Master's thesis

NTNU
Norwegian University of Science and Technology
Faculty of Economics and Management
Dept. of Industrial Economics and Technology Management

Amelie Eder, Finja Nelemarie Stampa

A New Prescription for Change

Leveraging Startup Innovation for Sustainable Transformation in the Pharmaceutical Industry

Master's thesis in Entrepreneurship
Supervisor: Elli Verhulst
Co-supervisor: Sara Maryami
June 2024

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Preface

This master thesis is the final project of the double degree program shared between the Technical University of Berlin (MSc. Innovation Management, Entrepreneurship, and Sustainability) and NTNU (MSc. Entrepreneurship). The study is written for those studying the intersection between startups and sustainability, particularly in the pharmaceutical industry, as well as stakeholders of said industry.

We would like to thank our supervisors, Elli Verhulst and Sara Maryami, for their ongoing support and valuable guidance throughout this process. They always found time to discuss any questions or concerns of ours. This research project would not be the same without their invaluable contributions.

Trondheim, 17.06.2024

Finja Nelemarie Stampa Amelie Eder

Abstract

This thesis explores how startups can facilitate the adoption of sustainability practices within the pharmaceutical industry, a sector known for its substantial environmental impact. The research investigates the role of innovative startups in driving sustainable transformation against the background of the industry's high carbon emissions and extensive waste production. The study uses a mixed methods approach, combining surveys for quantitative data and case studies for qualitative insights, to investigate how startups can influence sustainability practices in a traditionally resource-intensive industry. The quantitative surveys help establish a basic understanding of the current sustainability practices and perceptions within the startups of the industry, while the qualitative case studies provide a deeper insight into the innovative strategies and challenges faced by startups attempting to implement sustainable solutions. The findings highlight the key role startups play in introducing new technologies and business models aimed at reducing environmental impacts. Despite the innovative nature of startups, the study identifies several barriers to sustainability, including regulatory hurdles, market resistance, and technological challenges. The thesis contributes to a better understanding of these dynamics and offers strategic recommendations for industry stakeholders. It also highlights the need for further research into effective collaboration between startups and long-established pharmaceutical companies to advance the adoption of sustainable practices across the industry.

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Abbreviations

AI	Artificial Intelligence
API	Active Pharmaceutical Ingredient
B2B	Business to Business
BMI	Business Model Innovation
CBM	Circular Business Model
CE	Circular Economy
CLSC	Closed-loop Supply Chain Network
CO_2	Carbon Dioxide
CSR	Corporate Sustainability Report
EOL	End of Life
EOU	End of Use
EQ	Environmental Quotient
ESG	Environment Social Governance
EU	European Union
GEB	Green Elephant Biotech
GHG	Greenhouse Gas
GMP	Good Manufacturing Practice
GRI	Global Reporting Initiative
GSCM	Green Supply Chain Management
IMES	Innovation Management, Entrepreneurship and Sustainability
IoT	Internet of Things
IP	Intellectual Property
LCA	Life Cycle Assessment
ML	Machine Learning

NTNU	Norwegian University of Science and Technology
OECD	Organisation for Economic Co-operation and Development
PLA	Polyamide
PM	Pharmaceutical Manufacturing
PMI	Process Mass Intensity
PPE	Personal Protective Equipment
PSCM	Pharmaceutical Supply Chain Management
PSCND	Pharmaceutical Supply Chain Network Design
R&D	Research & Development
RTI	Returnable Transport Item
SAM	Sustainable Assessment Model
SASB	Sustainability Accounting Standards Board
SBM	Sustainable Business Model
SDG	Sustainable Development Goal
SME	Small and Medium-sized Enterprises
SPSS	Statistical Package for Social Sciences
SSCM	Sustainable Supply Chain Management
TBL	Triple Bottom Line
UN	United Nations
US	United States
USP	Unique Selling Point
VC	Venture Capital
VUCA	Volatile, Uncertain, Complex, and Ambiguous
WMO	World Meteorological Organization

1. Introduction

"We are sleepwalking to climate catastrophe".

- António Guterres, leader of the United Nations (UN)

Since the 1960s, environmental impacts have emerged as a global concern and the conflict between economic development and environmental protection seems to become a major evaluation criterion of human activity (Matemilola & Alabi, 2021). Just in April 2023, the European Union (EU) proposed a new directive to promote sustainability, innovation, and competitiveness (A Pharmaceutical Strategy for Europe, 2023). In 2023, the World Meteorological Organization (WMO) reported that the last eight years were the warmest on record and that the sea level rise and ocean warming reached new record highs (United Nations, 2023). The UN also warned that biodiversity is about to collapse as one million species are on the verge of extinction. Additionally, the Antarctic Sea ice fell in 2022 to the lowest ever measured level and the melting of some European glaciers was beyond measurable limits.

"In our globally connected world, no country and no corporation, can insulate itself from these levels of chaos."

- António Guterres, leader of the United Nations (UN)

The socio-economic impacts are huge. East Africa experienced five consecutive years of drought leading to devastating food insecurity for 20 million people (United Nations, 2023). The human-caused climate change triggers dangerous and extensive disruption in nature, leading to an urgent need for all economic sectors to become more environmentally friendly (United Nations, 2023). Many sectors have acted towards a sustainability transformation, like the food sector, or the automotive industry (Fritsch, 2022). While attempts are already being made in many fields to reduce the human impact on the environment, one industry has so far received remarkably little attention: the pharmaceutical industry (Belkhir & Elmeligi, 2019).

The pharmaceutical industry plays a crucial role in the well-being of people around the world with the creation, production, marketing, and distribution of medications and treatments (Peña et al., 2021). The sector is essential in treating illnesses, extending life and delivering medical products that have a direct impact on people's health. For instance, around 73% of the rise in life expectancy from 2000-2009 is attributable to developments in pharmaceutical products

(Bruke, 2020). As a result, it is vital to ensure that medical products are available and affordable (Silva et al., 2023; Saxena et al., 2021).

However, while the pharmaceutical industry plays an important role in global health, it presents significant environmental challenges. The production of pharmaceutical products consumes huge amounts of energy, water, resources and reliance on dangerous materials, contributing to extremely large environmental deterioration (Desai et al., 2022). The United States (US) alone generates approximately 5–6 million tons of healthcare waste each year, often disposed of through incineration, landfilling, and chemical and thermal disinfection (Desai et al., 2022). In 2015, the pharmaceutical sector emitted around 52 million metric tons of CO_2 and is responsible for 4% of the global CO_2 emissions, showing an intensity 55% higher than the automotive sector (Belkhir & Elmeligi, 2019; Lorenzini et al., 2018; Waghmode et al., 2022). In 2016, 16 active medical substances were detected in surface, ground and drinking water in all regions of the world, highlighting the severe consequences of pharmaceutical residues on water quality and human health due to improper disposal (Baltruks et al., 2023).

A possible reason why the pharmaceutical industry is lagging in its sustainability efforts is that sustainability is less relevant in intra-sectoral competition than in other sectors as the end customer attaches more importance to the effectiveness of medical products than their environmental footprint (Bade et al., 2023). Nevertheless, the industry's environmental impact highlights its relevance in a broader perspective and the urgent need for a sustainability transformation through innovative and sustainable solutions to mitigate its environmental impacts (Baltruks et al., 2023; Kaylor, 2023).

In the literature, there is extensive coverage of papers addressing sustainability initiatives in the pharmaceutical sector, as the authors discovered in their literature review for their project thesis at the Norwegian University of Science and Technology (NTNU) in the subject Project Specialization (TIØ4530) in autumn 2023. Although, this research field is still very immature with most articles in the “Scopus.com” and “WebofScience.com” databases having a publication date after 2017 (Eder & Stampa, 2023). The novelty of this research area presents a lack of established frameworks and a comprehensive understanding of sustainable practices. Additionally, Eder and Stampa’s review showed significant geographical discrepancies in the research, with a notable lack of contributions from Europe and other Western countries. While the articles they found mainly talked about drivers for sustainability activities, supply chain management, technological development and business models, the concrete implementation of

how the industry can develop the necessary innovative solutions has not been described in detail. Furthermore, Belkhir & Elmeligi (2019) highlight that there is no literature on the effective implementation of innovative practices in the pharmaceutical industry. This exposes an enormous research gap in the research field of sustainability transformation in the pharmaceutical industry. Due to the topic's underrepresentation in literature, this study acts as an exploration of the topic and aims to be a guide to further, more detailed studies.

The authors' motivation to further investigate this research gap stems from personal interests in sustainability-related topics, their academic background and their professional experience. During the master studies at the Technical University Berlin in the field "Innovation Management, Entrepreneurship and Sustainability" (IMES), they were able to deepen their knowledge about sustainability and innovation. In the double degree program at NTNU's School of Entrepreneurship, their interest in the innovation and influence potential of startups was further awakened. As the authors study entrepreneurship and have a strong connection to startups in their business life, it seemed apparent to investigate startups as enablers for innovative solutions for the pharmaceutical industry. After all, the founder and head of the IMES study programme Prof. Dr. Jan Kratzer at Technical University Berlin has already established that startups can drive innovation and agility (Kratzer, 2020). He describes that startups offer new technologies and approaches that established companies might struggle to implement quickly due to their size and complexity, which could be used as a catalyst for the transformation of an industry towards greater sustainability.

The pivotal role of startups in the pharmaceutical industry became evident during the COVID-19 pandemic, particularly illustrated by the collaboration between the small biotechnology firm BioNTech and the pharmaceutical giant Pfizer. BioNTech, leveraging its expertise in mRNA technology, developed one of the first effective COVID-19 vaccines. However, it was the partnership with Pfizer that enabled the rapid scaling and global distribution of the vaccine. Pfizer provided the necessary resources, infrastructure, and logistical capabilities to produce and distribute millions of vaccine doses efficiently (Kate, n.d.; Savage, 2021). This collaboration highlights how innovative startups can drive breakthrough developments in drug discovery, while established pharmaceutical companies can facilitate large-scale production and distribution, significantly impacting public health outcomes during global crises (Kate, n.d.; Savage, 2021). Nevertheless, while the need for startups and small biotech companies in the industry is undisputed, there is no paper in the literature on how these startup-specific

capabilities can be utilised in the sustainability transformation of the pharmaceutical industry (Eder & Stampa, 2023).

Thus, to address this gap, the research question of this thesis is as follows: *How can startups enable the pharmaceutical industry to transform towards sustainability?* To consolidate and focalize the main research question, the impact a startup can have on the pharmaceutical industry is divided into direct and indirect impacts. A mixed methods approach is applied and the direct impacts are addressed using a quantitative survey among all pharmaceutical startups in the EU to answer the first sub-question: *What key strategies do startups in the European Union pharmaceutical industry utilize to facilitate the transition towards sustainability?* The indirect impacts are addressed using a multi-case study of five startups that have a sustainable solution as their core product to answer a second sub-question, namely: *How does a startup successfully address sustainability challenges of the pharmaceutical industry and* how *can it influence the whole industry?* The thesis follows a convergent design that enhances the validity and reliability of the results through triangulation, combining quantitative survey data and qualitative multiple case studies. The data was collected and analysed separately, using descriptive statistics and thematic analysis, then merged for comparison and interpretation, providing a thorough exploration of the research questions.

When speaking about sustainability, it is referred to the Brundtland Report which describes sustainability as meeting "the needs of the present without compromising the ability of future generations to meet their own needs" (General World Commission on Environment and Development, 1987). John Elkington specified in 1998 the dimensions of sustainability, namely economic prosperity, environmental quality, and social justice. Certainly, to stay within the scope and limits of a master thesis, the authors focus solely on the environmental dimension of sustainability in this study.

For the definition of startups, it is referred to Skawińska and Zalewski (2020) who define startups as an innovative micro venture that can be in a phase between the early seed phases and market maturity. However, since the definition of a startup is non-standardized, a number-based rule was added, to draw clear research boundaries for thematic delimitation. This rule, created by Alex Wilhelm in 2014, says that a startup has to meet the following three criteria: 1. Revenue is below US$ 50 million; 2. Less than 100 people employed; 3. Company worth is below US$ 500 million (Wilhelm, 2014).

What makes the pharmaceutical industry special, justifying a distinguished examination, are its unique characteristics such as high intensity of research and development (R&D), complex regulatory and ethical environments, significant environmental impact, intricate product lifecycle, and multifaceted supply chain (Ang et al., 2021; Chomać-Pierzecka, 2023; Harada et al., 2021; Janatyan et al., 2018; Paulick et al., 2022; Saxena et al., 2021).

The scope of this study is limited to the EU due to its important role in the pharmaceutical industry. The sector directly employs hundreds of thousands of people and invests approximately €44.500 million in R&D annually (EFPIA, 2023; Statista, 2023). The presence of a unified regulatory body in Europe, which includes environmental considerations in its regulations, provides a unique perspective for researching the integration of sustainability in pharmaceutical practices (European Commission, 2023). Additionally, the increasing competition from countries like Korea and China highlights the importance of focusing on Europe to understand its strategic responses within a highly competitive global market (EFPIA, 2023). This context makes the EU a suitable scope for the authors' intended research.

The aim of this research is to understand which role and potential startups have in the sustainability transformation of the pharmaceutical industry to reduce its environmental impacts by investigating which sustainability approaches are used to reduce the direct impact of a startup and how a startup has an indirect impact of the whole industry though its product, network and other market activities. The goal is to contribute to the existing literature about possible opportunities of making a rigid and sluggish industry like the pharmaceutical one more environmentally friendly and inspire further research in this area.

The results of this thesis can contribute to both academic knowledge and practical solutions, promoting a future where healthcare innovation and environmental responsibility go hand in hand. They are relevant to companies of all sizes in the pharmaceutical industry or industries with similar characteristics, policy makers and other market participants. Possible implications include the adaptation of political decision-making processes, steering investment decisions by investors and companies and potentially also influencing consumer demand. Above all, however, this work shows that there is a better way of manufacturing, distributing and disposing of pharmaceutical products, the responsible ones just must take it.

Finally, the thesis is structured as follows: After the introduction, the theoretical background provides background information for the research question including a review of the existing literature and the main theoretical insights and concepts that will lead through the subsequent

chapters. This is followed by the methodology section, which details the mixed-methods research approach used for data collection and analysis. The results chapter then presents findings from both the quantitative surveys and qualitative case studies. Subsequently, the discussion integrates these findings in the context of existing literature and considers any policy and research implications. The thesis concludes with a summary of the main findings and future recommendations, noting any study limitations.

2. Theoretical Background

This chapter of the thesis provides a comprehensive review of the existing literature across three interconnected areas: sustainability, the pharmaceutical industry, and startups. The aim is to establish a basis for understanding the interconnectedness between those three dimensions, to then dive further into the research.

2.1 Sustainability

Research into sustainability and its associated sub-topics has grown so significantly over the last 20 years that the literature has now opened a separate section for this type of research, namely 'sustainability science' (Purvis et al., 2018). Based on the United Nations Report of the World Commission on Environment and Development in the year 1987, commonly known as "Brundtland Report", sustainability can be defined as meeting "the needs of the present without compromising the ability of future generations to meet their own needs" (General World Commission on Environment and Development, 1987). To specify the dimensions of sustainability, John Elkington introduced in 1998 the term "triple bottom line" (TBL) which includes economic prosperity, environmental quality, and social justice in the sustainability agenda, placing the term sustainability as the intersection of these three factors (Elkington, 1998).

2.1.1 Introduction to Sustainability Transitions

Unsustainable consumption and production patterns cause environmental problems such as climate change, loss of biodiversity and resource depletion and with that, huge societal challenges (Elkington, 1998). These challenges require radical shifts to new kinds of socio-technical systems including a "fundamental re-orientation of societal development, which involves a wide set of changes and interlinked transformations in markets, state, society, science and technology." (Gottinger et al., 2020, p.4). In the context of sustainable development, those shifts are called 'sustainability transitions' (Gottinger et al., 2020; Köhler et al., 2019)

Since 2009, there has been a significant increase in research on sustainability transitions, with more diverse topics and geographical applications, a deeper exploration of theories and methods, scope expansion and the strengthening of connections to established disciplines (Köhler et al., 2019). The main objective of this research field is to conceptualize and explain the occurrence of radical changes in how societal functions are fulfilled. Thus, sustainability transitions are placed primarily at the meso level of socio-technical systems. With that, sustainability transition research differs from long-standing sustainability debates at the macro-

level (e.g. changing the nature of capitalism) or the micro-level (e.g. changing individual choices and motivations). To analyse sustainability transitions, research in the past has developed theoretical frameworks originated from innovation studies (Gottinger et al., 2020). While innovation research helps understand the emergence of sustainable practices, sustainability transition frameworks extend beyond technological knowledge to include transformation knowledge into the entire production and consumption systems.

2.1.2 Sustainability Transition Characteristics

Sustainability transitions have various characteristics that differentiate them in sustainability discussions and the broader field of social sciences. Köhler et al. (2019) summarized them as follows:

- **Multi-dimensionality and co-evolution**: Transitions are not a linear process but involve interconnected developments and the simultaneous evolution of multiple elements, including technologies, markets, policies, infrastructures, supply and distribution chains, user practices and cultural interpretations.
- **Multi-actor process**: Transitions are driven by several actors and groups from academia, politics, industry and civil society, each of them having different capabilities, strategies, interests, and resources.
- **Stability and change relationship**: Despite many green innovations (e.g. electric vehicles), their deeply rooted "dirty" alternatives (e.g. petrol cars) created locked-in production and consumption patterns that result in path-dependent trajectories. Understanding those complex interactions within a system and the impact of radical changes on overall stability is crucial.
- **Long-term process**: Transitions can take decades to unfold. Radical ‘green’ innovations need time to develop from small application niches to widespread usage and the destabilization of existing systems including the overcoming of incumbents' resistance.
- **Open-endedness and uncertainty**: During a transformation process there are multiple innovations and initiatives for change but without guarantee of success. That creates multiple transition pathways and a general uncertainty about the future.
- **Values, contestation, and disagreement**: Sustainability is a controversial topic with differing opinions on how to achieve it. Major industries like oil, automotive, and electric utilities are resistant to sustainability transitions due to potential economic consequences.

- **Normative directionality**: Public institutions must take the lead in addressing sustainability issues due to the lack of motivation for private individuals and businesses. This can be done through regulations, standards, taxes, subsidies, and innovation policies.

2.1.3 Transition Barriers

Gottinger et al. (2020) have identified and categorized barriers to an industry's transformation towards sustainability. They can be summarized into six primary categories of barriers. Firstly, policies and regulations emerge as a significant hurdle, encompassing issues related to the inappropriateness or absence of policies or regulations, and challenges in implementing them. Secondly, technology and materials point to technical challenges in technology application, product development, input materials availability, supplier structures, and physical infrastructure insufficiencies. Thirdly, the market and investment conditions barriers were mentioned, associated with market demand, market creation, and the challenges in mobilizing and accessing financial resources. The fourth barrier is social acceptance. It highlights the critical role of public awareness, interest, engagement, and the potential for public opposition, indicating the importance of societal support for a successful transition. Knowledge and networks form the fifth challenge and include challenges in knowledge creation and application, as well as the development and existence of efficient networks essential for facilitating the transition. The last barrier category is sectoral routines and structures, pointing at the resistance from incumbents, lock-ins developed over time, and challenges associated with dominant standards, which all play a pivotal role in shaping the transition setting.

2.1.4 Direct and Indirect Environmental Impacts

The impacts of a company on the environment are twofold and can be either direct or indirect (Matemilola & Alabi, 2021). A direct environmental impact describes a direct interaction between a specific human activity and an environmental component that establishes a cause-and-effect relationship, making detection and prediction relatively straightforward. As an example, the loss of biodiversity resulting from local deforestation activities has direct effects on specific environmental components, leading to observable changes or consequences. Indirect environmental impacts, also known as secondary or chain impacts, are less apparent and more challenging to anticipate compared to direct impacts. These impacts arise when an action causes a secondary or chain reaction, leading to consequences that are not immediately visible but emerge over time through networks of interactions or complex impact pathways. Unlike direct impacts, indirect impacts can become visible in a very different place then its

initial cause source or after a long period of time after the action that caused the impact happened.

2.2 The Pharmaceutical Industry

The pharmaceutical industry is a major component of global health, contributing significantly to the well-being of people worldwide (Peña et al., 2021). This sector is essential to treating illnesses and extending life because of its extensive participation in the creation, production, marketing, and distribution of medications and treatments. Next to that, the pharma industry is an important asset within the European economy. The leading pharmaceutical markets in Europe are Germany, France, and Italy, with revenues of 52, 40.9, and 35.4 billion euros, respectively (Statista, 2023). However, Europe is now facing an increase in competitors from emerging markets like Korea or China that are experiencing a rapid expansion in the market and their pharmaceutical research (EFPIA, 2023). Additionally, entry prices for new drugs have increased in some therapeutic categories without real health benefits, and they might not be available to all patients due to their costs (OECD, n.d.). Yet, the consumption of pharmaceutical products is still increasing, caused by ageing-related needs, a shift in clinical practices, as well as global population growth. Overall, the pharmaceutical market operates at an annual growth rate of about 6% which leads to a rise in the strain on the environment (Peña et al., 2021).

2.2.1 Specific Characteristics of this Industry

The environmental footprint of pharmaceutical manufacturing is substantial, with the industry being a major contributor to global greenhouse gas emissions, surpassing even the automotive sector in its environmental impact and the disposal of pharmaceutical wastewater without adequate treatment intensifies environmental concerns (Belkhir & Elmeligi, 2019; Lorenzini et al., 2018). The pharmaceutical industry operates within a highly complex business environment, characterized by multiple decision-makers, intense competition, and challenges in effectively communicating value to all stakeholders (Pérez la Rotta & Campos Herrera, 2011). In addition to market forces, companies must also navigate non-market and regulatory issues (Pérez la Rotta & Campos Herrera, 2011). When investigating sustainability transformation, the pharmaceutical industry needs special attention for several reasons.

First, R&D within the pharmaceutical sector is characterized by high costs, lengthy timelines, and considerable risks, distinguishing it from other industries (Harada et al., 2021; Paulick et al., 2022). The detection of new drugs is capital-intensive, with the average development cost running into billions and the probability of market success being slim (Paulick et al., 2022).

This intense focus on R&D, while essential for medical advancements, often makes sustainability a secondary priority, despite its growing importance in the evaluation of innovation processes (Bade et al., 2023).

Second, the regulatory environment for pharmaceuticals is complex and rigorous, designed to ensure drug safety, efficacy, and quality (Saxena et al., 2021). In the pharma industry, many regulations need to be considered during every step of a drug's journey, from initial assessment to ongoing monitoring after it is on the market (Olson, 2014). The European Union has recently introduced measures to integrate environmental concerns into these regulations, highlighting a heightened awareness of the industry's influence on sustainability (European Commission, 2023).

Third, the pharmaceutical industry needs to reflect ethical considerations and has a certain responsibility to focus its innovation on improving existing drugs or developing new products that support health in society (Saxena et al., 2021). It directly impacts human health, highlighting the importance of this sector which is in line with the United Nations' Sustainable Development Goals (SDGs) promoting sustainability, prosperity, and peace for people and the environment. Therefore, the pharmaceutical industry's efforts directly contribute to achieving SDG 3, “Good Health and Well-being” (General Assembly, 2015). Furthermore, access to medicines and pricing policies are unique to this sector (Paulick et al., 2022). The industrial countries are responsible for supporting low- and middle-income countries with affordable, safe, and effective treatments. In addition, global challenges such as pandemics and the democratic distribution of treatments exert pressure on the pharmaceutical industry. Between these disruptive factors, it is challenging for pharmaceutical companies to follow the push towards sustainable development.

Fourth, product lifecycle management in the pharmaceutical industry is much more complicated than in other industries, from drug discovery to patent expiry and the transition to generic drugs (Ang et al., 2021). The industry's efforts to manage this lifecycle sustainably are hindered by high intellectual property risks, regulatory constraints, and the complexities of implementing sustainable manufacturing practices.

Finally, the pharmaceutical supply chain is particularly complex because it involves various stakeholders, from raw material providers to the final consumers (Janatyan et al., 2018). It includes diverse elements, including market warehouses, distribution centres, wholesalers, retailers, and hospitals, making it a multifaceted network (Janatyan et al., 2018). Figure 1 shows

a visualization of the full pharmaceutical supply chain. Effective management of this supply chain is essential for promoting market growth and driving innovation in healthcare (Ahmad et al., 2022). Sustaining this chain efficiently is particularly challenging during crises when there is a need for rapid expansion in production capabilities (Yu et al., 2020). The COVID-19 pandemic has emphasized the vital role of the pharmaceutical industry in global health and its susceptibility to interruptions, thus highlighting the importance of resilient and sustainable supply chain practices (Kayani et al., 2023a). Decision-makers and managers understand the importance of creating a sustainable Pharmaceutical Supply Chain Management (PSCM) network that supports the development of crucial policies and strategies to integrate sustainable practices across the organization (Ahmad et al., 2022).

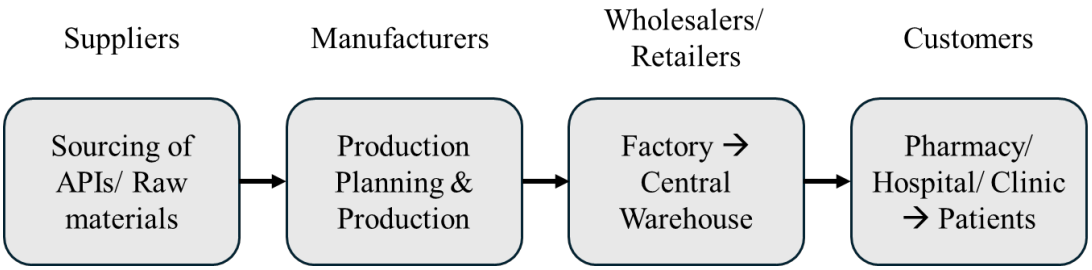

Figure 1: Pharmaceutical Supply Chain[1]

2.2.2 Sustainability Challenges in the Pharma Industry

To understand how the transformation of an industry can be empowered, is it crucial to understand the challenges hindering it from implementing sustainability (Köhler et al., 2019). During the systematic literature review conducted by the authors for the course Specialization Subject (TIØ4530) at NTNU's School of Entrepreneurship in the autumn of 2023, they were able to gain a comprehensive insight into the sustainability challenges of the pharmaceutical industry. Figure 2 shows an overview of all the challenges found during the process that resulted from an extensive and detailed literature analysis. The methodological approach can be found in the document itself (Eder & Stampa, 2023). The analysis resulted in a list of challenges related to environmental sustainability in the pharmaceutical industry, which built parts of the foundation for this study's design.

[1] (Adapted from Haque & Islam, 2018, p.2)

1. General waste
Producing a large amount of general waste, that does not pose any additional harm to human health or the environment.

2. Medical & Hazardous waste
Causing waste that may be contaminated, is very expensive to dispose properly and falsely disposed in household waste.

3. Lack of awareness
Existence of a gap in public understanding regarding the causes & significance of pharma emissions and environmental impact of pharmaceutical residues.

4. Outsourcing
Relocating production to countries with lax regulation & corruption pose s ecological risks and loss of control over production process & waste management.

5. Environmental Pollution
Using substantial amounts of energy, water, & resources, and being the second -largest source of greenhouse gas emissions in the healthcare sector.

6. Existing regulations
Following strict hygiene regulations hampers the compliancy of environmental regulations, leading to a deprioritisation of green solutions.

7. Rushed manufacturing
Relying on patents pushes a fast development of new follow -up products as generic companies replicate cheaper versions, which limits the time for green innovations.

8. Reporting
Existing discrepancies among reporting content and limited standardization hinders accurate assessment and target -setting.

9. Supply Chain Complexity
Managing long supply chains across many countries and suppliers makes it difficult to measure the whole environmental footprint of a product.

10. R&D intensity
Creating new products needs time, causes a lot of costs and is connected to high risks while its effectiveness is the decisive factor for success, not environmental factors.

Figure 2: Sustainability Challenges in the Pharma Industry[2]

The following sections will explore in detail the ten different challenges within the pharmaceutical industry, highlighting their complexities and impacts across various dimensions of sustainability.

General waste. Approximately 80% of pharmaceutical waste is considered general waste and does not pose any additional harm to human health or the environment (Kane et al., 2018). However, its impact is huge. Already in 1994, the first report about waste from the pharmaceutical industry stated that the pharmaceutical industry generates the most waste per unit of product compared to other chemical industry sectors (Veleva et al., 2018). To be more specific, producing one kilogram of active pharmaceutical ingredient (API) resulted in 25 kg and 100 kg of waste, meaning that up to 99% of used material was turned into waste. Yet, the

[2] (Own illustration, based on the literature review conducted by the authors 2023)

production process in the pharmaceutical industry is only one waste generator in the pharmaceutical industry.

Companies and hospitals are increasingly using single-use products to ensure clean and safe products for patients but also because it creates a stable revenue stream for the producing companies. While some disposable products can be sterilized and reused, the design and cost of recovery make some items remain disposable. Many products that are labelled as single-use products could be reused after sterilization because the manufacturer can decide how to label its products but the possibility for re-usage is lowered as the products can get damaged during repeated mechanical or chemical sterilization. Thus, it is estimated that the cost of purchasing new equipment has increased by more than 5 % annually over the last 20 years. (Klein, 2005)

Medical & Hazardous waste. There is no globally standardized definition of medical waste, creating difficulty when trying to compare different countries or regions within countries and resulting in a lack of standardization in handling medical waste (Windfeld & Brooks, 2015). To create consistency and clarity, in this thesis, the definition of medical waste refers to the United States Environmental Protection Agency defining medical waste as "a subset of wastes generated at health care facilities, such as hospitals, physicians' offices, dental practices, blood banks […]. Generally, medical waste is healthcare waste that may be contaminated by blood, body fluids or other potentially infectious materials […]" (US EPA, 2023).

The issue of medical waste disposal is significant. The improved access to medical services in the developing world and the shift from reusable medical devices to safer, single-use ones spurs the sharp increase in medical waste production and thus the cost of its disposal for the pharmaceutical industry. This has led to illegal shipping and dumping of pharma waste to save costs with excruciating for the environment, highlighting a huge incentive to treat medical waste safely and properly. (Windfeld & Brooks, 2015)

Another big challenge is the amount of medical waste that is disposed of in the household waste. A study in the US discovered that around 90 % of households dispose of their leftover medicines in the regular trash bin or water stream causing an additional 50,000 tons of waste annually (Ding, 2018; Kane et al., 2018). The main reason is that medical products need to be sorted and disposed of in special containers, which can be time consuming and lowers the willingness of consumers for proper disposal (Ding, 2018). In addition, many medical products are temperature sensitive. Failure of a continuous cooling chain during the transport of medicine means that the entire contents of the transport must be discarded.

Due to the potential negative environmental impacts and penalties for supplier companies in case of mishandling, it is the responsibility of the pharmaceutical supplier to collect and dispose of outdated medications appropriately (Tat & Heydari, 2021a). To reduce overall product returns, it is crucial to implement risk-sharing mechanisms and improve information feedback within the distribution network to facilitate product take-back initiatives for relocation purposes. In the pharmaceutical industry, it is important to capitalize on the risk-sharing nature of the industry. A proactive approach to redistributing slow-moving or non-moving drugs to alternative markets at reduced prices can have a dual benefit (Narayana et al., 2019). It not only reduces environmental and disposal costs but also makes affordable drugs available to underserved segments of society.

