Is the Irish Pharmaceutical Industry Prepared for the Future of Water Use in Ireland?

By

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DECLARATION

I, Deirdre M Cournane, declare that this thesis has been composed solely by myself and that it has not been submitted, in whole or in part, in any previous application for a degree or professional qualification. Except where stated otherwise by reference or acknowledgement, the work presented is entirely my own.

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ABSTRACT

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In this study the Irish pharmaceutical industry was assessed as being in a state of preparedness for implementation of water sustainability strategies.

Water use by industrial sites is at a transitionary phase. Global climate change, new legislative requirements, and the continuing pressures of faster production are all impacting water use. Sustainable use of water is a holistic stakeholder-inclusive process, which is balanced from a social and cultural viewpoint. It benefits both the environment and economy. The main study objective was to evaluate the preparedness of the Irish pharmaceutical industry in adoption of water sustainability practices and to identify the critical success factors which may be recommended for the industry.

Through an exploratory quantitative and qualitative mixed methods approach aligned with an interpretivist research philosophy, primary data was collected from participants who were purposively selected from a homogenous sampling pool. This consisted of those directly employed in the pharmaceutical industry. Primary data produced from this study highlighted that there were good levels of, understanding of what water sustainability means; support from senior management; and diverse sustainability strategies employed at the surveyed sites.

Dissatisfaction with the current incentive structures by government was also found. These incentives are necessary to build greater awareness of, and the benefits to, water sustainability, and to develop an enabling environment. The biggest challenges and barriers experienced by these sites were capital investment, industry knowledge and understanding of the sustainability concept, and resources at the site.

Critical success factors were identified as the *understanding of the concept* of water sustainability, which encompasses the water lifecycle both in- and out-side the site, and *engagement with peers and regulatory bodies* to facilitate education, training, and peer-to-peer learning in a stakeholder enabled-environment.

This study's conclusive determination was the Irish pharmaceutical industry is well placed for implementation of water sustainability practices, but that concerns remain regarding financial investment and increased understanding of the concept across the industry. Further research is necessary to address the shortfalls of the incentivization structure from government and to understand how challenges within the industry may be overcome to increase wider uptake of water sustainability strategies.

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Chapter 1

Introduction

1.1 Background of Study

Water is one of the most fundamentally precious resources on the planet. At COP 27 the criticality of water and its impact to the environment was one of the main topics of discussion (UNFCCC, 2023). The current global water situation outlined by (United Nations Climate Change, 2021) indicates that by 2050, 52 per cent of the global population will be living in regions of water-scarcity.

Within the pharmaceutical and biopharmaceutical (hereafter in this report referred together as pharmaceutical) industries in Ireland the use of water is critical to the manufacture and production of human and veterinary medicinal products and devices. This industry is required to treat potable water to a higher purity level. In 2021 the Irish pharmaceutical industry was worth more than 74 billion to the Irish economy (Central Statistics Office, Ireland, 2023). Therefore, any risk to business in this industry pose an economic threat to Ireland.

Ireland is legally required under the European Commission's Water Framework Directive to protect and restore water quality across Europe and does this through the River Basin Management Plan (RBMP). The current structure of water governance in Ireland evolved to encompass multi-disciplinary agencies whose roles vary in principle (Department of Housing, Planning and Local Government, 2021). These are:

- **An Foram Uisce**: statutory body who advises the Minister for Housing, Local Government, and Heritage on water policy, management and governance.
- **Water Policy Advisory Committee (WPAC)**: guide high-level policy and oversight of the river basin management plan.
- **National Coordination and Management Committee (NCMC)**: advises the WPAC on future policy needs and manages overall program delivery addressing obstacles.
- **National Technical Implementation Group**: implements the river basin management plan at national level, addressing operational barriers, and a forum for information sharing.
- **Environmental Protection Agency**: national coordination and oversight of the Water Framework Directive and statutory responsibility for reporting Irelands' progress to the European Commission.

- **Local Authority Waters Program (LAWPRO)**: shared initiative comprised of Ireland's five regional local authorities who coordinate water policy at local level.
- **Uisce Eireann**: no management function but whose responsibility is to deliver water services to domestic and non-domestic customers in Ireland.
- **Water Stewardship Ireland**: as is the case with Uisce Eireann no management function, but is a voluntary, industry-led network of more than 300 large water users who work together to develop and maintain good water management practices in operations; including peer-to-peer engagement, programs/innovations for water sustainability, and certification.

This governance structure a coordinated response of the RBMP (O'Riordan *et al.*, 2022).

Many challenges exist which impact the supply of water to the Irish pharmaceutical industry, not limited to geographic location, scale of local demand, and water infrastructure as described by (Byrne *et al.*, 2019). Therefore, to future-proof the supply, treatment, use and possible reuse, of water in the Irish pharmaceutical industry, mitigation strategies need to be employed at local, industrial, and government levels (Stockil *et al.*, 2018). The focus of this research study is on the current state of water sustainability practices by pharmaceutical sites in Ireland. The research topic impacts all pharmaceutical companies in Ireland as they all use water to some capacity in the production of medicinal and veterinary products. Therefore, reducing the risk to their water supply is critical to maintain production output. There are also additional positive impacts to the company such as achieving water targets set out in environmental, social and governance (ESG) policies and perceived public perception. One of the objectives of this research study is to identify the critical success factors which sites may use as a benchmark for successful implementation of water sustainability practices.

Gaps in the literature involve a lack of water data in Ireland and a lack of regulatory oversight of water sustainability strategies employed across sites as mentioned by both (Stockil *et al.*, 2018) and (Byrne *et al.*, 2019).

The incentive structures in place by government to promote adoption of water sustainability strategies may not be sufficient for the industry. It may be hypothesized that the financial incentives in the form of grant and funding support may not meet current costs. There may be a lack of awareness within the industry of the education and training initiatives which are in place, or lack of participation in national award programs aimed at showcasing water sustainability practices.

1.2 Research Purpose

The aim of the research study is to evaluate the preparedness of the Irish pharmaceutical industry in adoption of water sustainability strategies, specifically the infrastructure and practices currently in place and to identify the critical success factors which may be used as recommendations for the industry. Current challenges identified by industry personnel will be examined to ascertain if there are barriers to implementation.

To assess the current landscape of the pharmaceutical industry, study participants will include those working within pharmaceutical sites who are involved in water management as these represent a key source of primary insight into the research topic. Literature is explored to understand the extent of water sustainability practices in Irish industry, the level of regulatory engagement here, and whether frameworks or policies are in place to promote practices. Through qualitative and quantitative research, the specific issues and challenges of water sustainability will be investigated, and the status of the industry will be evaluated to determine critical success factors.

1.3 Research Objectives

The research objectives of this study are as follows:

1) Identify what infrastructure and water sustainability practices are in place by the Irish pharmaceutical industry.
2) Evaluate if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites.
3) Identify the challenges and barriers professionals within the pharmaceutical industry are experiencing in relation to implementing water sustainability strategies at their sites.
4) Considering all the above, identify the critical success factors, and thus recommendations, which sites can use as a benchmark for implementation of future water sustainability strategies.

1.4 Justification of the Study

This research is undertaken to explore the current industrial landscape regarding water sustainability practices by Irish pharmaceutical sites. Risks to business continuity within this industry needs to be mitigated with appropriate strategies at site, industrial and governmental level. The continuous supply of water to the pharmaceutical industry is a threat identified across literature.

Though it may be argued that Ireland has an abundance of water sources, climate change, aging infrastructure, and expanding populations are all contributing to increase the risk associated with the safe continuous supply of water. Water and energy are intrinsically linked. This water: energy relationship is best illustrated by a “water footprint”. Thus, to ascertain if the industry appreciates this co-dependent relationship, this study will identify if sites are actively establishing their water footprint, and what infrastructure and practices they are implementing.

Drivers to initiate new strategies at any commercial enterprise usually involve financial incentives. The literature shows that by implementing water sustainability strategies a site may save millions of cubic litres of water and make operational savings. This study will seek out the current challenges and barriers that industry professionals are experiencing and whether the role of Irish regulatory bodies is having a positive impact to the uptake of water sustainability strategies.

For an industry to fully embrace strategic management of a shared resource, like water, there needs to be effective adoption by all stakeholders within the industry of best available technologies and management policies. It is the intent of this study to provide a snapshot of current trends, activities, and attitudes within the Irish pharmaceutical industry to ascertain if changes concerning water sustainability are occurring. The study also aims to identify recommendations for industry to use for implementation of future water sustainability strategies.

1.5 Structure of the Study

Chapter 1 is the introductory chapter and provides a brief background of the topic of water sustainability and water as a scarce resource. The purpose for the study is explored in the research questions asked, the objectives and justification of the research, and the structure of the dissertation.

Chapter 2 follows next comprising of a literature review discussing the pharmaceutical industry in Ireland, and the topic of water use within this industry. A critical review of topic areas such as Water as a Scarce Resource, the Association between Water and Energy, the Drivers for Water Reuse, and the Impacts of an Efficient Water Management Strategy is undertaken. Key findings from each topic area and gaps in the available literature enable a conclusion of the review to be drawn. This conclusion establishes the study objectives and their justification. Finally, a conceptual framework is included.

Chapter 3 details the mixed-methods approach used, the interpretivist philosophy chosen, and the exploratory nature of the strategy. The purposive sampling method is discussed and justified. Participants were selected with purpose and represented those with experience in management of water or site at a pharmaceutical facility. Methods of analysis for quantitative and qualitative data are included. Details of how validity and reliability was incorporated into the study by use of a pilot test is explained, as well as the ethical considerations.

Chapter 4 contains an evaluation of the results obtained from the study methodologies and links to the research objectives. Thematic analysis is applied to detect themes arising from the interviews and from qualitative responses of the online survey. A discussion of the findings and insights is included at the end. Links are made to secondary review findings and correlations are highlighted between primary and secondary research data.

Chapter 5 contains the conclusions of the study considering the findings of the primary data and linking them to findings of the secondary research. How the study conclusions relate to the gaps in the research is mentioned. The critical success factors identified from the primary research are outlined, including the impact they may have as recommendations for the industry. The limitations of the study are briefly mentioned and some recommendations for future study in this topic area are included.

Chapter 2

Literature Review

2.1 Introduction

This chapter outlines the topics that are relevant to the subject area of water sustainability in the Irish pharmaceutical industry and goes on to explore the relevant literature to allow objectives for the study to be drawn. The research topics explored are an overview of the Pharmaceutical Industry in Ireland such that an understanding of the scale and impact this industry has to the Irish economy may be garnered. This will give the reader an appreciation of how important an industry it is to Ireland and lay the foundation which supports the study aim of providing a "snapshot" of the current industrial situation. The important role water plays in the production of human and veterinary medicines is briefly explained, which leads into the concept of water as a scarce resource.

There is much literature globally concerning the scarcity of water, as drought conditions and climate change exacerbate many areas around the world. In Ireland, the general assumption is that we are water rich. However, literature from the Environmental Protection Agency and Uisce Eireann verify that water in Ireland is a commodity which requires additional protection. The public perception of water conservation is in its infancy in many ways, with public information programs underway to promote a wiser use of water including conservation, as detailed in (Uisce Eireann, 2023) and (Rolston, 2020).

It is recognised that industries in Ireland also have a role to play in protecting water in Ireland. The pharmaceutical industry is considered an obvious choice in instigating change at an industrial level, as described by (Byrne *et al.*, 2019). Discovering if the Irish pharmaceutical industry sees water as a scarce resource or of high value will identify whether this is a driver for implementation of water sustainability strategies. This links to the research objective of identifying the infrastructure and practices currently in place by the industry. It also links to the research objective of evaluating the role of regulatory bodies to promote uptake of strategies across the industry. Regulatory bodies need to ensure there is widespread industry understanding of the high value of water.

Going deeper into the subject of water in industry the topic of water and energy is explored. The concept of the water: energy relationship is considered in terms of a "water footprint". Using this information, energy inputs along the chain may be calculated to understand the amount of energy being consumed (or generated) in the water system at

the site. This topic area links to the overall aim of gaining a “snapshot” of the pharmaceutical industry and what strategies are being implemented.

The drivers for implementation by Irish pharmaceutical sites are next investigated. Reasons related to saving of operational costs and meeting goals set in Environmental, Social and Governance (ESG) policies are all documented in literature as the main drivers for water sustainability. This topic area ties in with the research objective of evaluating the role Irish regulatory bodies play in harnessing these drivers to promote adoption of strategies.

The last topic area discussed is the Impact of an Efficient Water Management Strategy and how this benefits a pharmaceutical firm in an economic, environmental, competitiveness, and reduced pricing perspective. Understanding this topic area connects the research objectives of identifying the current water sustainability practices in place by Irish sites and determining the specific challenges and barriers currently being experienced by professionals in the industry. This will enable identification of critical success factors for implementation of water sustainability strategies and may lead to recommendations for industry.

Key findings of the literature are then discussed followed by identification of gaps in the research, and finally the conceptual framework of the study is included.

2.2 Pharmaceutical Industry in Ireland

The pharmaceutical industry in Ireland is the third largest exporter of pharmaceuticals in the world according to the UN International Trade Statistics database (IDA Ireland, 2023), and the third largest in the EU in 2021 with exports worth 38 billion (Engineers Ireland, 2022). There are over 60,000 people employed here in the industry across approximately 120 companies: including 9 of the 10 largest pharmaceutical companies in the world (Innopharma, 2023). Ireland is also the largest medical technology employer in Europe. Ireland’s ability to attract pharmaceutical companies may be accredited to its 12.5 per cent corporation tax rate, the 25 per cent research and development tax credit scheme, a well-educated and highly skilled workforce with approximately 65 per cent of those employed having a tertiary qualification, access to the whole of the EU for labour pool, and our physical proximity to major European markets as well as the US, with short-haul flights possible in both directions (McCall, 2020).

It was worth 58 billion in 2021 (Central Statistics Office, Ireland, 2022) and between January and November 2022 garnered export sales in excess of 74 billion (Central Statistics Office, Ireland, 2023). Therefore, it is important for the Irish government to ensure that the appropriate resources and infrastructure required by this industry meet capacity requirements and are future-proofed to allow for continued growth in this industry.

Water in the pharmaceutical industry is a raw material and is the most used excipient in medicinal products. There are three quality grades of water used in this industry: water-for-injection (WFI), purified water, and water for preparation of herbal drug extracts. WFI, a high-purity water, is added during manufacture of active substances and at final formulation (EC, 2018).

Water is of vital importance to the pharmaceutical industry as both a raw material and in cleaning processes of equipment, laboratory, and manufacturing areas. Water in Ireland may not be considered a scarce resource, however the security of supply here is a matter of importance. As attested by (Byrne *et al.*, 2019) and (Stockil *et al.*, 2018) the lack of water data available for the pharmaceutical industry effects the level of prioritization the topic is receiving across this industry. Before the establishment of Uisce Éireann, Irelands national water utility in 2013, water services were provided by Local Authorities. A report by (Uisce Eireann, 2021) describes how ongoing collation of this data into a centralized system is required to facilitate understanding of water usage in Ireland by both domestic and non-domestic users. Uisce Eireann have identified this ongoing data collation, and the addition of more current data as vital to development of a strategic water framework for Ireland. As described by (Smart Water Magazine, 2021) water charges exist for the non-domestic sector in Ireland, which includes the pharmaceutical industry, however the charges here are minimal in comparison to other European countries. (Walsh *et al.*, 2015) discussed how excessive water use may not have the same financial penalties in the pharmaceutical industry as it does in commercial and retail businesses. Therefore, the incentive to conserve water in the pharmaceutical industry may be low. However, this may soon change, as Uisce Éireann and the Commission for Regulation of Utilities are preparing proposals to government for increases to water charges for non-domestic users and aim for full cost recovery as described in (Uisce Eireann, 2015). (Murray *et al.*, 2010) referenced Irelands need to adopt full cost recovery as they currently have in countries like Germany and Denmark.

Even though water charges here may be low, the pharmaceutical industry does contribute to water treatment prior to discharge; therefore, a significant financial cost is

associated with the amount of water consumed. Unlike water data, energy data is much more readily available for the pharmaceutical industry as it involves a much larger industry and is a more obvious financial onus to the pharmaceutical firm, as discussed by (Trubetskaya *et al.*, 2021). Many company websites such as (Eli Lilly, 2022) and (Pfizer, 2021a) indicate that globally they are now establishing commitments to improve water efficiencies. By the end of 2025, Regeneron is implementing a global water mapping strategy and water stewardship program at all its locations (Regeneron, 2021). A paper by Engineers Ireland (Sheehan, 2021) indicates that there is agreement in the industry that water sustainability practices are important to business and some in the industry are instigating change at site level. At the time of writing, there is little evidence in literature that the Irish pharmaceutical industry is specifically being evaluated for implementation of water sustainability practices.

2.3 Water as a Scarce Resource

Nowadays it is widely accepted that water is becoming a scarce resource globally and needs to be protected (United Nations, 2023) (UNICEF, 2023) (American Geosciences Institute, 2016). Water is considered scarce when the demand for water exceeds supply. A report by McKinsey called “Charting our Water Future” (Addams *et al.*, 2009) concurs the publications of the UN and gives a stark overview of the current global water situation. The paper predicts that by 2030, based on current trends in demand and assuming no gains are achieved in efficiency, water supply will have a shortfall of 40 per cent. The report outlines the value chain of water and how the identification and engagement of key stakeholders plays a major part in how we tackle the issue of water conservation at a governmental, industrial, and corporate level. The concept of engaging all stakeholders is a common theme found in the literature.

