MAKING THE BIGGEST IMPACT VIA FOCUSED PRODUCT STEWARDSHIP STRATEGY FOR PHARMACEUTICAL DEVICE AND PACKAGING DEVELOPMENT

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ABSTRACT

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Abstract
Through increasing scrutiny regarding sustainability efforts, many pharmaceutical companies are adopting an environmental management strategy called product stewardship. Product stewardship is a sustainable manufacturing practice that aims to minimize risks, and social and environmental impacts throughout a product's life cycle and utilizes the concept of shared responsibility. This thesis is of case study nature and deals with a pharmaceutical case department that is responsible for the design and development of pharmaceutical devices and packaging. Product stewardship has been implemented on corporate level at the case organization but not yet officially on functional level at the specific case department. Therefore, this thesis aims to develop a product stewardship strategy for the case department by first identifying a suitable strategic model for product stewardship implementation before conducting a current situation analysis and gap analysis of the case department in terms of how far the product stewardship integration has already been developed. First, a literature review of 39 academic articles and book chapters was done to identify the overall framework of product stewardship and how it is portrayed in literature. Second, a quantitative pulse survey was done in the case department to receive insights into the current level of product stewardship integration. Third, 14 semi-structured interviews with experts from device development, packaging development, leadership, and sustainability were conducted to gain further insights and establish potential themes and content for the product stewardship strategy. Lastly, the findings of the survey were integrated into the interview findings to build on the literature framework for the strategy formulation. The product stewardship strategy for the case department is built on five strategic pillars which are Design for Environment, Extended Producer Responsibility, collection & recycling, education, and collaboration & partnership as well as the prerequisite of leadership and includes a total of 12 different goals that are further split into action items for short-term, mid-term, and long-term to ensure sustainable product design and full integration of product stewardship at the case department.

Keywords
Product stewardship, environmental management strategy, pharmaceutical packaging development, pharmaceutical device development, sustainable product design

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ABBREVIATIONS

General Abbreviations

CSR	Corporate Social Responsibility
DfE	Design for Environment
E-factor	Environmental Factor
Etc.	Et cetera
EPR	Extended Producer Responsibility
FDA	U.S. Food and Drug Administration
GMP	Good Manufacturing Practice
LCA	Life Cycle Assessment
Resp.	Respectively
WHO	World Health Organization

Case Department-Specific Abbreviations

DA	Process Engineering Chapter
DC	Product Care Chapter
DE	Device Engineering Chapter
DH	Human Factors Engineering Chapter
DM	Device and Packaging Engineering Synthetic Molecules Chapter
DP	Packaging Engineering Chapter
DS	Primary Container Engineering Chapter
DV	Verification Engineering Chapter
EC	Enabling Circle Chapter
Group SHE	Safety, Security, Health & Environmental Protection Department

1 INTRODUCTION

With the progression of the climate crisis, the question of its origin, perpetrators, and how to try to improve the situation is increasingly coming into focus. One industry, that only in recent years has come under scrutiny regarding its sustainability efforts, is the pharmaceutical industry. Sustainability or sustainable development is defined as *"meeting the needs of the present without compromising the ability of future generations to meet their own needs"* (World Commission on Environment and Development, 1987, p. 16). While at the core, the pharmaceutical industry, in short pharma, is trying to improve the health of people through researching, developing, producing, and marketing pharmaceutical drugs, vaccines, and treatments for common and rare diseases, it can only do so with a healthy planet. But like all major industries, the pharmaceutical industry could potentially be contributing to the deterioration of the planet through unsustainable practices, potentially wrongful disposal of drugs on customer side and, or generating substantial amounts of waste and wastewater. These all lead to increasing environmental consequences and therefore, are threatening the very thing pharma seeks to improve – global health (Moermond et al., 2022; Tao et al., 2023).

To minimize risks and liabilities as well as improve the environmental footprint of products, many pharmaceutical companies are nowadays deploying specific environmental management strategies to achieve these goals. One specific strategy that aims at minimizing the environmental and social impact of a product throughout its entire life cycle is called product stewardship. Product stewardship is a sustainable manufacturing practice that extends beyond the manufacturing process of a product but rather includes the whole supply chain across all life cycle stages and additionally includes end-of-life considerations; cradle-to-cradle (de Bakker et al., 2002; Hart, 1995; Jensen & Remmen, 2017). It is based on the principle that all stakeholders in a product life cycle have shared responsibility to reduce the environmental impact of that product (Lewis, 2005). In theory, this approach seems straightforward. In practice, however, the introduction of product stewardship is more difficult, especially at the functional, departmental level. The actual integration and implementation of corporate strategies at departmental level and the derivation of targeted activities for day-to-day business are often associated with challenges. This is also true at the device and packaging development department of a pharmaceutical company that currently struggles with the integration of product stewardship. Therefore, this thesis takes a closer look at how the theory behind product stewardship is best tailored and implemented to match the needs of this specific case department.

In this chapter, a brief background on the pharmaceutical industry as well as the rationale for doing this research are given. This is followed by introducing the research questions, research boundaries, and the motivation for doing this study.

1.1 Background

In this section, key information regarding the pharmaceutical industry is shared. This includes introducing the industry itself as well as current research on the sustainability status and efforts in pharma. The topic of product stewardship is presented as one possible effort to not only improve the sustainability reputation of pharma companies, but to also manage risks and liabilities, and to reduce the social and environmental footprint of pharma products during their entire life cycle. Next, the case department, a device and packaging development department of a multinational pharma company that is also trying to get a foot in the door regarding the topic of product stewardship, is introduced. Lastly, this section gives reasons as to why the proposed research problem is worth being studied not only from a practical point of view but also from an academic viewpoint.

The pharmaceutical industry comprises over 234 publicly listed companies and includes names such as Pfizer, Merck & Co, Johnson & Johnson, Novartis, AbbVie, Roche, Bristol Myers Squibb, AstraZeneca, Sanofi, or GSK. (Connelly et al. 2021; Plieth, 2023). The production of pharmaceuticals requires the use of a lot of chemicals and solvents, and usually generates substantial amounts of wastewater and chemical residues, which obviously makes the pharmaceutical industry unsustainable and is confirmed based on the environmental factor (E-factor) by Sheldon et al. (2007). According to Sheldon et al. (2007), the E-factor is the amount of waste generated in a process and is defined as everything except the desired output product itself. Consequently, a higher E-factor means more waste and thus a higher negative environmental impact. In the pharmaceutical industry, the E-factor ranges from 25 to over 100 kilograms of waste per 1 kilogram of product (Sheldon et al. 2007). Based on this, Chaturvedi et al. (2017) state that the pharmaceutical industry is one of the most polluting industries. Yet, according to Belkir and Elmeligi (2019) and Booth et al. (2023), the healthcare sector in general, and especially the pharmaceutical industry has received little attention from peer-reviewed literature regarding their sustainability. Only recently a handful of studies looked at the environmental impact of the pharma industry. Belkir and Elmeligi (2019), for example, analyzed the pharma industry over four years from 2012 to 2015. Out of the two hundred companies in scope of the study, only 25 major companies reported their Scope 1 and 2 emissions, and of those only 15 reported their emissions consistently during the set period. This lack of completeness and transparency in reporting is also accredited by Booth et al. (2023). Based on their findings and to receive a better picture of the pharmaceutical market and its impact on the natural environment, Belkir and Elmeligi (2019) estimated the aggregated global emissions of the pharma industry to be about 52 MMt-CO2e in 2015. This result is about 12% higher than that of the automotive industry; about 46.4 MMt-CO2e, for the same year (Belkir & Elmeligi, 2019). According to Murray (2022), one of the main differentiating factors between the two industries lies in the adoption of digital technologies. According to Wieland

(2023), the global healthcare sector, to which the pharma industry belongs, contributes to about 5% of global emissions, with 50% of the emissions created in the supply chain.

To comply with the Paris Agreement, Belkir and Elmeligi (2019) estimate the pharma sector needs to reduce its emissions by 59% by 2025. Connelly et al. (2021) notice a positive trend for the largest pharma companies to already have decreased their annual Scope 1 and Scope 2 emissions by 5.63% per year in the past 5 years since 2015. In the same period, the top 15 companies on average managed to decrease their carbon emissions by 9.26% per year (Connelly et al. 2021). These deductions in emissions stem from switches to green electricity, increasing energy efficiency in manufacturing and operations, sustainable sourcing of raw materials, the decrease and recycling of waste, and a decrease in water usage (Booth et al., 2023). While the 'quick wins' of reducing emissions through switching to renewable energy, reducing the amount of water used, managing waste better, etc. have been achieved by many companies, the necessary next steps to further advance sustainable changes are more challenging. Therefore, many pharmaceutical companies are nowadays deploying specific environmental management strategies to manage risks, reduce liabilities, and decrease the environmental footprint of their products. One of those strategies is product stewardship, which aims at minimizing the environmental and social impact of a product throughout its entire life cycle and is about shared responsibility with all stakeholders of the product's life cycle (Lewis, 2019; Nicol & Thompson, 2007). Because of its responsibility-sharing nature, the strategy has implications for all stages, functions and stakeholders that contribute or appear in the life cycle of a product (Lewis, 2019; Nicol & Thompson, 2007). When looking at the life cycle of drug products, according to Wieland (2023), more than 50% of the emissions are created along the supply chain. Although impacts occur at every stage of a product's life cycle, the majority are captured during the design stage (Lewis et al., 2001) which can account for up to 80% of the total emissions for pharmaceutical products (Lovsin, 2023). Therefore, the integration of product stewardship especially during the development and design stage of the drug product is important for the overall footprint.

This has also been recognized by this thesis' case organization, a Swiss multinational pharmaceutical company. The company has publicly committed to a product stewardship strategy, has time-bound goals to measure and improve the footprint of its existing products, and plans to apply lessons learned across its product portfolio. These goals are set at corporate level; however, the implementation and execution of those goals occurs at functional level; and are strongly focused on various design and development departments within the organization. One of those departments is the device and packaging development department, which, in this thesis, is referred to as case department. The case department's main objective is to develop and design pharmaceutical packaging and devices for future drug products that are currently in development. Pharmaceutical packaging and devices play an important role in the quality of drug products. Adequate pharmaceutical packaging has four main roles. It must protect

against external influences which could alter the properties of the drug products such as moisture, light, oxygen, or temperature variations, it must protect against contamination and physical damage, and it must be labeled with the correct information and identification of the product (Ibrahim et al., 2022; WHO, 2002). Pharmaceutical devices entail instruments used to deliver drugs to the body such as injectors, inhalers, implants, etc. The types of materials used to manufacture pharmaceutical packaging and devices range from plastics, paper, glass, metals, cardboard, etc., to the use of batteries and electronics. As the pharmaceutical industry is one of the most highly regulated industries (Handoo et al., 2012), a simple switch from current materials to more environmentally friendly alternatives proves to be difficult. This is especially true for changing material compositions of devices that often contain various kinds of plastic. However, with increasing liabilities and a potential for raw material shortages, pharmaceutical companies are prompted to act now and to best prepare themselves for the future.

This is also what the case organization and subsequently, the case department are currently doing. They want to prepare themselves as good as possible for the future. However, the case department is facing some challenges in doing that. Preparing for the future through product stewardship, entails the development of a respective strategy, which needs to be in line with the corporate product stewardship strategy. Yet, this poses a great challenge for the case department, as it lacks the necessary expertise, time, resources, and knowledge to identify and realize product stewardship opportunities into sustainable product development and how to best develop a tailored strategy that is focusing not only on the department's strengths, but also on its weak spots. The main objective of the case department is to develop effective pharmaceutical packaging and devices for future medicine to ensure the drug products are protected, secured, and designed to ideally have as small of an environmental footprint as possible. Therefore, this thesis examines the case department's problem closely and suggests solutions to assist the department in translating the concept of product stewardship into specific action items to follow and to help with the integration of the company's product stewardship strategy at functional level with a mix of utilizing existing product stewardship literature and gathered primary data.

Although designing a product stewardship strategy for the development of pharmaceutical devices and packaging may seem odd, as the production of the actual drug is more emission-intensive, there are good reasons for it. All positive changes regarding sustainability aspects in a product's life cycle have an impact on the total footprint, no matter how small. However, in the case of pharmaceutical packaging and devices, there is a concerning aspect. Current market trends indicate a change in how medicine will be used. There is a clear trend away from hospitals and clinics towards at-home-administered medicine and self-testing, and additionally, a trend towards self-managed and self-administered medicine instead of health professionals (Kulkova et al., 2023; Lewis, 2022). This will influence the injectable segment such as autoinjectors or pens. Therefore, that market segment is anticipated to propel in the next years (Grand View Research, n.d.; Kulkova et al., 2023). Through the expected growth, subsequently, an increase in

waste is to be expected as smaller dosages and more devices and packaging are necessary to administer those injections. With that the need for virgin materials and the amount of waste generated is expected to increase similarly which poses several additional problems. First, more virgin materials will be needed to meet the demand, however, shortages in raw materials and delivery delays through increased severe weather events and climate change could be potential roadblocks in meeting this higher demand (Lawrence et al., 2020). Second, the increased usage of raw materials and waste is in direct competition with achieving the set net zero goals of many pharmaceutical companies. Third, policymakers and countries are establishing more requirements and regulations for the production, selling, and disposal of pharmaceutical products (Alajärvi et al., 2022; Rusinko, 2007). One example is the EU Directive 94/62/EC on packaging and packaging waste. Lastly, there is a growing interest in consumers wanting to know more about the social and environmental impacts of products, which can present challenges as well as opportunities for companies to sell products (Lewis, 2016; Rusinko, 2007).

Therefore, the development and design phase of devices and packaging can be an important lever to apply sustainability-thinking and decrease the environmental and social footprint of the overall drug product. Additionally, with what is known from the pharma industry regarding its emissions, every strategy that has the potential to decrease and/ or save emissions, is worth trying to be applied. From an academic perspective, the current research problem is worth investigating, as there seems to be little to no pre-existing academic literature on how to design and apply a product stewardship strategy on functional level. Therefore, this research might be able to close a gap and perhaps even function as a form of inspiration for other departments which are struggling to translate a corporate product stewardship strategy into tangible action items on functional level.

1.2 Research Questions

The focus of my research lies on the development of a product stewardship strategy in a case department that develops pharmaceutical devices and packaging. My research aims to answer the following main research question:

> *How does a focused functional-level product stewardship strategy for a device and packaging development case department in the pharmaceutical industry look like?*

To answer this question, the following sub-questions need to be answered first:

1. *How can a theoretical framework about the integration of product stewardship on functional level look like?*
2. *What is the current situation of the case department in terms of product stewardship integration and where are the gaps?*
3. *What are the key focus areas for the case department to achieve sustainable device and packaging development in pharma?*

This research is targeted at a specific case department in a large pharmaceutical company and focuses on a product stewardship strategy for the development of pharmaceutical devices and packaging. The aim is to define a strategy to ensure sustainable design is achieved and that the department knows how to best prepare itself for the future to be able to continue making sustainable design choices. I aim to give recommendations on key focus areas and objectives based on a literature review, and primary data gathering. The goal is for the case department to receive a strategic plan that entails the most important pillars with timed key action items. Ideally, this should enable the department to incorporate product stewardship better into its existing strategic landscape. It should also ensure that the case department and employees are equipped to actively use and apply product stewardship without taking away the focus of their main task; to develop pharmaceutical packaging and devices.

1.3 Research Boundaries

The principle of this thesis is to bring together a practical, applied approach of investigating how a good-fitted product stewardship strategy on functional level could look like for a respective case department based on existing theoretical literature on corporate level and what implications these findings have on product stewardship research. My research is directed towards assessing the current situation at the case department and designing a product stewardship strategy that utilizes research findings while addressing and tailoring it to the case department's needs. Since this study is of case-specific nature, my research is limited to this specific case study, which is a device and packaging development department at a multinational pharma company in Switzerland. Although there is a similar department in the United States of America, the focus lies solely on the Swiss department. The theoretic part of my research focuses on the necessary parts and details of a product stewardship strategy that can be applied on functional level. The practical part of this research is focused on developing a tailored product stewardship strategy for the case department based on the current implementation stage of product stewardship at the case department and utilizes the opinion and expertise of case department employees and topic matter experts of the case organization. This is to ensure that in the end, the strategy makes sense, fits to the case department, and best prepares the department by drawing up focus areas that need time, investment, and consideration. This study excludes a mere theoretical approach and is predominantly focused on the specific case department and the development and design of pharmaceutical packaging and devices. The research and manufacturing efforts of the drug itself are excluded.

1.4 Motivation for Research

The motivation behind this research is twofold and explained hereafter. First, as the current production of pharmaceutical drugs is highly unsustainable but necessary, the supporting parts around the drug itself must designed and manufactured in the least impactful way. I am motivated to do this research and apply it to a specific case department, knowing that with my contribution I can not only support the case department in improving its sustainability impact but also try to contribute to active change within the pharma industry. Secondly, from an academic point of view, it is interesting to investigate a topic where there is not a lot of previous research done. As stated by Belkir and Elmeligi (2019), Booth et al. (2023), and other scholars, the pharmaceutical industry has not received much attention until recently regarding its sustainability efforts. Similarly, there is not much data and literature found on the topic of implementing product stewardship on functional level. Therefore, it is intriguing to research a topic where there is not that much pre-existing information available and thus contributing to potentially minimize a research gap.

1.5 Thesis Structure

This thesis is structured into seven chapters. In the first chapter, background information about the pharma industry and an initial introduction of product stewardship are given. Additionally, the research questions, boundaries, purpose, and motivation for this thesis are explained. The second chapter introduces the theoretical framework of product stewardship by conducting a literature review. The chapter includes the definition of key terms and describes where product stewardship evolved from. It furthermore contains information on the developed strategic framework of product stewardship and what possible benefits and drawbacks of product stewardship are. In Chapter 3, the case organization and case department are further introduced to better understand the current status quo and what this case study is dealing with. These first three chapters build the basis and background for the data and methodology section in Chapter 4. In that section, the research design and methodologies used for this thesis are described. It is also explained why a mixed research design of quantitative and qualitative research was chosen. In Chapter 5, the research findings of both the quantitative and qualitative data gathering are presented. These findings are then combined and integrated with the theoretical framework of Chapter 2, looking to answer the posed research questions, and designing the case specific product stewardship strategy. Furthermore, the theoretical and practical implications, as well as limitations of this study are presented before summarizing and concluding the thesis in the final chapter No. 7.

2 PRODUCT STEWARDSHIP

In this chapter, the theoretical framework of product stewardship is provided, and the environmental manufacturing strategy behind product stewardship is explained. The information for this was gathered in a literature review. Based on the available literature on product stewardship, a review was conducted to form a deeper understanding and identify drivers and strategic pillars behind product stewardship. Two main databases were used for the search of multidisciplinary articles: Web of Science and Google Scholar. A keyword search helped find relevant articles from the chosen databases which resulted in a long list of articles that required further examination for relevance. The main condition for articles to be chosen was that they must explain product stewardship in a strategic sense, shed light on its background, or give a definition for it. Only mentioning the term product stewardship but not explaining its implications or importance resulted in not considering the article for this search. The chosen literature consists of book chapters and academic articles. The review is based on 39 articles from multiple authors between 1995 and 2023 that matched the search criteria. To help categorize the information, a synthesis matrix was used.

In this chapter, to gain a better understanding of product stewardship and what it entails, first the two terms stewardship and product stewardship are defined. The definitions function as a basis to then explain the background of product stewardship which lies in three developments of shared responsibility which are further introduced. As scholars disagree regarding the nature of product stewardship and Extended Producer Responsibility, EPR is further explored, and distinctions to product stewardship are drawn. In a third step, based on the findings from the literature review, a strategic framework for product stewardship is developed, connecting, and utilizing strategic approaches from various scholars on the topic of product stewardship. This strategic framework introduces five main pillars and prerequisites which are needed in every product stewardship strategy on functional level. Lastly, benefits and opportunities of product stewardship are explained before potential drawbacks are presented.

2.1 Definition

Product stewardship is composed of the terms "product" and "stewardship". Stewardship is defined as "*the careful and responsible management of something entrusted to one's care*" (Merriam-Webster, n.d.). Lane and Watson (2012) argue that the term stewardship problematizes the concept of individual ownership and, by extension, its rights, and responsibilities. According to Carlsson and Berkes (2005), stewardship as a term is at the forefront of a movement for community-based governance approaches and co-management of resources. In the business

environment, there are different forms of stewardship that companies can apply. They can apply product stewardship, ecosystem/ environmental stewardship, or water stewardship. In a literal sense product stewardship, based on the definition of the term stewardship, means the careful and responsible use and management of a product that has been entrusted to one. Ecosystem stewardship is the responsible use and protection of the environment through sustainable practices and conservation (Chapin et al., 2010). The United Nations Industrial Development Organization defines water stewardship as a socially equitable, environmentally sound, and economically beneficial use of water through a process that includes all stakeholder (n.d.). What becomes visible when looking at the definitions of the three types of stewardship mentioned is that they each have a different focus on what needs to be carefully and responsibly used and managed within their strategy. For this thesis, the focus lies on product stewardship and is defined using the following definition from Lewis (2016):

> ...product stewardship refers to the principle that manufacturers, retailers and other organizations involved in a product supply chain have a responsibility to minimize the environmental and social impacts of that product over its life cycle. It encompasses government policies that mandate EPR in some form, as well as individual or collective industry programs that aim to improve the environmental or social sustainability of a product. (p. 9)

In the business world, product stewardship is a sustainable environmental manufacturing practice that aims at reducing the environmental and social impacts beyond the mere manufacturing process of a product (de Bakker et al., 2002; Hart, 1995; Jensen & Remmen, 2017; Lewis, 2016). According to Ehrenfeld (2000), product stewardship symbolizes a shift in a company's responsibility away from simply delivering a product to being responsible for its entire life cycle, which is further attested by other scholars like de Bakker et al. (2002), Hart (1995), Jensen and Remmen (2017), or Lewis (2005). The scope of product stewardship goes beyond pollution prevention (Hart and Dowell, 2011; Fowler and Hope, 2007) and therefore, embodies a cradle-to-grave or cradle-to-cradle responsibility for a product's life cycle (Angell & Klassen, 1999; Ashby et al., 2012; Pujari et al., 2003). Product stewardship is a voluntary strategy/ system in which responsibility for the negative environmental impacts of products is shared by all involved parties in the life cycle of the product (Curtis et al., 2014).

