"An Analysis of The Use of Wearable Technology as A Means of Controlling Drug Delivery Systems and The Challenges Facing Its Usage in Ireland"

By

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A thesis submitted in partial fulfilment of the requirements for **MSc in Pharmaceutical Business & Technology** (*QQI*)

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CANDIDATE DECLARATION

I hereby certify that this material, which I now submit for assessment on the programme of study leading to the award of the MSc in Pharmaceutical Business & Technology, is my own; based on my personal study and/or research, and that I have acknowledged all material and sources used in its preparation. I also certify that I have not copied in part or whole or otherwise plagiarised the work of anyone else, including other students.

Signed: _____

Dated: _____

Supervisor: Mark Campbell

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ABSTRACT

An Analysis of The Use of Wearable Technology as A Means of Controlling Drug Delivery Systems And The Challenges Facing Its Usage In Ireland

by Adewumi Bolatito Temitayo

In this study, the possible/existing use (in Ireland) of wearables (such as the smartwatches, patches, and contact lenses) in controlling drug delivery systems (such as pumps and nanoparticles) was analysed. The challenges affecting the use of this technology in Ireland were determined. The public and potential customers' perception of the novel technology was examined along with how the creation will be potentially received in the market. Ireland was the country of choice because the researcher resides there and because of the heavy presence of many pharmaceutical companies in the country.

The secondary research was conducted by looking into the concept of controlled drug delivery and how it works. The history, uses and the market for wearable devices was explored globally and in Ireland. The concept of wearable device-controlled drug delivery systems was then introduced. The different commercially available ones were analysed and the challenges facing the use were examined. The data collection involved quantitative research via questionnaire (219 participants) to establish the challenges facing the development and manufacture of this type of drug delivery system. The knowledge and views of Irish consumers concerning the use of this technology were established. Qualitative data was also collected via interviews (of 3 industry experts) to further explain these technologies and determine the level of progress in the research & development and manufacture of the devices in Ireland.

The use of wearable devices in controlling drug delivery systems is still at its early stage in Ireland and some people have little or no knowledge of the use of this type of drug delivery system. Majority of the participants were interested in using the technology (83.5%), 65.6% would rather use this wearable device-controlled drug delivery system because more than half of the participants trust that this type of drug delivery system is more effective. Some of the limitations of the use of this type of drug delivery system from the consumers' point of view are based on the concerns on the high cost, efficiency, and accuracy of this type of drug delivery system. The size, look, comfort, and ease of use of these devices influence the use of this type of drug delivery system. According to the industry experts, challenges like heavy regulations and the massive amount of time, money, and resources involved in the Research & Development affect the manufacture and use of wearable device-controlled drug delivery systems in Ireland.

Keywords: Drug Delivery, Wearable Technology, Wearable Devices, Ireland, Drug Delivery Devices, Controlled Drug Delivery, Drug Delivery Systems, Pharmaceuticals, Therapeutic Substances, Drug Substances

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LIST OF ABBREVIATIONS

API- Active Pharmaceutical Ingredient

ISO- International Organization for Standardization

IDA Ireland- Industrial Development Authority Ireland

CHAPTER 1: INTRODUCTION

1.1. OVERVIEW

This research is based on using wearable devices in controlled drug delivery and the challenges involved in the design, manufacturing, and sales of the devices. It is only focused on controlled drug delivery systems and does not include its use in other forms of drug delivery.

This dissertation is also aimed at determining the challenges affecting the use of this technology by discussing with experts the pharmaceutical and medical devices industry, especially in Ireland because of the heavy presence of frontier pharmaceutical companies in Ireland. It will examine how the public and potential customers perceive such creation and how it will be potentially received in the market.

1.1.1. INTRODUCTION TO WEARABLE TECHNOLOGY

Wearable technology otherwise know has wearable devices can be described as an item that has electronics and computers incorporated into it (Wright and Keith, 2014). A wearable device is usually worn as an accessory that has an implant that has an interface to perform simple tasks but provides its initial aesthetics purpose (Wilson and Laing, 2018). These devices carry out functions like our smartphones and laptops and more because they possess sensory and scanning characteristics such as biofeedback. They can be in the form of clothes, watches, headbands, jewelleries, etc, or in invasive forms like microchips and smart tattoos which can be implanted in the body and are used for different purposes across all aspects of life (Wright and Keith, 2014).

Technology has been immensely used in the improvement of the quality of life and has transformed the healthcare sector. One of the technologies used in the improvement of the healthcare sector is the Wearable Motherboard™ (Sungmee Park and Jayaraman, 2003).

With the continuous innovation in the technological industry, advancement has been seen in the measurement of physiological and biochemical activities in the body such as blood oxygen saturation and protein levels making it possible for them to be determined outside the hospital laboratory (Chiauzzi et al., 2015).

The need to provide accessible and affordable healthcare has increased the demand for portable medical devices that can be used by both patients and professionals anywhere. To achieve this, a portable and effective monitoring system that be specific for individuals is needed. These portable devices are in the form of wearable devices that can collect, analyse, store, and disseminate data such as body vital signs. Technology has been able to provide information that can be used by health professionals to provide fast and effective treatment (Sungmee Park and Jayaraman, 2003).

Over the past few years, different technological developments have been made regarding the use of wearables such as smartwatches and fitness bands for several functions. These functions range from its use to pay for goods and services promoting the cashless policy e.g. FitPay to its use to monitor body vital signs such as sleeping patterns, heart rate, and the number of calories burned to mention a few. The functions on the wearable devices have made them useful in different fields like the education, entertainment, and healthcare sectors (Wright and Keith, 2014). For this research, the use of wearable devices in healthcare will be the focal point.

Examples Wearable Devices includes:

i. Wearable Motherboard™
ii. Activity Trackers
iii. Smart Watches
iv. Smart Clothing
v. Smart Patches
vi. Ingestibles
vii. Smart Implants

viii. Google Glass

1.1.2. INTRODUCTION TO DRUG DELIVERY SYSTEMS

The Mechanism of Drug Delivery can be described as all the different methods used to get therapeutic substances into a living organism to enhance drug therapy thereby boosting the overall clinical response of the organism (Bruschi, 2015).

Drug delivery systems are very important in the treatment of different types of diseases as it is responsible for the ensuring that the site in the body that needs the therapeutic substance get the substance in time and in the right concentration. Because of its importance, there has been constant research and development of novel and effective drug delivery methods (Nayak *et al.*, 2018). These new developments in drug delivery systems also provide an alternative to the development of new drugs as new delivery methods can help in using the same therapeutic substance to treat different other diseases. This is a better alternative for pharmaceutical companies as the cost of developing new delivery methods is lower than the cost of developing a new drug substance (Tiwari *et al.*, 2012). The importance of choosing and improving the right drug delivery system includes the following:

a) Helps to enhance the patient and product safety
b) Improves the convenience of the use of the drug.
c) Controls drug exposure overtime (Bruschi, 2015).

Some of the popular materials used in novel drug delivery systems include Liposomes, Proliposomes, Microspheres, Gels, Prodrugs, Cyclodextrins, Nanoparticles(Tiwari *et al.*, 2012).

For this research, the controlled drug delivery system also known as the controlled-release technology (CRT) will be focused on. CRTs are new drug delivery systems that include iontophoretic devices for administering drugs through the skin, some programmable and implanted drug delivery devices, and others such as:

i. Beaded delivery system
ii. Transdermal and transmucosal controlled-release delivery systems,
iii. Drug-impregnated lozenges
iv. Encapsulated cells
v. Oral soft gels (Tiwari *et al.*, 2012)

1.1.3. WHY IRELAND?

Ireland can be considered home to many big and small pharmaceutical companies. These companies all fall between the 3 divisions of the pharmaceutical industry namely:

- Biopharmaceuticals (Biotechnology)
- Medical Devices and Diagnostics
- Oral/ Solid Pharmaceutical companies

The Pharmaceutical sector in Ireland can be dated to as far back as the 1960s and currently employs over 30,000 people and has contributed to about $10billion in capital investment in Ireland over the last 10 years. Ireland boasts of having about 75 pharmaceutical companies which include 10 out of the top 10 pharmaceutical companies in the world (IDA Ireland, 2020). The pharmaceutical industry has carved a niche in the Irish economy to be a successful cornerstone. This sector has been a major source of employment creating splendid careers for Irish youths and attracting foreigners into the country. There are about 40 companies that have been approved by the FDA that are operating in Ireland and about 20 under construction (Daly, 2019).

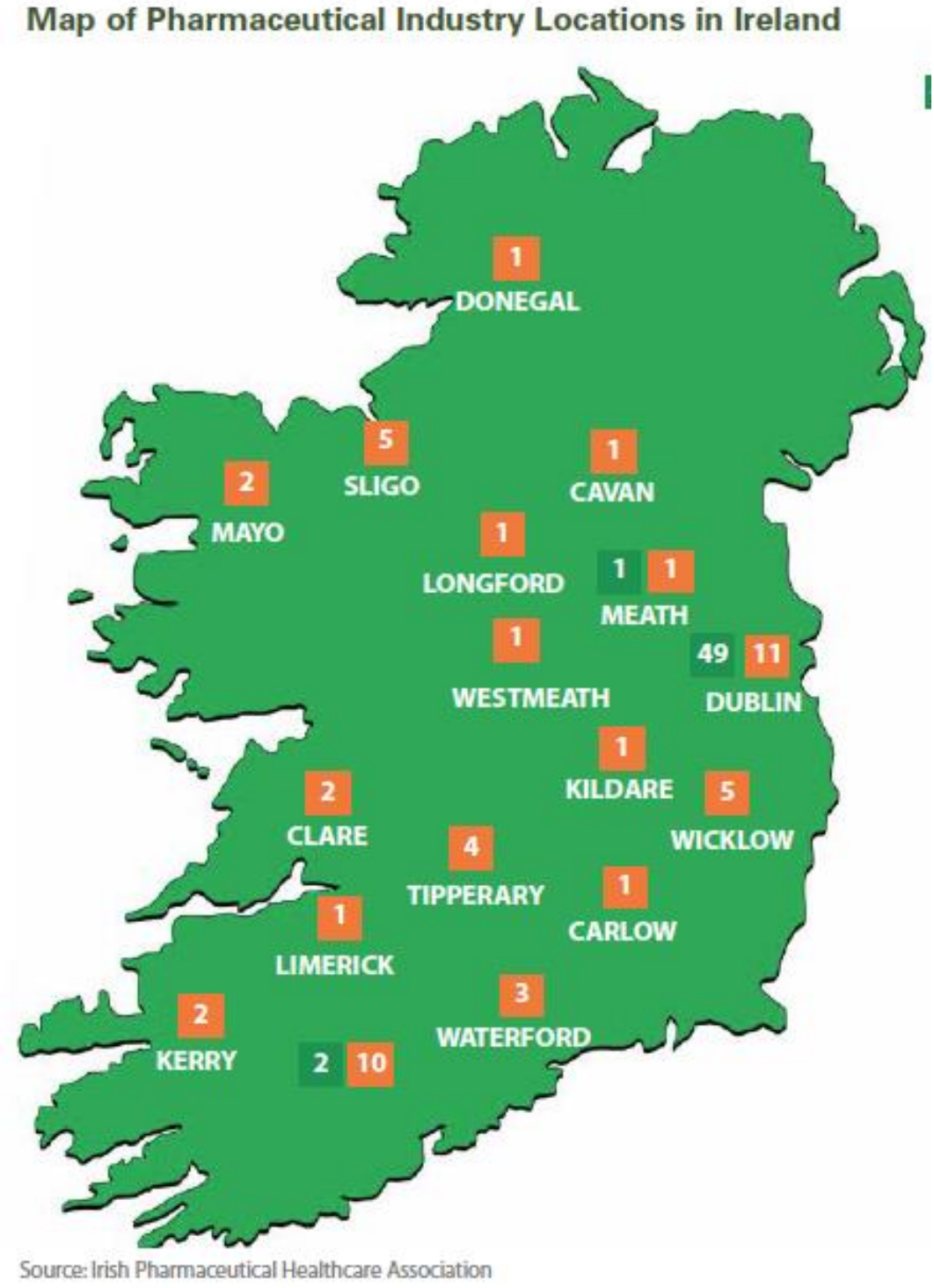

Figure 1a: Pharmaceutical Industries in Ireland and its location (Ribbink, 2015).

Dublin
49 Share Services Sites
Aboott Laboratories
A Menarini Pharmaceuticals
Amgen
Astellas Pharma
AstraZeneca Pharmaceuticals
Bayer Consumer Care
Bayer Schering Pharma
Biogen Idec
Boehringer Ingelheim
Bristol Myers Squibb
Celgene
Cephalon
Daiichi Sankyo Ireland
Eisai
Eli Lily & Company
GlaxoSmithKline Consumer Healthcare
Grunenthal Pharma
Ipsen Pharmaceuticals
Janssen-Cilag (J&J)
Labopharm Europe
LEO Pharma
Lundbeck
McNeil Healthcare (J&J)
Merck Serono
MSD
Mundipharma
Novartis
Novartis Consumer Health
Novo Nordisk
Nycomed
Organon Laboratories
Pfizer (2 sites)
Pierre Fabre
Protecter and Gamble
Reckitt Benckiser
Roche Products
Sanofi Pasteur MSD
Sanofi-Aventis
Schering Plough (MSD)
Servier Laboratories
Shire Pharmaceuticals
Solvay Healthcare
SSL Healthcare
Stiefel Laboratories
Tillotts Pharma
UCB Pharma
11 Manufacturing Sites
Bristol Myers Squibb
Covidien (J&J)
Helsinn Birex
Ipsen
Merrion Pharmaceuticals
Pfizer (3 sites)
Rottapharm
Schering Plough (MSD)
Swords Laboratories (BMS)

Meath
1 Share Services Sites
MEDA
1 Manufacturing Sites
BASF Ireland

Weastmeath
1 Manufacturing Sites
Elan

Kildare
1 Manufacturing Sites
Pfizer

Wicklow
5 Manufacturing Sites
Schering Plough (MSD)
Pharmaceuticals (MSD) (2 Sites)
Sigma Aldrich Ireland Ltd
Servier Laboratories
Takeda

Carlow
1 Manufacturing Sites
MSD

Waterford
3 Manufacturing Sites
Genzyme
GlaxoSmithKline
TEVA

Tipperary
4 Manufacturing Sites
Abbott
Alza Ireland (j&j)
Clonmel Healthcare
MSD

Mayo
2 Manufacturing Sites
Allergan
Charles River Laboratories
Services

Sligo
3 Manufacturing Sites
Stiefel Laboratories
Abbott Laboratories (3 Sites)
Pfizer

Clare
2 Manufacturing Sites
Roche
Schwartz Pharma Ltd

Cork
2 Share Services Sites
GlaxoSmithKline
Pfizer
20 Manufacturing Sites
Cara Partners
Centocor Biologics
Eli Lilly & Company
FMC International
Fournier Pharma
GE Healthcare
Gilead Services
GlaxonSmithKline
Hovione
Ipsen
Janssen-Pharmaceuticals (J&J)
Novartis
Recordati Ireland Ltd
Pfizer (5 Sites)
Schering Plough (MSD)
Leo Pharma Wexport

Kerry
2 Manufacturing Sites
Astellas Ireland
Temmier

Limerick
1 Manufacturing Sites
Pfizer

Cavan
1 Manufacturing Sites
Abbott

Longford
1 Manufacturing Sites
Abbott

Donegal
1 Manufacturing Sites
Abbott

Figure 2b: Pharmaceutical Industries in Ireland and its location (Ribbink, 2015).

Ireland is ranked 7th among the exporter of pharmaceutical products in the world bring about €39 billion export revenue to the country (IDA Ireland, 2020).

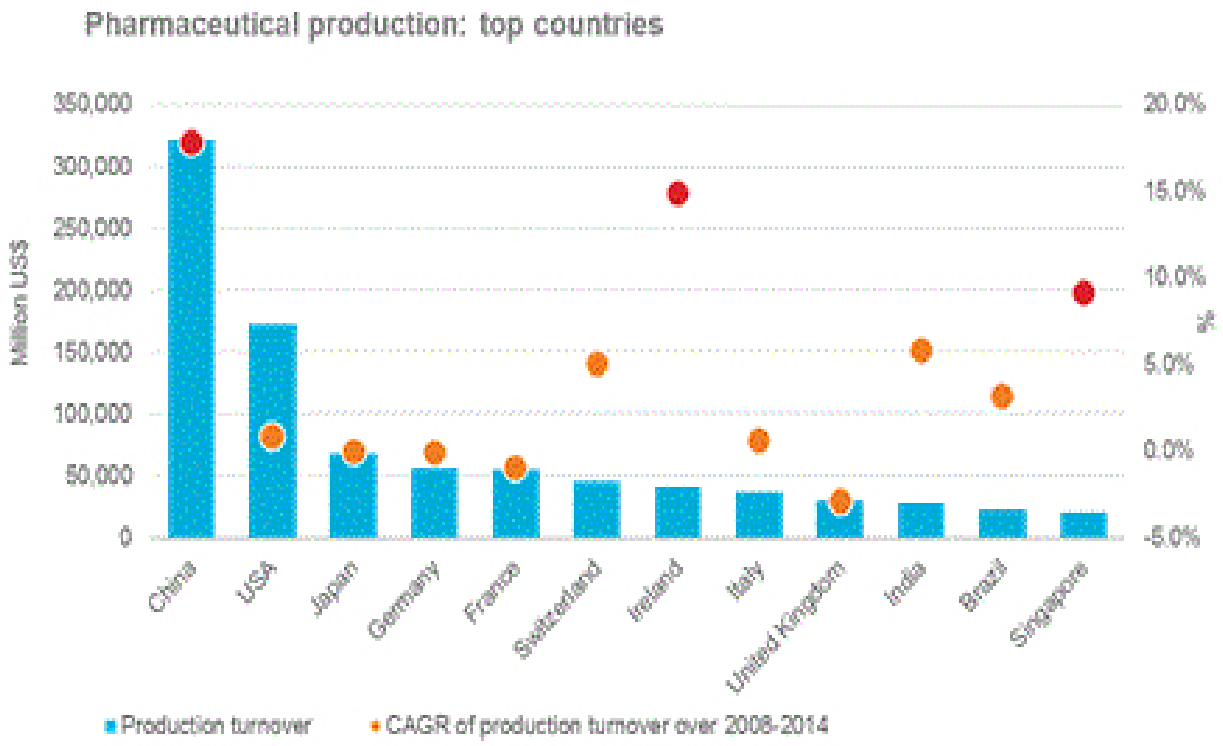

Figure 3: Ireland's ranking in pharmaceutical production (Liorančaitė, 2015).

1.2. AIMS AND OBJECTIVES OF DISSERTATION

The research was embarked to identify the innovative ways to deliver drugs to target sites of actions with much less frequency in the administration of the medicine. New developments have resulted in the use of controlled drug delivery systems in modern drug delivery, for example, wireless Microelectromechanical systems (MEMS) are been used in drug delivery in the pharmaceutical industry. The use of wearable devices in healthcare has opened the way for their use in drug delivery. The use of wearable devices can be a form of solution to controlling drug administration and delivery systems. This research aims at exploring how wearables devices can be incorporated in the control of drug delivery systems.

The objectives of this research are to:

1. To define the process involved in the research, development, manufacture, and sale of the wearable device-controlled drug delivery system in Ireland.

2. To identify the risks and challenges involved in the process in Ireland.

3. To examine the effectiveness of this novel technology in Ireland.

4. To define the potential market target and general view about the technology in Ireland.

1.3. RESEARCH QUESTIONS

In recent times, several technological advancements are constantly been achieved and one such is the evolution of wearable devices such as smartwatches and fitness bands to monitor body vital signs. This technology has been incorporated into the pharmaceutical industry by using it to control the drug delivery system through different means of controlled-release dosage forms. The wearable device can detect the shortage of the therapeutic substance and sends a signal to the drug delivery system to release the therapeutic substance in a controlled manner according to the predetermined dosage.

However, the use of this technology in Ireland has not been well established despite the heavy presence of many pharmaceutical companies in the country. This dissertation examined the challenges affecting the use of this technology, especially in Ireland. It also looked at how the public and potential customers perceive such creation and how it will be potentially received in the market.

For this reason, the research questions for this research are:

1. How can wearable devices be used to control drug delivery systems?

2. What type of industrial collaborations are involved in the creation of these devices in Ireland and how will a synergy between the industries by certified?

3. What are the challenges that can affect the use of wearable devices to control drug delivery in Ireland?

4. Who is the potential target market for this wearable device-controlled drug delivery system in Ireland?

5. How will this new technology be received in the market in Ireland?

1.4. SIGNIFICANCE OF THE RESEARCH.

The delivery of drugs using new technologies is a constantly changing area in drug development a part of pharmaceutical studies that the author has always found fascinating. In the same way, the use of wearables has exponentially increased over the past few years, this has prompted many studies about their use in healthcare. This research will help enlighten and enable further understanding of the different studies that have been done to find innovative ways to deliver drugs to target sites of actions with much less frequency in the administration of the medicine.

This research will explore how patients can administer their drugs at home using simple procedures with help from their wearable devices. The wearable device can detect the shortage of the therapeutic substance and sends a signal to the drug delivery system to release the therapeutic substance in a controlled manner according to the predetermined dosage. This will help reduce the length patients will have to stay in the hospitals leading to a better overall healthcare system has more people will be able to access it. The use of wearable device-controlled drug delivery systems will improve the convenience of the use of the drug which will lead to better compliance which will result in better treatment outcomes.

