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IMPROVEMENT OF PRODUCTION PROCESSES BY MEASURING

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ABSTRACT

Riku Vakoniemi: Improvement of production processes by measuring
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The purpose of the thesis was to find out how the production processes of a company that manufactures medical devices can be improved by measuring. Unambiguity, usefulness, and ease of use were important features of the indicators for the company. These goals were answered with the following research questions: which of the company's functions are significant for improving production processes, what important indicators are available for the significant functions, and which important indicators can be reported automatically.

The research material was compiled by literature review and observation. The literature review presented background theory of research methods, economical manufacturing, management information systems, and databases. Information on the company's production processes, information systems and the indicators in use was collected through observation.

The research material was analyzed by correlation analysis, thematic analysis, and classification. Correlation analysis was used to determine which departments and functions are relevant for improving production processes. Correlation analysis was also used to find causal links between existing indicators and their benefits in order to find new indicators for the company and automation opportunities for reporting the indicators. Thematic analysis examined the relevance of all the indicators found at a general level. Finally, classification was used to examine the relevance of the indicators to the company's strategy.

The study found that the company's most significant functions in improving production processes are quality assurance, production, and maintenance and technology development. A total of 30 important indicators were discovered, of which 24 were found to be suitable for automated reporting. The resulting indicators were found to be reliable at three different levels: the reliability of the data sources, the general relevance, and the relevance to the company's strategy. Six of the indicators found were highlighted in terms of general relevance and ten in terms of business strategy.

Of all the indicators found, OEE and inventory turnover, which were not yet used by the company, were particularly prominent in terms of general relevance. The most relevant indicators for the company's strategy were energy efficiency, resolved CAPA cases in relation to all cases, production profit, and net profit or loss on investment. It was also seen as useful for the strategy to derive efficiency indices from the above-mentioned indicators and the costs of each significant function, so that the efficiency of each function can be measured in a comparable way.

Keywords: measurement, KPI, economy, lean, six sigma, manufacturing industry, quality assurance, production, maintenance, technology development, information system, security, database, data warehouse, automated reporting

TIIVISTELMÄ

Riku Vakoniemi: Tuotantoprosessien parantaminen mittaamalla
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Diplomityön tarkoituksena oli selvittää, kuinka erään lääkinnällisiä laitteita valmistavan yrityksen tuotantoprosesseja voidaan parantaa mittaamalla. Yksiselitteisyys, hyödyllisyys ja helppokäyttöisyys olivat yritykselle tärkeitä ominaisuuksia mittareissa. Näihin tavoitteisiin vastattiin seuraavilla tutkimuskysymyksillä: mitkä yrityksen toiminnoista ovat merkittäviä tuotantoprosessien parantamisen kannalta, mitä tärkeitä mittareita on saatavilla merkittäville toiminnoille ja mitkä tärkeät mittarit voidaan raportoida automaattisesti.

Tutkimusaineisto koostettiin kirjallisuuskatsauksella ja havainnoimalla. Kirjallisuuskatsauksessa esiteltiin taustateoriaa tutkimusmenetelmistä, taloudellisesta valmistuksesta, johtamisen tietojärjestelmistä ja tietokannoista. Yrityksen tuotantoprosesseista, tietojärjestelmistä ja käytössä olevista mittareista kerättiin tietoa havainnoimalla.

Tutkimusaineistoa analysoitiin korrelaatioanalyysilla, temaattisella analyysilla ja luokittelulla. Korrelaatioanalyysin avulla selvitettiin mitkä osastot ja toiminnot ovat merkityksellisiä tuotantoprosessien parantamisen kannalta. Korrelaatioanalyysin avulla etsittiin myös syy-yhteyksiä käytössä olevien mittareiden ja niiden hyötyjen välillä pyrkien löytämään uusia mittareita yritykselle sekä automatisointimahdollisuuksia mittareiden raportoinnille. Temaattisella analyysilla tutkittiin kaikkien löydettyjen mittareiden merkityksellisyyttä yleisellä tasolla. Luokittelulla tutkittiin lopuksi mittareiden merkityksellisyyttä yrityksen strategian kannalta.

Tutkimuksessa todettiin, että yrityksen tärkeimmät toiminnot tuotantoprosessien parantamisessa ovat laadunvarmistus, tuotanto sekä kunnossapito ja teknologian kehitys. Tärkeitä mittareita löydettiin yhteensä 30, joista 24 havaittiin olevan automatisoituun raportointiin soveltuvia. Tuloksena saadut mittarit todettiin luotettaviksi kolmella eri tasolla: tietolähteiden luotettavuus, yleinen merkityksellisyys ja merkityksellisyys yrityksen strategian kannalta. Löydetyistä mittareista korostui yleiseltä merkityksellisyydeltä kuusi ja liiketoimintastrategian kannalta kymmenen mittaria.

Kaikista löydetyistä mittareista OEE ja varaston liikevaihto, jotka eivät olleet vielä yrityksen käytössä, korostuivat erityisesti yleiseltä merkityksellisyydeltään. Yrityksen strategian kannalta merkityksellisimmiksi mittareiksi osoittautuivat energiatehokkuus, ratkaistut CAPA-tapaukset suhteessa kaikkiin tapauksiin, tuotannon liikevoitto ja investointien nettovoitto tai -tappio. Strategian kannalta hyödylliseksi nähtiin myös johtaa tehokkuusindeksit edellä mainituista mittareista ja merkittävien toimintojen kustannuksista, jotta kunkin toiminnon tehokkuutta voidaan mitata vertailukelpoisesti.

Avainsanat: mittaus, KPI, taloudellisuus, lean, six sigma, valmistusteollisuus, laadunvarmistus, tuotanto, kunnossapito, teknologian kehitys, tietojärjestelmä, tietoturva, tietokanta, tietovarasto, automatisoitu raportointi

PREFACE

This research was carried out as a thesis in the field of mechanical engineering at the *Tampere University*. The research process was rewarding and through it I was able to apply the new knowledge gained through my studies to my previous work experience.

I would like to thank Hasse Nylund and Minna Lanz, who acted as reviewers of my work and helped to define and structure the contents of this thesis. In addition, I thank my friend A.M. for providing inspiration during my work.

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Riku Vakoniemi

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ABBREVIATIONS AND MARKINGS

APS	Advanced Planning & Scheduling
BOM	Bill of Materials
CAPA	Corrective and Preventive Action
CMMS	Computerized Maintenance Management System
CRM	Customer Relationship Management
DBMS	Database Management System
DCS	Distributed Control System
DFSS	Design for Sig Sixma
DPS	Demand Planning System
ERP	Enterprise Resource Planning
ETL	Extract-Transform-Load
HRMS	Human Resource Management System
IED	Intelligent Electronic Device
ISA	International Society of Automation
KM	Knowledge Management
KPI	Key Performance Indicator
MDBMS	Multidimensional Database Management System
MES	Manufacturing Execution System
MIS	Management Information System
MTS [1]	Machine Tracking System
MTU	Master Terminal Unit
OEE	Overall Equipment Effectiveness
OLAP	On-Line Analytical Processing
OPC UA	Open Platform Communications Unified Architecture
PLC	Programmable Logic Controller
PLM	Product Lifecycle Management
QMS	Quality Management System
RDMS	Relational Database Management System
RTU	Remote Terminal Unit
SCADA	Supervisory Control and Data Acquisition
SCM	Supply Chain Management
SQL	Structured Query Language
VPN	Virtual Private Network
XML	Extensive Markup Language
Customer Company	The company that is the subject of this research
€, k€, M€	Currency; EUR, 1 000 EUR, 1 000 000 EUR
g, kg, Mg	Mass; gram, kilogram (10^3 *g*), megagram (10^6 *g*)
pcs	Number of pieces
%, ppm	Ratio; Percentage (10^{-2}), Parts per million (10^{-6})
d, m, y	Time, long interval; day, month (30 *d*), year (365 *d*)
s, min, h	Time, short interval; second, minute (60 *s*), hour (3600 *s*)
W, kW, MW	Energy; watt, kilowatt (10^3 *W*), megawatt (10^6 *W*)

[1] This abbreviation was invented to reduce repetition in this report and is not generally known.

1. INTRODUCTION

Measurement is a broad concept and has become increasingly important both in the management of companies and in the performance of individual tasks. The reason for this is that measurement-based decisions are based on facts and finding the facts out of the mass of data available in today's world is otherwise challenging. Measurement is usually meant either to find out the unknown magnitude of an object or to confirm the supposedly known magnitude of an object. In addition to these, a change in one measurand relative to another can also be determined by measurement. Practical examples of these applications in working life are the measurement of production volume, the inspection of manufactured products, and the monitoring of changes in production efficiency over time.

This thesis presents a study on improving production processes by measurement. The company under investigation, referred to in the thesis as the *Customer Company*, operates in the field of medical devices and has been in business for a long time. The main products are delivered worldwide, which means that their production volumes are high and the processes involve a lot of automation. In the market of this industry, competition is particularly fierce and international regulations are constantly intensifying, which means that running a business requires constant investment and starting new businesses is almost impossible unless the product to be manufactured is a world-changing innovation.

The study is reported in the thesis with the following structure:

- Introduction
- Presentation of the research material and methods
    - Literature review
    - Observation
    - Data-analysis
- Results
- Reflections
- Summary

The goal of the study was to find out which of the company's functions are important for the improvement of production processes, how these functions can be measured and how the indicators can be best utilized. It was important for the *Customer Company* that the resulting indicators are unambiguous, useful, and easy to use. Three research questions were derived from these goals:

1. Which of the company's functions are significant for improving production processes?
2. What important indicators are available for the significant functions?
3. Which important indicators can be reported automatically?

The three research methods used to solve the above questions were literature review, observation, and data analysis. The literary review focused on the research methods, economical manufacturing, management information systems, and databases. The purpose of the literature review was to get acquainted with the background theory relevant to the study. Sources for the literature review were selected on the assumption that published peer reviewed scientific articles and non-fiction books are, as such, reliable sources. Other sources, such as websites and training materials, were used as support, when it was deemed necessary to consider alternative perspectives. The actual production processes, management information systems and important indicators in use were examined by observation to gain knowledge of the research subjects. Finally, data analysis was used to find connections in the data collected by literature review and observation. In this case, the data analysis was qualitative research, and it combined the methods of correlation analysis, thematic analysis, and classification. The purpose of the data analysis was to provide a deeper understanding of the strategies involved in the production processes, to identify other potential indicators in addition to those already in use, and to evaluate the reliability of the indicators discovered by this research.

The knowledge gained from the above research methods was used to summarize the important indicators found, which is the main result of the study. Each indicator included in the summary was presented with its rationale, application, and calculation formula in the observation and data analysis sections of the thesis so that the *Customer Company* can easily utilize them as desired. The reflections at the end of the thesis assessed the importance, overall reliability, reproducibility, generalizability and follow-up of the study.

The whole research process is illustrated in Figure 1.

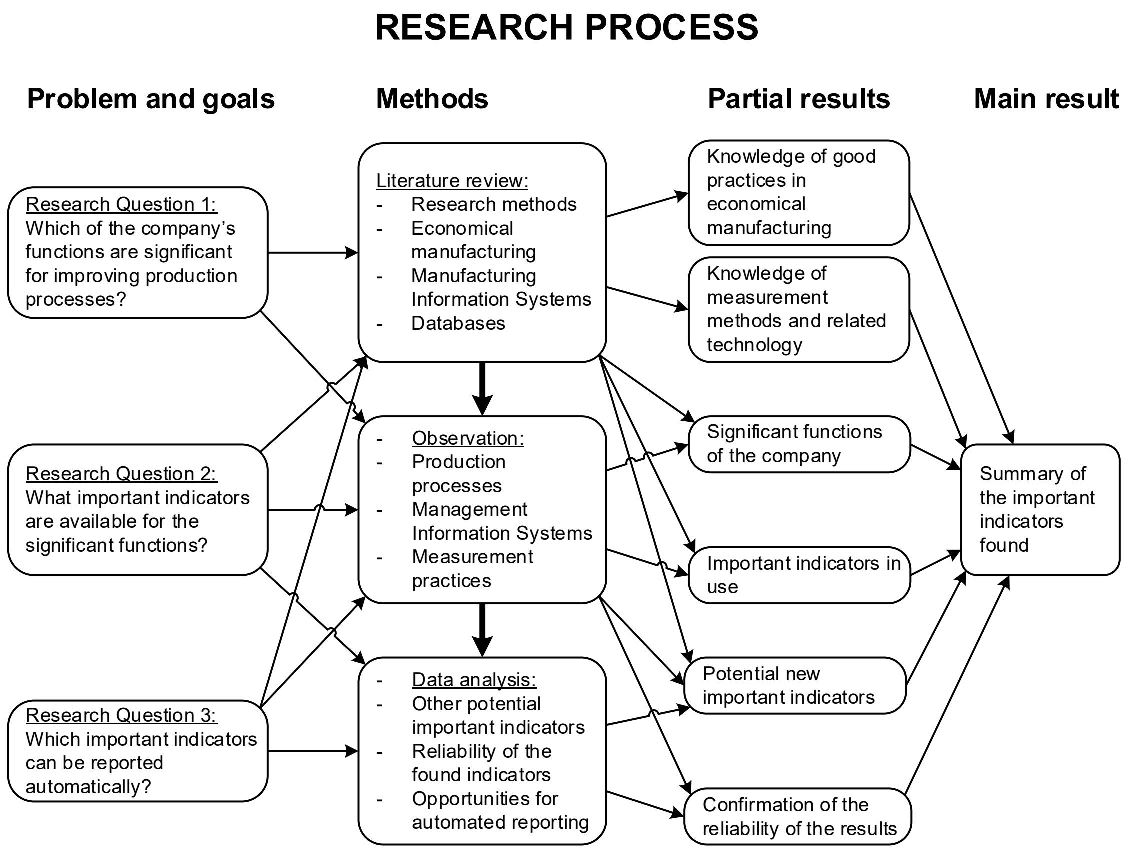

Figure 1: *Research process diagram*

2. LITERATURE REVIEW

The literature review of this thesis includes the following topics: Research methods, economical manufacturing, management information systems and databases. The underlying philosophies, available options, and generally accepted practices are presented for each subject. Related advantages, possible disadvantages, and illustrative examples are also highlighted on a case-by-case basis. Familiarity with these topics provides comprehensive background information and the prerequisites for conducting this type of research. Due to the holistic nature of the research problem, theories related to the practical implementation of measurement are not of great importance. Thus, hands-on topics such as programming and computation are kept to a minimum and are highlighted only in situations where they add value to illustrate research findings.

2.1 Research methods

The ultimate goal of research is for people to understand the world more broadly. Research can be done in many different ways, but usually the process is carried out in a planned, ethical, reliable manner and by presenting the results objectively. Typically, a research strategy follows some branch of either rationalist or empirical philosophy [64] [68].

Understanding the nature of the data is crucial to the validity of the research. For the researcher, the underlying data is always either primary or secondary in nature. Primary data is information that the researcher receives firsthand and secondary data is information that has already been recorded or interpreted. In principle, primary data sources are more reliable than secondary data sources if the same amount of data is available. However, it is important to note that primary data sources are prone to misinterpretations by the researcher. For this reason, secondary data sources should also be used whenever possible. [64] [68].

A research project should always start with a plan. The research plan sets out the research questions that are essentially related to the problem to be solved, on the basis of which the data collection and data analysis methods are selected. The researcher collects data from either existing or self-produced material and analyzes it using either qualitative or quantitative methods, depending on what is best suited to the research strategy. The final results of the study are compiled from the partial results obtained through data analysis [68].

2.1.1 Literature review

The literature review presents the theoretical background relevant to the research from several different secondary data sources. By conducting a literature review, the researcher becomes acquainted with previous research that is in some way related to the new research. The purpose of the literature review is to validate the researcher's viewpoints and the importance of the study, as well as to serve as a reference for possible new research. The scope of the literature review is based on the research plan, which includes key research questions, research strategies, and research methods. During the research, the content of the literature review may expand or shrink compared to the initial situation as the topic becomes more familiar to the researcher. However, regardless of the scope of the literature review, it should never present topics that the researcher has become familiar with during the research but that are not relevant to the study [12] [66] [68].

2.1.2 Observation

Observation is a method of collecting primary data in which the researcher tracks an object or phenomenon and documents the findings for later analysis. While performing observation the researcher takes an outsider or insider point of view depending on which one is expected to produce better results. The outsider tries to stay away from the object and not influence its activities, while the insider, in turn, tries to actively participate in the activities of the object, for example in the form of field work. Observation is very versatile and efficient method for collecting preliminary and explorational data, and it is suitable method for both qualitative and quantitative research methods. However, if the observed activity is not constant, observation may become very time consuming and difficult. If observation proves to be ineffective, asking questions or doing experiments should be considered instead [64] [65] [68].

2.1.3 Data-analysis

Data-analysis can be categorized as either quantitative or qualitative. Quantitative analysis is a straightforward approach which deals with numerical data and statistics, while qualitative analysis is more abstract and examines the research subject holistically to find new dependencies, traits, meanings, and themes. This study is qualitative and makes particular use of correlation analysis, thematic analysis, and classification [64] [68].

Correlation analysis seeks to find relations between two or more variables. In addition to finding relations, correlation analysis may also indicate the intensity of the relationship. Pure correlation analysis does not require experiments as it does not measure causality. Thematic analysis seeks to identify themes from the data. Themes are topics that appear in some form repeatedly in the source material. Once the themes have been identified, they can be categorized, allowing the data to be utilized in more detail in the study. Classification aims to divide a large group of data into smaller classes in which the objects share similar properties between each other but differ collectively from the main group. The purpose of classification is to highlight patterns and differences between objects that are otherwise difficult to detect from the main group [64] [68].

2.2 Economical manufacturing

Economical manufacturing is a practice in which a business strives to maximize its productivity with the available resources. This results in a number of benefits, such as shorter delivery times, lower payback times, and lower fixed operating costs. All these benefits are cumulative and contribute to the profitability of the business. Since economical manufacturing provides significant competitive advantage and growth potential, it should be pursued by every manufacturing company. The best-known philosophical approaches to economical manufacturing are six sigma and lean manufacturing. These philosophies define certain goals, which are important for economics, as well as practices for reaching them. Six sigma and lean manufacturing can be applied as such or together as a so called lean six sigma method. It is also important to establish indicators to monitor progress towards strategic goals. Otherwise, the progress cannot be objectively proven to be due to the actions taken. The most important economic indicators are known as KPIs (Key Performance Indicator). Out of all different KPIs, OEE (Overall Equipment Efficiency) is particularly good, because it serves as a summary of overall productivity and is suitable for many different applications and industries [7] [29] [42].

2.2.1 Six sigma

Six sigma means striving to manufacture products with minimal variation in quality. Six sigma was developed and introduced by the mobile phone manufacturer *Motorola* in 1986. Since then, it has been adopted by many other companies. The name six sigma is derived from statistics in which the standard deviation is denoted by the Greek letter sigma (σ). Large standard deviation implies that the data is further away from the mean and vice versa. If the number of valid manufactured products follows a normal distribution within six sigma, virtually no defective products are produced. This level of quality is an ideal goal for any manufacturing company [29].

The premise of six sigma is that all errors should be measurable. If a measurement method does not yet exist, a new method must first be defined. Once the measurement data is made available, the standard deviation of the error can be reduced. After reducing the standard deviation, the next step is to reduce the incidence of errors. After these actions the only remaining task it to determine the root cause of the quality problems. Once the root cause is finally determined, the error can be completely eliminated. Adjusting the sight of a firearm is a good analogy for this process. To do this, the firearm must first be placed in a fixed position so that multiple bullets can be fired at the center of the target. The fixed position eliminates the human error during firing and minimizes the scatter of the hits. The visible bullet holes then reveal the error between the concentration of the hits and the center of the target. Once the error has been measured and compensated for with the sight adjustments, the process is repeated until the concentration of hits matches the center of the target [20].