The overall goal of product stewardship is to ensure that products have minimized negative social and environmental impact throughout their life cycle while meeting the needs of customers, and that they can be recovered at the end of their life through either reusing or recycling (Albino et al., 2009; Ashby et al., 2012; de Bakker et al., 2002; Hart, 1995; Lewis, 2019; Pande & Adil, 2023; Paulraj et al., 2023; Sarkis et al., 2010; Snir, 2009). Examples of possible product stewardship activities are the reduction of environmental burdens through using less hazardous and non-renewable materials during the design phase (Pande & Adil, 2023; Paul et al, 2014; Snir, 2009), redesigning products and processes to be more environmentally friendly (Ashby et al. 2012; Paul et al., 2014; Rusinko, 2007), or

promoting recycling and reusing of products and components (Paul et al., 2014) and the adoption of take-back schemes (Bhupendra & Sangle, 2017; Lane & Watson, 2012; Lewis, 2016; Lewis, 2019; Paulraj et al., 2023; Wong et al., 2012). Since product stewardship is about shared responsibility that aims at minimizing impacts throughout the entire product life cycle, the strategy has implications on all stages, functions, and stakeholders that appear and contribute to that life cycle (Lewis, 2019; Nicol & Thompson, 2007). Stakeholders can include groups such as producers, manufacturers, suppliers, retailers, distributors, customers, NGOs, authorities, or recyclers (Sheehan & Spiegelman in Nicol & Thompson, 2007). According to Thorpe et al. (2004), responsibility is ideally divided and matches the specific stakeholder's expertise i.e., governments set standards, producer provide collection and recycling infrastructure, consumers are educated on how and where to dispose of products, etc. (in Nicol & Thompson, 2007).

2.2 Background

This section provides background information on product stewardship. It explains how the concept of product stewardship originated and how it relates to the Responsible Care Act of the chemical industry, as well as the concept of Extended Product Responsibility (EPR). As some scholars use the terms product stewardship and EPR interchangeably, EPR is further introduced and possible distinctions between the two concepts are presented.

According to Lane and Watson (2012), product stewardship has gained traction since the 1990s due to its interwoven nature with material responsibility (Hart, 1995) as well as through the adoption of companies such as Xerox and Hewlett-Packard (Maslennikova & Foley, 2000; Preston, 2001). Curtis et al. (2014) argue that product stewardship was introduced in the 1990s by companies to weaken the EPR concept and distribute responsibility to the supply chain rather than having to bear the full responsibility themselves. In contrast to Curtis et al. (2014), Lane and Watson (2012) note that the product stewardship discourse has been incorporated into corporate commitments and, increasingly, into legal obligations formulated as EPRs. Product stewardship is one of the three strategic capabilities under the Natural-Resource-Based View next to pollution prevention and sustainable development (Hart & Dowell, 2011).

The origin of product stewardship, according to Lewis (2005), lies in three developments of shared responsibility. First, "stewardship" was used to introduce a new life cycle management approach called Responsible Care which was developed in the late 1970s/ mid-1980s by the Canadian and American chemical industry associations and emerged through public image concerns (Ehrenfeld, 2000; Lane and Watson, 2012; Lewis, 2005). Under Responsible Care, product stewardship presents the sixth and final code for the chemical industry and is employed in a minimum of 40 countries (Lewis, 2016; Snir, 2009). Not complying with the codes can lead to severe sanctions, however, the codes are not mandated

by public authorities (Ehrenfeld, 2000). Second, in the United States of America "product stewardship" is adopted as a generic term for a method to manage products at their end-of-life with shared responsibility (Lewis, 2005). Lastly, in Europe a policy framework called EPR that managed products at their end-of-life phase was introduced (Lewis 2005). EPR is a concept under which manufacturers are liable for the environmental impacts and damages of their products and responsible for their end-of-life waste management (Lindhqvist, 2000).

Lewis (2019) states that most often product stewardship is introduced because of newly implemented regulations or pressure from external stakeholders in addition to changing business goals, new company priorities, or evidence of current product impact. Most schemes are either industry-driven or involve some type of collaboration between industry and government organizations (Lane & Watson, 2012). While Nicol and Thompson (2007) state that product stewardship and EPR are policies with different results, Hickle (2007) and Tasaki et al. (2019) view them as similar policies. Tasaki et al. (2019) are going one step further and use the term product stewardship and EPR interchangeably. Lewis (2016) notes that product stewardship and EPR are often used interchangeably, however there are important differences between them, even though they also have some overlap. Since there seems to be a disagreement amongst scholars between the nature of product stewardship and EPR, EPR is further explored in the subsequent section as well as distinctions between the two concepts are described.

2.2.1 Extended Producer Responsibility (EPR)

The concept of EPR was first introduced by a Swedish graduate student named Thomas Lindhqvist in a report for the Swedish Ministry of Environment in which he called for making manufacturers responsible for the entire life cycle of their products (Curtis et al., 2014; Lewis, 2016; Lindhqvist, 2000). The EPR proposal was defined as an environmental-protection-policy and was aimed at reducing the environmental impact of products during their entire life cycle (Lindhqvist, 2000). Manufacturers were especially responsible for take-back, recycling, and final disposal of their products (Curtis et al., 2014; Lewis, 2016; Lindhqvist, 2000). According to Lindhqvist (2000), the manufacturers are liable for proved environmental damages caused by their products and their liability was threefold.

First, the manufacturers are economically responsible, meaning that they will cover the costs for collection, recycling, and final disposal of the manufactured products (Lindhqvist, 2000). This includes direct or indirect handling of products including take-back schemes or recycling (Toffel as cited in Nicol & Thompson, 2007). Second, the manufacturers have a physical responsibility for the environmental impacts of their products and lastly, they have an informative responsibility, through which they need to supply information on the environmental risks of their products (Lindhqvist, 2000). For manufacturers, EPR includes product recycling, regulations, and redesigning to ensure more sustainability for their products (Nicol & Thompson, 2007). Nowadays EPR is widely accepted within the European Union for product-related environmental policies as

well as in countries such as Canada, Australia, New Zealand, Japan, South Korea, Taiwan, and Norway (Curtis et al., 2014; Lewis, 2016). According to Nicol and Thompson (2007) EPR policies are characterized with a focus on end-of-life waste management, a shift of physical and/ or financial responsibilities; away from taxpayers/ consumer towards manufacturers, and targets for waste management and reduction.

2.2.2 Distinction to Product Stewardship

As mentioned, the terms EPR and product stewardship sometimes are used interchangeably. However, there are differences in the two concepts that show that even though the basis might be similar, they are two different concepts. According to Lewis (2016) and many other scholars (Curtis et al., 2014; Ehrenfeld, 2000; Nicol & Thompson, 2007; Wagner, 2013) agree that product stewardship is overall broader than EPR. Reasons for that are, first, product stewardship entails voluntary actions by companies in addition to mandated schemes while EPR is generally mandatory (Curtis et al., 2014; Ehrenfeld, 2000; Lewis, 2016). Second, under EPR the end-of-life stage of products is in focus, whereas with product stewardship the responsibilities are within each stage of the whole life cycle of a product (Lewis, 2016; Nicol & Thompson, 2007; Wagner, 2013). Third, product stewardship includes also social impacts and not just environmental impacts (Lewis, 2016). Fourth, product stewardship involves internal and external stakeholders along the retail and supply chain, whereas with EPR only the manufacturers are in focus (Curtis et al., 2014). Lastly, according to Ehrenfeld (2000), although the differences between EPR and product stewardship are largely semantic, the language of product stewardship is held more generally.

2.3 Strategic Framework

In this section, the strategic framework for a functional product stewardship strategy is introduced. Based on the review of the 39 articles and book chapters, a strategic framework of potential strategic pillars for a functional product stewardship strategy is created, as the existing frameworks are only focused on corporate level. The review included filtering out strategic pathways, activities, and initiatives companies should or are doing/ following when adopting a product stewardship strategy and what that strategy entails. Based on the review, five strategy pillars emerged including individual actions and pathways within those pillars. Additionally, the review also showed that there are some prerequisites necessary that support companies in the successful implementation of the product stewardship strategy. Figure 1 provides an overview of the created pillars, which are labelled as follows: prerequisites, Design for Environment (DfE), EPR, collection & recycling, education, and collaboration & partnerships. In the following subsections, each pillar is introduced before discussing the individual

strategy points a company can choose to follow in the context of product stewardship.

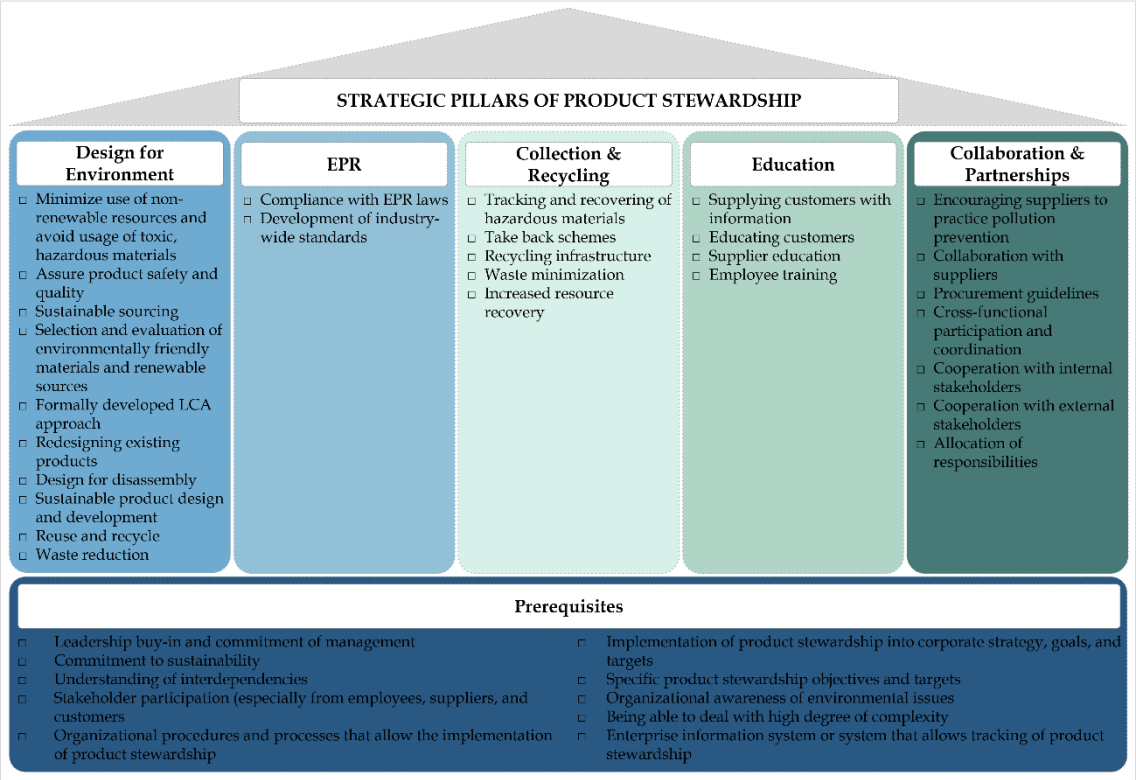

Figure 1: Strategic pillars of product stewardship

2.3.1 Prerequisites

To successfully introduce product stewardship, certain prerequisites must be met before introducing the actual strategy. This became evident in the literature review. Followingly, these prerequisites are explained. First, the success of product stewardship greatly depends on the leadership buy-in and commitment of management as well as the participation from various stakeholders such as employees, suppliers, and customers (Bhupendra & Sangle, 2017; Lee et al., 2015; Pujari et al., 2003; Takhar & Liyanage, 2021). Management buy-in and commitment are required not only for financial reasons but also to integrate product stewardship into overall corporate strategy, company culture, and functional-level goals (Jensen & Remmen, 2017; Lee et al., 2015; Lewis, 2019). As mentioned by Lewis (2019) and Nicol and Thompson (2007), product stewardship has implications for all functions of an organization and must therefore be implemented accordingly everywhere, which requires effort and commitment from management. Second, product stewardship not only requires to be added into the corporate strategy, but it also needs specific goals and targets that guide the organization and the individual functions (Jensen & Remmen, 2017; Lee et al., 2015; Lewis, 2019). However, objectives and targets alone are not sufficient. To follow and achieve product stewardship targets, procedures and functional strategies need to be in place which guide the implementation of product stewardship in existing processes

such as during the design phase of a product (Jensen & Remmen, 2017; Lee et al., 2015; Lewis, 2019). Third, since product stewardship is of very complex nature, organizations need to be able to manage conflicting goals, interactions, and underlying issues among the many different levels, layers, and stakeholder groups (Matos & Hall, 2007; Paulraj et al., 2023; Pujari et al., 2003). This also requires being able to understand interdependencies (Kühl et al., 2023). Fourth, an important prerequisite is the commitment to sustainability and the awareness of environmental and social issues the organization is causing indirectly or directly (Kühl et al., 2023; Matos & Hall, 2007; Takhar & Liyanage, 2021). Finally, the organization needs to be able to track the progress of product stewardship somehow. According to Degenstein et al. (2023) and Jensen and Remmen (2017), an enterprise information system such as a product life cycle management software might be a good fit to handle, track, and analyze the abundance of information. However, an enterprise information system is not a prerequisite per se, the importance lies in tracking and managing the information that accumulates through the adoption of product stewardship. How this is overseen, can be decided by each organization.

2.3.2 Design for Environment (DfE)

The first strategic pillar, Design for Environment (DfE), includes design for sustainability and eco-design which are processes that cover systematic design activities that aim at improving the environmental impact of a product (Hauschild et al., 2004). DfE together with eco-design was mentioned most often by various scholars when it came to effective product stewardship strategies (Albino et al., 2009; Ashby et al., 2012; Bhupendra & Sangle, 2017; Degenstein et al., 2023; Lewis et al., 2001; Maslennikova & Foley, 2000; Pande & Adil, 2023; Paulraj et al., 2023; Takhar & Liyanage, 2021; Wong et al., 2012). It includes many of the following activities which is why it was decided to also use DfE as a strategic pillar.

The main objective of DfE is to design and develop a product that has minimal environmental impacts (Bhupendra & Sangle, 2017). The way to achieve this is manyfold. First, organizations can try to minimize the use of non-renewable sources and avoid the use of toxic or (potentially) hazardous materials (Bhupendra & Sangle, 2017; Degenstein et al., 2023; Jensen & Remmen, 2017; Lewis et al., 2001; Snir, 2009; Takhar & Liyanage, 2021; Wong et al., 2012). Second, manufacturers can redesign products and processes to make them more environmentally friendly (Bhupendra & Sangle, 2017; Maslennikova & Foley, 2000; Rusinko, 2007). Third, the selection and evaluation of renewable sources and environmentally conscious materials are also an important lever, producers can choose to achieve DfE (Bhupendra & Sangle, 2017; Lewis et al., 2001; Paulraj et al., 2023; Rusinko, 2007; Wong et al., 2012). This can also include sustainable sourcing of materials (Degenstein et al., 2023; Lewis, 2016; Pande & Adil, 2023). Fourth, manufacturers can try to reduce the amount of waste during design, development, or production phase (Tasaki et al., 2019) and try to reuse and recycle as much as possible (Bhupendra & Sangle, 2017; Degenstein et al., 2023; Jensen & Remmen, 2017; Lewis,

2016; Paulraj et al., 2023; Wong et al., 2012). According to Snir (2009), to assure product safety and quality, manufacturers should ensure enough testing is done during research and development. Another strategic pathway is to adopt a formally developed LCA approach to measure and ensure that the product impacts can be measured and that the potential product changes are more sustainable (Ashby et al. 2012; Bhupendra & Sangle, 2017; Degenstein et al., 2023; Fowler & Hope, 2007; Hart, 1995; Lewis et al., 2001; Lewis, 2016; Lewis, 2019; Paulraj et al., 2023; Sarkis, 2001). Lastly, organizations can try to apply life cycle design (Degenstein et al., 2023; Paulraj et al., 2023) and ensure that the products are designed in a way so that they can be easily disassembled (Lewis, 2016; Paulraj et al., 2023; Takhar & Liyanage, 2021).

2.3.3 Extended Producer Responsibility (EPR)

The second pillar is EPR. As previously mentioned, EPR is about laws and regulations, specially tailored to the end-of-life of products. Since an array of information has been given already in Chapter 2.2.1, the second strategic pillar is held short. There are two activities an organization can choose to follow. The first one is ensuring that the organization is complying with current EPR laws (Lewis, 2016). Reasons for that are rather obvious since an infringement can entail great negative consequences for the organization. Second, organizations can choose to participate and initiate the development of industry-wide recycling and other standards (Lewis, 2016; Lewis, 2019). An organization might pursue this strategy to ensure that it does not have to bear the responsibility of i.e., waste collection individually but rather that an industry solution is implemented.

2.3.4 Collection & Recycling

The third strategic pillar is about recycling and collection of waste. Although companies are trying to avoid the use of hazardous materials, it cannot always be avoided. Therefore, it is imperative that companies who still use hazardous materials track and recover them at the end-of-life (Lane & Watson, 2012; Snir, 2009). Organizations can also employ a take-back scheme to take back their products once they reach their end-of life (Lane & Watson, 2012; Lewis, 2016; Lewis, 2019; Maslennikova & Foley, 2000; Takhar & Liyanage, 2021; Tasaki et al., 2019). According to Lewis (2019), there are three types of take-back models.

Industry-led and industry-managed take-back models are the most common ones and usually involve a group of companies that aim to meet compliance requirements (Lewis, 2019). Producers can also outsource their take-back model and oversee it through a logistics company that provides the service in their name (Lewis, 2019). The third type of take-back scheme is usually initiated on a voluntary basis by an entrepreneurial organization to answer a perceived need rather than a compliance responsibility (Lewis, 2019). According to Degenstein et al. (2023) and Wyssusek and Avudainayagam (2023), companies can also aim to increase their resource recovery and through that minimize waste going to landfills.

2.3.5 Education

Education is the fourth strategic pillar of product stewardship on functional level and entails an informative, educational aspect. Since product stewardship is multi-faceted, bringing awareness, sharing information, and educating stakeholders is an important endeavor, three main activities have emerged from the literature review. First, organizations should supply their customers with information about the safe use, transportation, storing, and disposal of products (Degenstein et al., 2023; Jensen & Remmen, 2017; Lee et al., 2015; Lewis, 2016; Sarkis et al., 2010; Snir, 2009). This could include providing written or visual information in the form of videos, labels, or package leaflets. By providing information on how to store products, companies can ensure that they do not end up in the trash because they have gone bad. By providing information about proper disposal, companies can ensure that customers are aware of the correct form of disposal. This is especially important if the products are to be returned to the manufacturer or taken to a take-back system. The second activity under the education pillar is the education of suppliers (Lewis, 2016). This can entail bringing suppliers up to date and educating them about what the organization is looking for in terms of raw materials, sourcing of materials, standards, goals, requirements, etc. Lastly, according to Lee et al. (2015), Rusinko (2007), Sarkis et al. (2010), and Snir (2009), training employees in sustainability and product stewardship is an important aspect in ensuring that the respective employees know what is asked from them. Through knowledge and training, employees might feel empowered to do more for sustainability and product stewardship than required by the existing processes. It can lead to raised awareness and enable employees to apply their new sustainability and product stewardship knowledge to their daily work, because, after all, they are usually topic matter experts and know best how and where to apply and deploy certain activities to achieve sustainability.

2.3.6 Collaboration & Partnerships

The final strategic pillar is collaboration and partnerships. For product stewardship to be effective, it needs to be adopted in every function and aspect of the company, i.e., in the corporate strategy, product design and development, procurement, distribution, etc. (Lewis, 2019). This integration of product stewardship in all business aspects requires not only internal cooperation and coordination but also cross-functional participation and cooperation with external stakeholders (Hart & Dowell, 2011; Paulraj et al. 2023; Rusinko, 2007; Sarkis, 2001; Wong et al., 2012). The allocation of responsibilities amongst the many stakeholders can lead to confusion (Thorp et al. in Nicol & Thompson, 2007). According to Rusinko (2007), this requires various initiatives on different corporate levels. As previously mentioned, an important prerequisite is the support from top management (Pujari et al., 2003) which also requires some form of collaboration. As an example, the redesign of processes and products often requires top management support and approval as stated by Rusinko (2007).

Since companies are increasingly being held accountable for actions from suppliers even though these might be out of control for them, collaboration with suppliers is imperative (Lewis, 2019). According to Degenstein et al. (2023) and Lewis (2019), collaboration with suppliers is an important cornerstone in the achievement of many product stewardship objectives, especially in terms of raw materials, material components, or emissions. There are several ways companies can collaborate and take influence over supplier activities. Firstly, companies can define procurement standards to which suppliers must adhere to (Lewis, 2019). Secondly, companies can encourage or demand from their suppliers to practice pollution prevention or product stewardship (Rusinko, 2007). Thirdly, organizations can jointly develop specific minimum standards or formal codes of practice agreements with their suppliers to ensure liability and adhering to important regulations (Fowler & Hope, 2007; Lewis, 2019).

Through product stewardship, organizations are forced to be able to integrate sometimes contradicting perspectives from an array of different key stakeholders into decisions about research, development, or design of a product (Fowler & Hope, 2007). It is vital for organizations to actively collaborate with value chain partners and key stakeholders and engage with them on a meaningful level (Bhupendra & Sangle, 2017). One aspect that was not directly mentioned in the review of the articles on product stewardship was the collaboration and forming of partnerships amongst industry peers. However, the collaboration with industry peers might be implied through the nature of EPR or industry-initiated take-back schemes.

2.4 Benefits & Opportunities

Benefits and opportunities that arise through the successful adoption of product stewardship are manyfold and are presented hereafter. Products can be better designed and developed, the more information and knowledge manufacturers receive from external stakeholders earlier in the supply chain (Lewis, 2016; Paulraj et al., 2023). Receiving knowledge from internal and external stakeholders such as suppliers can lead to enhanced understanding of impacts and process steps which can turn into additional emissions and impact savings or the reduction of process steps (Lewis, 2016; Paulraj et al., 2023). According to Hart and Dowell (2011), since under product stewardship active stakeholder engagement and management is necessary, "the voice of the environment" is part of the design and development process which leads to decreases in the products' environmental and social impact. Therefore, the products are more sustainable than before the use of product stewardship and through redesign of products potential quality improvements can be achieved (Lewis, 2016; Rusinko, 2007). According to Baines et al. (2012) and Pande and Adil (2023), product stewardship can also enhance a product's productivity, recyclability, disassembly, and disposability.

