



GRIFFITH COLLEGE

**CHALLENGES OF GREEN PRODUCTION
IN
THE IRISH PHARMACEUTICAL COMPANIES**

by

DUC BUI

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Abstract

In this dissertation, an exploration of the challenges of green production practices in the Irish pharma companies was researched. The study was constructed by the descriptive primary exploratory research design while a qualitative research method was applied to discover the in-depth knowledge from the decision-makers who are actually working in the Irish pharma companies. By this research, there are at least five (5) main objectives are comprehended, including the review of current state of green production practices in the Irish pharma companies, then the primary drivers and key barriers, next certain examples of green production implementations, last but not least, the recommendations for promoting and monitoring the green production practices overtime.

To achieve those aims, the interviews were organized by the participation of five (5) experts, including consultants, site heads, COO, and team leaders from the Irish pharma companies. the interviewees went over eight (8) research questions by which the deeper understanding about the issues were disclosed by the real experiences. The interviews were recorded, transcribed, then analyzed by method of thematic analysis. By this analysis tool, the answers were then categorized by the themes which were current state, primary drivers, key barriers, how to overcome, and recommendations. In the following, these five major themes shall be briefly summarized.

After the thematic analysis, there are five main themes. First of all, the current state of green production practices was explained. Ireland is one of the leading countries within the Europe in green production. Secondly, the next big theme is primary drivers. There are several drivers were found, including regulatory driver, financial driver, reputational driver, and company culture driver. All companies must apply green production to satisfy the environmental regulation. Subsequently, the primary drivers are also the key barriers. Successively, some specific examples to overcome the challenges are mentioned. Lastly, some recommendations are suggested by the interviewees to promote the green concepts and monitor the green practices over time.

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List of Abbreviations

BITC	Business In the Community Ireland
CSR	Corporate Social Responsibility
ECHA	European Chemicals Agency
EFPIA	The European Federation of Pharmaceutical Industries and Associations
EHS&S	Environment, Health, Safety, And Sustainability
EMA	The European Medicines Agency
EPA	Environmental Protection Agency
EPS	Eco-Pharmaco-Stewardship
ERA	Environmental Risk Assessment
ESG	Environment, Social, And Governance
ESG	Environment, Social, And Governance
HSA	Health Safety Authority
IDA	The Industrial Development Agency
IOT	The Internet of Things
IPHA	Irish Pharmaceutical Health Association
NGOS	Non-Government Organizations
PIE	Pharmaceuticals In The Environment
PT	Patient Trust
REACH	Registration, Evaluation, Authorization, And Restriction Of Chemicals
SEAI	Sustainable Energy Authority of Ireland
UN	The United Nations

CHAPTER 1 INTRODUCTION

1.1 RESEARCH BACKGROUND

In the pharma industry, the production, utilization, and disposal of medicinal products are sources of concern to environment, human health, and safety, which make the pharma business one of the most strongly regulated industry in the world. Although pharma companies are meant to make curable drugs to the health and welfare of people, it also notably contributes to resource depletion and environmental pollution, particularly through the utilization of API and other solvents, the consumption of energy and water, the production of waste and emissions (Clarke *et al.*, 1994). In order to reduce their environmental effect and maintain or improve their economic and social performance, pharmaceutical businesses are increasingly required to adopt sustainable production methods.

With over 30 pharmaceutical companies working there and accounting for around 50% of exports, the pharmaceutical business in Ireland significantly contributes to the nation's economy. Despite the industry's economic importance, some global pharmaceutical businesses have not always used sustainable production methods (Milanesi *et al.*, 2020a). According to recent research, the pharmaceutical businesses encounter numerous obstacles when attempting to incorporate green production techniques. These obstacles include a lack of knowledge and commitment, insufficient incentives and regulatory frameworks, and technological and financial limitations. (TMM, 2022)

Research that examines the obstacles to and potential for implementing green production methods in the Irish pharmaceutical businesses as well as suggests strategies and policies for fostering sustainable manufacturing in the sector are needed to solve these difficulties. The pharmaceutical business in Ireland may become more sustainable and competitive with the aid of this research, which will also help the world's efforts to attain sustainable development goals.

1.2 RESEARCH PURPOSES

The research purposes of the topic of challenges of green production in Irish pharmaceutical companies may include:

1. To comprehend the difficulties that Irish pharmaceutical firms must overcome to implement green production and to identify the causes of these difficulties.
2. To investigate the potential advantages of green production in terms of social, economic, and environmental sustainability and to determine the degree to which Irish pharmaceutical companies are now experiencing these advantages.
3. To determine the strategies and approaches that Irish green pharmaceutical companies have found to be most effective in overcoming the barriers to the adoption of sustainable practices, and to suggest these tactics to other businesses.
4. To assess the efficacy of current legislative initiatives and regulations in developing environmentally friendly manufacturing methods in the Irish pharmaceutical sector and, where necessary, to make improvement suggestions.
5. To increase awareness of the significance of sustainable practices in the pharmaceutical sector among stakeholders, such as workers, suppliers, customers, and regulators, and to promote their involvement in promoting these practices.

1.3 SIGNIFICANCE OF THE STUDY

The study of challenges of green production in Irish pharmaceutical companies is significant for several reasons:

1. Environmental sustainability: The study emphasizes encouraging environmentally sound business practices in the Irish pharmaceutical sector, which is a key step in reducing the industry's negative environmental impact.
2. Economic sustainability: Irish pharmaceutical firms can lower their costs and boost their competitiveness by employing green production techniques, which can enhance economic sustainability and long-term profitability.
3. Social sustainability: Implementation of green production may bring a large benefit on social effects, such as strengthening the reputation of the companies and enriching the health and well-being of the workers and communities.
4. Compliance with regulatory requirements: The study can assist Irish pharmaceutical firms in navigating the complex regulatory frameworks and policies that apply to sustainable production and ensuring compliance with local, state, and federal laws.
5. Knowledge generation: The study can contribute to the advancement of the field of sustainability in the pharmaceutical business by generating new knowledge and

understanding about the difficulties and potential of sustainable production in the pharmaceutical sector.

1.4 RESEARCH AIMS AND OBJECTIVES

Research Aim: To explore the challenges faced by Irish pharmaceutical companies in implementing green production practices and identify strategies for overcoming these challenges.

Research Objectives and Research Questions:

Research Objective 1: To review the current state of sustainable production practices in the Irish pharmaceutical industry.

- How would you describe the current state of sustainable production practices in the Irish pharmaceutical industry?
- What sustainable practices are currently being implemented in Irish pharmaceutical companies?

Research Objective 2: To identify the key drivers and barriers to implementing sustainable production practices in Irish pharmaceutical companies.

- What are the primary drivers for implementing sustainable production practices in Irish pharmaceutical companies?
- What are the key barriers to implementing sustainable production practices in Irish pharmaceutical companies?
- What are the potential costs and benefits associated with implementing sustainable production practices in Irish pharmaceutical companies?

Research Objective 3: To investigate the strategies and best practices that successful green pharmaceutical companies in Ireland have adopted to overcome the challenges of implementing sustainable practices.

- What specific strategies have successful green pharmaceutical companies in Ireland implemented to overcome the challenges of sustainable production practices?

Research Objective 4: To develop recommendations for Irish pharmaceutical companies and policymakers on strategies and policies to promote sustainable production practices in the industry.

- What specific strategies and policies would you recommend promoting sustainable production practices in Irish pharmaceutical companies?
- How can these strategies and policies be effectively implemented and monitored over time?

1.5 METHODOLOGY

Qualitative research is a research methodology that aims to explore people's subjective experiences and perspectives on a particular phenomenon. In the context of studying the challenges of green production in Irish pharmaceutical companies, qualitative research could involve conducting interviews or focus groups with key stakeholders in the industry, such as industry executives, employees, and regulators, to explore their views on the challenges and opportunities of sustainable production practices. (Sandelowski, 1995)

Using qualitative research may bring several advantages, including rich and in-depth data that generated by the professional's experiences and perspectives This can be particularly useful in exploring complex phenomena, such as the challenges of green production, that are difficult to measure quantitatively. (Janice M. Morse, 2016)

The process of conducting qualitative research typically involves several stages, including:

1. Research design: This involves defining the research question, selecting the sample of participants, and designing the interview or focus group guide.
2. Data collection: This involves conducting the interviews or focus groups with the selected participants and recording the data.
3. Data analysis: This involves transcribing the interviews or focus groups, coding the data into themes or categories, and analysing the themes to identify patterns and insights.
4. Reporting: This involves summarizing the findings in a report or paper and interpreting the implications of the findings.

1.6 STRUCTURE OF THE STUDY

Chapter 1 Introduction

Background of the study, including a brief overview of the Irish pharmaceutical industry and the importance of green production practices. Next, research problem, including the main challenges facing Irish pharmaceutical companies in implementing sustainable production practices. Then, research objectives, including the overall aim and specific research questions that the study aims to address. Finally, the significance of the study is the potential contributions to the sustainable development by practicing green production in Irish pharma industry.

Chapter 2 Literature Review

Overview of the theoretical and empirical literature related to green production in the pharmaceutical industry, including the potential benefits and barriers of sustainable production practices. Furthermore, discussion of the existing literature related to green production practices in Irish pharmaceutical companies and the key challenges faced by these companies in implementing sustainable production practices.

Chapter 3 Research Methodology

Research design, including the approach to data collection and analysis. Participants, including the 5 people working in Irish pharmaceutical companies that will be interviewed for the study. Data collection methods, including semi-structured interviews and document analysis. Data analysis methods, including a thematic analysis of the interview transcripts. Finally, ethical considerations, including informed consent and confidentiality of the participants.

Chapter 4 Findings And Analysis

Presentation of the findings, including a summary of the challenges facing Irish pharmaceutical companies in implementing green production practices and the strategies used by some companies to overcome these challenges. Then, illustrative quotes and examples from the interview data to support the findings.

Chapter 5 Conclusions And Recommendations

Summary of the key findings and their implications for the sustainable development of the Irish pharmaceutical industry and limitations of the study and potential areas for future research.

CHAPTER 2 LITERATURE REVIEW

2.1 OVERVIEW OF SUSTAINABLE PRODUCTION PRACTICES IN THE PHARMA INDUSTRY

The pharmaceutical sector is one of the most essential contributors to the global economic growth, and it is also affecting on the environmental conditions. In recent years, the concern about the industrial sustainability has been raised, urging the pharmaceutical companies, social organizations, and authorities should take part in this race to keep the production practices and healthy environment in balance. (Milanesi *et al.*, 2020b)

The literature on sustainable production in pharma industry focuses on the range of topics, including reducing energy consumption, minimizing waste generation, and developing eco-friendly manufacturing processes. The researchers have discovered different approaches to achieve the sustainability, such as green chemistry and process intensification. Furthermore, the consumption of renewable energy and alternative energy in the production to reduce the reliance on non-renewable energy. The application of biocatalysts and bioprocessing are increased as the means of reducing negative environmental impact. (Sudripet Sharma, 2020)

Several regulatory bodies have also introduced the policies to promote the green production and sustainability in pharma industry. For instance, in Europe, the European Union adopts the REACH regulation which stands for registration, evaluation, authorization, and restriction of chemicals mentioned in the EC 1907/2006. With the slogan “no data, no market”, REACH regulation impulses the responsibility from the pharma players in Europe to monitor the foreseeable risks of chemicals to provide the safety information of chemical substances. Moreover, both the manufactures and importers must collect the originators of their chemicals assuring the safely handling, and submit the database in European Chemicals Agency (ECHA). (EC, 2008). On the other hand, the US environmental protection agency (EPA) has been run to encourage the pharma companies adopt the alternative design of chemicals and processes which are designed to be green chemistry. This can enable the manufacturing processes to reduce or minimize the hazardous substances, which

can lead to the significantly environmental advantages, innovation, and supported economy. (US EPA, 2013)

As the European Federation of Pharmaceutical Industries and Associations (EFPIA) which has approximately all pharma/biopharma companies within Europe as the members, the term of EHS&S refers as the practices of Environment, Health, Safety, and Sustainability inspired to keep the health, safety of the workers and public in safe conditions. While the environmental protection is highly managed to assess and monitor the potential risks of hazards generated from the processes and systems in companies. The development of new medicines must go hand in hand with the environmental responsibility. In the integration of EHS&S, there are at least four main areas needed to achieve with the purpose of evolution and sustainability.

From the European point of view, EFPIA described the Green Agenda, the participated members have committed to bring the positive impacts on the health of patients in the sustainably good manner. The value chain of EHS&S has indicated water, chemicals, climate change, and circular economy. The first attempt is water which is the essential roles being most concerned in Pharmaceuticals in the Environment (PiE). Certain projects created by the collaboration of organizations are conducted to address the potential risks in water pollution including the Eco-Pharmaco-Stewardship (EPS) framework. The second factor contributing to the Green Agenda is Chemicals. The pharmaceutical industry is one of the most strictly regulated in Europe and over the world. The regulation is applied from the very first stages of plant construction to marketing authorizations. The companies have committed to practice the essential initiatives to minimize the significant impacts of chemicals to the natural habits by using greener solvents and promoting the emerging chemical legislation globally and locally. The next issue which is considered as the reasons of extreme weathers and natural disaster, is climate change caused by the surge of carbon dioxide emissions. The pharmaceutical sector is also a factor contributing to the healthy environmental condition by initiating the mitigate actions. The commitments of EFPIA members are to practice the climate change policies, reduce the CO₂ emissions, and increase energy efficiency and the use of energy from renewable resources. Last but not least, the circular economy is one of the policies established to build the long run of

environmental sustainability and development plans of the pharmaceutical companies. (EFPIA, 2019)

However, as the literature review from the researchers such as Edward Weaver *et al.*, 2022 and Saxena *et al.*, 2021, the adoption of green production methodologies is still slow while the awareness of green production should be promoted and raised from among the participants in pharma sector, including regulatory bodies, and stakeholders .