Six sigma is a continuous process of improving product quality and is usually done after production has started. However, six sigma can also be taken into account already during the product development stage. This process is called DFSS (Design for Six Sigma). In DFSS, potential quality problems are identified and analyzed in advance before the product goes into production. Product design and production methods are then optimized to proactively minimize the identified errors. DFSS offers all six sigma benefits, but at a lower cost because there is likely no need to significantly change the chosen production methods or product design afterwards to improve quality [29].

The benefits of six sigma are realized through manufacturing cost savings and customer satisfaction. Because fewer of the manufactured products are defective, the amount of remanufacturing is also minimized. Remanufacturing in this context means additional costs in the form of warranty service or other compensations for faulty products. Poor customer satisfaction can also lead to even greater problems as negative customer experiences spread very effectively and can develop into, for example, boycott campaigns. Cleaning up a bad reputation will always cost more than gaining a reputation from the start [29].

2.2.2 Lean manufacturing

Lean manufacturing, lean thinking or simply lean is the principle of manufacturing products in such a way that activities that do not add value from the customer’s point of view use as few resources as possible. The lean manufacturing practices evolved over the last century in mass-production facilities looking for new ways to increase productivity. The early forms of lean date back to the early days of *Ford Motor Company* in the 1910s. However, the most significant organization in the development of lean has been *Toyota* with their original *Toyota Production System*, which can be considered the predecessor of lean. The general lean mindset, as the concept is known today and unrelated to the practices of any single company, was described in the 1990s when James Womack and Daniel Jones compiled the ideas of *Toyota Production System* and other similar systems into books in which the term lean manufacturing was first introduced [29] [40].

In lean thinking, everything that does not add value to the product from the customer's perspective is considered waste. There are seven main categories of waste, which can be remembered by the acronym *TIMWOOD*: *Transportation*, *Inventory*, *Motion*, *Waiting*, *Overproduction*, *Overprocessing* and *Defects*. These categories describe waste that forms when products are either overworked, defective or not processed at all [20].

The products are not processed when they need to be moved or stored. While transportation of products and parts is often necessary, its effective arrangement is easily overlooked especially in the early stages of production start-up. Ideally, transports should be carried out at the shortest possible distances and in parallel flow to avoid back and forth movement and detours. Similar to transportation, some form of inventory is necessary for warehouse-driven businesses to ensure that the products sold are delivered on time. However, excessive storage is only an unintentional investment of capital and an indication of a lack of knowledge of the market and supply chains. Motion related waste, which is similar to transportation, forms when people or equipment move on to the products rather than products moving on to them. Motion is not limited to moving from one place to another inside the production facilities but also includes unnecessary movements from an ergonomic point of view. Basically, any extra movement is a waste of time and energy. Finally, waiting is a waste of the opportunity to work. In manufacturing there are many reasons for waiting, such as waiting for materials to arrive, waiting for the machine cycles to end, waiting for service personnel in a problem situation, etc., but none of these adds value to the product. It is important to also notice that the only party that has to wait constantly is the customer. In order for production to be smooth and delivery times short, waiting must be kept to a minimum [20].

Waste by overworking is made either by overproduction or overprocessing. Overproduction is the excessive use of resources in manufacturing. There are many forms of overproduction and detecting them can be challenging. For example, ordering more spare parts because the existing ones cannot be found in a cluttered warehouse, and filling the raw material feeding hoppers before they are empty, are both overproduction but for different reasons. When resources are used in the right place, at the right time and in the right amount, less waste is generated. Overprocessing, on the other hand, is waste by delivering additional or higher quality products than the customer wants. While customers are generally happy to receive any additional products, they do not pay for them. Overprocessing not only produces waste in the final products, but also at all stages of production [20].

The final category of waste, defects, are incomplete products delivered to customers. While some customers may overlook defects, it is safe to assume that the majority will make complaints sooner or later and expect compensation. Complaint handling is important to ensure customer satisfaction, but it is also a significant waste because the process is very laborious and time consuming. There are various ways to reduce defects, such as root cause analysis or utilizing statistics as in six sigma method [20].

Unlike six sigma, lean does not rely solely on statistics and problem solving as the tools of waste reduction, but rather on continuous improvement and transparency. Tools such as *5s*, *Heijunka*, *Jidoka*, *Kaizen*, *Kamishibai*, *Kanban*, *Standardized work*, *Single Minute Die Exhance*, *Total Productive Maintenance,* and *Value Stream Mapping* are commonly used in lean manufacturing and many of them were also part of the original *Toyota Production System*. Typical lean measures to reduce waste usually begin with a thorough mapping of the processes to make the problem areas more visible. Appropriate targets are then set for waste reduction and methods are introduced to achieve the targets. It is particularly important that the results are monitored, updated regularly, and visible to everyone. In addition, the sponsor or the person responsible for waste reduction must always be strongly involved to keep the other participants motivated. If good results are observed, the measures should then become a well-established approach in order for the reduction in waste to become a permanent benefit. This can also be called the development of a work culture. If no progress is made, it is worth considering whether the measures have been correct and sufficient, and then retrying [20] [29].

Properly applied, lean always increases a company’s profitability. Even if there is no urgent need to increase productivity, cutting costs without compromising performance is always beneficial. If the company has benefited from six sigma or lean, extending the work culture to lean six sigma is a worthwhile option because it combines the methods and benefits of both mindsets. However, because lean methods require precision and perseverance, their application can easily fail. Typical pitfalls for lean experiments and projects include strong resistance to change in the work environment, poor sponsor involvement and impatience in getting results. It is also important to understand that lean is the sum of its parts. Failure to reduce one loss can easily render other measures irrelevant [20] [29].

2.2.3 Good general practices for measurement

Measurement becomes an effective tool for improving production processes when the indicators are chosen judiciously and on good grounds. In order to succeed in this, the following points should be considered on a case-by-case basis [42]:

- What are the reasons for measuring?
- What are the measurement methods?
- What type of measurement is being made?
- What is the measurement quality?

Reasons for measuring

The initiator of measuring a company's production processes is either external pressure, such as market regulations, or self-initiative to develop the profitability of operations. In the case of the *Customer Company*, both factors motivate to measure production processes. As competition in the medical device market is fierce, increasing profitability is vital for business. Measurement is a great way to find opportunities to increase efficiency. With regard to external pressure, the widely applied *ISO 13485:2016 (Medical devices – Quality management systems – requirements for regulatory purposes)* standard requires companies to continuously measure production and QMS (Quality Management System) performance. The purpose of these requirements is to determine whether the company has a well-managed manufacturing process and does it invest in improving operations. These indicators, or the absence of them, make it clear whether a company is eligible for *ISO 13485* certification and can be considered to be in the public interest in the medical field [8] [32] [42].

Measurement methods

The minimal requirements for measuring a production process are the definition of measurement points and methods. The measurement points can be either inside or outside the process. For example, sensors and counters are internal measurement points, but visually determined observation points are external. Furthermore, measurement points may be mere indicators for operators, or they could be continuously saving data for later use. Production processes can be measured both manually and to varying degrees automatically. In manual measurement, all types of measurement points can be used to collect data. Automatic measurement, on the other hand, requires in-process measurement points and a system that stores measurement data. At its simplest, manual measurement can be done with a spreadsheet. However, the ideal data sources for both manual and automatic methods are information systems and databases. Measurements can also be made in real time or with a delay, as well as at different intervals, depending on the availability of data and the resources used for the measurement. In principle, real-time measurement and long intervals require more robust systems, and are also more cumbersome and expensive to implement compared to processing the data at short intervals or with a delay [42].

Measurement types

As with research methods and the nature of data in general, measurements can also be broken down to either quantitative or qualitative types. Quantitative measuring involves numerical data and drawing conclusions based on calculations. Qualitative measuring, on the other hand, involves contextual data and drawing conclusions based on abstract concepts. Continuous improvement of production processes requires both types of measurements. First, several qualitative measurements need to be used together to gain an understanding of the context of production efficiency. Factors that reduce production efficiency can then be identified through root cause analysis and eventually eliminated. Next, quantitative measurements are used to determine whether production efficiency has improved, i.e., whether the measures were sufficient. This process is continued cyclically to maintain and improve the level of production efficiency. Finally, qualitative measurements are applied recursively to the previously described process in order to improve the process as a whole. For example, if the root cause analysis fails repeatedly or the problem-solving time is increasing, further training of staff should be considered [20] [42].

Measurement quality

The quality of measurement is the last important aspect in terms of general measurement practices. High-quality measurement processes are reliable, timely and valid. Reliability indicates that the measurement is reproducible, timeliness indicates that the measurement is performed at the appropriate frequency, and validity indicated how accurately the data reflects the phenomenon under study. Quality is a particularly important factor when measurement results are used as a direct source for drawing conclusions or calculating derived indicators. However, if this is not the case, then quality may not be very important. For example, if measurement results are used only for rough estimates, then quality is not an important priority [63] [70].

2.2.4 Key Performance Indicator

KPI (Key Performance Indicator) is a term that refers to the indicators that provide an organization with the most information about its progress toward its goals. Although KPIs have mostly been used in business finances, they are also suitable for operational activities such as production and maintenance. KPIs are designed to simplify complex performance data into small manageable numbers that are relevant and easy to use in decision making. Therefore, when defining KPIs, an organization should focus on objectively identifying the necessary data, how it can be measured, and how it should be presented. A common pitfall in the implementation of KPIs is to focus on collecting data that is readily available, as it is might not be relevant to improving performance [42].

There are several benefits to using KPIs in operational decision making. Most importantly, KPIs present facts, that change the nature of decision-making from opinion-based to logical. This greatly reduces the risk of making bad decisions. KPIs also provide information on the company's most critical topics. Therefore, decisions are made efficiently and focus on the most advantageous areas for development. KPIs are also great for measuring improvement. When the same indicators are monitored over the long term, the direction of development is easily seen from the trend. This can be useful in assessing whether the current strategy should be continued or changed. This type of historical data is also very useful for communicating outside the organization, for example, when reporting to external stakeholders or when it is necessary to demonstrate compliance with certain standards [42].

There are virtually no disadvantages in using KPIs in decision-making but defining and implementing appropriate metrics can prove challenging. If the metrics do not support the strategy or give a misleading impression of achieving the objectives, KPIs will in fact become disruptive to the decision-making process. Resistance to change is also common, as data collection may be considered irrelevant because the benefits are not immediately apparent. Data collection also requires additional work, which can be considerably burdensome at first because the data collection tools are either rudimentary or non-existent [42].

It is very important to use only KPIs that support the company's strategy. Copying KPIs directly from another company is not useful because the metrics are based on different goals. However, if a company has never used KPIs before, it may be helpful to look at which metrics have typically been selected for different uses. A good starting point for brainstorming is to get to know the different application areas in general. An example of the classification of indicators by application area can be found in Table 1 [42] [57].

Table 1: *Suitable KPI types by application area*

APPLICATION AREA	SUITABLE KPI TYPES
Investments	KPIs that measure costs of production equipment in relation to profits.
Improvements	KPIs that measure utilization, losses and costs by product, process, location, time, or date in a way that the effects of improvements made are visible.
Efficiency	KPIs that measure the general utilization of production and maintenance resources.
Quality	KPIs that measure the quality of products manufactured and marketed.
Customer satisfaction	KPIs that measure customer satisfaction.

When choosing KPIs it is important to focus only on the information that is important to the decision makers of the organization. It is also worth noting that different departments are likely to have a number of useful KPIs, but at higher management levels the number of useful indicators is much smaller. For example, a shift manager may want to see several different KPIs during a shift, but the production manager is only interested in a few KPIs that show the overall production situation during a week or month. Similarly, the CEO probably wants to see only one KPI per function to get an idea of how well each department has achieved its goals during a quarter or year [42] [57].

As the use or absence of KPIs in business does not have adverse effects on, for example, the environment, there has been no need to develop a standard for defining KPIs. However, in a well-organized, large-scale, and highly automated business it is worth striving for a hierarchical pyramid-like implementation. In a hierarchical KPI structure, entry-level KPIs are calculated from data that is important to a particular business function. These KPIs are then summarized by compiling them into higher-level derivate KPIs that represent specific functions or results areas as a whole. The higher-level KPIs will continue to be derived when moving to a higher level of management. Ideally, each decision maker will see only one KPI that summarizes the performance of their entire area of responsibility [3] [36] [42].

There are several advantages to the hierarchical approach. Since summaries of the lower management level activities are built into the higher-level derivate KPIs, there is no need to produce additional one-time reports. This will allow experts to focus fully on ensuring that the quality of entry-level data and accounting functions remains high. In addition, experts will have more time for routine tasks and general operational development in the future. At the management level, it is also immediately apparent that if the key figures look good, everything can be assumed to be in order on the field as well. Similarly, if even one area fails to reach the targets, it will show up immediately. Management can then locate the problem directly by drilling down to lower-level KPIs. When the root cause of the problem is resolved quickly, there is more time to determine the upcoming corrective and preventive actions. Hierarchy can also be used as a visualization tool, for example in the design of KPI dashboards. In that case, the KPIs should also be classified according to the roles of each target group in the company. Each class gets its own dashboard to which all KPIs are allocated. Operational KPIs are placed at the lowest level of the hierarchy, tactical KPIs at the middle level and strategic KPIs at the highest level. Operational dashboard is monitored by workers, tactical dashboard by department managers, and strategical dashboard by executives. In very large organizations, additional levels can be formed as needed [3] [36] [60].

Despite the advantages mentioned above, it is important to understand that the KPI hierarchy should not be applied to small and low-automation companies, as the hierarchy would only cause extra work with little benefit. In such companies, the best results are obtained by focusing on the basics, i.e., selecting a few strategically important KPIs and using them as the primary decision-making tools [42].

Overall Equipment Efficiency (OEE)

OEE (Overall Equipment Efficiency) is an indicator that expresses the performance of the equipment or process being measured as a single numerical value. OEE is a suitable KPI for many different industries and is especially popular among manufacturing companies. Due to its popularity, OEE is often included in the systems that are closely integrated to the production equipment [13].

OEE is calculated by multiplying the factors of usability, speed, and quality. Each of these factors gets values between 0-100 % and represents a specific key feature that increases equipment efficiency. Usability indicates the proportion of actual operating time of all planned production time, speed indicates how close the actual production speed is to the theoretical maximum, and quality indicates the share of good products in all products produced. Since OEE is calculated in this way, it only gets high values if each coefficient is at a high level. The measurement accuracy of OEE is thus only sufficient to show that the efficiency of the equipment is either good in all respects or that there is waste somewhere. In order to determine the actual cause of the waste, each factor must be inspected separately [13].

Monitoring OEE is useful in maintaining efficiency, but for that purpose alone its benefits remain limited. First and foremost, OEE should be used as a tool for continuous improvement, which means that the values are continuously recorded to represent the baseline state of production. After the improvements, the new recorded values are compared to the baseline to see the real effect on efficiency [13].

There are several methods to increase OEE. Waterfall analysis is very effective for continuous improvement of usability. To perform this type of analysis, the reasons for failures or stoppage, as well their incidence and duration should be recorded first. Then, on the basis of this information, usability development activities should be targeted at the biggest cause of losses, followed by the next largest, and so on. This process is repeated until usability is at the desired level. The most effective way to increase speed is to balance the production line, as delays are usually caused by bottlenecks. After the production process is balanced, lean manufacturing methods and preventive maintenance work best when the goal is to achieve the highest possible manufacturing speed. Finally, quality can be improved with both six sigma and lean manufacturing methods. It is also important to note that poor quality can also be a by-product of the same factors that result in poor manufacturing speed or usability [13].

The downsides of OEE are that it is laborious, somewhat inaccurate and error prone to calculate manually. Inaccurate OEE will eventually cause bigger problems, for example if it was used as a basis for an investment decision. In addition to these, OEE users may face the same challenges as with the six sigma and lean methods, because improving OEE also aims to minimize losses. However, since OEE can also be calculated automatically with a proper information system, the above-mentioned disadvantages can be eliminated [57].

2.3 Management Information Systems

MIS (Management Information System) is a computerized system in which a company stores business information. The early computerized systems were developed in the 1950s and 1960s to assist various individual business processes, such as accounting. The development progressed from the mid-1960s to the late 1980s into larger systems that could handle larger entities such as inventory management and production scheduling. These systems were called *Material Requirements Planning* and *Manufacturing Resource Planning*. In the early 1990s the trend to integrate financial and operational management began to surface, resulting in the development of ERP (Enterprise Resource Planning). Since then, ERP has continued to become more widespread and has come to be seen as a basic tool for managing large companies. Today, there are countless different MISs, but most are still based on ERP or support it in some way [50] [53] [69].

2.3.1 ISA-95 standard

Due to the growing number of MISs, the varying scope, and the level of integration between them can easily confuse companies looking to upgrade. Functional overlaps and incompatibilities between systems make cost-effective expansion very difficult. Because of these problems, the International Society of Automation developed a framework for integrating MISs, known as the *ISA-95* standard [23].

According to *ISA-95*, there is a five-level hierarchy between different MISs according to their scope and purpose. This hierarchy is visualized in Figure 2 [23] [44].

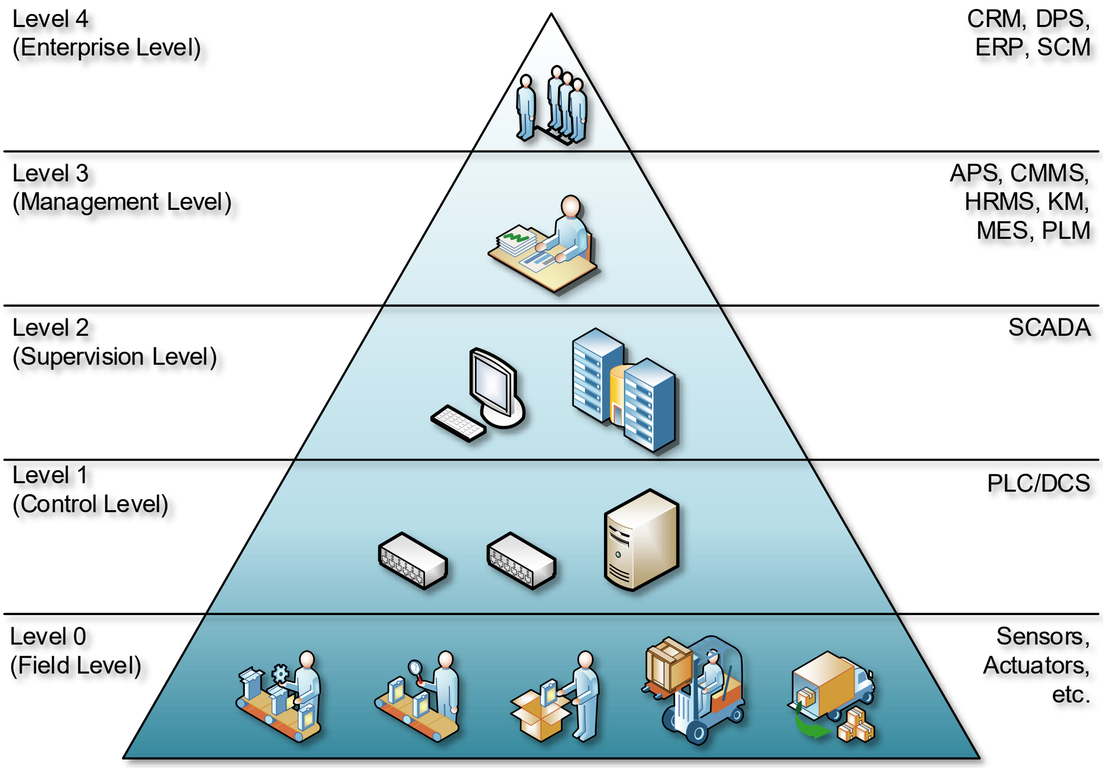

Figure 2: *ISA-95 hierarchy levels*

The top two levels focus on the management of the upper level. Level four deals with business planning and external stakeholders, while level three deals with the integral management of the company. The three lowest levels focus on process management. Level two deals with monitoring, level one with sensing, and level zero with individual processes. In addition to the management scale, the *ISA-95* hierarchy levels also represent the time horizon of plans and controls. Level four deals with long-term plans (months, weeks), level three with medium-term plans (days, working shifts), level two with short-term monitoring (hours, minutes), and levels one and zero with real-time process controlling (seconds) [23] [37].

