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The adoption of e-Maintenance in a pharmaceutical company

A case study analyzing decision-making and the technological, organizational, and environmental factors affecting the adoption of e-Maintenance technologies.

Emil Hørlyck
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Nicklas Bruttin
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Character count: 177,537
Page count: 101

Submitted on
(13/09/2021)

Msc in Business Administration and E-Business - CBUSO2000E
Contract number: 18027 - Supervisor: Chee-wee tan

1 Abstract

Title: The adoption of e-Maintenance in a pharmaceutical company

Subtitle: A case study analyzing decision-making and the technological, organizational, and environmental factors affecting the adoption of e-Maintenance technologies.

Authors: Emil Hørlyck Akselsen & Nicklas Børglum Bruttin

Background: The pharmaceutical industry is experiencing an increasing amount of pressure through growing regulatory requirements and a governmental demand to lower drug prices. The time of the blockbuster business model era in which the pharmaceutical industries were able to demand high margins on their products is coming to an end, increasing the need to improve effectiveness in the production maintenance operations.

Purpose: This thesis aims to identify how and to what extent data is supporting the decision-making in maintenance operations to increase effectiveness. Additionally, this thesis sets out to determine the factors influencing the adoption of e-Maintenance.

Method: This thesis is an exploratory qualitative single-case study with a research philosophy of critical realism, based on semi structured interviews, unstructured team meetings, and site visits.

Findings & conclusion: Firstly, we found that the extent to which data was used in the decision-making process was limited to the steps of identifying and defining problems. Despite the limited application of data across the decision-making process, a world class effectiveness measured in OEE of 86.7% was still achieved using data in Lean improvement kata. Lastly the context specific factors affecting the adoption of e-Maintenance were identified as: (1) Compatibility, (2) Data exchange and Interoperability, (3) Data quality, (4) Perceived complexity, (5) Cost, (6) Management support, (7) Skills, (8) Government regulation, and (9) Competitive environment.

Keywords: e-Maintenance, Data-driven, Decision-making, Effectiveness, Preventive maintenance, Reactive maintenance, Industry 4.0, Maintenance, Pharma, Pharmaceutical, Adoption, Lean.

2 Introduction

For many decades the pharmaceutical industry has benefited from the development of blockbuster drugs and the patenting of intellectual property (Marques et al., 2020), giving them market exclusivity for years, entailing a significant source of cash flow (Berk et al., 2013; Friedli et al., 2010; Marques et al., 2020).
This era is often called the blockbuster era, due to the pharmaceutical industry having a “blockbuster business model”, where they would spend large amounts of money on R&D (research and development), hoping to create a successful blockbuster drug that would generate high returns. The norm was that the pharmaceutical companies had a few products with a high-profit margin and steadily increasing demand. The primary competition was within innovative product development, leading to a significant portion of the profit being reinvested in R&D (Marques et al., 2020).
The cost of creating medical treatments can reach up to 1 billion USD and takes around ten years to develop, on average. Usually, the patents for these drugs last for 20 years, thus allowing the companies a time of monopoly and an opportunity to sell the drugs exclusively at high prices, before the patent of the drug expires and generic drugs swamps the market and impacts sales negatively (Chen, 2020). Therefore, pharmaceutical companies historically needed to reinvest heavily in R&D to either develop new blockbuster drugs or create incremental enhancement to the existing product.

A consequence thereof was that the production operations were neglected in terms of optimization as it was considered to be a relatively small cost compared to the profit generated from the blockbuster drugs. The “blockbuster era” has lived on for an extended period of time, but an increasing number of external factors are now forcing a shift in the business model (Marques et al., 2020). Healthcare stakeholders’ traditional roles and dynamics have changed dramatically over the recent years (Champagne et al., 2015). Beforehand, the pharmaceutical companies were able to set their price tag without any complaints.

"It's a pricing model that only exists because of government protections that we granted the industry to ensure innovation. But now those laws are being used to shield drug makers from pricing their products responsibly" (Tyson, 2015)

According to the CEO of Kaiser Permanente, America's leading non-profit health plan provider, other industries have been shaken up and "done better for less", understanding that technology and productivity gains must benefit the consumer (Tyson, 2015). According to Tyson (2015) the pharmaceutical industry remains the only industry that has not done this yet, which their prices reflect. A recent study on general pharmaceutical challenges by Marques (2020), stated that the poor production effectiveness within the pharmaceutical industry is longer acceptable and that there is a need to create overall improvements within the industry. This finding is also supported by Friedli, Basu, Gronauer, and Werani (2010) who stated that pharmaceutical companies were entering an era that other industries reached decades ago, highlighting the need for change.

Understanding these industry-related historical and environmental factors is essential, as they have laid the foundation for the pharmaceutical industry's future. A future that, according to Friedli et al. (2010) is characterized by "*... cost-reduction initiatives from payer organizations, mostly driven by governmental pressure, shifting global growth, increased regulatory requirements and loss of market exclusivity for many of the late 20th century blockbuster drugs*".

Concurrently to the increasing pressure on the pharmaceutical world to lower drug prices and "doing better for less", the world has seen many technological advancements (Erol et al., 2016; Vaidya et al., 2018). These technological advancements are often referred to as the fourth industrial revolution or industry 4.0. A field where practitioners and researchers promise significant efficiency gains through the digital integration and intelligent manufacturing processes (Vaidya et al., 2018; Zhou, 2013). The general purpose of industry 4.0 is to promote the connection of physical items, including company assets, devices, and sensors, to each other and the internet (Sipsas et al., 2016).

The combination of the need for more efficient pharmaceutical manufacturing operations and the increase in advanced technologies has directed attention to the area of maintenance. The pressure on “doing better for less” makes maintenance an extremely relevant area to look into, as it has a crucial impact on the products’ performance, safety, and quality (Emmanouilidis et al., 2011; Sipsas et al., 2016). Decision-making plays a significant role in the maintenance of any complex manufacturing line, as this requires upholding an acceptable asset condition while meeting safety, cost, quality, as well as legislative and performance requirements - creating a complex decision landscape (Emmanouilidis et al., 2011; Ni & Jin, 2012). Therefore, supporting maintenance operations in the pharmaceutical industry, by implementing new innovative solutions, can potentially help the pharmaceutical industry optimize their production, thus creating the changes needed to stay competitive. Nevertheless, research is needed to understand the current state of this transformation and understand the specific industry barriers to adopting these new technologies.

The above section provides an understanding of the general motivation for this thesis and provides a fundamental understanding of the research topic. Building on this, the problem discussion will be presented in the following section.

2.1 Problem discussion

This section will discuss and illustrate the gap in the literature and the relevancy of the research questions below.

The literature used in this project, covers both production and manufacturing, which is why it is important to clarify the relation between production and manufacturing, as the literature referred to in this project, covers both. The production covers the entire process from any input to a given output, where manufacturing refers to a subprocess of production (Black, 2000). With this clear definition of manufacturing as a subset of production, the manufacturing literature can be applied in this research.

Extensive research exists on industry 4.0 and how it will revolutionize manufacturing by transforming the manufacturing process, making it fully digitized and intelligent (Erol, Vaidya, Bokrantz). There is a widespread consensus that this is bound to happen and will lead to greater efficiency within the manufacturing industry. According to Porter and Heppelman, the changes that industry 4.0 brings, will radically reshape companies, the competition and create what they call “*the first discontinuity in the organization of manufacturing firms in modern business history*” (2015, p. 18).

Despite the extensive literature within the realm of manufacturing and the effect of industry 4.0, Bokrantz, Skoogh, Berlin, and Stahre (2017) mention a lack of understanding expected concerning changes in maintenance-related operations. According to Bokrantz et al. (2017), there is a striking gap in scientific and business literature on how this revolution will affect maintenance. Bokrantz et al. (2017) emphasize the need to understand what a digitized manufacturing entails for maintenance operations in terms of a technical and social dimension, thus highlighting the urgent need to shed light on the uncertain future of how digital transformation will affect maintenance.

Fraser et al. (2015) created a study, examining the empirical evidence of maintenance journals and analyzing the empirical evidence rate (EER), which expresses the amount of research that addresses social needs and real-world problems. Their study found that the empirical evidence rates were as low as 1,5 percent for some journals, which drew attention to the need for practical-focused papers investigating real-world problems.

In addition to this, a lot of research on the specific characteristics of the pharmaceutical industry and the environmental change they are currently facing, has been conducted (Champagne et al., 2015; Chen, 2020; Marques et al., 2020; Tyson, 2015).

Marques (2020) mentions how the current literature on achieving higher operational efficiency within the pharmaceutical industry is not fully aligned with the changing environmental factors that impact the pharmaceutical industry. According to Marques (2020) there is a lack of addressing how technological developments, of disruptive nature, can be expected to change such a highly conservative industry.

The combination of lack of literature on how maintenance will be affected by the revolutionizing industry 4.0 and the lack of literature aligning the external factors currently impacting the pharmaceutical industry, provides evidence and relevance for this study as well as the research questions that will guide the paper.

2.1.1 Research questions

The first research question seeks to provide an understanding of how data supports the decision-making process in pharmaceutical maintenance operations. This question will thus explain the current state of the adoption of data and innovative e-Maintenance, which support maintenance in the complex decision-making landscape.

RQ 1: How is decision-making in pharmaceutical maintenance operation supported by data to improve effectiveness?

The second research question aims to understand the adoption challenges that the pharmaceutical industry is facing. As scholars have stated that changes need to happen in the pharmaceutical business model and that they lag behind other industries in terms of manufacturing efficiency, it is relevant to seek an understanding of this gap, by identifying the predominant factors influencing the adoption of e-Maintenance technologies within pharmaceutical maintenance operations.

RQ 2: What are the technological, organizational, and environmental factors affecting the adoption of e-Maintenance technologies within pharmaceutical maintenance operations?

2.1.2 Thesis structure

In this section the thesis structure will be presented. Section 3 will present the background for the thesis, including the unique characteristics of the pharmaceutical industry and a literature review on Maintenance, Decision Support Systems, Data-driven decision-making, OEE and Data quality. In addition this section will present the two frameworks used to answer the research question in the respective order of the decision-making framework leading into the Technological-Organizational-Environmental framework (T-O-E). Section 4 will present the methodological choices of the thesis. Section 5 will present the case description leading into the case analysis of the decision-making framework and the empirical evidence to answer RQ1. Afterwards the T-O-E Framework used in conjunction with the empirical evidence to answer RQ2. Finally section 6 will present a discussion of the findings leading into the conclusion in section 7. Figure 2.1.2.1 graphically represents the structure of the thesis.

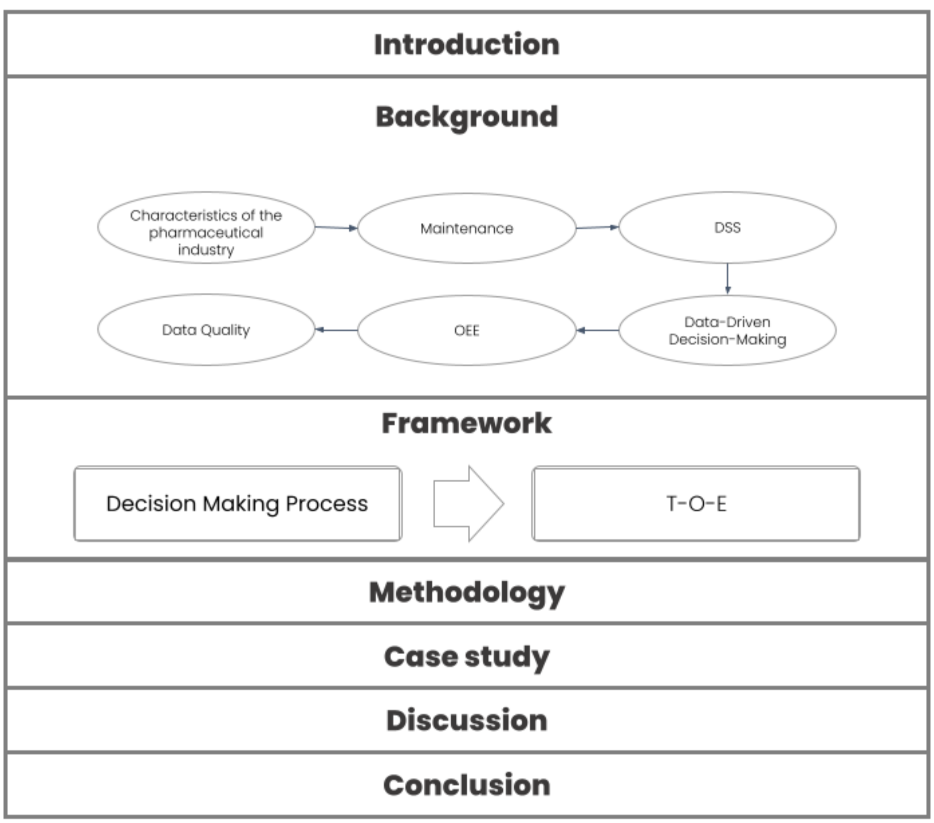

Figure 2.1.2.1 - Thesis structure.

3 Background

This section will introduce the relevant terms and the terminology required to understand the applied theory and the context of the study.

In order to answer the research questions, this study will establish a foundation of domain knowledge in the pharmaceutical industry and provide information about some of the unique features of the pharmaceutical industry. Subsequently, the core concepts of the study will be presented, to provide clear theoretical definitions and insights into the relevance in this study. Based on the core concepts, the area of exploration will be presented in the form of a union set, describing the exact area of research. Lastly, the analytical frameworks will be described.

3.1 Unique characteristics of the pharmaceutical industry

The pharmaceutical industry has certain unique features that separates it from other industries. The following section provides the necessary contextual understanding of the industry which is needed for the analysis.

General characteristics

An undeniable characteristic of the pharmaceutical industry, as previously mentioned, is the ongoing paradigm shift away from the “blockbuster era” (Friedli et al., 2010; Marques et al., 2020). This shift challenges the entire industry and creates an overdue incentive for change.

To understand the pharmaceutical industry it is important to understand the supply chain structure, to help clarify the complex network of stakeholders and processes. Figure 3.1.0.1 by Marques (2020) provides a visualization of how a typical pharmaceutical industry looks like.

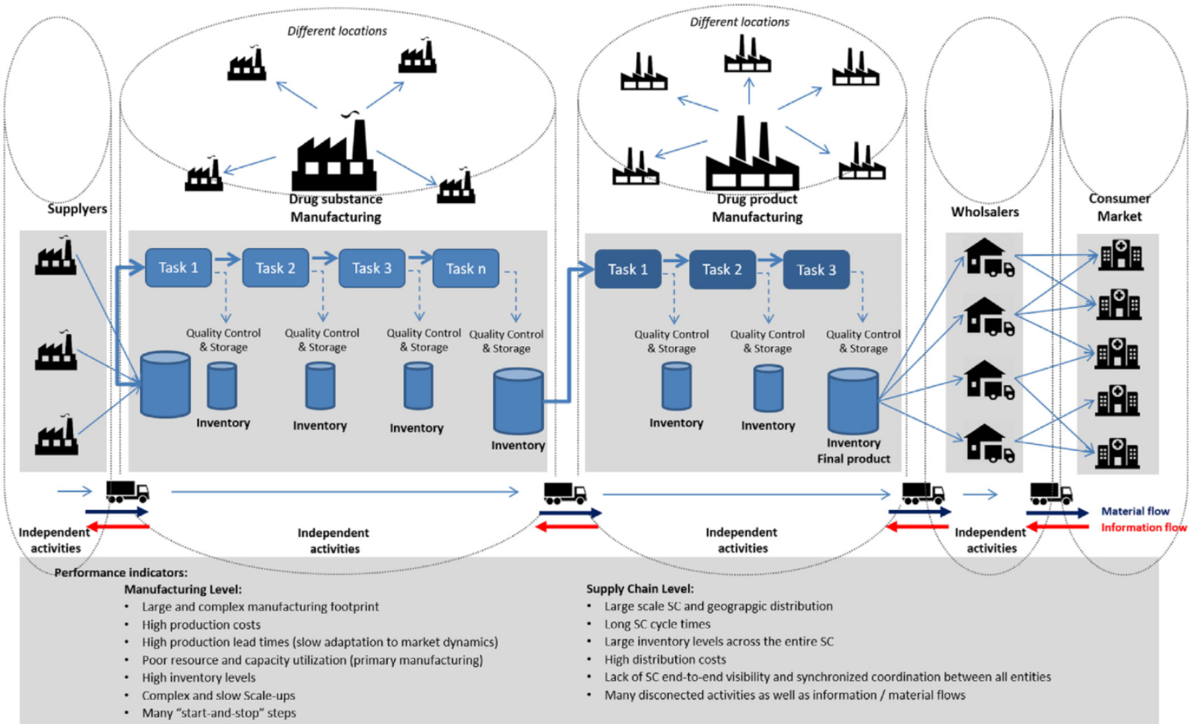

Figure 3.1.0.1 - Current supply chain structure based on the traditional batch production mode Source - (Marques et al., 2020)

As seen in Figure 3.1.0.1 there are many steps and stakeholders involved in the supply chain structure. Pharmaceutical companies use a traditional batch production process, which creates many "start-and-stop" steps in the manufacturing processes from the delivery of raw products to the delivery to the end consumer resulting in long manufacturing lead time (Marques et al., 2020; nVentic, 2017).

Some pharmaceutical companies provide products that are essential to their end users' health or life, making it crucial to have constant availability of products. Alongside the need for constant availability, many chemical ingredients have a low shelf life, making the inventory management even more complex and costly (Marques et al., 2020; nVentic, 2017). This need to guarantee deliveries with a low shelf life, illustrates the complex nature of the pharmaceutical industry and highlights the importance of a predictable and consistent production line, with a high level of effectiveness (Marques et al., 2020; nVentic, 2017).

Another unique area of the pharmaceutical industry is the value chain, in which the wholesalers have a critical role. Most pharmaceutical industries do not deliver their product directly to the consumer. Pharmaceutical companies often have governmentally regulated contracts with wholesalers, to whom they deliver their products. In turn, these wholesalers provide the products to healthcare providers such as hospitals, pharmacies etc. (Marques et al., 2020). In figure 3.1.0.2, the value chain of a pharmaceutical company is illustrated. The figure gives an indication of the various stakeholders and how the flow of money, information and products are organized.

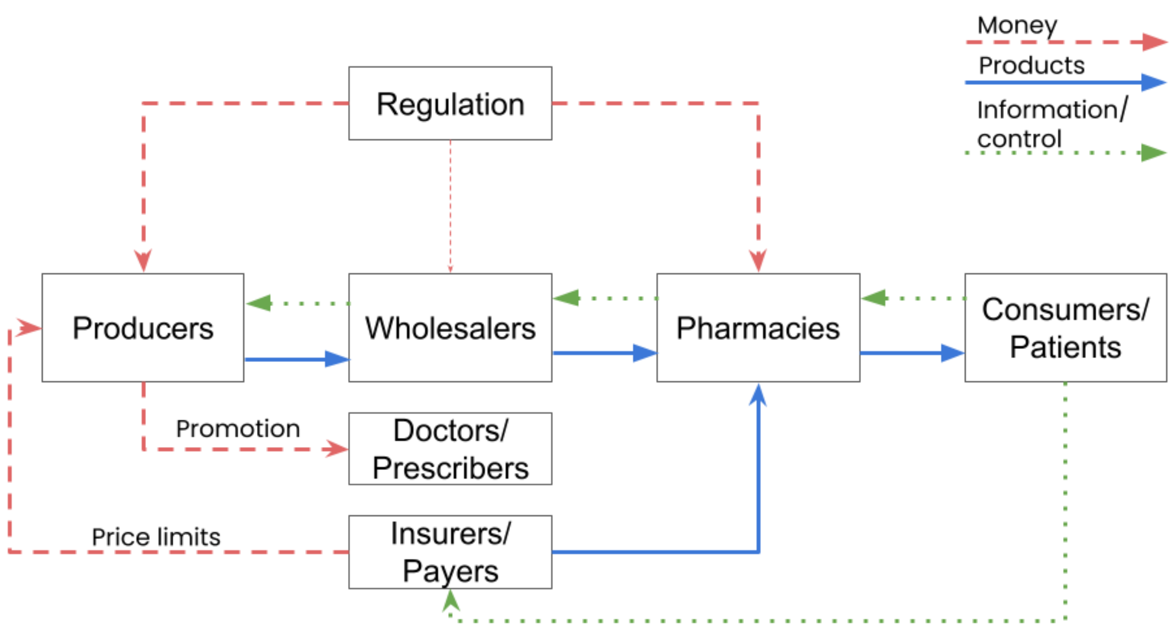

Figure 3.1.0.2 - The pharmaceutical value chain: flow of Goods, Information and Money (adoption of (Danzon, 2014)).

Regulation

One of the primary differentiating factors between the pharmaceutical industry and other industries is the fact that they are heavily regulated (Handoo et al., 2012; Hooper, n.d.). The pharmaceutical industry has to operate under an extensive amount of regulations enforced by the government, with the purpose of protecting the health and well-being of the public. Among these regulations is GxP. GxP is a set of regulations and guidelines, introduced by the Food and Drug Administration (FDA), that attempts to ensure the safety and quality of pharmaceutical products (Choudhary, n.d.).

