

Jan Sjögren

Process Improvement Analysis of Sysmex Dealership in Roche Diagnostics Oy

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<p>This thesis is a process improvement analysis of operational work processes used to manage a global dealership contract in a Finnish company. It aims to improve the efficiency of the workflow, ensure policy compliancy and identify and reduce risks embedded in the process. The changes suggested to the processes also consider minimizing the differences between other processes.</p> <p>The thesis is as a practical development project and is highly pragmatic. Its deliverables are detailed process description at its current state, change plan and change control document.</p> <p>The scope of the research is limited to the work performed by the Order Management Coordinator responsible of Sysmex dealership management and further limited to few relevant product groups. The process flow starts from forecasting purchases and continues in their procurement, warehousing and delivery. The process is first described as it is currently, followed by qualitative research on possible improvement areas and concludes in description of suggested changes to the process.</p> <p>The research utilizes relevant operations management and process management techniques and theory. Main approach is that process is analysed in greatest detail and visualised by using flowcharts.</p>	
Keywords	Process improvement analysis

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List of abbreviations

3 rd Party	Person or entity that is not actively involved in relationship
DMS	Diagnostics Master System
EMEA	Europe Middle East and Africa regions
KAM	Key Account Manager
OM	Order Management, a department in Roche Diagnostics Oy
OMT	Order Management Team
OMC	Order Management Coordinator
SAP	Enterprise Resource Management software
SO	Sales Order
PO	Purchase Order
PPM	Purchasing Proposal Master-file
RPD	Roche Professional Diagnostics
SKM	Sysmex Kontrollikäyttäjät Master-file
WDOM	Warehousing and Distribution Outsourcing Manual

1 Introduction

1.1 Objectives and the scope

This document is a thesis work of Jan Sjögren, International Business and Logistics student in Metropolia Business School, currently employed in Roche Diagnostics Oy as Order Management Coordinator, in the Order Management Team (Later OMT). Roche Diagnostics Oy represents Sysmex Corporation as a retailer in Finland and Sysmex product catalog has a special significance in the Order Management Team. The dealership as a whole has grown in value and volumes since its beginning 1999 and from the perspective of the OMT there is need to analyze and update the business processes. This is especially important now when a new contract for distribution, sales and service has been established between the companies for the next 10 years.

In this thesis the current purchasing, warehousing and sales processes of a chosen product groups of Roche Diagnostics Oy in Finland are described. The main target of this qualitative research is to identify the current situation in the case company and to analyze it based on both secondary and primary research. Secondary research is based on literature about process development theories and primary research mainly on interviews and observations made by the writer himself. The target is to make a development proposal and a change plan for the case company accompanied with a change control document (see Appendix 1).

Due to its special nature the Sysmex dealership has developed apart from the rest of the core business of Roche Diagnostics Oy and can be considered to have special case stigma. This stigma has led into a situation where the dealership is a responsibility of just one person and most of the knowledge required to run the daily operations are not documented.

In addition to the main goal of this thesis, which was to get an in-depth look into the dealership process and to analyze it based on the process improvement theories and tools, the secondary goal is also to create new metrics for follow-up and to

improve the speed, efficiency and security of the workflow. This will be achieved by very detailed description of the different parts of the process and by using process mapping tools such as flow charts in order to visualize the different processes and to identify wastes in time, potential risk points and general weaknesses. The final target of this thesis is to suggest changes to correct and to improve the current processes.

One objective of the research is that the processes will be evaluated against current internal policy documents and thus secured that the different phases of the processes will comply with them. There are several internal policy documents that are relevant for the research and these documents demand certain changes to the processes. The documents will be named and described in more detail in the later part of the thesis.

Another objective is to identify such changes to certain parts of the process that would remove the special stigma of the dealership and make the process more dynamically manageable by the whole Order Management Team without product specific knowledge or training.

The thesis and the processes analyzed within will limit its scope to cover only the work performed by the Order Management Coordinator responsible of Sysmex dealership management, only the work that is related to the dealership, and only the Reagent and Control blood product groups. Other intertwined processes are described, but they will be only evaluated and analyzed from the perspective of the Order Management Team. This thesis will limit outside the scope the environment in, and tools the processes are performed with, considering them as static and unchangeable.

1.2 Reliability and validity

As the dealership was the responsibility of the researcher of this thesis from April 1st 2012 to September 30th, most of the research was done during that time with help of open interviews and conversations with the members of the Order Management Team. Due to the confidentiality of the research results no numerical data about the dealership is allowed to be published in this thesis and all the names of the people involved with the dealership have been altered or removed in order to protect the privacy and to follow the rules of the case company.

Company information was collected from publicly available information, combined with public press releases and reliable internal documents. Relevant theory has been collected from publicly available university course books and publications. Approaches and techniques learned from the theory have been applied to the qualitative research. A small number of supply chain management specialists surveyed the progress of the research and have evaluated the results to increase the validity of the research. The open interviews with the key personnel were conducted to answer specific questions and to get input or guidance

As the motive of the research was to find solutions to existing problems the motive itself contained some of its results. The narrow scope of the research and the casually connected problems brought to light by it would suggest strong reliability of the findings. Strong reliability is also provided by the fact that majority of the suggested changes conform to the company policies and guidance received from the managers of the operation.

The narrow scope of the research and the fairly specific case in general lower the generalization value of the results. However, the aptitude of the systematic approach, the techniques used can be generalized to any similar office processes.

1.3 Roche Diagnostics

Headquartered in Basel, Switzerland, the case company of this thesis, Roche Diagnostics is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, and metabolism. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 81,000 employees worldwide and sells its products in over 150 countries. The Group posted total sales of 35 billion EUR. Roche Group is divided into Pharmaceutical division and Diagnostics division, the Diagnostics division is responsible of 22% of the group's sales equaling to 7 billion EUR in 2011. Exactly 50% of this is derived from what is known as EMEA: Europe Middle East and Africa regions. (Hoffmann-La Roche Ltd., 2012)

Roche Diagnostics is active in all market segments from point-of-care testing devices at doctor's office to high-throughput analyzers for hospitals and commercial diagnostics laboratories and state-of-the-art instruments for all life science research. (Hoffmann-La Roche Ltd., 2012)

The product portfolio is categorized by business areas. Roche Professional Diagnostics' (RPD) products support clinical decision making in commercial and hospital labs, medical centers and laboratory networks. These products utilize blood serum testing, cardiac markers, blood gases and blood glucose. Combined with other diagnostic disciplines such as hematology and urinalysis RPD provides fully to all parts of in-vitro diagnostics (diagnosis from samples). (Hoffmann-La Roche Ltd., 2012)

Roche's Molecular Diagnostics develops and manufactures innovative tests based on the Nobel Prize winning polymerase chain reaction (PCR) technology. These tests concentrate on the molecular characteristics of a disease or sample and allow doctors to monitor patient response to therapy, identify chemicals in samples or

ensure safety of products used in medical procedures. (Hoffmann-La Roche Ltd., 2012)

Ventana Medical Systems Inc., a member of the Roche group, provides Roche Diagnostic with Tissue Diagnostics knowhow and innovates and manufactures instruments and reagents that automate tissue processing and slide staining for cancer diagnostics. (Hoffmann-La Roche Ltd., 2012)

Roche Applied Science supplies a broad and growing range of instruments and highly specific reagents and test kits for use in the life science research market and for industrial applications. These products are especially strong in genomics and cellomics, sciences that are crucial in understanding and treatment of diseases. (Hoffmann-La Roche Ltd., 2012)

Roche Diabetes Care product portfolio covers every aspect of diabetes, helping diabetes patients to live healthy, productive lives and to manage diabetes easier. These products integrate blood glucose monitoring and dynamic insulin delivery mimicking as close as possible a healthy pancreas. (Hoffmann-La Roche Ltd., 2011)

In Finland Roche Diagnostics' portfolio is sold and distributed by Roche Diagnostics Oy the offices of which are located in Espoo and in Kuopio. Employing approximately 70 people Roche Diagnostics Oy reports net sales of 72million EUR at 2011. From the 70 people 19 are working in service support, rest are divided up into marketing, sales and support functions. Currently there is no R&D in Finland. (Annual Report 2011)

Roche Diagnostics' four largest customers are HUSLAB, a public sector organization for capital region health care district, ISLAB which is similar for eastern Finland, VSSHP for western Finland and FIMLAB which is the largest private laboratory network in the country, located most in Pirkanmaa and Kanta-Häme regions. (Hoffmann-La Roche Ltd., 2012)

1.4 Sysmex Corporation and Alliance with Roche Diagnostics

Sysmex Corporation is a world leader in clinical laboratory systemization and solutions, including laboratory diagnostics, laboratory automation and clinical information systems. The company was created in 1968 with a name TOA Medical Electronics as part of TOA Corporation and separated as its own brand in 1978. Sysmex focuses on technological leadership in diagnostic science, information systems and manufacture and sale of laboratory testing reagents and laboratory equipment. The company, headquartered in Kobe, Japan, has 48 subsidiaries in 29 countries and employs more than 4,500 employees worldwide. The company boasts 1,32 billion EUR net sales at 2011, from which net income was 117,6 million EUR. (Sysmex Corporation, 2012)

Since its establishment Sysmex has concentrated on field of in-vitro diagnostics, where the Company has played integral role in the testing of blood and urine samples. While also strong in research and development, Sysmex has also expanded in the fields of hemostasis, immunochemistry, and clinical chemistry. The product line up of hematology and urinalysis instruments, software and reagents provides for everyone from small practitioners' office to large-scale hospitals and testing centers. Sysmex Corporation is by a vast gap the leading company in hematology and urinalysis markets. (Sysmex Corporation, 2012)

Sysmex Europe GmbH is a subsidiary of Sysmex Corporation, located in Hamburg Germany the subsidiary co-ordinates marketing and service activities and supplies the European market with all Sysmex products. Majority of the reagents sold in Europe are made just 70km outside Hamburg in a city of Neumünster. 1999 Sysmex Corporation entered into Distribution Sales and Service (DDS) agreement with Roche Diagnostics in 1999. This successful agreement was renewed in April 2012. Since this agreement Sysmex and Roche have applied their mutual strengths to expand market share while building favorable relationship. Leaders of both parties agree that there is a unique synergy between the companies:

Based on Sysmex' industry leadership allied with Roche's unique position as the global market leader in in vitro diagnostics, the collaboration underlines our objective of

bringing a maximum of industry expertise in hematology to health professionals Hisashi Ietsugu, President and CEO of Sysmex Corporation. (Hoffmann-La Roche Ltd. 2012)

“The breadth of the Sysmex portfolio combined with Roche’s Cobas analyzer platforms allow customers to choose from the broadest set of instruments available for each laboratory setting. This embraces our goal to strengthen and to expand Roche’s offering in central laboratories in hospitals and commercial laboratories” Colin Brown, Head of Roche Professional Diagnostics (Hoffmann-La Roche Ltd. 2012)

In Finland Sysmex Corporation is represented through Roche Diagnostics Oy in all marketing, sales and support activities. Based on 2009 Market Analysis by Roche Diagnostics Oy Roche’s hematology market share was 76% from total 4,8 million EUR market, since then the market has grown close to 6 million EUR. In Urinalysis Roche’s market share was 30% at 2009 and has since grown significantly. (Roche Diagnostics Oy, 2009)

Combining hematology and urinalysis portfolios the products can be categorized into three categories:

1. Instruments: the diagnostics machinery and their parts
2. Reagents: the chemicals the machines consume
3. Controls: specific products that are used in calibrating the instruments for perfect function.

Roche Diagnostics Oy buys these products from Sysmex Europe and stores a local stock of them in a warehouse in the south-west of Finland and all sales go through Roche Diagnostics Oy. (Roche Diagnostics Oy, 2009)

2 Process Improvement

The idea that work should be optimized and some of its components eliminated is not new. It can be traced to the scientific management approach used by Frederic Talyor (1856-1915) who originally used the approach to optimize the speed of work of individual workers in a factory environment. However, the core ideas of this approach are still valid today and make up the fundamentals of process improvement theory.

Any type of process can be studied for the purpose of improving its efficiency and all improving activities can be categorized under the following three groups:

- Eliminate non-value-adding aspects of the activity
- Reduce the number of repetitions of the activity
- Increase the speed at which the activity is performed

It is an obvious observation that some of the work done in a process is not essential for the product or service provided, thus is it natural for individuals involved to identify and attempt to eliminate the unnecessary steps or avoid non-essential tasks. It is not always apparent which tasks do add value to the customer or the organization. (Ravi Anupindi et al. 2004)

One significant advantage of process analysis and improvement is that each activity can be systematically challenged in attempt to improve the process. In this thesis the whole workflow of a single 3rd party dealership inside an organization is studied. In the highest level the process flow (figure 1) looks solid and it would be impossible to reduce any phases.



Figure 1. The highest level the Sysmex dealership process.

When observed closer and by utilization of tools from operations management and process management theory one can find that the processes that together make the whole there is much that can be improved.