2.3.2 Enterprise Resource Planning

The main benefit and driving force in the development of ERP was the need for business decision makers to get the information they needed in real time. Prior to ERP, managers had to consult with different departments to get information. Since all of this was done manually, data collection was very slow and expensive. The right and fast business decisions made possible by ERP meant a significant competitive advantage in the market, which attracted more and more companies to acquire ERP [50].

The evolution of information systems in general is also reflected in the different ways of implementing ERP. The first implementations were fully integrated into the computers running the systems. The implementation gradually shifted to a distributed client-server environment where the server maintained all data processing and provided data to clients upon request. However, specific computers running the client software and database were still required. The current trend is to decentralize the information system with a virtual cloud service and provide a user interface via an Internet browser. When the information system is implemented virtually, it is no longer bound to a single server. This allows for scalable data processing and better reliability. The browser-based interface, in turn, makes it easier to access the data because a specific client application is no longer needed. Because ERP is so widely used, the important issues to consider when purchasing a system are well established and should always be considered when planning a major upgrade to an existing system or switching to a completely new system. The same principles can be applied to some extent in other subsystems supporting ERP [15] [50] [53].

The basic requirements for an effective ERP system are unique item identification, as well as information on supply, demand, and material dependencies. Unique item identification is the practice of giving each item in the system a different identifier, which ensures data integrity and prevents confusion. Supply indicates the quantity of goods available for use and demand, respectively, the need for products or components. Material dependencies describe the amount of supplies required to make each product. This interdependency between products and supplies is typically described in the form of BOM (Bill of Materials) documents. The data for each of these basic elements must be accurate for ERP to work. Data accuracy is crucial for ERP because if the users cannot trust the system in decision making, they will shift towards using other more reliable data sources for the problematic purposes and eventually stop using the ERP completely, making it an unnecessary and costly acquisition. Thus, the data accuracy of inventory records, BOMs, routing, sales orders, work orders, purchase orders, and all transactions must be validated. It should also be noted that one-off verification is not sufficient to ensure consistent data accuracy. The accuracy of the data should be tested and improved regularly, especially if changes have been made to the system [50].

The goal of implementing ERP should always be to improve the overall performance of the company. It is important to notice that in this sense, ERP is basically just a software tool and does not in itself improve anything. Thus, improvement can only be achieved by first acknowledging the existing performance constraints and then attempting to remove them through ERP. A constraint might be, for example, a bottleneck in an important process or a new resource that has not yet been discovered. An open attitude to reform work practices is also important. It is very common that people do not change their behavior on their own initiative, even if there is a significant benefit to the change. Therefore, companies using ERP should periodically analyze their existing processes to see if there are any practices that have become obsolete but are still used out of habit. An example of this could be a company that has ERP in use, but whose management still instructs to end every work card at the end of the month to ease monthly manual reporting, even though the same information has become available from ERP in real time [50].

First step in choosing the most suitable ERP is to be aware of the type of business the company is doing. ERP made for use by make-to-order companies is not well suited to make-to-stock companies and vice versa. It should also be noted that off-the-shelf software rarely meets all the requirements of a company, even if they are the right type. In addition to choosing the right type, it is also necessary to prepare for customization and make a plan for the implementation of all important functions already at the software acquisition stage [50].

Important aspects to consider in ERP implementation are the level of control, system structure and the database specifications. The level of control is defined by various user and legal requirements. Users may, for example, require drill-down capabilities in the system, which means that data processing capabilities need to be further defined. A legal requirement, on the other hand, is a feature that users may not need at all, but that is required by the authorities. For example, the continuous availability of information related to process approval chains from the system is one such requirement. The structure of ERP may not be relevant for small businesses, but it is an important factor for large international companies. This is because if a large global company wants to integrate its operations tightly, it must take into account structural factors, such as different languages, number formats, currencies, tax policies, and time zones, when deploying ERP [50].

The last consideration, database specifications, includes selecting the database type, the level of detail in which the data is stored, and how often the data must be available. The standard in modern ERP systems is to use a relational database. This allows quick access to information by making direct queries to the database in addition to a dedicated software user interface. Data transfer between other relational databases is also possible if there is, for example, a need to transfer information automatically out of ERP or from other systems to ERP. The level of detail in which the data is stored is important, because if a certain level is sufficient, implementing more detailed data storage is extra work. On the other hand, if the future uses of the data are not fully considered, important data may be left out of the database, in which case the whole implementation process would have to be repeated. If there are time slots when data does not need to be accessed, large batch operations, such as database synchronization, can be scheduled there. However, if data availability is always required, the ERP platform must be mirrored so that it can also be used during maintenance. Mirrored systems are not technically challenging to implement, but they are remarkably expensive [50].

2.3.3 Information systems supporting ERP

Subsystems supporting ERP have also been developed. These systems both facilitate certain operations and provide information to the ERP when needed. Common subsystems that deal with higher level management include CMMS (Computerized Maintenance Management System), CRM (Customer Relationship Management, DPS (Demand Planning System), HRMS (Human Resource Management System), KM (Knowledge Management), PLM (Product Lifecycle Management), and SCM (Supply Chain Management). Each of these systems is very distinctive but they share common goals of either optimizing resource management, seizing opportunities, or streamlining access to business-related information [16] [33] [49] [67].

The main supporting information systems for optimizing resource management within businesses are CMMS, DPS, and HRMS. CMMS is a computerized system for managing the key tasks of maintenance, such as equipment register, inspections, repairs, service documentation, and spare parts. By integrating these tasks to a single system, maintenance management requires less time and is significantly simplified. In addition, it is also possible to save on costs incurred due to poor communication. For example, the absence of a critical spare part or the failure to carry out scheduled maintenance are additional costs of this type. DPS, on the other hand, is a tool for evaluating sales volumes which in turn is essential information for planning the resources allocated to manufacturing and inventory management. Without DPS, a company may have a lot of inventory and production staff in times of poor demand or little in times of good demand, leading to costs due to either overcapacity or loss of sales. Finally, HRMS is an information system for human resource management. Typical information stored in HRMS includes basic staff information, training register, hours worked, and payroll. HRMS is a powerful tool for harnessing the full potential of staff and preventing latent problems such as inequality and skill gaps [33] [49] [67].

Information systems that seek to seize opportunities are CRM and SCM. CRM is a system that manages customer information, such as trade agreements, product catalogs and service tasks. The purpose of CRM is to integrate market intelligence with business management. By identifying the needs, loyalty and value of each customer, a company can prioritize important customers and maximize the profits available through the demand chain. The other information system, SCM, is for managing the supply chain of the materials and components needed in manufacturing. In principle, SCM is very similar to CRM, but instead of maximizing profits at the customer interface, the system operates at the vendor interface in an effort to find the most reliable and affordable suppliers [16].

The systems that focus primarily on providing access to business-relevant information for various function of the company are PLM and KM. PLM is an information system that centralizes all product lifecycle related processes. The purpose of PLM is to streamline the management of product information and simplify its use in other systems and applications. Key processes managed with PLM include product development, design, definition, manufacturing planning, quality management, customer support, service, and recycling. The remaining system, KM, is otherwise similar in operation to PLM, but there are no clear restrictions on the data that can be stored there. Typically, KM is used to bridge together different operations and knowledge related to all other information systems used in the business. However, it is recommended that the data be unique to KM and not managed in other information systems. This prevents duplication of data. Typical examples of data managed in KM are quality management system guidelines and instructions for using other information systems [16].

In addition to all the above information systems supporting ERP, there are also three nested subsystems that gradually facilitate production management. These are generally known as APS (Advanced Planning & Scheduling), MES (Manufacturing Execution System), and SCADA (Supervisory Control and Data Acquisition), each of which involves managing a smaller entity at a more detailed level. Briefly explained, MES monitors the progress of manufacturing, APS works as the interface between ERP and MES and SCADA works as the interface between MES and production automation [4] [25] [37] [50].

2.3.4 Advanced Scheduled Planning

APS is an information system with a built-in planning engine that is specifically used for production planning. Unlike ERP or MES, APS does not have any other uses, such as staff or quality assurance management. Reliable production planning requires accurate data of capacity and constraints to be entered into the system. Ideally, this is accomplished through integration between ERP and MES, as all the necessary information is already recorded in these systems. The planning engine of APS is based on complex mathematical optimization and constraint-based algorithms. When drawing up the production plan, APS proposes an optimal solution based on the available resources and defined constraints. The initial plan can be further optimized manually, if there are for example, some strategic objectives that require higher prioritization. In addition to planning, APS can also be used to simulate the production plan before it is launched. The biggest benefit of simulation is the increase in the transparency of the production process, which in turn significantly helps to identify production problems and areas for development. Simulation also helps to refine the accuracy of the data entered into the system, as the simulation can afterwards be compared to the realized production plan [25].

Unfortunately, there is no standardized framework that defines the scope of APS. However, it can be argued that based on the functionality of APS, it acts at the interface between *ISA-95* hierarchy levels four and three, or pragmatically, between ERP and MES [37]. Due to the lack of standards, systems from various software vendors may vary considerably. For example, one system might have a planning range that covers everything from sourcing to logistics, while another system might only be capable of production equipment scheduling. In addition, it is also possible to embed the APS planning engine in another larger system, such as MES. Therefore, when purchasing APS or MES, it is important to find out exactly how extensive the system is to best meet the needs of the company [11] [25].

The most significant benefits of APS are typically an increase in manufacturing speed, resource utilization, and inventory efficiency. With these benefits combined, the system can potentially pay for itself many times over in a relatively short period of time. However, this is only possible if the system has been successfully implemented. The complexity of the software, the challenges of data accuracy, or the lack of training, information, or support from the software vendor easily lead to the desired benefits not being achieved [25].

2.3.5 Manufacturing Execution System

MES is a networked data collection system which combines data elements of production management, personnel management, and quality assurance. The role of MES is to exchange data between business management and production automation. In this case, business management refers to ERP and production automation to control systems and field equipment. As with APS, MES also lacks standardized framework. As a result, systems designed by different vendors may have functional overlaps with APS and ERP. The purpose of MES is to ensure that production is managed as economically as possible. This is realized when MES complies with the so called 6-R rule: *"The Right resources are available at the Right time, in the Right place, in the Right quantity, with the Right quality, and with the Right costs"* [37].

The operation of MES is based on finite schedulers, of which there are three basic types: event-based, job-based, and resource-based scheduling. The event-based scheduler reserves the immediately available resources to upcoming work orders in a best possible sequence. The purpose of the event-based scheduler is to utilize all available capacity. The downside to this scheduler is that it does not conserve resources for high priority work orders, which can extend lead times in unpredictable situations. The job-based scheduler, in turn, allocates resources based entirely on work priority. The purpose of the job-based scheduler is to ensure that prioritized work orders are completed on time. Typically, the priority of work orders is defined by their impact to the business. Finally, the resource-based scheduler organizes work orders based on their due dates. The purpose of the resource-based scheduler is to minimize overall lead time. Resource-based scheduling is important when the resources are strictly limited and multiple work orders require same resources at the same time. Using the best suited scheduling function to each situation makes MES a very powerful production planning tool [50].

The main benefit of MES is that it helps to predict production problems and find counter measures in real time. This means that if changes are required in the production plan, it is possible to make them much closer to the delivery date than with ERP alone. In addition to the increased reliability of production plans, MES can be also used to increase machine utilization, as it records unscheduled downtime with much greater accuracy than manual recording and makes production process more transparent. This will help identify and eliminate the root causes of downtime or identify other latent opportunities to reduce production costs. Even the slightest improvement in machine utilization may in itself be enough to repay the system [37].

2.3.6 Supervisory Control and Data Acquisition

SCADA is a system that combines telemetry, data acquisition, and software for industrial process monitoring and control. SCADA evolved from centralized management and control systems used in large industrial facilities such as power plants. The initial monitoring systems were control rooms filled with analog devices, such as lights and gauges wired directly into sensors that monitor the important processes. While this implementation was simple and reliable, it had serious drawbacks because wire management, reconfiguration, and simulations were not possible. The system also required operators to be always present as off-site monitoring or alarms were not feasible. As significant cost savings could be achieved with IT-based solutions, the trend towards modern SCADA systems proceeded practically at the same pace as the necessary technology became available [4].

SCADA enables supervising large industrial plants in the same way as a directly wired control room, but with more advantages as the operator can now monitor, control, or simulate processes remotely. Since the overall system can get quite complex, hierarchy levels are used to outline the structure of SCADA. The levels listed from top to bottom are commercial data processing, master stations, communications, marshalling terminals, and field level instruments. In terms of technology, either a PLC (Programmable Control Logic) or DCS (Distributed Control System) is typically used to centralize sensor data in the field. If there are many sensors and they are scattered, RTUs (Remote Terminal Unit) may be used to further bundle sensor data into logical entities. The PLC or DCS is then connected to other external systems via fieldbus or local area network. Wireless network solutions for PLCs also exist and are convenient for monitoring purposes, but their availability in the market is still quite limited. MTU (Master Terminal Unit) is the final device that connects the field devices to the SCADA network [4] [46].

PLC and DCS are limited in terms of monitoring because the network users only see these units, but not the devices connected to them. If the operator needs to see up to individual sensor level, for example to remotely retrieve the serial number or installation date, SCADA should be implemented using IED (Intelligent Electronic Device) sensors, that include memory, basic control, and communication functions. It is also worth noting that if the implementation with the IED is simple enough, a PLC or DCS may not be needed at all. Because the benefits of these implementation options do not differ significantly on a large scale, the decision is often made on the basis of total cost, complexity, and available space [4].

To ensure proper data transmission, SCADA systems must be wired with properly shielded cables, as the cables may need to be routed in the vicinity of high voltage electric equipment, which increases risks of interference. Shielding also works against other sources of interference, such as temperature and stray signals. In addition to shielding, losses due to cable length must also be taken into account. If the distance to cover is considerably large, signal amplifiers or repeaters should be placed at sufficient intervals. This is especially true for implementations that include wireless communication, such as radio transmitters. Another reason to use signal amplification is to match input ranges during conversion, such as from analog to digital [4].

A separate SCADA network is used to transfer data from field devices to the control room. In addition to the analytic computers in the control room, data often needs to be transferred to external servers, such as a historian or data warehouse. As a general rule, the SCADA network may not be used for any other purposes, such as an office network. This is because network management is challenging in itself and adding network policies to different uses would make management even more challenging. If access to SCADA from an office network is necessary, the connection should preferably be established with special firewall rules from one network to another [59].

The structure of a typical SCADA network is illustrated in Figure 3 [59].

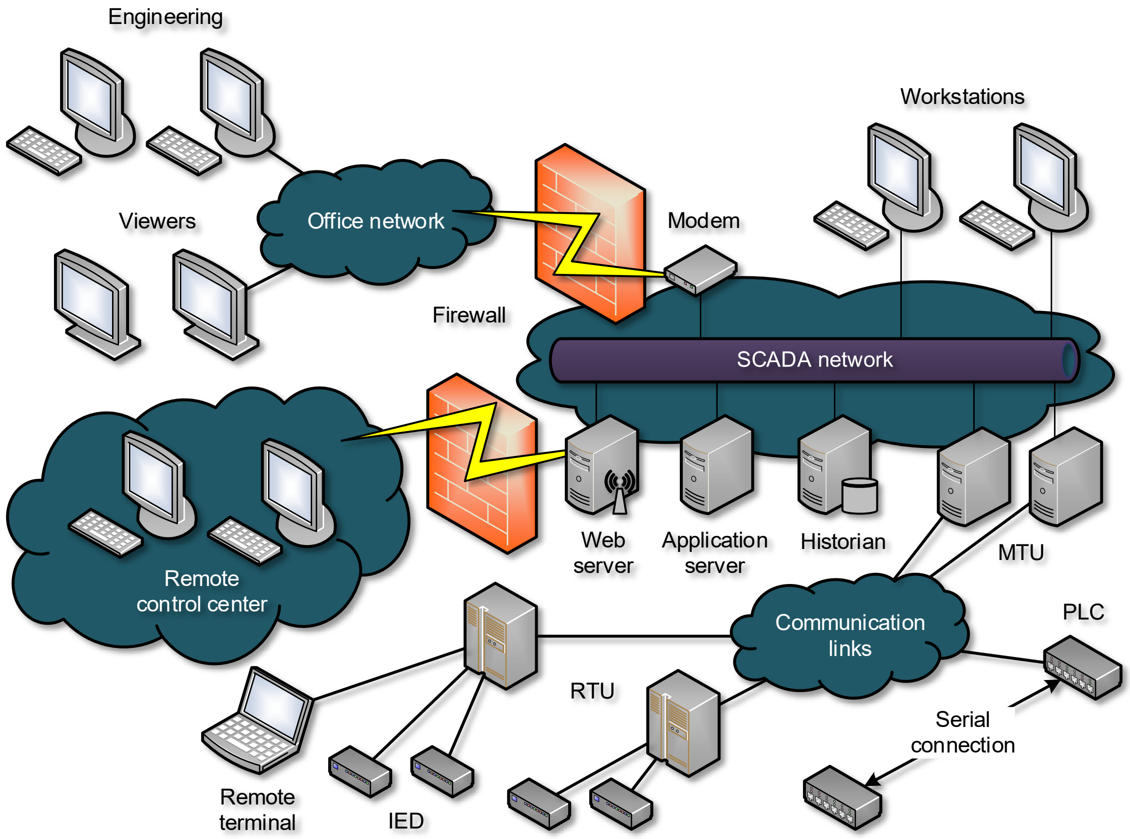

Figure 3: *SCADA network*

Security and reliability of SCADA systems

The disadvantage of SCADA is that it is a significant security risk for companies. Because most of the devices are interconnected, one breach is enough for an intruder to potentially gain access to any device and data in the system. Depending on the extent of the breach, an intruder can cause a variety of damages, such as data leakage, equipment failures, prolonged plant shutdowns, and in some cases, even significant environmental damage. This is why SCADA systems are valuable targets for terrorist and military organizations. In recent history, there have been several cases of attacks on large facilities, such as oil refineries, power plants and chemical factories, by breaking into their control systems through SCADA. Primarily targets for hacking are systems that contain outdated security protocols. This is because security protocols that are several months old have some vulnerabilities that have been fixed in the latest versions, and protocols that are several years old have even more of these vulnerabilities. Some vulnerabilities, also known as zero-day vulnerabilities, go unnoticed by system developers even in the latest versions. While zero-day attacks are very rare, they are also the most dangerous, because maintaining a security system never eliminates the threat. A notable example of zero-day exploitation is the *Stuxnet* virus discovered in 2010, which targeted certain carefully selected PLC models. *Stuxnet* operated by autonomously modifying the program code contained in a PLC. After infecting one device, it could potentially spread to all other similar devices unnoticed. After the infection phase, *Stuxnet* could help the intruder to spy on or damage the processes at the target facility [9] [24] [27] [28] [59].