Through adequate communication of the decreased impacts, it can lead to an enhanced company image and green reputation (Ashby et al., 2012; Bhupendra & Sangle 2017; Degenstein et al., 2023; Lewis, 2016; Pande & Adil, 2023, Rusinko, 2007). Furthermore, it can attract a new customer base through the new-found green image, product innovation, or lower life cycle costs (Baines et al., 2012; Degenstein et al., 2023; Hart 1995, Hart & Dowell, 2011; Rusinko, 2007). The green image can also attract other stakeholders who are interested in environmentally sustainable products such as additional shareholders, potential employees, etc. (Degenstein et al., 2023; Rusinko, 2007).

Many scholars agree, that one of the greatest opportunities that can be achieved through product stewardship is to gain competitive advantage through strategic preemption (Ashby et al., 2012; Baines et al., 2012; Hart, 1995; Hart & Dowell, 2011; Lewis, 2016; Pande & Adil, 2023; Paulraj et al., 2023; Rusinko, 2007). Strategic preemption is about leading change and creating value through being one of the first ones to move into a certain direction (Hart, 1995; Pande & Adil, 2023). It can be achieved through securing special resources such as green raw materials, creating new sustainable product standards, or by becoming a frontrunner/ early mover (Hart & Dowell, 2011; Rusinko, 2007). A green product can also lead to differentiation advantages since the product can be differentiated through other aspects than simply price or performance (Bhupendra & Sangle, 2007; Lewis, 2016; Pande & Adil, 2023). Another opportunity is being able to charge more for the products that are produced under product stewardship (Lane & Watson, 2012). However, this does not necessarily lead to higher profits as the production, sourcing of the materials, and potential certificates involved also cost more than under the previous production. Nonetheless, product stewardship can lead to lower life cycle costs through the implementation of sustainable design development and stakeholder integration (Baines et al., 2012; Pande & Adil, 2023). Product stewardship can also be employed to ensure compliance with regulations and therefore, identifying and mitigating potential liability issues (Lewis, 2016; Snir, 2009). Lastly, it can support the business in exiting a potentially hazardous environment and venture into more sustainable business branches (Pande & Adil, 2023).

2.5 Drawbacks & Shortcomings

Based on the review of the 39 articles, some drawbacks/ negative aspects regarding product stewardship or the available literature were identified, which are presented hereafter.

Hickle (2007), states that although there is evidence that product stewardship can encourage sustainable design changes, there is an ongoing debate whether these design modifications are actually triggered through product stewardship or are more likely to be financially or strategically driven. Similarly, De-

genstein et al. (2023) raise the point of financial dependency of product stewardship adoption and sustainability efforts in general. Financial concerns, costs, or complexity can be seen as barriers to product stewardship. On the topic of finances, Wong et al. (2012) state that product stewardship causes a counterintuitive negative financial impact. Although product stewardship aims at minimizing waste and improving the use of resources in terms of efficiency, Lewis et al. (2001) argue that there are restraints in terms of cost savings and pollution prevention/ control. According to Wong et al. (2012), additional costs incur when reusable packaging needs to be returned to manufacturers. Although product stewardship can increase recycling rates, it however, according to Nicol and Thompson (2007), does not reduce consumption or clearly prevent pollution. Russo and Fouts (1997) use an example from the electronics industry and state that achieving economies of scale in the introduction state of a new product through developing environmentally friendly electronics based environmentally conscious parts is difficult (in Wong et al., 2012, p. 290). Lastly, Bhupendra and Sangle (2017) criticize the current literature on product stewardship and say that it fails to include strategic elements to achieve product stewardship goals. Accordingly, only few articles provide some sort of scaling or measuring.

Although these mentioned drawbacks are valid, I, however, think that they should not deter from the implementation of product stewardship. The current set up might not yet be ideal, but it is a step into the right direction when manufacturers need to become more aware of their processes, stakeholders, types of materials that they are using, and what happens to the product once it reaches the end-of-life stage.

3 CASE STUDY

In this chapter, the case study for this thesis is further outlined by introducing the case study organization and case department. Firstly, the case study organization is introduced. Information is shared about the organization's overall sustainability activities as well as how and where product stewardship is located. Secondly, the case department, a device and packaging development department, is further introduced and more information about the specific case and its current challenges are given.

Since this case study is conducted under a high-level anonymity agreement, the case study organization and case department can only be partially presented to ensure the necessary level of anonymity. Therefore, the name of the case company, cannot be mentioned. For the remainder of this thesis, the overall organization is therefore referred to as either case organization or case company. Similarly, the concerned device and packaging development department is referred to as either synergy or case department.

3.1 Case Study Organization

The case organization is a global multinational public pharmaceutical company, belonging to the top ten pharmaceutical companies worldwide (Burke, 2023). The organization is part of the Dow Jones Sustainability World Index, Science Based Targets Initiative (SBTI), and has some of its pharmaceutical laboratories certified with the *My Green Lab Certification* from the UN's Race to Zero campaign. In general, sustainability has a high priority in the company and is also anchored as one of the top values in the corporate culture. The organization is also known for its corporate philanthropy program and has a dedicated corporate sustainability strategy.

One theme within the corporate sustainability strategy is the adoption of product stewardship for all new products during the development phase. The organization has time-bound goals to measure and improve the footprint of its existing products and aims to apply the learnings to its greater product portfolio on practical, departmental-level. The measuring of the products is done through its own product stewardship performance (PSP) tool and encompasses eight different stages from customer needs to manufacturing and production to product usage, and finally disassembly and disposal. Product stewardship at the case organization is defined as actions taken to ensure that the drug and diagnostic products are developed, used, and managed in a responsible manner throughout their entire life cycle (Case Organization, n.d.). According to the corporate product stewardship strategy, every department along the life cycle phase of the case

company is responsible in adhering, following, and implementing the product stewardship principles.

3.2 Case Department

In this thesis, the focus is on a specific department within the case organization. The case department or synergy is a department responsible for the development of pharmaceutical devices and packaging. Its objective is to develop effective pharmaceutical packaging and devices for future medicines to ensure the drug products are protected, secured, and designed to have the smallest possible environmental footprint.

There are three different types of pharmaceutical packaging for drug products: primary, secondary, and tertiary packaging. Primary packaging refers to packaging which is in direct contact with the drug product such as vials, blisters, or bottles (Ibrahim et al., 2022; WHO, 2002). For primary packaging, the case department designs vials, blisters, glass bottles, and combination products. Secondary packaging entails packaging that encloses both the drug product and the primary packaging. It provides additional protection and serves to inform the patient about the dosage regimen, potential side effects, storage conditions, and the specific labeling and identification of the product (WHO, 2002). Under secondary packaging, the case department develops cardboard boxes, and trays containing all relevant information as well as the respective product's branding and corporate logo Tertiary packaging is used for shipping and transportation purposes such as cardboard boxes, pallets, and shrink films (WHO, 2002).

The case department's device products are about safe drug delivery. This entails the design and development of medical devices that either support the drug delivery or are the "container" through which patients take the medication. The devices range from ancillary/ supporting devices to injectable devices. Examples for ancillary devices are vial adapters, minitablet dispensers, measuring cups, needle safety devices, or oral dispensers. Examples for injectable devices are auto-injectors and variable dose injection devices.

The case department is compiled of eight different teams, which are referred to as chapters and employs 120 people. These chapters are process engineering (DA), product care (DC), device engineering (DE), human factors engineering (DH), device and packaging engineering synthetic molecules (DM), packaging engineering (DP), primary container engineering (DS), verification engineering (DV). Overviewing these eight chapters is the enabling circle (EC). The chapters have differing objectives and tasks during different stages of the development of pharmaceutical packaging and devices. Therefore, the individual chapters' contribution to product stewardship differs. However, as stated in the corporate strategy for product stewardship, each department/ chapter is responsible in adhering and following the principles and trying to minimize the prod-

uct's footprint (Case Department, n.d.). Therefore, it is important that each chapter is aware of product stewardship and plays their part in adopting product stewardship practices. However, from initial meetings with the two case department supervisors for this thesis, it has become evident that perhaps not all chapters are yet familiar with the concept of product stewardship.

The biggest challenge of the case department is that it lacks the time and knowledge to properly introduce and adopt it. However, this does not mean that there are no sustainability projects. On the contrary, the case department has various sustainability projects ongoing that go into the direction of DfE; investigating sustainable fibers and how pharmaceutical packaging and devices can be designed in a more environmentally friendly way. The case department does its own LCA assessments and has people that drive the topic of sustainability within and outside of the case department. Recently, a guideline regarding sustainable design development was introduced to the department. It is yet unclear however, how many people from the case department are following this sustainable design guide. Furthermore, each year, the department recruits at least one thesis student to write their thesis about a sustainability topic the case department wants to know more about or needs to find a solution to. This is also the case for this current thesis and the reason for my hiring to the case department. As previously mentioned, I have two case department supervisors. The term "case department supervisors" refers to the two people that are supervising me during my employment with the case company. These supervisors are supporting me through sharing insights on the case department, the case department's work around device and packaging development, and overall onboarding to the case organization. Additionally, they are the topic providers for this thesis, so they ensure that my research overall matches with the case department's expectations and problem statement. According to the research questions in Chapter 1.2, my main objective is to investigate how a product stewardship strategy for the case department can look like so that the department is strategically positioned to ensure adoption, contribution, and fulfillment of the overall corporate product stewardship strategy of the case organization.

4 DATA AND METHODOLOGY

This chapter focuses on the empirical part of doing research. Since the goals of this study are manyfold, a sequential mixed method design of first doing quantitative research followed by doing qualitative research (QUAN → QUAL) is used as methodology. In this chapter, the quantitative and qualitative methodologies including the research design are introduced. The research design includes aspects of case study research, characteristics, and reasoning for choosing a mixed method approach, and the description of what method triangulation entails. Since this research uses a QUAN → QUAL approach, first the quantitative methodology is explained by sharing insights into the survey questionnaire, sampling process, the data gathering, as well as the data analysis. This is followed by explaining the approach for the qualitative methodology which includes the reasoning behind choosing semi-structured interviews, the interviewee selection, the design of the semi-structured interview questionnaires, the data gathering, as well as how the interviews were conducted, transcribed, and analyzed

4.1 Research Design

In this section, the research design is explained. Firstly, general insights into exploratory research, case study research and the reasoning for choosing this research design are given. This is followed by explaining the approach of utilizing mixed methods and sequential method triangulation in this thesis.

Although product stewardship seems to be on the rise in the pharmaceutical industry with big corporations like Bayer, Eli Lilly, Johnson & Johnson, Roche, or Bristol Myers Squibb all committed to having deployed such a strategy, little to no information can publicly be found from scholars or the respective companies themselves about how product stewardship can look like on functional level, especially for developing pharmaceutical packaging and devices. Therefore, it is crucial to develop a better understanding of the overall topic. Thus, an exploratory research design has been chosen. According to Hair et al (2015), exploratory research is meant to discover new themes, ideas, or relationships and is often performed when there is little pre-existing information concerning a topic. This is applicable to this thesis, as there is lacking knowledge regarding the current situation of how far and successful the case department has been in terms of product stewardship integration and how the overall corporate product stewardship strategy is meant to be applied on functional level. Therefore, new data needs to be collected, which is called collecting primary data (Eriksson & Kovalainen, 2008). According to Eriksson and Kovalainen (2008), when collecting primary data, the researcher must decide on the method of data collection, while

the research questions play a crucial role. In this case, looking at the research question, the overall goal of my study seems multi-faceted.

First, the research questions deal with a specific case, which is tailored to a case department. Scholars call this case-study-specific research (Eriksson & Kovalainen, 2008; Robson & McCartan, 2016). Case study research deals with the construction of a case within a context and the research questions being related to the understanding and solving of that case (Eriksson & Kovalainen, 2008; Robson & McCartan, 2016). According to Eriksson and Kovalainen (2008) and Robson and McCartan (2016), case study research should be understood rather as a research approach or strategy than a method. Yin (2009) argues that it is a suitable approach, especially for exploring the social world with unclear boundaries regarding the phenomenon. Therefore, case study research is also applicable for this research purpose since the idea is to investigate how a focused product stewardship strategy for a specific design and development department of pharmaceutical devices and packaging should look like. Since case study research is a rather flexible research approach (Robson & McCartan, 2016), the research design of this study is also flexible. However, because of its high flexibility and dependability on context, one important aspect of case study research is that it cannot be generalized and populated onto a wide mass (Eriksson & Kovalainen, 2008).

Second, before the product stewardship strategy can be developed, I first need to assess the current situation at the case department itself. On first glance, this may not seem straightforward as the current situation does not appear to have anything to do with how the case department is situated. However, in order to tailor the later developed strategy to the case department, I need to know the current situation, challenges, and opportunities regarding product stewardship. To do this, I need to hear as many voices and opinions from the case department as possible to get as close of a picture as possible of the current situation. However, for the actual strategy itself I cannot want to hear perhaps biased or uninformed opinions of everybody, but rather hear the opinion of topic matter experts. Since these two situations are contradictory, it becomes evident that a different methodology is needed for each scenario. For scenario No. 1, since as many people as possible need to be asked about their opinions on the integration of product stewardship at the case department in order to obtain as realistic a picture as possible, qualitative methodology seems to be well suited. For scenario No. 2, on the other hand, qualitative interviews with topic matter experts seems more appropriate. The combination of using quantitative and qualitative research methods within a research project is called "mixed methods". According to Morse and Niehaus (2016, p. 9), "*mixed methods design refers to the use of two (or more) research methods in a single study, when one (or more) of the methods is not complete in itself*". This statement is applicable to the two scenarios in this study. Choosing an only quantitative or qualitative approach to answer both scenarios would not be well suited as potentially important information could not be recorded, biasing the data gathering process. By using two different research methods, research gaps can be filled through the collection of more holistic information, making the study more extensive (Kelle 2022). According to Morse and Niehaus (2016), the

combination of using qualitative and quantitative methods is the most difficult, compared to using two or more qualitative or quantitative methods, as the mixing of paradigms means that the researcher needs to use contradictory rules and assumptions for investigation. Although I am aware of the difficulties of using both quantitative and qualitative research and the effort that goes into doing two different sub-studies, I am following the procedure of how to best answer the research questions of this thesis, as stated by Eriksson and Kovalainen (2008), and this seems to be doing both a quantitative and qualitative sub-study. Since the two sub-studies are done sequentially, researchers such as Hair et al. (2019) speak about sequential method triangulation. I first need to assess the current situation before I can gather more information about how a tailored product stewardship strategy can look like for the case department. Therefore, I am depending on the findings from the quantitative sub-study before I can start with the qualitative sub-study. Morse (1991) states that sequential method triangulation is the approach where the usage of one method's results is used as an essential prerequisite for the planning of the next. According to Morse (1991), the first step in sequential method triangulation is to establish if the research problem is of primarily qualitative or quantitative nature. The characteristics of a qualitative research problem are that the research concept is immature due to a lack of theory, and/ or there is an assumption that the available theory may be inaccurate, and/ or the nature of the phenomenon might not be suited for quantitative research, and/ or there exists a need to describe the phenomenon and develop theory (Morse, 1991). Since this research project fulfils more than one of those characteristics, it can be argued that the research problem must be primarily qualitative. Therefore, the main method for this study is of qualitative nature and the quantitative method is used as a prerequisite, utilizing three phases (Ivankova & Stick, 2007).

To summarize, this research design is of exploratory and case study nature, utilizing a mixed methods approach as well as sequential method triangulation. The research is divided into three phases. In the first phase, a quantitative survey is done. In phase two, qualitative semi-structured interviews follow. An integral part of doing quantitative and qualitative sub-studies in one overall study is the alignment and combination of the results of these individual phases and their interpretation (Ivankova & Stick, 2007). In this thesis, this is done in the third phase, where the findings from the two previous phases are linked together. This mentioned data and methodology procedure is visible in Figure 2. Followingly, the first two phases are further explained. The third phase is visible in Chapter 6.

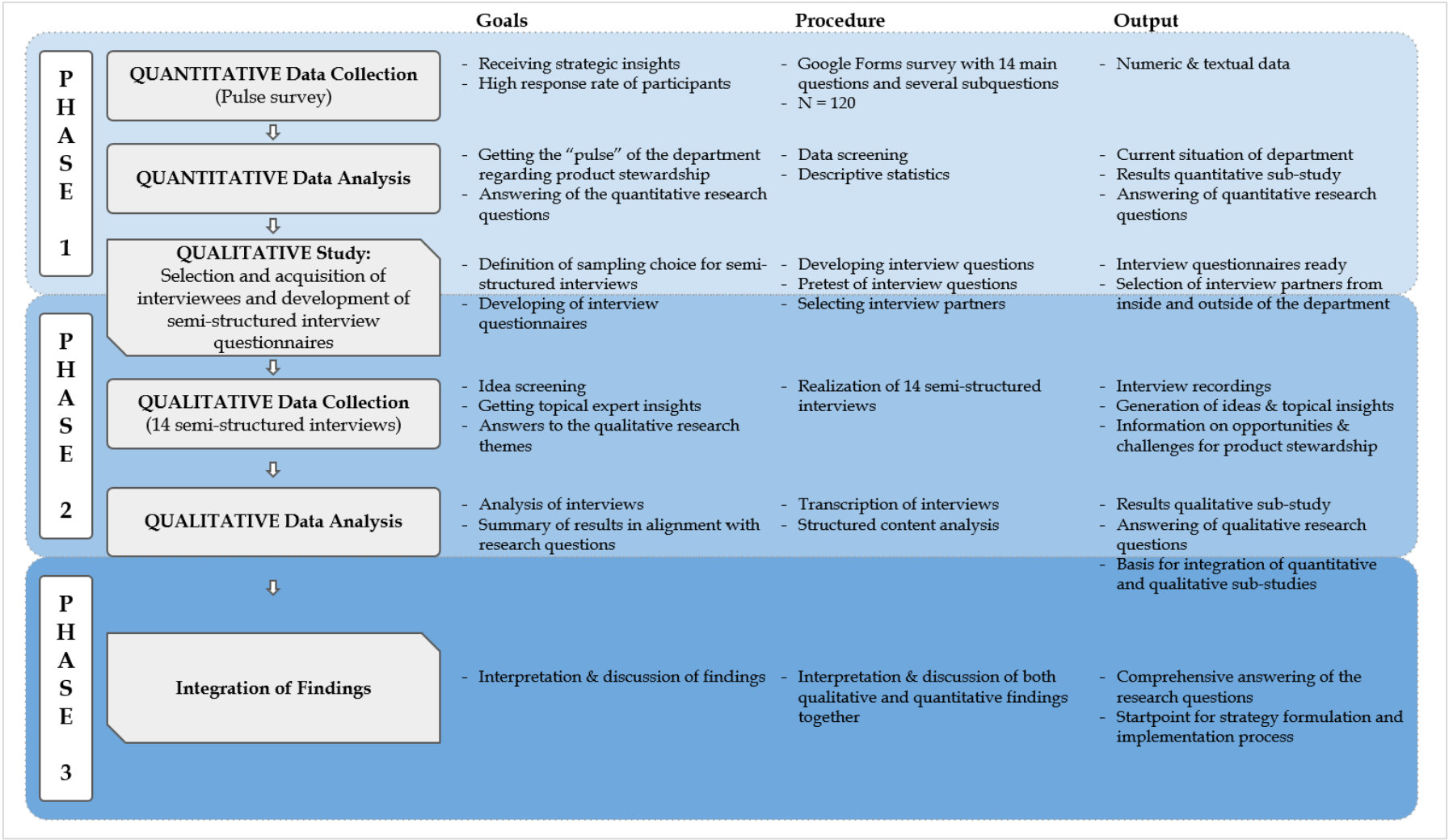

Figure 2: Research design overview

4.2 Quantitative Methodology

This section aims to introduce pulse surveys as a quantitative method, followed by the sampling and data collection approach. Lastly, more details about the data analysis are given. The quantitative methodology is based on a pulse survey that investigates the current level of how product stewardship is known, implemented, and used within the case department. The research questions are:

A. *What is the current level of awareness and engagement for product stewardship within the case department?*
B. *What can significantly impede/facilitate the further implementation of product stewardship within the department?*

4.2.1 Pulse Survey

In quantitative data gathering, researchers collect data by using structured questionnaires or observation guides (Hair et al., 2019). These questionnaires are convenient when data from a large number of individuals needs to be collected in a quick and convenient manner (Eriksson & Kovalainen, 2008). This is also the reason a structured questionnaire was chosen for the evaluation of the current situation in this thesis, as the aim is to obtain answers from as many employees of the case department as possible, which is why it can be classified as an employee survey (Huebner & Zacher, 2021). One form of employee surveys are pulse surveys, which are intended as short and timely indicators to get the "pulse" of an organization and can provide increased flexibility and insights at strategic level (Allen et al., 2020; Garg et al., 2021). Because of their flexible nature and their "pulse" indication, I decided to use a pulse survey for this present case study.

The survey is done in the first phase of the empirical data gathering. The findings of it will function as the base for the qualitative research in the second phase. Since the survey uses not only closed questions but also open-ended questions which are of qualitative nature, the nature of the survey is not strictly quantitative but a mix of qualitative and quantitative. This special mix of disciplines and questions is addressed in the data analysis section. The reason for including open-ended questions is that biases can be avoided, and it can be ensured that all possible response options are included (Schuman & Presser, 1979). According to Singer and Couper (2017), open-ended questions can provide vital information that closed questions cannot provide as these questions offer better understanding of reasons, testing of methodological theories and hypotheses, encouraging of honest answers, and opportunity for giving feedback, which is the exact intended outcome for those specific questions in my survey questionnaire.

