Process Development Using the Lean Six Sigma Methodology

Case: Oy AGA Ab, Linde Healthcare

HÄMEEN AMMATTIKORKEAKOULU
HÄME UNIVERSITY OF APPLIED SCIENCES

Bachelor’s thesis

Information and Communication Technology

Riihimäki spring 2015

Terhi Vaanila

HÄMEEN AMMATTIKORKEAKOULU
HÄME UNIVERSITY OF APPLIED SCIENCES

ABSTRACT

RIIHIMÄKI
Information and Communication Technology
Software Engineering

Author Terhi Vaanila **Year** 2015

Subject of Bachelor's thesis Process development using the Lean Six Sigma methodology
Case: Oy AGA Ab, Linde Healthcare

ABSTRACT

The commissioner of this study was Oy AGA Ab, Linde Healthcare. The main objective was process development, via finding the best practices and process harmonization in the northern European region. The goal of the commissioner was to provide a development plan, the individual goal was to increase personal development within the Lean Six Sigma methodology itself and the application of the theory to everyday life.

The Lean Six Sigma methodology is used in improvement projects throughout AGA. This report covers the tools and methods that are used during this particular project. Detailed studies and results are classified as confidential, therefore they are not presented in this report. The knowledge about the Lean Six Sigma theory was acquired during the training offered by AGA and via literature.

Altogether the project was successful. Most of the time was spent defining the project and gathering measurements. AGA has a very good application for presenting, approving and storing project documentation. Project reporting was done simultaneously with the project. The documentation has been available for the project team, as well as for other employees, since the project started. All the project data stays available and usable in that application.

The development plan, which has been created as a result of the study, includes development proposals for the process and, additionally, the plan for controlling the changes if they are implemented.

Keywords Lean, Six Sigma, DMAIC, projects

Pages 24 p. + appendices 1 p.

HÄMEEN AMMATTIKORKEAKOULU
HÄME UNIVERSITY OF APPLIED SCIENCES

TIIVISTELMÄ

RIIHIMÄKI
Tieto- ja viestintätekniikka
Ohjelmistotekniikka

Tekijä Terhi Vaanila **Vuosi** 2015

Työn nimi Process development using the Lean Six Sigma methodology
Case: Oy AGA Ab, Linde Healthcare

TIIVISTELMÄ

Tämän tutkimuksen teettäjä oli Oy AGA Ab, Linde Healthcare. Tutkimuksen tarkoituksena oli prosessin kehittäminen, löytämällä parhaat käytännöt ja harmonisoimalla prosessi Pohjois-Euroopan alueella. Työn teettäjän tavoitteena oli saada kehityssuunnitelma, työn laatijan henkilökohtaisena tavoitteena oli kehittää osaamistaan Lean Six Sigma menetelmästä ja teorian soveltaminen päivittäiseen työhön.

AGA käyttää Lean Six Sigma metodologiaa kehitysprojekteissaan. Tämä raportti kattaa työkalut ja metodit, joita on käytetty tässä tutkimuksessa. Yksityiskohtaiset tutkimukset ja tulokset on luokiteltu luottamuksellisiksi. Tästä syystä niitä ei ole esitetty tässä raportissa. Lean Six Sigma teoriaan on perehdytty AGAn tarjoamassa koulutuksessa ja kirjallisuuden kautta.

Kokonaisuudessaan projekti onnistui hyvin. Suurin osa käytetystä ajasta kului projektin määrittelyvaiheessa, sekä mittausten suorittamisessa. AGAlla on käytössään erittäin hyvä sovellus projektidokumentaation esittämiseen, hyväksyntään sekä tallentamiseen. Projektin raportointi suoritettiin yhtäaikaisesti projektin etenemisen kanssa. Dokumentaatio oli projektiryhmän sekä muiden yrityksessä työskentelevien saatavilla projektin alusta alkaen. Kaikki projektiin liittyvä materiaali säilyy käytettävissä sovelluksessa.

Kehityssuunnitelma, joka laadittiin tämän tutkimuksen tuloksena, sisältää prosessin kehitysehdotukset sekä suunnitelman, miten mahdollisesti toteutettuja muutoksia kontrolloidaan.

Avainsanat Lean, Six Sigma, DMAIC, projektit

Sivut 24 s. + liitteet 1 s.

DEFINITIONS AND ABBREVIATIONS

CEO	Chief Executive Officer
CTC	Critical to Customer
CTQ	Critical to Quality
DDC	Define, Deliver and Control
DEDIC	Define, Explore, Develop, Implement and Control
DMAIC	Define, Measure, Analyze, Improve and Control
DPMO	Defects per million opportunities
GMP	Good Manufacturing Practice
LCL	Lower Control Limit
LSL	Lower Specification Limit
NVA	Non-value added work in other words process steps that are non-essentials.
QRA	Quality and Regulatory Affairs
RACI	Responsible, Accountable, to be Consulted and to be Informed
REN	Region Europe North
SIPOC	Supplier, Inputs, Processes, Outputs and Customer
SMART	Specific, Measurable, Agreed upon, Realistic and Time-based
UCL	Upper Control Limit
USL	Upper Specification Limit
VoC	Voice of Customer
X	Relates to process inputs
Y	Relates to process outputs

CONTENTS

1 INTRODUCTION

This study is conducted on behalf of Oy AGA Ab, Linde Healthcare. Main purpose is the improvement of release process of liquid pharmaceutical products. The release process is crucial from quality and regulatory (QRA), and transportation planning, perspective. This process ensures continuous on time deliveries for healthcare customers.

The study itself is carried out as a project, and all deliverables are handed over to the commissioner. Because all project documentation is classified as confidential this report will focus on project work and methods.

Linde Group former CEO, Professor Dr. W. Reitzle says “It’s not about doing more. It’s about doing it differently. Now, more than ever, it’s important that we establish lean and competitive processes in every corner of the Linde Group – supported by our Lean Six Sigma approach” (Reitzle 2012.)

European Commission has introduced directions for the interpretation of the principles and guidelines of good manufacturing practices (GMP) for medicinal product for human use as laid down in Commission Directive 91/356/EEC. These principles and guidelines must be taken into consideration while developing process concerning pharmaceutical products. (European Commission n.d.)

1.1 Oy AGA Ab Company Presentation

AGA is a member of The Linde Group

> The Linde Group is a world-leading gases and engineering company with around 65,500 employees working in more than 100 countries worldwide. In the 2014 financial year, it achieved sales of €17,047 billion. The strategy of The Linde Group is geared towards sustainable earnings-based growth and focuses on the expansion of its international business with forward-looking products and services. Linde acts responsibly towards its shareholders, business partners, employees, society and the environment - in every one of its business areas, regions and locations across the globe. Linde is committed to technologies and products that unite the goals of customer value and sustainable development. (AGA 2015.)

1.2 Linde Healthcare

Linde Healthcare is one of the business segments in Linde Group.

> Linde Healthcare is dedicated to pharmaceutical and medical gas products, services and patient-care programmes. Linde Healthcare is active in more than 50 countries and greatly benefits from the cross-fertilization of ideas that comes from an international, multicultural organization. (Linde Healthcare 2015.)

2 BACKGROUND AND OBJECTIVE

The objective of this work is to find out process steps for development by using tools that Lean Six Sigma methodology offers. The theoretical framework of this thesis will be focused on the methodology itself.

The process that is going to be improved will be examined very deeply and therefore all studies and results are classified as confidential.

Lean Six Sigma tools that the author, as a Lean Six Sigma Green Belt, was using while doing the project are described in this report. However the Lean Six Sigma provides a lot of other tools that are not presented in this report. Notable is also that the author has several years experience working with common quality tools and because of that in the theoretical framework there are some statements from the author without separately referenced sources.