By defining and analysing potential market targets, pharmaceutical and medical devices companies will be able to better understand what their customers want. This will help in reducing the time spent on the research and development of the technology thereby making a tremendous advancement in the overall pharmaceutical pipeline.

Finally, although the use of wearable devices in healthcare has been extensively researched, its use is a means of controlling drug delivery systems is still at its early stage, this research will bring to light the benefits and challenges involved in using these devices for drug delivery. This research hopes to help hasten the use of technology in Ireland.

1.5. ACCESS AND RESEARCH ETHICS ISSUES

For this research, both primary and secondary data were collected. The secondary data was collected by going through the previous works done on the topic and finding out more about all the elements involved in this research. This information was accessed by looking through different journals, articles, thesis, and books. The primary data was collected by interviewing experts from both the pharmaceutical and medical device industry. Because of the COVID-19 pandemic, face to face interview could not be done, all the interview was done via Zoom. This affected getting non-verbal communication like body language, environment, tone of voice, and gestures could not be determined. Also, the initial plan of physically handing out and filling of questionnaires was moved to an online platform.

During this research, all ethical guidelines were followed. All the data collected were treated with uttermost confidentiality and anonymity. Good behaviour and professionalism were displayed, and the people involved did so willingly.

1.6. STRUCTURE OF THE RESEARCH

The second chapter of this research will be the literature review focusing the controlled drug delivery and wearables. The history, uses and the global and Irish market for wearable devices (especially in healthcare) will also be explored. The concept of wearable device-controlled drug delivery systems, its different applications, and the different commercially available ones will be investigated. The challenges facing the design, manufacture, and use of this type of drug delivery system will be examined. This chapter also includes the conceptual framework for this thesis.

The third chapter is focused on the method of data collection. For the primary research of this dissertation, the qualitative approach using interviews and questionnaires was used. The interview was focus on experts from both pharmaceutical and medical device industries exploring the experience and knowledge in the area and establishing the progress made in the research and development of the technology so far. Quantitative data (questionnaires) with 219 participants involving the general Irish population focusing on the views of people about the new technology and how well/ ready they are for it.

The fourth chapter of this research consists of the analysis and findings from the data collected, while the fifth chapter concludes the whole research with results and recommendations.

2. LITERATURE REVIEW

The constant evolution of mobile and digital technology has transformed the world and the quest to have it further incorporated into more parts of our life has birthed wearable technology also known as wearable devices. Wearable technology can be defined as the presence of computers in clothes and/or clothing accessories and its origin can be dated to as far back as 1960. The use of wearable devices has been on the increase all around the world and Ireland is not left behind (Weng, 2016).

In a publication titled "*Wearable Technology: Present and Future",* the author gave a summary of the state of wearable technology. This research focused on the components of wearable devices, history, and the application of wearable devices. Data in the paper were collected by conducting a thorough literature review of 100 research papers, 10 market reports, and 30 company websites. The author concluded that the major components/ elements needed in making a wearable device a wearable device include sensors, microchips, power sources, and software. Sensors are used to measure or detect biological and environmental variables such as temperature, heart rate, respiration rate, activity, or presence of a substance. It can also be used to produce signal or indication and to launch responses to a change in the level of a variable. Other components vary depending on the type of accessory the wearable device would be (Wilson and Laing, 2018).

2.1. MARKET FOR WEARABLE DEVICES

In the publication "*Wearable Technology: Present and Future",* the author also gave an insight into the progression of wearable technology and how it was adopted by the society the progression of wearables was as follows:

TIMELINE	WEARABLES
16th century	Introduction of wristwatch basically for women as men were still using pocket watches. Development continued even to the 20th century.
17th Century	Smart ring (abacus)
1890	Hearing aids that progressed to digital hearing aids and now smart hearing aids in 2016.
1960	The use of timing devices and hidden cameras for cheating in casinos.
1965	Development of pedometers
1970	Calculator watches
1979	Walkman®
1985	Electronic devices in clothes
1996	Smart garment such as the Georgia Institute of Technology Wearable Motherboard™ which has been improved to birth other smart clothing
2009	The launch of fitness bands/activity trackers as an improvement from pedometers
2010	Smartwatches with the ability to text, call and access internet among other features
2013	The beginning of smart spectacles: Google™ Project Glass
2015	Introduction of smart patches for medical application
2016	Smart sporting gears such as swimming tracker, golf band, and cycling band.

Table 1: Timeline of developments of wearable devices (Wilson and Laing, 2018).

North America and Europe are one of the leading markets for wearable devices, but Asia is projected to lead the market soon according to market projections. The market in North America is associated with its large population and disposable income while the market in Europe is associated with the awareness of the importance of the devices especially in monitoring healthcare (Dunkley, 2020).

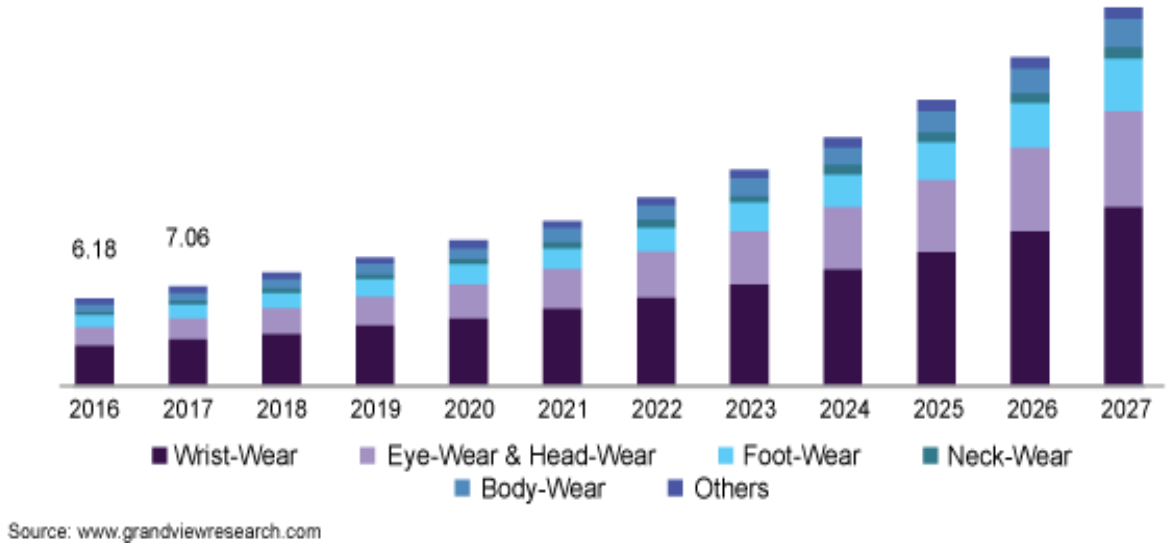

Figure 4: Market Size by Products of US Wearable Technology 2016-2027 (USD Billion) (Grand View Research, 2020)

The wearable technology market was in 2019 worth over $50 billion globally and the number of people using this technology (connected to a 4G network) was 526 million and this is expected to increase to 900 million by 2022 (Pindel, 2020). Smartwatches were recorded to be the most successful wearable device in 2017 (Wilson and Laing, 2018).

According to a survey carried out in the United State for wearable fitness technology, it was concluded that the factors influencing the use of these devices are (Pindel, 2020):

- Income**-** About 50% of high-income earners own one, 30% of middle-income earners use it and only 25% of low-income earners use one.
- Location- People living in urban areas tend to use it more than those living in rural areas
- Gender- More women use these devices more than men.
- Age- People below 55 years were twice likely to use the device more than people above 55 years.

In a report titled "Wearables 2019: Advanced Wearables Pick Up Pace as Fitness Trackers Slow", the author looked at the consumer trends in the wearable market and presented a forecast on the use of wearable devices in America. In the report, the market for wearable devices were younger people (Wurmer, 2019).

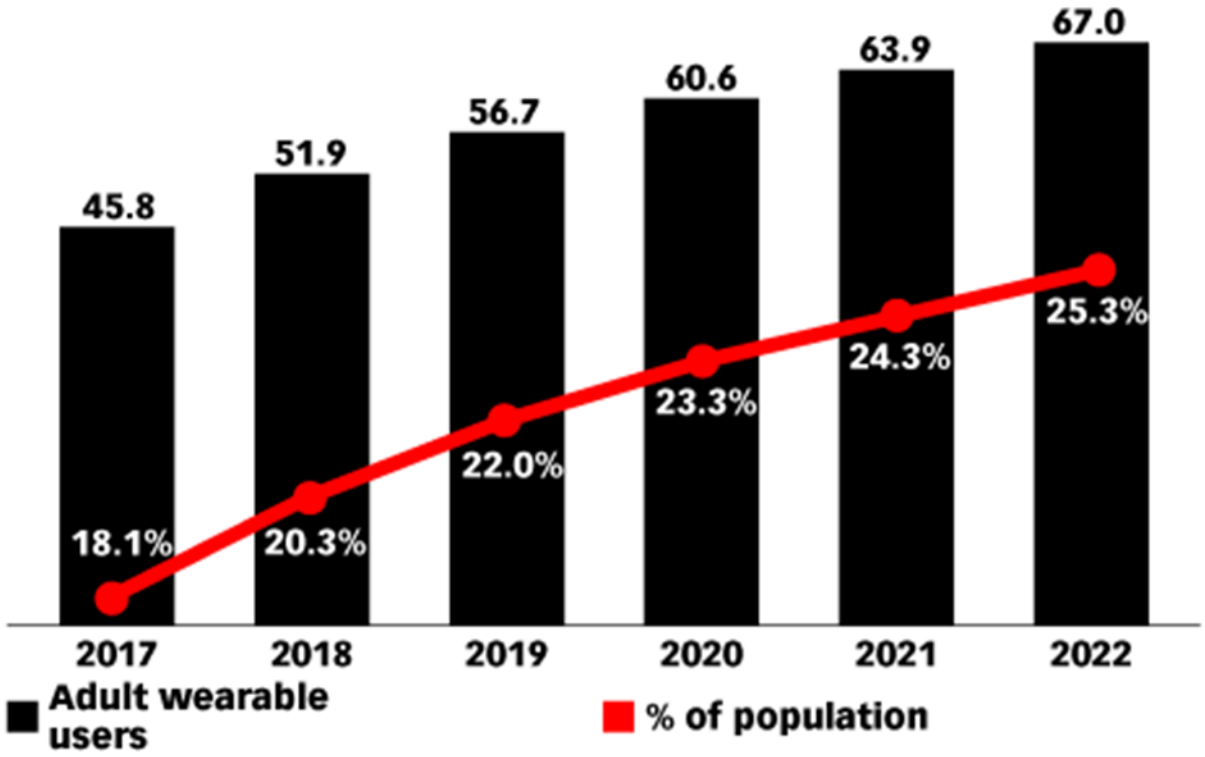

Figure 5: Wearable Users and Penetration among US Adults between 2017 and 2022 (in millions and % of population) (Wurmer, 2019).

In 2015, 24% of people aged 25 to 34 had a wearable device, while 6.5% of those aged 55 to 64 had one. A forecast of about 25% of American adults is estimated to use wearable devices in 2019 was given and the largest age group was still going to be the younger generation with about 38% owning one. The market penetration among older consumers is also projected to double with a market estimation of 13.2% users (Wurmer, 2019).

2.1.1. USE IN IRELAND

In 2015, a nationwide survey was carried out in Ireland to understand the usage and impact of technology in Irish homes. The survey by *eir* telecommunication company, aimed at documenting the social changes experienced in Ireland because of technology and innovation including the rise in the use of digital devices. The survey used a quantitative approach and it included 1,013 Irish households. The participants were all aged above 16. The survey concluded that about 8% of the participating household had at least one wearable device in the household. Also, 20% of the adults were interested in getting one. People aged 16-24 years old were the most interested in getting a wearable device while people over 65 years were the least interested with only 4% interested. The other age brackets 25-34, 35-44, and 50-64 recorded the following percentages respectively 29%, 19%, and 10% showing a decline in interest in older people (eir, 2015).

This survey shows the history of the use of wearable devices in Ireland and is very useful in determining the use of wearable device-controlled drug delivery systems in Ireland.

2.2. COMMERCIALLY AVAILABLE WEARABLE DEVICES IN HEALTHCARE

The use of wearable devices in healthcare can be dated as far back as 1996 when the Wearable Motherboard also refer to as the smart shirt was developed by Georgia Institute of Technology, sponsored by a U.S. Navy Defense Research Grant. This technology like many other technologies has evolved over the years from large-sized and uncomfortable devices to smaller, portable, sleek, and fashionable devices (Wright and Keith, 2014). Their use has been seen in areas such as diagnosing, treatment, and monitoring of patients. It also enables the transfer of medical care from hospitals to other external environments which in turn reduces hospital stays and allows for better healthcare systems in the society. It also facilitates constant care for the elderly and those living with chronic disease, therefore, reducing death rate and increase life expectancy (Wilson and Laing, 2018).

2.2.1. WEARABLE MOTHERBOARD™

This is a "Smart Shirt" that make use of sensors and other forms of monitoring devices to discreetly observe the overall wellbeing of people. It was originally designed to detect bullet wounds and monitor the vital signs during combat but was then converted for civilian use. The sensors are used to measure things like the heart rate, body temperature, pulse, etc, and can be positioned anywhere on the body. The information generated from the smart shirt is collected, processed, and transmitted to the desired location such as the hospital. Information can also be sent back to the smart shirt giving suitable directions for the situation. The shirt was built in a way that any sensor can be added to it depending on the use such as health and fitness and public safety (Sungmee Park and Jayaraman, 2003).

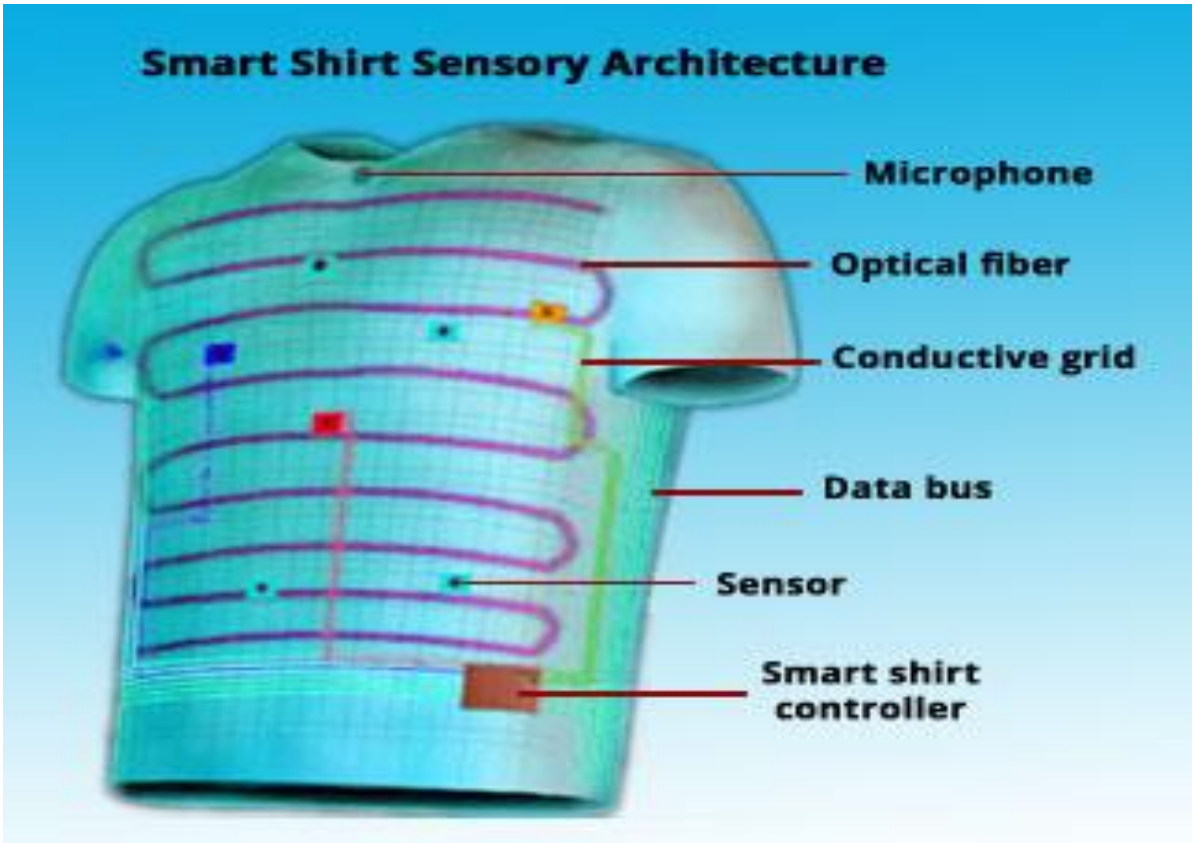

Figure 6: A diagrammatic representation of the sensors in a Wearable Motherboard (Haroon, 2017).

2.2.2. ACTIVITY TRACKERS

Activity trackers can be in different forms and can be used to measure different health activities like the mobility of patients. In an experiment carried out using Fitbit® wireless accelerometers to monitor the mobility of post-surgical patients, it was noticed that the data monitoring was easier. The activity tracker also made it possible for early discovery and treatment of post-surgical outcomes (Cook et al., 2013).

Figure 7:Jawbone UP24 and its Apple app (Hussain, 2014).

These devices are made available as bracelets, wrist bands and are usually synchronised with mobile phones and/or computers. some of the commercially available ones are Jawbone's UP24, Misfit's Shine, Samsung's Gear Fit, etc (Wright and Keith, 2014).

2.2.3. SMART GLASSES (GOOGLE GLASS)

Google Glass is a glass incorporated with processing units, flash memory, high-resolution display, and capable of taking pictures and videos. It is rechargeable, equipped with connectivity to both Wi-Fi and Bluetooth with a memory of about 12GB that can be synchronised with Google Cloud. This type of wearable device is being used by healthcare professionals for different activities such as streaming operations online, hold video consultations with colleagues during a difficult medical operation, view patient records/ test records without leaving the room or patient (Wright and Keith, 2014).

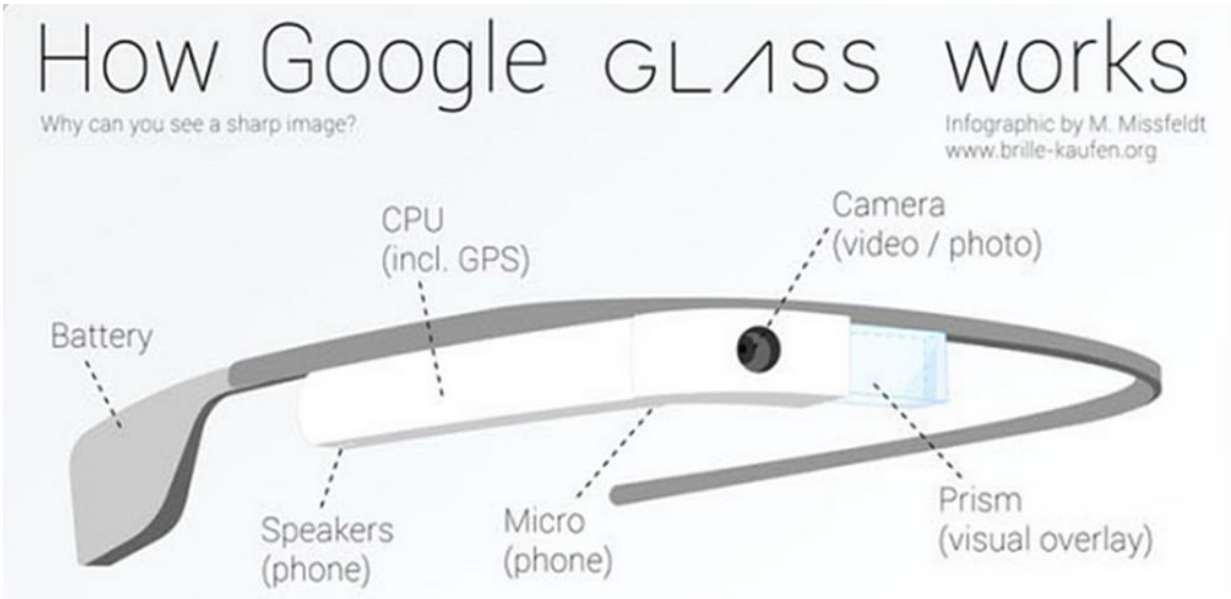

Figure 8: A diagram outlining the components of Google Glass (Purcher, 2014)

The Evena Medical's Eyes-On Glasses helps in the placement of intravenous lies by showing the anatomical images to the health professionals which could in turn prevent mistakes and multiple needle punches. Also, smart glasses for partial and fully blind people are being developed by scientists at the University of Oxford. These glasses will make use of 3D cameras to notify the wearer about objects ahead. Another commercially available smart glasses are "the Vuzix glasses" which possess voice recognition, sensors, connection to Wi-Fi ad Bluetooth and can be paired with an Android device. (Wright and Keith, 2014).

2.2.4. SMARTWATCHES

These are watches that have the same abilities as a smartphone including the ability to run mobile apps (Wright and Keith, 2014). Fitbit®, Amazfit®, and Apple Watch® are popular examples of smartwatches that are being used to monitor vital body signs like activity level, blood pressure, heartbeat, sleeping patterns, etc. it has been used in improving fitness and enhancing the monitor of health (Chiauzzi et al., 2015).