2.2 CURRENT STATE OF SUSTAINABLE PRODUCTION PRACTICES IN THE IRISH PHARMA INDUSTRY

A glimpse of pharma industry in Ireland is described in the report of Irish Pharmaceutical Health Association (IPHA) in 2022, Ireland is one of the leading countries in pharma sector within Europe. As the record, there are around 120 globally pharmaceutical companies have located in Ireland among of which 9 companies are ranked the largest pharma companies over the world. The pharma sector plays the significant role in the Irish economy in terms of exports and employment. As other industry, the energy consumption, water usage, and waste generation are three main factors raising the environmental concern about sustainability in pharma industry around the world, including in Ireland.

This literature review will reveal the current awareness of sustainable production of green production performances in Irish pharma companies. The adoption of green production challenges they face, and regulatory initiatives that promote the green production shall be examined.

2.3 THE ADOPTION OF GREEN PRODUCTION IN IRISH PHARMA COMPANIES

Ibec is the biggest lobby and business representative organization in Ireland. By influencing, supporting, and delivering for business success, their goal is to contribute to the creation of a better, more sustainable future. Ibec, which employs over 260 people, interacts with important stakeholders both domestically and abroad through its six regional offices, its office in Brussels, and its vast international network in the UK and the US.

In the strategy for sector 2023 – 2027, the vision of Ibec expectation is that Ireland will be a global pioneered center of excellence for innovation and development in the sustainable production and supply of (bio)pharma/chemical. (IBEC, 2022). However, as the survey conducted by RTE news, while 43% of Irish organizations and companies have prepared plans for carbon-neutral or the achievement of net zero, 38% of surveyed participants saying that their companies do not conduct sustainable plan in Environment, Social, and Governance (ESG) strategy. The number is conducted the IT company DataSolutions. (RTE, 2021).

Green production is not fully practiced among the Irish pharma industry or the global pharma industry since the conservative nature of the industry focusing on profit maximization which often conflicts with the environmental sustainability (Haessler, 2020). Moreover, the performance of green production require the huge investment in state-of-art technology, personnel, and time, which is challenging for the small and medium pharma companies (Rizos *et al.*, 2016). However, some Irish pharma companies have adopted the green performance in sustainability. For instance, the case study of Eli Lilly Kinsale with the project of Dunderrow Solar Farm will be examined as the model for green energy. The Dunderrow Solar Farm is located in a suburb area from Lilly site. It is around 500m from the farm to residence area. All wild grass and natural diversity around the farm are preserved and maintained during the farm construction. All construction plant was covered and invisible to the residents. This plan is controlled in the good manner proved by the absence of objections or complaints. Moreover, this plan is also to protect the archaeological anomalies in the surrounding area. This projects' budget cost more than 7 million euros investment by Lilly and Enerpower supported by Sustainable Energy Authority of Ireland (SEAI) under the Better Energy Communities scheme. The project builds over 20,000 solar panels spreading over four fields. With this solar panel installation, the maximum output can reach to 8.0 MWp DC which can excessively generate for the people in Kinsale Town. This project is seemed like the essential contributor to Lilly's sustainability by reducing the carbon footprint. After this phase, the company has planned to commit to 2030 sustainable goals which source 100% of the consumed electricity from the renewable energy. (IBEC, 2022)

2.4 DRIVERS AND BARRIERS TO SUSTAINABLE PRODUCTION IN THE IRISH PHARMA INDUSTRY

The pharma sector has been playing the significant contributor in the Irish economy. Hence, in the long run, it requires the implementation of green production to ensure the sustainable production not only for the companies, but also for the natural environment, and peoples' health. In this part, the drivers and barriers which are interfering the implementation of green production in Ireland, including the impacts of regulatory frameworks, market pressure, and internal company factors.

Regulatory frameworks

To encourage environmentally friendly manufacturing techniques in the pharmaceutical sector, the Irish government has put in place a number of legislative frameworks. The Green Enterprise Program of the Environmental Protection Agency (EPA) offers financial and technical support to businesses that embrace ecologically friendly practices. The European Medicines Agency (EMA) has designed the risk assessment standards specifically used for the pharma industry, which mandate that their environmental effects from medicinal products must be examined. These rules encourage businesses to use sustainable manufacturing methods, which boosts the industry's adoption of sustainable practices.

For the Green Enterprise Program which are funded to enable the companies conduct the innovative projects, there are four main polluted areas which are prioritized to limit and recycle, including plastic waste, food waste, resources and raw materials, and construction and demolition (C&D)(EPA, 2022). As the EMA in 2015 have introduced the guidelines about the risk assessment of medicines which affect the environment. All pharma companies must conduct the environmental risk assessment (ERA) to identify the limit potentially harmful effects of manufacturing processes to the environment. The ERA must be done when the kickoff of research of new medicines starts. Beside the scientific data of quality, efficacy, and safety of the drug, the ERA is an obligatory document for the submission dossier to the EMA, supporting the marketing authorization of the concerned drugs. A stepwise approach is used to perform the ERA which initiates with screening phase (phase 1). In this phase, the

chemicals exposure shall be examined for chemical accumulation and how they impact on the environment. The next step shall be preliminary assessment after the identification of potential risks. The profound assessment shall be performed based on the risks identified in the first phase. The traits of drugs shall be examined for the impacts on the environmental organisms, including fishes, or aquatic environment. After the refined assessment, the mitigation plan shall be prepared for the appropriate treatment by the environmental professors. Moreover, this assessment can be used to design the disposal method applied for the healthcare professors, pharmacists, and patients. (EMA, 2018a)(EMA, 2018b)

Market pressures

Market pressures from the stakeholders of pharma industry are one of the factors driving the adoption of green production in the sector. Recently, the customers preferred the sustainable products and services which are increasingly demanded among the community. The companies fail to meet the expectation shall be risked losing the market share and customers' loyalty. (Juliet Roper, 2012). As the survey conducted by Simon-Kucher & Partners in 2021, 85% of the customers have shifted their purchase behaviors towards the companies which apply environmental-friendly strategy. In the same study, the results have indicated that around 34% of participants are willing to pay more money on the products which are sustainable products or services. Moreover, the "mission-driven green" companies are rising which require the companies should invest, innovate, and transform their business concepts towards greener, more stable to protect the long-term profitability and viability, as the author saying. Furthermore, the adoption of renewable energy practices also brings the massive economic benefits to the companies in terms of cost savings and efficiency (U.S EPA, 2017). The cost-saving and energy efficiency can be the results in both primary and secondary electricity system benefits. First of all, when the energy is efficiently utilized, it will be less generated in the first time, leading to primary advantages. For instance, in a household, the quantity of electricity produced by power grid can be decreased if the energy-efficient equipment is installed. Also, elimination of the extra power is one of the reasons helping to secure the electrical bills resulting in cost savings for the companies and energy suppliers. Second, because the demand on the power system is decreased as a consequence of energy efficiency, there may

be further advantages. High electrical demand can overwhelm the power grid, resulting in power failures or outages. The need for expensive improvements and maintenance can be decreased by lowering demand through energy efficiency measures, allowing the power system to run more smoothly and dependably. Moreover, decreased demand might assist in stabilizing power costs since it can lessen market volatility. (López-Gamero *et al.*, 2009), (Wang *et al.*, 2020)

The advantages of energy efficiency in both primary and secondary power networks are well supported by the available data. For example, a study run by the Lawrence Berkeley National Laboratory discovered that thank to the energy efficiency policies in California from 1975 to 2016, the consuming amount of electricity is reduced 50% per person equivalently saving \$90 billion during the research period (EMP, 2021). Similarly, the program called an Energy-Efficient Economy organized by the American Council saying that the energy efficiency measures may help the country cut 30% of power demanded by 2030, resulting in saving money for both customers and suppliers (IEA, 2022).

Internal company factors

Sustainable manufacturing methods are also significantly influenced by internal firm missions, such as management commitment to sustainability, staff participation, and environmental training. These aspects are particularly important in the Irish pharmaceutical sector. According to studies, businesses with robust environmental management systems—including objectives for decreasing environmental effect, frequent audits, and monitoring and reporting systems—are more likely to adopt sustainable manufacturing methods. Internal obstacles to sustainable manufacturing do exist, nevertheless, such as the belief that such methods can have a detrimental influence on productivity and revenue. As the report from Business in the Community Ireland (BITC) in 2014, over 80% of companies in Ireland has committed with Environmental policies which focus on two main areas, including general environmental management and waste management, followed by the energy and climate change/carbon management.

One EY (Ernst & Young) study from 2018 discovered that two of the most significant drivers of sustainability in the pharmaceutical business were leadership commitment

and workforce engagement (Falco Weidemeyer and Barry Perkins, 2021). Most pharmaceutical businesses in Ireland were questioned for this study, and it was discovered that those with excellent leadership and employee involvement were more likely to adopt sustainable measures and report on their success in this area.

Similar findings were made in research conducted by the University of Limerick in 2020, which discovered that staff involvement and training were crucial in encouraging the Irish pharmaceutical business to embrace sustainable practices. When the Irish pharmaceutical businesses were questioned for the study, it was discovered that those with greater levels of staff involvement and training were more likely to implement sustainable practices and to take a more thorough approach to sustainability. (UL, 2020)

In further research released in 2019, the European Federation of Pharmaceutical Industries and Associations (EFPIA) discovered that sustainability leadership and governance were key factors in the pharmaceutical sector's sustainability. According to the study, which polled 23 EFPIA member firms, including many in Ireland, those with strong sustainability governance structures and clear leadership commitments were more likely to adopt sustainable practices and report on their sustainability performance. (EFPIA, 2017)

2.5 ENVIRONMENTAL, ECONOMIC, AND SOCIAL IMPACTS OF GREEN PRODUCTION

Recently, the concept of green production or sustainable production is highly spotlighted because of the emerging industrial activities which raise the concern about the impacts on environment, economy, and society. Moreover, pharma sector contributes the significant percentage in Irish economy. Therefore, it shall be deeply examined to ensure the long-life development in the country economy and biodiversity.

First of all, the **environmental impacts** of green production shall be examined by the publish from Zobel in 2008. As the manufacturing operation running, large amount of water and energy must be utilized, eventually release industrial waste and greenhouse gas. The challenges that the industry facing are to reduce the adverse environmental

impacts. Some proposed green production practices are energy-efficient technologies, waste reduction, and water conservation measures.

Certain environmental impacts can be considered including energy consumption, resource depletion, waste generation, greenhouse gas emissions, and biodiversity loss (Edgar Hertwich, 2010). As the traditional energy consumption, fossil fuels are the energy-intensive processes to product and operate the equipment used in the manufacturing processes. Nevertheless, the renewable energy sources, including solar, wind, and hydroelectric power are evaluated have less impact on the environment. Particularly, installation and operation of renewable energy are concerned cheaper than the non-renewable energy due to the competition and the price of non-renewable energy is more fluctuate than the renewable ones (IRENA, 2022). Technical advancement is the first factor to help the production of renewable energy is cheaper and more efficient. For instance, the solar panel technology have greatly lowered the price of solar energy production. (Kabir *et al.*, 2018).

The next aspect contributing to lower the price of renewable energy is economies of scale. As the market of renewable energy has been expanded, resulting in the economies of scale. Hence it leads to lower the price of renewable energy. Furthermore, there are certain countries implement the assistance policy for the use of renewable energy, aiming to encourage and create the financial conditions, including mandates, tax breaks, and subsidies. The next environmental impact is resource depletion (Prior *et al.*, 2012). By practicing the green production, the aim is to reduce the number of resources utilized by the manufacturing processes. **However, certain undeniable realities caused by exploiting environmental resources can be deforestation, soil erosion, and water pollution.** As the results of extraction of natural resources, biodiversity can be at risk. Along with the circumstances, climate change caused by greenhouse gas emissions because of using fossil fuels for energy production. Due to the expansion of industrial size, the changes in land use may cause the deforestation and repurposing of natural ecosystems. Hence, it can damage the ecosystem services and biodiversity. The next environmental impact is waste generation, which is followed by the principle of reuse, recycle, and reduce materials. At the meantime, green production enhances the improvement of efficiency in manufacturing processes. However, by any circumstances, waste is still produced and

having the potentially harmful impacts on water and soil (Damjan Krajnc and Peter Glavič, 2003). Greenhouse gas emissions is the next impact that the companies shall cope with by applying the green production. Green production can be practiced by implicating renewable energy and improving energy efficiency. Last but not least, green production practices enable the pharma companies preserve and enhance the biodiversity while the intensive farming practices may result the habitat loss and bio-destruction.

