevance for improving the way in which materials are cleaned in the ultrasonic baths. In Section 4.5.2 we elaborate on the possibility of creating several sections in the baskets. In Section 4.5.3 we discuss the possibility to transport the materials directly in the ultrasonic baskets.

4.5.1 Relevance for improvement

The ultrasonic baths are a reason why materials damage. Especially the step when materials must be placed in and out the ultrasonic baths is critical. The way in which the materials are handled differ per operator. Some operators load them in the baskets in a rough way, while others do not. By making this process more shatterproof, we decrease the human influence of damaging the materials.

The ultrasonic baths are necessary to guarantee that the materials are cleaned in a proper way. In Section 4.2 we shortly mentioned the effect of separating the materials at the WVB.

4.5.2 Separation of the basket

A possibility is that we create separate sections in the basket. This prevents that the robust materials might not end up on each other.

4.5.3 Transport in baskets of ultrasonic bath

It is excluded, due to regulations, to move the baskets from the ultrasonic baths outside the WVB. A solution in which we take the baskets to the lines and gather the materials directly in the baskets is therefore impossible.

4.6 Transportation in boxes

This section elaborates on the method cause of Figure 13. In section 4.6.1 we explain the relevance for improving the cause that the boxes result in damage on the materials. Section 4.6.2 discusses the options for the amount of boxes. In section 4.6.3 we elaborate on several methods for separating the materials. Section 4.6.4 introduces an additional solution besides the boxes.

4.6.1 Relevance for improvement

The current transportation method from machine 1 or 2 to the WVB has an impact on damaging the materials. There is no sequence about the division of materials in the 2 boxes. The robust materials and fragile materials are mixed up in the 2 red boxes. This damages the fragile materials. We should make the way in which materials are transported in the boxes shatterproof, to prevent that materials might end up mixed through each other. Shatterproof means that the materials can no longer damage during the transport from the line to the WVB.

Operators at the WVB still have to separate the materials since each material is dedicated to an ultrasonic bath. Separating the materials in this way at the WVB even results in damage. the boxes, might decrease the number of damaged materials. We can divide the materials based on several reasons.

4.6.2 Choice between 1 or 2 boxes

The materials can be transported from the WVB in 1 or 2 boxes.

- **1 box**

In the past, the materials were transported by means of 1 box. This was not an ideal method. It turns out the be heavy and large. This was a reason to switch to the current red boxes.

- **2 boxes**

The current method is to transport the materials in 2 boxes. This is preferable in terms of the division of weight.

- **3 or more boxes**

It is not preferable to use 3 or more boxes. The more boxes there are, the more boxes needs to be transported. This is not efficient.

4.6.3 Division of materials

Dividing the materials over the boxes can be done in multiple ways. We discuss two possibilities below.

- **Division based on the dedicated ultrasonic baths**

A division based on the use in the ultrasonic baths basically means that the product contact and non-product contact materials are separated. Separating them directly in this way eliminates the step of separate the materials just before loading the ultrasonic baths. This prevents that the operators have to search for the right materials in the ultrasonic bath since they are already separated.

- **Division based on fragile and robust materials**

Another possibility is to make a division based fragile and the robust materials. The fragile materials might come into contact with robust materials. According to operators it is more likely that a heavy robust pump will damage a filling needle than an insertion pipe does. Separate the materials between robust and fragile materials might decreases the chance of damage. In the end, the operators at the WVB still have to divide the materials for the ultrasonic baths.

4.6.4 Implementation of racks

Creating a smart division of the materials might not be enough to decrease the chance of damage. To increase the effect of the division, it is also beneficial to separate each material. When the materials are separated at their position in the boxes, the chance of damage during the transport decreases.

In the past, the transportation of materials took place by means of special trays. For each individual material there was a niche to put it in. This method was not very successful. It took much time to put each individual material in their niche and the trays were heavy. Additionally, it was hard to clean the tray itself due to the many niches in it. Taking this into account, we set up a few requirements for the design of the new racks.