Figure 9: An Apple Smartwatch showing some of its applications(Allison, 2017)

2.2.5. SMART TEXTILES

This is a type of clothing developed mainly for fitness users. In 2014, OMsignal, a company based in Montreal came up with a shirt containing sensors that can be used to check and monitor breathing and heart rates, calculate calories burned and determine different stress levels. It is a machine washable and comes with a module that is used to

power it (Wright and Keith, 2014). An example is the range of t-shirts, vests, and other sports clothing developed by a smart clothing company called AiQ. One of their products, Bioman+ is an upper-body garment made using "conductive fibre-based textile electrodes" that carry, process, and transmits electric signals. It is known for its use in monitoring heart rate and ECG (AiQ Smart Clothing, 2017).

Figure 10: A Bioman+ female vest (AiQ Smart Clothing, 2017).

2.2.6. FASHION ACCESSORIES

There is a range of bracelets, bands, and necklaces that have information technology capacities. An example is a product called CuffLinc by Cuff (a wearable device company). CuffLinc is embedded into these accessories and is connected to the mobile phone via Bluetooth and serves as a remote for the smartphone. When the wearer touches the

designated area on the accessory, the device sends a distress message and to an appointed person (as set by the wearer). It is primarily used for personal security and is very useful for elderly people living alone in crisis to reach loved ones. This device has improved from having a non-rechargeable battery that lasts for about a year to a device that can also check vitals and is chargeable (Wright and Keith, 2014).

2.2.7. OTHERS

Many other devices are being used in healthcare and many more a still being discovered and developed to improve the overall quality of health of patients. An example is a bionic glove that is being used to rehabilitate patients with spinal cord injuries and stroke by creating electrical stimulation to allow them to regain the use of their hands (Wilson and Laing, 2018). Other available devices are Patches and Tattoos, Ingestibles, and Smart Implants (Chiauzzi et al., 2015).

2.3. CONTROLLED DELIVERY OF DRUGS

For the drug delivery system to work, it makes use of one or more biological processes like diffusion, osmosis, and partitioning. Controlled drug delivery systems are usually classified based on the type of process used (Bruschi, 2015).

2.3.1. OSMOSIS

This very useful in rate-controlled drug release systems which can span from as short as 24 hours to as long as several months or years. It can be used in combination with other systems. It is the movement of solvent through a semipermeable membrane diluting a solution to an equal concentration. The solvent in an organism is usually water that moves across the biological membrane and is an important process in living organisms. It is used by the drug release system to absorb water from the body into the osmotic material causing it to swell and leads to a slow release of the drug. This process is commonly found in drug pumps (Keraliya *et al.*, 2012).

2.3.2. DISSOLUTION

This is a process that involves dissolving the API in a solvent leading to the ionization of the molecules of the API into the medium. The drug's dissolution rate can be used to predict the release rate of the drug and used as a tool for the controlled drug delivery system. This is achieved by coating the drug substance with materials of varying thickness or by scattering them in a polymeric matrix (Gandhi, 2013).

2.3.3. SWELLING

This the reaction between water molecules and the molecule of a substance. The substance used for controlled drug delivery systems is usually polymers and when these polymers are surrounded by water, the components expand creating chemical/physical bonds. This expansion is used to control the drug release from its polymeric component. Hydrophobic polymers don't usually swell substantially, it's swelling velocity can be used to control the release of the drug (Ranga Rao and Padmalatha Devi, 1988). It makes use of hydrogels which when taken orally incorporates other processes such as drug dissolution, water diffusion, and polymer chain relaxation to release the drug substance (Caccavo *et al.*, 2016).

2.3.4. PARTITIONING

This involves the use of affinity and polarity of molecules to move them from one phase to another. This is important especially for APIs that have to move between aqueous and lipid bio phases. This property can be used to design micelles drugs with hydrophobic cores and hydrophilic coronas controlling the time for each release of the API (Bruschi, 2015).

2.3.5. DIFFUSION

This is the movement of molecules from one end of a system to the other in random motions using the concentration gradient reducing the difference in concentration in the system. Diffusion is essential to get APIs across cell membranes and for it to be metabolized and excreted from the body. It can also be used in controlling drug release.

It is more effective in short distances losing its efficiency over long distances (Gandhi, 2013).

2.3.6. EROSION

Some polymers undergo erosion when they go through chemical reactions such as the hydrolysis of bonds, releasing the API embedded in them. The erosion of these biodegradable membranes controls the rate of drug release. If the rate of erosion is high, the quantity of API released maybe too much and if the rate is low then the possibility of elimination of the whole system from the organism without the release of the API is possible (Kamaly *et al.*, 2016).

2.3.7. TARGETING

This the ability of an API to gather all or most of its concentration at the site of action only no matter the site or the route of administration. It can be done at organ, tissue, cellular, or organelle levels. Targeted drug delivery can be described as the accumulation of APIs in the site of action by retaining, evading, targeting, and releasing (Bruschi, 2015).

2.4. WHY WEARABLE DEVICE-CONTROLLED DRUG DELIVERY SYSTEM

2.4.1. EASE OF USE

No matter how good or effective a delivery system is, the device should be relatively easy to use such that anyone can use it effectively. It should be that a patient or caregiver should be able to use the devices with little or no help from physicians. The ease of use goes a long way in determining the consistency of use by the patient as it influences the patient's behaviour and interest to use. It is also expected that the device should be capable of providing a prolonged dose of the drug substance so that the rate at which it will be changed is reduced (Siew, 2018).

2.4.2. BETTER TREATMENT OUTCOME

If this technology is used correctly, it increases the number of patients that will adhere to the prescribed regimen which in turn will boost the success rate of the treatment which gives the patient a better outcome. This will be also useful for the pharmaceutical

companies as it will increase the market for the product which is needed in the highly competitive pharmaceutical industry and also increases the asset value of the company (Huddleston *et al.*, 2019).

2.4.3. COMFORT

One of the aims of wearable device-controlled drug delivery systems is to reduce the pain and discomfort that comes with conventional drug delivery methods like injections and drips. It aims at reducing the discomfort such that self-administration can be achieved with maximum compliance to the use of the drug substance. For example, wearable injectors help reduce the discomfort by decreasing the flow rate of the drug substance as pain increases with the flow rate (Siew, 2018).

2.4.4. ECONOMICAL

In the US, the cost of healthcare increases yearly by about 4%. This could be avoided if more therapies are done from home. Using this technology enables self-administration which reduces the time for in-clinic visitation. It also decreases the travelling expenses, administration costs, disruption of the lifestyle of the patient (Huddleston *et al.*, 2019).

2.4.5. INTERNET OF THINGS (IoT)

This technological progression has allowed the interconnectivity of many devices and daily activities to make life easier (Dunkley, 2020). Moving the delivery of drugs into this circle will help solve problems of non-compliance of patients (Chourasia and Jain, 2003).

2.4.1. INCREASE IN RESEARCH AND DEVELOPMENT

The constant technological advancements in pharmaceuticals are very important to improve the way the diseases are been treated in these new times (Huddleston *et al.*, 2019). This constant research and use of these new technologies help birth other technologies which would be very useful in combatting many of the problems that still facing mankind (Dunkley, 2020). For example, thanks to these advancements in drug

bioavailability, drugs that in the past required large doses before plasma concentration could be achieved now require smaller (Huddleston *et al.*, 2019).

2.5. EXAMPLES OF WEARABLE DEVICE-CONTROLLED DRUG DELIVERY SYSTEMS

2.5.1. WEARABLE INJECTORS

Most of the drugs in recent times are biologics and are becoming more focused on personalized medicine. Although they have excellent safety and efficacy profiles, it is quite difficult to administer to patients and is usually taken in the form of intravenous injections (Siew, 2018). The delivery system helps move the API across physiological barriers, protects it from untimely excretion, and delivers it to the active site (Bruschi, 2015).

Also, self-administration has become a popular trend among patients in recent times leading to a search for novel delivery systems by the pharmaceutical companies. Delivery systems such as autoinjectors and prefilled syringes are aimed at improving the ease of usage and ensure it meets all the required regulations (Siew, 2018). Challenges such as the large volume and dosage repetition affect the use of prefilled syringes and autoinjectors leading to a demand for a better delivery system that is safe and accommodates high volume drugs. This led to the innovation of wearable injectors which are stress-free, comfortable, and convenient. A wearable system can be used for a large volume of drugs and will be delivered at the right dosages over some time. The wearable device can be time-controlled and delivers drugs automatically at the set interval. This can also be removed when the dosage is completed (Siew, 2018).

An example of a wearable injector is a device called enFuse developed by Enable Injections. It is a small single-use wearable device that delivers up to 50ml of high viscosity drugs subcutaneously. The container holding the drug and the delivery system are contained in a small device that is comfortable to wear and is discretely hidden by the patient's clothing. This smart device is also able to reconstitute lyophilized drugs and

delivers the mixture using a very small needle that will not be visible to the patient which therefore reduces the anxiety associated with needle picking (Siew, 2018).

Figure 11: A Wearable Injector showing its size (Huddleston et al.*, 2019).*

The device has variations that allow it to be used for multiple drug substances and be used to deliver varying doses specific to each patient. The device also possesses connectivity to mobile apps to more and control compliance (Siew, 2018).

The device makes use of a sequential elastomeric toroid pump and therefore, does not need batteries to function. This attribute enables the device to maintain a small size and increased efficiency (Huddleston *et al.*, 2019).

Another commercially available example is a device called SmartDose developed by West which is a delivery device that is worn on the stomach of the patient that provides a hands-free administration (Siew, 2018).

2.5.2. ORAL AND PARENTERAL DELIVERY SYSTEM

This makes use of biodegradable polymeric devices to control the release of drug substances. It has been used for protein/peptide drug substances using intestine selective microspheres. This system does not disintegrate in the stomach but in the intestine allow the drug to stay up to 6 times longer in the body. The biodegradable polymers are usually chosen based on their mechanical strength, biocompatibility, and biodegradability and some of the polymers used are poly (lactide-co-glycolide) (PLGA), poly (glycolide) (PGA) and poly (lactide) (PLA). A single dose of the drug in these polymers can last for days (Tiwari *et al.*, 2012).

An example of this delivery system is a project called **IntelliDrug** which involves developing a smart drug system implanted in the oral cavity. It was used to control the delivery of drug substances that get repressed because of the actions of the gastrointestinal/hepatic activities leading to low availability in the plasma. The model drug used in the project is called *Naltrexone,* a drug used in treating addiction alcohol and opioids, it is also to be used in the treatment of chronic diseases. In vivo testing established about 64% bioavailability of the drug in circulation and up to 10 times higher plasma levels. This is because the delivery system supplies the drug substance directly to fatty tissues or directly to blood circulation or the central nervous system. Increased bioavailability and the automation of the drug administration would increase patient's compliance to the drug. This drug delivery system is small enough to be incorporated into a synthetic denture. It is also strong enough to withstand the force from chewing and the unconducive nature of the mouth. It contains a drug reservoir made of stainless steel and has an osmotic pump that could be filled and refilled with drug pills. The drug is to be controlled using a microvalve which has a flow sensor to control the amount of drug

to be released it also has a fill-level sensor that determines when the reservoir is empty. (Goettsche, 2016).

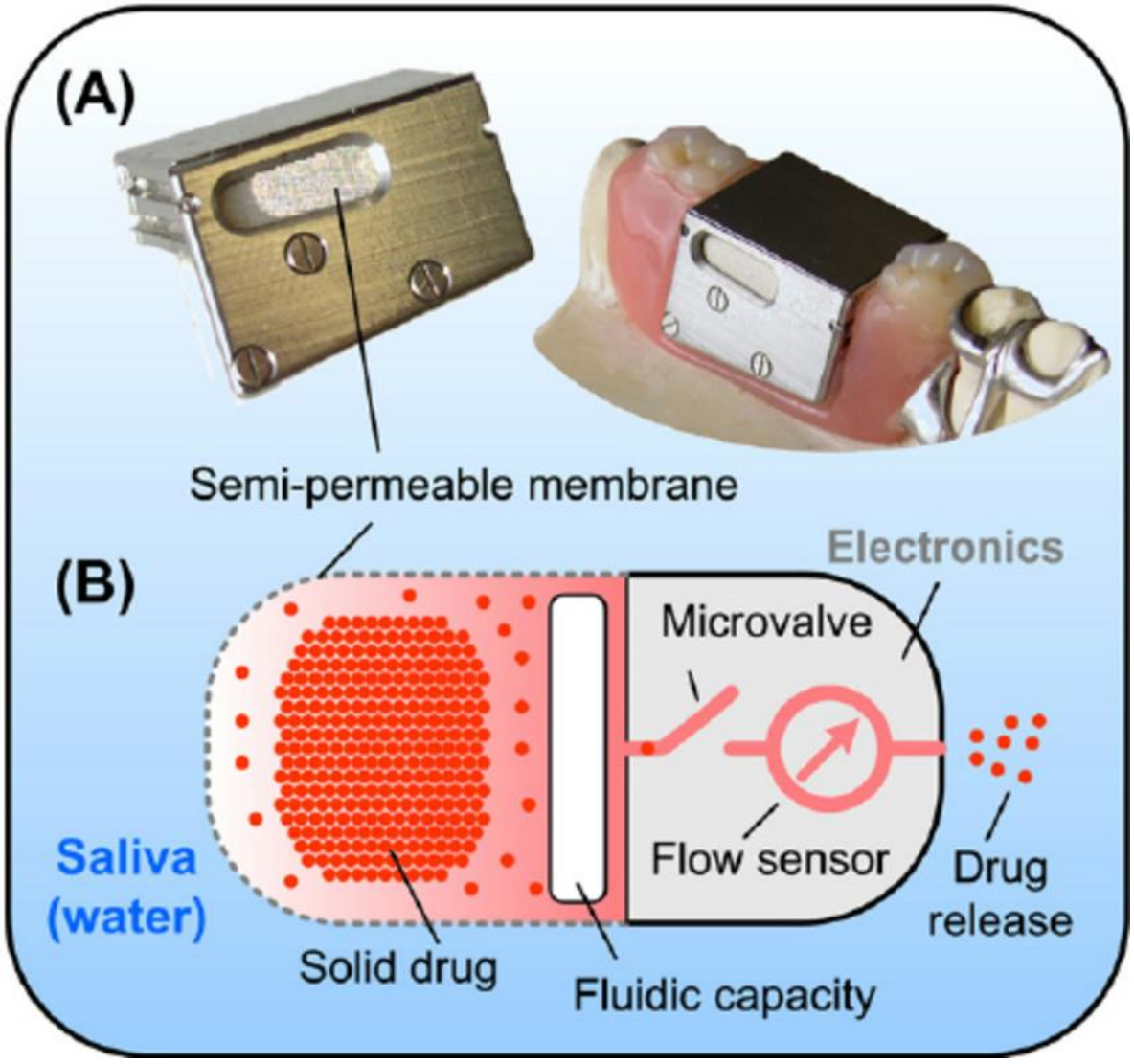

Figure 12: Prototype and Operation Principle Of The Intraoral Drug Delivery System Intellidrug (Herrlich et al.*, 2012).*

The sensors and controls send signals and are monitored using a wireless IR-communication through the cheeks. The release of the is based on the pressure difference in the valve and once a pressure of 50PKa is achieved then the valve membrane opens

up allowing a flow of the drug at about 1.8 ml/h after which the valve is shut close (Goettsche, 2016).

2.5.3. TARGETED DRUG DELIVERY SYSTEM

Molecular targeting is also a type of drug delivery system that is been extensively researched as it is capable of tumour recognition through ligand facilitated interactions. This is made possible by the conjugation of liposomes with ligands such as fragments of antibodies, hormones, and vitamins. Studies have shown that this type of interaction is possible, and they provide effective delivery of encapsulated drug substances between cells. It has been targeted towards different organs such as ***lungs*** for the treatment of different respiratory diseases by reducing the side effect of the drugs, ***brain*** for addressing the issue of the blood-brain barrier where the water-soluble parts of the drug affect the necessary conversion (into lipid-soluble) needed to overcome the blood-brain barrier, ***skin*** for a controlled but faster delivery of drug across the skin and the **colon** to bypass the gastric pH and effective for the treatment of colonic diseases like Ulcerative Colitis, Colorectal Cancer and Crohn's disease (Tiwari *et al.*, 2012).

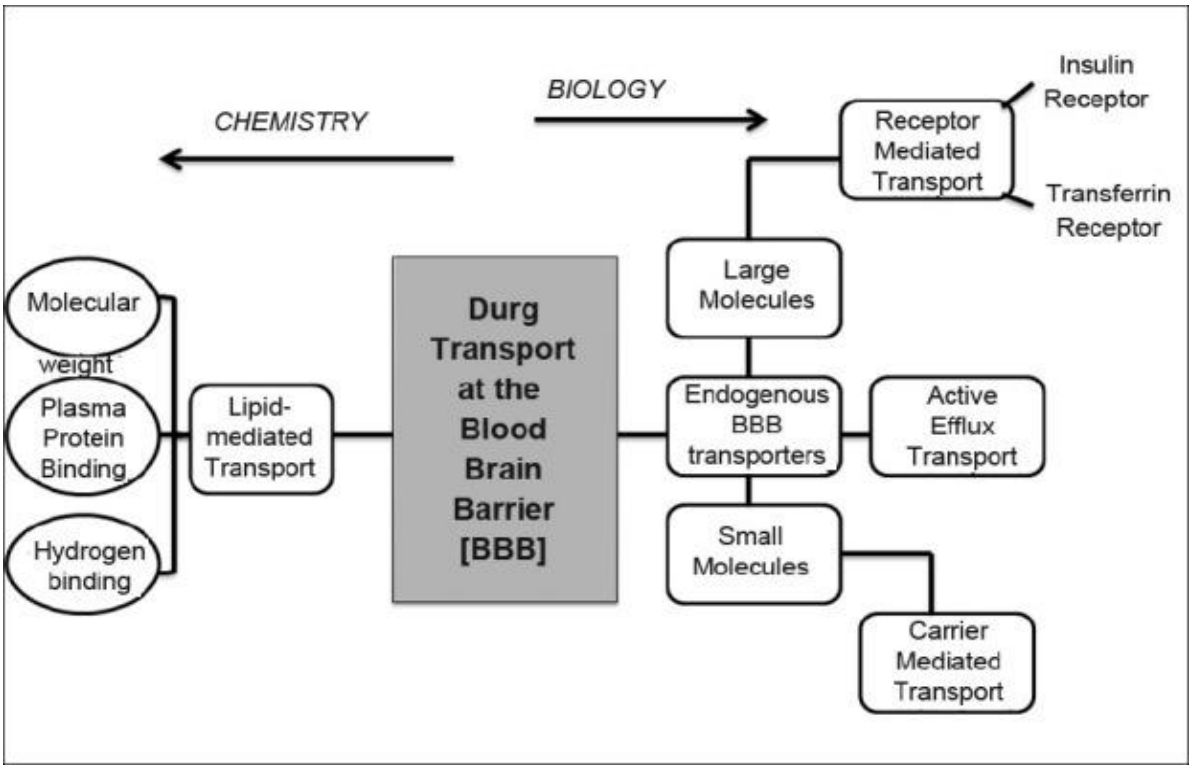

Figure 13: Outline of a program for developing blood-brain drug targeting strategies derived from either chemistry-based or biology-based disciplines (Tiwari et al.*, 2012).*

Some drugs like Ventavis (used in the treatment of Pulmonary Arterial Hypertension) have short half-life which means they need to be used frequently – up to 9 times a day. But this form of controlled drug delivery system help provides prolonged drug release and improved biological distribution of the drug substance leading to a longer half-life and ensures convenience and compliance of the patient. Also, polymer-based drug delivery systems have helped in enhancing the direct delivery of drugs to the brain.

Targeted delivery systems have led to the discovery of devices such as ***Metered Dose Inhaler*** which has revolutionized the treatment of lung diseases; ***Plastic reservoir*** connected to the blood vessels in the brain through an outlet catheter; **Nanoparticles** which have been used successfully in gene therapy, radiotherapy, antibiotics, etc to pass the blood-brain barrier; the **Liposomal reservoir system** is used in the controlled delivery of anaesthetic benzocaine through the topical (skin) route. Azo hydrogels and

pressure-controlled colon delivery capsules (PCDCs) are some systems used for treating colonic diseases (Chourasia and Jain, 2003).

2.5.4. IMPLANTABLE SYSTEMS

This system is usually used for a controlled but continuous application of a therapeutic substance over many years (long-term therapy). It is an automated system and does not have any form of attachment on the patient's skin and therefore does not require regular maintenance but rather the catheters are implanted in the desired site of target e.g. an insulin pump will be put in the adipose tissue. The drug is continuously delivered in small quantities but the quantity (i.e. plasma concentration) could be adjusted depending on the need of the patient (Goettsche, 2016).