It is common that existing processes are not always well defined or described. This may be because they have developed over time without being formally recorded or they might have also been changed informally by the individuals who work in the process. Processes that are not formally defined or are not defined at the depth level they are performed can be interpreted in different ways, leading to confusion and hindering their improvement. So it is important to obtain a view from all individuals involved in the process and to be able to visualize the process in a way that all can understand and agree upon.

2.1 Process perspective

All companies produce goods or services by transforming inputs to outputs through an operation, or transformation process. Figure 2 shows the general transformation process model that can describe any company, any of its operations or any processes there within. A laboratory in a hospital has very different inputs and outputs than a construction company, but if you look far away enough from them, they will adhere to the model.

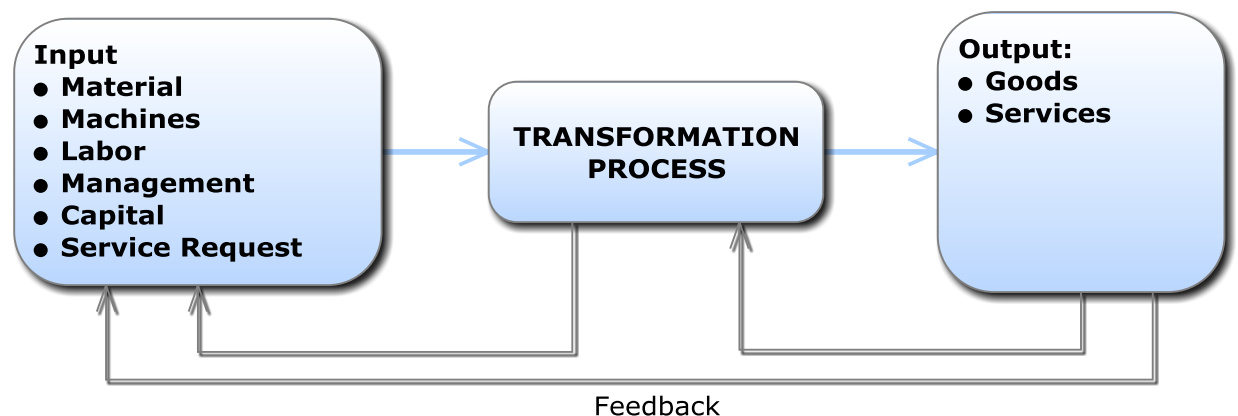


Figure 2. Transformation process model (Nigel Slack 2001)

When analyzing any company, operation or process, it is fundamentally important to be able to identify the dominant input, and output unit of the target of analysis. A

post office devotes part of its time to serve customers, taking in packages for delivery and delivering them. A customer could be considered one post office's input units. Post also spends considerable amount of its energy to communicate its customers about the state of the delivery, the information is definitely its throughput unit. As customers we might be unhappy about the service we receive, or the lack of information we receive from our delivery, but we would be most unhappy if the package is lost or damaged. This would mean that the most important, dominant throughput unit is the package. (Nigel Slack 2001)

To design a new process, or to analyze and existing one, it is crucial to be able to define the layers and hierarchies of the processes that make up the operation. By defining the inputs of the process we can categorize the process itself into being a material process, an information process or a customer process. Identifying the dominant throughput unit makes us center on only single unit throughout the process, and perhaps consider defining other throughput units separately. Defining the building blocks that allow the transformation process to happen, the staff and facilities, we also define the resource requirements, risk areas and costs. Describing the expected output creates also the performance meters that allow the whole process to be evaluated against. (Nigel Slack 2001)

In reality following the throughput unit can be difficult, or it can travel between departments or change form that it is difficult to recognize. Concentrating on the transformation process model at all levels of the operation allows construction of a logical big picture of the flow of throughput units through all processes. At single process levels the model makes sure that factors are defined and each possibility of improvement is brought to in the open. When the throughput unit is followed through many processes, the problems between the processes come to light. Analysis of this sort also allows contrast of each phase of the process against market requirements, ask if it aids to fill customer needs or question its purposefulness totally. (Nigel Slack 2001)

2.2 Analysing a process

2.2.1 Process types

Oxford University professor of Operations Management Terry Hill, who is an author of broad range of operations management and process analysis theory, suggests that processes can be categorized into five main groups.

- Project processes. Highly customized products, relatively long timescale for manufacturing, significant interval between production cycles. Example: Buildings.
- Jobbing processes. High variety, low volumes, shared resources with other similar products. Never repeating exactly the same outcome. Example: Cars, hand crafts.
- Batch processes. More than one exactly the same as another product, generally consists of repetition. Example: Restaurant meals, industry machinery.
- Mass processes. High volume production, narrow variety, product always fundamentally same. Example: Car production
- Continuous processes. Higher volume than mass processes, even less variety, usually long periods of ongoing operation. Example: Electricity generation, steel making.

Even as these process groups are derived from manufacturing concepts, Terry Hill argues that the typology could be equally used also for service delivery processes and in his books he gives examples of both sectors. (Terry Hill, 2005)

Other operations management authors recognize that there is distinction between the manufacturing and service sectors, and their processes are fundamentally so different that they cannot be categorized the same way. Less of an agreement exists on what the groups should be called, but Nigel Slack proposes the following three:

- Professional services. High contact time with the customer, high levels of customization and adaptation to customer needs. Usually people based services. Usually provided by specialists. Example: Consulting.

- Mass services. Limited contact time with limited little customization. Product or equipment based. Usually provided by non-professionals, based on preset procedures. Example: Ticket sales
- Service shops. Belong between mass services and professional services. Generally provided by professionals, for longer period of times than mass services, with medium level of customization or options for it. Example: Banks, schools. (Slack, 2001)

The processes described and analyzed in this thesis are micro level parts of a larger service shop type of process. Some customer service phases of the processes could be considered a jobbing process for their nature of having high variety and low volume, but in principle delivering similar outcomes. Alternatively a recording or documenting process could be considered a batch process, as it is fundamentally repetition of the same with very little variation in the outcome.

2.2.2 Performance objectives of a process

The performance objectives fall down to the process level from all the way to the top. The reason for a company to exist is to satisfy its stakeholders, this idea is behind all the decisions that create the strategy, and strategy then translates down to operational level. At business plan and strategy level the objectives might appear different, but at the operational level they appear more or less the same across all companies. There are five performance objectives for any company, any operation and any process therein.

The quality objective stands for doing things the right way. One would not want to make mistakes or provide the customer with faulty products, but rather deliver services that suit their needs or produce products that meet or exceed their expectations. The things that should be done the right way vary between companies, but the quality objective is always present. Doing things the right way also directly reduces the costs because of fewer defects or less conflicts within the processes and high quality process would also take into consideration all possible risks, increasing the total dependability of the process. High quality performance is

particularly important object in reaching customer satisfaction, which is a direct source for competitive advantage.

The speed objective culminates to achieving the shortest time between customers intent of purchase to customers receiving the product in full. This can be achieved in many ways, such as increasing availability or shortening production times, reducing queue lengths or increasing capacity. Inside the company speed has other beneficial effects. Being able to deliver one process cycle of any kind quicker will reduce the need of inventories, as also the inventories would be refilled quicker. The less time the customer or the inventory spends in the process lesser the risks involved. Speedier process cycle will also speed up the time required to spot defects and mistakes, and to correct them.

Dependability objective means keeping your promises. Dependability is generally judged at the end of a transaction with the customer, when the product is delivered or the invoice arrives. If your product, service or organization is not dependable the judgment will be negative, over time this will remove the possibility to sustain the business. Unpredictable or negative outcomes of any processes will have a negative effect on anything around them internally as well, in the end any lack in dependability of the processes will cost the organization valuable time. With maintaining high level of dependability performance, the company can start building customer and internal relations based on trust, which can act as a multiplier in the bottom line values.

The flexibility objective means the ability to change the operation some way to react to external pressure of any kind. This might be changing what the operation does, or how it is done. In practice this translates into having flexible products/services, having variety of types and variety of quantities available and being able to deliver with different means and times.

Ultimately combining the above and adding its own objectives is the cost objective. Even if all the four above also improve cost effectiveness, there is staff, facilities, technology, equipment and material costs to be considered. In some organizations the other objectives have large effect on the costs, in others the costs can change without negative or even with positive change on the other objectives.

The performance here is defined as how well a process fulfills the five performance objectives at any point in time, to fulfill the market requirements. The market requirements vary depending on each process, so to quantify the objectives to relevant measures we have to define them for each process. For sales order creation process (defined in detail later) of Roche Diagnostics Oy, these performance metrics could be for example:

- Quality: Customer satisfaction, errors in the sales order document
- Speed: The speed at which the sales order process is completed
- Dependability: Amount of backorders, amount of late deliveries
- Flexibility: Options for delivery types or times, throughput capacity, delivery speed
- Cost: Utilization of resources, labor productivity. (Nigel Slack 2009)

Figure 3 is an example that describes the performance objectives of the sales order creation process against imaginary market expectations. This kind of visualizing makes apparent which objectives are met, and where there is still room for improvement.

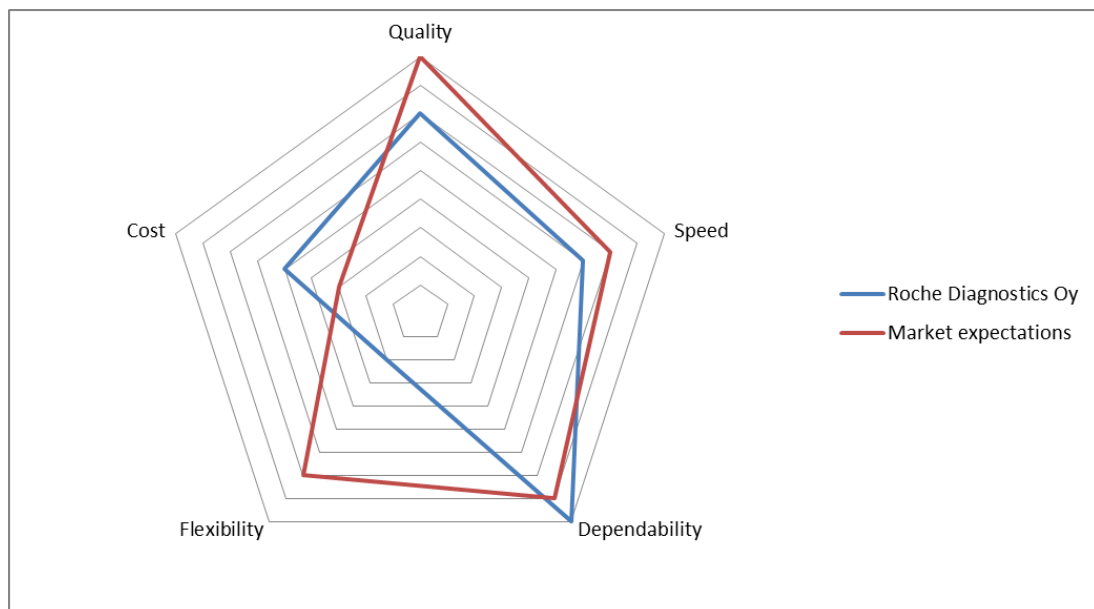


Figure 3. Performance objectives

2.3. Improvement priorities

Monitoring and improving performance of a process alone is not enough. Limited time and resources usually make it hard to be able to excel at everything, it is also not economically wise to waste time on increasing performance that does not bring benefits. An organization must decide which performance metrics require particular attention and they should be compared against the needs and preferences of the customers and the performance and activities of the direct competition.

Both importance and performance must be analyzed together in order to make good decisions. It might be that a performance metric is extremely important to the customer, but it might already be performing at optimal level, making improving it only economically unwise. Judging the importance of a performance metrics to customers can be thought as the likelihood of this performance metric to causing the customer to choose our product. The order winning performance metric provides the crucial competitive advantages over competition, and if the performance of that metric declines lower than the competitors it becomes higher priority for improvement. A qualifying performance metric means for example an industry standard, which as such does not cause product to be selected, but without it the product would be in big trouble to make sales. This can also be considered a business standard or being within the expected norm.