Globally many companies are recognising water as a risk to business continuity (Pfizer, 2021b) (Regeneron, 2021) (Eli Lilly, 2022) and are including water usage in their environmental policies (Stockil *et al.*, 2018). The types of water projects being implemented may take years to see efficiency gains and cost reductions for the company (GE Healthcare, 2007). In Ireland water may not be considered scarce, especially as we receive a substantial annual rainfall with most of the public water supply (approximately 83 per cent) coming from surface sources like rivers, lakes, and streams (Uisce Eireann, 2021). However, the concept of water scarcity is a relative one. As supply and demand fluctuates this has an impact on the amount of water which may be physically accessed

at any time. Water scarcity will therefore intensify as demand increases and/or if the decreasing quality or quantity of water affects supply.

Existing infrastructure of our water system here must also be considered. According to (Rolston, 2020) approximately 43 per cent of all water provided by Uisce Eireann is lost due to leakages. The report by (Uisce Eireann, 2018) clearly agrees, and details how currently they are in the process of upgrading water systems and replacing old, damaged, or obsolete infrastructure with a planned investment of 6.1 billion. Uisce Éireann estimates that up to 30 per cent of water treatment sites here are “at risk” of failure in quality parameters and that many of the water systems here do not meet drinking water standards (Uisce Eireann, 2015). Two of Irelands largest cities, Dublin, and Cork, still rely on nineteenth century piping systems which are no longer fit for purpose. This report by (Uisce Eireann, 2023) describes how the supply of water to Dublin County is of concern as currently there are only three sources of water supplying this region with an extreme reliance, approximately 85 per cent, on the river Liffey for potable water. Uisce Eireann has said that meeting capacity requirements in Dublin County including sufficient headroom (available capacity over current demand) is an issue with growth in population.

Often pharmaceutical companies are concentrated in certain areas of Ireland such as Cork harbour and Dublin County – this will consequently increase the concentration of pharmaceutical contaminants present in wastewater, which will exacerbate local wastewater treatment plants. Treatment to maintain quality standards will undoubtably put additional pressure on availability of supply at given times, according to (Miarov *et al.*, 2020).

(Gleeson *et al.*, 2013) discuss how future climate change in Ireland predict that winters will become wetter and summers drier, and that changes in precipitation will likely have significant impacts on catchment areas. This is likely to impact future water supply in Ireland at certain times of the year. (O Connor, 2020) discusses water usage in the Irish dairy industry as an important comparator industry for modelling purposes when addressing the need for value stream mapping of water use, real-time measurement of water data, and incorporating different technologies at site level to address water management strategies. (Trubetskaya *et al.*, 2021) similarly discusses how the dairy industry like the pharmaceutical industry consumes a significant amount of water. Both previous citations discuss how successful water management in the agricultural industry

may serve to educate and promote uptake of water sustainability practices by other industries.

There are many challenges facing the pharmaceutical industry for implementation of water sustainability practices. The poor infrastructure currently supplying water in Ireland is a major challenge to the industry, as is the capital investment required at the site. However, one prevalent theme in the literature is that water is fast becoming a scarce resource, and that industries need to take proactive and effective steps to manage that resource.

2.4 Association between Water and Energy

According to a 2016 Special Report the amount of energy needed by the water sector is expected to double in the next 25 years as per (World Energy Outlook, 2016). This is mostly due to increased reliance on desalination of water sources due to growing demand for fresh water, climate change effects on available freshwater sources, and growing global populations. This report estimates the water sector uses approximately 4 per cent of the total electricity produced globally. A critical aspect to address when discussing water conservation is the concept of the water-energy nexus. This is the co-dependency of energy and water, for the generation of the former and the treatment and distribution of the latter (Walsh *et al.*, 2015). The water sector is estimated to use approximately 25 per cent of its total electricity use in the treatment of water (United Nations Climate Change, 2021). The energy required for water processing depends on variables such as the type of water required, the quality of the source water, and the location of the water (distribution to site).

The pharmaceutical industry uses processes such as filtration, reverse osmosis, ultraviolet radiation and ozonation to treat potable (drinkable) water to become a higher purity water for internal distribution at the site in closed-loop networks (World Health Organisation, 2021). This is both expensive and labour intensive, consuming a lot of energy and time. Although some cleaning and sanitization processes at the site require a lower standard of water, these processes still require a final rinse with high-grade water. Steam made from high-purity water is also used across the pharmaceutical site for sanitization of equipment, infrastructure, and at final product fill. Production of steam using high grade water is extremely energy intensive and consequently expensive.

The pharmaceutical industry also needs to meet certain regulatory requirements for its standard of water (EC, 2018) (FDA, 1986). Therefore, it is important for the industry to understand where energy use is imbedded in the value stream and to consciously look across the whole water system. This will allow the site to calculate what is referred to as a “water footprint”. A water footprint is defined as the total volume of fresh water used to produce the goods or services consumed by the pharmaceutical site and includes all aspects of the business (ISO, 2014). Using lifecycle assessment tools, a pharmaceutical site may consider both direct and indirect uses of water to calculate a water footprint.

(Trubetskaya *et al.*, 2021) explains how pumping and distribution of water is estimated to use approximately 80 to 85 per cent of the total amount of energy of the water sector. By challenging its water footprint, a pharmaceutical site can identify the areas where they can reduce the energy impact in their water value stream and identify key areas to integrate new technologies for water minimizations, reclamation, reduction, and reuse strategies. As agreed by (Trubetskaya *et al.*, 2021) and (Voulvoulis, 2018) the long-term goal for an industrial site, including pharmaceutical, would be to improve the energy efficiencies in their water footprint (specifically targeting the pumping system and steam production), increasing their use of renewable energy sources on-site such as solar and wind, and recirculation of treated wastewater at the site. Energy intensity reductions would lead to lower costs for the site, reduction of pressure at source for local water providers, and help the site to meets its own environmental goals.

A key target of the Irish Government is a reduction on overall carbon emissions in Ireland by 2050 (Department of the Environment, Climate and Communications, 2020b). This reduction in carbon emissions follows the requirements imposed by the European Union (EC, 2000) to both protect water sources and improve water quality. This is a major driver behind the need to implement water sustainability practices by industry. Ireland has specific targets to meet by 2030 and engagement of the pharmaceutical industry is a significant step to achieving those emission targets.

Within the literature there are limitations and gaps specifically related to water footprint in the pharmaceutical industry. There is much information online related to the agricultural sector, specifically dairy production (O Connor, 2020). However, many literature sources such as (Frijns, 2012) and (Stockil *et al.*, 2018) confirm that there is a lack of commercial data related to the pharmaceutical industry, a lack of common assessment strategies within the industry and lack of clearly defined boundaries. These literature sources all indicate that this lack of data is contributing to poor understanding of how this industry is implementing water sustainability strategies.

2.5 Drivers for Water Reuse

A circular economy is defined as an economy whereby resources, materials, and products are maintained within the economy for as long as they are viable, to reduce waste, and create a more sustainable, economic, efficient, and low-carbon generating economy (EC, 2015). The EU is a proponent of the circular economy. Reuse of water is one initiative to adopt in a circular economy. Water reuse is often referred to as used recycling water, reclaimed water, or treated wastewater reuse (Byrne *et al.*, 2019). According to the Byrne report commissioned by the Irish Environmental Protection Agency, the pharmaceutical industry is a “low-hanging fruit” option for the initiation or expansion of water reuse projects. Not only does this industry have the expertise to lead these water reuse projects but also will benefit financially in reducing water treatment costs and mitigating risks to production output. Reuse of water by industrial sites will also have an impact on the gross annual saving of millions of cubic meters of the public water supply (Byrne *et al.*, 2019).

One of the main drivers for water reuse by the Irish Government is its obligation to meet the European Directive for countries to have a water framework in place (EC, 2000) and urges the adoption of water reuse strategies as a way to meet sustainability goals. The highly valuable Irish pharmaceutical industry will thus be a target for any government initiative for water conservation. The security of water supply in Ireland is of primary concern to a pharmaceutical site. Risks to supply may occur due to water stress from abrupt localised failures and aging infrastructure, as discussed by (Byrne *et al.*, 2019). Emission limit values are set by the Environmental Protection Agency for wastewater discharge from industry. Should a pharmaceutical site wish to expand its production, resulting in an increase to its wastewater output, it may not be granted approval for an increase in its emission limit values. This is a challenge for any site and therefore, they must find other options to reduce wastewater; water reuse being one such option.

Currently industrial sites are required to submit in Annual Environmental Reports the quantity of water reused at each site that is under licence by the Environmental Protection Agency, however this information is a single annual figure and does not elaborate on the scale or treatment strategies employed at the site, as per (Byrne *et al.*, 2019). This contributes to the lack of water data available on the pharmaceutical industry. Without accurate data it is not possible to assess at what stage the Irish pharmaceutical industry is at in its water sustainability lifecycle.

Uisce Éireann in its published *National Water Resources Plan: Framework Plan* in 2021 explicitly mentions water reuse as one of the options available for a sustainable and reliable future source of water (Uisce Eireann, 2021). However, it does not go into detail as to the scale and methodology that industrial sites may employ. Uisce Éireann is also investigating the need for a tariff pricing for non-domestic water and wastewater customers, of whom geographic influence on charges, customer classification, and exactly how tariffs will be structured has yet to be established. Uisce Éireann has indicated that a lack of base data is contributing to delays in understanding how these tariffs could contribute to water use in the non-domestic sector.

Sustainability policies and a firm's environmental, social and governance (ESG) report are another reason why water reuse strategies may be employed at a pharmaceutical site. Pfizer is an example of one firm putting sustainable water management into its ESG report (Pfizer, 2021b). Pfizer identifies water scarcity and drought conditions as an acute and chronic physical risk to their operations. Pfizer also estimates annual savings of millions through emission reduction projects which include wastewater treatment (Pfizer, 2021a). Pfizer's approach to water sustainability practices aligns with the available literature.

There is also a regulatory disclosure obligation for EU companies which will come into effect in 2024 (EC, 2023b). This means that companies based in the EU will be required to declare their sustainable activities across 6 key areas including environmental objectives of sustainable use and protection of water and marine resources. Therefore, the disclosure of water sustainability practices will soon become legally required in a firm's ESG report.

This regulation ties in the information seen in the literature and shows that the EU's plan to safeguard water resources (EC, 2012), the promotion of activities which constitute a circular economy (in this context water reuse), and the Irish government's 2030 low carbon energy targets all signify that governments are all moving in one direction: promotion of water sustainability practices by businesses.

2.6 Impacts of an Efficient Water Management Strategy

EU environmental and water policy influences the technological development and innovative processes which are used by pharmaceutical companies in favour of more advanced or “smarter” technology responses. The pharmaceutical industry here is required to demonstrate that they follow the competent authority’s permit licence using the “best available techniques” and can provide evidence to the competent authority (in this case the Environmental Protection Agency) of suitable release-monitoring requirements, specific measurement methodologies and frequency, and an evaluation plan (EC, 2009). Therefore, a sound and detailed water management strategy at each pharmaceutical site is both legally required and intrinsic to the site effectively managing its water use and being able to demonstrate to a regulatory authority an effort in continuous improvement of their management plan. Corporate stakeholder engagement in this process is vital such that the impact of the whole water system is appreciated, as described by (Newborn and Dalton, 2016).

Monitoring of site wastewater for evidence of pharmaceutical contaminants is another important aspect of an efficient water management at a pharmaceutical site and must be considered during any water reuse plan, as described by (Miarov *et al.*, 2020). Contaminants found in water is a well-documented phenomenon (Ghernaout and Elboughdiri, 2019) and has impacts on both the environment and to the public. It is in the interest of the pharmaceutical company to ensure that wastewater is being effectively and appropriately treated prior to release or reuse (EPA, 1992) so that not only the environment and public are kept safe, but also that the company is being compliant to its regulatory obligations, their reputation is maintained, and they do not risk excessive fines (polluter pays principle), or increased taxes to mitigate additional water treatment expenses (EFPIA, 2023). The excessive cost of infrastructure investment may prevent a site implementing reuse strategies. Therefore, challenges exist which impact a site implementing water reuse strategies.

Uisce Éireann promotes a water stewardship program (Uisce Eireann, 2022) where companies who consume greater than 10,000 cubic meters of public supply water can sponsor employees to be educated and certified in best practise of water stewardship. It involves tailored training in reducing water consumption and operating costs, and preparation of a company charter which will outline water saving opportunities and an

agreed action plan. These types of educational and awareness programs are vital in removing a barrier for greater uptake of water sustainability programs nationwide. Successful case studies included in *A Guide to Water Efficiency* by GE Healthcare (GE Healthcare, 2007) which outlines their framework for companies to set water efficiency objectives, shows that some within the pharmaceutical industry are leading the way for a more environmentally friendly stance.

The Paris Agreement is a legally binding international treaty on climate change and seeks to transform how individual countries take active steps to protect resources like water by strengthening basin management of rivers, lakes or aquifers (United Nations Climate Change, 2015). This is followed up in legislature, (EC, 2012), which puts the onus on individual governments to achieve good water management practices. Ireland's nationally determined contributions, or NDC, to the Paris Agreement are to reduce greenhouse gas emissions by 30 per cent by 2030, and contribute to the overall EU objective of reduction by 40 per cent by 2030 (Department of the Environment, Climate and Communications, 2020a). An (EPA, 2021) report believes that Ireland will struggle to meet these goals. As water and energy are intrinsically linked, water reduction strategies impact energy savings thus reduction in greenhouse gas emission.

Environmental management - including water management - is a strategic business issue for pharmaceutical companies and cannot be downgraded in importance according to (Newborn and Dalton, 2016). A pharmaceutical site that is not able to implement an effective water management plan risks reducing its flexibility and capability for dynamic change (Teece, 2007).

2.7 Key Findings

Below is a list of the key findings discovered from the literature related to each topic area:

- **The Pharmaceutical Industry in Ireland**
  The key finding of this topic area is that this industry is worth more than 50 billion annually to the Irish economy. Therefore, any threat to the industry needs to be mitigated with appropriate strategies at an industrial and governmental level. The continuous supply of water to the pharmaceutical industry is a threat identified in the literature and explored in this study. Many companies do engage in some water sustainability practices, however there is no national framework in place to regulate and monitor these practices, and thus the incentivization for wide uptake

suffers. These findings will be further explored in this study by means of the primary objective of identifying the infrastructure and processes for water sustainability currently in place by pharmaceutical sites.

- **Water as a Scarce Resource**

  The key finding of this topic area is that it is commonly regarded in literature that water is in many parts of the world fast becoming a scarce resource. Though it may be argued that Ireland is water rich; aging infrastructure, expanding populations, and climate change are all contributing to increase the risk associated with the safe, continuous supply of water to industries. This finding will be investigated further with the primary objective of identifying the current infrastructure in place by pharmaceutical sites and establishing the challenges and barriers they are facing. If water is seen as a high value resource, this will impact the current practices in place by these sites, and what challenges they are experiencing.

- **Association of Water and Energy**

  The key finding of this topic area is that establishing a water footprint of a pharmaceutical site is key to understanding the relationship between water and energy at that site. By elucidating the water footprint across the whole site, a firm can target key areas within the water system for implementation of energy reduction strategies. One of the objectives of this study is to identify if Irish pharmaceutical sites are actively establishing their water footprint and if they are targeting the full lifecycle at the site.

- **Drivers for Water Reuse**

  The key finding of this topic area is that drivers to implement water sustainability strategies mostly come down to savings of operational costs and reducing risk to business continuity. Due to the high cost and long payback associated with these types of strategies there may be a low incentivization to implement them. This study seeks to identify the current drivers for the Irish pharmaceutical industry to implement these strategies. Without a national framework there is also low encouragement coming from government to affect an industry uptake. One of the objectives of this study is to identify if industry professionals believe current regulatory guidance on water sustainability strategies is sufficient for providing leadership to sites.

- **Impact of an Efficient Water Management Strategy**
  The key finding of this topic is that an efficient water management strategy is now a crucial component of any companies' environmental, social, and governance policy. Many companies have identified water scarcity or drought conditions as a risk to business and undergo risk resilience planning to mitigate the risks. The study aim is to establish the current prevalence and scale of water sustainability strategies across Irish pharmaceutical sites. The study objective of identifying the challenges and barriers which the sites are experiencing will enable an understanding of the current landscape to be drawn.

2.8 Gaps in the Research

Below summarizes the gaps in the literature related to water sustainability practices in the Irish pharmaceutical industry:

- **Lack of Water Data** specific to the Irish pharmaceutical industry: it is not possible to fully understand uptake of water sustainability strategies within this industry if there is not enough current data related to pharmaceutical sites.

- **Lack of Incentives**: without clear incentives from government water sustainability strategies employed across the pharmaceutical industry may not be at an effective level to instigate real industrial change and meet government and European carbon reduction goals.

- **No National Framework**: change within any industry needs to be led to induce full engagement of all stakeholders. Water is a public resource and a precious one, thus it would be beneficial for all stakeholders if more guidance and action was received from the Irish government to promote water sustainability practices by industrial sites, such that water - as a scarce resource - may be protected.