2.1 Scope

The project scope will be defined during the first step of the project. At this point it is known that the improvement plan will cover REN area. Financial calculations are not in scope of this report.

3 LEAN SIX SIGMA

The Lean methodology is an operational philosophy with a focus on identifying and eliminating all waste in the organization. The Six Sigma methodology is a business-management strategy designed to improve the quality of process outputs by minimizing the variation and causes of defects in processes. Lean Six Sigma is an organization-wide operational philosophy that combines the two above mentioned methodologies. All these methodologies contain a number of tools, techniques and concepts that are designed to improve organizational performance. (Voehl, Harrington, Mignosa & Charron 2014, 9–10.)

Lean Six Sigma is a way to continuously improve the Linde Group processes. By using Lean Six Sigma as a methodology the aim is to reach continuous development that focuses on fact based decision making and finding always the root causes of problems.

Lean Six Sigma project success is ensured as it combines technical problem solving methods and tools, and project management techniques to execute, with the acceptance by all people who are affected or will be affected by the solution. The most of Lean Six Sigma tools are the same as common quality tools.

Working in project is always synonymous to working as a team. The power of a team lies in the utilization of its diversity.

In this work the Six Sigma Define, Measure, Analyze, Improve and Control (DMAIC) approach is used. This approach is the best for problems where the causes and solutions are unknown. Define, Explore, Develop, Implement and Control (DEDIC) road map is used when the causes are known and solutions are unknown. Define, Deliver and Control (DDC) is used when both causes and solutions are known. (Pihl 2013.)

DMAIC roadmap, and most important tasks for each step, is presented in appendix 1.

The acronym DMAIC represents the five steps that are shown in figure 1.

Figure 1 DMAIC steps (Graves 2012.)

In the Six Sigma world there are several technical competency levels. The number of levels as well as the level names differ depending on the source. Voehl, Harrington, Mignosa and Charron (2014, 16–17) introduce five expertise levels as follows:

- Blue Belt
- Yellow Belt
- Green Belt
- Black Belt
- Master Black Belt

These five levels differ from each other in terms of training requirements. Blue Belts are trained with basics. Yellow Belts are capable to participate in Six Sigma projects as members of the team. Green Belts have completed Six Sigma training and can lead small Six Sigma projects, usually Green Belts work as part time project managers. Black Belts have had advanced Six Sigma training and work as full time project managers. Master Black Belts have additionally extensive experience and they are capable of teaching the Six Sigma methodology. (Voehl etc. 2014, 16–25.)

3.1 Define

The Define phase is performed when the project is still at the level of an idea. The project goal and customer deliverables are defined.

In the Define phase a project charter is created. The project charter is the project team's contract with business management and it defines what, when, how and by whom the project is delivered. (Phil 2013)

A well defined problem is an outcome of the Define phase. When the problem is well defined it is almost solved.

3.1.1 Business Background

The business background section describes where the project is located geographically and organizationally and what is the business context and background of the project. It also tells why it is important to work on the project now. (Phil 2013)

3.1.2 Problem Statement

The problem statement is more specific than the business background and it includes already quantified information.

The problem statement names the process that is under improvement and the defects that are associated with the process. It describes how it is known that there is a problem and what is the impact of the problem.

The statement does not contain a solution and should not make assumptions that cannot be supported with data. (Phil 2013)

3.1.3 Knowledge Base Search

At AGA there is web based database for all Lean Six Sigma projects. Review of the past projects helps to find out if there is already project for the same process that can be helpful when leading the project. It is also good to review if there are earlier researches within the same area to avoid double work.

3.1.4 Elevator Speech

Prepare to present your project in less than a minute. The Elevator Speech explains why this project is needed and what are the benefits for the project. The explanation must be understandable in a way that everyone who doesn't know anything about the particular business or process should understand the point. (Phil 2013.)

3.1.5 Voice of Customer (VoC)

Each project starts with understanding the customer needs and defining customer requirements, the customer can be external or internal. The processes are measured and compared to meet customer requirements. The defects in the process are actually anything which is outside the customer requirements. Without understanding who is the customer and what are the customer requirements the process improvement is impossible.

Customer requirements can be established for example by interviewing, by survey, market research or audits (Pande, Neuman & Cavanagh 2000, 181.). By interviewing the customer there is bigger possibility to learn about customer and process itself.

Requirements can be divided into two groups, critical to quality (CTQ) and critical to customer (CTC). These two are not the same. Critical to quality requirements ensure the quality of the process and thus the issues that are important to the customer. (i Six Sigma n.d.a). E.George Woodley (2009) describes the difference of these two "Once the Voice of the Customer is understood, we can attempt to translate it into quantitative terms known as Critical to Quality characteristics."

Kano analysis is a useful tool to organize and evaluate the Voice of the Customer data to discern CTQ's. Kano model divides requirements into three types:

- must be or basic requirements
- performance of satisfiers
- delighters (excitement).

Basic requirements can dissatisfy the customer but cannot increase satisfaction. The more satisfiers are met the more the customer is satisfied. If delighters are absent it does not cause dissatisfaction but it will delight the customer if present. As shown in figure 2 time has an influence to the amount of satisfaction. Over the time delighters will become satisfiers and later basic requirements. (Woodley 2009.)

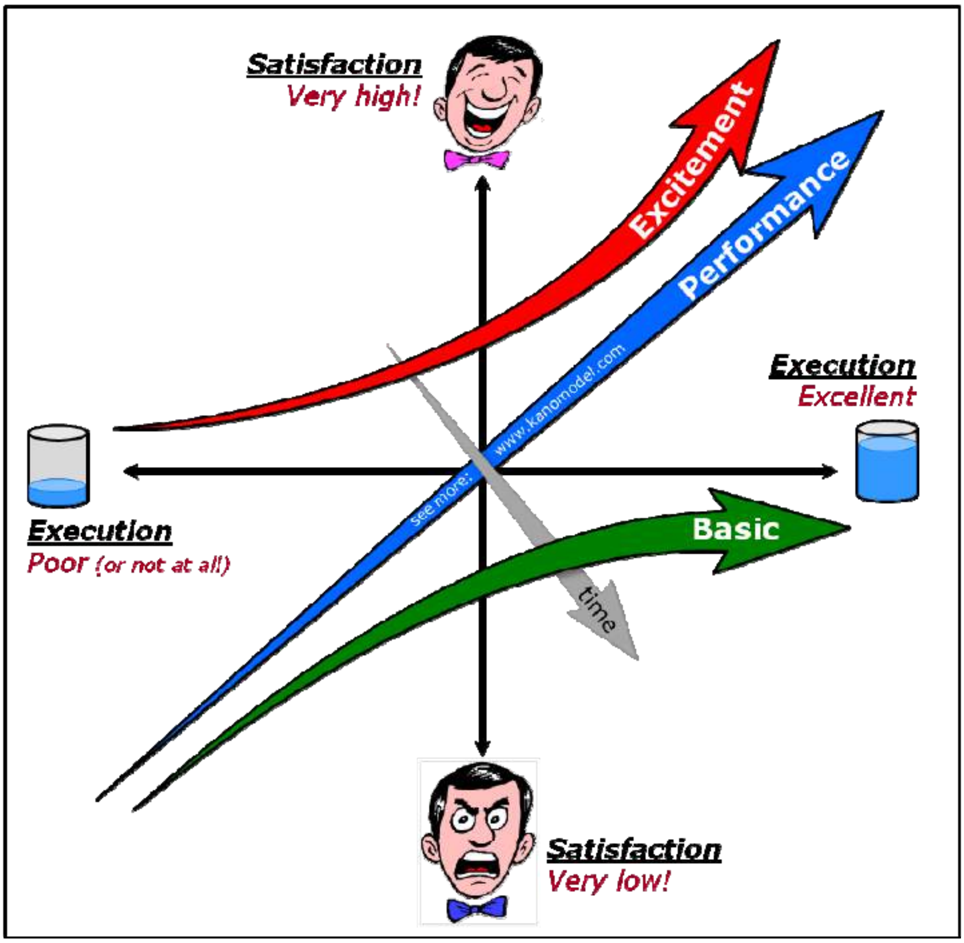


Figure 2 Kano model (Kanomodel.com n.d.)