20% of medical waste is classified as hazardous materials, so waste that is infectious, toxic, or radioactive (Windfeld & Brooks, 2015). Examples of hazardous waste include items such as sharp objects, infectious waste, body parts or radioactive materials (Georgescu, 2011). It is estimated that up to 25% of medical waste is made of plastics that can be recycled but due to inadequate waste sorting processes 70-80% of hazardous waste is mixed with non-hazardous waste, contaminating the whole bunch of waste (Kane et al., 2018; Windfeld & Brooks, 2015). Strict policies for the disposal of potentially contaminated medical waste make incineration, where the waste is burned at high temperatures, the most common method of handling dangerous waste in developed countries (Windfeld and Brooks, 2015). These burning processes release harmful toxins and are responsible for a large amount of man-made mercury emissions. E.g. in North America, the incineration of waste is responsible for around 13% of man-made mercury emissions.

Lack of Awareness. There is a critical gap in public awareness and regulatory oversight concerning the environmental impact of pharmaceutical waste. Significant health and ecosystem hazards are associated with the disposal of substances which are oftentimes neglected (Mathew and Unnikrishnan, 2012). Due to the lack of regulations, workers within the healthcare system oftentimes come up with their waste waste-sorting systems (Windfeld and Brooks, 2015). Even manufacturers in pharmaceutical companies lack the awareness and expertise to implement greener processes into production (Veleva et al., 2018). Furthermore, there is a lack of understanding regarding the root causes and significance of different sources of pharmaceutical emissions, leading to a need for public education on the various sources and impacts of pharmaceutical residues (Alajärvi et al., 2021). However, informed consumer

choices for environmentally responsible products become difficult due to the confidentiality regarding the production of pharmaceutical products (Bengtsson-Palme et al, 2018).

Outsourcing. The pressure of lowering production costs and economic advantages for pharmaceutical manufacturers associated with outsourcing has caused the relocation of pharmaceutical manufacturing to Asian companies with potential environmental risks in regions with lax regulations or corruption, to India in particular (Bengtsson-Palme et al., 2018; Mathew & Unnikrishnan, 2012). Today, India produces 40% of the world's pharmaceutical products and 90% of its domestic pharmaceuticals. This shift leads to a loss of control both over the manufacturing process and waste management of the pharmaceutical waste. As giving this control to regions with lax regulations or corruption can cause health and environmental crises, Sweden's Medical Products Agency stresses the significance of monitoring and reviewing manufacturing processes in developing countries and minimizing outsourcing (Bengtsson-Palme et al., 2018).

Environmental Pollution. The production and manufacturing of pharmaceutical products consume substantial amounts of energy, water, and resources, and are the second-largest source of greenhouse gas emissions in the healthcare sector (Lorenzini et al., 2018). A relatively large carbon footprint can be attributed to a very high energy requirement (Ritchie, 2020). An analysis by (Kayani et al., 2023a) reveals varying environmental impacts across transportation modes in the pharma industry, with sea transport showing the least impact (8.2%), while rail transportation exhibits the highest environmental impact (62.5%), followed by road transport (29.5%). Inland transportation predominantly relies on rail as the preferred mode, especially among suppliers situated in geographically contiguous nations. This preference for rail transportation underlines its significance in pharmaceutical supply chains, despite its relatively higher environmental impact, highlighting the trade-off between environmental concerns and logistical preferences that is oftentimes prominent in this industry (Kayani et al., 2023a).

Apart from greenhouse gas emissions, pharmaceutical residues, particularly in water, also have a significant influence on both the environment and human health. Human medicines often find their way into the environment due to excretion and inappropriate disposal (Baltruks et al., 2023). Roughly half of all wastewater that is used in the pharmaceutical production process is discarded without any specific treatment (Gadipelly et al., 2014). Human and veterinary drugs end up in the environment, causing negative effects, for example, on the development of antibiotic-resistant microbes, as well as increased toxicity of chemicals. The drug’s microbes

have the potential to kill beneficial microbes that can be found within compostable organic waste (Mathew & Unnikrishnan, 2012). Currently, there is no existing system or machine that can filter out pharmaceutical residues from wastewater (Gadipelly et al., 2014).

Existing Regulations. The pharmaceutical industry must follow strict hygiene regulations and has a certain responsibility to focus its innovation on improving existing drugs or developing new products that support health in society (Saxena et al., 2021). This is achieved through various activities that occur throughout a drug's lifespan, including premarket screening and evaluation, manufacturing facility inspections, regulation of labelling and promotion, and post-marketing surveillance (Olson, 2014). These regulations, including clinical trials, manufacturing standards, and post-marketing surveillance, are more comprehensive compared to other sectors.

Furthermore, the issue of increasing environmental impact from the pharmaceutical industry has been taken into consideration by the European Union. Just in April of 2023, the EU Commission adopted a proposal for a new directive in the pharmaceutical sector (European Commission, 2023). It is meant to support competitiveness, innovation, and sustainability, amongst other important factors. As a key motivator for companies to push toward more sustainability, regulations can help pharmaceutical companies face systemic challenges, such as the cost pressures on hospitals, scarcity of sustainable alternatives in supplies dominated by near-monopolies, and regulations contributing to stock mismanagement and consequent waste, require attention from regulatory bodies (Bade et al., 2023). However, pharmaceutical companies struggle with the compliance of current rules and regulations leading to inconsistent reports that hinder accurate comparisons between companies (Veleva et al., 2018).

Rushed manufacturing. The product lifecycle management of pharmaceuticals is unique, from drug discovery to patent expiry and the transition to generic drugs (Kopach, 2018). Managing this lifecycle sustainably involves considerations like extending the life of drugs through new formulations which involves a great effort and initiates a complex transformation process (Ang et al., 2021). The lack of industrial-scale simulation and cost analysis studies, which are crucial for upscaling sustainable pharmaceutical manufacturing, create producibility risks of pharmaceuticals from a company’s perspective. Those risks include high intellectual property (IP) risks related to the implementation of alternative chemistry and processes, market risk associated with strict regulations and forces companies to approve any changes in chemistry, making the product lifecycle management inflexible and complex.

Furthermore, pharmaceutical companies follow a one-patent, one-product approach (Olk and West, 2019). This means that when one patent expires, it needs to immediately be replaced with a follow-up "blockbuster" product because generic pharmaceutical companies will step in to produce significantly cheaper versions of the same product. This creates rushed production and manufacturing processes to stay competitive, leading to a higher burden on the environment (Kopach, 2018).

Reporting. The variety of what and how pharmaceutical companies report, is huge with discrepancies in disclosure content, limited standardization and no regulatory oversight in sustainability reporting (Demir & Min, 2019). This leads to a lack of consensus among industry peers on material topics, accurate assessment of the environmental impact of a company and the inability to follow a strategic target-setting plan (Demir & Min, 2019. Following the logic of "If you can´t measure it, you can´t improve it", which is often cited as a statement from Peter Drucker, it is difficult for companies to make data-driven decisions to manage or improve their environmental impact if they can't measure them (Lavinsky, n.d.).

Belkhir & Elmeligi (2019) analysed CO2 emission reporting of pharmaceutical companies in the time span of 2012 to 2015. Their results show that out of over 200 observed pharmaceutical companies, only 25 reported on scope 1 and scope 2 emissions in 2015, and only 15 companies consistently reported from 2012 to 2015 (Belkhir & Elmeligi, 2019). The terms "Scope 1 and 2" emissions refer to the GHG Protocol which categorizes the different kinds of carbon emissions of a company into direct, indirect, and supply chain indirect emissions. However, there is a need for transparency and accountability in reporting emissions at a more granular level, ideally at the firm's division level.

Another reporting issue lies in the waste reporting of pharmaceutical companies due to two reasons: First, as mentioned before, there is no globally standardized definition of medical waste (Windfeld & Brooks, 2015); and second, the "Global Reporting Initiative" (GRI) guidelines provide standardized indicators for measuring waste reduction but the indicators do not include impacts of social, environmental, and economic actions (Veleva et al., 2018). Thus, pharmaceutical companies report inconsistent waste data due to a lack of standardized indicators and measurement methods. Finally, the reporting activity on sustainability issues varies significantly across different countries (Azim & Azam, 2013).

Supply Chain Complexity. The pharmaceutical supply chain is complex, involving numerous stakeholders, including raw material suppliers, manufacturers, distributors, healthcare

providers, and patients, and comprising a variety of components such as market warehouses, distribution centres, wholesalers, and retailers or hospitals (Janatyan et al., 2018). Ensuring sustainability throughout the supply chain, from sourcing raw materials to delivering products to end-users, presents unique challenges. One key focus area of pharmaceutical companies is to enhance their sustainable performance and efficient management to promote market growth and drive innovation in the healthcare industry (Ahmad et al., 2022). In highly competitive markets, the importance of sustainable supply chain management is highlighted by the shorter lifespan of products and timely delivery. Finally, the impact of sustainable practices invested by one member of the supply chain extends beyond their own profitability, affecting the profitability of other members and the overall channel.

There are 20 potential barriers for pharmaceutical companies to implement sustainability in the supply chain that are categorized into material, operational, logistics, human, funding, and exogenous issues (Patil et al., 2021). To address these challenges, it is recommended to encourage long-term collaborations, advocate cash-based donations, inform media about appropriate practices, build local capacity, design coordination mechanisms, and develop performance measurement systems while incorporating triple-bottom-line sustainability. Time constraints are the most significant barrier to implementing sustainability initiatives, while lack of interest by pharmaceutical managers is only a minor deterrent (Derqui et al., 2021).

Furthermore, in times of crises, pharmaceutical firms face the need to increase production to meet a growing demand, which then leads to disruptions in global supply chains, arising from labour and raw material shortages (Yu et al., 2020). The COVID-19 pandemic is the most recent disruption that put a spotlight on the pharmaceutical industry's crucial role in global healthcare and its susceptibility to disruption due to the industry's complex and extensive international supply chain networks (Kayani et al., 2023a).

Finally, two phenomena that are specific to the pharmaceutical industry and increase its supply chain´s CO_2 footprint are “parallel trade” and “re-import”. Parallel trade is the process of reselling goods across borders without the authorization of the manufacturer as a response to international price differences (Birg, 2023). Europe has big price differences in medicines across countries due to regulations that impose limits or pricing rules (Saethre & Dubois, 2020). Thus, it can make economic sense for pharmaceutical distributors to buy products cheaply in one country and sell them expensively in another, leading to additional transportation routes. If the country to which the product is finally sold is the country of production, this is referred to

as re-import (B2B Medical, n.d.). In reality, the product was simply transported from one country to another and back, but the distributor makes a profit from this due to the different price levels. However, this financial gain for the distributor is at the expense of the environment, as each transport route generates additional CO_2.

R&D Intensity. To advance sustainable practices within the pharmaceutical sector, it is essential for companies to assess the environmental footprint of their products throughout the development process. However, individuals in research and development often lack the necessary environmental knowledge to incorporate these considerations into their workflow (Luu et al., 2022). In addition, pharmaceutical companies need to invest significantly in R&D and the burden of creating new products through R&D in the pharmaceutical industry is large due to three main reasons: 1. Time: The development period of creating the seeds of new drugs is very long with more than 10 years on average (Harada et al., 2021). The average time until a newly developed drug is approved is 13 years (Paulick et al., 2022); 2. Costs: Developing new drugs, i.e. finding a promising therapy or vaccination, is a huge investment and extremely expensive. Different strategies need to be tested and millions of molecules need to be screened "The mean cost of drug development is estimated to be USD 1336 million" (Paulick et al., 2022); and 3. Risks: The probability of success in bringing the product to market after entering clinical trials is low, on average less than 10% (Harada et al., 2021).

Furthermore, there is a significant decrease in R&D productivity within the industry stemming from the saturation of drug discovery and the increased focus on more unknown diseases. It is becoming progressively more difficult and costly to develop new medications, even though technological advancements support and streamline the process (Scannell, 2012).

These aspects differentiate the pharmaceutical industry from other industries where product development cycles are shorter and less capital-intensive. In addition, sustainability is often of secondary importance in the development process, as the effectiveness of a newly developed substance is the decisive factor when it comes to evaluating the success of an innovation process (Bade et al., 2023).

2.2.3 Approaches to Tackle Sustainability in the Pharma Industry

Several approaches have already been identified in the literature that companies in the pharmaceutical industry could use to become more sustainable (Bade et al., 2023). Figure 3 and the following sections summarize the current sustainability initiatives for the pharmaceutical industry based on the previous literature review done by Eder & Stampa (2023).

Sustainable Business Models
- Business Model Innovation

Sustainable Assessment Models
- Environmental Quotient
- Environmental Factor
- Green Chemistry model
- Life Cycle Assessment
- Process Mass Intensity Metric

Sustainability Reporting
- Sustainability Reporting
- CSR Reporting

Circular Business Models
- Closed-Loop Approaches
- Circular Economy Strategies
- Reverse Logistics

Supply Chain Management
- Pharmaceutical Supply Chain Management Model
- Sustainable Supply Chain Management
- Green Supply Chain Management

Sustainable Production
- Green Chemistry
- Eco-Design

Technology Integration
- Digital Manufacturing
- Industry 4.0
  - Internet of Things
  - Artificial Intelligence
  - Big Data Analytics
  - Blockchain Technology

Resilience to disruptions
- Sustainable Inventory Strategies

Figure 3: Approaches to Address Sustainability in the Pharma Industry[3]

Sustainable Business Models. Sustainable Business Models (SBMs) focus on generating value not only for shareholders but also for other stakeholders, aiming to balance economic performance with social equity and environmental sustainability (Geissdoerfer et al., 2018). There is limited knowledge about the key factors for success in SBMs and empirical studies on business model innovation (BMI) and SBMs are scarce, resulting in a lack of clear and consistent definitions (Ahmed et al., 2021). Chuang et al. (2022) explore the relationship between BMI and SBMs, focusing specifically on pharmaceutical companies. They establish three dimensions for SBMs: technological, social, and organizational. Cavicchi & Vagnoni (2020) examine the potential structure of an SBM tailored to community pharmacies. These pharmacies are typically located in local communities and serve as accessible points of contact for individuals seeking medication and health advice.

Sustainable Assessment Models. The production and manufacturing stages of pharmaceuticals are significant consumers of energy and other resources, ranking as the healthcare sector's second-highest emitter of greenhouse gases (Lorenzini et al., 2018). To evaluate and improve the environmental impact of these processes, the industry uses a variety of models: the Environmental Quotient (EQ) as introduced by Sheldon (1994), the

[3] (Own illustration)

Environmental factor (E factor) updated by Sheldon (2007), the Green Chemistry model developed by Anastas and Eghbali (2010) and expanded upon by Lozano et al. (2018), Life Cycle Assessment (LCA) methodologies detailed by Heijungs et al. (2010), and the Process Mass Intensity (PMI) metric refined by Jimenez-Gonzalez et al. (2013) and Sheldon (2017).

Sustainability Reporting. Demir & Min (2019) have discovered that the pharmaceutical industry outperforms other industries in terms of the overall exhaustiveness of sustainability reporting by providing more wide-ranging and in-depth information on several significant sustainability aspects than other companies. Malay (2021) specifies that to date and on average, pharmaceutical industries report 30% more problems than firms in other sectors. Chomać-Pierzecka (2023) adds that sustainable reporting is simply a link to care about the image of a pharmaceutical company as it involves substantial expenditures to validate initiatives aligned with the sustainable development policy. Demir and Min, 2019, further elaborate on the legitimacy strategies as a reason for the popularity of CSR reporting in the pharma industry, as the nature of the pharmaceutical industry results in greater exposure to public pressure from stakeholder groups. That can lead to a series of ethical scandals, resulting in companies trying to increase stakeholder tolerance for bad news by decreasing the withholding of information. Hence, pharmaceutical companies use CSR reporting as an opportunity to discuss the limitations of their business and how they deal with them with their audience, which is usually not possible under “conventional”, strict, and legally binding financial reporting.

Circular Business Models. The concept of a circular economy revolves around a regenerative framework that seeks to minimize the consumption of resources and the generation of waste by establishing closed loops for materials and energy (Soomro et al., 2022). Its potential benefits extend to environmental conservation, economic well-being, and societal fairness (Soomro et al., 2022). In this regard, circular economy strategies are becoming increasingly popular among cities and businesses worldwide, as demonstrated by initiatives such as the European Union's waste reduction plan (Veleva et al., 2017). Due to the potential negative environmental impacts and penalties for supplier companies in case of mishandling, it is the responsibility of the pharmaceutical supplier to collect and dispose of outdated medications appropriately (Tat & Heydari, 2021). Thus, in recent years, there has been a significant amount of research dedicated to the topic of reverse logistics. While researchers anticipate its potential to aid in environmental preservation, it also plays a role in achieving cost-effectiveness in the production of goods (Soomro et al., 2022).

Supply Chain Management. Decision-makers and managers recognize the significance of creating a sustainable Pharmaceutical Supply Chain Management network, as it allows them to develop essential policies and strategies for implementing sustainable practices throughout the organization (Ahmad et al., 2022). The PSCM model contributes to a pharmaceutical company's product distribution while curbing environmental impacts by optimizing customer service coverage distance to promote maximum product consumption directly from the manufacturing plant and distribution centre. It adopts a conservative approach to environmental preservation, effectively balancing the trade-offs among TBL objectives.

The Triple Bottom Line goals, which encompass economic cost, social matters, and environmental effects, are essential for promoting sustainable development (Ahmad et al., 2022). In the pharmaceutical industry, Sustainable Supply Chain Management (SSCM) plays a crucial role in tackling those social, economic, and environmental issues. The primary objective of SSCM is to minimize material wastage and diminish the negative environmental consequences across the entire value chain of an organization (Patil et al., 2021).

A narrower definition of SSCM is the Green Supply Chain Management (GSCM), serving the purpose of optimizing material and information flows across the supply chain, and aims to promote sustainable supply chains while at the same time mitigating environmental risks. GSCM contains diverse practices such as green procurement, green manufacturing, green distribution, and green logistics, all designed to ensure environmentally conscious approaches at various stages (Al-Awamleh et al., 2022).

Finally, to reduce the environmental effects of the supply chain, it is important to strategically optimize the placement of manufacturing centres, distribution centres, and points of demand. Zahiri et al. (2017) demonstrated that expanding the capacity of critical junctions, like manufacturing and distribution centres, greatly reduces the environmental impact. It is crucial to study the transportation costs associated with moving products from main distribution centres to local distribution centres and ultimately to customers in order to create a sustainable distribution network in the pharmaceutical supply chain.

Sustainable Production. The development and production of new pharmaceutical products in an environmentally friendly manner, aiming at minimizing their negative impact on human health, can be done with the help of various concepts, such as, for instance, “Green chemistry” (Waghmode et al., 2023). This presents a significant opportunity to make a positive impact on society as a whole (Fortunak, 2009). Implementing green chemistry practices, such as waste

prevention, the design of safer chemicals, and the use of renewable resources, contribute to improved sustainability while ensuring a safe workplace for employees. Additionally, these practices offer the potential to reduce manufacturing costs and enhance long-term profitability in the pharmaceutical sector (Sneddon et al., 2019). Manley et al. (2008) have recognized the potential of green chemistry to be applied at a molecular level, playing a crucial role in integrating sustainability into scientific innovation.

The "Eco-design" approach takes the environmental aspects throughout the entire lifecycle of a pharmaceutical product into account. This approach divides the R&D process in pharmaceutical companies into three major design stages: discovery, clinical manufacturing, and industrialization. Decisions made during the discovery stage have indirect implications on the product's lifecycle, given the high level of uncertainty about the outcome of the product.
In the phase of clinical production, the eco-design process gains more precision as information regarding various aspects such as raw materials, energy usage, waste production, and transportation becomes available. In the end, the data that is collected during the industrialization stage helps enhance the accuracy of the eco-design process. (Luu et al., 2020).

Technology Integration. In the world of ecological concerns, innovation serves as the key to attaining desired outcomes within set time limits. This is particularly true for the pharmaceutical sector, which leans on technological advancements and new approaches to ensure access to innovative and cost-effective drugs for all (Chomać-Pierzecka, 2023). Long-term solutions for decreasing CO_2 emissions have been identified through technological advancements (Xu & Tan, 2022). Digital manufacturing has a critical role in promoting sustainability objectives within the pharmaceutical industry (Waghmode et al., 2022). The integration of digital tools lets stakeholders collaborate effectively, advancing the implementation of protocols, designs, and comprehensive analyses. This convergence of technology not only improves efficiency but also promotes sustainable practices within pharmaceutical operations.
The integration of Industry 4.0, including digital enablers like the Internet of Things (IoT), artificial intelligence (AI), big data analytics, and blockchain technology has enabled the pharmaceutical industry to gain a competitive advantage and resulted in the introduction of new business models and procedures (Schneikart et al., 2023). This transformative movement introduced a more sustainable supply chain for pharmaceuticals, ensuring efficient management of products from production to disposal (Djunaedi, 2019; Shashi, 2023).

The continuous digitalization of procedures can enable the adoption of circular economy practices. By employing Returnable Transport Item (RTI) technology, automated sorting and delivery processes can be achieved during the distribution phase, leading to savings in time and costs. Additionally, the use of RTI can simplify assembly and temperature monitoring, although implementing a return transport system may pose organizational challenges. To successfully incorporate circular economies into pharmaceutical logistics through technological advancements, it is crucial for stakeholders to collaborate and prioritize cost efficiency and sustainability (Schneikart et al., 2023).

Resilience Strategies. Furthermore, addressing disruptions within the pharmaceutical industry holds the potential to enhance healthcare system resilience and better meet existing demands. Investigating disruption risks from various perspectives, including transportation costs and environmental concerns, facilitates systematic and comprehensive decision-making of pharma companies (Abdolazimi et al. 2023). Priyan et al. (2024) find that health systems should increase their inventory levels to handle the significant increase in demand. This calls for the implementation of sustainable inventory strategies that prioritize the size of orders, delivery time, and investments in eco-friendly solutions, aiming to reduce both CO_2 emissions and overall expenses. These measures enhance resilience by reducing disruption duration, albeit at the expense of heightened waste generation and overall supply chain costs. Although this leads to higher unused inventory, it cushions minor demand fluctuations, consequently decreasing transportation costs (Silva et al., 2023). Hence, these firms strategically commit to various levels of sustainability practices to fortify the resilience of their supply chains (Janatyan et al., 2018).

2.3 Startups

Globally, the number of startups is estimated to be around 150 million, with 50 million new ones emerging every year, according to data collection by Microsoft (Microsoft CEE Multi-Country News Center, 2022). They are oftentimes looked at as key figures in economic development, due to their high levels of new innovations and technologies (Skala, 2019). This constitutes a need to define such new companies, to be able to conduct studies on them. While researching, it became apparent that there is still an ongoing debate amongst scholars as to what exactly makes a startup. However, there is somewhat of a consensus when it comes to certain characteristics and attributes that can be found in most entrepreneurial ventures.

2.3.1 Characteristics of Startups

Based on their literature research, Skawińska and Zalewski (2020) created the overarching definition of a startup being a "young, small, independent enterprise, which is creative, innovative, conducting research and development activity to solve actual problems, and proposing prospective solutions, striving for talented employees, and sales growth, with an attractive business model". A startup's high level of innovation is one of its most defining factors. As opposed to small and medium-sized enterprises (SMEs), startups revolutionize their technologies, internal structures and overall business model (Aulet and Murray, 2013). Oftentimes, resources are somewhat limited in a startup's operations, leading to an innovative and more efficient approach to development. This forward-thinking mindset can then also be translated into the creation of more value for consumers (Hongtao, 2020). Moreover, Aminova and Marchi (2021) found that there is a direct positive correlation between the level of innovation and startup performance. Factors that influence innovation are the founders' educational background, the startup's size, as well as the degree of investments.

Successful startups are the ones made up of people who have an entrepreneurial spirit consisting of risk-taking tendencies. They can identify market needs and use them to their own advantage (Hongtao, 2020). A high work ethic is expected of all employees working in the venture. In turn, startups employ a combination of informality and flat hierarchies within the company's structure (Cockayne, 2019). Another approach to the definition of startups comes from Nurcahyo et al., 2018, in which they use four different dimensions to explain their identified characteristics. Organizationally, startups are small, young companies with informal structures and centralized decision-making. They are typically owner-managed, and characterized by intuitive decision-making and direct supervision. Strategically, startups focus on niche markets, risk-taking, and rapid innovation to quickly capture market opportunities, oftentimes without extensive product research. Financially, startups face significant constraints, relying on personal savings and family support in their early stages.

The literature does not specify hard figures as to when a company is still a startup and when it is not. Nevertheless, to draw a clear line in this thesis as to when a startup is a startup, the authors of this thesis refer to Alex Wilhelm, Editor in Chief at the US American news outlet "Techcrunch" which covers topics about technology, startups, and venture capital funding. He coined the 50-100-500 rule: a startup can only be considered as such if its revenue does not exceed US$ 50 million, it does not employ more than 100 people, and it is not worth more than US$ 500 million (Wilhelm, 2014).

2.3.2 Role of Startups in an Industry's Transition Towards Sustainability

Entrepreneurship and innovation are acknowledged as incremental drivers of economic growth and progress in society (Chillakuri et al., 2020). An important trend is the growing popularity of startups that are rooted in sustainability, like those involved in organic farming, or clean energy. These enterprises are increasingly designing their business models with the Triple Bottom Line approach, which marks a clear shift towards integrating sustainability. A myriad of stakeholders — including shareholders, customers, employees, suppliers, society, the environment, government, and competitors — benefit from the startups' sustainability-oriented business models (da Silva Nunes et al., 2022).

Nowadays, startups are predominantly adopting 'green' business models, such as Green Producer, Green Retailer, and Integrated Solar Solutions (Palmié, 2021). Startups with a strong environmental focus tend to show higher levels of innovativeness. This environmental orientation is an essential yet often overlooked predictor of a startup's overall quality and innovative abilities (Neumann, 2023). The dynamic nature of startups contributes to the creation of new jobs, animates competition, stimulates innovation, and can drive economic renewal across a variety of sectors. Consequently, they are vital to the cultivation of a sustainable economic ecosystem (Ressin, 2022).

However, startups promoting sustainable business models face considerable barriers to raising market awareness and understanding of their offerings (Olteanu and Fichter, 2022). The challenge becomes particularly profound in remanufacturing and circular economy contexts, where market demands for product quality and performance can be intensely rigorous. Complexities in these areas may arise from the need to align traditional operational processes with the principles of sustainability, which often require systemic changes and innovative logistical solutions.

One of those systemic changes that can be implemented to strengthen sustainable change is the circular economy (Henry et al., 2020). Circular startups often adopt innovative circular business model strategies that are superior to traditional business methods. These strategies are multifaceted, involving a shift in socio-institutional norms, the introduction of ground-breaking technological advancements, and a proactive engagement of consumers in circular practices.

An increasing consumer shift towards eco-friendly products, driven by heightened awareness of environmental pollution and its impacts, shows a notable change in buying attitudes. This shift, influenced by environmental knowledge and education, leads to an increased demand for

green products and the development of the green market. In this context, the role of green entrepreneurs becomes increasingly crucial. Hence, environmental entrepreneurs, or "enviropreneurs," have emerged as vital agents of change. They blend entrepreneurship with a commitment to environmental sustainability, positioning themselves at the forefront of economic development, job creation, and the green innovation movement. Enviropreneurs are distinguished by their ability to serve as a driving force for change, introducing innovative solutions that respond to environmental challenges more rapidly and flexibly than their larger counterparts. (Sharma, 2015)

Startups, with their inherent innovative drive and commitment to social responsibility, have been found to positively influence employment rates, social equity, and community development (Ressin, 2022). They often pioneer advancements in critical social sectors such as education, healthcare, and social services, thereby bolstering the foundations of social sustainability. Moreover, startups often act as catalysts for policy reform, champion transparency, and promote ethical practices, thus contributing to the development of robust, accountable, and sustainable institutional structures. Furthermore, when collaborating with larger corporations, startups have the potential to bring about radical changes (Kratzer, 2020). The emergence of new and disruptive products can contribute to the SDGs. Disruptive entrepreneurship is positioned as a potential catalyst for a sustainable turnaround in industries marked by significant digital, circular, and sustainable transformations.

Nonetheless, contrary to the formerly stated assumption that startups are the sole drivers of disruptive transformations, Palmié (2021) emphasizes the critical roles that both startups and incumbents play. Systematic differences are evident in their respective business models, with startups typically pioneering customer-oriented, digital, and 'green' models. The environmental influence of new ventures can exceed even their own operational boundaries, establishing expansive sustainability initiatives in larger firms via corporate venture capital investments. This interconnectedness highlights the strategic role of such investments in crafting a sustainable business ecosystem. Within this ecosystem, startups and incumbents not only contribute to but also share in the collective pursuit of sustainability goals (Bendig et al., 2022). Without the proactive involvement of startups, the industry's shift towards sustainability may stall, failing to realize substantial change (Palmié, 2021).

2.3.3 Startups in the Pharmaceutical Industry

The global market for health tech is expected to grow to USD 639.4 billion by 2026 (Ehlers & Offermanns, 2020). This growth will be driven by new information and communication technologies as well as supporting government initiatives. Accordingly, there is a substantial increase in health tech startups, with digital health emerging as the fastest-growing segment (Chakraborty et al., 2023a). Key insights include the vital role played by AI, IoT, and blockchain in driving innovation, as well as the significance of venture capital in supporting growth. This is reflected in the requirement for a robust technological infrastructure. Such infrastructure is essential for enabling the scalability and security of health-tech solutions, ensuring their ability to meet evolving demands and maintain data integrity (Chakraborty et al., 2023b). Startups serve as novel spaces for knowledge production, extending beyond traditional academic and industrial domains (Fochler, 2016).

Following the COVID-19 pandemic, there has been a noticeable surge in health technology startups that have aimed to address gaps within the healthcare sector by offering innovative solutions (OECD, 2020). These startups are witnessing advancements in digital health, medical technology, and biotech sectors (Chakraborty et al., 2023a). They are playing an increasingly important role in the healthcare industry by revolutionizing the way healthcare is delivered, monitored and received. They offer potential solutions to reduce healthcare costs and increase the speed of service delivery (Ehlers & Offermanns, 2020). Furthermore, these startups focus on developing new drugs through more agile and innovative approaches, emphasizing the translation of academic discoveries into therapeutic products (Barden & Weaver, 2010). Biotechnology firms enable researchers to cultivate sustainable, long-term research strategies, attributed to the alternative funding structures that empower companies to establish research priorities without the constraints of higher management (Fochler, 2016).

However, there are challenges that startups within the pharmaceutical sector face. Those include the need to disrupt well-established pharmaceutical development practices, navigate the complexities of drug discovery within a new ecosystem, nurture interdisciplinary collaboration among scientists, and secure funding. These challenges highlight the transition from traditional to more dynamic and flexible drug development paradigms (Barden & Weaver, 2010).