Requirements for racks:

- Racks should prevent the materials from damage
- Materials should fit in the rack easily

- Rack should fit in the boxes that are used for transporting the materials from the machine 1 or 2 to the WVB.
- Racks should fit in the ultrasonic bath
- Racks should be made from stainless steel.
- Rack should be effective. There is no need to create racks for materials that cannot damage.
- The number that fits in the rack should be equal to the number of materials that fits on the line.

4.7 Visual quality check

This section elaborates on the man and measure cause of the Ishikawa diagram. The gray area of damaged materials is closely related to the detection of damages during the visual quality check. The relevance for improving the visual quality check is discussed in section 4.7.1. In section 4.7.2, the efficiency is described related to theory. Section 4.7.3 identifies the stages during the quality check.

4.7.1 Relevance for improvement

The visual controls at the WVB can be seen as a cause of the problem as well. These are the only 2 options when the materials can be checked to prevent the action problem. We can improve the visual quality control in 2 ways. Firstly, we can focus on the quality and efficiency of the controls. Secondly, they can focus on the quantity of the controls.

4.7.2 Efficiency of the quality check

Kajuwinska and Vogt (2015) identify 5 factors that influences the efficiency of a visual quality check. These 5 factors are: technical, psychophysical, organizational, workplace environment and social. Improve one of these factors improves the efficiency of the quality check as well.

The technical factors include all the physical parts within the inspection. We do not see any space for improve this aspect since the materials are clearly visible during the inspection. The psychophysical includes elements such as the intelligence and ago of the operators. We do not have any influence on these aspects, so we cannot improve this aspect. The organizational factor focusses on how the inspections are supported in terms of organization. We do not see any time pressure for the inspection. The workplace environment factor deals with the workplace itself. The quality of the environment is sufficient according to the employees. Therefore, this aspects has no room for improvement as well.

4.7.3 Stages during the quality check

Fox (1975) distinguishes 4 stages during a visual inspection. We recognize those 4 stages in the visual quality inspection at the WVB.

The first stage is the search for potential damages. There are 2 quality checks at the WVB. The first one is before storing the materials. The second one is before sending them to the line. The second check is the most important one according to the operators at the WVB. This one is always performed according to the operators at the WVB. The quality check before storing the materials is less important. This one is not always performed.

The second stage is the detection of the damage. Improving this stage is not necessary. It turns out that the damage of materials is clearly visible when an operator checks the materials.

The third stage is to classify the damages. This turns out to be difficult. Operators can see the damage but are not always able to judge whether this material is still useful or not. In some cases, when operators doubt about this, they damage the materials themselves. In this case, the material is useless anyway.

The last stage is the decision about the damages. In case the material is judged as damaged and useless, the operator throws the material away.

4.8 Impact-effort matrix

To decide whether it is beneficial to focus on which solutions, we make use of an impact-effort matrix. This matrix positions the solutions based on the impact it has and the effort needed to implement the solution (Greenbelt, n.d.).

