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Economics

# **Analyzing understanding and role of sustainability in the pharmaceutical industry**

With a contract development and manufacturing organization focus

International Business

Master's thesis

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The aim of this study is to gain a comprehensive understanding of sustainability and its role for contract development and manufacturing organizations (CDMOs) operating in the pharmaceutical industry. Sustainability is a multidimensional concept that includes multiple different topics. It has evolved out of the narrower concept of Corporate Social Responsibility (CSR) to be understood as a broader concept that includes multiple different aspects, such as environmental, social, economic, and governance aspects.

The significance of this study is highlighted by the growth of the industry in the past 20 years and the expected maintenance of growth in upcoming years. This past and expected growth have been exacerbated by macro-level indicators such as aging populations and an emerging middle class. As the industry has been growing, pharmaceutical companies have started to rely on external partners. Outsourcing has been seen as a means to control costs and expedite development and manufacturing processes. Currently, the main determinants for CDMO partner choice are a good cultural fit, industry reputation, and scientific expertise.

The industry has a controversial image, as it must balance profits with developing and manufacturing new, possibly life-altering, drugs. The Covid-19 pandemic raised further into discussion the ethical challenges of the industry such as the unequitable distribution of vaccines. People have not previously demanded green pharmaceuticals, but as general awareness of stakeholders has increased and as investors have started to take into consideration ESG-related matters in their investment decisions, companies in the pharmaceutical industry ought to regard sustainability in their business. Depending on the level of integration of sustainability in business, organizations can use sustainability as a business advantage. Advantages can range from savings from eco-efficiencies to an increase in brand image and brand value.

This study is a commissioned work for a Nordic bio-CDMO. It was conducted as a qualitative study incorporating both interviews and content analysis. Interviewees for this study included employees from the commissioning company and representatives from their client companies. Content for the content analysis was from selected CDMO websites and their social media. Sustainability in the pharmaceutical industry has been gaining traction, however, there were no previous studies conducted that concentrate on what the role of sustainability for CDMOs is.

Based on the results from the empirical research from interviews and content analysis conducted for this thesis, CDMOs, for the most part, are not currently integrating sustainability in their business and thus, not using it as a business advantage. As CDMO clients prioritize quality and fast market entry, they often overlook sustainability-related matters. As sustainability is overlooked by client companies, and the regulatory sphere is not advocating for a more sustainable field, CDMOs are not incentivized to integrate sustainability any further. This being stated, sustainability-related matters are gaining traction and thus, there are opportunities to be gained from sustainability in business.

**Key words:** sustainability, ESG, pharmaceutical industry, CDMO

Pro gradu -tutkielma

**Oppiaine:** Kansainvälinen liiketoiminta

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**Otsikko:** Analyysi vastuullisuudesta ja sen roolista lääkealalla – sopimuskehittäjä- ja valmistajaorganisaatiofokos

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Tämän tutkielman tarkoituksena on saada kokonaisvaltainen ymmärrys vastuullisuudesta ja sen roolista sopimusvalmistaja- ja kehitysorganisaatioilla (CDMO) lääketeollisuudessa. Vastuullisuus on moniulotteinen konsepti, joka on kehittynyt kapeammasta yrityksen yhteiskuntavastuun konseptista laajempaan konseptiin, joka sisältää niin eri aihealueita kuten ympäristövastuu, sosiaalinen vastuu ja taloudellinen vastuu.

Lääketeollisuus on kasvanut viimeisten 20 vuoden aikana ja on odotettavissa jatkavan kasvuaan tulevana vuosina kasvavan keskiluokan ja ikääntyvien sukupolvien takia. Teollisuuden kasvun seurauksena, lääketeollisuuden yrityksen ovat siirtäneet kehitys- ja valmistusprosessejaan ulkoisille kumppaneille. Ulkoistaminen on nähty keinona hallita kustannuksia sekä nopeuttaa kehitys- ja valmistusprosessia. Merkittävimmät tekijät kumppanien valinnassa ovat tällä hetkellä olleet hyvä yhteensopivuus yrityskulttuurien välillä sekä kumppaniehdokkaan tieteellinen asiantuntemus ja maine alalla.

Lääketeollisuudella on kiistelty imago, sillä se tasapainoilee tuottavuuden sekä elämää mullistavan lääkekehityksen kustannusten välillä. Covid-19 pandemia nosti esiin alan eettisiä ongelmia, kuten rokotteiden epätasa-arvoisen jakautumisen kehittyvien ja kehittyneiden valtioiden välillä. Yleinen tietoisuus vastuullisemmasta liiketoiminnasta on lisääntynyt. Tämä näkyy erityisesti siinä, miten sidosryhmät vaativat vastuullisuuden ottamista huomioon liiketoiminnassa ja sijoittajien lisääntyneessä huomiossa ympäristöasioihin, sosiaaliseen vastuuseen liittyvien tekijöiden sekä hallintotapa-asioihin liittyen. Riippuen siitä, miten vastuullisuus on integroitu liiketoimintaan, yritykset voivat hyötyä vastuullisesta liiketoiminnasta. Nämä hyödyt voivat sisältää esimerkiksi säästöjä sähkö- ja vesikustannuksissa tai parantuneessa brändi-imagossa tai -arvossa.

Tämä tutkielma on tehty toimeksiantoja pohjoismaalaiselle bio-CDMO-yritykselle ja on toteutettu laadullisin menetelmin. Tämä tutkielma hyödyntää niin haastatteluja kuin sisältöanalyysia valituista kilpailevista CDMO yrityksistä. Toimeksiantoyritys valitsi niin haastateltavat kuin sisältöanalyysiin valitut yritykset.

Empiiriseen tutkimukseen nojautuen, suurin osa CDMO-yrityksistä ei integroi vastuullisuutta liiketoimintaansa eikä näin ollen hyödynnä vastuullisuutta kilpailuetuna. CDMO-yritykset priorisoivat laatua, potilasturvallisuutta ja nopeaa markkinoille pääsyä ja näin ollen jättävät huomioimatta vastuullisuuden laajemman käsityksen. Koska CDMO-yrityksillä asiakkaat eivät vaadi vastuullisempaa liiketoimintaa, eikä alan sääntely ohjaa liiketoimintaa vastuullisempaan suuntaan, CDMO-yrityksillä ei ole kannustimia integroida vastuullisuutta liiketoimintaansa. Tämä huomioon ottaen, vastuullisuuden tärkeys tiedostetaan. Vastuullisuus on kuitenkin kiristämässä otettaan ja näin ollen, siitä on vielä otettavissa kilpailuetua liiketoimintaan.

**Avainsanat:** vastuullisuus, ESG, lääketeollisuus, CDMO

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## **LIST OF ABBREVIATIONS**

API – Active Pharmaceutical Ingredient

CDMO – Contract Development and Manufacturing Organization

CFP – Company Financial Performance

cGMP – Current Good Manufacturing Practice

CMO – Contract Manufacturing Organization

CRO – Contract Research Organization

EMA – European Medicines Agency

ESG – Environmental, Social, Governance

ESG – Environmental, Social, Governance

EU – European Union

FDA – US Food and Drug Administration

GMP – Good Manufacturing Practice

SDGs – Sustainable Development Goals

TBL – Triple Bottom Line

UN – United Nations





# 1 Introduction

## 1.1 Background to the topic

The Covid-19 pandemic has raised into discussion ethical issues in the pharmaceutical industry. These issues range from the unequitable distribution of pharmaceuticals and the inequality in drug accessibility that the patents pharmaceutical companies hold create (Sung et al. 2021; De George 2005). The pharmaceutical industry is seen as a vital contributor to global wellbeing and improved quality of life, as it can improve the lives and wellbeing of people with the drugs it provides. The industry recognizes its controversial nature, as it needs to balance prioritizing patient wellbeing and drug availability with profits. Due to this controversy, the pharmaceutical industry is among the most regulated domains in the EU and globally. (Durrant 2001.) Even though the topic has gained increased traction in recent years, a lack of academic research on sustainability in the pharmaceutical industry persists. (Milanesi et al. 2020).

Sustainability is a multidimensional concept that includes different aspects, such as environmental, social, and economic aspects. This multidimensionality of sustainability is apparent in e.g., the United Nations (UN) 17 Sustainable Development Goals (SDGs). These goals cover multiple different segments of sustainability encompassing environmental, social, and economic aspects. (UN SDGs.) In today's business, sustainability can be understood as a business necessity. People, in general, expect businesses to act responsibly and in a sustainable way, even though trust towards businesses has been diminishing. Sustainability is to be integrated into all business operations to be seen as credible. (Rake & Grayson 2009.) Sustainability can provide business opportunities and thus, sustainability ought to be viewed as a vital part of business. What started as a voluntary initiative for businesses to report sustainability-related matters, can be seen as a business necessity today. (Veleva et al. 2003.)

The concept of sustainability has evolved from the narrower concept of Corporate Social Responsibility (CSR) to be understood as a broader, more overarching concept. Even though the origins and development of the concept of CSR and sustainability are different, they can be understood as complimentary to each other. (Ziolo 2021, 1.) The abbreviation ESG, relating to environmental, social, and governance, does not have one single definition, but it is often used when discussing sustainability and responsibility in

business. ESG offers a set of relevant elements that allow the analysis of long-term investments. These elements consist of nonfinancial data metrics that are used in addition to financial data that provide further information on the performance of the company. (Bassen & Kovács 2008.) For the purpose of this thesis, sustainability will be used as an umbrella term that incorporates all environmental, economic, social, and governance matters. This is to be able to take into consideration the multidimensionality and interlinkages with the different dimensions that impact the industry and that ought to be considered when discussing matters related to sustainability.

People, in general, have not required green manufacturing for their drugs, but the amount of environmental pollution from manufacturing and developing drugs have raised concerns (Carroll 2020, Belkhir & Elmeligi 2019). Pharmaceutical pollution, such as active pharmaceutical ingredients (APIs), has been detected widespread in the environment. APIs can contaminate the environment through manufacturing processes, use, and improper disposal of drugs. APIs have been linked to causing ecological damage to wildlife and to the environment in addition to humans by creating antibiotic-resistant bacteria. (Wilkinson et al. 2022.) Social issues related to the industry include the inequality in access to medicine in some countries and the need for efforts toward the management of human capital, including promoting diversity and inclusion and talent retention in workplaces (Milanesi et al. 2020, Shah et al. 2021.) Matters related to governance in the pharmaceutical industry extend to regulators and policymakers, however, it is up to the pharmaceutical companies to make sure they stay current in compliance in a transparent way. Good governance models can be used to combat corruption and thus increase governance-related sustainability. (GlobalData 2021.)

The pharmaceutical industry has been continuously growing. Globally, it has grown from 390 billion USD in 2001 to 1.27 trillion USD as of year-end in 2020 (Statista 2022). This has especially been due to macro-level indicators, such as aging populations and an emerging middle class that create an upcoming need to create new effective pharmaceuticals. This demographic change is likely to lead to new market opportunities that will most likely further exacerbate growth in the industry (Souza et al. 2021.) Due to this expected growth in the industry, the pharmaceutical industry can potentially become even more significant. This being stated, it is responsible to operate in a sustainable way as sustainability can bring longevity to the operations of the company and bring long-term value into business.

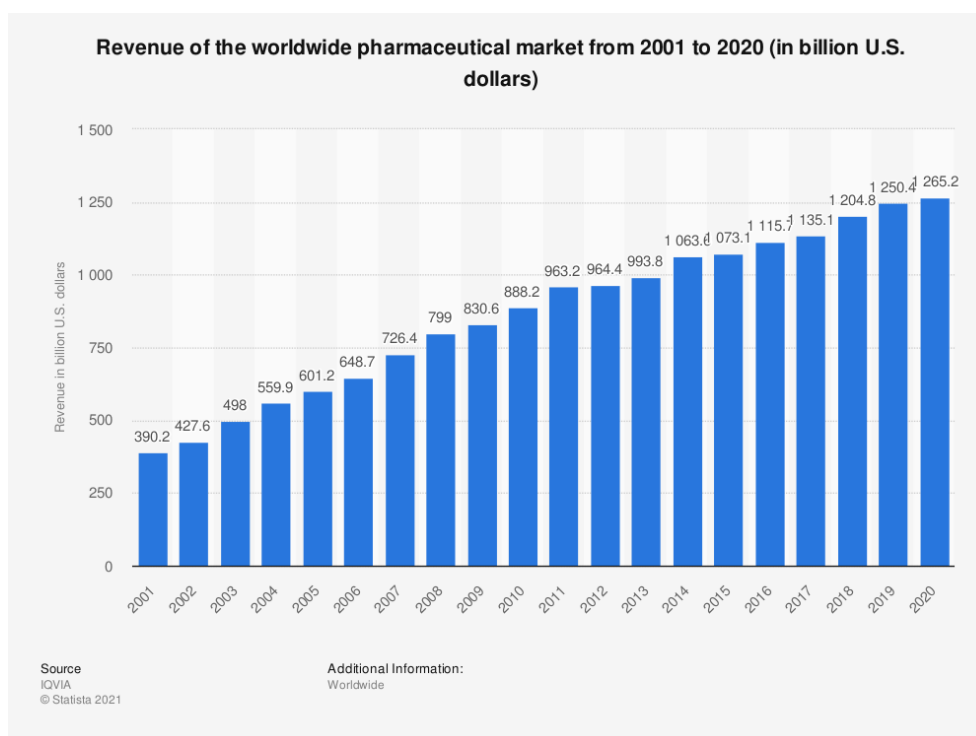


Figure 1 Revenue of the worldwide pharmaceutical market from 2001-2020 (Statista 2022)

As the pharmaceutical industry has grown, and there are macro-level indicators that signal further potential growth, more and more pharmaceutical and biotechnology companies are relying on external partners for organizations' activities such as research and development (R&D) and manufacturing. There is a need to rethink supply chains and whether to invest in own infrastructure or utilize an external partner. (Principe 2017.) Outsourcing operations to external partners can bring many different advantages to companies. It can minimize capital investments needed in facilities and R&D and thus, reduce overall costs leading to better financial earnings and can enable bigger pharmaceutical companies to focus on other areas of business, like marketing. However, there are risks related to outsourcing. Companies might be faced with e.g., quality issues, delays, or poor communication with the outsourcing company. When outsourcing is unsuccessful, it can have serious impact on patient safety, thus it is vital to choose the right company fit. (Marinkovic et al. 2020.)

A contract development and manufacturing organization (CDMO) serves as an external partner to other pharmaceutical companies. CDMOs are often used for outsourcing manufacturing and development of drugs. There are other models, such as Contract

Manufacturing Organizations (CMO) and the Contract Research Organization (CRO), but for the purpose of this research, the focus will be on CDMOs. CDMOs work on a contract basis with their customers depending on the customer needs. Depending on the CDMO and contract, they can provide extensive services ranging from drug development to drug manufacturing. As CDMOs are at the grassroots level of pharmaceutical innovation and manufacturing, they can plan development and manufacturing on a sustainable ground. (CDMO Evolution 2019.) There are various metrics that define the threshold for choosing a CDMO partner including project fit, quality of work, track record, and regulatory history. Sustainability has not yet been seen as a threshold requirement for CDMO companies. (Hammeke 2020.)