4.2.2 Sampling Process

The quantitative data gathering is based on an online self-completion survey. The sampling process followed the procedure established by Hair et al. (2019). First, the target population needs to be identified before choosing a sampling frame, and the method of sampling (Hair et al., 2019). For this thesis, the target population is all employees working in the case department which is also the common characteristics. When sending out the survey, the case department had 120 employees (N=120). As a sampling frame, the whole case department was chosen. Reason for that is that the strategy will affect the whole department. It is, therefore, necessary to receive feedback from as many case department employees as possible to be able to assess the situation as close to reality as possible. The collection of data from all members of a target population is called a census (Hair et al., 2019). Since a specific sampling frame does not need to be selected in a census, there is no need to establish a method of sampling.

4.2.3 Data Collection

The data collection process for the survey is split into four stages. An overview of those four stages is visible in Table 1 and described subsequently.

Table 1**:** Overview and timeline of pulse survey

Overview & Timeline of Pulse Survey		
Phase	**Activity**	**Time**
Planning	Designing the questionnaire and goal setting	March 15, 2023
	First draft sent to case department supervisors, integration of feedback, survey creation	End of March 2023
	Final adjustments before pre-tests	April 4, 2023
Preparation	Creating awareness for the survey in the chapters	April, 2023
	Pretesting the survey	April 5, 2023
	Integration of feedback from pretesting	April 11, 2023
Data Gathering	Go live of survey	April 12, 2023
	Participation reminder sent	April 21, 2023
	Closing of survey	April 26, 2023
Data Analysis	Developing questionnaire for interviews	April 24, 2023
	Start selection process for interviewees	April 28, 2023
	Quantitative data analysis complete	May 12, 2023

The planning phase for the survey started with setting the aim for the survey and developing the questionnaire in English language, as this is the main language in the department. After submitting the questionnaire draft to the case supervisors and receiving their feedback, improvements were made accordingly. The survey was created in Google Forms; the main survey tool used at the case organization. Since it was important to receive honest and raw responses, the survey mode was set to anonymous. The questionnaire, visible in Appendix 1, consisted of 14 main questions. Depending on the answer given, follow up questions for clarification appeared. For the questions where the respondents needed to rate a statement, an ordinal Likert scale of five points was used. Likert scales are used when the goal is to measure the respondent's attitudes and opinions about a particular topic (Ruel et al., 2016). Ordinal refers to the level of agreement, going from least amount to most amount of agreement (Sapsford, 2007). The reason for choosing a five-point scale instead of a seven-point scale was, that although with a seven-point scale finer differences in judgement can be made, it however can be more difficult for respondents to distinguish the differences between the categories (Moors, 2008; Sapsford, 2007). Therefore, to simplify the answering process for the respondents and to ensure a common understanding of the categories, a five-point scale was chosen. The survey started with an introduction about the thesis and contained data privacy information.

The preparation phase involved three main activities. First, to generate as many responses as possible awareness needed to be created in the chapters. This was done by contacting the responsible chapter leads to inform them about the upcoming survey and asking the leader to inform their chapter members to participate. Second, the online survey was pretested. Pretesting is an approach to determine the problem areas of a survey, reduce complexity for the respondents, determine if respondents interpret the questions correctly, and to ensure that the technical setup works (Ruel et al., 2016). According to Weichbold (2022), pretesting is especially done in quantitative research as a quality control. Subsequently, the feedback from the pretest needs to be incorporated into the final version of the survey (Ruel et al., 2016). Therefore, pretesting and the integration of pretesting were planned action steps done during the preparation phase. According to Ruel et al. (2016), a survey should be tested on 12 to 50 people, but they also state that one person is better than no person pretesting a survey at all. Since there was some time constraint, I decided to pretest the questionnaire on only three people and integrate their feedback into the final survey.

On April 12, the actual data gathering started with the go-live of the survey. After a week, I reminded the employees of the synergy how vital their survey participation is during a department synergy meeting. A few days later, a final reminder was sent to boost participation once more. In the end, 56 people participated in the survey, which equates to a response rate of 46.7%.

In the last phase, the data of the survey was analyzed. This was done simultaneously while designing the questionnaire for the qualitative part. Therefore, there is some overlap between the quantitative and qualitative sub-studies.

4.2.4 Data Analysis

Since the pulse survey had two main categories of answer possibilities - numerical and textual, the analysis needs to use means of both quantitative and qualitative research. Because of the survey's nature and since the survey was predominantly done as a prerequisite for the semi-structured interviews, the data analysis for the quantitative survey part is only of descriptive statistical nature. For that reason, the analysis and calculations were done purely in Excel – using Pivot tables and other functions. Before the analysis could start, the raw data first needed to be prepared. This included the correction of typographical errors and checking for data gaps. The pre-analysis showed that some questions were left blank. Since missing data can impact the validity of the findings, the respective questions needed to be assessed. The assessment showed that only the last three questions, where respondents needed to write their own answer, had some gaps. According to Hair et al. (2019), there are two approaches for dealing with missing data, whereas one approach can only be done with numerical data. Therefore, the only available approach was to identify the share of missing data for each question. If the share exceeds 15% or more, these respondents should be eliminated from the analysis. For two out of three questions under examination, only two respondents' answers were missing which accounts to only 3.5%. For the last question, there were 36 missing answers, which is clearly over the 15% share. However, since this closing question was not mandatory to answer, a low response rate was already anticipated during the questionnaire development.

The main analysis focused on gaging the current situation in the case department regarding product stewardship, comparing the overall responses, and trying to identify significant differences between them. The comparisons were made using the background questions about the case department - question 1 to 3b to make sense of the different responses. As mentioned, for the main quantitative data analysis, descriptive statistics was used. Descriptive statistics is often used to create an understanding of the data (Hair et al., 2019). By visualizing the data through frequency distributions, histograms, pie charts, etc. the data is oftentimes easier to interpret (Hair et al., 2019). For the questions that were of qualitative nature, conventional content analysis was used. Conventional content analysis can be used as a quantitative or qualitative method of data analysis that can be applied to textual data which is not just interviews (Mayring, 2000; Robson & McCartan, 2016). Instead of using predetermined, theory-based categories and concepts, the researcher creates the categories that emerge from the data itself during data interpretation (Kuckartz, 2019; Mayring, 2000). This approach is called data-driven 'inductive' development of categories (Fenzl & Mayring, 2022; Kuckartz, 2019; Mayring, 2000). According to Hsieh and Shannon (2005), qualitative content analysis is used when there is a scarcity of existing literature on the phenomenon and is especially suitable for case study research (Kohlbacher, 2005). The workflow for conducting the content analysis in this thesis consisted of 5 steps and was based on Kuckartz (2019). The first phase involved intensive reading and familiarization with the gathered data from the survey. Then, a coding

framework was created. Third, the data is coded accordingly before being analyzed in a fourth step. Finally, the content analysis is presented. To ensure that the categories chosen were clear and understandable, the content analysis was presented to the two case supervisors for approval/disapproval. This workflow of the first four steps was repeated several times before the outcome was presented to the case department supervisors. After reviewing and implementing their feedback, the workflow was worked through a final time before the finalized content analysis was completed and documented accordingly.

4.3 Qualitative Methodology

This section introduces the topic of semi-structured interviews and why they were chosen, the procedure for defining the interviewing fields and development of interview questionnaires, as well as the interviewee selection. Additionally, the data collection and data analysis approaches are explained.

The qualitative sub-study is based on semi-structured interviews. The sub-study aims to further develop the insights generated from the quantitative analysis and to receive topical insights into; potential facilitating factors and roadblocks in the integration of product stewardship, best practices and good examples of role model pharmaceutical companies, important sustainability regulations that could influence a product stewardship strategy, general idea screening of strategic pillars, market insights into the pharmaceutical device and packaging market, and general improvement areas for the case department. These themes were derived from the overall research questions of this thesis as well as the findings from the pulse survey.

4.3.1 Semi-Structured Interviews

Qualitative research is used to discover novel phenomena and to build on existing knowledge in context-specific settings (Hair et al., 2019). There are two broad approaches to collecting qualitative data – observation and interviews. Semi-structured interviews were chosen as the data collection method for this study because observation or a quantitative approach seemed inappropriate for the goal of this sub-study and because interviews were deemed most appropriate for answering the research questions. Another reason was, that according to Hair et al. (2019), interviews are particularly suitable when dealing with sensitive or complex issues where a lot of elaboration is necessary. Semi-structured interviews were chosen, as they can be used to study both "what" and "how" questions (Eriksson & & Kovalainen, 2008). According to Eriksson and Kovalainen (2008), an advantage of semi-structured interviews is that through their semi-structured nature, there is a somewhat systematic approach. However, the researcher still has the opportunity to adjust the wording and order of the questions, being able to adapt to each interview scenario, which is not possible in structured

interviews. However, a disadvantage is that if the interviewer keeps too close to the preplanned questionnaire, important topics could be missed as there is little space for them to be naturally raised (Hair et al., 2019).
The semi-structured interviews are done in the second phase of the data gathering. The development of the interview questionnaire as well as the interviewee selection rely on the findings from the pulse survey. There is some concurrency between analyzing the pulse survey and the development of the questionnaire and interviewee selection.

4.3.2 Interviewing Fields & Interview Questionnaires

The primary qualitative data gathering is based on semi-structured interviews of topic matter experts. The aim of the interviews is to receive topical insights and do some idea screening. Since the current field of research is relatively broad and to obtain as many insights as possible, four areas were identified in which experts needed to be interviewed. The area of 'device development' and 'packaging development' are obvious topic areas, since this thesis deals with designing a strategy for the sustainable development of pharmaceutical devices and packaging and therefore, experts from that area are needed to be interviewed. The topic of 'sustainability' is also an area that was clear almost from the beginning of this research that it is going to be important to interview experts with pharmaceutical sustainability knowledge. The last area, 'leadership', however, only emerged after combining the knowledge from the literature review and the results of the pulse survey. From the literature review, leadership was evident as an important prerequisite for enabling product stewardship strategies. However, the need to interview leadership experts only really became evident after analyzing the pulse survey. The topic got mentioned in several ways; praising and criticizing the current leadership efforts on the topic of sustainability integration within the case department. Therefore, it became evident to include experts from that area to receive more insights.

As mentioned, the results of the survey functioned as a basis for designing the interview questionnaires and the selection of the interviewees. For each interviewing field a specific semi-structured questionnaire was designed, visible in Appendix 2. The questionnaires were designed in English to ensure rigor of findings (McKenna, 2022). Additionally, it is also to avoid unconscious bias arising from translating concepts which may not be directly translatable into English language such as metaphors or jargon (McKenna, 2022). The interview questionnaires are utilizing mainly open-ended questions. However, for some questions quantitative rating questions are used to rate statements. The reason for using quantitative questions in qualitative semi-structured interviews is that it makes the respective answers better comparable (Frels & Onwuegbuzie, 2013). According to Frels and Onwuegbuzie (2013), combining qualitative open-ended questions with quantitative instruments such as Likert scales allow researchers to further contextualize the qualitative interview responses. Additionally, this mixed

methods approach can enhance both legitimation and representation of the phenomenon of interest (Frels & Onwuegbuzie, 2013). Each questionnaire consists of three sections. In the first section, identical in all four questionnaires, the aim is to break the ice and receive general insights into the topic of sustainability and product stewardship, the experts' understanding of it, and their contribution to sustainability integration at the case organization. The second part of the questionnaires is topic specific and deals with questions that are related to the respective field. The third section, identical in all four questionnaires, is about closing the interview and giving the experts the chance to clarify or add additional information they view important. The interview questionnaires are prepared to be answered within a timeframe of 20-45 minutes, due to the restricted availability of the interviewees and contain around 15 questions. The questionnaires were pretested on three people, following the process after Weichbold (2022) for qualitative questionnaires.

4.3.3 Interviewee Selection

Since this research is of case study nature, only employees of the case company were interviewed as it was believed that this would provide the best insights for the case department's product stewardship strategy. The process for the interviewee selection and execution of the interviews is described subsequently.

The objective was to interview at least two experts from each field to achieve some balance. The interviewee selection was based on their respective roles and was done in collaboration with the two case department supervisors. The interviewees were contacted by email Mid-May which contained background information about the research project and why their expertise is needed to be interviewed in June. Once they agreed, an invitation was sent for either a face-to-face interview or an online virtual interview. The experts in device and packaging development were selected based on their current role and needed to have a strong interest in sustainability and already have done some sustainability projects for sustainable device development/ packaging development. The leadership experts were people in a leadership position within the case department as either synergy lead over the case department or as chapter lead. The sustainability experts were chosen based on their function in the case company. Since the survey showed that a closer collaboration with people from the Safety, Security, Health, and Environmental Protection Department (SHE) is desired, two SHE experts were chosen to be interviewed. Additionally, four other sustainability experts were selected, all with a background or relation to product stewardship. In total, 14 experts agreed to be interviewed. Since the interviewees were promised confidentiality, no detailed information or name can be given other than their position. To differentiate and trace the interviews, codes and numbers were given instead – device development (D), packaging development (P), leadership (L), and sustainability (S). Table 2 summarizes the 14 interviews.

Table 2: Details & characteristics of interviewees

Semi-structured Expert Interviews Overview:					
No	**ID**	**Expertise**	**Position**	**Date**	**Length**
1	D1	Device Development	Device Engineer	June 13	40 min
2	D2	Device Development	Device Engineer	June 14	42 min
3	L1	Leadership	Synergy Lead Device & Packaging Development	June 13	19 min
4	L2	Leadership	Packaging Engineering Lead	June 15	40 min
5	L3	Leadership	Verification Engineering Lead	June 15	28 min
6	L4	Leadership	Device Engineering Lead	June 16	19 min
7	P1	Packaging Development	Packaging Engineer	June 13	40min
8	P2	Packaging Development	Packaging Engineer	June 14	41 min
9	S1	Sustainability	SHE Lead	June 13	33 min
10	S2	Sustainability	Portfolio Manager	June 13	30 min
11	S3	Sustainability	SHE Expert	June 14	51 min
12	S4	Sustainability	Head of Supply Chain Sustainability	June 14	33 min
13	S5	Sustainability	Product Stewardship Functional Lead	June 16	46 min
14	S6	Sustainability	Supply Chain Transformation & Project Management Lead	June 19	38 min

4.3.4 Data Collection

The 14 interviews were all conducted in June 2023. Before starting each interview, the interviewee got asked for consent to record the interview. Additionally, the interviewee received information about data protection and the confidential use of their data (Gläser & Laudel, 2009). The interviews started with an explanation of the topic and a description of the objectives of the thesis, followed by an ice-breaker question and ended with the question if the interviewee had anything else they would like to mention (Gläser & Laudel, 2009). The interviews were conducted following the semi-structured questionnaires. In some of the interviews, as it is the case in semi-structured interviews, additional questions were added during the conversation, and sometimes questions were skipped. The data records consisted of audio recordings and notes taken during the interviews (Gläser & Laudel, 2009). After each interview, the interview was transcribed and added to the data analysis.

4.3.5 Data Analysis

For the data analysis of the 14 interviews, the recordings were transcribed using the software Good Tape. To assure the promised data privacy for the individual interviewees and case company, the transcripts are not included in the appendix and personal information was anonymized. The transcripts were analyzed using the web-based software QCAmap by Fenzl and Mayring (2020). Reason for choosing to analyze the transcript with QCAmap was that, first the software was freely available and relatively intuitive to use. Secondly, the software allowed for a better overview and marking of the themes. Lastly, as both Fenzl and Mayring are experts in the field of qualitative research, I trusted their expertise in designing a software that meets the needs for qualitative data analysis.

For the analysis itself, it was contemplated between choosing thematic analysis or inductive content analysis. In thematic analysis, the researcher analyzes the data sets and aims to identify themes, codes, and patterns in the data (Braun & Clarke, 2006; Hair et al., 2019; Nowell et al., 2017). Thematic analysis can further be used to understand the relationship between themes and how they manifest themselves in the data and can generate new insights about a particular phenomenon through developing a concept or theory around the found themes and patterns (Nowell et al., 2017). Inductive content analysis was already described in Chapter 4.2.4 and therefore, is not further explained here. The decision for choosing either approach was based on the fact that some studies indicate that thematic analysis is more suitable for examining novel phenomena. Because of the characteristics of thematic analysis, the characteristics of this study, and because Braun and Clarke (2006) recommend thematic analysis to novice researchers, thematic analysis was chosen as data analysis method over inductive content analysis. For the analysis itself, the transcripts were first read and reread to make sure that I understood and generally knew the content (Robson & McCartan, 2016). The transcripts were then analyzed by identifying characteristics and generating codes to passages of text. According to Nowell et al. (2019), coding allows researchers to focus on specific data characteristics. As a next step, the gathered codes were grouped, and themes were searched between these codes. This procedure continued until no more codes, categories and topics emerged and everything was grouped and labelled. During the data analysis process, it was vital to keep the goals of this research in mind.

5 RESEARCH FINDINGS

In this chapter, the research findings of both the quantitative and qualitative data gathering are presented. The presentation of findings, as previously mentioned according to the research design, is done separately for each method. First, the findings from the pulse survey are presented. These findings are setting the scene and are giving insights into how far product stewardship is currently integrated at the case department and how familiar the employees of the case department are with the topic. Based on the outcome of those findings, the qualitative interviews were conducted. The findings of the interviews, which were analyzed by doing a thematic analysis, are presented in a second section of this chapter. Through the thematic analysis, eight possible strategic pillars and themes for the case department's new product stewardship strategy emerged. Each possible strategy theme is presented separately and is enhanced with direct quotes from the interview transcripts.

5.1 Quantitative Findings

This section covers the findings of the previously conducted analysis for the pulse survey. In order to present the findings, it is necessary to first revisit the aim of the survey. Second, key characteristics of the survey are presented such as overall participation rate, chapter participation rate, and what those numbers already indicate. Followingly, the main findings from the survey are presented. To assess the current situation of product stewardship integration at the case department, all asked questions in the survey play together to give an idea of what the situation looks like. These findings are split into three sub-sections. First, the case department's employees' current level of awareness and engagement for product stewardship, second the employees' perception about the case department, and lastly, the combination of both sections to assess what the current situation regarding product stewardship integration at the case department looks like.

5.1.1 Background Information

The goal of the pulse survey was to assess the current situation of product stewardship in the case department by identifying chances and roadblocks for its further implementation. This was done by asking the case department employees about their professional connections and knowledge about product stewardship and to receive more strategic insights into the case department in general. By asking the case department employees a mix of questions regarding the case department itself but also about their personal awareness, knowledge, and interest in product stewardship, I was hoping to get a sense of their general attitude regarding the topic of product stewardship, which can create valuable insights to

consider also later on during the development of the strategy itself. For example, it could indicate how much groundwork needs to be done to ensure that there is a common knowledge about product stewardship which can support the implementation and acceptance of strategy.

The survey was sent to the 120 employees of the case department and was answered by 56 employees which equates to a response rate of 46.7%. Employees from all eight chapters participated in the survey, however, the individual participation rate of the chapters differs greatly. As visible in Figure 3 the chapter participation ranges from 2% to 19.6%, however, the participation rate of the individual chapters ranges from 29% to 100%. The survey as well as informal talks with various chapter employees indicate that there seems to be a correlation between the individual employee's perceived influence of the chapter to significantly impact the physical product along the design and development process and the active participation in the sent pulse survey. For chapters that come later in the process or that do not have anything to do with the design of the physical product, such as DH, DA, or DC, less than 35% of chapter employees participated in the survey. This could possibly be an indicator that perhaps not all chapters are equally aware or engaged when it comes to the topic of product stewardship. However, that is not for certain, but only an observation.

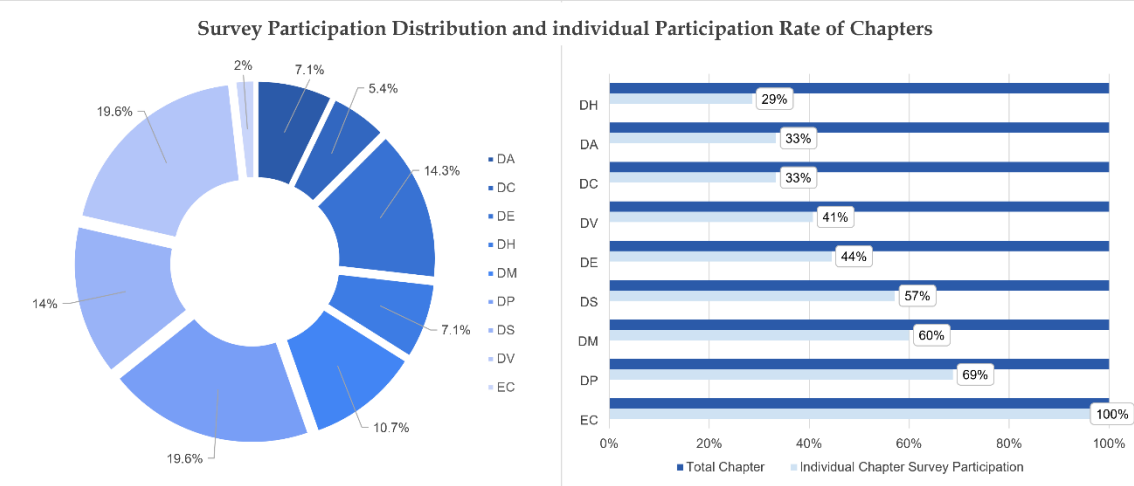

Figure 3: Survey participation distribution

5.1.2 Current Level of Awareness & Engagement: Employees

To summarize the main finding already in the beginning; there are great differences among the individual chapters and individual case department employees' level of awareness and engagement regarding product stewardship.

On one hand, there are over 62% of employees who, when it comes to product stewardship and sustainability in general, are highly engaged and motivated. They seem to have a vast interest and knowledge about product stewardship and take various measures to include product stewardship considerations in their job. These considerations range from staying updated regarding sustainability regu-

lations (4-times mentioned), sustainable product design choices (11-times mentioned), sustainable alternative material selection (11-times mentioned), avoiding/ reusing/ recycling of materials and products (8-times mentioned), or doing life cycle assessments (8-times mentioned). Out of all the survey participants, 44% mentioned that they currently have sustainability and product stewardship-related goals in their yearly performance evaluation. These goals are pretty similar with what was previously mentioned as product stewardship considerations taken during their job. Out of the 56% that do not yet have such a goal in their yearly performance evaluation, 64% wish to have such goals in the future. More than 83% of survey participants are familiar with the tools and initiatives regarding sustainability and product stewardship. As visible in Figure 4, the three initiatives that were mentioned the most are projects regarding take-back programs and recycling (12-times mentioned), life cycle assessment (12-times mentioned), and material selection of products (10-times mentioned). Similarly, the most mentioned known tools are the PIQET LCA software (32-times mentioned), the LCA Center of Excellence (28-times mentioned), and with 24 mentions the sustainable design guide and the internal Eco Alliance circle.