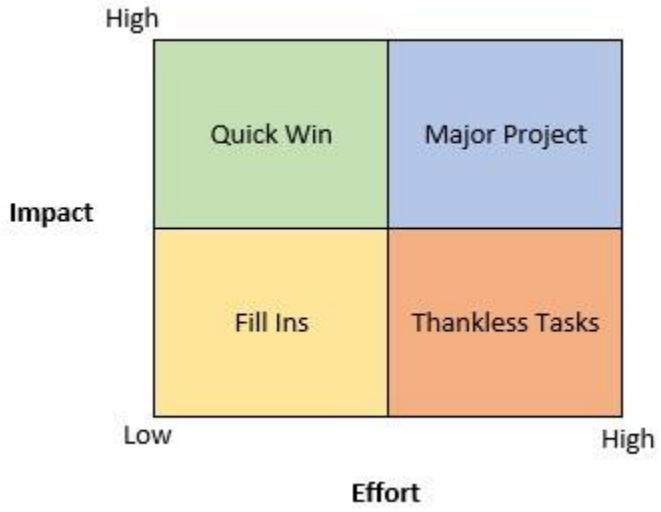

Figure 14 Impact-Effort matrix

Boxes

The current method with the red boxes does not prevent damage on the materials. Implementing new boxes with separate parts to prevent damage can be identified as a quick win since we expect it to have a high impact while the effort is low. It is advisable to replace the current 2 red boxes for 2 other boxes with separate compartments. The materials should be divided over these boxes based on product contact materials and non-product contact materials since the materials end up in the ultrasonic bath in this division as well. Implement 2 boxes each in another colour is the easiest way to distinguish the boxes.

- **Box 1**

Box 1 is meant for the product contact materials. The box needs 3 compartments.

- Rack

The first compartment is meant for the rack with filling needles.

- Manifold

The second compartment is meant for the manifold.

- Pumps

The third compartment is for the pumps.

- **Box 2**

Box 2 is meant for the non-product contact materials. This one need 3 compartments as well.

- Rack

The first compartment is meant for the rack with insertion pipes and placing pens.

- Other materials

The second compartment is meant for the other non-product contact materials. This includes tools, the plungerbar and other materials. Beside the existence of these materials, it is not relevant the know the characteristics of these materials.

- Other materials

The third tool is meant for the other non-product contact materials as well.

Racks

Create the new racks for the filling needles, insertion pipes and placing pens is a quick win as well. In general, it is most beneficial to focus on the prevention of damage. We advise to create 2 separate racks since the materials end up in 2 separate ultrasonic baths in the end. The first rack is for 10 placing pens and 10 insertion pipes. These are the materials that come from the line after a batch. These materials are not damaged. Limit the number of materials fitting in the rack to this number prevents that other materials end up in the racks. Any other material that does not come from the line by disassembling has probably damage. The second tool is for the filling needles only. This rack is meant to carry 10 filling needles. We identify the effort as low and the impact as high.

Visual quality control

Improving the visual quality check is hard. The visual quality check can only be done by humans. It turns out that it is hard to improve the factors that influences the efficiency of the visual quality control. We always have to deal with the human factor of making mistakes. The current level that 5% of the damaged materials is not detected is in line with a general error rate of 3-10% (Drury and Sinclair, 1975). The impact can be identified as low. Since we do not have a good clue to improve the visual quality check, the effort can be identified as high.

4.9 Plan for implementation

We focus on the implementation of the racks and the new boxes. For the rack for the insertion pipes, placing pens and filling needles we create a few sketches in Solidworks. In case for the boxes, we search for 2 suitable boxes and accessory sub-boxes that can be ordered online.

4.9.1 Implementation rack

In case for the 2 racks for the insertion pipes, placing pens and filling needles we created sketches in Solidworks. Due to time limitations, we were not able to implement the racks. By delivering the sketches and their dimensions to the technical warehouse of company X, they will be able to order it at a third party. There should be 2 racks of the insertion pipes and placing pens and 2 racks for the filling needles, so that both machine 1 and 2 has their own pair of racks. It is most likely to make the racks from stainless steel since other materials in production, such as trolleys, are even made of stainless steel. The diameter of the frame is 5 millimetre in the sketches.

Implementation of insertion tubes and placing pens racks

The first rack is meant for the insertion pipes and placing pens. This racks is designed in such a way that the materials are below the water level of the ultrasonic bath. The pins on the left side can be used to situate the insertion pipes on. The holes on the right side are meant to situate the placing pens in. The insertion pipes do have an angle of 50 degrees with the bottom. In Appendix A there is a visualisation of the racks for the insertion tubes and placing pens.

Implementation of filling needles rack

The second rack carries the filling needles. The dimensions of the rack can be found in figure 21 and figure 22. These dimensions are in millimetres. The angle of the materials and the bottom is 65 degrees. In Appendix B there is a visualisation of the racks for the filling needles.