The demanding and regulated pharmaceutical market requires compliance with various regulations such as the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), and Good Manufacturing Practice (GMP) that necessitate manufacturers and developers to take steps to ensure their products are safe and effective (Boukouvala et al. 2011, Sismondo 2015, ISPE). The Covid-19 pandemic brought forth a need for even faster development of new drugs and vaccines whilst being able to maintain regulatory compliance in all areas of development. It is important that the quality and safety i.e., the compliance of new pharmaceuticals, are not overlooked by the desire to enter the market too hastily. If compliance is neglected at any stage, a CDMO could lose its license to manufacture, the new drug might be disapproved from market entry or there could be delays in approval. As CDMOs are experienced in manufacturing and developing new pharmaceuticals and are aware of differing regulations they can increase ease in compliance with differing global regulations for other pharmaceutical companies. (Womack 2021.)

Even though outsourcing in pharma has been continuously growing, at an expected compound annual growth rate of 5.5% from 2022 to 2030 (GrandViewResearch), the industry is losing several companies that are participating in pharma R&D. During 2019, the total number of pharma companies participating was 4323, with 722 new firms entering the market. However, the total number of firms rose by only 189. This means that a total of 533 companies were lost due to mergers, acquisitions, failures, or hibernation. (Pharma R&D Annual Review 2019.) In this fluctuating industry, differentiation is one key method in being able to stand out from the growing mass of CDMOs. A key differentiator currently has been a one-stop-shop model, where a CDMO

provides services throughout the lifecycle of a product. However, as sustainability has been growing its importance and its economic impacts are increasing and becoming more apparent, sustainability could be one way for CDMOs to differentiate themselves from other service providers in a highly competitive field. (DeYoung 2020.)

## **1.2 The aim and objectives of the study**

The aim of this study is to gain a comprehensive understanding of sustainability and its role for CDMO companies operating in the pharmaceutical industry. To be able to deconstruct and achieve the aim of the thesis, three objectives were identified. These objectives will enable a more thorough view of the topic at hand. The objectives are as follows:

- 1) To examine how the concept of sustainability is understood in CDMOs in the context of the pharmaceutical industry
- 2) To examine how relationships between CDMOs and contractor pharmaceutical companies influence the sustainability of CDMOs
- 3) To examine how sustainability-related actions taken by companies are influenced by their underlying motivations

As the role of sustainability has increased in business and the structure of the pharmaceutical industry has shifted towards an increase in outsourcing, especially with CDMOs, there has become an evident need to study how sustainability is understood in the CDMO field. In continuation, it is important to study the potential impacts CDMO and contractor company relationships can impact sustainability in CDMOs. Furthermore, to understand the sustainability-related actions taken by companies, it is important to understand the motivations behind them in companies. Do companies have a proactive or reactive approach to sustainability, are companies doing the bare minimum, or are they looking at sustainability as a means towards long-term business sustainability and, longevity and where the pressure towards more sustainable business comes from.

The topicality of this study is evident as there is a gap in academic research in considering the relationships between CDMOs and contract givers, how the relationships influence the sustainability actions CDMOs do, and what impacts the decisions towards sustainable businesses. Even though sustainability has been a growing trend in the pharmaceutical

industry, sustainability or ESG track record has not been seen as a requirement or a basis for choosing to partner with a certain CDMO at this moment. This thesis is a commissioned work. The commissioning company of this thesis is a Nordic bio-CDMO that has been operating for around 20 years. It is a CDMO that focuses on process development and GMP manufacturing of viral vectors and microbially produced recombinant proteins, for use in clinical studies.

The structure of this thesis is built in a way that supports the reader in understanding the specific nature of the pharmaceutical industry and how sustainability is perceived in this industry as well as how CDMOs and outsourcing function. The structure of this thesis is as follows: there will be a brief overview of the research context of this study including the pharmaceutical industry and CDMOs. Next, there will be an overview of the concept of sustainability and how sustainability can be integrated with business and could be used as a business advantage. Following this, the methodology of the thesis will be discussed, including research approach, data collection, data analysis, and data evaluation and ethics. After methodology, there will be a discussion on the findings of the data gathered for this thesis. Following this, conclusions are discussed. This includes the theoretical and practical contributions of the study, limitations, and recommendations for future research. The final chapter is a summary of the abovementioned chapters and study.

## **2 Pharmaceutical outsourcing**

### **2.1 The pharmaceutical industry as a research context**

The pharmaceutical industry is responsible for contributing to the health and wellbeing of people around the world. It is a significant industry as it impacts the lives of people by researching, developing, producing, and marketing pharmaceuticals for various illnesses and diseases. As the population of the world is aging and new markets are emerging through improved healthcare systems, the industry keeps growing and faces deeper scrutiny towards sustainability. (Milanesi et al. 2020.) As an example, in the EU, patients are not able to fully benefit from pharmaceutical innovations due to medicine being unaffordable or unavailable (COM/2020/761). This indicates a clear need to assess the industry and its issues.

To address issues related to the pharmaceutical industry, the EU has launched a Pharmaceutical Strategy for Europe. This strategy aims to take into consideration many different aspects that are linked to the industry. The social impacts of the industry are targeted by e.g., enabling better access to innovative and affordable medicines while taking into consideration the change in demographics and the strategic framework of the EU towards a Union of Equality. It also targets the need to support competitiveness, the capacity to innovate in the pharmaceutical industry, and security of supply chains in the EU, especially in times of crisis. The strategy also indicates a need to address governance in the industry, mainly a need to increase transparency in fiscal matters, create safeguards in patient access to medicine and create a flexible and fertile, yet stable regulatory environment in the industry that fosters innovation. (COM/2020/761).

Covid-19 particularly expressed a need to secure medicine supplies and avoid shortages that can potentially lead to compromises in patient healthcare. The strategy acknowledges the complex supply chains of the industry and aims to create measures to address this need for diversification through dialogue with key actors throughout the values chains of the industry. The industry strategy has been created in line with the EU Green Deal, which is the EU-level strategy that aims to transform the EU economy into a more sustainable model. Through this alignment and other measures, such as promoting GMP and fostering innovations for environmentally sustainable and carbon neutral manufacturing and

pharmaceuticals, the demand for environmental sustainability is also recognized. (COM/2020/761).

There has been a general increase in awareness, attention, and concern from different stakeholders of the pharmaceutical industry towards sustainability. (Demir & Min 2019). The concerns raised are often mainly focused on environmental matters such as the development of products that create less environmental risks, waste management, recyclable packaging, and sustainable manufacturing practices. However, aspects relating to governance and social matters need to be addressed as well. Especially as the environmental and social impacts of the industry are portrayed in the media to draw into focus the need for change in how the industry addresses sustainability. (Milanesi et al. 2020.)

Furthermore, there are ethical aspects that ought to be considered. Often ethics in the pharmaceutical industry are linked with the ethics of drug pricing, drug safety, and clinical trials however, the ethics of the industry are more widespread. (Marmat et al 2020). This wider ethical perspective can be linked to the unequitable distribution of medicine to some countries. This unequitable distribution became especially imminent due to Covid-19. Vaccines that were deemed safe and effective for people were developed fast, however; the vaccines were not equitably shared. The majority of vaccines were primarily administered in upper-middle to high-income countries, leaving the poorest and most vulnerable at more risk. (WHO).

Deficiencies in quality in the pharmaceutical industry can have a severe impact on the patient's welfare, hence, making sure that quality guidelines are followed, is essential. Quality in the pharmaceutical industry is benchmarked by GMP. GMP can be best understood as a system that ensures the consistency and quality of products. It is also used to protect consumers, i.e., patients, from purchasing unsafe or ineffective pharmaceuticals. GMP or Current GMP (cGMP) is a safety guard that ensures regulations are followed through quality management systems in all steps of production. Because technologies and systems evolve and develop, cGMP requires compliance with up-to-date technologies and systems to ensure quality. Failure to comply and adhere to GMP can lead to consequences that can be detrimental to business such as recalls, seizures, and fines. (ISPE.)



The pharmaceutical industry in general is facing a talent gap. As the industry has been growing, there has become a need for more skilled workforce. The complexity and number of new therapeutic solutions have increased, and new technologies have been introduced, leading to an increase in the requirements for new talent. After hiring, companies must also give adequate training to new employees on GMP standards and practices and compliance, which can slow down processes in drug development in an environment that aims to bring new drugs to the market at a growing pace. (Cini 2022.) CDMOs face the challenge of employing experienced employees as they are in high demand in the industry. CDMOs are not only competing with other CDMOs for a skilled workforce but also with larger pharmaceutical companies. (PWC.)

## **2.2 Contract development and manufacturing organizations**

CDMOs have been linked to the growth of the pharmaceutical industry, but the importance of CDMOs showed its prevalence in the past 20 years. The growth in CDMOs in the past years can be mainly contributed by three factors. The first factor is a reduction in excess capacity by global pharma companies. CDMOs were offered and sold facilities at a nominal price with a contract for legacy products of bigger pharma companies. This was further exacerbated by patents going off for drugs and the opening of the regulatory sphere that enabled freer cross-border trade in drugs. The second factor was the emergence and expansion in the early-stage bio/pharma company field. These companies often relied on CDMOs as partners as they were unwilling or unable to establish their own manufacturing operations. Finally, the success of clinical research companies validated the outsourcing of critical activities of pharma companies and brought experience in contract service relationships. These three factors especially contributed to the growth and launch of the CDMO industry in the 1996-2007 period. (Miller 2017.)

Outsourcing is one of the main business models for businesses to reduce costs or improve efficiency (McCarthy & Anagnostou 2004). Outsourcing is an act of transferring part of a company's activities to another actor in the field that can do the same activity with less resources. However, due to the complex nature of outsourcing, it can increase risks as well. The main losses are often financial; however, they can extend from technical to administrative ones as well. In the pharmaceutical industry, the risks of outsourcing mainly include financial losses, however, due to the nature of the industry, risks

correspondingly include threats towards the health and safety of end clients, i.e., patients. (Marinkovic 2020.)

When companies are looking for the right partner in the CDMO industry, a good cultural fit with experienced employees is seen as one important way of assessing possible partners (Meyers 2019). Other metrics that companies often assess and value in CDMO partners are project fit in relation to facility capacity and capability, industry reputation, scientific expertise, regulatory history and on-time and in-full delivery (Hammeke 2020). However, the choice of partner and its services also depends on the needs of the pharma company. CDMOs offer an array of services ranging from e.g., product and indication analysis, clinical development and manufacturing strategy to regulatory strategies and program management. (Babbitt et al. 2003.)

The most common activities that are outsourced in the pharma industry are manufacturing processes and clinical studies. Conversely, as the regulatory framework has increased, outsourcing has been also used to address and ease compliance. In the pharmaceutical industry, supply chains are often complex and demand specificity. (Marinkovic 2020.) Even though in general there is a relatively great focus on quality, productivity and efficacy have been lacking (Santos Bravo & Crespo de Carvalho 2013). Bigger pharmaceutical companies that use outsourcing often aim to cooperate with partners that consider sustainability in their operations to ensure the responsibility of value chains. Not participating in sustainability or corporate responsibility activities can be seen as a supply chain risk as organizations face overarching pressure from stakeholders to participate in corporate responsibility. (Howard & Humbery 2008.)

Big pharmaceutical companies have previously had significant investments and have tied up their capital in doing all activities in-house. However, by outsourcing activities, big pharma has been able to reduce costs and ensure good quality and offer competitive costs, since contractors need to earn their business after each contract to avoid losing business to lower-cost competitors. (Fioravanti 2019.) Pharmaceutical companies see the value of utilizing a CDMO as they can offer faster turnaround times and high quality in manufacturing and thus, further success. Small to medium-sized pharmaceutical companies offer new market opportunities for CDMOs as well. Smaller pharma companies have been responsible for a growing number of approvals for new

pharmaceuticals. These smaller companies often do not have their own facilities for manufacturing and thus, often outsource this activity to CDMOs. (PWC.)

CDMOs serve as partners for bigger and smaller pharma companies. For smaller pharma companies especially, the stringent requirements for preparations and launch of e.g., human trials, require resources and expertise in multiple disciplines. Even if there is strong scientific, academic, or entrepreneurial background in the personnel of a smaller company, they might not be able to answer to the requirements for regulations, clinical development, manufacturing, and marketing, due to a lack of resources. Furthermore, smaller pharma companies often face reliance on a single product and limited funding and thus, have a need to find investors or partners that can help move a product along. By partnering with a CDMO smaller pharma companies can bridge the gaps in knowledge and resources and move their products along in a more efficient way. Lacks in regulatory compliance can lead to delays in market access that these companies rarely can afford. (Babbitt et al. 2003.)

### **3 Analyzing and implementing sustainability in business**

#### **3.1 The evolution of the concept of sustainability**

##### **3.1.1 Sustainability as a concept**

There is no one single consensus on the definition of sustainability. The United Nations (UN) and the European Union (EU) define sustainability as development that meets the needs of today without compromising the need of future generations (EU Sustainable Development, United Nations Brundtland Commission 1987). Sustainability and sustainable development have been used interchangeably as well. Often private businesses and governments have used the term sustainable development which inherently links to growth, whereas academia and non-governmental organizations (NGOs) have been prone to use the term sustainability that focuses its attention on the interlinkage of human actions and the constraints of our environment. (Robinson 2004.)

The focus of sustainability has shifted through time and it, alongside related concepts, has developed accordingly. Post recognizing the limitations of the resources of our environment and the need to incorporate sustainability in business, there was a shift to focus on the ability to communicate about sustainability. (Ziolo 2021 1;12.) CSR aimed to answer to the growing need for businesses to act more responsibly. As with sustainability, there is no single definition for CSR, however, it can be understood as a self-regulatory framework of different actions firms take to create a positive impact on society. (Sheehy 2015.) CSR commitments were often communicated in marketing to bring awareness into what the company is doing to be more responsible. However, these were often misleading and hard to quantify. Furthermore, as there were no principles CSR was based on, communication of CSR could mislead consumers to view a company to be more responsible than it was. CSR efforts also often came at a cost to another area, such as a focus on green energy usage could lead to overlooking workplace safety issues. (Sheehy 2013.)

The second shift in sustainability is the shift from separate, company-chosen aspects of sustainability in only selected sections of business, to a more complete and intersectional outlook of sustainability in business. The Triple Bottom Line (TBL) by Elkington (1998) is a popularized view on sustainability for businesses. The Triple Bottom Line incorporates the social, economic, and environmental bottom lines. Elkington recognized

that the three bottom lines are not stable, but rather in continuous fluctuation due to pressures, cycles, and conflicts in social, political, economic, and environmental spheres. As global sustainability issues that were put at the forefront of discussion were not delimited to environmental matters anymore, sustainability was seen as a 21<sup>st</sup>-century paradigm. Even though governments, policymakers, and regulators were seen as the main contributors to a more sustainable future, businesses were expected to make their own contributions toward a better future. Participating in sustainability was seen as necessary for businesses, as businesses need stable markets to operate in. (Elkington 1998, 20, 73.) Climate change, as an example, can create distress for businesses as there can be changes in the supply of raw materials. Thus, mitigating the impacts of climate change could develop stability in business environments.