Facing the adverse environmental impacts, green chemistry is one of the most effective to maintain the sustainable production in Irish pharma industry (Roschangar *et al.*, 2015). Green chemistry is considered as the sustainable chemistry which contains a series of principles helping to reduce or eliminate the hazardous substances within and during the manufacturing processes. Green chemistry is aimed to generate the safe, efficient, and sustainable processes which can reduce the adverse environmental impacts (Sudripet Sharma *et al.*, 2020). There are at least 12 principles applied for design, manufacture, and deal with the chemicals. First of all, waste creation should be prevented until the minimum limit rather than being treated or clean up. **Next, the manufacturing process should be optimized in order to maximize the use of materials and minimize waste.** Moreover, the chemical processes and synthesis must be designed to minimize the toxicity and improve the human health in the community. During the manufacturing or testing, solvents are tremendously necessary for the chemical processes. The use of solvents should be studied to choose the safer solvents for the processes. Another aspect of green chemistry is energy which should be used efficiently and minimizing the environmental impacts. The other principles of green chemistry are listed as the followings, including use of renewable feedstocks, reduce derivatives, catalysis, design for degradation, real-time analysis for pollution prevention, and inherently safer chemistry for accident prevention. Application of green chemistry brings out several benefits, including reducing the environmental impacts of chemicals, enhancing health and safety of habitants, and minimize the cost of manufacturing. Green chemistry is believed as the essential factor to establish a more sustainable future for the planet. For instance, using renewable feedstocks, such as plant materials or waste products, to replace petroleum-based materials, this is the typical example in the energy-formed transition aiming to develop the safer and more efficient chemical reactions. Furthermore, the

biodegradable, environmentally friendly chemical products should be properly designed and developed. The witness of sustainability and environmental responsibility is driving more companies, especially pharma companies, which is the bright spot to adopt the green chemistry. (Jiménez-González *et al.*, 2012)(Manley *et al.*, 2008)(Kar *et al.*, 2022)

The next investigation of impacts which bring benefits to the pharma companies thanks to green production is the **economy**. Waste reduction is not an odd concept to the industries over the worlds. Companies have their own significant strategies to practice waste reduction. The purposes are to minimize the number of materials, energy, and other resources in the manufacturing of goods but reducing the creation of waste and pollution. Some proposed strategies in the businesses can apply to reduce waste. For examples, lean manufacturing focuses on the streaming production processes by eliminating non-value-added activities and minimizing waste. Another example is recycling and reuse. This involves recovering and reusing materials instead of discarding as waste.(Yu and Kopcha, 2017). Saving cost relates to one of the economic benefits of green production, which enables the companies reducing waste and improving efficiency on utility bills. Practicing green production is saving money and cost cutting. On another hand, adoption of green production may satisfy the demand of customers who desire the environmentally friendly products and services. Currently, customers are intending to purchase products which are environmentally sustainable, meaning that the commitment of green production can result in competitive advantages (Ammenberg and Sundin, 2005). Furthermore, in regulatory aspect, when the companies comply with the environmental regulations, it may be finically beneficial in cost savings associated with regulatory compliance. Additionally, supply chain management is more improved due to the reduction risks associated with resource scarcity and environmental impacts. Green production involves the secure sustainable supply chains which are less vulnerable to fluctuations in resource availability and price. Likewise, green production practices create the valuable conditions for innovation and development in new technologies and processes. It stimulates the new product development, upgraded production processes, and great efficiency. Finally, employee productivity is more enhanced since the working condition is qualitatively increased by reducing the workplace hazards and creating a

more positive work environment. (István T. Horváth and Paul T. Anastas, 2007), (Jiménez-González *et al.*, 2011)(Watson, 2012).

Last but not least, the essential benefit of practicing green production is related to **social** areas. As McEniff *et al.*, 2015 explained when the companies apply green production activities, it is not only beneficial for the workers, but also the surrounding communities since green production practices enable the manufacturing operations reduce the hazardous conditions including air, water and working conditions. Furthermore, the practices of green production bring the community engagement and empowerment by providing the communities with access to information, resources, and decision-making process. By engaging to the communities, pharma companies are able to gain insights about local needs and priorities in order to develop more effective and sustainable production practices. Another aspect of society is improved by practicing the green production is social equity which is promoted by fair and equitable access to resources, including land, water, and energy. The ultimate of green production is sustainable and environmental-friendly production which contributes to an enhanced quality of life by reducing pollution, improving access to clean water and air, and promoting a healthier lifestyle as the mission and vision from certain pharma companies. By green initiatives, the natural resources and biodiversity are preserved, which can bring the higher quality of life for everybody. Lastly believe or not, stakeholder relations are improved by building trust and credibility with customers, employees, and communities. By demonstrating a commitment to sustainability, companies can earn stakeholder support and loyalty, which can lead to greater success and longevity. (John L. Tucker and Margaret M. Faul, 2016)

2.6 STRATEGIES AND POLICIES FOR PROMOTING SUSTAINABLE PRODUCTION IN THE IRISH PHARMA INDUSTRY

Existing strategies and policies aiming to address various social issues are often implemented by different stakeholders, including governments, industrial associations, and corporations. These initiatives include wide range of measures, such as laws, regulations, industry standards, and corporate social responsibility (CSR) program. First of all, the government initiatives was indicated and planned by the EEA, 2020 as a specific example. The European Union's 2020 Climate and Energy Package, which

is created to reduce greenhouse gas emissions and increase the utilization of renewable energy sources. After this project started, the effectiveness was measured based on the key sustainability metrics such as greenhouse gas emissions, energy use, and resource consumption (the EC, 2020). The next main factor contributing to promotion of green production is industry associations. An example of Fashion Industry Charter for the Climate change, which organize the connection between the fashion industry contributors aimed to reduce the industry's carbon footprint. The effectiveness is then measured by the level of participation and the extent to which they lead to alteration in business practices. Furthermore, the CSR programs are implemented by many companies with the purpose of promoting sustainability. For instance, a project run by Unilever called Unilever's Living Plan, which intends to reduce the company's environmental impact and improve its social impact. The effectiveness of such programs can be assessed based on the metrics planned prior starting the plan, as well as the extent to which they lead to alterations in business practices. (Hjeresen *et al.*, 2002)(Alexandra A. Taylor, 2022)

In general, the concept of green production is broadly encouraged among the industries in every country through the activities of certain organizations. Some particular projects are running. Specifically, "corporate social responsibility and environmental management" (Richard Welford, 2023) is established as a peer-reviewed journal that focus on corporate sustainability and social responsibility. This channel publishes articles on various fields of sustainability, including environmental management, climate change, and corporate social responsibility programs. The second program called "the state of green business" (Joel Makower, 2022). This program collects and reviews the state of green business practices. The reports generated include insights on the effectiveness of government initiatives, industry associations, and corporate social responsibility programs. The next typical organization playing the role in promoting sustainable business is "the world business council for sustainable development" (wbcSD, 2023). Some activities of the organization are to provide various resources, including case studies and research reports, on the effectiveness of green production implementation. Broadly, the United Nations (UN) also launch the project "the UN sustainable development goals" (UN, 2023) generate the framework for green development and a blueprint for achieving a better and more sustainable future for all. Besides, "the carbon disclosure project"

(CDP, 2023) monitor and collect the data from the companies which choose to follow the green plan. The results collected based on the environmental platform to collect the related information of carbon emissions. By this initiative, the effectiveness of green practices is assessed, insights shall be gained after the data analysis. Last but not least, “the European Union’s circular economy action plan” (the EC, 2022) is a broad strategy created to accelerate the transition to circular economy within Europe. The circular economy is an economic model that preserves the natural resources in use for as long as possible, reducing waste, and promoting green production and consumption. Discuss about circular economy, this topic consists of several aspects. The first purpose is to design products for circularity. It means that the materials should be sustainable and environmentally friendly, reducing waste, and improving the recyclability of products or packages. The second field is extending the lifespan of products. The products or packages are designed to reuse, repair, and refurbish. The next one is sustainable consumption which encourages customers choose the sustainable-designed products such as a longer lifespan and using the reuse or recycle services. On another hand, circular economy focuses on a circular business model, aiming to inspire businesses to practice using renewable energy and sustainable materials, and reducing waste. Finally, sustainable or green infrastructure must be equipped such as recycling facilities and waste management systems.

2.7 FUTURE DIRECTIONS FOR GREEN PRODUCTION IN THE IRISH PHARMA INDUSTRY

In recent years, the Irish pharma industry has made massively strides towards sustainability and green production. However, there are still several issues need implementing to reduce its environmental impact and improve its sustainability in pharma industry. In this part, certain potential areas suggested contributing to innovation in sustainable production practices, including circular economy, digitalization, sustainable energy, and sustainable packaging (Reinhardt *et al.*, 2020). First of all, circular economy, as explained, focuses pm reducing waste and reuse resources instead of the linear economy which generates large amounts of waste and emissions. in the long run, circular economy should be developed into a circular business model, such as product-service systems, which stimulate resource efficiency and eliminate waste (the EC, 2022). The second important cluster is digitalization,

which involves several digital technologies, such as artificial intelligence, the internet of things (IoT), and blockchain. Thanks to the adoption of those technologies, the efficiency and sustainability of production processes are much enhanced. In the future, these technologies should be optimized to use resources, reduce waste, and improve supply chain transparency (Marr, 2022). The next direction should be empathized is sustainable energy (Jacobson and Delucchi, 2009). This cluster is tremendously significant and constantly discussed about the transition to renewable energy, aiming to reduce greenhouse gas emissions and rise the witness of energy security. The future trends of sustainable energy are to develop innovative renewable energy technologies, such as floating solar farms, and wind turbines along with improving energy storage systems. Lastly, sustainable packaging is an issue which leads to waste and pollution if there are no solutions existed. Hence, the future demand of developing sustainable packaging materials shall be designed and researched to provide bioplastics and circular packaging which are recyclable, biodegradable, and safe for the environment (Ibrahim *et al.*, 2022).

Looking forward to the years to come, there are potential challenges and opportunities in the pharma industry, including Irish pharma industry. First and foremost, in the view of regulation, the regulatory bodies over the world are striving to promote and implement the environmental policies to encourage green production practices. Any companies who fail to satisfy these regulations may be fined or damage to their reputation. In contrast, the companies who apply strictly the innovative environmental practices, shall be beneficial in reducing regulatory penalty, and increasing the market opportunities (the EC, 2023). Secondly, in the customer market, people, now, are more conscious about friendly environmental concepts and increasingly demanding greenly produced products. The customer loyalty is earned when the company policies meet the environmental benefits (Emmert, 2021). The next issue is supply chain transparency when the consumers more increasingly expect to know where the drugs come from and how they are produced so that it will be a benefit if the companies display the supply chain transparency (Bateman and Bonanni, 2019). Believe or not, the resource scarcity is becoming a major challenge when the global population is considerably growing. Facing this situation, companies can optimize resource use and reduce waste. This is beneficial from increased efficiency and reduced costs (the EC, 2018). Finally, collaboration is a key to practice green production among various

stakeholders, including governments, NGOs, and other businesses. Building partnerships many bring enormous advantages of increased values, reduced cost, and improved ecosystem loss, addressing environmental protection throughout the production streams (Nidumolu *et al.*, 2014).

CHAPTER 3 RESEARCH METHOD

3.1 RESEARCH OVERVIEW AND STUDY DESIGN

Ireland's economy greatly benefits from the pharmaceutical sector, which employs a large number of businesses in the development and manufacture of medicinal products. In response to escalating regulatory demands and customer demands for sustainable products, there has been an increased focus on the implementation of green manufacturing processes in the sector in recent years. The difficulties with green production in Irish pharmaceutical businesses are complicated and stem from a number of causes. The high cost of implementing green manufacturing processes, which might need major investment in new technology and infrastructure, is one of the key obstacles. Due to worries about how investing in green manufacturing processes would affect their bottom line and ability to compete in the global market, many businesses are likewise reluctant to do so. The extensive regulatory framework in which pharmaceutical businesses must operate presents another difficulty. A complicated network of rules governing waste disposal, pollutants, and dangerous chemicals must also be navigated by businesses. Green manufacturing strategies may also be hindered by organizational and cultural constraints. Some businesses might not fully comprehend the advantages of sustainable manufacturing or can be reluctant to change. Others can have trouble getting top management's support or involving workers in the process of implementing green manufacturing techniques. Notwithstanding these obstacles, the pharmaceutical sector is beginning to recognize the value of green production, and many businesses are moving toward adopting more sustainable processes. Among these are actions like cutting back on waste and pollution, enhancing energy efficiency, and putting money into renewable energy sources.

Since it enables researchers to get a basic knowledge of the topic and suggest possible fields of additional investigation, an exploratory research methodology is beneficial for studying the challenges of green production in Irish pharmaceutical companies. The subject of green manufacturing in the pharmaceutical sector is sophisticated and varied, with a wide range of possible difficulties and growth prospects. The researchers may earn the deep knowledge from collecting data from a wide range of sources and viewpoints, including published articles, reports, and

interview with the key participants such as managers, industry experts from pharma companies. The exploratory research design is suitable for subjects that have not been studied in-depth or when there is a dearth of data. Although there may be little study on the particular difficulties encountered by Irish pharmaceutical businesses, there is rising awareness of the value of sustainability in the context of green manufacturing in the pharmaceutical sector. Researchers might find new research issues and regions that needed more study by using an exploratory research methodology.