In pharmaceutical R&D, machine learning (ML) stands out as the predominant AI technology employed. It plays a crucial role in various aspects of drug discovery and development processes. Startups emerge as important reservoirs of AI expertise within the pharmaceutical

sector. They specialize in providing AI services specifically designed for drug discovery purposes (Schuhmacher et al, 2020). In recent years, the pharmaceutical industry has gone through the transition from predominantly conducting in-house R&D to actively engaging with external innovation sources, particularly smaller biotech startups. More and more large pharmaceutical companies acquire or license products from smaller firms, with nearly half of all approved drugs in 2018 originating from these smaller businesses. Such reliance on external innovation shows a departure from the traditional model of focusing on in-house development, driven by the rapid advancement of new technologies that facilitate the integration of external innovations into large pharma pipelines (Von Dydiowa et al., 2021).

In today's volatile, uncertain, complex, and ambiguous (VUCA) environment, organizations, especially those in the pharmaceutical sector, must prioritize innovation to stay competitive and resilient. Innovation serves as a foundation for sustaining competitive advantage and ensuring long-term viability in the global economy, enabling companies to navigate through changes and challenges (Mohammed & Viswanathan, 2019). Consortia, alliances between multiple organizations, play an important role in enabling cooperative value creation within the pharmaceutical industry while maintaining existing value capture mechanisms. By adopting a collaborative approach, pharmaceutical consortia encourage the sharing of research and development (R&D) outcomes among members and even non-members, thereby increasing the impact of innovation across the industry (Olk and West, 2019). These collaborations showcase the potential to accelerate drug discovery processes, optimize treatment efficiency, and ultimately improve patient outcomes (Schuhmacher et al., 2021).

In recent years, traditional closed innovation models, where ideas are mainly developed internally, are being replaced by more dynamic approaches due to technological advancements and increasing interconnectivity on a global scale (Hunter & Stephens, 2010). Open innovation has emerged as a paradigm shift, advocating for the sourcing of ideas from both internal and external sources, promoting collaboration, and enabling internal ideas to be leveraged beyond organizational boundaries (Mohammed & Viswanathan, 2019).

Open innovation offers a pathway for startups to collaborate with large pharmaceutical companies, leveraging their resources, expertise, and networks to improve their development and enhance their innovation potential. These collaborations can provide startups with access to critical tools, technologies, and markets, significantly impacting their growth and success in the competitive pharmaceutical industry (Mohammed & Viswanathan, 2019).

Conicella et al. (2021) examine the dynamic relationship between large pharmaceutical companies and startups through open innovation models. They describe eight models of collaboration employed by corporations to engage with startups and encourage innovation: It includes a marketing model that enhances brand awareness through hackathons and competitions, offering networking and promotional benefits. Corporations also use external platforms to scout and source startups for collaboration, quickly integrating into the startup ecosystem. Internally, they scout startups to identify synergies and form partnerships. Additionally, corporate venture funds directly invest in startups for financial returns and strategic benefits. Acceleration and investment models provide mentorship and seed funding in exchange for equity, preparing startups for further investment. Venture building studios help develop research projects into investable startups with long-term corporate involvement. The corporate intrapreneurship model encourages employees to innovate within the company, encouraging a culture of innovation. Finally, innovation centres or hubs provide spaces for collaborative innovation, speeding up therapeutic discoveries and encouraging potential investments or mergers.

In terms of sustainability, open innovation contributes to pharmaceutical research and development by optimizing resource utilization through shared expertise and infrastructure. This collaborative approach reduces redundancy and enhances R&D efficiency. Additionally, open innovation accelerates the development of healthcare solutions, potentially cutting down the time and cost associated with bringing new treatments to market. (Yeung et al., 2021)

Finally, the theoretical insights highlight the challenges and approaches for sustainability in the pharmaceutical sectors and acknowledge the role of startups in their transformation towards more sustainability. However, empirical data on how startups address the challenges and which sustainability approaches are applied in practice, are currently lacking, forming the starting point of this thesis.

3. Methodology

This chapter outlines the methodology used in this study to explore startups' innovative roles in the pharmaceutical industry concerning sustainability transformation. It details the general methodology of the mixed method research, as well as the detailed quantitative and qualitative approaches.

3.1 General Methodology

This study used the mixed methods design, which is a research technique that integrates both qualitative and quantitative research practices into a single study (Hussy, Schreier, & Echterhoff, 2013). According to Creswell and Plano Clark (2018), this technique provides a comprehensive understanding of the research problem by combining the strengths of both quantitative and qualitative data. They state that quantitative methods can provide generalizable data about a phenomenon, while qualitative methods can examine the contextual and nuanced understanding, leading to a more comprehensive exploration of a research question. Further, triangulation is applied that enhances the validity and reliability of the results by cross-verifying data from multiple sources which is especially helpful for immature research fields where theoretical frameworks are still developing and one data source may be insufficient (Creswell & Plano Clark, 2018). Thus, mixed method approaches can provide the breadth and depth necessary to explore new and complex issues more thoroughly and understand both the scope and underlying mechanisms of new issues (Creswell & Plano Clark, 2018).

The thesis followed a convergent design according to Creswell and Plano Clark (2018) where the researchers brought the results of the quantitative and qualitative results together and compared and combined them to get a more comprehensive answer to the research question. This design allows the integration of insights from qualitative sources like interviews and observation efficiently and reports statistical trends relevant to the research question. The research question of this thesis sounds as follows: "*How can startups enable the pharmaceutical industry to transform towards sustainability?*". In parallel mixed methods studies, it is the norm to establish an overarching research question and to break it down into separate quantitative and qualitative sub questions to discover the different facets of the question (Teddlie & Tashakkori, 2009). The authors used this concept to investigate the direct and indirect environmental impact of a startup using two devoted sub research questions. The first sub question sounds as follows: "*What key strategies do startups in the European Union pharmaceutical industry utilize to facilitate the transition towards sustainability?*". It explored

which sustainability approaches startups in the pharmaceutical industry utilize, representing their direct environmental impact. The second sub question is: "*How does a startup successfully address sustainability challenges of the pharmaceutical industry and* how *can it influence the whole industry?*". It investigated the products, business models and behaviours of five startups within the pharmaceutical industry very closely to finally explore the indirect impacts startups can have on the pharmaceutical industry.

The convergent design procedure is outlined in Figure 4, following the structure proposed by Creswell & Plano Clark (2018). At first, the qualitative and quantitative data were collected, where one data collection process did not depend on the other, following the parallel-database variant described by Creswell & Plano Clark (2018). To address the direct impacts (sub question 1), a quantitative approach in the form of a survey was chosen. The indirect impacts (sub question 2) were investigated using a qualitative approach that included a multiple case study, sourcing data from interviews and documents. Second, the two data sets were analysed individually using descriptive statistics and a thematic analysis. In a third step, the analysis results were summarized and interpreted in their respective context to answer each of their respective sub questions. Finally, both results were merged, directly compared and interpreted in the discussion to answer the overall research question. To point out the similarities and differences between the results of both approaches the results are presented in passages organized by major topics, as proposed by Creswell & Plano Clark (2018).

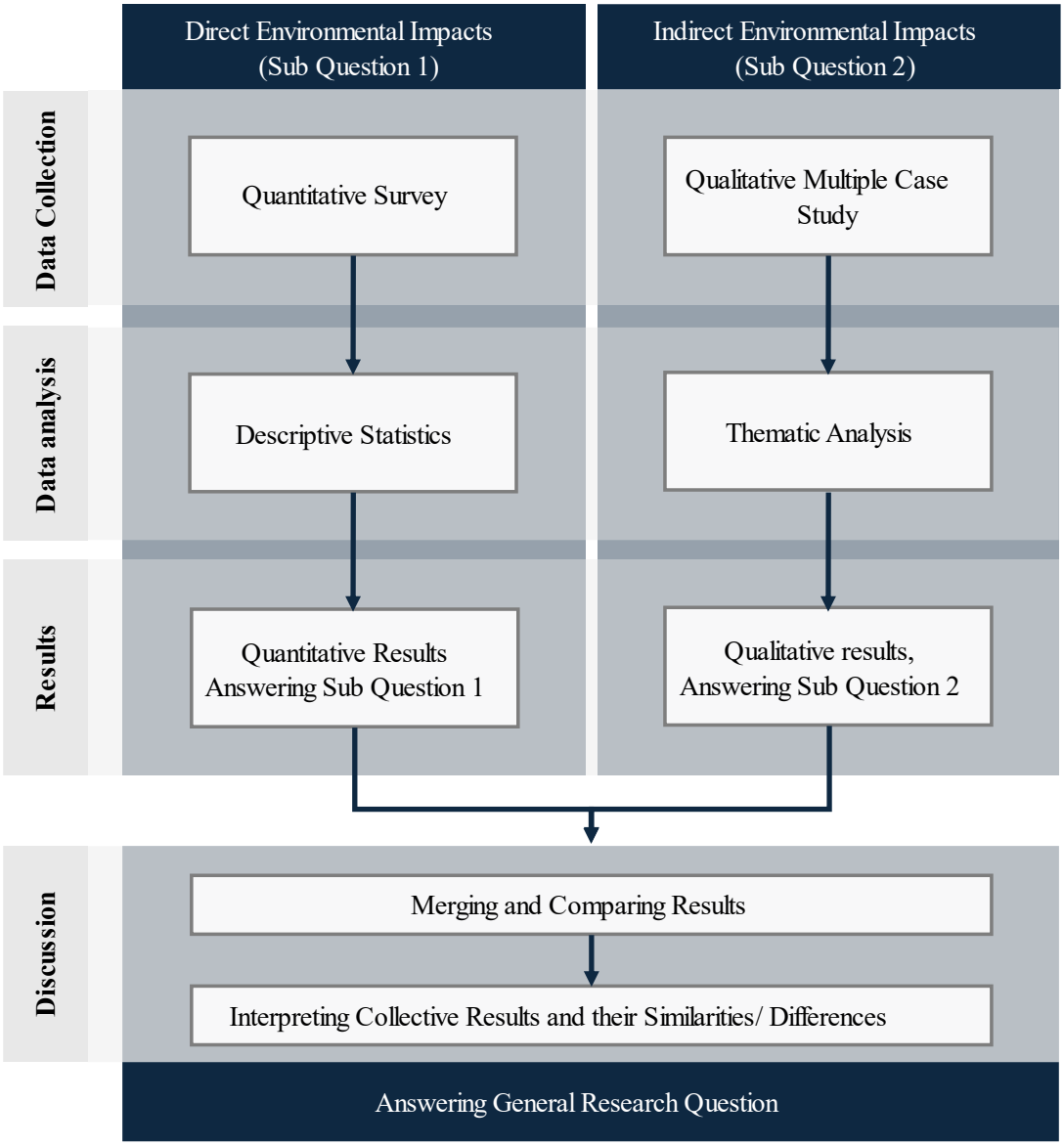

Figure 4: Flowchart of the Convergent Design Procedure[4]

3.2 Quantitative Methodology

This section outlines the methodological approach adopted in this research to investigate the following sub-research question: *What key strategies do startups in the European Union pharmaceutical industry utilize to facilitate the transition towards sustainability?* The goal of this approach was to understand the current sustainability trends and initiatives that happen within pharmaceutical startups. The authors wanted to identify and quantify the frequency, effectiveness, and extent of use of different sustainability strategies. To accomplish this, quantitative research was conducted. In the following sections, the research design, population

[4] (Adapted from Creswell & Plano Clark, 2018, p. 121)

and sampling methods, data collection procedures, the approach to data analysis, ethical considerations, and validity and reliability are described.

3.2.1 Quantitative Research Design

The research followed a deductive approach for this part of the study, as it used existing literature as a framework for its construct. The usage of a quantitative approach is appropriate for this segment of the study due to its ability to include a larger population's opinions (Jensen et al., 2018). A cross-sectional survey was conducted to collect data at a single point in time from a sample of pharmaceutical startups across Europe. The design was chosen for its effectiveness in providing a snapshot of current practices and innovations related to sustainability within the industry (Wang & Cheng, 2020). This method offers a numerical portrayal of a population's trends, attitudes, and opinions by investigating a part of that population, and it is frequently used in various fields of research (Van Biljon, 2014).

Applying the previously defined criteria of a startup, the population of interest for this study consists of 918 pharmaceutical startups, as of mid-March 2024. These are startups not necessarily focused on sustainability, with headquarters in the European Union, as identified through the Crunchbase database (Crunchbase, 2024). To achieve a representative sample, a simple random sampling approach was employed. Simple random sampling is a commonly used technique in surveys and quantitative research, ensuring that each member of the population has an equal opportunity to be chosen and take part in the study (Rahi, 2017; Reitermanova, 2010). This approach is effective, especially when the group of people is similar and there is a complete list of potential participants (Cohen et al., 2002; Barreiro & Albandoz, 2001). Crunchbase has compiled a comprehensive inventory of pharmaceutical startups in the EU and offers best-in-class live data about startups worldwide, making it a reliable database for this thesis (Crunchbase, n.d.). Randomizing within this method is also advantageous because it helps reduce the impact of both known and unknown factors, ensuring that the sample represents the population accurately (Stockemer et al., 2019).

The sample size was determined to reflect a 95% confidence level with a 10% margin of error. The 10% margin of error was chosen since it allows a more manageable and efficient sample size, while at the same time still giving valuable insights into the research topic (Imai, 1998). The population is relatively homogeneous due to the shared characteristics of similar occupations, operating in the same industry, and facing an identical regulatory body in the shape of the EU. This made the larger margin of error applicable, as well as sufficient to understand

the overlaying trends (Pirani, 2024). Since there is still a lack of research on startups leveraging sustainability in the pharmaceutical industry, this body of work acts as an exploration of the topic. Rather than making precise deductions, it aims to be a guide to further, more detailed studies, thereby justifying the 10% margin of error (Roy et al., 2016). The calculation was performed using statistical formulas that account for the estimated population size, desired confidence level, and margin of error (Cochran, 1977):

$$n_0 = \left(\frac{z^2 \cdot p \cdot (1-p)}{e^2}\right)$$

$$n_0 = \left(\frac{1.96^2 \cdot 0.5 \cdot (1-0.5)}{0.1^2}\right)$$

$$n_0 = 96.04$$

e = margin of error
n_0 = initial sample size
p = estimated proportion of population with attribute of interest
z = z-score corresponding to the desired confidence level (1.96 for 95% confidence)

However, the sample size surpassed 5% of the total population (918*.05=46). Therefore, to determine the ultimate sample size, Cochran's (1977) adjustment formula must be applied, which was calculated using the following equation:

$$n = \left(\frac{n^0}{1 + \frac{n^0}{N}}\right)$$

$$n = \left(\frac{96.04}{1 + \frac{96.04}{918}}\right)$$

$$n \approx 87$$

n_0 = initial sample size
N = total population
n = sample size

Accordingly, the calculated sample size for the survey, with a population of 918, a confidence level of 95%, and a margin of error of 10%, is approximately 87.

The primary data collection instrument was a structured questionnaire (found in Appendix A), developed based on the research objective of finding the key strategies startups in the European pharmaceutical industry use to facilitate the transformation towards sustainability. The content of the questionnaire was derived from the eight approaches to sustainability found in the literature. The survey was divided into two sections:

Section A: This section included six demographic questions that aimed at reaffirming the status as a startup in the pharmaceutical industry, as well as ensuring the respondent is knowledgeable

in the field of question. Questions comprised, for instance, the startup's annual revenue, the number of employed people, and the respondents' role within the startup.

Section B: This part covered the eight different sustainability approaches and included a combination of five-point Likert scales and closed-ended questions, designed to capture quantitative data on sustainability practices. For each sustainability approach, respondents were asked whether the startup engages in the sustainability initiative, as seen before in studies such as Blum-Klusterer & Hussain (2001). Furthermore, they were asked to rate how the respective approach has positively affected the company's sustainability efforts. The five-item Likert Scale was used to provide distinct options for respondents to express their level of agreement, ranging from "strongly agree" to "strongly disagree", and to convert the values into a standard ordinal scale (Likert, 1974). In previous research within this field of study, this approach of using Likert scales to determine levels of agreement towards sustainability practices has already demonstrated its effectiveness (Yigitcanlar & Dur, 2010).

3.2.2 Quantitative Data Collection

The questionnaire was created with the help of Google Forms, a survey administration software. It was chosen due to several beneficial features: The inclusion of a timestamp feature was important for tracking the respondent's time to finish the survey, a critical element especially in the pilot study. Additionally, the platform's intuitive design allowed for accessibility through various devices like laptops and smartphones, ensuring easy participation. Importantly, Google Forms' capability to automatically collect the data into a Google Sheet simplified the data processing procedure. Most significantly, it allowed respondent anonymity, an important factor in receiving genuine and uninhibited responses from individuals. The survey did not need intricate in-depth analytics, making Google Forms the ideal tool for these uncomplicated data gathering requirements. Participation was voluntary, with an informed consent process in place. The survey included a cover letter explaining the study's purpose, the anonymous and confidential nature of participation, and contact information for any questions or concerns.

Crunchbase offered a comprehensive list of all pharmaceutical startups within the EU, as well as contact information in the form of E-Mail addresses and LinkedIn profiles. Therefore, an Excel sheet comprised of all contact information was created. The survey was initially distributed through a mailing list to all chosen startups. Most of the email addresses given by Crunchbase were directed towards online ticketing systems rather than actual individuals. Despite two subsequent follow-up emails, only a few responses were received. Hence, people

with decision-making power (like Chief Executive Officers (CEOs), Chief Operating Officers (COOs), Managing Directors etc.) were located through their respective company's LinkedIn pages. These people were contacted specifically due to their assumed high knowledge about their startup's structure and operational practices. At the beginning of March, the survey was then administered to 523 people via contact requests with a personalized message in which the link to the questionnaire was included. Those people who accepted the contact request received follow-up messages at an interval of three days.

3.2.3 Quantitative Data Analysis

To ensure the accuracy and relevance of the analysis, the first steps involved the cleaning of the dataset. The focus was to verify that all respondents meet the previously defined criteria for this research - namely being a startup and actively operating within the pharmaceutical industry. This verification ensured the analysis to be conducted on a relevant sample and therefore enhancing the validity of the study's findings. Data was analysed via IBM's statistical analytics software Statistical Package for Social Sciences (SPSS) which is widely used in quantitative research due to its wide range of statistical tests (Wagner, 2019). Descriptive statistics was used to summarize the data, including means, medians, standard deviations, and skewness for continuous variables, as well as frequencies and percentages for categorical variables. Data transformation was necessary for effectively analysing the responses. The ordinal responses from questions with options such as "yes," "no," and "I'm unsure" were recoded to numerical values to enable quantitative analysis. Specifically, "no" responses were recoded as 0, "yes" responses as 1, and "I'm unsure" responses were treated as missing values (left blank). For each question with ordinal data (recoded as above), frequencies of responses were calculated. This step provided an overview of the distribution of answers, giving insights into the popularity of each sustainability approach among the surveyed startups.

For questions measured on a five-point Likert scale (nominal data), more comprehensive statistics were calculated, including:

- Means and Medians: to determine the central tendency of responses, indicating the average and midpoint of perceptions towards different sustainability strategies
- Standard Deviations: to assess the variability in responses and highlight how responses differ from the mean
- Skewness: to assess the asymmetry of the response distribution around the mean, providing insights into the tendency of the responses

The interpretation of these results focused on understanding the trends and patterns within the data, particularly how different sustainability strategies are used and perceived by startups in the pharmaceutical industry. (Eckstein, 2014)

3.2.4 Ethical Considerations in Quantitative Research

The research was conducted following ethical guidelines, ensuring informed consent, data privacy, and confidentiality. Participation was voluntary, with participants informed of their rights and the purpose of the research. Upon distribution of the survey, participants were assured of anonymity and asked to provide their consent to participate. The survey was conducted online and included a cover letter detailing the study's objectives, data collection methods, and utilization of the information obtained. The research plan, including the informed consent process, data gathering techniques, and data management protocols, was reviewed and approved by SIKT, a Norwegian government agency and service provider for the academic field, to guarantee adherence to ethical standards and Norwegian laws.

3.2.5 Reflection on Validity, Reliability and Objectivity in Quantitative Research

Reliability measures the consistency and accuracy of a measurement device by assessing the degree of random error (Mehmood et al., 2012). Measures were taken to ensure reliability within the research findings: Before the main data collection, the survey underwent a pilot test to ensure clarity, reliability, and validity before being finalized, as well as measuring the time it took to complete the form. It was administered to five individual experts from NTNU who provided feedback. This process helped refine the questions, ensuring that they were clearly understood and interpreted in the right way by different respondents. The feedback from the pilot test was used to make necessary optimizations to the questionnaire.

Validity refers to the accuracy of a measurement device in representing a concept. It represents a scale's ability to measure what it is intended to measure (Mehmood et al., 2012). To ensure validity, several measures were taken:

A) Content Validity: This evaluates whether the test items provide a representative sample concerning relevance and full coverage (Gregory, 2015). The content of this survey was based on an extensive literature review, guaranteeing that the questionnaire covered key sustainability strategies relevant to the key population
B) Construct Validity: This refers to whether the concept is measured in the way it was intended, ensuring that the results accurately represent the theory (Gregory, 2015). The questionnaire was constructed in such a way that each sustainability approach was evaluated

with a binary question, followed by a five-point Likert-scale question for users of the respective strategy. This was done to ensure that each question assesses the intended aspect of sustainability practice.

Objectivity in the data collection process was assured, acknowledging potential biases, namely non-response bias and social desirability bias. Non-response biases refer to the growing uncertainty about the reliability and validity of survey results arising from low response rates (Wittwer & Hubrich, 2015). To decrease drop-out rates, the survey was designed in a concise and engaging way. Furthermore, social desirability is the tendency for individuals to report socially acceptable attitudes and behaviours while denying socially unacceptable ones which can lead to inaccurate self-reporting and misrepresentation of true attitudes and behaviours (Krumpal, 2011). Consumers care for companies' environmental sustainability initiatives and implementing them becomes increasingly critical (Salnikova et al., 2022). Accordingly, some startups might not want to disclose and admit their lack thereof. To mitigate this bias, anonymity and confidentiality were emphasized in the survey to give the respondents security. Additionally, the wording of the questions was formulated in a neutral non-judgmental way to reduce the pressure to answer in a socially desirable manner. Also, there might be a bias since the LinkedIn profile used to contact participants is German, making responses from compatriots more likely. This goes in accordance with affinity bias, wherein people favour and trust others who have the same or similar background (Turnbull, 2014).

3.3 Qualitative Methodology

This section outlines the methodological approach applied to investigate the following sub-research question: *How does a startup successfully address sustainability challenges of the pharmaceutical industry and how can it influence the whole industry?* With this question, the authors wanted to explore startups that successfully address sustainability challenges in the pharmaceutical industry and get a comprehensive and detailed understanding of their potential indirect impact on the environment, which speaks for a qualitative approach (Creswell, 2013). To accomplish this, qualitative research was conducted. The following sections describe the research design, data collection process and data analysis approach of this part of the thesis, followed by a description of how ethical issues, validity and reliability of the results were addressed.

3.3.1 Qualitative Research Design

To understand in depth what makes a successful startup that tackles sustainability in this industry effectively and to be able to illustrate the influence of startups on the pharmaceutical industry using concrete examples, the authors applied case study research. Yin (2008) defines case studies as a research method that "[…] tries to illuminate a decision or set of decisions: why they were taken, how they were implemented, and with what result." (Yin, 2008), which fits exactly to the aim of the research question. Moreover, Yin (2008) suggests using a case study when the research question is a "How" or "Why" question. A case study enabled the authors to directly observe the cases within their boundaries, get a deep understanding of them and interview the persons who are relevant to the research question (Creswell, 2013; Yin, 2008). A major strength of case studies is the opportunity to use several sources of evidence like documents, artefacts, observations and interviews to develop converging lines of inquiry. It can be applied to provide a description, test a theory or generate a theory (Eisenhardt, 1989). In this thesis, the approach was used to provide a description of specific circumstances of best-practice example cases and derive practical implications from that.

Yin (2008) defines four different types of case studies. For this thesis, a type was chosen that enabled a comprehensive understanding of the research question and robust overall study results, namely a multiple-case design with a holistic approach (shown in Figure 5) (Yin, 2008). This approach allowed direct replication and more powerful conclusions, erasing the possibility of choosing just a single case with unique conditions that bias the result.

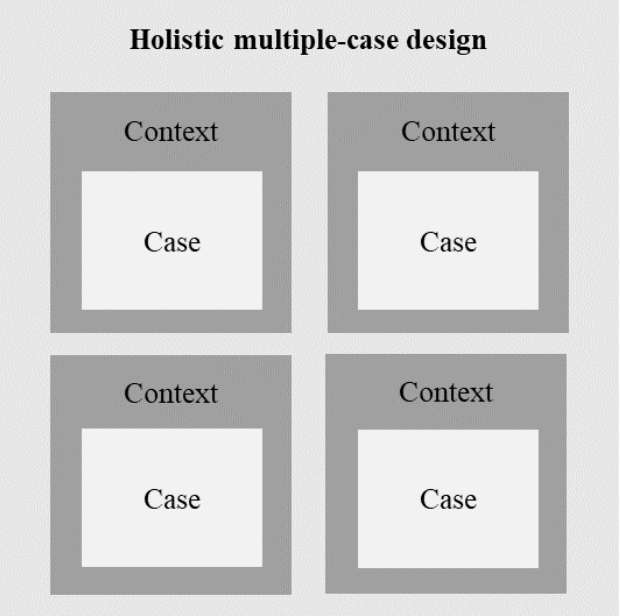

Figure 5: Holistic Multiple-Case Design[5]

The number of cases for a multiple-case study depends on the desired certainty of the results, as with a higher number of cases, the certainty of reliability of the results increases (Yin, 2008). In consideration of the limited time of the master thesis, the authors decided to limit the research to five cases, which delivers a "high degree of certainty" according to Yin (2008). The startup selection process followed the purposeful sampling strategy, selecting cases deliberately to provide information that could not have been gotten as well from other choices (Light, et al., 1990). Thus, the selection criteria for the startups included a) the three criteria that define a startup (explained in the theoretical background); b) the focus on the pharmaceutical industry with their product/ service; c) that sustainability is one key characteristic of the product/service; d) that the headquarters are located in the EU. Those selection criteria were applied in the Crunchbase database where 67 startups matched the criteria. However, after examining each startup, the authors found that many of the startups did either not include environmental sustainability at their core or were already "inactive" (no website or contact could be found). Therefore, the number of potential startups decreased to twelve startups that met the research objective.

Subsequently, the startups were contacted via LinkedIn or email, asking for a short phone call with the founder or CEO to talk about the potential of integrating the startups into a research project. Only six of the startups answered with a positive response while the others expressed a general disinterest in such co-operation. In those six introductory calls with the CEO/ founder

[5] (Adopted from Yin, 2008, p. 90)

of the startups, the authors explained the scope and purpose of the thesis, why the specific startup is relevant to the study, the scope and how much time and effort is needed from the CEO/ founder. While one startup expressed the fear that this project could have negative consequences for their reputation, even if anonymisation were to be carried out, the other five startups agreed to be part of the case study and participate in a follow-up interview. Those five startups formed the unit of analysis, each of them in an individual context as their customers, suppliers and market environment differ, but all within the EU pharmaceutical market. After reviewing the interview questions together with the CEO/ founder in the introductory call, the authors and participants concluded that a single interview with the CEO/founder would be sufficient to answer all relevant questions, as the questions are very strategic and best answered by the highest management position with the longest company experience. However, one startup wished to be anonymised in the thesis so that statements could not be proven. Table 1 presents an overview of the selected startups and interviewees.

Number of Employees	**Revenue**	**Product**	**Interviewee Name**	**Position**
11 to 50	/	Greener supply of active pharmaceuticals (APIs) and their intermediates	*(Anonymous)*	Founder &CEO
1 to 10	/	Medical Grade Bioplastic	Julian Lotz	Co-founder & CEO
11 to 50	$1M to $10M	GENERATIONS™, a green technology to recover biohazardous laboratory waste	Malcolm Bell	Founder & CEO
1 to 10	$1M to $10M	Labware from plant-based plastic & patented CellScrew design	Felix Wollenhaupt	Co-Founder & Managing Director
1 to 10	$1M to $10M	Sustainable produced gold nanoparticles for cancer treatment	Anne-Laure Morel	Founder & CEO

Startup Name	Founding Year	Location
(Anonymous)	2019	Europe
BIOVOX	2021	Darmstadt, Hessen, Germany
Envetec	2021	Birdhill, Tipperary, Ireland
Green Elephant Biotech	2021	Gießen, Hessen, Germany
TORSKAL	2015	Saint-Denis, La Réunion, France

Table 1: Overview of Startups and Interviewees[6]

3.3.2 Qualitative Data Collection

There are six primary sources of evidence for a case study, as identified by Yin (2008): archival records, direct observations, documentation, interviews, participant observation, and physical artefacts. In this thesis, documents and interviews were used as the sources of evidence because they were the only available evidence in this strategic context that would lead to answering the research question. The data collection process of the documents and interviews was a parallel process which took place between the beginning of March and the end of April 2024.

Documentation is a robust method in case study research due to its stability, allowing repeated reviews, exact details, and broad coverage (Yin, 2008). In this case study, documentation comprised all information about a startup that was publicly available, including primary sources like the company website, and secondary sources like newspaper articles, press releases and any other information that was available on the internet. To find that information, the authors read every Google entry of the first 20 Google pages (Which in total contain approx. 200 Google entries) that appeared, when searching for the startups' name. In addition, at the end of the interviews, the participants were asked if there were other sustainability-related documents about the startup that could not have been found on the website or via a Google search. In four of the five cases, documents were sent by e-mail after the interview. For an overview of which websites and documents were used to collect the written information, see Appendix B.

[6] (Own illustration)

Beyond that, interviews offered targeted insights directly related to the study topics and provided valuable explanations (Yin, 2008). This made them the perfect evidence type to generate primary data. To be more specific, semi-structured interviews were chosen that have a core set of questions but allow follow-up questions based on the responses of the interviewees (Kallio et al., 2016). This enabled the authors to keep the interview open-ended and ask questions about yet unknown circumstances (e.g. reaction of investors) while still following a set of questions derived from the case study protocol to verify certain facts (e.g. about the sustainability characteristics of the product which are already extensively described on the website) (Yin, 2008). Finally, this approach created a balance between consistency and flexibility while capturing detailed information and maintaining comparability (Kallio et al., 2016).

Before executing the case study interviews, three pilot interviews were conducted in February 2024, as a best practice of case study research (Yin, 2008), to validate the functionality of the semi-structured interview questions and their correct targeting. Two startups were selected to cover both focal points (pharmaceutical industry and sustainability) of this master's thesis, thus one that focuses strongly on sustainability through a circular business model and one that focuses on the pharma & health industry. Both startups were founded at the School of Entrepreneurship at NTNU and selected because prior personal contact enabled easy access to these startups, which Yin (2008) describes as a valid reason for selecting candidates for pilot interviews. The three pilot interviews were particularly helpful in improving the research design and in formulating clear, relevant questions for the participants to gain meaningful insights in the subsequent data collection.