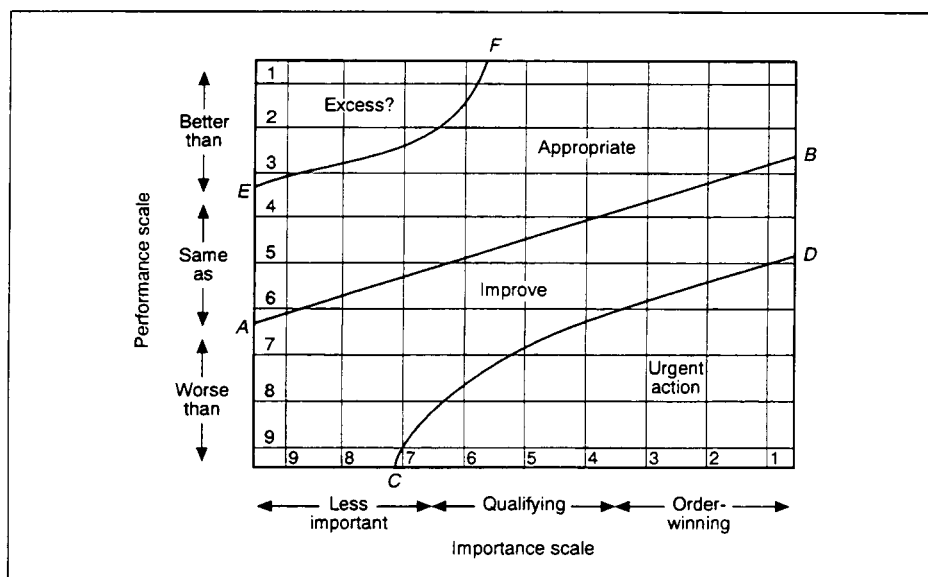


Figure 4. The importance-performance matrix. (Nigel Slack 1994)

As figure 4 illustrates, the performance metric can also be on the level of excess, where its improvement would not bring any gains. In the other hand a performance can also show values of worse than competition, but the metric itself is not crucial in gaining business, so it is not a priority for improvement. (Nigel Slack 1994)

2.4 Approaches to Change

2.4.1 Breakthrough or Continuous improvement

The breakthrough improvement or innovation-based improvement is the idea that change should happen dramatically in ground shaking waves. It could be an introduction to completely new software of the whole organization, or new generation of machinery. The effects of change done this way are generally sudden and possibly even drastic. Because of the idea being fast leaps of change every so often it requires a different set of competences and strategies to manage its challenges its counterpart.

The continuous improvement ideology adopts the idea of small steps of change whenever possible. Continuous improvement ideology has become popular in past decade and it is now also known by Japanese word "Kaizen", which promptly means continuing improvement involving everything and everyone. For the Kaizen, momentum of change is more important than the rate of it. (Nigel Slack 2001)

While the breakthrough ideology is straight forward bringing a new idea into reality, managing the change period and reaping the benefits, the Kaizen ideology is considered to be more fundamentally intertwined organizational change. It suggests that organizations should adapt skills and attitudes that allow and support continuous improvement. Professor Joseph Tidd jr. Brighton University specify six generic organizational abilities that make up the CI ideology (Jote Tidd, 2005)

- Making continuous improvement a habit. Developing ways to keep employees constantly involved in change projects
- Focusing on continuous improvement. Generating the link between continuous change and strategic goals of the company
- Spreading the word. Generating cross functional groups for continuous improvement projects, tearing down the organizational boundaries.
- Creating a CI system. Defined CI process than can be monitored, developed and used as strategic tool.

- Walking the talk. Management style has to reflect the CI atmosphere, share the belief of small step change, value of everyone's contribution and learning from mistakes.
- Building a learning organization. Generate the ability to learn through CI projects, all learning is shared, management accepts and deploy learned behaviors across the organization.

The breakthrough ideology encourages free thinking and individualism without much respect to what is possible. Starting from empty table or rethinking the fundamentals is normal for this ideology. Typical is also utilization of business process re-engineering principles, which stands for radically rethinking the way something is done, taking it into parts and rebuilding it from the beginning to strive for dramatic improvements. The continuous improvement appears less ambitious in the short run, however as it supports teamwork, attention to detail, and making the organization a self-evolving community its achievements in the long run can surpass those of the breakthrough ideology. (Jote Tidd, 2005)

2.4.2 The PDCA Cycle

The never ending nature of continuous improvement ideology has been by what is called the PDCA cycle. It is a mnemonic that stands for Plan, Do, Check Act and is visualized in figure 5

The plan stage involves examination of the current way of doing things that has caused a problem or could be improved. In this stage one collect enough information that a plan of improvement can be devised. The do phase naturally is the implementation of the plan and trying it in practice. In the check phase the performance of the new way of doing things is evaluated in the act phase the new way is consolidated into new standard and a new cycle starts. So in the wake of PDCA cycle there is always a new standard of doing things, and the quality (or performance metrics) of the process is improved. (Nigel Slack 2001)



Figure 5. The PDCA Cycle adaptation based on Nigel Slack

2.5 Improvement tools and techniques s620

The tools given by the operations management and process management theory are ones that concentrate on clarifying the process steps and force the researcher to take into consideration each aspect and possibility of otherwise simple matters and to maintain concentration on the key issues through the change projects. Key underlying purpose of all these techniques and tools is systematic definition and challenging of each step of the process against what actually increases value. (Nigel Slack 2001)

2.5.1 Input-Output Analysis

Clearly identifying the inputs and outputs define the process that particular throughput unit goes through. Knowing the sources of inputs and the destination of output puts the process into its place in the greater web of processes. Identifying the outputs performance metrics against customer's requirements will tell how well the process is set up and what might be needed from the quality of the input and the transformation process to improve the performance of the process.

Input-output analysis also defines the dominant throughput units that may shift concentration from less relevant processes to the more relevant ones. Conducting this analysis can also bring up outputs that are not used anywhere, or that might be

worth productizing. For example a professional company that provides specialized equipment can be producing documentation or waste materials that are no longer relevant or not used anywhere. Same company can also consider productizing and selling separately the excess staff capacity if some exists. (Nigel Slack 2001)

2.5.2 Flow Charts

1921 Frank Gilbreth (1868-1924) invented a Structured Method for Documenting Process Flow and introduced the Flow Process Chart as a tool to analyze and enhance industrial engineering process flow by using unique symbols. (Data Education.com) Since then tools has been modified and improved by many management theorists and its symbols altered to follow somewhat of a standard coming from Frederic Taylor's Scientific Management Theory. (Data Education, 2012) (Legend seen in figure 6)






	Value adding operations
	Inspections or checks
	Delay or bottleneck
	Moving, transferring sending or receiving
	Deliberate storing

Figure 6. Legend of symbols based by Frank Gilbreth

The flow process chart is excellent at illustrating detailed steps and categorizing them by their purpose, clearly highlighting which parts of the flow are actually crucial and which are likely wastes. When creating flow process chart from the original state of the process and after picture, it can also be used to illustrate the

significance of achieved change and to ensure that the process outcome remains the same.

Each of the process steps is categorized into operations, checking activities, delays, moving and storing. Making these distinctions one is always forced to consider which parts of the process truly add value. The value considered here is the value to the correctness of the outcome of the process and it does not always directly mean money. Inspections and delays are the most common unnecessary steps but they might be crucial the outcome or to the following steps. In a process that has to do with physical materials such as manufacturing, the moving of goods is often measured also in distance, time and quantity. (Nigel Slack 2009)

2.5.3 Scatter Diagrams

If the process analyzed is such that it has many repetitions and different types of results can be measured, scatter plots can be used to quickly identify if there is a correlation between how it was done and the result. Scatter plots are generally used when vast amount of data is available to identify if example different materials make different amount of defect end product in a production mill. Scatter diagram measures the strength at which two or more events increase the likelihood of another, as such they are fully relying the type of data collected and the formula they are meant to solve, therefore a scatter diagram can only show correlation and never a causality of the events. (Nigel Slack 2001)

2.5.4 Cause - Effect Diagrams

Cause-effect diagram is meant to prove the existence of causality between events. The cause-effect diagram is built by defining a problem, and giving possible reason groups that might have caused the problem and then asking the what, when, where, how and why questions from the individuals involved and collecting this data under the reason groups. The main purpose of cause-effect diagram is to identify the areas where further information is needed, or where a blind spot might exist. (Nigel Slack 2001)

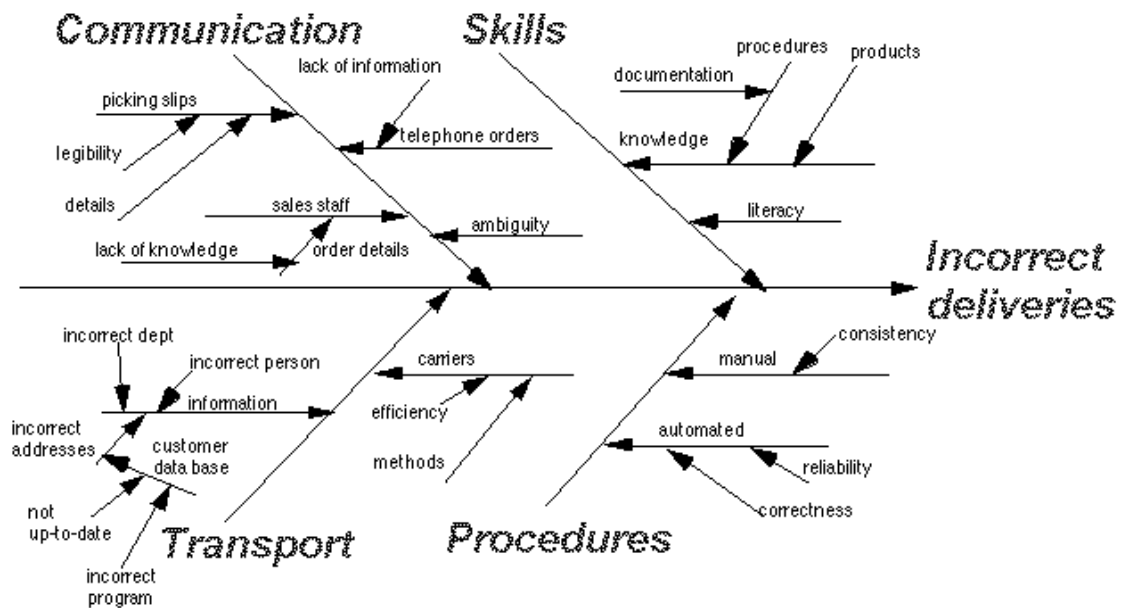


Figure 7. Cause-effect diagram adaptation based on Nickel Slack

In cause-effect diagram the possible reasons for the problem are gathered as arrows that visualize the causality of the reasons that cause the problem. Figure 7 shows possible reasons for incorrect deliveries, these reasons can be found out from customer feedback or doing a dedicated questionnaire. After the reasons have been collected, their importance or impact to the process quality can be weighted with Pareto diagram. (Nigel Slack 2001)

2.5.5 Pareto Diagrams

Pareto diagrams main purpose is to give perspective of the importance of a problem among many. Pareto analysis is based on the frequently occurring phenomenon of relatively few reasons explaining the majority of problems. The figure 8 illustrates a Pareto diagram visualizing the amount of occurrence of problems of different reasons, it is normal that relatively few of the reason cause majority of the occurrence. This information can be used to prioritize what problems should be concentrated before others, it is necessary however to consider the importance of the most common problem in the importance-performance matrix as well.

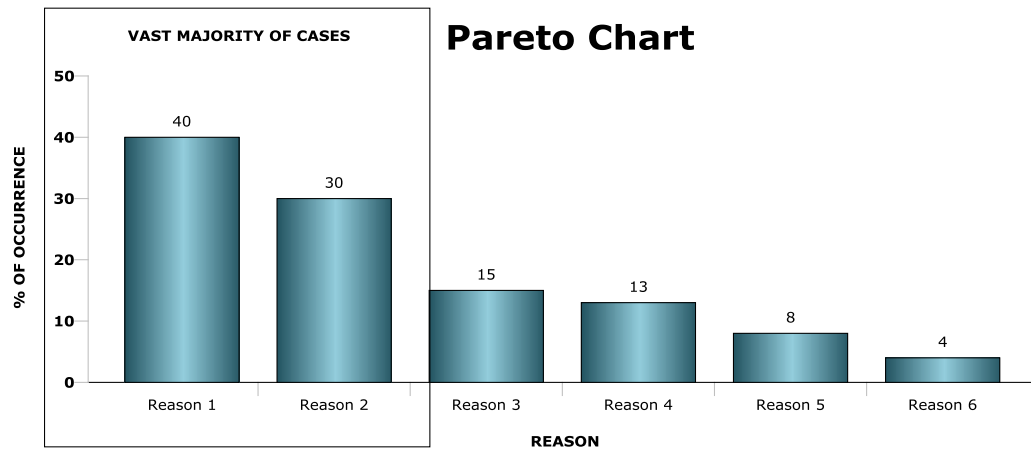


Figure 8. A Pareto chart example

3 Current process description

The process mapping techniques and flow chart tool from the Frank Gilbreth's Structured Method for Documenting Process Flow was chosen to this research since it defines the current process in required detail. This process mapping tool was selected for its ability to bring forth the errors in process of this type, and that all three processes in the scope of the research could be analyzed comparably and side by side. It also allows delivering of the results of the change suggestions in clear visualized manner. Current process steps can be seen in the figure 9

In the following chapters these different processes are explained and opened up in more detail, and in the end of the document there is a similar process chart where unnecessary steps are removed and the process is developed so that with fewer steps the same process output is delivered.