3.2 RESEARCH ONION FRAMEWORK

A popular model in research methodology that aids in structuring the many phases of a research project is the "onion research" framework (Saunders *et al.*, 2009). The framework is widely used to direct the creation of research questions as well as the gathering and analysis of data. The framework is composed of the following six levels or stages:

- Research philosophy: The first layer of the research onion is choosing the type of strategy or principles that will be used to conduct the investigation. Positivism, interpretivism, and critical realism are the three primary research philosophies. Whereas interpretivism focuses on utilizing qualitative research techniques to understand social processes, positivism emphasizes testing hypotheses using quantitative approaches. A combination of the two, critical realism looks for the fundamental causes of social occurrences.
- Making judgments on the overall research method is covered in the second layer of the research onion. This entails choosing the data collection and analysis techniques, such as surveys, interviews, or case studies.
- Decision regarding the overall study approach, such as whether to utilize a cross-sectional or continuous design, are made in this layer of the onion.
- Making choices concerning the study's temporal range, such as whether to concentrate on historical data or current trends, falls under this layer of the onion.
- Making judgments regarding the techniques to be utilized to gather data, such as surveys, interviews, or observations, is the fifth layer of the onion.

- Making decisions about how the data will be evaluated, such as utilizing statistical methods or qualitative analysis approaches, is the last layer of the research onion.

3.2.1 RESEARCH PHILOSOPHY

According to Saunders *et al.*, 2009 and Howell in 2012, using the assumption that social phenomena cannot be researched in the same way as natural phenomena, interpretivism is a research philosophy. In order to comprehend the significance and context of social conduct, it focuses on the subjective experiences of individuals.

Researchers gather and evaluate data in interpretivist research using techniques including focus groups, interviews, and case studies. These techniques are frequently qualitative in character, which means that they seek to understand the individualized feelings and perceptions rather than putting behavior into a numerical context. For instance, an interpretivist researcher would conduct in-depth interviews with staff members of a pharmaceutical business to see how they view the benefits and problems of adopting sustainable production methods.

For examining sophisticated social phenomena, such as sustainability in the pharmaceutical sector, interpretivism is a relevant study methodology. It enables researchers to learn about people's subjective experiences and viewpoints, which might offer insightful information about the difficulties and possibilities of sustainable manufacturing.

3.2.2 RESEARCH APPROACH

Data might be gathered by the researcher using a number of techniques, including interviews. For instance, the researcher may speak with staff members of Irish pharmaceutical firms to learn about their experiences implementing sustainable production practices and the difficulties they encounter. To find recurring themes and patterns, the researcher might also analyze the body of literature on sustainable manufacturing methods in the pharmaceutical sector.

The researcher would next evaluate the data to look for patterns, trends, and linkages that might help establish a theory or hypothesis. The researcher may find issues like regulatory restrictions, a lack of knowledge, or financial factors that are experienced

by many Irish pharmaceutical enterprises. Based on these trends, the researcher can construct a theory or a hypothesis regarding the elements that contribute to the difficulties Irish pharmaceutical businesses have in implementing sustainable manufacturing methods. (Howell, 2012) (Saunders *et al.*, 2009)

In exploratory research, when the objective is to produce fresh ideas and understanding about a topic, the inductive technique is helpful. In this instance, the researcher is letting the facts lead the creation of a theory rather than starting with a predefined theory or hypothesis. When there is little information available on a subject or when the research issue is wide and undefined, as is the case with the topic of "challenges of green production in Irish pharma companies," the inductive technique is also helpful.

3.2.3 RESEACH STRATEGY

In order to build theories from the high-quality data being collected from respondents, a grounded theory research was adopted for this study. In addition to enabling the creation of research interview questions based on inductive reasoning, the choice of this research strategy is in line with the interpretivism research philosophy, and the inductive research technique used for this study.

3.2.4 RESEARCH METHOD

Qualitative research method is the one chosen for this project since it can help to reveal the research queries. Although the quantitative method is more reliable as it is shown because of the numeric evidence, and avoiding the objective ideas by the researchers, quantitative method shall assist the researchers comprehend the people's beliefs, knowledges, and experiences. It shows no numeric data, for sure (Pathak *et al.*, 2013). For this topic, "Challenges of Green Production in Irish pharma companies", qualitative research method is the most suitable because the researcher may have time to communicate with the professionals, and pharma workers in the industry. All experts are working in big Irish pharma companies shall engage in the separate interviews. The collected data shall be gathered as themes, of which the theories shall be constructed.

3.2.5 TIME HORIZON

This study is a cross-sectional study which means this research is studied at the moment and conducted by interviewing the experts working in Irish pharma companies with the list of research questions as the interview questions.

3.3 COLLECTIONS OF PRIMARY DATA

In this research, interviews shall be adopted. The participants shall share their opinions about the research questions. To gather qualitative or quantitative data, interviews might be organized, semi-structured, or unstructured.

It's crucial to protect the data's objectivity by avoiding prejudice and inaccuracy throughout data collection, processing, and reporting.

The data must then be properly statistically or qualitatively examined after collection. The research issue or hypothesis is then addressed using the analyses' findings. Future research, policy, or practice can then be informed by the findings from the main research. (Saunders *et al.*, 2015) (Howell, 2012)

3.3.1 SOURCE

A STUDY POPULATION AND RESEARCH INSTRUMENT DEVELOPMENT

Employees, managers, and executives from various pharmaceutical businesses in Ireland would probably make up the research population for the investigation into the "challenges of green manufacturing in the Irish pharma companies." These people would be selected based on their roles and responsibilities in their respective firms' green production or sustainability strategies.

The researcher would need to decide on the precise research questions and study objectives before developing the research instrument. The researcher would next decide which data gathering technique(s) would be most suited, such as surveys or interviews. The next step is for the researcher to draft the precise survey or interview questions or subjects. See the table:

Research objective	Research questions
To review the current state of sustainable production practices in the Irish pharmaceutical industry.	<ul style="list-style-type: none">• How would you describe the current state of sustainable production

	<p>practices in the Irish pharmaceutical industry?</p> <ul style="list-style-type: none"> • What sustainable practices are currently being implemented in the Irish pharmaceutical companies?
<p>To identify the key drivers and barriers to implementing sustainable production practices in the Irish pharmaceutical companies.</p>	<ul style="list-style-type: none"> • What are the primary drivers for implementing sustainable production practices in the Irish pharmaceutical companies? • What are the key barriers to implementing sustainable production practices in the Irish pharmaceutical companies? • What are the potential costs and benefits associated with implementing sustainable production practices in the Irish pharmaceutical companies?
<p>To investigate the strategies and best practices that successful green pharmaceutical companies in Ireland have adopted to overcome the challenges of implementing sustainable practices.</p>	<ul style="list-style-type: none"> • What specific strategies have successful green pharmaceutical companies in Ireland implemented to overcome the challenges of sustainable production practices?
<p>To develop recommendations for the Irish pharmaceutical companies and policymakers on strategies and policies to promote sustainable production practices in the industry.</p>	<ul style="list-style-type: none"> • What specific strategies and policies would you recommend promoting sustainable production practices in Irish pharmaceutical companies? • How can these strategies and policies be effectively implemented and monitored over time?

Table 1 The research objectives and research questions

B INTERVIEWEE SELECTION AND DATA COLLECTION PROCESS

Interviewee selection: The researcher would need to locate possible interview subjects from different Irish pharmaceutical firms who are aware about sustainable and green production methods. These people might be CEOs, managers, or staff members who are in charge of putting green production techniques into effect or supervising them. To get additional viewpoints, the researcher can also think about including outside parties like regulators, business leaders, and environmental organizations.

Semi-structured interviews with the chosen participants would be conducted as part of the data gathering procedure. The interview questions would be created to obtain details on the participants' perspectives, experiences, and attitudes toward environmentally friendly pharmaceutical manufacture. The participants may choose the schedule which is suitable for them to do the interviews by Google meet. These entire interviews will be recorded as the primary research.

3. 3.2 ACCESS AND ETHICAL ISSUES

A RESEARCH PRIMARY ACCESS

As was previously said, in order to collect primary research data, the researcher may interview 5 members of the pharmaceutical sector in-depth. These interviews can offer in-depth understandings of the difficulties and possibilities associated with green production in the sector in Ireland.

B INFORMED CONSENT AND PARTICIPANTS' CONFIDENTIALITY

The process of telling research participants about the study and receiving their voluntarily consent to participate is known as informed consent. An ethical document that describes the study's purposes, the risks and meanings of participation, and the participants' right as part of this approach. Before data is collected, the researcher must prepare the written consent forms which are sent to the participants to inform about the study's purposes.

Each research project must take participant confidentiality into account. The researcher is required to take the necessary precautions to safeguard participant confidentiality and data collection privacy. This can entail getting consent documents with confidentiality clauses signed, keeping data safely, and making sure that only

authorized people can access the data. To maintain anonymity, participant identifying information should be maintained apart from the study data and coded.

It is essential to protect the participants' information avoiding information leak or revealing the participants without the consent. The researcher must assure all collected data is exclusively used for the study's goals. All sharing that is potentially jeopardize the privacy or confidentiality must be prohibited.

3.4 APPROACHES TO DATA ANALYSIS

Thematic content analysis (Rosemarie Anderson, 2007)(Castleberry and Nolen, 2018) offers a disciplined and methodical way to discovering patterns and themes within textual material, making it a useful tool for studying qualitative data. It enables researchers to go beyond descriptive analysis and produce more insightful understandings of participant attitudes, beliefs, and experiences.

Transcribing or otherwise capturing the data that has been gathered, such as interview transcripts, or focus group recordings is the first stage in doing a thematic content analysis. The data is then examined and analyzed to spot any patterns or recurring themes. In order to find important concepts, ideas, or problems that are prevalent among participants or data sources, this may include reviewing and rereading the data.

After these topics have been determined, it is possible to group them into a thematic framework that offers a precise foundation for data analysis. Each subject should have clear definitions and illustrations in the framework, as well as a mechanism for categorizing the data in accordance with the themes that have been defined.

The data will next be analyzed inside the framework to determine the frequency and distribution of each topic within the data set. The data may then be manually coded or software applications may be used to aid in the analysis.

The themes are then utilized to produce insights and conclusions on the difficulties of green manufacturing in Irish pharmaceutical businesses. The data is then analyzed within the framework of the research question or hypothesis.

3.5 CONCLUSIONS

The study's planned methodologies and procedures for data collection and analysis are outlined in the research method chapter in a clear and thorough manner. With the use of this material, the chapter enables readers to comprehend the research methodology, assess the study's reliability and validity, and derive valuable inferences from the findings.

CHAPTER 4 FINDINGS

In this chapter, the findings shall be gathered and discussed to clarify the initial scopes of the research.

4.1 INTERVIEW PROCESS SUMMARY

There are 4 respondents in the interviews which were conducted virtually. All respondents provide the in-depth interviews which generate the knowledgeable and insightful information in Irish pharma sector. All respondents in the interviews are experts working in the pharma industry having the 30-min interviews in which 8 (eight) research questions were asked in the study by Google meet application. In the table below which is showing the brief personal information in the research. All respondents were going through all initial questions. In the table below, a summary of the profiles of the interviewees who engaged in the interviews.

Interviewee	Gender	Role	Years of experience
Interviewee 1	Male	Consultant	Over 10 years
Interviewee 2	Male	Consultant	Over 25 years
Interviewee 3	Male	Site Head	Over 20 years
Interviewee 4	Male	Chief Operating Officer (COO)	Over 30 years
Interviewee 5	Male	Team Leader	Over 15 years

Table 2 The interviewee characteristics

All records throughout the interviews shall be transcribed into text, then thematic data analysis will be applied as the tool to identify the key themes which contribute to the knowledge of green production in Irish pharma companies. There are certain themes defined by the interviews with respondents which were asked about the research questions.

4.2 THEMATIC CONTENT ANALYSIS RESULTS

The audiotaped answers which are collected from the participated individuals, then transcribed into text and used as the incoming data for the thematic data analysis. The key themes are identified to reflect the challenges of green production in Irish pharmaceutical companies.

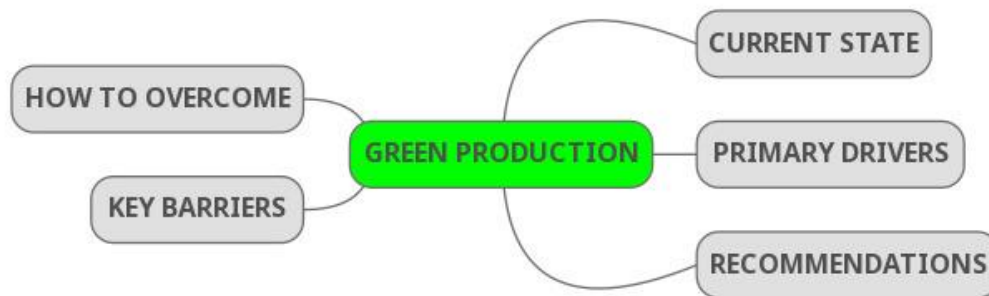


Figure 1 Thematic framework

There is main five themes as the following which were shown in the respondents' interviews over eight research questions.