4.9.2 Implementation of boxes

There exists a broad scale of boxes with dividable compartments within. Company X can order the boxes at multiple sites. In total, company X should order 4 sets of boxes. This means that there are 2 boxes with sub-boxes available for both machine 1 and 2, which is discussed before. In order to be able to carry all the materials, boxes with the dimension of 40x60 cm are most suitable. Appendix C visualizes the box. The accessory sub-boxes that can be placed in the box can be found in Appendix D and Appendix E. From the sub-boxes 1 we need 2 pieces. From the sub-box 2 we need 1 piece per set. The dimensions of sub-box 1 are 278 by 178 by 99 millimetres. The dimensions of the second sub-box are 554 by 177 by 99 millimetres.

4.10 Impact of the solution

The actual impact of the solution is hard to predict. The goal is to decrease the current rate of 5% to 4%. In the Ishikawa diagram, we describe 8 possible causes that result in the current error rate of 5%. We solve at least 2 of these causes: the problem of loading the ultrasonic baths and the transportation in the red boxes. If we assume that all causes have the same influence on this error rate of 5%, we can compute that the new error rate will be 3.75%.

4.11 Conclusion

By means of the Ishikawa diagram, we summarize the potential causes for the action problem. We elaborate on each causes in the following sections and conclude that solutions are possible for the problem with boxes and ultrasonic baths. We implement new boxes with separate departments and 2 special racks to prevent the damage on materials during the transport. In the end, we assume that these solutions will drop the error rate from 5% to 3.75%.

5. Conclusion, recommendation and further research

In Section 5.1 we draw the conclusions from our research. In Section 5.2 we discuss the limitations the research has. Section 5.3 contains other recommendations and further research.

5.1 Conclusion

The action problem in this research is: "*Damaged materials are on the line during the set-up for a new production batch*". Currently, in 5% of the set-ups there are damaged materials. The goal is to reduce this number to 4%. We summarize the global conclusions of this report for each chapter.

- **Analysis**

The main research question in this chapter is: *What is the current situation at company X regarding the use and process of production materials?*

It turns out that the process flow for machine 1 and 2 is most critical. The amount of materials used at machine 1 and 2 is more complex. The most fragile materials in the process are the filling needles and the insertion tubes. The manifold, placing pens and pumps are more robust and are more resistant against damage. Most damage occurs during the use of the red boxes and during the use of the ultrasonic baths. The visual control happens during 3 points: before storing the materials at the WVB, before preparing them and at the line itself.

- **Literature**

The research question in this chapter is: *What literature is available to improve the process to and at the WVB?*

In the literature chapter we describe 2 frameworks that might be useful. These are the Total Quality Management framework and the First Time Right framework from Six Sigma. It turns out that the First Time Right framework is most efficient in tackling the causes of the problem.

- **Improve**

The research question in this chapter is: *How can we improve the process flow of production materials to and at the WVB?*

The visual quality control has limited room for improvement. To reach our goal, we focus on the prevention of damage. The less damaged materials there are around, the less damaged materials will be at the line during the set-up. Therefore, we create racks for these fragile materials to prevent them from damage. Additionally, we implement other boxes for the transport of the materials. The fragile materials go in these racks right after they leave machine 1 or 2 and go out when they are ready to store.

5.2 Limitation

Below, we describe the limitation of the research we did.

- Describing the norm and reality in an accurate way was difficult. The frequency of the actual core problem was a bit of a guess. The frequency is estimated by means of interviews with people. In the end, it is hard to proof the effect of the solutions. We cannot make really accurate calculations of the effect it has.

- The production happens in 5 shifts. This means that there a lot of different people on the work floor. The information we gathered came from many people. These people might not always provide information that is in line with each other. Looking how a single operator performs the quality check does not means that all other operators perform the quality check in the same way.
- The research takes place when machine 1 and 2 were not running most of the time. This influenced the data gathering method. There was no real time to set up a plan of measuring the damaged materials coming from the line, since the lines were not running.
- Overall, it was hard to support results and findings with data. This was especially the case for the damage of materials. Linking the damage of materials to a specific process is not possible in terms of data. The only way to support this conclusion are the interviews with people.