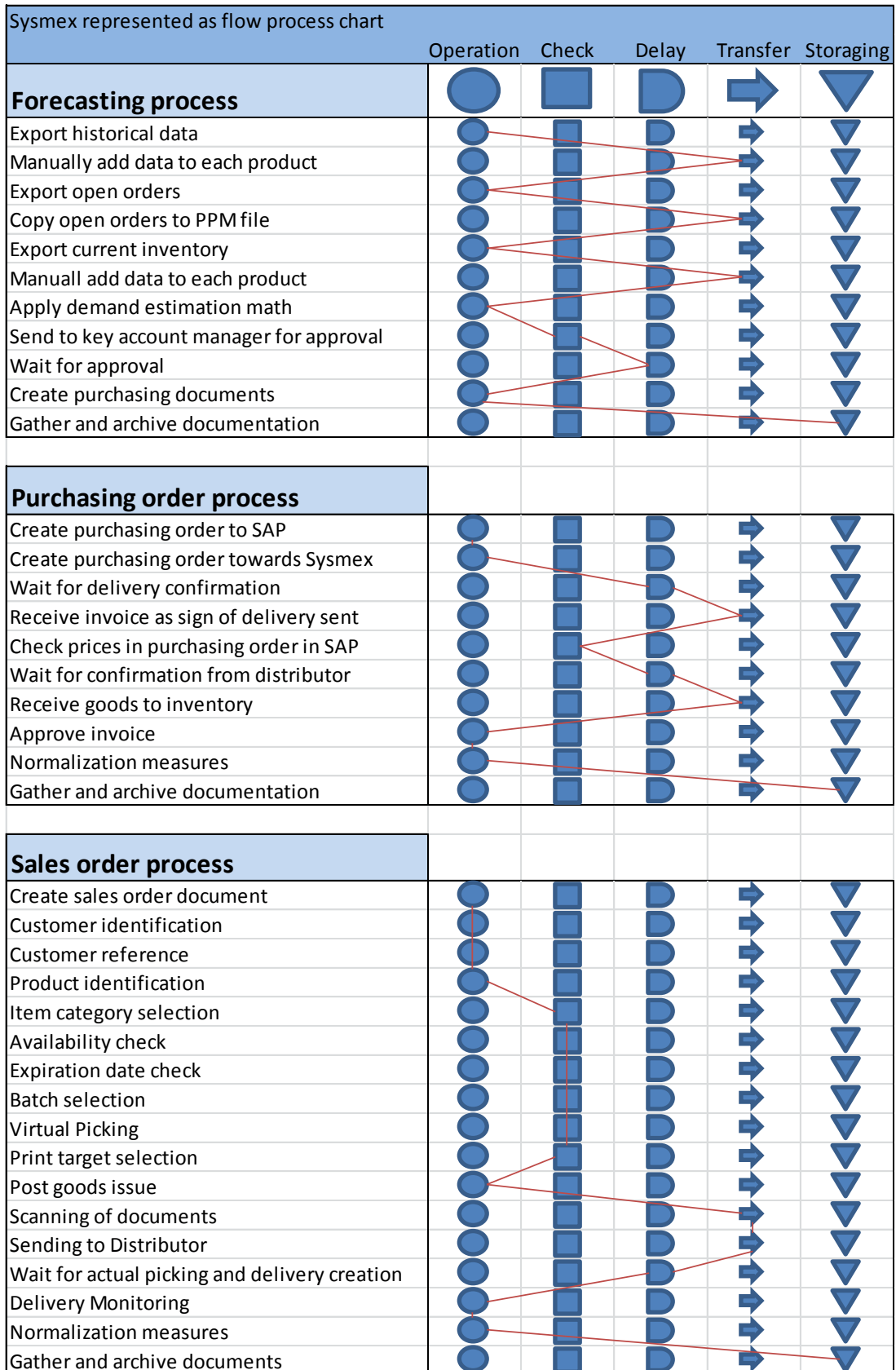


Figure 9. Flow process charts of the current work processes of Sysmex dealership

3.1 Product information management

Product master data management is the fundamental requisite for all other parts of the process to function smoothly. Many of the problems that arise in other parts of the process can be traced back to, or could be fixed by modifying the way product data is managed in the system.

For all normal products Roche Diagnostics Oy uses single backbone SAP server, known as Diagnostics Master System at its Global Material Master department in the corporation headquarters that contains all the product information master data. Products are opened and changed there and DMS feeds all other regionally used SAP versions with this data (Global Supply Chain manual). This kind of setup is mandatory for the purposes of statistical data extraction from the system for the purposes of financial reporting and internal metrics.

In the interview with Eija M. and Brien L., who are responsible for the product master data change requests, several weaknesses of the Sysmex product material data was identified. These weaknesses have become apparent one by one through the analysis of the other parts of the process. When collected into a single package they show a clear prolonged state of mismanagement of product information of the Sysmex dealership products. This is most likely due to the special nature of the dealership and minimal amount of people involved in the Sysmex process.

Both Eija M. and Lampen-Smith agreed that one of the main reasons why Sysmex has a special nature-status is the expertise required in the product information at system level. Other product groups do not require similar knowledge of the products themselves for their sales order creation process. This barrier of knowledge is mostly artificial and caused by missing or broken information in the master data.

Main problems in filling the product data into the SAP-system are listed below:

1. The purchasing prices of the majority of the products are not updated to the latest price. This creates a wrong valuation of the open purchasing orders,

as in the purchasing process the price on the open purchasing order is corrected only moments before accepting the order. Some of the products have no purchasing prices set at all

2. Products which have been added during the past year have not had their weights set into the system. This causes an extra step to the process of creating both a purchasing order and a sales order, one step for each product bought or sold. This causes a major delay in order creation for no justified reason.
3. All products have their item category set to a wrong default value. This creates again an extra step, one per item, every time when creating a sales order as the order needs to be modified every time to change the default value to the actual correct value.
4. All products have their default source warehouse value set to none. Another extra step easily avoided by defaulting it to the only warehouse in use.

3.2 Forecasting

Forecasting process in Roche Diagnostics is governed by Compendium Forecasting Process & Forecast Accuracy manual. This document mainly sets the rules and standards for the internal forecasting process within the Roche Corporation and it is applied primarily for Roche's own product lines. However, it also sets the standards of forecasting to all third parties to follow as well.

Forecasting and purchasing of Sysmex products is separated into two separate processes due to the differences in product categories. These two processes for reagents and Control bloods are described in more detail in chapters 3.2.1 and 3.2.2.

3.2.1 Forecasting for Reagents

Reagent is a product group in which there are 100 different articles most of which chemicals which the diagnostics instruments will consume in normal day to day usage to produce test results. However, this product group consists of also common spare parts and accessories. These chemicals share the characteristic of similar long expiration dates and have mostly the same transportation requirements.

Reagents are ordered 90 days in advance and they have on average of 180 days of usage time when they arrive. New order is created every 30 days. In case of emergency there is an emergency stock from which a small amount of each reagent can be ordered but with significantly higher delivery costs.

For Reagents there exists an excel file known as the Purchasing Proposal Master file which turns all information inputs into the purchasing proposal.

There are five stages to creating a purchasing proposal as can be seen in figure 10

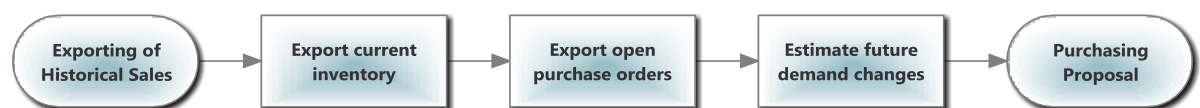


Figure 10. From forecast to purchasing proposal

Historical data is extracted from software tool known as Pro Clarity into which SAP-system exports all sales related data for reporting purposes. The extraction process requires a creation of a template of database query which explains to Pro Clarity, effectively only data storage, what data is requested and in what order it should be represented. This template can be saved for further use but it has to be modified for each usage. Historical sales data is searched for the previous month, for the past two months in total and for the rolling last 12 months total. Pro Clarity can only create a report based on its own item category limitations, which in this case are hematology and urinalysis. These two reports are then exported to two separate report files from which the meaningful information is manually copied into the Purchasing Proposal Master file. Based on the researcher's own experience from

the past 6 months updating new sales values into the PPM-file takes on average 30 minutes.

Current inventory data is searched from the SAP database. Currently it has proven to be fastest to extract the data directly from the SAP by taking a full list of products in stock and simply updating the PPM-file manually for each product. This part of the process takes on average 10 minutes.

Before demand estimation can be conducted the user has to extract purchasing order data from the past monthly orders and add them to the PPM-file and modify the file itself so that it is ready to be used to process the inputs. This part of the process takes no more than 5 minutes.

Demand estimation is currently managed within the PPM-file by a simple equation, shown in figure 11

$$\left(\frac{\left(\frac{Roll12Mth}{12} \right) + \left(\frac{PastMth1 + PastMth2}{2} \right)}{2} \right) \times 3 - (CrntInv + NextOrd1 + NextOrd2)$$

Figure 11. Mathematical function for forecasting

The equation calculates an average of the sales quantity of the past 12 months and combines it with the average of the past two months in order to create an average expected demand with weight effect on past two months. Then it compares the threefold of expected demand with the total of current inventory and already placed orders of the next two months. The total of this equation represents the change in estimated demand compared to what is expected to be in a warehouse after three months. When added to the value of an average monthly consumption the total will show if the order amount should be increased or lowered and by how much.

Finally the excel file produces a Purchasing Proposal, which is then sent to the Key Account Manager (later KAM). KAM then adds to this suggestion those values that are known to come in in three months' time, such as coming new customers or

instrument installations and their effect on the future demand. The file as a whole is sent to the KAM for inspection, and it returns with added input and comments on each product line. From the experience of the researcher, there can be a significant delay before the KAM has the time to approve the purchasing proposal and there is some proof that would justify that this approval does not necessarily increase the reliability of the process, even though the commentary input to the predictable demand changes is considered as valuable information.

PPM-File must then be modified one more time with updated values after which a PO (Purchase Order) is placed in the SAP and the PPM-file generates a document with agreed template which is then sent to the Sysmex sales representative. Finally PO document is combined with order confirmation and all commentary from the KAM and it is then placed into a binder. The PPM-file is saved into agreed location.

3.2.2 Forecasting for Control bloods

A product group of chemically treated and stabilized blood is known as the Control blood. This blood is created from normal donated human blood which is treated to have a certain level of certain characteristics, such as known red blood cell count. They are used to test and control that the instruments used give out the desired results. Controls come in 5 different varieties, which each have their own separate ordering cycle. All Control bloods are produced according to pre-orders, hardly any buffers exist on the manufacturer's site.

The delivery time is from 80 to 100 days on a pre-agreed cut off and delivery dates. All the controls share the requirement of having cold chain from the supplier's warehouse all the way to the instrument at the customer's site. They are all small in quantity and size but require that strict safety protocols are followed. Controls have also long delivery time and very limited expiration dates and due to this they are generally not held in stock. For Control bloods customer information and order management there exists a Sysmex Kontrollikäyttäjät Master File (later SKM-file) which is the source of all necessary information needed to maintain the flow of Control bloods to the customers.

The SKM-file contains data of all the customers who have Sysmex instruments which demand Control blood for operation, as well as the information of how much of the control blood they need. Each type of blood has its own customer lists and the file compiles this information into purchasing proposal template separately for each blood type. Each blood type has their own ordering cycle but they all share the same characteristics of 90 days delivery time and direct delivery from the supplier to the end customer. Updating of the SKM-file, demand estimation, purchasing proposal creation and purchasing is a part of the daily operation of the Order Manager Coordinator.

A minimal buffer of one or two units of each product type is allowed and this is usually enough to support a new customer until they become a natural part of the ongoing cycle. There exists also the option to order more of each blood from the supplier with greatly increased price in such a case that the local buffer stock runs out.

3.3 Purchasing Process and inbound logistics

Purchasing of Sysmex reagents and controls is part of ongoing daily tasks due to the nature of Control bloods but also because unpredictable changes in demand of reagents. The long delivery times and spread out ordering cycles mean that OMC is faced with a situation where ten to twenty purchase orders are open and in different phases of their ordering cycle. This demands a strong documentation during the purchasing process cycle.

Currently purchasing process as a process is well planned and documented and mistakes happen rarely and managing the different phases has been taken into consideration. There are few steps taken that are unnecessary and some that should be added to meet the Global Supply Chain standards. For example the documentation process does not comply with the policy of collecting data of errors.

3.3.1 Purchase order process of reagents

Purchasing process of 3rd party reagents is a normal part of OMC's daily operation, however due to the nature of Sysmex products and the management of a separate warehouse, purchasing of these products has different level of importance. This is also the only part of Sysmex process which is currently documented and where a user manual exists.