1. The current state of green production in Irish pharma companies.
2. The primary drivers for implementing green production practices in Irish pharma companies.
3. The key barriers for implementing green production practices in Irish pharma companies.
4. Certain specific strategies to help the companies overcome those challenges in Irish pharma companies.
5. The recommendations for promoting and monitoring the implementation of green production in Irish pharma companies.

4.3 RESEARCH FINDINGS

4.3.1 THEME 1: CURRENT STATE OF GREEN PRODUCTION PRACTICES IN IRISH PHARMA COMPANIES

4.3.1.1 Overview of findings

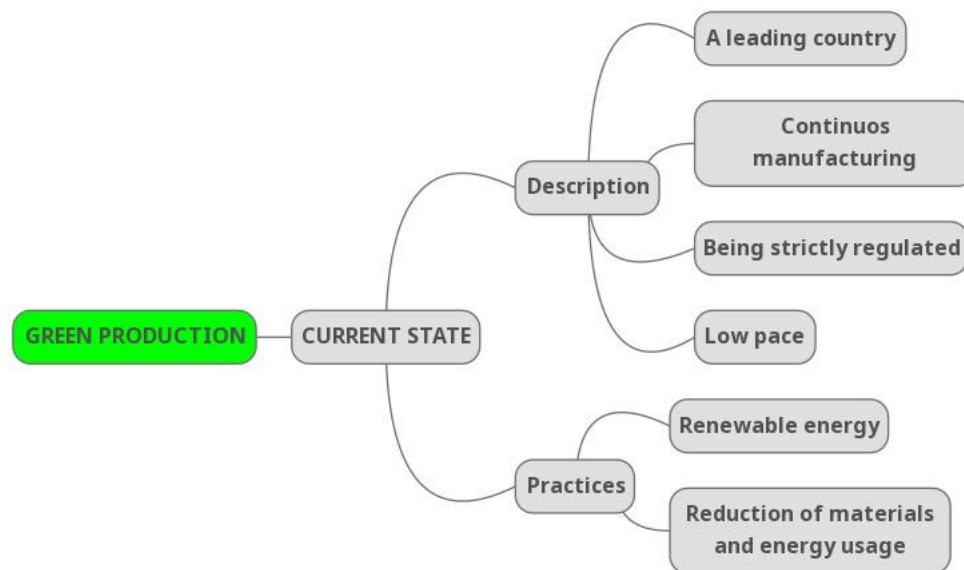


Figure 2 Thematic framework of theme 1

The following are the findings in the first theme, including the a description about current state of green production, and certain examples of green practices being implemented in the Irish pharma companies. The interviewees expressed their opinions by answering the question 1 and question 2 in the research question list.

In the sub-theme of description, Ireland is considered as one of the leading countries in the area of green practices within the EU. In the long run, the pharma companies learn themselves to adapt with environmental sustainability. However, the application of renewable energy, one of the significant green practices, is fairly low. In the meantime, ecosystem is strictly regulated and monitored by the government and regulatory bodies.

There is also certain impressive application which has been used in the industry, including energy reduction, energy generation, and material reduction.

4.3.1.2 Description and Evidence

Leading country in green production practices

According to *the interviewee 1*, there are around 37% of Irish pharma companies are categorized in class 1 and class 2 in the green production system. The classes are classified by the Industrial Development Agency (IDA) Ireland. As the IDA Ireland

statement, class 1 of green production system belongs to the regeneration system while class 2 is for those companies using a partner to help recover and reduce their energy usage.

Interviewee 1: “Ireland is one of the leading countries that is trying to use alternative methods and reduce its reliance on fossil fuels and other carbon intensive energy production industries”.

Continuous manufacturing in Biopharma industry.

In the biopharmaceutical production, **the interviewee 2** has stated that the biopharma industry “learn itself to sustainability”, “we can be done Sustainability of materials, sustainability of energy or water conservation, minimizing the footprint of our cleanrooms, reducing the energy consumption of our HVAC systems. Water is very hard, it is very expensive to produce and purify and generate, store, and distribute”. Giving the general comments about the biopharma industry, he said: “The biopharma industry is clean because it's aqueous processing. We do not use much of chemicals. Nowadays, the industry has drifted away from chemical processing. Cell biological processing which is using mostly aqueous material instead of chemicals.”

The interviewee 2 is also saying the green production practices are not a problem to the biopharma industry since “fortunately, the biological industry is all water-based. Therefore, it turns the industry into more environmentally friendly”.

The only concern in biopharma industry is the huge need of single-use plastic bags which is very essential in prevention of cross-contamination between multiple products. The reason can be due to toxicity purposes or using live viruses for gene therapies. However, wastewater treatment is seriously needed a strong attention because of genetically modified organisms (GMOs) or different strains of viruses which can damage groundwater.

Being strictly regulated

There are certain regulatory initiatives, including Environmental Protection Agency (EPA), Health Safety Authority (HSA) and other local councils and governing bodies, who are monitoring and regulating the companies’ activities whether those activities are badly affective to the ecosystem. Recently, the pharma companies must operate

and follow the green manufacturing, which is one of the legal requirements, as saying “there is a real change now in a swing from companies from doing what they should do to doing what they have to do”, added ***the interviewee 1***.

Low pace

Come into the fourth sub-theme of low pace, ***the interviewee 4*** stated “Ireland is probably average compared to other countries because the application of renewable energy within the pharma sector is pretty low”. Moreover, the awareness of green production in the Irish industry is changing with the low pace. One of the reasons explained by the ***interviewee 4*** is “the bureaucracy of government for policy change takes a lot of time”, he said: “We’re good in the concept and what we want to do lower on what we have actually executed so far” while Ireland is ranked the third manufacturer and exported of pharmaceutical products globally.

Renewable energy

From the ***interviewee 1***, the application of renewable energy is one of the practices being implemented in green production projects. For instance, MSD installs solar panels which is pulling off the actual grid from burning fossil fuels. At Johnson and Johnson, wind turbine application which is in conjunction with local houses to produce electricity. There are two basic ways of green energy, including wind energy and solar energy. Among them, wind energy is more preferred in Ireland than the solar one due to the weather conditions.

Takeda is one of the examples of green production practices shown in the certain projects.

“Takeda is taking a very strong approach and drive towards green manufacturing and sustainability. Takeda is one of the leaders in pharmaceutical in terms of driving green manufacturing. Currently, Takeda uses only green energy, green certified energy, no waste to landfill, all air emissions are scrubbed and cleaned. Moreover, Takeda has a single licensed emissions which are managed or issued by EPA. The target of Takeda is to achieve the whole site to be carbon neutral by 2035. Soon, the company aims to be net neutral and carbon footprint by 2025” – ***the interviewee 3***

Reduction of material and energy usage

Most of the interviewees agree with the fact that waste and single-use plastics should be reduced. There should be recycle plans for plastic bags in various ways.

In the packaging line, **the interviewee 1** said: “electronic patient information leaflets can be transformed from physical paper to online forms. It helps to reduce the huge amount of paper in the industry”. Moreover, in the packaging steps, the cooperation of sustainable suppliers who are adequately tested and ethically sourced, is essential in the green production practices.

Not only does the materials need to be reduced, but the energy usage is also recommended to limitation, including water, gas, and electricity. With the idea of “less water in less water out”. There are number of projects run aiming to reuse and reduce water. “For example, waterless urinals. Measuring the supplied and used water to know where water is being used or wasted” – said **the interviewee 3**. For electricity, the energy efficient equipment is purchased and installed in the operating lines. Furthermore, **the interviewee 3** also responded: “Application of gas is minimized as it generates a significant carbon footprint. Hence, gas is replaced by electricity utilized for electrical boilers instead of gas boilers”.

Waste treatment

In the interview, **the interviewee 1** shared an example from Veolia Ireland, “waste manufacturers apply the new techniques to recycle and reuse solvents”. There are other different treatments of the disposals, including liquids, solids, and gases.

As **the interviewee 3** said “liquid wastes must be processed, cleaned or sent for incineration or neutralized. Solid wastes are not acceptable to landfill which is dramatically expensive and bad for environment. Similarly, gas emission must be treated to ensure that pollution will not happen, or the local floor is not damaged.”

In term of waste treatment in biopharma industry, **the interviewee 2** said “it is mainly aqueous waste or the biomass from bioreactors where the mammalian cells or bacterial cells are either transfected or genetically modified. However, the cells must be chemically inactivated prior to discharge to a waste treatment plants. Hence, the waste itself is proteinaceous which has no harm to natural habitants or human beings. Similarly, all the viruses must be inactivated or killed before discharging to the waste plants. Other source of waste is boxes from raw materials. However, those boxes shall

be recycled. Another biggest issue is single used plastic bags which are collected at the end of the process, autoclaved, and incinerated”.

4.3.1.3 Discussion

The first objective of this research is to understand the current state of implementation of green production in the Irish pharma companies which is a significant contributor to country's economy and a vital role in driving innovation and research. There is a limited knowledge in published literature about the current state of green production in the Irish pharma companies. By interviewing the professionals who working in the sector, the Irish pharma companies have comprehended their essential roles in implementation of green production to the environmental factors. The industry has developed in the positive way by shifting from the conventional methods to greener methods in the concepts of energy usage and waste treatment. Despite of developing fairly slow, the government and the pharma sector are continuously upgrading their facilities to align with the new environmental regulations generated by the environmental authorities.

In general, as mentioned in the literature review about the glimpse of green production, the IBEC strategy has been working so well by spreading their expectations to the companies. furthermore, in term of practices, the actual practices were asked in the second question. Some typical companies, including MSD and Takeda specifically, have implemented certain green applications which contribute to the green achievement in the Irish pharma sector. The up-to-date techniques are recently applied in the industry aiming to release less amount of carbon footprint which is considered as the factor contributing to the environmental degradation, including climate change, urban air pollution, toxic acid rain, and coastal acidification.

By the interviews, the Irish pharma sector has been widely conscious of green production. Although the pace is considered low, the practices are still renovated among the industry which is encouraged to keep the waste level in range, and to improve the energy usage efficiency.

4.3.2 THEME 2: THE PRIMARY DRIVERS FOR IMPLEMENTING GREEN PRODUCTION PRACTICES IN IRISH PHARMA COMPANIES.

4.3.2.1 Overview of findings

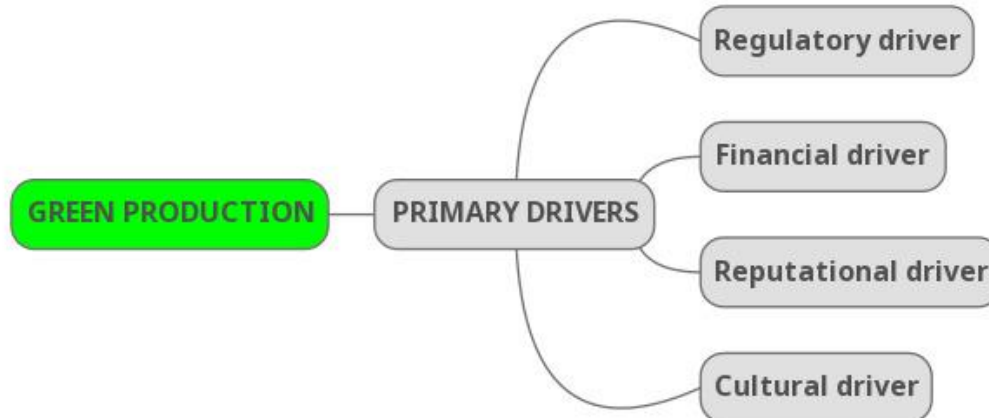


Figure 3 Thematic framework of theme 2

The next theme was researched about the primary drivers for implementing green production in the Irish pharma industry. The answers were collected and analyzed by asking the question 3 in the research question list. In the big theme of primary drivers, there are at least four sub-themes which are driving the green practices, including finance, regulation, reputation, and manpower.

4.3.2.2 Description and Evidence

Regulatory driver

First and foremost, the first pillar was mentioned about the regulation. “Waste management must be monitored and regulated”- said **the Interviewee 4**. Also, the annual reports are required to all big companies which are listed by the legislative bodies. Besides, Non-government organizations (NGOs), like Environment, social, and governance (ESG), is probably one of the biggest drivers. The NGOs start to drive activities at sites “because the pharmaceutical sector is predominantly made up of multinationals”, said **the interviewee 4**.

Moreover, the Environmental Protection Agency (EPA) has also played an essential role in the environmental policy, **the interviewee 3** mentioned: “EPA becomes more hardline and applying larger fines”. One of the sustainable aspects is sustainability of

biodiversity which is accomplished by both the regulated and unforced laws. Green carbon credits are the indicator which allow the site owners emit a certain amount of carbon dioxide or other greenhouse gases.