The third shift in sustainability in business is viewing sustainability as means to create value in business and to not only see it as means for cost savings. Cost savings by participating in sustainability range from e.g., changing to more efficient energy sources and waste reduction to developing more efficient ways of production. Even though focusing on sustainability matters in business has previously been linked to poorer corporate financial performance (CFP) (Clarke et al. 1994), there have been more recent studies that provide support on the contrary. A study by Friede et al. (2015) assessed numerous studies that evaluate CFP and its relation to ESG. Based on their analysis, they found that around 90% of studies assessed found a non-negative ESG-CFP relation. Furthermore, they report that a large majority of the studies report positive findings. This positive relation was noted by Elkington (1998, 20), who recognized an upcoming shift in the financial market that would begin to insist upon more sustainable practices i.e., delivering results against the backdrop of the triple bottom line.

### 3.1.2 The concept of sustainability in business

The shift towards sustainability in the financial markets that Elkington forecast in 1998, is becoming even more apparent today. Sustainable finance has been growing interest in recent years. As an example, the EU published a report that offered a comprehensive view of how a sustainable finance strategy could be built for the EU. According to the report, sustainability is about two focus points: *“improving the contribution of finance to sustainable and inclusive growth by funding society's long-term needs”* and *“strengthening financial stability by incorporating environmental, social and governance*

*(ESG) factors into investment decision-making.*” (COM/2018/097 final.) Sustainable finance is defined by the EU “*as the process of taking environmental, social and governance aspects into account when making investment decisions in the financial sector, leading to more long-term investments in sustainable economic activities and projects*” (EU Commission, Overview of sustainable finance).

As with the concept of sustainability, ESG does not have one unified definition. However, ESG can be conceptualized as a means of assessing sustainability in business, especially for investors in assessing their long-term investments and their sustainability. This is due to the fact that ESG does not only consider environmental matters but looks at various social and governance aspects in business that could impact investments. (van Duuren et al. 2016.) The elements, environmental, social, and governance, are intertwined with each other through social awareness, even though they are separate elements. The environmental factors can include e.g., waste and pollution, greenhouse gas emissions, climate change, and its mitigation. Social factors include employee relations and diversity, working conditions throughout the value chain, how companies impact local communities, and health and safety. Governance factors include e.g. diversity in the board of a company, transparency, auditing, and executive remuneration. (Taliento et al. 2019; Ziolo 2021, 46.)

These paradigm shifts have been motivated by multiple different factors such as the increase in consumer awareness towards more sustainable business practices. Especially younger generations have been advocating for sustainable investing and employees and stakeholders are looking for businesses that share their own values and beliefs. (Alonso-Almeida & Llach 2019.) Furthermore, more regulatory frameworks are expected to rise as the demand and pressure toward a more sustainable business continue to grow. This has been evident in the EU by e.g., the EU Green Deal which is a strategy and roadmap for EU climate actions. The Green Deal includes legislations and policies that have been created in regard to sustainability to support the transition towards zero net emissions. (European Green Deal.) However, the common thread throughout the evolution of sustainability is that it has been recognized that sustainability is not only of one element, such as the environmental impacts of an industry, rather it is something that takes into consideration multiple different aspects. The role that businesses have towards a more sustainable future has grown, as development towards a more sustainable future is not left for only governments and intergovernmental organizations any longer.

As is evident, sustainability as a concept has been evolving. It is not only a means to enhance brand image or only to be used only in marketing. Businesses have understood the multidimensionality of the concept and thus have begun to see the importance of participating in all dimensions of sustainability in an industry-relevant manner. Furthermore, there is growing pressure from stakeholders of firms to participate in sustainable actions, and it is not enough anymore to only use sustainability in communication to stakeholders. Actions are expected. As the pharmaceutical industry is one that has faced criticism for multiple dimensions of sustainability, e.g., lack of transparency in governance-related matters, unethical distribution and pricing of pharmaceuticals, reliance on financial markets, and the environmental impact it has, using only one definition of sustainability would not be sufficient. Thus, sustainability is used as an umbrella term. There are different ways of integrating sustainability into business to be to realize the possible business advantages from it. The possible business advantages and ways of integrating sustainability into business are discussed in the following subchapter.

## **3.2 Sustainability in business**

### **3.2.1 Integration of sustainability and business**

There are different types of models that can be used to analyze business sustainability. However, these often look at how businesses can increase shareholder value by reducing the footprint of a company in comparison to looking at how businesses can contribute to solving global issues (Gyllick & Muff 2016). For the purpose of this thesis, two different frameworks are presented as complimentary to each other. The model by Dyllick and Muff (2016) aims to clarify the different types of business sustainability whereas the model by Willard (2012) demonstrates the different phases companies go through in the journey to a truly sustainable business. Companies can gain different type of business advantages depending on where they are on their sustainability journey.

The first stage Willard (2012) presents in the move from an unsustainable business is the phase of pre-compliance. Here, companies ignore the bare minimum where they adhere to policies and regulations that are set for them. It aims to disregard regulations so that they can create savings by not complying with regulations. However, if caught, companies in the pre-compliance stage are subject to fines and a poor brand image.

Remaining in the pre-compliance stage is risky for a business, so the transition to the next phase is often done quite quickly or skipped altogether. The first step in the model by Dyllick and Muff (2016), is business-as-usual, where a company is only looked at and analyzed from an economic perspective. If a company streamlines its processes or gains access to cheaper resources, these are seen to increase economic value. Externalities of these decisions are not deliberated.

The business-as-usual is not dissimilar to the second stage Willard (2012) presents in the transition toward a more sustainable business. The second stage here is compliance with regulations. Companies adhere to local policies and regulations, i.e., adhere to the legally binding regulations their business environment requires. The outlook on sustainability is a more reactive one, where sustainability-related actions are more reactive to new regulatory policies in comparison to a more proactive approach. Sustainability is addressed to avoid fines and bad PR, which could diminish economic value of a company. (Willard 2012, 20-21.)

As the second stage in the sustainability journey is enough to avoid bad PR and fines, the move from the second phase to the third stage must be a conscious choice for a company. The third phase has a more proactive point of view toward sustainability and the regulations that might emerge. In the third stage of the transition, companies can realize some of the benefits that come from a more sustainable business model. These benefits include, but are not delimited to, savings in energy, water, manufacturing costs, and waste management. (Willard 2012, 20-21.) Dyllick and Muff (2016) introduce Business Sustainability 1.0. where companies realize that there are business challenges that derive from environmental and social concerns. These concerns create both economic risks and opportunities for businesses. In sustainability 1.0, businesses address these concerns by integrating them into their existing processes. Even though these can lead to an increase in reputation and attractiveness for employees, the main objective of recognizing and addressing these are economic benefits. Unless businesses can integrate sustainability into their strategy, businesses can find it difficult to be able to fulfill further benefits from sustainability actions.

Business Sustainability 2.0 recognizes a need to address environmental and social aspects in addition to economic aspects. It enables businesses to integrate sustainability into its business by aligning environmental, social, and economic aspects in the value a business



creates. It is not about creating only economic value for a shareholder, but rather a broader view of creating value for stakeholders. (Dyllick and Muff 2016.) The model by Willard (2012) is similar to this. In the fourth stage, sustainability and its related actions are integrated into the strategy of a company. It is used to enhance company value and its prosperity. Here, finances directed related to sustainability are not only viewed as costs, rather they are seen as investment opportunities. As sustainability is integrated into the strategy throughout the company and through its value chain, they are able to gain competitive advantages from it.

The final stages in the model by Willard (2012) are similar in behavior, however, the motivation behind doing good is different. In stage four, the end goal of participating in sustainability is to be a successful company and the means to this is by contributing to a better world, whereas in stage five the end goal is to contribute to a better world by being a successful company. This is similar to the thinking in Business Sustainability 3.0. where it is not only about minimizing the negative impacts a company creates, but rather how to create a positive impact on the society and environment a company operates in. Businesses consider critical sustainability issues and transform these into business opportunities. These Business Sustainability 3.0. companies engage with different actors on different levels. On a company level, they are able to e.g., increase transparency and improve and innovate their processes. To increase the reach of activities they can engage also on a sectoral or cross-sectoral level, where they are able to collaborate with competitors and through value chains to share best practices. However, as there are some limitations in addressing sustainability due to regulations, businesses ought to participate in advocating for change in the regulations themselves to drive towards a more incentivized regulatory sphere. (Dyllick and Muff 2016.)

Table 1 Summary of the Five-Stage Sustainability Journey and Business Sustainability Typology (Willard 2012, Dyllick & Muff 2016)

<b>Stages</b>	<b>Five-Stage Sustainability Journey (Willard 2012)</b>	<b>Business Sustainability Typology (Dyllick &amp; Muff 2016)</b>
<b>1<sup>st</sup> stage</b>	Pre-compliance: companies do not adhere to policies or regulations	
<b>2<sup>nd</sup> stage</b>	Compliance: companies adhere to regulations to avoid fines, prosecution, and bad PR	Business-as-usual: companies aim for economic savings from process streamlining
<b>3<sup>rd</sup> stage</b>	Beyond Compliance: savings through ecological alternatives or processes, proactive outlook on sustainability	Business Sustainability 1.0: recognizes business risks and opportunities from environmental and social challenges. Addresses these challenges by integrating them into existing processes. Main objective is economic gains
<b>4<sup>th</sup> stage</b>	Integrated strategy: End goal is to be a more successful company by integrating sustainability into the strategy and contributing towards a better world	Business Sustainability 2.0: Aims to create not only value for shareholders, but stakeholders in general. Integrates sustainability in business by aligning environmental, social, and economic aspects in the value the business creates
<b>5<sup>th</sup> stage</b>	Purpose/Passion: End goal is to create a better world by being a more successful company	Business Sustainability 3.0: Transforms sustainability-related issues into business opportunities. Aims to create a positive impact in the society and environment, not only minimize negative impacts

The impact that a single company can have on sustainable development relies highly on how the company views the advantages of sustainability strategies and following this, the practices they implement (Cantele & Zardini 2018). Furthermore, as companies are choosing business partners, they are in increasing amounts taking into regard sustainability-related matters that their partners are doing. It is not only the offering the company provides, but rather the offering and whether their potential partners do business

in an ethical and socially responsible way. Climate crisis, modern slavery, corruption, and health and safety through supply chains can create risks for businesses that can impact the bottom line of a company. Thus, investors are also recognizing the potential risk in investing in a business that is non-conforming to sustainability. Investors making investment decisions are increasingly asserting the importance of ESG data collection and analysis for companies to be able to manage risk and recognize and take advantage of opportunities to create more long-term success. (Ziolo 2021, 28.)

### 3.2.2 Sustainability as a business advantage

Overall, in business, sustainability has become a central point of interest in reviewing the performance of a company. Especially in financial markets, ESG factors have been increasing in valuation (Friede et al. 2015). However, literature shows controversial results in using sustainability as a business advantage (Cantele & Zardini 2018). On one hand, policies that adhere to sustainability and are socially viewed as responsible have been linked to positive impacts on corporate performance. This is through several different factors such as reduced operating costs and financial risks, increase in corporate image and consumer confidence in a company, and enhanced competitiveness and efficiency. (van Beurden & Goessling 2008; Kiron et al. 2015; Bhattacharya & Polman 2017.) On the other hand, in past literature sustainability-related actions have been linked to only an increase in costs and create a decrease in company financial returns (Clarke et al. 1994; James 2015). Mackey et al. (2007) argue that it could be necessary for companies to participate in sustainability-related actions, especially in a competitive environment as stakeholders require sustainable business practices, even if they would lead to an increase in costs and without a guarantee for better performance. What ought to be considered is that even though there would be no significant benefits from participating in sustainability-related actions, is it ethical business, if companies do not participate in sustainability?

Participating in sustainability can be looked at as a business advantage. On the one hand, participating in sustainability by adhering to minimum regulations and incremental change in business practices such as transparency of offshore suppliers or just philanthropy can be a source of competitive advantage. This type of sustainability in business is relatively easy to copy by competitors and could be understood as the narrower concept of CSR rather than a broader concept of sustainability. CSR focuses more on the

messaging toward consumers rather than the meaningful work behind it. On the other hand, when businesses move towards a more sustainable business by integrating sustainability in their business or by fully reinventing their business models, they could create advantages that other companies could view as hard to mimic. These advantages could be e.g., first mover advantages or a more persistent competitive advantage as the change in business is greater than incremental change for only better messaging or increase in reputation. (Parhankangas et al. 2015).

Often the benefits of sustainability are more apparent with larger companies, yet as the majority of businesses are small to medium-sized enterprises (SMEs), smaller companies could potentially create a larger impact on sustainability. According to the EU definition, the staff headcount and turnover or balance sheet total are the main factors that determine if a company is a SME. According to the EU Commission definition “*SMEs have less than 250 employees, turnover that is less than or equal to 50 million or balance sheet total less than or equal to 43 million*”. (European Commission.) However, SMEs are often constrained by their size and lack of human and financial resources and do not face as much pressure from stakeholders to participate in sustainability-related actions (Masurel 2006). Smaller companies are more agile and often do not face the same constraints of e.g., older technology that could be very costly to upgrade to a more sustainable option that bigger companies face (Parhankangas et al. 2015).

Businesses have the option to disregard sustainable business practices and consequently, can reap short-term benefits such as quick profits. However, this can lead to long-term disadvantages. These disadvantages can impact the business of a company detrimentally by e.g., influencing the brand image of the company in a negative way or leading to a situation where consumers are more likely to choose the products or services of a competitor. (Taliento et al. 2019.) Utilizing sustainability to create value for, not just a company’s customers, but also for larger sections of society and the environment, can lead to a company gaining trust by its stakeholders and further legitimizing its business. Looking at full value chains is an imperative part of analyzing the business advantage of sustainability. Businesses often view that sustainability is out of their reach in value chains and thus, not their responsibility. By collaborating with the value chain of companies, it is possible to see where the biggest impacts come from. It can be difficult for one company to address sustainability, but with collaboration and pressure throughout value chains to make a shift towards a more sustainable business, it could be more likely

to create change. It is argued that the top-level management and the CEO should drive the shift towards more sustainable practices and make these practices a part of the job for every employee. (Bhattacharya et al. 2017.) There are different ways of integrating sustainability thinking in business. One method is the Sustainable business model canvas that will be discussed in the following chapter.

### **3.3 Sustainable business model canvas**

Once competitive advantage is gained by companies, it is important to understand that it is not permanent. When companies look to gain and maintain competitive advantage, analyzing and tracking changes in the micro and macro level of their environment is important to uphold with changes in the market. Different sustainability-related challenges require businesses to continuously adapt and change their processes and business model. (Ziolo 2021, 44-45.) The concept of a business model is generally understood as the way a company does its business. Furthermore, it explains the value creation, value delivery, and value capturing of its business. (Magretta 2002, Teece 2010.) This value creation of businesses often regards only the economic value, rather than having a more holistic view on value, i.e., considering other value created, such as environmental and social value by the company (Cardeal et al. 2020.) Sustainable business models have gained increasing attraction in literature (Geissdoerfer et al. 2018; Ziolo 2021, 46-47). A study by Geissdoerfer et al. (2018, 403-404) analyzed different definitions of sustainable business models, and based on this, they define sustainable business models as “...as business models that incorporate pro-active multi-stakeholder management, the creation of monetary and non-monetary value for a broad range of stakeholders and hold a long-term perspective.”