GxP stands for Good x Practice, in which the x is a variable that, within the realm of pharmaceuticals, can represent manufacturing, laboratory, documentation or clinical. The Concept of GxP has become the global standard, and has improved the safety and quality of the medicinal drug industry. A table showing the different regulatory agencies in various countries can be seen in appendix Appendix P.

The FDA in the U.S and the European Medicines Agency (EMA) in Europe are some of the largest regulatory agencies that exist. These agencies have increased their focus on the efficacy evaluation of drug testing and pre-approval safety, which entails more demanding quality criteria and protocols before market approval. In addition, the FDA has increased their effort in terms of ensuring a high level of product manufacturing regarding design, monitoring and control of maintenance processes and facilities. An example of the increased Government regulation that affects the pharmaceutical manufacturing and supply chain operation, is a 2004 report from the FDA focusing on improving drug manufacturing quality (FDA, 2004). The report outlined a vision to modernize the regulation of the pharmaceutical manufacturing and supply chain process. The report introduced the current Good Manufacturing Practices (cGMP) that established formalized regulation on monitoring, design, control and maintenance of manufacturing processes to guarantee uniformity of all products. Yearly inspections of compliance with the cGMP are now conducted by the FDA.

Other regulatory initiatives, such as Quality by Design (QbD) and the newly founded Knowledge Aided Assessment and Structured Application (KASA), are also emerging (Marques et al., 2020). According to the EMA, QbD is an approach where statistical, analytical and risk management is used to ensure the quality in the design, development and manufacturing of medicines (European Medicines Agency, 2018).
Likewise, KASA is a system for ensuring the safety and efficacy of drugs (Yu et al., 2019). Additionally, regional areas can have their own compulsory regulations and protocols, creating more constraints and complexity as the Government regulation increases for the pharmaceutical industry.

In general, Government regulation is both expensive and time consuming and therefore seen as an impediment to innovation in the pharmaceutical industry (Marques et al., 2020). At the same time the increasing requirements are forcing them to adapt and develop new strategies, while still maintaining a high level of productivity and operational efficiency (Marques et al., 2020). The increasing Government regulation has led to a delay in the time-to-market of new drugs, which in turn impacts the time between regulatory approval and the patent expiration. The effective patent life is extremely important for the pharmaceutical industry, as this is the time that they can recover their investment under market exclusivity. The decrease in effective patent life due to increase in regulatory requirements is one of the reasons pharmaceutical companies need to increase their focus on increasing productivity and effectiveness (Marques et al., 2020).

Government regulation is extremely important to understand, as innovation of Good manufacturing process (GmP) related production or maintenance processes are subject to heavy regulation and documentation. Thus making it more challenging to implement innovative solutions as the risk of non-compliance is high. A breach of compliance could entail potential cost. Safe operations is paramount in the pharmaceutical industry, even more so compared to many other industries. Srai et al. (2015) conducted a paper on the opportunities and challenges facing the pharmaceutical industry, in which organizational inertia was one of the challenges particularly of highly regulated industries. Organizational inertia refers to the organization's ability to make internal changes when facing external changes. This finding on pharmaceutical organizational inertia is also supported by Friedli, Basu, Gronauer and Werani (2010), who states the pharmaceutical industry is facing a new reality and cannot rely on success from intellectual property, market exclusivity and a blockbuster business model (2010, p. 1).

When inertia occurs, the organization automatically reacts on the basis of previous experience and resists the changes. According to Srai et al. (2015), heavy regulations preserve the behaviours and preference for the established processes. Therefore when innovative solutions are presented, it will most likely be down-prioritized over the existing processes that are in place, which fulfills the GxP requirements. Srai et al. (2015) additionally mentions how large organizations operating under heavily regulated settings, often tend to adopt *"committee-based decision-making, often through multi-layer matrix organizations... This has driven a risk avoidance and tick-boxing culture"* (2015, p. 847).

Pharmaceutical companies are also characterized as being organized in functional silos (Eames, 2020; Garguilo, 2015). The functional "silos" in such an organization can potentially create quality and safety concerns and hinder end-to-end visibility leading to operational inefficiencies (Srai et al., 2015).

Another unique characteristic of the pharmaceutical industry is the increased pricing pressure from governments across the world. The pharmaceutical industry has a significant impact on countries' healthcare structure, as they provide the medicines and vaccines that directly impacts the populations quality of life. The medicine and vaccines they provide also represent a significant healthcare cost for each country, thus highlighting that the pharmaceutical industry is a key player in the economic sustainability of each country's healthcare system. The report "Global Medicine Spending and Usage Trends - Outlook to 2025" by IQVIA, indicates that after the recent Covid-19 pandemic, the dollar growth forecast invoice spent globally will return to pre-pandemic projections by 2025 (Figure 3.1.0.3).

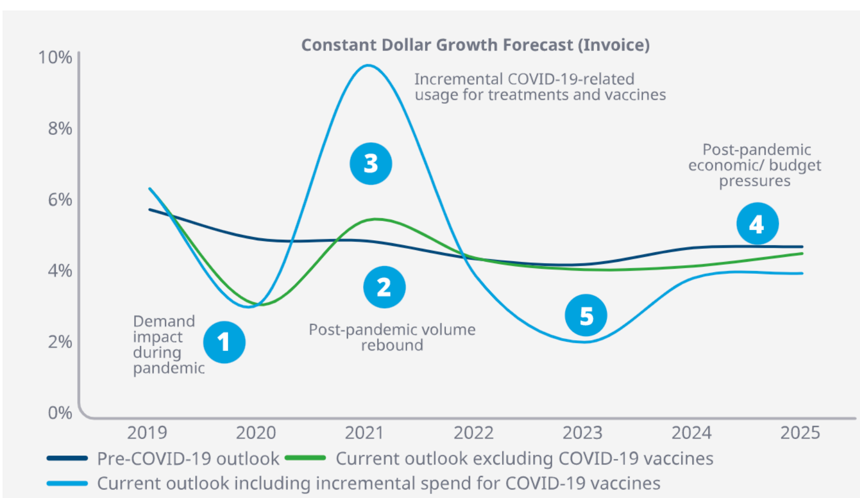

Figure 3.1.0.3 - Comparison of Current Outlook to Pre-COVID-19 - global invoice spending (IQVIA, 2021).

Despite this, there is an uncertainty in terms of the impact of economic factors from countries' budgeting bringing shifts in medicine spending and in healthcare policies (IQVIA, 2021). According to the report it is expected that the value and pricing of medicines will be under an increasing amount of scrutiny which has been an ongoing event underway in many markets and has been a key issue in the United States. As the high drug prices impose a significant burden on government spending, governments and payers are constantly putting pressure on pharmaceutical companies to lower their prices and introducing price cap regulations to limit the expenditures on medicaments, thus influencing the profit margin of the pharmaceutical companies (Marques et al., 2020).

This trend and uncertainty of whether the price pressure from governments will play a significant role in the future of the pharmaceutical industry and force the industry to re-think their business model and optimize their performance and effectiveness wherever possible.

To summarize, the pharmaceutical industry differentiates themselves through (1) complex regulatory landscape with GxP requirements, (2) buyers with a lot of power and an increasing demand to lower the drug prices due a need to reduce global healthcare spending and (3) a low shelf life and a need to be able to secure delivery of products creating high inventory cost. These unique characteristics emphasize the need for an effective and consistent production and highlights the importance of the concept of maintenance which will be further described below.

3.2 Maintenance

As described in sections 2 and 3.1, the time when the blockbuster drug prices could compensate for production inefficiencies has passed (Walker, 2018). The need to increase the productivity of the manufacturing processes makes maintenance an interesting area, as the industrial equipment cannot function forever producing goods of high quality at a fast pace (Gopalakrishnan, 2018). This highlights the importance of maintenance to repair and restore the equipment. The academic and theoretical domain of maintenance is an extensive and highly researched area that has become one of the most important in the business environment (Kutucuoglu et al., 2001).

Maintenance can be described in various ways; Pintelon & Gelders (1992) describes maintenance as *“all activities necessary to restore equipment to, or keep it in, a specified operating condition.”*. Maintenance is responsible for the cost of material, tools, overhead, and manpower (Pintelon & Gelders, 1992). To highlight the importance and impact of maintenance. One study estimates that 15% to 40% of production cost is attributed to maintenance cost, while another goes to suggest that maintenance department cost can represent between 15% to 70% of the total production cost (Fraser et al., 2015).
Others describe maintenance not only as avoiding equipment breakdown but also as a process to improve business performance, such as productivity and elimination of malfunctions (Bousdekis et al., 2021). In a historical sense, the cost of maintenance has been seen as a necessary evil, but with the new paradigm shift, this sentiment is changing as organizations see maintenance as critically important for the long term success of the company (Fraser et al., 2015).

The evolution of the manufacturing process within the field of pharmaceuticals, as underscored, cannot remain stale (Friedli et al., 2010). Therefore the area of maintenance has gained the attention of many industry front runners who now see this as highly relevant to stay competitive. Maintenance is thus playing an increasingly more prominent role for pharmaceutical companies to stay competitive (Gopalakrishnan, 2018). The growing importance of maintenance is also discussed and acknowledged in the literature (Gopalakrishnan, 2018). However, the current research seems to be focusing on the possibilities of an optimal scenario rather than addressing and mitigating the challenges seen in practice (Fraser et al., 2015).

Focusing on maintenance can help reduce manufacturing downtime and increase production efficiency, making it an area of profit generation rather than just a cost center. Gopalakrishnan (2018) explains that the focus should shift to a more holistic one, from maximizing machine availability and reliability to maximizing productivity and cost-efficiency.

One of the significant attributions to the high maintenance cost is a lack of reasonable maintenance management, which leads to downtime (Salonen & Deleryd, 2011). Downtime can be described as any period where a facility output is stopped (*Manufacturing Downtime | AspenTech*, n.d.). Downtime includes planned downtime for scheduled maintenance but also unplanned downtime from equipment failure or other events. In the U.S, a study estimates that the cost of downtime for pharmaceutical companies, in general, can cost from USD 100.000 to USD 500.000 an hour (*Pharmaceutical Industry Perspective » Denison Technologies*, 2019). In conclusion, as The cost of maintenance is high, but the cost of poor maintenance is even higher, which is supported by Salonen & Deleryd (2011).

3.2.1 Types of maintenance

Having outlined the cruciality of maintenance to be competitive in the future, it is essential to understand the complex landscape of maintenance.
According to the European Standard of Maintenance terminology, there are many different types of maintenance (BS EN 13306, 2010, n.d.). Rastegari and Mobin (2016) published a model called the Decision Making Grid (DMG) visualized in Figure 3.2.1.1 and elaborated in Table 3.2.1.2.

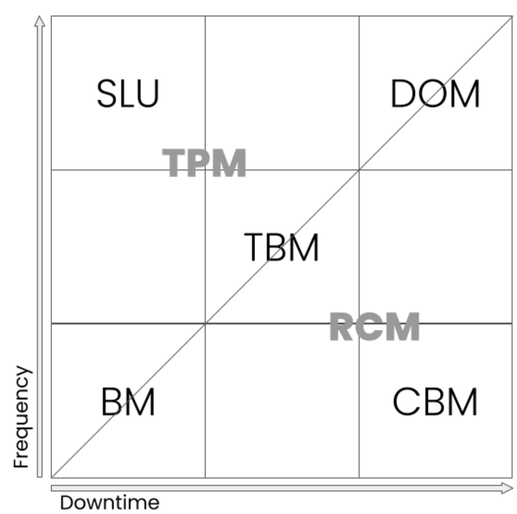

Figure 3.2.1.1 - Decision Making Grid modified from Rastegari and Mobin (2016)

Rastegari and Mobin (2016) defines 5 maintenance types which are used in the DMG, these are described in table 3.2.1.2 below:

Maintenance type	**Abbreviation**	**Description**
Design-Out Maintenance	DOM	Design out is a maintenance policy that focuses on improving the design of the production equipment to make maintenance easier.
Condition Based Maintenance	CBM	Condition Based Maintenance is defined as preventive maintenance based on parameter or performance monitoring.
Skill-Level Upgrade	SLU	Skill-Level Upgrade relates to improving the competence of the Operators on the line.
Time Based Maintenance	TBM	Total Based Maintenance is when the maintenance is performed according to a specific time or calendar.
Breakdown Maintenance	BM	Breakdown Maintenance is a corrective maintenance also known as run-to-failure, where the strategy is to restore the equipment to its original condition after it has failed.

Table 3.2.1.2 - 5 maintenance types by Rastegari and Mobin (2016)

According to the DMG these five types are sorted into two overall categories of Total Productive Maintenance and Reliability Centred Maintenance which are described below.

Total Productive Maintenance (TPM) is a Japanese philosophy, first introduced by Nakajima (1988). It is a comprehensive but innovative maintenance model that focuses on optimizing equipment effectiveness, eliminating breakdowns and promoting Operators' autonomous maintenance (Ahuja & Khamba, 2008). The goal of TPM is ultimately to increase production while increasing employee morale and job satisfaction A typical benchmarking score used in TPM is Overall Equipment Effectiveness (OEE), further described in section 3.5.

Reliability Centred Maintenance (RCM) is defined as a *"structured, logical process for developing or optimizing the maintenance requirements of a physical resource in its operating context to realize its inherent reliability"* (Ahuja & Khamba, 2008). In other words, it is a process to establish a safe minimum level of maintenance.

The DMG model looks at how organizations can select the best applicable maintenance policy for a given machine, based on the two dimensions of downtime and frequency of failure. By placing the machines in the DMG, companies can get an overview of which maintenance policy to use.

As most articles within maintenance are purely theory based, according to Fraser et al. (2015), this paper will look into maintenance in its simple form of either being preventive or reactive, in order to focus on providing empirical evidence, rather than creating a purely theoretical. Preventive maintenance concerns prevention of failures before they occur, while reactive maintenance aims to restore or repair equipment the moment failure has occurred. (Gopalakrishnan, 2018).

Maintenance prioritization is another crucial task for production systems as it is common for companies to have more maintenance work orders than resources to handle them. It thus becomes essential to prioritize the different tasks, as a poor prioritization can lead to additional manufacturing downtime, waste of maintenance labor and resources, leading to reduced production and decreased profit (Ni & Jin, 2012). Studies by

(Gopalakrishnan, 2018) and Ni & Jin (2012) argue that the general prioritization method used in maintenance operation is based on experience or heuristic rules; thus, the maintenance is highly dependable on the skills of the specific Operator. This reliance on experience and skills indicate that most companies currently rely on skill-level upgrades (SLU). This maintenance prioritization creates an unstable fluctuation in the effectiveness, dependent on experience and personal experience, which can be an inefficient process in some instances. This finding is also supported by Gopalakrishnan (2018), whose research indicates that the central problem in maintenance prioritization is the lack of support in the decision-making process as the central problem in maintenance prioritization is the lack of support in the decision-making process as *"having the wrong priorities can potentially reduce system throughput to even lower levels than with a first-come-first-served work order."* (2018, p. 64). Gopalakrishnan (2018) states that fact-based or data-driven maintenance decisions are crucial to increasing productivity.

Over the last couple of decades, the literature within maintenance has evolved with the integration of mobile and wireless technologies, creating easier accessible data (Emmanouilidis et al., 2011). The evolution and integration of technologies are of great interest to many companies as it provides new opportunities to enhance their maintenance further. One specific area is the emergence of e-Maintenance, which will be described further in the next section.

3.2.2 e-Maintenance

With today's technological advances, we see more and more opportunities to implement digital technologies to digitize the maintenance process allowing organizations to gather much more data they can use to support decision-making and increase the effectiveness of their maintenance operations (Jantunen et al., 2017; Nordal & El-Thalji, 2021). In parallel with the technological advances, e-Maintenance has since the year 2000 gained increasing attention, as a new area of research. e-Maintenance is not consistently defined in existing literature, but the consensus of the concept, according to Muller et al. (2008), refers to the integration of IT in the maintenance strategy or plan.

Muller et al. (2008) investigated the current research within and the concept of e-Maintenance and defined it as:

"*Maintenance support which includes the resources, services and management necessary to enable proactive decision process execution. This support includes e-technologies (i.e. ICT, Web-based, tether-free, wireless, infotronics technologies) but also, e-Maintenance activities (operations or processes) such as e-monitoring, e-diagnosis, e-prognosis, etc.*" (Muller et al., 2008, p. 1167)

Telecommunication, web services, mobile, wireless and portable devices are thus part of the e-Maintenance concept. Linking these technologies with the general maintenance principles can enable companies to increase productivity and effectiveness of their production line, through the efficient collection and exchange of real-time data. If used correctly, it can provide detailed knowledge for cost-effective and productivity-enhancing decision-making, thus minimizing the use of decision-making based on heuristic rules and experiences from individual Operators (Gopalakrishnan, 2018; Jantunen et al., 2010).

e-Maintenance is often associated with industry 4.0 and sometimes referred to as maintenance 4.0 (Disruptive Technologies, n.d.; Nordal & El-Thalji, 2021). The consensus is that the technologies associated with e-Maintenance and the new maintenance types will revolutionize maintenance: *"The increasing popularity of predictive maintenance strategies is preceded with the necessity of an improved Overall Equipment Efficiency (OEE)"* (Emmanouilidis et al., 2011; Jantunen et al., 2017, 2010).

The maintenance revolution, associated with industry 4.0, is moving from a focus on reactive maintenance to preventive maintenance and more specific innovative technologies that allow for predictive maintenance. (Emmanouilidis et al., 2011; Jantunen et al., 2017). Predictive maintenance is performed by monitoring equipment with smart sensors that monitor parameters such as heat, vibration, weight, humidity etc. An extensive and expensive enigma for production lines is to understand when their equipment will develop a fault or crash, thus potentially forcing a costly unplanned downtime on the line. Advances in mobile and internet technologies lay the foundation for predictive maintenance, potentially saving a lot of downtime and faulty products through an increasing amount of data and advanced analytics, to predict degradation of the equipment. The most leading form of advanced analytics, artificial intelligence, is mentioned by some scholars and encouraged to be used not only within manufacturing, but maintenance as well (Bodenstab, 2018; Turner et al., 2019). Turner et al., (2019) also mentions that machine learning will have a significant influence in the delivery of intelligently maintained decision-making systems.

It is evident that predictive maintenance has become increasingly popular and is seen as a necessity to improve the overall equipment effectiveness instead of relying on corrective or responsive maintenance (Jantunen et al., 2017). This is also reflected in the increasing number of papers released on predictive maintenance, as seen in figure 3.2.2.1.

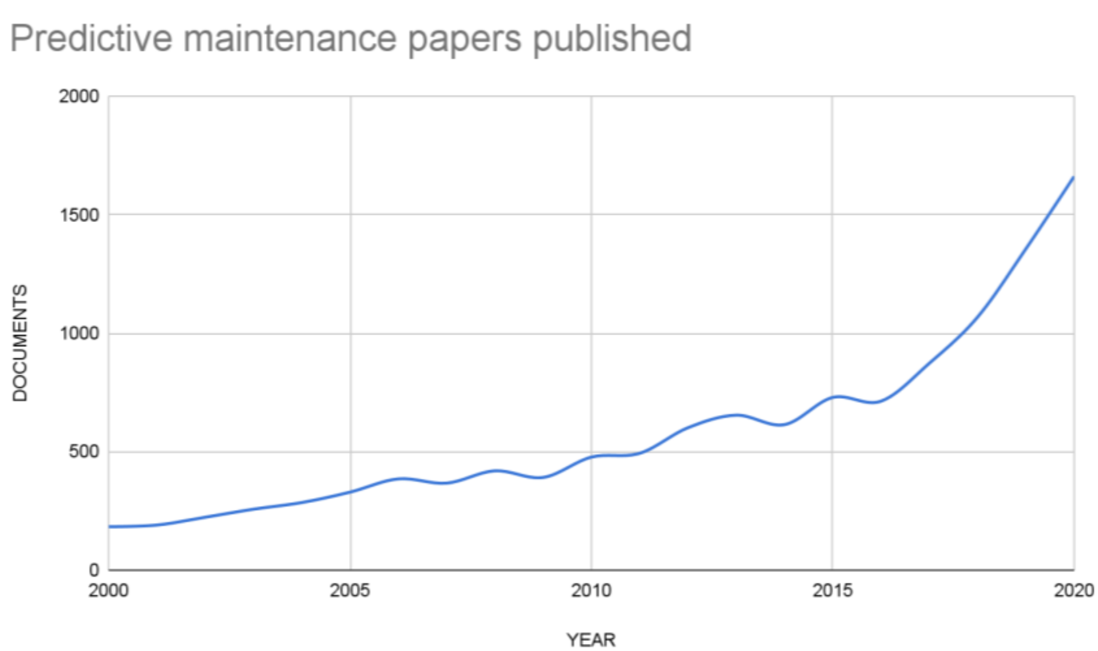

Figure 3.2.2.1 - Predictive maintenance papers published between between 2000 – 2020 (Source: Scopus).

Emmanouilidis et al. (2011) explains what types of services that e-Maintenance can provide for organizations; Maintenance documentation, Predictive health monitoring, Performance assessment, and Training and Knowledge management.