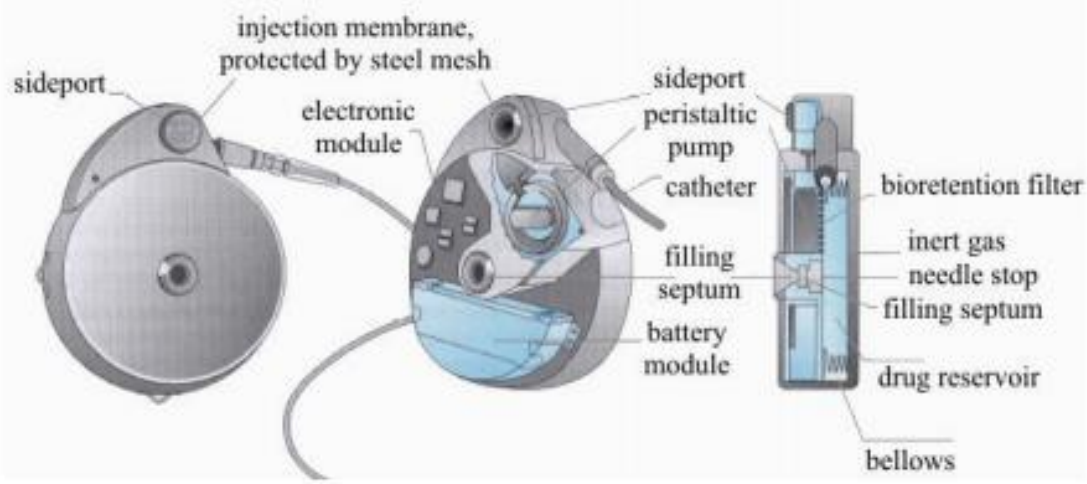

Figure 14: Setup of the controllable, implantable pump SynchroMed EL by Medtronic [D-MED1-09] (Goettsche, 2016).

The reservoir with varying volumes and is made from titanium is located in the middle of the system. The reservoir is placed in a pressure chamber containing a pressurized medium and the release of the drug is controlled by the pressure of the pressurized medium on the reservoir. The presence of flow resistors helps to control the drug flow rate based on the value selected before the implantation of the system. A commercial

example of this system is the SynchroMed series manufactured by Medtronic. This model contains a syringe that is used to refill the drug reservoir and a bioretention filter is used to prevent bacterial invasion into the drug. The battery of the system can last for up to 7 years which is how long it could take before there is a need to refill the system (Goettsche, 2016).

2.5.5. EXTRACORPORAL SYSTEM (WEARABLE INFUSION PUMPS)

This type of drug delivery system is done without surgery. They provide solutions for the continuous delivering infusible drugs over a long period e.g. insulin. They also provide information about optimal drug concentration and dosing parameters for implantable pumps before the surgery is carried out (Goettsche, 2016).

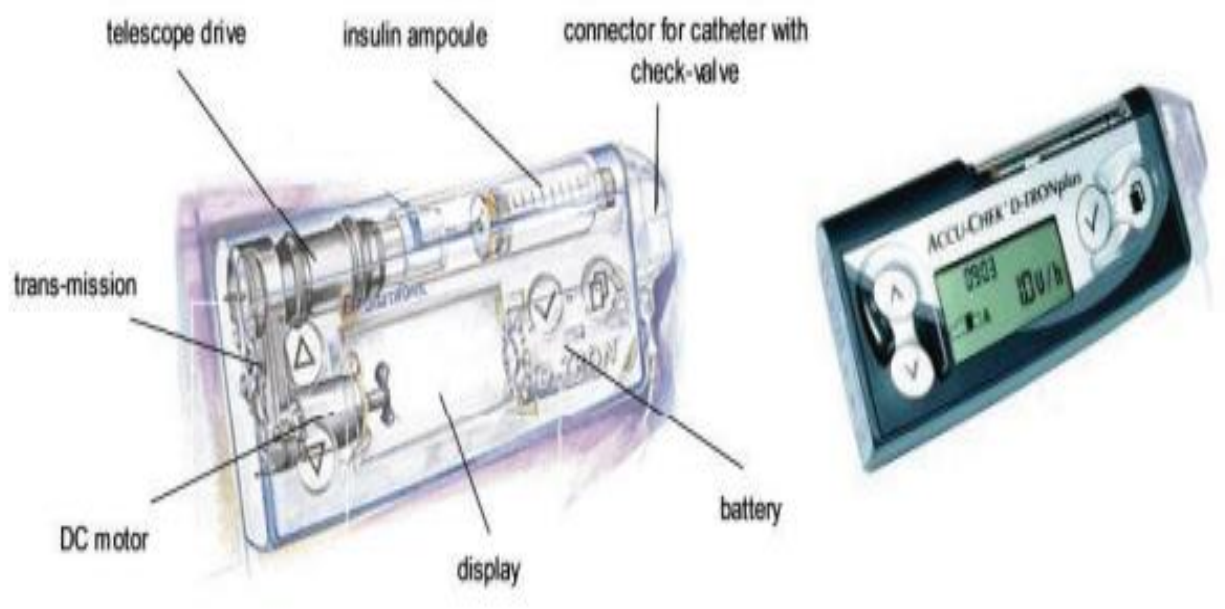

Figure 15: Schematic illustration of the extracorporeal insulin pump D-Tron-plus by Roche (Goettsche, 2016).

An example is an insulin pump called the D-Tron-plus by Roche. It has a programmable microprocessor that controls the motor involved in pushing the piston in the ampoules in

the prefilled drug reservoirs. The dispensation of the drug is usually based on the rotating motion of the motor which is effective in control medical safety (Goettsche, 2016).

2.5.6. OSMOTIC SYSTEMS (OSMOTIC DRUG DELIVERY PUMPS)

This type of drug delivery system has been around for over 70 years. An example of a commercially available one is the Rose-Nelson pump [D-MAT-99], a single-use drug delivery system developed in 1955. It consists of 3 different compartments:

- a solute (e.g. water) section of adjustable volume
- an osmotic section, filled with an osmotic agent (e.g. solute of NaCl)
- a drug section, filled with a solute of the drug

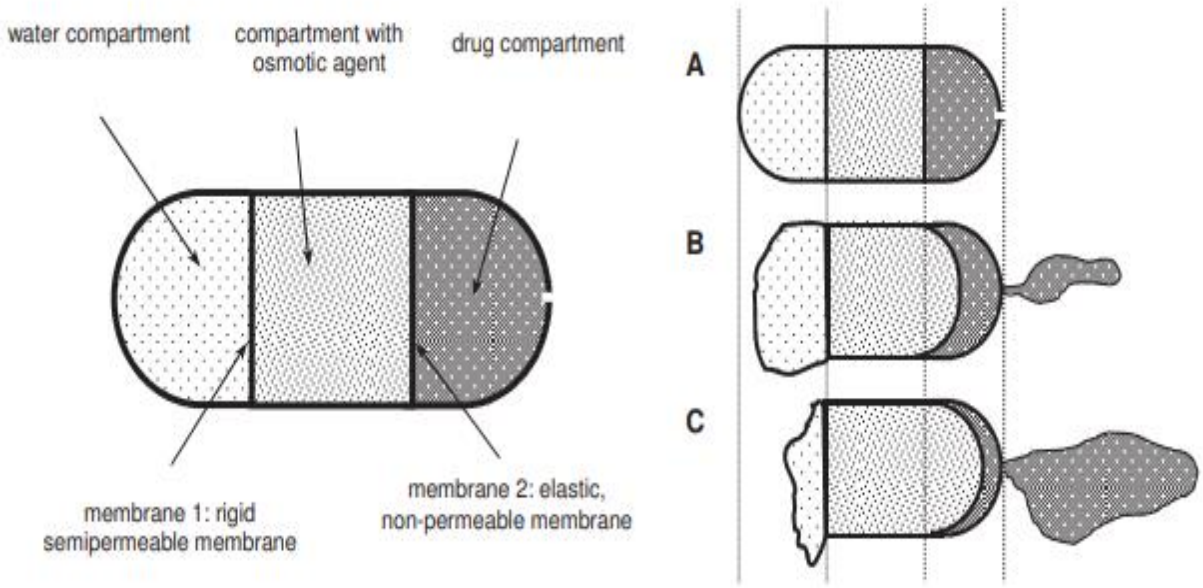

Figure 16: Working principle of the Rose-Nelson pump (Goettsche, 2016)

The solute section and the osmotic section are separated by a stiff semipermeable membrane which allows a volumetric rise in the osmotic section because the osmotic flow of water moves through the semipermeable membrane. This volumetric increase causes a deformation of the flexible nonpermeable membrane that separates the drug section and the osmotic section. This deformation is what causes the release of the drug

substance. Different modifications that involve the complete replacement of the water and osmotic sections with in-vivo environmental conditions and a shell around the drug substance has been seen.

Other examples of this system are ALZET® pumps by ALZA, the VITS system (Veterinary Implant System) designed for companion animals, and the DUROS® system (Goettsche, 2016).

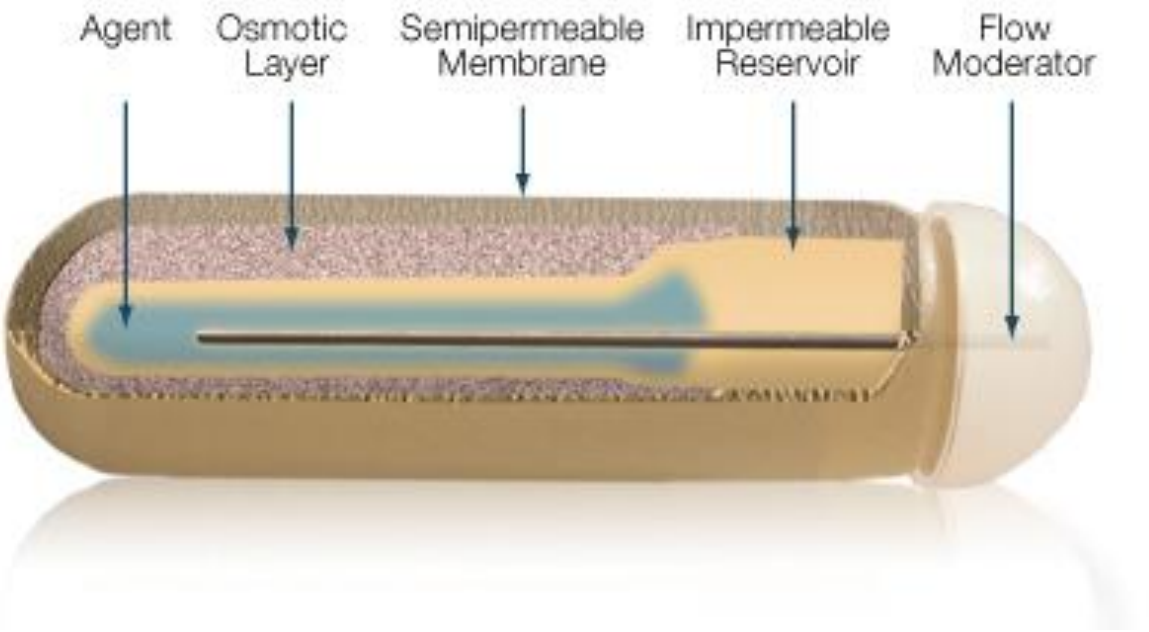

Figure 17: ALZET® pumps by ALZA (DURECT Corporation, 2020).

2.5.7. LIPOSOMAL DRUG DELIVERY SYSTEM

This drug delivery system makes use of liposomes and other circulating macromolecules that have high permeability and retention. They are popular for reducing toxicity and enhancing the efficacy of anti-cancer agents because of their extravasating ability from tumour vessels. For example, anthracyclines are a group of highly efficient anticancer agents but its efficacy has been limited because it was found to lead to irreversible heart failures, but liposomal anthracyclines have been able to deliver substantial drug activity

and elongated blood circulation at a largely reduced cardiotoxicity as a result of drug encapsulation. It has also been used in the treatment of infectious diseases.

Liposomal drug delivery systems are also been used in physiological and passive targeting of tumour tissues but unfortunately not tumour cells. This is because the delivery system in the bead of protecting the liposome prevents the interaction with some metabolites including the tumour cells. Instead after extravasation, the liposome undergoes enzymatic degradation which is how the drug is released (Tiwari *et al.*, 2012).

2.5.8. BEADED DELIVERY SYSTEM

This is used mainly for medications that require once a day intake. This system has been tested on tolterodine tartrate and is available as *DETROL LA*, a medication used to treat an overactive bladder by relaxing the muscle leading to control over the frequency of bathroom visits. The mechanism involves small beads carrying the active drug substance. The beads are made from inert substances and are enclosed in a delivery capsule. The release of the drug is controlled based on the acidity of the stomach (Tiwari *et al.*, 2012).

There are plenty of other different types of new technologies in drug delivery systems that are too many to mention. The method of drug delivery may be controlled or pulsatile release patterns which could be based on different mechanisms of action such as enzymatic, pH, temperature, electric, or polymer-chemical activation.

2.6. CHALLENGES FACING THE USAGE OF THESE DEVICES

2.6.1. SIZE

When dealing with a wearable device-controlled drug delivery system, the size is essential. It determines the volume of the drug substance that will be contained in the device. If the volume is too small, it could lead to regular visits to the physicians to replace the finished drug substance which will end up defeating the purpose for the device. If the volume is also too big, the size could lead to the discomfort of the patient which could reduce the compliance to the use of the device (Siew, 2018). Also, the beauty and practicableness of a wearable drug delivery device are usually based on how small the

device is. A small sized device ensured optimum energy consumption which determines the battery life and subsequently the size of the battery to be used. Getting the devices to a miniature size sometimes proves difficult as many of the drug delivery systems have a lot of very important components (Goettsche, 2016).

2.6.2. STABILITY

The most important element of any drug delivery system is the maintenance of the integrity of the drug substance (Huddleston *et al.*, 2019). The stability of the drug substance is very vital therefore suitable primary containers should be used for holding the drug substance. This is because there is a possibility of a reaction between the container and the drug which could either affect the concentration, quality, or efficacy of the drug substance and/ or destroy the holding container (Siew, 2018). Sometimes the stability of the delivery device in the long term is quite questionable. An in-depth analysis and research need to be carried out before the different components of the devices are used to avoid harm to the user (Goettsche, 2016). The device needs to be stable to prevent sterility issues which could be fatal for patients. Also, packaging and transport challenges could occur as a result of unstable products (Huddleston *et al.*, 2019).

2.6.3. COMPLEXITY

The formulation of many drug delivery systems is complex. For example, in a lung-targeted drug delivery system, creating and putting the substance in aerosolized form is quite difficult. Also, nanoparticles that are used in drug loading, target, release, transport, etc are quite unstable and exhibit cytotoxicity (Tiwari *et al.*, 2012). The device to be used by the patient should be extremely easy to use to ensure compliance with the drug and not affect the day to day activity of the patient (Goettsche, 2016). If the device is not easy to use it can also lead to human errors which could disastrous and also discourage patients from using the device (Huddleston *et al.*, 2019).

2.6.4. ACCURACY

The delivery device must be accurate in delivering the prescribed dose drug substances because if the drug substance is too little it may not elicit the desired therapeutic response and if the drug is too much it could be harmful/fatal to the patient. Getting the device to deliver the exact amount of drug substance needed without error is very tricky as the device must be equipped to account for every drop of the drug substance. Also, the device is required to deliver the drug in the right anatomical space (Huddleston *et al.*, 2019).

2.6.5. THERAPEUTIC EFFECT

One of the challenges poised in using novel drug delivery systems is ensuring the efficiency of the drug substance. The success of the device depends on the bioavailability of the drug in the body and this is measured through plasma concentration. If the concentration of the drug substance is not within the therapeutic window, it will result to a poor drug efficiency. Also, if the bioavailability of the drug is too high then it can lead to an overdose of the drug (Goettsche, 2016).

2.6.6. DATA ACCURACY SECURITY AND PRIVACY

There are concerns about patient's data integrity and security (how it would be protected) (Wright and Keith, 2014). There are also concerns that some of the data collected could be inaccurate leading to misguided treatment. Also, there is a potential problem with the logging of the measured data (Weng, 2016). Before the device can be used, everything that has to do with data integrity needs to be tested. The ability of the device to produce and reproduce data that are accurate, valid, and reliable is one of the things that are collected and compared to conventional methods of drug delivery during clinical trials. The data generated needs to be protected from hacking and software malfunctions to ensure the security of the data (Wilson and Laing, 2018).

2.6.7. MARKET PENETRATION

Consumer acceptance is crucial to penetrate any market, this can be hindered by little or no understanding of the function and capability of the product. Attention should also be paid to the users' requirements as this is what ultimately influences the decision to buy. The consumers need adequate awareness because nobody will buy what they don't know about (Wilson and Laing, 2018). Researches carried out in China in 2014 has shown that 40.5% of the respondents felt that the use of wearable devices in healthcare is not yet fully developed to the point of usage (Weng, 2016).

2.6.8. SAFETY

The drug delivery devices to be used should be simple to understand and safe for the users, i.e. the health professional that will activate the device and the patient on which the devices would be used. Developing a system/device that will not cause any type of pain to the patient requires sophisticated technologies like micro-needling (Goettsche, 2016). If the product is not perceived as safe and reliable by the patients, it can reduce the purchasing decision of the consumer (Wilson and Laing, 2018).

2.6.9. SUSTAINABLE POWER

Many of this type of drug delivery system uses high voltage power therefore finding the right energy source for the device is very important and can serve as a threat to the marketability of the devices (Dunkley, 2020). Most wearables are electronic devices that need a source of energy such as batteries. These sources of energy need to be recharged, replaced, or refilled. The frequency of the need to replace the energy source is also one of the challenges involved in the design of drug delivery systems (Goettsche, 2016).

2.6.10. CONNECTIVITY

Connecting the wearable device to external devices such as apps on other wearables e.g. smartphones are one of the issues that needs to be overcome to ensure seamless use of the device (Wilson and Laing, 2018). This connectivity helps in setting the timing for the

drug delivery, monitor the administration of the drug substance, and also provide assistance when using the drug delivery system (Huddleston *et al.*, 2019).

2.6.11. COST

This is one of the reasons for the reluctance of consumers using the devices (Dunkley, 2020). Pharmaceutical companies have the challenge of reducing the cost of development and manufacture. They also have to maximise the speed at which the devices get to the market so that they will be able to make development and manufacturing costs plus profit (Huddleston *et al.*, 2019). These types of drug delivery systems are relatively very expensive to make and to own (Wright and Keith, 2014).

2.6.12. CONSISTENCY OF USE

Another problem is to tackle the issue of ensuring constant usage of the wearable device as the studies show that about 45.7% of users abandon the wearable e.g. Smartwatch within the first month of use (Weng, 2016).

2.7. WHAT INDUSTRIES ARE INVOLVED IN MAKING THESE DEVICES

Intel, an electronic company specializes in microchips worked along with AIQ a company that develops electronic-based clothing (AiQ Smart Clothing, 2017). Their collaboration helped develop a t-shirt that makes use of conductive fibre to track heart rates which can be sent to a smartphone. The electronic part of the cloth is in a detachable small side pouch (for easy removal during washing). This shirt is estimated by the manufacturer to be used in constant monitoring of people with health conditions, the elderly, and children (Wright and Keith, 2014).

The creation of a wearable device-controlled drug delivery system also involves the careful selection and partnership between companies that provide the high-quality container systems such as vials or cartridges needed to hold the drug substance and also the various components needed to make the devices (Siew, 2018).

2.8. CONCEPTUAL FRAMEWORK

An Analysis of The Use of Wearable Technology as A Means of Controlling Drug Delivery Systems and The Challenges Facing Its Usage in Ireland

Literature Review

Wearable Devices

- The use can be dated back to 19th Century.
- Being used in different sectors especially healthcare
- Examples includes Activity Trackers, Smart Watches, Google Glass, etc.
- Used by many people in the world and Ireland but most common in people below the 55 years.

Controlled Drug Delivery

- Uses pharmacokinetics and pharmacodynamics to control the rate at which drug substance is delivered to the body.
- More effective than conventional methods
- Cuts across different routes of administration.
- Examples include Nanoparticles, Liposomes, Millispheres, etc

The Use of Wearable Technology as A Means of Controlling Drug Delivery Systems

- Enables patients' compliance to treatment because it is easy, comfortable, and convenient.
- Wearable device-controlled drug delivery systems are commercially available.
- Different challenges affect the use of this technology globally.

Primary Research

Literature Gaps

- Industries involved in the development and manufacturing of the wearable device-controlled drug delivery system in Ireland.
- Process involved in the development and manufacture of the wearable device-controlled drug delivery system in Ireland.
- Risks and challenges involved in the process in Ireland.
- Effectiveness of this novel technology in Ireland.
- Potential market target and general views about the technology in Ireland.

2.9. CONCLUSION

From the different works of literature read, wearable devices have been seen to take the world by storm especially in the 21st century although its history dates to the 16th century. Its use in different sectors can be considered as one of the reasons for its exponential growth. Initially, the use of wearable devices among the older generation was low, recent times has seen a turnaround. This can be associated with the use of wearable devices in healthcare monitoring where body vitals are constantly being measured. The constant measurement of these body vitals has been helpful in the early detection of disease and quick treatment which helps contribute to the quality of life and increase overall life expectancy.

Controlled drug delivery is the way to modern drug delivery methods because it has been shown to solve many of the problems affecting the conventional methods of drug delivery. The conventional methods are usually uncomfortable and unreliable has the body tends to inhibit the performance. For example, conventional tablets taken orally have the probability of been degraded in the digestive tracts by some gastrointestinal juice and therefore the drug loses its efficacy. Controlled drug delivery systems make use of pharmacokinetics and pharmacodynamics which helps control the rate at which drug substance is delivered to the target site leading to increased plasma concentration. This enables the drug substance to be more effective and therefore reduces the quantity of the therapeutic substance to be consumed by the patients. Controlled drug delivery is not limited and is being used across various routes of drug administration.