3.1.6 Goal Statement

The goal statement describes the specific improvements that are to be achieved. Improvements are expressed precisely, with a baseline, goal and time.

As in any other project Six Sigma project goal setting is crucial. Goals need to be SMART. The acronym SMART has many letter descriptions Duncan Haughey (n.d.) describes the acronym SMART as shown in figure 3.

Figure 3 SMART goal setting (Haughey n.d.)

3.1.7 Business Case

The business case determines the benefits and cost of the project. When defining the benefits it is actually identifying the value of the project. There are some useful questions that can be used when creating a business case. Where do the savings come from? What are other positive effects of the project?

3.1.8 Project Scope

The project scope defines the start and end points and the boundaries of the process to be improved. When defining the scope it is good to keep in mind the time limits for the project. A good method is to describe out of scope parts as well. The project scope must kept in mind clearly through-out the project, if the scope is not followed the costs and time will exceed rapidly.

The project scope is visualized with SIPOC (see 3.1.11).

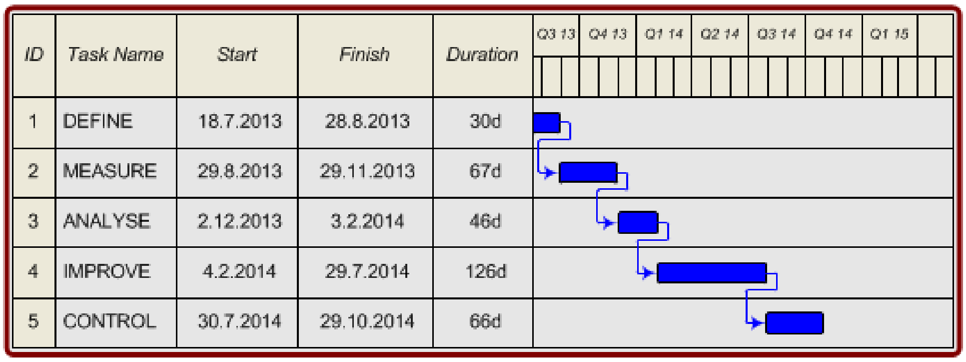
3.1.9 Project Team

A formal approval from project team member's manager is recommended in order to guarantee the availability of the team during the project. A pre-liminary plan for the project including timetable is good to have ready in early phase. Then there is the possibility to define what kind of recourses are needed, how long and how much.

Project team should consist of experts from different areas. The regular team there is a small number of people and ad hoc team members are invited when their expertise is needed. A third type of team members are resources that are sources of information or coaching and are invited separately. (McIntyre n.d.)

3.1.10 Project Schedule

The project schedule displays phases according to DMAIC roadmap. Detailed information is available in a detailed project plan. Below, in figure 4, there is an example of how a project schedule can look like in this phase. The schedule is drawn as a Gantt chart, which is a good way to display activities against time.



ID	Task Name	Start	Finish	Duration
1	DEFINE	18.7.2013	28.8.2013	30d
2	MEASURE	29.8.2013	29.11.2013	67d
3	ANALYSE	2.12.2013	3.2.2014	46d
4	IMPROVE	4.2.2014	29.7.2014	126d
5	CONTROL	30.7.2014	29.10.2014	66d

Figure 4 Project schedule example

3.1.11 SIPOC

SIPOC (Supplier, Inputs, Processes, Outputs, and Customer) is a high level map of the process that clarifies the scope. The objective of SIPOC is to identify all relevant elements of a process and distinguish the interfaces. (Phil 2013.)

In order to improve the company has to view its business with a process perspective. In a process perspective the workflow is horizontal and can involve many departments. Process mapping is the graphic display of the steps, events and operations that builds a process. Graphical example of SIPOC steps are described in figure 5.

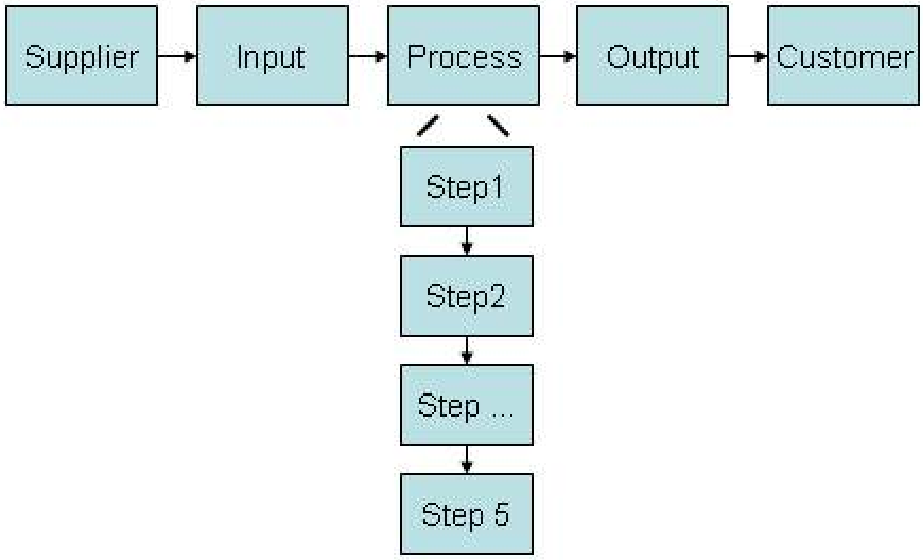


Figure 5 SIPOC process model (SIX SIGMA.SE n.d.)

The supplier provides inputs to the process. An input can be material, resources or data that are necessary to the process. The process is a collection of activities that use one or more inputs to produce the outputs. The output is the product or service that results from the process. The customer is the recipient of the process outputs.

3.2 Measure

The Measure phase maps out the current process. Measurements that can be valuated in the Analyze phase must be found. It is important not to jump to solutions and conclusions. Measurements are the basis for fact-based decision making.

The Measure phase is the XY prioritization. Y relates to the process output and Xs relates to the process inputs. The correlation between process output and process input can be presented as a function (formula 1). (Voehl etc. 2014, 266–267.)

$$Y=f(X1, X2, X3....Xn) \qquad (1)$$

3.2.1 Detailed Process Flow

Mapping the process shows how things really are and it can generate quick wins to drive the change. Mapping is used to document and analyze processes and to identify the process flow. In processes there is always an input and it delivers an output. In between there is an activity or group of activities. A process needs resources from the organization to accomplish results.

There are many different formats to choose from. This report presents cross-functional mapping also known as a swim lane chart or functional deployment flow chart. Some other common formats are classical process maps (flow diagram) and physical flows (spaghetti diagram). Cross-functional map shows interfaces between departments, possible overlaps and also interfaces outside the organization. There is an example of a cross-functional process map in figure 6.