Financial driver

The second pillar is believed as the most significant driver which is finance. The companies apply the green practices aiming to reduce the cost while oil price is flexibly risen. **The respondent 1** said: “The benefits will be greater green credentialling. The production lines will be more sustainable in long term. By using the alternative methods, the companies will pay less tax due to the government and encourage the green regulations”. The companies must accept the fact that it will be more costly at the start, but eventually it will become cheaper overall. **The interviewee 1** assumed “the industry has a huge demand of energy grid currently. Companies that are able to generate their own electricity are able to continue to manufacture on their own because they can supply their own electricity do not get an offshore”. Additionally, the productivity is enhanced “because they had their own energy systems, they have actually been able to manufacture still 24/7” – **the interviewee 1** added

In another idea of financial driver, **the interviewee 4** supposed the regulatory driver and financial driver are going together because the companies must change to adopt the latest regulation. If the companies fail to fulfill the new requirements, they are going to get charged more. For instance, the companies are not able to put too much waste on landfill. Furthermore, saving money from electricity, gas, and water is also an extensive driver, **the interviewee 4** said “Pharma companies are heavy users of energy from electricity, gas, and water to waste. Eventually, heavy costs associated with energy consumption and waste”. Talking about renewable energy in saving cost, **the interviewee 4** revealed “The renewable energy helps to reduce costs and less dependence on national grid”.

By the respond from **the interviewee 3**, less water usage is being applied to earn the economic benefits in term of cost. “Furthermore, it is related to the cost aspect. The more sustainable methods are applied, the less energy shall be consumed. It could also mean that less waste is generated which is beneficial in term of cost”. In the long run, cost reduction can be the result from reducing waste to landfill, waste to air, waste

for incineration. Mention about the carbon credits, **the interviewee 3** stated “The earlier the companies apply green production, the more beneficial cost the companies shall earn. The reason is that many other companies saying they are green or high carbon credits without applying green production until the carbon credits dry up so that they have buy credits with the expensive cost”. Finally, **the interviewee 3** also confirmed “Those technologies are expensive to start with, but it becomes coming down, incrementally or exponentially.”

Reputational driver

Application of green production can be valuable for the reputation of the companies. **The interviewee 4** said: “Green tag is a bonus if green production practices are applied, reputation will be seen as the leading way”

The interviewee 3 also responded: “The decision-making principle called PT (patient trust), reputation, and business. Without trust, there is no business and reputation. The company believe the reputation will not be built and trust will not be earned by the patients unless the sustainable implementation is achieved”

The interviewee 1 said “Obviously, the brand reputation will be saved and more creditable on the market. However, doing so, it requires a lot of reworks to ensure the actual production systems are free from damaged, how to actually implement it, and who will be running and maintaining the system”.

Another aspect was mentioned by **the interviewee 1** was about the quality of product. The sustainability is decently crucial in the pharma sector. However, the quality of products should be a considerable to drive the green production as well. “Risk assessment should be placed before implementing the changes in the factory to ensure the quality of product is stable and complying with the original standards”.

Cultural driver

The next driver is cultural drive which places in the heritage of the companies. **The interviewee 3** expressed: “The primary driver place in the heritage, culture, and society. For example, Takeda is an international global company with a strong Japanese heritage which is value-based culture and society”. Cultural driver is also

connected to the strategy or leadership of the companies. For example, in Takeda, ***the interviewee 3*** gave the specific example of sustainable strategy, “The primary drivers place in strategy and directions of companies. For example, Takeda has three pillars including patient, people, and planet. If the planet is harmful and dangerous, patient and people will be put in high damage”. Besides, the implementation of green production is also driven by the employees in the companies because “The employment is affected by the sustainable strategy since people nowadays are more aware of environmental crisis”.

Similarly, ***the interviewee 4*** also shared his opinion “environmental awareness with employees, especially some of the younger cohort of employees, which is we tried to recruit people into the business. They’re very much more socially being environmentally aware”. He also added that leadership in renewable energy cannot be denied in green production implementation.

4.3.2.3 Discussion

After completing the second theme of primary driver, most of the interviewees agree the environmental activities are implemented, which are driven by several factors, including regulatory driver, financial driver, reputational driver, and cultural driver. The companies follow the guidance from regulatory bodies in maintaining the sustainable ecosystem and diversity. Some environmental activists and NGOs are actively working in the industrial sector to regulate the waste management and waste treatment. Therefore, force and fines are heavily applied for those who fail to comply with the regulations. Furthermore, the companies desire to save money from renewable energy while the other energy sources, like fossil fuels, become more expensive and pricier. The companies choose green production which helps them not depend on the national power suppliers. From that point of view, the production lines are made best use of time, manpower, and materials, which profoundly contribute to the sustainable supply chain for the patients in need.

The green production is not accomplished within one day, but it shall be achieved progressively which highly depends on the leadership and company culture. For example, Takada has declared themselves that environmental sustainability is one of

the targets must be included in the development strategy. From that foundation, reputation is earned not only by physical income but also the social values.

The collected data is obviously supportive to the research objective which is desired to understand why the companies must improve their own facility to adapt the requirement from the government, to put less dependence on national grid, to earn their credits from the patients, and to raise their own voices to the other companies in the environmental sustainability in the pharma sector in Ireland.

4.3.3 THEME 3: THE KEY BARRIERS FOR IMPLEMENTING GREEN PRODUCTION PRACTICES IN IRISH PHARMA COMPANIES.

4.3.3.1 Overview of findings

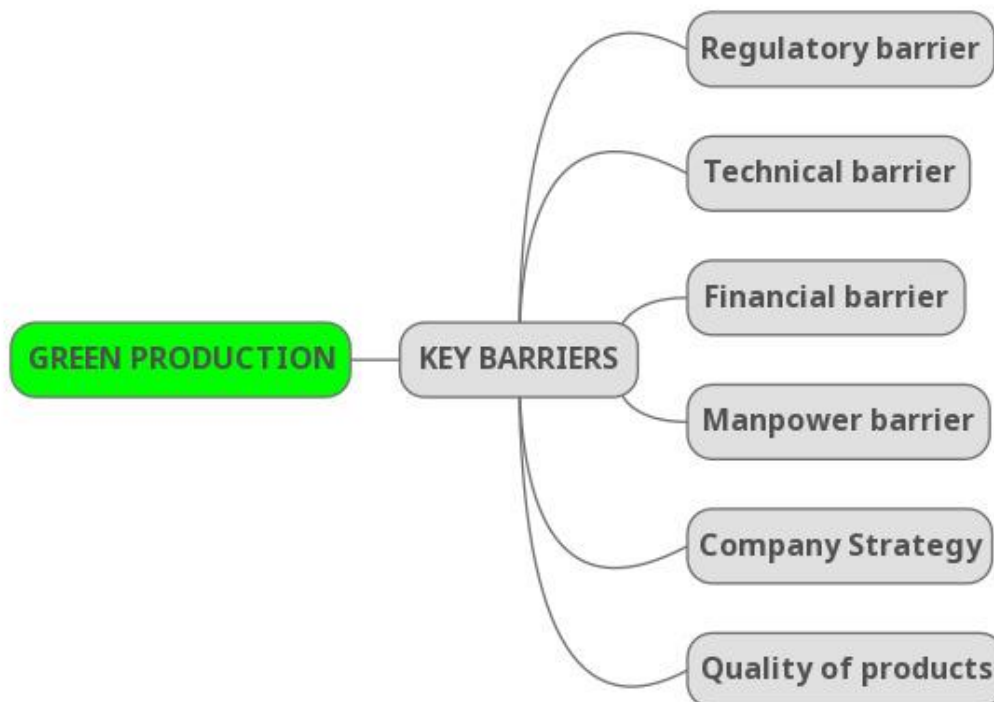


Figure 4 Thematic framework of theme 3

The next objective is key barriers which hinder the implementation of green production in the companies. When the interviewees were asked about key barriers, their answers are sorted out to at least six pillars, including regulatory barrier, financial barrier, manpower barrier, technical barrier, strategy barrier, and quality of products.

4.3.3.2 Description and Evidence

Regulatory barrier

The first sub-theme was mentioned is regulatory barrier. *The interviewee 1* stated “Barriers are new regulations”. The limitation of newly environmental regulations places in the unfair circulation among different countries within EU. For instance, “If the cost is applied only in specific countries, the pharma companies may move their sites to another country within EU to avoid the cost. It may lead to regulatory complications without generating the effective results in both natural environment and the Irish economy”. Moreover, “it is lack of green credentials and all green work is in invalidation cycles. The supranational government in EU should enforce some of these green credentials”. *The interviewee 1* added “There are some forces including carbon credits and carbon taxes. However, to change the business, the supranational government should have a common law or regulation to force the compliance of companies”. The climate change is real and global warming is obvious. However, the industry has been slowly adopting the new technologies. The more they are forced, the more they are restrained unless they have seen the tragic circumstances, like the COVID-19 which the companies quickly adopt the basis.

Also, *the interviewee 4* assumed “Government policy in Ireland has not kept pace with what the ESG need”. To move towards green production, the legislative bodies need to force the companies who are take main part in action and proceeding the green projects, “It doesn't financially need to make those changes, quite often the only time to make changes when regulation forced them to do it”.

Financial barrier

the next barrier is financial barrier. As mentioned in the primary drivers. Green production will be highly cost in the beginning. *The interviewee 3* said “In the beginning, there can be increased costs in terms of using technology and introduction of new technology, costly materials, higher cost materials to be green. Costs can be from adding new technology, training people, and educating them to use this new technology. Talking about barriers, cost is first and foremost issue in implementation of green production. In the past, the pharma companies desire to bring the medicinal products with the lower cost for their patients. However, to achieve green processes, green materials, green solvents, this creates more cost”.

Mentioned about financial barrier, ***the interviewee 4*** responded “Pharma is a little fast, I would say, the pharma companies, they make a lot of money, they make a lot of profits. And on the back of that, they're not as lean as, tech companies.”

The financial barrier does not only come from the green investment, but also place in the reworking and revalidation of the new system. For example, in the biopharma sector, “moving away from applying single plastics or disposable equipment is so challenging”, said ***the interviewee 2***.

Manpower barrier

Next, according to ***the interviewee 1***, the lack of experts in the green area is the next barrier. In the industry, the people who are working in green production are still short and the industry needs more motivation to implement the green practices.

By ***the interviewee 3***, “Barriers can be found in human mindset. People are not likely to change. Hence, if the companies decide to be more sustainable, the companies should make it easy for people to practice, not make it a burden on workers”.

Technical barrier

As some technologies are still limited which led to barriers in environmental sustainability. A specific example given by ***the interviewee 1*** about the pyrogenic testing in biopharma industry, horseshoe crab has been used as the catalyst in pyrogenic testing to see if there is a bacterial infection or bacterial contamination in their products. However, currently, there is no alternative methods to replace the actual blood of live animal. The population of horseshoe crab is in damage unless the alternative catalyst is found out. The new technology or method should be discovered to replace the conventional catalyst in the biopharma industry. Another barrier is old-fashioned machines operated in the factory spoken ***by the interviewee 5***. The old-fashioned machines are tended to utilize more energy than the modern ones. Hence, the energy-efficient tools are recommended in the operating lines.

Strategy barrier

Subsequently, green production practices are also limited by the strategy of the companies which focus on the short-term gains rather than being long-term gains, saying the **interviewee 3**.

Quality of products

The final sub-theme of key barriers is quality of products. **The interviewee 2** strongly pay attention on the quality of products instead of other factors. Talking about the single use disposal bags, he said: “single use disposable bags are barely replaceable because of prevention of cross contamination between products and batches. Other reasons will be toxicity purposes or using live viruses for gene therapies vaccine production. So, the most prioritized in terms of the facility design, and the equipment design is cross-contamination controls. So, to a very large extent, sustainability is not a key parameter in designing these facilities. 20 years ago, we probably had a more focus on sustainability for large scale manufacturing. Whereas I said biological processing nowadays, its sustainability is not really our primary consideration. Yes, maybe when we get more advanced and more experienced with the technologies, we can certainly bring sustainability or we can certainly bring, environmental innovations into our production processes. But our products are not continuous manufacturing. It's batches, small volumes, high value products. And sometimes the environment is probably our biggest cost, our cleanroom footprints, and HVAC requirements are heating, cooling or dehumidification processes. So, the environmental air within a biological facility is much larger. Cleanroom footprint and chemical processing where we do not necessarily need controlled environments and such”.

4.3.3.3 Discussion

After completing the interviews about the key barriers in green production practices, the respondents were showing their own opinions gained by real experiences. There are various reasons which hinder the green practices, including regulation, finance, manpower, techniques, company strategy, and quality of products. The green production practices can be apparently achieved in some extents. However, it is particularly ambitious for the industry to ensure the “all-green concepts”.

The company strategy plays a key role in driving the operating activities towards green production. All activities are done to support the common mission and vision. Green

production or environmental sustainability cannot be done unless the sustainability is prioritized as one of the ultimate goals in the wide horizon. For example, as the explanation of ***the interview 3***, Takeda is working hard in the pharma sector to bring a whole value to the patients who are vulnerable not only by their health conditions but also the environmental-related factors. Therefore, it is obvious to say the green production cannot be approached if the companies underestimate the significance of sustainability. The actions cannot be done unless the board of leaders have a strong intention on environmental sustainability.

As it can be seen, the driven factors are also the obstruction in green practices somehow. Every aspect has its own issue. First and foremost, the regulation is unfair or unequally applied within the Europe, creating the negative complications for the companies. The government should be engaged with the business to run the green projects to keep pace with the ESG and the business. The next one is financial barrier, cost is an undeniable factor which is required for hiring, training, and transforming from conventional methods to more energy-efficient manufacturing lines.