Recent technological advancement has allowed for a further upgrade to controlled drug delivery systems. This involves using some wearable devices both internal and external and infusing them with Active Pharmaceutical Ingredient (API) so that they help release this therapeutic substance in a controlled manner and over a period in the predetermined quantity. Others make use of various connectivity methods such as Wi-Fi and Bluetooth to signals to and from the drug delivery system enabling it to monitor and detect a low concentration of the therapeutic substance and allowing the release of the drug substance

to the target site. It can also alert the user when the delivery system is empty or low in power. There are many benefits to the use of wearable device-controlled drug delivery systems such as comfort, ease of use, safety, and effectiveness. Only a few of this type of drug delivery system are commercially available now due to the different challenges facing its manufacture and use such as cost, data integrity and safety, size, and lack of awareness among consumers.

Also, there is a lot of information on the different types of new drug delivery be discovered constantly there is no data on the use of all these technologies among the Irish population. There is also no literature on the consumers/ patients' perception on the use of wearable devices in the control of drug delivery in Ireland. To effectively analysis the use of this device in Ireland, the primary research will focus on defining the process and the risk involved in the development and manufacture of this type of drug delivery system, determine the effectiveness of the technology and analyse the view of the Irish population on the use of this type of drug delivery system.

3. RESEARCH DESIGN/ METHODOLOGY

3.1. OVERVIEW

Philosophy	Pragmatism	
Approach	Inductive	
Strategy	Survey	
Methods	Questionnaire distributed online	Interviews via Zoom
Structure	5 sections with 26 questions	10 – 30 minutes of conversations
Response Rate	**73%** (Sent 300 questionnaire got 219 respondents)	**50%** (Sent messages to 6 people and got response from 3 people)
Participants	219 People Who are Currently Living in Ireland	3 People Who Are Vast in Knowledge of The Technology

Table 2: An Overview of the Research Methodology

3.2. RESEARCH PHILOSOPHY

The philosophy for this research was Pragmatism as the research was based on the insight on social and experiential levels since the research was aimed to explore people's points of view, from a different perspective across the industry and different people in the society.

The questionnaires provided quantifiable data which was analysed and used in reaching various conclusions for the research. The interviews provided qualitative data by providing information that reflects the processes and effectiveness of the topic.

During the research, the author ensured that there was no bias or interference of personal interest in the study, and only the data collected were used. This was promoted by using an online questionnaire which limited the interaction with the participant of the surveys thereby reducing the risk of the author influence on the outcome of the data provided in the questionnaires.

Interviews were conducted to collect qualitative data which was focused on the honest opinions of the people with experience and knowledge of drug delivery systems to understand the effectiveness and level of the implementation of this technology in Ireland. The interview questions were asked in such a way that it was free from any form of bias from the author.

3.3. RESEARCH APPROACH

To determine the process and risks involved in the research, development, manufacture, and sale of the wearable device-controlled drug delivery system, the author applied the qualitative research method by carrying out interviews. The author also used a quantitative research method to define the potential market target and general views about the technology by questionnaire surveys. Therefore, the approach for the research was the inductive approach and the type of data collected was both qualitative and quantitative.

The survey was distributed electronically to different people all over Ireland and they were requested to fill the questionnaire. The questions in the questionnaire were to decode the general perceptions of consumers/patients towards the use of wearable devices for the control of drug delivery systems. This allowed the author to identify how the wearable device-controlled drug systems are perceived leading to a recommendation that can be used by manufacturers has a starting for market survey.

Although the process involved in the research, development, manufacture, and sale of the wearable device-controlled drug delivery system had been established by some literature read by the author, interviews were carried out to better understand how the whole process works. The interview was also conducted to get the opinion of the industry experts on the effectiveness of the technology.

The data collected from the primary research was analysed and compared with the findings from the literatures and the outcome was used to conclude the research.

3.4. RESEARCH STRATEGY

The overall strategy for the research was to identify the level of the implementation of wearable technologies in the control of the drug delivery system and to establish the readiness and willingness of the use of this technology in Ireland. According to the literature review, no research has been made on the consumer perception of the Irish society on the use of this technology, neither is there a research on the challenges affecting the implementation of the technology in Ireland. The researcher, therefore, chose to use surveys in the form of interviews and questionnaires to get the data needed.

Everyone who got the questionnaire was given a simple yet brief introduction to the research and that the research was in the fulfilment of a master's degree in Pharmaceutical Business and Technology at Griffith College Dublin. The dynamics of the questionnaire was in such a way that is was easy to understand and follow with technical words and phrases explained.

The questionnaire had 5 sections with 26 structured questions aimed at determining the general perceptions in the form of the willingness of consumers/patients to use wearable devices for the control of drug delivery systems. The questionnaire was dispatched electronically through Google Forms and the link was sent to different people. The questionnaires were filled without any input from the author to abolish any form of bias.

The 1st section of the questionnaire was a letter to the respondent giving all the basic information. The letter was to gain an informed consent and to assure the participants that their data will be stored in line with the General Data Protection Regulation (GDPR). To further participate in the survey, the participant had to answer the question ensuring that they agree to informed consent.

3.5. DATA COLLECTION METHOD

All the questions in the questionnaire were directed at getting the opinion of consumers about the usage of wearable technology in line with the research objectives.

The 2nd section of the questionnaire was focused on getting General Data of the participants. The five questions in this section were aimed at classifying the participants based on gender, age, educational background, income, and field of work.

The 3rd section was on the Introduction to Wearable Devices and it was made up of eight questions that established the relationship between the participant and technology. The questions were targeted to determine the frequency of use and what influences the use of these wearable devices.

The 4th section which was titled Introduction to Drug Delivery System was aimed at determining the knowledge and relationship of the participants with drug delivery systems. The section contains five questions that examine the type of conventional drug intake method the participants are familiar with and how well they adhere to taking the drugs.

The 5th and final section ties the wearable devices to controlled drug delivery and is made up of eight questions. The questions in this section were aimed at determining the popularity of these novel technologies among the Irish residents and to ascertain the opinion of the participants regarding the use of these wearable technologies. The section was also aimed at getting what influences the participants to use or not to use the technology including their concerns about the technology.

The final question in the questionnaire was poised to get people that had experiences in these types of technologies and would like to be interviewed.

The second part of the primary data collection which was the interview involved the selection of the experts will be based on their knowledge, skills, or influence in the manufacturing of such technologies. The open-ended interview involved 3 people with experience and knowledge of the manufacture and use of wearable device-controlled drug delivery systems.

Although the literature review provided the answers to the research question:

How can wearable devices be used to control drug delivery systems?

The interview was aimed at getting experts' opinions on the manufacture and usage of these technologies, the companies involved, and what type of challenges that may be faced during and after development. It was also used to determine the readiness of the Irish society in using this type of technology

The open-ended questions enabled the interviewees to express openly their views and perceptions. The interview was conducted via Zoom.

3.6. SOURCES

The questionnaire generated by the author was distributed among different people living in Dublin via the internet. Google Form was used to make the form that contained all the questions to be asked and a link was generated. It was this link that was sent to people online. The participants were obtained via LinkedIn and the author's contacts. Also, all participants were asked to share the form with their contacts in Ireland too. The total number of participants was 219 involving different people of varying ages and occupations. The author then made use of Microsoft Excel sheet to evaluate the data obtained and they were collated in pictorial statistical charts such as pie and bar charts.

For the interviews, positive responses from the final question in the questionnaire, and about 20 responses showed interest to be interviewed. The author went on to contact the 20 responses to ascertain their level of understanding and expertise on the research questions and 14 of the participant were dismissed because they didn't have enough experience needed for them to answer the interview questions. Out of the 6 participants deemed qualified for the interview, 3 did not reply to the follow-up emails sent to fix the dates for the interview. In the end, only 3 experts were interviewed.

For the secondary data collection, the researcher analysed the different types of drug delivery systems, how they are controlled, different wearable technologies, how wearable technologies will be integrated with drug delivery systems, and the existing challenges

affecting its usage. The data was collected from academic literature and industry-related, publicly available documentation.

3.7. ACCESS AND ETHICAL ISSUES

Before taking part in the research via questionnaires or interviews, all the participants were provided with a brief introduction to the research explaining what the research is about and that the research was in fulfilment of her master's degree. The data were collected in such a way that maintained the participant's anonymity and all the questions asked were relevant to the research and aimed to attain the objectives set out to be achieved. Participation in the research was completely voluntary and the participants were informed of the right to withdraw from participating at any time.

The data generated from the questionnaires and interviews were treated confidentially. During the interviews, the researcher ensured that the interviews are timely and comfortable for the participants, only asked questions related to the research, and ensured that the interviews were transcribed correctly. The research was done according to the Griffith College Ethics Committee Guiding Principles.

The participants were mainly from LinkedIn, involving the researcher posting her questionnaire link on her LinkedIn page and sending connection requests which included a note containing her introduction and link to over 200 people. The researcher also sent the link to her contacts all over Ireland. With all these, the researcher was able to get 219 responses. The researcher was only able to get one response from people that were aged 61 and over.

3.8. INCLUSION AND EXCLUSION CRITERIA

The questionnaire was opened to everyone living in Ireland only. Anyone who did not respond to the link that was sent was automatically excluded from the research. This was the only inclusion and exclusion criteria put in place.

Also, after reading the introductory letter in the questionnaire, the participants were asked if they understood and wanted to carry on with the participation, if they chose the NO option, then they were automatically withdrawn from the survey.

3.9. CONCLUSION.

For this research, a mixed method of data collection was used. First, a quantitative approach using questionnaires for the consumers in Ireland, and a qualitative approach of open-ended interviews was used. These methods are in line with the overall research philosophy which is **Pragmatism.** The data collected were analysed and linked to the literature review carried out by the researcher in the secondary research and overall provided insights, perceptions and views that helped answer the research questions.

4. ANALYSIS AND FINDINGS

4.1. OVERVIEW

In this chapter, the answers from the surveys will be analysed appropriately to achieve the objectives of this research. The objectives encompass the investigation of the various challenges affecting the use of wearable devices in the control of the drug delivery system in Ireland and to determine the components involved in the connections between the wearables and the drug delivery system. The research also examines the type of industries that are involved in the development and production of the devices and the Irish society's responsiveness for the new technology based on if they will use it.

4.2. QUANTITATIVE ANALYSIS

The analysis of the data from the questionnaires helped to define the general knowledge of the use of wearable device-controlled drug delivery systems, potential market target, and general view about the technology such as what will influence or prevent decisions to use the devices.

4.2.1. GENERAL DATA (Question 1 to 5)

The total number of responses to the questionnaire was 219, one of the participants withdrew from stopped the survey midway so the data collected from the remaining 218 responses is what was analysed. The number of female participants was 115 and the number of male participants was 103. Most of the participants were young people between the ages of 18 to 30 and the responses were mainly from postgraduates.

Variable	Category	Number of responses	Percent (%)
Gender	Male	103	47.2
	Female	115	52.8
Age	18-30	121	55.5
	31-40	50	22.9
	41-50	36	16.5
	51-60	10	4.6
	61 and over	1	0.5
Level of Education	No Formal Education	0	0
	Secondary Education	1	0.5
	Undergraduate	42	19.3
	Post-Graduate	175	80.2
Yearly income (Euros)	Less than 15,000	107	51.7
	15,001 – 30,000	32	15.5
	30,001– 45,000	31	14
	45,001 – 60,000	29	3.9
	60,001 and above	8	15
Field of Work	Students	41	18.8
	Healthcare	25	11.5
	Pharmaceuticals	28	12.8
	IT	21	9.6
	Construction	14	6.4
	Food and Beverages	4	1.8
	Education	10	4.6
	Finance	16	7.3
	Law	3	1.4
	Others	56	25.7

Table 3: Summary of the Participant Demographics (Question 1-5)

4.2.2. INTRODUCTION TO WEARABLE DEVICES (Question 6 to 13)

This section of the questionnaire was included to determine the rate of the use of smartphones and other wearables in Ireland to understand how technological forward the Irish society is.

Question 6, 7 and 8

This question is to determine the participants' eagerness to try new technology and to determine the experience of using mobile phones and wearables. 214 participants (98.2%) made use of their mobile phones every day. Most of the participants (202) said they love getting acquainted with new technology. Also, 52.3% of the respondents have experience using wearables with 77 participants still using it and 37 people had the device but have abandoned it. 76 people (34.9%) have not used it but are interested while are 12.8% of the participant not considering using wearables at all.

Variable	**Category**	**Number of responses**	**Percent (%)**
Using my phone is an important part of my daily activities	Yes	214	98.2
	No	4	1.8
I love getting acquainted with new technology	Yes	202	92.7
	No	16	7.3
Experience of using smart bands	Yes, and I am still using it now	77	35.3
	Yes, but I abandoned it	37	17.0
	No, but I am interested	76	34.9
	No, I never wanted to use	28	12.8

Table 4: Experience with mobile phone and wearable devices

The analysis above shows that mobile phones and wearable devices are not a new phenomenon in Irish society as majority of the population is using or ready to use them. They are also interested in getting new technologies which is a good thing for the acceptance of wearable device-controlled drug delivery devices.

Question 9

This question is a follow-up question that helps determine the type of wearable device that is most common/ accepted by the Irish population. The top 4 most wanted/used wearable devices in Ireland are Smartwatches (71.6%), Activity Tracker (39.4%), Goggle Glass (14.7%), and Smart Clothing (11.0%).

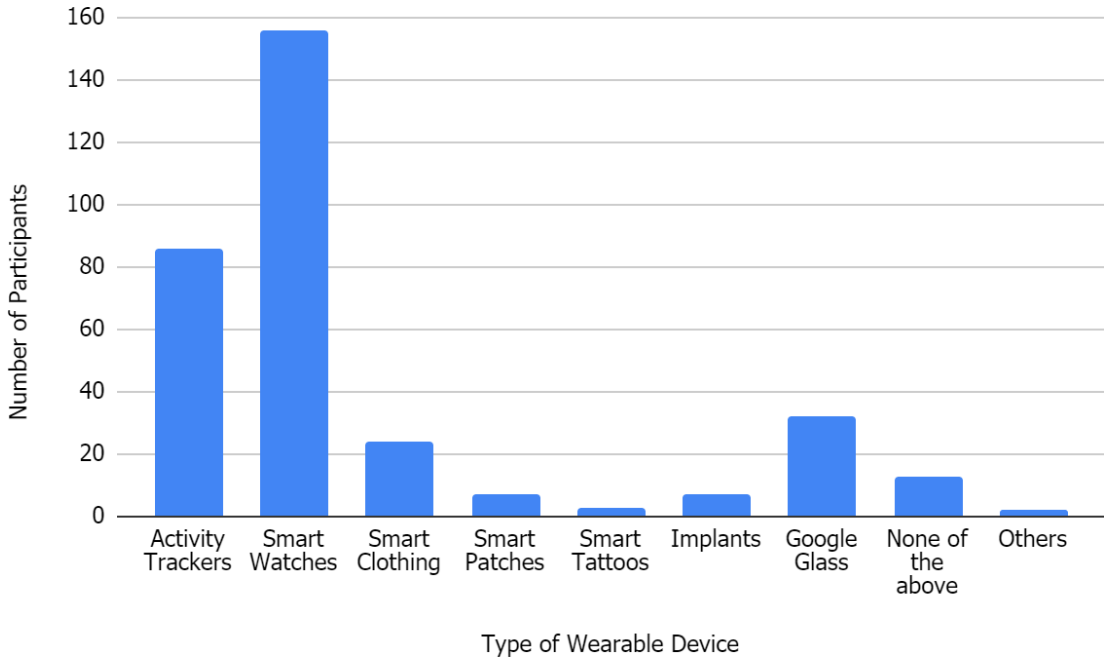

Figure 18: A Graph Showing the Popularity of Different Wearable Devices in Ireland.

The graph above shows the most popular wearable devices. Companies involved in the development and manufacture of wearable device-controlled systems can make use of some of these popular wearables for their product. This can, therefore, ease market penetration in Ireland.

Question 10 and 11

The data from these questions help to determine when the participant (that own a wearable device) started using the device and the frequency of use of the said wearable device.

34 participants have owned a wearable device for over 2 years, 31 participants have owned for between 1-2 years, 12 respondents have had it from between 7-12 months and 32 people have owned it for between 1 to 6 months. 5 people have owned the device for less than a week while the question did not apply to people who have never owned the device.

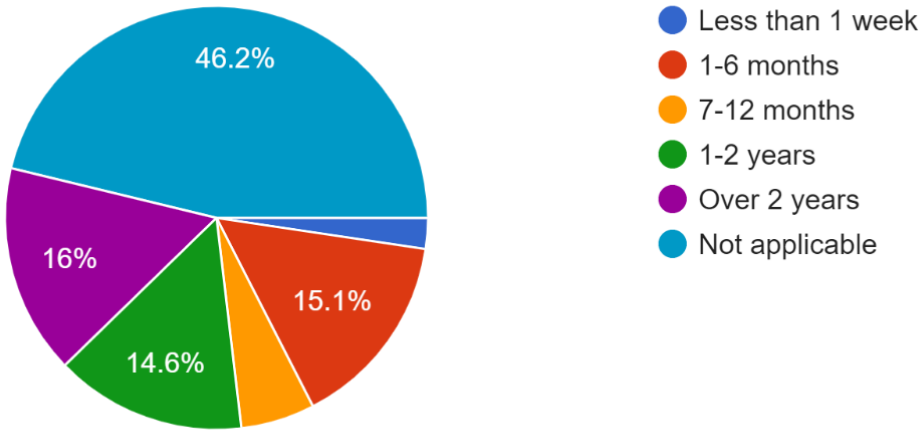

Figure 19: Length of Use of Wearable Device

52 participants declared that they often wear their wearable device while 28 people said they always had it on. 25 people said they only wear the device sometimes and 15 participants said they rarely wear the device. Like the previous question, this question did not apply to people who have never owned the device while 5 people who had the device never wear their device.

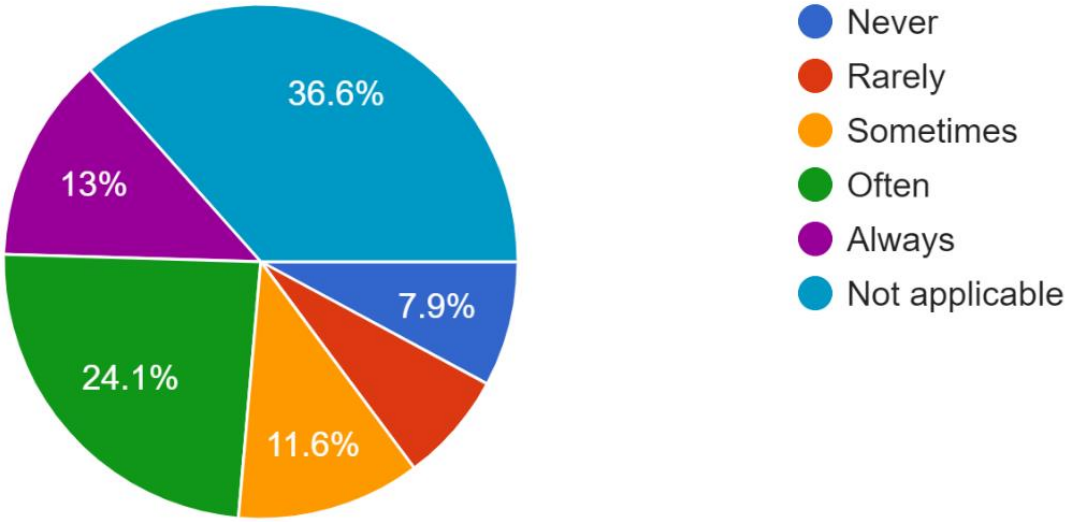

Figure 20: Frequency of Use of Wearable Device.

The data shows that many of those who own these wearable devices make use of them, using them frequently no matter the length of ownership of the device.

Question 12

This question helps in understanding the views of Irish society about wearable devices. Many of the respondents (118) found wearable devices to be very easy to use and 111 participants believe that wearable devices are very helpful in improving physical health.

Variable	Category	Number of responses	Percent (%)
Which of these are true about Wearable devices?	They are easy to use	118	54.1
	They are very easy to get	44	20.2
	They are useful in improving physical health	112	51.3
	They are very effective	70	32.1
	They are very reliable for data recording and data security	76	34.9
	They are expensive	1	0.5
	I have no idea	39	17.9

Table 5: Views about Wearable Devices.

From the data above, it can be concluded that there is a strong affinity for wearable devices as it is considered to be easy to use which is very important as it helps increase the tendency of people using it. If incorporated in the wearable device-controlled drug delivery systems will also allow patients to adhere to the use of their medications.