After the design of the interview was refined, a data protection letter, a consent form and the questions from the interview guide were sent to the participants. This enabled the interviewees to know what kind of questions they were going to be asked and decide beforehand if they wanted their name, company name and position published in the thesis. Furthermore, it gives the interviewees the chance to prepare and provide detailed and precise answers during the interview. Table 2 shows the interviewee's name, position in the startup, the duration of the interview, its format, and the date when it took place.

Startup Name	**Interviewee name**	**Position**	**Interview duration**	**Format**	**Date**
(Anonymous)	*(Anonymous)*	Founder & CEO	44:23:00	Zoom	12.04.2024

BIOVOX	Julian Lotz	Co-founder & CEO	55:48:00	Zoom	21.03.2024
Envetec	Malcolm Bell	Founder & CEO	40:37:00	Zoom	23.04.2024
Green Elephant Biotech	Felix Wollenhaupt	Co-Founder & Managing Director	24:50:00	Zoom	22.03.2424
TORSKAL	Anne-Laure Morel	Founder & CEO	32:42:00	Zoom	20.03.2024

Table 2: Interviews Data[7]

During the interviews, the questions' main theme aimed at the experiences, strategies, and impacts of the startups, particularly focusing on their journey from founding to scale-up, key success factors, engagement with investors, and their role in addressing and influencing sustainability challenges within the industry. The full interview guidelines can be found in Appendix C while the order of which question was asked first was adapted to the flow of the conversation, which is acceptable in a semi-structured interview process (Kallio et al., 2016). Each interview lasted 24 to 56 minutes while the different duration of the interviews cannot be attributed to a different interview process but merely to the precision of the interviewee's answers and their personal preference for storytelling. The interviews were conducted online via the video communication platform "Zoom", electronically recorded and transcribed within 24 hours. For the transcribing process, the integrated transcription tool in Word was used to reduce the time needed to transcribe the recording, allowing the user to upload a voice recording and generate the interview in written text. To make sure that the transcription is accurate, a data cleaning process followed where any transcription errors were corrected manually (Saunders et al., 2016). The interviews with BIOVOX, Green Elephant Biotech and the anonymous one were conducted in German as both the interviewees and researchers are native Germans, while the interviews with Envetec and TORSKAL were conducted in English. After transcribing the German interviews, the transcript was accurately translated into English with the support of the machine translation program "DeepL.com".

Finally, all information from the documents and the interviews were collected in Excel. Then, each startup received a summarised overview of all the information that had been collected individually via mail to give them the opportunity to revise the information and make sure no wrong or confidential information was processed in the data analysis.

[7] (Own illustration)

3.3.3 Qualitative Data Analysis

The qualitative data analysis follows an exploratory method to understand a phenomenon of which the authors had limited prior understanding. According to Saunders et al. (2016), one of the benefits of this research type is its flexibility and adaptability. Hence, a researcher can adjust the direction of the analysis process to be more applicable to new data or unexpected insights. A thematic analysis was employed which is an iterative data analysis process that develops themes that are relevant to the specific research questions and context through the recognition of patterns within the collected data (Braun & Clarke, 2006; Roberts et al. 2019). It allows for both describing and interpreting the data for meaningful insights and is a common method for analysing semi-structured interviews (Roberts et al. 2019, Thomas & Harden, 2008). The overall analysis approach was deductive, or theoretical, where researchers use a framework, often referred to as a start list, to organise the themes for the coding process (Bradley et al., 2007; Braun & Clarke, 2006; Miles et al., 2019). The list comprises core concepts or codes that can be anticipated in the data based on the existing literature about the research questions (Bradley et al., 2007). Finally, a semantic approach was applied where themes were derived from the explicit content of the data, without attempting to uncover anything more profound or implicit (Braun & Clarke, 2006).

The data analysis process followed a step-by-step guide provided by Braun & Clarke (2006), including six phases of analysis in a non-linear, recursive process, moving back and forwards between different phases. The process started by reviewing all information from the documents and the interviews that were collected in the Excel sheet to become extensively familiar with the data while taking notes about the first interesting characteristics. Then, a start list of initial codes was generated based on the data that seemed to be relevant to the sustainability challenges and approaches of the pharmaceutical industry or the characteristics of a startup found in the literature. In the third step, techniques such as pattern analysis and thematic grouping were used to sort different codes into potential themes and allocate relevant data to the different themes. Then, the authors reviewed, combined or divided the themes to ensure a shared understanding of their meanings and identifiable distinctions between themes. Finally, themes were defined and renamed, resulting in a final list of codes that clarified what aspect of the analysis the themes captured. During this process, the main topics of the coding scheme are closely aligned with the qualitative sub question, namely “How does a startup look like that successfully addresses sustainability challenges of the pharmaceutical industry” and “How can it influence

the whole industry". The coding scheme can be found in Appendix D. Appendix E shows an exemplary screenshot of the Excel document used during the manual coding process.

The results of the analysis were first summarised individually for each case to cope with the large volume of data and can be found in the respective "Single-Case Results" section (Eisenhardt, 1989). Then a cross-case analysis followed, using data triangulation to compare the insights of each case with each other and identify similarities and differences across the five cases. The cross-case conclusions and answer the qualitative research question. This comparative analysis aimed at generating broader insights and enhancing the generalizability of the findings. At first, identified themes from the single-case analysis were aggregated to create a comprehensive list of themes across all cases. This step involved reviewing the themes from each case and combining similar themes while maintaining the uniqueness of context-specific themes. Then, for each theme, one table was created that summarized the respective key points from each case and analysed to identify common patterns and variations across the cases. Finally, similar key points were categorized into broader thematic areas and outlined in a "Cross-Case Report" which forms the foundation to answer the qualitative sub research question.

3.3.4 Ethical Considerations in Qualitative Research

The authors of this thesis paid special attention to gaining informed consent prior to data collection from all persons who were part of this case study, by informing them about the nature of the case study, its purpose, procedures, potential risks, and benefits. They were assured of their voluntary participation and their right to withdraw from the study at any time without giving a reason. Before commencing the research, the research protocol, including the informed consent process, data collection methods, and data management procedures, were reviewed and approved by SIKT, a Norwegian government agency and service provider for the knowledge sector, to ensure compliance with ethical standards and Norwegian laws.

To obtain written consent, each interview participant received a data protection information letter, based on a template from SIKT. The letter included a consent form where the interviewees had to sign that they give consent to participate in the interview, for the personal data to be processed and stored and that their personal name, position in the startup and the startup's name can be published in the thesis. One startup disagreed with the last point and wanted to stay anonymous. To ensure confidentiality, no company or personal name of this specific startup were included in the case study results and the CEO is referred to as "they/

them" to reveal no gender. Nevertheless, the startup explicitly acknowledged that it is acceptable if the case description can lead to assumptions about which startup it is. In this regard, the anonymous startup received and approved the exact wording of the section "4.2.2 Single-Case Report: Anonymous".

Finally, all data was stored securely on password-protected devices and encrypted cloud storage platforms accessible only to the research team and their supervising team. Confidentiality agreements were upheld throughout the research process, ensuring that sensitive information shared by participants remained confidential and protected from unauthorized access.

During the research process, participants were treated with respect while their perspectives were valued and considered in the analysis. Close attention was paid to possible vulnerabilities to reduce any kind of pressure or unfair behaviour. In addition, efforts were made to minimize potential harm or discomfort, and participants were given opportunities to ask questions, seek clarification, and express concerns. Sensitive topics were approached with care and sensitivity, and transparency and integrity were present throughout the whole research process. Finally, the findings were reported accurately and honestly, reflecting the data collected and analysed without distortion or manipulation. After summarizing each single case, each startup received their single-case results to check, whether incorrect/ misleading sentences or any confidential information were included.

3.3.5 Reflection on Validity, Reliability and Objectivity in Qualitative Research

To meet construct validity, the specific terms related to the research questions were defined in the theoretical part. Furthermore, multiple sources of evidence were used to encourage convergent lines of inquiry and build a robust database. Moreover, sending out the results from every single case to the CEO of the startup before the insights were processed further, ensured that no wrong or misleading information was included in the cases.

Internal validity was ensured in two ways. Firstly, using several sources of evidence led to a data triangulation process, comparing the evidence that was found in the interviews with the one from the documents and the documents among each other. This enabled the development of converging lines of inquiry. And secondly, investigator triangulation was applied, so that the authors independently coded the data and discussed the allocation results, as required by established case study methodology researchers (Yin, 2008; Denzin, 2006). Any discrepancies in coding were resolved through discussion and consensus between the coders. To do so, the authors started the data analysis process by reviewing all collected data to get familiar with each

case and then independently coded each section. Finally, they performed a dyadic within-case analysis, followed by a cross-case analysis to find reoccurring descriptions and patterns.

To enable external validity, a multi-case method was used so that possible single-case specific characteristics do not distort the result regarding generalisation. Moreover, to establish communicative validity within the interviews (Kvale, 1995), the interviews started with an explanation of the term environmental sustainability and each of the challenges and approaches in the pharmaceutical industry concerning sustainability that had been found in the literature.

Furthermore, to increase the reliability of the information that was collected during the case study, the principle of "Maintaining the chain of evidence" presented by (Yin, 2008) was used (shown in Figure 6). This principle enables the reader to trace the development of evidence from the initial research question to the final conclusions drawn in the case study and vice versa. Thus, the results use citations referring back to the case study database (see Appendix B) that lists all used sources, enabling the reader to distinguish between biased interview results and objective facts and allowing future researchers to separate different results for secondary analysis (Yin, 2008). With that, the authors used their highest ambition to ensure quality control during the whole data collection process.

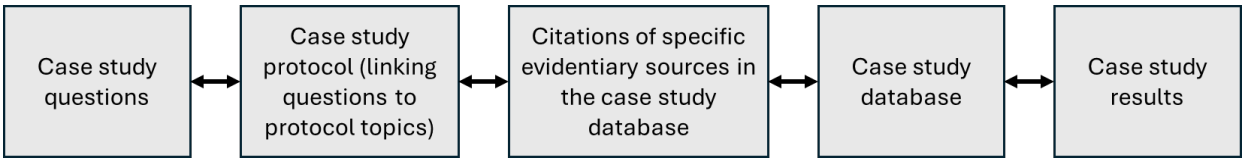

Figure 6: Chain of Evidence[8]

Finally, potential biases were acknowledged to ensure objectivity in the qualitative data collection process. To address selection biases**,** decreasing the representative of a study´s result for the broader population, a purposeful sampling strategy was applied, selecting cases based on specific characteristics that are relevant to the research question (Creswell, 2013). Furthermore, social desirability biases were considered as interviewees might give responses that are favourable for their startup (Krumpal, 2011). Therefore, the interviewers established rapport and trust during the introduction call and triangulated data sources.

[8] (Own illustration)

4. Results

In this chapter, the outcomes of the mixed methods research that aimed to investigate how startups contribute to sustainability in the pharmaceutical industry are presented. It includes the analysis and interpretation of survey responses, and the findings of the case study.

4.1 Quantitative Results

This section contains the findings of the quantitative study. The outcomes of the survey will be examined and presented alongside the findings. Within this chapter, the findings are displayed as descriptive statistics and tables generated by the SPSS software. The subsections are organized based on the framework of the research, namely the eight approaches to sustainability. The initial section focuses on the demographic variables of the survey, solely used to reaffirm the companies' role as startups per Alex Wilhelm's definition (Wilhelm, 2014), as well as their activity in the pharmaceutical sector. The final section demonstrates the findings of the descriptive statistics. This evaluation serves as the basis for answering the sub-question of which key strategies startups in the European pharmaceutical industry utilize to facilitate the transition towards sustainability.

The survey, which was employed due to its provision of a snapshot of sustainability measures in the industry (Wang & Cheng, 2020), was individually sent out to 523 people via LinkedIn inMail messages. Out of those, approximately 16.06% (n=84) filled out the questionnaire (as seen in Table 3).

Response Rate	**N**	**%**
Sent Out Surveys	523	100
Filled Out Questionnaires	84	16.06

Table 3: Survey Response Rate[9]

4.1.1 Demographic Variables

Roles of Participants. Due to the business strategic nature of the questions within the questionnaire, the survey was mainly sent out to higher-level stakeholders of startups in roles such as CEO, Development Manager, or Managing Director. Resultingly, the biggest percentage of participants inhabit the position of CEO within their companies at 69.0% (n=58). This number is followed by 7.1% (n=6) Chief Scientific Officers, and then Managing Directors

[9] (Own illustration)

who make up 6.0% (n=5) of the total participants. The other percentages of roles participants stated range between 1.2% (n=1) and 3.6% (n=3). The majority of C-level positions ensured that the survey was answered by the startup-relevant people. Figure 7 shows the detailed distribution of respondents' roles within their startups.

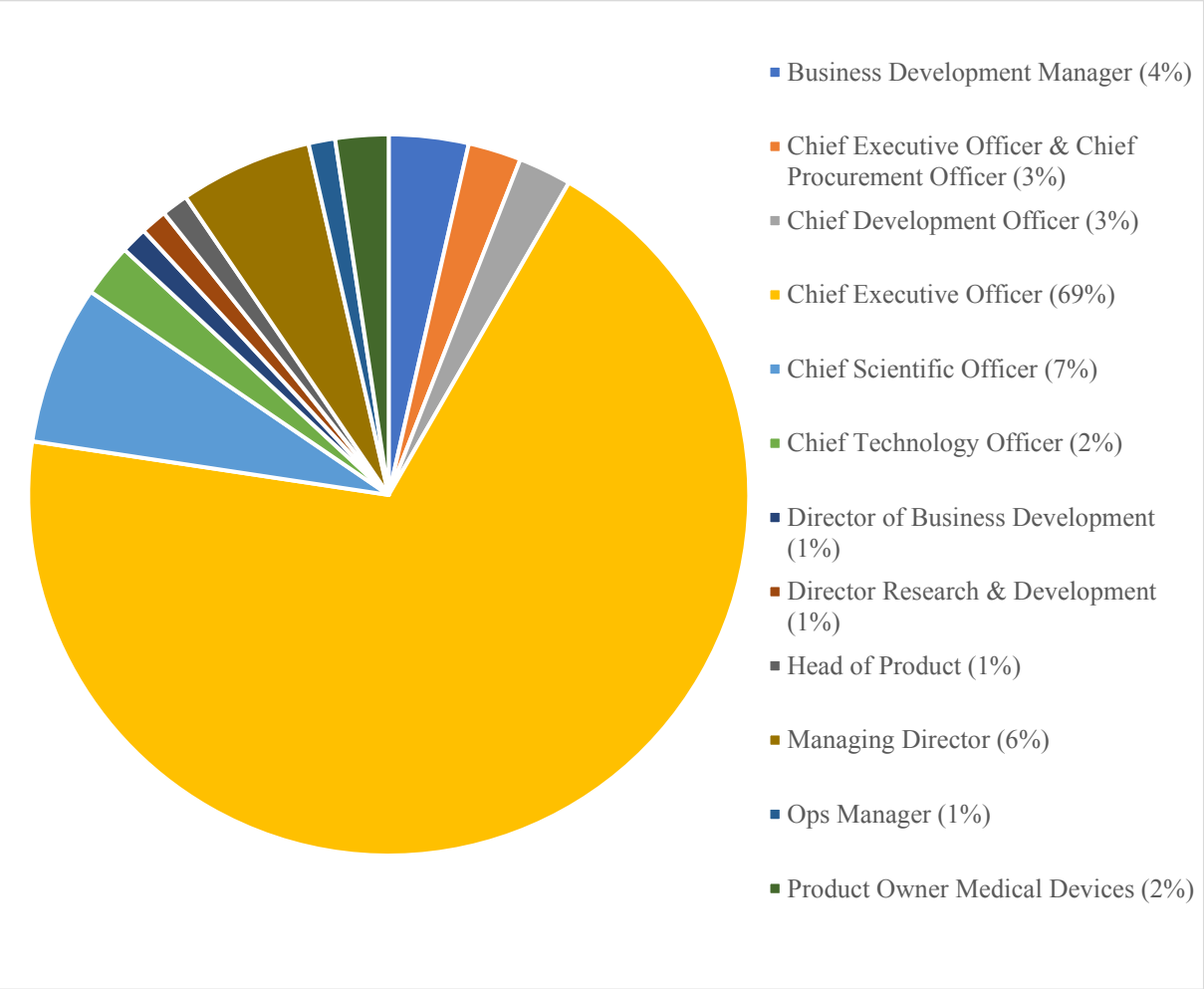

Figure 7: Roles of Respondents[10]

Locations of Startups. The study focuses on startups within the European Union. Since the sampling followed a simple random sampling method, the participants were chosen at random, without taking their startup's country of origin into consideration. Figure 8 shows the detailed distribution of the startups' countries of origin. Germany makes up the biggest percentage with 28.6% (n=24), followed by participants from France and the Netherlands with 11.9% (n=10) each. The breakdown of the countries' share in the overall population can be understood by looking at the proportional contribution of each nation. This provides insights into how the different countries are represented within the demography. According to Crunchbase, German

[10] (Own illustration)

pharmaceutical startups make up approximately 16% (n=148), France 14.6% (n=134), and the Netherlands 8.28% (n=76) of the population (Crunchbase, 2024).

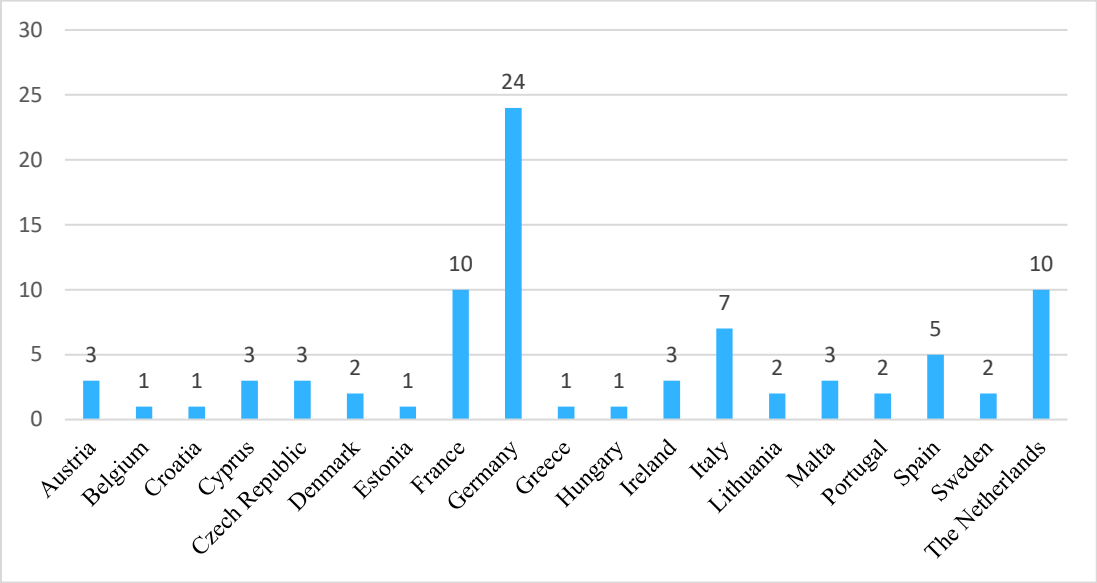

Figure 8: Locations of Surveyed Startups[11]

4.1.2 Sustainability Approaches

The main section of the questionnaire follows the framework of the eight approaches to sustainability. For each approach, the first question was whether the startups in question make use of the approach within their operations. To analyse the outcome in SPSS, the responses were coded: for every "no", a 0 was put into place; for every "yes", a 1 was used. "Missing" variables are instances where participants chose the answer "I am unsure".

In the next step, respondents were asked to indicate a value on a 5-point Likert scale to what extent they believe the approaches have positively impacted their startup's sustainability performance. The scale ranges from 1 to 5, with the former meaning "Strongly Agree", and the latter "Strongly Disagree". Below Table 4 depicts the detailed output received for each of the sustainability approaches.

[11] (Own illustration)

		Sustainable Business Model	Sustainable Assessment Model	Sustainability Reporting	Circular Business Model	Green Supply Chain Management	Sustainability Production	Technology Integration	Resilience Strategies
N	Yes	45	32	28	20	24	34	66	23
	No	39	52	56	64	60	50	18	61
Mean		2.42	2.75	2.71	2.60	2.25	2.24	2.14	2.35
Std. Error Of Mean		.151	.191	.191	.311	.173	.216	.148	.173
Median		3.00	3.00	3.00	2.00	2.00	2.00	2.00	2.00
Std. Deviation		1.011	1.078	1.013	1.392	.847	1.257	1.201	.832
Variance		1.022	1.161	1.026	1.937	.717	1.579	1.443	.692
Skewness		-.123	-.289	-.061	.812	-.059	.304	.718	.792
Std. Error Of Skewness		.354	.414	.441	.512	.472	.403	.295	.481

Table 4: Summary of Descriptive Statistics[12]

In the following section, data about each sustainability approach will be analysed and interpreted individually.

[12] (Own illustration)

Sustainable Business Models. SBMs include various criteria along technological, social, and organizational dimensions to achieve corporate sustainability objectives (Chomać-Pierzecka, 2023). About half of the respondents (53.6%) claimed to use sustainable business models (SBMs) while the other half (46.4%) did not (shown in Table 5). Although SBMs are becoming increasingly popular, there are still many companies that have not embraced them. It shows that there is room for growth in the implementation of sustainable practices, but it also suggests that there are obstacles or doubts that need to be addressed when it comes to SBMs. With an average score of 2.42, participants who use SBMs tend to agree that they are a helpful way to incorporate sustainability into business practices. However, the median score of 3.00 shows that opinions are mixed. While there is some agreement on the usefulness of SBMs, opinions are still divided.

	N	%
No	39	46.4%
Yes	45	53.6%

Table 5: Frequency of Sustainable Business Models[13]

Moderate variability in responses, as indicated by the standard deviation of 1.011, implies that individual experiences with SBMs may differ (Schendera, 2015). These differences indicate contrasting levels of commitment, implementation quality, or the particular sustainability criteria addressed by various SBMs. The slight negative skewness of -0.123 in the responses shows that more respondents tend to agree (lower end of the scale), although not significantly so (Schendera, 2015). While the median is balanced, this minor skew suggests a cautious but overall agreement on the positive impact of SBMs in promoting sustainability. The standard error of skewness, which is 0.354, supports the notion that opinions are distributed symmetrically. This indicates that there is no significant bias towards either agreement or disagreement among respondents. These values are illustrated in Figure 9.

[13] (Own illustration)

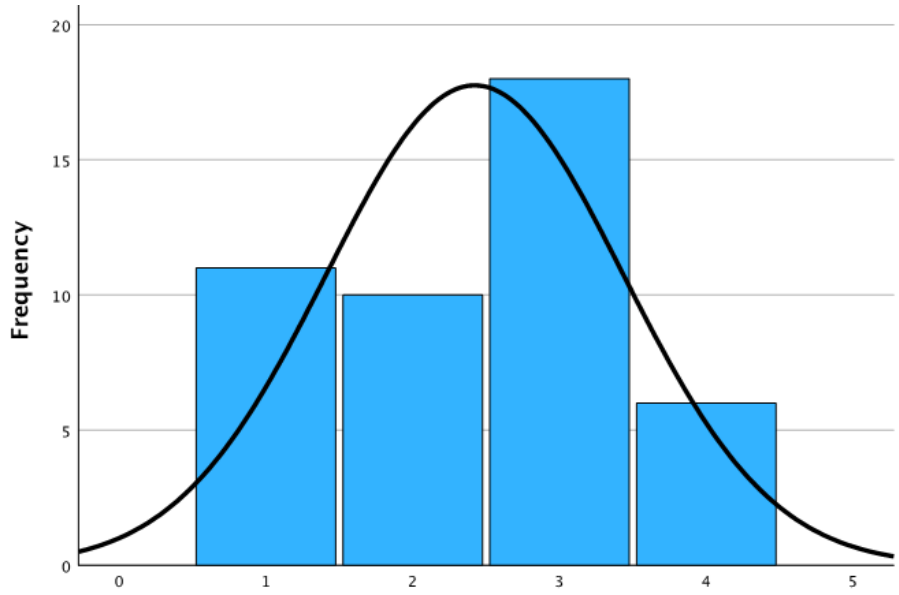

Figure 9: Histogram of Sustainable Business Models[14]

In general, the results show that SBMs can contribute to making companies more sustainable, but with caution. Although many companies have adopted SBMs and view them positively, the mixed and moderately varied responses indicate that more research is needed to determine what factors make SBMs more effective or attractive to different types of businesses.

Sustainable Assessment Models. Sustainable Assessment Models are used to evaluate and improve the environmental impact of production and manufacturing stages (Lozano et al., 2018; Heijungs et al., 2010). According to the data of this study (shown in Table 6), most participants (58.3%) don't use SAMs, while 38.1% do. A small percentage of respondents (3.6%) were unsure about their use of them. This suggests that while some people are aware of and use SAMs, a significant portion of those surveyed either don't see the value or don't have enough information about them. The mean response to the effectiveness of SAMs is 2.75, which is close to the median of 3.00. This suggests that opinions are divided and there is no clear consensus on the effectiveness of SAMs. Users seem to have a balanced view overall. Hence, there is no clear indication as to whether the implementation of Sustainable Assessment Models positively benefits a company's sustainability efforts.

	N	%
No	49	58.3%
Yes	32	38.1%
I'm unsure	3	3.6%

Table 6: Frequency of Sustainable Business Models[15]

[14] (Own illustration)
[15] (Own illustration)

The standard deviation is recorded as 1.078, indicating a moderate range of responses around the mean (Schendera, 2015). The skewness of the data is -0.289, indicating a slight leftward (negative) skew, suggesting a slight inclination for responses to cluster towards the higher end of the scale, disagreeing with the questionnaire's statement (Schendera, 2015). However, this inclination is so minimal that it may not hold statistical significance. This notion is further supported by the standard error of skewness, which is 0.414, a relatively large value compared to the level of skewness. Thus, it can be further solidified that the distribution of responses and therefore the opinions on whether Sustainable Assessment Models encourage sustainability follow a symmetrical distribution. These values are illustrated in Figure 10.

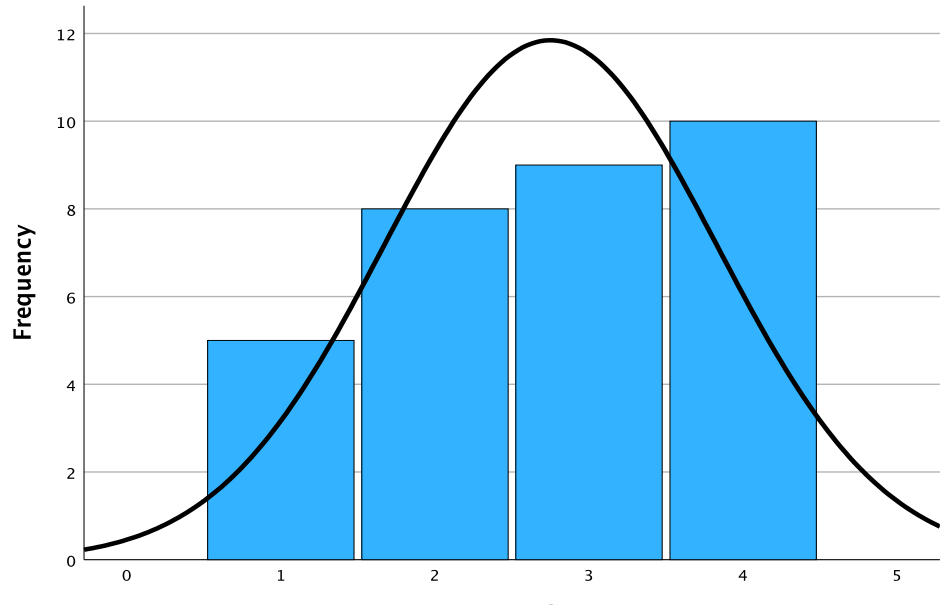

Figure 10: Histogram of Sustainable Assessment Models[16]

Overall, the results provide a nuanced view of the role of SAMs in pharmaceutical startup's sustainability initiatives. The nearly equal distribution of opinions highlights the complexity of implementing environmental assessments. The slightly negative trend suggests some reservations about the models' effectiveness, which indicates gaps in their implementation or the need for models that are better made for specific sector requirements.

Sustainability Reporting. This approach refers to the practice of providing wide-ranging and in-depth information on sustainability aspects, in which companies from the pharmaceutical industry are forerunners (Demir

	N	%
No	56	66.7%
Yes	28	33.3%

Table 7: Frequency of Sustainability Reporting[17]

[16] (Own illustration)
[17] (Own illustration)

and Min, 2019). In the survey, it was discovered that 66.7% (n=56) of startups do not partake in Sustainability Reporting, while the remaining 33.3% (n=28) do (as shown in Table 7). This finding is unexpected since previous research, like the one conducted by Demir and Min (2019), suggests that companies, especially in the pharmaceutical industry, are at the forefront of this practice. This inconsistency could indicate startup-specific trends or obstacles to adoption, such as limited resources or a lack of perceived immediate benefits. The mean response of 2.71 on the Likert scale, which is slightly below the median of 3.00, implies a slight inclination towards agreement that Sustainability Reporting supports sustainability initiatives. However, the nearly equivalent median value suggests a balanced distribution of opinions, indicating that there is no clear consensus either way (Schendera, 2015).

Furthermore, the standard deviation, calculated to be 1.013, indicates a moderate variability in the responses (Schendera, 2015). This suggests that the participants' answers were somewhat dispersed across the scale, although not to an extreme extent. The skewness level is at -0.061 which is close to zero, showing the rather symmetrical distribution of responses (Schendera, 2015). However, since it is negative, there is a very slight tendency towards the lower end of the scale. This does show a slight indication of participants agreeing with the notion that Sustainability Reporting aids in sustainability efforts. Nonetheless, the standard error of skewness lies at 0.441 which is relatively large compared to the value of skewness. It therefore suggests that the skewness level is not significantly different from zero and the authors cannot confidently say that the distribution is not symmetrical based on this sample. Overall, the sample suggests that there is a minute agreement among respondents that sustainability reporting helps increase sustainability efforts. These values are illustrated in Figure 11.

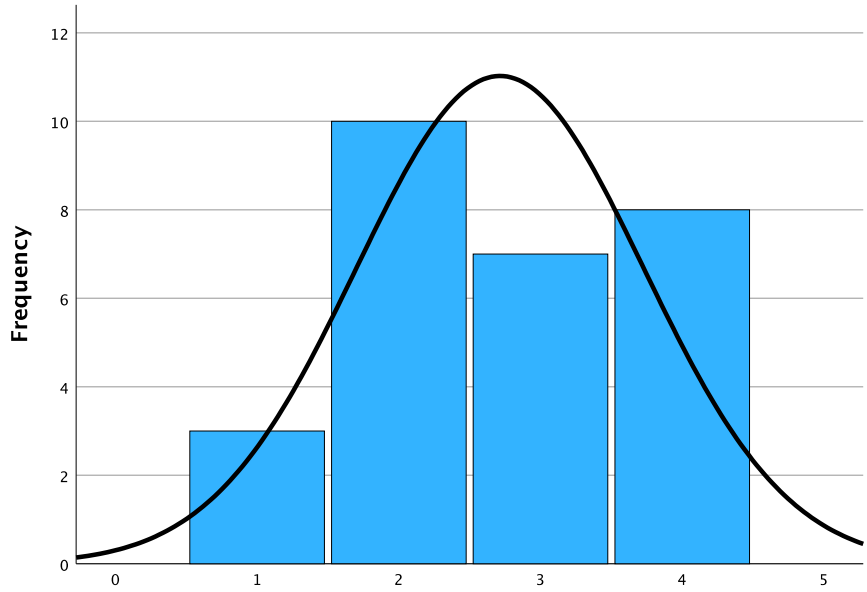

Figure 11: Histogram of Sustainability Reporting[18]

In general, the data shows that only a few startups participate in Sustainability Reporting. Among those that do, there is a bit of disagreement about whether it actually helps sustainability efforts, though it leans towards a positive view.