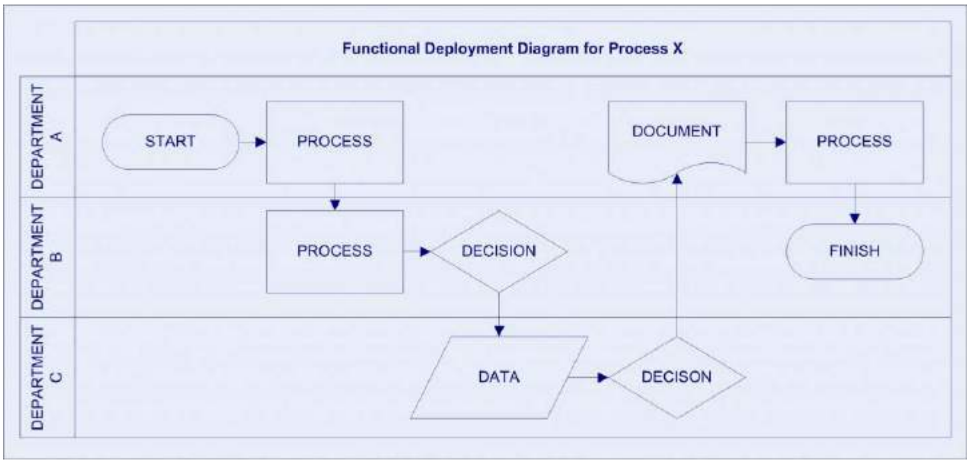


Figure 6 Example of cross functional process map (Lean processes n.d.)

While doing the detailed process map it is good to identify possible measuring points in order to collect data.

If process mapping is done at the same time in different sites or countries the benchmarking of the process is done in parallel. Benchmarking is presented later in section 3.3.2.

3.2.2 Validity Check of Y

Ys are problems with process outputs, in other words project goals. In this phase project Y is verified and its validity against to the voice of customer is confirmed.

3.2.3 Measurement System Analysis

Measurement System Analysis determines variations caused by the measurement system itself. Measurements should be both accurate and precise. Accuracy consists of bias, linearity and stability and precision contains repeatability and reproducibility. (iSixSigma n.d.c).

Picture 7 below represents the difference between accuracy and precision.

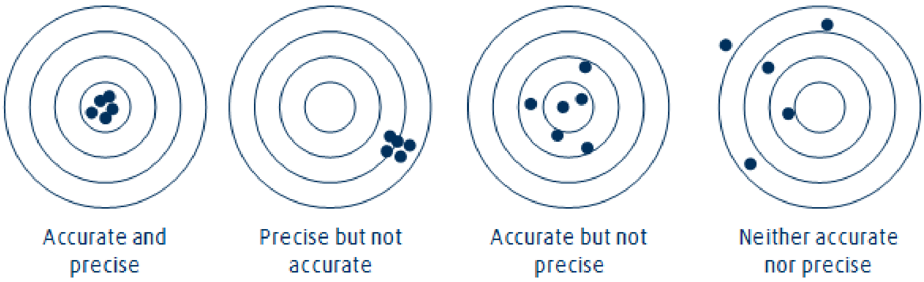


Figure 7 Accuracy vs. precision (Pihl 2013)

3.2.4 Data Collection Plan

Data collection is collecting Ys. Y data describes process results as time, cost or quantity. This information tells how the process is performing and establishes the baseline.

Planning the data collection process will ensure that collected data is meaningful, it is in the right format and with the right frequency. The data must be easy to collect. The plan illustrates the precise description what to measure and how the measurements are performed, that is the measurement method. It is important to define the collection operations so that measurements are done right first time. (Pihl 2013.)

The data collection plan describes the sample size, sample selection method and measurement frequency. It advises what is the format and what kind of tools are needed. The plan includes also information about who will collect the data, where it is located and when the collection is conducted.

The data that is planned to collect can be divided into continuous and discrete data. Continuous data is measured as a value in a specified range e.g. time. Discrete data is only certain values like yes/no. (iSixSigma n.d.b.)

When creating the data collection plan it is good to think in advance how the data is going to be presented, that could have an influence on the plan.

3.2.5 Data Collection Process

All data collectors are trained to make sure that people understand why and how the data is collected. It is good to have instructions available. The instructions provide guidance how, when and what data is collected. Collection must be easy and tested beforehand in case of errors. It is important to minimize data collection variation, and ensure that the person who does the collection does not impact its validity.

The data collection can be performed automatically or manually. Automatically collected data eliminates possible person effect from the process but can be expensive to execute. In most cases paper log is the most efficient alternative.

3.2.6 Collect Xs; 6M and 5 why's

Xs are problems from process inputs. Xs helps to locate problems and supports to isolate root causes of problems.

Brainstorming, which is introduced more detailed in section 3.3.1 is one method to find Xs.

Results can be presented with Ishikawa diagram. An example of an Ishikawa diagram, which is also known as fishbone diagram or cause and effect diagram, is presented in figure 8. Here is presented the so called 6M's Ishikawa diagram. These 6M's are:

- Man
- Machine
- Management (sometimes is used Mother Nature instead)
- Measurement
- Material
- Method.

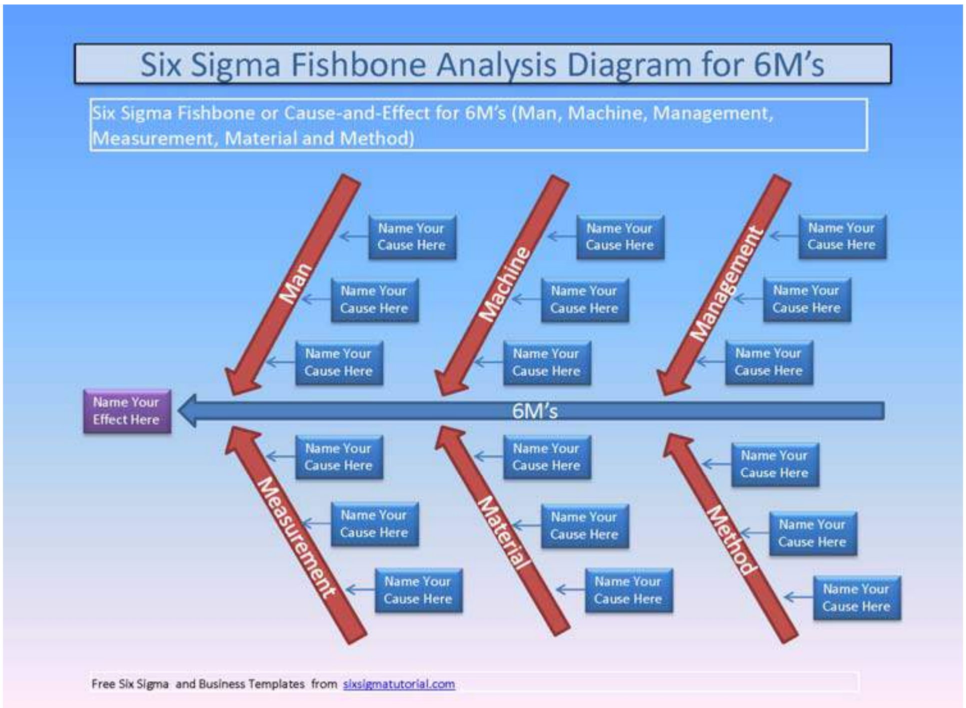


Figure 8 Ishivawa diagram example (Six Sigma Tutorial 2011a)

Once the problems are defined and documented, one should try to figure out root causes. Most probably those are found using the 5 whys method. In the 5 whys method you continue asking "why" for five times, that will lead you near the root cause. Depending on the circumstances it can be more, or less whys.

3.2.7 Cause and Effect Matrix

Collected Xs are classified with the cause and effect matrix. This work is good to do in a group which consists of specialists from different areas. In the matrix all XY combinations are rated. In figure 9 it is presented how a matrix can look like. After the key requirements (customer requirements) are rated from scale 1 to 10 and the process inputs (Xs) are identified, you can assign scores of 0, 1, 3 or 9 to each combination of X and key requirement. (Pihl 2013.)

		Rating of Importance																
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
	Key Requirements		Requirement	Requirement	Requirement	Requirement	Requirement	Requirement										Total
	Process Step	Process Inputs																
1																		0
2																		0
3																		0
4																		0
5																		0

Figure 9 Cause and Effect matrix (Pihl 2013)

Process inputs are ranked in descending order according to total value.