Question 13

The data from this question is to help determine what influences the decision of the participants in purchasing wearable devices. Most of the respondents (67.4%) said that the internet/social media were the greatest influence. Advertisement and word of mouth were the other most common influence with 43.1% and 33.9% respectively. Other influences include:

- Usefulness/ Necessity
- Reviews and Scientific Studies

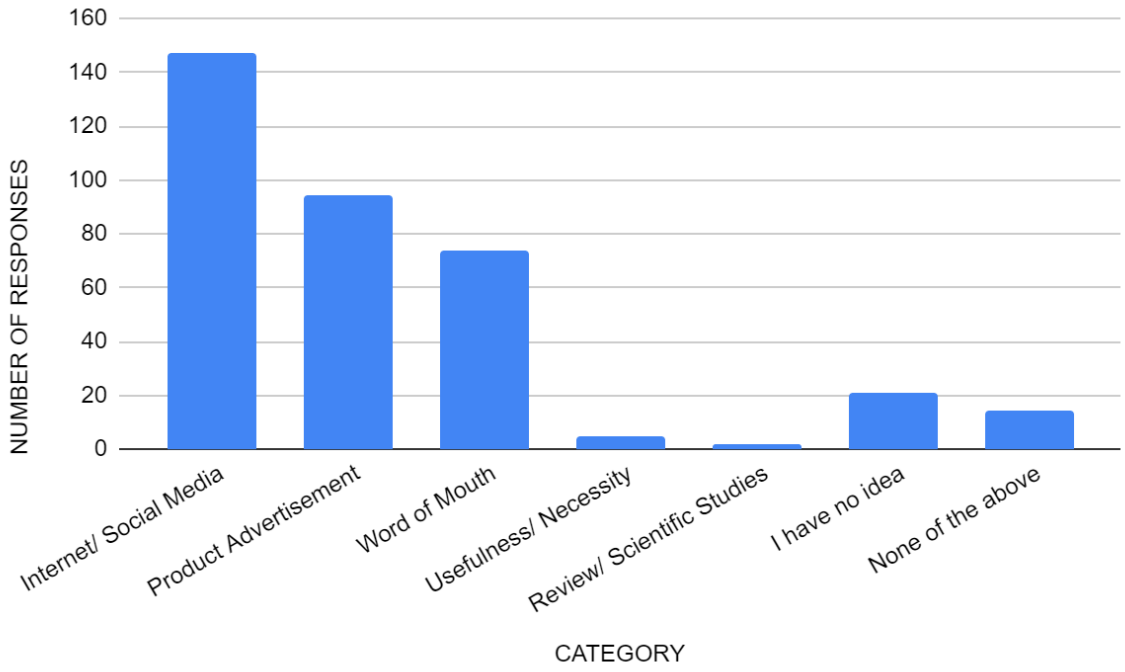

Figure 21: A Graph Showing What Influences the Use of Wearable Devices in Ireland

The data above shows social input on the behaviour and decision making of the Irish consumers in wearable devices. It can be deduced that the use of wearable devices and subsequently wearable device-controlled drug delivery systems depend heavily on the social perception of the devices.

4.2.3. INTRODUCTION TO DRUG DELIVERY SYSTEMS (Question 14 to 18)

This section is to help examine the conventional methods of taking mediation in Ireland which is useful in determining the views of consumers on wearable device-controlled drug delivery systems. The uses, popularity, and limitation are to be determined.

Question 14

The most common type of conventional drug delivery system in Ireland needs to first determine. The participants are mostly familiar with tablets (93.1%) and the second most common conventional drug delivery system with 79.4% familiar with it is the use

of injections (Intramuscular, Intravenous, or Subcutaneous). Other conventional drug delivery systems are Cream/lotion, Inhalers, Liquid drops, and Patches with the percentage familiarity of 56.9%, 56.4%, 52.8%, and 31.2% respectively.

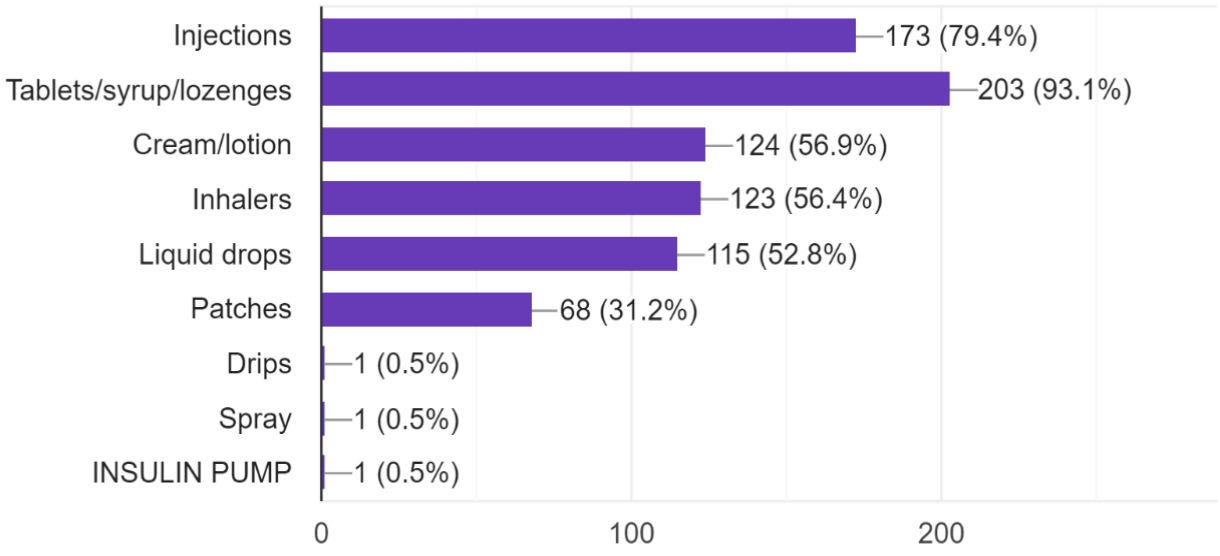

Figure 22: Common Conventional Drug Delivery Methods

For the above data, oral dosage forms and injectables are the most common drug delivery method. From this, we could deduce that the novel drug delivery system using these routes may allow for wider acceptance as the consumers are already familiar with these methods.

Question 15 and 16

A Wearable device-controlled drug delivery system is best used for treating or stabilizing prolonged illness. These questions were to ascertain the different types of prolonged ailment in Irish society.

Variable	Category	Number of responses	Percent (%)
Have you ever been required to take medications for more than 2 weeks?	Yes	114	52.3
	No	104	47.7
What was the medication for?	Not Applicable	99	45.4
	Fever/ Flu	24	11.0
	Infection	21	9.6
	Asthma	3	1.4
	Hypertension	16	7.3
	Ulcer	4	1.8
	Vitamins & Supplements	5	2.3
	Food Poisoning	5	2.3
	Pre and Post Natal	6	2.8
	Others	31	14.2

Table 6:Common Illness with Prolonged Treatment

The data above can be used to determine the different treatment areas that the wearable device-controlled drug delivery systems can be used. These treatment areas can be targeted to help improve the quality of life among the Irish population so that they do not require frequent visits to the hospitals.

Question 17 and 18

These questions are to help determine the compliance rate of patients in Ireland. First, the number of times required to take the medication for the prolonged illness is determined and 59.6% of the patients were required to take the medication daily while 25.2% used the medication several times in a day. 3.2%, 2.8%, and 0.5% of the patients were required to use their medication monthly, several times a week, and weekly respectively.

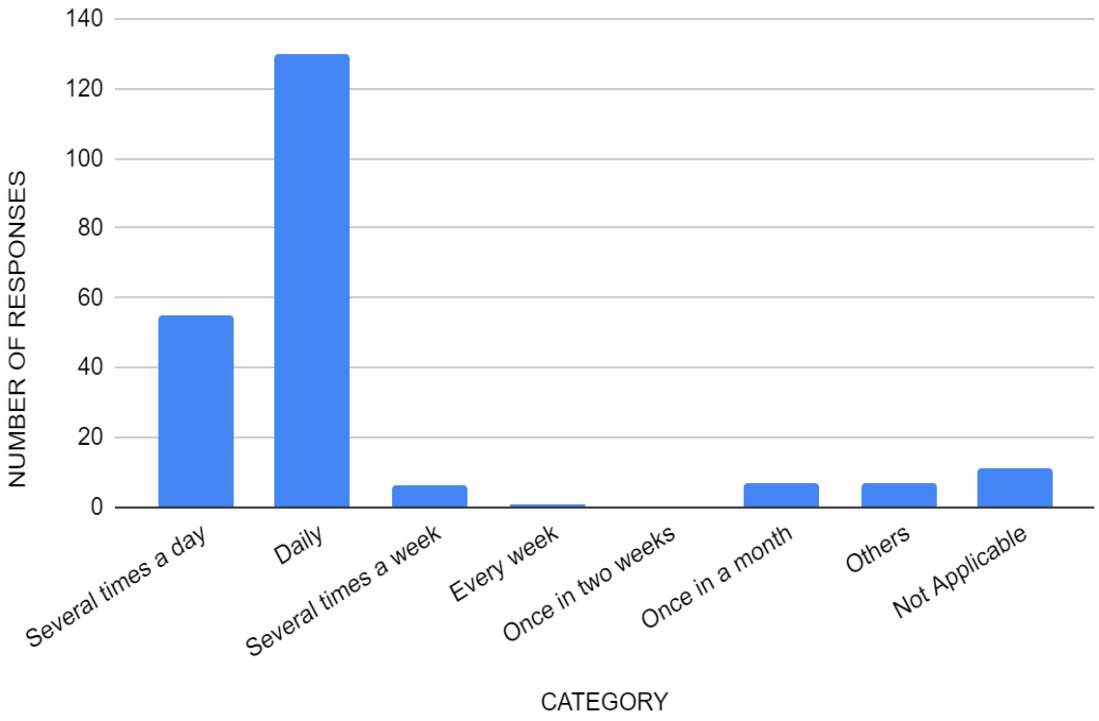

Figure 23: How Often Were You Required to Take Your Medication?

Secondly, these participants were asked how often they forget to take their medications, which is the major question to determine their compliance rate to their treatment. 78 participants said they sometimes forget to take their medicine while 83 participants rarely forget to take their medicine.

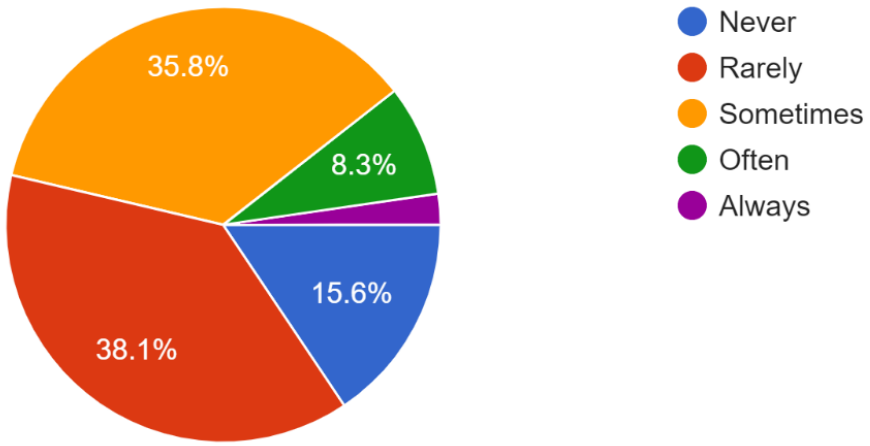

Figure 24:How often do you forget to take your medicine?

The information given above shows that with many of the conventional drug delivery systems, the chances of patients missing their medications is high. By using wearable device-controlled drug delivery systems, the patients will only be required to make use of the device which will automatically control the doses and will prevent them from forgetting to take their medication.

4.2.4. USE OF WEARABLE DEVICE CONTROLLED DRUG SYSTEM (Question 19 to 25)

This is the main section of the questionnaire that determines the present state of the knowledge of the use of wearable technology as a means of controlling drug delivery systems in Ireland. It also provides insights into the views of the Irish population regarding the technology.

Question 19

This is to determine the popularity of the use of wearable devices in controlling drug delivery systems. Only 46 participants were familiar with this type of technology while others (172) have no idea what the technology is about.

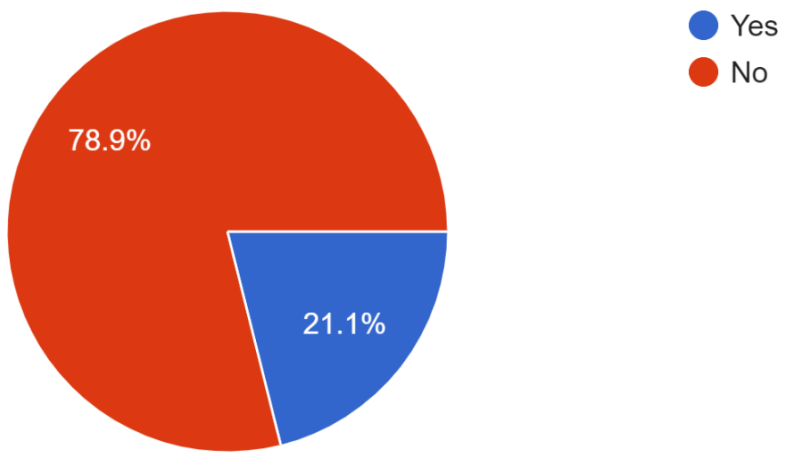

Figure 25: Knowledge about the Use of Wearable Devices in Controlling Drug Delivery Systems

From this information, it can be concluded that many people in Ireland have no idea or are not aware of this technology. This, therefore, shows the present market for the technology is very small.

Question 20

This is a follow-up question that gives the participants the chance to name the type of wearable device-controlled drug delivery systems. Drug pumps especially Insulin Pumps were the most common with 7 respondents familiar with the technology. 6 participants also knew about smart patches. Other wearable device-controlled drug delivery systems known include API infused Contact Lens, Nanoparticles, Subcutaneous Chips, Digital Pills, Wearable Injectors, and Liposome.

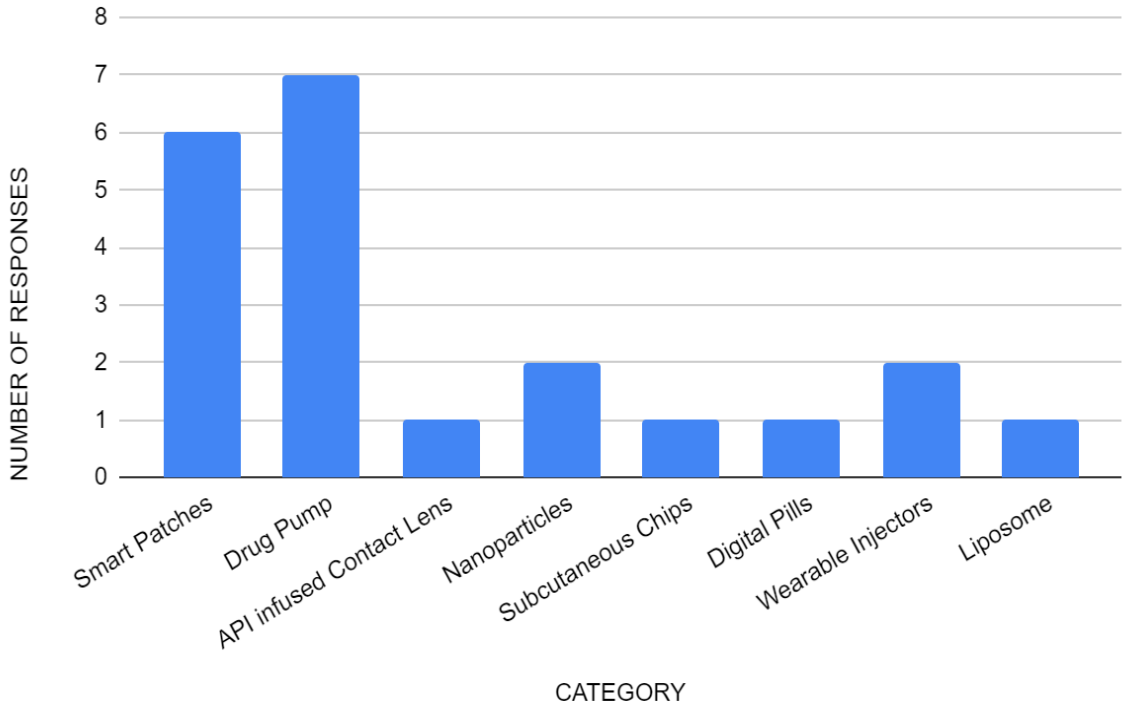

Figure 26: Types of Wearable Device-Controlled Drug Delivery System.

The information above shows that many of the other types of wearable device-controlled drug delivery systems are not very common. The most known device is the insulin pump.

Question 21

This question was to help determine the willingness of the participant to buy or use this technology. 182 participants would consider using this technology while 36 people said they would not consider using the technology. Those who were not interested in trying wearable device-controlled drug delivery systems were made up of 16.5% of the people aged 18-30, 18% of the people aged 31-40, 13% of the people aged 41-50, and 10% of the people aged 51-60.

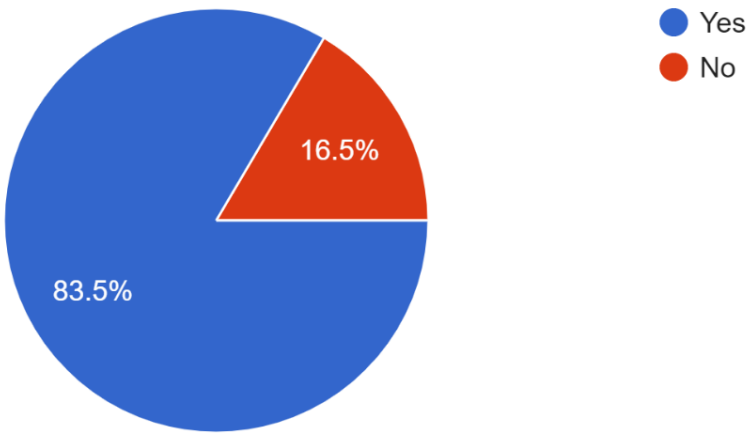

Figure 27: Would You Consider Trying This New Technology?

This shows the acceptance of this type of drug delivery system in Ireland in that majority of the population will not refuse to use it if they need to.

Question 22

To better understand the views of Irish society on the use of wearable technology as a means of controlling drug delivery systems, the factors influencing the choice of the device needs to be determined. 73.9% of the participant thought Comfort was very important and Effectiveness was considered important by 71.6% of the respondents. Also, Ease of use was judged to be essential by 65.6% of the participants and 58.7% of the respondents believed Cost to be essential. Size, Look, And Reduced Side Effect was perceived by 50%, 36.2%, and 49.5% of the respondents respectively as vital.

One of the participants added that safety should also be considered as important in the choice and manufacture of wearable device-controlled drug delivery systems.

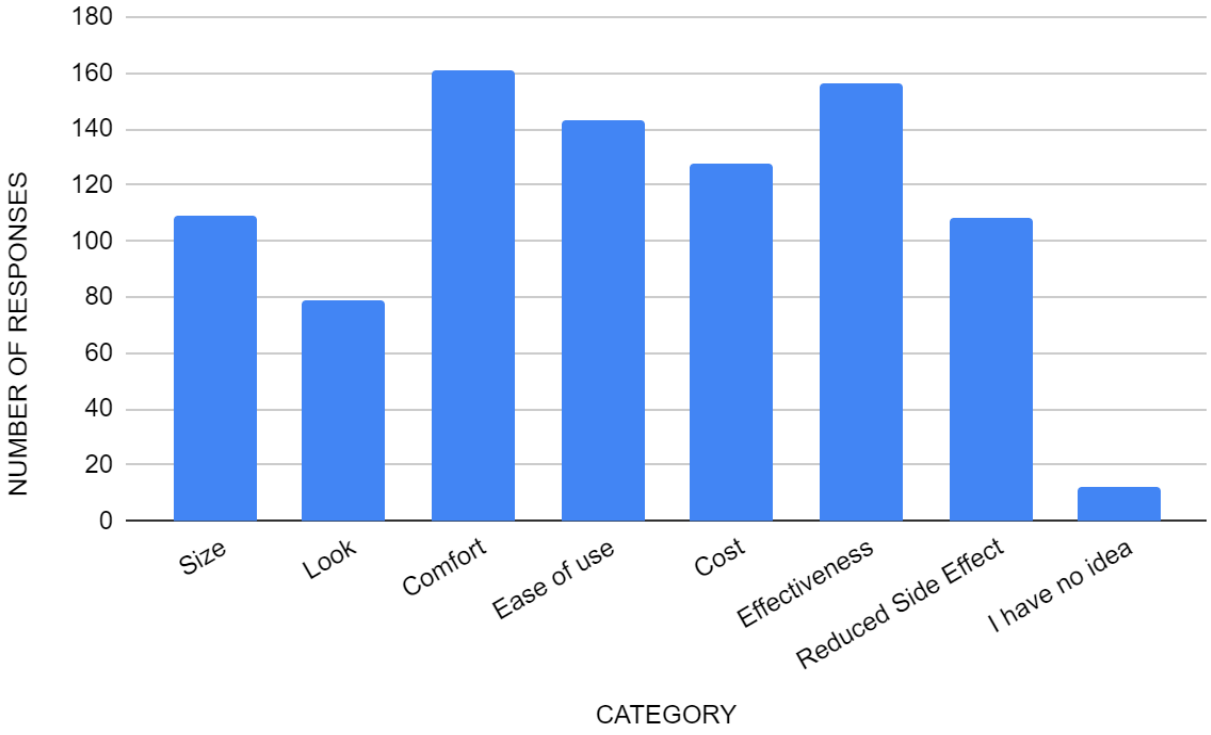

Figure 28: Factor Influencing the Choice of Wearable Device-Controlled Drug Delivery Systems.

It can be deduced that the Size, Look, Comfort, Ease of use, Cost, Effectiveness, Reduced Side Effect, and Safety are part of the things that influence the use of wearable device-controlled drug delivery systems in Ireland. It shows that before the technology can be accepted, information about these listed above is needed to influence the decision of the buyer.