This process is initiated several times over the duration of a month but culminates at the time when a monthly order is started by receiving accepted PPM-file from the KAM. Purchase Order document is created into the SAP system based on the information on the PPM-file. This creates a PO document print which is a key document when the rest of the process phases are followed and when trying to avoid losing the track of any of the initiated purchases. The purchase order process flow of reagents is visualized in figure 12

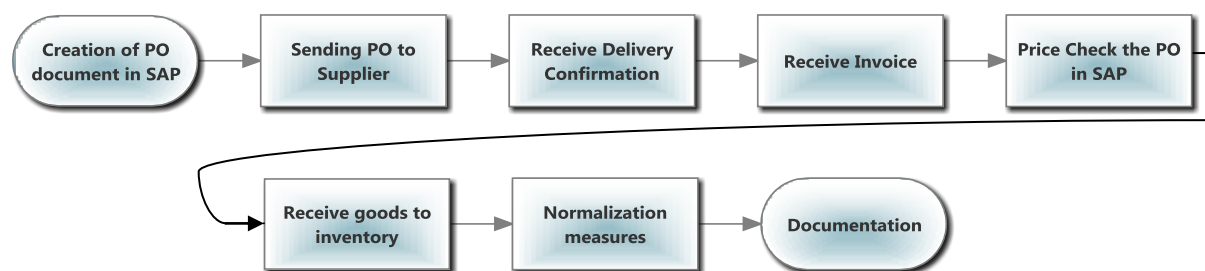


Figure 12. Purchase order process for reagents

A copy of the PO is translated into Sysmex product numbers with the help of the PPM-file and then e-mailed to the representative of the supplier, who answers with delivery confirmation on those products that can be delivered at requested times or discussion ensues of those that cannot. Usually not later than two days later a delivery confirmation document will be received and it is connected with the PO document to track the progress of the purchase.

Invoice will be generated at the same time as the delivery leaves the suppliers site and OMC receives this document by email. It is normal that delivery will be split into several vehicles depending on the characteristics of the products, so it is normal

that several invoices are normally targeting a single purchase order document. These documents are collected together with the purchase order until the whole order can be confirmed fulfilled. At the arrival of the invoice it is also normal to notify the distribution warehouse about the inbound delivery, especially if it is significant in quantity.

The invoice also acts as a price check between supplier's price and price in the SAP-system. The prices in the SAP system for Sysmex products have not been updated properly and their fluctuations are mainly ignored. OMC has to change prices in the PO document in the SAP-System so that they match with the ones in the invoice. Missing this step would cause the invoice to differ from the purchasing documents value, and thus when the invoice is paid the value of the goods in the stock will be wrong. This inherently causes further problems in accounting, financial reporting and stock insurance costs.

When goods arrive at the distribution warehouse their representative sends a copy of the packing list to the Order Management Team. The packing list contains the batch number and expiration date data of each product and it is then used to accept the goods stated on the document into inventory with correct information. Next the packing list is connected with the printed PO document to note that goods have been received.

The distributor company checks the delivery for damages and. When goods can be agreed to have been received in good condition and this is communicated back to the OM, the invoices are released for payment. Copies of the invoices are connected to the original PO document and archived as to indicate a completed process.

3.3.2 Purchase order process of Controls

The purchase order process for Control bloods revolves around the SKM-file in which all the customers are listed. Next to the customer information is the number and types of Control bloods they require and this information is used as a simple list of the amount of Controls to order. As stated earlier all Control bloods are produced

according to pre-orders and the delivery time is from 80 to 100 days and the manufacturer keeps hardly any buffer stocks. The Control blood process flow is visualized in the figure 13

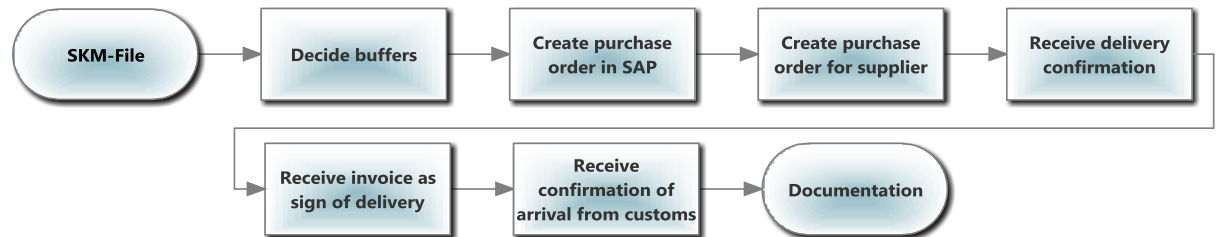


Figure 13. The purchasing process of the Control blood products

It falls on Roche Diagnostics to be responsible for maintaining a buffer for new instrument installations or replacements in case of damages to or errors in the product. As the flow of the goods is constantly known and new instrument installations are generally also known the buffer is maintained manually as flat 1-2 units of each product type. By far the buffer has been enough to maintain all installation events and to guarantee high customer satisfactions.

3.4 Warehousing

Sysmex products are stored mainly in outsourced distribution center in South West Finland. The 3rd party operator manages inbound clearance, storage, picking & packing and distribution of all Sysmex reagents and instruments from this location. Roche Diagnostics follows “Warehousing and Distribution Outsourcing Manual” in managing the outsourced warehousing activities. This document states the policies, limitations and requirements for the operator.

The general ideology in the manual is that the operator must become a part of Roche Diagnostics Supply Chain, and adhere to all its requirements:

Whenever the local warehousing and distribution function is outsourced to an external partner, this partner will become an integrated part of the Roche Diagnostics Global Supply Chain and therefore has to be in full compliance with the Roche Diagnostics Global Supply Chain requirements as well as with local laws and regulations. (Warehousing and Distribution Outsourcing Manual, 2011).

Due to the different nature of the control blood products they come by airplane directly from the manufacturer. When they arrive at the Finnish customs the representative of the operator at the airport is sent all the sales orders and relevant documentation so that these blood products can be delivered straight to the customer's sites.

3.4.1 Warehousing operator

The representative of the distributor, Mr. Virtanen, was interviewed. Based on this interview the current situation, its challenges, strengths and shortcomings is described in the following chapters.

The operator has not changed in nearly a decade but the processes have been changing and Sysmex dealership has been growing over the time. However, the operator's daily activities are mostly routine tasks. The responsibility of the operator begins from receiving the incoming delivery and continues by physical inspection of the goods. This is followed by requirement maintain the storing of the goods and ends at successful delivery of the goods to the customer based on sales orders received from the Order Management Team. It hardly could be a simpler process but with high quality requirements and demand on perfect accuracy and with limited manpower, it quickly gets difficult to deliver.

Mr. Virtanen operates as Special Customer Manager and is concentrating on the responsibility of Roche Diagnostics as a customer and all to the customer service aspects from unloading, picking, packing and delivering of shipments, communicating with Order Management team and managing the warehouse. During the discussion with Mr. Virtanen the current situation was clarified as to be a result of evolution of a long co-operation and that most routines have been established

through trial and error. The strength of the current situation is this co-operation that has allowed the warehouse and respectfully large throughput amount to be managed by just one dedicated employer but with full organizational support. At the same time this is the greatest challenge of the current setup since the limit of throughput capacity is causing significant problems when customer demand cannot be predicted and delivery assignments pile up more than can be managed by a single employee.

Together with Mr. Virtanen we substantiated the notion that currently the operator together with the Order Management team does not fulfill all the monitoring requirements of Roche Diagnostics Distribution and Outsourcing manual.

In several conversations in the Order Management team members it has also become apparent that the warehousing operator has a weak capability for adjusting to demand fluctuation and to special delivery situations. In multiple occasions the operator has failed in providing on time delivery because of lack of manpower or it has failed to fulfill quality requirements on special delivery situation. This is especially alarming notion when Sysmex dealership's constant growth and importance of the products is taken into consideration.

3.4.2 Inbound Activities and Storage Management

When received, each incoming delivery is checked against the relevant purchasing order and each pallet and box is physically verified for contamination, tampering and damage. The quality, quantity, required warning labels, batch numbers and expiration dates are all documented and photos are taken where possible, these documents are then shared with the Order Management team. Receiving of inbound delivery by the operator has been errorless and it that part of the process fully complies with the standards stated in the Warehousing and Distribution Outsourcing Manual and in the Global Supply Chain standards.

The operator lacks warehousing software which would be capable of interfacing with Roche Diagnostic's IT- systems or offering an online interface so that all inventory

management could be handled over email. After inspection inbound deliveries are reported to the Order Management Team and the sales order documents are delivered to the operator by email and twice a week a general inventory level checkup is done manually by sending inventory lists over email. This is not an optimal situation but it fulfills the current needs and the relevant requirements.

Topic 7.1.3 in the Warehousing and Distribution Outsourcing Manual states that the storage area must be temperature controlled, records of controlled values and records of the calibration of the controlling equipment should be available for review at all times. These parameters are critical to the quality of the products and they are currently not monitored or recorded at all. Currently also no financial control or verifying of the invoicing correctness demanded by the outsourcing manual exists.

3.5 Sales order process and outbound logistics

Sales Order (SO) is a document in the SAP system which defines the following information: customer as “sold-to”, customer's delivery address as “ship-to”, additional references and markings expected by the customer in the relevant documents and the products ordered. The process starts from the purchase order received from the customer, from which then the SO document is created and ends when the completed document is archived.

Sales Order creation, monitoring of distribution and error correction is the majority of Order Management team's daily activities and therefore a fast and risk free creation process is crucial for reducing the work load. Currently Sysmex product group requires specific knowledge of each of its products in the SO creation process. This is mainly due to the mismanagement of product information in the SAP system and lack of process development effort.

From sales order creation perspective the products themselves are not drastically different when Control bloods are excluded. The SO creation process follows the same general structure as other Roche Diagnostics products. However there currently exist few steps in the process that make it unique from the others and for this reason Sysmex SO creation has been dedicated to just one person. In case of

sick leave or vacations this one-person-approach increases the risk of problems when they're gone and multiplies the efforts trying to normalize the situation later. It is also considered a business risk if this person is forced resign for some unforeseen reason.

3.5.1 Standing Orders

Standing orders are pre-agreed contracts with the key customers for preset deliveries at preset intervals and they are a key component at enabling non-stop functioning of the instruments at the customers' sites. The share of value of standing orders from all deliveries is roughly 50 to 70% and thus they act as a primary source for purchase order creation process.

Customers often contact the order management team to adjust the standing orders according to the fluctuations of the reagent consumption of the instruments in use. A standing order can thus effectively change the question from the customer's perspective from "Should I order more or not" to "How much should I order in order to be able to conduct all foreseeable tests". Thus standing orders are the preferred ordering style when possible. Standing order model also ensures the least possible amount of special orders and situations where the laboratory has ran out of reagents that effectively might save lives. Having a functioning and well managed standing order system is a basis for steady, safe and on time deliveries while greatly also supporting sales growth.

Currently standing orders are managed as documents in binders that describe the customer, the products, amounts and arrival dates the customer expects for these goods. The binder is accompanied by a standing order timetable document which shows to the employee responsible of them the order dates in chronological order for simple overview of coming orders and for other team members a quick access to the correct information. The current situation is considered strong and stable.

The timetable document is used to notify the distributor about the dates when the standing orders are piled up on same dates. This is done to avoid situations where the distributor's resources for packing and delivery would become a bottleneck.

3.5.2 Sales order creation process for reagents

At first stage the ordering party must be identified. From the perspective of Order Management Team the ordering party represents the end point where the delivery is to be made, so the ordering party is identified through the delivery address. The SAP system then automatically links this delivery address to the actual sales customer in its own database. This part of the process is the weakest point in the process as wrong customer identification leads into multiplication in all following work. Figure 14 illustrates the process flow for creating a single sales order document

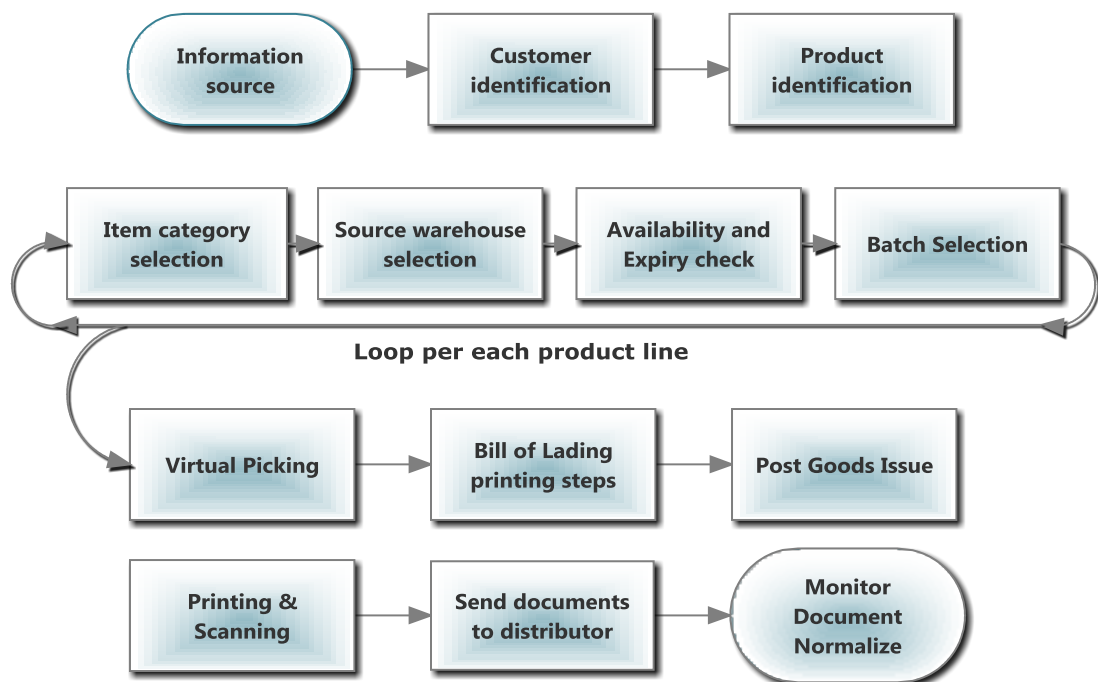


Figure 14. Sales order process

Second stage is registering customer's markings, reference numbers or internal comments to the SO document. Followed by the identification of the products customer wishes to order. Identification is done preferably by product numbers, which in a vast majority of the cases the customer knows beforehand.