Maintenance documentation refers to the opportunity to use IT tools to handle the documentation, which is a critical part of maintenance management practices. Documentation involves information about procurement, installation, and operations. It can range from technical data to maintenance manuals, asset registers, scheduling information, inspection etc. e-Maintenance provides ubiquitous availability of maintenance documentation.

Predictive health monitoring relates to the equipment assets on the production lines' operational condition. Monitoring the assets on the production lines is a critical aspect to maintain production and avoid unplanned downtime. It is a crucial area to meet demands for cost-efficiency, quality, and safety (Emmanouilidis et al., 2011). With the use of sensors, software, and hardware components, integrating them into a system enables companies to diagnose the equipment, detect impending faults, and anticipate how the condition will evolve. These elements provide an opportunity to perform predictive maintenance and provide data that the employees can include in their decision-making.

Performance Assessment is an area that differentiates itself from other e-Maintenance services, as it focuses on creating new business opportunities rather than merely focusing on maintenance as a cost center. According to Emmanouilidis et al. (2011), maintenance processes have larger optimization margins than operational processes. The optimization is often measured through performance indicators such as Overall Equipment Effectiveness, further explained in section 3.5. According to Wireman (2004) evidence suggests that employee’s time spent on monitoring tools, processes, and machinery is approximately 35%. e-Maintenance provides the tool for companies to improve performance measurement, which is a crucial factor in demonstrating that implementing e-Maintenance tools increases production effectiveness.

Training and Knowledge management are essential as maintenance management is a complex field requiring multidisciplinary skills (Emmanouilidis et al., 2011). Training within maintenance is often through vocational education and training (VET), but as maintenance tasks often happen under time and space constraints, digital tools such as augmented reality can help. E-learning can also help support the maintenance training task in a more cost-efficient way.

Knowledge management refers to how competencies and experience are strengthened through training as well as the collective knowledge and practice in the enterprise. Maintenance knowledge often shows itself when experienced staff leaves the enterprise, thus bringing this problem to the surface as it can be difficult to replace. With e-Maintenance, organizations can benefit from integrating key technologies, methodologies, and software tools to retain and enhance enterprise maintenance knowledge capabilities (Emmanouilidis et al., 2011).

For many companies, e-Maintenance is overestimated in the short run but underestimated in the long run (Muller et al., 2008, p. 1167). A prerequisite for e-Maintenance is the use of data to support decision-making in maintenance. This is where decision support systems become relevant to explore.Decision support systems (DSS) are often mentioned in relation to e-Maintenance as a link between decision processes and the tools that e-Maintenance provides. According to Ni and Jin (2012) DSS is essential for an effective maintenance operation; thus a requirement to understand the meaning behind decision support systems and their linkage to maintenance.

3.3 Decision support system

Maintaining a production line adequately for it to have an excellent operational condition while simultaneously meeting performance, cost, safety, and quality requirements defines the complex decision-making landscape of maintenance (Emmanouilidis et al., 2011). As previously described, maintenance is a dynamic field involving many different processes, and maintenance decision-making is therefore rather complex. The different decision-making actors need to consider several elements such as maintenance schedule, manning schedule, planned downtime, production targets, budget constraints, tools, system integration, equipment degradation, and health condition of the equipment (Gopalakrishnan, 2018; Ni & Jin, 2012). Basing the decision-making only on heuristic methods and experience can be error-prone. Thus, there is a need to include data to support decision-making, so it is essential to include decision support systems.

Decision support systems (DSS) is a field of academia that has been investigated for decades (H. B. Eom & Lee, 1990; Simon, 1960). The field covers computer systems that handle data to support decision-makers. The application of DSS in production has been a significant and growing field of research. The DSS term has evolved and has, according to Eom (2020), even been replaced in some aspects by business intelligence (BI) and data analytics (DA). Other researchers support our use of DSS and describe BI and DA as subdomains or elements of DSS (Felsberger et al., 2016). This understanding of BI and DA as subdomains aligns Sprague and Carlson (1982) definition of DSS as:

"A class of information system that draws on transaction processing systems and interacts with the other parts of the overall information system to support the decision-making activities of managers and other knowledge workers in organizations"
(Sprague & Carlson, 1982)

Scholars such as Power (2008) defines DSS *"as interactive computer-based-systems that help people use computer communications, data, documents, knowledge, and models to solve problems and make decisions"*

This thesis uses the definition by Power (2008) which can be seen as an updated and modernized version of the proposed definition by Sprague & Carlson (1982).

DSS have been differentiated into three categories essential to understand; Passive, Active, and Cooperative (Haettenschwiler, 1999).

The passive DSS processes information to support the decision-making process but does not provide suggestions or products that can serve as a complete or partial solution. The active DSS can provide suggestions and solutions, where the cooperative DSS enables the decision-maker to modify suggestions and solutions provided.

Understanding the different categories of DSS enables the analysis of the different implementations, indicating how advanced the implemented DSS are. Adopting innovative DSS is thereby the natural foundation for operationalizing data in decision-making to achieve data-driven decision-making, further described in the following section.

3.4 Data-driven decision-making

According to traditional principles, decision problems refer to finding an optimal solution to a so-called decision-making model (Lu et al., 2019). The accuracy of the model determines the reliability and quality of the decision. In its simplest form, data-driven decision-making refers to the use of facts, metrics, and data to support decisions (Lu et al., 2019).

As the real world often proves to be intrinsically complex, decision-making models often lack the quality and reliability needed (Lu et al., 2019). To increase the quality and reliability of decision-making, practitioners and researchers are looking into the opportunities that have come with the information age and how it can benefit the decision-making process. With the plethora of sensors, automated manufacturing systems, and IoT-enabled machines, data availability is increasing at a fast rate. This immense volume, variety, and velocity challenges the existing methods of decision-making that are highly dependable on heuristic methods (Bousdekis et al., 2021).

An opportunity lies in using DSSs to facilitate the use of data to support the decision-making process, thus potentially increasing the quality and reliability of the decision-making. Data-driven decision-making is a wide research field and is in this thesis only considered in a maintenance context.

According to a study by Gopalakrishnan (2018), most companies prioritize their maintenance work orders ad-hoc, or randomly based on the Operators' or Skilled workers' experience or influence. This unstructured process can often lead to increased production downtime and cause productivity losses (Ni & Jin, 2012), which indicates a need to support the decision-making process with data rather than intuition and experience.

Many scholars have, for the last decade, been focused on explaining the future of maintenance, by developing new maintenance models and concepts, to explain how new IT tools can provide new opportunities (Gopalakrishnan, 2018). Most of these elements are intended to support the decision-making process in enabling performance, efficiency, and profitability within the maintenance domain, thus supporting the importance of investigating the decision-making process regarding maintenance.

A literature review on data-driven decision-making methods for industry 4.0 maintenance applications by Bousdekis et al. (2021), examines how industry 4.0 enables the use of algorithms that analyze data, predict emerging situations, and recommend mitigating actions. Bousdekis et al. (2021) investigates how maintenance operation will be affected through the nine pillars of industry 4.0 seen in figure 3.4.0.1 and converge with data-driven decision-making.

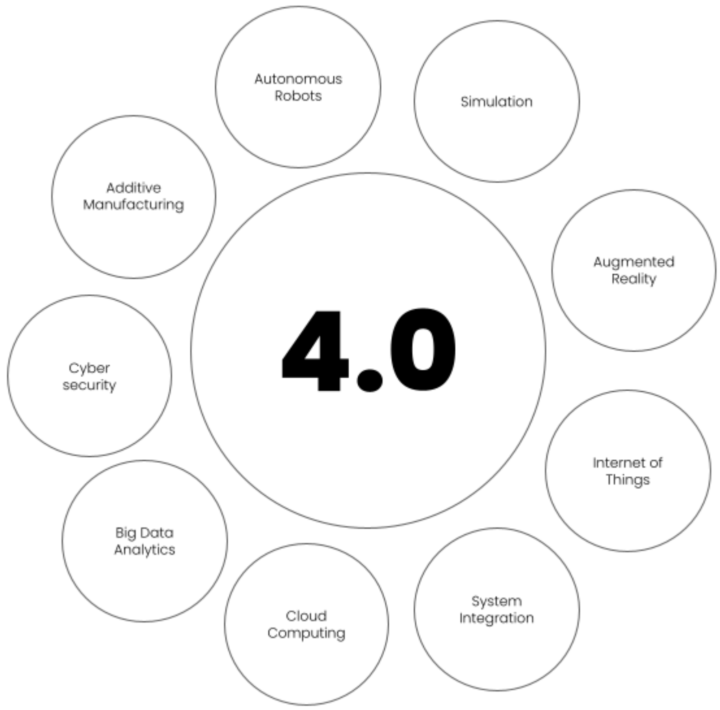

Figure 3.4.0.1 - The nine pillars of industry 4.0 (Modified from Bousdekis et al., 2021)

The research by Bousdekis et al. (2021) states that the next generation of decision-making in maintenance will be influenced by innovative technologies, becoming more capable of facilitating accurate and proactive decisions and achieving more responsiveness.

The primary goal of implementing data-driven decision-making, is to increase the effectiveness on the production lines. However, without a benchmarking KPI this is extremely difficult. Therefore, many companies have implemented the key performance indicator called overall equipment effectiveness (OEE) as a benchmark KPI. This KPI, will be introduced in the following section, as it opens up the possibility for companies to measure the effectiveness of their production line.

3.5 Overall equipment effectiveness

Overall equipment effectiveness (OEE) is a measure used as a metric for performance and a natural key performance indicator. The fundamentals of OEE can be explained as a ratio or fraction of what is actually manufactured compared to what should have been manufactured, ideally (Braglia et al., 2009). The term was introduced with the total productive maintenance concept in the 1980s, which is described in section 3.2.1 above (Nakajima & Bodek, 1988). OEE is centered around the topics of availability, performance, and rate of quality.

The base model of OEE has been adapted several times over the years, and according to Ng Corrales et al. (2020), these modifications have led to at least 36 models based on OEE. Two of the main parameters, which are adjusted across models, are the scope of application and the focus on effectiveness or efficiency.

Effectiveness, not efficiency

According to (Muchiri & Pintelon, 2008), the original model argues that OEE focuses on effectiveness based on a definition of effectiveness as *“a process characteristic that indicates the degree to which the process output conforms to the requirements.”* (Muchiri & Pintelon, 2008). The alternate option of efficiency is in their work defined as *“a process characteristic indicating the degree to which the process produces the required output at minimum resource cost”* (Muchiri & Pintelon, 2008). This distinction is important to make, since some of the modified versions focus on efficiency rather than effectiveness as the original model.

Ideal application

The application is one of the main differences when comparing the 36 models based on OEE, highlighted by Ng Corrales et al. (2020). The initial application of OEE to measure equipment productivity has been altered in many models, derived from the original OEE. Abbreviations such as OFE, OPE, and OTE cover application areas of factories, plants, and throughput. One of the modified models is OEEML which is targeted at manufacturing lines and thereby named the overall equipment effectiveness of a manufacturing line (Braglia et al., 2009). The reason why this specific variation is especially interesting is that it considers the entire manufacturing line and not the individual machine.

Fundamental calculations and metrics

The core elements of calculating the OEE are Availability, Performance, and Quality. These elements can be used to calculate the OEE, as illustrated in Appendix D - Calculation of OEE.

To provide an even deeper understanding and insight into the workings of OEE, it is important to understand the six big losses (Braglia et al., 2009). Figure 3.5.0.1 is an overview of these losses and the aim of reduction.

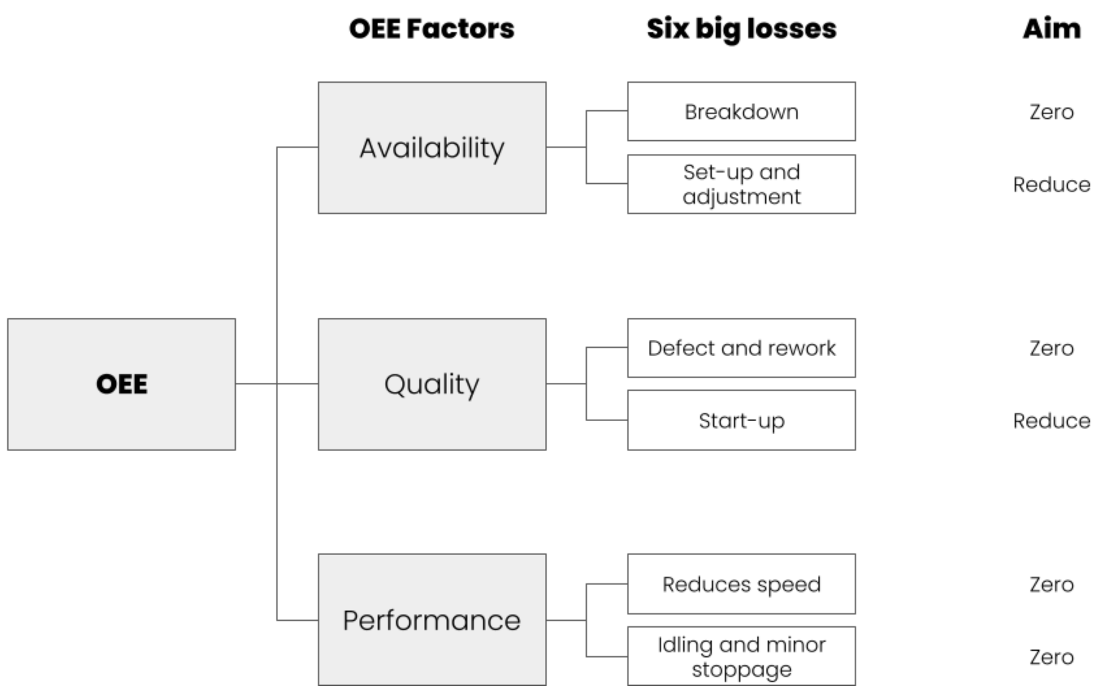

Figure 3.5.0.1 - Mapping of OEE factors, losses, and maintenance aim.

As illustrated above and shown in Appendix D - Calculation of OEE, the six losses are associated with Availability, Performance, and Quality, respectively. Many of the innovative technologies mentioned in e-Maintenance have, according to literature, a high probability of reducing some of the six losses based on advanced analytics, such as machine learning or artificial intelligence (Turner et al., 2019).

OEE to support decisions

The ability to quantify the production performance has been seen as the primary factor for the adoption of OEE (De Carlo et al., 2014). A result of quantifying the process and structuring the collected data is that computers can be used to analyze the information and supply insights for decision-makers. Using data to make decisions reduces the need for intuition which requires a higher level of domain expertise (Dane et al., 2012). Thus data-driven support for decisions can increase the effectiveness of decisions made by employees with less domain expertise.

The basis for using data to gain valuable insights is a credible source with sufficient quality. The subject of Data quality will be defined and elaborated in the section below.

OEE in pharma

World class OEE is set to be anything above 85% (Availability 90%, Performance 95%, and Quality 99%) (Chikwendu et al., 2020). Although this figure acts as a benchmark for performance it is still important to understand the context of the organization and industry. Most manufacturing companies score closer to 60% and it is more common to see companies with OEE scores below 45% than it is to see companies with OEE scores above 85% (oee.com, n.d.). As some industries, like the pharmaceutical industry, produce their products in batches, there are more stops and changes than industries that use continuous manufacturing with no change in products (oee.com, n.d.). Therefore there will be more availability loss of a production line with different products and products in batches, thus resulting in a lower OEE (oee.com, n.d.). Therefore, it is important to take the characteristics of the industry into account when benchmarking.

In general, the pharmaceutical industry is underperforming in terms of OEE not only due to batch production but also due to a lack of technological advancements (Friedli et al., 2010). Within the pharmaceutical industry you seldom see OEE above 70% and the world class is by some considered to be between 65% and 70% (Thomas, n.d.; Zubair et al., 2021). Studies by Chikwendu et al. (2020) and Zubair et al. (2021) have even found OEE numbers within the pharmaceutical companies as low as 31,7% and 23%.

3.6 Data quality

A central prerequisite for data-driven decisions and credibility in the OEE measure is accuracy and Data quality (Muchiri & Pintelon, 2008). The specific need and focus on accuracy when collecting data for OEE calculations has been stressed by several researchers (Eldridge et al., 2005; Jeong & Phillips, 2001; Muchiri & Pintelon, 2008; T.-Y. Wang & Pan, 2011) . This requirement of high quality data is valid for all utilization of data.

To clearly define Data quality, we use the six dimensions of Data quality from the US Census Bureau (T.-Y. Wang & Pan, 2011). In table 3.6.0.1 below, you can see the dimensions defined by the US Census Bureau.

Accessibility	The ease in which customers can identify, obtain, and use the information in this data.
Accuracy	The difference between estimated and true value.
Interpretability	The availability of documentation to aid customers in understanding and using the data products.
Relevance	The degree to which the data provides information that meets the needs.
Timeliness	The length of time between the reference periods of the information
Transparency	The existence of evidence that can be used to assess the accuracy of the data product.

Table 3.6.0.1 - Dimensions of Data quality defined by the US Census Bureau (T.-Y. Wang & Pan, 2011)

The challenge of collecting accurate information has been broadly recognized in the literature with a commonly suggested solution to automate the data collection (Muchiri & Pintelon, 2008).
Besides automating the data collection, the culture should be taken into consideration since a resistive culture has been documented to lead to inaccurate data and, as a result, hurt employees' motivation (Aminuddin et al., 2016).

The importance of Data quality is only increased with the subjects presented in the sections above. The following section will bring together the topics presented so far in the background section, to specify the scope of this research. With the scope presented below the importance of Data quality will only be emphasised.

3.7 Scoping and concept clarification

This section aims to describe how the different subjects and concepts interact, to form the field of data-driven decision-making in e-Maintenance. The first part of the thesis seeks to explore how decision-making in pharmaceutical maintenance operation is supported by data to improve effectiveness. The intersection of Decision support systems (DSS), Decision-making, and Maintenance will here be logically deducted with support in the existing literature presented above.

The intersection of DSS and Decision-making
Intersecting DSS and decision-making is here presented as data-driven decision-making. The concept of data-driven decision-making is here seen as the activity of making decisions based on systematic information and analysis in the form of DSS. DSS is in its widest definition defined as:

"a class of information system that draws on transaction processing systems and interacts with the other parts of the overall information system to support the decision-making activities of managers and other knowledge workers in organisations".
(Felsberger et al., 2016)

Combining DSS with the decision-making framework by Felsberger et al. (2016) , which is based on the work of Simon (1960), fits with the widely used definition for data-driven decision-making, found in the article by Provost and Fawcett (2013, p. 53): *“Data-driven decision making refers to the practice of basing decisions on the analysis of data rather than purely on intuition.”.*

Data-driven decision-making as the product of the interaction between DSS and decision-making is also illustrated in figure 3.7.0.1.

Intersecting DSS and Maintenance

The intersection between DSS and Maintenance is, in this report, described by the concept of e-Maintenance. By approaching DSS as a source of information to be used in guiding maintenance operations the concept of e-Maintenance, which is presented in section 3.2.2, presents itself as the defining concept of the intersection to maintenance.

Intersecting Decision-making and Maintenance

The intersection of decision-making and maintenance is found to be the prioritization of maintenance. The importance of maintenance prioritization is highlighted in the maintenance section 3.2. Besides appearing obvious, the link from maintenance prioritization to decision-making can be seen in the first three phases in the decision-making process, emphasizing the steps of Alternative analysis and the Choice of decision design.

Data-driven decision-making in e-Maintenance

Lastly, the central interaction of all the mentioned concepts leads to data-driven decision-making in e-Maintenance. This scope is considered the union set of all the involved concepts and the scope of our research.

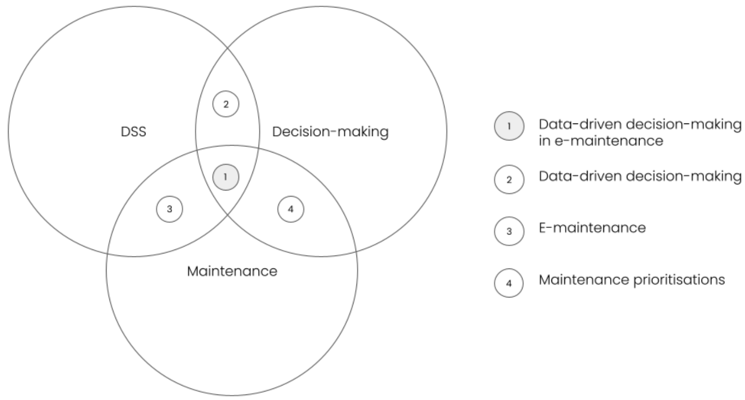

Figure 3.7.0.1 - Illustration the intersections of concepts which scope out the field of data-driven decision-making in e-Maintenance

To further elaborate on the scope of data-driven decision-making in e-Maintenance, it comes down to using e-Maintenance systems to identify and define problems or failures as early as possible, then prioritize the maintenance effort using data-driven decision-making.

An essential illustration of detecting failures over time within maintenance is the Potential Failure and Functional Failure (P-F) curve illustrated in figure 3.7.0.2.