- **No Regulatory Monitoring**: Irish regulatory bodies such as the Environmental Protection Agency have a role to play in the monitoring of water sustainability and water reuse strategies utilized by pharmaceutical sites. This would lead to additional protection of Ireland's water supply and function to provide leadership and foster uptake of strategies across industrial sites.

2.9 Conclusion of Literature

The concept of water scarcity and the need for water conservation is found in extensive literature sources (United Nations, 2023) (United Nations Climate Change, 2015). Climate change and drought conditions are affecting many countries globally and Ireland is not exempt (Murphy and Noone, 2020). Protection and conservation of water in Ireland falls under the remit of four government agencies according to the (Commission for Regulation of Utilities, 2023), see Chapter 1.

Together these bodies must ensure that the future of water supply in Ireland is protected, and that industries in Ireland like the pharmaceutical industry are all provided an uninterrupted quality supply of water. However, users of water in Ireland – both domestic and industry – also have a role to play in conservation and protection of water. This study will explore the current approach of the Irish pharmaceutical industry for water sustainability.

The lack of water data in Ireland and the absence of a national framework to promote and engage stakeholders within the industry to implement water sustainability practices presents as a gap in the literature. It is postulated that until there is a cohesive action plan and regulatory framework in place, sites will only invest in water sustainability practices if there is an apparent financially or environmental benefit. The poor incentivization framework by government targeting the pharmaceutical industry is also postulated in the literature to contribute to reduced uptake of water sustainability strategies across the industry. The lack of monitoring of water sustainability and water reuse strategies by regulatory bodies (Stockil *et al.*, 2018) is also contributing to the lack of water data and is likely adding to the challenges and barriers experienced by those in industry.

This study seeks to understand the current Irish pharmaceutical industry landscape and assess where it stands in relation to water sustainability practices; by identifying the current infrastructure and practices and engaging directly with industry professionals to determine the current challenges and barriers they are experiencing, and if they believe more incentives are required to promote engagement across the industry. This is expected to contribute to filling the gap in research concerning water data in Ireland. Finally, research from this study may aid to identify the critical success factors which Irish

pharmaceutical firms need to be aware of to ensure water sustainability strategies are both effective and robust to ensure long term benefits at the site.

2.10 Conceptual Framework

Figure 1 below illustrates the conceptual framework. One of the key findings from the literature is the lack of water data for the Irish pharmaceutical industry. This will form the fundamental reasoning behind the research being undertaken. To date, from the observed literature, there has been no qualitative or quantitative research directly from Irish pharmaceutical sites that evaluates and examines the current prevalence and scale of water sustainability practices in this industry or specifically details the challenges the industry is facing.

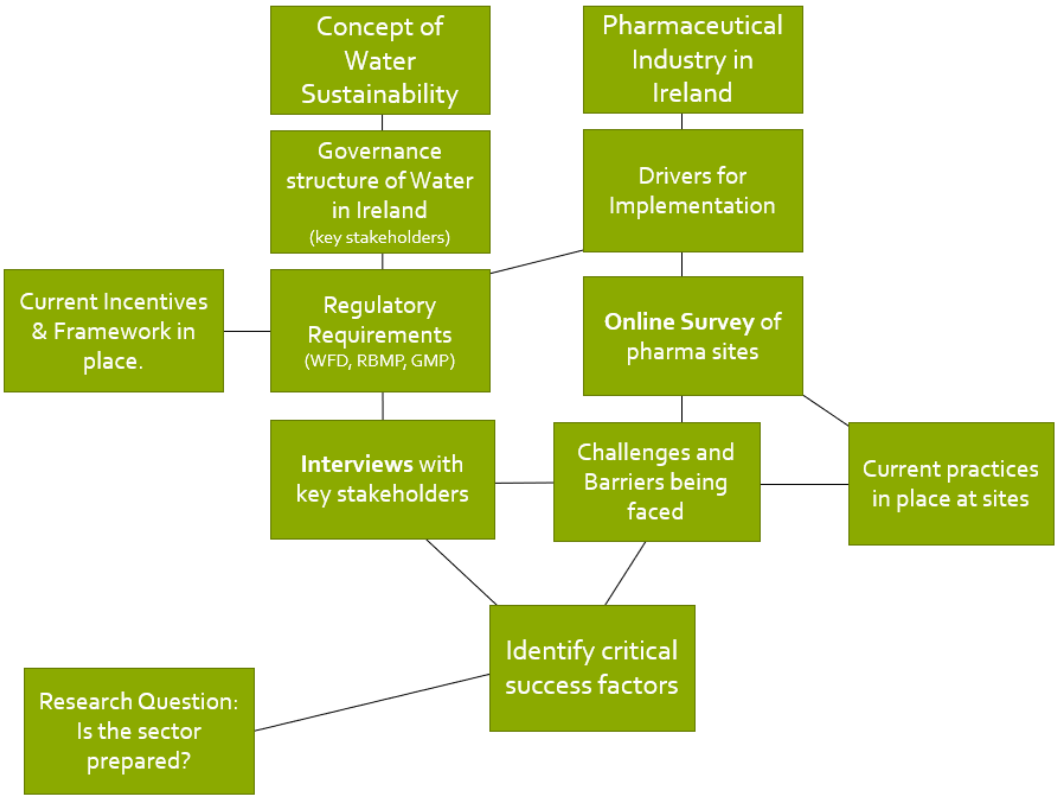

Figure 1 Conceptual Framework created by the Author.

Chapter 3

Methodology

3.1 Methodology Outline

The overall aim of this research was to provide a snapshot of the preparedness of the pharmaceutical industry for implementation of water sustainability practices. The research objectives include:

- Identify the infrastructure and water sustainability practices in place by the Irish pharmaceutical industry.
- Evaluate if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites.
- Identify the challenges and barriers professionals within the pharmaceutical industry are experiencing in relation to implementing water sustainability strategies at their sites.
- Considering all the above, identify the critical success factors, and thus recommendations, which sites can use as a benchmark for implementation of future water sustainability strategies.

A mixed method approach was used to explore the above objectives first-hand from pharmaceutical personnel. The information gained from the above research objectives allowed for critical success factors and thus recommendations for industry to emerge from the research. Selection criteria was used to include study participants.

This research study addresses the gaps identified during literature review, those being a lack of water data related to the Irish pharmaceutical industry, poor incentive structure, no national framework in place to promote adoption of water sustainability strategies in the pharmaceutical industry, and no regulatory monitoring of the water sustainability practices in use by Irish pharmaceutical sites.

The chosen research philosophy, strategy and purpose are outlined in this chapter along with the research process and logic. Next the approach to methodology is explained which includes details on the sources of data, the sampling methods, the analysis strategy, and a reference to access and ethical issues. This study involved an interpretivist inductive approach with an exploratory research purpose.

The research was conducted in two phases which ran in parallel; phase 1 involved qualitative interviews with key stakeholders and phase 2 involved an online survey of

participants comprising those employed within the Irish pharmaceutical industry. These participants are directly involved with water management at a pharmaceutical site or are involved in decision-making of sustainability strategies at their site.

A complementary quantitative and qualitative mixed methods approach was employed as the research method such that information garnered through quantitative means could be improved upon by ensuring that any limitations were balanced by the strengths of including a qualitative approach. The sampling methods used were non-random, purposive homogenous sampling.

Qualitative data was analysed using thematic analysis. For the quantitative data bar charts and pie charts were used to display the data appropriately and allow for meaning and understanding to be developed.

The results of the interview phase were used to augment and give insight into the results generated from the online survey.

3.2 Research Philosophy

Considering the areas of research assumption: ontology, epistemology, and axiology the researcher looked at the continua of beliefs that have two sets of extremes; objectivism and subjectivism.

The nature of this research subject is best described with the subjectivist viewpoint as per the assumption areas described in (Saunders *et al.*, 2019): Ontology (potential for multiple realists exists in this industry), Epistemology (opinions of the pharmaceutical personnel directly involved in water management at a site and the stakeholders in the water lifecycle in Ireland are the best example of knowledge in this area) and Axiology (nature of the water sustainability phenomenon gives rise to a value-bound approach, phenomenon seen to be beneficial for both society and environment).

Of the four major research philosophies available, positivism, realism, interpretivism, and pragmatism, an interpretivist philosophy was chosen for this research study. This approach best suits the way in which complex and rich knowledge about the phenomenon of water sustainability practices in the Irish pharmaceutical industry may be acquired.

By considering that there are various social opinions and narratives within the Irish pharmaceutical industry it is assumed there are different social realities to be explored, which is detailed in (Saunders *et al.*, 2019) as the phenomenologist belief.

3.2.1 Research Design

The overall approach of this research was exploratory; to achieve a deeper understanding of the current water sustainability practices by the Irish pharmaceutical industry. The exploratory nature of the research included first understanding the current regulatory requirements surrounding water management and water sustainability practices in Ireland from both an Irish regulatory perspective via the River Basins Management Plan (RBMP), and a European regulatory perspective via the Water Framework Directive (WFD).

Following this, an online survey of pharmaceutical personnel who were involved directly in management of water was performed so that a representation of the current industrial situation could be attained. Concurrently, interviews with key stakeholders identified in the literature review were conducted so that further insight and understanding may be garnered from the data generated. The exploratory nature of this study was best suited to bring clarity to this research phenomenon as explained by (Saunders *et al.*, 2019), and allowed various realities as to the current state of industrial water sustainability practices to be realised.

3.2.2 Research Process and Research Logic

For this research a mixed-method process was used and was combined with an inductive logical approach. This allowed rich data to be generated and enabled theories to be built from this, which suited the interpretivist philosophy of the study. This approach increased the flexibility of the research study.

The mixed-method approach also added complexity and depth to the data generated as described by (Saunders *et al.*, 2019) as it balanced any shortcomings in one approach by the strength of including a second approach. A quantitative approach was taken to tackle the first objective of identifying the infrastructure and processes currently in place by the pharmaceutical industry and was the best method to gain a snapshot. Following

from this the other objectives were best achieved by using both quantitative and qualitative methods to evaluate the role of regulatory bodies and identify the challenges and barriers the sites were facing in implementation of water sustainability practices. The qualitative questions allowed the responders to give their opinions, experiences, and beliefs concerning the research topic and enabled a deeper understanding and clarity to be achieved.

The quantitative and qualitative questions included in the online survey are shown in Appendix 7. The qualitative questions put to the interviewees are shown in Appendix 6.

The interviews with key stakeholders identified during literature review were undertaken to broaden the understanding of the topic area and add meaning to the survey results. The researcher also wanted to ensure the other side of the coin was represented; namely the regulatory and statutory bodies who enforce and drive water policy in Ireland regarding management, sustainability practices and protection.

Use of the mixed-method approach was not employed to produce empirical or statistical data to represent a target population. Rather the intention of the research was to be exploratory and discover themes as they arose from the research population.

3.3 Sources of Data

Data collection was acquired in two phases which were run in parallel. The first phase involved a series of interviews with key stakeholders identified during the literature review. The second phase involved an online survey with Irish pharmaceutical industry professionals directly involved in water management or facilities/operations management or environmental health and safety (EHS) at pharmaceutical or medical device sites.

Online Survey

The design of the survey was linked to the primary objective of evaluating the current landscape in the Irish pharmaceutical industry by assessing the prevalence and scale of water sustainability practices and to identify the challenges and barriers they may currently be facing. Using a survey platform allows for an insightful mixed-method approach, for both qualitative and quantitative data, as questions that are more open-ended may be included along with more direct closed questions, as detailed in (Saunders *et al.*, 2019). The number of survey respondents was unfortunately limited and therefore

it cannot be deemed reflective of the Irish pharmaceutical industry in general. However, the intention of the study was to gain a snapshot of the current industrial landscape; thus, the number of survey respondents, the company's repute, and the quality of the respondent's professional standing was sufficient to provide this insight.

The questions were designed to be based on the specific observations and opinion of the respondents. Questions which were open-ended in nature allowed these participants to share their own personal opinion based on their experience, knowledge, and perception of the industry they work in (Saunders *et al.*, 2019), illustrating the exploratory and inductive nature of this research.

Interviews

In conjunction with the online survey 6 agencies identified as key stakeholders of the research subject were approached for interview. Those agencies being the Environmental Protection Agency (EPA), Uisce Eireann (Irish Water), An Fóram Uisce (The Water Forum), 20fifty Partners (formerly known as Central Solutions) - a training provider of water stewardship certification, the Local Authorities Waters Programme (LAWPRO), and Water Systems and Services Innovation Centre (Nimbus Research Centre, Cork). Of those approached, 3 agreed to take part in interviews: An Fóram Uisce, 20fifty Partners, and the Local Authorities Waters Programme. With regards to An Fóram Uisce, interviewees were research staff as opposed to members of An Fóram Uisce. A confidence level was not applied to the interview phase as there are a limited number of stakeholders involved in water governance in Ireland.

The one-on-one internet-medicated interviews were conducted in a semi-structured style. Using an interpretivist approach, themes were identified in the literature review. Key questions relating to these thematic areas and to the research objectives were developed to guide the interview, as described in (Saunders *et al.*, 2019). This allowed the interviewee responses to naturally alter the flow of the interview depending on the professional experience of the interviewee. To reduce issues of interviewer and interviewee bias in the process the questions were provided to interviewees ahead of time such that they could add to or modify the questions as they related to the themes. This allowed the interviewees evaluate the researchers frame of reference and credibility, gave them a level of control over the intrusiveness of the questions, and helped to build trust in the process.

3.4 Sampling Methods

A mixed-method exploratory research approach was taken for this study. A non-random purposive homogenous sampling technique was used. The author purposively selected participants whose profession directly involves water management or operational management decision-making at a pharmaceutical site; site/ plant manager or director, or environmental health and safety (EHS) specialist/ manager/ director. The headcount of the site and the amount/scale of water consumed at the site were not used as selection criteria.

Participants for the online survey were found based on their professional job title as listed on the social media platform LinkedIn and by contacting companies directly by phone. In addition, participants were identified from attendance at relevant conferences such as *The National Sustainability Summit* held on February 23rd, 2023, in Dublin and the *BioPharma & Lifesciences Connected Live* held on January 25th, 2023, in Cork. Peer networks within Innopharma Education were also accessed.

A total of 130 companies were identified online as being relevant to include as study participants; they had sites in Ireland and were engaged in the manufacturing of either pharmaceuticals or biopharmaceuticals or medical devices. A sampling size calculation was performed using a confidence level of 95 per cent, a margin of error of 5 per cent and the above population size of 130. This resulted in a recommended sample size of 98 for the online survey.

Requests to participate in the online survey were sent out to each of these 130 companies over the course of six weeks resulting in a total of 31 participants engaging and then agreeing to take part. Of these, 25 survey complete responses were finally received; 6 failed to respond in the given timeframe. This pool of 25 study participants meant that the homogenous sampling approach allowed generalizations to be made from the non-probability sampling, but they were not based on statistical grounds (Saunders *et al.*, 2019).

Regarding the interviewees, these were selected also using non-random sampling and were distinguished as key stakeholders in protection and management of water in Ireland from literature sources of Chapter 2, and subsequently from searches of profession titles on LinkedIn. A total of 3 interviews were conducted with employees of An Fóram Uisce, 20fifty Partners, and the Local Authorities Waters Programme (LAWPRO).

3.5 Reliability and Validity

The reliability of a study is the indication that the results of a study are consistently reproducible as described by (Saunders *et al.*, 2019). Issues related to a mixed-method approach which may affect the reliability of a study are when participants are affected by factors which interfere with their willingness to complete a survey or their focus whilst undertaking a survey (Saunders *et al.*, 2019). This is particularly true for qualitative questions, as unlike quantitative questions they need more time to process and answer.

To enhance the reliability of this study, the sampling pool was increased to the maximum identified number of relevant companies with sites in Ireland, which was 130. However due to time limitations and lack of response from many sites, the final sampling size was relatively low at 25. Reliability was increased by sending unique email links for the survey directly to participants.

A further increase to reliability was achieved by ensuring responders had the pre-requisite professional experience to know and then answer the questions specific to their company. Use of a self-completed survey also served to increase reliability as responders are less likely to answer questions to please the researcher as can happen with one-on-one interviews (Saunders *et al.*, 2019). Reliability to the survey response was promoted by designing unambiguous questions such that they were understood and answered as was intended, thus increasing the interpretability of the answers.

Validity of the study was achieved by directly reaching out to pharmaceutical sites in Ireland for participation; allowing the researcher to answer the research objectives (Saunders *et al.*, 2019). Survey questions were initially developed during completion of the literature review. Questions were subsequently refined and designed in the best possible way to ensure that their relevance met the research objectives. Validity of the survey responses was also increased by pilot testing the survey.

With regards the interview process, reliability and validity was achieved by only selecting interviewees identified as key stakeholders in the governance of water in Ireland. The proposed interviewees were explained the research objectives. The interview phase was primarily to give further insight and understanding to this research area as it involves a subject matter with many stakeholders in its life cycle. The interview process was not intended to garner generalisations. The reliability of the interview process was not seen

as an issue as the interviews were not intended to be repeatable, but to be reflective of the interviewee's reality at the time of interview recording.

3.5.1 Pilot Testing Survey and Alterations

Originally the research was intended to be an online survey only of professionals within the Irish pharmaceutical industry, but as the area of research has many diverse stakeholders' it was proposed to also include interviews with stakeholders who were identified as subject matter experts. Information from these key stakeholders was deemed to contribute to the research objectives and add context and relevance to the data generated. Interviews with the subject matter experts included questions related to their professional opinion of the research subject.