For every product identified follows a loop of follow up actions special for Sysmex product group. They take place on each and every product line of this type, but depending on the individual product the options selected in each phase differ. They are, however, always the same for each time.

- Item category must be changed to identify the product as 3rd party
- Source warehouse must be selected.
- Availability check
- Expiring date check
- Batch selection

After the full list of products has been created, the order must be virtually picked in the system, which means filling up the order document with the amount of products to be picked. Actual picking happens later at the distributor's warehouse but the system demands picking before the posting of the delivery documentation can be created. The creation of packing list in SAP is currently a manual process and takes quite a while. It is also repeated exactly the same way for each following order so its meaningfulness it is constantly questioned.

The printed packing list documents are then scanned as email attachments and sent to the distributor where they are used as picking lists and attached to the delivery as bills of lading. A copy of the packing list represents the SO document in the system and is archived in Order Management Team office with all necessary reference material, such as the source of the order document.

3.5.3 Sales order process for Control bloods

Control bloods follow the same sales order creation process with the difference that the information source for order creation is always the Sysmex Kontrollikäyttäjät

Master File (SKM-file) and the distributor is a different entity. These sales orders are created in large batches at the time of delivery from the supplier and add significantly to the repetitive stress of the process. Up to 100 sales orders are created at once, up to three times a month. As shown in figure 15, receiving the arrival confirmation from the airport customs is what starts the creation process for all the bloods to be shipped out to the customers.



Figure 15. Sales order creation process for Control bloods

When sales orders have been created they are sent to the distributor's team that manages the shipments. Upon completion of the actual unpacking, repacking and delivery to the customer this team sends a delivery confirmation to the Order Management Team listing all the deliveries.

3.6 Distribution Management & Delivery monitoring

The qualification, quality and monitoring requirements for outsourced warehouse or distribution provider are described in the Warehousing and Distribution Outsourcing Manual (later WDOM) of Roche Diagnostics. The document lists minimum requirements for the outsourcing party and merely touches the topic of distribution.

The current provider of distribution management for Roche Diagnostics Oy owns the warehouse hubs and trucks that work as links between the hubs. Actual delivery from the hubs to the customer is outsourced to small local companies. WDOM document limits the depth of outsourcing to 2nd level service providers. Currently there is no control if this rule is followed but there are documented cases which prove that this rule has been broken.

WDOM document under topic 7.1.4.Outbound Activities states “*Where appropriate, the use of temperature monitoring devices is required to assure the product integrity*”. At the topic 7.2.2 Ground Transportation it states clearly that it is distributor’s responsibility to maintain temperature logging and proof of cold chain management throughout the delivery. Currently the cold chain for refrigerated products is not monitored at all. Cold chain is ensured by only allowing the cold products to leave from Monday to Wednesday, so that theoretically they are not left at the hubs on the route over the weekend, there are no documented cases when this precaution has not been enough. However, there exists an unacceptable amount of documented cases where products have been frozen during the delivery at winter, clearly stating that the special requirement of the products is not properly under Roche Diagnostic’s control. These events cause the product to be unacceptable for use, cause minor expenses from its destruction and major expenses and delays in operation from the need to replace the product at the customer site as fast as possible, free of charge. The distributor in general takes the responsibility of these events but the contract allows crediting only based on weight of the delivery, and the general trend with the reagents is that the less it weighs the higher the value.

The manual demands documented procedures for picking and packing. These documents do not exist. Due to the nature of the outsourcing having unknown 3rd party companies handling the last part the delivery, it is rare but repeating occurrence that deliveries are piled up on top of each other even against the rules and markings on the deliveries themselves. The main reason for of the damages caused this way might be connected with the lack of clearly documented instructions of the picking and packing procedures.

Documentation of completed dispatches is required by the company policy. Currently this documentation is freely available only for Control blood deliveries. This connects together with the IT-system interface issue described under the chapter 3.5.1. Sales order process. The issue will be cleared out when the It-systems of both companies will be connected. This documentation supports product traceability throughout the supply chain and falls also under the quality policy for storage of relevant documentation.

WDOM describes at topic 10. Complaints & Logistics Claims Handling and topic 11 Deviation Handling that the outsourced distributor is responsible of resolving customer complaints and recording them, as well as having an adequate deviation management and reporting system. In Finland's case the Order Management Team manages all complaints, claims and deviations in co-operation with the distributor.

Even as OMT manages the complaints, they should be recorded as described in the policy. The WDOM lists the following topics to be recorded:

- A procedure which ensures that all complaints (oral & written) are processed and evaluated in a uniform and timely manner
- A procedure which ensures that all complaints are documented and maintained in designated files or a validated IT system.
- There should be a written report available which documents all complaints related to Roche products and customers.
- The deviation report shall include a brief description of the event, determination of the cause, quality impact and possible corrective and/or preventive actions.
- The distributor must trend its deviations on a regular basis to monitor the performance and the quality of its processes. This trending shall be performed in written form and will be available for Roche on a regular basis.
- Deviations in delivery or customer complaints are currently not recorded in single designated location with the required detail. The distributor does not trend its deviations nor report the quality of its processes at set intervals as demanded by the policy.

4 Analysis of the desired process state

The desired state of the purchasing and inbound logistics process of the Sysmex dealership in Order Management team is as much simplified and automated as possible with a detailed documentation that allows the process to be handled by anyone without significant special skills or product knowledge required. Being the only major process where 3rd party supplier is involved in the processes of Roche Diagnostics, the Sysmex dealership process should be refined to a point where it can function as a benchmark against which other later evolving 3rd party supplier relationships can be compared to. The complete process from forecasting to invoicing must be brought into the extent of Roche Diagnostics Global Supply Chain Standards.

4.1 Product Management

In the desired state of product information there would be no extra steps required in creation of purchasing and sales documents. Each product would have all required information placed in the master data file in such detail that the steps would not be necessary. Due to the nature of the product data coming from DMS and same product information being in use in the whole EMEA region it might not be possible to change all the variables. Product information should also follow the Roche Diagnostics Global Logistics Standards document.

4.2 Forecasting

The biggest weakness in forecasting is the Purchasing Proposal Master file. It requires experienced user to maintain and utilize it and it still provides mediocre results at best for forecasting purposes. Without a working forecasting tool many decisions have to be made based on educated guess and experience. This is an obvious business risk in case of unforeseen absences or change in the personnel. A mistake done in forecasting of demand or simply managing the file can cause drastic financial results if the mistake is allowed to go over to purchasing phase.

There exist no rules of when the current inventory is taken from the SAP system, so the information uploaded to the PPM-file does not always represent a cycle of whole month. A week's difference can cause that previous month's delivery has just arrived to the stock, causing a situation where it would appear that stock is more full than it actually is, which then causes the PPM-file to suggest minimal order size and thus directly causing drastic problem when it is delivered in 3 months

The current forecasting math in the PPM-file also takes under consideration a yearly average and rolling past two months. This is inadequate if the order amounts should be adjusted to seasonal changes in demand. The math also ignores minimum order quantity, minimum stock level, efficient delivery quantity and shelf life of products. Ignoring these factors directly causes price differences in the delivery costs and in the scrapping amounts.

There is also no input from KAM or other external sources about the changes in demand such as new instrument installations or instrument removals. These factors are dependent completely on memory of the user.

The information input structure of the PPM-file should also be completely redesigned so that it can create purchasing proposals directly from exported information from the Clarify- and the SAP systems to reduce the amount of manual work that is mandatory for its maintenance. This way a more holistic amount of information could be uploaded with less manual work and at the same time providing clearer foundation, control over and quality for the purchase proposal.

Forecasting for Control blood products currently operates at peak performance. Kontrollikäyttäjät Master File (later SKM-file) holds all relevant customer information and the process which brings new customers to the list already takes into consideration the long lead time. Current buffer levels are adequate, and no performance would be gained by changing the current situation.

4.3 Purchasing Process and Inbound Logistics

Roche Diagnostics Finland does not have consolidated purchasing, so currently Order Management Team purchases from contract vendors without consideration or control compared to the level of responsibility and risk. Due to perhaps this fact certain normal aspects of purchasing are missing from the process. Inbound deliveries should be followed more clearly since the Global Logistics Standards document expects an affiliate to record all errors in the purchasing process. There might also be possible bottom line gains to be made in additional concentration on the prices, values and volumes purchased. Obtaining any significant benefits from purchasing would require special concentration on the matter, perhaps combined together with purchasing from all suppliers.

Most Sysmex products have not had their prices managed properly in the SAP-system. Changing price information manually when creating a purchase order document is a completely unnecessary step. A minor error in this part of the process causes problems in invoice handling when the invoice value does not match with the purchasing value. Usually the invoice bounces back to the owner of the purchasing process and causes double amount of work for both. In such a case where an invoice goes through invoice handling without being bounced back the problem moves to accounting and finance reporting where differences in invoicing start to grow. Open purchasing documents also create metrics for expected purchases and wrong item values in the system cause errors on the financial forecasting and consolidated purchase amount reports.

Unlike risk effects coming from the above described purchasing process of reagents, the purchasing process of Control blood products is in a very good state and leaves very little room for improvement.

4.4. Warehousing

From the perspective of purely warehousing and inventory management of Sysmex products the current setup with the 3rd party operator is considered acceptable and does not require any drastic changes. There are only minor monitoring issues with the Roche Diagnostics requirements that need improvement and the contract with the operator demands changes so that it can be adjusted to the growing demand of the products.

The incapability of the warehouse operator to provide a data interface to their system and this way constantly up to date information of the current inventory and storage conditions is a clear shortcoming at this day and age. The manual labor required to maintain two inventory lists and to provide the finance department and auditors monthly inventory reports is costly and cumbersome. This is a hindrance which could be easily overcome by creating a data interface between the IT-systems of the warehouse operator and Roche Diagnostics.

Ability to react dynamically to changes in the demand is expected from a warehouse operator. The current situation where only one person has specific experience about Sysmex as customer in the operator end is also an unbearable business risk. Both parties must be in clear understanding of the important nature of the products and the operator must be capable of appointing more employees without special arrangements to ensure secure on time deliveries even in peak demand days.

The operator must also be capable of execute, record and report all the required temperature monitoring tasks set by the Warehousing and Distribution Outsourcing Manual.

4.5 Inbound Activities and Storage Management

By large part the current situation resembles the desired situation when it comes to inbound activities and storage management of the current operator. However, the provider does not comply with the policy about the temperature monitoring and

recordkeeping. This is a strict Roche Diagnostics guideline and it has or can have direct effect to the quality of the products and to the capability of Roche Diagnostics to demand reconciliation from the provider of warehousing services.

Environmental conditions shall be regularly monitored, recorded and validated. All measuring equipment that is critical to (product) quality shall be subject to a calibration and qualification procedure. Calibration methods shall be documented and these should relate to an international or national standard (where no such standard is available, validated, documented methods shall be used). Instruments that do not meet calibration criteria should not be used. (Warehousing and Distribution Manual, 2011)

The Order Management Team and the provider together should also have in place a process for documenting and recording errors in inbound deliveries and damages in the storing phase. These metrics should be collected for better view over the provider's performance, and to be able to further enhance the processes where most errors occur. This record keeping is also demanded by the Roche Diagnostics policies.

“On receipt, each incoming delivery shall be checked against the relevant purchase order and each pallet / box must be physically verified. The consignment shall be examined for uniformity of boxes and carefully inspected for possible contamination, tampering, damage.”