To increase the security of SCADA, several features have been added over time. Communication between devices based on the latest protocols enables message authentication, which significantly increases security. It is also considered a good rule of thumb that all systems should have strict user access control. This allows access to different parts of the system to be restricted according to user roles. The purpose of user access control is primarily to combat external threats, but it also protects against internal threats, such as damage caused by an inexperienced user. Restricting external access points with a firewall is also an effective way to improve security. A firewall protects the network from all unauthorized traffic and allows access only through certain ports. Alternatively, the system can also be completely disconnected from the Internet if there is no need for remote access. A security breach to an isolated system can only occur if an intruder makes a physical connection to the network from within the facility. As a last resort, a separate intrusion detection system that detects anomalies in network traffic can be used to ensure security [9] [24] [27] [28] [59].

In addition to SCADA's security risks, the system also involves risks in terms of reliability. As SCADA is often used as the main source of information for rapid decision-making on the operation of a facility, the information transmitted to the control room must be accurate. The control commands transmitted to the field devices must also remain operational at all times in order to avoid dangerous situations that may arise, for example, in high-energy processes. Reliability can be increased through regular inspections, maintenance, and backup systems. Typically, backup systems are at least in place to secure power supply and important process controls. In addition, some advanced SCADA systems, used especially in power plants, have a separate energy management system that focuses on maintaining energy balance. It is also important to prepare for emergencies such as fire when planning security measures. Emergency and security plans are usually a good starting point for preparation [9].

Although effective measures to ensure security and reliability are available, the massive scale of SCADA may obscure the division of responsibilities, which in turn increases the likelihood of some form of negligence. The security issues may often appear to be at a good level on the surface, but a single repeated omission is enough to jeopardize the entire system. It is not uncommon to find guest accounts with default passwords, unclear firewall rules, and unlocked control cabinets in otherwise highly secure industrial facilities. Regular security checks and audits are effective ways to detect these types of errors before they cause problems [27].

2.4 Databases

Databases are systematic collections of electronic information maintained and used by computer systems. The purpose of databases is to store large amounts of data and predefined dependencies between data elements so that all data is easily accessible afterwards. The software used as the main database management tool is called DBMS (Database Management System). DBMSs allow users to create, edit, and access databases regardless of where and how the data is physically stored. Although some DBMSs have graphic user interfaces and introductory tools, the most common and widely supported way to manage databases is by using query languages, such as SQL (Structured Query Language) [21].

The database architecture can be either centralized, client-server-based, distributed, or web-based. The centralized database is the original architecture, where all processing and user interaction is done on the same computer. Currently, this implementation is rare because other options, especially client-server architecture, are significantly better in terms of performance and usability. In the client-server architecture, data processing and user interaction are decentralized to separate computers, making computing much more efficient and allowing multiple users to connect to the database simultaneously. The distributed and web-based architectures operate on the same principle, but on a larger scale. In terms of user interaction, there are virtually no differences between the architectures. However, the servers differ in that the distributed database is shared between multiple computers locally and the web-based database virtually. Due to the virtual server structure, the web-based architecture is also known as cloud database. All three of the above architectures are highly efficient, reliable and user-friendly. However, the distributed and web-based implementations are much more expensive options. Unless there is a specific risk- or capacity-based reason for decentralizing the servers, the client-server architecture is the most cost-effective solution for simple and lightweight databases [21].

2.4.1 Structured Query Language

SQL is a query language developed by *IBM* in the early 1970s. SQL was *ANSI* and *ISO* standardized in 1986 and has been widely supported ever since. Based on its main function, SQL is divided into three language groups known as data definition, data manipulation, and data control languages. The data definition language is used to define the database schema, the data manipulation language for queries and editing data, and finally the data control language for controlling permissions and managing transactions. SQL is simple yet versatile in nature, making it a very powerful tool for database management. The SQL queries consist of statements, clauses, predicates, and expressions. A statement retrieves data based on the criteria defined in clauses that refer to specific database elements. Clauses may include predicates that are logical conditions for delimiting the results of a query. Furthermore, predicates may contain expressions that produce certain values or sets of values from the referred database elements. The elements of SQL queries are illustrated in Figure 4 [5].

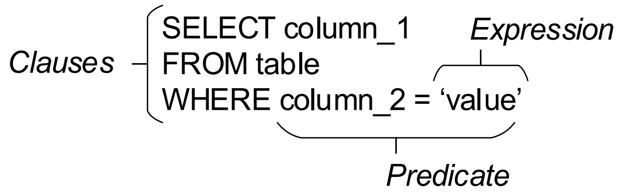

Figure 4: *An example of a SQL statement*

2.4.2 Data models

Based on the data model, databases belong to either relational or multidimensional databases. Relational databases, which were developed alongside SQL in the 1970s, can be considered the basic form of databases. Relational databases are simple and suitable for many uses, such as maintaining transactions, archiving data, and generating reports on recorded data. In the 1990s multidimensional databases were developed as an extension of relational databases. Multidimensional databases are more complex and their sole purpose is to analyze data [17] [34].

Relational databases

The basic structure of a relational database is a table. The columns in the table are used to specify data types and the rows to record data. The intersection of a column and a row is called a field and it represents a single data point or a value. Each table in a database has a specific purpose. Typically, tables are used either to record data or create dependencies with other tables. When designing relational databases, enforcing data integrity is an essential practice to ensure that the data is accurate and consistent. Otherwise, the database records cannot be trusted. Data integrity is an important consideration right from the start of database design, as it cannot be corrected retrospectively without losing data. Typical methods of enforcement include guidelines, procedures, and constraints, such as DBMS keys. Keys are constraints that only allow certain types of values to be recorded in the database. The most common ways to use keys are to set value ranges, prevent duplicate or null values, and maintain relationships between linked columns in tables [5].

The system that manages relational databases is called RDMS (Relational Database Management System). The most commonly used RDMSs are Oracle, MySQL, Microsoft SQL Server, and PostgreSQL. There are various differences between RDMSs in terms of pricing, usability, functionality, and connectivity to different operating systems or software. It is also important to note that although SQL is a standardized query language, there are some differences between RDMSs in query language commands as well. However, the query language is usually applied so that the basic functions correspond to the standard and the differences only become apparent when using the special features of the RDMSs. In order for a company to choose the system that best suits its information systems management strategy, it is a good idea to carefully study all the available options [5].

Multidimensional databases

The multidimensional data model utilizes the data in relational databases to find new information, such as causal relationships. The definition of a multidimensional database begins with the classification of the data found in the relational databases connected to it. All relevant data is classified as belonging to either facts, measures, or dimensions. Facts represent items, measures represent the quantity of items, and dimensions represent the context of items in a database. For example, a table containing a bank transaction log can be converted to the following multidimensional data: The transaction is a fact, the number of transactions is a measure, and a sample for one year is a dimension [21] [34].

A Multidimensional database is a logical entity combined from one or more relational databases utilizing the above classification. The combination of facts, measures and dimensions in the same context is known as a cube, which is the basic structure of the multidimensional data model, similar to the two-dimensional table of the relational model. As the name suggests, a cube contains at least three elements: fact, measure, and dimension. However, there is no upper limit to the number of dimensions of a cube. A cube with multiple dimensions is sometimes called a hypercube to distinguish it from the simple three-dimensional cubes [21] [34].

Systems that manage multidimensional databases are called MDBMSs (Multidimensional Database Management System). Many software vendors whose products include RDMS, such as Microsoft SQL Server and Oracle Database, also offer MDBMS. In other respects, the same considerations apply to MDBMSs as to RDMSs [34].

The multidimensional data model has three important application areas in data analytics. The first is data warehousing, the second is OLAP (On-Line Analytical Processing), and the third is data mining. Data warehousing is the practice of forming new multidimensional databases from multiple data sources by modifying the existing structure and relationships to make the data more suitable for analytical purposes. Data warehouses are created and maintained by a predefined three-step process known as ETL (Extract-Transform-Load). ETL extracts data from sources such as relational databases, cleans it, converts and integrates it, and finally uploads the data to the data warehouse. A particular benefit of the ETL is that the process is automated. As a result, analytics based on the data warehouse, such as reports, are updated simultaneously. Therefore, there is no need to manually change or update the report templates, unless the structure of the data warehouse changes. This feature is typically included in all modern RDMSs. It should also be noted that ETL is a cumbersome process, as a result of which data warehouses are usually updated much less frequently than their sources [21] [34].

The second application area, OLAP, provides quick responses to queries that look for trends in stored data. The use of OLAP requires that the data warehouse is also implemented, as the query structure between multiple relational databases would otherwise be very complex and slow to process. Queries in OLAP applications can be performed using either extended SQL or multidimensional query languages developed specifically for this purpose. Because trends are difficult to understand without a visual representation, many OLAP applications include a graphical user interface for presenting diagrams [21] [34].

The third main application is data mining, which aims to explore the multidimensional database and find new data or causal relationships that would be difficult, incomplete, or impossible to detect using a relational database alone. Data warehousing is not essential for data mining, but its deployment prior to mining is recommended, especially in large multidimensional databases, as processing speeds would otherwise be significantly slower. In data mining, a base data set is grouped by attributes, properties, or variables of interest. Similarities or differences between groups can then be found by binning or discretizing attributes. For example, cars could be grouped by manufacturer, and further sub-grouped at 10-year intervals by year of manufacture. Mathematical formulas and algebra can also be used to find patterns that reveal underlying similarities or differences between groups. Patterns that reveal significant differences between groups or highlight a particular group are known as emerging patterns. Emerging patterns are solutions to specific data mining problems and can be used to find more corresponding patterns. A very useful and simple way to present data mining results is a 2-dimensional pivot table. Pivot table is very versatile, as it is suitable for presenting truth tables or tables with numerical results. Pivot tables can also be easily transposed or divided into rows and columns in different order. In addition, if the results need to be further clarified, they can also be presented graphically [14] [34].

2.4.3 OPC UA

OPC UA (Open Process Communications Unified Architecture) is a cross-platform communication protocol for machines and information systems. It is developed and maintained by the organization *Open Platform Communications*, formerly known as the *OPC Foundation*. The development of OPC UA began in the 1990s with the goal of standardizing data exchange between information systems in industrial environments. However, the first published version turned out to be limited, because it was based on *Microsoft's Distributed Component Object Model*, which was incompatible with firewall and dependent on *Microsoft* platforms. In the early 2000s, the availability of XML (Extensive Markup Language) and web service technologies opened up new opportunities and led to the development of the truly platform- and technology-independent OPC UA [6] [43].

In principle, OPC UA acts as a client-server application. The application can operate either by the server sending scheduled update requests to the client, or by the client sending data to the server when the content of the data, such as the value of a variable, changes. OPC UA messages are delivered in a structured Object Meta Model format similar to XML. The most common data types are built into the model, which means that variable data can be included in messages without the need to specify data types or constraints. In addition, OPC UA has a layered architecture that allows compatibility with new technologies by simply mapping the outermost layers [6] [43].

OPC UA has several uses and can be applied in many different industries, such as building automation and manufacturing. The most common use of OPC UA is to transfer and store data from field devices to a database for later analysis or reporting. The communication standard also works the other way around if, for example, it is necessary to parameterize field devices using a database as the source of parameters. In addition to these, OPC UA is well suited for applications that monitor field devices in real time, as well as for troubleshooting, as it is possible to compile an event log of the transmitted messages. In terms of security, OPC UA has a security model that allows the use of encrypted or signed messages, client-server authentication, and user access control as needed. However, it should be noted that increasing security measures will degrade communication performance. For this reason, security or performance is given priority depending on the application. For example, a connection to ERP may not require a frequent update interval, but is highly critical for security, while the prioritization may be reversed in an application that monitors field devices [6] [22] [43].

2.4.4 Security and reliability of databases

Security is crucial in database management as it is the only way to ensure the confidentiality, integrity, and availability of data. In terms of security threats, their management, and prevention, databases are very similar to SCADA systems. The difference is mainly due to the consequences of the security breach, which in the case of databases can cause serious, indirect, inconspicuous, and long-term harm. For this reason, security should always be treated as an essential resource for databases. Typical internal security threats include hardware damage and accidental or intentional deletion of data by an employee. Effective ways to prepare for hardware failure or theft include encrypting and mirroring hard drives and keeping servers in locked and well-ventilated facilities. Password protection, user access control, and systematic backups are effective ways to prevent unintentional and intentional harm caused by users [1] [18] [21].

In addition to insider threats there is a growing need to prepare for external security threats as well. Because databases often contain information, such as trade secrets, that are not intended to be leaked to outsiders, external threats should always be taken seriously. It should also be noted that many government regulations rule the administrators or owners of the database responsible for the confidentiality of sensitive information. This means that a security breach could result in severe penalty, such as imprisonment. External security threats to databases are usually prevented in a layered fashion. The first step is to prevent unauthorized connections to the network. This is ensured by using an encrypted connection, such as VPN (Virtual Private Network), a firewall, or an authentication server. The second step is to ensure that unauthorized personnel cannot access any network devices. Anti-malware applications and intrusion detection systems can be used to prevent this. The third step is the prevent unauthorized access to the data. This is handled by access control, i.e., granting access only to the specific data the user needs. Finally, password protection and regular hardware and software updates are effective additional measures that can be applied at all three layers to increase security. Because database servers operate on the same principle as other computerized systems, the above measures can also be applied elsewhere in the organization [1] [21].

The most significant problem for the reliability of databases is that companies usually have an interest in retaining all recorded data, but due to the aging of technology, systems will sooner or later have to be completely overhauled. However, transferring data from legacy systems is an expensive and difficult process, which is why especially growing businesses often use legacy systems as long as they are operational. As this situation continues, the option to transfer all data as such becomes increasingly unprofitable and more difficult to implement. Eventually, when the old hardware stops working, the only option left is to archive the salvageable data to a middleware as a compromise. Archiving saves the legacy data to some extent, but it will be hard to access and there is a risk of data integrity being compromised. To prevent these problems, companies should consider migrating data to a new platform before the technology in use becomes obsolete [21].

It is also important to note that attitudes towards security threats also play an important role in the quality of preparedness. If management support, budget, or expertise is lacking in terms of security, the level of preparedness will naturally decrease. These factors must be in place to ensure a good security framework in the organization. In addition, it is important to be aware that security threats are constantly evolving, which is why security systems also need to be regularly updated. Awareness of potential threats, identification of realized threats and adherence to security policies, as well as testing the effectiveness of countermeasures, are good ways to continuously improve security [1].

3. OBSERVATION

This section presents observations on the *Customer Company's* production processes, MISs, and measurement methods in use. The purpose of observation is to collect primary data on which functions of the company's main manufacturing process are relevant to improving production and which KPIs are currently used by the departments responsible for these functions.

3.1 Production processes

The manufactured products have been on the market for more than 20 years, which puts the production process at a mature stage in its life cycle. This means that major changes in manufacturing methods are no longer likely to occur, but small improvements can be found by experimenting with different approaches and taking advantage of technological advances. The market demands high quality products, which is why product quality is constantly monitored. High volume sales require that production lines operate at the planned speed and for as much of the planned production time as possible. Due to the above requirements, maintenance plays an important role, as critical spare parts and service personnel must be immediately available in case of problems.

The main stages of the manufacturing process are:

- procurement of materials
- manufacture of semi-finished products
- product assembly
- inspection
- packaging
- warehouse
- customer deliveries

The first step in the production process is the procurement of materials, which ensures that all the materials needed for the planned production batches are available. The products are completed either during the manufacture of semi-finished products or product assembly. This is because some products are so simple that they consist of only one component and thus do not require a separate assembly step. Each finished product then goes through inspection. Products that pass the inspection proceed to packaging, while defective products are discarded. Discarded products are not reprocessed on the production line because it is not profitable. However, the scrapped material is sorted because some of the components can be recycled. Finally, the products are transferred to the warehouse and from there to customer deliveries after the production batch is approved.

The production lines have been implemented mainly with technologies related to injection molding, heating, welding, feeding, conveying, robotics, linear motion, and sensing. Machine vision has also been utilized on newer production lines. The devices are controlled by several PLCs, which are operated centrally from separate control panels. In addition to the operating functions, the control panels have various monitoring views that can be used to check, for example, counters or log data. Most of the production process involves automatic assembly of products on a production line. However, product inspection, packaging, and filling of material feeders are done manually.

Manufacturing is part of global operations management, which is divided into production planning, plant management and shift supervising. These are the main functions of production and are managed by the *Production* department. The following support processes, managed by their own departments, also operate around global operations management:

- Sourcing (*Supply Chain* department)
- Quality assurance (*Quality and Regulatory Affairs* department)
- Maintenance (*Operative Maintenance* department)
- Technology development (*Technology Development* department)
- Product development (*Research and Development* department)
- Innovation (*Product Group and Innovation* department)
- Sales (*Sales Operations* department)
- Marketing (*Marketing and Digitalization* department)

All of the above departments report to the business management. The *Production* department has the biggest impact on production efficiency. The next most important support processes regarding opportunities to improve efficiency are quality assurance, maintenance, and technology development. For the managers of these processes, monitoring productivity with KPI measurement is somewhat familiar. It should be noted that for new products, innovation, and product development play very important roles in manufacturing efficiency, as products have to be designed to be assembled. However, as the product design in this case is at the mature stage of its life cycle, the need for further product development is very low. For this reason, the KPIs for these two supporting processes are not reviewed.

The observed main manufacturing process and related key stakeholders are illustrated in Figure 5. The background color highlights the main manufacturing steps and supporting processes that are explored in this thesis.

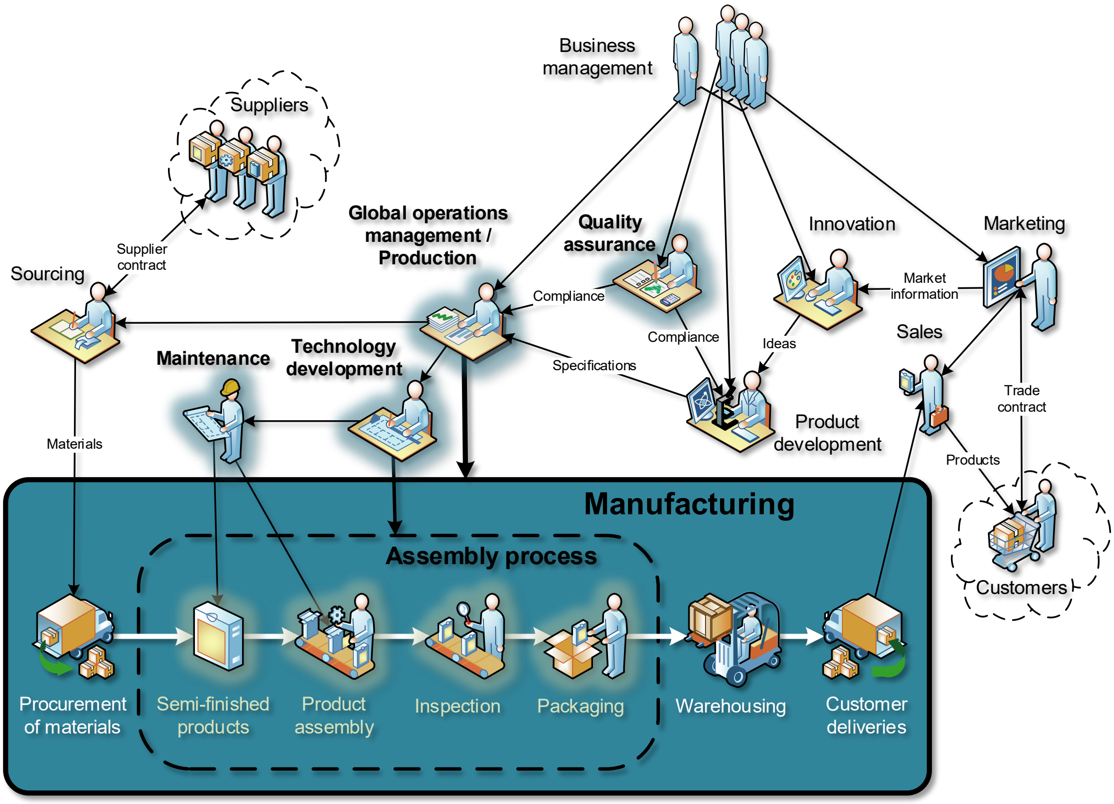

Figure 5: *Observed main manufacturing process and key stakeholders*

3.2 Management Information Systems

Many of the common MISs are used by the *Customer Company*. Manufacturing processes are mainly managed through ERP and APS, and are supported by CMMS, CRM, DPS, HRMS, KM and PLM. In addition to the above, there is also a special information system called MTS (Machine Tracking System) that combines some of the functions of MES and SCADA. ERP and DPS make it possible to measure many factors related to production and sales, as the systems provide a lot of general information about production batches, inventory, and deliveries. CRM and KM are used to report quality assurance issues, such as complaints and audit findings. CMMS and MTS provide maintenance-related information such as maintenance orders, spare parts, and production line performance. Finally, HRMS provides information on human resources, such as hours worked and payroll, that are essential for all major departments. Of the MISs in use, PLM and APS are not used for measurement. PLM is excluded because it is primarily a product development tool and product development is not a target group of this study. APS, on the other hand, is excluded because it is used to schedule work orders and not as a system for storing permanent production data.