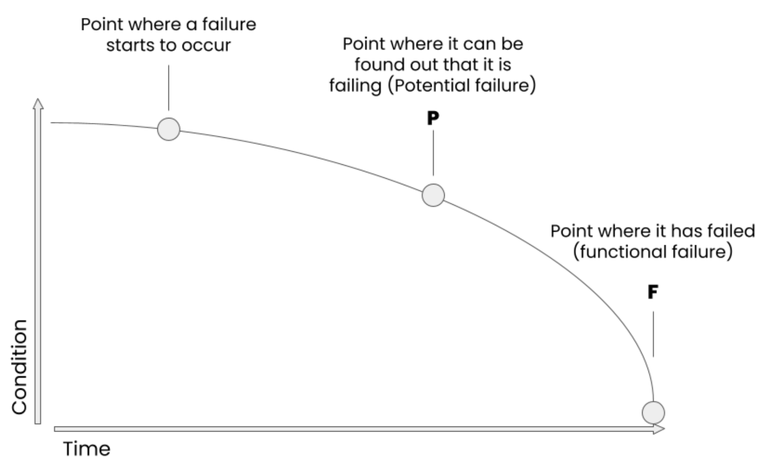

Figure 3.7.0.2 - Potential Failure and Functional Failure (P-F) curve modified from (Bousdekis et al., 2021, p. 2)

The P-F curve illustrates how a piece of equipment or machine degrades over time to the point where failures can be found out (**P**otential failure) to the point where it has failed (**Functional** failure).

The stretch from the potential failure to the functional failure is called the P-F interval, and this is where the equipment or machine, if no proper action has been taken, will deteriorate at a usually accelerating rate. The PF curve is relevant because it gives a good understanding of the importance of predictive maintenance. Predictive maintenance relies on condition monitoring and is exceptionally relevant to point to the potential failure of equipment or machine. With the emergence of industry 4.0 technologies, CBM techniques have evolved from manual analysis and visual inspection to sensors outputting real-time data at a high frequency on several parameters. Based on that data, advanced analytical techniques can be applied to support the decision-making process allowing for data-driven decisions based on real-time predictions (Bousdekis et al., 2021). Such structured data presented using a DSS, enables the decision-maker to generate proactive recommendations about the maintenance tasks. The concepts presented in this and the previous section are brought together in the following, to clarify the link between elements.

3.7.1 Linking the practical elements of data-driven decision-making in e-Maintenance

This section serves to present how all the previously presented concepts tie together in this study. The content of this section is visualised in figure 3.7.1.1 and can be seen in full size in Appendix L.

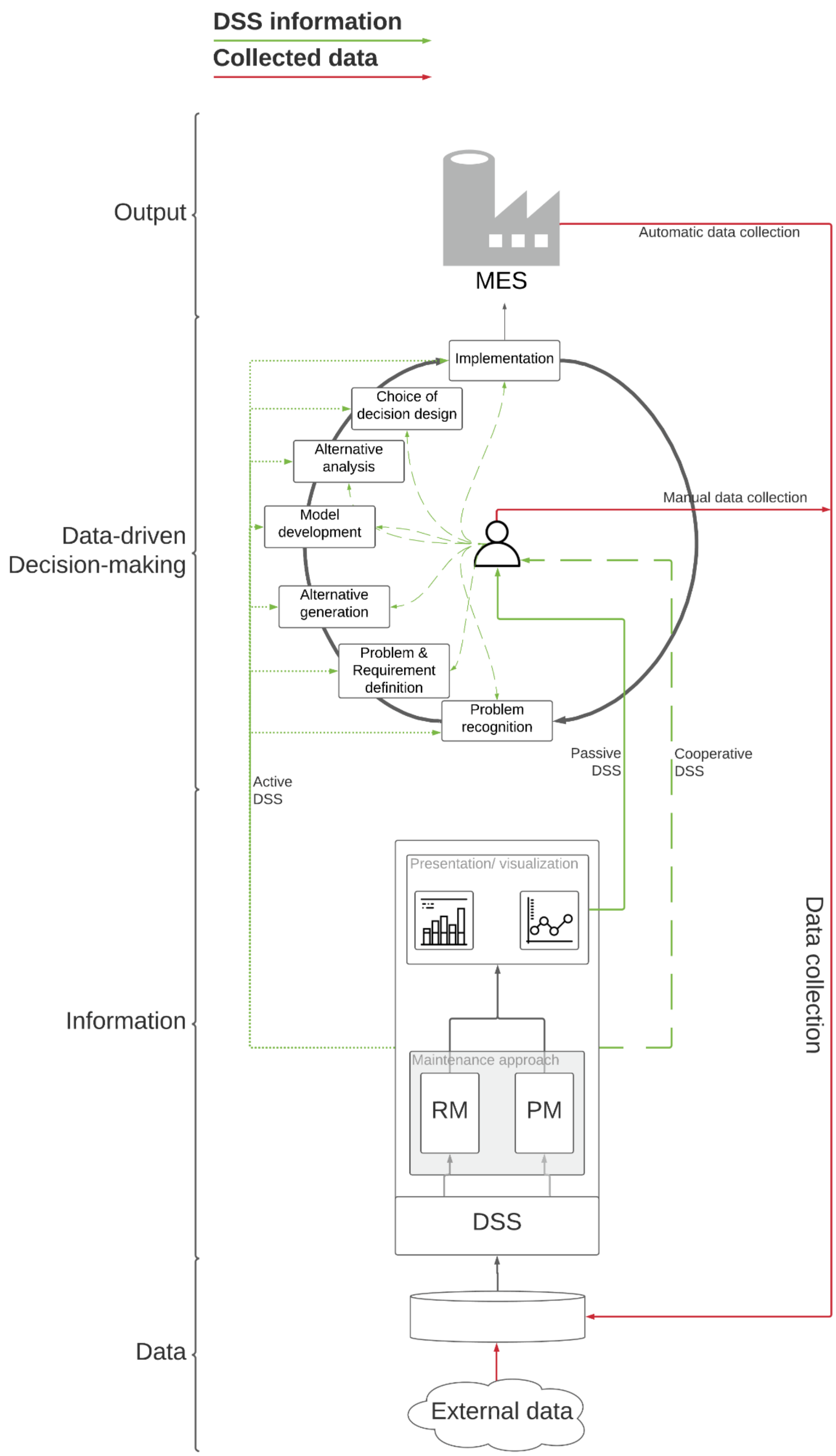

Figure 3.7.1.1 - Scope in practice and the relation of concepts and processes. Full size version is available in appendix L

The data foundation which is depicted in the bottom of the illustration in figure 3.7.1.1, is a combination of data collected on site and additional external data from sources such as ERP and MES systems. This stage is where the concept of Data quality becomes highly relevant. All the following stages depend on said quality and the provided Data quality sets the bar for how advanced and reliable the subsequent use of data can be. At this stage the collected data is no more than data as described by Qvortrup (1993). The next step is where data is turned into information.

Using DSS The second stage in the process is where data is prepared to be operationalized. The data becomes information so to say (Qvortrup, 1993). This stage heavily reflects the practical application of section 3.3. The DSS cover both reactive and preventive maintenance approaches, which are the high level abstraction of underlying maintenance types presented in section 3.2.1 (Gopalakrishnan, 2018). In relation to the PF curve presented in section 3.7 above the reactive maintenance (RM) is only capable of covering maintenance after P, whereas preventive maintenance (PM) covers maintenance efforts prior to P.
DSS as a system category can cover multiple systems which can have any level of data exchange with each other. For a user to consume information from a passive DSS, it must be presented in a way the user can consume the information. This presentation of information is often achieved through visualizations, which the user can operationalize in their decision-making. The cooperative DSS also relies on the user to take action which in figure 3.7.1.1 is visualized with the dashed line passing through the user. The active DSS is not limited to going through the user and is therefore represented as the dotted line which can affect the entire data-driven decision-making process.

Data-driven decision-making is as described in section 3.4 related to finding an optimal solution to a so-called decision-making model (Lu et al., 2019). The data-driven decision-making process is illustrated as a cyclic process according to the Decision-making process model which is elaborated in the following section 3.8. Within this cyclic decision-making process the user is depicted to illustrate the central position of the decision-maker, and how the user is able to manually input data back into the system which is considered a part of the next stage of measuring the output.

Measuring the output is done through a combination of the manual input from the user as described above and automatic data collection through sensors. The output is a wide term, selected to cover both the production output, which leads to the calculation of OEE, and output of additional data containing event and process data. The collected data is fed back to the data stage.

With the scope defined and linked to practice, the following two sections will describe how this scope will be analyzed to determine the extent to which data is used in the decision-making and the factors for adoption of e-Maintenance technologies.

3.8 The decision-making model

Decision-making was found to be a central part of the scope of this research, and to examine the use of data in decision-making we need to establish a structured understanding of the decision-making process.

The decision-making process presented by Felsberger et al. (2016), will therefore be used to fully understand the complex web of interaction between humans and DSS that affect the decision-making process.

This framework is inspired by the work of Simon (1960) and Shim et al. (2002).Simon (1960) who described three decision phases that reflect the decision-making process; Intelligence, Design and Choice*. Intelligence* is the search for problems, *Design* is the development of alternatives, and *choice* is the selection of a solution for the implementation (Shim et al., 2002). In later years Simon (2013) included the fourth phase of implementation making it a cyclic model illustrated in figure 3.8.0.1 below.

Research by Shim et al.(2002) and Merkert et al. (2015) shows that existing research on decision support systems has had a focus on the technological aspect, but lacks a more holistic or comprehensive view of the decision-making process. To provide the more holistic analysis this paper will include the findings from this decision-making framework in the overarching Technological Organization Environment (T-O-E) Framework, which will be described in section 3.9 below.

Each individual step in the decision-making process will be used to analyze how the use of data impacts the decision-making with regards to increasing the effectiveness. The steps are visualized in figure 3.8.0.1 below.

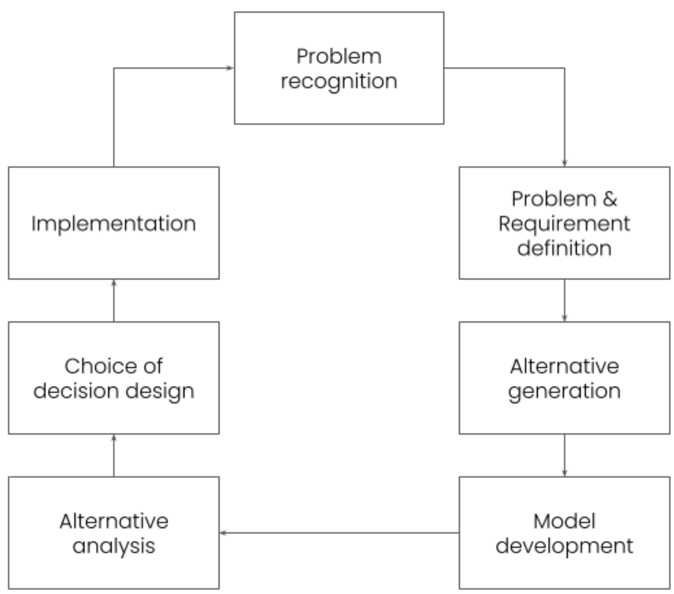

Figure 3.8.0.1 - The decision-making process modified from (Felsberger et al., 2016)

Using this framework will enable a thorough exploration of the data-driven decision process that effectively enhances the production line and increases the OEE. The dissection of the decision-making process on the line enabled a structured analysis of how this specific line has reached a high level of OEE while taking a more holistic view with the following T-O-E analysis.

It is important to note that almost no decision-making process is perfectly sequential as presented in figure 3.8.0.1 (Shim et al., 2002). Often in practice the steps overlap and blend together and can loop back to earlier stages. Each step will be explained respectively below.

The first step is the fundamental **Problem recognition** where the problem essentially is recognized. The second step can be seen as the defining step, since it covers two distinct elements of **defining the problem and** determining the **requirements**. The first element of defining the problem is described as defining a statement of the problem that describes the initial state and the desired conditions. The second element regarding the requirement determination is materialised in a list of the most urgent needs and goals (Felsberger et al., 2016).

The third step consists of **alternative generation** and entails the generation of possible alternative solutions for the uncertainties within the decision-making process. It is crucial that the generation of alternative possible solutions all meet the requirement definition from step one.

In short, the first three steps aim to find, identify and formulate the problem and summarize it in the form of a decision statement.

Model development as the fourth step is used to create models of the generated alternatives, which can be evaluated simultaneously according to the same set of criterias. The best model to compare against is the one which meets the goals, requirements, and criterias first.The fifth step is to evaluate the alternatives in an **Alternative analysis** using the created models. This comparison can be done in many ways, spanning from a simple pros and cons analysis to a complex MultiAttribute Utility Theory Analysis (Felsberger et al., 2016). The last part of the Alternative analysis is to verify that the alternative actually solves the problem by comparing the alternative to the initial problem statement.

The output from the fourth and fifth step is a set of analysed alternatives which are validated to solve the problem and compared against each other on a fixed set of criterias. The sixth step is named **Choice of decision design.** This step simply covers the selection of the alternatives analyzed in the previous step and sets the direction for the last step. The seventh step is simply called **Implementation.** The aim and purpose of these two steps are to create a solution to address the initial problem: *"The solution should satisfy the desired state, meet requirements and best achieve the goals within the values of the decision process."* (Felsberger et al., 2016).

This framework will be used to analyze how and to what extent data is used in decision-making. The result from that analysis will then feed into the subsequent analysis of factors influencing the adoption of e-Maintenance technologies which directly impact the operationalization of data to improve effectiveness. The framework for this main analysis will be presented in the following section.

3.9 Technological-Organization-Environment Framework

This section will introduce the framework used for the analysis. First, the framework will be introduced and described, whereafter an argumentation for its relevance in this case study will be made.

The T-O-E framework was introduced in 1990 by Louis G. Tornatzky and Mitchell Fleischer (1990). The purpose of the theoretical framework that describes potential factors that influence technological adoption. T-O-E provides a description of how the technological context, organizational context, and environmental context influence the process of how companies implement and adopt technological innovation (Tornatzky et al., 1990).

Figure 3.9.0.1 visually presents the three elements that influence the adoption and implementation of technological innovations.

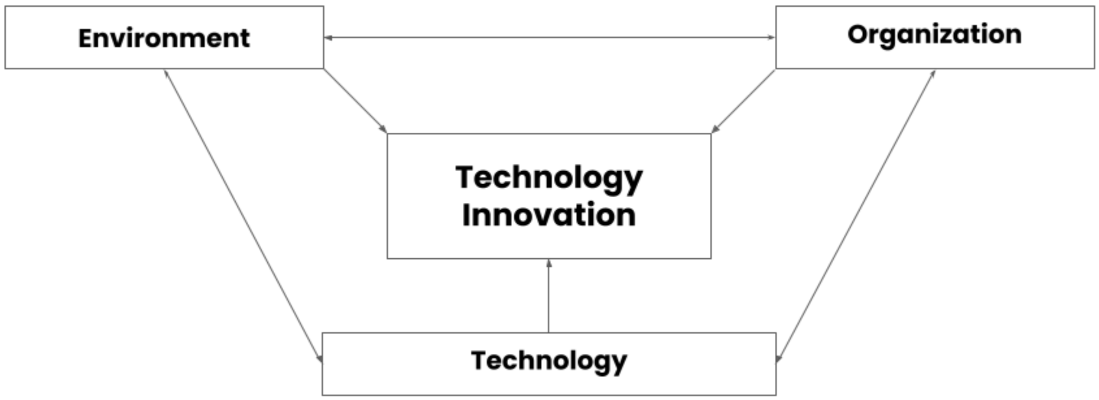

Figure 3.9.0.1 - T-O-E Framework - adopted from Source (Tornatzky et al., 1990)

3.9.1 Technological context

The technological context entails the existing technologies that the company currently have but also available emerging technologies relevant to the firm in the future that are not currently in use. The existing technologies are important to understand as they can create a challenge to the pace of technological adoption (Collins et al., 1988).

In the same way, it is important to understand the future possibilities as it can be a factor influencing technological innovation by *“demarcating the limits of what is possible as well as by showing firm ways in which technology can enable them to evolve and adapt”* Baker (2012).

3.9.2 Organizational context

The organization's context concerns the characteristics and resources of the firm. This can involve factors such as Skills, Management support, Size or Cost that influences technological innovation adoption.

3.9.3 Environmental context

The environmental context includes factors related to the industry at which the organization operates. According to Tornatzky et al., (1990), a company is to a high extent influenced by the ecosystem they operate in, both in terms of competitors, governments and regulations, standards, etc. Environmental factors such as regulation can constrain an organization's innovation technology adoption.

Other factors like competition or external support, can create synergy effects within the industry supporting the innovative technology adoption.

According to Baker (2012) and Wang, Wang and Yang (2010) the T-O-E framework extant research, has been conducted using the T-O-E framework showing its broad applicability. It is important to note that in the many empirical studies conducted, the researchers have different factors for the technological, organizational and environmental context. Most of the empirical research all conclude that the three T-O-E elements influence the innovative technological adoption but researchers have for each context being studied found a unique set of factors or measures. This indicates that the factors within the three general elements can vary, based on type of technology, industry, nation etc. Thus it can be concluded that the context is really important to understand when looking at adoption of technological innovation. This is also in alignment with Rahayu and Day (2015) who states that the T-O-E model covers many different dimensions, and has a greater explanatory power than other models, as the framework has an interactive perspective.

The T-O-E framework aids the researcher to treat different factors and their interactions in one dynamic framework and aids to explain the adoption of technological innovations more comprehensively (Awa et al., 2017; Molla & Licker, 2005). Thus being in alignment with the scope of the project and supporting the findings in the pre-analysis.
The T-O-E framework is well aligned with the choice of case study as case studies are beneficial in investigating a phenomenon where it is necessary to study the dynamics of the contexts (Halinen & Törnroos, 2005). The T-O-E framework is especially relevant when wanting to understand the various contexts and factors that influence the technological adoption of a firm within that firm's respective context.

Another prominent technology adoption framework is the diffusion of innovation theory (DOI) presented by Rogers (2003). The DOI and T-O-E framework are closely related to each other according to researchers (Baker, 2012). The main difference between the two frameworks is however the fact that T-O-E includes the environmental context.

Research suggests that the environmental constructs can be a significant barrier or driver towards innovative technology. As this thesis was motivated by the paradigm shift in the pharmaceutical industry described in sections 2 and 3.1, it makes sense to include this additional element, hence the argument for choosing T-O-E over DOI.

In conclusion, T-O-E allows for a comprehensive study enabling the authors to analyse the various factors influencing the adoption of innovative technologies such as e-Maintenance. The framework gives a good starting point, but allows the authors to find more specific factors within the three elements that are relevant for the context which is being analysed. In addition, T-O-E has a strong empirical support through the many papers using the framework, showing its broad applicability and strength. It is important to understand that different types of innovation or different industries will have differing factors (Baker, 2012). The innovation specifically looked at in this thesis is that related to maintenance within the pharmaceutical industry.

4 Methodology

This section will provide an understanding of the method of research chosen for this thesis from the research philosophy to the data analysis techniques employed. In addition the ethical considerations will also be provided. Finally, a summary of the methodological choices will be presented.

4.1 Research philosophy

The research philosophy is important to understand as it contains fundamental assumptions describing the way the authors view the world. The research philosophy will influence the research strategy and method chosen, and in general influence the entire thesis.

The overarching research philosophy chosen for this thesis is critical realism. By adopting the critical type of realism, we argue that what we perceive is the experience and sensations of reality and that we as humans can be deceived (Saunders et al., 2009).

As critical realism focuses on explaining a phenomenon within a context it aligns with the scope of the thesis. In addition, critical realists accept that a phenomena creates different sensations which are open to misinterpretation. As the research area involves several stakeholders with different educational backgrounds and views of the world, it is important for us to acknowledge that misinterpretation can happen, thus making it important to validate the findings across different stakeholders.

The ontology entailed by realism is objective and defines the world as independent of the observer. The critical aspect emphasizes the observer and thereby the perceived reality, which is susceptible to misinterpretation.

The idea of an interpreting observer differentiates the philosophy from the standpoint of positivism. In contrast, the core of realism as an objective ontology aligns it with positivism and distances it from interpretivism. We also acknowledge and support the inherent axiology, which describes the research as value-laden and that the researchers are biased by world views, experience and upringings which will influence the research. This biased worldview is taken into consideration in the following section 4.3 of research design. The explicit focus from a critical realist on explaining phenomena within a context enabled us to address the criticism by Fraser (2015, p. 655) on how maintenance research is detached from the real world - making critical realism the ideal research philosophy (Saunders et al., 2009).

4.2 Research approach

The research approach is the choice between whether the thesis will take a deductive approach where the research design will be to test the developed a theory or hypothesis or the inductive approach where data is collected and the development of theory is the result of the data (Saunders et al., 2009). It's important to note that although there are major differences and that the deductive owes more to the positivist philosophy whereas the inductive owes more to the interpretivist view, they are not completely distinctively and should be thought of as tendencies more than limiting set direction.

The selected research approach for this thesis is inductive, as the thesis aims to explore and understand the research context primarily through qualitative data. As this study is highly dependent on the context in which the phenomenon operates, and consists of a small sample an inductive approach is better suited (Saunders et al., 2009, p. 126). In addition, this study strives to achieve an in-depth understanding and to establish various views of the phenomena rather than seeking generalisability (Easterby-Smith et al., 2008). In addition this inductive approach is also in alignment with the choice of research philosophy of critical realism as with the inductive approach the researcher realises that they are part of the research process.