3.2.8 Pareto Chart

The Pareto Chart is used when prioritizing Xs. It will help choose the most significant problems and tell where to focus improvements. The most common finding is that 20 % of defects bring on 80 % of problems (Taghizadegan 2006, 117.)

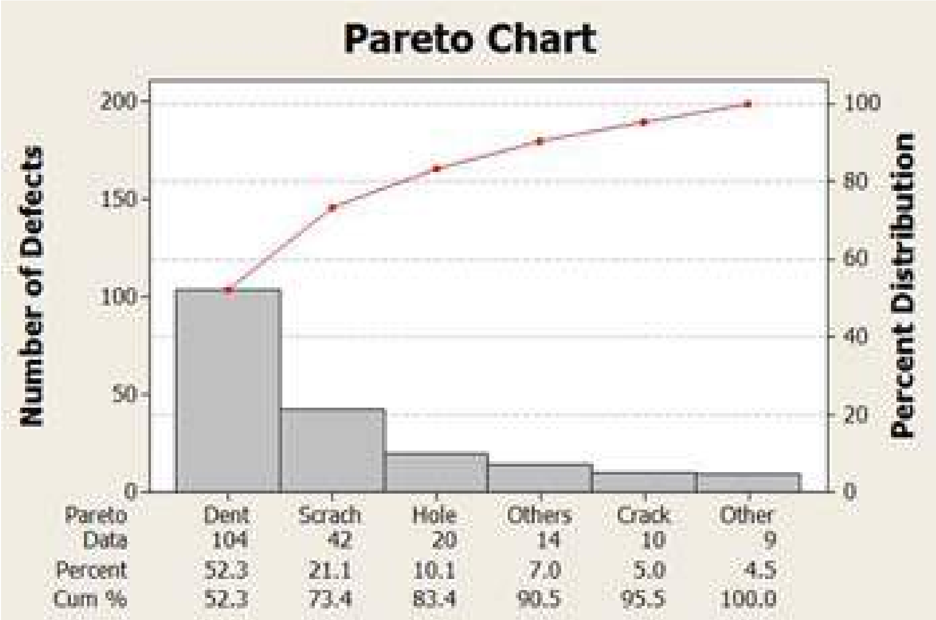


Figure 10 Example of Pareto Chart (Bonacorsi 2011)

In figure 10 above is Steve Bonacorsi's (2011) example on how a Pareto Chart presents which defect is most significant. Graphical analysis clearly demonstrates how a picture tells more than a thousand words.

3.2.9 First List of Ranked Xs

After the process input problems (Xs) are analyzed with the help of the Cause and Effect Matrix and Pareto Chart, this will produce a list of the vital few.

3.2.10 Determine Process Baseline – Control Chart

The process baseline presents what is the current process performance and how well the customer requirements are fulfilled (Pande etc. 2000, 198).

One option to present the baseline is the Control Chart. It is a time-oriented plot of data that helps to manage variation and monitor the process. It is easy to understand and it is the visual indicator of the process performance. In figure 11 there is an example of the Control Chart that is drawn using the Minitab statistical software. In the example, additionally, upper control limit (UCL) and lower control limit (LCL) are added. The software calculates control limits and the mean value. Normally the control limits are set at $\pm 3\sigma$ from the mean. Control limits are used to identify whether the process is in control or not. (Minitab 17 Support n.d.)

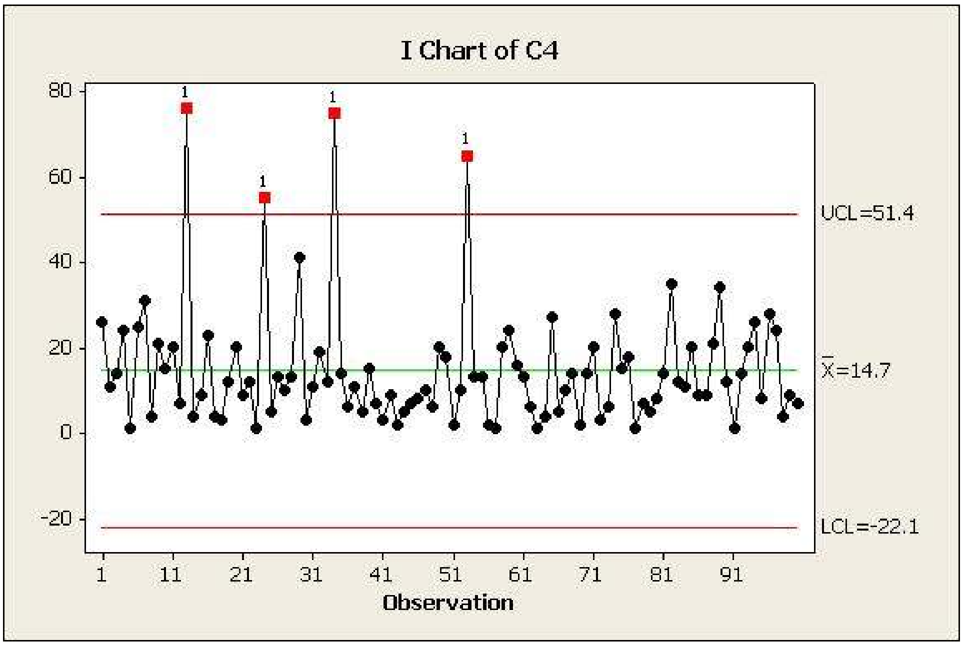


Figure 11 Control chart example with UCL and LCL

3.2.11 Histogram

Histograms can also be used when managing data. Histograms are used to present distribution of data. The histogram example in figure 12 presents 50 tire pressure measurements in a motorcycle factory.

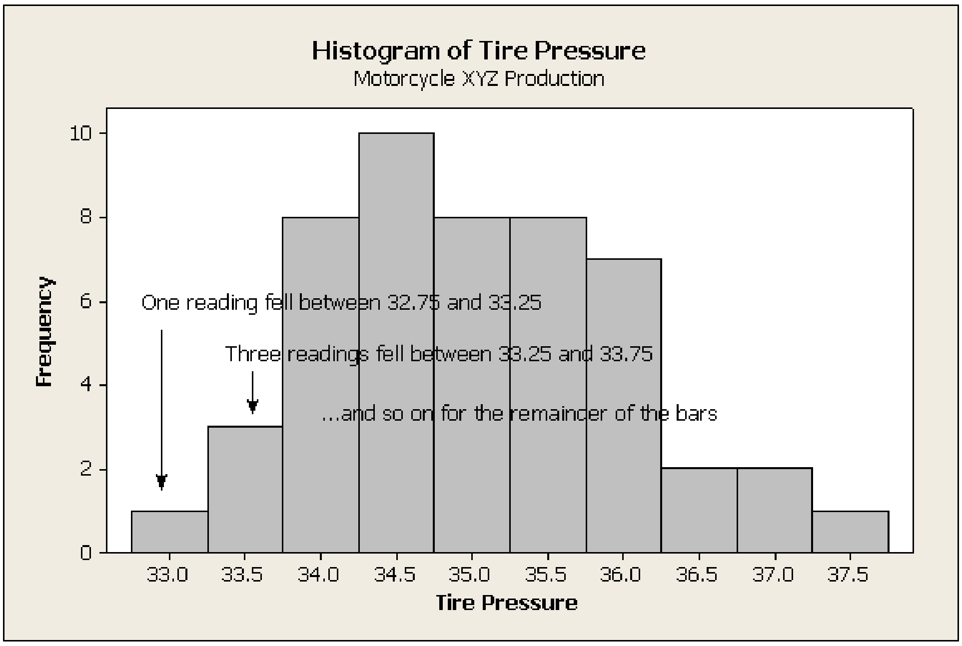


Figure 12 Histogram example (DMAIC Tools n.d.)