Records shall be kept for each delivery. They shall include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt, assigned batch number and the expiry date. (Warehousing and Distribution Manual, 2011)

4.6 Sales order process and outbound logistics

General goal in the Order Management team is to change Sysmex SO creation into a process in which there is no or very little difference to the sales order creation process of other Roche Diagnostics products. This would ensure that the SO creation process and all related processes do follow the RD guidelines and policies

and when less specific knowledge is needed it allows the Order Management team to take more dynamically responsibility of Sysmex orders.

4.6.1 Standing Orders

The predictability of standing order system is a strength that cannot be ignored. Currently the predictability is not necessarily used to its full capacity. Mainly the reason is that they're done by many individuals separately, this has resulted to a situation where standing order delivery dates pile up to certain, albeit logical, dates such as the beginning or the end of the month. It is the whole Order Management Team's desire to message to the Key Account Managers the situation on the standing order timetable, so that it could be used as the basis to change the delivery dates of some of the standing orders in order to reduce congestion at key dates.

The predictability of standing orders could also be tied up to the forecasting procedure and with the Purchasing Proposal Master-file. Even with customer's ability and right to change the standing order quantities at their whim, the average consumption of the standing orders could be used as foundation for forecasting.

As is the nature of documents managed in several places, especially on paper, some of the standing order templates stored in the binders are helplessly outdated. Customer and product identification relies only on the standing order template and if the document is outdated or unclear, the ability for anyone in the team to take the responsibility of them is jeopardized.

4.6.2 Sales order creation process

The source of information for SO creation is no different than with other Roche Diagnostics products. The key element that makes SO creation with Sysmex reagent products to require special knowledge is that there are small steps which have to be taken when entering the product lines in the orders. Managing these products in the SAP system would remove the barrier for the whole Order Management team to create SO's for Sysmex. In the desired process state the steps of item category selection, warehouse selection, availability and batch selection should not exist.

Based on the personal experience of the researcher the reagent orders can be changed in a way that will make them a normal part of whole Order Management team's daily operations without loss in reliability and even greatly lowering the risk of accidentally selecting wrong values to the product line.

In the conversations with the co-workers of the OMT and Logistics Manager Jaana N. it became apparent that there is also a desire to find a way to connect our system with the distributors system for the purposes of automated communication. The steps of printing, scanning and emailing packing list documents to the distributor should be handled through an interface between the organizations IT-systems. This change would bring reliability by removing the risk of forgetting to print, scan or send the document. In the current situation the virtual picking also is the trigger that starts the invoicing process. An interface between the systems would force the invoice trigger to take place only after real picking has occurred.

As Control bloods require holistic understanding and monitoring from the forecasting perspective all the way to the delivery to the customer, they should be considered as a separate responsibility area. A clear understanding of the situation, stock level and customer information changes makes it unwise to separate the sales order creation phase from the responsibility package. Regardless, all the desired changes would also affect the creation of Control blood sales orders in the same fashion.

4.7 Distribution Management & Delivery monitoring

The relationship with the distributor has also been affected by the growth of Roche Diagnostics and the inherited uncontrolled change it brought with it. Clearly a review of the distribution relevant policies together with the service provider is required and relevant policies should be brought into the daily routine.

The service provider has currently not been actively encouraged to or is not entrepreneurial enough to develop the relationship naturally. The changes expected by the Warehousing and Distribution Outsourcing Manual are minimum requirements and any normal process development activity would come to the same

conclusions that those requirements should be established at their first opportunity. There are also no other desired changes to the distribution from the Roche Diagnostics behalf, as following the minimum policy requirement would solve vast majority of the existing problems that occur in the deliveries.

In discussion with the Logistics Manager Jaana N. about the quality of current distribution system she described several improvement ideas. Currently Roche Diagnostics delivers goods to a HUSLAB Meilahti at approximately 2,4 times a day, or 12 times a week. There would be obvious benefits of lowering that number to at least the level of once a day by grouping together deliveries. Jaana N. and the rest of the Order Management Team would also like to lower the current delivery times by redesigning supply chain for big or important customers. There is also pressure of looking into cheaper and more standardized way to manage special deliveries. It came apparent that these development plans are secondary and will not be addressed before full policy compliance has been achieved with the distributor.

5 Conclusions and the process change plan

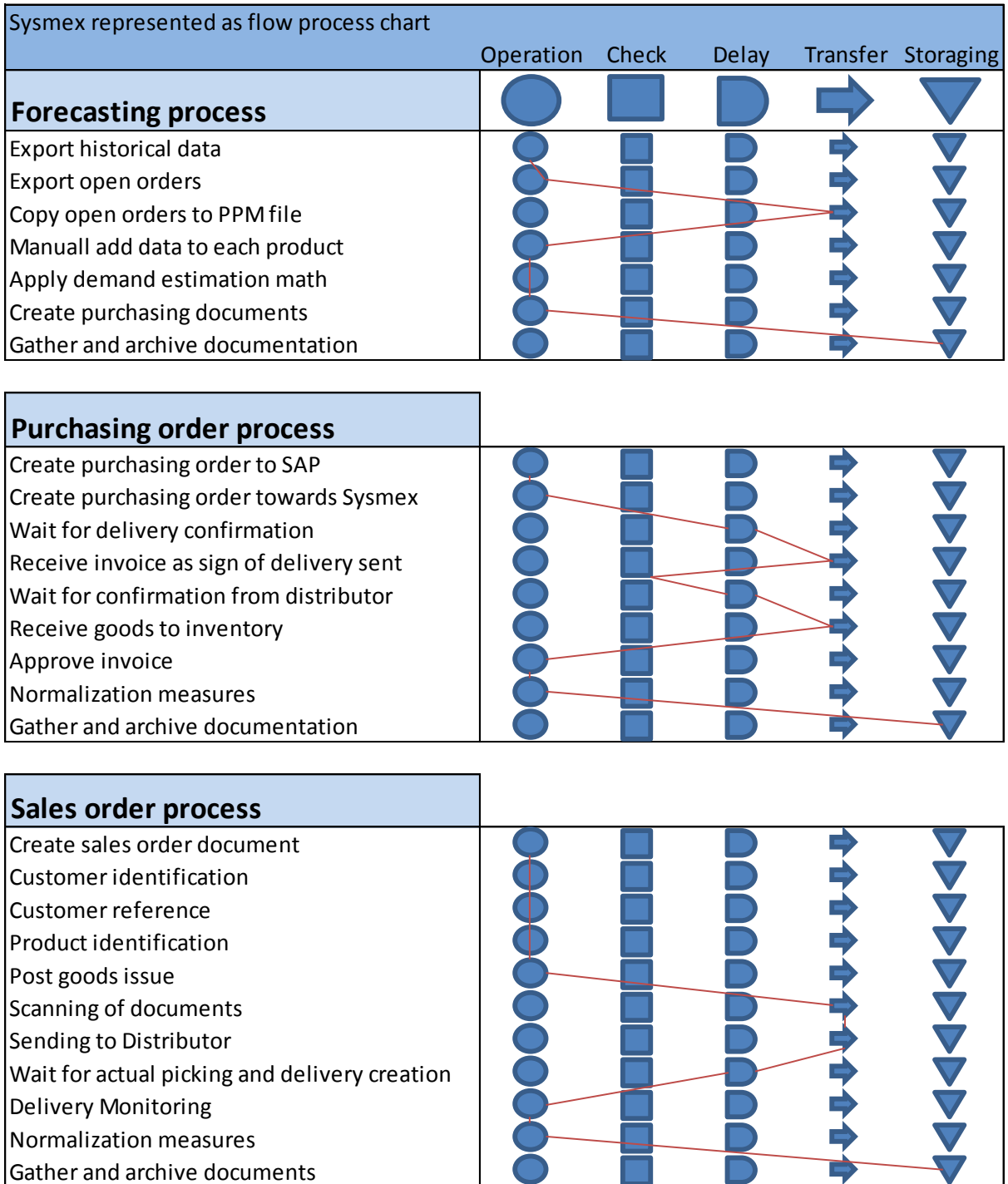


Figure 16. Flow process chart after the suggested changes

Figure 16 describes the flow process chart after the suggested (and feasible) changes to the current processes. The forecasting process can be shortened by four steps when the updates to the Purchasing Proposal Master file are done and the approval of the Key Account Manager is removed. It can be seen that the forecasting process is heavily concentrated on operations that add value to the output of the process. If a way to export open orders directly to the PPM-file without doing it product by product is invented then this part of the process concentrates only to its outcome and becomes very streamlined. Additionally to the qualitative changes to the forecasting process the outcome is reliable regardless of who conducts the process.

The purchasing order creation process would lose only one of the steps, which is the price check of each product before receiving the goods to inventory. Removing this step also directly affects the reliability of the output of the process and removes the risk of ending up correcting the same errors multiple times in other departments.

Six steps could be removed from the sales order creation process changing the process to resemble the sales order processes of Roche's other product groups and thus achieving one of the main goals of this thesis. The approximately 50% speed increase in creation of these sales documents is also considered as direct improvement in the work efficiency of the team.

Adding all the metrics, reporting and recording changes throughout the process brings the processes of Sysmex dealership a long way closer to comply with the company policy standards. These metrics will also have direct use in the further development of the dealership relationship and delivery accuracy. Completion of the planned changes would allow Sysmex dealership a controlled growth again for years to come. Unfortunately the IT-Systems of the distributor are at least for now not up to date to support those parts of the development that rely on modern IT.

The suggested changes to the different processes are described in more detail in the following chapters.

5.1 Product Management

Conducting all these changes will change Sysmex products from being special products to being similar with majority of the other products when looked at from the perspective of the sales order creation process.

All Sysmex products should have their price information checked and updated to the latest price. This removes the error in valuation of currently open purchasing orders. Updated prices remove the need for repetitive work of changing the prices when creating new purchasing orders. Correct prices checked in the system lower the risk that price check is forgotten in the process before accepting and before inbound delivery. This has in turn directly caused more work to the finance department in the form of mismatch between invoice and purchasing order value. This change also reduces the values added into the price differential account in bookkeeping and removes the wrong values shown by open purchase orders. Updating prices will bring the product management of Sysmex products into accordance with the Global Supply Chain Standards policy.

All Sysmex products which are missing their weight and other product information should have their information updated. This removes repetitive work in sales order creation process and lowers the need of special product knowledge.

Sysmex products should have their default item category set to the most commonly used item category instead of a default value. This removes repetitive work in the sales order creation process and lowers the need of special product knowledge. It also removes the risk of order being stuck in the SAP system due to faulty processing without correct item category value and saves time when all item category relevant issues are being handled.

Sysmex products should have their default warehouse value set to the most common value instead of none or simply wrong value. This removes extra step in sales and purchase order creation process and reduces the risk of order being stuck in the SAP due to incorrect saving without the information about the source warehouse.

5.2 Forecasting

Purchasing Proposal Master-file should be completely recreated. The new file should aim to be able to create purchasing proposal which can be trusted as such to create a purchase order, even without presence of experienced user. It should be able to understand exports from information source systems and directly convert this into relevant information. The math in the PPM-file should be rewritten so that it takes into consideration the rolling past 12 months, yearly average, and estimates next 3 months seasonal changes as established multipliers. The current stock needs to be reduced in importance in the math to avoid the inherited risk of choosing a wrong date in stock take. Minimum stock level and shelf life's effect on order quantity should be added to the math. It is important to resolve with the supplier if minimum order quantity and efficient delivery quantity has an effect to the delivery costs.

The step of sending the PPM-file to the KAM for approval can be considered unnecessary due to the fact that the knowledge, control and responsibility for the stock levels and maintaining the PPM-file is on the Order Management Team. There is usually a delay in waiting for the approval that can be a day or longer if the Key Account Manager is not available to accept the suggestion. Based on the OMT's experience and documented mistakes from the past, it can be seen that the approval step does not always increase reliability of the purchase order proposal.

5.3 Purchasing Process and Inbound Logistics

The changes in the product information will remove the repetitive work in the creation process of purchase orders. Changes to the forecasting document described in the chapter 5.2 will give a reliable information source on what grounds to create the document even without prior knowledge of the dealership. Purchasing order creation process is also the only Sysmex process that has a manual for it.

Inbound delivery related errors in the delivery process should be documented at agreed consolidated location together with distribution performance monitoring. This provides information to supplier performance analysis and makes purchasing process comply with the Global Logistics Standards.

Metrics that should be followed in the purchasing process are:

- Delivery time, duration in days
- Damages in inbound delivery, quantity and value
- Fault rates, values
- Picking errors, quantity over period

5.4 Warehousing & the warehouse operator

Development of the interface between the IT-systems used by Roche and the warehouse operator is strongly suggested. Currently the distributor does not use a system capable for this, so no process change plan can be made for this.

Temperature monitoring demanded by the Roche policies must be set to place at the distributor's refrigerators. This process change ties closely with the suggested change of temperature monitoring during the outbound deliveries. The instrument used for this should be certified as is expected by the policy and it should be capable of producing graphical reports of the temperatures. The records of the installed instruments should be gathered together with all other distributor performance metrics in calendar month basis.