All of the above MISs store data in relational databases. All servers are distributed as either locally hosted virtual servers or external cloud servers. In addition, the *Customer Company* has experience in data warehousing and multidimensional databases, which have been used to analyze production volume data found in ERP, for example. Experience in information systems management and data warehousing provides an excellent framework for automated reporting.

3.2.1 Security and reliability of information systems

The *Customer Company* is well prepared for a variety of security threats and reliability issues. All MIS servers are stored in locked spaces, have backup power supplies, and are automatically backed up. These measures are very effective in preventing the loss of data due to hardware failure. All MISs also operate in separate networks that are not directly connected to the office network. In addition to improved security, a distributed network architecture also prevents large-scale connectivity issues. All networks are protected by a firewall and external connections are made via an encrypted VPN. With these tools, the *Customer Company* prepares for external security threats. The company is also well prepared for internal security threats. Every server and workstation in use is password protected and the passwords must be changed regularly. User access control has also been widely applied on workstations and databases.

As an additional security note, the MTS server combining the functions of MES and SCADA is constantly connected to the control unit of each production line, which exposes the production lines to external attacks in the same way as in traditional SCADA systems. This threat has been addressed by establishing connections between the server and the hardware using the OPC-UA protocol. The OPC-UA connection is configured to allow data transfer only from the PLCs to the server. Thus, a security breach can, in the worst case, lead to a data leak, but it is not possible to hijack production line controllers through this connection. Although data leakage can be a serious threat, it should be noted that in this case, the PLCs or the MTS server database do not contain personal information or easily identifiable trade secrets. Thus, the data is virtually useless to a third party without context.

In terms of data accuracy, all MISs used by the company to demonstrate the quality, or traceability of medical devices or competence of personnel involved in production have been validated. These systems include ERP, CRM, HRMS and KM. Validation is generally considered to be strong evidence of the accuracy of the data stored in the systems. For non-validated systems CMMS, DPS and MTS, the accuracy of the data has been roughly checked during implementation. In addition, problems later encountered by users have also typically been fixed over time. However, these measures are not sufficient to unequivocally prove the accuracy of the data. It is therefore recommended that the systems listed above be validated if the data collected from them will be used to measure production processes.

3.3 Current state of measurement and important indicators

The *Customer Company* uses KPIs at different management levels and there are various indicators for each function. The functions most strongly related to the production processes under study are quality assurance, maintenance, technology development, and production. Therefore, in order to improve the main production process, it is appropriate to start by observing the KPIs already used by the departments responsible for these functions, analyze their benefits, and propose potentially useful additional or alternative indicators. Based on these findings, it is possible to draw conclusions about what can be measured with existing MISs and how the systems should be developed to simplify measurement, for example through automation. The observed KPIs are referred to by the initials of each significant function (***Q****uality assurance*, ***P****roduction*, and ***M****aintenance* and *technology development*) and sequential numbering. The units of each indicator are marked in square brackets. Note that because maintenance and technological development have much in common, they are treated as a whole in terms of measurement.

3.3.1 Quality assurance

The KPIs of *Quality and Regulatory Affairs* department are included in the annual *Quality Management Review* report, which is presented to the business management. This report summarizes the most important issues related to quality assurance, regulations, and the environment. The report currently includes the following KPIs:

- *Q1 Complaints (external nonconformities) in relation to the products delivered [% or ppm]*
- *Q2 Internal nonconformities in relation to the products manufactured [% or ppm]*

The number of complaints is measured in relation to sales volumes and internal nonconformities in relation to production volumes so that the KPIs can be scaled to changes in the market situation or production capacity. This is a very good implementation because there is no need to readjust the indicators to changing situations. The purpose of these KPIs is to monitor and ensure that the ratios remain as low as possible. If the trend of nonconforming products starts to grow, action must be taken. The reasons for introducing these indicators were not necessarily directly based on any general principle of economical manufacturing, but it can be argued that such a systematic minimization of deviating products is clearly in line with the six sigma principles.

The *Quality and Regulatory Affairs* department also reports to the business management on the following environmental indicators:

- *Q3 The share of waste in the total material used in manufacture [%]*
- *Q4 The share of recyclable material in the waste [%]*
- *Q5 Energy efficiency [MWh per Mg]*
    - *Q5.1 Energy consumption [MWh]*
- *Q6 The share of renewable energy in total energy used [%]*

Waste minimization, recycling, energy efficiency, and the use of renewable energy are all related to compliance with *ISO 14001:2015 (Environmental management systems)* standard, which in turn guarantees compliance with international agreements on minimizing emissions and pollution. Sustainability is also good for the brand of a globally operating company. In addition, all of these factors affect production efficiency and business profitability but this may not be self-evident. The lower the energy requirement and the amount of waste in the manufacturing process, the cheaper it is to manufacture. Recycling of materials and renewable energy are also somewhat cheaper than the use of non-renewable resources. If not as such, then at least because of the higher taxation imposed by the country of manufacture.

All of the above KPIs have annual targets and their development is monitored. In principle, the business goal for the environmental system is to make manufacturing as sustainable as possible. In addition, the management report includes a summary of the audit results and CAPA (Corrective and Preventive Action) reports at a general level, but there are no indicators or well-defined targets for these items.

Below are examples of formulas for calculating KPIs *Q1* to *Q6*:

$$Q1 = \frac{Complaints\ [pcs]}{Products\ delivered\ [pcs]}$$

$$Q2 = \frac{Internal\ nonconformities\ [pcs]}{Products\ manufactured\ [pcs]}$$

$$Q3 = \frac{Waste\ [Mg]}{Material\ used\ in\ manufacture\ [Mg]}$$

$$Q4 = \frac{Recyclable\ material\ [Mg]}{Waste\ [Mg]}$$

$$Q5 = \frac{Q5.1\ [MWh]}{Materials\ used\ in\ manufacture\ [Mg]}$$

$$Q5.1 = Instantaneous\ energy\ demand\ in\ manufacturing\ [MW] * Energy\ use\ time\ [h]$$

$$Q6 = \frac{Renewable\ energy\ provided\ [MWh]}{Q5.1\ [MWh]}$$

The data used to calculate the above KPIs are available from the following sources:

- KM → Complaints (*Q1*) and Internal nonconformities (*Q2*)
- ERP → Products delivered (*Q1*), Products manufactured *Q2*), Waste (*Q3* and *Q4*), and Materials used in manufacture (*Q3* to *Q5*),
- Energy bills and information provided by the energy supplier → Energy consumption (*Q5.1*) and Renewable energy provided (*Q6*)

3.3.2 Production

The *Production* department uses KPIs that measure efficiency and reliability to develop its own operations. These KPIs are presented to the business management upon request or to other personnel at monthly staff meetings. However, the indicators are not compiled in a single report, as *Quality and Regulatory Affairs* has done. Currently, the following KPIs are established as content for staff briefing materials:

- *P1 Labor efficiency [pcs per h]*
  - *P1.1 Net production [pcs]*
  - *P1.2 Hours worked in payroll [h]*
- *P2 Production profit [M€]*
  - *P2.1 Production gross income [M€]*
  - *P2.2 Deducted from production gross income [M€]*
- *P3 Sales forecast [pcs per m]*
- *P4 Warehouse levels [pcs per m]*
- *P5 Deliveries on time [%]*
- *P6 Supplies delivered on time [%]*

The purpose of labor efficiency is to monitor the development of labor input regardless of the variation in the number of hours worked or the number of products produced due to the world market situation. As the labor efficiency increases, work becomes more profitable for the company and it increases competitiveness. The disadvantage of the indicator is that it does not state unambiguously whether the change in efficiency is due to the operation of the equipment or its use. It is also important to note that, for practical reasons, labor efficiency is calculated from the total labor input of all employees involved in operational work. Therefore, the KPI is not only for *Production*, but also for the *Operative Maintenance* department.

Production profit is a measure of business profitability and particularly important information for the business management, as the *Production* department has the greatest impact on the company's turnover. Production profit can be used to measure the development of overall efficiency over time similar to labor efficiency, but it also directly shows the amount of cash flow from the *Production* department's activities, which is useful in planning business strategies and investments. It should be noted, however, that this indicator is not the same thing as the profitability of the business as a whole.

The sales forecast shows what deliveries are expected from the *Production* department over a given period of time. In general, forecasts are presented on a monthly basis for the current and subsequent calendar years. Forecasts will be updated over time as new market information becomes available. The direct purpose of the sales forecast is to serve as a tool for determining the required production capacity. Sales forecasts can also be used to measure a company's market knowledge by comparing projected sales volumes with actual sales. The interpretation of this KPI is straightforward: The more accurate the forecasts, the better the conditions for the business to succeed in a changing market.

Warehouse levels indicates the number of finished products that have been taken into storage but have not yet been sold to customers. The purpose of the warehouse is to ensure the security of supply to customers. By monitoring warehouse levels, the production planner gets a better idea of how the available capacity can be utilized in the most efficient way. If the warehouse starts to fill up on certain products, capacity can be diverted elsewhere. Correspondingly, when the warehouse runs out, manufacturing of these products will start again, regardless of the number of confirmed deliveries.

Security of supply and delivery indicates the reliability of production planning, sourcing, and the entire production process. The ideal goal is that all deliveries are made on time, because then the business is as smooth as possible. Delays in sourcing slow down production and late deliveries to customers reduce customer satisfaction. Negative customer satisfaction can then lead to the loss of existing customers and reduces the chances of acquiring new partners if the company's reputation is damaged. Alternative suppliers and emergency stocks are effective ways to reduce the risk of delivery delays. However, these security measures are a major additional cost to the company, which is why these KPIs should be used to find cost-effective and optimal solutions to the problem. The need to increase security is easy to see from the deteriorating ratios of these KPIs. However, if the situation is such that a perfect ratio has been achieved, then potentially excessive security measures cannot be verified by monitoring these KPIs alone. Instead, the need to reduce security measures should be assessed by monitoring sales forecasts and warehouse levels in parallel.

Below are examples of formulas for calculating KPIs *P1* to *P6*:

$$P1 = \frac{P1.1\ [pcs]}{P1.2\ [h]}$$

$$P1.1 = (Manufactured\ products - Discarded\ products)[pcs]$$

$$P1.2 = Hours\ worked\ in\ manufacturing\ [h]$$

$$P2 = (P2.1 - P2.2)[M€]$$

$$P2.1 = Delivered\ products\ [pcs] * Product\ prices\ [€]$$

$$P2.2 = Discarded\ products\ [pcs] * Product\ prices\ [€] + Material\ costs\ [M€] + Payroll\ [M€]$$

$$P3 = \frac{Estimated\ sales\ volumes\ [pcs]}{Time\ period\ [m]}$$

$$P4 = \frac{Produts\ in\ warehouse\ [pcs]}{Time\ period\ [m]}$$

$$P5 = \frac{Products\ delivered\ on\ time\ [pcs]}{Delivered\ products\ [pcs]}$$

$$P6 = \frac{Supplies\ delivered\ on\ time\ [pcs]}{Delivered\ supplies\ [pcs]}$$

The data used to calculate the above KPIs are available from the following sources:

- ERP → Manufactured products (*P1*, *P2*, *P4*, and *P5*), Discarded products (*P1.1* and *P2.2*), Hours worked in manufacturing (*P1.2*), Product prices (*P2*), Products delivered (*P2.1* and *P5*), Material costs (*P2.2*), and Supplies delivered (*P6*)
- HRMS → Payroll (*P2.2*)
- DPS → Sales volumes (*P3*)

3.3.3 Maintenance and technology development

Like the *Production* department, the *Operative Maintenance* and *Technology Development* departments do not have annual KPI reports for the business management. However, productivity, losses, maintenance costs, and investment costs are reviewed annually because the payback periods for investments are based on these factors. When making new investment decisions, it is important to be aware of how well previous investments have yielded so that lessons can be learned from purchasing decisions. If the current state of measurement for maintenance and technology development is converted to the KPI mindset, the following indicators are obtained:

- *M1 Net profit or loss on investment [k€ or M€]*
    - *M1.1 Return on investment [k€ or M€]*
    - *M1.2 Investment costs [k€ or M€]*
- *M2 Yield of production lines [pcs per h]*
- *M3 Scrap rate of production lines [%]*
- *M4 Hourly rate of production lines [€ per h]*
    - *M4.1 Production line costs [k€ or M€]*
    - *M4.2 Production line uptime [h]*

Net profit or loss on investment is the most important indicator of technology development, as investing in new technologies and productivity are prerequisites for the growth of a manufacturing company. The next most important indicator is the total cost of maintenance. These KPIs reflect the state of the maintenance and technology development on a large scale and should therefore be reported to the business management. Yield, scrap rate and hourly rate of production lines are important indicators in the overview of each production line subject to maintenance activities. These indicators are excluded from the report to the business management, as they are relevant only to the internal operations of the *Operative Maintenance* department. As an additional note, the hourly rate of production lines is typically always an estimate over the life cycle of the production line and can only be verified after decommissioning. Unfortunately, the final verified hourly rate is not relevant to streamlining production but can be very in future investment decisions.

Below are examples of formulas for calculating KPIs *M1* to *M4*:

$$M1 = (M1.1 - M1.2)[k€ \; or \; M€]$$

$$M1.1 = Annual \; return \; on \; investment \; [k€ \; or \; M€] * Payback \; time \; in \; years \; [pcs]$$

$$M1.2 = Annual \; investment \; running \; costs \; [k€ \; or \; M€] * Payback \; time \; in \; years \; [pcs] + Acquisition \; costs [k€ \; or \; M€]$$

$$M2 = \frac{Manufactured \; products \; [pcs]}{Production \; time \; [h]}$$

$$M3 = \frac{Discarded \; products \; [pcs]}{Manufactured \; products \; [pcs]}$$

$$M4 = \frac{M4.1 \; [k€ \; or \; M€]}{M4.2 \; [h]}$$

$$M4.1 = Sum \; of \; all \; production \; line \; costs \; during \; its \; service \; life [k€ \; or \; M€] = (Energy \; costs + Property \; costs \; per \; floor \; area + Purchase \; price \; of \; the \; production \; line + Service \; costs + Spare \; parts)[k€ \; or \; M€]$$

$$M4.2 = Production \; line \; service \; life \; [h] * Utilization \; rate [\%]$$

The data used to calculate the above KPIs are available from the following sources:

- Annual return on investment (*M1.1*) is a share of Production profit (*P2*)
    - The effects of the investment on production and the corresponding profit margin are not always unambiguous and must be assessed on a case-by-case basis
- Investment documentation → Acquisition costs (*M1.2*)
- ERP → Production time (*M2),* Manufactured products (*M2* and *M3*), and Discarded products (*M3*)
- CMMS → Service costs and Spare parts (*M4.1*)
- Energy and property bills → Energy costs and Property costs per floor area (M4.1)
- MTS → Utilization rate (*M4.2*, verified)
- Production line documentation → Purchase price of the production line (*M4.1*), Production line service life, and Utilization rate (*M4.2*, estimated)

4. DATA ANALYSIS

This section presents data analysis in which the practices presented in the literature review are applied to the observations reported in the previous chapter. The data analysis methods used are correlation analysis, thematic analysis, and classification. The purpose of data analysis is to find new potential KPIs, determine the reliability of all found KPIs, and identify opportunities for automated KPI reporting.

4.1 Identification of new potential indicators

New KPIs for each department are identified using correlation analysis. The analysis is based on the assumption that new indicators that correlate the purpose of existing indicators are equally useful. The correlation is illustrated by summarizing the relevance of previously observed indicators for the activities of each department, proposing new indicators following the same logic in terms of relevance, and further justifying the usefulness of each indicator in improving production processes.

4.1.1 Quality assurance

In order to keep the level of the QMS high, it would be beneficial to define new KPIs with targets and trend monitoring for both external and internal audits, the CAPA process and the handling of complaints. A high level QMS has a positive effect on customer satisfaction and is the most important prerequisite for demonstrating compliance. For the above reasons, the following additional KPIs are proposed:

- *Q7 The number of external audit deviations [pcs]*
- *Q8 The number of internal audit deviations [pcs]*
- *Q9 Resolved CAPA cases in relation to all cases [%]*
- *Q10 Complaints handled on time [%]*
- *Q11 Internal nonconformities handled on time [%]*
- *Q12 The share of quality assurance in total business costs [%]*
    - *Q12.1 Quality assurance costs [M€]*

By monitoring the results of external and internal audits annually, it is easy to see how the QMS is performing in accordance with the standard. The problem, however, is that the audit results are given in different formats depending on the standard. For example, in *ISO 13485*, which is applicable to these production processes, the results are expressed as deviations from the standard. In recording the nonconformance, the auditor also takes into account the degree of severity, which is determined on a risk-based basis. In this case, the risk is assessed in terms of patient safety, in other words, the worst-case consequences for the patient being treated when using products that do not comply with the standard. Such results cannot be comprehensively summarized in a single indicator that shows the development of audit results over time.

The easiest way to measure the results of audits is to add up all the deviations found during the audits. For practical reasons, this is chosen as the method to be used, although it ignores the severity of the deviations. This means that by observing this indicator alone, it is not possible to measure the amount of work required to correct the deviations. However, since trade-offs are needed in any case, the number of deviations is a sufficient measure in the sense that deviations are not recorded more than once for the same topic. Thus, the trend of audit deviations shows the most important thing, which is how well the QMS generally meets the standard.

The ratio of the number of CAPA cases handled to the total number of cases helps to see if continuous improvement is effective. If the trend is downward, there is a risk that CAPA cases will start to pile up. This, in turn, can lead to cases not being handled properly and development activities not producing the desired benefits. Complaint and internal nonconformity handling processes should also be monitored on the same basis as the CAPA process. However, as complaints and nonconformities are handled much more frequently and the overall process is lighter, it is appropriate to measure the timeliness of the handling process rather than the ratio between the number of cases resolved and the total number of cases.