Circular Business Models. The idea of a circular economy is centred on a regenerative structure that aims to reduce the use of resources and the creation of waste by creating closed systems for materials and energy (Soomro et al., 2022). According to the survey, 76.2% (n=64) of those who participated do not incorporate Circular Business Models in their company, while only 23.8% (n=20) do (as shown in Table 8). This implies that even though a circular economy is gaining attention in academic and policy discussions, it is not yet widely utilized in practical business settings. The majority of the respondents, with a mean score of 2.6 and a median of 2.00 on the Likert scale, tend to agree that CBMs have a positive effect on sustainability. The lower median compared to the mean indicates that a significant proportion of the responses are located at the lower end of the scale. This response pattern shows a stronger agreement among those who are familiar with CBMs regarding their benefits on sustainability compared to other sustainability practices previously surveyed.

	N	%
No	64	76.2%
Yes	20	23.8%

Table 8: Frequency of Circular Business Models[19]

[18] (Own illustration)
[19] (Own illustration)

The standard deviation stands at a value of 1.392. This means that there is a high spread of responses along the mean (Schendera, 2015). The skewness of 0.812 indicates a moderately positive skew and a longer tail on the right side of the distribution with more respondents selecting options on the lower end of the scale (Schendera, 2015). The standard error of skewness lies at 0.512. Generally, a skewness value that is twice as high as its standard error counts as a significant skew. Here, it is only slightly larger than the standard error which makes its significance ambiguous. These values are illustrated in Figure 12.

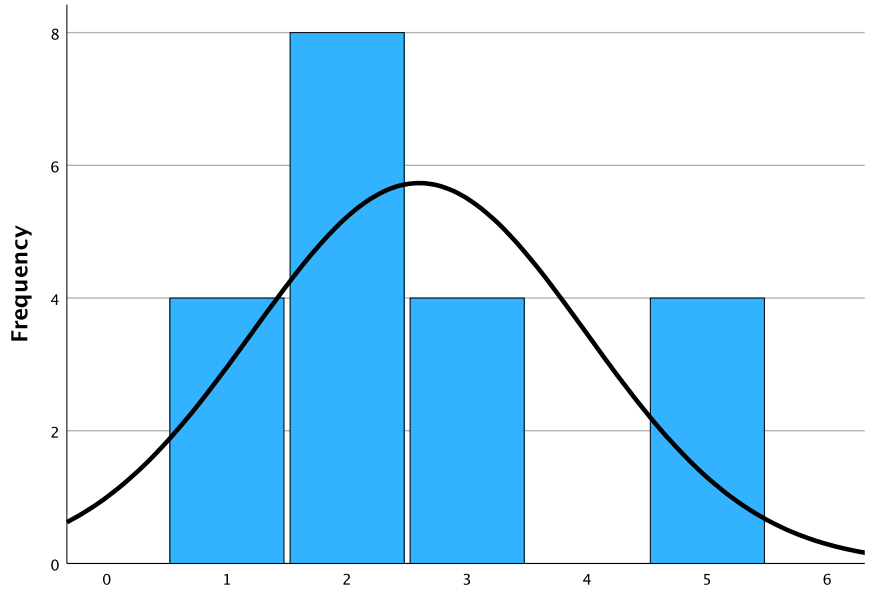

Figure 12: Histogram of Circular Business Models[20]

The data suggests a cautious but positive perception of Circular Business Models among the participants who have adopted them, with a clear agreement on their potential to be beneficial to sustainability efforts.

Green Supply Chain Management. Sustainable Supply Chain Management empowers decision-makers and managers to formulate crucial guidelines and plans for integrating sustainable methods across the entire organization (Ahmad et al., 2022). Similarly to the sustainability approach before, most of the respondents, 69% (n=58), do not utilize Green Supply Chain Management in their business operations. Meanwhile, 28.6% (n=24) of the surveyed

	N	%
No	58	69.0%
Yes	24	28.6%
I'm unsure	2	2.4%

Table 9: Frequency of Green Supply Chain Management[21]

[20] (Own illustration)
[21] (Own illustration)

entities engaged in GSCM, and 2.4% (n=2) were unsure. This data is depicted in Table 9. This indicates that while GSCM is considered a crucial aspect of sustainable practices, it has yet to be widely adopted. The mean response on the Likert scale is 2.25, with a median of 2.00, both of which fall below the midpoint of 3.00. These figures reveal that most respondents agree that GSCM benefits sustainability efforts, as their responses are mainly clustered towards the lower end of the scale.

The standard deviation of 0.847 shows moderate variability in responses, meaning that while there is a general consensus on the positive effects of GSCM, experiences and opinions still differ to some degree (Schendera, 2015). Furthermore, the skewness level amounts to -0.059 which suggests a slight skew to the left. However, this value is quite close to zero, so the distribution is approximately symmetrical (Schendera, 2015). With a standard error of 0.472, the skewness is not significantly different from zero because the standard error is larger than the skewness value itself. Due to the small sample, the outcome may be biased. However, there is an indication that introducing Green Supply Chain Management into the operations may help facilitate sustainability efforts. These values are illustrated in Figure 13.

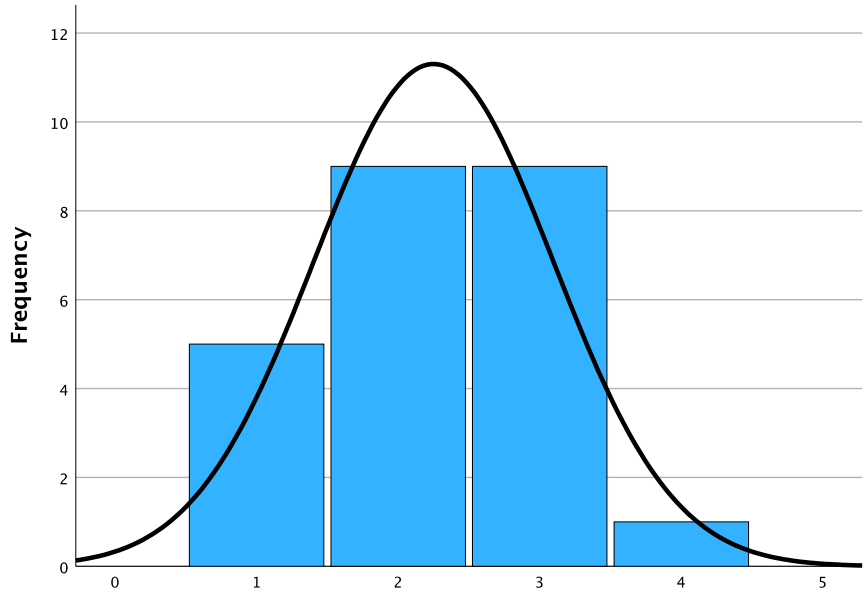

Figure 13: Histogram of Green Supply Chain Management[22]

The results indicate that Green Supply Chain Management is well-regarded by adopters, consistent with existing literature that emphasizes its role in promoting sustainability. However, the significant percentage of non-adopters highlights the need for more awareness and resources to help businesses overcome obstacles to implementation.

[22] (Own illustration)

Sustainable Production. This idea centres around creating and manufacturing pharmaceutical products in an environmentally friendly way, intending to reduce any harm they may cause to people's health (Waghmode et al., 2023). The responses of whether startups use sustainable production principles were again slightly more balanced than the two approaches before. 59.5% (n=50) of all 84 respondents do not use such principles, while 40.5% (n=34) do (as shown in Table 10). This relatively balanced distribution shows an interest in sustainable practices, though a majority still do not adopt them. The reasons behind this might be challenges with changing production processes or higher initial costs The mean response on the Likert scale is 2.24, with a median of 2.00. Both figures are on the lower end of the scale, showing that respondents generally agree that sustainable production practices benefit their sustainability efforts. This indicates that there is a recognition of the value of sustainable production, even though a majority are not currently implementing these practices. Furthermore, with a value of 1.257 as the standard deviation, there is a considerable variation in responses around the mean (Schendera, 2015). Hence, some respondents may find Sustainable Production principles to be greatly enhancing sustainability efforts, while others may not see such a benefit. The skewness level of 0.304 indicates a slightly positive skew. This points to a longer tail of responses on the higher tail of the distribution, meaning that while the consensus is favourable, a smaller group possibly sees a detriment (Schendera, 2015). The value is relatively close to zero which means that the skew is not particularly pronounced. The standard error of skewness amounts to 0.403. The level of skewness is not significantly larger than this value, leading to the assumption that the skew might not be statistically significant. These values are illustrated in Figure 14.

	N	%
No	50	59.5%
Yes	34	40.5%

Table 10: Frequency of Sustainable Production[23]

[23] (Own illustration)

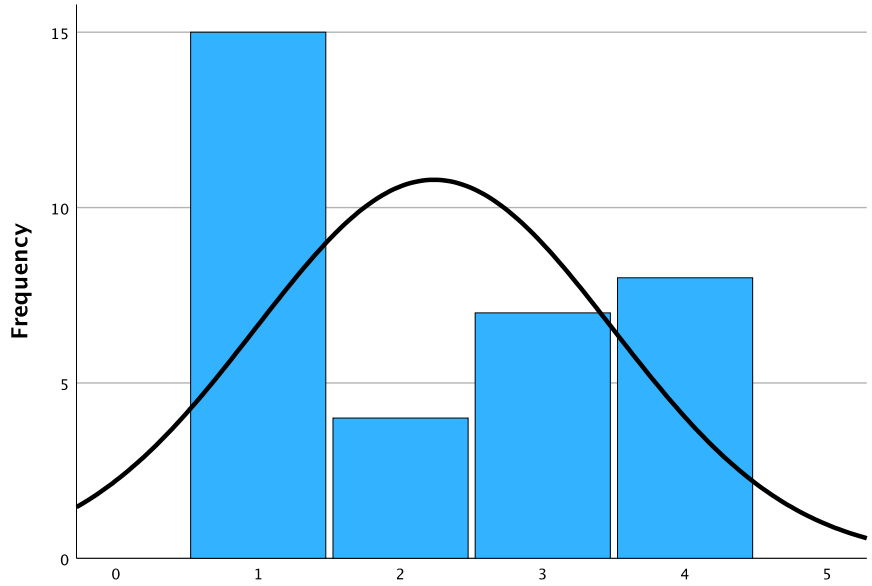

Figure 14: Histogram of Sustainable Production[24]

The data shows that pharmaceutical startups are increasingly recognizing the importance of Sustainable Production practices. Nevertheless, the varying response rates and adoption levels highlight the complex and challenging nature of fully integrating these practices.

Technology Integration. Technological advancements ensure access to innovative and cost-effective drugs for everyone (Chomać-Pierzecka, 2023), and offer long-term solutions for decreasing CO_2 emissions (Xu & Tan, 2022). As opposed to the other approaches, there is a distinctly larger sample of respondents using the integration of digital tools in their operations. 79.8% (n=67) of participants use such technology, as opposed to the 20.2% (n=17) of respondents who do not (as depicted in Table 11). This high adoption rate contrasts with other areas like Sustainable Production or GSCM, suggesting that Technology Integration is viewed as a more accessible or immediately beneficial approach. The high usage likely reflects the recognized benefits of Technology in improving efficiency, reducing costs, and potentially decreasing environmental impacts, which align with the long-term sustainability goals of reducing CO_2 emissions as stated by Xu & Tan (2022). The mean stands at 2.14, indicating that participants generally answered on the lower end of values. Furthermore, the median is 2.00 which further

	N	%
No	17	20.2%
Yes	67	79.8%

Table 11: Frequency of Technology Integration[25]

[24] (Own illustration)
[25] (Own illustration)

solidifies the tendency for participants to vote for values below that point. Hence, people seem to perceive the integration of new technologies as beneficial in their sustainability efforts.

With a standard deviation of 1.201, the responses show a significant spread around the mean (Schendera, 2015). This points to diverse experiences with Technology Integration among respondents. Despite the generally positive perception, the variation suggests differences in how technology is used or its perceived effectiveness in different contexts. The skewness of 0.718, with a standard error of skewness at 0.295, shows a moderately positive skew, suggesting that while many responses are positive, there is a considerable number of less positive responses (Schendera, 2015). The skewness being statistically significant indicates that responses are not symmetrically distributed, with a longer tail of less positive assessments. These values are illustrated in Figure 15.

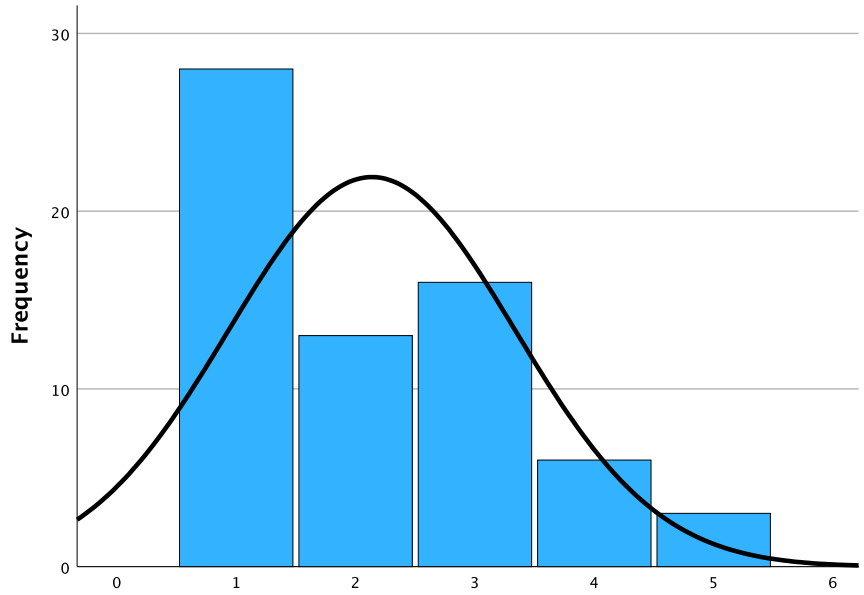

Figure 15: Histogram of Technology Integration[26]

Overall, the data supports the idea that technology integration is an important tool for increasing sustainability within business operations. The findings suggest that most companies acknowledge the advantages of technology in promoting sustainable practices, such as optimizing efficiency and minimizing environmental impacts.

[26] (Own illustration)

Resilience Strategies. By examining the potential risks posed by disruptions, such as analysing transportation expenses and considering environmental impacts, pharmaceutical companies can make well-informed and systematic decisions (Abdolazimi et al. 2023). Out of the 84 participants, 65.5% (n=55) said they do not use any resilience strategies within their operations, while 27.4% (n=23) responded the opposite, and 7.1% (n=6) were unsure about their answer (as shown in Table 12). This distribution suggests that a significant number of companies might not be very well prepared to handle disruptions, which could include logistical issues, environmental factors, or other unpredictable challenges that might impact their operations. The mean of this sample is 2.34 which is slightly above the scale's median of 2.00. This highlights a recognition of the importance of such strategies, even though not all respondents have adopted them.

	N	%
No	55	65.5%
Yes	23	27.4%
I'm unsure	6	7.1%

Table 12: Frequency of Resilience Strategies[27]

The standard deviation is 0.832, showing a moderate spread of responses around the mean, suggesting that while there is consensus that Resilience Strategies aid sustainability efforts, opinions vary among participants (Schendera, 2015). At 0.792, the level of skewness indicates a moderate positive skew (Schendera, 2015). This confirms that there are more responses at the lower end of the scale. However, with a standard error of skewness at 0.481, the skewness detected might not be statistically significant. Since the sample is rather small, the outcome may be biased. Nevertheless, there is an indication that using resilience might help facilitate sustainability efforts. These values are illustrated in Figure 16.

[27] (Own illustration)

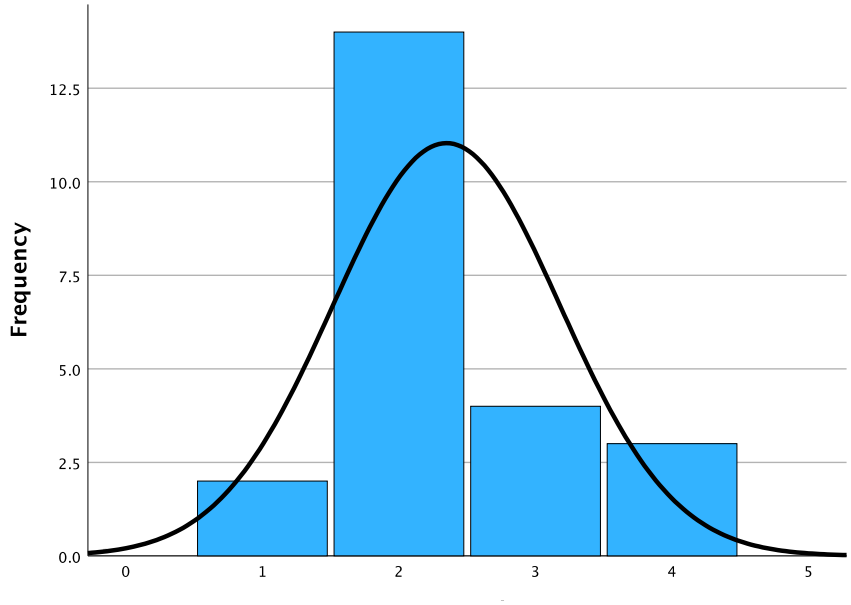

Figure 16: Histogram of Resilience Strategies[28]

Overall, the findings show that while some pharmaceutical startups recognize the benefits of implementing Resilience Strategies to manage risks and ensure sustainability, a majority do not employ these strategies.

4.1.3 Response to Sub Question I

The focus of the quantitative analysis is on the strategies employed by European Union pharmaceutical startups to move towards sustainability. The findings of the analysis centre on the eight different approaches to sustainability, of which the distribution can be seen in Figure 17.

[28] (Own illustration)

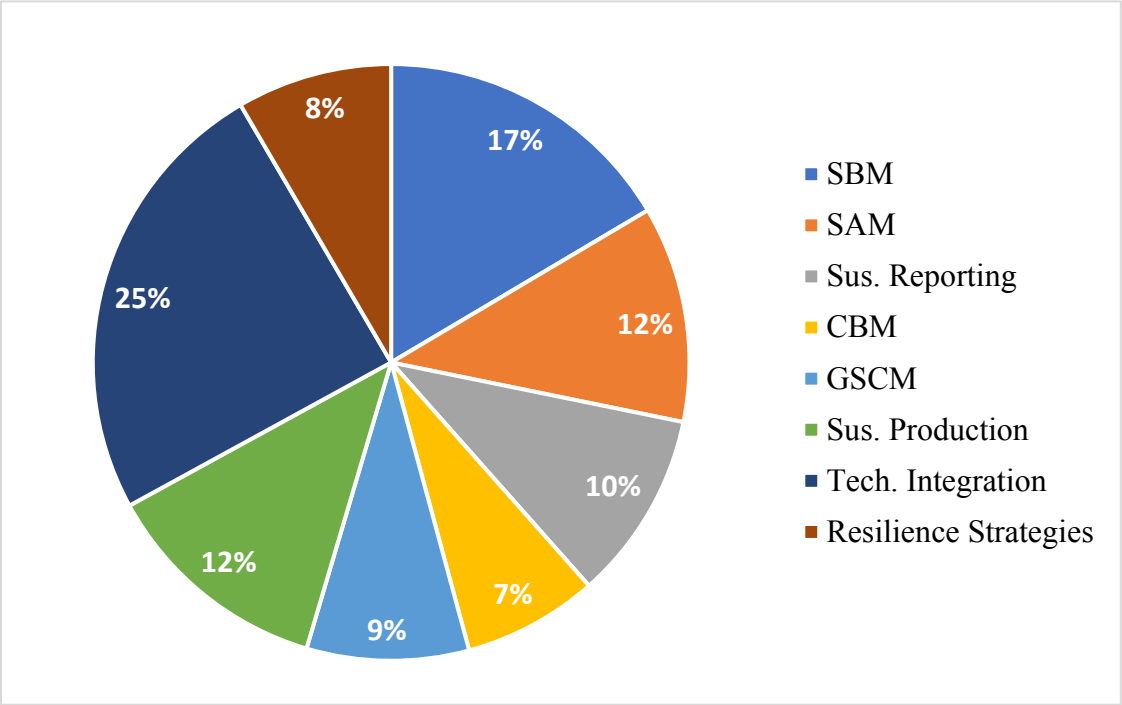

Figure 17: Distribution of Sustainability Approaches[29]

According to the preceding in-depth analysis, the research question for this quantitative part of the study (*What key strategies do startups in the European Union pharmaceutical industry utilize to facilitate the transition towards sustainability?*) can be answered: Out of all sustainability approaches, Sustainable Business Models, and Technological Integration were adopted at the highest rate by startups, closely followed by Sustainable Production, as well as Sustainable Assessment Models. Approaches that find less favour are Sustainability Reporting, Green Supply Chain Management, Resilience Strategies, and Circular Business Models.

4.2 Qualitative Results

This section contains the findings of the qualitative multiple-case study about five pharmaceutical startups with a sustainable core product in the EU. The results are divided into five single-case reports and one overall cross-case report. The single-case reports follow a consistent layout: At first, each section provides information about the company in general, its product and its mission. Then the specific characteristics of the products are applied to the sustainability challenges and approaches of the pharmaceutical industry that had been found in the literature. Afterwards, each single report highlights the general challenges and success factors the startup faced since its foundation, the reactions from investors and (potential) clients and the advantages of focusing on sustainability from the startup's perspective. Finally, each

[29] (Own illustration)

case addresses the current and potential influence of the startup and what is needed for the industry to change from the founder´s perspective. Subsequently, in a cross-case comparison, the cases are compared among each other. Differences and similarities are highlighted, and trends are emphasised, following the same content structure as in the single case descriptions.

The results serve as the basis for answering the sub-question of how startups look that successfully tackle sustainability challenges in the pharmaceutical industry, applying sustainability approaches, and how they can have an impact on the whole industry. The main data sources include primary data from the interviews with the founder/CEO of the startups (presented in Table 13). The number in the first column allows information in the results section to be assigned to the respective interview, as the transcripts of the interviews could not be attached to this thesis for data protection reasons. As advised by the supervisor of the thesis, any other information not referring to a self-conducted interview is not attributed to an explicit source, as the reader can find the general list of all analysed documents including the startup's website, newspaper articles and other publicly available sources in Appendix B.

Number	Company Name	Interviewee Name
#1	*(Anonymous)*	*(Anonymous)*
#2	BIOVOX	Julian Lotz
#3	Green Elephant Biotech	Felix Wollenhaupt
#4	TORSKAL	Anne-Laure Morel
#5	Envetec	Malcolm Bell

Table 13: Interview Numbering[30]

4.2.1 Single-Case Report: Anonymous[31]

Company. The anonymous startup is located in Europe and was founded in November 2019 but began operations in November 2021 focusing on a greener supply of APIs and their intermediates. Today, the startup has a 17-strong team, and it is planned to extend this number to 30 by the end of 2025. The idea for the startup stemmed from the founders' previous experience in a company they founded as a spin-off from a university in the field of Green Chemicals and Manufacturing. Thereby they observed a lack of sustainability and innovation in traditional chemical production and recognized an opportunity to scale up sustainable

[30] (Own illustration)
[31] The detailed description and exact wording of this section was approved by the CEO.

processes across the industry to bring about meaningful change. However, the team decided not to build their own plants to address this gap but to partner with existing producers to integrate sustainable practices into their operations. The CEO explained: “[...] we made a conscious decision not to build our own plants because we believe that you can't scale quickly enough and have a real impact on the industry fast enough that way.”. (Interview #1)

The company's patented approach includes a toolbox of innovative technologies and methodologies developed both through experience and acquisitions. The founder created a breakthrough method for producing complex molecules using water instead of petroleum-based solvents, laying the groundwork for sustainable chemical manufacturing. Building on this initial invention, the company continuously searches for additional technologies to enhance its portfolio, including acquiring technologies from external sources and internally developing new solutions. They assess these technologies against the green chemistry principles, developed by Professor John Warner, who is now part of their development team. This rigorous evaluation ensures that the company's innovations prioritize sustainability and environmental responsibility. Finally, the reason for choosing a flexible business model is the extremely fast dynamics of the sustainability sector in general and that of green chemistry. “[…] green chemistry is […] continues to develop because knowledge is constantly increasing. And things that you develop today, the things that you would call "green", may no longer be green in 10 years because there are much better things.” (Interview #1), explained the founder. (Interview #2)

Product. The startup utilizes cutting-edge computational chemistry and digitalization technology along with the green chemistry principles to offer a technology toolbox, that can repurpose costly resources, accelerate synthesis design and scaling, and oversee chemical production processes to guarantee optimal quality and efficiency. By leveraging machine learning, AI models, and quantum chemical simulations, the company´s patented chemical manufacturing processes reduce costs by up to 30% compared to traditional methods. Furthermore, their methodologies have the potential to minimize waste generation by up to 70% and reduce CO_2 emissions from drug development by up to 40%.

Mission. The startup's mission relates both to sustainability-related goals and to supply chain-related aspects. “The aim is to build up a green chemical industry” (Interview #1), said the CEO and explained that the startup’s ambition is to re-establish Europe as a prominent hub for chemical-pharmaceutical production, safeguarding critical infrastructure in the process. To

fulfil their mission, the startup wants to make green chemistry a trend. “Investors are herd animals, they always follow trends” (Interview #1) explained the founder, which is the reason why they engage in cross-industry organisations to represent the industrial interests of entrepreneurs and startup associations. (Interview #1)

Sustainability Challenges Tackled

Medical & Hazardous Waste	Through the startup´s technology toolbox, customers have achieved a waste reduction during chemical production of up to 71% (Interview #1).
Lack of Awareness	The startup, and especially its CEO, who is involved in many decision-making institutions like the Fraunhofer Institute, create awareness for green chemistry not only among the startup's customers but also among industrial policymakers. They explained: “You have to start encouraging people to see [sustainability] as a pool of innovation, you can generate competitive advantages by producing more sustainably”. (Interview #1)
Outsourcing	The startup's molecule formulas deliver cost reductions of no less than 10% for innovative APIs. The startup collaborates with European manufacturers to facilitate the decreased production costs. This ensures competitive pricing for generic APIs produced in Europe or the USA. Moreover, the startup formulated chemical manufacturing processes that are approx. 30% more cost-effective than conventional methods. Thanks to this cost reduction, European companies can keep up with Asian manufacturers in price competition or even undercut them, so that the EU can regain its position as a major player in pharmaceutical production. This approach has already proved successful in one of their biggest projects, bringing the production of one API producer back from Asia to Europe. (Interview #1)
Environmental Pollution	In addition to reducing hazardous waste, the startup´s customers can reduce the CO_2 emission generated through the production of APIs and their intermediates by up to 40%, depending on which alternative production process was used before.
Rushed Manufacturing	The company uses AI models and quantum chemical simulations to drastically reduce the time to develop a new API. Upon implementation of a process, the company utilizes data analytics to oversee plant output data, supplying clients with immediate insights into sustainability objectives and facilitating the prompt identification of potential errors in what is referred to

	as "first-time-right" production. The CEO summarized: “We help with this rushed manufacturing because we can develop the processes better from the outset and then get them into the plants more quickly”. (Interview #1)
Reporting	The CEO explained that there is a lack of data on the production level of APIs so it is impossible the give the CO_2 footprint of a specific production plant (Interview #1). “But we have this data and can also do this kind of reporting “, explained the founder. This can greatly refine the reporting of such companies and make it more precise and accurate.
Supply Chain Complexity	The startup has a huge network of many manufacturers for the supply of greener manufactured chemicals so that it is the single point of contact for your customers. This greatly simplifies the supply chain for their customers, as they do not have to search through all the different manufacturers to find sustainably produced APIs. (Interview #1)
R&D Intensity	Using AI and simulations, the company´s technologies not only enable pharmaceutical manufacturers to reduce the time to develop a new API but subsequently also the costs and even more importantly the success rate of an experiment during the R&D process by quickly identifying potential errors in pants.

Table 14: Anonymous Sustainability Challenges[32]

Sustainability Approaches Used

Sustainable Production	The startup uses the twelve green chemistry principles, a well-known approach in the literature, to integrate sustainability in the pharmaceutical industry. Thus**,** the use and generation of hazardous substances in the production of chemical processes can be reduced or even eliminated.
Technology Integration	The startup’s key advantage emerges from the integration of technological advancements, employment of advanced computer modelling techniques and a patented green tech toolbox to internally develop, refine, and scale up novel chemical processes and synthesis routes.
Reporting Approaches	Due to the high degree of technological integration, the company can monitor and measure its production processes very precisely and thus receive specific data about the environmental footprint. In addition, the startup enables others

[32] (Own illustration)

	to do the same by offering their technology toolbox. That enables both the startup and its customers to enhance their reporting approaches.
Resilience to Disruptions	Speaking about the startup´s supply chain, the CEO explained that they "[…] have a network of manufacturers and if something breaks down somewhere, [they] can access others much more flexibly" (Interview #1). In this way, the startup can achieve resilience against unforeseeable failures and crises to some extent.
Sustainable Business Models	The startup has built a business model that is both environmentally and economically sustainable, including the reduction of CO_2 emissions, waste and costs.