Sustainable business models (SBMs) have been linked to higher risk resilience and further value co-creation in terms of environmental, social, and economic benefits (Ziolo 2021, 58). As sustainability is a multidimensional concept, a sustainable business model (SBM) needs to assess multidimensional aspects. The original business model canvas by Osterwalder and Pigneur (2010) is a well-known tool to show how a business model works. The focus of the original business model canvas is mostly on economic aspects, which is why there have been several attempts in expanding the original business models canvas see e.g., Osterwalder and Pigneur (2010), Jones and Upward (2014), Fichter and Tiemann (2015), Joyce and Paquin (2016). However, many of these only consider some

elements of the canvas to be sustainability orientated and lack thoroughness and multidimensionality of sustainability. Cardeal et al. (2020) have adapted and extended from the original business model canvas. Their business model canvas includes the nine dimensions from the original BMC, which are all assessed by environmental, economic, and social aspects.

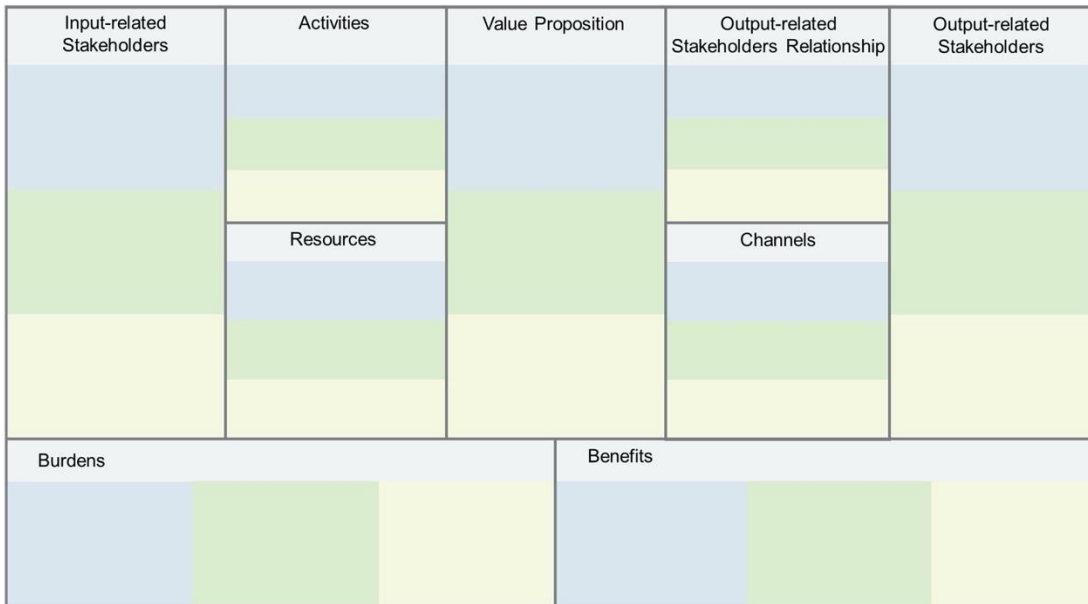


Figure 2 Business model canvas for sustainability. Based on Osterwalder & Pigneur 2010, (Cardeal et al. 2020)

In the model by Cardeal et al. (2020), sustainability is integrated in the model. In line with the original business model canvas, the value proposition is designed to describe the inherent value that the analyzed product or service creates. In the Business Model Canvas for Sustainability, the economic value is customer-centric, the social aspect ought to depict the positive impact the organization creates to its stakeholders and society in general and the environmental factor addresses the environmental impacts throughout the full life cycle of a product or service.

The input-related stakeholders are used to describe the different associates that are a part of the upstream activities of the company core. The environmental aspects that could be incorporated are e.g., water and electricity consumption whereas the social aspect are the different relationships with stakeholders. These can include local communities and local employment, i.e., could the product or service impact changes in the local community.

Outsourcing activities and suppliers are key to an organization; however, they are often not in the core of business. (Cardeal et al. 2020.)

The activities element of the original business model canvas includes all key activities that create economic value to an organization, such as production, logistics, and marketing. In the sustainable business model canvas, the environmental dimension assesses the key activities from an environmental point of view. As such, it analyses the environmental impacts of the key activities. The social dimension of activities considers the organizational structure and governance, for example, the diversity and gender balance of an organization. (Cardeal et al. 2020.)

In the original business model canvas, the resources element defines what the necessary resources, including physical, human, and financial resources, are for organizations' core economic activities (Osterwalder and Pigneur 2010). Different resources have different types of impacts on the environment. Raw materials have a different impact compared to e.g., human capital, but nonetheless, all resources are assessed on their environmental impact. The social dimension focuses more on the employees i.e., the human capital of the company. It assesses the relationship between the employees and the organization. Studies have shown that when employees are committed to an organization, they are more likely to be more efficient and thus, an important aspect to assess. (Shahid & Azhar 2013; Cardeal et al. 2020.)

The element that assesses output-related stakeholders in the model by Cardeal et al. (2020) is an adaptation of the customer segment from the original business model canvas. Here, the model has a broader understanding of a customer in comparison to the original model. The output stakeholders' element consists of all stakeholders that are impacted in some way of the product or service offered throughout the lifecycle. The environmental dimension views people and the planet as the main stakeholder, including green policies that might impact business. The social dimension considers all people that are impacted throughout the lifecycle of a service and product, both in a positive and negative way. Here, a company can e.g., promote sustainable consumption habits or consider how the company can impact societies. The economic dimension often focuses on the customers and their relationship and the cost of obtaining customers. (Cardeal et al. 2020.)

The business model canvas also assesses the different channels that are needed to be able to provide the offering to a customer including the physical transportation and the costs

that come from the way a product or service is sold in different distribution channels (Osterwalder and Pigneur 2010). It depends on the business model how the channels are to be assessed; however, it is good to consider how e.g., different types of sales channels impact the people that are a part of it, how different sales channels impact the environmental footprint and what are the economic consequences of a chosen model. The final elements, burdens, and benefits, considers all three, environmental, economic, and social dimensions of the selected business model on both input and output side. (Cardeal et al. 2020.)

The business model canvas for sustainability by Cardeal et al. (2020) is one tool to analyze the state of sustainability of a business model in addition to be used as a tool for business model creation. It allows the integration of sustainability to all aspects of a company or product. As sustainability has different dimensions that overlap each other, a broad spectrum on sustainability thinking is important. It is not enough to consider only one dimension of sustainability. Besides the sustainable business model canvas, it is possible to analyze the integration of sustainability in an organization in other ways as well. Businesses of all sizes have become increasingly aware of including ESG factors in their business models and realized that this can benefit the company and the economy as a whole. However, the main incentives to implement a sustainable business model still remain to be reducing the cost of finance or increase the value of business. Thus, there is a need to incentivize introduction of ESG factors on a national or supranational level, leading to a situation where the companies that take into consideration ESG factors would increase market attractiveness. (Ziolo 2021, 56-58.)

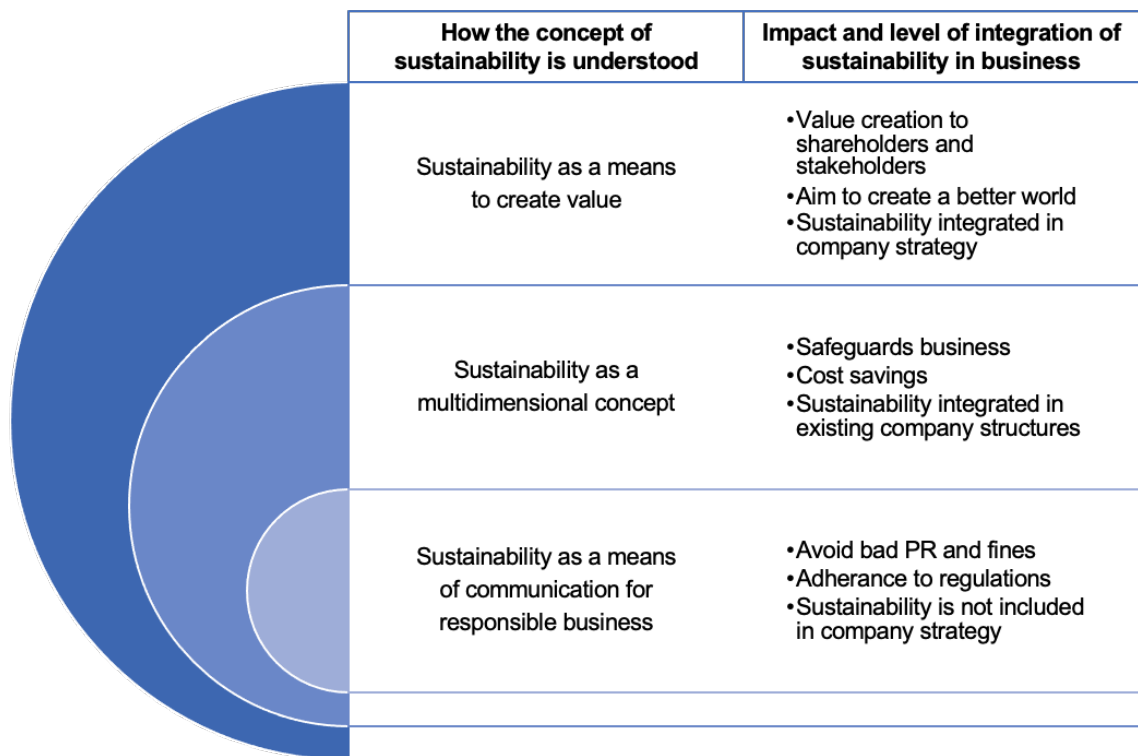
### **3.4 Synthesis of theoretical framework**

Sustainability, in general, has grown in importance through time and in the pharmaceutical industry, it is no different. Due to macro-level changes, such as the aging population and new growing markets arising, the pharmaceutical industry is expected to continue growing, and thus, the need to critically examine the industry's sustainability is necessary. Outsourcing pharmaceutical manufacturing and development has increased in popularity as it has been seen as a means to reduce costs and need for investments in addition to increase compliance and ease. The main criteria that are used for partner selection in the CDMO field have been, but are not delimited to, good cultural fit,



experience, and industry reputation. Sustainability has not been a threshold in partner selection thus far.

Even though there have been controversial results in using sustainability as a business advantage, more and more businesses and investors have realized that there is a business case to integrate ESG matters in business models. The extent of advantages that a company can gain from sustainability depends on how they look at sustainability and how they have integrated it into their business. When a company addresses sustainability-related matters by adhering to minimum regulations, they are only able to avoid bad PR and possibly create minimum cost saving, whereas when a company has integrated sustainability in their business strategy and aims to participate in creating a better world, companies are able to create value, not only to shareholders due to increase in company value, but also to stakeholders in a broader sense.



How the concept of sustainability is understood	Impact and level of integration of sustainability in business
Sustainability as a means to create value	<ul style="list-style-type: none"> <li>• Value creation to shareholders and stakeholders</li> <li>• Aim to create a better world</li> <li>• Sustainability integrated in company strategy</li> </ul>
Sustainability as a multidimensional concept	<ul style="list-style-type: none"> <li>• Safeguards business</li> <li>• Cost savings</li> <li>• Sustainability integrated in existing company structures</li> </ul>
Sustainability as a means of communication for responsible business	<ul style="list-style-type: none"> <li>• Avoid bad PR and fines</li> <li>• Adherence to regulations</li> <li>• Sustainability is not included in company strategy</li> </ul>

Figure 3 How the understanding of the concept of sustainability impacts its integration in business

How the concept of sustainability is understood in companies can potentially impact business as well as the level of integration of sustainability in business. Where sustainability is viewed as a means of communication of responsible business, companies

are not often integrating sustainability in their company strategy and can only benefit from avoiding fines and bad PR, while they adhere to minimum regulations. If sustainability is seen as more than a means of communication, and seen as multidimensional, it can safeguard business as well as create cost savings while introducing sustainability into existing company structures. Further, if sustainability is viewed as a means to create value and is integrated into a company strategy, sustainability can increase value to shareholders and stakeholders in addition to aim to create a better world through business.

As policies to incentivize towards more sustainable business and investment practices are increasing and as businesses of all sizes are beginning to understand the long-term value of integrating sustainability in their business, businesses need ways to analyze themselves. One way for companies to analyze and integrate sustainability in their business is to use the Business Model Canvas for Sustainability. This model enables businesses to look at different sections of their business or products and to analyze these sections through the multidimensional standpoint of sustainability. CDMOs are often a part of a bigger value chain in the pharmaceutical industry and thus, this model enables CDMOs to consider not only their part of the value chain, but also how their part interacts with the full value chain and how sustainability could be addressed in each part.

## 4 Methodology

### 4.1 Research approach

The chosen research method should not be a predetermined choice, rather the choice should be made based on what you are trying to find out (Silverman 2009, 10). The way research objectives or questions have been formulated has a major role in methodological decisions (Arbnor & Bjerke 1997, 8; Ghauri & Grønhaug 2005, 87). Quantitative research methods often are seen to dominate scientific work in business research, as quantitative data are easier to compare. However, where quantitative methods are more disposed to structured and standardized methods in data collection and analysis, qualitative methods aim to gather and gain a more holistic view of the subject matter studied. Qualitative research methods are often seen as a complimentary research method to quantitative research. However, qualitative research methods are often linked to gaining further and deeper knowledge that quantitative methods are not able to indicate, such as a socially constructed understanding of matters researched. Qualitative methods focus more on understanding and interpreting information. (Eriksson & Kovalainen 2016, 4-5.)

Qualitative research includes multiple different types of methods and approaches of research. The type of data gained from qualitative research is often in the form of, but not limited to the following: interview notes and transcripts, field notes, and internet sites. In qualitative research, it is possible to use only one data collection method or to use more than one. In using more than one method, it is possible to gather a wider variety of data to enhance the credibility and trustworthiness of the study. (Saldana 2011, 31–32.) Qualitative research methods can provide deeper insights towards research as they are often able to answer the question “why.” (Rosenthal 2016).

The chosen research method for this study is a qualitative method, more specifically this study will incorporate two different research methods: content analysis and semi-structured interviews. According to Saldana (2011, 10) content analysis can be defined as a “systematic examination of texts and visuals”. Content analysis can be either quantitative or qualitative or both, but the research method ought to be chosen based on the purpose of research. Berg (2004, 265) states that content analysis can be used to create data that is comparable and analyzable.

There are different types of interviews in qualitative research; structured, semi-structured, and open interviews. The first one is suitable for interviews that aim to gain factual information and if there are multiple interviewers conducting the study, yet it limits flexibility during interviews and thus might limit results. (Eriksson & Kovalainen 2016, 81–83.) A semi-structured interview is a method where the questions are the same, they are open-ended, and the interviewer has the possibility to change the order of questions and request clarifications (Berg & Lune 2012, 109– 114.) In semi-structured interviews, the interviewer often prepares interview questions beforehand. They are created as open-ended questions, to encourage and motivate more dialogue between the interviewer and interviewee. This way is possible to gain more information from the interviewee (Silverman 2013.) Open interviews are often informal and useful to explore different topics in a broad sense, however, as they are not systematic, they require ample time for analysis in covering all interviews (Eriksson & Kovalainen 2016, 83).

For the purpose of this thesis, a semi-structured interview method was selected. This was to allow variation in question order and wording if necessary and gave the option to clarify and go deeper into subject matters discussed with interviewees. This also maintained some structure in interviews, which would have been limited in structured and open interviews. The interviews were semi-structured to enable deeper conversation and reflection on the topic.