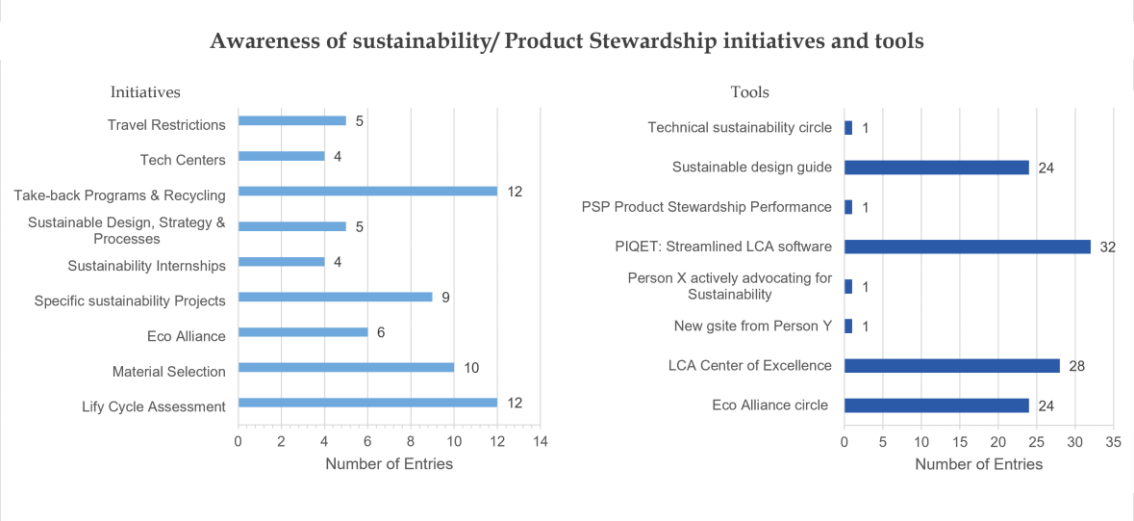

Figure 4: Awareness of initiatives and tools

Although there seems to be a high awareness regarding tools and product stewardship initiatives as well as many employees already contributing to sustainability and product stewardship, still 53% of survey respondents said that there are certain resources or support measures that would help them to embed even more sustainability-thinking in their jobs. Resources and support measures like having product stewardship be part of strategy and goals (9-times mentioned), having a dedicated sustainability expert and change makers for support (9-times mentioned), receiving specific guidelines and tools (6-times mentioned), or more communication, knowledge sharing and through that, staying up to date (6-times mentioned) would enable the survey participants to further embed sustainability-thinking in their jobs. The complete list of mentioned support measures and resources wished for by the survey participants is visible in Figure 5.

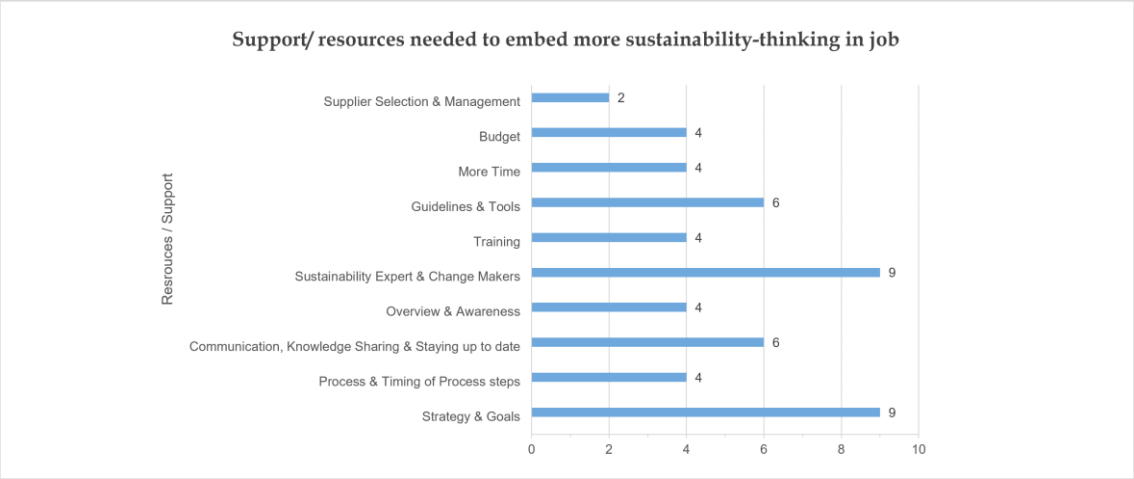

Figure 5: Support/ resources for sustainability-thinking

On the other hand, there are case department employees who seem less engaged, interested, or familiar with the topic of product stewardship. The survey showed that around one fifth of survey participators has no or only limited knowledge about what product stewardship is, and all of them have never come across product stewardship at the case department itself. This result, of 20% of survey participants not having heard of product stewardship at the case department, is rather surprising. Especially, given the fact that product stewardship is a central strategy of the case organization and that there even is a strategic paper out, signed by the CEO of the case organization. Furthermore, sustainability-topics but also product stewardship commitment is communicated regularly during synergy meetings. However, this result also partly confirms the indicator mentioned above regarding not all chapters recognizing their role in the integration and implementation of product stewardship at the case department and therefore, the individual employees not being aware of the topic or the employees not knowing that this topic should also be of interest to them. This was especially visible in asking for reasons as to why 37% of survey participants are not taking any product stewardship considerations in their jobs. The most answered reason was that it is "not part of my job" and that it has "no priority". Other reasons were lack of knowledge and too high complexity regarding the topic of product stewardship.

While there are large differences concerning the current level of awareness and engagement in the case department, in a group of 120 people with varying jobs, roles and responsibilities, homogeneity cannot be expected. There are always people who share a bigger passion or interest in a topic than others. In this case here, lacking engagement could be attributed to lacking awareness and knowledge, which it seems is not only a problem on individual personal level, but also on chapter-level. It appears that it depends on the perceived influence of the individual employee's chapter to be able to significantly influence the physical product along the design and development process, and thus to direct and impact the sustainability efforts with respect to the product. Perhaps for some

the active connection between what product stewardship entails and the activities employees are doing in their job is also somewhat missing. There are currently 23 projects ongoing regarding sustainable material alternatives, alternative fibers, or grammage reduction. Yet maybe some employees do not see projects like that as belonging to product stewardship efforts. What has become evident is the necessity to bridge certain knowledge gaps and awareness through adequate communication. The fact about lacking knowledge or too high complexity could easily be changed through targeted information and learning sessions, explaining the rationale behind product stewardship and what the implications are on the work of the individual chapters. Lastly, it is also worth mentioning that based on the survey, more than the majority of survey participants belong to the first mentioned group of employees who are aware of product stewardship, seem to be engaged and motivated regarding the topic, and want to have and to do more in that space.

5.1.3 Employee Perception of the Case Department

In order to better assess the current situation of the case department, it can be useful to gather information and feedback from the employees working there. This section presents how the survey participants see the case department's effort in product stewardship integration compared to general sustainability initiatives. Secondly, where the participants see improvement potential, and lastly, what their biggest perceived roadblocks in product stewardship integration are.

In general, survey participants rated the case department's effort regarding sustainability and product stewardship about the same as average, meaning there are some considerations taken but the topics are not integrated into every aspect of the case department, as visible in Figure 6. Two respondents rated the sustainability integration with a 1, meaning there is no perceived sustainability thinking in the case department. 18 compared to 10 respondents rated the case department with a 2 in terms of perceived product stewardship thinking respectively sustainability thinking, which means that there are few considerations made for the respective topic. A total of 16 respectively 13 people rated the case department's perceived sustainability-thinking/ product stewardship thinking with a 4 or 5, meaning that these considerations are part of (almost) all decisions. Overall, there are only slight differences between the respondents' perception of the case department's sustainability efforts and its product stewardship efforts. When multiplying the scale with the number of answers; sustainability-thinking receives 172 points, while product stewardship-thinking scores 165 points. Therefore, the case department's sustainability efforts were viewed slightly higher than its product stewardship efforts by the survey respondents. The mean for perceived sustainability-thinking was 3.07 compared to 2.95 for product stewardship-thinking, which is slightly higher. However, overall, the different results show that there are only minor differences how the case department is perceived in terms of sustainability and product stewardship. Most respondents perceive that the department does some product stewardship and sustainability activities,

however, these are not yet considered in all aspects of the department, therefore, there is room for improvement for better integration of both topics. However, since most respondents gave a 3, there is also the possibility of a middle option bias, where people choose the middle option more often than not (Moors, 2008). Whether such a bias is the case here in Figure 6 was further analyzed. Data experts from the case organization recommended conducting a sensitivity analysis whereby the value of three is removed to check if the results stay consistent. When excluding the value three, the new mean for perceived sustainability-thinking is 3.14 and for product stewardship 2.90. Since the results show a similar tendency and only differ 0.07 respectively 0.05 from the previously calculated mean, it can be said that no bias can be determined.

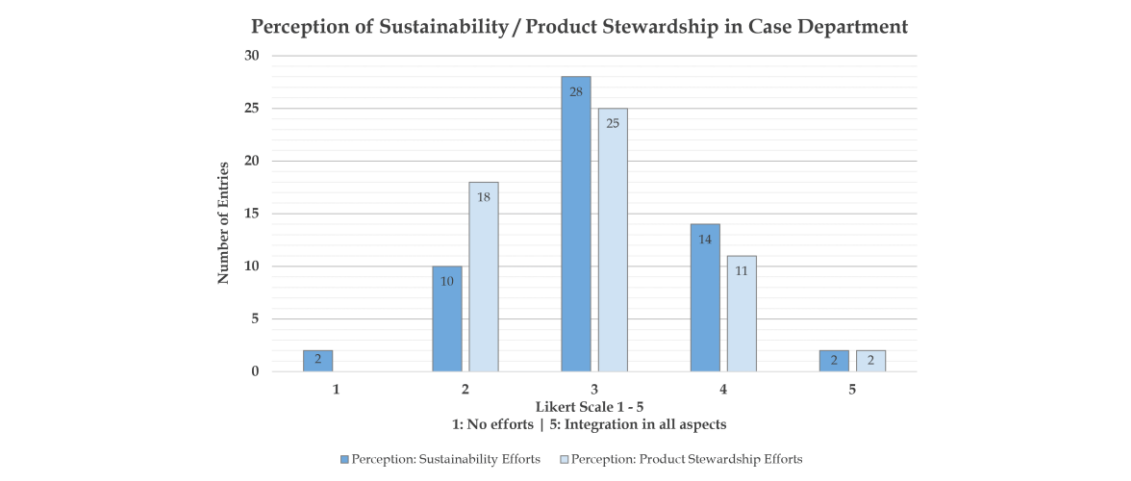

Figure 6: Perception of sustainability/ product stewardship

In terms of product stewardship integration, many survey participants shared ideas on possible topics the case department needs to improve. Only ten respondents did not have any improvements for the case department. The other 46 respondents raised 63 topics across ten different improvement areas. For clarity, during the content analysis, I realized that all the proposed improvement suggestions could be gathered and clustered in improvement areas and those areas could be applied to match the strategic framework from Chapter 2.3. The improvement areas are visible in Table 3 and the distinct colors used resemble the colors from the strategic framework. However, for clarity, subsequently it is explained to which strategic pillar the individual improvement areas belong. According to the survey participants, the areas with the biggest improvement potential according to total number of topics mentioned within is the strategic pillar of Design for Environment. Within DfE, topics such as material selection, design phase, innovation, samples & testing, and life cycle assessment were mentioned as areas with potential for further product stewardship integration. Topics within DfE were mentioned most frequently compared to other possible topics. In terms of number of individual mentions, strategy & frameworks as part of prerequisites were mentioned most often by the survey participants. Logistics & suppliers, waste management, training & knowledge, and regulations & standards were also mentioned as areas that could support in the further implementation of

product stewardship based on the inputs from the case department survey participants.

Table 3: Potential improvement areas for product stewardship

Potential improvement areas for Product Stewardship			
Improvement Areas	**Mentioned**	**Improvement Areas**	**Mentioned**
Strategy & frameworks	18	Regulations & standards	5
Material selection	7	Waste Management	4
Design Phase	6	Training and knowledge	4
Innovation	5	Logistics & suppliers	5
Samples and testing	5	No potential/ ideas	10
Life Cycle Assessment	4		

To summarize the findings, the biggest facilitating factors for the better integration of product stewardship are first, a tailored product stewardship strategy for the case department together with respective goals and second, sustainability experts or change makers to ask for guidance, support, or sharing of best practices. The biggest lever to further implement product stewardship is within Design for Environment, which means during material selection, design phase, innovation, testing, and life cycle assessment of the respective products.

Regarding potential roadblocks, the findings of the survey show that six survey participants do not see any roadblocks for product stewardship integration at the case department. However, the other 50 respondents raised eleven potential roadblocks. Similarly, as for the improvement areas, challenges and topics mentioned by the survey participants were clustered during the inductive content analysis and matched on a high-level overview with the strategic pillars from Chapter 2.3. This is visible in Table 4 and subsequently explained. Most perceived challenges and hurdles for the integration of product stewardship at the case department seem to be within the general topic of prerequisites. The survey respondents mentioned topics belonging to budget & economic reasons, time, and process & responsibilities the most within that area. In terms of number of mentions, budget & economic reasons as well as regulations & requirements within Extended Producer Responsibility were the most frequently mentioned. Similarly, to the findings of the previous section, eight survey respondents saw lacking knowledge, wanting to hold on to status quo, and lacking motivation as roadblocks for the integration of product stewardship at the case department. Five respondents mentioned the topic of suppliers as a challenge in the integration of product stewardship. What is meant by that is, that suppliers currently hold a lot of negotiation and innovation power over the case department. As mentioned by one survey participant, suppliers currently can make or break product innovation regarding for example alternative material options, as the

case department does not manufacture the pharmaceutical devices and packaging themselves but rely for that on its suppliers. Apparently, the case department currently has some suppliers who seem reluctant to invest in product innovation or test out new technologies, materials, or novice approaches in the manufacturing of their products.

Table 4: Roadblocks for product stewardship

Roadblocks for Product Stewardship			
Roadblocks	**Mentioned**	**Roadblocks**	**Mentioned**
Budget & economic reasons	13	Risks	5
Time	9	Prioritization	5
Process & responsibilities	8	KPIs and impact	3
Contradictions and focus	7	Regulations & requirements	13
Knowledge and availability	5	Status quo & motivation	3
Supplier	5	No limitations	6

To summarize the findings, the biggest roadblocks for the further integration of product stewardship at the case department seems to be around prerequisites, especially around the topics of budget and financial reasons, time, process and responsibilities, and the overall focus and positioning of the case department. However, while regulations & requirements can only partly be converted into opportunities as the case department needs to adhere to regulations and requirements, the mentioned roadblocks under prerequisites are all topics that the case department can try to neutralize or at least reduce through adequate positioning, commitment, and communication from management.

5.1.4 Current Situation

Based on the findings from the survey, the current situation regarding product stewardship integration at the case department seems to be the following.
While there are differences between the individual chapters and individual employees regarding their motivation, awareness, and knowledge for product stewardship, I would generally classify the awareness and knowledge as relatively high. Of course, a further assessment among the individual chapters and also talking to each chapter lead would make sense to further investigate their view and role in product stewardship. This, however, is not in scope for this project but could be a potential job for the case department leaders make sure that this prerequisite of having all chapters onboarded and committed to product stewardship is fulfilled. Nonetheless, I would assess the general situation as positive regarding employee motivation. The lacking knowledge and awareness can be improved through information sessions and showing the relevance of product

stewardship. In general, I do not see much opposition against the further integration of product stewardship at the case department from an employee perspective. However, what has become visible is that the integration of product stewardship is still at the beginning. While there seem to be ongoing initiatives, especially in the space of Design for Environment, not much has yet been done in the other aspects of product stewardship and even less has been recognized by the survey participants; be it communication wise or commitment from leadership. Therefore, improving communication and public leadership commitment are two areas that will need to be improved to ensure the new product stewardship strategy can successfully be implemented. However, this assessment is only an initial snapshot of the case department's situation and will build the basis for the development of the product stewardship strategy. Of course, the findings from the survey will need to be further analyzed and integrated with the results from the qualitative study. Only after integrating the findings from both sub-studies can a clear picture be drawn of the current situation of the case department regarding the integration of product stewardship and a possible strategy for the further implementation for it be designed.

5.2 Qualitative Findings

The aim of the semi-structured interviews was to receive insights and expert opinions about potential strategy topics for the new product stewardship strategy. Since a thematic analysis was done, concepts and categories emerged from the transcribed data itself. In total, nine potential strategy themes with an array of pathways emerged from the gathered and analyzed qualitative data. This section presents the results by introducing the identified strategy themes and explains possible strategic pathways and actions within these themes to introduce product stewardship and further the sustainability efforts of the case department. For data privacy reasons and to ensure the anonymity of the case company, one specific theme cannot be discussed in the following section. The reason for this is that the case department has a specific structure through which its identity could be found out. However, this does not mean that the aspects of this specific strategy theme are excluded in this thesis. The general findings will be discussed later along with all other results after the quantitative and qualitative results have been integrated in Chapter 6. However, in the subsequent sections, eight out of the nine strategy themes are presented.

5.2.1 Product Level

Product level as a strategic theme arose relatively quickly during the interviews, as the topic of reducing environmental impacts of products is one of the biggest aims in sustainability and of product stewardship itself. While analyzing the transcripts, 13 different action items, pathways, or ideas were mentioned during

the interviews of how the environmental impacts of pharmaceutical packaging and devices can potentially be reduced. Of all the experts, those from packaging development (P1 and P2) and device development (D1 and D2) are most familiar with the design and development of pharmaceutical packaging and devices and therefore, also already have some experience with trying to make existing products more sustainable. Therefore, most of the identified levers/ ideas on how to reduce environmental impacts on product level come from the analysis of the transcripts of these four experts. However, in a broader sense, many other experts recognized the general necessity of identifying improvement areas on product level for device and packaging (L1; L2; L4; P1; P2; S1; S5). According to L4, reusability in general but especially for auto-injectors was mentioned as a possibility to make devices more sustainable as less devices would need to be produced since the existing devices could be used multiple times before they would see their end of life. D2 had a similar view on this and explained:

> There are ongoing initiatives, targeted at the future. So, we are looking at reusable auto-injectors vs. existing single-use auto-injectors to see and I guess to try quantifying how firstly, if they are better, and then if they are better, to quantify by how much better (D2).

Another approach that was mentioned in the interviews, is to design products with their end of life in mind. The goal would be that they either can be easier taken apart and the individual components be correctly recycled or to design the products in a way and with the necessary infrastructure in place so that they can be taken back via a take-back scheme (D1; D2). The following interview extract exemplifies how the idea was presented by using an example from a competitor:

> And we have probably seen that a couple of times in some recent industry projects about auto-injectors with electronics attached, where it is designed so you can take that electronic bit off and put it in electrical waste. I guess that is quite promising. And then also take back schemes, I guess. I mean, again, you look at lots of suppliers like Novo Nordisk, there are a lot of these working groups that are being formed between companies to try and put in infrastructure to take products back. And obviously it is something that we are looking at as well (D1).

Additional ideas mentioned in the interviews to reduce the environmental impacts of pharmaceutical packaging and devices on product level was to explore alternative materials which can replace emission-intensive or unsustainable materials such as the use of certain polymers or PVC by introducing recycled contents or alternative fibers (D2; P1). On the topic of PVC, the case department is currently investigating PVC-free blisters by using alternative materials that still have the same material integrity and act similarly to PVC. Regarding the use of alternative fibers, alternative materials from new suppliers, and the use of recycled contents the case department has currently several projects ongoing that investigate those areas. On the topic of polymers, P1 and P2 stated that the use of polymers needs to be decreased and overall improved, especially for packaging. This could mean the avoidance of polymers in general or the introduction of monolayers through which recycling would become easier again. P1 said the following to this:

> Definitely, if we could somehow find improvements for polymers. I know it is critical, but maybe just to at least somehow assess if there would be an option in the future for some monolayer polymers. But in the meantime, we are working with our supplier to look at implementing biopolymers instead (P1).

However, some experts mentioned that currently, there is not a possibility to get away from polymers. This is because of the attributes of polymers and the high compliance rules in pharma about what kind of materials can and should be used for devices and packaging and how that material is allowed to behave under severe circumstances. However, there is currently a project ongoing at the case department regarding grammage reduction to use less raw materials.

Some experts mentioned that if the case department needs to use polymer materials, it should ensure that these materials were produced using the mass balance approach (D2; P1; P2; S1). Mass balance approaches use a similar principle as when buying renewable electricity from the grid. Although consumers cannot be certain that the electricity, they use in their homes is coming from green sources but trough purchasing green electricity the share of renewable electricity increases as manufacturers can only sell as much green electricity as they can generate. Similarly, through the manufacturing of polymers in a mass balance approach, fossil-based feedstock is combined with renewable or circular feedstock to form polymers (European Chemical Industry Council, 2023). The following interview extract shows how the mass balance idea was expressed:

> But then there is this whole mass balance approach, which really everybody should do but the material at the end of it is exactly the same chemical composition as when you compare it against the fossil-based one. So, in terms of all the work that we have done on verifying and validating with the FDA and other agencies, none of that is impacted. Because the material, the output is exactly the same. It is just the feedstock that goes into the pyrolysis that is different (D2).

Lastly, especially for packaging, experts mentioned the idea of also reducing the product in quantity, meaning number of packaging (P1; S1). This also can positively influence the environmental impact of the overall product, as less needs to be produced. This could be achieved through designing packaging that fits the devices closer which would result in fewer hollow spaces and gaps within the box, for which in turn less quantity of material would be used through which primary, secondary and tertiary packaging would be positively affected.