Question 23 and 24

These questions are follow-up questions on the views of the Irish population on the use of the technology. 143 participants believed they would prefer to use the wearable device-controlled drug delivery systems instead of the traditional method of drug intake while 75 respondents said they will rather stick to the traditional method of drug intake.

Also, 123 participants believe that wearable device-controlled drug delivery systems will be more effective than the traditional method of drug intake and 7 respondents do not agree that wearable device-controlled drug delivery systems will be more effective while 88 people simply have no idea of what the efficacy would be.

Variable	Category	Number of responses	Percent (%)
Would you prefer this new technology to the traditional method of drug intake?	Yes	143	65.6
	No	75	34.4
Do you think these new drug delivery systems will be effective?	Yes	123	56.4
	No	7	3.2
	I do not know	88	40.4

Table 7: Preference and Effectiveness of Wearable Device-Controlled Drug Delivery Systems.

It can be concluded that in Ireland, people are ready for the use of wearable technology as a means of controlling drug delivery systems. They would prefer to use these systems instead of the regular old method of using medications.

Question 25 and 26

To fully understand the views of the people in Ireland on the use of wearable technology as a means of controlling drug delivery systems, their fears about the technology needs to be captured.

When asked about their fears, 85 participants indicated to be indifferent about having fears, and 73 respondents alleged to have concerns as regards using wearable device-controlled drug delivery systems while 60 participants were confident in the technology with no concerns about using the technology.

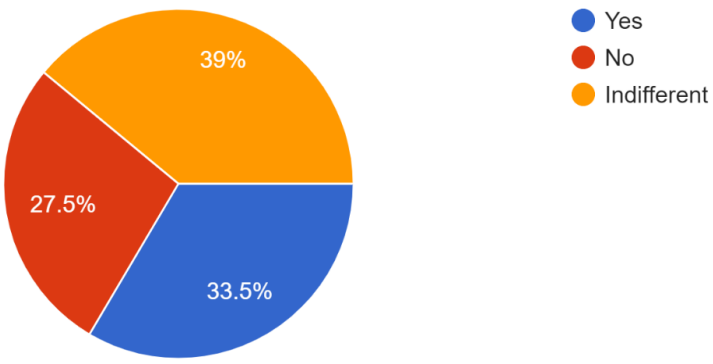

Figure 29: Do You Have Fears Concerning Using These New Delivery Systems?

The participants were then asked to list their fears and concerns about the use of wearable technology as a means of controlling drug delivery systems. The cost was a major concern, but the following are the list of the other fears/ concerns mentioned by the participants:

1. Effectiveness, efficiency, and accuracy
2. Unknown or unexpected negative side effects including those caused by radiation or adverse reactions to the device.
3. Infections produced from microorganisms that invade tissue.
4. Negative environmental effects.
5. Malfunctioning of the device for example software/hardware/form ware faults which can result in drug over/under dose.
6. Data privacy, storage, and security like malicious tampering, hacking that can put the patient's life at risk, and unauthorised access to patients' medical history.
7. The potential risks for error at the beginning and lack of validation and approval for all the range of patients.
8. Difficulty to use and Maintenance e.g. Water resistance, Power source, Ease of replacement in case of damage, and the Internet.

4.3. QUALITATIVE ANALYSIS

The data from the interviews helped establish any connection between the literature review, the result of the questionnaire, and an advanced viewpoint on the effectiveness, process, risks, and challenges in the development and manufacture of wearable device-controlled drug delivery systems.

Participant 1 had experience in manufacturing API infused contact lens in Johnson & Johnson, one of the leading Pharmaceutical companies in Ireland. Participant 2 has worked in the medical device industry for over 15 years (in senior management roles) and had a start-up company that developed medical devices for medical diagnostics. Participant 3 has been the medical device and pharmaceutical industries for over 20 years in the areas of Validation and Quality Assurance.

The analysis and observation of the body language, pitch, and tone of the participants were inhibited/ not effective has the interview was carried out via Zoom (because of COVID 19).

The interviews with the 3 experts were analysed based on the words and phrases common to the response of all the participants. There were 10 recurring themes found and they are elaborated below:

4.3.1. CURRENT TRENDS

There are different novel Drug Delivery technologies being developed and manufactured in the pharmaceutical industries now. All the participants said there are a lot of drivers for these new trends in drug delivery, they proceeded to name the ones they were familiar with and what drives the current trends in this type of drug delivery system. According to **Participant 2**:

"I think what is driving the current trends are:

- *Commercial opportunities: Pharmaceutical and medical device industries are identifying compelling unmet needs within a therapeutic space and matching that with a suitable device that can deliver something.*
- *Technology innovation*

I am familiar with wearable device from the implantable type devices, stent coated therapeutics. Other are not licensed drug delivery device on the market.

Over the last 20 years, there has been growth in implantable devices such as drug-coated stent and I think it will continue to grow as there are still growth and market opportunities in endovascular implantable devices. Not only for these devices themselves to evolve but also for the therapeutic to evolve and become more sophisticated as well.

The stents usually come in various sizes, design, material, and it is used in different locations in the body. The stent coated therapeutics is made up of

- *The therapeutic substance,*
- *The delivery apparatus for the correct placing of the stent in the right location of the body*
- *The stent itself."*

Also, **Participant 3** mentioned that:

" The current trends among patients is that they want reduced trauma, comfort, and reduced stress when it comes to disease treatment and monitoring. I would be familiar with the use of wearable devices in controlling drug delivery e.g. Glucose Monitoring devices and Insulin Pumps."

Participant 1 simply answered with the type of wearable device familiar to him:

"There are many of these types of devices available now, but I am most familiar with API infused contact lenses because I worked in a company that manufactures it. This contact lens is a wearable device that can be either worn for fashion or medical purposes."

4.3.2. COMPANIES AND PARTNERSHIP

From the interviews, it could be deduced that there are pharmaceuticals and medical device companies in Ireland that are involved in the development and manufacture of wearable device-controlled drug delivery systems. Each participant mentioned the companies they are familiar with and their products. **Participants 2 and 3** mentioned Abbott but the products named by the two participants talked about different products manufactured by the company. **Participant 2** mentioned the company regarding drug-coated stent:

"Yes, there are medical device companies that produce stents such as Abbott and Stryker. Johnson& Johnson in Limerick also intends to bring a drug-coated product to market. Another company in Athlone is producing an implantable device which is an osmotic pump for insulin that is at the preapproval stage with the regulatory bodies."

While **Participant 3** talked about their glucose monitoring system:

"Abbott manufactures the FreeStyle Libre System which monitors glucose levels in the blood. Many multinational companies manufacture this type of device in the world, but Abbott's is the market major at the moment. Medtronic in Galway manufacture insulin pumps which are used to administer insulin to the body in response to variations in glucose levels. Medtronic also manufactures ventilators."

Participant 1 talked mainly about companies involved in the manufacture of contact lenses in Ireland:

"The Acuvue contact lenses are manufactured by Vision Care, a branch of Johnson & Johnson located in Limerick. Alcon, a UK company in Ireland also produces this device."

When asked about the partnerships involved in the manufacture of these technologies, all the participants mentioned that it involves the **medical device companies** who will be responsible for creating the wearable device and the **pharmaceutical companies** which will provide the drug substances needed for the treatment of the patients. For example, **Participant 1** mentioned that:

"In the production of Acuvue lenses, a pharmaceutical company called Amel partnered with Johnson & Johnson, Amel will produce the API while Johnson & Johnson will put the API into the contact lenses."

Participants 2 and 3 further explained that some of the components of the device can be outsourced and then the components could be consolidated for final assembly at the point of manufacture. It was also suggested that companies should get more than one supplier and test the quality.

Participant 2 added that:

"These types of devices are called combination devices and the therapeutic substance provided by the pharmaceutical company is usually one that has already been tried and approved in another form of administration. This technology typically involves taking a known drug substance and combining it with a delivery device like the drug-coated stent. This a less risky product development strategy. It is also possible that a new drug is being developed and the only way of delivering the drug is by combining it with a medical device e.g. Inhaler. This will involve the medical company working hand in hand with the pharmaceutical companies at the development stage.

A pharmaceutical company is usually needed for the drug discovery and development process involved to get the therapeutic substance approved. While the medical device company is needed to design the device that delivers the drug substance.

Some companies are both medical devices and pharmaceutical companies e.g. GSK and Johnson &Johnson that have the means to do everything in-house.

Sometimes these partnerships can be in the form of a joint venture where they set up a separate company allowing them to manage intellectual property issues and share the revenue to bring the product to market."

Participant 3 provided another insight that:

"Information technology is very import because a lot of these devices use form-ware and software and they must be robustly tested so that when the devices get to the market it doesn't fail.

Also, there should be a good and strong supply chain of the components. For example, one part (the microchip) that goes into the Abbot glucose monitoring device is made in Donegal.

Apart from company partnerships, there has to be a strong collaboration between different departments in the company like the research and development and product development departments so that design and testing work hand in hand at every stage of development."

4.3.3. PROCESS AND RESOURCES INVOLVED

According to all the participants, the process for the development and manufacture of wearable device-controlled drug delivery systems varies depending on the type of wearable device that would be used to control the drug delivery system. For example, **Participant 2** stated that:

"I can give you 101 different processes for 101 different products in terms of individual steps. It depends on the device itself and the material used in constructing it."

He further gave a brief narrative of the basic development steps before the manufacturing stage:

*"The first step is the **clinical development phase** that involves finding molecules and drug substances with therapeutic effects. These molecules are then moved through basic and applied research discovery. The next step is the **Preclinical stage** followed by the **clinical trials /drug safety** up until the **Market authorization** is filed for and acquired before the device can be manufacture for commercial purposes."*

Participant 3 gave a general description of what the manufacturing process would involve:

"…These would include:

- *Manufacture of circuit boards and computer chips in cleanroom environments.*
- *Manufacture of device components by extrusion or injection moulding*
- *Assembly of devices*
- *Testing of devices in line with international standards such as ISO standards.*
- *All manufacturing activities must be performed per an accredited Quality Management System e.g. ISO13485 for Medical Devices and Eudralex Annex 1 for Pharmaceuticals.*
- *Design review and validation should be done at every stage."*

But **Participant 1** was able to list the manufacturing steps specific for the manufacture of API infused contact lenses:

"These contact lenses are made from plastic resins. Generally, the drug is added into the contact lenses during production. The contact lenses are usually produced in different specifications according to the intensity of the eyes. The manufacturing process starts with the use of specialized plastic resins.

- *The plastic resins are fist moulded into concave shapes based on the specifications.*
- *Then the front and back cup of the contact lenses are merged in a process called Lens Fabrication.*
- *The API is added during the Len fabrication process, it is placed between the front and back cups. The lens takes its shape after this process.*
- *The next step is sterilization for 48 hrs to prevent bacteria formulation.*
- *The content lenses are then cooled and packaged"*

When asked about the general resources needed to ensure the development and manufacture of the effective and efficient wearable device-controlled drug delivery systems, **Participant 2** said:

"Typically with all of these, you have the drug substances which need to be produced and it is usually produced separately and then you have the device itself which usually contains several subcomponents that may or may not be produced on-site."

While **Participant 3** provided a different approach by revealing that:

"…This would include:

- *Innovative research and development and product design*
- *Relevant Funding*
- *Strong focus on Ergonomics ensuring the device is compact fits well to the body.*
- *Strong focus on ensuring the device is safe and effective."*

While talking about future processes that will be involved in the manufacture of these technologies, **Participant 2** projected that:

"I think it is something that is rapidly changing. The traditional methods involved the use of various types of plastics for medical devices and alliods for implantable to

prevent autoimmune responses. But we were getting to a new age of advanced manufacturing where the likes of 3D printing are used as a means of rapid prototyping and scale-up manufacturing. These areas are improving and innovating as much as the products."

4.3.4. EFFECTIVENESS

When asked about the overall effectiveness of the use of wearable technology as a means of controlling drug delivery systems, all the participants agreed to the fact that wearable device-controlled drug delivery systems are very effective in increase the treatment outcome of diseases and generally improving the quality of life. For example, **Participants 3** stated that:

"Yes, I think it is very effective. In my opinion, any wearable drug delivery device that reduces the trauma associated with conventional treatments is of great benefit to the patient and their families. These types of devices can replace or minimize injections and allow people to go about their normal day without having to visit the hospital in some occasions. This ultimately takes the pressure off the hospitals and frees up beds for other serious cases.

I would say these technologies in Ireland has improved the lives of patients to date and has been quite successful. Especially those with lifelong illnesses such as diabetes and kidney failure. As with any Technology as it evolves it will lead to greater success.

For example, the glucose monitoring device is a leading measure instead of a lagging measure because if using the conventional method, the glucose level could be high one minute and low the next minute but this device is worn under the elbow and when a smartphone is placed there, it scans and shows the glucose levels throughout the day and gives real information not just a one-point reading but a trend giving a more accurate result that can be acted on quickly.

Also, insulin pumps are used instead of the conventional method of going to the hospital, given a bed, and hooked up on an insulin pump. These insulin pumps can be tucked under the shirt and once the monitor detects low insulin levels, it sends signals to the pumps which then releases some insulin into the body. It is a close loop system that is very effective."

Participant 2 also provide another thought based on patient safety and safety, innovative and economic benefits where he mentioned that:

"These technologies are good for improving patient safety and compliance. It has also reduced the overall burden on the healthcare system.

Also, the drug-coated stent would be considered effective because there are no competitive lower-cost means of providing equivalent benefits. No tablet or injection provides equivalent medical benefits at a lower cost. The effectiveness of these drug-coated stents is backed by data-driven, evidence-based, peer-reviewed papers that demonstrate randomised double-blinded studies that show the benefits of these technologies when compared with the alternative therapeutics. It has completely changed how we practice medicine and improved patient survivability, reduced long term side effects, and complications.

Also, there are opportunities around oncology where you have a therapeutic design for a small cohort of cancer patients. Many of these therapeutics are highly potent and oncologist usually wants to maximise the dose so that they can safely deliver it to the patient in other to maximise the therapeutic benefit which could be made possible by the use of drug delivery device rather than the traditional methods."

4.3.5. THERAPEUTIC IMPACT

The use of wearable technology as a means of controlling drug delivery systems is very versatile has it can be used in different therapeutic areas. All the participants talked about the use of this technology in Diabetes as a therapeutic area with devices such as insulin pumps, patches, and injectors. For example, **Participant 3** explained that:

"I think a great impact has been on the treatment of diabetes. Instead of numerous finger pricks during the day, the Abbott glucose monitor is attached to the back of the elbow and can monitor glucose levels without breaking the skin. The device is so lightweight and compact that the patient does not even realize that they are wearing it. Diabetes is a disease that is increasing due to lifestyles in the modern world and through education and the use of wearable devices, it appears that it can be treated effectively and efficiently with little trauma to the patient."

Participant 2 expatiated on other areas of impact of the use of wearable technology as a means of controlling drug delivery systems. For example, he stated that:

"Globally, there has been a huge growth in the use of drug-coated stents leading to a shift away from open cardiothoracic surgeries to endovascular and intervention type surgeries. Drug coated stents are now being offered to patients that about 20 years ago will not have to be able to use them because of reasons like risk profile, age, location, or other parameters. The lack of use of stents could also be due to inexperienced

healthcare systems on the use of stents or because the products were not developed enough for such cases.

Other areas where the use of wearable technology as a means of controlling drug delivery systems has been of impact are:

- *There is big growth potential in oncology. In that, the oncology therapeutic are usually expensive so the cost of the drug delivery device would be marginal in proportion to the price of the actual drug itself.*
- *It can be used in chronic ailments where the patients must take their drugs at the right time, for example, epilepsy patients.*
- *I would say that there has being a lot of success in the manufacture and use of wearable devices in terms of diagnostics in Ireland. There would also be a stronger future and a lot more success for the use of wearables in diagnostics in Ireland."*

Another therapeutic area was introduced by **Participant 1**:

"The contact lenses are prescribed by medical professionals (opticians) for delivering drugs into the eyes. It is used to treat maladies such as cataracts. Different APIs are infused into the contact lenses based on the eye ailment.

During its production, a mechanism for drug release has been provided so when the patient wears the lenses, upon contact with the eyes, the API gradually diffuses into the eyes and the therapeutic process begins. The API could last for as little as 24 hours (single use) up until 72 hours."

4.3.6. POPULARITY AND USE IN IRELAND

The popularity of these devices in Ireland can be analysed based on the number of companies producing the technologies and the rate at which people in Ireland use these technologies.

All the participants agree that these technologies are commonly developed and manufactured in Ireland as there are some very successful products made in Ireland but sold globally. For example, according to **Participant 3**:

"Ireland for a small country is high profiled in the field of medical devices, pharmaceutical devices, and wearable devices. It may not be up to the top 4 or 5 but it in the top 10 or 15 countries. There are a lot of multinational companies in Ireland and

they invested for different reasons such as good educational services tailored to suit the roles in their companies and the tax benefits they get is good too."

When talking about the Glucose Monitoring Device manufactured by Abbot, **Participant 3** stated that:

"The device has taken the market by storm. There are good projections for all of Europe. One country ordered a full amount and they had to go back and order some more"

Furthermore, **Participant 2** provided insights into what is to be expected in the area of manufacture of these technologies:

"There is a huge success on the technologies that are present now, but there is also huge potential in terms of the future of these types of technologies with new therapeutic, new benefits, innovative designs, and improvement to the technology. There are also a lot of new applications of these technologies. The innovative culture is expected to continue especially when it comes to medical devices especially from the implantable point of view. Although the case may not be the same for pharmaceuticals as drug discovery is limited in Ireland."

Participant 1 further stated that:

"The API infused contact lenses are very popular and can be bought from accredited stores and online. About 30% of the people using glasses in Ireland use this device. The are many brands of these types of devices in Ireland. An example is one made by Alcon a UK company in Ireland. Hence, Acuvue lenses although produced over 1 million products monthly in Ireland, the product is used more in Asia especially in Japan and China because of the high market competition."

Participant 3 added that although these technologies are being manufactured in Ireland, its use is not as common as seen in other parts of the world:

"Regarding where we are in using these technologies I believe we are not where we should be."

Participant 2 gave a different opinion when talking about the popularity of drug-coated stents:

"If we talk about drug-coated stents, they are very accessible in Ireland. This has led to a huge shift to its use in Ireland."

Also, according to **Participant 2**, the use of wearable devices in diagnosis such as blood pressure monitoring is commonly used in Ireland. This device is considered more effective than the alternative method because of the ability to record data over time and with the recent development in artificial intelligence, these data can be interpreted in real-time.

4.3.7. MANUFACTURING CHALLENGES

All the participants said there are challenges involved in the manufacture of wearable device-controlled drug delivery systems. These challenges like the processes involved depend on the type of device being manufactured. **Participant 1** mentioned the challenges involved in manufacturing the API infused contact lenses as:

"The presence of heavy regulations and difficulty in getting the API into the wearable device (lenses)."

While **Participant 2 and 3** pronounced that time, money, and resources (especially in Research and Development) has the major challenges faced by manufacturers when developing and manufacturing wearable device-controlled drug delivery systems.

Participant 2 mentioned some other challenges and risks involved in manufacturing has:

- *"Commercial risks: The market for the device may not exist and the product may not be as novel as the manufacturer thought and could be a 'me too' technology that will end up having a market competition. Market forces determine if the business is viable for the said product line.*
- *Timing: Delay in entering the market which could be due to reasons such as wrong or delayed clinical data or incorrect 'go to market' launch plan will have an impact on the success of the product.*
- *Product Lifecycle: After developing and launching a product, the manufacturer cannot determine how long it will take for the product to establish, grow and maintain market share before a competing technology comes around and knock out the product from the market.*

- *Technical risks: The manufacturers try to engine out these risks by knowing and understanding their product and manufacturing process. They must identify, minimise, and mitigate them.*
- *Quality risk: This is the risk of making defective products and the impact that will have on the market of the product.*
- *Regulatory risks: Regulations are constantly changing during a product's lifecycle and even if the product already gets approval, the rules could still change and affect the manufacturing process, the product market, and even marketing license.*
- *Unlike America, where it is perfectly lawful to promote and market drugs directly to patients that need the product, here in Ireland, it is the Medical professionals and HPRA that need to be convinced. A strong case needs to be presented to prove the safety, effectiveness, efficacy, and economics of the new technologies when compared to the traditional methods.*
- *Intellectual property risks: Competitors can use different strategies to keep a manufacturer from getting to the market and the competitors could also, even when the product enters the market, try can kick their competitors out through aggressive Intellectual property strategies.*

Participant 3 also included that some of the challenges include:

"Bigger companies may bring devices to market quicker which could make devices that are still in the development stage obsolete. Also, delays are often incurred during validation. However, this can be addressed by taking more time during research and development using techniques such as Quality by Design"

4.3.8. SOLUTIONS TO CHALLENGES

All the participants were able to provide some insights into how to improve the use of wearable technology as a means of controlling drug delivery systems. Some of the solutions provided by the participants were directed at making the wearable device-controlled drug delivery systems more accessible to patients. **Participants 2 and 3** thought that since these technologies are mainly prescribed products, to penetrate the market, the manufacturers have to direct their marketing, promotions, and awareness to prescribe physicians and healthcare systems and not focus on selling to patients

Participant 3 anticipated that:

"The use of these technologies could be improved

- *By the government subsidizing these to make them widely available and less expensive. Also, the companies making these devices in Ireland could make the devices affordable through subsidies.*
- *Governments and Companies providing grants for R&D and Product development which will encourage more companies to invest in this sector.*
- *Companies should provide free training on the use of these devices.*
- *Companies should advertise the benefits of these devices.*

Participant 2 included:

- *"Regulatory satisfaction: A lot needs to happen for the use of wearable technology as a means of controlling drug delivery systems to become mainstream and it involved the regulators being comfortable with the technologies.*
- *The right approach: Correct physician education and training and ethical sponsored researches provide benefits that have a huge impact on the marketability of these wearable device-controlled drug delivery systems. Societal believes should also be considered when marketing these products among different demographics.*
- *Emphasis should be made on the effectiveness and efficacy of these wearable device-controlled drug delivery systems especially when compared with the alternatives. This tends to improve confidence in the product and justify the overall cost of the devices particularly when the alternatives are cheaper.*
- *Timing: Companies need to hit the market with the product at the right time before competitors get to the market with an exact technology or something better."*

Participant 1 added that:

"The use of process validation will help ensure that the product is always made according to specifications."