The online survey was pilot tested prior to finalization for study participants. This pilot test was performed following two interviews with subject matter experts as the outcomes of the interviews resulted in minor alteration of some questions. On behalf of the author, two individuals pilot tested the survey prior to sending to participants to check for grammatical clarity and typos in the questions. Two individuals from the participant pool were then selected to do an additional pilot test to ensure the relevance and logic of the questions. Some minor alterations to questions were made following the pilot test to improve clarity in the phrasing of questions and the sequence order. Minor alterations to questions included addition of dropdown options to the question regarding current sustainability practices in place at the site and changing the survey options to include a "must answer" notification if a question was skipped. An option of "other" was also added to all quantitative questions.

3.5.2 Data Collection Methods

An online survey of participants currently employed in pharmaceutical, biopharmaceutical, or medical device sites was used to collect quantitative and qualitative primary data for this research study. Participants were selected by the author based on specific criteria as outlined in Section 3.4. The online survey was circulated to each participant with access in a unique email link via the platform SurveyMonkey.

Online interviews with key stakeholders identified during the literature review were conducted to augment and give insight into the data generated during the online survey. The online interviews comprised of purely qualitative questions. The online interviews were held on the platform Zoom using the author's unique meeting room link, and were audio recorded.

3.6 Analysis of Data

The online survey consisted of questions that were both quantitative and qualitative, which were designed to be complementary. This mixed-method approach was used to produce data that supported the objectives of the research and were analysed together.

Qualitative data: To identify and analyse the qualitative responses from online survey participants and interviewees a thematic analysis approach was used as described in (Saunders *et al.*, 2019). Themes were identified in the qualitative data as those which represent important elements of the overall objective of the study. These themes were based on the authors perception of the research subject and how it relates to the participants. Themes explored during literature review allowed for gaps in the research to be identified and these were used as a foundation to find themes within the data generated from the online survey and interview phase; those gaps being lack of water data, poor incentive structure, no national framework, and no regulatory monitoring.

A thematic approach was taken as this research subject is exploratory in nature. The qualitative data was visually displayed using word cloud to contextualize the information and identify themes. As the themes emerged, each were grouped together using a process of inductive coding. The author's knowledge of the topic area is limited, therefore inductive coding supported the exploratory nature of the study as described by (Braun and Clarke, 2006).

Quantitative data: The quantitative data was visually presented in appropriate data display options such as pie charts and bar charts to identify patterns and meaning in the data. For the quantitative Likert-scale questions a chi square test was performed to determine if the observed result was in line with the expected result, and to thereby rule out chance. The quantitative data was analysed along with the qualitative data to support conclusions being drawn.

3.7 Access and Ethical Issues

This research includes questioning participants employed in private commercial enterprises of the current operational processes used at their sites for the purposes of water sustainability. Therefore, intellectual property, privacy, and ethical considerations are important to include in the research process. Research questions were designed so as not to elicit any direct information pertinent to the enterprise's private activities or business affairs. In this study, the participant's anonymity was guaranteed including their right to withdraw unchallenged for any reason from the study, as described in (Saunders *et al.*, 2019).

The research was conducted with integrity and without deception such that the data and findings were wholly unbiased and truthful. The Griffith College ethics policy and procedures were implemented during the conduction of this research study. The participants were introduced to research objectives and informed data collection would remain anonymous, and that no personal information would be shared or reported.

Chapter 4

Findings and Discussion

4.1 Topic Outline

The primary objectives of this research study were to evaluate the current landscape in the Irish pharmaceutical industry of water sustainability practices by assessing the prevalence and scale of these practices and to identify the challenges and barriers professionals within the industry may currently be facing. Following this, critical success factors were identified which could be used by the industry to evaluate where they stand in relation to their peers. Collection of primary data occurred in two concurrent phases: an online survey directly with pharmaceutical sites and interviews with stakeholders involved in water governance in Ireland.

The online survey comprised of both quantitative and qualitative questions of industry professionals in roles which involve the direct management of water at a site, or decision-making capacities of water sustainability or water management practices at a site. The survey responses provided an insight into the current state of water sustainability practices at the sites and the challenges and barriers these participants are experiencing in implementation of these practices. The current relationship between sites and Irish regulatory bodies was also explored. The findings presented in this chapter follow the sequence in which questions were presented to participants in the survey.

4.2 Participants

Interviews were conducted with 3 key stakeholders in total. These interviewees added insight and augmented the information garnered from the survey responses. Of the interviewees, these were individuals currently employed at either 20fifty Partners, An Fóram Uisce, and the Local Authorities Waters Programme.

25 survey responders were achieved in total. Of these, 11 worked in environmental health and safety at managerial, specialist, or director-level, 7 were involved in management of the site/plant, 4 were from a facilities and engineering role, and 3 were described as sustainability leads. While there is variety in these roles, they were considered a non-probability and homogenous participant pool.

4.3 Findings of the Interview phase

Thematic analysis was performed on the information gathered during the interview phase. Each of the 3 interviewees represented a different key stakeholder in the governance structure of water in Ireland. Therefore, searching for commonalities in keywords and phrases amongst the interviews proved difficult. Each interviewee brought a unique knowledge, experience, and viewpoint to water sustainability based on their role and responsibility within the governance life cycle. When stepping back and looking holistically at the interviews some common threads were isolated and thematic areas developed from these. Themes identified from the 3 interviews are outlined in bold in the table below, with the commonalities of phrase between the interviewees given as bullet points. These themes are discussed in the subsequent sections. Appendix 6 includes the qualitative questions put to the interviewees.

Maturity of the pharmaceutical industry

This theme links to the primary objective of identifying the infrastructure and water sustainability practices currently in place by the Irish pharmaceutical industry.

- Very high engagement across the pharma industry.
- Most beneficial engagement model for industries was the peer-to-peer.
- Greater level of maturity of managing water resources in the pharmaceutical industry
- Pharma industry is driven by risk avoidance when it comes to water.

Beyond Compliance

This theme links to the primary objective of evaluating if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites.

- Going beyond compliance; understanding of water sustainability in the broader sense, such as concept of custodianship, the environment, and the catchment area.
- Beyond a question of just quantity of water, but water quality and risks to quality.
- Corporate responsibility; concept of engagement at the catchment level.
- Unpredictability of the climate impact; real challenge will be to adapt to this

Suite of measures/tools

This theme links to the primary objective of evaluating if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites.

- Favouring of an outcomes-based approach to mandating, rather than a legislative approach. Mandatory in terms of the action to take.
- The need for supports is constantly evolving because the challenge is constantly evolving.
- Incentivization: suite of measures; not always financial; needs to be about behaviours and attitudes.
- Always scope for more education/awareness.

Prioritization of Water Sustainability

This theme links to the primary objective of identifying the challenges and barriers professionals within the pharmaceutical industry are experiencing in relation to implementing water sustainability strategies at their sites.

- The transparency of water data is part of water sustainability practices. Will lead to increased resilience in water supply.
- Water industry in Ireland not as mature as the Energy industry in Ireland. It should be higher up the Government's agenda list. It should be an even playing field.
- Return-on-Investment is difficult for Water. Not easy to make and justify a business case for water sustainability.

Figure 2 Themes identified during Interview phase.

4.3.1 Maturity of the pharmaceutical industry

Although there is a lack of direct interaction between the pharmaceutical industry and the interviewees, there was agreement between all 3 interviewees that the Irish pharmaceutical industry is at a greater level of maturity with regards managing its water resources, than other industries in Ireland. Not least because as a large water user they are required to pay for their water use but also the benefits to them from a reputational perspective. It was observed that overall, there is a high level of engagement of the pharmaceutical industry with educational and training initiatives like the certified program from *Water Stewardship Ireland*/Uisce Eireann.

All 3 interviewees cited peer to peer learning as being an important engagement model to facilitate learning across this industry to promote information and knowledge sharing and for the demonstration of successful water sustainability practices with peers. The

engagement of the pharmaceutical industry with the network *Water Stewardship Ireland* was noted as being high, though exact numbers were unavailable. 2 interviewees observed that the pharmaceutical industry understands the challenges of their own industry best and thus are better placed to put water sustainability practices into that context. 1 interviewee observed that outside consultation with water sustainability experts would give the pharmaceutical industry a greater understanding of putting water sustainability into practice. It was noted that companies are much more likely to actuate a process or method if they can see the physical benefits of it in action.

4.3.2 Beyond compliance

All 3 interviewees discussed the concept of what water sustainability means to the pharmaceutical industry. They all acknowledged that there is a challenge in understanding the broader aspect of water sustainability and the need to look beyond or outside the site and include the surrounding environment and the catchment area in how water sustainability is defined. Interviewees observed that pharmaceutical sites need to go beyond the minimum that is required as per their environmental licencing agreements. All 3 interviewees agreed that water in Ireland is largely taken for granted, not least by the non-paying public, and that water is seen as a commodity rather than a resource over which we are custodians.

The concept of water quantity and water conservation was noted by all interviewees as being a lens through which the concept of water sustainability was often exclusively viewed. However, the quality of water and risks to quality were noted as being of vital importance to this concept. The pharmaceutical industry is largely driven by risk-avoidance, thus risks to the quality of water it uses and discharges are an intrinsic part of the conversation. Corporate responsibility was noted by all interviewees as being another key driver for water sustainability practices in this industry. Many of these sites have their own targets related to water sustainability which the interviewees noted contribute to reputational benefit and risk avoidance to investment portfolios.

4.3.3 Suite of measures and tools

The use of legislation to incentivize the uptake of water sustainability practices across the industry was not favoured by any of the interviewees as being effective on its own. It was noted that there may be a place for legislation to mandate certain actions on the

part of these companies, an example being each site having several designated water stewards. But that legislation would only be effective if used as part of a suite of measures. All 3 interviewees were in favour of an outcomes-based approach to facilitate promotion and uptake of sustainability practices, an example being each site must have a water stewardship plan in place. It was observed by 2 interviewees that soft supports play an important part in filling knowledge gaps.

There was consensus from all 3 interviewees that unless there is a change in behaviour and attitudes then use of legislation is not an appropriate tool. Likewise, the use of financial penalties as dissuasive tools or a financial incentive structure as a persuasive tool was also deemed insufficient alone by all interviewees. Rather these tools and measures needed to be implemented as a part of a framework of actions such that the value in these actions were recognized. One interviewee noted that it is better to view mandates and outcomes from the concept of water custodianship, or most accurately joint custodianship; meaning there are roles to play for regulatory bodies and industry.

4.3.4 Prioritization of Water Sustainability

All 3 interviewees agreed that water is lower on the government's agenda as compared to the energy industry. When compared to the energy industry in Ireland, the water industry is much less mature. It was agreed by all interviewees that water and energy in Ireland need to be on a level playing field to actuate significant change.

When asked about the concept of transparency of water data all interviewees agreed that transparency is part of the practice of water sustainability. Data which can inform decision making was remarked by 1 interviewee as being important. Current reporting requirements to the Environmental Protection Agency exist as part of abstraction and discharge license requirements, but the interviewees were unsure of which data was specifically reported. It was hoped that interviews with Uisce Eireann or the Environmental Protection Agency would shed light on these reporting requirements, but unfortunately these interviews were not possible at the time of this dissertation.

All 3 interviewees cited that there may be difficulty in justifying investment in water sustainability. In the energy industry, there is a much clearer business case for investing in energy saving infrastructure with better financial supports and soft supports available to businesses. 2 interviewees commented on the slow return-on-investment as being a hurdle for industry, while 1 interviewee mentioned the cost of infrastructure as a challenge as well as justifying it as a good business case.

One interviewee noted that though the return-on-investment may be slow or long for water sustainability practices; the benefits to reducing risk in your water footprint were worth the investment for these sites. Risk to business continuity was observed by 1 interviewee as being a vital driver for uptake of water sustainability practices by pharmaceutical sites.

The incoming European Union directive on *Corporate Sustainability Reporting* (CSRD), which will require listed companies with greater than 500 employees to report environmental risks they face and how their activities impact the environment and society, was predicted by one interviewee to play a significant part in reporting of water data in the coming decade. Thus, it may be concluded that the prioritization level of water sustainability practices in Ireland may be set to change.

4.4 Findings of the online survey

The survey comprised of quantitative and qualitative questions. The quantitative questions were aimed at understanding the current water sustainability practices in place at the site and are presented in bar charts and pie charts in this chapter. Where appropriate a chi square test was performed on the quantitative analysis results. Appendix 7 includes the online survey questions.

The qualitative questions relate to developing on the responders' opinions and allowing them room for expansion on challenges and barriers in the industry. Thematic analysis was applied to the qualitative questions from the survey. Although themes identified during the interview phase were used as a guide for analysis of the qualitative survey questions, new themes emerged based on the survey data.

The survey was divided into three parts:

- the first part to establish the current water sustainability infrastructure and practices in place at the site
- the second part to ascertain the role of the regulatory body in promotion of practices in the industry and if current incentivisation and support structures were sufficient, and
- the last part focussed on the challenges and barriers which the site has faced in implementing water sustainability practices.

4.4.1 Current practices in water sustainability

4.4.1.1 Understanding of water management versus water sustainability

From secondary research and owing to the insights gained during the interview phase it was acknowledged that the understanding of the fundamental difference between the management of water at a site versus water sustainability practices at a site was essential to the psychological mindset of site personnel and their ability to embrace change successfully in the approach to water governance. Due to the research objective of providing a "snapshot" of the industry it was vital to include this question but also to phrase it in such a way that the researcher was not first educating the participant that there is a difference but instead capturing as close as possible the current level of understanding that a) there is a difference in these approaches to water governance at the site, and b) these participants are self-aware that they understand this difference. To provide some clarity to responders as to what the researcher understood water sustainability to mean, a definition of it was included in the question based on the (Alliance for Water Stewardship, 2023) "*We define water stewardship as the use of water that is socially and culturally equitable, environmentally sustainable and economically beneficial, achieved through a stakeholder-inclusive process that includes both site- and catchment-based actions*."

The first question was then presented as "Do you think currently there is a clear understanding at your site as to what water sustainability practices are versus the management of water at the site?", the results of which are outlined in Figure 3. For the selections *extremely clear* and *very clear* 4 and 8 responders, respectively, cited this level of understanding at the site. Less than half of all respondent's claimed understanding was either *somewhat clear* (9 responders) or *not so clear* (3 responders). One respondent who chose to skip this question later answered "not currently discussed" when asked about the level of support/buy-in from senior management concerning water sustainability practices at the site. This may imply that understanding at the site is low.

For this question an assumption, or null hypothesis, is that there is a moderate to low level of understanding as to the meaning of what water sustainability practices are at the site. A chi-square test indicates that the observed and expected distribution of results of this question are statistically significant (refer to Appendix 8), as the chi-square value (41.98) is greater than the critical value (5.991). The data allows for rejection of the null hypothesis and provides support for the alternative hypothesis, which is that there is

good to high level of understanding of the meaning of water sustainability. As identified during the interview phase, the psychological understanding of the differences between sustainability practices and the management of water were considered by the key stakeholders to be fundamental for successful implementation of practices.

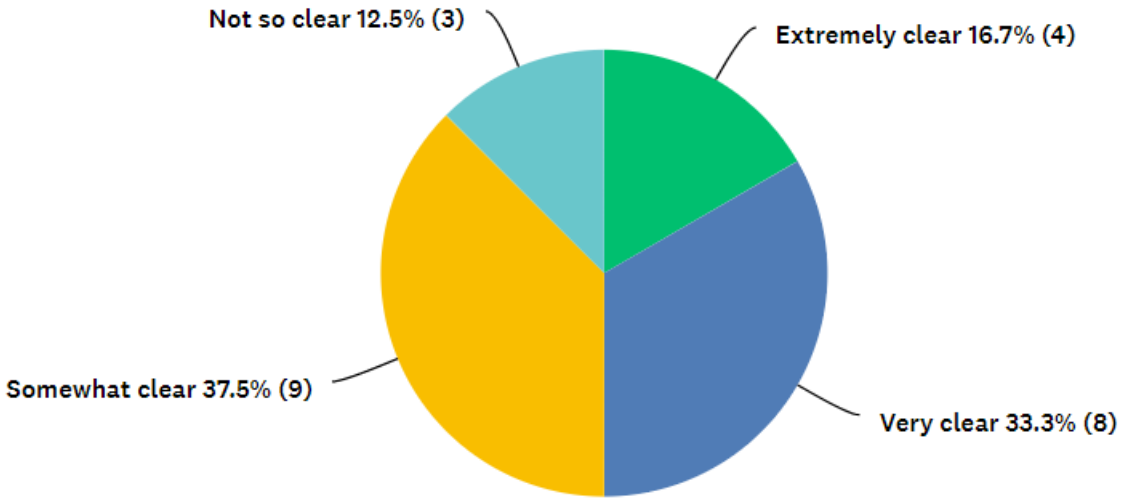

Figure 3 Pie chart representing the responses from participants when asked if they thought there was a clear understanding of what water sustainability practices are versus the management of water at the site.