The most arguing factor is quality of products. It is quite questionable to put this factor in primary driver or key barrier since both ways are logical and rational. The ultimate purposes of green production are to preserve the natural habitats and protect the human life. Hence, the quality of products should be most prioritized in any changes or new concepts. It is the real challenge for the industry to come over.

As ***the interviewee 2*** saying, “the biopharma industrial technology has been developing in the single use technology which is not replaced by any alternatives to serve the purpose of environmental sustainability. It is challenging to design the multi-used plastic bag purposes. If the companies choose to clean the bags after using, the step must take a lot of water. Besides, the cleaning validation must be taken place and the potential risks are obvious”.

The sustainability can only be achieved at the certain levels. In the long run, it requires a huge effort in research and development stage to generate more replaceable methods. A particular example in the biopharma was expressed by ***the interviewee 2***. A tag question was asked “What are the potential costs and benefits associated

with implementing sustainable production practices in the Irish pharmaceutical companies?”, ***the interviewee 2*** said: “The argument places in the cost. Water supplied to clean the stainless-steel tank is more expensive in comparison with single plastic bags. Second of all, water used in biopharma is water for injection (WFI) and purified water (PW) which are highly controlled by complicatedly multiple steps including reverse osmosis or electrolyzers and others. Hence, water in biopharma industry is extremely expensive and costly. The companies are trying to cut-down cost and single use plastic bags are the currently cost-effective solution by which 10 - 20-fold quantity water the company needs”.

As the research showing, the single-use plastics have numerous negative effects on the environment, including pollution, harm to wildlife, resource depletion, landfill space, and economic cost. Whenever plastic bags are dumped, it can persist for hundreds of years (Sang, 2010). However, the potential cost and benefits are considered before starting any green projects. “Technically, single use system has its own benefits in reduction of risk about mix-ups, carry-over, and cost”- continued ***the interviewee 2***.

Unquestionably, the industry, or biopharma particularly, must comply with the minimum requirements from the locally and globally environmental regulations, but the fundamental priority in the industry is patient safety. “All actions must be decided and followed the risk management to ensure that there is no contamination happens in the final products.”, said ***the interviewee 2***. In certain circumstances, the sustainability is not a ideal option. It depends on the seriousness of the events. “For instance, in the open-heart surgery, the environment, gowns, and the materials must comply with the safety standards not sustainable concepts”, said ***the interviewee 2***. Especially, to the biopharma, most of products are injections. When the invasive medicines are made, the process has to be designed to avoid completely the introduction of impurities into the final products or semi-products. That is the primary driver not sustainability”. As the final point, “The environmental sustainability should not be declined but product quality and patient safety are more highlighted”, responded ***the interviewee 2***.

The sustainability is the vital principle which shall be driving the (bio)pharma industry. Nevertheless, there are certain issues which need to be addressed and researched to enhance the living environment. The slogan of the industry is “patient safety first”, both

factors environment and products must be integrated and mutually affected each other. The mindset of environmental sustainability should be practical at some ways. The obstacles are visible and tangible in the industry. The next theme shall be explained and clarified to understand how the industry overcome those challenges.

4.3.4 THEME 4: CERTAIN SPECIFIC STRATEGIES TO HELP THE COMPANIES OVERCOME THOSE CHALLENGES IN IRISH PHARMA COMPANIES

4.3.4.1 Overview of findings

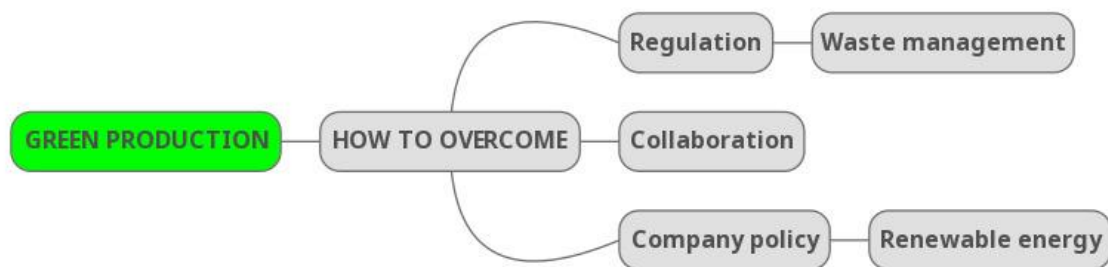


Figure 5 Thematic framework of theme 4

After successfully finding out the key barriers in green production practices, the next question was asked to the interviewees about “What specific strategies have successful green pharmaceutical companies in Ireland implemented to overcome the challenges of sustainable production practices?”. Obviously, the theme is “how to overcome” the key barriers to carry out the green production.

Similarly, through various interview, there are several sub-themes are subsequently identified during the data analysis, including, regulation, collaboration, company policy, and carrot and stick approach. These are the actual strategy recommended or practiced in the certain companies.

4.3.4.2 Description and Evidence

Regulation

In reality, *the interviewee 3* assumed: “The Irish government have done a little bit in terms of supporting sustainability. For example, SEAI (sustainable energy authority of Ireland) in Ireland provides grants for people who are retrofitting homes, retrofitting companies, becoming greener and implementing new technology within company”.

The interviewee 4 also added “Regulations must work properly while waste management protocols should be in place”.

Collaboration

The green project cannot be done by the companies alone, but “The involvement of stakeholders is a must. It should be the corporation of company, government and consultation. It's a strategy really is having a multi stakeholder, multi-agency policy, that that actually has more benefits than it has cons. The companies may liaise with the actual policymakers. For example: REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) program regulates certain chemicals in Europe”, said **the interviewee 1**.

Company policy

In the company size, the leadership is driving the entire operating strategy in the business. Since it is extremely essential, **the interviewee 3** said: “A clear set of targets and goals which must be site company wide, strict, and ambitious have indicated the companies have the well sustainable mindset”. Look at Takeda’s actual case, **the interviewee 3** said: “in Takeda, they have three scopes of emission reduction. Scope 1 and 2 are within manufacturing network while scope 3 is around the suppliers and vendors. The sustainable plan should be holistic and focused in entire areas, including water, air, solid waste, operations, transportation, people, people movement.”. The plan shall be in place and ready, which should be “very clear set of goals, timeline, and achievement”. Also, “A preparation of big budgets to support environmental sustainability should be ready in place”, said **the interviewee 3**.

The interviewee 4 also shared the common ideas. He said: “The innovation and strategy from the top management, so all companies will follow and aim to put actions in practices. The individual companies have already taken the lead and started to put green plans in practices. For example, Eli Lilly implemented a huge solar panel, wind, and solar panel farm at their sites. MSD is trying to put in solar farms”. Mentioned about the renewable energy, **the interviewee 4** said: “Certainly, the renewable energy is applied by a lot of companies who are going down that road and driving sustainable practices”.

4.3.4.3 Discussion

Within this theme, the methods applied to carry on the green production are not only dependent on the companies alone, but also it should be related from other bodies, including government, and consultant companies.

As mentioned in the previous theme, the company's strategies may focus totally on the quality of products. That would be absolutely true in some extents, however, the sustainability cannot be declined and ignored in the industry pace, which is developing with the high speed.

The environmental sustainability comes from various sources which can be simply practices in the business in several aspects, including waste management, and renewable energy. The specific green practices are recommended in the previous chapter which shows the intentional methods to be applied.

In comparison with the literature review, the company, like Takeda, has been following the green projects which are the green model for the pharma industry in Ireland. The consultants from the agencies are also valuable in green practices, which collaborate with the companies to bring the green values fulfilling the requirements from the government and environmental authorities.

These points discussed above lead to the recommendations shall be examined in the next theme which assist the companies practice green production and suggest some approaches to control and monitor the waste flows and green implementation of the companies.

4.3.5 THEME 5: THE RECOMMENDATIONS FOR PROMOTING AND MONITORING THE IMPLEMENTATION OF GREEN PRODUCTION IN IRISH PHARMA COMPANIES.

4.3.5.1 Overview of findings

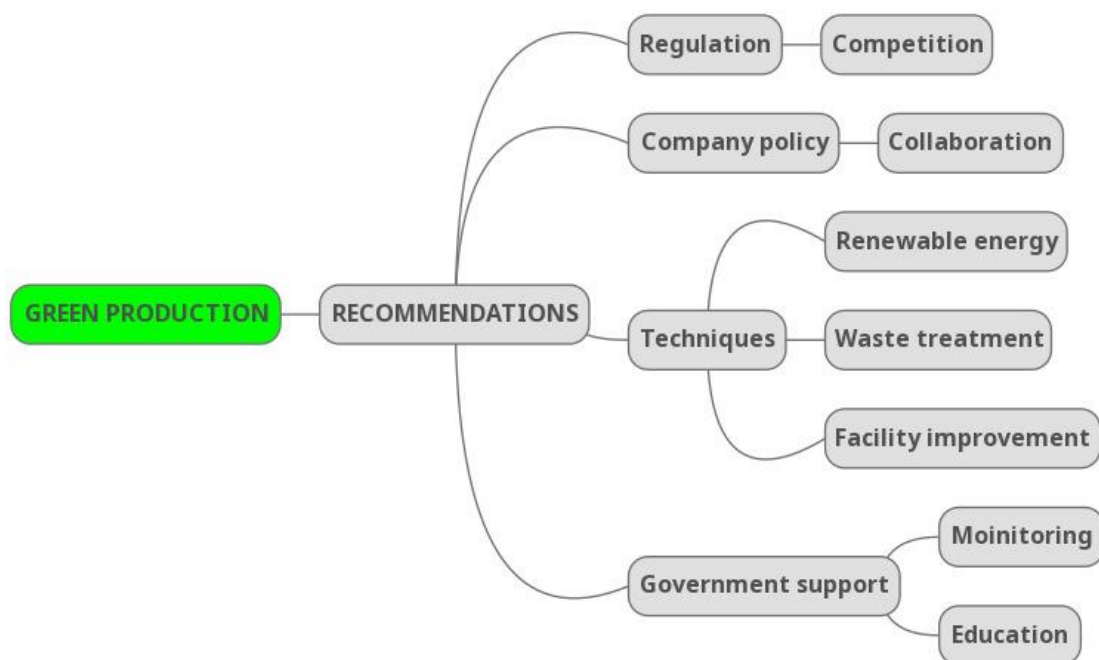


Figure 6 Thematic framework of theme 5

The final theme of this project is the recommendations for promoting and ensuring the implementation of green production in well-organized monitoring, which comply with the regulation over time. In the stage of data analysis, there are at least four themes mentioned by the interviewees, including regulation, company policy, techniques, and government support.

There were two questions were asked “What specific strategies and policies would you recommend promoting sustainable production practices in the Irish pharmaceutical companies?” and “How can these strategies and policies be effectively implemented and monitored over time?”. In general, *the interviewee 1* initially responded “In term of environmental sustainability, the initiatives must be implemented slowly and gradually. The consequences of swift application will be shortage of medicines because the companies cannot be able to implement the initiatives overnight.”

4.3.5.2 Description and Evidence

Regulation

First and foremost, the most significant factor which contributes to the successful implementation of green production is regulation. It is radical because as discussed above, regulation is the most essential driver in the green production. Therefore, all interviewees also support the fact that regulation should be in place and push the green production towards the right direction.

The interviewee 1 said: “The ban should be provided in the EU level. At the national level, it can be acceptable at some extents. However, the issue placed in the difference in law between multi-nations. For instance, to avoid being banned of single use plastics in Ireland or Germany, the companies may move their sites to France or somewhere else in EU to avoid being banned. Therefore, the law should be applied in supranational policy which establish the barrier before pharma companies’ entry within Europe. When the laws are made, it should be applicable for entire cohort but not individually as the international agreements. Otherwise, the country is just making its economy deficit and weaker”.

The interviewee 1 also responded: “the regulation should put their requirements in either mandatory or voluntary list. If it is a voluntary system, you are just slowly encouraging and promote monitoring them. It is easier way if it is mandatory because every company has to be subject to mandatory inspections. For example, in Ireland, all pharmaceutical manufacturing companies are inspected regularly by the HPRA. Or EPA, EPA monitors Sulphur dioxide gas released on a regular base and only one company. And nitrous oxide is another one. And as a few other gases that they use, companies have to raise reports and give monthly updates to the EPA. Besides, there is a mandatory system on voluntary system. Both systems of water and electricity are encouraged to use less whereby Sulphur dioxide and other gases must be in the mandatory limits which are monitored. The whitelist and blacklist of which the companies are listed down in the lists. The whitelists are used for the companies who voluntarily implement the environmental treatments while those companies who fail to monitor the mandatory limits. Because of sustainability and promotional piece on the brand damage, the companies shall try to avoid being on the blacklist. It is totally dependent on the regulator because they take the responsibility to ensure the limits are met and recorded. Similarly, to air quality, especially during the winter, mostly comes down to you have to know what it is set a limit, and maybe set a limit that is the

best in class, and then set a minimum level. And if you fall below the mean level, if it is voluntary, you're going to you could be called out, but if it is mandatory, you can actually be fined and immediately pressed or pulled back on it.”

The interviewee 3 said: “Regulatory bodies, like the EPA, who are doing their best to make sure that companies like ours are sustainable and following the rules and following the legal requirements. Green manufacturing in term of manufacturing ecosystem which is policed by regulatory bodies like EPA, Health and safety authority (HAS) and other local councils and government bodies”

The next sub-theme in the big theme of regulation is competition. There is a carrot and stick approach. As **the interviewee 3** shared: “The carrot and stick approach. Stick is to penalize and punish. Carrot is to give the companies recognition, awards, excellent green company of the year. The reward for those who implement the green project in the early state should be granted since the real consequences are planet damaged”.