5.3 Recommendations and further research

- For some materials, it is possible to change their characteristics. In case of the filling needle, it is possible to shorten the needle itself. The shorter the needle, the less it can deviate from the original position. In addition, less materials means that less can be damaged.
- Currently, there are 2 cases for the reserve materials. When there is the need for reserve materials, mostly only 1 or 2 materials are needed. The other 8 or 9 materials are not needed, but they must be cleaned again. This can be seen as a waste and is not optimal. Company X can investigate the possibility of decrease the number of materials in the reserve cases. It might even be possible to combine the separate materials into 1 case.
- The current method of storing the insertion pipes, placing pens and filling needles is not ideal. Materials with different CHT can be swapped easily. This makes the process not 100% secure. If the materials are stored in cases, this method is safer.

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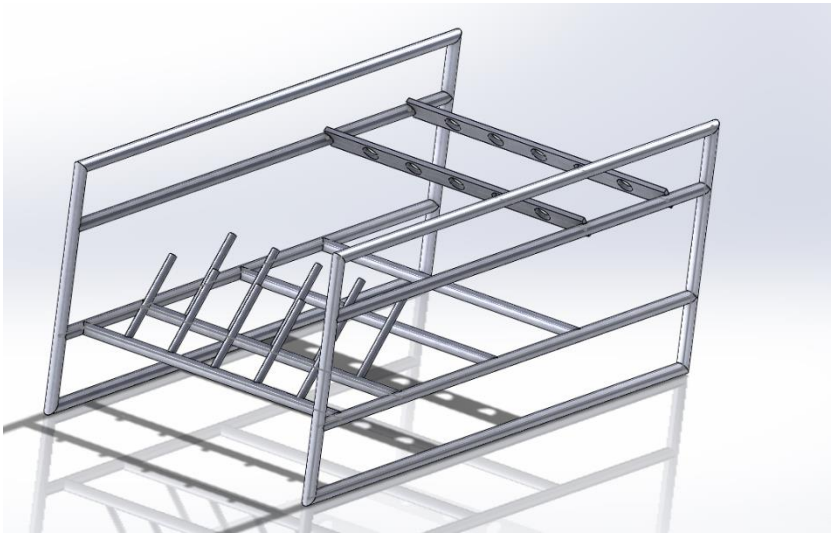
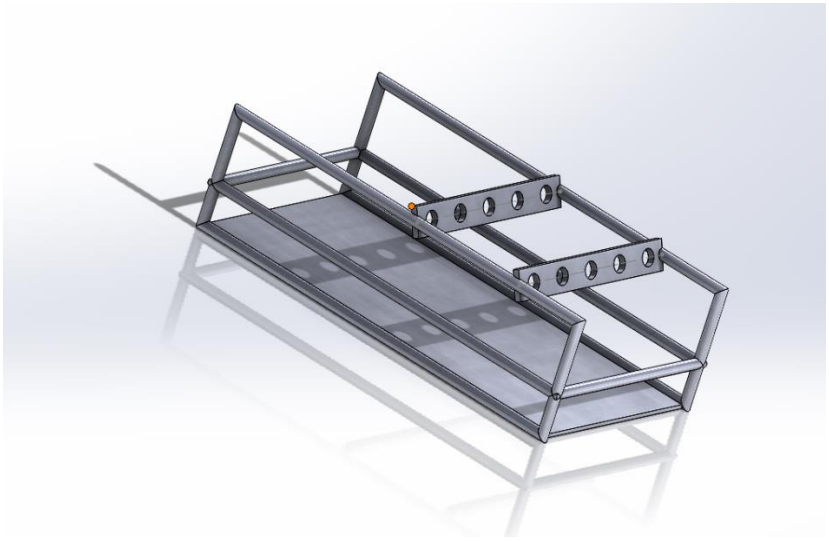
Appendix

Appendix A: Rack for insertion tubes and filling needles



Appendix B: Rack for filling needles



Appendix C

Appendix D

Appendix E