The aim of this thesis is to gain a deeper understanding of sustainability and its role for CDMO companies in the pharmaceutical industry. Qualitative research methods support the research aim in a more complete manner in contrast to quantitative methods. Interviews allow for more in-depth knowledge gathering whereas content analysis provides a thorough look into the field of CDMOs and how sustainability is viewed and discussed in the field at the time of the study. The aim and objectives of this study are aligned with the background literature and interview themes.

Table 2 Operationalization table

Aim of the study	Research objectives	Background literature and theoretical framework	Interview themes	Content analysis
To gain a comprehensive understanding of sustainability and its role for CDMO companies operating in the pharmaceutical industry	1) To examine how relationships between CDMOs and contractor pharmaceutical companies influence the sustainability of CDMOs	Pharmaceutical industry CDMOs	CDMO relations	Examination of what aspects of sustainability are discussed by benchmarking companies
	2) To examine how the concept of sustainability is understood in CDMOs in the context of the pharmaceutical industry	Sustainability as a concept	Sustainability	
	3) To examine how sustainability-related actions taken by companies are influenced by their underlying motivations	Sustainability in business Sustainable business model canvas	Sustainability as a business advantage	

The first objective of the study is to examine how relationships between CDMOs and contractor pharmaceutical companies influence the sustainability of CDMOs. Background literature in chapter 2 discusses the intricacies of the pharmaceutical industry and CDMOs. These topics were discussed in the interviews under the theme of CDMO relations. The second objective of this study is to examine how the concept of sustainability is understood in CDMOs in the context of the pharmaceutical industry. The evolution of the concept of sustainability and the concept of sustainability in business is discussed in chapter 3.1 and discussed in interviews under the theme of sustainability. The third objective of this study was to examine how sustainability-related actions taken by companies are influenced by their underlying motivations. Using sustainability-related actions as a business advantage, analyzing business sustainability, and the Sustainable Business Model Canvas are discussed in chapters 3.2 and 3.3. These topics were discussed in interviews under the theme sustainability as a business advantage. Content

analysis enabled reflection upon objectives and background literature while providing insights on the specific field studied. The following chapter will discuss in more detail how this data from interviews and content analysis was collected.

## **4.2 Data collection**

For qualitative research, it is possible to use either primary or secondary data sources. The former is data that has been produced for the purpose of the research conducted and the latter are data from other research. (Hirsjärvi et al. 1996.) In this research, both primary and secondary data are used. Interviews i.e., the primary data source, are conducted for the purpose of this research and content analysis i.e., the secondary data source is material gathered from online sources. Using data from both primary and secondary sources enables analysis of data on a deeper level and can lead to insights that would not be possible when using only one data source.

For the purpose of this thesis, a semi-structured interview method was selected. This was to allow variation in question order and wording if necessary and gave the option to clarify and go deeper in subject matters discussed with interviewees while maintaining some structure in interviews, which would have been limited in structured and open interviews. The interviews were semi-structured to enable deeper conversation and reflection on the topic. Interviewees for this study included four employees from the commissioning company and three select client representatives of the commissioning company. One commissioning company employee did not reply to requests for interviews and thus did not participate in this study. All interviewees were selected by the commissioning company. From the commissioning company, the interviewees were chosen from different business areas to gain understanding of how employees from different areas might have different ways of thinking about sustainability. Furthermore, as the relationships between CDMOs and their clients and how it can impact sustainability-related actions are under study in this study, it was important to interview clients as well. This client point of view helps align understanding of sustainability and expectations for sustainability-related actions from different perspectives. Three representatives from existing clients were selected by the commissioning company. This study excluded specialist interviews to be able to focus on CDMO and client relationships in a more in-depth way.

The interview questions were similar for both commissioning company employees and their clients, however, were modified slightly for each group to be able to address both commissioning company and contractor viewpoints. Furthermore, the interview questions were divided into three categories: sustainability, CDMO relations, and business advantage. This division was done so the structure of the interview is clearer, however, it leaves room for further clarifications if necessary. The interview questions for both groups are provided in Appendix 2, however, it ought to be noted that as the interviews were semi-structured, there were some additional questions and clarifications that were discussed during the interviews.

Table 3 Interview details

<b>CDMO Customers:</b>	<b>Interviewee code:</b>	<b>Date:</b>	<b>Duration:</b>
	Customer 1	7.4.2022	36 min
	Customer 2	20.4.2022	28 min
	Customer 3	6.5.2022	37 min
<b>CDMO Employees:</b>	<b>Interviewee code:</b>	<b>Date:</b>	<b>Duration:</b>
	Project manager 1	6.4.2022	48 min
	Chief business officer	4.4.2022	47 min
	Manager, Sales and Business Development	8.4.2022	38 min
	Director, Manufacturing and development	7.4.2022	28 min
	Project manager 2	Did not respond	

Prior to interviews, a brief overview of the topic was given to all interviewees so that they are knowledgeable about the topic to be discussed. The interview questions were not provided beforehand so that more open discussion and dialogue would be encouraged. Furthermore, this allows for more spontaneous answers in the interview in comparison to readily rehearsed answers. The interviews and benchmarking were conducted during April and May 2022. The interviews were held remotely via Zoom and Teams for the convenience of the interviewees and due to some interviewees placed abroad. During the interviews there were technical connectivity issues, however, these did not impact the interviews. Permission for recording the interviews was asked in the beginning of each interview. According to Patton (1989, 247), as long as recording is justified to the

interviewee, recording can increase the focus of the interviewer to the interviewee. These recordings were transcribed after the interviews for further analysis.

The content analysis of selected pharmaceutical companies was conducted based on publicly available information on websites. The commissioning company selected the companies to be analyzed and selected the following companies: *Fujifilm diosynth*, *Celonic*, *Halix*, *Batavia Biosciences*, *Rentschler biopharma*. The selected companies are similar to the commissioning company and operate in relevant market areas and represent current important competitors in the field of CDMOs for the commissioning company. These content analysis companies were not interviewed.

Content analysis benchmarking was done through analysis of different ESG factors that were mentioned on the websites and social media posts on Facebook and LinkedIn from January 2020 to May 2022. The websites were analyzed on multiple levels and looked through from different aspects related to sustainability. All sustainability-related mentions and posts were gathered in an excel sheet and grouped under respective ESG themes. By collecting different aspects of sustainability under respective themes, it was possible to gain a clear image of sustainability-related actions that these selected companies were currently doing. Even though some companies are a part of a bigger group, only the selected company websites were analyzed. This was to ensure equal level of analysis for all companies. It is noteworthy, that even though some companies did not mention sustainability or ESG factors at all on their own websites, on a group level they were discussed. However, due to the limitations of this study, this data has been left out. Detailed information of ESG actions on benchmarking companies is provided in Appendix 1.

### **4.3 Data analysis**

Data analysis has an important and critical role in qualitative research. Differences and similarities in addition to relationships with different sections can be highlighted in data analysis by identifying, coding, and retrieving. (Lu & Schulman 2008, 105.) There are many types of qualitative analysis, but their commonalities are description and interpretation of data. According to Eriksson and Kovalainen (2015, 120) qualitative content data analysis has two main purposes. The first one is to gain a comprehensive depiction of the topic that is studied, and the second purpose is to gain a detailed



interpretation of the data that is studied. Factual descriptions are often seen as a good beginning for analysis and then continue toward a more detailed analysis.

The data from interviews was analyzed by using a thematic analysis approach. Thematic analysis is a well-justified method for the purpose of this thesis as it is a valuable tool in identifying, reviewing, and analyzing themes. (Braun & Clarke 2006, 79.) By coding the data, it is possible to make the analysis process more tangible (Pierre and Jackson (2014, 174). After the data collection, the first process of the data analysis began. The first step for this was transcribing data from the interviews. Eriksson & Kovalainen (2008, 85) recommends transcribing the interviews as soon as the interviews were conducted to familiarize and improve data management. Transcription was done through the dictate feature in Word.

After transcription of interviews was finalized, the data was formed into a more manageable form by color-coding the data into the same themes the semi-structured interviews were based upon. The themes were *sustainability*, *CDMO relationships*, and *sustainability as a business advantage*. These themes are also aligned with the background literature and theoretical framework discussed in chapters 2 and 3. *Green* was used for sustainability-related matters, *yellow* was used for CDMO and client relationship, and *blue* for business advantage. These themes were then gathered and grouped together and cross-referenced with the literature discussed in chapters 2 and 3. This cross-referencing included looking for similarities and differences between theory and data. Some notions from the interviews echoed theories strongly, such as the difficulty in defining sustainability whereas others, such as the non-existent demand for more sustainable CDMO practices, were discussed in the interviews, yet hardly mentioned in background literature.

Analyzing data for the content analysis began with structuring the content for the content analysis. Initially, all sustainability-related actions were grouped under the benchmarking company, however, by structuring the content under ESG factors, it was possible to visualize what the focus points of benchmarking companies are in relation to sustainability and how much are they bringing it forth. These sustainability-related actions of benchmarking companies are available in Appendix 1.

Finally, after color-coding and structuring data from the content analysis and interviews, notions from both were gathered under three different categories to be able to answer to

the research objectives and aim set for this study. The categories used to group all data from both sources were equal to the ones used in the semi-structured interviews and that were used for color-coding transcriptions. These themes were: sustainability, CDMO relationships, and sustainability as a business advantage. Both similarities and discrepancies found in data and reflected with the theory provide ground for results and conclusions in this study. By cross-referencing both content analysis data and interview data with theory, it was possible to look at underlying factors that were not present in the theory. In all studies, it is important to evaluate data. The means of evaluating this study is discussed in the following chapter.

#### **4.4 Data evaluation**

Qualitative research can often leave room for interpretation and more freedom in data interpretation. Moreover, the preconceptions, prior experiences, and underlying assumptions of a researcher are prone to impact the analysis done by the researcher. Thus, data evaluation is an integral part of a study. (Eskola & Suoranta 1998.) In this research, the data evaluation is done based on the criteria by Lincoln and Guba (1985). This criterion that evaluates the trustworthiness of a study includes an analysis of *credibility, transferability, dependability, and confirmability*.

*Credibility* of findings refers to the degree that the research and its findings relate to reality. By studying the subject of research, it is possible for a researcher to increase credibility of a study. (Lincoln & Cuba 1985.) The qualitative content analysis and interview questions were carefully conducted and formulated in a way that supports the answering the research aim and objectives. The theoretical research background chosen for this study is aligned with the aim of this research. By incorporating interviewees from both, the commissioning company, and their clientele, it was possible to gain understanding of how both sides view ESG and how their relationship can impact ESG actions. Furthermore, by incorporating interviewees from different business areas, it was possible to see how their views differ from each other within the company. By doing qualitative content analysis benchmarking, it was possible to see what actions competitors are doing regarding sustainability and how they bring forth these matters. However, the interviews for this study only reflect the views and relationships of one CDMO. Since different companies do different ESG actions and bring them forth in different ways, interviewing other CDMOs and their clients could increase the credibility of this study.

*Transferability* of a study refers to the degree that the findings of a given research can be transferred to another context, i.e., if the study would be repeated by the same or other researchers, the same findings would be reached. It is important to note that research is done in a certain situation and time and thus, reflects upon the ideas and interpretations of the time of research. Authors or researchers are prone to certain biases, but with a detailed description of the research process and its methodology, it is possible to help guide evaluations by outsiders of the decisions and thought processes behind the study. (Lincoln & Cuba 1985.) In this study, the motivation and purpose of are outlined in the introduction. The theoretical background and methodology and decisions are rationalized in the study. All decisions ought to be justifiable to increase the transferability of the study.

*Dependability* in research is evaluated by the examinations of transparency of the research setting. This can be measured by e.g., analysis of how the researcher and the context of research have impacted findings. As a research method, qualitative content analysis and interviews can be viewed as methods of research that can be influenced by the unconscious bias of the researcher, it is crucial for the researcher to remain as unbiased and objective as possible. (Lincoln & Cuba 1985.) This research builds on previously created frameworks and theoretical background and as such, increases dependability. However, as all interviews were separate and the information on websites of companies can change through time, it is possible that when recreating this study, the results could vary. As the findings of this research rely on the interpretation of data by researcher, this can decrease dependability of research, even if full transparency is sought through the research process.

The final criteria, *confirmability*, measures the findings on whether they are based on the participants' sayings and if they are not affected by the researchers' own opinions or potential biases. It is possible to increase confirmability of a study by having a clear structure. This facilitates the audit process as the clear structure makes it easier to follow the research process from the beginning until results. (Lincoln & Cuba 1985). In this research, the gathering of data and its analysis has been thoroughly explored which increases confirmability of this research. The choices made by the researcher in this study are correspondingly justified throughout this study. Triangulation of data i.e., using data from multiple sources is another form of increasing confirmability of a study (Joubert & Webber 2020.) This study incorporates data from two sources, information from websites

and social media of companies and interviews. This triangulation of data is a further way to increase confirmability as it can be used as means to reassure research results.

Ethical issues are a dimension all research ought to acknowledge. The foundation of qualitative research, especially interviews, are looking to conceptualizing and generalizing the private. This generalization of the private needs to be done in a manner that respects the privacy of the participants of a study. (Orb et al. 2003.) This is where research ethics especially comes into place. Ramos (1989) brought forth issues that can possibly impact a qualitative study. These include the relationship between the researcher and participant, the research design and the unconscious bias and subjective interpretation of the researcher.

Ethical difficulties that are inherent in qualitative research can be addressed by use of ethical principles. The principles include *autonomy*, *beneficence*, and *justice*. (Orb et al. 2003.) *Autonomy* in qualitative research refers to the participants right to accept or refuse to participate in a study. In this study, all interviewees were given the option to choose to participate in study. All interviewees in this study were voluntary. One suggested interviewee chose not to respond to inquiries to participate in this study. *Beneficence* i.e., preventing harm and doing good for others, as an ethical principle in qualitative studies refers to the moral obligation of the researcher to consider the possible implications for the interviewees of participating in the study. This includes e.g. the possible anonymity of participants and restriction of circulation of the study. In this study, all participants for the interviews are anonymous. Furthermore, the commissioning company for this thesis is also completely anonymous throughout this study. *Justice* i.e. equal share and fairness is crucial in research. A feature of this principle is to avoid exploitation and abuse of participants in the study. This is done by acknowledging the susceptibility of participants of the study and avoiding creating further burden of participating in the study. (Orb et al. 2003.) The interviews were conducted in a way that aimed to respect the time and contribution of participants.

## 5 Findings

### 5.1 CDMO and contractor pharmaceutical companies' relationship and sustainability

Quality is vital in the pharma industry and something that cannot be disregarded. Quality and patient safety were highlighted in the answers from the representatives of the client companies as part of the main criteria for choosing a CDMO partner. Other matters that were noted as important in CDMO choice were previous experience, culture fit, good communication, and cost. Especially due to the Covid-19 pandemic, the security of supply chains was also noted as a big attribute that clients and CDMOs are looking for in partners in general. The commissioning company interviewees recognize that sustainability is not one of the main things evaluated in partner selection at this moment, yet they believe that in the future it could be. The client company interviewees confirmed this by stating that in a selection of partners, all other attributes being equal, they would choose the more sustainable choice. Interviewees pointed out that as the requirements and standards for items are relatively high, it might be difficult to incorporate sustainability in the decision-making process at this moment.