Table 15: Anonymous Sustainability Approaches[33]

General Challenges. During the last years of development, the startup faced four main challenges: Acquiring the first customers, securing investment due to limited investor interest, experiencing gender bias in the investment industry, and building a reputation within the venture capital community. The founder explained that it is generally more difficult to acquire the first customer in Europe than in the US. Even though the founding team had already built up a good customer network when founding the startup, the CEO remembers the strains of founding their previous startup on which the anonymous startup is based. "Nobody wants to be the first customer, everyone always says 'show me pilot projects, show me reference customers.'" (Interview #1), they say. It took the startup one and a half years to convince the first customer, leading to financial strain and uncertainty about the survival of the startup. The second challenge was the limited interest investors showed and the struggle to secure investment, as few investors were specializing in chemistry and production. The CEO highlighted the scarcity of venture capitalists (VCs) investing in this sector, with most preferring areas like FinTech or MedTech. Beyond that, the CEO had to experience bias and discrimination in the investment industry, particularly due to their gender. They recounted instances where their credibility and abilities were questioned by male investors, reflecting a broader issue of gender bias in the tech startup scene of the European country, in which the startup is located. Finally, the CEO highlighted the importance of building a reputation in the VC community to gain investor trust. Despite the startup´s achievements in the industry, the founder felt that their background was not well-known among investors, leading to challenges

[33] (Own illustration)

in being taken seriously and noting the significance of networking and familiarity with VC language to improve their standing in the investor community. (Interview #1)

Success Factors. Many success factors have made the company the success it is today. Firstly, as this startup is the CEO´s second startup, the team benefited from the beginning from strong relationships and a well-established network within the pharmaceutical and chemical market. Furthermore, the company's success in securing investment was attributed to the fair and unbiased assessment by certain venture capitalists, particularly women who focused on hard key facts rather than biases. “[...] we were lucky that the VCs who invested with us in the end were women who did the assessment, and they weren't biased and just looked at the hard key facts” (Interview #1), explained the CEO. The startup had accumulated expertise and validated its technology in the market over the years so that they “could no longer be taken off the hook”, explained the founder. This combination of knowledge and market validation strengthened their position and made it difficult for investors to dismiss their proposition. Finally, the CEO highlighted the need to continually learn about the industry and understand the decision-making processes involved. (Interview #1)

Reactions. The startups witnessed a shift in the reactions of industry players and potential customers. At first, the startup faced scepticism and ridicule from customers when presenting their innovative method. The founder remembered: "Ten years ago, people laughed at us" (Interview #1). However, over time, there has been a notable shift in attitudes, with companies like Evonik, the third-largest German chemical company, adopting similar strategies. Speaking about investors´ reactions, the CEO highlighted the discrepancy between rhetoric and evaluation criteria concerning sustainability by impact and sustainability-focused VCs. While VCs admit the importance of sustainability, they ultimately assess startups based on traditional metrics such as market potential, competitive advantage, and scalability, like every other VC, and just ask for sustainability aspects in addition, without putting it in the centre of their evaluation method. (Interview #1)

Sustainability Advantages. The CEO believes that focusing on sustainable solutions in the pharmaceutical industry is a significant advantage. Sustainability is an unstoppable global megatrend, meaning that companies that position themselves well in this space will benefit from a secure and steady business income, as these trends are inevitable. They concluded: “The question is not whether something will happen with megatrends, but in the end it's just a question of who will benefit from them.” (Interview #1)

Industry Influence. The founder stated that the startup has emerged as one of the most significant influencers in the chemical industry, due to their adherence to the green chemistry principles and the collaboration with well-known and important figures. Their involvement in major initiatives such as advising the Chemical Strategy of the UN highlights their credibility and reputation. Further, the CEO suspected that there is probably no top manager who is responsible for production at a large chemical manufacturing company in their operating country who does not know the startup, illustrating the extent of the startup's reach and influence. Finally, the CEO was convinced that a startup has the potential to change the whole pharmaceutical industry as they have proven it with this startup. They highlighted the transformative potential of startups like their own by challenging conventional practices and promoting sustainability as a source of innovation and competitive advantage. (Interview #1)

Need for Change. The founder expressed doubt regarding the ability of their founding country to transform the chemical industry towards sustainability due to deep-rooted mindsets and technological limitations. They believed that while some companies may successfully undergo transformation, many will struggle due to their lack of flexibility and innovation. The CEO emphasized the importance of not solely focusing on transformation but also promoting a new industry through support for startups, suggesting that offering pilot projects could be crucial in driving innovation and industry evolution. Finally, the founder highlighted the need for established companies, including pharmaceutical firms, to invest in and collaborate with startups to drive progress and change. (Interview #1)

4.2.2 Single-Case Report: BIOVOX

Company. BIOVOX is a German startup, located in Darmstadt, that produces bioplastics for medical and laboratory use. The startup was officially founded in the year 2021 by Julian Lotz, Vinzent Nienhaus and Carmen Rommel with a focus on addressing sustainability challenges in the medical plastics industry. Their motivation to found the startup emerged from the founders' dissatisfaction with the slow pace and lack of innovation in their previous corporate environment. The initial business idea came from the founders' collaboration with a former colleague who was exploring biopolymers for therapeutic purposes. The founders recognized the potential of sustainable biopolymers in the context of an ageing population, increased medical care needs, and the growing demand for sustainability. The startup developed into a Business to Business (B2B) concept, selling different kinds of sustainable bioplastics to medical device producers, currently to produce medical components (instrument handles, surgical

equipment, diagnostic tools, and pharmaceutical packaging) or laboratory consumables (tubes, connectors, valves, etc.).

Product. One of BIOVOX's key selling points is its expertise and comprehensive approach to sustainability. Unlike traditional polymer manufacturers, BIOVOX offers a diverse range of materials tailored to specific customer needs, taking into account technical requirements, sustainability considerations, and regulatory compliance. The startup offers three different kinds of bioplastics that differ in their stiffness, surface hardness, heat resistance and transparency while prioritizing sustainability and environmental impact reduction. This versatility allows BIOVOX to provide recommendations that optimize the entire product lifecycle, from production to disposal, while ensuring environmental and biological safety.
All of BIOVOX´s products are 100% biobased, as the main ingredient is sugar cane, and parts of the product portfolio are biodegradable. What makes the bioplastic sustainable is that even if the plastic is not recycled but incinerated, the CO_2 that is emitted during incineration is only as much CO_2 as the plant has extracted from the atmosphere during growth. This leads to an overall net zero CO_2 footprint. Thus, while in use and before being incinerated, their MedEco products can even be seen as a carbon sink as they absorb and store carbon dioxide from the atmosphere.

In addition to reducing the CO_2 footprint, BIOVOX also pays special attention to the protection of biodiversity and rainforests, energy-efficient processing, less material usage due to high strength and rigidity, and material recyclability. Today, the team continues to innovate in recycling solutions and expand its presence in markets such as pharmaceutical packaging, as Lotz explains.

Mission. BIOVOX's mission revolves around developing medical plastics that not only meet commercial goals but also align with stringent sustainability objectives, as Lotz states: “[…] Our goal is to have net-zero products and […] not through residual emissions that are offset or something. […] And that we get to a point where medical plastics no longer use up more than the planet's capacity, but only within the framework in which the planet can regenerate, so that we can achieve real sustainability” (Interview #2).

Sustainability Challenges Tackled

Medical & Hazardous Waste	BIOVOX bioplastics are suitable for chemical recycling, in which the plastic is broken down into a monomer or raw material and purified (Interview #2). Lotz explained: "[…] [We] try to sell materials that fit well into recycling technologies for medical and hazardous waste, for example, simply so that the circular economy can be achieved" (Interview #2). If this method of recycling becomes profitable, the generation of medical & hazardous waste can be avoided (Interview #2).
Lack of Awareness	BIOVOX informs pharmaceutical manufacturers on trade fares about their impact on the environment, who are often not aware of it (Interview #2). With the company's initiative called BIOVOX Connect, the company is a co-founder of a sustainability network aimed at encouraging collaboration and knowledge-sharing among industry stakeholders. It organizes "[…] online sessions on current topics from and with players in the healthcare sector", described the company website.
Environmental Pollution	By switching from fossil-based plastic to BIOVOX bioplastic in the production of medical products and packaging, customers can save up to 85% of their production-related CO_2 emission, depending on which specific type of plastic has been used before. Replacing fossil-based packaging of pharmaceutical products with BIOVOX bioplastics ensures that the waste can either be composted or, if it accidentally ends up in the environment, does not pose a long-term risk to the environment.
Reporting	The company website offers an online calculator that calculates the current CO_2 footprint and potential savings of a production process, enabling the customers to collect those data for reporting purposes.
Supply Chain Complexity	It can be difficult for producers of medical products to find a supplier that offers different materials for different applications, all of which are already certified according to medical standards and are sustainable. "We help to address and offer good solutions […] without customers having to deal with dozens of different suppliers, none of whom have anything to do with medicals and who first have to qualify and ensure quality" (Interview #2), said Lotz.

Table 16: BIOVOX Sustainability Challenges[34]

[34] (Own illustration)

Sustainability Approaches Used

Sustainable Production	The BIOVOX team brings experience in sustainable production from previous employers. "Carmen is an expert in sustainable production and has brought bioplastics and recycled plastics into series production at Mercedes Benz" (Interview #2), said Lotz. The company used this experience to produce the bioplastic as environmentally friendly as possible.
Circular Business Initiatives	"Mechanical recycling is not possible for most medical applications: traceability and consistent quality are practically impossible to achieve on an industrial scale", stated the BIOVOX plastics compendium. The startup solves this problem by creating a sugar cane-based PLA (Polylactide). It can be chemically recycled using energy-efficient monomer recycling that fulfils quality and purity standards for medical grades (interview #2). "The [final] material is absolutely identical to the virgin material. This saves CO_2 & land use - with consistent quality" (Interview #2), stated Lotz. Furthermore, circularity in the healthcare sector is a core focus of the company: "Our part in this is to put the right materials into the cycle. These are currently bio-based plastics, but in time they will also include recycled plastics.", explained Lotz. In the future, the startup wants to extract raw materials from CO_2 and offer a medically safe bio-based recycling material (Interview #2)
Green Supply Chain Management	BIOVOX pays special attention to the impact of its upstream supply chain. All of their raw materials are certified to ensure zero deforestation and the protection of biodiversity, soil, water and air. Further, the startup calculated the land utilisation if every plastic would be replaced with bioplastics. Their bioplastic compendium stated: "All plastics worldwide could be grown on 13.9% of the world's arable land. […] There is no competition for land between bioplastics and the cultivation of food".
Sustainable Business Models	BIOVOX uses sustainable practices as an effective way for a stable competitive position. Their entire business model is based on offering the customer a more sustainable solution than their competitors.

Table 17: BIOVOX Sustainability Approaches[35]

General Challenges. Understanding the complex interface between medical requirements and product development posed a significant hurdle for BIOVOX. "You have an extremely broad

[35] (Own illustration)

field where you work at a lot of interfaces [...]" (Interview #2) said Lotz. Additionally, implementing a robust quality management system demanded considerable effort and expertise. Initially, there was resistance towards sustainability initiatives in healthcare, though this gradually shifted over time. Lotz described the reaction of pharmaceutical players a few years ago: "When we started out, sustainability was still a very tender plant in the healthcare sector. […] You often heard ´No, we're saving people's lives, what's the point? The jungle doesn't matter right now´ […] or ´ […] Cars and airplanes have to become sustainable. We can't, that's not possible at all´" (Interview #2). However, he explained, the most difficult thing was to find investors due to the market's heavy reliance on references and the unique positioning of their product. "If you don't yet have anything in series production that is medically approved, then everyone is sceptical at first as to whether it will work and can work at all." (Interview #2) Lotz explained. Impact investors hesitated due to the regulatory complexities of the medical field, while MedTech and pharma funds were deterred by the lack of therapeutic focus and patented products. Generic funds lacked understanding and had short lead times unsuitable for BIOVOX's needs. Only deep tech funds showed potential interest, but their limited availability and stringent criteria made fundraising a significant challenge. Lastly, the long business cycles inherent in the industry tested the company's patience and strategic planning abilities. Lotz explained "So the time that passes from the first contact with the customer to the start of series production is two years or even longer, which means that we simply have to be really patient for a long, long time.". (Interview #2)

Success Factors. Lotz highlighted the team's resilience and pragmatism as essential qualities and their quick problem-solving approach including agility in responding to market demands. Moreover, maintaining a sharp focus on the healthcare niche allowed BIOVOX to refine their value proposition and business model effectively. While networking can be valuable, Lotz acknowledged that most interactions yield minimal direct benefits, emphasizing instead the importance of visibility and integration within their target community. Finally, prioritizing simplicity in the product development process and strategically selecting materials to address a broad market share efficiently enabled the team to streamline their operations and avoid unnecessary complexities, facilitating their early growth and success. (Interview #2)

Reactions. BIOVOX's idea of selling bioplastic for the healthcare sector met with a great deal of scepticism and little interest from potential customers. However, this mindset shifted relatively quickly as stakeholders recognized the significance of sustainability in the industry. BIOVOX's first investors initially invested in the startup when their business idea was still

centred on the production of biodegradable implants. However, as the company evolved, investors embraced the sustainability-driven direction and actively engaged with BIOVOX to align the business model with sustainability goals. (Interview #2)

Sustainability Advantages. Focussing on sustainability in the pharmaceutical sector brought two main advantages for BIOVOX. Firstly, Lotz stated that the effort and time to create sustainable solutions in this sector is very high, resulting in fewer startups pursuing this goal and less competition, leaving the market unsaturated. Secondly, the focus on health and sustainability creates a purpose-driven working environment in the startup that attracts job applications from highly qualified employees, leading to a positive recruitment outcome. (Interview #2)

Industry Influence. BIOVOX has been instrumental in driving sustainability awareness and action within the pharmaceutical industry through initiatives like BIOVOX Connect. By organizing events and working sessions, BIOVOX has facilitated discussions on sustainability challenges and solutions, prompting a positive shift in industry attitudes towards sustainability integration. The growing number of participants in sustainability-focused sessions within BIOVOX Connect reflects the industry interest in the topic. (Interview #2)

Need for Change. Looking ahead, BIOVOX highlights the need for a supportive regulatory framework to incentivize sustainability adoption on a broader scale. By creating policies that encourage sustainable practices and incorporate sustainability criteria into public procurement processes, the pharmaceutical industry can move towards greater environmental responsibility. This, Lotz thinks, will also enable more startups to realise a sustainability-related business idea in this industry as he sees a clear desire among young Entrepreneurs for more sustainable solutions. (Interview #2)

4.2.3 Single-Case Report: Envetec

Company. Envetec Sustainable Technologies Limited (Envetec) is an Irish business startup, founded in Birdhill in 2021 by Malcolm Bell. Today the startup counts 16 employees. It is a spin-out from Technopath Clinical Diagnostics, a leader in clinical diagnostics focused on the treatment and recycling of biohazardous waste. The startup's flagship product is called GENERATIONS™, a green technology to treat and recycle biohazardous laboratory waste. Bell had been investigating biohazardous and healthcare waste for over ten years before founding Envetec. The startup is led by a team of extremely experienced executives and

industry experts who bring knowledge in diagnostics, pharma, healthcare, and veterinary. Bell described that he was looking on the market for technologies, that enable the recycling of biohazardous waste but “none of them actually worked”. After discovering this gap, he decided to develop his own technology. (Interview #3)

Product. The standard way of treating biohazardous waste is autoclaving, a sterilization process that uses high-pressure steam at high temperatures which damages the polymer, making its recycling impossible. GENERATIONS offers a non-thermal, low-energy, non-toxic solution for shredding and disinfecting biohazardous waste at its source. The patented technology simultaneously reduces waste volume, eliminates biohazardous agents, and produces recyclable materials suitable for further processing. It treats plastics, glass, sharps containers, and other general laboratory consumables and is designed to be installed and operated at the customer's facility. The resulting end product is a mixture of non-hazardous, recyclable polymer flake, metals and glass that can be easily separated and recycled. Next to its unique functionality, the product brings several sustainability-related benefits: 1. Installing the technology on-site eliminates the public health risk of transporting untreated biohazardous waste on public roads and eliminating the GHG emission from transportation; 2. The technology uses significantly less water compared to existing biohazardous waste treatment technologies.

Mission. Envetec’s mission is to enable all laboratories to move towards zero waste and create a circular economy for biohazardous laboratory waste, stated the company’s website. Bell highlighted that the whole purpose of the startup is having an impact while profit is not his sole focus. To achieve this mission, Envetec established strategic partnerships with leading organizations and institutions, including Northwell Health, New York State’s largest healthcare provider. Today, the company is already working with eight of the top ten pharmaceutical companies in the world, said Bell, who has high expectations regarding the sales figures of his product within the next years. He is confident that the sustainable advantages that the GENERATIONS solution delivers, will make this machine the standard solution for pharmaceutical manufacturers to treat their waste and explains “At the moment autoclaves are the standard. Autoclaves are horrible, and then they don't do a very good job either. They have poor reliability, high cost, high maintenance. So, I think when people are specking new buildings rather than putting in an autoclave, they'll just put in an Envetec system.” (Interview #3).

Sustainability Challenges Tackled

Medical & Hazardous Waste	The core functionality of the GENERATIONS solution is to reduce biohazardous waste and create a recyclable non-hazardous end product. Third parties confirmed that the technology can reduce the volume of the biohazardous waste by up to 90% after its processing, leading to several practical and environmental benefits, if the waste is not recycled.
Lack of Awareness	Envetec conducts full audits of their customers' waste streams, generating data about their CO_2 emissions and water usage caused by the current disposal methods to inform them about their environmental impact. This creates awareness among the customers who usually outsource the waste treatment and never think about its consequences. Bell stated that he thinks that his customers never thought about recycling "because they didn't know what happened to the waste" (Interview #3). The startup explains to its customers the massive negative impact the waste has on the environment. Considering that the startup is in contact with eight of the ten largest pharmaceutical companies worldwide, its potential to raise awareness among major industry players is huge. (Interview #3)
Outsourcing	Many pharmaceutical companies outsource their waste treatment to other companies (Interview #3). GENERATIONS is installed on-site, enabling the recycling of the plastics at source, stated the startup's website, enabling the pharmaceutical companies to have full control over their biohazardous waste management. This further eliminates the risk of transporting untreated biohazardous waste and the resulting GHG emission (Interview #3).
Environmental Pollution	Independent third-party assessments evaluated the environmental benefits of this technology and concluded that the GENERATIONS technology can lower GHG emissions from waste treatment by up to 95% and uses 70% less water per cycle compared with traditional methods of autoclaving.
Reporting	The startup generates reports on energy usage, water usage, chemical usage, and CO_2 reduction, explained Bell and with that supports companies in reporting on waste management-related figures. (Interview #3)

Table 18: Envetec Sustainability Challenges[36]

[36] (Own illustration)

Sustainability Approaches Used

Technology Integration	Envetec uses a unique technology to shred biohazardous waste into small recyclable flakes. Integrating that technology in form of the GENERATIONS solution enables the customer to benefit from the advantages mentioned.
Circular Business Initiatives	Creating a cycle from waste to production would be a best-case scenario that can be made possible with the GENERATIONS solution. Bell explained that full circularity might not be possible with all products but at least with the majority, giving an example of one of their current customers: "We have customers treating all their Petri dishes with our product, and polymer is being pelletized and then remanufactured remoulded into Petri dishes." (Interview #3). Finally, he emphasises the uniqueness of the technology: "We're now able to recycle product that was never recycled previously" (Interview #3).
Sustainable Business Models	The startup has built a business model with a positive impact at its core. The product is environmentally sustainable, reducing the CO_2 emissions and water usage of waste treatment methods and decreasing the overall waste volumes.

Table 19: Envetec Sustainability Approaches[37]

General Challenges. A significant hurdle for Envetec was to develop a shredding technology that can handle the wide range of waste types present across various industries including sharp containers, glass vials, blood tubes or bioreactors, explained Bell. Additionally, he pointed out the conservativeness of the pharmaceutical industry in terms of introducing their innovation. Despite acknowledging the importance of sustainability, many pharmaceutical manufacturers are hesitant to adopt new waste treatment methods. Moreover, Bell highlighted the financial constraints and pricing sensitivity of their customers. As the GENERATIONS solution ´only´ deals with waste in a more sustainable way, it is neglectable in the profit-generating production process of the customers and therefore sales are not unconditionally guaranteed. This highlights the importance of cost-effectiveness and financial viability. Finally, Bell recognized the need to navigate various stakeholder interests to achieve widespread adoption as another challenge.

Success Factors. The success of Envetec to get where they are today can be traced back to the company's emphasis on delivering high-quality solutions that earned it a reputation for reliability and excellence. This, coupled with extensive industry experience and a proven track record of success, causes confidence among clients and stakeholders. In addition, the network

[37] (Own illustration)

Envetec's leadership team established provides access to important decision-makers in the pharmaceutical and other target industries, facilitating meaningful engagements. Bell elaborated: “We can get to the C-Suite of any of the diagnostic companies, the pharma companies, the veterinary companies, because among our leadership team, we have contacts, and we are known” (Interview #3)

Reactions. Envetec has no external investors, as all investments in the startup have been made by shareholders so the startup was never dependent on the opinion of other investors. However, Bell outlined a shift in the mindset of customers from acknowledging the need for improved waste management techniques to a greater focus on sustainability, including recycling high-value single-use plastics. Major medical device manufacturers are actively seeking solutions that reclaim and reuse polymers as they understood that incorporating recycled materials into their production processes is essential for maintaining consumer trust and competitiveness. Bell highlighted the extremely positive feedback the startup receives from C-Suite executives and industry stakeholders, with appreciation for the system's performance and its environmental benefits. He reported an overall growing awareness among stakeholders about the need for sustainable waste management solutions in the healthcare and pharmaceutical industries, driven by both environmental and economic considerations. (Interview #3)

Sustainability Advantages. Bell highlighted the need for sustainable solutions in the pharmaceutical market that creates a huge market. Today pharmaceutical companies might still be restrained from investing in not profit-generating technologies like GENERATIONS due to the revenue losses they experienced during the pandemic. However, Bell was certain that this would change within the next twelve months and said that “there is definitely a future there, but it always takes a little bit longer than you hope and you have to be patient”. (Interview #3)

Industry Influence. Envetec's current influence on the pharmaceutical industry lies in its awareness-raising activities about the potential savings and sustainability benefits of their technology as many customers have never thought about the environmental impact of their waste treatment. Bell explained: “I think that's really what we're bringing to the table, an awareness of a practice which everybody knows is unsustainable” (Interview #3). Looking into the future, Bell was certain that Envetec will make a very significant impact over the next three years and emphasises the company's collaborative efforts with pharmaceutical manufacturers, facilities management companies, and product manufacturers to promote sustainable waste handling practices. (Interview #3)

Need for Change. The CEO highlights that companies require stronger regulatory incentives to prioritize sustainability over profitability. He suggested implementing tax breaks and funding initiatives similar to those in the United States to encourage the use of recycled materials. Bell emphasized the complexity of the regulatory environment in Europe and highlighted that overcoming regulatory barriers and promoting a regulatory environment that is in favour of sustainable solutions is crucial for motivating more startups to focus on sustainability and driving industry-wide change. (Interview #3)

4.2.4 Single-Case Report: Green Elephant Biotech

Company. Green Elephant Biotech (GEB) is a spin-off from the University of Applied Science Mittelhessen in Gießen and was founded in 2021 by Dr. Joel Eichmann and Felix Wollenhaupt. Today, the startup operates with a team of 14 employees across two locations, Gießen and Berlin. The startup focuses on the production of plant-based labware and has one patented pioneer product called CellScrew®. Eichmann, who has a master's degree in cellular and molecular biology, had the idea for the CellScrew® during his PhD program. He approached Wollenhaupt with a first prototype of the idea, who was convinced that this idea had huge potential. The decisive factor for the duo to found GEB was their intrinsic motivation to create a better product and work environment as they had experienced with their past employers.

Product. The CellScrew®, which looks like a big bottle, is a scalable solution for large-scale adherent cell expansion. It is used for cell and gene therapy, vaccine manufacturing, and drug screening and development. The product offers a large cell culture area formed by concentric cylinders with many favourable production characteristics like easy handling due to compact design and excellent mixing and gas exchange facilitated by an Archimedes screw. The USP of the CellScrew® is both functional and sustainable, including reduced manufacturing costs, time to market and environmental impact. One CellScrew® replaces up to twelve conventional standard roller bottles because of its patented structure on the inside, enabling easy handling by one person without additional equipment. In addition, it has the potential to be fully automated by a platform that monitors and controls all critical parameters of the process. Finally, the bottle is 3D printed using plant-based polylactic (PLA) from renewable crops which is fully recyclable and biodegradable if no restricted cells, viruses or chemicals are involved.

Today, the CellScrew® is still research-grade, so it is not yet authorised for the industrial production of pharmaceuticals and active ingredients. However, the startup expects Good Manufacturing Practice (GMP) compliance, which is needed for industrial production, very

soon. However, the startup already extended its product portfolio and offers a second labware product, a plant-based 96-well plate. It is also made 100% from renewable polymer, which reduces its carbon footprint by more than 50% compared to traditional polystyrene plates due to the CO_2 absorption of the used plants to produce the PLA and its energy and water-efficient manufacturing process.

Mission. Sustainability is one of the company´s five guiding principles. The startup's website stated that the company's mission is to be "the world's first company that produces labware from plant-based plastic, [to] empower the biopharmaceutical industry to embrace sustainability". Further, it stated that the startup wants to "address the bottleneck in biopharmaceutical production by enhancing production capacity, ultimately increasing patient access and affordability to life-changing novel therapies." (Interview #4).

Sustainability Challenges Tackled

General Waste	The unique structure of the CellScrew® and its 3D printing manufacturing process leads to great material savings and can reduce the lab waste of its users by 80%**.** In addition, the plant-based PLA can be composted or chemically recycled, as written on the startup's website and thus makes further waste reduction possible. This is especially helpful for standard laboratory consumables, explains Wollenhaupt (Interview #4).
Lack of Awareness	GEB offers a service for the calculation of the CO_2 emissions caused by the customer's consumption and use of its labware on its website. Thus, customers can receive tangible figures about possible sustainability improvements when switching to more environmentally friendly labware alternatives.
Outsourcing	The whole production process for GEB´s plant-based labware takes place in Europe. Thus, GEB offers their customers a product which follows all regulatory standards of the EU and therefore has control over evidence of composition and production process.
Environmental Pollution	GEB replaces fossil fuel-based materials in the production of the CellScrew® with bio-based, recyclable PLA. Even though the products from GEB are often incinerated after use and not recycled, the product's carbon footprint is still smaller than that of the fossil fuel-based alternatives, as the incineration process only releases the CO_2 that was bound beforehand by the plant. This characteristic, combined with the enormous material savings, enables the

	customer to reduce their CO_2 emissions caused during a cell cultivation process by 90%. Moreover, the production of PLA is 25-55% less energy-consuming than that of petroleum-based plastics and uses 85% less water than for production of plastics such as Nylon.
Rushed Manufacturing	The CellScrew® streamlines the cell cultivation process of its users with an expansive growth surface inside a compact vessel, freeing up incubator space, and reducing media exchange cycles and the risk of contamination. In addition, the CellScrews® large surface area and small volume enable the customer to scale the cell expansion without developing complex process adjustments. Further, the startup works on a system to fully automate the cell cultivation process using the CellScrew® allowing the customer to monitor and control all critical cultivation parameters in real-time. These advancements enable the customers to decrease the need for expensive reagents and lab space, leading to noticeable cost reduction, and reducing their processing times.

Table 20: Green Elephant Biotech Sustainability Challenges[38]

Sustainability Approaches Used

Sustainable Production	The startup uses a material-efficient manufacturing 3D printing method and PLA as the material for the production of the CellScrew® so that the production process is designed to be as sustainable as possible.
Technology Integration	With the CellScrew®, customers are prepared to automate their cell cultivation process through technological integration. The shape and nature of alternative cell cultivation products simply do not allow automation. Only the specific shape and small air ducts in the CellScrew® make an automatic rotation process suitable for this type of chemical procedure.
Green Supply Chain Management	GEB tries to make its whole supply chain sustainable. Wollenhaupt elaborates: “It starts with electricity generation, water consumption and packaging - these are all relevant issues that we incorporate in order to work as sustainably as possible” (Interview #4). This also includes a remote work concept, where employees can choose if they want to work in the office or whether they are. (Interview #4)

[38] (Own illustration)

Resilience to Disruptions	The startup's whole supply chain is located in Europe and has a contract manufacturer for the CellScrew® in southern Germany. Recognizing the supply problems many companies experienced with the current political developments, the startup tried to avoid sea routes and long supply chains. Therefore, everything from the production of raw materials to production, post-treatment, packaging and sterilization takes place in Europe.
Sustainable Business Models	GEB has a very holistic approach to sustainability and highlights it as the core of their company. Wollenhaupt elaborates: "We are trying to manufacture a product throughout the company that is actually sustainable, that not only has sustainability written all over it [...]. However, we also try to make the entire value chain as sustainable as possible" (Interview #4).

Table 21: Green Elephant Biotech Sustainability Approaches[39]

General Challenges. The process of securing the first round of financing turned out to be a significant challenge as it took much longer than anticipated, which hindered the initial progress of the company. Wollenhaupt explained: "Especially this VC game, finding out how it works, that took a bit of time if you've never done it before." (Interview #4). In addition, the pharmaceutical industry is very risk-averse, particularly regarding new technologies. As GEB implements various dimensions of technology that are new, including new material and geometry, the startup had difficulties in convincing potential customers to adopt their innovative products, as they required validation and assurance of efficacy. Moreover, despite being in the biotech sector, the importance of sustainability was often overshadowed by other factors such as product quality and regulatory compliance, and only seen as "a nice add-on" (Interview #4) but never as the deciding factor for a particular technology. Finally, bringing the product to market caused high costs, primarily due to the necessity of complying with quality and safety standards and regulations, presenting another industry-specific challenge. (Interview #4)

Success Factors. Wollenhaupt emphasized the importance of deeply understanding customer needs and ensuring that the products offer real added value as one of their success factors. Further, prioritizing sustainability in their product development and business operations, recognizing the urgency of addressing the climate crisis was essential. Besides that, Wollenhaupt acknowledged the importance of approaching the founding process with a sense of openness to change. He explained that it is crucial to talk to potential customers early on and

[39] (Own illustration)

“allow iterations both in the business idea and in the product ide." (Interview #4) to adapt the concept of the product if needed. In addition, rigorous research, conducting comparative studies, and generating proprietary data before starting the first product launch are inevitable. Finally, nurturing long-term customer relationships and understanding that building trust and rapport with customers is a gradual process, was an important step. (Interview #4)

Reactions. Even though GEB had problems securing the first round of financing, investors expressed strong enthusiasm for the startup's focus on a sustainable solution. However, customers’ reactions to GEB´s product were at the beginning very negative. Wollenhaupt remembered: “We really got responses from large companies saying ´That's great that you have a sustainable product, but who cares? It really doesn't matter as long as you don't have any technological advantages´” (Interview #4). Often, pharmaceutical companies described sustainability as a “*nice add-on*” (Interview #4), but not as the deciding factor for a particular technology. However, during recent years, GEB observed increasing interest and positive reactions from various sectors, including academia, biotech pharma, and the cultivation foods industry, particularly in the context of reducing Scope 3 emissions and addressing climate-related issues. (Interview #4).

Sustainability Advantages. From a startup’s perspective, the focus on a sustainable solution is beneficial as it enables the startup to differentiate itself from other startups and “opens the door to getting into conversations.” (Interview #4). It helps to create a recognition effect and to give the brand a positive logo, as standing up for the environment is always welcomed. Wollenhaupt describes it as follows: “Often when we exhibit at trade fairs, people come up to us and say ´Ah, you're the green elephants´!” (Interview #4). This association is a great opportunity for the startup to “stand out a little from the crowd” (Interview #4).

Industry Influence. While Wollenhaupt acknowledged that their current influence on the pharmaceutical industry is rather small, he recognizes their role in leading a sustainability movement within the sector and sees GEB at the forefront of this shift. However, he is unsure whether startups have the potential to catalyse industry-wide change due to entrenched relationships and the dominance of large companies in the pharmaceutical sector, making it difficult for smaller and new companies to compete in the market. Nevertheless, he emphasised that a collective effort from multiple startups, each addressing different aspects of the industry, could create a significant counterforce to the established giants and “form a certain counterweight to the big giants of the industry” (Interview #4).