4.4.1.2 Current practices in place

To ascertain what infrastructure and practices were in place at the site the participants were asked whether they had calculated a water footprint across the whole site. To distinguish whether this action had taken place across the whole site or not was important to understand the level of knowledge at the site of their own water usage. This knowledge can only be gained through the completion of a water foot-printing activity in which all areas where water is used are identified and the amount of water consumed at each area is calculated. The second question was presented as “Has your site calculated its “water footprint” or created a water map across the whole site?”, the results of which are outlined in Figure 4.

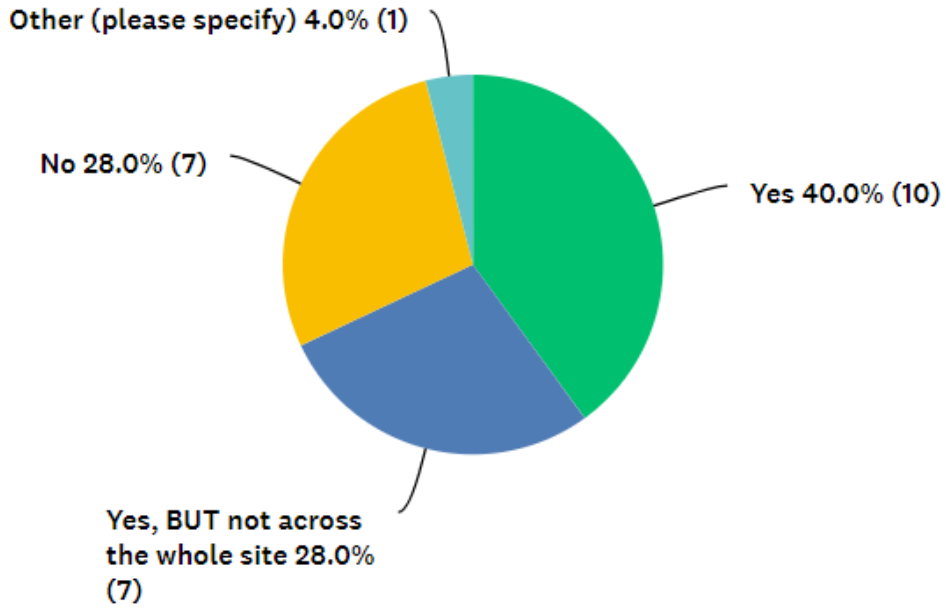

Figure 4 Pie chart representing the responses from participants when asked if they had calculated their water footprint across the whole site.

10 responders claimed to have completed a water footprint across the whole site, with 7 claiming they had completed a water footprint but not across the whole site. 1 responder used the option of other to specify water foot printing across the whole site was actively ongoing. 7 responders claimed they had not done any water foot-printing activity. This indicates that of the sites included in this survey 72 per cent have mapped or are mapping their water usage at the site. This high percentage shows the positive position of these sites in understanding water usage and is the first step to implementing water sustainability processes at a site. However, due to the small participant pool, it is possible that of the 130 sites which were requested to take part, those which declined may represent sites which have not undertaken any water foot-printing activities.

To expand upon this the quantitative third question was asked of participants; what types of strategies are in place at their site, with a series of options presented to responders based on secondary research, the results of which are outlined in Figure 5. These options are common strategies which may be used in pharmaceutical sites to reduce water consumption and increase the recycle value of each water usage. The responders were able to select all the options that applied to their site. The option of *none of the above* was also given to allow sites with no water sustainability practices in place to identify as such. This question highlighted the current processes in place at sites and was essential to being able to provide a snapshot of the current industrial situation.

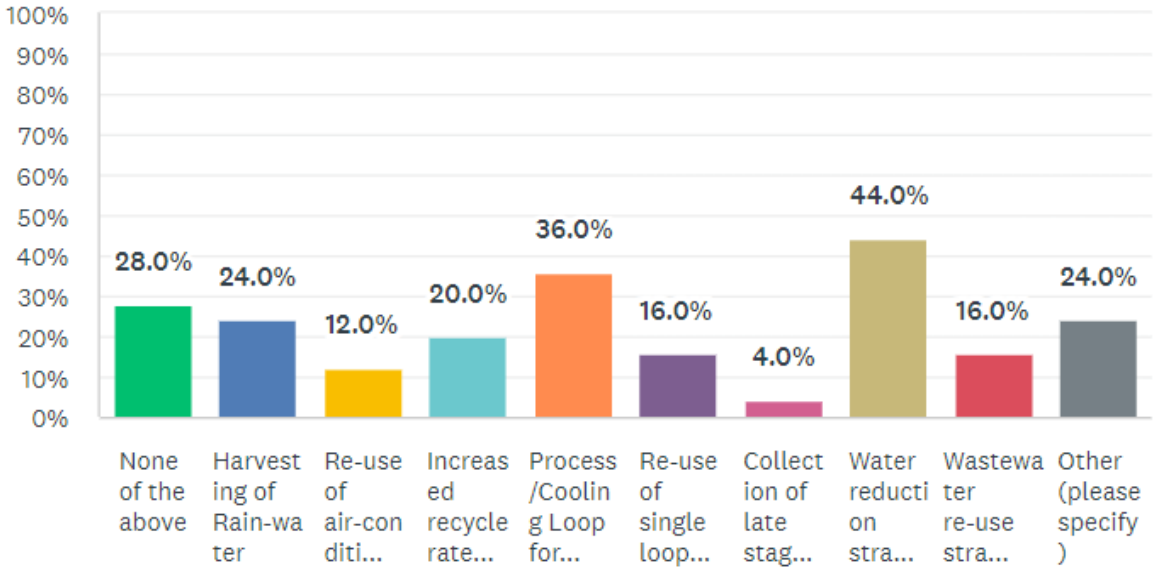

Figure 5 Bar chart representing the responses from participants when asked what current water sustainability strategies they had in place at the site.

Of the sites surveyed 72 per cent had water sustainability practices in place. The most common strategies employed were:

- An *unspecified* Water Reduction strategy (11 responders)
- Process/Cooling Loop for Equipment cooling systems (9 responders)
- Harvesting of Rainwater (6 responders)
- Increased recycle rate of Cooling Towers (5 responders)

The less common strategies employed by sites were:

- An *unspecified* Wastewater re-use strategy (4 responders)
- Re-use of single loop discharge water for irrigation (4 responders)
- Re-use of air-conditioning condensate (3 responders)
- Collection of late-stage equipment rinse/clean discharge (1 responder)

Sites with none of these strategies in place totalled 7, representing 28 per cent of all participants. The option of other was used by responders to clarify unique strategies employed at their site. These included:

- A Water for Injection upgrade project to re-use site water.
- Extended sanitization using ozone instead of chemicals.
- Recovery of RO water from rinse mode.
- Harvesting spring water.

- Use of water from the sprinkler storage tank in a looped cooling system for use in a process with high water usage.
- Re-use of the waste RO stream.
- Increased reporting of water use from each section, and charge to each cost centre.

The breath of answers from participants who are actively implementing water sustainability practices at the site is extremely positive. It shows the diverse approach many sites are taking.

The inclusion of “unspecified wastewater reuse strategy” and “unspecified water reduction strategy” were to allow sites who did not wish to elaborate on their practices to still address the question.

To ascertain if sites were considering the expansion of strategies at their site or if they had reached capacity at the current time regarding sustainability strategies at their site, the fourth question was put to participants; “Do you currently have plans in place to expand any of the above strategies into other areas at the site?”, the results of which are outlined in Figure 6.

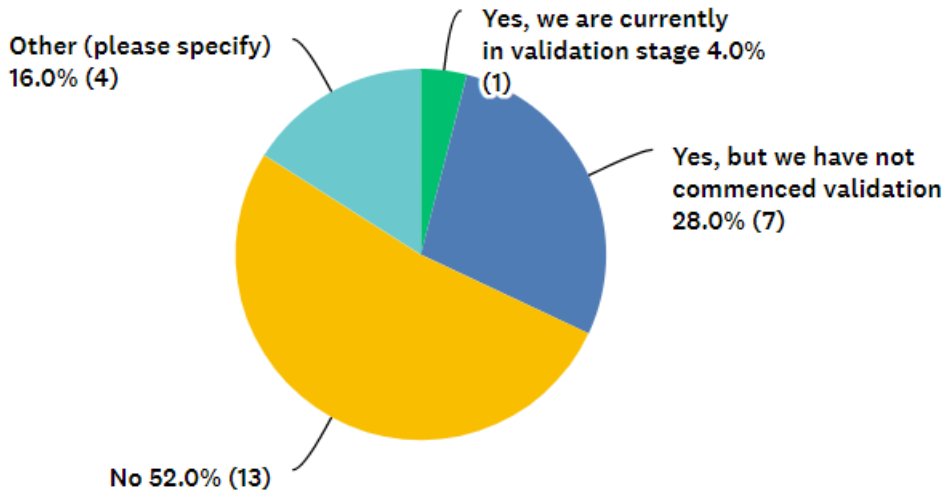

Figure 6 Pie chart representing the responses from participants when asked if they had plans in place to expand current water sustainability strategies into other areas at the site.

This question highlighted that some sites were actively planning the expansion of strategies into other areas at the site, with 9 out of 25 responders answering yes. However, the majority of these (7) had not instigated validation of these strategies at the

current time. Only 2 sites were currently validating strategies in other areas of the site. Conversely 13 responders, or 52 per cent, indicated that they did not have plans to expand strategies into other areas of the site. This implies that there may be barriers impacting expansion of activities. 4 responders used the option of other to clarify their site's position at this time: with 3 of these responders describing themselves as currently in early planning phase for water sustainability strategies. The fourth responder clarified that expansion was into one specific area of the site, therefore this data point was added to the "Yes, we are currently in the validation stage" selection.

4.4.2 The role of Regulatory bodies

The next part of the survey aimed to evaluate the role of regulatory bodies in promoting water sustainability at pharmaceutical sites and whether participants thought this engagement was sufficient to encourage adoption of strategies within their industry. These questions are discussed in the next three sub-sections 4.4.2.1 - 4.4.2.3.

4.4.2.1 Peer-to-Peer Engagement

As a result of the interview phase the concept of peer-to-peer learning was identified as vital to facilitate learning and uptake of water sustainability practices in an industry environment. To address this and to identify whether these sites were engaging in established peer-to-peer networks the participants were asked the fifth question; were they a member of any network body, with *Water Stewardship Ireland* being given as an example, the results of which are outlined in Figure 7.

It was important to include this question to understand the level of engagement by the site with industry peers. Peer engagement may help in the identification and resolution of challenges to adopting sustainability practices and help with finding best practice techniques and technologies.

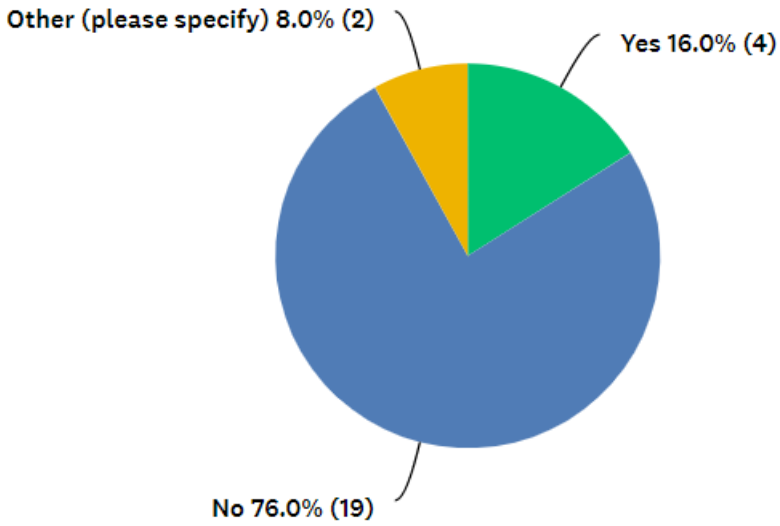

Figure 7 Pie chart representing the responses from participants when asked if they were a member of a peer-to-peer network for knowledge sharing of best practice tools or techniques.

4 responders cited being a member of a peer-to-peer network, though not necessarily *Water Stewardship Ireland*. Whereas 19 responders cited not being a member of a peer-to-peer network. 2 responders used the option of other; 1 to clarify that they did not know if their site was a member of a network, and the other to specify that though their site was not a member of a peer-to-peer network the responding individual was a certified water steward. This results in a final of 84 per cent of the surveyed sites not being a member of a peer-to-peer network of companies.

4.4.2.2 Regulatory Engagement

Expanding on this the participants were next asked their opinion on the level of regulatory engagement with their industry via the quantitative sixth question; “How would you rate the level of engagement of Irish regulators with your industry regarding water sustainability practices?”, the results of which are outlined in Figure 8.

Determining the current opinions and thinking of industry professionals regarding their viewpoint of how well regulatory bodies are interacting with them is important to interpret the current landscape. Some sites may be at a more mature stage in implementation of water sustainability practices; thus, their level of knowledge of the role of regulators to encourage adoption may be more acute than other sites.

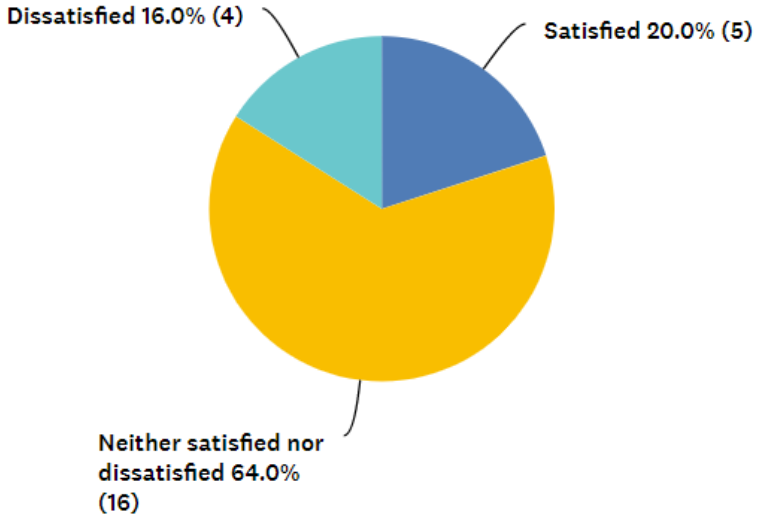

Figure 8 Pie chart representing the responses from participants when asked their opinion of the level of regulatory engagement with their industry regarding implementation of water sustainability practices.

5 responders claimed themselves to be "*satisfied*" with the level of engagement with regulatory bodies, with 4 claiming to be "*dissatisfied*". Most responders, 64 per cent, cited being "*neither satisfied nor dissatisfied*". No participant used the option of other to clarify their opinion.

For this question an assumption, or null hypothesis, is that there is dissatisfaction with the level of engagement from Irish regulators with pharmaceutical sites for implementation of water sustainability practices. A chi-square test indicates that the observed and expected distribution of results of this question are statistically significant (refer to Appendix 8), as the chi-square value (37.11) is greater than the critical value (5.991). The data allows for rejection of the null hypothesis and provides support for the alternative hypothesis, which is there is good to some satisfaction as to the level of engagement from Irish regulators with pharmaceutical sites for implementation of water sustainability practices.

The response of *neither satisfied nor dissatisfied* may also indicate a level of detachment from this question; the responders do not have a strong opinion on this topic. Or the responders may be unsure as to what benefits may be achieved from an effective engagement model with regulators. Consequently, they believe the current engagement framework to be sufficient.

4.4.2.3 Drivers and incentivisation for change

To assess the opinions of the participants regarding the role of Irish regulators for incentivising change within the industry the quantitative seventh question: “Do you think currently there are sufficient drivers in place by the Irish government to encourage your industry to implement water sustainability practices?”, the results of which are outlined in Figure 9.

This question allowed the participants to consider the current drivers that are in place to encourage or facilitate adoption of water sustainability strategies in their industry and was a means of assessing if these participants were aware of any drivers from government. An option of “other” was included to allow for participants to include additional information in their response.

12 participants responded “To some extent” to there being currently sufficient drivers in place. With 13 participants responding “No”, thereby indicating that they are unhappy with the current framework in place by government to encourage and facilitate industry uptake of water sustainability practices. The “to some extent” response indicates a level of dissatisfaction with the current drivers in place and implies the participants may like to see improvement in the incentive structure or scope of incentives offered by government.

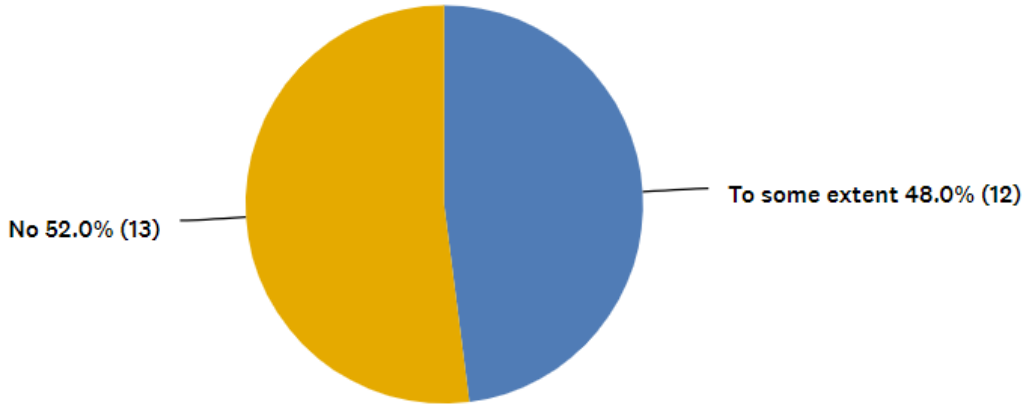

Figure 9 Pie chart representing the responses from participants when asked if they thought there were sufficient drivers in place to encourage the industry to implement water sustainability practices.