Both the commissioning company and client interviewees noted that sustainability or any of its aspects are not discussed or brought forth in any way in CDMO relations. What came apparent in the interviews was that both client and commissioning company view that the vast number of regulations and multiple steps necessary for a drug to move from drug discovery to clinical trials, are enough to make sure companies could not adhere to all regulations. Furthermore, both parties recognize that the risk of not adhering to all regulations could be detrimental to their business, and thus are not willing to take any risks in non-compliance. Even though sustainability is not directly discussed in CDMO relations, some aspects of sustainability, such as bribery and child labor matters, are occasionally discussed.

“Well, we never asked our clients about their sustainability profiles or targets or, or plans. And they, most of the time, don't ask for ours. It's more common that they ask for anti-bribery and child labor and that kind of things.” (Chief business officer)

This lack of discussion of sustainability in other aspects than child labor and bribery was also replicated in benchmarking of CDMOs. Some companies had declarations such as

the modern-day slavery act, but the term “sustainability” was not mentioned. Neither party, the commissioning company, nor their clients, were not aware of any sustainability actions that the other party might be active in. Sustainability in general is not discussed in business transaction situations as the industry is mutually seen as inherently doing good. What was noted by both sides, was that there is a mutual expectation that everyone acts in a sustainable way and therefore, do not see a need to discuss sustainability at all.

“We don’t have any single guidance available; the baseline is that we presume that actors we work with are reliable.” (Manager, Sales and Business Development)

This expectation of reliable partners could be linked to cultural matters as the business environment the companies are present in are linked to countries where laws and regulations are generally presumed to be respected and where actors are presumed to do responsible decisions. One client company interviewee stated that they do not do any sustainability actions and do not believe that it is their or the industry’s responsibility to do any sustainability related actions whereas another client company representative brought forth that they have done a sustainability/ESG audit in the past year. In this audit they evaluated e.g., their environmental impact, employee gender diversity and corruption and expect that different sustainability related aspects are to be introduced and evaluated in their future business. Even though they acknowledged that doing a ESG audit is important, they believed that the reasoning behind the audit were that in future business, it is valuable to analyze and take into consideration sustainability related matters. This client company has a more proactive approach to sustainability related matters, while the other client company has a more reactive and negligent approach to sustainability.

Even though sustainability is not currently a threshold for CDMO partner choice, it has been noted that in the industry in general, more and more companies are coming out with sustainability related statements. Some benchmarking companies did not mention sustainability directly, however, they do promote sustainability related actions on their social media. Many companies linked their work especially to the social aspect of sustainability. Here companies pledged support to e.g., world rare disease day, which links their business to a relevant cause and women’s day that links to aspirations to a more gender balanced company. Celonic as an example focuses on a strong company culture that they bring forth as a competitive advantage. Albeit at this moment sustainability is not seen as a criterion for CDMO choice and sustainability does not guide CDMO choice,

some client companies have done sustainability audits for themselves. As internal sustainability/ESG audits gain popularity, it could be that sustainability will be introduced in CDMO partner choice as well.

The client responsibility regarding sustainability was also discussed. Unless the market i.e., clients of CDMOs are not demanding more sustainable business practices or do not take into consideration sustainability related matters in choosing partners, CDMOs are not incentivized to invest further in sustainable business. Outsourcing pharmaceutical development and manufacturing for CDMO clients is not only about not having your own factory or not having to invest costs in them, but also about accountability.

“You know the customer holds the ultimate voting rights. And actually, if the customer doesn't care yet, it is an interesting space to be in. Because if I don't care, I'm not generating market for any of my CDMOs to behave better”  
(Customer 3)

When CDMO clients choose partners, they are able to shift the responsibility of sustainability to the CDMO. It could be stated that the client company ought to take accountability on sustainability-related matters and ask the difficult questions and demand more sustainable behavior. From the benchmarking study, the main items that were brought forth as values or competitive advantage were communication, good and proven track record, quality, and flexibility. Some benchmarking companies brought forth that they are a full-service CDMOs that can create ease for clients. These attributes brought forth by benchmarking company websites and social media reflect the answers of interviewed client companies of what they look for in CDMO partners. Of the benchmarking companies only one company had a sustainability-related certificate that they brought forth on their website. Even though CDMOs do sustainability-related matters, the industry at this moment might not be mature enough to be able to understand the potential of using sustainability as leverage in business relationships.

“I do not know if we are able to choose or actually make an impact in for example material choices because there are certain standards for material, and we do not have a lineup of companies available from which we could pick and choose the most sustainable one. I just do not know if we would be able to do that even if we wanted to.” (Customer 1)

When discussing with the commissioning company representatives whether they would work with a client that was non-conforming to sustainability, it was seen in different ways. There had been a case that included bribery, which concluded in terminating that

client relationship. In another case, a client was looking into the sustainability and possible alternatives to a raw material that ultimately led to no action. It was also discussed that it is hard to define what the level of non-conformance of sustainability would be, which would impact client relationships. Even though the commissioning company does not have any sustainability-related requirements for their clients, anything that would compromise patient safety and quality were brought forth as issues that they would see as their responsibility to address. CDMOs work on a contract basis, and it can be hard for them to evaluate how sustainability has been considered before they are contracted or after their contract ends and thus, see it difficult to impact these steps. The length of the client-CDMO relationship was perceived to impact how much CDMOs are able to discuss matters not related to staying on schedule and budget and fulfilling certain GMP standards. If the relationship is longer, with a record of completing multiple projects together, it is easier to discuss matters more broadly and openly in comparison to clients with a shorter history. In any situation, the main priority CDMOs often have at this moment is patient safety.

## **5.2 The concept of sustainability in CDMOs**

The multidimensionality of sustainability is reflected throughout the interviews with both the commissioning company and its client representatives. Many participants understood that sustainability as a concept is difficult and hard to conceptualize. It is broad and engulfs multiple different aspects. One interviewee emphasized that sustainability is everything, and possibly even one of the most important questions of our time currently. Environmental matters, such as waste disposal and water and energy usage, were often noted as the primary aspect that comes to mind when discussing sustainability, however, interviewees brought forth many different aspects that they understand sustainability to consist of. These aspects included e.g., social, economic, and governance-related matters. Social aspects that were discussed included working conditions and employee wellbeing in addition to educational sustainability such as collaboration with students. Economic sustainability included financial stability that was noted as necessary for businesses to continue their business and its development. One interviewee noted that the more they thought of sustainability, the more aspects seemed to be linked to the matter. The same interviewee also noted that there are different aspects of sustainability depending on whether it is discussed long term versus short term.



“I see it (sustainability) as a broad concept, of course there is the employee - employer aspects, as in how the company treats its employees, how the company in general functions in its own environment and then there is of course the environmental aspect and how they are taken into consideration. Perhaps also a good citizen aspect, as in how we function in the legal environment and here, how we take into consideration all legal requirements of the environment” (Manager, Sales and Business Development)

For the pharmaceutical industry, one of the most important aspects of sustainability was reported to be patient safety. Creating and manufacturing new pharmaceuticals in a responsible way that adheres to regulations and with high respect to quality was seen as a central aspect of sustainability in the industry. Some interviewees reported that for the pharmaceutical industry, creating new and better drugs to improve and save lives ought to be the main priority of the whole industry and this aspect ought to take precedence over other sustainability-related matters. Even though sustainability is not often discussed in the pharmaceutical industry, the industry, in general, is seen to be participating in generating a better future, due to the inherent value of creating new life-enhancing and saving drugs.

When discussing sustainability, interviewees noted that the industry is very regulated. This means that almost all aspects of their business are subject to the regulatory field. Some aspects of sustainability, such as environmental matters are addressed indirectly due to these regulations. There are regulations that dictate how pharmaceutical waste ought to be discarded and how e.g., the sterility of instruments used in manufacturing and development needs to be secured. Thus, there is little leeway in certain aspects of sustainability that pharma companies can address. Big pharma companies report sustainability; however, it is mainly done due to regulations that require reporting sustainability in certain ways and due to requirements from shareholders. Regulations were also seen to restrict incorporating sustainability in business.

There was no consensus on whose responsibility sustainability is specifically, but there were similarities in responses. Some interviewees stated that sustainability is the responsibility of everyone yet indicated that there are different levels in who and how different actors can address and impact sustainability. One interviewee stated that the responsibility for sustainability is largely a political matter where the developed world has a greater responsibility for sustainability compared to the developing world due to historical matters. Another interviewee expressed that especially in the pharmaceutical

industry, as it is very regulated, the responsibility of sustainability is largely on political actors that are creating the regulatory atmosphere of the industry. Smaller companies in the pharma industry put the burden of making the industry more sustainable to big pharma companies. Interviewees argued that as big pharma has more resources and are able to create bigger change, they ought to be obliged to pave the way for a more sustainable industry for smaller companies.

“I think it's very difficult for us to be a small company to lead the way. It has to be the big ones, we talked about that touched about the government, but also big pharma, the big players in the field should be the ones that lead the way for our company “(Customer 2)

What was not dissimilar in responses was that many interviewees noted that there are different hierarchical levels where different actors are able to take responsibility of sustainability in different ways. Employees have a responsibility to inform their superiors if they see something that is not according to sustainability principles and values of the company. Superiors have the responsibility to take this information forwards to the leaders of the company, from where it is the responsibility of the leaders to address this matter and communicate it to stakeholders. In company and client relations, it is a shared responsibility to act in a sustainable way, nonetheless, as one interviewee expressed, we are all responsible for our actions. If we view a company as a part of its environment, legislation and regulations are formed and used to guide companies to act in a more sustainable way, and here the responsibility of creating an environment that supports sustainable actions is the responsibility of political actors. On a company level, however, interviewees stated that the main responsibility towards more sustainable practices ought to come from the leaders of the company that shape the values of a company.

“Well, individual people cannot impact here that much. Everything we do, they have guidelines and quality control and when creating pharmaceuticals, we must act according to these guidelines. So, the responsibility comes from the guidelines and then we act upon them. But the way the guidelines are created, that is where the greater responsibility comes from.” (Director, Manufacturing and development)

The pharmaceutical industry has a controversial image and many of the interviewees recognized this controversy. They noted that the baseline of the industry is to do good through pharmaceuticals, however, they understand that there is a balance that needs to be maintained in between making profits and creating responsible pharmaceuticals. Even though patient safety was highlighted as one of the most important aspects of

sustainability in the pharmaceutical industry, interviewees found it difficult to define what aspect of sustainability would be the most important one. For business, profits i.e., economic sustainability, is the main purpose of business, yet it was noted that it might not be acting in an economically sustainable way if businesses reap short-term profits that can diminish long-term value.

“From the point of view of a company, unfortunately the economic aspect of sustainability would be the most important one, because the basic principle of a company is to create as much profit as possible. However, here comes the time perspective; it could be that if we want to reap short term profits, it can diminish long term profits, which could come from focusing on certain matters and taking care of them.” (Project manager 1)

Businesses are also responsible for their employees and one interviewee argued that a company can increase employee wellbeing with small things. As an example, they stated that by discussing how sustainability is addressed in the company, employee wellbeing could increase because people find it valuable to work in a place that works towards a more sustainable future and shares the same values. Especially as the amount of waste pharmaceutical development and manufacturing creates is vast, and how regulated the waste disposal standards in the industry are, it could be important for employees to know that the company they work for aims to lessen the amount of waste and takes sustainability seriously. Environmental sustainability is important as well as there are high risks in contamination of the environment if waste disposal is not handled properly. In continuation, energy consumption and extremely high use of single-use plastics were discussed as important matters, especially in the pharmaceutical industry. The multidimensionality of sustainability is reflected in these answers as well, as interviewees found it difficult to pinpoint the most important aspect of sustainability.

Even though many interviewees recognized that the responsibility of participating in sustainability-related actions belong to all, many participants shift their responsibility to other actors. The idea that the industry is inherently doing good by providing new and better pharmaceuticals is perceived as a reason to not address sustainability that much. Furthermore, other industries, such as the oil industry, are seen as more pressing industries that should address sustainability. This takes away the main responsibility and shifts it towards other industries.

“But it's probably also because biological pharmaceutical development and manufacture is not such, it's not one of the lowest hanging fruits. I mean, if

you want to make a change, it's in the oil industry, in the metal industry, it's a new clothing and colors and dyes and so on. So that's probably the ones to target first. What we do is, is maybe not so bad for the industry.” (Chief business officer)

In the content analysis benchmarking section of data, it is apparent that different companies address sustainability in different ways. Out of the five companies analyzed, two, Fujifilm Diosynth and Rentschler Biopharma, mentioned environmental sustainability in some way. Pharmaceutical manufacturing and development are high in energy and water usage. These two companies aim to reduce energy consumption by shifting towards energy-efficient alternatives such as LED lights, by introducing a combined heat and power plant that enables them to produce 70% of their own power supply, or by incorporating renewable solar energy in their new facilities that are under construction. Out of the two companies that address environmental sustainability, only one addressed water usage. In the cGMP biopharmaceutical production, highly purified water (HPW) is a key resource. One company has dedicated experts to ensure sustainable and reliable use and supply of water. Other ways these companies address environmental sustainability are by participating their own employees in e.g., litter picking activities during their lunchtime, bringing awareness of the World Groundwater Day on their social media, and adopting a greenway that they pledge to clean and maintain.

The social aspect of sustainability is addressed by all companies in benchmarking in some way. The same two companies, Fujifilm Diosynth and Rentschler Biopharma, that address environmental sustainability, address social sustainability more extensively than others. Out of these two companies the first one, Fujifilm Diosynth focuses on e.g., gender equality by highlighting their women on their social media and have women in STEM (Science, Technology, Engineering, Mathematics) activation for children to create early interest towards science. They create awareness for rare diseases and sponsored MassBio Rare Disease Day, which that year focused on addressing health inequality and racial disparities. They also received a Disability Confident Committed Employer recognition, for becoming a more inclusive employer. The latter also participates in gender equality in their social media by highlighting Women's Day and Women in STEM Day. They support rare disease day and world cancer day on their social media as well. For their employees, they offer parent-child programs to support employees with children and offer yoga and fitness to employees. They also participate by having their employees hold

lectures about pharmaceutical biotechnology in different educational institutions in their region and donate their speaker fees to different support causes.

Two benchmarking companies, Celonic and Halix participate in the social aspect by stating on their website that they focus on employee wellbeing through different initiatives such as good work-life balance, having introduced a people development manager and promoting employee health in different ways. Batavia Biosciences was the only company that participated in the social aspect of sustainability by only a social media post to promote awareness of World Polio Day. None of the companies mention the governance aspect of sustainability on their website or on their social media. Four out of the five companies do not mention sustainability at all on their websites. Even though Fujifilm Diosynth does not discuss sustainability on their website, they have a separate Earth Day 2022 website, which discusses all ESG actions they do. Rentschler Biopharma is the only company from the benchmarking that addresses sustainability clearly on their website and received a Silver Ecovadis sustainability rating for the first time in 2021, which they bring forth on their website.