4.2.1 Pre-analysis

The pre-analysis had two main objectives: (1) validate the direction of research, and access to data (2) Identify factors affecting the adoption of e-Maintenance in the pharmaceutical industry.

Validation of direction and access

The initial idea of studying how data was used to improve effectiveness was the basis of the first meeting with the case company. This idea matured into the presented research question in section 2.1 through several meetings with SMEs from the case company. The relevance and importance of the study was confirmed from the first meeting while the research question evolved to guide the study in a more specific direction.

The case company also provided unrestricted access to relevant internal information after signing non-disclosure agreements. We were also provided with points of contact at the best performing production line and the top level SMEs.

Identifying factors

The second purpose of identifying factors affecting the adoption was applied in hindsight as the direction of study settled. From the first interview it became apparent that this study would not be a single dimensional study on technology. The influence and importance of the context was emphasized from the beginning.

Beside the technological factors which we identified and later summarized to be (1) Compatibility, (2) Data exchange and Interoperability, (3) Data quality, and (4) Perceived complexity, we also found (5) Cost, (6) Management support, and (7) Skills,. We later grouped these to be the organizational factors in the T-O-E analysis.

The last two factors used in the T-O-E analysis (8) Government regulation, and (9) Competitive environment was a factor identified early in the pre-analysis and solidified in retrospect, when comparing the literature to the pre-analysis, as visualized in figure 4.6.0.1 in section 4.6 Data collection.

4.3 Research design

The research design relates to how the researcher plans to answer their research question, whether the study is using quantitative, qualitative or a mixed method design (Saunders et al., 2009). The research design impacts the data sources, the research objective and analysis method. The research design chosen for this thesis consists of primarily qualitative data, which is well aligned with the inductive research approach. Some quantitative data will also be implemented but the primary design used to answer the research question will be qualitative.

4.4 Research purpose

The research purpose relates to what type of question you wish to answer. The most often used research purposes are exploratory, descriptive or explanatory research (Saunders et al., 2009). As the purpose of the research derives from the type of research question this studies research purpose is exploratory. Exploratory studies are valuable in seeking new insights, understanding what is happening or to ask questions to assess phenomena in new light (Robson, 2002). Exploratory studies are also especially valuable when you want to clarify an understanding of a problem, in the case where you are unsure of the precise nature of the problem. The selection of the exploratory study also suits the research question which starts with how and then what.

4.5 Research strategy

The research strategy relates to how you want to answer your particular research question. The research strategy is guided by the RQ, the amount of time and resources available and the existing knowledge (Saunders et al., 2009). No research strategy iis inferior, but some are better suited to answer some questions than others. Among popular research strategies are, experiments, surveys, case studies, grounded theory, action research and ethnographic research.

The selected research strategy for this thesis is the case study strategy. A case study is often used when the investigator has little control over the events and when there is a focus on creating an in depth analysis of a contemporary phenomenon in a real life context (Yin 2003, p. 3).

Case studies are often criticized for the lack of accuracy (Ellram, 1996) and the lack of statistical methods as used in quantitative research.
The reason behind choosing a case study design as our research strategy is to assess a real-world example, and case studies are *“excellent in providing detailed explanations of 'best practices'”* (Ellram, 1996; McCutcheon & Meredith, 1993).

Voss et al,. (2002, p. 196) argues that case study research has consistently been one of the most powerful research methods in the field of operations management which covers *“administration of business practices to create the highest level of efficiency possible within an organization”* (Hayes, n.d.). As this study looks into the maintenance efficiency it is thus within the scope of the project.

In addition, case studies are especially beneficial in investigating a phenomenon that cannot be separated from its context and where it is necessary to study the dynamics of the setting (Halinen & Törnroos, 2005). As Marques et al. (2020, p. 3) explains, manufacturing in the pharmaceutical industry is very complex as it consists of a complex network of agents not always obvious or easy to understand that have to work together.

Thereby supporting the strategy to choose a case study, as we need to understand the phenomenon within the context that it operates in. In addition, research has shown that case studies are specifically valuable within the field of supply chain management, logistics, and operations management which again aligns with the scope of this thesis (Seuring, 2008)

4.5.1 Case study design

The following section is inspired by Yin's (2003) book on case study research, design and methods, which is described by author renowned scholars such as Myers (2013, p. 94) as one of the most valuable books on case study methodology. The book by Yin is widely cited and used by researchers in most business disciplines, proving its legitimacy and value. Thus by using the designs and methods on case study of Yin and creating a systematic procedure during the report the authors aim to create a high quality case study. This methodology section is divided into three sections based on Yin (2003); *(1) Research Design, (2) Data collection and (3) Data analysis.* These sections are

Research Design, which has partly already been presented in 4.3 Research design, will in this section go into more depth based on Yin (2003) regarding the type of case study chosen. The second section, (2) Data Collection, provides an overview of how the preparation of the data was done in order to ensure a high quality case study by using the five topics presented by Yin (2003, p. 57-81). The third section (3) Data analysis will describe which analytic techniques are used to analyse the data and which specific techniques and procedures are used.

Designing the research in a case study is an extremely important task in order to ensure a good quality case study that mitigates the critique of case study research. According to Yin (2003) the quality of a case study can to a large extent be fulfilled if the case study is conducted by using his techniques to design decisions and methods.

Yin (2003) describes four basic types of designs for case studies based the two parameters Single vs. multiple and holistic vs. embedded; The different designs are (1) single case (holistic) designs, (2) single case (embedded) designs, (3) multiple case (holistic) designs, (4) multiple case (embedded) designs as illustrated in figure 4.5.1.1.

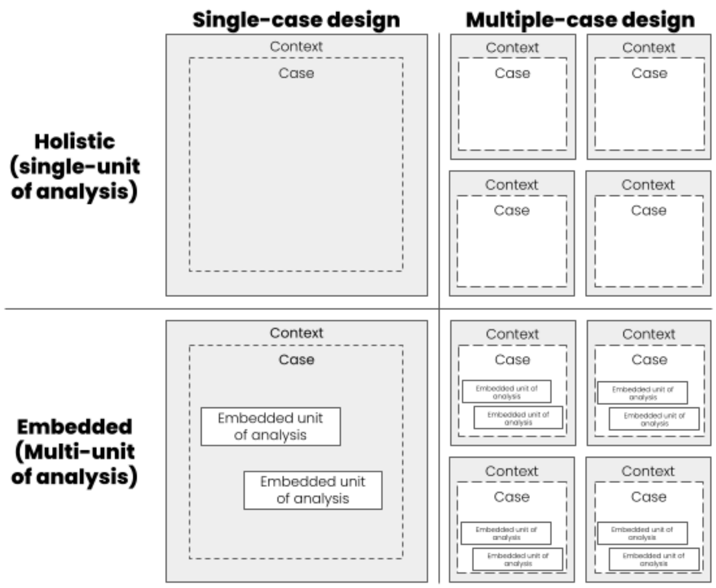

Figure 4.5.1.1 - Basis Types of Design for Case Studies (adopted from Yin, 2003, p 40).

This research will be based on a single case design with a focus on the organization as a whole. Yin (2003) argues that the holistic design is advantageous when no logical subunit can be identified.

According to Yin (2003, p. 53) multiple case studies have some advantages over a single case design as it is considered to be more robust, less vulnerable and more generalizable than a single case study design. Yin (2003) mentions 5 different rationales for choosing a single case study if the case is a critical case, unique, representative or typical, revelatory or longitudinal. This case investigates one of many typical discrete production lines in the company, thereby the rationale for this single case study is that of the case being typical.

Choosing a single case study creates the potential vulnerability of being misinterpreted in that the case may not turn out to be the case it first was thought to be (Yin, 2003, p. 42). One way to mitigate this is to maximize the access to needed data and to carefully investigate the potential case before fully committing to the case. In order to ensure this, several interviews were conducted in the pre-analysis phase to find the most interesting area of research with the maximum data access possible. The pre-analysis included interviews with subject matter experts (SMEs) who are responsible for rolling out the company's many digital solutions to all production lines. The respective SMEs who have rolled out the solution to all the sites have been a big part of analysing, communicating, and transforming the production lines hence having obtained a broad and extensive knowledge about the area. Involving the SMEs allows for increased generalizability since they can validate our findings as a general phenomenon seen across multiple cases. Additionally, it allowed us to focus our effort on one line and include multiple sources of information from different levels of the organization. As our research aims to investigate the complex web of interaction between digital solutions and the human decision-making process, it was also an advantage to use a single case study design as it enabled us to get the necessary in-depth understanding. Hence, mitigating the vulnerability of conducting a single case study.

In response to the criticism that case study often gets, Yin (2003) presents four criterias or tests for judging the quality of the research design in case studies based on Kidder and Judd (1986 pp. 26-20). The four tests are; **Construct validity, internal validity, external validity and reliability.**

Construct validity aims to address one of the more problematic areas in case study research. It concerns the lack of developing sufficiently operational set measures in order to eliminate subjective judgement. In order to address this problematic area, the authors of this report have focused on using multiple different sources of evidence, establishing a chain of evidence in the form of transcribs and attached case study documents and notes and other tabular materials.

In addition by using SMEs to constantly review and validate the case study report and direction taken, construct validity was also increased.

Internal validity is less important in this study as it is an exploratory study. Internal validity is primarily a concern in explanatory case studies where the researcher is trying to determine whether one event led to another event according to (Yin, 2003).

External validity is regarding the generalizability of the study. Many critics argue that single case study research has a bad basis for generalizing. This is often due to the fact that it is compared to survey studies which rely on statistical generalization. Case studies rely on analytical generalization in the form that the investigator tries to generalize a particular set of results into a broader theory (Yin, 2003). In order to establish a high level of external validity the authors of this report have used an extensive amount of existing theory in order to ensure a more generalisable conclusion. The fact remains that as this is an exploratory study, the primary aim of the thesis is not to generalize but to discover and understand something of the specific case.

Reliability concerns the need to demonstrate that the data collection procedures can be repeated and come up with the same results. In order to achieve this a case study protocol (9 Appendix A) has been developed and a case study database was also created in the form of using google drive to all relevant materials such as notes, documents etc.

The above research design explains the general areas of attention the authors have focused on as they have played a consistently important role in the report. The following section will introduce the data collection process in terms of the good practice actions to take when collecting data and finally the actual data evidence collected.

4.6 Data collection

The preparation for the data collection was inspired and prepared through the 5 topics presented by Yin (2003, p. 57); *Desired skills, Training, Protocol development, screening and pilot case study.*

Desired skills

Conducting a case study is commonly believed to be “easy” but according to Yin (2003) this is far from the truth as the data collection procedures are not routinized, thus requiring a well trained investigator who knows how to navigate within the rules of case studies. Therefore Yin (2003) presents a set of desired skills that the researchers must develop before undertaking the case study. *Question asking, Listening, adaptability and flexibility, Grasp of issues being studied, and lack of bias.* What stood out during this case study was managing the skill of adaptiveness and flexibility, as many shifts occurred during the case study which often lead to new areas of interest or problems. The need to balance adaptiveness with rigor to the original research area was especially difficult to achieve as we had little information about the specific line prior to the research. This was mitigated through the pre-analysis interviews with the SMEs who provided insights and clarity to the area of interest where our research question and their case would match.

Training

In the case of training, Yin (2003) refers to the fact that every investigator should be able to act intelligently independent of guidance from others. As there were only two researchers two carry out this report, both researchers were a part of establishing the case study design. With continuous and intense collaboration it enabled us to get a good understanding of the case, thereby having the necessary training and knowledge to act independently of the other researcher. In addition to this we co-authored the case study protocol which allowed us to get additional structured knowledge within the case study and the direction taken.

Protocol development

According to Yin (2003) a case study protocol will increase the reliability of the study as it helps guide the investigator conducting the data collection.

The case study protocol can be seen in appendix A and includes the interview guide, evidence obtained and the different steps of the research process.

Screening

The screening process for the paper was simple as we already had an exclusive arrangement with great access to the case company, due to professional relations with the case company.

Pre-analysis

As this is a single case study the pilot case study was performed as a pre-analysis. with multiple subject matter experts to clearly define the scope and focus of the paper and to ensure that we could access data within the company to investigate our case. This enabled us to align the scope of the project with the information available. Furthermore this pre-analysis was used in conjunction with literature to determine the union set of parameters or so called predominant factors to be used for coding the interview. This union set is visualized in figure 4.6.0.1 below.

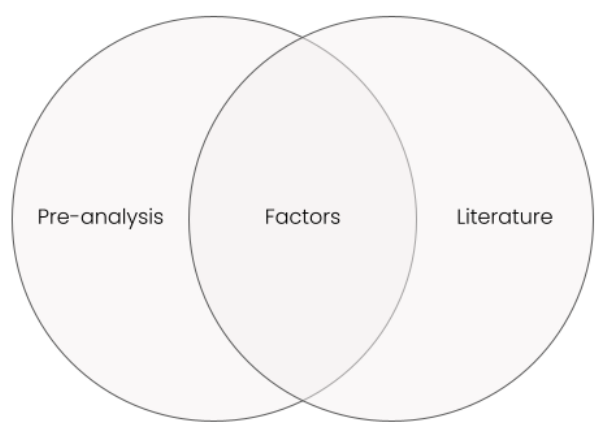

Figure 4.6.0.1 - Identifying predominant factors as the union set from the pre-analysis and the literatur to be used as codes for the interview.

Understanding the five topics presented by Yin (2003), allowed us to be prepared and focussed during the actual data collection which will be described in the next section.

Actual data collection

This study is designed with an inductive and qualitative approach with supporting quantitative data. This study has aggregated knowledge from different sources from the case company and outside of the company.

The data collection process was inspired by Yin (2003) in which we followed his three principles of data collection. *(1) Use multiple sources, (2) Create a case study database and (3) Maintain a chain of evidence.* By following these three principles the problems of establishing a high level of validity and reliability were addressed (Yin, 2003, p. 97).

1. **Multiple sources**

The data collected originated from multiple sources in accordance with the first principle presented by Yin (2003). Using multiple sources of evidence allowed us to benefit from the strength of each individual data source thus establishing the optimal opportunity for data triangulation. Using multiple sources is especially beneficial during a case study as any findings and conclusion is much more likely to be convincing and accurate (Yin, 2003, p. 98).

It was necessary to use multiple respondents as it enabled us to identify different perceptions and understandings of the case (Dubois & Araujo, 2007). In the case study several different actors were interviewed with extensive knowledge on the subject; Line Operator and Skilled workers, Process supporters, and various subject matter experts from the global Manufacturing intelligence team responsible for rolling out the digital solutions. In addition an interview was conducted with the business development partner responsible for increasing the effectiveness on alle production lines with a digital scope, who had conducted an extensive scan of all current digital solutions on the +40 lines and which innovative e-Maintenance technologies were in the scope.

Interviewing several different knowledgeable informants with different perspectives on the focal phenomena helped limit the interview bias (Eisenhardt & Graebner, 2007). Although, as we aim to be true to the research philosophy of critical realism chosen in the thesis, the authors understand that we are biased by our worldviews, cultural experiences, and upbringings.

As the case study required a rich and profound understanding of the business context the primary source of evidence came from interviews. In this case we conducted 9 interviews with the company's personnel where 6 were unstructured team meetings, and 3 were semi-structured Face-to-Face meetings.

Before undertaking the interviews, the interview questions were validated in a review process by the SMEs from the case company which led to some modifications to the questions allowing us to better legitimise the relevance of the question to the context analysed. Most interviews were semi-structured as this allowed us to work within the analytical framework and still be adaptive and flexible as per the desired skill presented by Yin (2003). The interviews were separated into three phases.

Phase one - pre analysis

Two unstructured interviews were conducted where the agenda was of an exploratory nature in which an informal presentation was given within the general area of research by different SMEs and other stakeholders. This helped us scope our research and enabled us to identify the limitation of data access in the case company while introducing us to new constructs and settings necessary to understand the case. Some of the SMEs were interviewed several times as more in depth answers were needed.

Phase two - Site visit

This phase was primarily used to get an understanding of the manufacturing lines in question and to understand the maintenance operation. Simultaneously we mapped the various data sources and DSS and got an understanding of the e-Maintenance tools available for them. By conducting a field visit and interviewing process supporters on the site of interest we were able to get a clear overview of the processes and systems used. This enabled us to assess a “real world” example of how a manufacturing line operates and the correlated maintenance operation process. It was especially beneficial as it allowed us to get a better understanding of the complex web of dynamic interactions between systems, data sources, processes and humans that affects the line, while simultaneously getting various hints towards the factors influencing the adoption of e-Maintenance. This phase was a prerequisite before going into the next phase as we were able to be more precise and context relevant questions.

Phase three - Validating findings

In phase three we conducted semi-structured interviews with interviewees 7, 8, and 9 based on the set of questions from the case study protocol seen in appendix Appendix A. This allowed us to get a more in depth understanding of the maintenance operations, while also getting an understanding of some of the barriers and enablers. In addition unstructured interviews with SMEs in which the purpose was to validate the findings from the semi-structured interviews were also conducted.

Figure 4.6.0.2 - Research phases.

SMEs were selected based on their knowledge of the digital solutions, their knowledge
The research participants were selected based on their active role in the company.

of general challenges and overall understanding of the performance differences on the different lines etc. (Phase 1).

The process supporter on the line is only responsible for increasing the effectiveness on the represented lines with a tactical and strategic mindset rather than an operational mindset. Thus being able to provide us with a great deal of knowledge of the different decision support systems solutions in place and their effect on the production lines. In addition experienced Operators and Skilled workers were selected to get a better understanding of the day to day operations and their experience with the new digital solutions and the general challenges of increasing the effectiveness on the lines.
A limitation to the report's reliability could be the lack of having studied several other sites. Due to time and accessibility limits, only one site was possible. This was however mitigated based on the many interviews with the SMEs who continuously were able to validate the report ensuring reliability. The unstructured interview with the Business Development Partner in the area Technology transformation who had conducted an extensive analysis of the digital situation of the company gave a strategic understanding of the current state of e-Maintenance technologies and provided key insights to the predominant factors influencing the adoption.
Data triangulation was achieved during the interview by combining primary data sources from the site visit and interviews with secondary data. The empirical data collected besides interviews consisted of; (1) access to internal records and intranet (2) presentation slides on strategies and roll-outs (3) various company information, (4) annual reports, (5) and various pharmaceutical industry reports and studies regarding the business of the case industry.

Although most of the study is based on qualitative data, quantitative data was also used in the form of numerical data such as various market statistics providing an understanding of the pharmaceutical industry.

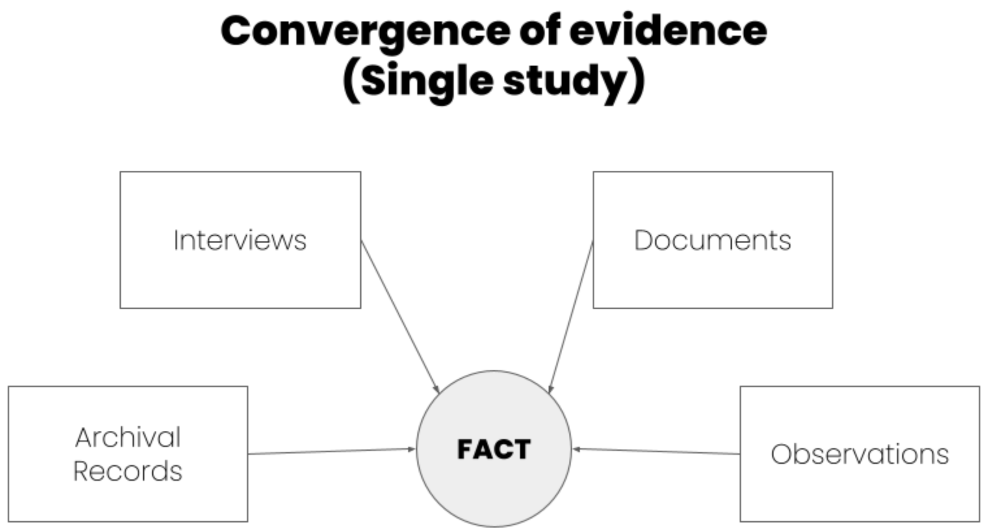

Figure 4.6.0.3 - Convergence of evidence from multiple sources - source Yin (2003, p. 100).

2. **Create a case study database**

The creation of a study database is the second principle presented by Yin (2003) and allows for the reader to inspect the raw data that has led to the study's finding.
The study database was created in the form of shared file storage in google drive and a collaborative research annotation tool, which includes case study notes, case study documents and tabular material. Thus fulfilling the requirement of organizing and documenting the data collected during the case study.

3. **Maintain a chain of evidence**

Maintaining a chain of evidence has a substantial effect on the reliability of the study (Yin, 2003, p. 105). Establishing a chain of evidence is to allow external observers to read and follow the chain of evidence of the arguments in the case going from initial research question to the conclusion of the report. Thus the reader of the report should be able to move from one part of the case study to another with a clear understanding of the evidence used to argue for that specific argument.