As explored during the interview phase, drivers and incentives from government come in many forms such as financial supports as well as soft supports; which one stakeholder interviewee noted as being vital for filling knowledge gaps in industry. It is necessary to engage effectively with regulatory bodies, whose responsibility it is to enforce

government policy, and share with them what support structures and soft supports are required by the industry to ensure successful uptake of water sustainability strategies.

To further probe the participants' experience with regulatory bodies they were asked the qualitative eighth question "What incentives would you like to see offered to your industry? Briefly explain your answer", the results of which are outlined in Figure 10.

This question allowed the participants to add their own thoughts and opinions as to the various tools for incentivisation which they believe could be beneficial for their industry.

Government Funding

- There aren't many small businesses in pharma but ones who have the least and are trying the most should be given an amount to help upgrade their water systems.
- Government funding for water sustainability projects.
- Grant aid to improve the return on investment for water saving projects.
- Initiatives. e.g., to be grant funded.
- Grants to support water saving systems.
- Increased incentives for rainwater harvesting is a must whether it is by grants or any other benefit (tax break etc).
- We have rainwater harvesting on-site but in order to expand it across all buildings on-site there is a capital cost which the company is slow to invest in.
- Tax credits.
- Tax breaks.
- More funding towards projects.
- More grants.
- Financial benefits to implement changes.
- Grants for water reduction or water re-use programs.
- More grants.
- Grants.
- Capital grants.
- Funding for bespoke water recovery units.

Education/Training

- Incentives to promote collection and use of rainwater.
- End User awareness.
- Greater awareness and information on possible water sustainability projects.
- Greater touch point opportunities with other companies who have implemented water sustainability projects.
- Education about water sustainability.
- Knowledge sharing.
- Sponsored Information events.
- Use of Water consultants.
- Promotion of best practices.
- Free site surveys to feed into potential water saving projects.

Comparison to Energy Industry

- Something similar to SEAI for water would be great. We have added water to our ISO 50001 process.
- Similar fashion to energy reduction where grants of 30% of spend is recouped.
- Support from SEAI
- Addition to ESG Strategy

Other:

- Allow easy access for companies to monitor own water use.
- More tiered water tariff to encourage reduction in usage.
- An award ceremony/system like Water Industry Award. Reputational gain as well as an award would be sufficient.
- Incentivise companies / others for leak repairs.

Figure 10 Thematic areas identified in the responses of what incentives participants would like to see offered to their industry to encourage and facilitate implementation of water sustainability practices.

As identified and explored in the interview phase the idea of financial incentives was muted to the various stakeholders as a tool to promote adoption of strategies by government. However, there was a strong opinion that this was not a valuable tool on its own, but that as part of a suite of measures could to some extent be beneficial. It was noted that large pharmaceutical corporations may be the least inclined to take up financial incentives as they already experience high profit turnover, but for more medium-sized and smaller sites financial incentives may prove a valuable tool. This observation may be corroborated by 17 responders who cited grants or funding as an incentive they would like offered (see Figure 10).

Another incentive which participants suggested includes education and training, cited by 10 participants. This response is made the more interesting as based on results shown in Figure 7, 84 per cent of the participants surveyed were not a member of a peer-to-peer network like *Water Stewardship Ireland*. The function of these network programs, which are supported by the Environmental Protection Agency, is to promote awareness and training of water sustainability programs and practices and to facilitate peer engagement. 4 participants made comparison to the energy industry in terms of the grants and supports available in that context, and there was also a reference to adding water sustainability to Environmental Social Governance policy. Finally, 4 participants made more specific references to easy access to their water use data, improvements to water tariffs as an incentive, the use of an award system to promote recognition of practices, and a general comment on incentives needed for leak repairs.

Engagement with regulators is a two-way street and thus it was necessary to include a question which required the participant to self-evaluate their site's role in this process. The quantitative ninth question "Do you think there should be more transparency with regulators as to the scale and nature of water sustainability practices being used at your site?", the results of which are outlined in Figure 11.

This question allowed the participant to assess if more involvement from their site via the provision of information and data of the type and scale of water sustainability activities on their site could be beneficial for promotion of strategies across their industry. An option of other was included to allow participants to add additional information.

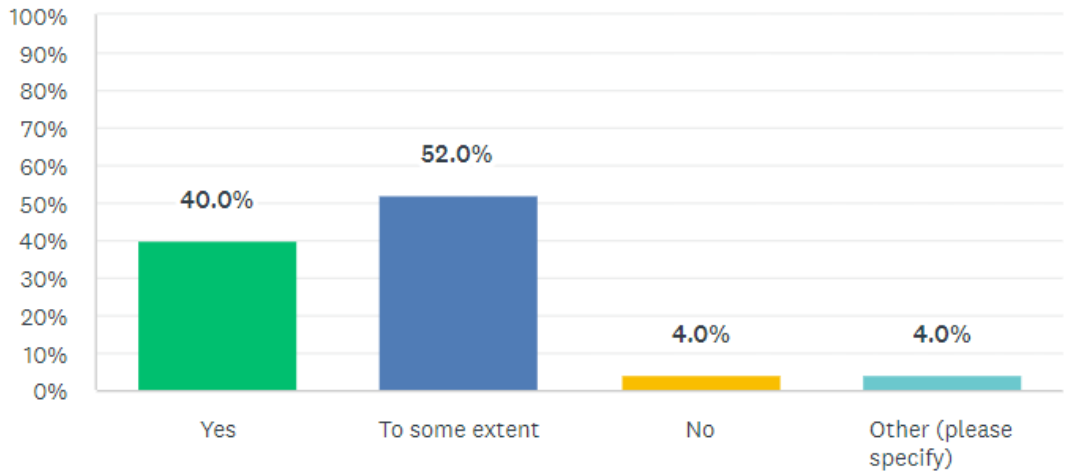

Figure 11 Bar chart representing the responses from participants when asked if they thought there should be more transparency with regulators as to the scale and nature of water sustainability practices being used at their site.

10 responders, or 40 per cent, agreed that there should be more transparency with regulators, with 13 responders, or 52 per cent, indicating their agreement to this question "to some extent". It may be that these 12 responders are unsure of the impact to the site, either financial or logistical, which may result from an increase in specific reporting requirements related to site activities.

The participant who answered "no" to more transparency with regulators, interestingly cited "more funding towards projects" when asked in question 10 about incentives they would like to see offered to their industry. This leads the author to observe whether the government would fund projects at the site if there were less transparency of the site's activities. Another participant used the option of other to answer "unknown" to this question, indicating they were unsure of the answer. This participant answered no to

both having completed water foot printing activities and having sustainable strategies in place at the site.

As identified during literature review there is a gap of available water data in Ireland. EPA-licenced sites are required to report a minimum of information relating to abstraction and discharge licences. It may be concluded that the information available to regulators of water sustainability practices employed at the site, and the scale of such practices, is sparse.

4.4.3 Challenges and Barriers faced by the Industry

The final part of the survey aimed to identify the types of challenges and barriers professionals within the industry were facing in the implementation of water sustainability practices. Given the diverse range of manufacturing processes between the study participants the range of responses was expected to be diverse but at the same time some commonalities were seen amongst responders. These questions are discussed in the next three sub-sections 4.4.3.1 - 4.4.3.3.

Based on the interview phase, challenges associated with cost of infrastructure, return on investment, and validation requirements were identified by stakeholders as common challenges experienced by highly regulated industries, like the pharmaceutical industry.

4.4.3.1 Senior management engagement

As identified in the literature review (Stockil *et al.*, 2018) engagement of senior management is considered vital for successful implementation of water sustainability strategies. To understand how each respondent assessed the level of engagement from senior management at their site the quantitative tenth question was asked: “How would you rate the level of buy-in and support from senior management regarding implementation of water sustainability practices at your site?”, the results of which are outlined in Figure 12.

This question allowed the participants to explore the effectiveness of their site’s senior leadership team to progress current water sustainability strategies. The question also encouraged the participant to reflect on the site’s organisational culture and consider whether the senior management team have assimilated the principles of water sustainability into the day-to-day activities of the site.

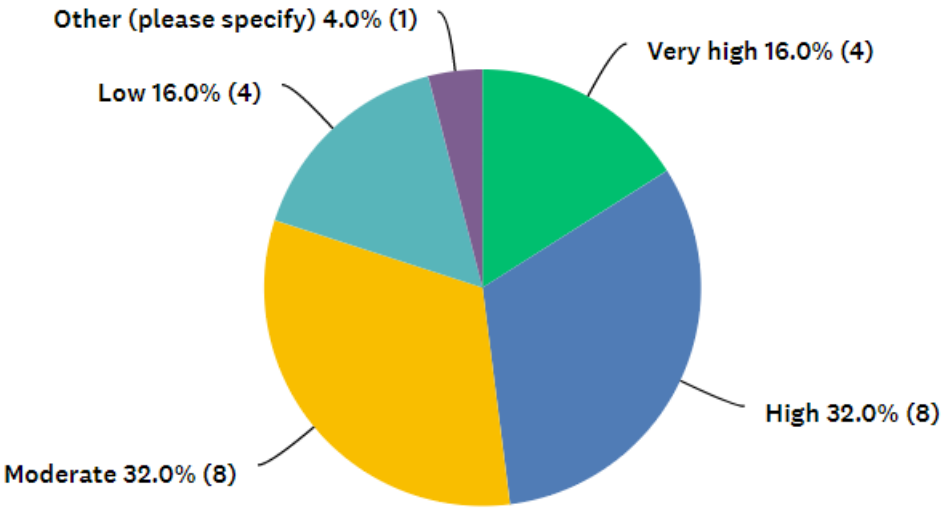

Figure 12 Pie chart representing the responses from participants when asked to rate the level of buy-in and support from senior management regarding implementation of water sustainability practices at the site.

4 participants rated the engagement of their senior management team to be “Very High”, while 8 participants rated the engagement level as “High”. Both combined represent 48 per cent of either high or very high buy-in from senior management, which is a very good position for any organisation to be in to ensure successful implementation of change. 8 participants responded “Moderate”, and 3 participants responded “Low”. One participant used the option of other to answer “not currently discussed” which implies water sustainability strategies are not even on the agenda of the organisation’s management board.

For this question an assumption, or null hypothesis, is that there is good to high level of buy-in and support from senior management regarding implementation of water sustainability practices at the site. A chi-square test indicates that the observed and expected distribution of results of this question are not statistically significant (refer to Appendix 8), as the chi-square value (3.13) is less than the critical value (5.991). The data does not allow for rejection of the null hypothesis. Therefore, this sample size supports the null hypothesis, that there currently is good to high level of buy-in and support from senior management regarding implementation of water sustainability practices at the sites.

4.4.3.2 Challenges faced in the Industry

To further probe the participants' experience with implementation of water sustainability practices and processes at their site the respondents were asked the qualitative eleventh question "What are the biggest challenges your site has faced in implementing water sustainability practices? Briefly explain your answer", the results of which are outlined in Figure 13.

Capital

- Financial limits
- Availability of capital funding due to long cost return timelines
- Water is a relatively low cost for the site but capital projects to make improvements to water use are often expensive.
- Investment required to install rain collection and use.
- Water is cheap. Calculating true cost of water really helps here.
- There are no grant supports that would support further action.
- The cost of capital investment to implement sustainability projects.
- Cost
- Capital investment.
- Replacement of equipment.
- Cost.
- Capital availability.

Knowledge

- Lack of knowledge/training
- Developing Culture
- Lack of knowledge. Lack of ownership
- Knowledge sharing
- Culture
- Reframing mindset within society to water and sustainability.
- Lack of knowledge currently.
- Senior management have interests as there are significant cost savings to be had; but imparting that level of interest or dedication further down the line is sometimes a challenge.

Return on Investment

- Difficulties with making water savings to validate processes due to long re-qualification timelines.
- Demonstrating the cost/benefit for delivering water projects.
- Long return on investment
- Savings
- Only interested if its financially viable

Production/Business demands:

- As we expand our site and production lines, we need more resources (water).
- Priority due to business demands and tight scheduling coupled with resources.
- Production requirements.

Planning permission / site size:

- Space and ease of planning permission to install storage and treatment facilities.
- Feasibility based on the size of the site.
- Lack of space onsite.

Supply Chain:

- Quality of water required on site with little feedback from Irish water.
- Dependability of some vendors (water harvesting vendor).

Figure 13 Thematic areas identified in the responses of participants of what are the biggest challenges the sites have faced in implementation of water sustainability practices.

The thematic areas identified challenges of implementing water sustainability practices as investment in capital, with 12 participants citing availability of capital and grants as their biggest challenge; whilst 8 participants cited knowledge and training as a challenge with culture at the site also being given as an example. The return-on-investment was referenced by 5 participants as a challenge, with a long wait required to justify investment in these types of projects. 3 participants referred to challenges of meeting production and business demands, while another 3 participants cited challenges with planning permission and the size of the site. 2 participants indicated that challenges exist in the water supply chain concerning engagement with vendors of water infrastructure and engagement with service providers Uisce Eireann.

It is not surprising that many of the participants referred to either investment in capital or return-on-investment, or both, as the biggest challenge their site has faced for implementation of water sustainability practices. This may indicate that at present for some companies there is low interest from boards of management in water sustainability practices. Consequently, they may not currently be allocating capital investment, or have difficulty in justifying investments, into these projects. This may imply a low incentivization from government directed at these companies to encourage investment; the value of water sustainability practices is not conveyed to these companies effectively.

The next most cited challenge was lack of knowledge and understanding at the site. This links back to investment in capital and return-on-investment, as ultimately the success

of water sustainability practices is reliant on a change in behaviour or perspective. The meaning of water sustainability is beyond the concept of supply and demand but involves an understanding of water custodianship; meaning we are not consumers of water but custodians of water in the broader environment. When the knowledge and understanding of this custodianship, and thus the value in water sustainability practices, is achieved the challenges associated with capital investment and justifying long return-on-investment may be overcome.

4.4.3.3 Barriers to implementing water sustainability practices

To identify the barriers which each participant has experienced at their site in implementation of water sustainability practices the respondents were asked the qualitative twelfth and final question “Are there barriers which have affected your site implementing water sustainability practices?”, the results of which are outlined in Figure 14. This question was put qualitatively to afford the participants the opportunity to develop their answers naturally.

Financial

- Financial limits.
- Long ROI, insufficient information on the true cost of water. Water cost is only understood up to the cost of metering at the gate. The cost for pumping and treating on site is not considered or difficult to calculate.
- Funding, costs for planning and infrastructure.
- Initial Costs.
- Funding towards projects.
- Cost.
- Payback on investment.

Resources

- Practicality, as in what can actually work most efficiently for us.
- Resources.
- Knowledge.
- Resources.
- Complexity of automation in some cases. Validation of changes.
- Single source of water to site makes modifications to the system difficult without shutting down the plant.

Business demands

- “Getting ahead” mentality - Quotas for production.

- Site priorities. CO2 reduction priority currently. Ireland not water stressed region.
- Regulated & Licensed Processes.
- Culture.
- Competing priorities.

Issues with clarity of the question:

- As above.
- None
- As above.
- No.
- No.
- No.
- As above

Figure 14 Thematic areas identified in the responses of participants to barriers the site has faced in the implementation of water sustainability practices.

When reviewing barriers which each site had experienced the following thematic areas were identified: financial concerns, resources, and business demands. It is not surprising that financial concerns were the most cited barrier, by 7 participants, as this was also referenced during interviews with key stakeholders. Difficulty with justifying investment in water sustainability practices may be a result of the long wait to see return-on-the investment and the high cost of capital infrastructure. 6 participants referred to "resources" as being a barrier. The author interprets resources as possibly relating to issues such as specialized personnel for water sustainability projects, current infrastructure at the site, and water sources at the site, time to complete projects, or knowledge/training of staff in implementing these types of projects.

Business demands was also cited by 5 participants as a barrier the site has experienced, with production output, and priorities being focussed on other areas like energy (CO2) projects. The reference to "culture" was included in this thematic area as the attitudes of senior management and staff play an important part for successful implementation of change; the culture of the site may be focused at meeting the business requirements of the site with little focus outside that.

4 responders cited "no" to experiencing barriers in the implementation of water sustainability practices at the site, although the complexity and scale of the processes they have implemented is unknown.

In retrospect, the question may have been phrased better, as a further 3 participants referred to their answers from the previous question, shown in Figure 13. Although, a challenge in implementing a process/technology may be overcome, a barrier on the other hand must be removed to implement a process/technology. It is possible that for these 3 participants the question was mis-understood. It may have been preferable for this question to instead propose a series of dropdowns of possible barriers, which were identified from literature and during interview phase, and participants were instead asked to select the most common.

This same barrier question was also put to the interviewees, and although 2 of the 3 interviewees did not interact directly with industry, the following areas were cited as likely barriers which industry may experience when implementing water sustainability practices:

- Knowledge/understanding of water sustainability.
- Validation of change (change control).
- Cost of infrastructure.
- Return-on-Investment, justification of the business case.