Need for Change. To drive change in the pharmaceutical towards more sustainable practices, Wollenhaupt believed that legislative measures and increased social pressure are necessary He advocated for stricter regulations limiting the use of petroleum-based materials to incentivize companies to innovate. Finally, he suggested that politicians should prioritize expanding the startup ecosystem, facilitating spin-offs, and offering support to young founders to encourage sustainable solutions in the industry. (Interview #4)

4.2.5 Single-Case Report: TORSKAL

Company. TORSKAL is a French startup, founded in 2015 by Anne-Laure Morel in Saint-Denis, La Réunion, and has sites in the US, France and China. Its focus lies on revolutionizing cancer therapy through the development of non-toxic and eco-friendly gold nanoparticles. The startup is committed to reducing the environmental impact of cancer treatment while enhancing its effectiveness. Therefore, the startup applies the green chemistry principles and leverages the benefits of medicinal plants that are endemic to the Indian Ocean region to synthesize the gold nanoparticles. The motivation for this business idea lies in the conviction of the founder that nature offers all the resources needed for health treatments. Morel explained: “As a chemist, my point of view is that we could find in the nature all the relevant elements to produce health product” (Interview #5). The scientific team with more than 7 years of experience operates in laboratories in Reunion Island and Paris and provides scientific research and development services in nanotechnology, biology, and phytochemistry.

Product. TORSKAL offers two ranges of gold nanoparticles to visualize surface and deep cancers cancer cells, monitor them and treat them with hyperthermia. This patented method to treat tumours with hyperthermia and selectively destroy cancer cells minimizes the side effects of cancer treatment for the patient´s body. The nanoparticles are non-toxic to the organism and biocompatible while the treatment only attacks the cancer cells without affecting healthy cells. They can be customized in terms of coating, size, and shape to meet specific research or medical requirements. To produce the unique nanoparticles, the startup uses mainly gold salt, water and plants whose biomolecules are used to coat the gold nanoparticles. TORSKAL´s USP lies in its focus on environmental sustainability throughout all of its operations, sourcing the medicinal plants from agricultural cooperatives and promoting plant biodiversity while respecting local ecosystems. Furthermore, with the commitment to sourcing ethical and responsible gold from fair-minded certified mines, ensuring transparency and ethical practices in the gold supply chain, the startup also pays special attention to social sustainability aspects.

Mission. With a focus on sustainability, innovation, and social responsibility, TORSKAL´s mission is to transform cancer therapy on a global scale while contributing to the advancement of green nanomedicine. To do so, it expands its sales channels and market presence, leveraging partnerships and innovative financing mechanisms to support its growth trajectory. The website states: "TORSKAL's ambition is to participate actively in the emergence of green nanomedicine around the world by creating an alliance with major Chinese and European partners" (Interview #5).

Sustainability Challenges Tackled

Environmental Pollution	TORSKAL´s plant-based nanotechnology offers an alternative to the currently very toxic cancer treatment with a "natural resource, in order to avoid the production of a toxic product, a toxic chemical for the environment" (Interview #5). The plants that the startup uses for the production of the nanoparticles come from small farms that use untreated natural wasteland and support natural regrowth. The website explains: "Priority is given to the valorisation of endemic/indigenous species already cultivated in Reunion".
Supply Chain Complexity	TORSKAL wants to enable hospitals and medical practices to produce gold nanoparticles themselves. Morel elaborates: "I would like to offer this opportunity to the hospital in each country, to produce themselves this health product that does not require any huge industrial equipment. It is cost-effective!" (Interview #5). This would enable cancer treatment facilities to become independent of suppliers of chemical substances from abroad and streamline their supply chain.

Table 22: TORSKAL Sustainability Challenges[40]

Sustainability Approaches Used

Sustainable Production	TROSKAL applies the green chemistry principles to synthesize the gold nanoparticles. Next to gold salt, plants and water it only uses very few chemical products to cause as little pollution as possible and make the production process as biologically compatible as possible.
Green Supply Chain Management	TORSKAL pays close attention to the social conditions under which the gold salt is produced and can ensure that the plants they use in their production grow in harmony with nature, as the plants grow in the immediate surroundings of its laboratories in Reunion Island.

[40] (Own illustration)

Resilience to Disruptions	As the ingredients for the production of nanoparticles are simple, TORSKAL´s supply chain is relatively stable against economic changes and crises. In addition, the startup uses local plants that grow very close to their laboratory, shorter supply chain is hardly possible.
Sustainable Business Models	Even though TORSKAL´s invention to treat cancer in a non-toxic way implies huge benefits for the patient, its focus is on sourcing the plants in an environmentally friendly way. The creation of biocompatible nanoparticles gives the startup a strong competitive advantage and testifies to a sustainable business model.

Table 23: TORSKAL Sustainability Approaches[41]

General Challenges. Finding private equity investors during the proof-of-concept stage was a huge challenge for TORSKAL, especially due to its location on Reunion Island. Morel elaborated: "[Reunion Island] it is not well known, and we have a lack of credibility. Working here was like something that was not relevant, not important, second line of countries" (Interview #5). She further explained that their focus on green nanotechnology was seen by European investors and customers more as an "accessory" (Interview #5) and not a competitive advantage. Moreover, Morel described how potential customers in Europe questioned her ability to supply enough products due to her dependence on nature. She remembered: "they preferred working with companies that rely on […] conventional chemicals because they are afraid that one day we could have a problem of providing*"* (Interview #5). Another big challenge was the progressing from animal testing to human trials, known as crossing the "valley of death" (Interview #5). This phase heavily depends on funding as human trials are a necessity to be able to make pharmaceutical partnerships but demand huge financial investments. Finally, Morel highlighted regional disparities in resource allocation and innovation funding from the French government. She said it is much more difficult for French overseas territories like Reunion Island to access governmental support than for metropolitan areas like Paris.

Success Factors. Morel emphasized only one key success factor, which is to present tangible outcomes. She recounted that her only chance to convince customers to apply her technology was to demonstrate superior results compared to conventional treatments or nanoparticles. (Interview #5)

[41] (Own illustration)

Reactions. Morel expressed her frustration about the low importance investors gave sustainability and their little trust in nature. She said that investors thought that nature was too vulnerable to make chemical supply chains depend on it. Further, they doubted nature's ability to provide enough plants in the long term, which Morel describes as nonsense as the production process only needs very few quantities of medicinal plants. Also, initial customer reactions were less enthusiastic, while Morel highlighted strong geographical disparities among them. She said: "I think that it is a problem of culture […]. In Africa and in Asia, for example, they use medicinal plants from million years. They know all the results and the efficacy of such products. [...] And trust them." (Interview #5). Therefore, the startup focuses today on working with Asian customers.

Sustainability Advantages. Even though TORSKAL was probably ten years ahead of the industry at the beginning of 2015 and encountered a lot of scepticism, Morel highlighted the economic benefits sustainable solutions have that can serve as an incentive for pharmaceutical startups, companies and governmental bodies to focus more on sustainable practices in the pharmaceutical industry. (Interview #5)

Industry Influence. Overall, Morel was sceptical, about if one startup could change the whole pharmaceutical industry but believed in the strength of a collective of several startups. She said, "a group of startups, a community can change the world of course" (Interview #5).

Need for Change. Morel highlighted that to change the pharmaceutical industry, startups need persistent effort, patience, resilience, and courage, with a focus on economic incentives to persuade pharmaceutical companies and governments. The founder believed that as the community evolves, its members can collectively advocate for and enact changes in industry standards and regulations while acknowledging that this transformation will be a lengthy process. That is why she advocates support from industry and the government for sustainable startup communities. (Interview #5)

4.2.6 Cross-Case Comparison

Company. The analysed startups tend to focus more on the early stages of the pharmaceutical supply chain (as shown in Figure 18). They often prioritize the initial development and production processes over the downstream distribution and delivery aspects. The anonymous startup concentrates on the sustainable production of APIs while TORSKAL focuses on the sustainable production of raw materials for cancer treatment. Both startups support

pharmaceutical suppliers in becoming more sustainable. BIOVOX, Envetec and GEB enable pharmaceutical manufacturers to become more sustainable. Whereas BIOVOX and GEB tackle the input of the pharmaceutical production process, Envetec addresses the output of it.

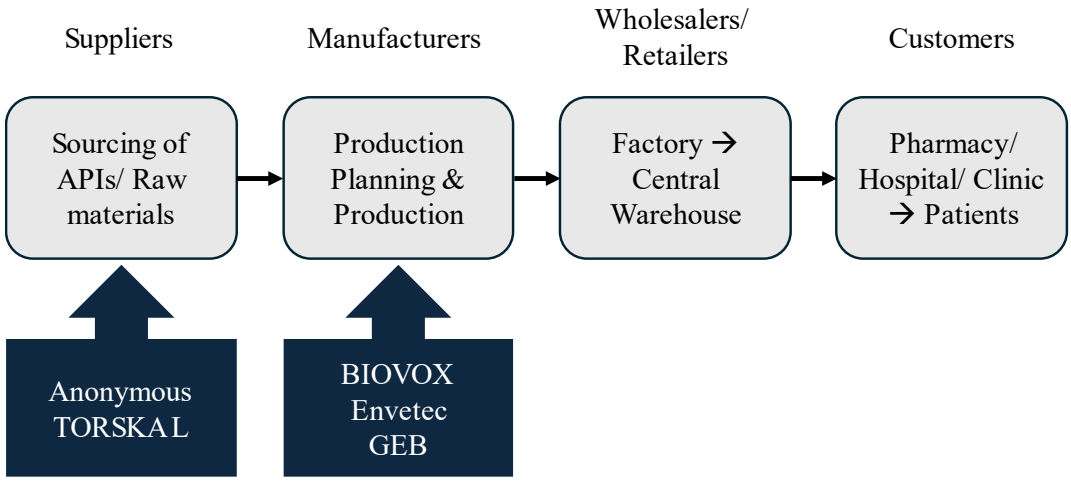

Figure 18: Startup Positioning in Pharmaceutical Manufacturing Process[42]

Product. Each company integrates sustainability not just as a part of its operational strategy but as a core component of its business models and products. This integration is aimed at achieving significant environmental impacts, such as reducing carbon footprints (BIOVOX, GEB and Anonymous), decreasing hazardous waste (Envetec), and promoting non-toxic medical treatments (TORSKAL).

Mission. Overall, the strategic goals of the startups extend beyond environmental benefits, aiming to establish new industry standards and practices that could lead to a broader transformation within their respective fields.

Sustainability Challenges Tackled.

	Anonymous	BIOVOX	Envetec	GEB	TORSKAL
General Waste				X	
Medical & Hazardous Waste	X	X	X		
Lack of Awareness	X	X	X	X	

[42] (Adapted from Haque & Islam, 2018, p.2)

Outsourcing	X		X	X	
Environmental Pollution	X	X	X	X	X
Existing Regulations					
Rushed Manufacturing	X			X	
Reporting	X	X	X		
Supply Chain Complexity	X	X			X
R&D Intensity	X				

Table 24: Overview Addressed Challenges[43]

While only GEB focusses on the reduction of **"General waste"** with recyclable labware, BOIVOX, Envetec and the anonymous startup tackle the reduction of **"Medical & Hazardous Waste"**. BIOVOX´s bioplastics enable the integration of medical waste into a circular economy model and Envetec's the integration of biohazardous waste. The anonymous startup focuses on improving the production process to already prevent generation at the beginning. BIOVOX and GEB address a **"Lack of Awareness"** among B2B customers about the environmental impacts of their current practices, whereas Envetec actively educates its clients about the sustainability benefits of their waste management system. The anonymous startup plays more of an educational role, influencing both policy and practice. Apart from that, **"Outsourcing"** is also a commonly tackled challenge. The anonymous startup manages a complex supply chain by partnering with European manufacturers to localize production and reduce costs and TORSKAL has streamlined its supply chain by enabling hospitals to produce their required gold nanoparticles on-site. Finally, both GEB and Envetec manage their supply chains locally.

The common goal among all cases is the reduction of **"Environmental pollution"**, although through the application of different strategies. BIOVOX and GEB replace fossil-based plastics with bioplastics that offer significant reductions in CO_2 emissions. While the anonymous startup enhances energy efficiency using AI and digital technologies, Envetec reduces CO_2

[43] (Own illustration)

emissions and water use with its waste treatment technology. Finally, TORSKAL employs a whole new treatment method to enable environmentally friendly cancer treatment.

Certainly, no startup addresses the challenge of the **"Existing Regulation"**. "**Rushed manufacturing**" is addressed by the anonymous startup and GEB. Their common theme is the utilization of innovative technologies to streamline processes and improve efficiency, while the anonymous startup focuses on the importance of data analytics and GEB automation benefits. BIOVOX, Envetec and the anonymous startup tackle the **"Reporting"** challenge and enable their customers to report on their environmental impacts more accurately. Each company offers solutions tailored to specific aspects of reporting, such as CO_2 emissions, energy usage, water usage, chemical usage, and waste management.

"Supply Chain Complexity" is tackled by BIOVOX, the anonymous startup and TORSKAL. All the startups' products lead to a simplification and consolidation of sourcing processes for medical products or chemicals, aiming to streamline operations and ensure quality and sustainability standards are met. While BIOVOX offers a curated selection of certified and sustainable materials to medical product producers, Anonymous acts as a central point of contact for sourcing greener chemicals from its network of manufacturers, and TORSKAL enables hospitals to reduce their reliance on external suppliers. Finally, only the anonymous startup tackles the **"R&D Intensity"** challenge with their smart simulations to reduce the development time and costs of new API.

Sustainability Approaches Used.

	Anonymous	BIOVOX	Envetec	GEB	TORSKAL
Sustainable Production	X	X		X	X
Sustainable Assessment Models					
Technology Integration	X		X	X	
Circular Business Initiatives		X	X		
Reporting Approaches	X				

Green Supply Chain Management		X		X	X
Resilience to Disruptions	X			X	X
Sustainable Business Models	X	X	X	X	X

Table 25: Overview Sustainability Approach Application[44]

The sustainability approaches of BIOVOX, Anonymous, Envetec, GEB, and Torskal present a diverse environment of strategies, showcasing varied emphases on different elements of sustainability. Four of the five companies emphasize **"Sustainable production"** techniques, either utilizing plant-based materials or applying the green chemistry principles. In contrast, no startup uses the **"Sustainable Assessment Models"** approach. The anonymous startup stands out using its **"Technology Integration"** like AI to improve process efficiencies. But also, Envetec and GEB apply technological benefits to enhance the sustainable impact of their customers.

"Circular Business Initiative" are major focus areas of BIOVOX and Envetec; BIOVOX through chemical recycling of bioplastics and Envetec through recycling medical waste into reusable materials. Further, **"Reporting Approaches"** are only applied by the anonymous startup the generates data with its technological toolbox that was never generated before, including the CO2 footprint of single pharmaceutical production plants. In contrast, BIOVOX, GEB, and TORSKAL show less emphasis on reporting, focusing more on **"Green Supply Chain Management"** paying close attention to the environmental impact of their suppliers. Moreover, the anonymous startup, GEB and TORSKAL increase their startups'"**Resilience to Disruptions**" through a localised and short supply chain. Finally, each startup created a **"Sustainable Business Model"** either through innovating the materials they use or the processes they implement.

General Challenges.

	Anonymous	BIOVOX	Envetec	GEB	TORSKAL
Acquiring Customers	X	X	X	X	X
Financing	X	X		X	X

[44] (Own illustration)

Product development		X	X	X	X
Business Cycles		X			
Investment Industry	X				
Price sensitivity			X		
Location					X

Table 26: General Challenges Comparison[45]

The left column of Table 26 shows the general challenges the startups faced, as described in the interviews. Three challenges clearly stand out, as they were mentioned by almost every startup: Acquiring the first customers, receiving the first financial investments, and developing the product to market maturity with all necessary functions. All startups faced initial scepticism from potential clients, particularly due to the novel nature of their products, the risk adversity of the pharmaceutical industry and its heavy reliance on references. Furthermore, the specificity of their industries and the novelty of their technologies made it difficult to attract traditional investors who were either sceptical of their sustainability angle or unfamiliar with the technical complexities of their products. Most startups faced the challenge of developing their product to a market-ready state, due to a stringent regulatory environment regarding quality and safety and the lack of adequate financial support during this crucial time. Beyond that, startups have mentioned other challenges, including long business cycles from first customer contact to series production, understanding and integrating into the Venture Capital community, the price sensitivity of customer, and the specific location of a startup.

Success Factors.

	Anonymous	BIOVOX	Envetec	GEB	TORSKAL
Sustainability Differentiator	X	X	X	X	X
Industry Network	X	X	X	X	
Delivering Results			X		X
Team Skills		X		X	
Product Simplicity		X			

[45] (Own illustration)

Fair Assessments	X
Rigorous Research	X

Table 27: Success Factors Comparison[46]

The success factors described by the interviewees are listed in the left column of Table 27, showing similarities and differences among the five startups. All startups used their commitment to sustainability not just as a compliance measure but as a key differentiator in the market. This strategy was particularly effective in attracting niche investors and clients interested in green solutions. Additionally, the majority of startups highlight the importance of leveraging their industry networks to navigate complex market dynamics. This approach helped mitigate the risk aversion typically seen among potential clients in highly regulated industries. Beyond that, Envetec and TORSKAL emphasised that delivering tangible benefits for their customers to gain a reliable reputation was crucial. Moreover, BIOVOX and GEB underlined essential skills of the founders including resilience, pragmatism and openness to change. Finally, the anonymous startup saw the fair assessment in investment rounds as a decisive factor while GEB underscored the importance of rigorous research during the early development phase.

Reactions.

		Anonymous	BIOVOX	Envetec	GEB	TORSKAL
Customer Reaction	Positive			X		
	Positive shift	X	X		X	
	Negative					X
Investors Reaction	Positive		X			
	Positive shift				X	
	Negative	X				X

Table 28: Reactions Comparison[47]

Initially, many of the startups faced indifference or scepticism from customers concerning the sustainability effort made by the startups, as traditional industries were slow to recognize the importance of sustainability. Over time, however, as global awareness of environmental issues grew, BIOVOX, the anonymous startup and GEB began to see a shift in customer attitudes.

[46] (Own illustration)
[47] (Own illustration)

Based on that also the engagement of investors grew and often helped pivot the startups towards more sustainable practices and broader market acceptance. However, the anonymous startup and TORSKAL still believe that sustainability is not valued enough in the investment industry.

Sustainability Advantages. All startups agreed that focusing on a sustainability-related product has advantages from a strategic perspective. Lotz highlighted that there is little competition among startups that offer a sustainability-related solution in the pharmaceutical industry and how this concept attracts high-quality employees leading to recruitment advantages. The anonymous CEO, Malcolm Bell and Anne-Laure Morel all highlighted that there is a huge need for sustainable solutions in the pharmaceutical industry ensuring a steady demand. Lastly, there's a mutual recognition of the branding and differentiation benefits associated with sustainability efforts. Whether it's Wollenhaupt´s acknowledgement of sustainability as a conversation starter or Morel's emphasis on the positive association with environmentally conscious values, startups recognize the strategic advantage of standing out in a crowded market through their commitment to sustainability.

Industry Influence. Finally, there is a consensus about the ability of one or a group of startups to change the pharmaceutical industry. The investigated startups are at the forefront of integrating sustainable practices within the pharmaceutical industry, setting precedents for environmental responsibility. Their efforts are gradually reshaping industry standards and expectations, particularly as they demonstrate that sustainable practices can also enhance economic viability and compliance readiness.

Need for Change. All startups describe that more extensive regulatory support and incentives are necessary to encourage the widespread adoption of sustainable innovations. They advocate for policies that not only promote sustainability directly but also support the ecosystem of startups and small businesses focused on innovative green solutions.

4.2.7 Response to Sub Question II

In conclusion, and to answer the sub-research question "*How does a startup successfully address sustainability challenges of the pharmaceutical industry and how can it influence the whole industry?*", the investigated cases show best practice examples of implementing sustainable solutions into a conservative and risk-averse industry. The impact that an individual startup or a community of startups can have on the entire pharmaceutical industry is evident. This influence is manifested through their innovative approaches, disruptive technologies, and

the new market paradigms they create, which collectively drive shifts in industry standards and practices.

5. Discussion

In the following chapter, the authors discuss the empirical results in context with theoretical findings and existing literature with the objective of answering the research question of how startups can enable the pharmaceutical industry to become more environmentally friendly and identify effective strategies that startups use to encourage that shift.

5.1 Summary of Findings

In the quantitative part of the empirical results the investigated European pharmaceutical startups show a range of engagement levels with sustainability practices. Over half of the respondents have adopted Sustainable Business Models, indicating a moderate consensus on their effectiveness. However, adoption rates for Sustainable Assessment Models and Sustainability Reporting are lower, with mixed opinions on their impact. Surprisingly, few startups engage in Sustainability Reporting despite its importance for transparency. Circular Business Models and Green Supply Chain Management have lower adoption rates but are viewed positively by those who have implemented them. Technology Integration was the most popular strategy, with about 80% of respondents embracing it. This strategy received the highest positive impact rating of 2.14, indicating that startups see it as an effective way to enhance sustainability. Resilience Strategies, on the other hand, are used by approximately 27.4% of participants, with a reasonably positive effectiveness rating of 2.34, highlighting their value in sustainable risk management. The overall findings highlight the complex nature of sustainability in this sector which largely focuses on the social aspect of sustainability (Saxena et al., 2021).

The qualitative analysis complements these findings by showing innovative techniques used by five European startups to apply pharmaceutical sustainability approaches, particularly through innovating the materials they use or the processes they implement. The application of sustainable business models and sustainable production outweighs other approaches, which aligns with the quantitative data showing a significant adoption of Sustainable Business Models. Addressing pharmaceutical challenges, the case studies present innovative ways of reducing different types of waste and how their solutions tackle the lack of awareness and streamline supply chains. This correlates with the lower adoption rates of Circular Business Models and Green Supply Chain Management seen in the quantitative results but highlights their positive reception among implementers. Furthermore, all cases share a common goal of reducing environmental pollution, use advanced techniques for manufacturing, and provide

solutions for accurate reporting of environmental impacts. This supports the quantitative finding that Sustainability Reporting, despite low adoption, is viewed positively.

The main challenges identified in the qualitative data include scepticism from potential clients and traditional investors, particularly due to the novelty of their products and technologies, and stringent regulatory environments. This is echoed in the quantitative data where lower adoption rates for certain sustainability practices may reflect these challenges. The qualitative analysis also identifies success factors such as extensive industry networks to gain credibility, utilizing sustainability efforts as a market differentiator, and educating the markets about the benefits of sustainable technologies. These strategies align with the high adoption rate of Technology Integration in the quantitative results, suggesting that startups view technological advancement as a key to achieving sustainability.

Finally, both the quantitative and qualitative data indicate a global shift in customer opinion towards environmentally friendly solutions, though the qualitative data notes regional differences. The case studies reveal that startups can collectively challenge the major players in the pharmaceutical industry and lay the foundation for its transformation towards sustainability. However, both sets of data suggest that more regulations are needed to ensure sustainability efforts become standard practice and are not penalized by competitive disadvantages. The combined analysis of quantitative and qualitative data highlights the differences and similarities in sustainability integration within the pharmaceutical sector and identifies specific areas where coordinated actions are required to improve sustainability practices industry-wide.

5.2 Underrepresented Sustainability

Startups are often viewed as pioneers of innovation and sustainability within their respective industries, due to their agility and innovation-driven nature (Ressin, 2022). Without startups, the move towards sustainable practices may stall, making them all the more vital in their industries (Palmié, 2021). Chillakuri et al. (2020) and da Silva Nunes et al. (2022) have highlighted how startups can integrate the TBL approach to promote economic, social, and environmental growth. This view is supported by Palmié (2021), who noted that startups often implement eco-friendly business models that boost their innovation and sustainability. However, the results from this study's quantitative research of the pharmaceutical industry in the EU portray a different reality, suggesting that startups may not always drive environmental sustainability.

This research on pharmaceutical startups reveals that most startups are involved in sustainability to some extent; however, the degree and scope of their sustainable initiatives differ widely. Technology Integration ranks as the most popular sustainability strategy, with a 79.8% adoption rate of all the startups that were surveyed. This trend reflects the focus on immediate and measurable benefits, like cost reduction and an increase in efficiency, which is consistent with Ressin's (2022) findings on startups' economic contributions.

However, based on this study's findings, Circular Business Models and Sustainability Reporting are not commonly used sustainability approaches, as only 23.8% and 33.3% of businesses have adopted them. This shows a disconnect between the potential for startups to promote sustainability on a larger scale and the current situation. It's possible that economic restraints, market forces, and a lack of regulatory encouragement may restrict their ability to implement these methods fully. This is validated by Olteanu and Fichter (2022), who found that startups encounter major obstacles in promoting their eco-friendly products and services to potential customers. Furthermore, the fact that approaches like Circular Business Models and comprehensive Sustainability Reporting are not widely adopted, suggests that many companies may be underestimating the challenges associated with implementing these strategies. Although startups might implement specific technologies to increase efficiency and decrease expenses, successfully integrating sustainable business models requires significant changes to business processes, supply chain management, and customer interaction, in addition to technological innovation.

The qualitative analysis, however, shows deeper insights into the sustainability efforts of specific startups focused on the early stages of the pharmaceutical supply chain. These startups, such as the anonymous startup utilizing computational chemistry for API development, and TORSKAL, which applies green chemistry in developing cancer therapies, highlight a strong commitment to environmental sustainability from the beginning of product development. These efforts can minimize environmental footprints directly through reduced hazardous waste and enhanced resource efficiency. In contrast, companies like BIOVOX and Envetec, which are more involved in the manufacturing processes, direct their sustainability efforts towards optimizing existing operations to mitigate environmental impact. They focus their efforts on optimizing operations to mitigate indirect environmental impacts such as emissions and energy use.

These qualitative findings highlight the innovative approaches of startups that not only fulfil current environmental standards but also try to push the boundaries to set new benchmarks within the industry. For instance, Envetec's waste treatment solutions and BIOVOX's bioplastics both represent important improvements in reducing environmental impact. Yet, the broader adoption and integration of these practices across the industry are still limited, influenced by factors such as regulatory challenges, market readiness, and the risks associated with implementing new technologies.

This discrepancy between the general startups and the select few highlighted in the qualitative cases shows a critical gap: while some startups are at the forefront of sustainability, the overall industry's progress towards sustainable practices is less than what might be expected from the literature. Therefore, this section not only reflects on the different levels of sustainability integration among startups but also calls attention to the need for more support mechanisms, including regulatory incentives and market education, to promote a more sustainable industry.

5.3 Sustainable Product Development

The creation of sustainable pharmaceutical products enables other players along the supply chain, as well as customers, to act more sustainably by offering an alternative that can be both cost- and time-efficient, which is shown by all five cases of sustainability-focused companies in this research.

However, according to this study's qualitative results, the move towards sustainable products often encounters resistance due to the industry's conservative nature and reliance on proven methods. The industry is generally hesitant to take on innovations that lack reference cases or lack medical approval. As a result, startups, as seen with GEB and TORSKAL, may struggle to attract investors and customers because the industry prefers already established solutions. One founder being laughed at when proposing a water-based method instead of using petroleum-based solvents, highlights the challenge of overcoming scepticism that views new, sustainable methods as risky or unproven. This notion is also supported in Gottinger et al.'s (2020) research of barriers to an industry to transform towards sustainability, in which it was found that sectoral routines and structures, upholding the dominant standards, are key barriers.

The question of who will be the first to adopt sustainable innovations often leads to a cautious approach, obstructing progress and downgrading sustainability to a "nice-to-have" rather than a necessity, as described by the GEB's founder in this study. Despite presenting sustainable products, startups often face indifference from large companies who prioritize technological

superiority over sustainability. This scepticism poses a significant challenge to sustainability in the pharmaceutical industry, where sustainable practices are viewed as secondary to technological and economic advantages. The startup founders of this study are of the conviction that to gain more traction, sustainability must prove its worth not just environmentally but also technologically and economically as a critical component of innovation driving the industry forward.

Chomać-Pierzecka (2023) highlighted that in the pharmaceutical sector, technological advancements are crucial to have access to cost-effective drugs. For instance, "Digital manufacturing" lets stakeholders collaborate effectively and improves the implementation of protocols, designs, and comprehensive analyses which leads to an overall efficiency increase in the manufacturing process (Waghmode et al., 2022). In addition, the integration of Industry 4.0 enabled the pharmaceutical industry to gain a competitive advantage and establish the efficient management of products from production to disposal (Djunaedi, 2019; Schneikart et al., 2023; Shashi, 2023). The quantitative data of this study shows a substantial adoption of technology integration, which serves as a foundation for startups to develop products that directly improve sustainability. These products often leverage advanced technologies to reduce environmental impact, showcasing a shift towards more sustainable industry practices.

However, new technologies are not fully trusted by pharmaceutical industry professionals and investors, as Riedel (2024) has found. In his study, he researches the adoption of blockchain to advance sustainability in the industry. The unfamiliarity and the stakeholders' lack of trust in the technology lead to unfulfilled potential in sustainability practices. Similarly, Tetteh-Caesar et al. (2024) identified change of resistance and lack of resources as the main barriers to the adoption of Industry 4.0 technologies in the pharmaceutical industry, further solidifying the industry's conservative approach to innovations. This is also corroborated in Gottinger et al.'s (2020) research, in which another identified key barrier is technical challenges in technology application.

For startups in the pharmaceutical industry, receiving funding proves to be a barrier, particularly for those that prioritize sustainability through innovative technologies. The use of established benchmarks and medically approved mass production creates a high entry point for newcomers, making it difficult for startups with unique or unconventional products to attract investor attention. Seconding this notion, Ahn (2017) found that novel botanical drugs building on

traditional medication suffer from a lack of trust from investors, leading to a hindrance in development.

According to this study, most venture capitalists prefer to invest in more conventional or popular sectors such as fintech or MedTech. Hence, startups that focus on the intersection of sustainability and pharmaceuticals often find themselves in a difficult position, as described by BIOVOX's CEO as falling "right between all the stools," where their focus on sustainability does not align with the primary investment categories. Even investors who express interest in such ventures tend to evaluate them based on traditional business metrics like market potential, competitive advantage, and scalability, rather than prioritizing sustainability as a fundamental aspect of the business. Milanesi et al. (2020) support this in their study reviewing challenges and opportunities in the pharmaceutical industry. There, they see that one of the major challenges is the inconsistency in long-term investments, due to scepticism about the tangible returns of sustainability and the high upfront cost. Additionally, Gottinger et al. (2020) identified market and investment conditions as another barrier to transforming an industry towards sustainability, which is consistent with this study's findings.

Furthermore, according to one case study in this research, there is a presence of bias within the investment community, particularly regarding gender. This bias can undermine the credibility and apparent capability of female founders, making it even more difficult for them to succeed in fields like tech and pharmaceuticals. This notion is validated in a report by the World Economic Forum that found that female-founded companies only receive 2% of all venture capital investments annually (Al-Saleh, 2023). This poses an issue, especially considering that female entrepreneurs tend to focus on incorporating sustainability into their ventures, which in turn accelerates the progress towards a sustainable future (Lammers et al., 2022). These challenges show how financial and cultural barriers can obstruct the progress of innovative and sustainable solutions.