5.2.2 Communication

The second strategy theme with six different pathways and examples mentioned during the interviews is the topic of communication. Based on the semi-structured interviews, communication plays a vital part in the integration of product stewardship at the case organization and thus should also play a vital role at the case department itself. So far, information sharing and collaboration across the different chapters at the case department has often times been done through announcements during the monthly synergy meetings (D1; D2; S1; S3). In this monthly synergy meeting people present projects and topics of all kinds, which

is often used to also present activities and projects around sustainability. However, in the interviews with L1, L3, and S3, a point was raised by all of them that they believe that communication about sustainability activities, especially at product stewardship level, needs to be improved, particularly by sharing practical findings from life cycle assessments that have been conducted, ideally by those who conducted them, the LCA experts. Connecting to their idea, this could start with case-based examples of previous assessments and what the general learnings out of those assessments are and what implications these learnings have on similar projects. The following interview extract exemplifies the thoughts behind the idea:

> We need to find a strategy to move away from that volunteering approach to a consistent one. But the thing is, if you do not start sharing learnings, it is very difficult. Those learnings need to be ready and tangible from doing LCA, so that you can argue about them and compare them. Look, we have now a few years with a lot of learnings, and we see it is possible and these are the improvements we can make (S3).

This mentioned idea could then also lead to those LCA experts, which are part of the LCA super user group at the case department, providing support for technical questions and generally leading to more visibility and awareness at the case department. Because some experts have questioned the current visibility of product stewardship at the case department, as there has not been that much communication or sharing of case-based examples about it (D2; L4; P2; S3), which becomes evident when looking at the following interview excerpt:

> We also need the right level of visibility. So, it is important that we always bring these topics also to the synergy meetings and to the project teams. I think there is quite much we can do there because product stewardship is still quite a new topic. Or so it feels for me, for the people, for the employees, even though it has been discussed for quite a long time. I think we need to really learn what it actually means and where we actually can make an impact. And I think that is where we still have an opportunity, I think, for education, especially visibility and communication (L4).

Subsequently, on the topic of visibility, P2, S4, and S6 pointed out the potential need for a product stewardship pledge of the case department to showcase its commitment and give product stewardship more visibility inside and outside of the case department. The following excerpt showcases how the idea was presented:

> Make a commitment saying, this is what we want to achieve. We have something to aim for. A direction. And making sure that it is suitably staffed, that we can achieve it (P2).

When staying on the topic of visibility, D1 and L4 questioned the case department's awareness for the sustainable design guideline that was established to guide people in how to make more sustainable design choices. According to them, there has not been that much communication around the implementation of the guideline. Although 24 out of the 56 survey respondents said that they were aware of the guideline existing, the experts question whether the guideline is used and useful, or if it is more of a checkbox activity, or simply neglected (D1, L4). P2 stated this:

> When I look into the sort of project documentation done by the engineers, for example, they are supposed to do sustainability assessments and consider sustainable options according to the sustainable design guideline, but very rarely do you see things explicitly being mentioned (P2).

What has become evident from analyzing the interviews, many experts agree that in general, there is room for improvement when it comes to communication and awareness for product stewardship at the case department.

5.2.3 Design Phase

Topics around the design phase for pharmaceutical packaging and devices emerged as a third potential strategy theme for the product stewardship strategy. Based on the findings from the interviews, three activities can support the integration of product stewardship during the design phase at the case department.

Firstly, it is by having concrete sustainability selection criteria when designing or choosing new devices, packaging, or platform solutions that are the same for all projects (D1; D2; L2; L3; P1; P2; S1; S2). These selection criteria should contain sustainability requirements and requirements that are in line with the corporate product stewardship strategy to ensure that sustainability is part of the discussion (D1; L1; L3; L4; P2; S2). The following interview excerpt showcases the reasoning behind this idea:

> So, making selection criteria for your next device or your next platform device to consider sustainability at its core mandatory. So, when you look at the criteria from which devices are chosen from, like track record of the company, development cost, time to market, all of these things, I think, they are very highly weighted, and so should sustainability be (D1).

For that mentioned idea, the case department would even already have some existing resources that could support in this, as there are packaging scorecards available but not necessarily used, according to L2.

The second suggestion was to do life cycle assessment upfront during the design phase of the potential products. This seems to be critical, especially in combination with wanting to have sustainability criteria, as the criteria will need to be measurable (D1; D2; P1; P2). However, according to D1, so far, the assessment has been done only in later stages:

> In most cases, it is very late. The device is already developed, and we just have a footprint. Which means we are just collecting data by doing the assessment but not actively improving anything anymore (D1).

Therefore, knowing the impacts and implications of the case department's products is vital from the beginning and especially during the design phase. Because what is not measured, cannot be improved later. However, in packaging, the situation is slightly different as P1 mentioned this:

> What I really like is that we, in packaging, are really trying to implement things that we assessed before. So, we are also requesting money and budget for those projects based on past assessments and try to improve the products accordingly (P1).

These two differing examples from device and packaging development teams showcase, that there is a need to ensure that, if the case department is committed

to do life cycle assessments, the assessments need to be done already during the design phase of the project for both teams. However, a reason this is not yet the case is, that there are different LCA approaches between packaging development and device development. These two chapters are set up differently and use different life cycle assessment tools. For packaging development, the chapter has its own LCA super user group that does all the packaging assessments for the chapter. For device development there currently is no LCA super user group in place. Their projects get outsourced to different departments within the case organization who have the needed resources and knowledge to perform the life cycle assessment. One of the main reasons for the difference in set up is the easiness of the tools used. While for the assessment of devices SimaPro is used, in packaging assessments the LCA super user group uses PIQET. PIQET is a streamlined LCA tool specifically designed for assessing packaging. On that topic S2 said:

> We have implemented both PIQET and SimaPro. While PIQET is a quick assessment for packaging, SimaPro is used for device assessments and is way more complex, needing much more data input than with PIQET and therefore also more knowledge in handling the tool itself (S2).

Lastly, according to D1, the department needs to ensure that when decisions are made based on assumptions taken, that these assumptions then also come to life:

> So, I would say looking at which assumptions have to be made, like assumed supply chain, assumed usage scenario, assumed transportation, and assumed end of life. What is the impact of this product with and without a take back scheme? Assuming that you might say, oh, it is great if you have a take back scheme, so you choose the device with take back scheme. But then later when the take back scheme decision is made, it is not done, and you are stuck having chosen the less environmentally friendly device option. Therefore, I would try to compare apples with apples (D1).

5.2.4 Life Cycle Assessment

Since life cycle assessment is a big topic and has already been mentioned a few times in previous ideas as an important factor of potential strategy themes, I decided, based on the analysis of the interview transcripts, to give the deserved visibility and importance and make it its own potential strategy topic for the case department. In this section, four ideas are presented. These are new ideas that have not been mentioned in the previous sections. First, D1, P 1 as well as S5 identified the need for the case department to ensure that there is a mutual understanding of how to use life cycle assessment and how to use the available sustainability tools in a standardized way. This is to ensure comparability of assessments and to factor out potential user biases, as in past assessments the results from the same project varied greatly depending on which super user did the assessment. As a side note, the head of LCA at the case organization is currently implementing a guidance document on how to use LCA in a streamlined and standardized way. Here is an interview excerpt that supports the idea regarding a standardized way of doing LCA at the case department and why it is important:

> We need to get better at doing life cycle assessments and having really standardized approaches to how we do it that we have comparable, reproducible results. Depending on

> where you go, and what you include, you can get different outcomes. And that is what we have been talking to [name anonymized] about as well. It is about sort of setting a standard, so that we can have comparability between the products. So that we are always doing the assessment the same way, that we include the same things. Because otherwise, it is a bit questionable about how valid the output is that we get (P1).

Second, the availability of all necessary data is something that, according to the experts needs to be considered as well. Having important supplier product information available for the products the case department is using and trying to make an assessment on, is a key requirement to ensure that the assessment is not based on assumptions. When taking assumptions, they probably do not reflect the true values and impacts of the products (D1; P1; S5). Additionally, according to P2, S2, and S5, it is vital that the assessments are not only done but that they then also get processed and further analyzed for hotspots for the case department to derive learnings and insights which can be further used and applied to other projects.

> There is a lot of happy engineering in this space as well. And still more and more people like to focus more on what can I report? What can I sell and not what can I do? We need more doing. And that is what I am trying to focus on right now to get more firm with the measuring and the learnings out of the assessments. And really insisting on, hey, we need to have the output, we need to have clarity. What needs to change? Where are the components in our systems which are driving a certain, energy consumption, water consumption, or other impacts (S5).

Lastly, these two previously mentioned suggestions from the interviews, would ensure, as P1 said before: „...that we have comparable, reproducible results" based on which the individual products can be compared against. This could possibly lead to having an internal benchmarking for the existing packaging and device solutions (D1; P2; S5). With benchmarking products and deriving learnings, the case department could ensure continuous improvement and innovation, as well as ensuring that only solutions with favorable environmental impacts end up getting chosen.

5.2.5 Product Stewardship Resources & Ambassadors

The fifth theme that appeared during the thematic analysis which could support the product stewardship integration at the case department was about product stewardship resources and ambassadors. Three related topics were discussed during the interviews. D1 and P2 raised the need for having a standing resource who deals with product stewardship and life cycle assessments at the case department. According to D1, this way, the case department could prevent the loss of knowledge, as previously sustainability work has mainly been done by interns through internships or thesis projects. By having a dedicated standing resource in the case department, supporting people and projects in sustainability and product stewardship matters, this person could gather learnings across the various chapters and therefore, increase the learnings for the department even more. The following interview excerpt shows the importance of this idea:

> With all the things we are doing regarding product stewardship, ambassadors are very important. Ideally, the ambassadors would have a bit more time to focus on the topics because I did not see the interns coming to us a lot in terms of ideas around the business. It would be great if the ambassadors would be able to feed their ideas and learnings back to us developers (D2).

Additionally, by having a standing resource, the case department could ensure that there is always a person working at the case department that deals with the topic of sustainability and product stewardship. Thus, there would be continuous improvement and learnings. Similarly, L3 suggested the introduction of a sustainability circle with people from various chapters of the case department to ensure sustainability and product stewardship integration across the department and to potentially decrease the occurrence of silo-thinking, which was also mentioned as a finding from the pulse survey as well. Followingly, an extract from the interviews that better explains the idea of a sustainability circle:

> They would be taking care about what is coming from outside a little bit, help to bring the topics also to teams. Kind of a circle, kind of a self-organized team, taking care about these different roles, where overall strategy could be a topic, but also communication towards the synergy and to the outer organization, taking up what is coming from outside, looking into options, seeing potentials, driving those within the synergy. But then also the overall synergy strategy and keeping an overview about ongoing projects (L3).

Similarly, along the same lines as a sustainability circle was proposal No. 3 to use the already existing LCA super user group from packaging development as ambassadors for product stewardship at the whole case department because of their existing knowledge (D1; L1; L2; P1; P2). The following interview excerpt showcases how this idea was presented and gives reasons for it too:

> And that is something that we need to keep in mind because [name anonymized]is now leaving, [different name anonymized] was familiar with the concept and left. So, we need to have the super user group who is really capable of using the LCA tools and based on that, providing guidance, support, and information to others in the department (L1).

Lastly, one aspect that became evident during the data analysis was, that whenever experts raised the topic of having a potential product stewardship resource or ambassadors, they always mentioned the importance of having people in charge who are passionate about sustainability and product stewardship and who want to see the case department improve in those areas (D1; D2; L1; L3; L4; P1; S1; S4; S5). This is confirmed by the following interview extract:

> I think we need support first. I think it is important to have the right drivers and we need to have passionate people who are really driving the topic (L4).

5.2.6 Leadership

For a successful integration of product stewardship at the case department, leadership was recognized as a potential strategy theme during the data analysis. In nine out of the 14 interviews, the expert emphasized the need to define clear goals, assign tasks, monitor the progress, and evaluate the situation to ensure the case department is on track regarding its product stewardship integration (L1; L3; L4;

S2; S3; S5; S6). These tasks need to be enforced, assigned, supervised, and financed which is usually the responsibility of management. In the case of the case department this would be the enabling circle as well as the individual chapter leads. An important characteristic that was mentioned by some of the experts regarding these potential goals and tasks regarding product stewardship is the visible connection to existing goals on corporate level as well as goals from Group SHE (L1; S1; S3; S5; S6). They emphasized that this is to ensure acceptance but also accountability. However, defining tasks, setting goals, and monitoring progress are not sufficient. As L1 said:

> Leadership buy-in and support are necessary. This means for sure resources, space, budget, awareness but also appreciation is important. If you appreciate what is being done, people are motivated. They want to do it, they feel that they do something that is helpful, that makes sense (L1).

This was also visible from the pulse survey results. Case department employees want active leadership buy-in for product stewardship which means that there is visible and adequate support and resources from management when it comes to product stewardship topics (L1; L4; S5). The following excerpt exemplifies this:

> There is this bigger push from the very top. So, now we need to engage the middle. We need middle management, senior leaders, functional leaders, department leaders to get on board. And so, there has been a big change in how people working on sustainability are starting to communicate it. People are asking for functional level goals, both from the bottom up and from the top down (S5).

Furthermore, according to L1, it is also the role of leadership to continuously remind people from the case department that product stewardship is an important topic at the case organization and that it is therefore vital for the case department to contribute.

5.2.7 Supplier & Procurement

Based on the interview analysis, suppliers and procurement seem to play a vital role in the further integration of product stewardship at the case department. Therefore, this topic was identified as a seventh potential strategic theme for the product stewardship strategy.

According to D1, D2, P1, P2, as well as L2, procurement at the case organization has taken a rather passive approach when it comes to sustainability requirements and enforcing them from suppliers. Apparently, it is usually people from the case department who need to deal with suppliers to try and receive necessary product-relevant and sustainability-relevant data to ensure life cycle assessments are based on facts and not assumptions. In addition, procurement forces the case department to deliver Scope 3 relevant information and calculations, even though these calculations are neither necessary nor required by the case department itself. Additionally, so far, suppliers have not voluntarily or efficiently been sharing the required information with the case department (D1; D2;

P1; P2). Unfortunately, procurement, so far, has not yet been of support in enforcing the required information from suppliers. P2 said the following regarding that situation:

> Procurement is not pushing at all. You would think that with the targets they set on carbon reduction, they would become a bit more proactive. But no, they are just sort of following up and are not even supporting us in doing the carbon reduction calculations or anything like that, even though they are the ones needing those calculations. It is not us; we do not need these calculations for our work. So, the situation with procurement is very light touch, sort of just hoovering up the activities of other departments (P2).

Several interview experts agree, that together with procurement, the case department could increase its negotiating powers regarding suppliers to receive the necessary supplier information. Additionally, the experts recommend that procurement and the case department start collaborating by defining which sustainability requirements and information for supplier products are necessary so that product stewardship and its integration can be ensured and actively followed at the case department (D2; L2; P2; S4; S5). One positive example mentioned about an existing collaboration with procurement was from P2, which showcases the dependency on procurement:

> Working with procurement, we are now switching all of our fiber-based material to FSC, which by ourselves, we would have never been able to achieve (P2).

5.2.8 External Collaboration

The eighth strategic theme that might be vital for the new product stewardship strategy is external collaboration. External in this case refers to collaboration outside of the case department itself. This can mean collaboration with departments inside of the case organization or with stakeholders that are not part of the case organization but are really external as for example a competitor.

According to D2, S1, and S3, the case department should collaborate with other pharmaceutical companies on the topic of take-back schemes. There are already collaborations and partnerships between pharmaceutical companies ongoing. One example is the launch of a cross-industry partnership between Novo Nordisk, Eli Lilly, Sanofi, and Merck Group to recycle materials from injection pens in Denmark (Due Karlsson, 2023). Followingly, an interview excerpt about why the case department should join other companies on the topic of take-back schemes:

> So, I guess you also see trends in this whole collaborative working between companies that have kind of identified they cannot do this alone and they need to collaborate because the infrastructure piece is so challenging, especially for something like take-back, which I think we should try to join somewhere too, before it is too late and we are the only ones not having done something in that space. (D2)

Additionally, according to the interviews, the case department should also join some industry working groups to ensure that the case department stays up to date with what is happening in the industry as well as having the chance to col-

laborate with peers and other stakeholders on potential legislation or other initiatives (D2; S1). One example of an industry working group that could be beneficial for the case department is the Healthcare Compliance Packaging Council.

Lastly, according to five interview experts (D1; L2; S1; S2; S3), the case department should improve its collaboration and active exchange with other departments within the case organization. These departments could be for example the Group SHE department, as previously mentioned in the pulse survey results as well, to discuss and work together on environmental topics. Collaboration with other departments that are also adopting product stewardship, could be beneficial. As the case department could exchange on progress, tips, pitfalls, etc., as the wheel does not always need to be reinvented. Oftentimes it is useful to use the synergies within an organization. On the topic of collaboration, S3 mentioned the following:

> Do not forget about communication and process communication, with which I mean start talking about it continuously if you want to involve others that are critical. Tell them this is where we want to go and this is where we currently are, this is where the hurdles are, and that is why we need to collaborate with you. I think this is currently missing (S3).

6 INTEGRATION OF FINDINGS

The overall goal of this study was to develop a focused product stewardship strategy for a case department of a pharmaceutical company that deals with the development and design of pharmaceutical devices and packaging. In this chapter, the findings of the quantitative sub-study and the qualitative sub-study are combined and integrated to form the case department-specific product stewardship strategy. The pulse survey showed that there is a good basis for implementing product stewardship, with many case department employees being highly motivated and aware of the topic. Smaller improvement areas exist; however, they should not impede or ruin the implementation of the strategy in the department. Regarding the semi-structured interviews, nine potential strategy themes were identified for the case department. For the integration of findings, the previous theoretical framework from Chapter 2.3 is taken into consideration.
In this chapter, first the combination of findings is presented. This builds the base for the product stewardship strategy formulation which includes first a review of the research questions for this study as well as the actual strategy formulation. Lastly, this chapter also presents practical implications, theoretical implications, as well as research limitations of this study.

6.1 Combining the Findings

As described in the previous chapter, the findings of the pulse survey and semi-structured interviews were first individually introduced. However, the main method for this study was of qualitative nature and therefore the quantitative method was used as a prerequisite. For the integration of findings, the previously identified strategy themes from Chapter 5.2 were used as a basis and were enriched with information and additional pulse survey findings from Chapter 5.1. This was done by reviewing the survey results and looking for topic matches between the two sub-studies. For better traceability, each survey participant received an identification code, containing their chapter abbreviation and a number. If their answer was a match with a theme or strategic pathway from the interviews, the respective survey participant's identification number was noted down. Additionally, existing live projects that are currently ongoing at the case department were also added to the list to give a better overview of what the case department is already doing and where there have not yet been any initiatives or projects. The allocation of existing projects was done by the two case department supervisors since they have a better overview of what is going on in the department. In total, 23 existing live projects were identified, and they all belong to the topic of Design for Environment.

Once the cross-check for strategy topics was done from interview strategy topics to survey results, the survey results were analyzed once more for strategy themes that were perhaps not yet included. Through this approach, an additional strategy theme as well as several strategic pathways could be identified. This procedure also entailed revisiting the interview transcripts and looking for indications in the interviews for the newly found themes and topics. After no further potential strategy topics arose, the topics were sorted to match the strategic model from Chapter 2.3. These strategy themes and the strategic model were then used as the basis for the formulation of the product stewardship strategy itself. An overview of the results of this integration of findings is visible in Appendix 3.

6.2 Strategy Formulation

This section introduces the strategy formulation approach. First, the three sub-research questions are revisited and answered. Based on the answers to the sub-research questions and by combining the results from the pulse survey and the semi-structured interviews, the strategy formulation itself started. The output of this, the product stewardship strategy for the case department, is presented and described in the second part of this section.

6.2.1 Reviewing the Research Questions

In this thesis, I aimed to design a product stewardship strategy by answering the following sub-questions first:

1. *How can a theoretical framework about the integration of product stewardship on functional level look like?*
2. *What is the current situation of the case department in terms of product stewardship integration and where are the gaps?*
3. *What are the key focus areas for the case department to achieve sustainable device and packaging development in pharma?*

Based on the available academic literature and research, a theoretical framework was designed. The reason a new strategic model needed to be developed was that the existing literature mainly talks about product stewardship and its implementation on corporate level. By reviewing the available literature, it became evident that for this thesis, there needed to be an additional model on functional level. Therefore, the available research was used and tailored to fit a strategy on functional departmental level with pharmaceutical device and packaging development in mind.

The current situation of the case department was assessed using the insights from the pulse survey as well as outside perspectives of sustainability experts of the case organization which were gathered during the semi-structured interviews. Based on the analysis and integration of both sub-studies as well as using

the insights from the literature review, the current situation of product stewardship at the case department was assessed. The introduced theory in Chapter 2 gave a lot of insights and was helpful in assessing the case department, which is the following. While many case department employees are aware and do show some level of knowledge about product stewardship, this awareness greatly differs among the different chapters of the case department. In general, it can be said that chapters that deal with the design and development of the products themselves, such as packaging engineering or the device engineering chapter, show a better understanding and more thorough implementation activities of product stewardship compared to chapters that are not directly responsible for the development of the device and packaging products.

The 23 existing sustainability projects in DfE are an indicator that sustainability innovation on the product level is highly prioritized in the case department. It furthermore shows that DfE is the strongest existing area within product stewardship integration for the case department. On the other hand, when taking the strategic model to hand, the case department currently is lacking in the areas of EPR, collaboration, and education as there are no ongoing or past projects in those aspects. This has also become visible in the survey results with the survey participants stating that regulations and product requirements pose one of the highest roadblocks for product stewardship integration. The survey furthermore uncovered that there is a misconnection between leadership activities and how those are perceived as many survey participants rated time, budget, risks, contradictions, focus, and responsibilities as hurdles in the product stewardship integration at the case department. However, according to the interviews with the leadership experts, these topics do not necessarily pose a roadblock to the integration of product stewardship. For example, a development project usually lasts three years, which means that there should be sufficient time for sustainability considerations and the active integration of product stewardship (L1; L2; L4). This was also attested by P2:

> Even with SimaPro for devices, I was talking to a couple of people about how much time we need for the data gathering and they said about 80 hours per assessment. 80 hours over the course of three years should be feasible(P2).

Therefore, product stewardship and including sustainability requirements in projects perhaps is currently more of a responsibility of management, to ensure that these get adopted and integrated at the case department. Additionally, survey participants also wished for more and clear commitment of leaders regarding product stewardship. To summarize, leadership seems to be another area where the case department should improve as there are clear mismatches between the perception of the leaders and the remaining case department staff.