4.7 Data analysis

It is important to define a general analytic strategy to clarify the priorities of what to analyze and why (Yin, 2003). Different helpful analytic manipulations have been described by Miles and Huberman (1994), such as putting information into different arrays, making matrices of categories with evidence within each category, creating data displays, tabulation of data, putting information in chronological order etc. Many of these data manipulation techniques can be valuable to apply in the early stages of the case study as it might lead to novel findings or prevent you from going down a wrong path (Yin, 2003). This paper used the techniques presented by Miles and Huberman (1994) who suggest that data reduction, data display and conclusion drawing can be used as data-analysis techniques.

We used the software tool MarginNote which tools for books and various text for annotation, mind mapping and more. This tool helped us in data reduction and data display which was very helpful during the analysis as it helped visually present the connections between the themes identified and the literature. A screenshot of the data reduction and data display obtained by using MarginNote can be seen in Appendix N - MarginNotes.
In addition to this, after having coded the data, we used sticky notes to map out all the different themes, categorize them and display them thus allowing us to better see the connections and dependencies. The brainstorming mind mapping process can be seen in Appendix O - Data reduction and simplification.

In this case study, 3 of the interviews were audio recorded and transcribed. The product of the transcription produced over 50 pages averaging approximately 18 pages per interview. The other unstructured interviews were not audio recorded but documented through memoranda from notes taken during the meeting which were also analysed (Appendix E - Memoranda). After transcribing the interviews the transcription and notes were read by both authors several times and pre-coding was done based on the interview themes identified. The final coding was done using the steps described in the decision-making process model seen in figure 3.8.0.1 and T-O-E factors were coded using the table 4.7.0.1 as seen below.

	Factor	Description	Source
Technical	Compatibility	The degree to which a technology is consistent with the infrastructure, hardware and software, middleware and applications	(Bouwman, 2005, p. 192)
	Data exchange and Interoperability	Sharing data and interconnecting all involved systems in e-Maintenance	(Razmi-Farooji et al., 2019, p. 382)
	Data quality	The degree to which relevant data is collected from all stakeholders in the e-Maintenance system to provide cleaned data fit-for-use	(Razmi-Farooji et al., 2019, p. 382)
	Perceived complexity	The degree to which an innovation is perceived as difficult to understand and use	(Rogers, 2003, p. 15)
Organizational	Cost	Something that is given, needed, or lost in order to get a particular thing	(Cambridge Dictionary, n.d.)
	Management support	The degree to which the management supports an adoption of an innovative technology Support from management can be in the form of willingness to invest funds, willingness to accept risk or support in thinking of the adoptive technology to improve the competitive advantage or indicating the strategic importance of the technology	Wang et al., 2010 and Soliman & Janz, 2004
	Skills	the competencies needed from employees by their employer	Pereira and Romero, 2017
Environmental	Government regulation	Stringent safety and testing requirements from the government that can potentially retard innovation.	Baker et al., (2012)
	Competitive environment	The degree of rivalry among existing competitors based on factors such as bargaining power of suppliers or buyers, threat of new entrants and substitute products	Zhu et al., 2004 and M. E. Porter, 1998

Figure 4.7.0.1 - Coding table for T-O-E factors.

The analytical technique used was coding of the data using color coding inspired by (Kahkonen, 2014). The coding was done in phrases, sentences and whole paragraphs. This specific analytical technique is one of the more simpler ones but is useful for retrieving and organizing the data. The analysis took inspiration from Ryan and Bernard (2000) six fundamental tasks with coding;

1. *Sampling*: identifying text to be analysed
2. *Identifying themes*: identify themes from interviews or literature
3. *Building codebooks*: organizing lists of codes and definitions
4. *Marking texts*: assigning codes to units of text
5. *Constructing models*: identify links between themes, concepts, beliefs or behaviour.
6. *Testing models*: test the constructed models (step 5) with a larger data set

The data collection and data analysis was conducted in parallel with each other in order to regularly adjust our understanding and to continuously test or check the emerging themes based on the new obtained data (Shaw, 1999).

In addition to this, to heighten our awareness of patterns, themes and the different categories found in the analysis the transcripts were re-read to re-classified to test the models continuously with the other data collected as per step 6 in the fundamental tasks with coding by Ryan and Bernard (2000).

4.8 Summary of methodological choices

A summary of the methodological choices can be illustrated through the Saunders research onion figure 4.8.0.1.

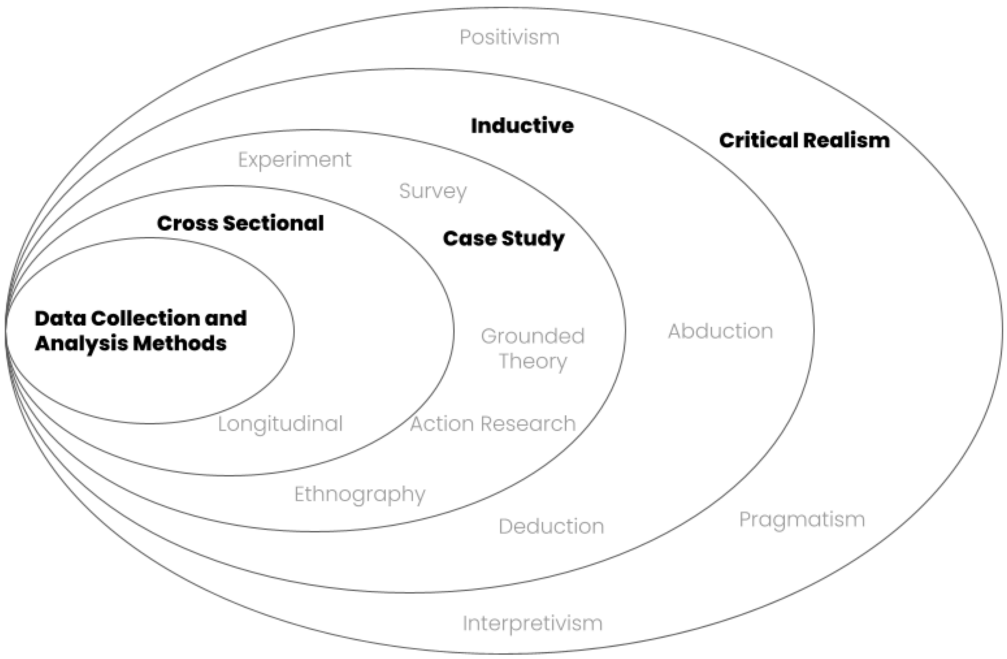

Figure 4.8.0.1 - Summary of Methodological Choices (adopted from Saunders, Lewis and Thornhill (2009, p. 108))

The research onion is helpful in visualising the methodological choices. It was developed by Saunders, Lewis and Thornhill (2009, p. 108) to identify the issues and possibilities in combining different methodological choices.

In addition to the research onion illustration, table 4.8.0.2 illustrates the primary methodological choices in the order of the subchapters.

Methodology	Choices
Research philosophy	Critical realism
Research approach	Inductive
Research design	Qualitative
Research purpose	Exploratory
Research method	Holistic single case study
Data collection	Semi-structured interviews and archival documents, observations (primary and secondary data)
Data analysis	Explanation building - color coding, data reduction, data display

Table 4.8.0.2 - summary of primary methodological choices.

5 Case study

This case description will present the company and provide a cross sectional view of the current state of their best performing line. The description will serve as a reference point for the following sections under the case analysis.

5.1 Case description

This descriptive section is presenting the case company in general and the current state of how data is operationalized to improve effectiveness.

5.1.1 Company description

Company X is a large pharmaceutical company with +40.000 employees spread out over 100 countries. For many years company X has been able to post quarterly double digit sales growth, but due to the environmental factors described in section 3.1, with an emphasis on Government regulation and Competitive environment that era has ended. This has forced the company to lay off thousands of employees in an attempt to reduce the Cost.

Company X has, for many decades, like most of the pharmaceutical industry, had a focus on the development of blockbuster drugs, and has had a successful run with this strategy, in which most of the attention was given to R&D and marketing. However, as a result of declining growth and increasing number of environmental factors, the company has been forced to change course and improve the effectiveness of other areas within the company. One of the areas that has become an essential, to minimize Cost and increase effectiveness, is that of maintenance on production sites:

"...at the whole company we optimised what we had, and we did that for a long time, and we were really good at it, and we were extremely successful… I think it's fair to say that the big turbulent crisis where everything was up in the air, that gave more perspectives... the company was open for new ideas and for different ideas different ways of working and different products and in general different ways of doing things in manufacturing" - (Video transcript 1 - Executive Vice President)

The effectiveness of the production lines in company X are measured in OEE, which is described in section 3.5, and is the benchmark KPI used to compare the production lines and sites against each other. The case company does not differentiate between OEE and OEEML but uses OEE as per the definition of OEEML by (Braglia et al., 2009).

The production lines of company X constitute a large part of the company's costs, therefore a big incentive lies in reducing this cost. The biggest cause of loss/decline in effectiveness is equipment failure. The company has historically tried to mitigate this through different types of maintenance. As defined in Table 3.2.1.2, SLU has been the primary focus for the case company used to reduce the level of BM on the production line.

In recent years company X has increased its focus on the implementation of industry 4.0 technologies, which enables the implementation of CBM to further reduce the BM.

The goal of company X is to become first mover within digitalization and they have great ambition and plans to use the industry 4.0 technologies to reduce cost and increase the effectiveness of their operations. This becomes especially clear in the video of an executive vice president of company X, who, referring to the digitalization, states: *“we have decided then instead of being what we called fast followers we want to be leaders”* - (Video transcript 2 - Executive Vice President)

A large part of their focus is to use data to support the decision-making process with data-driven decision-making. The company's production site, with the best performance and adoption e-Maintenance, will be presented in the following section.

5.2 Case analysis

This section covers the analyses of both research questions. The first part is a presentation of how data is used on a high performing production line, based on the data collected from company X. The subsequent section then dives into analyzing how decision-making in pharmaceutical maintenance operation is supported by data to improve effectiveness. After the decision-making analysis, the identified factors for adoption of e-Maintenance technologies are analysed. The factors are analyzed using the T-O-E framework covering the technological, organisation, and environmental factors influencing the adoption of e-Maintenance.

5.2.1 World-class production line

This section is an in-depth description of the overall best performing line which can provide the clearest picture of how decision-making in pharmaceutical maintenance operations are supported by data to improve effectiveness and where exactly in the decision-making process data is used. During the pre-analysis we were presented with technical solutions and practices from other production lines, which in some cases, had a more elaborate and complex system than those used at the examined line.

Despite not having the most advanced systems and equipment in all categories, this line is the one that performs the best, with an OEE of 86.7%.
This section will present the system in its current state, how it is used in decision-making, and describe the underlying Data quality, to give an insight into the context of the case study.

Using data in decision-making

Despite being the best performing site and line in company x, the use of data in the decision-making process was found to be limited to the process of identifying and describing the problem.
In practice the sensors on the line are monitoring if a certain threshold is exceeded and to generate an event which is logged together with stops on the line. To describe the level of data-driven decision-making the PF curve by Bousdekis et al. (2021) presented in section 3.7, can be used. The basic use of data has enabled the workers to discover events before failure (F) by identifying potential failures (P).

This information is then used to assess how an interaction with the line affects these same events and amount of production line stops. This is done through their Lean Kata practice. The Kata process is a structured process of methodically testing incremental improvements (Marchwinski et al., 2003). In terms of the decision-making model, the areas where data is used is limited to the Problem recognition and the Problem & Requirement definition steps highlighted in figure 5.2.1.1. As one of the interviewed Skilled workers said, *“From there [the Problem & Requirement definition] we take it on experience.” - Appendix F - Transcript of interview 8*

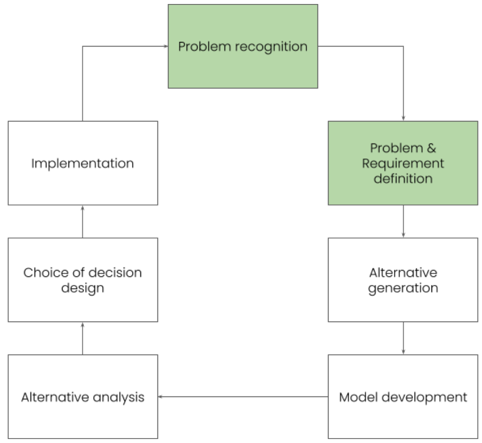

Figure 5.2.1.1 - The decision-making model highlighting Problem recognition and the Problem & Requirement definition.

This finding has proved to be evident throughout the exploratory analysis. Data is rarely used beyond describing a problem and measuring the outcome of an action, which can be seen as the Problem recognition step. Despite the lack of preventive maintenance the studied line had an OEE of 86.7%, which is considered as a world class OEE in the pharmaceutical industry (oee.com, n.d.; *Understanding OEE in Lean Manufacturing | Lean Production*, n.d.). The improvements were attributed to the compounding effect of maticules optimizations using data from the Passive DSS in the Lean improvement Kata. *"So we did a crazy improvement on it [A unit on the production line causing stops]. I mean really really really a lot of small improvements." - Translated from Appendix G - Transcript of interview 9.*

The current passive DSS is a part of the complex system surrounding the production line, elaborated below.

The system - from data registration to decision-making

The entire system as a complex network of agents, including software, hardware and the users, is an entity too complex to exhaustively describe in this section. This exploratory research has focused on all the touchpoints, from data being registered until it is used in a decision-making process to increase the effectiveness of the production. This scope is described in section 3.7.1 and visualized in figure 3.7.1.1.

Additionally, we have also investigated on which foundation decisions are made. This was done to determine where decisions are made, based on other parameters than the formalized data collection. This section aims to describe the current state and capabilities of said system.

First and foremost, it is important to describe what type of data is collected on the line. In general terms all data collected, to be used in their DSS solution, can be classified as event data. These events are triggered when certain criterias are met in the machine's programmable logic controller (PLC). Due to technical limitations on these PLCs, it has not yet been possible to extract the raw process data.

The collected event data is collected into a company-wide system, designed to store and present historical event data. This system will, in the following, be called Decision support system1 (DSS1). DSS1 is the data backbone, and provides data for other DSS’s implemented across all the sites. DSS1 is a non interfering system to the production process, which is a requirement to the GxP pharmaceutical production imposed by the environmental factor of regulation as described in 3.1.

DSS1 aggregates the event data to calculate the OEE, which is the company standard KPI for comparing effectiveness between lines and sites.

The second DSS, hereafter referred to as Decision support system 2 (DSS2), is based on data from DSS1 and ERP systems. DSS2 focuses on presenting the most relevant failure diagnostics in close to real-time, which is currently brought down to a 10 minute delay, or after every 1000 units produced. DSS2 is still in active development as an agile development process where the users on the site are included to improve the solution further. The third DSS, hereafter named DSS3, is a visualization and gamification of the batch change over process with data being pulled from DSS1 and the company ERP systems. The relationship between these three DSSs, which are developed in-house, is visualized in figure 5.2.1.2 below.

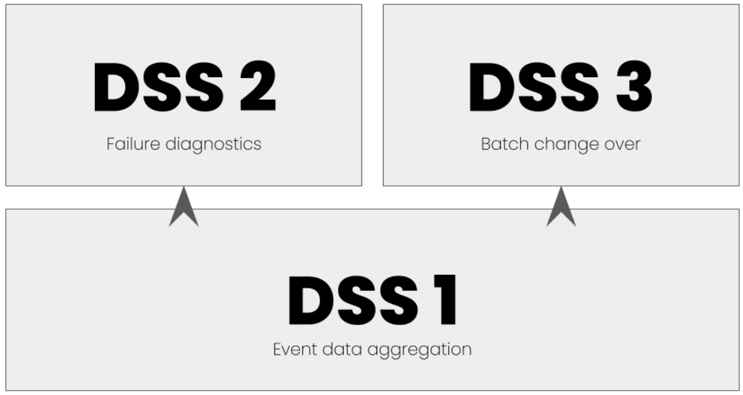

Figure 5.2.1.2 - Relation between the in house developed DSS's.

DSS1, DSS2, and DSS3 provide quantified common reference points, which enables data-supported communication. The data enables the workers to measure the effect of their interactions with the production line, as previously mentioned. Furthermore, the quantification allows for precise comparison of information and enables explicit knowledge sharing across teams. Lastly, this formalized measure produces the OEE, which serves as the core KPI on the production line.

According to the interviews, the increased use and availability of certain data has also reduced the need for experience to identify errors on the line. The experience of the Operators is still found to be necessary when solving the problem. *".. It's only half of the truth that data can replace experience. Because it helps you to the right place, but you still have to make the improvement."* - Translated from *Appendix G - Transcript of interview 9*

Nevertheless, the use of data was found to reduce the need to exclusively have highly experienced Skilled workers. The effect of data reducing the need of experience to make qualified decisions, is also supported by the findings in existing literature on when to rely on experience (Dane et al., 2012).

Data is currently presented to the users through Tableau visualization dashboards and locally developed Excel sheets. These dashboards allow for some interaction with data, such that the user, to some extent, can specify what data to present in a given time frame.

The users are currently only somewhat satisfied with the Tableau solution. The main complaint is that even though the data exists and the visualizations are built, some users still struggle with finding and using these visualizations. Some of the key issues identified are lack of training, technical inefficiencies such as loading time, and the Perceived complexity in navigating interfaces. Both loading time and the Perceived complexity is elaborated with regard to Data quality in the following sections.
The issue of systems running in parallel without integrations, has been pointed out as one of the main barriers. The users are currently using a plethora of systems, which are scattered across the spectrums of analog to digital, and local initiatives to company wide implementations. Based on interviews and site visits this seems to be the result of multiple factors such as Compatibility, Data exchange and Interoperability, Perceived complexity, agile development processes, and promotion of local innovation. In general, systems are described to work “stand alone” (Appendix H - Transcript of interview 10).

One instance of this issue of separated systems has been challenged. A recent project used very simple, locally developed visualization to mitigate the practical issue of the Operators not being able to physically see all the status lights of the individual machines in the production line. This issue was simply solved by providing a single screen with an overview of the status lights. This simple initiative has been measured to improve the OEE by 1.5 points during testing. The testing phase only had a buzzer to alert the Operator to find the light, so even further improvement is now expected. To highlight and compare, the most advanced solutions should also be mentioned. Currently an image recognition setup is monitoring a step in the production to identify damaged plastic parts. This initiative has been significantly more expensive, while the effect on the OEE has not been identified.

A current local project has started to install data collectors, which are able to extract raw live process data from the machine PLCs. The ambitions and expectations are high for this project among users and management. This project is still at a very early stage and has not been formally integrated into the workflow and decision-making process.

This could potentially improve the Data quality significantly. The quality of data is crucial to such a system, which will be elaborated below.

Data quality

This section will be describing the quality of data using the six dimensions established by the US Census Bureau, which is described in section 3.6 Data quality and table 3.6.0.1.

Accessibility is without a doubt a central point of the current Data quality. The underlying actions in accessibility of identifying, obtaining, and using the data will here be described individually.

The users are currently, to a great extent, able to identify the data they need. Since the users are domain experts, they have a very clear mental image of what they are searching for. The challenging aspect of identifying the data they need, is found to be in close relation to obtaining the data. In practice, some users are simply unsure where to look for the data, and they express that it is complex to navigate multiple systems, which do not communicate together. This Complexity is, to some users, a hindrance when attempting to obtain the desired information. Another crucial point to make, when describing the “obtain” element of accessibility, is the granularity of data. The current data is event data, which naturally provides less granularity, than raw process data would. This is currently not perceived negatively by the users, but more as a possibility for future improvements.

As long as the user knows what they are searching for and where to look, they describe the information as fairly easy to obtain. The primary challenge is then the, previously mentioned, technical inefficiency where certain loading times can be as long as 10 minutes.

The ease of using the information to make decisions, has unanimously been described positively. This overwhelmingly positive response has to be seen in the scope of how they currently use data in decision-making.

The extent to which they use data in decision-making, is as initially presented limited to the first two steps in the decision-making model.

Within the scope of using data to recognize and describe problems, the accessibility is found to be fairly good. At the same time, accessibility has also proven to be one of the most mentioned limiting factors for future improvements.

Accuracy is also a central point in describing the current use of data. Despite the simplicity of the definition, the practical implementation has been found to be crucial. A commonly described improvement in accuracy has been the automation of data collection, limiting the human element of registering data. Human registration could introduce such inaccuracy, that it could be argued that even the accessibility would be affected. A banal practical example could be an Operator not registering an event.

Interpretability of data is mainly supported by using visualizations. Since the users are domain experts, the need for documentation describing what data represent, is found to be less important. The aspect, where documentation seems to be highly important, is to describe the use of the data products in the sense of utilizing the actual DSS. Lastly, the importance of consistent naming in the DSS, which corresponds to the naming used on the line, was mentioned as an important factor.

Relevance was generally found to be high. The users of the system are included in the agile and iterative development, which enables them to influence the prioritization of features to best meet their needs. Relevance was not found to be a limiting factor with the current setup.

Timeliness differs between systems. The longest gap between two periods of information is currently 10 minutes due to the sampling sizes of event data. This sampling size limitation is present in DSS2, while the events are logged continuously in DSS1 and 3. Timeliness is an area of focus in the company's development effort, and the team is actively working to improve this further. The 10 minute delay is described as an improvement while still being a limitation.