The above KPIs may not be required to be reported to the business management unless specifically requested, as review by the *Quality and Regulatory Affairs* department is sufficient. The share of quality assurance in total business costs is proposed as the last new KPI related to quality assurance. The costs of quality assurance are essential to the business management and should be included in the management report. This KPI itself is not very informative, but when used in conjunction with other indicators it is useful in assessing the profitability of the QMS. For example, if trends in both costs and quality problems increase, there is a competence problem in the system. Similarly, if costs are declining but problems persist, there is a lack of capacity.

KPIs *Q7* and *Q8* do not need to be derived from formulas. Below are examples of formulas for calculating KPIs *Q9* to *Q12*:

$$Q9 = \frac{Resolved\ CAPA\ cases\ [pcs]}{CAPA\ cases\ [pcs]}$$

$$Q10 = \frac{Complaints\ handled\ on\ time\ [pcs]}{Complaints\ handled\ [pcs]}$$

$$Q11 = \frac{Internal\ nonconformities\ handled\ on\ time\ [pcs]}{Internal\ nonconformities\ handled\ [pcs]}$$

$$Q12 = \frac{Q12.1\ [M€]}{Total\ business\ costs\ [M€]}$$

$$\begin{aligned} Q12.1 &= Sum\ of\ quality\ assurance\ costs[M€] \\ &= (Certifications + Information\ systems + Office\ costs \\ &\quad + Payroll + Third\ party\ quality\ assurance\ work)[M€] \end{aligned}$$

The data used to calculate the above KPIs are available from the following sources:

- CRM and KM → Audit results (*Q7* and *Q8*), CAPAs (*Q8*), Complaints (*Q10*), and Internal nonconformities (*Q11*)
- Financial management → Total business costs (*Q12*)
- Invoices → Certifications, Information systems, and Third-party quality assurance work (*Q12.1*)
- HRMS → Payroll (*Q12.1*)
- Property bills → Office costs (*Q12.1*)

4.1.2 Production

The *Production* department has very good indicators, but the security measures to ensure deliveries on time and the overall impact of production on business costs could be clarified. For the above reasons, the following additional KPIs are proposed:

- *P7 Inventory turnover [%]*
- *P8 The share of production in total business costs [%]*
    - *P8.1 Production costs [M€]*

The inventory turnover rate shows how many times the current inventory has been sold in the selected time period. In the long run, this KPI directly shows whether warehousing is efficient and sufficient to secure deliveries in time. If the turnover ratio is increasing, the inventory is insufficient compared to the sales volumes and if the ratio decreases, the inventory is oversized. Inventory performance can also be assessed by monitoring inventory levels and sales volumes on a product-by-product basis, as is currently the case, but this process requires considerable effort and the information obtained is only useful to production planners. With inventory turnover, the same information is converted into an easy-to-understand ratio that is convenient to report to the business management or other staff.

Finally, the share of production in total business costs is proposed for the same reasons as the corresponding quality assurance KPI. A regularly updated overview of total production costs would greatly simplify annual planning.

Below are examples of formulas for calculating KPIs *P7* to *P8*:

$$P7 = \frac{Value\ of\ products\ sold\ [M€]}{Inventory\ value\ [M€]}$$

$$P8 = \frac{P8.1\ [M€]}{Total\ business\ costs\ [M€]}$$

$$\begin{aligned} P8.1 &= Sum\ of\ production\ costs[M€] \\ &= (Information\ systems + Material\ costs + Office\ costs \\ &\quad + Payroll + Production\ equipment + Property\ costs \\ &\quad + Subcontracting)[M€] \end{aligned}$$

The data used to calculate the above KPIs are available from the following sources:

- DPS → Value of products sold (*P7*)
- ERP → Inventory value (*P7*) and Material costs (*P8.1*)
- Financial management → Total business costs (*P8*)
- Invoices → Information systems, Production equipment, and Subcontracting (*P8.1*)
- HRMS → Payroll (*P8.1*)
- Property bills → Office costs and Property costs (*P8.1*)

4.1.3 Maintenance and technology development

In addition to investment and repayment indicators, the *Operative Maintenance* department has a strong interest in streamlining various functions, as it affects the total cost of maintenance, which in turn is a significant expense item for the company. If maintenance is not efficient, indirect side effects are not only reflected in a decline in productivity but are also reflected in the reliability of the equipment.

For the above reasons, the following additional KPIs are proposed:

- *M5 Preventive maintenance on time [%]*
- *M6 OEE [%]*
    - *M6.1 OEE-Quality [%]*
    - *M6.2 OEE-Usability [%]*
    - *M6.3 OEE-Speed [%]*
        - *M6.3.1 Actual manufacturing speed [pcs per h]*
        - *M6.3.2 Theoretical maximum manufacturing speed [pcs per h]*
- *M7 The share of maintenance and technology development in total business costs [%]*
    - *M7.1 Maintenance and technology development costs [M€]*

Preventive maintenance on time is a good indicator of the consistency of maintenance activities. When preventive maintenance is performed on time, faults are reduced and the overall reliability of the equipment can be kept at the same level in the long run. If, on the other hand, the trend of timely preventive maintenance declines, there is either a lack of resources for maintenance or the production lines are constantly overloaded.

OEE is very useful for monitoring the efficiency of production lines and comparing them with each other. If there is a downward trend in the OEE, the next step is to look at the development of the ratios of its components, which can then be used to decide on the actual corrective action. When monitoring OEE, it should be noted that if the target is achieved too easily or seems impossible to achieve, the components may be miscalculated. For example, the speed reference values must be strictly based on the production speed definitions approved at the time of commissioning of each production line. Otherwise, the value is an estimate that is not based on facts.

In addition to *Operative Maintenance*, OEE is also a useful tool for production shift managers. Prior to the introduction of comprehensive information systems, shift managers have manually recorded the development of cycle times, waste, and machine uptime to determine production equipment performance. OEE simplifies this process by combining quality, speed, and usability factors into a single indicator for each production line. In addition, the OEE indicators can be multiplied, for example, to create a general index of the production efficiency of the entire plant. This may not be very significant within a plant, but is very beneficial to the business management, especially if the business involves several plants.

As with quality assurance and production, it would also be useful to measure the share of maintenance and technology development in total business costs. The rationale for using the KPI is also the same. The total annual cost of maintenance and technology investment proposals is, of course, communicated to the business management in the context of annual planning, but a separate regularly updated indicator would significantly clarify communication.

Below are examples of formulas for calculating KPIs *M5* to *M7*:

$$M5 = \frac{Preventive\ maintenance\ work\ orders\ on\ time\ [pcs]}{Preventive\ maintenance\ work\ orders\ [pcs]}$$

$$M6 = (M6.1 * M6.2 * M6.3)[\%]$$

$$M6.1 = \frac{(Manufactured\ products - \ Discarded\ products)\ [pcs]}{Manufactured\ products\ [pcs]}$$

$$M6.2 = \frac{Production\ line\ uptime\ [h]}{Production\ line\ load\ time\ [h]}$$

$$M6.3 = \frac{M6.3.1\ [pcs\ per\ h]}{M6.3.2\ [pcs\ per\ h]}$$

$$M6.3.1 = \frac{Manufactured\ products\ [pcs]}{Working\ hours\ [h] * \ M7.2[\%]}$$

$$M6.3.2 = \frac{Maximum\ production\ volume\ [pcs]}{Working\ hours\ [h]}$$

$$M7 = \frac{M7.1\ [M€]}{Total\ business\ costs\ [M€]}$$

$$\begin{aligned} M7.1 &= Sum\ of\ maintenance\ and\ technology\ development\ costs[M€] \\ &= (Information\ systems + Spare\ parts + Office + Payroll \\ &+ Repairs + Tools + Property\ costs \\ &+ Third\ party\ service\ contracts)[M€] \end{aligned}$$

The data used to calculate the above KPIs are available from the following sources:

- CMMS → Maintenance work orders (*M5*) and Spare parts (*M7.1*)
- MTS → OEE (*M6*)
- Production line documentation → Maximum production volume (*M6.3.2*, estimate)
- Financial management → Total business costs (*M7*)
- HRMS → Payroll (*M7.1*)
- Invoices → Information systems, Repairs, Tools, and Third-party service contracts (*M7.1*)
- Property bills → Office and Property costs (*M7.1*)

4.2 Exploring the general relevance of the found indicators

In addition to the rationale for the potential benefits and uses of all the proposed KPIs, their general relevance to the industry should also be taken into account. The reason for this is that generally accepted solutions are most likely to be the simplest and most efficient. The general relevance is explored through thematic analysis. The analysis is assessed by reviewing the prevalence of each proposed KPI in different publications on manufacturing KPIs. Frequently occurring KPIs can be considered as generally relevant themes in the measurement of the manufacturing industry. Similarly, rarer KPIs may be considered less relevant.

The review consisted of 30 different publications. The sources included, but were not limited to, books and scientific articles. Non-peer-reviewed online publications from different organizations were also used, as they provided alternative perspectives on KPI measurement and naming practices. The occurrence of each KPI in the source material was recorded and divided into the following categories:

a) the KPI is promoted clearly
b) the KPI is vaguely or partially presented
c) the KPI is mentioned in some form

The last category indicates the total occurrence, as it includes both clearly and vaguely presented KPIs. The occurrence is interpreted on the assumption that the clearer and more frequent the KPI, the more relevant it is considered at the general level. Vaguely or partially presented KPIs were separated into their own category because these measurable items can be considered relevant as a general theme in the manufacturing industry, but the method of measurement or calculation varies. Due to the variability, it was also worth examining whether the proposed measurement methods were appropriate.

The results of the general relevance assessment and references to publications are detailed in Table 2, Table 3, and Table 4.

Table 2: *Results of the general relevance assessment 1/3*

KPI	REFERENCES TO THE PUBLICATIONS									
	[2]	[3]	[8]	[10]	[19]	[26]	[30]	[31]	[32]	[35]
Q1	occurs									
Q2										
Q3					13	p. 14*				
Q4										p. 554
Q5								28*		p. 554*
Q6										
Q7					14*					
Q8					14*					
Q9			occurs*							
Q19			occurs*					24*	occurs*	
Q11			occurs*					24*	occurs*	
Q12										
P1				occurs*	20, 21*	p. 14*				p. 554*
P2								10		
P3		p. 25								
P4		p. 25				p. 13				
P5	occurs			occurs	15	p. 13		21		p. 554*
P6										
P7		p. 25			4			4		
P8				occurs*				27		p. 556*
M1				occurs						
M2	occurs			occurs*						p. 556
M3	occurs	p. 25		occurs*	13	p. 14		30		
M4				occurs*				26		
M5							occurs			
M6	occurs	p. 25	occurs*	occurs	3		occurs	16		
M7										

Note: ** The KPI is vaguely or partially presented*

Table 3: *Results of the general relevance assessment 2/3*

KPI	REFERENCES TO THE PUBLICATIONS									
	[36]	[38]	[39]	[41]	[42]	[45]	[47]	[48]	[51]	[52]
Q1		p. 25286	TE21		p. 451	occurs			occurs*	
Q2		p. 25286*	TE23		p. 451	occurs				
Q3			TE17	p. 1786	p. 445					
Q4			EN23*		p. 445					
Q5			EN37	p. 1786	p. 445*					
Q6			EN35*							
Q7		p. 25287							occurs*	
Q8		p. 25287							occurs*	
Q9		p. 25286							occurs	
Q19										
Q11										
Q12										occurs*
P1	p. 6339*		TE53*		p. 523*					occurs*
P2					p. 278					occurs
P3										
P4			TE46		p. 470					occurs
P5			TE2*		p. 467		occurs			
P6			TE3*				occurs			
P7			TE45	p. 1787*	p. 470*		occurs			occurs
P8										occurs*
M1			TE51		p. 332					occurs
M2	p. 6340		TE54				occurs*			
M3	p. 6337		TE27		p. 459*	occurs*	occurs*			
M4			TE32*							
M5			TE81*						occurs	
M6	p. 6342		TE71	p. 1787	p. 445		occurs	p. 159		
M7				p. 1787						occurs*

Note: ** The KPI is vaguely or partially presented*

Table 4: *Results of the general relevance assessment 3/3*

KPI	**REFERENCES TO THE PUBLICATIONS**									
	[54]	[55]	[56]	[57]	[58]	[60]	[61]	[62]	[71]	[72]
Q1						p. 622*	p. 207*	p. 3*		
Q2							p. 207*	p. 3*		
Q3				O1.3.1.3*						
Q4										
Q5									EC	
Q6										
Q7			O6.2.1.3*		H1.2.2*			p. 3		
Q8			O6.2.1.3*		H1.2.2*			p. 3		
Q9							p. 207*			
Q19										
Q11										
Q12		F1.2.0.1*								
P1										
P2		F1.3.1.1		L2.1.5.1		p. 622				
P3										
P4										
P5			O7.1.3.1		O7.1.3.1	p. 622				
P6			O6.3.1.1							
P7		F1.4.1.2								p. 85
P8		F1.2.0.1*								
M1				I1.1.1.2						
M2	p. 683									
M3	p. 686			O1.2.3.2*					SR	p. 85
M4										
M5										p. 85*
M6	p. 683			O1.2.2.3		p. 622				p. 85
M7		F1.2.0.1*		O9.2.1.2*						

Note: ** The KPI is vaguely or partially presented*

The results presented above are summarized in Table 5.

Table 5: *Summary of the results of the general relevance assessment*

The number of publications reviewed where…

KPI	a) the KPI is promoted clearly	b) the KPI is vaguely or partially presented	c) the KPI is mentioned in some form (=Total occurrence)
Q1	5	4	9
Q2	3	3	6
Q3	4	2	6
Q4	2	1	3
Q5	3	3	6
Q6	0	1	1
Q7	2	4	6
Q8	2	4	6
Q9	2	2	4
Q10	0	3	3
Q11	0	3	3
Q12	0	2	2
P1	0	8	8
P2	6	0	6
P3	1	0	1
P4	5	0	5
P5	10	2	12
P6	2	1	3
P7	8	2	10
P8	1	4	5
M1	4	0	4
M2	5	2	7
M3	10	5	15
M4	1	2	3
M5	2	2	4
M6	16	1	17
M7	1	3	4

Based on the results of the assessment, the most generally relevant KPIs are:

- *M6 OEE [%]*, total occurrence of 17
- *M3 Scrap rate of production lines [%]*, total occurrence of 15
- *P5 Deliveries on time [%]*, total occurrence of 12
- *P7 Inventory turnover [%]*, total occurrence of 10
- *P1 Labor efficiency [pcs per h]*, total occurrence of 8
- *Q1 Complaints in relation to the products delivered [% or ppm]*, total occurrence of 9

Of the above KPIs, *M6* and *P7* are not yet in use in the *Operative Maintenance* and *Production* departments. Thus, there is a strong reason for their introduction on this basis alone. Many of these generally relevant KPIs have already been established in some way in each department, which is a positive finding. As mentioned earlier, these indicators only need to be presented more clearly, for example in the form of a management report.

The assessment also shows that of the prominent KPIs, *P1*, *Q1* and *M3* occurred to a significant extent with different calculation or measurement techniques. Labor efficiency (*P1*) was mainly calculated by comparing the time spent by the employees at the workstation to the total working time. The reason for the difference in the calculation method is probably that such a rough labor efficiency indicator can be estimated much more simply. However, the proposed *P1* calculation method is a much more realistic measure, as it also takes into account labor productivity.

Next, the KPI for complaints (*Q1*) was mainly measured by calculating the total number of complaints. This difference is also likely due to the fact that pooling complaint cases is the easiest way to measure this problem. However, as in *P1*, the calculation method for *Q1* is better because it is scalable in relation to the volume of production. Otherwise, the increase in complaints due to the increase in production volumes can be interpreted as a problem, even though this is a normal phenomenon.

Finally, scrap ratios (*M3*) were generally shown as inverted. These KPIs were also often named differently, such as *First Time Through*. This difference is probably due to the fact that in manufacturing companies where defective products can be reprocessed, it is considered necessary to differentiate products that have passed directly through the production chain from scrap, as both scrap and reprocessed products are forms of loss in the lean mindset. However, as the *Customer Company* does not reprocess the discarded products, the calculation method and naming policy used for this KPI are fully valid for this purpose.

Although the other proposed KPIs do not appear to be generally relevant, each KPI was presented at least vaguely or partially, indicating that they are not completely unknown or useless indicators. In any case, KPIs do not have to be well known to be useful, as long as the need to use them is justified. The final decision to implement new KPIs should be made by assessing their underlying rationale and compatibility with the company's strategy.

4.3 Classification of the found indicators

In addition to general relevance factor, the proposed KPIs should also be classified on the basis of their interconnectivity in order to identify which of them are particularly relevant to the business strategy. Classification is necessary so that the data analysis is not limited to the department breakdown created by the company. Classification is done by placing KPIs in a hierarchy, mapping their interdependencies, and identifying clusters of related KPIs.

In this case, the classification used the same three-level hierarchy divided into operational, tactical, and strategic levels, as presented in Chapter 2.2.4 of the literature review. The problem with hierarchical breakdown is that not all KPIs necessarily belong to a certain level. KPIs *P1* and *M6* were difficult to place because OEE and labor efficiency are highly informative for those working at both the operational and tactical levels. As a compromise, these KPIs were placed between hierarchies. Once all KPIs were placed in the hierarchy, links were made between related indicators to represent interdependencies.

The KPI hierarchy is illustrated in Figure 6.

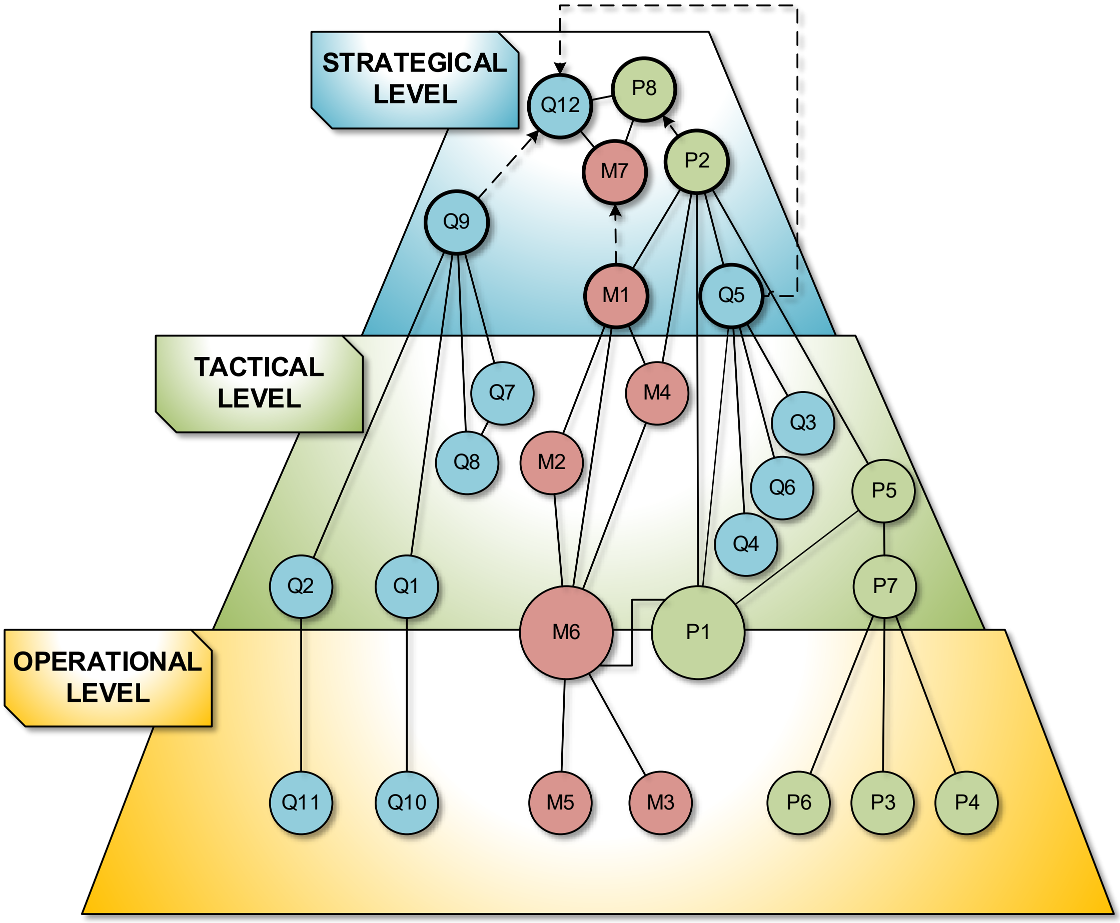

Figure 6: *Hierarchical classification of KPIs*

By looking at the links between each item in the hierarchy, the KPIs can be classified into clusters with different objectives. The review resulted in the following classes:

1) Compliance
2) Profitability
3) Finance

Class 1: Compliance

- Operational KPIs: *Q10* and *Q11*
- Tactical KPIs: *Q1*, *Q2*, *Q7*, and *Q8*
- Strategical KPIs: *Q9* and *Q12*

The KPIs in this class have the common goal of improving the QMS and ensuring that the company complies with the *ISO 13485:2016* standard, which is essential for a company manufacturing medical devices. *Q9* can be considered as the most important KPI in this class, as open CAPA processes reflect the significant ongoing work to maintain the QMS. In addition, customer complaints, internal deviations, internal audits, and external audits, as measured by other KPIs, are sources of new CAPA cases.