It is surprising that more participants did not reference difficulty in validation of change as only 2 participants referenced the following which most closely match this:

- Complexity of automation in some cases. Validation of changes.
- Regulated & Licensed Processes

Change control is a big concern for a pharmaceutical site as the industry is highly regulated and introducing any form of change in a process or system may have consequences to the quality of the water, which impacts the risk of contamination of the internal water supply. The pharmaceutical industry is largely driven by risk avoidance; therefore, it is difficult to balance the need to protect the quality of water at the site and the bigger question of water quality in the catchment area.

4.5 Discussion

Through qualitative and quantitative questioning some common concerns among participants were identified when considering the water sustainability practices currently in place. The thematic areas of concern which correlate the results of the interview phase and online survey include financial investment and knowledge/understanding.

Financial Investment

Concerns of the need for increased financial investment in water sustainability practices relate to the high cost of capital infrastructure, a long wait for return-on-investment and therefore a difficulty in justifying the business case for water sustainability practices. Most participants listed these as challenges or barriers to implementation of water sustainability practices. Similarly interviews with key stakeholders outlined the cost of infrastructure and justifying the business case, or value, of water sustainability as being a challenge to implementation. The conclusion for this theme is that there is a need to impart the value to the business for investing in water sustainability practices which is critical to implementation.

Knowledge/understanding

The value to the site for implementation of water sustainability projects is linked to the level of understanding and knowledge of the concept. Many participants listed lack of knowledge and understanding, culture, and a need for more information sharing as a challenge or barrier to implementation of water sustainability practices. Similarly interviews with key stakeholders discussed the psychological understanding of the meaning of water sustainability as fundamental to successful implementation. The conclusion for this theme is that justifying the business value of these projects and thus increasing financial investment in this area will be made easier if understanding and knowledge sharing is achieved.

Both thematic areas will be impacted by the EU legislation which is coming into effect from the fiscal year 2023 for the requirements of the Corporate Sustainability Reporting Directive (EC, 2023a). These reporting requirements arose from the objectives of the EU's Green Deal and will include environmentally sustainable actions such as the use and protection of water and marine resources. Similarly, the Irish government's 2030 goal for reduction in greenhouse gas emissions will be legally binding and enforceable

as outlined in the Climate Action Plan 2021 (Department of the Taoiseach, 2022). These changes in law will have an impact on the practices of companies in Ireland and how they interact with the environment. This may impact the justification for capital investment in water sustainability practices, making it more straightforward as a business case.

The first research objective of this study was to identify what infrastructure and water sustainability practices were in place by the Irish pharmaceutical industry. Primary data gained from this study presented the following summation:

- Nearly half of all participants believed there was an extremely or very clear understanding at the site as to the meaning of water sustainability practices.
- Nearly three quarters of participants indicated the site has calculated or is currently calculating a water foot-printing map at the site.
- Nearly three quarters of participants indicated that there currently were water sustainability practices in place at their site. The responses also indicated a diverse range in the strategies and processes the sites had in place.
- Nearly half of all participants indicated that their site was either currently validating or in the planning phase for expansion of water sustainability strategies to other areas of the site.

The above findings indicate that based on this sample size there is a good level of implementation of infrastructure and water sustainability practices currently in place. This indicates that these sites are in a good position for achieving goals of environmental climate action. It is not possible to generalise these findings across the industry as there are only 25 participants in the sample pool. These findings present the current industrial situation regarding implementation of water sustainability practices to be in a positive light, with good uptake of strategies but more improvements are needed in the level of understanding at the site as to the meaning of water sustainability.

The thematic finding of the interview phase regarding the high *maturity of the pharmaceutical industry* correlate to these results, and indicate the industry is in good standing. The thematic finding of *beyond compliance* identified during the interview phase, indicates the broader meaning of water sustainability may be achieved once sites understand the custodianship rather than consumer-ship mentality.

The second research objective of this study was to evaluate if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites. Primary data gained from this study presented the following summation:

- Over three quarters of participants indicated their site was NOT a member of a peer-to-peer industry network.
- Over half of participants indicated that they were neither satisfied nor dissatisfied with the level of engagement from Irish regulators with their industry regarding implementation of water sustainability practices.
- Over half of participants indicated that there were currently NOT sufficient drivers in place by government to encourage implementation of water sustainability practices. The other near half chose “to some extent”. No participant selected they were satisfied with the current drivers in place by government.
- The most cited incentives which participants would like to see offered to the industry to implement water sustainability practices were government funding/grant support and education/training.
- Nearly all participants indicated agreement or partial agreement that they would like to see more transparency with regulators as to the scale and nature of water sustainability practices in place at the site.

The above findings indicate that based on this sample size more is needed from the role of regulatory bodies to promote implementation of water sustainability practices. There is poor engagement with peer-to-peer networks, these are a vital tool to facilitate industry learning. This finding may indicate either these sites are unaware of these peer-to-peer networks or for some reason are reticent to engage. It is not possible to generalise these findings across the industry as there are only 25 participants in the sample pool. Although there is good conformity in the responses in relation to the need for more transparency with regulators as to what practices of water sustainability are in place. The ambiguity in the response to the level of satisfaction of engagement by regulators with their industry is difficult to explain. Either the participants do not see the value of an increased engagement model with regulators, or they are ambivalent as to the current engagement model which is in place. This finding is significant as engagement with stakeholders of water governance in Ireland, such as regulatory bodies, is the only way to ensure effective change in an industry.

The thematic finding of the interview phase regarding a *suite of measures/tools* correlate to these results from the survey. To promote uptake across the industry an outcomes-based approach is more likely to achieve positive action from sites. Regulatory bodies need to constantly evolve to meet the growing needs of the industry.

The third research objective of this study was to identify the challenges and barriers professionals within the pharmaceutical industry are experiencing in relation to

implementing water sustainability strategies at their sites. Primary data gained from this study presented the following summation:

- Nearly half of all participants indicated the level of buy-in and support from senior management for implementation of water sustainability practices was either high or very high at the site. With nearly a third of participants indicating the level of buy-in and support was moderate.
- The most cited challenges which participants had faced in implementing water sustainability practices were capital investment, knowledge/culture, and return-on-investment.
- The most cited barriers which participants had experienced in implementing water sustainability practices were financial concerns and resources.

The above findings indicate that based on this sample size there is a good level of buy-in and support from senior management for implementation of water sustainability practices, however this level could of course be improved upon. The level of buy-in and support from senior management may be linked to the availability of capital investment in these projects. If the value of these projects was fully realised and thus the business case easier to justify, there would be a corresponding increase to the level of buy-in from senior management.

The thematic finding of the interview phase regarding *prioritization of water sustainability* correlate to the above results of the survey. If water sustainability was higher up the agenda list of the government, then these pharmaceutical sites may find it easier to justify the value to business of spending on capital investment in these practices.

Considering all the above research objectives, critical success factors were identified which sites may use as recommendations to ensure success in implementation of future water sustainability strategies, as described in chapter 5, section 5.2.

Chapter 5

Conclusion

5.1 Study Conclusions

The main objective of this research study was to evaluate the preparedness of the Irish pharmaceutical industry in adoption of water sustainability practices and to identify the critical success factors which may be recommended for the industry.

The study intentions were met by directly engaging with Irish pharmaceutical sites to ascertain the level of awareness and perspectives of water sustainability and to determine if there was widespread uptake across the industry in Ireland.

The secondary research indicated the following key findings which formed the basis of this study:

- **The Irish pharmaceutical Industry** is worth a great deal to the Irish economy, thus any threat to this industry needs to be mitigated with appropriate strategies at an industrial and governmental level.
  (Central Statistics Office, Ireland, 2023) (McCall, 2020)
- **Water is fast becoming a global scarce resource** and though Ireland is often seen as water-rich we are not exempt from this. Ireland in the future will suffer from more prolonged and severe drought conditions, and we are currently implementing upgrades to aging and over-burdened water infrastructure assets.
  (United Nations, 2023) (Byrne *et al.*, 2019)
- **There is an association between water and energy**, referred to as the water: energy nexus. Calculating a complete water footprint (or map) of an industrial site is the first step in understanding how and where water is used at the site, and the relationship between water and energy at the site.
  (Trubetskaya *et al.*, 2021) (Voulvoulis, 2018)
- **Drivers for water reuse** primarily relate to savings of operational costs and reducing the risk to business continuity. The secondary data postulates that due to the high cost of infrastructure and long payback associated with these types of strategies there may be low incentivization to implement. (Byrne *et al.*, 2019) (Stockil *et al.*, 2018)
- **An efficient water management strategy** is a crucial component of any companies' environmental, social, and governance (ESG) policy. Water scarcity or drought conditions are seen as a risk to business and companies are

implementing risk resilience planning to mitigate risks associated with water resources at a site. (Stockil *et al.*, 2018) (Newborn and Dalton, 2016)

The primary findings of this research study are indicated below as per the study objectives set out in Chapter 1:

- **Identify what infrastructure and water sustainability practices are in place by the Irish pharmaceutical industry**.

The pharmaceutical industry in Ireland is very well positioned for implementation of water sustainability practices. The snapshot provided of the current industrial landscape indicates there is good level of understanding as to the meaning of water sustainability at these sites with very good buy-in from senior management. There is wide uptake of diverse strategy approaches at the sites with most sites planning further expansion into other areas.

- **Evaluate if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites.**

The role of regulatory bodies appears to be in a less favourable position. There is some dissatisfaction with the current incentive structure in place to encourage uptake by the industry with knowledge and understanding one of the biggest challenges cited by participants. The role of regulatory bodies, like the Environmental Protection Agency, in water stewardship policy, is to build greater awareness of the benefits of water stewardship and to develop an enabling environment. Key support agencies like Enterprise Ireland and IDA Ireland are also fundamental to creating this environment. Similarly, Uisce Eireann as the service provider and public face of water in Ireland, is fundamental to creating an ecosystem of support for pharmaceutical sites.

- **Identify the challenges and barriers professionals within the pharmaceutical industry are experiencing in relation to implementing water sustainability strategies at their sites**.

The biggest challenges and barriers which sites were experiencing was capital investment, knowledge and understanding of the sustainability concept across the industry, and resources at the site. To address these challenges and barriers an integrated support system is needed which involves multi-stakeholder participation. Bodies representing cross-departmental government agencies should be involved in the engagement process to fully understand the challenges and barriers experienced by the pharmaceutical industry, to develop mitigation plans and to facilitate signposting of

relevant funding and education supports. These bodies may include: the Department of Housing, Planning, Community, and Local Government (DHPCLG), the Environmental Protection Agency, key supports like Enterprise Ireland, IDA Ireland, SEAI, and the other key agency Uisce Eireann, along with pharmaceutical industry representatives. Key focus areas could be:

- an educational drive for all stakeholders to increase participation in education and training initiatives like the Uisce Eireann certification program.
- a recruitment drive spearheaded by the EPA for increased engagement in peer-to-peer networks like Water Stewardship Ireland, and
- an awareness program for increased uptake of financial supports from departments such as Enterprise Ireland, SEAI, and IDA Ireland, to mitigate the long return on investment and high capital cost of water sustainability practices.

The final study objective was to identify the critical success factors and thus recommendations which sites can use as a benchmark for implementation of future water sustainability strategies, and these are discussed in more detail in section 5.2.

The primary research also addressed the following gaps which were identified during the literature review in Chapter 2:

- **Lack of Water Data** the secondary research indicates that there is a gap in the available water data in Ireland. There does not appear to be a consolidated reporting of water sustainability practices to regulators, such as the Environmental Protection Agency. Outside of a company reporting as per its licensing requirements to the Environmental Protection Agency and reporting goals related to water efficiency in a Resource Efficiency Action Plan, there is little information available on water sustainability practices at a pharmaceutical site. Uisce Eireann indicated that they do not collect data of this kind from their non-domestic customers. A data-driven management of water stewardship practices at a national level is critical to promote adoption of water strategies by industry. Although addressing the lack of water data was outside the scope of this study, the primary research indicated that 92 per cent of participants agree for more data transparency with regulators. Increased transparency of data is significant as it is part of the practice of water sustainability and may be used to monitor and report on the progression of water stewardship polices nationally.

- **Lack of Incentives and No National Framework:** there is no specific national framework in place which is directed at promoting pharmaceutical sites to implement water sustainability practices. Rather, incentives of financial support appear in the form of *climate action and energy supports for businesses* from departments such as the Sustainable Energy Authority of Ireland (SEAI), IDA Ireland, Enterprise Ireland, and Skillnet Ireland. Incentives in the form of education and training initiatives are in place by Uisce Eireann and Lean and Green Skillnet for a certification course in water stewardship. The EPA also leads Ireland's Circular Economy Programme which includes water as a priority area and funds circular economy training programmes for businesses. Incentives in the form of recognition and award programs are in place via The Green Awards which includes *The Sustainable Water Achievement Award*, sponsored by Uisce Eireann. Winners must demonstrate year on year comparisons and a strategy in place for innovation and technology use, water sustainability, staff engagement, and effects on local community.

  However, it is justified to observe that outside of these supports the onus lies with the site to put water sustainability practices in place. Although addressing the incentives and national framework in place by government was outside the scope of this study, the primary research indicated grant and funding support was the most cited incentive participants would like to see offered to the industry, followed by education and training as the next cited incentive. The primary research indicated financial concerns and the long return-on-investment were the most cited barriers to implementation of water sustainability practices. It may be concluded that more research is required to assess the suitability of the current incentives and framework of engagement with industry.

- **No Regulatory Monitoring**: Outside of the reporting obligations to meet their Integrated Pollution Control (IPC) licence it may be observed that Irish regulatory bodies, namely the Environmental Protection Agency as the enforcement agency of water policy in Ireland, does not play a role in the monitoring of water sustainability practices in place by pharmaceutical sites.

Assessing why the current incentives in place may not be sufficient for the industry it may be hypothesized that:

- The current requirements of the grant and funding supports in place may not be applicable to projects for water sustainability practices.

- The current grant and funding supports are insufficient to meet current costs for water sustainability practices, or these sites do not meet the grant application criteria. Some grants are limited to small medium businesses and some of the grants relate specifically to reduction of energy consumed or carbon emissions.
- Lack of awareness of the education and training initiatives that are in place. Cost is not an issue as they are free, and operational reasons are less of an issue as the courses are often run online.
- Lack of awareness and consequently lack of participation in water sustainability categories in existing national award programs.

5.2 Critical success factors and recommendations for industry

Some critical success factors have been identified based on results of the online survey and the interviews with key stakeholders. These may serve as a benchmark for sites to accomplish their goals of implementation of water sustainability practices. These include the fundamental understanding of the concept of water sustainability and engagement of the site with peers and regulatory bodies. The reasons and benefits for these critical factors of success are outlined below:

Understanding the concept

- How the water governance structure in Ireland works, who are the key stakeholders and their roles and responsibilities.
- The concept of water sustainability involves the quantity AND quality of water and the border environmental impacts to the catchment area as well as habitats.
- There needs to be a dissociation of the supply-demand concept of water and a focus on the custodianship of water.

Engagement with peers and regulatory bodies

- Participation in peer-to-peer networks is fundamental to promote and facilitate understanding and engagement with others.
- Participation in certification programmes and peer-to-peer networks allows for engagement with regulatory bodies as these programs are all supported and facilitated by stakeholders of water governance in Ireland.

The more difficult issue of capital investment and justifying long return-on-investment may be overcome by these two critical success factors if the perspective of water is changed from consumer to custodian. Achieving understanding will highlight the value in these strategies for risk reduction and resource protection at the site.

The most effective way to engage with regulatory bodies and those involved in the governance of water in Ireland is through involvement in peer-to-peer network programs, such as *Water Stewardship Ireland*, which is supported by the Environmental Protection Agency. All pharmaceutical sites should be represented in these peer-to-peer networks. Engagement in peer networks will enable representation of the site and engagement in dialogue with government as to the industry's needs.

The most effective way to promote understanding and knowledge is to engage in water stewardship certification programmes which are facilitated in conjunction with Uisce Eireann. There are also education initiatives for understanding the circular economy, facilitated by the Environmental Protection Agency. The circular economy is a fundamental concept in water sustainability.

The benefits of these two critical success factors include knowledge sharing, education in best practice processes/tools, demonstration of environment credentials, reputational gain, and understanding the value to risk reduction. These benefits enable justification of the business value for capital investment in water sustainability projects.

It is important for the Irish government to ensure that the appropriate resources and infrastructure required by the pharmaceutical industry meets capacity requirements and is future-proofed to allow for continued growth in this industry as it is currently worth billions to the Irish economy.

In conclusion, the Irish pharmaceutical industry appears to be in a state of preparedness with regards implementation of water sustainability practices. However, support structures and programmes to promote adoption of these practices across the industry need to be evaluated for effectiveness in the long-term.

5.3 Limitations of the Study

The following points are given as limitations identified in this study:

- **Sample size**:
  Based on sample size calculations, a sample size of 98 was recommended. This was not achieved. The study sample size was relatively small at 25 participants.
- **Time for collection of raw data**:
  A longer raw data collection time would have been preferred. The responsiveness of participants may have been impacted by public holiday and the Easter period.
- **Interview phase**:
  Failure to engage the key stakeholders Uisce Eireann and the Environmental Protection Agency in an interview despite repeated requests.