3.2.12 Determine Process Baseline – Initial Process Capability

Process capability can be presented with the data validation chart that is illustrated in figure 13. The example is drawn with the help of Minitab software. Process capability tells if the process meets specifications. Capability analysis compares process variation, which can be presented as histogram and specification limits. The prerequisite for this kind of data analysis is that the data is normally distributed.

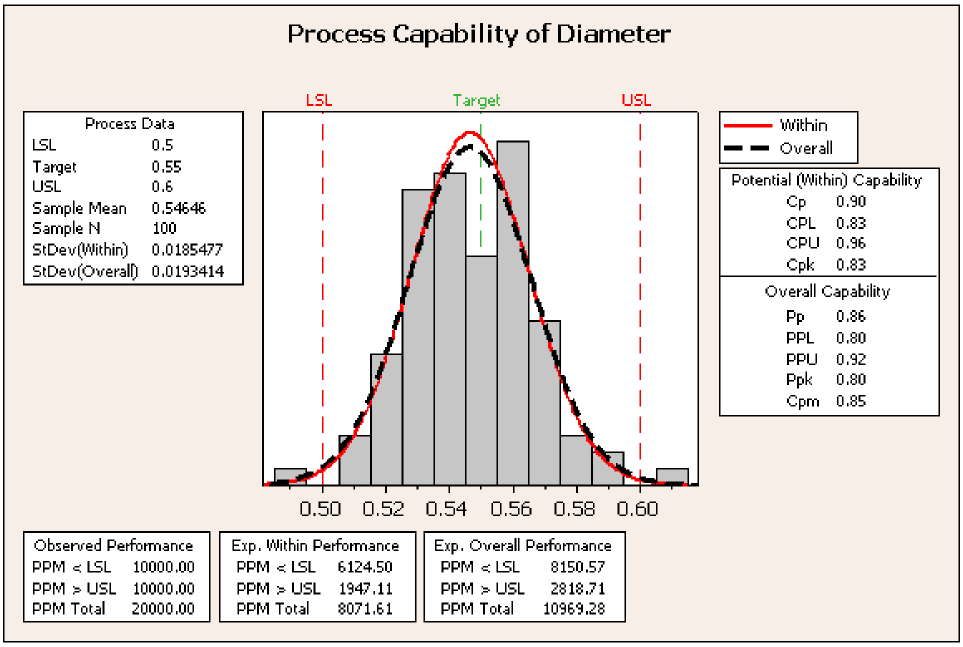


Figure 13 Data validation chart (Cheshire 2011)

Specification limits can be defined as sigma levels. The sigma levels show how many defects there are per million opportunities (DPMO). The levels are presented in figure 14. (Terry n.d.)

Sigma Performance Levels – One to Six Sigma	
Sigma Level	**Defects Per Million Opportunities (DPMO)**
1	690,000
2	308,537
3	66,807
4	6,210
5	233
6	3.4

Figure 14 Sigma levels (Terry n.d.)

In figure 15 there are real life examples of sigma levels.

Real-world Performance Levels			
Situation/Example	In 1 Sigma World	In 3 Sigma World	In 6 Sigma World
Pieces of your mail lost per year [1,600 opportunities per year]	1,106	107	Less than 1
Number of empty coffee pots at work (who didn't fill the coffee pot again?) [680 opportunities per year]	470	45	Less than 1
Number of telephone disconnections [7,000 talk minutes]	4,839	467	0.02
Erroneous business orders [250,000 opportunities per year]	172,924	16,694	0.9

Figure 15 Real world example sigma levels (Terry n.d.)

3.2.13 Quick Wins

When analyzing the process, quick wins might pop up. Quick wins are easy to implement, the change does not require a lot of coordination and planning. Quick wins are also fast and cheap to implement, the change does not require large investments or resources. The quick win change is within the project team control. The project team is able to support the people needed to implement the change.

It is good to create a separate action plan for quick wins. In the action plan are listed the implementation plan, responsibilities and deadlines for each action. The action plan is presented more detailed in section 3.4.3.

3.3 Analyze

In Analyze phase the task is to identify the cause of the problem. In Six Sigma projects all decisions are fact-based which means that all decisions are based on data analysis. In Analyze phase information about the base-line is available. Next step is to define entitlement level, meaning best imaginable level. Third step is to define a gap, meaning how much the baseline differs from entitlement level. At last the entitlement needs to be compared with the project objective. (Pihl 2013.)

In the Analyze phase many tools are used that are presented in other sections of this report. *Benchmarking*, which is covered in section 3.3.2, of processes can be done at the same time with *Process Mapping* (3.2.1) and also *Brainstorming*, which is presented later in section 3.3.1, can be used. *Cause and effect Analysis* is helpful also in Analyze phase and it is presented in Measure phase section 3.2.7. *Cycle Time Analysis* means how long time a process or its parts take, and it can be presented with a *Control Chart* (3.2.10). *Fast Action Solution Technique,* also called *Quick Wins,* presentation can be found from section 3.2.13. Worthwhile tools are also *Histograms* (3.2.11) and *Pareto analysis* (3.2.8). In Analyze phase *Root cause analysis* can be performed with *5 w's* (3.2.6) will lead to finalized list of Xs. (Voehl etc. 2014, 207–208.)

3.3.1 Brainstorming

Brainstorming sessions are meant to be the place for creative thinking and there should be the possibility to generate new ideas and new methods for working.

Pande, Neuman and Cavanagh are listing, in their book The Six Sigma Way, five key principles for a successful brainstorming session.

- Clarify the objective of your brainstorming session.
- Listen to and build on the ideas of others.
- Don't judge, criticize, or comment on ideas.
- Avoid self censorship.
- Abandon assumption and be wild. (Pande etc. 2000, 277–278.)

When organizing a brainstorm session, there are few things to take into account. How many people are needed? Is there a good mix of different skills and personalities? How much time is needed?

3.3.2 Benchmarking

Benchmarking is the organized method to find best practices. Benchmarking can be done internally or externally (Voehl 2014, 216).

Benchmarking needs a lot of resources but is still worth it, in other words the benefits are greater than the expenses. According to Voehl, Harrington, Mignosa and Charron some of the benefits of benchmarking are: customer satisfaction improvements, defining best applicable processes, possibility to improve own processes, identify own competitive position, helps with prioritizing improvements and creates continuous improvement culture. (Voehl 2014, 218–219.)

3.4 Improve

Improve phase can be divided into three steps: developing, verifying and implementing the solution. While developing the solution there are familiar tools used: *Brainstorming* (3.3.1) and future *process map* (3.2.1).

When verifying the solution it is good to pilot the new process if possible and necessary. Piloting is a good way to find possible problems with the implementation. Implementing the solution means to create an implementation plan and, as the project handover documentation, a control plan. The implementation plan consists of an *action plan* (3.4.3), implementation timetable as a *Gantt chart* (3.1.10) and task list presented as *RACI* (3.4.2). Handover documentation is a control plan that includes the *future process map* (3.2.1 and 3.4.1), *RACI* (3.4.2) and finally *data collection plan* (3.2.4).

3.4.1 Future Process Flow

Future process map documents new procedures and it will be a new “as is” map. This map will include all process changes that have been concluded to implement. The new map has fewer steps than the ones that has been drawn in the Define phase. All work loops that causes reworking, like all non-value adding (NVA) steps have been removed and excess processing is reduced.

3.4.2 RACI

RACI is the abbreviation for Responsible, Accountable, to be Consulted and to be Informed as shown in figure 16. RACI helps to identify who is responsible or accountable and who has to be consulted or to be informed for each process step in the implemented process.

Six Sigma RACI Matrix

Step	Tasks	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6
1	Task 1	C	C,I				R,A
2	Task 2	A		C,I		R	
3	Task 3			A	R		I
4	Task 4	R	C			A	
5	Task 5			R	A		
6	Task 6	A	R			C	

R	Responsible
A	Accountable
C	Consulted
I	Informed

Figure 16 RACI matrix (Six Sigma Tutorial 2011b.)