Class 2: Profitability

The second class consists of three subgroups: development, efficiency, and sustainability. The highest KPI in this class is *P2*, to which each subgroup is clearly linked.

Subgroup 2.1: Development

- Operational KPIs: *M3* and *M5*
- Tactical KPIs: *M2*, *M4*, and *M6*
- Strategical KPIs: *M1*

The KPIs in this subgroup relate to the development and maintenance of the technologies that enable business growth. The purpose of each KPI is to steer decision-making in a direction that maximizes the benefits of the production technology invested. The most important KPI is *M1,* as the profitability of each investment is the summary of all other profitability-related factors.

Subgroup 2.2: Efficiency

- Operational KPIs: *P3*, *P4*, and *P6*
- Tactical KPIs: *P1*, *P5*, and *P7*
- Strategical KPIs: *P2*

The KPIs in this subgroup relate to continuous improvement and reliability of the manufacturing processes. The most important KPI, *P2*, which is the same as for the whole

Class 2, clearly crystallizes the effects of both efficiency and reliability into a single indicator.

Subgroup 2.3: Sustainability

- Tactical KPIs: *Q3*, *Q4*, and *Q6*
- Strategical KPIs: *Q5*

The KPIs in this subgroup relate to energy-efficient and environmentally friendly manufacturing. The most important KPI is *Q5*, as energy efficiency shows the direction of sustainable development with one indicator.

Class 3: Finance

- Strategical KPIs: *M7*, *P8*, and *Q14*

The KPIs in this class show the weight of each department in the company's costs. By monitoring department-specific cost and performance indicators, it is easier for the business management to make decisions about how much resources should be allocated to each item. Based on the hierarchies and logical classes presented above, a comparison of cost and performance could be made as follows:

- Quality assurance: Compare *Q5* and *Q9* to *Q12.1*
- Production: Compare *P2* to *P8.1*
- Maintenance and technology development: Compare *M1* to *M7.1*

Because these KPIs use different units, they should first be converted to ratios to allow comparison. In other words, new types of KPIs should be derived for management, showing comparisons as individual numerical values for each activity relevant to improving production efficiency. An easy way to do this, for example, on an annual basis, is to divide the last year's value by the previous year's value. The new derived KPIs presented below apply the same referencing technique as all other previously presented KPIs.

- *Q13 Quality assurance performance index [% or no unit]*
    - *Q12.1 Quality assurance costs [M€]*
        - *Q12.1.1 Quality management system costs [M€]*
        - *Q12.1.2 Environmental management system costs [M€]*
- *P9 Production performance index [% or no unit]*
    - *P8.1 Production costs [M€]*
- *M8 Maintenance and technology development performance index [% or no unit]*
    - *M7.1 Maintenance and technology development costs [M€]*

Note that these indices may be expressed as percentages or in non-unit numbers, whichever is more convenient to the users. A closer look at the new KPIs also shows that the only one that is straightforward to calculate is *P9*. The problem with *Q13* is that *Q5* and *Q9* are not equally important, which can distort the ratio. As such, the use of this KPI may result in misinterpretation by the business management if its factors *Q5* and *Q9* are not reviewed separately. As a correction, the costs of quality assurance should also be clearly divided between the QMS (*Q9*) and the environmental system (*Q5*). *M9* is otherwise straightforward, but the profits on each investment have to be added together, which is laborious. If some investments are ignored, for example because they seem insignificant on a large scale, the same logic will have to be followed next year, and so on, which is challenging in a changing work environment. Otherwise, this KPI is also prone to misinterpretation during decision-making and would require a thorough review of all investments each time.

Including the considerations outlined above, here are example formulas for calculating the derived KPIs:

$$Q13 = \frac{\frac{Q9\ of\ the\ current\ year\ [\%]}{Q9\ of\ the\ last\ year\ [\%]}}{\frac{Q12.1.1\ of\ the\ current\ year\ [M€]}{Q12.1.1\ of\ the\ last\ year\ [M€]}} * \frac{\frac{Q5\ of\ the\ current\ year\ [\text{MWh per Mg}]}{Q5\ of\ the\ last\ year\ [\text{MWh per Mg}]}}{\frac{Q12.1.2\ of\ the\ current\ year\ [M€]}{Q12.1.2\ of\ the\ last\ year\ [M€]}}$$

$$P9 = \frac{\frac{P2\ of\ the\ current\ year\ [M€]}{P2\ of\ the\ last\ year\ [M€]}}{\frac{P8.1\ of\ the\ current\ year\ [M€]}{P8.1\ of\ the\ last\ year\ [M€]}}$$

$$M9 = \frac{\frac{Sum\ of\ all\ M1\ of\ the\ current\ year\ [M€]}{Sum\ of\ all\ M1\ of\ the\ last\ year\ [M€]}}{\frac{M7.1\ of\ the\ current\ year\ [M€]}{M7.1\ of\ the\ last\ year\ [M€]}}$$

Because the above KPIs are derivates, no new data sources are needed.

4.4 Opportunities for automated reporting

Correlation analysis is again used to explore the opportunities for automated KPI reporting. Automated KPI reports are potentially very useful for businesses because automatically updated indicators are always available in real time. In addition, the working time spent by employees collecting and processing data is available for other purposes. Thus, automated reporting makes the use of KPIs as practical as possible.

Based on Chapters 2.3 and 0 of the literature review, automated reporting requires that the underlying data on KPIs is available in tabular form, preferably in a relational database. The underlying data must also be centralized from all sources into a single multidimensional data warehouse, where it can be processed as needed to create readily available KPIs. After data warehousing, the repository can be configured to automatically update the latest data from all sources on a regular basis using ETL. During data warehousing, it is important to verify the purpose, identity, and reliability of the data that ends up in the data warehouse. Otherwise, significant data will be lost to the database over time due to system changes or staff turnover. Once the required KPI data is centralized in a multidimensional database, it can be used to create various dashboards with visualizations that update automatically. In addition, each dashboard can be filtered based on common factors between indicators or scaled to different time intervals to show underlying interdependences that may not be self-evident.

Because all MISs used in the *Customer Company* are based on relational databases, as observed in Chapter 3.2, all data obtained directly from these systems can be reported automatically through a data warehouse.

All discovered KPIs, their data sources, and compatibility with data warehousing are illustrated in Figure 7.

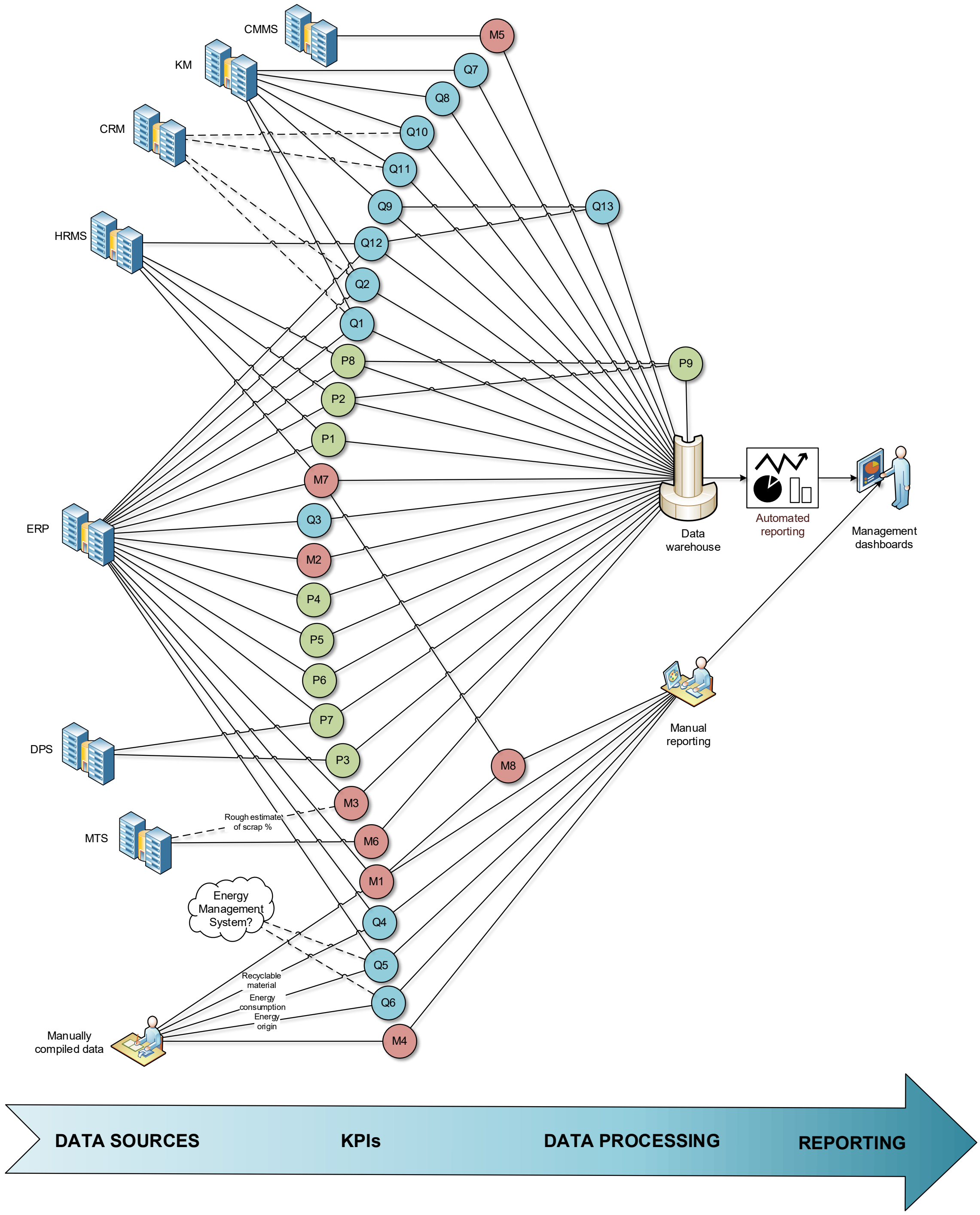

Figure 7: *Opportunities for automated reporting*

As can be seen from the figure above, most KPIs can be calculated directly from the data available in relational databases. A total of 24 indicators can be used as such for automated reporting. The remaining six indicators are not currently suitable for automation because they use manually compiled data sources. Of these indicators, *Q4*, *Q5* and *Q6* relate to sustainability and indicators *M1*, *M4* and *M8* relate to the return on technological investments. As these are strategically important issues for the *Customer Company*, it may be appropriate to consider acquiring information systems to manage this data.

While the framework for automated reporting is promising, its practical implementation requires a lot of work. Superficially, the most attractive option seems to be to consult database experts and system vendors in the implementation of the data warehouse. However, if all work is outsourced, the result will be at most mediocre and may hinder further development, as database experts do not have an in-depth view of what makes information systems practical for end users and useful for business strategy. It is very important for the success of the data warehouse that the *Customer Company* has at least some employees with basic database skills. The reason for this is that in addition to all the knowledge of information systems and business strategy, it is much easier to teach the basics of SQL queries and database structures to your own employees than to explain the highly customized strategic objectives of the information systems to system experts. Basic in-house database skills also make functional testing more flexible during data warehouse design and implementation. Finally, it is also worth noting that the users of the systems may also come up with ideas for further development of the data warehouse, which would otherwise be easily overlooked at a higher level.

5. RESULTS

As the literature review, observation, and data analysis have been completed, the results of the study are ready to be presented. The research questions and corresponding results are summarized in Table 6.

Table 6: *Summary of the research results*

RESEARCH QUESTION		RESULTS
1	Which of the company's functions are significant for improving production processes?	The study found that the most important functions of the *Customer Company* in improving production processes are quality assurance, production, and maintenance and technology development.
2	What important indicators are available for the significant functions?	A total of 30 important indicators were discovered. Six of these indicators were emphasized in terms of general relevance and ten in terms of business strategy.
3	Which important indicators can be reported automatically?	24 of the discovered important indicators were found to be suitable for automated reporting.

Further details on the results are presented in Table 7 on the next page. The identifiers of the 30 important indicators correspond to the activities presented in the results of research question 1. Indicators *Q1* to *Q13* are for quality assurance, *P1* to *P9* for production, and *M1* to *M8* for maintenance and technology development. The indicators that were found to have emphasis in terms of general relevance and business strategy in the results of research question 2 are marked in the corresponding columns. Same goes for the indicators which were found to be suitable for automated reporting in the results of research question 3. The table also shows the title and unit of measure for each indicator.

Table 7: *Summary of the important indicators found*

ID	TITLE OF THE IMPORTANT INDICATOR	UNIT OF MEASURE	EMPHASIZED GENERAL RELEVANCE	EMPHASIZED STRATEGIC RELEVANCE	SUITABLE FOR AUTOMATED REPORTING
Q1	*Complaints in relation to the products delivered*	*% or ppm*	X		X
Q2	*Internal nonconformities in relation to the products manufactured*	*% or ppm*			X
Q3	*The share of waste in the total material used in manufacture*	*%*			X
Q4	*The share of recyclable material in the waste*	*%*			
Q5	*Energy efficiency*	*MWh per Mg*		X	
Q6	*The share of renewable energy in total energy used*	*%*			
Q7	*The number of external audit deviations*	*pcs*			X
Q8	*The number of internal audit deviations*	*pcs*			X
Q9	*Resolved CAPA cases in relation to all cases*	*%*		X	X
Q10	*Complaints handled on time*	*%*			X
Q11	*Internal nonconformities handled on time*	*%*			X
Q12	*The share of quality assurance in total business costs*	*%*		X	X
Q13	*Quality assurance performance index*	*% or no unit*		X	X
P1	*Labor efficiency*	*pcs per h*	X		X
P2	*Production profit*	*M€*		X	X
P3	*Sales forecast*	*pcs per m*			X
P4	*Warehouse levels*	*pcs per m*			X
P5	*Deliveries on time*	*%*	X		X
P6	*Supplies delivered on time*	*%*			X
P7	*Inventory turnover*	*%*	X		X
P8	*The share of production in total business costs*	*%*		X	X
P9	*Production performance index*	*% or no unit*		X	X
M1	*Net profit or loss on investment*	*k€ or M€*		X	
M2	*Yield of production lines*	*pcs per h*			X
M3	*Scrap rate of production lines*	*%*	X		X
M4	*Hourly rate of production lines*	*€ per h*			
M5	*Preventive maintenance on time*	*%*			X
M6	*OEE*	*%*	X		X
M7	*The share of maintenance and technology development in total business costs*	*%*		X	X
M8	*Maintenance and technology development performance index*	*% or no unit*		X	

6. REFLECTIONS

Importance of the study

The significance of quality assurance, production, and maintenance and technology development in improving production processes is justified, as these functions play the most important roles in minimizing losses and product variations in production, as observed in Chapter 3.1. Elimination of losses and product variations are key principles for economical manufacturing, as stated in Chapters 0 and 2.2.2 of the literature review.

The resulting set of 30 indicators is a comprehensive sample, if not too large for a company of this size to improve production. On the other hand, a wide range of indicators offers choice for department heads. Although there are many indicators, it should also be noted that the *Customer Company* has previous experience in KPI measurement and the framework for automated reporting is excellent, as demonstrated by correlation analysis in Chapter 0. This argues that most, if not all, of the indicators can be deployed. Of course, if all indicators are to be used, there is a small risk that the measurement will not be carried out properly due to resistance to change or obscured objectives, as warned in Chapter 2.2.4 of the literature review.

The practicality of the resulting important indicators, which was presented as one of the *Customer Company's* requirements in Chapter 1, is supported by the wide applicability of automated reporting. If the indicators are implemented as automatically updated dashboards for each target group, their use is as practical as possible. In this context, it is also important to note that the implementation of the data warehouse required for automation still requires a lot of specification work. The introduction of automated reporting should therefore be considered as a future investment.

Reliability of the results

The reliability of the results can be assessed on the basis of the research methods, the data sources used, and the partial results produced by the data analysis. All research methods used are known and well-established practices, and their principles are presented in Chapter 2.1 of the literature review. Most of the literary sources used were published books and peer-reviewed scientific articles, which are generally considered to be sources of information. The use of other literature sources was justified in Chapter 4.2. The accuracy of the observations on production processes and information systems was verified with the *Customer Company* prior to reporting, although this is not separately documented in Chapters 3.

The reliability of the indicators found is primarily supported by the findings on the applied security measures as observed in Chapter 3.2.1. In addition, the information systems used as data sources for the important indicators are widely validated, which is a good way to ensure the accuracy of the data, as stated in Chapter 2.2.3 of the literature review. However, it is important to note that indicators *P3*, *P7*, *M5* and *M6*, which use data sources from unvalidated information systems, are only suitable for rough indicators until the systems have been validated.

In terms of partial results, considerable support for reliability was found through the thematic analysis in Chapter 4.2 and the classification in Chapter 4.3. The results of the thematic analysis suggest that all the indicators found are somewhat relevant in general and some even clearly relevant. As another positive finding, classification reveals that the indicators are roughly evenly distributed across the hierarchical levels of the *Customer Company* and no level has been disregarded. This is an indication that the overall range of important indicators fits well with the company's organizational model.

Reproducibility and generalizability

Based on the overall findings of this report, the research process is very likely reproducible under similar conditions. The study is also likely applicable to other activities of the *Customer Company* or to other companies in different industries. However, obtaining accurate results requires a thorough study of the basic theory of the relevant topics and observation of the client's processes and practices. Otherwise, the conclusions will not be based on factual information. In addition, the thematic analysis should use a sufficient variety and number of sources to avoid misunderstanding the general relevance of the indicators. In this case, finding quality sources is certainly challenging, as the articles published online are constantly changing and there seems to be little scientific literature on the subject. In addition to literature sources, it could be useful to extend data collection methods to gathering first-hand information directly from various companies in the field through surveys and interviews. The research could also be expanded, for example, by further clarifying the example calculation formulas or by delving into the practical implementation of automated reporting in the context of data warehousing and KPI dashboards.