Overall, product stewardship so far has been mainly integrated in terms of innovation around DfE at the case department. Additionally, there is an ongoing project about a potential takeback scheme for autoinjectors, therefore, also the aspect of collection and recycling is partly covered. However, in all other strategic aspects such as EPR, education, collaboration, and partnerships as well as in the topic of perceived leadership commitment, the case department so far seems

to have been lacking when it comes to active product stewardship integration. Therefore, these can be considered key areas for the case department to focus on.

6.2.2 Product Stewardship Strategy

With the integration of the survey results and findings from the semi-structured interviews, the strategy for the case department was developed in close relation to the strategic framework in Chapter 2.3. The literature review in general proved to be a close and useful guide for developing the strategy. The integration of findings in Appendix 3 was used a basis and enriched with the knowledge from answering the sub-research questions. While developing the product stewardship strategy, the strategy drafts were presented multiple times in review meetings to various stakeholders across the case department. This was to ensure that the strategy matches the case department, that the strategic pathways are clear and understandable for the different chapters, and to raise awareness and acceptance of the strategy.

The strategy is established in a way that each strategic pillar has at least one strategy topic for which there are certain goals/ commitments. These goals/ commitments are then further broken down into short-term, mid-term, and long-term action items that describe the main objectives, as well as the desired outcome and necessary requirements for reaching that milestone. The individual action items are not further explained, as they seem self-explanatory. The full strategy including strategic pathways and action items is visible in Appendix 4. Figure 7 shows a is a high-level graphic illustration of the product stewardship strategy for the case department. The strategic pillars as well as strategy topics and goals of the product stewardship strategy for the case department are explained hereafter.

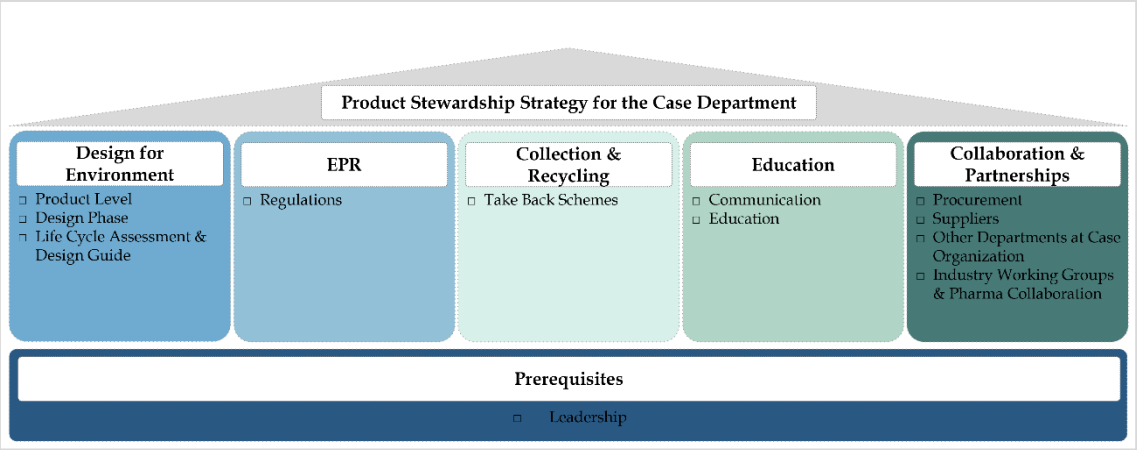

Figure 7: Product stewardship strategy for the case department

Leadership was chosen as a necessary prerequisite to ensure that the case department is aware of the management's commitment to product stewardship and to also ensure that there is further commitment towards time, resources, and budget for the topic. The strategy topics under Design for Environment are on product level, design phase, and life cycle assessment and design guide. On the topic of

product level, the case department was already showing a lot of commitment with the 23 ongoing sustainability projects. Although the case department is already active in that regard, it still felt vital to include this topic in the strategy to give it further visibility and to ensure that the case department keeps innovating in sustainable product alternatives. The topics of the design phase and LCA and design guide were newly added to the strategy. The pulse survey and findings from the interviews showed that these are two aspects where the case department needs to further improve and grow its capabilities to ensure and measure the sustainability impacts of its products.

For EPR, the topic of regulations was taken up as a strategy topic under which the goal is to set up a regulatory information-gathering service to be better prepared for regulatory changes. In the survey, regulations were mentioned as both a potential as well as a challenge. Additionally, survey participants as well as interview experts raised the topic of a regulatory information-gathering service making daily work easier as so far, the people from the case department had to stay up to date with necessary regulations themselves which takes a lot of time and effort (DE6; DM3; DP7; P2; S1). Time and effort that could be better spent on product innovation itself. For collection and recycling programs, take-back schemes were adopted as the focus topic. The goal is to keep in the loop on the topic of take-back schemes with the various case company locations and push for solutions from a device and packaging development point. Under education and awareness, the topics of communication and education need to be improved, which is why they were adopted into the strategy. For communication, the goal is to share information and collaborate based on case examples and projects. For education, the commitment is that everybody in the case department is aware of where to find information regarding product stewardship and sustainability and whom to reach out to for additional information. Lastly, for the strategic pillar of collaboration and partnerships, four topic areas were identified. The first topic is procurement. The goal is to (re)define the role of procurement in supplier relations when it comes to sustainability and product stewardship. According to interview experts D1, D2, P1, P2, and L2, procurement so far has taken a rather passive approach when it comes to sustainability requirements and enforcing those from suppliers. However, for the work of the case department, especially in doing life cycle assessments, supplier product information is necessary. So far, usually, assumptions have been taken, however, with taking assumptions across the whole assessment, the outcome of the LCA is rather unreliable. However, so far, suppliers have not yet been sharing the necessary information with the case department voluntarily. To have better negotiating powers, the case department needs the support and collaboration of procurement. The second topic is the topic of suppliers, which has just been briefly touched on. The goal is to reduce the power of suppliers and collaborate more with them to reduce Scope 3 emissions and receive necessary sustainability information on the respective products. The third topic is to increase collaboration with other departments at the case company and to ensure information is shared through which knowledge can be leveraged across the company. The last topic is the collaboration and forming of

potential partnerships with industry working groups and other pharmaceutical companies. The goal is to join industry working groups to ensure the case department and case organization stay connected with what is happening in the pharmaceutical industry. This is also to potentially leverage knowledge and resources for industrywide improvements.

6.3 Implications

This section presents the implications of this research regarding future research from a theoretical perspective as well as from a case department perspective and shows how the findings and developed strategy are helping the concept of product stewardship to grow. For future research, I recommend conducting further research internally at the case department and in the case organization, as well as conducting further theoretical and scientific research. From a theoretical and scientific perspective, future research could investigate the phenomena of product stewardship implementation in pharmaceutical companies on functional level. Research could focus more on practical application and trying to support organizations during the implementation process of product stewardship with practical examples and useful tips. Perhaps there are common strategy pillars and strategic pathways that are appropriate for all pharma companies. This could bridge the gap between academic research and practical application. It would also help companies gain a better understanding of how to adopt product stewardship and how to best integrate it into existing strategy structures and goals on departmental level. In general, as there is an array of pharmaceutical companies on the market and the environmental impact of the pharmaceutical industry is intensive, the topic of this study should be researched further for other cases and organizations. Regarding the concept of product stewardship, the proposed strategy helps the concept to grow, as it is an addition to the existing literature, which is predominantly focused on corporate level. Often the literature deals with the reasons as to why the strategy should be implemented, but not necessarily what should be included in such a strategy. The strategy proposed in this thesis, however, combines both. From an applied science perspective, it would be interesting to further accompany the implementation and realization of the proposed strategy at the case department. This could entail conducting additional research and doing more pulse surveys to see how the level of awareness changes over time. Additionally, further research could focus on the individual strategic pillars of the developed strategy, especially for the area of Design for Environment, and research relevant materials and innovation potentials. In addition to this, it is recommended that the case organization actively keeps track of the various departments that integrate product stewardship and that it tries to compare if there are genuine improvements in terms of risk reduction, social impacts, and environmental impacts of the manufactured drug products.

6.4 Research Limitations

In this section, the research limitations are presented. First, as this thesis is of case study-nature the research design of the study was flexible and depended on the context (Robson & McCartan, 2016), because of that the findings of this thesis cannot be generalized and populated onto a wide mass (Eriksson & Kovalainen, 2008). This means that the designed product stewardship strategy cannot be taken and implemented by another organization as the strategy was specifically designed based on the current analysis of the case department and how the case department is strategically situated. Therefore, the findings of this thesis are predominantly useful for the case department but not necessarily applicable to other organizations. Furthermore, because of the high anonymity agreement for this thesis, not all the used information and findings could be openly disclosed. This might affect the comprehensiveness of this thesis as well as the traceability of the findings for this study.

Regarding the quantitative analysis, a potential limitation poses the used Likert Scale. For the middle value 3 potentially having a subjective meaning and thus influencing the interpretability of the results was not considered before. However, by running a sensitivity analysis, it was possible to determine that similar tendencies exist overall, and, therefore, no bias could be detected. However, for future research, the scaling range will be closely examined to avoid a potential middle option bias. A further limitation is the amount of survey responses received. Although the survey had a response rate of 46%, there are certain risks with populating the survey results onto the whole case department of 120 employees. Therefore, it is possible that the current analysis about the current level of integration of product stewardship at the case department shows a wrong reality and does not represent the actual level of integration.

For the qualitative data gathering, a possible limitation could be that only people from the case company, and mainly from the case department were interviewed. It is possible that there is a potential bias in the given answers and subsequently the results as no experts from outside of the case company were interviewed. Additionally, although I as a researcher intended to be objective during the research process, it is possible that this objectivity was not always met 100%. I was employed in the case department and some of the chosen interview experts were colleagues from my team. Although I tried to be unbiased, it cannot be guaranteed that I was successful in that. Lastly, because the product stewardship strategy has gone through several rounds of review meetings, there is a possibility that the reviewers who will ultimately have to implement the strategy may have influenced the strategy in ways that are beneficial to them.

Overall, this study exhibits various weaknesses and strengths. However, given the low level of knowledge about the study topic, the case study-specific nature, and the usual limitations arising from the application of theoretical knowledge and available resources, the methodological approach seems appropriate overall.

7 CONCLUSIONS

In this master's thesis, the focus was on developing a focused product stewardship strategy on functional level for a pharmaceutical case department that develops devices and packaging for future drug products. This section summarizes and concludes this project. The aim of this study was to identify and develop a relevant strategic framework that helps with the implementation of product stewardship on departmental level. As the majority of existing frameworks only presented frameworks on corporate level, a new framework needed to be developed, based on the findings from my literature review. A current analysis including identification of key improvement areas for the case department were additional goals that were covered and have been answered in this thesis. Regarding the theoretical framework, the study used literature from 1995 until 2023. As there was no relevant literature on the topic of designing a strategy on functional/ departmental level, a strategic framework for the integration of product stewardship on functional level was designed. The model is utilizing the findings from the literature review. The framework includes as a basis the topic of prerequisites and entails five strategic pillars which are Design for Environment, Extended Producer Responsibility, collection & recycling, education, collaboration & partnerships.

Because of the exploratory and case study nature of this study, and since the research questions were manyfold, I decided that the best way to appropriately answer these research questions is by having a mixed-methods research design, based on a quantitative internal pulse survey as well as 14 qualitative semi-structured interviews. The individual analysis of both sub-studies raised important insights into the current level of product stewardship integration at the case department as well as potential improvement areas and strategic pillars for the further implementation of product stewardship.

In the integration of findings, the various findings from both sub-studies were combined and enriched with the developed theoretical strategic framework from the literature review. The integration showed that the biggest improvement areas for the case department lie in the areas of communication, collaboration, and education. In the area of DfE, the case department is well situated with over 23 ongoing sustainability innovation projects to make its existing device and packaging solutions more environmentally friendly. Overall, the biggest long-term impact the case department can make in designing devices and packaging is if it follows the proposed product stewardship strategy which is designed based on the integration of knowledge from academic literature, the internal pulse survey results, and the findings from the 14 expert interviews. The final strategy includes a total of 12 different topics with 14 goals that are further split into action items for short-term, mid-term, and long-term to ensure sustainable product design and full integration of product stewardship at the case department. The strategy can be used as a planning tool and should prepare the case

department well for the future, as all relevant aspects of a product stewardship strategy are included and because the strategy, on one hand, plays to the strengths of the department (DfE), but on the other hand, also includes focuses areas where there is room for improvement. However, how the actual implementation of the strategy will look like, is now out of my hands, as this was not in scope. Nonetheless, potential next steps on how to possibly implement the strategy were discussed with the two case supervisors and all relevant people were informed about the strategy. The majority of case department employees has heard about the product stewardship strategy, and many have attended the information session where the strategy was presented. This builds a good basis for the implementation of the strategy itself which is now back in the responsibility of the case department.

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APPENDIX 1: Pulse Survey Questionnaire

No.	Question	Theme of Question
1	To which chapter do you belong? - Answer type: multiple choice: - *Various chapter names* - Other	Identification
2	What is your understanding of product stewardship for device and packaging at *case company*? – Answer type: multiple choice - I have never heard of Product Stewardship - I have heard of Product Stewardship but not within *case department* - I have some knowledge about Product Stewardship at *case department* - I have some knowledge about Product Stewardship at *case department* and come across it in my job - I know that Product Stewardship at *case company* is our approach to integrate sustainability into our development processes. We as *case department* can make a difference because everyone involved in the life cycle of the product shares the responsibility to make our medicines more environmentally sustainable. Thus, Product Stewardship is part of my tasks.	Setting the scene - creating common understanding
3a	How do you perceive *case department* sustainability-wise on a scale of 1 to 5? (1 meaning there is no sustainability thinking, 5 sustainability thinking is at the core of every activity.) – Answer type: Likert scale of 1 to 5	Image/Strategy
3b	How do you perceive *case department* when it comes to Product Stewardship, on a scale of 1 to 5? (1 meaning there are no product stewardship actions, 5 meaning product stewardship is at the core of every activity.) – Answer type: Likert scale of 1 to 5	
4	On a scale of 1 to 5, how engaged/interested are you personally when it comes to product stewardship within *case department*? (1 being not engaged/interested at all, 5 being super engaged/interested) –	Engagement

	Answer type: Likert scale of 1 to 5	
5a	Do you take specific product stewardship in your job / tasks? – Answer type: YES / NO	Engagement
5b	If yes, what considerations do you take? – Answer type: open text field	
5c	If no, why not? – Answer type: open text field	
6a	Is there any support or resources you need to be able to embed more sustainability-thinking in your job? – Answer type: YES/NO	Support / Prerequisite
6b	If yes, what support or resources do you need? – Answer type: open text field	Support / Prerequisite
7a	Did you have a sustainability-related or product steward-ship-related goal as part of your performance evaluation? – Answer type: YES / NO	Leadership/ Openness
7b	If yes, what were those goals? – Answer type: open text field	
7c	If no, would you want to have sustainability-related or product stewardship-related goals in your performance evaluation? – Answer type: YES / NO	
8a	Are you aware of any product stewardship or sustainabil-ity initiatives within COMPANY device & packaging? – Answer type: YES / NO	Awareness
8b	If yes, which initiatives? – Answer type: open text field	
9	Which of the following tools have you used before/come across? – Answer type: multiple choice: - LCA Center of Excellence - PIQET: Streamlined LCA software for assessing	Awareness

	packaging and associated super user role - MSC-0201165: Guideline for sustainable development - Eco Alliance circle connecting sustainability across *case department*	
10	Where do you see potential for product stewardship / sustainability improvements in *case department* or your specific job? – Answer type: open text field	Potential
11	What limitations or roadblocks do you see for product stewardship / sustainability initiatives within *case department* or your specific job? – Answer type: open text field	Limitations
12	Is there anything else you would like to add to the topic of sustainability / product stewardship at *case department*? – Answer type: open text field	-

APPENDIX 2: Semi-Structured Interview Questionnaires

Leadership Questionnaire		
No.	**Question**	**Theme of Question**
Start of interview: - Welcome expert - Information about data protection and confidential use of data - Brief introduction into research and objectives (short presentation) - Asking permission to record *Start recording*		
General part: creating a common understanding		
1	What is your understanding of sustainability?	Create common understanding
2	On a scale of 1 to 5, how do you see the integration of sustainability, especially Product Stewardship at *Case Company*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Company
	If no explanation: please elaborate your choice	Clarification
3	What is your contribution to sustainability integration or Product Stewardship at *Case Company*?	Assess level of expertise; job role
4	On a scale of 1 to 5, how do you see the integration of sustainability at the *Case Department*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Department
	Is there a difference between sustainability integration and Product Stewardship?	Clarification
	If no explanation: please elaborate your choice	Clarification
Transition to 2nd Part: At *Case Department* Product Stewardship is partly implemented for some of the packaging and device products. This project aims to design a focused product stewardship strategy with strategic pillars and key focus areas that are structured in time and importance which should allow the *Case Department* to have a clear focus and objectives on what to work on to integrate sustainability and Product Stewardship better. Two important aspects in implementing any kind of strategy are culture and leadership.		
Topic specific part: receiving leadership specific insights		
5	On a scale of 1 to 5, how would you assess the synergy culture in terms of openness for change when it comes to sustainability / Product Stewardship at the *Case Department*? (1 meaning very poor culture & resistance for any type of	Assess level of synergy culture

	change, 5 meaning open culture & changes are fully embraced)	
	If no explanation: please elaborate your choice	Clarification
6	*If number given below 4;* What are you doing in your leadership role to actively improve the organizational culture of the *Case Department*?	Improvement areas for synergy culture
7	Based on your experience, how do you ensure that a strategy is successfully implemented at the *Case Department*?	Facilitating factors for strategy implementation
8	Are there any special factors needed to implement a sustainability strategy such as product stewardship at *Case Department*?	Facilitating factors for sustainability strategy implementation
9	What could significantly support or prevent sustainability implementation within the *Case Department*?	Facilitators & Roadblocks in sustainability integration
10	Why could it support / prevent sustainability implementation?	Factors for sustainability integration
11	In the recent employee survey, many respondents answered that lack of resources such as time, knowledge, or financial as well as processes and lack of responsibility are roadblocks, hindering them to further embed sustainability into their jobs. What are you as their (team) leader planning on doing to minimize those roadblocks?	Minimizing roadblocks
12	Another roadblock mentioned in the survey was contradicting focus and goals (e.g., sustainability vs. financial aspects, sustainability vs. patient centricity etc.). How do you ensure that these roadblocks are minimized and what are the tools/resources for that?	Minimizing roadblocks
13	What do you do or how do you as a (team) leader best support the *Case Department* in sustainability integration and Product Stewardship?	Support / Buy-in from leadership
14	What would you say are key areas and pillars to consider for the product stewardship strategy for the *Case Department*?	Idea screening
15	What are your expectations for the product stewardship vision and goals for packaging and device?	Expectation management
Transition to closing the interview: thank you very much for your valuable input.		
Closing the interview		
16	Is there anything else you would like to mention that is	Additional inputs

	necessary in implementing this strategy at *Case Department*?	
Interview ends: - Stop recording - Thank expert again - Explain further procedure		

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Sustainability Questionnaire		
No.	**Question**	**Theme of Question**
Start of interview: - Welcome expert - Information about data protection and confidential use of data - Brief introduction into research and objectives (short presentation) - Asking permission to record *Start recording*		
General part: creating a common understanding		
1	What is your understanding of sustainability?	Create common understanding
2	On a scale of 1 to 5, how do you see the integration of sustainability, especially Product Stewardship at *Case Company*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Company
	If no explanation: please elaborate your choice	Clarification
3	What is your contribution to sustainability integration or Product Stewardship at *Case Company*?	Assess level of expertise; job role
4	On a scale of 1 to 5, how do you see the integration of sustainability at the *Case Department*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Department
	Is there a difference between sustainability integration and Product Stewardship?	Clarification
	If no explanation: please elaborate your choice	Clarification
Transition to 2nd Part: At *Case Department* Product Stewardship is partly implemented for some of the packaging and device products. This project aims to design a focused product stewardship strategy with strategic pillars and key focus areas that are structured in time and importance which should allow the *Case Department* to have a clear focus and objectives on what to work on to integrate sustainability and Product Stewardship better. I know you are probably not too familiar with packaging and device development but based on your expertise...		