### **5.3 Sustainability-related actions and their underlying motivations**

Both advantages and disadvantages of participating in sustainability-related actions were brought forth by interviewees. It is not enough to discuss sustainability, or any actions related to sustainability if it is not possible to back up the discussion and actions. Without any actions to back up the sustainability-related statements, participating in and discussing about sustainability was viewed to potentially create more damage than good for businesses. Greenwashing, as in marketing a company to appear more sustainable than it in actuality is, is not accepted in any way and was perceived as detrimental to the credibility of a company. When CDMOs are facing decision-making processes, it seems to be harder to justify choosing the more sustainable alternative, if it in any way could slow down development or processes.

Some disadvantages that were discussed included the vast number of resources needed to do sustainability-related actions. Many interviewees stated that they are already rather full of work and could not add a layer of sustainability due to lack of time. Sustainability audits and actions require time and financial resources that smaller companies might not have. Rigid ways of working and bureaucracy to implement sustainability in business are understood as costly for businesses and if businesses are not able to transfer these costs

in the pricing model of their business, it might be hard to justify these actions. Companies are looking to gain returns on investments and as sustainability and investments related to it can be hard to quantify, it can be hard to justify these investments. Furthermore, there can be guidelines that prohibit changing from single-use to reusable materials.

The development and manufacturing of new pharmaceuticals are relatively expensive, and one interviewee stated that it might not be beneficial to prioritize sustainability before making sure a developmental drug is effective. This being stated, it might be difficult to implement sustainability thinking into a manufacturing process after the development is already done. As the expectations in the pace of development and manufacturing and getting them forwards are rising, incorporating sustainability is comprehended to slow down the pace of development. When companies are focused on being able to move to the markets first and gaining e.g., patents, companies are more focused on quality, safety, and speed in entering markets rather than building a product in a sustainable way.

“Is the competitive advantage worth it for a company that is focused on being first to market? In, you know, the competitive competition what they're looking at is; what are the other biotech's researching and where are they in their clinical trials and how close are they in getting, you know and I'm looking at a product right now that we are neck and neck with another company we're hitting issues on it, it's absolute focus on that and I think therein lies the problem because this starts from the top down” (Customer 3)

When companies are not able to utilize first movers' advantage, their share of profits might be considerably hindered. If the focus on drug development is only on gaining first entry to markets, leaders of companies are possibly not in the right headspace to discuss sustainability-related matters or do not understand the value of it. In some circumstances, bringing forth sustainability-related matters might diminish credibility as it is seen to take focus from the main business. Especially in an industry like the pharma industry, being seen as losing focus on the main core of the business, i.e., the inherent goodness of creating new drugs, can be bad for business. One interviewee stated that even though participating in sustainability would bring costs, both financially and in human capital, it would not be a disadvantage.

Perhaps as the industry is directly impacting social issues such as health disparities and the general wellbeing of people, the social aspect of sustainability is highlighted as a means to create business advantage both in interviews and in the benchmarking section. Environmental aspects of sustainability were addressed only by two companies, whereas

the social aspect was addressed by all companies in some way. Bringing awareness and externally communicating about social challenges such as rare diseases and how health disparities impact the world are some ways benchmarking companies address social sustainability. These can be used to positively impact the image a company has. Another way benchmarking companies address social sustainability is how they value and take care of their employees. This can also be used to shift the image a company has as an employer in a positive way to attract and retain its employees. Furthermore, generational differences were expressed, and one interviewee suspects that a generational change is necessary for the industry to shift towards a more comprehensive way of addressing sustainability.

Commissioning company interviewees stated that participating in sustainability-related actions can increase the image a company has as an employer. As sustainability, in general, has become more apparent in everyday life, interviewees stated that it is important that they work for a company that they believe to be doing good in addition to sharing values. Working for a company that employees believe to be doing good was seen to help with internal employee retention. Participating in some ways with educational institutes was seen as a means to participate in the social aspect of sustainability as well. It was stated that even though it could be in some ways time-consuming, it could be used to attract and potentially help in recruiting younger talents.

As the CDMO field is consolidating due to companies being bought and sold and mergers, acquisitions, and fusions are happening, having a proactive view towards sustainability could be a benefit. When these changes are happening, having an ESG audit and sustainability-related activities could be seen to increase company value. More and more investors are looking at ESG factors and taking them into regard in their investment decisions. It was noted however that as the industry has many regulations that can hinder opportunities to participate in sustainability, having a proactive approach toward sustainability can be difficult. An increase in company value can motivate companies to participate in sustainability. Other ways companies are motivated to participate in sustainability are legal regulations that are necessary to comply with and the sheer knowledge that the company is doing good, and the obligation in participating in creating a better world.

Even though there are benefits in participating in sustainability, capturing the essence of it to be able to reap the benefits is seen as difficult. Even though by participating in sustainability, a company could be perceived as a thought leader and would increase its brand profile, selling a more sustainable alternative was seen to be difficult and compared to selling happiness. Time was also discussed to impact how sustainability could be an advantage. Whether we are looking at the short-term or long-term, sustainability-related changes could either be understood as costs or investments. Short-term, changing development and manufacturing processes to decrease energy and water consumption or changing to a more sustainable source for these, can be viewed as a cost, when long-term, these changes can bring savings.

To be able to gain and reap benefits from sustainable business, communication is key. If a company addresses sustainability in some way, yet does not communicate it either internally or externally, it is not able to benefit from these actions in a comprehensive way. Commissioning company clients brought forth that if all else being equal, they would choose a more sustainable partner and commissioning company employees discussed that it would bring further meaningfulness for them to work for a company that shares its values and addresses sustainability. The commissioning company had done an ESG audit, however not all employees were aware of it and its results.

“If the actions are concrete, then it (sustainability) is a good thing and then you should also communicate about it. Then in the future, at some point, it could be a critical factor for a future client that they choose us” (Project manager 1)

Out of the five benchmarking companies, only one had a sustainability-related certificate that they communicate about and two discuss environmental matters on their website and social media. Even if other benchmarking companies were doing sustainability-related actions, if it is not available easily on their website and social media, possible clients cannot take these into consideration if they are not communicated about. Furthermore, if the participation in sustainability-related communication is only a few general awareness-bringing social media posts, are these seen to be enough to bring credibility to the actions a company does relating to sustainability.



#### 5.4 Barriers and motivational factors for sustainable CDMOs

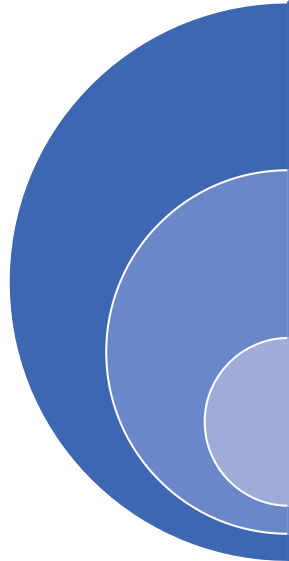
The highly regulated atmosphere of the pharmaceutical industry impacts the way CDMOs are addressing and understanding sustainability. As stated in chapter 3, sustainability has had shifts in what is focused upon. The first shift in sustainability was towards CSR. (Ziolo 2021 1;12.) CSR mainly aimed to answer to the need of companies to communicate about sustainability and acts as a self-regulatory framework (Sheehy 2015). Some of the benchmarking companies did address sustainability on some level, however, many CDMOs are not currently utilizing it to their advantage in communication. It was further noted in the interviews that sustainability is not communicated about in any way in business situations, even though the importance of sustainability is recognized. Businesses expect other actors to act in a sustainable way even though it is not discussed. The second shift in sustainability was the shift towards the TBL, which is a more intersectional outlook of sustainability. Here, businesses are expected to participate in sustainability, even if the main contributors were governments, policymakers, and regulators. (Elkington 1998, 20.) Interviewees stated that as the industry is highly regulated, the main contribution towards more sustainable business ought to come from regulations or bigger pharmaceutical companies, thus shifting the responsibility to participate in sustainability to other players in the field. Different aspects of sustainability are acknowledged, however, are not rigorously addressed. The third shift in sustainability was to understand sustainability as a means to create value. Interviewees viewed that by creating possibly lifesaving pharmaceuticals and adhering to regulations, they are already inherently creating value for a better world. Due to this, a proactive approach to further sustainability was not seen as necessary at this moment.

The interviews show that interviewees understand sustainability to be multidimensional and to include various aspects. Environmental factors regarding sustainability in the pharmaceutical industry mostly come from rigorous regulations. Furthermore, some benchmarking companies are e.g., changing to eco-efficient alternatives and by addressing environmental sustainability. Economic sustainability in business is a key factor for the longevity of business, which was also discussed in interviews. The social aspect, especially patient safety, and quality, of sustainability is highlighted in importance in this industry. All benchmarking companies in some way address social sustainability and social sustainability was highlighted in the interviews as well. However, sustainability is not viewed as a means to create further value. This being stated, the

multidimensionality and importance of sustainability are understood in the field. It is seen to bring cost savings and safeguard business and could in the future be a threshold for business. Patient safety and quality, i.e. one part of social sustainability in the CDMO field, is integrated into company strategies, however, the multidimensionality of sustainability is not yet largely integrated into CDMOs.

The contractors of CDMOs are not creating a market demand for more sustainable business and the regulatory sphere does not advocate for further steps into sustainability even though there are e.g., intragovernmental strategies launched such as the EU Green Deal or the Pharmaceutical Strategy for Europe. Thus, CDMOs are not highly incentivized to make shifts towards more sustainable business. Even if there have been controversial results in using sustainability as a business advantage (Cantele & Zardini 2018), and even if sustainability is not a threshold requirement for CDMOs at this moment, many investors are beginning to consider ESG factors in investment decisions. Even if customers are not creating a market demand for sustainability, investors are creating a market demand of their own.

To extend upon figure 3 in chapter 3 which addresses how the concept of sustainability is understood and the different impacts and levels of integration in business sustainability can create, barriers and motivational factors are introduced in figure 4. These barriers and motivational factors reflect in both theory and data gathered for this study.



How the concept of sustainability is understood	Impact and level of integration of sustainability in business	Barriers of integrating sustainability in CDMOs	Motivation of integrating sustainability in CDMOs
Sustainability as a means to create value	<ul style="list-style-type: none"> <li>• Value creation to shareholders and stakeholders</li> <li>• Aim to create a better world</li> <li>• Sustainability integrated in company strategy</li> </ul>	<ul style="list-style-type: none"> <li>• Clients do not value sustainability at this moment</li> <li>• Industry is seen to create a better world even without integrating sustainability</li> <li>• Company leaders do not value sustainability</li> </ul>	<ul style="list-style-type: none"> <li>• Higher employee engagement and motivation</li> <li>• Increase value for stakeholders</li> <li>• Responsibility of sustainable business</li> </ul>
Sustainability as a multidimensional concept	<ul style="list-style-type: none"> <li>• Safeguards business</li> <li>• Cost savings</li> <li>• Sustainability integrated in existing company structures</li> </ul>	<ul style="list-style-type: none"> <li>• Hard to integrate sustainability in existing processes</li> <li>• No market demand for sustainability</li> <li>• Regulatory field does not incentivize towards more sustainable business</li> </ul>	<ul style="list-style-type: none"> <li>• Understanding that in the future sustainability could be a threshold for business</li> <li>• Increase in brand value</li> </ul>
Sustainability as a means of communication for responsible business	<ul style="list-style-type: none"> <li>• Avoid bad PR and fines</li> <li>• Adherence to regulations</li> <li>• Sustainability is not included in company strategy</li> </ul>	<ul style="list-style-type: none"> <li>• Sustainability is not discussed in CDMO field</li> <li>• Lack of resources</li> <li>• Could hinder speed of market entry</li> <li>• Could lose credibility in field</li> </ul>	<ul style="list-style-type: none"> <li>• Safeguard adherence to regulations and patient safety</li> <li>• Avoid greenwashing</li> </ul>

Figure 4 Motivations and barriers to integrate sustainability in CDMO business

There are different types of barriers and motivational factors that can either hinder or aid in moving towards a more sustainable business. Specific to CDMOs, the main barriers towards more sustainable business are lack of resources, lack of discussion of sustainability in the industry, no market demand for sustainability and the understanding of the inherent value that pharmaceuticals create. In contrast, motivational factors include higher employee engagement, increase value for stakeholders, safeguard in adhering to regulations and the possibility of sustainability becoming a threshold in the CDMO business. Even as the multidimensionality and importance of sustainability is acknowledged, many CDMOs are not currently utilizing sustainability as a business advantage or a differentiating factor.

In addition to the inherent value of creating new lifesaving pharmaceuticals, many CDMOs are already in some way addressing sustainability. However, it is not yet communicated thoroughly to different stakeholders. The level of integration of sustainability in strategies can be seen to guide how well companies can benefit from sustainability. For CDMOs to make the steps towards more sustainable business and answer to the potentially growing role of sustainability in business, sustainability ought to be integrated in the strategy.

## 6 Conclusions

### 6.1 Theoretical contributions

The aim of this study was to gain a comprehensive understanding of sustainability and its role for CDMO companies operating in the pharmaceutical industry. To be able to achieve the aim of the thesis, three objectives were identified. The first objective was to examine how the concept of sustainability is understood in CDMOs in the context of the pharmaceutical industry. The interviews confirm the difficulty in defining sustainability as a concept and the multidimensionality of it. Many of the interviewees reflected upon the different dimensions of sustainability, environmental, social, and economic that are presented by the TBL by Elkington (1998, 73). Discussions related to sustainability have grown and especially in the personal lives of interviewees, they aim to contribute to a better world. Similarly, to what Elkington (1998, 20) recognized as an upcoming shift in financial markets, interviewees also recognized this shift. Business advantages related to sustainability were often related to financial cost savings and an increase in brand value which are valuable for financial institutes when evaluating their investments.

Even though sustainability as a multidimensional concept is not prevalent in communication in the CDMO field at this moment, the importance and multidimensionality of the concept are recognized. ESG audits have been starting to increase and interviewees expect that in the future, ESG matters will be taken into consideration in CDMO choice in an increasing rate. Furthermore, employees and stakeholders in younger generations have been advocating for sustainability-related matters in business (Alonso-Almeida & Llach 2019), which is prevalent in the interviews as well. Interviewees note that especially for attracting and retaining younger talent, addressing sustainability is important to create a better employer image. Due to this generational difference in values, it could be that a generational change is what is needed to create a more comprehensive outlook on sustainability in the industry, in comparison to being content in the idea that the drugs manufactured and developed themselves are enough. Overall, many of the businesses in the CDMO and pharmaceutical industry are in the stage of compliance (Willard 2012) or doing business-as-usual (Dyllick and Muff 2016). Thus, these companies are not able to utilize other possible advantages from sustainability relation actions other than economic savings.

The second objective was to examine how relationships between CDMOs and contractor pharmaceutical companies influence the sustainability of CDMOs. Markets have a big role in the way companies in this field take into consideration sustainability-related matters. If the clients of CDMOs do not require CDMOs to disclose their ESG actions or to integrate sustainability into the product from the start, it can be hard for a CDMO to find the motivation to bring up or disclose sustainability-related matters themselves in business situations, for the intrinsic value of sustainability. Here, CEOs and leaders in a CDMO are seen to be critical in paving the way toward more sustainable business practices and integrating it to daily work life. Additionally, big pharma companies are expected to pave the way and contribute on a political level to create incentives toward a more sustainable industry. If big pharma companies only comply to regulations and do not proactively look towards more sustainable business practices, they are not creating sustainable norms into the industry. It is necessary to find the balance between sustainability, profits, and creating new life-impacting drugs. Regulations can be used to guide pharma companies of various sizes towards more sustainable business practices and incentivize integrating sustainability in business further. Now pharmaceutical companies see the industry as already so regulated that they do not have the leeway to take further actions. Once the market demands more sustainable business practices, CDMOs have a clear need to alter their business models. If CDMOs have a reactive view on sustainability-related matters, they lose the opportunity to be a thought leader that could benefit them in the long run.