Follow-up

The *Customer Company* found the study useful and eye-opening, as there has been no previous scientific research on this topic in the company. Scientific research proved to be particularly useful in the sense that the rationale for the results generated through various data sources and data analysis is solid and non-opinion based. Measurement is a topical issue and related, albeit independent of this work, parallel projects are already underway in the company. Following the publication of the study, measures will be taken to communicate the findings within the company so that the report is not overlooked and forgotten in the archives. After this, the results of the study will be taken into account in the development of the company's strategy and day-to-day operations. Future projects for the company will most certainly be data warehousing and increasing the integration between existing information systems.

New information systems are also likely to be acquired, as all information relevant to the company should always be reliably stored and easily accessible. Because the energy and investment data are so important, but manually managed, they are probably the first new projects. Investment information is used purely within the organization and its management in an information system would improve transparency and fact-based decision making. Energy management system, on the other hand, would also provide information on sustainable development to significant third parties, such as notified bodies. Sustainability is a very important topic today and it is increasingly required to be demonstrated in order to enter certain markets.

As a final remark, the research also proved thought-provoking, and opened up new perspectives on leadership in the *Customer Company*. Major improvements in this field used to be achievable with little effort, and by feel and experience, but now that the products and processes have matured, opportunities for improvement are scarce and demanding. Most importantly, management has shifted towards leadership with concrete knowledge. Big leaps are, of course still possible in the company, but their preconditions have shifted more to product development and search for new markets.

7. SUMMARY

This thesis presented a study, which had the purpose of finding out how the production processes of the *Customer Company* could be improved by measuring. Unambiguity, usefulness, and ease of use were important features of the indicators for the company. These goals were answered with the following research questions: which of the company's functions are significant for improving production processes, what important indicators are available for the significant functions, and which important indicators can be reported automatically.

The research material was compiled by literature review and observation. The literature review presented background theory of research methods, economical manufacturing, management information systems, and databases. Information on the company's production processes, information systems and the indicators in use was collected through observation.

The research material was analyzed by correlation analysis, thematic analysis, and classification. Correlation analysis was used to determine which departments and functions are relevant for improving production processes. Correlation analysis was also used to find causal links between existing indicators and their benefits in order to find new indicators for the company and automation opportunities for reporting the indicators. Thematic analysis examined the relevance of all the indicators found at a general level. Finally, Classification was used to examine the relevance of the indicators to the company's strategy.

The study found that the company's most significant functions in improving production processes are quality assurance, production, and maintenance and technology development. A total of 30 important indicators were discovered, of which 24 were found to be suitable for automated reporting. The resulting indicators were found to be reliable at three different levels: the reliability of the data sources, the general relevance, and the relevance to the company's strategy. Six of the indicators found were highlighted in terms of general relevance and ten in terms of business strategy.

The research process was carried out in accordance with the research plan presented at the beginning of the thesis. Importance, overall reliability, reproducibility, generalizability and follow-up of the study were assessed in the reflections. Based on the research plan, results and reflections, the objectives set for the research were achieved at the expected and required level.

REFERENCES

[1] M. Al-Ibrahim, Y. Al-Deen, The Reality of Applying Security in Web Applications in Academia, International Journal of Advanced Computer Science and Applications, Vol.5(10), October 2014, p.7-15. Available at: https://doi.org/10.14569/IJACSA.2014.051002

[2] L. Andrews, TOP 12 Manufacturing KPIs to Track Operational Excellence, February 2019. Available at (referenced 2.2.2022): https://www.sensrtrx.com/top-manufacturing-kpis/

[3] G. Ante, F. Facchini, G. Mossa, S. Digiesi, Developing a key performance indicators tree for lean and smart production systems, IFAC-PapersOnLine, Vol.51(11), September 2018, p.13-18. Available at: https://doi.org/10.1016/j.ifacol.2018.08.227

[4] D. Bailey, E. Wright, Practical SCADA for industry, 2003, 298 p. ISBN: 1281222666

[5] J. Bush, Learn SQL Database Programming, 2020, 566 p. ISBN: 1838984763

[6] S. Cavalieri, F. Chiacchio, Analysis of OPC UA performances, Computer Standards & Interfaces, Vol.36(1), November 2013, p.165-177. Available at: https://doi.org/10.1016/j.csi.2013.06.004

[7] O. Chikwendu, A. Chima, Overall Equipment Effectiveness and the Six Big Losses in Total Productive Maintenance, Journal of Scientific and Engineering Research, Vol.5(4), April 2018, p.156-164. Available at: https://www.researchgate.net/publication/327645721_Overall_Equipment_Effectiveness_and_the_Six_Big_Losses_in_Total_Productive_Maintenance

[8] L. Columbus, A. Parise, Top 5 Quality Management Metrics In Medical Devices, web page, May 2018. Available at (referenced 2.2.2022): https://www.manufacturing.net/operations/article/13122624/top-5-quality-management-metrics-in-medical-devices

[9] J. Dagle, Supervisory Control and Data Acquisition (SCADA) Introduction, Pacific Northwest National Laboratory, September 2005, 97 p. Available at (referenced 2.2.2022): http://www.science.smith.edu/~jcardell/Readings/TRUST%20US/2005_09_15_Jeff_Dagle

[10] Datapine, Manufacturing Key Performance Indicators and Metrics, web page. Available at (referenced 2.2.2022): https://www.datapine.com/kpi-examples-and-templates/manufacturing

[11] Delfoi Oy, Accrol Group Holdings plc, New strategy and growth required sophisticated planning solutions, web page, November 2020. Available at (referenced 2.2.2022): https://www.delfoi.com/references/planner-references/new-strategy-and-growth-required-sophisticated-planning-solutions/

[12] A. Dellinger, N. Leech, Toward a Unified Validation Framework in Mixed Methods Research, Journal of Mixed Methods Research, Vol.1(4), October 2007, p.309-332. Available at: https://doi.org/10.1177/1558689807306147

[13] P. Dobra, J. János, OEE measurement at the automotive semi-automatic assembly lines, Acta Technicata Jaurinensis, Vol.14(1), February 2021, p.24-35. Available at: https://doi.org/10.14513/actatechjaur.00576

[14] G. Dong, Exploiting the Power of Group Differences: Using Patterns to Solve Data Analysis Problems, February 2019, 95 p. Available at: https://doi.org/10.2200/S00897ED1V01Y201901DMK016

[15] M. Elmonem, E. Nasr, M. Geith, Benefits and challenges of cloud ERP systems – A systematic literature review, Future Computing and Informatics Journal, Vol.1(1-2), December 2016, p.1-9. Available at: https://doi.org/10.1016/j.fcij.2017.03.003

[16] A. Fathallah, J. Cardinal, J. Ermine, J. Bocquet, Enterprise modelling: Building a product lifecycle management model as a component of the integrated vision of the enterprise, International Journal on Interactive Design and Manufacturing Vol.4(3), August 2010, p.201-209. Available at: https://doi.org/10.1007/s12008-010-0098-0

[17] N. Fatima, A Quick Overview of Different Types of Databases, web page, November 2020. Available at (referenced 2.2.2022): https://www.astera.com/type/blog/a-quick-overview-of-different-types-of-databases/

[18] E. Ferrari, Access Control in Data Management Systems, Synthesis Lectures on Data Management, 2010, 117 p. Available at: https://doi.org/10.2200/S00281ED1V01Y201005DTM004

[19] A. Gehringer, 21 Manufacturing KPIs and Metrics Updated for 2021 to Improve Production KPI Performance, web page, December 2020. Available at (referenced 2.2.2022): https://www.rhythmsystems.com/blog/21-production-kpi-examples-to-improve-manufacturing-performance

[20] M. George, The Lean Six Sigma Guide to Doing More with Less, February 2010, 352 p. ISBN: 9780470539576

[21] J. Harrington, Relational Database Design and Implementation, 2009, 441 p. ISBN: 9780080885018

[22] Y. He, P. Wu, Y. Wang, F. Tao, B. Hon, An OPC UA based framework for predicting energy consumption of machine tools, Procedia CIRP, Vol.90(1), 2020, p.568-572. Available at: https://doi.org/10.1016/j.procir.2020.02.133

[23] T. Hedberg, M. Helu, T. Sprock, A Standards and Technology Roadmap for Scalable Distributed Manufacturing Systems, International Manufacturing Science and Engineering Conference, June 2018, 9 p. Available at (referenced 2.2.2022): https://doi.org/10.1115/MSEC2018-6550

[24] A. Homay, C. Chrysoulas, B. El Boudani, M. de Sousa, M. Wollschlaeger, A security and authentication layer for SCADA/DCS applications, Microprocessors and Microsystems, unpublished research, November 2020, 8 p. Available at (referenced 2.2.2022): https://doi.org/10.1016/j.micpro.2020.103479

[25] H. Hvolby, K. Steger-Jenssen, Technical and industrial issues of Advanced Planning and Scheduling (APS) systems, Computers in Industry, Vol.61(9), December 2010, p.845-851. Available at: https://doi.org/10.1016/j.compind.2010.07.009

[26] G. Hwang, J. Han, T. Chang, An Integrated Key Performance Measurement for Manufacturing Operations Management, Sustainability, Vol.12(13), June 2020, 15 p. Available at: https://doi.org/10.3390/su12135260

[27] Idaho National Laboratory, Introduction SCADA Security for Managers and Operators, SANS SCADA Security Summit II, September 2006, 130 p. Available at (referenced 2.2.2022): https://www.energy.gov/oe/downloads/introduction-scada-security-managers-and-operators

[28] V. Igure, S. Laughter, R. Williams, Security issues in SCADA networks, Computers & security, Vol.25(7), 2006, p.498-506. Available at: https://doi.org/10.1016/j.cose.2006.03.001

[29] O. Ikumapayi, E. Akinlabi, F. Mwema, O. Ogbonna, Six sigma versus lean manufacturing – An overview, materialstoday: Proceedings, Vol.26(2), 2020, p.3275-3281. Available at: https://doi.org/10.1016/j.matpr.2020.02.986

[30] Infraspeak, Maintenance Indicators: The KPIs for Efficient Management, web page. Available at (referenced 2.2.2022): https://blog.infraspeak.com/maintenance-indicators-kpis/

[31] Insightsoftware, 30 Best Manufacturing KPIs & Metrics for 2021 Reporting, web page, January 2021. Available at (referenced 2.2.2022): https://insightsoftware.com/blog/30-manufacturing-kpis-and-metric-examples/

[32] Institute for Medical Device Compliance & Regulations, How to monitor and measure products and processes in ISO 13485, web page, December 2019. Available at (referenced 24.4.2021): https://imdcr.com/how-to-monitor-and-measure-products-and-processes-in-iso-13485/

[33] M. Jasiulewicz-Kaczmarek, M. Piechowski, P. Szafer, Improvement Maintenance Processes through CMMS System-Case study, Advances in Economics, Business and Management Research, Vol.31, January 2017, p.195-200. Available at: https://doi.org/10.2991/msmi-17.2017.43

[34] C. Jensen, T. Pedersen, C. Thomsen, Multidimensional Databases and Data Warehousing, Synthesis Lectures on Data Management, 2010, 111 p. Available at: https://doi.org/10.2200/S00299ED1V01Y201009DTM009

[35] V. Jovan, S. Zorzut, D. Gradišar, B. Dorneanu, Closed-loop production control of polymerization plant using production KPIs, IFAC Proceedings Volumes, Vol.40(18), September 2007, p.553-558. Available at: https://doi.org/10.3182/20070927-4-RO-3905.00092

[36] N. Kang, C. Zhao, J. Li, J. Horst, A Hierarchical structure of key performance indicators for operation management and continuous improvement in production systems, International Journal of Production Research, Vol.54(21), February 2016, p. 6333-6350. Available at: https://doi.org/10.1080/00207543.2015.1136082

[37] J. Kletti, Manufacturing Execution Systems — MES, 2007, 276 p. Available at: https://doi.org/10.1007/978-3-540-49744-8

[38] N. Kumar, Quality metrics and quality KPI of pharmaceutical industry, International Journal of Current Research, Vol.8(1), January 2016, p.25285-25288. Available at: https://www.researchgate.net/publication/308595216_QUALITY_METRICS_AND_QUALITY_KPI_OF_PHARMACEUTICAL_INDUSTRY

[39] M. Lanz, E. Järvenpää, H. Nylund, R. Tuokko, S. Torvinen, K. Georgoulias, Sustainability and Performance Indicators Landscape, International FAIM Conference, January 2014, 8 p. Available at: http://dx.doi.org/10.14809/faim.2014.0283

[40] Lean Enterprise Institute, A Brief History of Lean, web page, 2021. Available at (referenced 2.2.2022): https://www.lean.org/whatslean/history.cfm

[41] C. Lindberg, S. Tan, J. Yan, F. Starfelt, Key Performance Indicators Improve Industrial Performance, Energy Procedia, Vol.75(1), August 2015, p.1785-1790. Available at: https://doi.org/10.1016/j.egypro.2015.07.474

[42] B. Marr, Key Performance Indicators For Dummies, January 2015, 588 p. ISBN: 9781118913246

[43] S. Mathias, S. Schmied, D. Grossmann, An Investigation on Database Connections in OPC UA Applications, Procedia Computer Science, Vol.170(1), 2020, p.602-609. Available at: https://doi.org/10.1016/j.procs.2020.03.132

[44] M.I.A.C. Automation, Manufacturing Execution Systems (MES) Industrial 4.0, web page. Available at (referenced 2.2.2022): http://www.miac-automation.com/mes-oee-track-and-trace/

[45] G. Miglierini. The new FDA guidelines on Quality Metrics, web page, June 2017. Available at (referenced 2.2.2022): https://www.pharmaworldmagazine.com/new-fda-guidelines-quality-metrics/

[46] A. Moallim, J. Lee, D. Kim, Wireless control and monitoring using Programmable Logic Controller (PLC), International Conference on Control, Automation and Systems, October 2018, 5 p. Available at: https://doi.org/10.23919/ICCAS.2017.8204259

[47] MRPeasy, Top 10 Manufacturing KPIs in 2022, web page, November 2021. Available at (referenced 2.2.2022): https://manufacturing-software-blog.mrpeasy.com/manufacturing-performance-indicator/

[48] M. Oliveira, I. Lopes, C. Rodrigues, Use of maintenance performance indicators by companies of the industrial, Procedia CIRP, Vol.52, 20166, p.157-160. Available at: https://doi.org/10.1016/j.procir.2016.07.071

[49] H. Opatha, Human Resource Management, January 2009, 33 p. ISBN: 9789559588597. Available at: https://doi.org/10.31357/bkc.fmsc.00001

[50] C. Ptak, E. Schragenheim, Erp: Tools, Techniques, and Applications for Integrating the Supply Chain, Second Edition, 2004, 462 p. ISBN: 9781420056020

[51] QuontinuIm, KPIs for Optimal Quality Management, web page, March 2020. Available at (referenced 2.2.2022): https://www.quontinuim.com/en/blog/quality/kpis-for-optimal-quality-management

[52] Sensible Micro Corporation, 9 Key Medical Supply Chain KPIs For the Economic Recovery, web page, December 2020. Available at (referenced 2.2.2022): https://www.sensiblemicro.com/blog/9-key-medical-supply-chain-kpis

[53] E. Shehab, M. Sharp, L. Supramaniam, T. Spedding, Enterprise resource planning: An integrative review, Business Process Management Journal, Vol.10(4), August 2004, p.359-386. Available at: https://doi.org/10.1108/14637150410548056

[54] C. Siedler, P. Langlotz, J. Aurich, Modeling and assessing the effects of digital technologies on KPIs in manufacturing systems, Procedia CIRP, Vol.93, 2020, p.682-687. Available at: https://doi.org/10.1016/j.procir.2020.04.008

[55] B. Smith, Essential Financial KPIs, 2018, 58 p. ISBN: 9781910047132

[56] B. Smith, Essential Fulfillment and Warehouse KPIs, 2018, 77 p. ISBN: 9781910047231

[57] B. Smith, Essential Manufacturing KPIs, 2018, 136 p. ISBN: 9781910047071

[58] B. Smith, Essential Procurement KPIs, 2018, 66 p. ISBN: 9781910047279

[59] Z. Tari, I. Khalil, A. Almalawi, A. Fahad, A. Zomaya, A. Mahmood, C. Queiroz, Supervisory Control and Data Acquisition (SCADA): An Introduction, Wiley Encyclopedia of Electrical and Electronics Engineering, August 2016, 12 p. Available at: https://doi.org/10.1002/047134608X.W8319

[60] H. Tokola, C. Gröger, E. Järvenpää, E. Niemi, Designing Manufacturing Dashboards on the Basis of a Key Performance Indicator Survey, Procedia CIRP, Vol.57, 2016, p.619-624. Available at: https://doi.org/10.1016/j.procir.2016.11.107

[61] M. Torkko, N. Katajavuori, A. Linna, A. Juppo, Quality KPIs in Pharmaceutical and Food Industry, Journal of Pharmaceutical Innovation, Vol.8(4), December 2013, p.205-211. Available at: https://doi.org/10.1007/s12247-013-9159-9

[62] M. Torkko, N. Katajavuori, A. Linna, A. Juppo, The Utilization of Quality KPIs in the Pharmaceutical Industry, Journal of Pharmaceutical Innovation, Vol.9(3), September 2014, 8 p. Available at: https://doi.org/10.1007/s12247-014-9184-3

[63] W. Trochim, The Research Methods Knowledge Base, web page, April 2020. Available at (referenced 2.2.2022): https://conjointly.com/kb/

[64] University of Jyväskylä, Topics: Classification, Correlation Analysis, Data Analysis, Data Collection, Observations, Philosophy of Science, Research Process, Qualitative Analysis, Quantitative Analysis, Strategies, Thematic Analysis, web page. Available at (referenced 2.2.2022): https://koppa.jyu.fi/avoimet/hum/menetelmapolkuja/en/methodmap/data-analysis

[65] University of Jyväskylä, Data Collection, Total Research, Sampling and Purposive Sampling, Observation, web page. Available at (referenced 2.2.2022): https://koppa.jyu.fi/avoimet/hum/menetelmapolkuja/en/methodmap/data-collection/observations

[66] University of Jyväskylä, Literature review, web page. Available at (referenced 2.2.2022): https://koppa.jyu.fi/avoimet/kirjasto/en/library-tutorial/topic-and-search-terms/identify-key-concepts/literature-review

[67] V. Vlckova, M. Patak, Role of Demand Planning in Business Process Management, International Scientific Conference, May 2010, p. 1119-1126. Available at: https://www.researchgate.net/publication/228785945_Role_of_demand_planning_in_business_process_management

[68] N. Walliman, Research Methods: The Basics, November 2010, 208 p. Available at: https://doi.org/10.4324/9780203836071

[69] D. Weedmark, The History of Management Information Systems, web page, bizfluent, March 2019. Available at (referenced 2.2.2022): https://bizfluent.com/about-6706231-role-technology-crm.html

[70] M. White, Mastering Metrics and Key Performance Indicators (KPIs), web page, July 2020, Available at (referenced 2.2.2022): https://thebadoc.com/ba-techniques/f/mastering-metrics-and-key-performance-indicators-kpis

[71] L. Zhu, C. Johnsson, J. Mejvik, M. Varisco, M. Schiraldi, Key Performance Indicators for Manufacturing Operations Management in the Process Industry, IEEE International Conference on Industrial Engineering and Engineering, December 2017, 5 p. Available at: https://doi.org/10.1109/IEEM.2017.8290036

[72] L. Zhu, C. Johnsson, M. Varisco, M. Schiraldi, Key performance indicators for manufacturing operations management – gap analysis between process industrial needs and ISO 22400 standard, Procedia Manufacturing, Vol.25(1), July 2018, p.82-88. Available at: https://doi.org/10.1016/j.promfg.2018.06.060