5.4 Recommendations for future study

Any one of the following points may be taken as the basis for future study in this topic area:

- **Water data:**
  Engage in interview with Uisce Eireann and the Environmental Protection Agency on this topic, specifically regarding water data in Ireland. What are their plans to increase the available information to researchers on this topic and to facilitate information sharing with the industry. Investigate the scale and scope for effective and meaningful reporting. Assess the impact of the incoming CSRD requirements.

- **EPA Research project:**
  Collaborate with the Environmental Protection Agency (EPA) on a research project involving this topic; specifically aimed at pharmaceutical sites as large users of water. A collaboration with the EPA is more likely to be impactful and gain traction to increase participant involvement.

- **Incentive structure:**

  Focus on evaluating the current incentives in place by government to promote uptake of water sustainability practices across the pharmaceutical industry. Assess if these incentives and the framework for engagement with sites are effective.

- **Grant/Funding supports:**

  Evaluate the grant and funding supports available through support agencies like SEAI and Enterprise Ireland. Assess the uptake of these supports by Irish pharmaceutical sites and whether these supports are making a positive impact for implementing water sustainability strategies. Assess drawbacks of these supports.

- **Peer-to-Peer Network:**

  Collaborate in a project with the industry network *Water Stewardship Ireland* to directly engage with their members to ascertain challenges and barriers they may be currently facing in implementing water sustainability strategies. Identify recommendations from these members to promote an enabling environment.

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Appendices

7.1 Appendix 1: Initial Invite (LinkedIn) for Online Survey

Hi [name],

I would like to include [company name] in a research study about Water Sustainability practices in Irish pharmaceutical sites.

I am a part-time student currently pursuing a Masters in Pharmaceutical Business and Technology in conjunction with Griffith College (Dublin) and Innopharma Faculty of Pharmaceutical Sciences.

The focus of this research study is on:

- Current state of water sustainability by pharmaceutical/biopharmaceutical/medical device sites in Ireland.
- Preparedness of the industry for the future.
- Challenges and barriers they are currently facing to implement strong water stewardship practices, incl. water re-use strategies.
- Provide an overall snapshot of the current industrial situation.

The Online Survey will:

- Comprise approx. 12 questions (quantitative and qualitative).
- Relate to water stewardship practices at your site.
- Will take no more than 10 minutes of your time.
- Be sent via email link between the 13th - 24th March.

I would greatly appreciate and value your input and participation in the survey, by confirming by reply email.

Alternatively, if you know a colleague who is better placed to participate, please forward this email to them.

My email is [xxxxxxxxxxx@student.griffith.ie] and my phone number is: [xxx xxx xxxx].

I appreciate your time.

Kindest regards,

Deirdre Cournane

7.2 Appendix 2: Initial Request (LinkedIn) for Qualitative Interview

Note: There is a 300-character limit of messages to people who are not contacts in LinkedIn

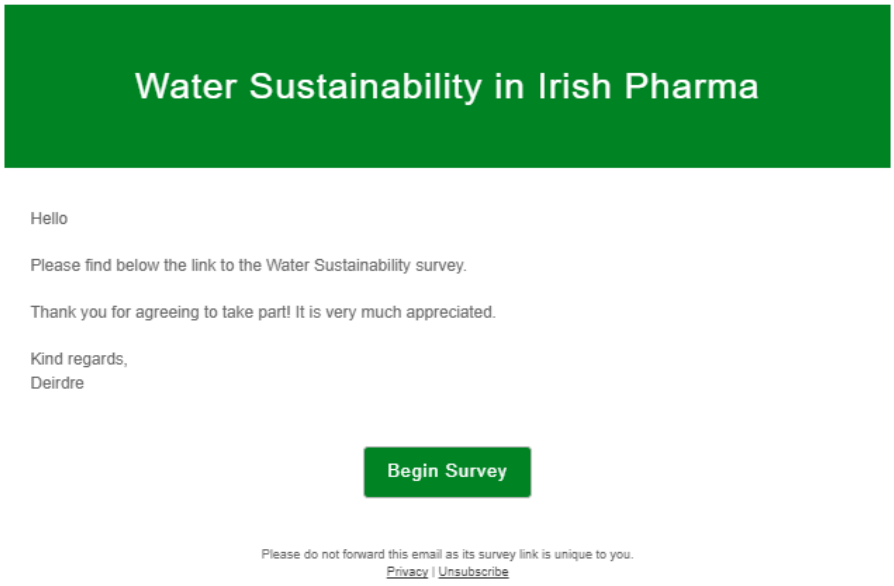
Hi [name],

I am conducting an MSc research study with Griffith College (Dublin) and Innopharma Faculty of Pharmaceutical Sciences on Water Sustainability practices in Irish pharma sites and would really appreciate if you could participate in an interview regarding your professional perspective.

Thank you for your time,

Deirdre

7.3 Appendix 3: Original Email Invite for Online Survey



7.4 Appendix 4: Participant Information Letter

GRIFFITH COLLEGE

Participant Information Letter (PIL)

IS THE IRISH PHARMACEUTICAL SECTOR PREPARED FOR REDUCTION IN WATER FOOTPRINT

I would like to invite you to take part in a research study I am conducting into the current state of water sustainability practises and water reuse by pharmaceutical sites across Ireland. Before you decide to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is **Deirdre Cournane,** and I am a part-time postgraduate student undertaking a research dissertation for the master's degree course *Pharmaceutical Business & Technology* with Griffith College/Innopharma Education. I am doing this research study to investigate the current state of how the Irish pharmaceutical sector practises water sustainability and if they are prepared for future water shortages.

WHAT WOULD TAKING PART INVOLVE?

If you decide to take part, I will invite you to a virtual interview lasting approximately 30 minutes where I will ask you a series of questions related to your experience/ knowledge of water sustainability practices by industrial sites in Ireland. The interview will be recorded for my only personal use only, so that I may transcribe the answers or re-play the recording, if necessary, when analysing all the interviewee answers. The interview will not be uploaded to any online platform, nor will the interview recording be published in any way. The interview will be scheduled around your time and may be on weekends or evenings - whichever is most convenient to you.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

I have identified you as a person who represents key stakeholders of the water lifecycle in Ireland; and may be knowledgeable of water sustainability practices in Ireland due to your profession and as listed on LinkedIn, and also through secondary research online.

DO YOU HAVE TO TAKE PART?

No, you do not have to take part. Please note

- that participation is **voluntary**
- that a decision not to consent will have **no adverse consequences**
- you may **withdraw consent at any time**

If you need to withdraw, please contact me directly on [redacted]**@student.griffith.ie**.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

The benefits of taking part are that you will help to facilitate me achieve my thesis as well as be a participant in a review of the current state of the Irish pharmaceutical sector's preparedness for the future of water use. Due to the subject nature of the research study (i.e., water sustainability) and how the research will be conducted (i.e., virtual interviews) I do not envisage any situation where a participant may come to any possible harm (physical or psychological). There will be no risk to confidentiality as all data included in the report will be anonymised for all participants.

WILL TAKING PART BE CONFIDENTIAL?

All data will be saved and handled in a confidential manner and apart from signed consent forms and recorded interviews all other data will be anonymised for all participants. There will be no confidential company data used and if some specific information of the company is mentioned during an interview, this may only be referenced in the data in the broadest or generalizable of terms (i.e., if use of a *specific type of* digital tool/technology is mentioned, only *use of* a digital tool/technology will be referenced). A copy of the recorded interviews will be made available to each company to review and approve for inclusion in the research study. This communicated approval will be saved by me the researcher in the form of an email to/from the individual company.

Due to the subject nature of the research study (i.e., water sustainability) I do not envisage any situation where I will need to break confidentiality. Signed consent forms and audio recordings of interviews will be collected and retained as part of the research process in a non-anonymised way (i.e., they will be saved as per participant name and date of interview). However, they will only be accessible to me the researcher and to my supervisor, should they wish to confer an observation.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms and original audio recordings will be retained in my Griffith College cloud platform (Moodle) which only I have access, in a password-protected folder, for a period of up to 2 years following completion of the research and until after my degree has been conferred. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this. Under freedom of information legalisation, you are entitled to access the information you have provided at any time.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of this research study are for the purpose of a thesis submission only. However, to be clear as part of submission and final acceptance of the thesis, the research results will be made accessible in the Griffith College library and could potentially be made available in online e-journals or repository. Nevertheless, there will be no personal identifiers used for any participant interviewed nor will identification of individual companies be made without the express permission from the company press office (not by the interviewee).

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

[redacted]**@student.griffith.ie** or call me on [redacted]

THANK YOU

7.5 Appendix 5: Privacy and Consent Agreement

The researcher retains one copy signed by herself and the participant. The participant should also receive a copy of the signed consent form as a record of what they have signed up to.

- I [name] voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can **withdraw at any time** or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that participation involves **answering questions relating to my experience and knowledge of water sustainability practises employed by the industrial industry in Ireland** in a virtual interview.
- I understand that I will not benefit directly from participating in this research.
- I understand that all information I provide for this study will be treated confidentially.
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I agree to my **interview being audio-recorded** on the platform of choice (i.e., Zoom)
- I understand that disguised extracts from my interview may be quoted in the dissertation, the viva presentation, e-journals, and in the Griffith College repository (as part of the submitted dissertation).
- I understand that I will adhere to all codes of conduct and employee confidentiality for my company, [company name], and there is no expectation to breach these by partaking in this research. I will include a signed confidentiality statement between my company and the researcher, Deirdre Cournane, if deemed necessary by my management.
- I understand that if I inform the researcher, Deirdre Cournane, that myself or someone else is at risk of harm, she may have to report this to the relevant authorities – she will discuss this with me first but may be required to report with or without my permission.
- I understand that signed consent forms and original audio recordings will be retained in the researcher's Griffith College cloud platform (Moodle) which only she has access to, in a password-protected folder, for a period of up to 2 years following completion of the research and until after her degree has been conferred.
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for a further two years after this.
- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact the researcher, Deirdre Cournane, to seek further clarification and information as per the below:

Researcher Details

Deirdre Cournane

Master of Pharmaceutical Business & Technology (MSCPT)

Griffith College / Innopharma Education

[mobile number]

[email address]

Signature of participant

Signature of research participant:

---------- ----------

[name] Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study:

Signature of research participant:

---------- ----------

Deirdre Cournane Date

7.6 Appendix 6: Interview Questions to Key Stakeholders

The below questions were used as a guide for the semi-structured interviews with key stakeholders of the governance structure of water in Ireland. The questions are grouped based on the study objectives:

Evaluate if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites.

1. Do you think there is sufficient engagement from Irish regulatory bodies with the Irish pharmaceutical industry to promote adoption of water sustainability strategies?
    a. Is this level of engagement effective?
2. Do you think more supports are needed and if so, what?
3. Do you think the Irish government should bring forward legislation to compel pharmaceutical sites to implement water sustainability practices?
    a. Would it increase uptake of these strategies by the industry?
4. Do you think there should be a legal obligation for pharmaceutical sites to report their water re-use practices to Irish regulators (like the EPA), including the scale and nature of the water sustainability practices employed?
5. In your experience, do you think there is sufficient engagement from the pharmaceutical industry in training/certification programmes for strong water stewardship practices such as the Water Stewardship Ireland/Uisce Eireann certified programme?

Identify the challenges and barriers professionals within the pharmaceutical industry are experiencing in relation to implementing water sustainability strategies at their sites.

6. In your experience, do you think there is sufficient understanding in the pharmaceutical industry of what water stewardship/sustainability is?
7. Apart from training/education (such as in the certification programme) how else do you think better understanding may be achieved?
8. What do you think are the biggest challenges to the Irish pharmaceutical industry for reducing consumption of water or better managing their consumption of water?
9. Do you think financial penalties would incentivise the Irish pharmaceutical industry to implement strategies?
10. Do you think financial incentives such as grants, and tax credits would encourage the Irish pharmaceutical industry to implement strategies?

Considering all the above, identify the critical success factors, and thus recommendations, which sites can use as a benchmark for implementation of future water sustainability strategies.

11. What do you think is critical for successful implementation of water sustainability practices at a company?
12. What do you think is the biggest obstacle for implementation of water sustainability practices at a company?
13. Education and training are very important, do you think it should be mandatory to participate in training programs such as the Water Stewardship Ireland/Uisce Eireann certified programme?
14. Do you think membership should be mandatory in peer-to-peer networks for large water users, such as in Water Stewardship Ireland to facilitate engagement/discussion/development of water sustainability practices?

7.7 Appendix 7: Online Survey Questions

The below twelve questions were included in the online survey sent to participants via email link. The questions are grouped based on the study objectives:

Identify what infrastructure and water sustainability practices are in place by the Irish pharmaceutical industry.

1. Do you think currently there is a clear understanding at your site as to what water sustainability practices are versus the management of water at the site? *[Extremely clear; Very clear; Somewhat clear; Not so clear; Not at all clear; Other]*
2. Has your site calculated its "water footprint" or created a water map across the whole site? *[Yes, No, Other]*
3. What types of strategies are in place at their site with a series of options presented to responders based on secondary research *[drop-down selection of 9 options was given as taken from sustainability strategies as listed on Uisce Eireann website; Other]*
4. Do you currently have plans in place to expand any of the above strategies into other areas at the site? *[Yes, we are currently in validation; Yes, but we have not commenced validation; No; Other]*

Evaluate if the role of Irish regulatory bodies is adequate to promote adoption of water sustainability strategies by Irish pharmaceutical sites.

5. Is your site a member of any network such as Water Stewardship Ireland? *[Yes; No; I don't know; Other]*
6. How would you rate the level of engagement from Irish regulators to your industry with regards water sustainability practices *[Very satisfied; Satisfied; Neither satisfied nor dissatisfied; Dissatisfied; Very dissatisfied; Other]*
7. Do you think currently there are sufficient drivers in place by the Irish government to encourage your industry to implement water sustainability practices? *[Yes; To Some Extent; No; Other]*
8. What incentives would you like to see offered to your industry? Briefly explain your answer.
9. Do you think there should be more transparency with regulators as to the scale and nature of water sustainability practices being used at your site? *[Yes; To Some Extent; No; Other]*

Identify the challenges and barriers professionals within the pharmaceutical industry are experiencing in relation to implementing water sustainability strategies at their sites.

10. How would you rate the level of buy-in and support from senior management regarding implementation of water sustainability practices at your site? *[Very High; High; Moderate; Low; Poor; Other]*
11. What are the biggest challenges your site has faced in implementing water sustainability practices? Briefly explain your answer.
12. Are there barriers which have affected your site implementing water sustainability practices? Briefly explain your answer.

7.8 Appendix 8: Results of Chi Square Test

Question 1

Responses	# participants	Actual Values	Expected Values	expected frequencies
Extremely Clear	4			
Very Clear	8	12	2.5	10%
Somewhat clear	9	9	10	40%
Not so clear	3	4	12.5	50%
Not at all clear	1			
Total # participants:		**25**	**25**	

Significance value: 0.05
Degree of Freedom: 2
X2 Critical Value: 5.991

(A-E)	(A-E)^2	(A-E)^2 / E
9.5	90.25	36.1
-1	1	0.1
-8.5	72.25	5.78
Chi-square value, X2:		41.98

Null hypothesis:
There is a moderate to low level of understanding as to the meaning of what water sustainability practices at the site.

Conclusion:
The x2 value is greater than the critical value, therefore the difference between the observed and expected distributions is statistically significant ($p < \alpha$).
The data allows for rejection of the null hypothesis and provides support for the alternative hypothesis; which is there is a good to high level of understanding about the meaning of water sustainability.

Question 6

Responses	# participants	Actual Values	Expected Values	expected frequencies
Very Satisfied	0			
Satisfied	5	5	2.5	10%
Neither satisfied or dissatisfied	16	16	5	20%
Dissatisfied	4	4	17.5	70%
Very dissatisfied	0			
Total # participants:		**25**	**25**	

Significance value: 0.05
Degree of Freedom: 2
X2 Critical Value: 5.991

(A-E)	(A-E)^2	(A-E)^2 / E
2.5	6.25	2.5
11	121	24.2
-13.5	182.25	10.41
Chi-square value, X2:		37.11

Null hypothesis:
There is dissatisfaction with the level of engagement from Irish regulators with pharmaceutical sites for implementation of water sustainability practices.

Conclusion:
The x2 value is greater than the critical value, therefore the difference between the observed and expected distributions is statistically significant ($p < \alpha$).
The data allows for rejection of the null hypothesis and provides support for the alternative hypothesis; which is that there is a good to some satisfaction with the level of enagement from Irish regulatory bodies for promotion of water sustainability practices.

Question 10

Responses	# participants	Actual Values	Expected Values	expected frequencies
Very High	4			
High	8	12	15	60%
Moderate	8	8	7.5	30%
Low	4	5	2.5	10%
Poor	1			
Total # participants:		**25**	**25**	

Significance value: 0.05
Degree of Freedom: 2
X2 Critical Value: 5.991

(A-E)	(A-E)^2	(A-E)^2 / E
-3	9	0.6
0.5	0.25	0.03
2.5	6.25	2.50
Chi-square value, X2:		3.13

Null hypothesis:
There is a good to high level of buy-in and suport from senior management regarding implementation of water sustainability practices at the site.

Conclusion:
The x2 value is less than the critical value, therefore the difference between the observed and expected distributions is not statistically significant ($p > \alpha$).
The data doesn't allow you to reject the null hypothesis and doesn't provide support for the alternative hypothesis.

<END>