Topic specific part: receiving sustainability specific insights		
5	What could significantly support or prevent sustainability implementation such as Product Stewardship within a department?	Facilitators & Roadblocks in sustainability integration
	Anything special for device and packaging?	
6	Why could it support / prevent sustainability implementation?	Factors in sustainability integration
7	What kind of best practices or good examples of pharma companies that are far in the sustainability integration, using Product Stewardship do you know?	Best practices & good examples of role model companies
8	Which current or upcoming internal or external sustainability regulations are especially important to be considered in the strategy?	Important regulations
9	In a recent employee survey, which I did in the *Case Department* one common answer was the necessity to collaborate across departments & functions and focus more on Group SHE and other departments that deal with sustainability. What do you think about this?	Idea feedback & screening
10	How could or does a potential collaboration between your department and the Case Department look like in terms of sustainability integration?	Idea feedback & screening
11	A roadblock mentioned was the topic of lacking knowledge, what kind of existing sources & training materials do we have at *Case Organization* on the topic of Product Stewardship and which department could support?	Existing sustainability resources that could be harnessed
12	What would you say are key areas and pillars to consider for a sustainability strategy such as product stewardship for the *Case Department*?	Idea screening
13	What are your expectations for the *Case Department*'s product stewardship strategy?	Expectation management
14	Based on your experience, how can we ensure that the strategy is successfully implemented?	Facilitating factors for strategy implementation
Transition to closing the interview: thank you very much for your valuable input.		
Closing the interview		
15	Is there anything else you would like to mention that is necessary in designing and implementing the strategy at *Case Organization*?	Additional inputs

Interview ends: - Stop recording - Thank expert again - Explain further procedure

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Device Development Questionnaire		
No.	**Question**	**Theme of Question**
Start of interview: - Welcome expert - Information about data protection and confidential use of data - Brief introduction into research and objectives (short presentation) - Asking permission to record *Start recording*		
General part: creating a common understanding		
1	What is your understanding of sustainability?	Create common understanding
2	On a scale of 1 to 5, how do you see the integration of sustainability, especially Product Stewardship at *Case Company*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Company
	If no explanation: please elaborate your choice	Clarification
3	What is your contribution to sustainability integration or Product Stewardship at *Case Company*?	Assess level of expertise; job role
4	On a scale of 1 to 5, how do you see the integration of sustainability at the *Case Department*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Department
	Is there a difference between sustainability integration and Product Stewardship?	Clarification
	If no explanation: please elaborate your choice	Clarification
Transition to 2nd Part: At *Case Department* Product Stewardship is partly implemented for some of the packaging and device products. This project aims to design a focused product stewardship strategy with strategic pillars and key focus areas that are structured in time and importance which should allow the *Case Department* to have a clear focus and objectives on what to work on to integrate sustainability and Product Stewardship better.		
Topic specific part: receiving device development specific insights		
5	On a scale of 1 to 5, what would you say is the current	Market insights: sustainability integration

	state of sustainability integration for pharmaceutical devices in the pharma industry? (1 meaning very poor integration - none, 5 meaning sustainability is integrated in every aspect)	
6	How does this show itself; could you name some examples?	Market insights: sustainability integration
7	Going back to the market, what kind of trends can you recognize when it comes to trying to make pharmaceutical devices more sustainable?	Market trends
8	What kind of best practices or good examples of pharma companies that are far in the sustainability integration, using Product Stewardship do you know?	Best practices & good examples of role model companies
9	Compared to our biggest competitors, how would you rate the level of sustainability integration of the *Case Department* on a scale of 1 to 5? (1 meaning *Case Department* is furthest behind, 5 meaning *Case Department* is far ahead of the competition)	Gap analysis
	If no explanation: please elaborate your choice	Clarification
10	What needs to happen to change that/ to keep the position?	Improvement areas
11	What would you say are key areas and pillars to consider for the product stewardship strategy for the *Case Department*?	Idea screening, strategy pillars
12	What is something that is good in the *Case Department* that we should continue doing when it comes to Product Stewardship or overall sustainability?	Strategy pillars
13	Are there any current or upcoming internal or external sustainability regulations that are especially important to be considered in the strategy?	Important regulations
14	Based on your experience, how can we ensure that the strategy is successfully implemented?	Facilitating factors for strategy implementation
Transition to closing the interview: thank you very much for your valuable input.		
Closing the interview		
15	Is there anything else you would like to mention that is necessary in designing and implementing the strategy at *Case Organization*?	Additional inputs
Interview ends: - Stop recording - Thank expert again - Explain further procedure		

Packaging Development Questionnaire		
No.	**Question**	**Theme of Question**
Start of interview: - Welcome expert - Information about data protection and confidential use of data - Brief introduction into research and objectives (short presentation) - Asking permission to record *Start recording*		
General part: creating a common understanding		
1	What is your understanding of sustainability?	Create common understanding
2	On a scale of 1 to 5, how do you see the integration of sustainability, especially Product Stewardship at *Case Company*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Company
	If no explanation: please elaborate your choice	Clarification
3	What is your contribution to sustainability integration or Product Stewardship at *Case Company*?	Assess level of expertise; job role
4	On a scale of 1 to 5, how do you see the integration of sustainability at the *Case Department*? (1 meaning very poor integration, 5 meaning sustainability is integrated in every aspect)	Perception of Case Department
	Is there a difference between sustainability integration and Product Stewardship?	Clarification
	If no explanation: please elaborate your choice	Clarification
Transition to 2nd Part: At *Case Department* Product Stewardship is partly implemented for some of the packaging and device products. This project aims to design a focused product stewardship strategy with strategic pillars and key focus areas that are structured in time and importance which should allow the *Case Department* to have a clear focus and objectives on what to work on to integrate sustainability and Product Stewardship better.		
Topic specific part: receiving packaging development specific insights		
5	On a scale of 1 to 5, what would you say is the current state of sustainability integration for pharmaceutical packaging in the pharma industry? (1 meaning very poor integration - none, 5 meaning sustainability is integrated in every aspect)	Market insights: sustainability integration

6	How does this show itself; could you name some examples?	Market insights: sustainability integration
7	Going back to the market, what kind of trends can you recognize when it comes to trying to make pharmaceutical packaging more sustainable?	Market trends
8	What kind of best practices or good examples of pharma companies that are far in the sustainability integration, using Product Stewardship do you know?	Best practices & good examples of role model companies
9	Compared to our biggest competitors, how would you rate the level of sustainability integration of the *Case Department* on a scale of 1 to 5? (1 meaning *Case Department* is furthest behind, 5 meaning *Case Department* is far ahead of the competition)	Gap analysis
	If no explanation: please elaborate your choice	Clarification
10	What needs to happen to change that/ to keep the position?	Improvement areas
11	What would you say are key areas and pillars to consider for a sustainability strategy such as product stewardship for the *Case Department*?	Idea screening, strategy pillars
12	What is something that is good in the *Case Department* that we should continue doing when it comes to Product Stewardship or overall sustainability?	Strategy pillars
13	Are there any current or upcoming internal or external sustainability regulations that are especially important to be considered in the strategy?	Important regulations
14	Based on your experience, how can we ensure that the strategy is successfully implemented?	Facilitating factors for strategy implementation
Transition to closing the interview: thank you very much for your valuable input.		
Closing the interview		
15	Is there anything else you would like to mention that is necessary in designing and implementing the strategy at *Case Organization*?	Additional inputs
Interview ends: - Stop recording - Thank expert again - Explain further procedure		

APPENDIX 3: Integration of Findings

Prerequisite: Leadership	Interview ID	Survey ID
Leadership buy-in (resources, budget)	L1, L4, S4, S5	DC3, DE6, DH3, DP8, DS4, DS5, DV7, DV9, EC1
Define goals, assign tasks, monitor, evaluate	D2, L1, L3, L4, P2, S2, S3, S5, S6	DC3, DP8, DP10, DS1, DS3, DV11
Connection to corporate goals and Group SHE	L1, S1, S3, S5, S6	DS3
DfE: Design Phase	**Interview ID**	**Survey ID**
Concrete selection criteria for new devices/ packaging/ platforms	D1, D2, L1, L2, L3, L4 P1, P2, S1, S2, S5	DA2, DC1, DE1, DE2, DE5, DE8, DP6, DP8, DV7
Putting more emphasis on sustainability in design reviews	P2, S3, S6	DA2, DC1, DE2, DE5, DE7, DE8, DP5, DP8, DC2
Enhance quality of briefing phase	P2	DA2, DE7, DE8, DP3, DP4
Do LCA upfront in beginning	D1, D2, P1, P2, S5	DC2, DC3, DM4, DP4, DP5, DP8, DV11
DfE: LCA	**ID Interviews**	**ID Survey**
common understanding of how to use LCA + tools in a standardized way	D1, P1, P2, S2, S3, S5, S6	DE7, DM5, DP8, DP9, DV7
Availability of data; smart LCAs	D1, P1, P2, S2, S5	DE7, DM4, DM5, DP8, DP9
Analysis of LCAs: lessons learned, hot spot analysis, best practice document, etc.	D1, P2, S2, S3, S5, S6	DC3, DE7, DP1, DP8, DS2, DV6, DV7
DfE: Tech Centers	**Interview ID**	**Survey ID**
LCA + PS need to be key requirements for Tech Center platforms	D1, D2, L2, L3, P1, P2	DA2, DC1, DE1, DE2, DM5, DS4, DV7
Process for Product Stewardship from TDL	L1, S4	DC1

DfE: Product Level	Interview ID	Survey ID
Identify improvement areas	P1, P2, L1, L2, L4, S1, S3, S5	-
Reusable auto-injector	D2, L4, S3	DA3, DE2
Design for end of life	D2, S3, S4, S5, S6	-
Reduction (quantity or grammage) of device/packaging	P1, P2, S1, S3	DV10
Reduce amount of test samples/size	-	DA1, DV1, DV2, DV10, DV11
Material selection:	D1, D2, P1, P2, S2, S5	DE5, DE6, DM5, DP9, DP11, DV9, DV10
-Explore alternatives (Material + Supplier)	*D2, P1, P2*	*DE5, DE6, DP11*
-Recycled materials	*P1, D2*	*DP7, DP9*
-Alternative fibers	*P1, D2,*	*DP9, DP11*
-Improvements for polymers	*P1, P2, S2*	*DE5, DP9, DV10*
-Mass Balance Approach	*D2, S5*	-
EPR: Pressure	**Interview ID**	**Survey ID**
Impact of SBTI on work	L2, S4, S5, S6	-
Impact of regulations on work	D1, D2, P1, P2, L1, S1, S2, S3, S4, S5, S6	DA4, DE6, DP6, DP7, DP9, DS5, DS6, DS7, DS8, DV7-DV10
Establish a regulatory information gathering service	P2, S1	DE6, DM3, DP7

Lived motto: patient 1st, sustainability 2nd before everything else	P2	DA2, DA4, DC1, DP10, DS5, DV3
Collection & Recycling Programs	**Interview ID**	**Survey ID**
Take-back schemes (Collection & Recycling	D1, D2, S3, S4, S6	-
Reduce energy, water, waste	S1, S3, S5	DV5, DV9, DV11
Education & Awareness: PS Resources & Ambassadors	**Interview ID**	**Survey ID**
Standing resource for LCA + PS	D1, P2, S3	DM2, DP1, DS2
LCA Super User Group	D1, L1, L2, P1, P2	DM2
Sustainability circle within PTDE-D	L3	DM2
Importance of passionate sustainability ambassadors / design champion	D1, D2, L3, P1, P2 S1	-
Collaboration & Partnerships: Supplier & Procurement	**Interview ID**	**Survey ID**
Sustainability requirements for supplier products	D2, L2, P2, S4, S5, S6	DE2, DH4, DM1
Role of Procurement? (Sustainability requirements, support for carbon reduction calculations, guidance etc.)	D1, D2, P1, P2, L2	-
Power of Supplier? (Push suppliers for alternative materials, data, LCA etc.)	D1, D2, P1, P2, S4, S5	DE2, DE3, DH3, DM1, DV2
Impact of tenders/countries regarding sustainability of products	S3, S4, S5	-
Increasing customer pressure regarding sustainability	S3, S4, S5	-
Education & Awareness: Communication	**Interview ID**	**Survey ID**
Visibility of PS within synergy	D2, L4, P2, S1, S3, S4	DM1, DP1
PS Pledge?	P2, S1, S4, S6	DM1, DP8
LCA people provide support + info for synergy & chapters	L1, L3, S5	DE1, DE7, DM1, DM4, DP1, DP4, DV7, DV8, DV9, DV10, DV11
Awareness of data availability	D1, P1	DE7, DM1, DP4, DV7
Design guidance: actively lived or check-box activity?	D1, L4, S3, S5, S6	DE8, DM1, DP6, DP8, DS8, DS2, DV6
Collaboration & information sharing (case-based examples)	D1, D2, S1, S3, S4, S5, S6	DE7, DM1, DP1, DV7, DV11
Collaboration & Partnerships: Collaboration	**Interview ID**	**Survey ID**
Join industry working groups	D2, S1, S3	DP8, DS5
Collaboration with Group SHE and other departments (e.g., supply chain, PT)	D1, L2, S1, S2, S3, S4, S5, S6	DE1, DM1, DM5, DP8, DS5, EC1
Collaboration with other companies (e.g., take-back schemes)	D2, S1, S3	DP8, DS5

APPENDIX 4: Product Stewardship Strategy for Case Department

PREREQUISITES										
Topic	**Goal/ Commitment**	**Short-term (0.5 – 1 year)**		**Outcome**	**Requirements**	**Mid-term (1-2 years)**	**Outcome**	**Requirements**	**Long-term (2-5 years)**	**Outcome**	**Requirements**
Leadership	Department-wide leadership buy-in and commitment regarding time, resources, budget, etc.	1.)	Public announcement by Head of EC about continuing commitment and investment for product stewardship and sustainability efforts	Awareness & Commitment for product stewardship	Speech of Head of EC	2.)	Continuous investment and resources for product stewardship and sustainability efforts for the case department			Continuous investments and improvements for product stewardship	Budget, resources, commitment

DESIGN FOR ENVIRONMENT											
Topic	**Goal/ Commitment**	**Short-term (0.5 – 1 year)**		**Outcome**	**Requirements**	**Mid-term (1-2 years)**	**Outcome**	**Requirements**	**Long-term (2-5 years)**	**Outcome**	**Requirements**
Product Level	Fit for future: keep innovating, testing, and finding alternative materials. Improving the material selection of case department products and designing products with end of life in mind	1.)	Per year: have at least 2 sustainability projects regarding improvement of material selection ongoing for packaging and at least 1 sustainability project for device selection → keep innovating in the space of product level, material selection, and end of life designs							Continuous improvement and innovation, less impactful materials are used	Budget, time, commitment, awareness, people resources
Design Phase	Enhance the quality of the early device and packaging selection phase and design reviews: sustainability/ product stewardship as an important factor in selection of all devices & packaging	1.)	Assess current quality of briefings and design reviews in terms of what is lacking. Input from team on a.) what is the appropriate criteria? b.) good data (e.g., LCA) for evaluating those criteria	Improvement areas are visible	Input from the team	2.)	Improve the quality of the briefing phase and design reviews through added criteria during the meetings to ensure patient-centricity and sustainability	Improved briefings and design reviews to ensure that sustainability and patient-centricity are not just buzzwords but active and lived requirements	List of additional criteria, adapted process, people that push/use the new criteria		
LCA & Design Guide	Common understanding of how to use Life Cycle Assessment and respective tools in a standardized way	1.)	Update the sustainable design guideline. Check the design guide from another department for differences and anything that could improve the case department's guideline	Updated and newest version of design guideline	Person from LCA super user group	2.)	Check the usefulness of the sustainable design guide through a pulse survey or a randomly chosen batch of people to ask; is the guideline lived and actively followed or more a checkbox activity? → adapt design guide accordingly	Useful and user-friendly sustainable design guideline	1 person from LCA super user group		

						3.)	Spread the "use" of the sustainable design guide within the synergy by sharing best practices, examples of previous projects, etc. and offering support to people not yet familiar with the guideline	More people following the guide, better integration of product stewardship	LCA Super User Group, awareness for design guideline	4.)	All packaging and device development projects are utilizing and following the sustainable design guide	sustainable design guide is followed, better integration of product stewardship during the design phase of products	Awareness for design guideline and sustainability in product design, case department employees follow design guidance
		1.)	Update of LCA guidance	LCA guidance for support	Specific person	2.)	LCA is done in a standardized way by all LCA super users					Standardized way to do LCA	LCA super user group follows LCA guidance
	Doing LCAs and considering learnings from previous LCAs is part of every project to ensure the sustainability aspect of the product is assessed. If not, all information is available by the time the LCA needs to be done, assumptions are taken. Once the information becomes available, the assessment gets updated with the respective information	1.)	Doing LCAs on a need basis with the data that is currently available. Trying to revisit older LCAs to complete them with the correct data	LCAs on a need basis	LCA Super User Group	2.)	LCA is becoming a requirement in projects and the number of assessments is increasing. During the assessment, assumptions are taken and later corrected with the appropriate data	Collection of reliable LCAs is growing	LCA Super User Group	3.)	Doing LCAs for every project, new material, new product, etc. is common practice within the Global Device & Packaging Department	Decision-making based on facts & numbers	LCA Super User Group
	Having a document/ learning space where all done LCAs are analyzed for hotspots. Out of the learnings a best practice guidance can be derived including literature reviews and other industry documents on what data is out there for similar devices/ packaging	1.)	Revisiting old LCAs and trying to exchange assumptions with actual data. Hotspot analysis for each LCA. Trying to extract general learnings and commonalities between the LCAs based on existing literature. Constantly adding new LCAs to the analysis and general learnings.					Hotspot analysis for each LCA, general learnings & best practices	LCA super user group-shared knowledge space	2.)	Have a collection of all LCAs done for every material/ product within the case department including hotspot analysis and a general best practice guidance	Knowledge sharing compilation of all LCAs	Shared knowledge space

EPR													
Topic	**Goal/ Commitment**	**Short-term (0.5 – 1 year)**		**Outcome**	**Requirements**	**Mid-term (1-2 years)**		**Outcome**	**Requirements**	**Long-term (2-5 years)**		**Outcome**	**Requirements**
Regulations	Establish a regulatory information gathering & analysis service to be better prepared and understand the implications of regulatory changes on the packaging and device products	1.)	Build a working group	Working group	2-3 people from the case department	4.)	Based on the decision-making from step 3; start building up the service with the chosen "agency"	Regulatory information gathering and analysis service	Budget	6.)	Receive relevant information regarding upcoming/changing regulations for device & packaging in a centralized way	Keeping up to date	Gsite, people maintaining the Gsite and implementing the news
		2.)	Assessment of what is needed; set up requirements, type of	Criteria list	20-40h	5.)	Build up a way to incorporate and share the regulatory	Everybody from the department is up to date and	Gsite, people maintaining the				

			information needed, how the information should/needs to be captured, how the information will be spread within the synergy, budget, etc.				information & news with the synergy	knows where to find the newest information	Gsite and implementing the news
		3.)	Assessment of whether the regulatory information gathering service can be done within the team, within Roche (from legal or Group SHE), or externally; identify potential service providers internally/externally	Overview of potential information providers	10-30h				

COLLECTION & RECYCLING PROGRAMS										
Topic	**Goal/ Commitment**	**Short-term (0.5 – 1 year)**		**Outcome**	**Requirements**	**Mid-term (1-2 years)**	**Outcome**	**Requirements**	**Long-term (2-5 years)**	**Outcome**	**Requirements**
Take-back schemes	To keep in the loop on the topic of take-back schemes with the case organization locations and push for solutions from a device and packaging development point	1.)	Identify internal partnerships, business cases, and other important information to keep up to date on the topic of take-back schemes. Give inputs and share knowledge regarding devices, device-set up, and packaging. Push for adoption and implementation of take-back schemes at case organization							Being informed & pushing for change	1-2 people from case department

EDUCATION & AWARENESS											
Topic	**Goal/ Commitment**	**Short-term (0.5 – 1 year)**		**Outcome**	**Requirements**	**Mid-term (1-2 years)**		**Outcome**	**Requirements**	**Long-term (2-5 years)**	**Outcome**	**Requirements**
Communication	Collaboration & information sharing based on case examples about sustainability and product stewardship	1.)	Start communicating more about product stewardship achievements and product/ material innovations during the synergy meetings. Book a slot in the synergy focus time (at least 2x per year per project) and ensure that the shared information is available on the case department Gsite	Increased awareness within the synergy for product stewardship implementation, inspiration for other case department employees to better integrate product stewardship in their work	People sharing their projects	2.)	Analyze and record learnings during projects regarding sustainability and product stewardship and share them with the synergy. Leverage with LCA super user group				Increased awareness within the synergy for product stewardship implementation, inspiration for other case department employees to better integrate product stewardship in their work, increased sustainability learnings, less impactful products	Lessons learned of projects, people sharing the lessons

Education	Everybody in the case department is aware of where to find information regarding product stewardship and sustainability or who to reach out to for more information	1.)	Continuous educating and sharing information about Product Stewardship and sustainability and how embed it into existing processes. People are aware where to find necessary information and who to reach out if additional information is needed								People are engaged and educated	Passionate people sharing and educating

COLLABORATION & PARTNERSHIPS												
Topic	**Goal/ Commitment**	**Short-term (0.5 – 1 year)**		**Outcome**	**Requirements**	**Mid-term (1-2 years)**		**Outcome**	**Requirements**	**Long-term (2-5 years)**		**Outcome**	**Requirements**
Procurement	(Re)defining the role of procurement in supplier relations when it comes to sustainability/ product stewardship	1.)	Synergy survey to figure out the current situation with procurement regarding supplier sustainability requirements, carbon reduction calculations, supplier selection, LCA, product data, etc. and what the improvement areas are to ensure more support from procurement with supplier relations	Answers from synergy	1-2 people from the case department	3.)	Have meetings with procurement to raise the findings from the survey. Find a common ground and way forward to get more support from procurement with supplier relations and ensure that suppliers deliver necessary sustainability data	More support from procurement	1-2 people from the case department			
		2.)	Analyzing the survey and drawing up conclusions to prepare a meeting with procurement	Current situation & improvement areas	1-2 people from the case department							
Suppliers	Reduce the power of suppliers and collaborate with them to reduce the case department's Scope 3 GHG emissions	1.)	Assess the type of sustainability information and data that is necessary to know about from PSP tool and other sources to make the work within the case department easier and to be able to better assess sustainability aspects of bought products/materials	List of relevant sustainability supplier data/information	1-2 people from the case department	3.)	Suppliers start sharing the agreed on "most important" information/ data/ LCA with the case department	More transparency, less effort for the case department to assess and compare various products/ materials from suppliers	Most important supplier and product information is shared	4.)	All packaging and device suppliers share the agreed on and needed information/ data/ LCAs with the case department	Increased transparency and decreased effort of the case department. More reliable basis for doing LCAs and comparing products and materials from different suppliers	Important supplier and product information is shared

		2.)	Start the conversation with suppliers with the help of procurement regarding expectations of sharing important data with the case department. Define and agree on the data/information that needs to be shared in terms of most important (shared by mid-term) and important (shared by long-term)	Suppliers are aware of the type of information/data that needs to be shared with the case department	1-2 people from the case department (+ 1-2 people from Procurement)		
Other Departments within Case Organization	Ensure information sharing and leveraging of knowledge regarding product stewardship and sustainable design development	1.)	Assess which other departments within the case organization are key stakeholders of/for the case department, who is in contact with them, what kind of information is/needs to be shared, etc. Identify improvement areas regarding communication/ stakeholder management, etc. and start improving those			As-is analysis of stakeholders & information sharing	1-2 people from the case department for each stakeholder group
Industry Working Groups & Pharma Collaboration	Join industry working groups to ensure the case department and case organization stay connected with what is happening in the industry. Potentially leverage knowledge and resources for industry-wide improvements	1.)	Assess what kind of industry working groups are out there that would fit the need for the case department. (e.g., Health Care Compliance Packaging Council)			The case department stays up to date with what is happening within the industry and is committed to potential industry initiatives	Budget, resources (depending on how many groups to join, several people from the case department)