3.4.3 Action Plan

In the action plan all necessary actions (what), needed when implementing solutions, are listed in a the table where is listed information about the owner of the action (who), plan date (when) and status (now). See example in figure 17.

Action Plan for Implementation of Solution(s)

Problem Statement:______________________________

Solution(s)/Practical Method(s):_____________________

Task/Project	Who	Due Date	Status

Figure 17 DMAIC Action plan template (Abilla 2010)

3.5 Control

The improved process should be monitored. The recommended control phase length varies depending on source, at least the Control phase lasts several months. After implementing new routines, there is a risk that the methods return back to old practices. If possible, it is good to control the changes continuously within the first months.

At the end of the project it is important to stop to think about the lessons learned. Evaluate your team members, including yourself. Were there technical challenges? Is all documentation completed? Are the results re-usable somewhere else? (Pihl 2013.)

4 DESCRIPTION OF THE RESEARCH PROCESS

Research results are not presented in this report because all studies and conclusions are classified as strictly confidential. Only the working methods are described in this report.

The deliverables of this study have been delivered in a separate development plan.

4.1 Starting Point

At the very beginning the task was to specify the changes needed to existing software and the scale of its validation, if all countries of the northern Europe region (REN) start to use the same application.

Quite soon it was clear that without a formal project there would be no possibility to make any changes without resources.

It was decided that the project should go ahead. At AGA the Lean Six Sigma methodology is used and at the same time there was Lean Six Sigma training available inside the company. It was decided that the author would participate in that training.

4.2 Define

The project charter was created on 18th of July 2013 containing:

- Business background and burning platform
- Problem statement
- Goal statement
- Business Case
- Project scope
- Project team
- Project schedule
- Business risks and limitations

In addition, the Define phase included: Knowledge base search, Elevator speech, SIPOC and Voice of customer. The Define phase was approved on 28th of October 2013 by both project champion and Master Black Belt.

4.3 Measure

When the project moved to the Measure phase, the project team’s regular meetings were started. The first kick-off meeting was held as a face to face meeting. During that meeting we drew up the detailed process flow. The process map’s working method is presented in figure 18. At the same meeting we collected the list of variables that affect the process, and for that we used the brainstorming method. We continued the project meetings as teleconferences which we had on a weekly basis. Every week we checked what had been done during the previous week and agreed the next steps for the following week.

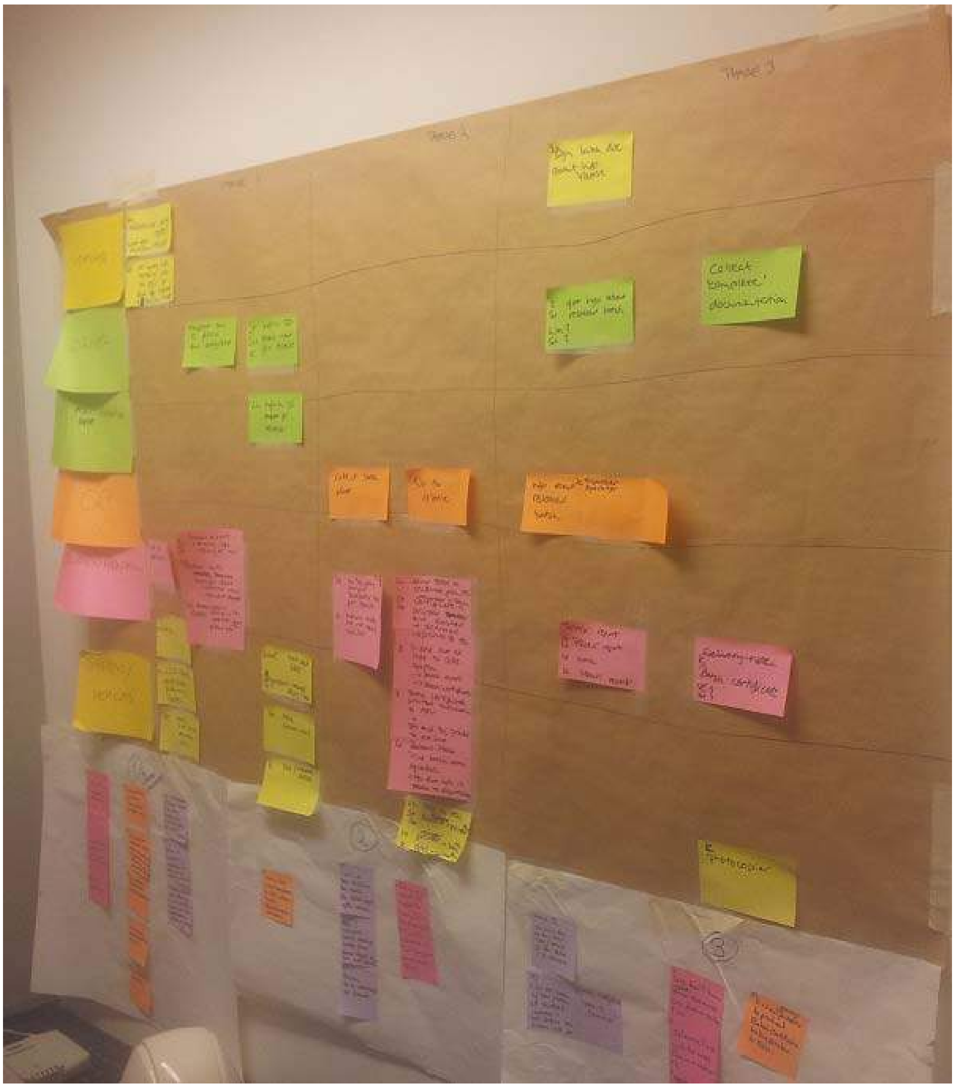


Figure 18 Detailed process map, working draft

Process variables were presented in a fishbone diagram and arranged with the aid of the cause and effect matrix. The arrangement of variables was expressed in a Pareto chart. As an outcome these came as the first list of ranked Xs.

The goals were reviewed and measurement method(s) for each goal defined. Accordingly the data collection plan was created.

Manual data collection started on 24th of February and continued for one month. Data was filed to a previously defined Excel Worksheet. Also, information from the databases was utilized.

In this phase of the project we found that there was one better way of working. We decided to spread the best practices and took quick wins for the project, and an action plan for quick wins was created.

4.4 Analyze

Process stability was analyzed using the Minitab software to determine the process baseline. Control Charts and Histograms were drawn. The Minitab software contains many quality tools. The Process Capability tool was used when the process ability was evaluated.

4.5 Improve

The deliverable of this study is the development plan, which contains proposals for the best practices. The plan presents future process flow, RACI matrix, implementation plan and an action plan.

The control plan is also created as a deliverable.

The software is intended as a support process and therefore the processes must be identical before there is a possibility to use shared software. If the plans will be put into action the process must be similar in all REN and it is ready for common software implementation.

5 CONCLUSIONS

The purpose of this study was to find the best practices and harmonize the process to commissioning company Oy AGA Ab, Linde Healthcare. Areas for improvement were probed by using the Lean Six Sigma methodology.

The thesis work can be divided into three separate phases. Formal Six Sigma training was followed by conducting the project, which includes areas for improvement as deliverables. The final part was creating this report in which the theoretical framework is introduced.

The importance of a well defined scope cannot be emphasized too much thanks to my thesis supervisor at AGA who reminded me to stay within the parameters and didn't allow me to lose focus. During this study I also realized the importance of processes in case of development. Without well defined and documented processes it is impossible to improve the business.