As indicated by this study, industry networks have become an important tool for pharmaceutical startups, especially those who seek to implement environmental sustainability. They help overcome barriers like scepticism towards innovation, as well as investment difficulties. Having a strong network in the pharmaceutical market can provide credibility and easier access to resources and partnerships, accelerating growth and innovation. Moreover, building a solid reputation within the venture capital community is crucial. Despite industry achievements, a

lesser-known background posed significant hurdles in securing trust and serious consideration from potential investors, as the founders' experience revealed in this research.

According to this study, investors can be instrumental in reshaping the startup into an operational business entity. This involvement of investors shows the significant benefits of having a network that not only funds but also collaborates and guides the strategic direction of a startup. Furthermore, some venture capitalists, particularly women, have taken an unbiased approach to evaluating startups, creating a more supportive environment for innovation. This highlights the key role that investment plays in enabling startups to refine their operations and market approach effectively.

These experiences show that industry networks with supportive, knowledgeable, and diverse members can offer solutions to the challenges faced by startups in the pharmaceutical sector. The networks not only provide financial backing, but also strategic insight, mentorship, and access to other industry connections. Therefore, encouraging and taking advantage of these networks is essential for startups aiming to innovate in the conservative pharmaceutical industry.

5.4 Building Awareness and Education

The transformation of the pharmaceutical industry necessitates awareness and recognition of its environmental impact by society and all market participants (Köhler et al., 2019). Alajärvi et al. (2021) investigated the awareness of the Finnish population as an example of an evolved European country regarding the environmental impact of pharmaceuticals and discovered a lack of understanding regarding the root causes and significance of different sources of pharmaceutical emissions. The study highlights the need for improved communication about the causes of environmental issues related to pharmaceuticals and public education on the sources and impacts of pharmaceutical residues. The authors suggest that such communication should extend beyond the general public to include healthcare professionals. Connecting to that suggestion, BIOVOX and Envetec delivered perfect examples of how this approach can work out. BIOVOX not only provides information at trade fairs but also co-founded the Alliance of Sustainable Medical Technology with BIOVOX Connect. This initiative serves as a platform for market participants to exchange information about the latest technologies and engage in online conferences on recent topics from and with players in the pharmaceutical and healthcare industry. Through these events, startups can bring together industry experts, investors, and entrepreneurs to discuss and showcase innovations that have the potential to revolutionize the

pharmaceutical industry. BIOVOX's alliances and educational programmes provide a unique opportunity for the industry to stay at the forefront of technological advancements and ensure that patients receive the best possible care.

Furthermore, Envetec takes a proactive approach to promote environmentally friendly waste disposal practices in the pharmaceutical industry. The startup established a strong network to engage with top executives of major pharmaceutical companies and challenge conventional thinking. Through these interactions, Envetec aims to raise awareness about the environmental impact of pharmaceutical waste and encourage producers to reconsider their current waste disposal practices. By highlighting the deficiencies of the existing waste disposal technologies, Envetec encourages pharmaceutical producers to explore alternative solutions that are more efficient and environmentally friendly in connection with significant cost savings. Ultimately, the influence of startups in the pharmaceutical industry goes beyond financial gains as startups have the potential to greatly impact the pharmaceutical industry through various events and initiatives aimed at promoting awareness and education in the sector.

A lot of the current literature focuses on the awareness of the population of pharmaceuticals in the environment, like Roig & Touraus (2010), who state that “Education and awareness on Pharmaceuticals in the Environment have to be integrated in medical and pharmaceutical education and according to the level of education” (Roig & Touraus, 2010). Further, Shaaban et al. (2018), Constantino et al. (2020), and Rogowska (2019) have shown that it is crucial to raise the awareness of proper disposal of household pharmaceuticals. However, to the best of the authors' knowledge, no research has yet investigated the awareness of society and pharmaceutical market players about the overall environmental impact of the whole pharmaceutical industry. This might be due to the fact, that there is a huge gap in transparency and accountability concerning sustainability reporting and the lack of standardized reporting frameworks and regulatory oversight, which leads to inconsistencies in reporting practices within the pharmaceutical sector industry (Belkhir & Elmeligi, 2019; Veleva et al., 2017). This makes it nearly impossible to state the impact of pharmaceutical companies in reliable, comparable numbers and the inability to summarize the environmental footprint of the whole pharmaceutical industry. Both the environmental impact of the pharmaceutical industry in numbers and the awareness of it among society need further investigation.

5.5 Delivering Data for Reporting

Building up on the topic of reporting, which plays a significant role in the transformation of an industry, previous research has shown that the pharmaceutical industry outperforms other industries concerning its general comprehensiveness of sustainability reporting by providing broader information on multiple major sustainability aspects than other companies (Demir & Min, 2019). According to Malay (2021), pharmaceutical companies tend to report about 30% more problems than companies in other sectors while Azim and Azam (2013), Demir and Min (2019) and Malay (2021) explain that sustainability reporting enables companies to improve their corporate image and discuss their limitations with investors.

However, the range of information included, and methods used in the sustainability reports varies greatly among different pharmaceutical companies on a national level and on a business level (Malay, 2021; Demir & Min, 2019). Both Schneider et al. (2010) and Demir and Min (2019) examined the reporting content priorities of pharmaceutical companies and concluded with different focus areas while both noticed in general a stronger focus on social issues. Demir and Min (2019) explain those discrepancies with the voluntariness of, and limited standardization and regulatory oversight in sustainability reporting and partly also with the non-availability of data and numbers that the reporting could be based on.

While the five investigated startups cannot influence the reporting consistency among pharmaceutical companies, they can provide their customers through the application of their technology with previously unknown data, allowing them to report fact and number-based issues, they simply haven't had the right data for before. Four of the five startups deliver concrete examples of what new data they generate and deliver. BIOVOX and GEB offer a CO_2 calculator with which the customer can calculate the CO_2 footprint of their medical products/labware and how much they can reduce it thought the application of the new products. Envetec conducts a full audit of the waste stream of its customers and delivers data on the CO_2 emissions and water usage of the implemented waste disposal methods. Finally, the anonymous startup elucidates that many pharmaceutical manufacturers don't have numbers to calculate the environmental footprint of their plants. However, the startup can monitor and measure their production processes very well and thus receives very specific data about the environmental impact of the plants of their customers. In addition, its customers are able to do the same by using the technology toolbox.

As a result, the startups help their customers to report more accurately and easily on their environmental impacts and contribute to filling gaps in sustainability reporting by offering data-driven insights previously unavailable to pharmaceutical companies. Thus, startups can significantly contribute though their innovative data-delivering technologies to the “normative directionality”, which Köhler et al. (2019) have named as a characteristic of sustainability transitions. In combination with the demands of the five cases and those of many researchers to establish universally applicable, mandatory regulations and standards for the pharmaceutical industry, the startups could address the problem of free-riding of polluting major players.

5.6 Success as a Role Model

In the quantitative analysis, more than 50% of the respondents replied that they adopt a sustainable business model, leading to an increase in the company’s efforts. In addition, the case study highlighted several benefits of developing a sustainable product from the startups‘ perspective. The dedication to providing sustainable solutions has set the analysed startups apart from their less sustainable competitors, presenting a valuable branding opportunity. The interviewees describe a low level of competition among startups offering sustainability-related solutions in the pharmaceutical industry, despite a high demand for such products. The companies also recognized that their commitment to sustainability helps initiate important conversations and reflects positively on their company's environmentally conscious values.

This aligns very well with the observation of several studies that investigated the correlation between a company´s focus on sustainability and its overall performance. Mihaiu et al. (2021) discovered a significantly positive relationship between a company's sustainability practices, measured by an Environment Social Governance (ESG) score, and its overall performance and success, with a specific focus on the pharmaceutical industry. Furthermore, Bade et al. (2023) found a positive connection between ESG maturity and net sales while Kong et al. (2023) found that companies with strong ESG disclosure practices outperformed their competitors in terms of stock market performance and return on equity. In addition, Min et al. (2017) analysed the impact of a company’s CSR score and revealed that companies benefit from engaging in CSR activities, as it positively impacts their profitability. Thus, researchers recommend viewing investments in CSR initiatives as long-term investments that will improve the company's overall profitability over time and function as a form of insurance against unforeseen disruptions, as companies that engage in CSR activities tend to lose less value during such events compared to those that do not. It is worth mentioning, however, that sustainability efforts might not always be initially beneficial for companies. Oftentimes, there is an economic burden

in the implementation of sustainable practices in the shape of high upfront costs, and the risk of not achieving immediate financial returns (Camilleri, 2017).

The examined startups have achieved great success by prioritising sustainability. Not only have they displayed the benefits of a sustainable business model to the industry, but they have also become an example for others to follow. Their decision to focus on sustainability has resulted in significant advantages. This is a lesson that larger market players can learn from. The CEO of the anonymous startup noted that investors tend to invest in a company if it follows a specific trend, whether they are venture capitalists or private investors. As more startups commit to sustainability, they reinforce the trend of the whole industry to focus on sustainable solutions and thus encourage investors to invest more in sustainable solutions. These startups have set themselves apart from the competition as not only the environment but also the businesses benefit from the sustainability activities. Their efforts have been rewarded with considerable advantages, serving as an example for all pharmaceutical companies to make a positive impact while achieving financial success.

5.7 Policy Implications

From a managerial point of view, there is a need for further research and development, followed by the adoption of new technologies, to reduce the environmental footprint of the pharmaceutical industry. Specifically, advancements in green chemistry, waste management, and energy efficiency are needed to address the environmental impacts that are associated with pharmaceutical production. By focusing on these areas, the industry can make substantial progress towards sustainability, improving not only its compliance with environmental regulations but also enhancing its overall ecological direction. Furthermore, to effectively manage the implemented sustainability strategies, companies require a monitoring system. Such a system should track the performance and benefits of sustainability practices, which makes these outcomes more tangible for stakeholders. By providing clear and reliable data, this approach not only improves the credibility of the company's sustainable efforts but also increases the public’s trust. This can encourage greater engagement and support from stakeholders, contributing to the overall success and acceptance of sustainability initiatives within the company.

5.8 Research Implications

There is a need for more research into the long-term impacts of sustainable practices within companies, focusing on business performance, consumer behaviour, and environmental

outcomes. Such studies would give valuable insights and evidence, enabling other startups and companies to clearly see the advantages of incorporating sustainability strategies into their operations. This understanding could facilitate broader adoption of sustainable practices across various industries, contributing to more environmentally responsible and economical businesses. The complexity of sustainability challenges leads to a need for comprehensive studies that cover environmental science, technology, sociology, and business. This approach is important for exploring how sustainability practices influence the pharmaceutical industry and for identifying effective strategies to overcome the technical and material barriers highlighted in this research. By integrating insights from these fields, a more thorough understanding of the current dynamics can be developed to create more effective solutions to promote sustainable development within the industry. Additionally, further research is needed to thoroughly research the symbiotic relationship between large pharmaceutical companies and startups, particularly in understanding how each influences the other in the area of innovative sustainability practices. This is critical to identifying how these two distinct business models can collaborate effectively, and then potentially lead to further implementations of sustainable innovations within the industry. Understanding this dynamic will provide valuable insights into the opportunities and challenges faced by both large pharmaceutical corporations and startups and could lead the way for more strategic partnerships and joint ventures that focus on sustainability.

6. Conclusion & Limitations

The study explored the role of startups in promoting sustainability in the pharmaceutical industry of the EU to answer the research question "*How can startups enable the pharmaceutical industry to transform towards sustainability?*". The results showed that startups are well-positioned to introduce sustainable practices, applying different kinds of implementation strategies. Nevertheless, the industry's conservative nature and regulatory complexities hinder a broader shift towards sustainability. Further, startups face several challenges in attracting investors and customers even though their products offer cost-efficient and environmentally friendly alternatives. Even though the integration of advanced technologies can enhance sustainability, scepticism and resource constraints can hinder their widespread adoption. Moreover, startups build awareness and educate major industry players about the environmental impacts of pharmaceuticals which is crucial for the industry´s push towards more sustainability. Finally, startups play a key role in the sustainability transformation of the pharmaceutical industry by providing innovative data for more accurate sustainability reporting and demonstrating the benefits of sustainable business models, which can inspire larger companies. Nevertheless, initial financial constraints and the need for long-term research into the impact of sustainable practices remain. Encouraging industry networks, supportive policies, and strategic collaborations are essential for driving sustainable innovation and transforming the pharmaceutical sector.

This research makes a valuable contribution to the academic discussion on sustainability in the pharmaceutical sector. It offers empirical evidence on the potential of startups to drive sustainable practices. It emphasizes the need for regulatory frameworks that incentivize sustainable innovation and acknowledges the crucial role of startups in setting new sustainability standards.

This study acknowledges several limitations that could affect the interpretation and generalization of its findings. There are limitations in the sample size in the quantitative study, where the desired number of responses was just marginally missed, as well as the qualitative study, in which there were only 5 cases, which might not have been representative. This could have potentially impacted the reliability of the empirical findings. Concerning the qualitative case study, there was a risk of subjective bias in the responses from the interviewees as they might have been inclined to portray their startups in an exaggerated positive light, due to subjective feelings and the chance to promote their startup. The study also recognizes the possibility of involuntary biases in both the conduction and interpretation phases of the

qualitative research. Furthermore, in both research designs, the diversity in pharmaceutical practices across different European countries may show variations that could have misrepresented the results, further complicating the interpretation of the data. Additionally, the research only examined successful startups, which potentially led to a biased perspective. The conclusions may have been different if the study had also considered startups that failed in their ventures. These constraints highlight the need for cautious application of the study's conclusions and show the necessity for further research in the field.

To mitigate the limitations, it would be useful to expand the sample sizes for both the quantitative and qualitative analyses. Diversifying the case studies to include a bigger range of startups from different European regions could provide a more representative overview of the industry's practices. Incorporating cross-country comparative studies, not limited to the EU, would also enable a deeper understanding of regional differences in pharmaceutical practices. Finally, conducting longitudinal studies could give insights into the sustainability of business practices over time and help further reduce biases, thereby improving the overall validity of the conclusions. These steps would significantly strengthen future research in this area.

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Appendix A – Survey Questionnaire

Section A: Demographic Questions

1. In which sector is your company active?
2. What is your role within the company?
3. Where are the headquarters of your company?
4. How many employees are currently employed at your company?
5. What is the estimated company value?
6. What is the annual revenue of your company?

Section B: Sustainability Approaches

1. Does your company currently have a **Sustainable Business Model** in place?
2. *If you answered with yes, to what extent do you agree with the following sentence*: A Sustainable Business Model has positively benefited my company's sustainability performance.

3. Does your company engage in the utilization of **Sustainable Assessment Models** to evaluate environmental performance?
4. *If you answered with yes, to what extent do you agree with the following sentence:* Using a sustainable assessment model has positively benefited my company's sustainability performance.

5. Does your company engage in the **reporting of sustainability**?
6. *If you answered with yes, to what extent do you agree with the following sentence:* Reporting sustainability practices has positively impacted my company's sustainability performance.

7. Has your company implemented a **Circular Business Model**?
8. *If you answered with yes, to what extent do you agree with the following sentence:* Implementing a Circular Business Model has positively benefited my company's sustainability performance.

9. Does your company integrate environmental considerations into its **supply chain management** practices?
10. *If you answered with yes, to what extent do you agree with the following sentence:* Incorporating green supply chain practices has positively benefited my company's sustainability performance.

11. Does your company incorporate **Sustainable Production Principles** into its operations?
12. *If you answered with yes, to what extent do you agree with the following sentence:* Utilizing sustainable production principles has positively impacted my company's sustainability performance.

13. Does your company use **innovative technologies** in its operations?
14. *If you answered with yes, to what extent do you agree with the following sentence:* Technological integration has positively impacted my company's sustainability performance.

15. Does your company incorporate **Resilience Strategies** to address environmental and operational risks?
16. *If you answered with yes, to what extent do you agree with the following sentence:* Incorporating resilience strategies has positively impacted my company's sustainability performance.

Appendix B – Case Study Database List

Anonymous
Interview with Founder & CEO
No further sources to not expose identity

BIOVOX
Interview with Co-founder & CEO
https://www.biovox.systems/
https://medizin-und-technik.industrie.de/technik/entwicklung/start-up-biovox-biokunststoffe-fuer-medizinprodukte/
https://www.technologieland-hessen.de/bp-biovox
https://www.starthub-hessen.de/aktuelles/biovox-biokunststoffe-in-medizinischer-qualitaet/
https://www.starthub-hessen.de/showcase/ask-a-start-up-biovox-entwickelt-nachhaltige-kunststoffe-mit-innovativen-eigenschaften/
https://www.youtube.com/watch?v=6MAXgMog0f8
https://www.youtube.com/watch?v=0gR0fZktxWw
BIOVOX Biokunststoff Kompendium, Auflage 2, 2023 (sent via e-mail)

Envetec
Interview with Founder & CEO
https://envetec.com/
https://envetec.com/news/2022/06/envetec-partners-with-my-green-lab-as-a-breakthrough-level-sponsor/
https://envetec.com/news/2022/04/envetec-sustainable-technologies-to-launch-generations/
https://envetec.com/news/2024/01/how-envetec-and-northwell-health-are-spearheading-the-treatment-of-regulated-medical-waste/
https://envetec.com/news/2023/03/ongoing-study-demonstrates-90-reduction-in-greenhouse-gas-emissions-for-the-treatment-of-biohazardous-waste-using-envetec-generations-technology/
Envetec's Clean Technology Shows a Substantial Reduction in Green House Gas Emissions by Over 90% for the Treatment of Biohazardous Waste - Envetec
Northwell targets medical waste (beckershospitalreview.com)

On the Road Blog Series: ACT Certification Label - Envetec
Envetec-amended-3.pdf (halstongroup.co)
https://pitchbook.com/profiles/company/520032-43
https://www.linkedin.com/posts/envetec-sustainable-technologies_envetec-takes-the-lead-in-advancing-research-activity-7115724354855821312-fop9/
https://wasteadvantagemag.com/northwell-collaborates-with-envetec-to-become-first-health-care-system-in-u-s-to-implement-innovative-clean-technology-to-treat-regulated-medical-waste/
https://www.siliconrepublic.com/start-ups/enda-kenny-envetec-board-of-directors-generations
https://springwise.com/innovation/health-wellbeing/treating-biohazardous-lab-waste-on-site/
https://www.3blmedia.com/news/envetec-partners-my-green-lab-breakthrough-level-sponsor-highlighting-companys-commitment
Recycling opportunities for Regulated Medical Waste / Clinical Waste: A comparison of output materials from Thermal and Non-Thermal treatment technologies (sent via e-mail)
GENERATIONS Brochure (sent via e-mail)
Carbon action "GHG COMPARISON ASSESSMENT Biohazardous Waste Processing Technologies" (sent via e-mail)

Green Elephant Biotech
Interview with Co-founder & Managing Director
https://www.greenelephantbiotech.com/
https://www.greenelephantbiotech.com/post/future-bioplastic-for-cell-culture
https://www.greenelephantbiotech.com/post/product-launch-green-elephant-biotech-gmbh-launches-the-world-s-first-plant-based-96-well-plate
https://www.atlaszero.earth/solution/green-elephant-biotech-gmbh
https://www.facebook.com/reel/570990031097293
https://www.uni-giessen.de/de/fbz/fb02/fb/einrichtungen/ecm/news/cc-green-elephant
https://www.chemanager-online.com/news/green-elephant-biotech-innovative-zellkultursysteme-aus-3d-gedrucktem-biobasiertem-kunststoff
https://www.technologieland-hessen.de/bp-greenelephant
https://www.pharmiweb.com/press-release/2024-01-31/green-elephant-biotech-launches-the-worlds-first-plant-based-96-well-plate-for-laboratory-sustainability

https://pitchbook.com/profiles/company/491562-55
https://www.giessener-anzeiger.de/stadt-giessen/innovation-im-gruenderpreis-finale-91871886.html
https://www.mittelhessen.de/lokales/kreis-giessen/giessen/giessen-team-green-elephant-biotech-der-thm-im-finale-von-hessen-ideen-1776296
https://commercialisation.esa.int/startups/green-elephant-biotech-gmbh/
https://analyticalscience.wiley.com/content/news-do/nachhaltiges-zellkultivierungssystem-trotz-single-use-cellscrew
https://www.innovationszentren.de/media/tr_2023_05_mai.pdf
https://european-biotechnology.com/up-to-date/latest-news/news/german-companies-to-revolutionise-lab-plastics-market.html
https://www.fr.de/wirtschaft/bioplastik-fuers-labor-91833560.html
https://www.regmednet.com/sustainability-in-pharma-an-interview-with-joel-eichmann/
https://firmeneintrag.creditreform.de/35394/6110556737/GREEN_ELEPHANT_BIOTECH_GMBH
https://www.northdata.de/Green+Elephant+Biotech+GmbH,+Gie%C3%9Fen/HRB+10837
https://www.plastverarbeiter.de/roh-und-zusatzstoffe/biokunststoffe/biopolymer-innovation-award-2023-platz-2-ein-zellkultursystem-aus-pla-730.html
https://www.system-c-bioprocess.com/en/produit/cellscrew-2/
https://podcasts.apple.com/us/podcast/episode-00-mit-green-elephant-biotech-gr%C3%BCnder-felix/id1719585522?i=1000637798205
https://www.youtube.com/watch?v=JXG5DfjYtlQ
https://www.youtube.com/watch?v=vu8E7ABGVtk
UN SDGs – Green Elephant Biotech (sent via e-mail)

TORSKAL
Interview with Founder & CEO
https://www.torskal.com/
https://www.torskal.com/press-release-torskal-extends-its-know-how-in-analysis-and-research-services-in-various-scientific-fields/
https://www.torskal.com/press-release-torskal-announces-its-collaboration-with-analytic-lab-for-the-sale-of-its-gold-nanoparticles/

https://www.torskal.com/torskal-launch-their-e-commerce-platform-to-sell-their-unique-gold-nanoparticles/
https://www.torskal.com/an-interview-with-usbeketrica-regarding-our-work-medicinal-plants-from-reunion-island/
https://www.torskal.com/a-complete-interview-with-lets-go-france/

Appendix C – Interview Guideline

Personal Background

1. Could you please briefly introduce yourself, including
   a) your position in your startup
   b) how long you have been part of the startup
   c) how much does sustainability play a role in your daily work live (e.g. you work in the product development where you try to make the carbon footprint of your product smaller or something simple like you follow company policies telling you to travel by train instead of plane)
2. What was your motivation to found/ join the startup?

Company background

3. Could you please introduce your startup, including
   a) mission and goals, particular in relation to sustainability
   b) competitive advantage
   c) market share

Company history

4. What were the main challenges and barriers during the founding and scale-up phase of your startup?
5. So, what would you say were the key success factors to get there were your startup is today?
6. How did you accomplish to develop the specific technology? (e.g. did the founders have a specific expertise in that field or did you buy it or did you find it in the literature)
7. Were/are external investors involved in the company and if yes, how did you convince them at the beginning to support your business?

Your startup in the pharma industry

8. What would you say which sustainability challenges of the pharmaceutical industry do you tackle with your startup?
9. Can you say which sustainability approaches of the pharmaceutical industry you use?

Industry Impact & Future outlook

10. Which influence do you think has your startup on the pharma industry? And how do you see/ recognize that?
11. How much power do you think does your startup has to transform the whole industry? And why?
12. Does your startup have goals or initiatives planned for the future concerning sustainability?

Other startups

13. What in your opinion would have to change in the industry to motivate more startups to create more sustainable solutions? E.g. politically or in the society
14. What advantages do you see in concentrating on a sustainable solution from a startups perspective that might motivate other startups to create more sustainable solutions?

Closing

15. Does your company have reports or other documents where I can read something about your sustainability approaches and efforts?

Is there anything you would like to add? Anything concerning sustainability in your startup or in the industry that lies on your tongue. You are free to say no.

Appendix D – Coding Scheme

A) “How does a startup look like that successfully addresses sustainability challenges of the pharmaceutical industry?”

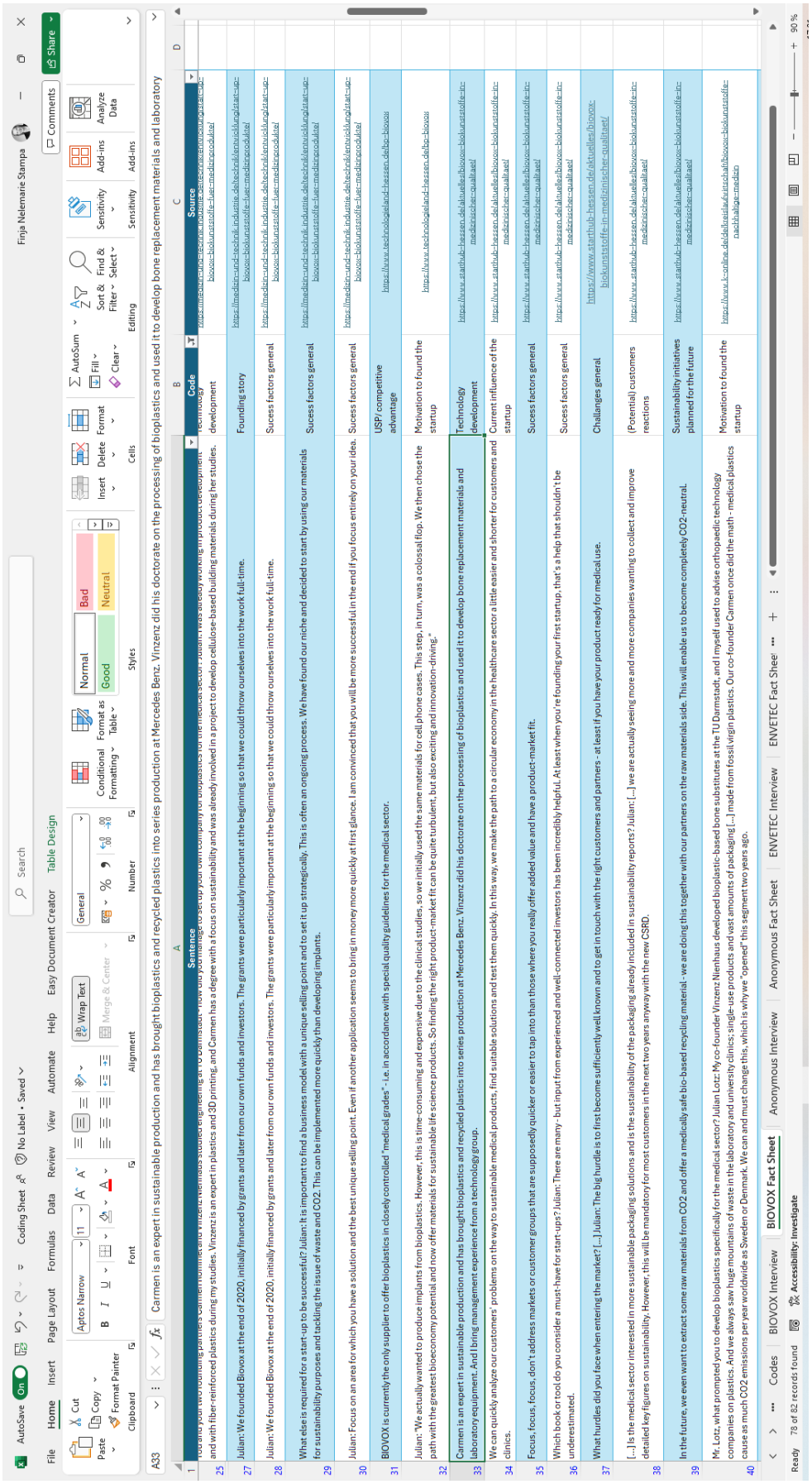
- Non-sustainability related company description
- Sustainability related company description
- Non-sustainability related product/ service description
- Sustainability facts about products/ services
- USP/ competitive advantage
- Mission & goals concerning sustainability today
- Technology development
- Sustainability initiatives planned for the future
- Founding story
- Motivation to found the startup
- Advantage from a company perspective to focus on sustainability
- Challenges general
- Success factors general
- Pharma challenge tackled
    - General Waste
    - Medical & Hazardous Waste
    - Lack of Awareness
    - Outsourcing
    - Environmental Pollution
    - Existing Regulations
    - Rushed Manufacturing
    - Reporting
    - Supply Chain Complexity
    - R&D Intensity
- Pharma approach applied
    - Sustainable Production
    - Sustainable Assessment Models
    - Technology Integration
    - Circular Business Initiatives

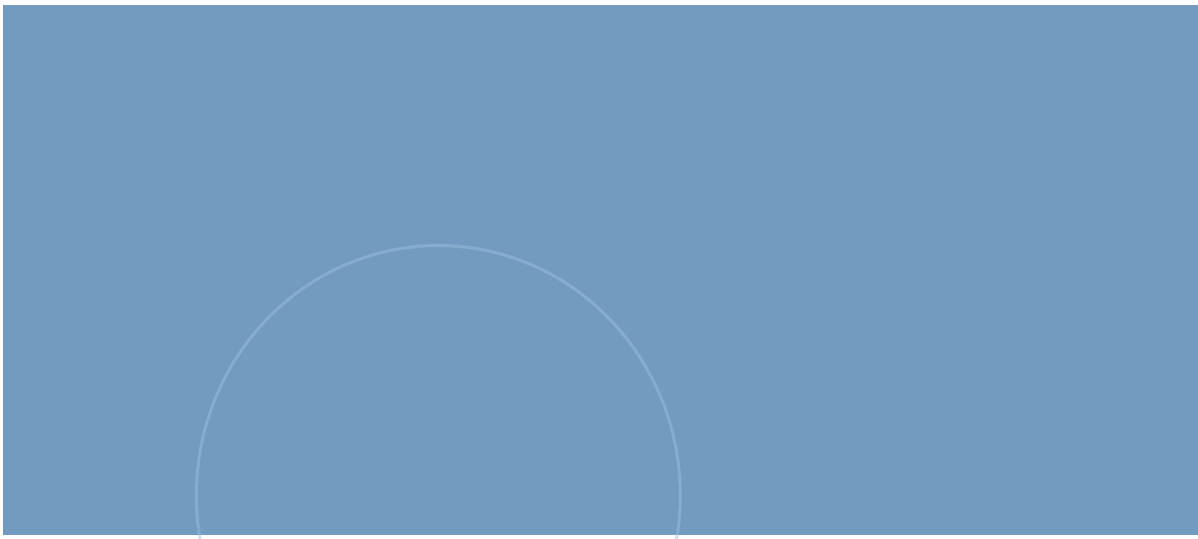
    - Reporting Approaches
    - Green Supply Chain Management
    - Resilience to Disruptions
    - Sustainable Business Models

B) “How can it influence the whole industry?”

- Investors reactions
- (Potential) customers reactions
- Suppliers’ reaction
- Current influence of the startup
- Possible influence of this/ any startup
- What is needed for the industry change?

Appendix E – Screenshot of the Excel Sheet for Coding Process





NTNU
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