Likewise, as **the interviewee 1** said: “The government applies the tax fee on pollution and reward on friendly environmental project. The more polluted disposal from the companies, the higher the tax is. The companies would like to competition especially in term of green awards. It will encourage best practices among industry”.

Company policy

Beside the requirements from the regulatory bodies, the business is recommended to put green strategy in their own “mission and vision” from which the green practices shall be carried on and practiced properly. As **the interviewee 1** responded: “For example, a device company is successful in reducing 50% the amount of packaging which is approximately around 1000 tons of carbon saved in transportation costs per year, this is the significant achievement. You are incentivizing them to move, or to adopt a new policy”.

Similarly, **the interviewee 4** strongly agreed with the influence of company policy on green production by saying: “The innovation and strategy from the top management, so all companies will follow and aim to put actions in practices. The individual companies have already taken the lead and started to put green plans in practices.

For example, Eli Lilly implemented a huge solar panel, wind, and solar panel farm at their sites. MSD is trying to put in solar farms”

Collaboration

Green production is the big project which require the huge demands of manpower and environmental bodies from other aspects. **The interviewee 2** said: “there should be good relationship with the local council and local community. Moreover, the future generation will be beneficial.”

The interviewee 3 also expressed his opinion about the role of collaboration. He said: “Cooperate with the suppliers to manage their own processes and reduce their carbon footprint. For example, Takeda is working with the suppliers to make sure that they have the specific targets in place and trying to manage their own processes and reduce carbon footprints. We are doing things like moving from air transport to sea transport, which is much more efficient, but that has some impacts and some risks. Band together and work together and learn together. Big community of pharmaceuticals in Ireland should come together and make sure they focus on sustainability together. Best practice sharing, partnering with companies which are either established or fledgling with new ideas for technology for sustainability. In production of medicines, companies tend to partner with small companies and innovate companies to produce new drugs. So, why not do the same for sustainability.”

Techniques

Renewable energy

It is the undeniable fact that “Certainly, the renewable energy is applied by a lot of companies who are going down that road and driving sustainable practices.”, said **the interviewee 3**.

Waste treatment

The interviewee 3 also mentioned about waste treatment, saying: “Waste streams of which exclusive dump and inclusive dump should be categorized. Waste management protocols should be in place.”

The interviewee 2 said: “When we were doing chemical processing, and we were handling large quantities of solvent those solvents would be mixed as part of the manufacturing process, particularly when we were separating and this decision step, we will have liquid extractions, we will be mixing a range of permissible solvents.”

Facility improvement

Talking about the facility improvement, **the interview 2** shared his experience about the impacts of cleanroom size and the facility which may help increase the energy efficiency. He said: “The next step is trying to minimize cleanroom size which contributes to the biggest energy consumption. Minimizing the cleanroom size may help in cost cutting and risk mitigation of environmental contamination. For facility equipment, the bespoke ceiling units are helpful in minimizing the need for laminar airflow. The purposes are not only getting those processes to minimize externally environmental contamination, but also to minimize the cleanroom footprints. Eventually, the costs including capital costs, operational costs, and energy costs required for the HVAC systems shall be reduced. Besides, there are certain domestic standard recycling including canteen, food waste, landscaping, and garden waste. Although the single-use technologies are applied more than ever, the amount of water is decreased by the innovations. Furthermore, the processing systems are designed closer, less dependence on HVAC system, leaner and smaller cleanroom environment.”

Government support

Mention the role of government in the green production, **the interviewee 3** said: “I think we need a much stronger drive and enforcement from from from government to start at the top. So at the top, our governments have to be supporting the drive for sustainability, but also meeting the targets that they themselves have agreed to set out as a country. That is leadership”

Monitoring

When the government participates with the business to run the green projects, the government is able to monitor the entire projects. As **the interviewee 4** said: “If the government puts money into these sorts of initiatives, they are able to track, the companies have to be full open disclosure of updates against the financial input, not

only internally but EU perspectives. When the government put money in renewable energy, how much energy usage will be shown as data captured and monitored on the implementations. Similarly, waste management and recycling plans with grant aid should be then tracked the performance over time”.

Education

Finally, education is the key in the sustainability. Discuss about this sub-theme, ***the interviewee 1*** said: “The change in public opinion in term of climate change should be made”. Likewise, ***the interviewee 1*** responded: “Education is the key and workforce on purposes. Educate internal staffs to be sustainable in their lives. Long term sustainable habit and intentional reasons to apply sustainable across the plans and across the globe as well.”

4.3.5.3 Discussion

The objective of recommendations in terms of promotion and monitoring the implementation of green production is successfully accomplished by the contribution of professionals who are actually working in the (bio)pharma sector. The findings are vastly supportive to the deep understanding of this topic. Particularly, regulation and support from the government should go hand in hand as the supervision and guidance. The pharma business should take green production or environmental sustainability serious as the climate change caused by the industry is undeniable and tangible. Education or training is also the bright points in recommendations in green production promotion. The staffs who working in the business must be aware of the green concepts. The green practices come from the little steps. There should be some green projects organized by the local authorities or the industrial zones, which aim to promote the green production to the companies in the area.

However, implementation of green production still involves several controversial. **As *the interviewee 2*** stated: “instead of practicing green production, lean six sigma or lean manufacturing should be more focused on”. It may be true in some extents. The outcomes of lean six sigma are to eliminate non-value-added activities, minimize variability, and improve the process flow. That would be certainly helpful in increasing productivity, reducing cost, and improve the quality of products. By doing so, the Lean Six Sigma also identify and eliminate waste while waste is one of the most essential

factors in pollution caused by the industry (Yadav and Desai, 2016). Hence, fairly speaking, Lean Six Sigma is extremely necessary in the industry. However, it is impossible to decline the responsibility of environmental protection. The impacts of industry to the environmental are tangible and actions are needed. In order to do it, the collaboration plays a tremendous role in the green area. As mentioned in the literature review, various environmental organizations organize numeral projects, including Corporate social responsibility (CSR) program, or the EU's 2020 Climate and Energy package. By those programs, the mindset of green production is broadly conveyed to the business, especially the Irish pharmaceutical companies, the vital role of green production in the current situation.

CHAPTER 5: CONCLUSION

5.1 OVERVIEW

This final chapter is to provide the summary of the findings which were collected from several interviews, followed by the contributions and recommendations from this research to the Irish pharmaceutical companies in green production implementations. Then, the limitations and future research shall be discussed. Finally, the research conclusion shall be presented in comparison with the earlier objectives which have been set out in the beginning.

5.2 SUMMARY OF FINDINGS

First and foremost, by interviewing with the professionals who are currently working in the (bio) pharma sector and the thematic analysis, the first objective is successfully disclosed by describing the current state of green production practices and exposing several actual practices which are being done in the industry. By describing the current state, Ireland has been one of the leading countries in the green production by several green projects run by the business. However, sustainability is a huge aspect which requires an enormous effort to adopt it. Presently, the industry has been strictly regulated by the regulatory bodies, including EPA, HAS. Although there are some achievements in green production, the industry is still in low progression. On another hand, the industry attempts the up-to-date technologies, including renewable energy, waste treatment. This would be the good signal from the industry because they learn themselves to fulfil the requirement and show the responsibility to the community and natural ecology.

Secondly, the reasons behind all green projects were also determined by answering the question “what are the primary drivers of green production”. All interviewees agree with the fact that they have to achieve green credentials because of the regulation. Fines are applied to those companies who fail to keep the environmental index in range. The regulatory bodies can be EPA, or ESG. The companies might have been asked to update the report of environmental factors periodically. Another reason for implementation of green production is financial driver, by doing so, the business may save money from the national grid. While the energy from conventional sources, like fossil fuels, has risen in price, the alternative energy brings the considerable profits for

the companies. Also, in order to earn the credits from stakeholders and customers, successful implementation of green production helps the companies earn more reputation and enhance their positions in the society and (bio) pharma market.

In the third theme, key barriers are displayed to identify the challenges of green production in the industry. There are at least six sub-themes were demonstrated among the interviews, including regulation, finance, manpower, techniques, strategy, and quality of products. The reasons behind every small sub-theme are tangible which hinder the successful of green production practices. Among them, the regulations between Ireland and Europe and supranational are not consistent, which lead to the unfair application on multiple countries. Meanwhile, the quality of products and green production are put in the dilemma situation which require the companies must choose the quality of products over the green production. For example, in the operating procedure, the use of single plastic bags is obviously compulsory in certain steps. However, it is barely to replace with alternative methods because of the technical and quality reasons. Besides, application of green practices will be highly cost in the beginning. It also depends on the strategy and culture of companies which have decided to include the environmental responsibility in their action plans or not.

In the next theme, there are some examples which are presently applied to overcome the challenges in green production practices. The first pillar was mentioned is regulation. The regulation should be provided within the EU level. The equality and fairness must be achieved before fines are applied to the companies. Moreover, the financial support from the government is also the bright point which show the importance of green production in the companies' operation. The collaboration among the stakeholders also enhances the activities within the industry. Furthermore, more and more companies aware of the significance of the green production to their business. The environmental protection becomes one of their concerns beside the quality of products. Once the strategy is set up the action plan eventually performed.

Lastly, the recommendations which are proposed by the interviewees, aiming to promote the green production and monitor it over time. There are at least 4 main pillars, including regulation, company policy, techniques, and government support. From the regulatory point of view, the regulation should be comprehensive and clearly

define whether the requirements are either mandatory or voluntarily. Also, competition should be organized to encourage the industry. This way is obviously advantageous to the company reputation if the businesses follow the green strategy, the carrot and stick approach. Furthermore, the collaboration is more focus on “band together, work together, and learn together”, said the interviewee 3. The state-of-the-art technology and equipment shall be equipped. Moreover, the government should get involved in the green practices, so that they can be able to monitor the progress with the companies over time. Finally, education is also recommended. Education is not only for students, but for staffs and workers who really working the industry, so that they might have fully aware of environmental protection in their operating lines. From that awareness, the green ideas shall become a part of strategy in the companies.

5.3 CONTRIBUTIONS AND RECOMMENDATIONS

The current study has been explored the challenges of green production in Irish pharmaceutical companies. Ireland has the fast development in pharma sector, but the deep understand about the green production is still limited. This area of green production is not optimally discussed recently. It is really difficult to find out article discuss about green production. Thanks to the interview and thematic analysis of this topic, the green production practices in Ireland has been revealed and the current situation is very clear. The research contributes to the knowledge and awareness of those who are regulating and working in this area. From that point, the main stakeholders, including regulatory bodies, companies, and patients, have a general point of view of the importance of environmental sustainability while the industry has been swiftly developing.

The following are recommendations of the study. First of all, it is necessary to cooperate in the regulatory bodies in the area. Not only does Ireland apply, but the countries within EU must comply with the specific requirements in environmental sustainability. Next, the companies should put a huge effort on driving the company strategy towards green production by introducing alternative methods and technologies which stimulate energy efficient use, and less disposals. Following, the involvement of government is certainly required. The support may come from financial support to technical consultancy from the environmental specialists. Lastly, the quality

of products cannot be declined, but the importance of green sustainability is also compulsory in the long run. Therefore, the companies have responsibility to apply green production in many ways and many methods to ensure the continual manufacturing and environmental protection.

5.4 LIMITATIONS AND FUTURE RESEARCH

Although there are no specific rules for sampling plan for the thematic analysis, it is quite limited number of participants. Five professionals were asked all questions, but only four people are able to provide very deep insight about their opinions.

On another hand, there are several future research on green production in the Irish pharma industry. First of all, life cycle assessment (LCA) of medicinal products is the topic which is used to assess the environmental factors of a product throughout its life cycle. The life cycle initiates from raw materials to disposals. This project may help the companies identify the methods to reduce environmental impacts from which some green chemistry principles, energy-efficient manufacturing processes can be applied to mitigate those negative impacts. Furthermore, assessment of green chemistry practices is also the potential areas in green production. Green chemistry focuses on the design of chemical processes which help reducing the production of hazardous substances. The investigation of adoption and effectiveness of green chemistry practices in the Irish pharmaceutical companies. Finally, the analysis of consumer behaviours towards the environmentally friendly medicinal products. By running the quantitative analytical method, the research shall disclose the customer behaviours in willingness of paying eco-labelling schemes, and potential barriers in green transformation.

5.5 CONCLUSION

The original objectives from this research have been revealed. The current state of green production practices in the Irish pharma companies was explained and explored by the contribution of the interviewees who actually working in the sector. Besides, certain factors which has been driving the companies adopting the green production are discovered. However, most primary drivers are also the key barriers which hinder the implementation of green production. Thanks to the information gathered from the

interviewees, numerous practices are recommended to push the industry towards greener practices. In my opinion, pharma industry should be the pioneer of green production as the ultimate purpose of healthcare system is to bring the good medical conditions to the patients. The environmental impacts play a vital role in keeping the community good health for people and sustainability for the business. Therefore, the immediate actions should not be underestimated but taken seriously and acted upon abruptly.

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