Transparency was primarily mentioned with reference to previous manual data collection. The current data collection is set up by the Skilled workers on the line, so they know exactly how data is captured. Furthermore, the data is mostly collected automatically, which provides consistent accuracy. The current state reflects the promises made in e-Maintenance of maintenance documentation, as presented in section 3.2.2. The limitations found in transparency relates closely to the technological factors of Compatibility, Data exchange and Interoperability, Perceived complexity which is covered in the T-O-E analysis in section 5.2.4.

Summary

This is the best performing production line in a globally renowned pharmaceutical company, achieving OEE numbers described by SMEs and the process supporters as world class - making this line a real-world state of the art example of high maintenance efficiency. Despite the focus in literature on preventive maintenance and the use of AI, ML, and advanced analytics to improve OEE, this production line has none of these technologies and still achieves tremendous effectiveness. This clearly shows a significant difference in the initiatives and issues faced in cutting edge practice, compared to the state of the art in literature. This discrepancy is also identified and supported by Fraser et al. (2015).

The examined production line has managed to operationalize data-driven decision-making in e-Maintenance, without using cutting edge technology. The following section will dive deeper into how data is used in decision-making.

5.2.2 Data-driven decision-making in maintenance operation

This section presents the steps that have steered the case company, and especially the investigated production site to the point where they are today. This analysis section is considered an extension of the previous section, highlighting how data is operationalized into data-driven decision-making aiming to increase the OEE.

The decision-making model from section 3.8 will be used to elaborate on the extent to which data is used.

Historically, the primary use of data, with regards to decision-making in the maintenance operation, was to identify problems as visualized in figure 5.2.2.1.

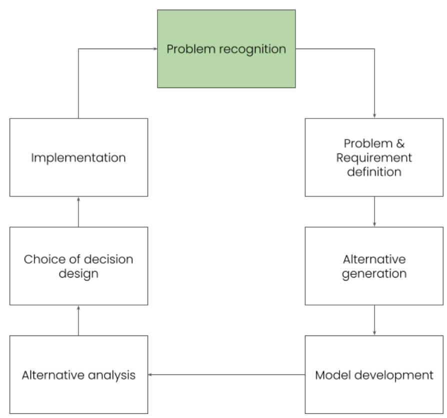

Figure 5.2.2.1 - The decision-making model highlighting Problem recognition as the only step in the process where data has been used historically.

The first DSS on the production site was a basic passive DSS. It simply prints out tables of event logs. The Operators and Skilled workers then had to rely on experience and experiments, to complete the decision-making process. At this point in time, the production line achieved an OEE below 60%.

With the introduction of additional sensors and systems, the amount of data available simply grew as described in section 5.2.1. As the foundation of data evolved, so did the ability to define the problem. With the ability to define a problem comes the ability to define the requirement for a solution (Felsberger et al., 2016). This step alone enables the ability to move away from reactive maintenance towards predictive maintenance.

This shift can be visualised both as a movement from F towards P on the PF curve in figure 3.7.0.2 and a move into the RCM side of the decision-making grid in figure 3.2.1.1.

As previously mentioned, the use of data in the decision-making process is still limited to identifying and defining the problem, despite being the best performing site in terms of OEE. The practical use is that data is used to monitor if a certain threshold is exceeded in terms of events and stops on the line. This information is presented through several visualizations, serving as passive DSSs. The same information is used to assess how a mechanical interaction with the line affects the same events and amount of stops. This is done through their Lean Kata practice. In terms of the decision-making model the areas where data is used are limited to the Problem recognition and the Problem & Requirement definition steps highlighted in figure 5.2.1.1.

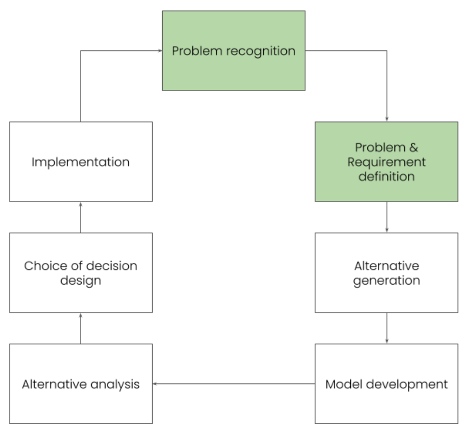

Figure 5.2.2.2 - The decision-making model highlighting Problem recognition and the Problem & Requirement definition.

This finding of only using data in the first two steps, has proven to be true through the entire exploratory analysis. Even though there is an extensive effort and investment in using data to improve effectiveness, there is still an undeniably significant discrepancy from the real-world best performers and the cutting edge literature describing preventive maintenance types.

The reasoning for why data is not used in the entire decision-making process appears to be linked to several factors. The predominant identified factors are elaborated and analyzed in the T-O-E analysis in section 5.2.4.

When presented with the finding that only two steps in the decision model are using data, one could be led to believe that the impact of using data has been insignificant. Despite this, in an operations context, time is also an essential parameter. With the increased collection of data the iterations through the decision-making model have been dramatically improved. When asked directly if the data had improved the time spent per iteration the answer was: *"Yes, so now it is way faster from when you discover something till you're there. And then even faster to the point where you have a solution."* Translated from *Appendix G - Transcript of interview 9*.

In this context, the topic of Data quality is unavoidable. The quality of data was already highlighted by SMEs in the pre-analysis. Throughout the entire study, Data quality has been mentioned as a precondition for any data-driven decision-making. The requirements to Data quality was mentioned as one of the primary reasons why AI and ML is not yet implemented successfully. One SME expressed the issue very plainly as *"shit in, is shit out squared"* - Translated form Appendix E - Memoranda, Interview 4 . Several references to failed implementations of ML and AI was mentioned throughout the interviews (see Memoranda in Appendix E - Memoranda)
When asked directly about the prerequisites for data-driven decision-making, one of the interview subjects described lack of Data quality as a hindrance.

The use of data as input for their Lean Kata processes, is how the maintenance Skilled workers operationalize the data-driven decision-making in their maintenance operation. By increasing the amount of usable data they can access, they have been able to implement solutions in minutes instead of spending hours or days. This data-infused Lean process has without a doubt been the central element of achieving their OEE of 86.7%.

This point was also highlighted by the process supporter on the production line:

"... It's interesting that there is such a big focus on all these cool buzzwords, but what really gives 80% are good LEAN processes and then visualization of data from the line. So why focus on getting lines from 80% to 90% when you can focus on those lines with an OEE of 40% up to 80%, which there are many who globally run with" - Translated from *Appendix F - Transcript of interview 8*

This data-driven decision-making, in what must be considered e-Maintenance, is visualized in figure 5.2.2.3 below, as an adapted version of the general visualization in section 3.7.1.

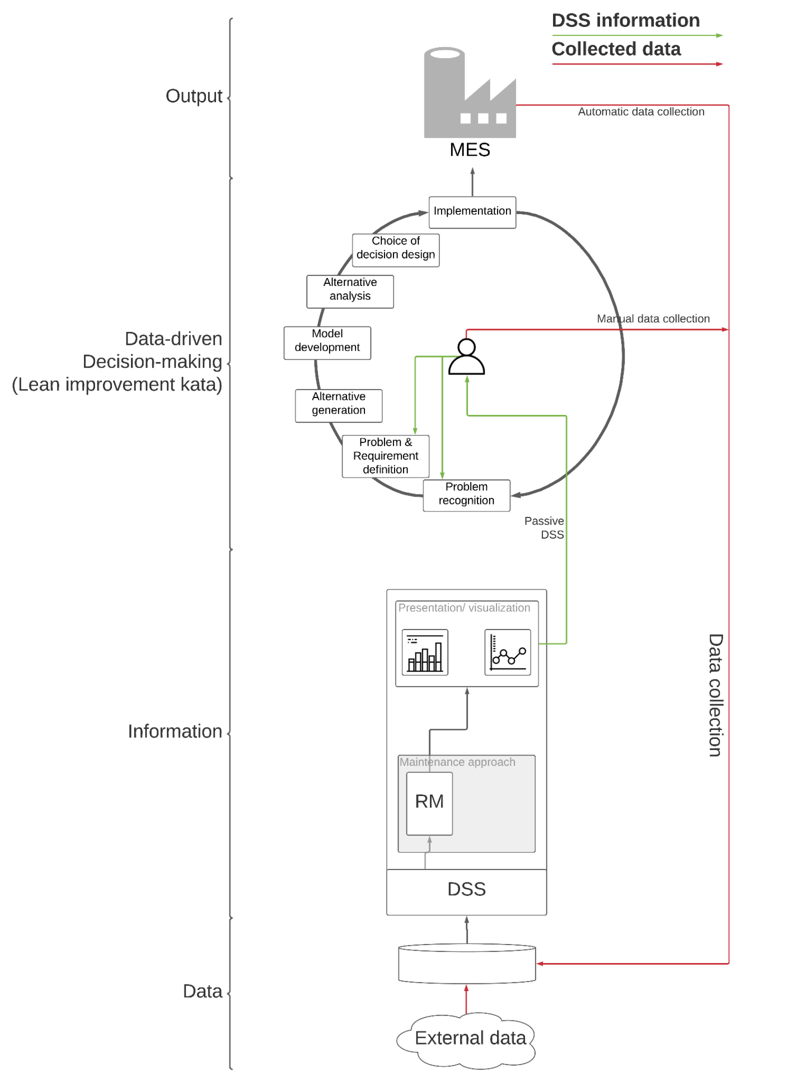

Figure 5.2.2.3 - The relation of concepts and processes found in the case study, modified from the generic version presented in section 3.7.1 will a full scale version available in Appendix M

The relation of concepts and processes found in this case study can be summarized using the stages illustrated in figure 5.2.2.3. Starting from the initial data stage, which consist of event data that are pulled in by the three DSSs. Due to the nature of this event data all the maintenance efforts supported by the DSS are based on reactive maintenance. All the current DSSs are classified as passive and are only found to be applied by the user in the first two steps in the decision-making process, during their lean improvement kata. The data collected is shifted to be predominantly automatic, with only few manual inputs. The collected data is then fed back into the loop supported by additional external data.

5.2.3 Findings - research question 1

Based on the analysis of how decision-making in pharmaceutical maintenance operations is supported by data, a few findings stood out. The first significant finding was how the use of data has significantly increased the speed of their improvement kata. The increased data has simply enabled the Skilled workers on the line to identify and define problems faster, and also enabled them to iterate faster over decision-making processes, to implement potential solutions and improvements at an unprecedented pace.

The second finding was the unavoidable need for Data quality. Even though this finding was more or less expected, due to the extensive mentions in existing literature, the importance is paramount. To be able to use data to support the decision-making process in maintenance operation, it has to be of a sufficiently high quality to serve as a foundation.

The third finding was unexpected, since it revealed that data was only used in two out of seven possible steps in the decision-making process. Even though data is only exposed through passive DSSs and used in such a relatively small part of the decision-making process, Problem recognition and problem requirement and definition, a world-class OEE of 86.7% is still achieved. Despite the high OEE, it is interesting and relevant to understand why data is limited to being used in the two first steps of the decision-making process. The factors for not adopting the use of data to a greater extent in the decision-making process, to implement both active and cooperative DSSs, will be presented and analysed in the following section covering the T-O-E analysis.

5.2.4 Analysis of T-O-E - factors influencing maintenance technology adoption

As previously described this section aims to understand the predominant factors influencing the adoption of innovative e-Maintenance technologies in the pharmaceutical industry.

Technological factors

This section will cover the technological factors, identified through the pre-analysis and the literature review as essential for the adoption of maintenance technology: (1) Compatibility, (2) Data exchange and Interoperability, (3) Data quality, (4) Complexity.

The most predominant technological factor, influencing the adoption of innovative e-Maintenance technologies discovered, was Compatibility. The way Compatibility is referred to in this case, is derived from the work of Bouwman (2005), where technical compatibility is described as "*The degree to which a technology is consistent with the infrastructure, hardware and software, middleware and applications"* (Bouwman, 2005, p. 192). The initial attention brought to this factor was in relation to the limitations imposed by the existing IT systems, used on the production lines. Due to limited resources in the machine PLC, a hard limit was imposed on how deep an integration was possible. This hardware limitation was discovered during the initial site visit and confirmed in an following interview with the process supporter (Appendix E - Memoranda, Appendix F - Transcript of interview 8).

This factor has been a recurring factor according to the research by Baker (2012), summarizing prior studies using the T-O-E framework. Furthermore it links directly to the nine pillars of industry 4.0 presented in section 3.4 Data-driven decision-making, specifically the pillar of system integration.

The case company’s adoption of technological advancement was very limited due to Compatibility issues. The focus on Compatibility was verified through SMEs and a CVP responsible for manufacturing IT (Appendix E - Memoranda). *“We are not ready [preventive maintenance]. We have a legacy situation both in processes and in systems and in complexity and diversification of technology”* (Video transcript 3 - Corporate Vice President - 0:31:30).

The issues created by lack of Compatibility, relates specifically to being able to scale new innovative solutions in the maintenance operations across the different sites:

“We have way too diverse a technology landscape, what that translates into, is that we need to spend time understanding the technological aspect of that, every time we need to implement something different and that of course we spend time and money on. At the same time, it is the age of those technologies that are problem that we need to address” - (Video transcript 2 - Corporate Vice President - 1:14:30)

A global initiative on establishing the foundation necessary to be able to scale faster and implement new innovative solutions, has been initiated. The initiative aims to upgrade the infrastructure in terms of making the hardware and software, middleware and applications compatible, to meet the needs of the future technologies. The initiative is bespoken as an enabler for business innovation. The importance of a solid data infrastructure was also highlighted during an interview with a SME, who had performed digital scans of all production sites in the company. The importance of standardized and harmonized sharing of data was directly linked to the overall Data quality (Appendix E - Memoranda, Interview 7).

The second factor relies heavily on Compatibility, and is referred to as Data exchange and Interoperability. Data exchange and Interoperability is defined by Razmi-fajoori et al. (2019, p. 382) as *“Sharing data and interconnecting all involved systems in e-Maintenance”.* This factor was found to be one of the most requested features of the DSSs. The current sharing of data between systems is largely unidirectional as a form of data aggregation. Data is collected, aggregated, and distributed by DSS1 for the other DSSs to use (Appendix E - Memoranda).

The desire was to move towards omnidirectional sharing of data between all relevant systems. The technical limiting factor was primarily attributed to the silo technologies with only sparse ability to share data. The segregation of systems and the potential value add of integrating them, was verified in the interviews: *“Yes, all systems around the line run stand alone. … So we actually have many good systems, but the cool thing would be if they could talk together.” - Translated from Appendix G - Transcript of interview 9*.

The most flexible solution was the ones developed in-house, which serves as the backbone in the DSS architecture. The importance of this highly interconnected sharing of data between systems, is expressed as a foundation for entering the industry 4.0 era (Klingenberg et al., 2019; Vaidya et al., 2018), and more specifically for utilizing e-Maintenance (Gopalakrishnan, 2018).

In relation to sharing data, the third factor was identified as Data Quality, a factor here referred to as *“the degree to which relevant data is collected from all stakeholders in the e-Maintenance system to provide clean data fit-for-use”* (Razmi-farooji et al. (2019, p. 382).

The importance of Data quality was already emphasized in the first meeting in the pre-analysis. Data quality was a recurring topic and also seen as a hindrance for implementing AI and ML (Appendix E - Memoranda). Data quality was also expressed to affect the use of DSS. The explanation from a validating interview with a SME was that poor Data quality led to distrust in the system, and thereby less usage and even worse Data quality (Appendix E - Memoranda, Interview 5).

With data being the foundation, this factor was dissected even further by using the six dimensions presented in section 3.6 Data quality, to produce the detailed finding for each dimension described in section 5.2.1. Key findings extracted were primarily concerned Accessibility and Accuracy. Accuracy was found to increase with the introduction of automated data collection. This correlates with findings in the existing literature (Aminuddin et al., 2016). The dimension of Accessibility had a profound challenge. With the initial state of little to no access to data, the accessibility was categorized as low. However, as the access to data grew, so did the Perceived complexity of identifying, obtaining and using the data. This Perceived complexity hurts the perceived accessibility, and is identified as the last technical factor influencing the adoption. This Perceived complexity was expressed clearly several times. *“I must admit I don’t always find it easy to find [the relevant data in the DSS], but that is how I feel. It’s probably not the system's fault, it’s most likely mine.” (Translated from* Appendix H - Transcript of interview 10).

Perceived complexity is here defined as *“The degree to which an innovation is perceived as difficult to understand and use”* based on Rogers (2003, p. 15) work on diffusion of innovations. Besides the Perceived complexity described above, in relation to the accessibility of data, several instances of Perceived complexity were identified in other areas. The Perceived complexity was evident through all phases of the exploratory study and seen as a key determining factor affecting the adoption. *“I have colleagues who have said that it [using the DSS] is to difficult, and that they don’t want to, and get others to do it”* - Translated from Appendix H - Transcript of interview 10

The Perceived complexity was a recurring theme throughout the interviews, with 7 out of 10 interviews having Perceived complexity as a central element. Perceived complexity was often expressed in relation to training or with a desire to improve user interfaces (see Appendix E - Memoranda and transcriptions in Appendix F, G, and H).

The impact of Perceived complexity is likewise recognised throughout the literature both regarding decision-making and as a factor in adoption (Bilgeri & Wortmann, 2017; Wally & Baum, Robert J., 1994; Zhang et al., 2019).

To summarize, the most predominant factor, influencing technological adoption in the pharmaceutical industry, was that of Compatibility. Due to the previous success of the case company, standardization and the creation of foundational IT infrastructure, has not been prioritised previously, which now creates an enormous amount of Compatibility issues. Even so, Compatibility is now considered a highly important factor. In relation to Compatibility the lack of Data exchange and Interoperability was also a factor that was detrimental to innovative solutions. The findings also present how the diverse technology landscape in the case company has inhibited the otherwise decent Data quality, due to the lack of Data exchange and Interoperability. Data quality is by it self found to be an extremely important factor to the adoption of new technologies.

Organizational factors

In this section the identified organizational factors will be presented. The most predominant factors found were: (1) Cost, (2) Management support, and (3) Skills.

One of the primary organizational factors affecting the adoption of new innovative technologies in the area of maintenance was **Cost** (Appendix E - Memoranda, interview 7). Cost in this context is defined as *"something that is given, needed, or lost in order to get a particular thing"* (Cambridge Dictionary, n.d.). This definition is chosen to extend the more narrow definition used by other scholars, only referring to Cost in context of either the monetary value (Olsson & Xu, 2018), or perceived financial cost (Kuan & Chau, 2001). The reason for the use of an alternative definition in this thesis, is that we observed other elements to Cost than only the monetary value, especially in relation to maintenance.

As an example, this became clear, in the first interview with the process supporter, where it was confirmed that the consequence of implementing a new PLC is too high in terms of downtime on the line. Not being able to deliver the set quotas for the month or week were highly critical for the management, and was prioritized over the need for potential benefits received from a new PLC which is a technical barrier for the adoption of more innovative maintenance technologies.

Weighing potential benefits against the expected cost was found to be a challenge. The core challenge was described to be estimation of potential gains, which made it difficult to calculate an estimated return on investment (ROI) (Appendix E - Memoranda, interview 7). With Cost being a complex multifaceted factor describing more than monetary value, this estimation of ROI became even more complex. In addition to this, the time spent on improvements on the line was very limited by management, as the cost of time on improvement was too high in terms of output delivered.

“We had what we called ‘white time’ on the line as improvement time. And there we had 4 hours in a week. That was what we had, but to do something it required that there was nothing else that was malfunctioning and took the time first. Because if there was something that had broken then it was subtracted from the white time. But as the output had to increase, the awareness increased that improvement time was much more important” (Translated from Appendix G - Transcript of interview 9).

As stated, when the need to increase the output increased, there was a higher focus on spending time on “white time” and improving the line, to become more effective in terms of the OEE KPI.

In addition to this, we saw a rather risk averse organization that was very reluctant in creating new processes in support of more innovative technologies, because the potential loss of control over how it would influence GmP requirements, was too high of a risk. The licence to operate is critical for the company, there is thus a high risk when implementing new maintenance equipment that are GxP critical (6 - Initial Site visit, *Appendix F - Transcript of interview 8*).

Each factor can lead back to a financial aspect, and the financial aspect was found to have an influence on the adoption of new e-Maintenance technologies. *“the implementation of [confidential solution] would require too large an investment in relation to the effect it could potentially have”* (translated from Appendix F - Transcript of interview 8). But besides the direct financial aspect it is important to note the other elements of downtime, white time and safety in terms of GmP are important especially in the realm of maintenance in the pharmaceutical industry.