The possible business risk of the distributor also having only one employee with product specific and customer (Roche) specific knowledge should be addressed in the next meeting with the distributor. This reveals possible need for further documentation of the process expected from the distributor. It would be crucial also to both parties to recognize the importance of the products for the greater good and to create measures to avoid situations in which the distributor's workforce is not able to deliver all orders at peak demand dates.

5.5 Sales order process and outbound logistics

5.5.1 Standing Orders

A collective meeting is suggested between the Order Management Team and the Key Account Managers on the topic of congestion on the agreed standing order delivery dates. Even if it is not really a change into the Sysmex or Order Management Team process, the effect from the process in which Key Account Managers create the standing order delivery dates has a direct effect on the quality of service that the Order Management can maintain. As many standing order customers are located at or nearly in the same physical location, this suggestion relates to tightly to the problems noted in distribution management, where one customer location is visited many times a day.

An update to all standing order template documents managed in the binder would improve the dynamic nature of the Sysmex dealership. A standard template with all relevant information for successful customer and product identification would remove the barrier for anyone in the team to handle these orders. As currently all Roche's standing orders are managed the same way, a standardized template could also be used as foundation to update all of them.

5.5.2 Sales order creation process

Process changes suggested in the chapter 4.1 about Product Management would effectively remove the repetition loop with item category selection and warehouse default. Availability check and batch selection is done in practice together with

expiration date check. These are possible to automate by modifying the SO creation transaction in the SAP system. A script should be created which inquires existing batch values in the warehouse location stated on the sales order and which, if set to correct default, will return available batch. Then the script looks if this batch fulfills set requirements for expiration date. A more detailed guide to how to create this script can be found in SAP SD Analyst Sweta Jain's guide "Automatic Batch Determination Based on Shelf Life"

In the interview with the distributor's representative A. Virtanen it came apparent that the warehouse management systems in use in their organization are not capable of creating a direct interface between the systems of Roche Diagnostics. An alternative suggestion from the Order Management team was that the virtual picking would be automated with a script that would simply always "pick fully" and that the same script would deliver the packing list directly to the distributor's printers, while also retaining a copy in the local office for archiving and monitoring purposes. This change suggestion is left out from the Change Control document (Appendix 1) due to the other ongoing projects that might suggest that any effort would be deemed waste of time. The suggested changes would however greatly affect the efficiency of creating Control blood sales order documents as the repetitive work is brought to minimum and the most time taking tasks are automated.

Creating a normal sales order document with 10 products took the researcher in 210 test runs an average of 2 minutes and 45 seconds. This number contained all originally existing phases of creating a single sales order and it would be significantly more if done during phone call with a customer.

Over 20 simulations with suggested changes took the researcher on average 1 minute and 25 seconds, effectively shortening the time spent on one cycle by 49%. For two product sales order the values were 1 minute and 45 seconds and 55 seconds. Every month the largest Control blood delivery totals to 94 sales orders, two product rows per order on average, in total 2 hours 44 minutes of continuous order punching at maximum rate. With the suggested changes this task would be reduced to 86 minutes or 47% less working time.

5.6 Distribution Management & Delivery Monitoring

If we consider how the IT-interface development handles the problem with confirming completed dispatches and bringing the traceability of the supply chain up to par with the policy expectations, a total of three other sections of improvement can be named for distribution management. These are temperature monitoring of deliveries, picking and packing procedure documentation and establishing delivery performance reporting process.

In all other Roche Diagnostics deliveries temperature recording devices are placed into the packages at spot checks and the records of the devices are consolidated at one location. Together with recorded events of temperature related issues in the deliveries the data from the recording devices gives an overall image of the status of temperature control of the service provider. These recording devices and the process of managing them exist already in the organization, so this improvement is at its simplest just applying the existing procedure to the Sysmex product category. This would have the benefit of not confusing the customer with a new process for temperature monitoring, as they are already used to the process with other products. This process change ties closely with the warehouse temperature control and the locations of the documentation should be consolidated together with that process change.

The service provider has already agreed on inheriting the quality requirements that Roche Diagnostics demands from itself and on maintaining those requirements at its own subsidiaries. As a concrete improvement to implement this document that defines the rules of picking, packing and delivery should be created. This document would define the requirements of different products, establish the way packing and delivery requirements are marked on the deliveries and what is generally expected to maintain the quality of the products through the delivery process. When both parties are agreeing and aware of this document it becomes easy to define at what point a deviation from the expected has happened and when it should be recorded.

Topic 3.5, of the Global Supply Chain Standards for Affiliates describes the delivery performance report currently in use for all Roche's own products. By adopting this

report to the basis for performance reporting of Sysmex products, the distributor and the OMT will make sure that all policies are followed. The document states that monitoring should be collected in a consolidated location at calendar month basis and from the following (relevant) indicators:

- % On Time in Full Delivery (Committed vs. Actual Delivered)
- Claim rate
- Number of special deliveries
- Backorder products as quantity of product shortages over period

From the Warehousing and Distribution Outsourcing Manual it can be derived also that deviations and damages should be recorded in greater detail, including brief description of the event and determination of the cause, quality impact and possible corrective and/or preventive actions. From the practical point of view the researched would like to suggest of adding all relevant document numbers that refer to the case. Collecting this information to fulfill the reporting requirement means additional work to the daily routine with all other relevant actions and adds time needed at the end of the agreed period cycle for consolidating the information.

As these cases are very often brought up by a customer complaint, the customer complaint should be recorded as suggested in the Quality Management Policy document and in internal guidelines.

6 Summary

Creating this thesis has taught me the difference of noticing an error in a process, or lack in its efficiency, and how to take a step back and systematically challenge the whole process. Only this way you see the larger picture, how the minor points interact in it and how ultimately changing the small points can and will actually turn into large valuable change. Conducting this research has brought me quicker and deeper to the Sysmex dealership contract than would in any other way been possible and I have managed to turn the results of the research into additional value for Roche Diagnostics Oy. In the future I will use same systematic challenging and process mapping tools to analyze any new larger process tree I meet, to understand it on a deeper level and to find if parts of it could be improved.

I feel that the goals of this thesis has been met, however I could have done more research with the policy compliance and quality requirements. Applying theory also proved to be significantly harder than expected, mostly due to the limited scope, nature of the process and depth of the analysis in it. I believe that without researching the whole process tree from start to end and collecting all the small changes into one controlled change project, most of these changes would have never been made.

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Appendix 1

The Change Control document

Process name	Change name	Description	Resource needed	Estimated duration		
Product management	Price information update	Complete check of whole product category's price information and update accordingly	Jan Sjögren, Eija Miettinen, Brian Lampen-Smith	8-12 work hours		
		Step 1	Step 2	Step 3	Step 4	Step 5
		Gather a full list of prod. No. to be changed.	Gather latest price information next to prod. No.	Run DMI price update process with new prices for each	Confirm correctness.	Upkeep price information regularly.
Current progress						
Process name	Change name	Description	Resource needed	Estimated duration		
Product management	Weight information update	Update master data for missing weight information	Jan Sjögren Eija Miettinen	8-12 work hours		
		Step 1	Step 2	Step 3	Step 4	
		Gather a full list of prod. No. to be changed.	Gather weight information next to prod. No.	Run DMI material information change process for each product	Confirm correctness.	
Current progress						
Process name	Change name	Description	Resource needed	Estimated duration		
Product management	Item Category default	Change default item category to most common as default	DMI approval, Jan Sjögren Eija Miettinen	4 work hours		
		Step 1	Step 2	Step 3		
		Gather a full list of prod. No. to be changed.	Run DMI material information change process for each product.	Confirm correctness.		
Current progress						
Process name	Change name	Description	Resource needed	Estimated duration		
Product management	Warehouse default	Change default warehouse number to most common as default	DMI approval, Jan Sjögren Eija Miettinen	4 work hours		
		Step 1	Step 2	Step 3		
		Gather a full list of prod. No. to be changed.	Run DMI material information change process for each product.	Confirm correctness.		
Current progress						
Process name	Change name	Description	Resource needed	Estimated duration		
Forecasting	Purchasing Proposal Master-file recreation	PPM-file recreation so that it can create an acceptable purchasing proposal without	Martti Kuusela, Jaana Numi, Jan Sjögren, OMI Team, Heikki Ahola	40 work hours		
		Step 1	Step 2	Step 3	Step 4	Step 5
		Establish detailed requirements for end product	Establish subtyping structure able to provide relevant information from	Create product groups that have similar forecasting needs	Input relevant variables from supplier: efficient order quantity, minimums, package	Create data source for seasonal change calculation

Process name	Change name	Description	Resource needed	Estimated duration
Purchasing	Establish monitoring	Monitor purchasing document handling errors and delivery times	Jan Sjögren, OM Team	1 work hour + daily routine
	Step 1	Step 2	Step 3	
	Have OM to agree consolidated location for error monitoring	Create error recording template and agree on monitored variables	Take into normal routine	
Current progress				
Reagents				
	Control Bloods			
Process name	Change name	Description	Resource needed	Estimated duration
Warehousing	Inbound logistics monitors	Monitor inbound delivery errors, handling errors, warehouse damages	Jan Sjögren, distributor	1 work hour + daily routine
	Step 1	Step 2	Step 3	
	Have OM to agree consolidated location for error monitoring	Create error recording template and agree on monitored variables	Take into normal routine	
Current progress				
	Temperature monitoring	Create process for temperature monitoring, equipment and result recording	Jaana Nurmi, Jan Sjögren, distributor, monitoring equipment, recording templates	8 work hours + daily routine
	Step 1	Step 2	Step 3	
	Have OM to agree consolidated location for error monitoring	Create error recording template and define process with the distributor	Take into normal routine	
Current progress				
Process name	Change name	Description	Resource needed	Estimated duration
Sales order	Availability check, batch selection	Setup SAP script to inquire availability and pick suitable batch.	EMEA ERP, Brian Lampen-Smith, Jan Sjögren	30-40 work hours
	Step 1	Step 2	Step 3	Step 4
	Inquire if script is already available	Request script to be added or created to test environment	Confirm correct functionality in test environment, change if necessary	Prepare failsafe process
Current progress				

Sales order	Automated picking	Setup SAP script to fully pick deliveries	EMEA ERP, Brian Lampen-Smith, Jan Sjögren	25 work hours		
	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
	Inquire if script is already available	Request script to be added or created to test environment	Confirm correct functionality in test environment, change if necessary	Prepare failsafe process	Change into production SAP system.	Monitor correct functionality in production system
Current progress						
Sales order	Print destination defaults	Setup SAP to have default print destination	EMEA ERP, Brian Lampen-Smith, OMT	5 work hours		
	Step 1	Step 2	Step 3	Step 4	Step 5	
	Inquire feasibility of the change and establish its effects on all processes	Create change request to EMEA ERP Management	Confirm correct functionality in test environment, change if necessary	Change into production SAP system.	Monitor correct functionality in production system	
Current progress						
Sales order	Update of Standing order Templates	Update Standing order templates with all relevant information for customer and product identification	Order Management Team, Key Account Managers	80 work hours		
	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
	Consult Key Account Managers for expectations, experience and customer perspective	Generate Standing Order Template with all relevant information slots	Confirm that the template is according to expectations of all parties	Construct a customer level order template for all customers with all relevant products and customer ID	Approach customers through Key Account Managers with the new template document	Take into normal routine
Current progress						
Process name	Change name	Description	Resource needed	Estimated duration		
Outbound	Temperature monitoring	Define the process for temperature monitoring in deliveries. Combine with warehouse temperature monitoring.	Jaana Nurmi, Jan Sjögren, distributor, monitoring equipment, record templates	24 work hours + daily routine		
	Step 1	Step 2	Step 3	Step 4	Step 5	
	Establish the feasibility of copying RDI delivery monitoring system to Sysmex products	Define process, establish communication chain, consider customer reactions	Test in practice, evaluate suitability against policy requirement	Combine recording with warehouse temperature recording	Take into normal routine	
Current progress						

Current progress					
Outbound Logistics	Picking, packing and delivery rules documentation	Define clearly the minimum requirements and rules for picking, packing and delivery of all types of products	OM Team, Distributors representative, Management Team if changes to contract	16 work hours	
	Step 1	Step 2	Step 3	Step 4	
	Define product groups that should have different rules	Define minimum requirements for packaging, markings and procedures	Get agreement of both parties	Add as attachment to the distribution contract	
Current progress					
Outbound Logistics	Delivery performance recording	Create delivery performance recording template for monthly monitoring	OM Team, distributor, possibly management team	30 work hours	
	Step 1	Step 2	Step 3	Step 4	Step 5
	Establish a template based on RDI Logistics manual standard, combine with other monitoring process if possible	Define a storage location for the monitoring documentation	Establish rules and communication process with distributor concerning information required	Test recording, ask relevant parties if they would benefit from more information. Research for possibilities to automate	Take into daily routine
Current progress					