The third objective was to examine how sustainability-related actions taken by companies are influenced by their underlying motivations. Developing and manufacturing new drugs can be costly in resources and due to the nature of the industry, being first in a market is important due to patents. Businesses are not in the mindset to take into consideration sustainability as it is not seen as a means to gain market entry faster. The first step toward a more sustainable business would be the shift from only complying to minimum regulations to avoid fines to recognizing the possible economic savings that could be available from a more sustainable mode of business. It is important to note that due to the regulatory field, implementing sustainability would require work and patient safety and quality are aspects that relate to sustainability and that cannot be overlooked. However, as sustainability is multidimensional, the actions CDMOs are already implementing, could be communicated of, albeit some are done only due to regulations. When companies

communicate about sustainability, it is necessary to back them up with actions. One could consider whether one social media post relating to some aspect of sustainability is enough to bring awareness and credibility to a company or on the contrary, hinder credibility in regard to sustainability.

There have been attempts to create models for companies to integrate sustainability in their business. In the Business Model Canvas for Sustainability, several critical dimensions are evaluated from environmental, economic, and social aspects. (Cardeal et al. 2020) An issue regarding the integration of sustainability in a CDMO or their product is that they only focus on patient safety, the viability of the product, and speed of market entry. These are important attributes however, once a product is already created, integrating sustainability posthumously can be difficult. Here comes the dilemma of the pharmaceutical industry and its controversial nature. CDMOs are in the business of creating and manufacturing new drugs, which is the final stage in the sustainability journey for businesses, and aim to transform social sustainability issues, yet many of their actions are in the second stage of compliance. (Willard 2012, Dyllick & Muff 2016).

Short-sightedness is evident when discussing sustainability-related matters, as many interviewees point out that sustainability takes time in the short term, while they fully acknowledge that in the long run, it might be good to participate in sustainability. However, creating long-term value for stakeholders, including the society and environment, and shareholders is integral to the profitability and future of a company. Even though CDMOs are providing services to develop and manufacture new life-altering drugs, it is important to assess the possible implications that sustainability-related challenges create and how they could impact their business. Climate change could as an example hinder the reliability in supply chains for various resources. Here, long-term assessment of sustainability and taking it into consideration in business and product development model could reduce or mitigate possible risks.

## **6.2 Practical contributions**

In addition to the theoretical contributions this thesis provides, it provides practical contributions and recommendations for CDMOs. The theoretical background and empirical findings that came from interviews and benchmarking suggest that there are steps that CDMOs could take towards more sustainable business practices and that there are ways to gain business advantages from sustainability. Current business practices in

CDMOs and the pharmaceutical industry in comparison to the general rise in awareness and demands from stakeholders imply that even though the industry does contribute to a better world by new and better drugs might not be enough to be able to state that businesses are participating in sustainability in the future. It seems that the majority of businesses in the CDMO field are not utilizing sustainability as a business advantage at this moment. Businesses in the industry are often fulfilling the minimum requirements regarding sustainability by adhering to regulations without truly taking advantage of it by integrating sustainability in business. First mover advantages and thought leadership could still be well obtained.

The first recommendation for CDMOs would be to *communicate* about sustainability and the related actions it already does. What was reflected from the interviews was that even internally, CDMOs or their clients, do not discuss sustainability. If employees are not aware of sustainability-related actions or thought processes behind business decisions that might have taken sustainability into consideration, it is not possible to utilize to motivate or engage employees on a deeper level. For instance, interviewees were not aware of ESG audits that had been done but were intrigued by the results and wanted to hear more. Tracking e.g., water and electricity consumption and their reduction or shift to more environmentally friendly options and communicating about it was seen as an integral matter to discuss. Externally, if a CDMO does not disclose sustainability-related actions on their website or social media, their clients are not aware of the actions CDMOs do that relate to sustainability. Moreover, sustainability was seen as a mean to improve brand image, yet if it is not communicated about, it is difficult to use it to enhance brand image. Furthermore, when a CDMO communicates about their sustainability-related actions, it could impact their relationships with their client companies in a positive way and lead the way for the market to start taking into regard sustainability-related actions further.

The second recommendation would be to *integrate* sustainability in business. Even if sustainability would not be considered in other ways than tracking the status, it would be a first step to recognizing the situation and in the long run, it could be easier to move the business or product to a more sustainable place if sustainability has been considered and integrated from the beginning. Even if fast entry to markets is a priority, it could be a viable option to create the processes of development and manufacturing in a way that has sustainability integrated in them. CDMOs are participating in a better world by providing and creating new drugs, however, they do have the possibility to participate in other ways



as well. As seen from benchmarking companies, one company had a sustainability rating and disclose their participation in the multidimensionality of sustainability. All companies in some way mention sustainability-related actions even without mentioning the concept of sustainability. Thus, sustainability is some ways is present, however, there is a need to clarify the role of it and how it is integrated into business.

The third recommendation is to *have a more proactive outlook on sustainability*. It is evident that there are more and more regulations that aim to shift businesses towards more sustainable business practices and the public demands this as well. As the CDMO field is consolidating, and as investors are integrating ESG into their investment decisions, having a proactive view on sustainability could increase company value. The commissioning company clients brought forth that even if sustainability is not a threshold at this moment, it most likely will be in the future. Here, the businesses that have sustainability integrated in their business gain thought leadership and could win business due to this. By only reacting to new regulations CDMOs can only benefit from no bad PR and avoid fines, whereas they could be benefiting from multiple factors such as improving their brand image and value, increase the image as an employer, especially for younger talents and create an even more meaningful workplace.

### **6.3 Limitations and future research**

This study recognizes that CDMOs and the relationship with their clients in general or sustainability in CDMOs has not been researched significantly and thus it addresses a research gap. However, as with all research, there are certain limitations to this study. A key limitation to this study is that this offers in-depth insights from one commissioning company CDMO and three of its client companies. Even though this study did include interviewees from different business areas to see how different business areas view the studied topic, it could be prosperous to conduct this study with other CDMOs and their clients as well.

This study does provide a good starting point to analyze how the relationships between these companies impact sustainability and how for example different regulations could be implemented to shift the industry towards a more sustainable one. Especially in this industry, the regulatory field is respected and could be leveraged towards more sustainable business practices. Another research avenue could be how the EU pharmaceutical strategy impacts the CDMO business. The interviews revealed how the

size and maturity of companies could impact how sustainability is viewed. One possible research opportunity could be to analyze how the maturity and size of CDMOs, and its client companies impact the way sustainability is viewed in business.

The theory and empirical findings suggest that it is important to be able to back up the discussion of sustainability with concrete sustainability-related actions. Despite this, there is no ample research of a way to measure the needed amount of participation to gain credibility. In benchmarking companies, some had one or few social media posts regarding social sustainability whereas some discussed sustainability in a broader sense and discuss the concrete measures they take toward more sustainable business. It could be a possible research avenue to gain an understanding of what is the needed amount of participation in sustainability is needed for credibility and how company size, maturity and industry impacts the required amount of concrete participation. Furthermore, through interviews it was recognized that personal attitudes and culture towards sustainability impact how it is viewed in business. As this study only interviewed the commissioning company employees and clients, it could be a possibility to include in future research expert opinions and interviews to gain another point of view.

As the understanding of sustainability reflects the level of integration of sustainability in company strategy, it could be fruitful to examine on a deeper level how sustainability is brought forth in strategies. Due to the limitations of this study, strategies were not analyzed here. Furthermore, as CEOs and other leaders of companies are seen as vital parts in the sustainability of companies, it would be insightful to compare the understanding of sustainability of CEOs and the level of sustainability integration in the strategy of their companies. This study only analyzed the view of CDMO sustainability. During the study, it was noted that there is no current market demand for sustainability on CDMOs. To be able to shift the whole market to a more sustainable pathway, a similar study could be conducted for CDMO contractor companies to be able to understand where their incentives for sustainability actions come from, as they reflect on CDMO sustainability and whole value chains.

## 7 Summary

The aim of this thesis was to gain a comprehensive understanding of sustainability and its role for CDMO companies operating in the pharmaceutical industry. Due to the nature of the industry, the social aspect of sustainability is highlighted as the most important aspect of sustainability through patient safety, quality, and employee satisfaction. Even as the social aspect is highlighted, sustainability and its other aspects are somewhat taken into consideration in some CDMOs. There are individuals in the pharmaceutical industry that see that participating in sustainability is a business necessity and that there are no disadvantages in it. Currently, sustainability is not thoroughly utilized as a business advantage in the CDMO field.

Sustainability has evolved from the narrower concept of CSR to being a multidimensional concept without one single unified definition. The general assumption in the pharmaceutical industry is, that it is enough to create new and better pharmaceuticals as participation regarding sustainability and for a better world. The pharmaceutical industry that CDMOs work in, was not seen as the worst polluter, and as such, it is not seen as critical to participate in the sustainability journey as it is for other industries. However, this is not enough anymore. Consumers, investors, and other stakeholders are beginning to demand more sustainable business.

From the development and manufacturing process, until the consumption and disposal of drugs, the pharmaceutical industry engulfs and impacts different aspects of sustainability. Balancing the need for profits with patient safety and sustainable business practices are at this moment lacking for most pharmaceutical companies. Many CDMOs are facing limitations due to resources and thus, prioritize other factors in business. At this moment, they do not see it necessary to participate in the shift towards more sustainable business practices or see the value in participation even though it is expected to become a threshold and source of business advantage in the future.

An increase in costs, difficulties in implementation, and an increase in workload were declared as disadvantages in participating in sustainability-related actions. However, it was noted that even if sustainability would increase costs, it should still be done. The main advantages that came forth were an increase in brand image and value, an increase in employer image, and an increase in meaningfulness for employees. Furthermore, it was

noted that sustainable business practices could be viewed as though leadership, as many CDMOs do not bring forth sustainability, and in the future, it could be used as a means to bring in and win new business and increase value for investors. Especially for gaining and retaining younger talent, addressing sustainability was seen to be important. Even if a generational change would be needed to shift the attitudes in the whole industry, there are evident possibilities to gain business advantages from integrating sustainability in business now.

The main motive behind acting in a more sustainable way comes from the regulatory sphere. As the clients of CDMOs are not requiring their CDMOs to participate in more sustainable business, CDMOs are not incentivized to change their business models. As the focus for pharmaceutical companies is on quality and rapid market entry, sustainability-related matters are often overlooked in the industry. To create a deeper shift towards a more sustainable industry in general, more regulations and incentives towards a shift for increase in sustainable business practices ought to be created on a national governmental or supranational level to be able to make changes in the industry and throughout supply chains.

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# Appendices

## Appendix 1 Benchmarking table

	Companies				
ESG ACTIONS	Fujifilm diosynth	Celonic	Halix	Batavia Biosciences	Rentschler biopharma
<b>Environmental</b>	<p>Plants trees</p> <p>UK facility converted to a 100% renewable energy source for the electricity supply to its main site, replaced regular light bulbs with LED bulb</p> <p>Adopted a greenway and are committed to cleaning and maintaining its beauty</p> <p>A facility under construction is ensuring sustainability is incorporated in their construction project by design by considering use of landfill gas, renewable solar energy, and utilization of electrical boilers</p> <p>lunchtime litter picking</p>				<p>In facilities they reduce waste and employ the most energy-efficient appliances.</p> <p>Operate own combined heat and power plant (CHP) on premises in Laupheim. The CHP provides sustainable and environmentally friendly heat and steam for facilities, and as a result, can reduce CO2 emissions by approximately 2,500 tons annually.</p> <p>LinkedIn post on world groundwater day and how they have reduced chemical use</p> <p>Mission to empower clients to help patients with serious and rare diseases but also contribute to the health of the planet.</p> <p>Have experts that are dedicated to ensuring the sustainable and reliable supply of water, to meet growing demands.</p>
<b>Social</b>	<p>Focus on gender equality</p> <p>Raises awareness of and sponsored MassBio Rare Disease Dayrare diseases</p> <p>Focus on how to better address health inequity and racial disparities among the rare disease community</p> <p>A series sponsor for the Courageous Conversations for Triangle Diversity, Equity and Inclusivity Alliance</p> <p>donate construction-themed or STEM toys to Meg's Smile Foundation to encourage an early interest in science</p> <p>Aims to become a more inclusive employer and is committed to promoting and championing a culture of diversity, inclusion and equality.</p> <p>A site located in the United Kingdom has become a Disability Confident Committed Employer.</p> <p>Pride post in Facebook</p> <p>Highlights importance of employee safety</p> <p>women in STEM activation for children</p> <p>Modern Slavery Act Statement</p> <p>science portal for kids</p>	<p>Strong focus on employee satisfaction (a people development manager introduced) participating in womens day in social media</p> <p>uses strong company culture as a differentiator from competitors</p>	<p>Focus on employee wellbeing through employee package (incl. Work-life balance, competitive salary, social activities, contribution to pension, promoting health)</p>	<p>Highlighting World Polio Day on social me</p>	<p>parent-child program for employees</p> <p>support rare disease day and world cancer day, womens day, women in STEM day in social media</p> <p>offers yoga and fitness to employees</p> <p>Their colleagues hold lectures in pharmaceutical biotechnology at regional educational institutions who chose to donate their speaker fee to support families in need via social fund initiatives.</p>
<b>Governance</b>					

## Appendix 2 Interview questions

### Interview questions

#### Customers:

**SUSTAINABILITY/ESG** What is your perception on sustainability?

Whose responsibility is sustainability?

From a customer perspective, what aspect of sustainability is the most important one, when choosing a CDMO?

**CDMO RELATIONS** What are your main criteria when selecting a CDMO partner?

Are there any sustainability related requirements for CDMOs, if so, what are they?

Are there any wishes regarding sustainability to CDMO partners?

**BUSINESS ADVANTAGE** How do you see the importance of sustainability in the future: business necessity due to regulation or business advantage or something else?

Who is driving the implementation of environmental sustainability in biologics manufacturing? Pharma unions, EU policies, or other country policies? What is its current/potential impact in of these policies into your business?

What is your stance on sustainability and how do you see sustainability in the future?

What opportunities of disadvantages could become of sustainable business?

#### Commissioning company:

**SUSTAINABILITY/ESG** What is your perception of sustainability?

Whose responsibility is sustainability

What is the most important aspect of sustainability?

**CDMO RELATIONS** If a client was non-conforming to sustainability, and you had the chance to decide, would you still work with them and why?

Do you have any sustainability related requirements for your clients and if so, what are they?

Do you know what type of sustainability related activities your clients do?

In business situations, do you bring forth sustainability related matters in contracts, and if so how, and if not, why not?

**BUSINESS ADVANTAGE**

What is your motivation to doing better in regard to sustainability?

What opportunities could sustainability in business bring?

Are there any disadvantages in participating in sustainability?

Do you have a more reactive or proactive look on sustainability?