It was challenging to work as a project manager without experience in managerial work. An eye-opening experience was to realize how many resources are needed outside the project group to achieve the goals. The research was educational. At first I thought that I knew the process well enough but that was found to be wrong. I learnt not to make assumptions. Despite the fact that in the project group we spoke the same language we still used different terms, therefore it was sometimes difficult to achieve a common understanding.

The project documentation was very easy to create due to Lean Six Sigma's excellent roadmap thanks to my Black Belt who has supported me with this methodology. A further challenge was creating this report because the execution of the project, including conclusions, was defined as confidential and can be neither presented nor referred to.

The project was successful and the objectives were achieved. AGA gained ideas for improvement and I got very valuable training in the Lean Six Sigma methodology and project management.

Future development of the process will be easier when it is harmonized. I'm ready to accept other projects and get to know tools that I didn't employed within this study. There is room for improvement in the area of managerial skills and ensuring that the project manager is the person who keeps everything organized, rather than the individual who has to carry out all tasks.

SOURCES

Abilla, P. 2010. Action Plan Template for DMAIC Projects. Accessed on 27th of April 2015. http://www.shmula.com/action-plan-template/7720/

Bonacorsi, S. 2011 . Step-by-Step Guide to Using Pareto Analysis. Accessed on 22nd of April 2015. http://www.processexcellencenetwork.com/lean-six-sigma-business-transformation/articles/using-pareto-analysis-to-divide-and-conquer-impro/

Cheshire, A. 2011. Questions about Capability Statistics. Accessed on 25th of April 2015. http://blog.minitab.com/blog/quality-data-analysis-and-statistics/capability-statistics-part-1

Kanomodel.com. n.d. Discovering the Kano Model. Accessed on 12th of April 2015. http://www.kanomodel.com/discovering-the-kano-model/

DMAIC tools/Measure/Histograms. n.d .Accessed on 23rd of April 2015. http://www.dmaictools.com/dmaic-measure/histograms

European Commission. n.d. Eudralex Volume 4 Good manufacturing practice (GMP) Guidelines. Accessed on 28th of March 2015. http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

Graves, A. 2012. What is DMAIC. Accessed on 6th of April 2015. http://www.sixsigmadaily.com/what-is-dmaic/

Haughey, D. n.d. SMART Goals. Accessed on 11th of April 2015. http://www.projectsmart.co.uk/smart-goals.php

i Six Sigma. n.d.b. Dictionary/Continuous Data. Accessed on 21st of April 2015. http://www.isixsigma.com/dictionary/continuous-data/

i Six Sigma. n.d.a. Dictionary/Critical to Quality (CTQ). Accessed on 12th of April 2015. http://www.isixsigma.com/dictionary/critical-to-quality-ctq/

i Six Sigma. n.d.c. Dictionary/Measurement System Analysis – MSA. Accessed on 23rd of April 2015. http://www.isixsigma.com/dictionary/measurement-system-analysis-msa/

Lean processes. n.d. Six Sigma Tools – Define Phase. Accessed on 20th of April 2015. http://www.leanprocess.net/six-sigma-tools-define-phase/

Linde Healthcare. Accessed on 29th of March 2015. www.linde-healthcare.fi .

McIntyre, W. n.d. Building a Six Sigma Project Team. Accessed on 12th of April 2015. http://www.isixsigma.com/implementation/teams/building-a-six-sigma-project-team/

Minitab 17 Support. n.d. Topic Library/Quality tools/Control charts/Basics/What are control limits? Accessed on 25th of April 2015. http://support.minitab.com/en-us/minitab/17/topic-library/quality-tools/control-charts/basics/what-are-control-limits/

Oy AGA Ab. Accessed on 29th of March 2015. www.aga.fi .

Pande, P.S., Neuman, R.P., Cavanagh, R.R. 2000. The Six Sigma Way. New York: McGraw-Hill

Pihl, P. 2013. Lean Six Sigma at the Linde Group. Green Belt training wave 13. Stora Brännbo, Sweden. 11.-14.6.2013 and 26.-28.8.2013. Training slides and notes.

Reitzle, W. 2012. Linde Management meeting. Shanghai

SIX-SIGMA.SE. n.d. Sipoc. Accessed on 12th of April 2015. http://www.six-sigma.se/SIPOC.html

Six Sigma Tutorial. 2011a. What is Fishbone Analysis. Accessed on 21st of April 2015. http://sixsigmatutorial.com/fishbone-analysis-download-diagrams-charts-in-excel-powerpoint/245/

Six Sigma Tutorial. 2011b. What is RACI. Accessed on 27th of April 2015. http://sixsigmatutorial.com/what-is-raci-download-raci-rasci-matrix-templates-six-sigma/141/

Taghizadegan, S. 2006. Essentials of Lean Six Sigma. Oxford: Elsevier Inc.

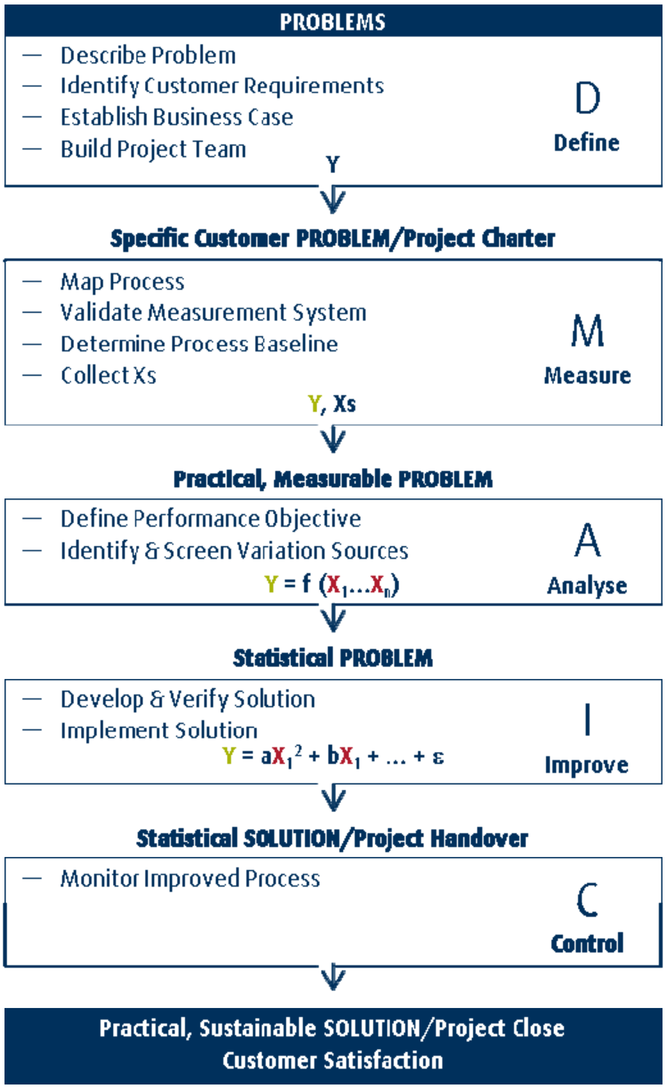
Terry, K. n.d. Sigma Performance Levels – One to Six Sigma. Accessed on 26th of April 2015. http://www.isixsigma.com/new-to-six-sigma/sigma-level/sigma-performance-levels-one-six-sigma/

Voehl, F., Harrington, H.J., Mignosa, C. & Charron, R. 2014. The Lean Six Sigma Black Belt Handbood: Tools and Methods for Process – Acceleration. Boca Raton: CRC Press Taylor & Francis Group, LLC

Woodley, E.G. 2009. The Kano Model: Critical to Quality Characteristics and VOC. Accessed on 12th of April 2015. http://www.processexcellencenetwork.com/lean-six-sigma-business-transformation/articles/the-kano-model-critical-to-quality-characteristics/

Appendix 1

DMAIC roadmap



(Pihl 2013)