Management support related to the degree to which the management supports an adoption of an innovative technology (Y.-M. Wang et al., 2010). Support from management can be in the form of willingness to invest funds, willingness to accept risk or support in thinking of the adoptive technology, to improve the competitive advantage or indicating the strategic importance of the technology (Soliman & Janz, 2004). The influence of top management support on innovation adoption has been well researched and supported (Jeyaraj et al., 2006; Soliman & Janz, 2004). Management support is especially relevant to consider in the realm of the pharmaceutical industry, as the risk averse culture generated by GxP requirement, especially GmP in relation to manufacturing, has a great influence on Management support. This finding was also supported by an executive vice president who stated the following during an interview about technological advancement within the company:

"When I look at other companies how they produce, not in a high GmP based production, but formulate and build something. They do that in a similar way and then we can start with all our excuses again about how we have GmP requirements to live up to, but my theory is that we're adding complexity on top of each other where we now cannot see how much complexity we have actually added… it is built over the years and is performed by many people so the whole system itself is too complicated. we answered tough requirements with complexity that leads to mistakes and then we need to correct them" (Video transcript 1 - Executive Vice President - 0:19:05).

This clearly indicates how the management support is influenced by the regulatory requirement they need to operate under, which has created an organizational inertia, where it is now difficult to respond to the changes needed. This is also supported by the lack of technical compatibility, in which the organization has created a complex and diverse landscape, to meet the tough requirements from the government, neglecting to prioritize a standardized global solution that can create the compatibility required to meet the needs of the future.

In addition, it became clear, through the interviews and data collection that the level of Management support clearly had an influence on the adoption of new innovative maintenance technologies: *“So the development is driven by the demand from management that we should be able to drive faster. And then be allowed to do something about it” (Appendix G - Transcript of interview 9.*). In addition, when asked what was a necessity for the improvement of efficiency on the production line and using data to improve decision-making, the answer *was: “Willingness to change from management and staff” (Appendix G - Transcript of interview 9.).* The case company showed a high level of Management support. During Interview 7 a recent initiative was presented of creating a dedicated department, to identify and align all the e-Maintenance activities, to increase OEE (Appendix E - Memoranda). The department is also tasked to support the production site to assess which e-Maintenance activities are feasible for them. The creation of the department shows how management acknowledges the strategic importance of innovative e-Maintenance solutions and acts accordingly.

It was also highlighted during one of the interviews that the wrong support could negatively impact the adoption. It was mentioned, by one of the SME, how one site manager linked the bonus of their staff to the OEE performance, which then resulted in a wrongful adoption of the solution with manipulated data (Appendix E - Memoranda). Therefore the accuracy of the data was reduced and did not reflect the real OEE.

Skills can be defined as the competencies needed from employees by their employer (Pereira and Romero, 2017). According to Erol et al. (2016), implementing the vision of industry 4.0 will require new competencies from the employees. With new technologies comes more automation and intelligence, thus a higher need for the employees to understand a complex network of systems and interact with it, rather than perform simpler tasks. The need to work with the systems in the decision-making process, will require new technical understandings and was shown to be a challenge in the studied case company: “*... some of us, including myself, who are computer dummies. So we are not that good at it.*” (Translated from Appendix H - Transcript of interview 10).

In addition this element was also highly supported by the SMEs interviews, where it was stated that the Skills and training of the employees was very important to consider, as they saw how the level of Skills affected the adoption of the DSS across production sites. The many various DSS's as well as the complex technological landscape, created a need for skilled workers or Operators. They need to understand the mechanical functionality of the production line, and know how to make decisions, by utilizing the available DSS. The importance of Operators and Skilled workers in the maintenance operation should not be underestimated. Currently, production lines at the case company have more than 300 stop causes (Appendix J), which the Operator or Skilled worker has accommodated for. Such expert knowledge is tremendously valuable and should, according to scholars, not be neglected in research of the adoption of e-Maintenance technologies (Turner et al., 2019).

In general, interdisciplinary orientation is needed, when working in a complex environment. The analysis found a high need from the skilled workers to be able to work with existing legacy systems that are vital for the operations in parallel with new innovative systems that are built to meet new challenges. This finding is also supported by Erol et al. (2016), who conducted a study on the competencies needed for the future of production with a focus on industry 4.0 technologies. His findings suggest the most critical competencies needed are the ability to work in parallel with old systems and new systems.

In relation to Skills it is of course important to mention the element of training to develop the Skills needed. When asked what the important criterias were for a successful adoption of a new technology on the line it was expressed that "*50% is that the technique works and the remaining 50% is training*" (Translated from Appendix H - Transcript of interview 10). This highlights the need for establishing good training, to successfully adopt new technologies. The lack of training was mentioned as a barrier to adopt the new systems on the production line:

“You need training and some insight into this PC world… So it [The provided DSS] is useful, but training is needed… To me, it's confusing, and it's not just me. Many of my colleagues say the same thing, but it's probably because we're a little bad at this PC stuff. There are many who do not understand it. We complain and say we can’t find it [The desired view of relevant data] or can we just get some help. it does not come as easily” (Appendix H - Transcript of interview 10).

The need for interdisciplinary Skilled workers becomes higher, with the level of complexity in the technological landscape. In this case study it was evident that the lack of skilled people, to some extent, created a barrier to the adoption of new technologies.

To summarize, one of the most predominant organizational factors influencing technological adoption in pharmaceutical maintenance operations was Cost. What differentiates this factor within the pharmaceutical industry from other industries is how the pharmaceutical industry needs to be able to secure the delivery of their products. Therefore, the cost of downtime to improve the maintenance operation or implement new innovative technologies, is often down prioritized. In addition, the risk associated with implementing new, potentially improving, technologies that might interfere with GmP requirements, is also often considered too high, and requires a lot of tests and documentation,making it more challenging to implement.
Management support was also found to be a significant factor influencing the adoption of innovative technologies. Due to the regulatory requirement and previous success, an organizational inertia has been created, in which change becomes more difficult. The support from management has thus, for far too long, been focused on increasing productivity and ensuring compliance within maintenance, with little attention paid to ensuring the company for future innovative technologies, to advance the maintenance operation.

The final factor identified was that of Skills. The skill level among the maintenance workers has for many been limited to the performance of manual tasks on the line.

With the increasing number of DSS’s there is a need for more interdisciplinary competencies due to the need for workers being able to navigate between the different DSS’s.

Environmental factors

This final section in the T-O-E analysis will cover the environmental factors: (1) Government regulation and (2) Competitive environment. The environmental factors can be either detrimental or beneficial for innovation (Baker, 2012). Some of the environmental factors have already been mentioned in the background section, including Government regulations and the pressure from buyers to reduce prices. It was the environmental factors that was the initial motivation for conducting this specific case study, as the authors observed a need for change in the case company, due to many of the environmental factors. In this section we will present a more in-depth analysis of which environmental factors influence the adoption while providing specific case examples in relation to maintenance.

The environmental factors were to a large extent identified as the initial trigger of the adoption and focus on new innovative maintenance technologies by management. The references to these factors were more subtle and indirect in the primary data collected, but the secondary data strongly suggested that the factors were substantiated.

Government regulation entails the stringent safety and testing requirements from the government that can potentially hinder innovation, as patients' health is the most important area for pharmaceutical companies to ensure to be able to supply products (Baker et al., 2012). The pharmaceutical industry, as previously mentioned in section 3.1, is characterized by having to operate in a heavily regulated environment, to ensure and document a high level of quality. It is evident that governmental regulation, more specifically GmP has influenced the adoption of new innovative processes.
Interview 7 highlighted how governmental regulation has a direct impact on adoption due to the need for approval of new technologies interfering in the production (Appendix E - Memoranda, Interview 7).

The influence of governmental regulation on the adoption of new technologies was also highlighted in an interview with an SVP in the case company, who stated the following:

*"...when we are introducing new technologies and the new ways of doing things, we are on the borderline of what the authorities are thinking, so we have to develop together with them and see new ways. I think we're already doing this, but we have to do it more and be even bolder - because if you want to follow it by the letter you can actually not introduce new technologies so we have to make that interpretation and have that dialogue with the authorities to succeeded with what we are setting up to do" (*Video transcript 3 - Senior Vice President - 0:56:23)

This finding is also supported by Friedli et al. (2010), whose study found that the pharmaceutical industry is reluctant to implement new production technologies, as a change in the production process or use of new technologies often has to be approved by regulatory bodies.

Linking back to Management support, we see how the organization has created complexity within their maintenance processes to meet the requirement: "*We answered tough requirements with complexity that leads to mistakes...*" (Video transcript 1 - Executive Vice President - 0:19:05). This factor has led to a very diverse technological landscape, which makes it extremely difficult to scale new innovative solutions within manufacturing globally.

During interviews multiple SMEs mentioned how it was important for their solution to be non-interfering with the current production line (Appendix E - Memoranda, Interview 3 and 7). This means that they are prohibited to make changes that influence the production line's ability to produce goods, even if it is for the better, in the long run. This is a good indication of how crucial it is not to interfere with the flow of the production, reiterating the importance of being able to guarantee the deliveries of their product. The fear of creating too much downtime and thus not being able to meet the quotas necessary, is creating a risk averse environment.

Competitive environment - One of the unique characteristics of the pharmaceutical industry was how the companies do not deliver their products directly to the consumer. The value chain presented in figure 3.1.0.2 shows the complexity of the many different stakeholders and that the buyers were not the end user of the product, but instead consisted of pharmacies, hospitals and governments. As previously mentioned, the cost of global medicine spending is creating an increasing burden on governments around the world, making them look to lower the prices of drugs within specific areas (Marques et al., 2020). The case company felt this impact of pricing pressure from the buyers and has recently had to go through several rounds of layoffs:

"The big turbulent crisis where everything was up in the air, that gave more perspectives… suddenly, the company was open for new ideas and for different ideas, different ways of working and different products and in general different ways of doing things in manufacturing" (Video transcript 1 - Executive Vice President).

This price pressure from the buyers has increased the intensity of the Competitive environment. Specifically, this factor created an incentive for the organization to change and to improve the efficiency within the organization without hiding behind the fact that the company is heavily influenced by governmental regulation. *"... the price pressure affects the profit. Then there is an increased willingness to spend time on improvements."* (Translated from *Appendix G - Transcript of interview 9*).

Despite the shift in environment, which has forced the case company to become more efficient, one EVP still reiterates the importance of compliance and productivity: *"I've learned that you need to communicate very clear and in few words what is important so it's compliance, its compliance, its compliance and then it's productivity, productivity and productivity"* (Video transcript 3 - Executive Vice President - 00:02:00).

The balance of achieving a high level of compliance, while introducing innovative technologies in e-Maintenance, is a difficult but non the less important task that if successful, can lead to a competitive advantage:

"Consumer goods industries, automotive fully, digitalised companies they are far far in front of what we're doing within technology and that we should basically copy and implement in a GMP environment - yeah that's different that's a little more difficult but on the other hand it creates competitive advantage if we are successful" (Video transcript 3 - Executive Vice President - 0:42:10)

Successfully adopting technological innovations can, in an intense and competitive environment, allow firms to alter the rules of the competition and create new ways to outperform their rivals, according to Porter and Millar (1985). This highlights the importance and relevance of adopting technologies despite the influence of the GmP environment.

To summarize, the case company is clearly influenced by the environment in which it operates. Ranging from the Government regulation of GmP that has created a risk averse environment, detrimental to innovation adoption, to a beneficial factor of the Competitive environment that has forced the case company to change focus on becoming more efficient by using innovative technologies.

5.2.5 Findings - research question 2

Based on the T-O-E analysis of the most predominant factors influencing the adoption of e-Maintenance technologies in pharmaceutical maintenance operations, the findings suggest a clear set of significant factors.

Starting out with the environmental factors, stated at the end of the analysis the findings showed both detrimental and beneficial factors to the adoption of e-Maintenance technologies in pharmaceutical maintenance operations.

The primary motivator for the case company to change, in terms of becoming more innovative, was the general pressure from various stakeholders, including governments, to reduce the prices or “do better for less”. This focus created a crisis for the company, thus increasing the focus on effectiveness within the organization by looking into innovative and emerging e-Maintenance technologies. Besides this, the factor of governmental regulations and insurance of GmP compliance is, to some extent, detrimental to the adoption of innovative e-Maintenance technologies.

The technological factors included were **Compatibility, Data exchange and Interoperability, Data quality and Perceived complexity**. Compatibility and Data exchange and Interoperability were linked to the scattered technological landscape and legacy systems. The lack of these factors had a detrimental effect on the adoption of e-Maintenance technologies and were at their current state a clear barrier for future development. The final factor of Perceived complexity, related to the perceived difficulty in understanding and using technologies, was found to be a relevant factor in the use and acceptance of DSS in the case company.

Finally, the organizational factors included to influence the adoption of e-Maintenance technologies were **Cost, Management support and Skills**. The element of Cost was found to be represented not only as of monetary value, but also in terms of downtime in relation to securing delivery as well as risk of breaking GmP compliance. Management support referred to the allocation of resources both in terms of investing money but also in order to change the internal organizational inertia. The factor of Skills relates to the interdisciplinary Skills needed to combine the knowledge of the mechanical function of the line, while using the DSS to support the decision-making.

Figure 5.2.5.1 summarizes the factors influencing the adoption of e-Maintenance technologies in the pharmaceutical maintenance operation based on findings from company X.

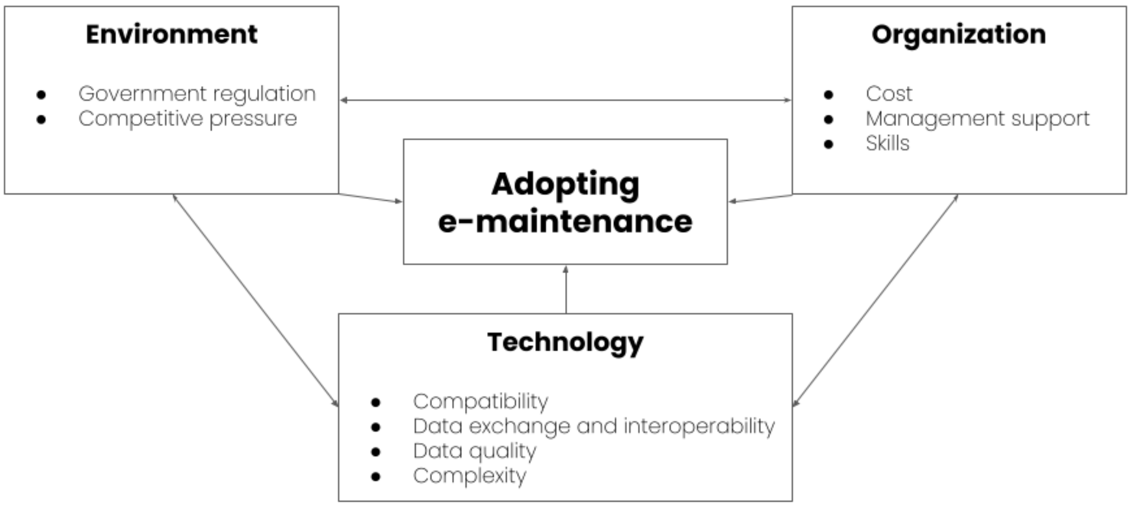

Figure 5.2.5.1 - T-O-E Framework - adopted from Tornatzky et al., 1990.

It is important to note that these factors do not exclude the potential for other factors, but are simply what this thesis found to be the most predominant factors influencing the adoption of e-Maintenance technologies.

6 Discussion

The following section will discuss the major findings derived from the previous sections in relation to the literature presented in section 3. In addition, we will discuss the practical and theoretical implications of the findings.

The study indicates that the use of DSS and the underlying data is limited to a small part of the decision-making process. Despite only using data in a smaller part of the decision-making process, it has still facilitated an increased OEE. Compared to the literature on maintenance types and the emergence of e-Maintenance, the study found an overwhelming focus, in the case study, on total productive maintenance types, with very limited use of preventive maintenance. The DSS and data was primarily found to improve the production site’s ability to iterate faster during the lean improvement katas, to see whether the corrective actions taken were successful. Nevertheless, the findings suggest that a very high OEE can still be achieved despite the lack of predictive maintenance, which to many scholars is seen as a necessity to achieve high OEE (Jantunen et al., 2017; Nordal & El‐Thalji, 2021). This finding highlights that the focus needs to lie on providing the right data, to the right person, at the right time and not implement preventive maintenance solutions. Despite the fact that the case company had limited use of predictive maintenance solutions, the need and focus on implementing it is clearly a priority to further increase the OEE.

The second part of the analysis relates to the factors in the T-O-E framework influencing the adoption of technologies, in order to understand why the pharmaceutical industry is having difficulties in using predictive maintenance, based on the findings of the first analysis. The selection of factors to be used in the T-O-E analysis is context specific. To confirm the validity and relevance of the chosen factors as a complete set, would thereby require an identical context. The factors have therefore been validated as subsets of factors by comparing the context of this study with existing literature (Baker, 2012; Rahayu & Day, 2015; Tornatzky et al., 1990; Y.-M. Wang et al., 2010).

The practical implications are first and foremost to understand the basic need of having lean processes in place in the maintenance operation. Most increases in OEE were achieved through thorough lean processes, rather than using data in their decision-making. Though a higher level of OEE can potentially be achieved using more advanced e-Maintenance tools, such as predictive maintenance solutions. This, however, is influenced by various technological, organizational and environmental factors. Specifically in relation to the pharmaceutical industry it is important to understand how the regulatory requirements have affected the technological infrastructure and organization, as this has an influence on the adoption of new e-Maintenance technologies. What was found to be especially interesting and of practical use, was the need to understand the influence of regulatory requirement on the technological infrastructure and management support, which according to the interviewees, had been a main cause for the scattered technological landscape and organizational inertia. By understanding this, organizations might have a better chance of creating the change needed to stay competitive.

The theoretical implications of this study suggest a need to investigate how e-Maintenance is built on top of the lean processes - as it was evident that the largest gain in OEE was not through the use of preventive maintenance, but comes from having competent lean processes with DSS and underlying data to support decision-making. Based on our case study, the empirical evidence suggests that lean processes should be perceived as a prerequisite and foundation for the successful implementation of predictive maintenance.

7 Conclusion

The choice of structuring the research around a single case study, has provided an in-depth understanding of how decision-making in pharmaceutical maintenance operation is supported by data. In addition, it has given explicit insights into the technological, organizational, and environmental factors affecting the adoption of e-Maintenance within the pharmaceutical industry.

Analysing the case using the decision-making model, has revealed a limited extent of data in the decision-making process, and revealed how improvements can be achieved without applying data in the entire decision-making process. The increased focus on using data in decision-making has enabled the examined production line to reach world-class OEE numbers. The increased effectiveness was found to be less attributed to how much of the decision-making process is based on data than expected. The primary effectiveness increase was instead achieved through the increase in pace of iterations in the lean manufacturing process. By focusing on solving the biggest issues first, through data supported maintenance operations, following the lean improvement kata, an OEE above 86.7% has been achieved without the use of advanced preventive maintenance technologies.

The research additionally uncovered what was found to be the predominant factors of adopting innovative technologies needed to achieve a data-driven maintenance operation. These factors were analysed using the T-O-E framework which provided a structure for assessing the identified factors.
The technological factors of Compatibility, Data exchange and Interoperability as well as Data quality, illustrated the need for a solid foundational IT-infrastructure with high quality data. The last technological factor of Perceived complexity highlighted the importance of considering the users' interaction with innovative technology. This factor also presented a potential future research path of investigating the acceptance and use of technology.

Through the analysis of the organizational factors, Cost was determined to be a multi facet parameter representing more than just monetary value. When assessing Cost in the context of adopting technologies in pharmaceutical maintenance operations, the factor spans from basic cost of equipment, to the risk of breaking GxP compliance. This includes several direct and indirect cost elements beyond monetary value, which all affect the adoption of innovative technologies in e-Maintenance.
The second organisational element was established to be Management support. This factor covers the willingness to commit to the declared ambition and allocate resources accordingly. The allocation of resources is more than simply investing money, since the adoption requires changes, which can be difficult due to organizational inertia. Management support was highlighted as a prerequisite to succeed in adopting e-Maintenance technologies.
The last organisational factor identified, covers the employees level of Skills. Skills are increasingly important with the increase of the technological factor of Perceived complexity. In relation to the investigation of Skills, the relevance of uncovering the acceptance and use of these technological advancements supports the potential of a future research on the topic of user acceptance of innovative technologies in pharmaceutical e-Maintenance operation.

The environmental factors identified and analysed, covers the Government regulation, which confines the possibilities of innovation and the Competitive environment, which imposes the need for innovation. The extensive regulation of the pharmaceutical industry has indirectly shaped processes in order to ensure compliance. The importance of compliance has resulted in a risk averse organisation, which has been challenging to change, due to organizational inertia. An acceptance of engaging with risk was found to be necessary to accommodate the second environmental factor of the increasing Competitive environment. The Competitive environment being the unavoidable factor triggering the need for innovation.

This study has hereby answered the second research question by identifying the factors affecting the adoption of e-Maintenance technologies within pharmaceutical maintenance operations to be: (1) Compatibility, (2) Data exchange and Interoperability, (3) Data quality, (4) Perceived complexity, (5) Cost, (6) Management support, (7) Skills, (8) Regulatory environment, and (9) Competitive environment.

To conclude, prioritizing the most significant maintenance issues and meticulously repeating the Lean improvement kata, the case company has found an effective way to systematically operationalize data to support the decision-making process. The world-class OEE is achieved by using data to support the decision-making process in accurately identifying and defining the problem - without the use of advanced preventive e-Maintenance solutions. Despite the effectiveness achieved with reactive maintenance, further increase in the OEE in the future might require preventive maintenance.

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