4.3.9. USAGE BARRIERS

The widespread of the use of wearable device-controlled drug delivery systems in Ireland has been inhibited because of various hurdles. All participants indicated that the high cost of the delivery devices was the most common barrier as listed by all the participants. According to **Participant 3**:

"This (common barriers) would include:

- *Difficulty in usage: Misuse of the device due to confusing instructions for use.*

- *Logistics: As often the patients that require the devices find it hard to reach locations where the devices are sold or dispensed therefore, they must rely on the existing conventional treatments instead.*
- *Availability: People sometimes don't like to use something new because they don't know if there will be a good steady supply of the product.*
- *How advanced the healthcare system is in a country can impact how easy patients can get access to these devices.*
- *Not ready for change: People are sometimes scared of something new and prefer what they had over the past years."*

Participant 2 added that:

- *"The no advertisement of prescription product regulatory limitations in Ireland is also responsible for the lack of awareness of these products among the patients that need the product.*
- *Safety concerns: Concerns regarding patient safety, adverse reaction, and product defect (recalls and withdrawals) can also kill off the market for these technologies."*

Participant 1 claimed that:

"The use of these technologies is based on the preference of the patient. I prefer to use glasses instead of contact lenses. This can be associated with the difficulty of using the device.

According to the market survey carried out by Johnson & Johnson on the use and popularity of these API infused contact lenses, the highest user was between age 18 and 35 and age 65 and above were the lowest so age could be a barrier."

4.3.10. IMPROVING ACCEPTANCE

As regards shifting the views of people in Ireland to accept and embrace the use of this technologies, all the participant believe that patients can be swayed by awareness about the product (exposing them to the result of clinical research and success of using this type of drug delivery system in the form articles or media reports for example).

All the participant provided insights has to the approaches to be taken by companies, for example, **Participant 3** suggested that:

"Patients are mostly going to go for the product of there is information on real-life experiences from using these devices (customer reviews). The patients also need to be educated that the device is more about ensuring that patients benefit from the technologies and not about profits for the manufacturers.

Also making more recyclable devices and helping the environment as well as the patients could help improve the acceptance of the devices in Ireland."

4.4. CONCLUSION

From the analysis of the findings provided above, it can be concluded that although mobile phones and wearable devices are not a new phenomenon in the Irish society as majority of the population are using or ready to use them, the use of these technologies by patients to deliver drug substance is still struggling. Oral dosage forms and injectables are the most common conventional drug delivery method. But many trends are seen that will potentially drive the use of wearable device-controlled systems such as the quest for reduced trauma, comfort, and reduced stress.

One of the reasons for the high use of wearable devices such as Smartwatches, Activity Tracker, Goggle Glass, and Smart Clothing, according to the data collected, could be associated with the ease of use. It increases the tendency of people using the devices which if incorporated in the wearable device-controlled drug delivery systems would allow patients to adhere to the use of their medications. It was also deduced that the use of wearable devices and subsequently wearable device-controlled drug delivery systems depend heavily on the social perception of the devices.

A Wearable device-controlled drug delivery system is best used for treating or stabilizing prolonged or chronic illness. The use of this technology has therefore been seen mainly in the monitoring and treatment of diabetes and high blood pressure in Ireland and has helped improve the quality of life of Irish society and reduces frequent visits to the hospitals. The patients will only be required to make use of the device which will automatically control the doses and will prevent them from forgetting to take their medication.

The present market for the wearable device-controlled drug delivery system is very small and the only commonly known one is the insulin pump. However, this study was able to demonstrate that many people in Ireland would like to use this new technology in Ireland. The Irish people would prefer to use these systems instead of the traditional method of using medications. But the choice of use of this type of drug delivery system in Ireland is based on the Size, Look, Comfort, Ease of use, Cost, Effectiveness, Reduced Side Effect and Safety of the devices. Fears and concerns like effectiveness, efficiency, and accuracy could also affect the use of wearable technology as a means of controlling drug delivery systems in Ireland.

It was also established that the manufacture of different drug delivery systems such as insulin pumps, API infused contact lenses and drug-coated stents by different medical devices companies are common in Ireland, and some of these devices are being sold globally. The production of these wearable device-controlled drug delivery systems involves collaboration between medical device companies and pharmaceutical companies. Some components of the device can be outsourced and then the components could be consolidated for final assembly at the point of manufacture. Some of these devices make use of software and connectivity such as Wi-Fi and Bluetooth hence the involvement of information technology departments/companies.

The process for the development and manufacture of wearable device-controlled drug delivery systems varies depending on the type of device. As seen, there are many challenges involved in the manufacture and use of wearable device-controlled drug delivery systems in Ireland such as heavy regulations and the time, money, and resources involved in the Research and Development is high. Also, to penetrate the market, manufacturers need to direct their marketing, promotions, and awareness to prescribing physicians and healthcare systems. Efforts should be made to make the wearable device-controlled drug delivery systems more accessible to patients.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1. CONCLUSION BY RESEARCH QUESTIONS

5.1.1. HOW CAN WEARABLE DEVICES BE USED TO CONTROL DRUG DELIVERY SYSTEMS?

The author through literature review and the use of qualitative and quantitative data has been able to determine that many different types of wearable devices are being used to control drug delivery systems such as stents, wearable injectors, implants, smart bracelets, and accessories. Some of these drug delivery systems are worn by the patients, attached to the body of the patients, or placed inside the body of the patient through surgically means.

The way each device works varies and is usually based on the drug substance to be delivered and the drug delivery system. Mechanisms such as osmosis, diffusion, and pumps enable the delivery of the drug substances. One of the benefits of this type of drug delivery system is that it is very versatile as one device can be used for different drug substances. The process involved in the development and manufacture of wearable device-controlled drug delivery systems also varies depending on the type of device.

The quest to satisfy the unmet needs within a therapeutic space and advancement in technology innovation are some of the drivers for these new trends in drug delivery. The search for reducing trauma and stress and increase comfort when it comes to disease treatment and monitoring also contributes to the growth in these technologies. It is also estimated that the use of wearable devices in controlling drug delivery systems will continue to increase not only for these devices themselves to evolve but also for the therapeutic to evolve and become more sophisticated as well.

5.1.2. WHAT TYPE OF INDUSTRIAL COLLABORATIONS ARE INVOLVED IN THE CREATION OF THESE DEVICES IN IRELAND AND HOW WILL A SYNERGY BETWEEN THE INDUSTRIES BY CERTIFIED?

The type of partnerships needed for the development and manufacture of wearable device-controlled drug delivery systems is determined by the type of process involved. Qualitative data collected established that the partnerships required in Ireland are usually between the pharmaceuticals and medical devices companies. The medical device companies are responsible for designing and creating the wearable device and the pharmaceutical companies provide the drug substances needed to be delivered to the patients. While the pharmaceutical company is usually needed for the drug discovery and development process involved to get the therapeutic substance approved. Most of the therapeutic substances used are usually one that has already been tried and approved in another form of administration which is a less risky product development strategy. Also, a new drug could be developed, and the only way of delivering the drug is by combining it with a medical device e.g. Inhaler. The medical company and pharmaceutical companies need to work hand in hand, especially at the development stage.

Furthermore, Information technology is very important because a lot of these devices use software and it is important that they are robustly tested so that when the devices get to the market it does not fail. A strong collaboration between different departments in the company like the research and development and product development departments are needed to ensure that the design and testing of the product are done at every stage of development and manufacture. Finally, some parts of the components of the device can be outsourced and the components would be consolidated for final assembly at the point of manufacture. This requires rigorous testing of the quality of the supplied components and a good supply chain which could be achieved by having more than one supplier.

Many of such partnerships have been seen in Ireland such as the one between Johnson & Johnson and Amel. Johnson & Johnson is the medical device company that produces

the wearable device (contact lenses) and Amel, the pharmaceutical company that produces the API. Some multinational companies have both medical device and pharmaceutical companies (e.g. GSK and Johnson &Johnson) and have the means to do everything in-house. Sometimes these partnerships can be in the form of a joint venture where they set up a separate company allowing them to manage intellectual property issues and share the revenue to bring the product to market.

5.1.3. WHAT ARE THE CHALLENGES THAT CAN AFFECT THE USE OF WEARABLE DEVICES TO CONTROL DRUG DELIVERY IN IRELAND?

The challenges affecting the use of wearable devices to control drug delivery in Ireland can be analysed from 2 perspectives:

1. **Manufacturers:** According to the interviewees, the challenges faced by manufacturers in Ireland regarding the development, manufacture, and market penetration are numerous and like the processes involved depend on the type of device being manufactured. The challenges range from things like the presence of heavy regulations to difficulty in getting the drug substance into the wearable device. Time, money, and resources (especially in Research and Development) are other major challenges facing development and manufacture wearable device-controlled drug delivery systems. Other challenges and risks as identified by the qualitative data are Commercial risks, Delay in entering the market, Quality risk, Product Lifecycle, Technical risks, and Intellectual property risks.
2. **Consumers:** The responses from the questionnaire proposed that the use of this type of drug delivery system by the people in Ireland has been inhibited because of various hurdles such as high cost, Difficulty in usage, Inaccessibility, Lack of steady supply, concerns about the patient safety such as adverse reaction to these devices and unreadiness to progress from Conventional Healthcare methods. Also, regulatory limitations on the advertisement of prescribed medication in Ireland are responsible for the lack of awareness of these products among the patients that need the product. Age could also be a barrier as seen in the case of the market survey carried out by Johnson

& Johnson on the use and popularity of these API infused contact lenses, the highest user was between age 18 and 35 and age 65 and above were the lowest.

5.1.4. WHO IS THE POTENTIAL TARGET MARKET FOR THIS WEARABLE DEVICE-CONTROLLED DRUG DELIVERY SYSTEM IN IRELAND?

According to the quantitative data collected, 85.3% of the participant indicated an interest in the use of a wearable device-controlled drug delivery system. When broken down according to the age groups, it was seen that the interest in this type of drug delivery system cuts across all the age as 83.5% of the people aged 18-30, 82% of the people aged 31-40, 87% of the people aged 41-50 and 90% of the people aged 51-60.

The versatility of wearable device-controlled drug delivery systems has led to its use across different therapeutic areas such as diabetes and hypertension. Devices such as pumps, patches, and automatic injectors being used in Ireland to deliver insulin to diabetic patients and is considered effective and efficient with little trauma to the patient. For example, instead of numerous finger pricks involved in the traditional method, the Abbott glucose monitor is attached to the back of the elbow and can monitor glucose levels without breaking the skin. The device is so lightweight and compact that the patient does not even realize that they are wearing it. Likewise, drug-coated stents are now being offered to patients that about 20 years ago will not have being able to use them because of reasons like risk profile, age, location, or other parameters. These technologies are also being targeted to other therapeutic areas such as oncology, chronic ailments (epilepsy patients), and real diagnostics and treatment combination.

On another note, many companies are producing these technologies in Ireland for use within and outside Ireland. This is due to the high number of medical devices, pharmaceutical, and wearable devices multinational companies in Ireland. Many of these companies are invested for different reasons such as good educational services tailored to suit the roles in their companies and the tax benefits they get.

5.1.5. HOW WILL THIS NEW TECHNOLOGY BE RECEIVED IN THE MARKET IN IRELAND?

This research was able to determine the views of people living in Ireland on wearable device-controlled drug delivery systems through quantitative and qualitative data. People in the industry because of their advanced knowledge about these technologies are confident that wearable device-controlled drug delivery systems are very effective. Their views are backed by data-driven, evidence-based, peer-reviewed papers which include randomised double-blinded studies that show the benefits of these technologies when compared with alternative therapeutics. It is believed that this type of drug delivery system has helped improved patient survivability, reduced long term side effects, and complications. These devices help to increase the treatment outcome of diseases and generally improving the quality of life of the patient and their families. They are can be used to replace conventional methods such as intravenous injections which ultimately help in improving patient safety and compliance and reduced the overall burden on the healthcare system. For example, insulin pumps can be tucked under the shirt and once the glucose monitoring device detects low insulin levels, it sends a signal to the pumps which then releases some insulin into the body. It is a close loop system that is very effective.

The quantitative data shows that the present market for the technology is very small in that majority of people in Ireland have no idea or are not aware of this technology. Nevertheless, there is a potential for an increase in the market share as a majority of the participant declared that they would be interested and would prefer in using this technology instead of the traditional methods. It was also determined that the existing and future use of these technologies depends heavily on the social perception of the devices. The decision to buy/use the wearable device-controlled drug delivery systems is based on mainly on the ease of use, size, look, comfort, ease of use, cost, effectiveness, reduced side effect and safety of the devices. Part of the inhibiting factors of the use of this type of drug delivery system in Ireland is the fears and concerns surrounding using these devices. They include (as listed above):

1. Effectiveness, efficiency, and accuracy
2. Unknown or unexpected negative side effects including those caused by radiation, adverse reaction to the device.
3. Infections created from microorganisms invading tissue from point of skin penetration.
4. Negative effect on the environment.
5. Malfunctioning of the device for example software/hardware/form ware faults which can result in drug over/under dose.
6. Data privacy, storage, and security like malicious tampering, hacking that can put the patient's life at risk and unauthorised access to a patient's medical history.
7. A potential risk for error at the beginning and lack of validation and approval for all the range of patients.
8. Difficulty to use and Maintenance e.g. Water resistance, Power source, Ease of replacement in case of damage, and the Internet.
9. Cost of the Devices

5.2. COMPARING AND CONTRASTING RESULTS FROM PRIMARY AND SECONDARY RESEARCH.

The use of wearable technology as a means of controlling drug delivery systems is taking over the pharmaceutical industry at an exponential rate and Ireland is not left behind. The different wearable devices used in healthcare to monitor and record patient's vitals are now been used in the delivery of drugs. In some cases, the use of wearables for monitoring and recording of patient's vitals have been incorporated with the capability to provide real-time accurate delivery of the drug. The use of wearable devices in controlling drug delivery systems has been seen according to this research, has been seen to be as beneficial as its use in healthcare monitoring. These benefits like an increase in quality of life and increase overall life expectancy are frequently emphasised by different pieces of literature (Chiauzzi *et al.*, 2015).

The challenges facing the manufacture use of wearable device-controlled drug delivery devices as seen in the different studies include size, stability, complexity, accuracy, therapeutic effect, data accuracy security, and privacy, market penetration, safety,

sustainable power, connectivity, cost and consistency of use (Goettsche, 2016). This research shows that apart from this, the regulation against the advertisement of prescribed medication in Ireland prevents direct contact between the manufacturing companies and the patients. This, therefore, requires that the attention companies on the awareness and education of physicians who can then provide access to the patients. Also, data integrity and safety and the access of patients to these technologies were uncovered as a major challenge for the use of wearable device-controlled drug delivery devices in Ireland. Although connectivity was mentioned as a challenge in the literature reviews it has been seen not to be important in all wearable device-controlled drug delivery devices such as contact lenses, stents, implantable.

Finally, although pieces of literature stated age as a barrier for the use of new technologies such wearables, in this research the willingness to use of wearable device-controlled drug delivery devices was not limited by age as the percentage of people who were interested in using the technology was above 80% across each age group 18-30, 31-40, 41-50 and 51-60.

5.3. CONTRIBUTIONS AND LIMITATIONS OF THE RESEARCH

The contribution and findings of this study focused on finding out the different types of wearable device-controlled drug delivery devices been used, especially in Ireland. While most research papers focus on the use, effectiveness, and benefit of the use of wearable devices in healthcare for vitals reading and monitoring, this research provided an analysis of its use in controlled drug delivery systems. It also provides an assessment on the acceptance and views of the use in Ireland. The process and challenges involved in the development and manufacture of this type of drug delivery system were determined through interviews. The study was also used to determine consumer behaviour and intention and general views of these devices through questionnaires involving 218 participants.

The author at the beginning of this research also wanted to measure the effectiveness of these novel drug delivery systems but acquiring this type of data required conducting/ accessing clinical studies. The author was limited by resources to continue in this line. The findings for this research also do not include people above 60 as only one participant was gotten for that age group and the number of participants interviewed was also limited The reason was that the author chose a convenient method for data collection (because of the COVID 19 pandemic) which involved the distribution of her questionnaire online limiting access to older people that are less tech-savvy. Also, the majority of the participants were young postgraduate degree holders therefore, to give a more generalized finding, the study can be imitated on a larger and more diverse sample.

5.4. RECOMMENDATIONS FOR PRACTICE

This research was able to reveal that quest for reduced trauma, comfort, and reduced stress are some of the drivers of the use of wearable device-controlled systems. It was also observed that these technologies enable the drug substance to be more effective, increasing the treatment outcome. When physicians and patients see a better result from these medications, it increases the popularity and use of the medication leading to an increase in the overall sales and profit of the drug product, boosting the market value of the manufacturer. According to data collected, the use of wearable devices depends heavily on the social perception of the devices and other things like the size, look, comfort, ease of use, cost, effectiveness, reduced side effect and safety of the device. This knowledge can be used by the pharmaceutical industry when developing these technologies promoting their acceptance. The fears and concerns of the patients should also be taken into consideration.

The use of wearable technology as a means of controlling drug delivery helps to reduce the quantity of the therapeutic substance to be consumed by the patients causing a reduction in the money been spent on the drug. It can also be easily used in drug combinations making it very useful for personalised medicine and micro-dosing which

are the new methods of improving treatment outcome specific to each patient. Also, by using this type of drug delivery system, the patients will only be required to make wear or attach the device which will automatically control the doses and will prevent them from forgetting to take their medication.

This research will help in increasing the awareness and knowledge of wearable device-controlled drug delivery systems as a lack of familiarity with these technologies is also responsible for the low usage of the devices. Efforts should be made to make the wearable device-controlled drug delivery systems more accessible to patients. The government should subsidize these devices to make them widely available and less expensive because it is cheaper in the long run if compared to the cost of in-hospital visits.

5.5. RECOMMENDATIONS FOR FUTURE RESEARCH

Further research needs to be done to determine the best and effective ways to educate people on the use of wearables for more than body vitals monitoring and fitness. The knowledge of these applications of wearable technology will further promote the already increasing market. Also, there can be a comparison study between / combination of the use of wearable devices for diagnostics and its use as a means of controlling drug delivery systems in Ireland and how these two applications can be used to further improve the treatment outcomes. The combination can enhance the use of wearable device-controlled drug delivery systems as the existing market of wearable devices in diagnostic can be used to drive the market for wearable device-controlled drug delivery systems.

Future research could consider more ways of distributing the questionnaire links and the involvement of older volunteers to participate in the filling questionnaire. The effectiveness of these devices should also be determined and backed with facts to ensure that the users trust the benefit of these devices.

5.6. FINAL CONCLUSION AND REFLECTIONS

During the course of this research, the author thoroughly went through exciting & insightful literature that was helpful in the understanding of the topic "An Analysis of the Use of Wearable Technology as a Means of Controlling Drug Delivery Systems and the Challenges Facing Its Use in Ireland". The review of different well-written literature provided an understanding of the different trends in drug delivery around the world. The different use of wearable devices and insight into the market for wearable devices were acquired. The author was found this process of this research very informative and was able to learn more about drug delivery, wearable devices, and numerous applications of the use of these technologies.

The theory and use of this type of drug delivery system have provided amazing benefits that will/are revolutionizing healthcare worldwide. The application of these technologies is endless, and it is expected to be the next era in pharmaceuticals especially with the advancement in technologies such as Artificial Intelligence and IoT. One of the reasons for this shift is the steady decline in the pharmaceutical pipeline in the last few years.

The use of wearable device-controlled drug delivery systems in Ireland is not where it should be considering that it houses many multinational companies producing these devices. The findings give hope that this will change very soon once the awareness of these products increased.

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APPENDICES

An Analysis of The Use of Wearable Technology as A Means of Controlling Drug Delivery Systems and The Challenges Facing Its Usage in Ireland.

Dear Respondent,

This questionnaire is to ascertain the level of use of wearable devices by the public and potential customers and to determine the readiness of consumers in using wearable devices for drug delivery in Ireland.

This research is in the fulfilment of a master's degree in Pharmaceutical Business and Technology at Griffith College Dublin.

The research is aimed at looking at the possible/existing use of wearable devices (such as the smartwatches) in controlling drug delivery devices (such as Micro reservoir And Micro/Nanofluidic Devices) that are used for controlled drug delivery in Ireland.

Participation in this research is completely voluntary, and your response will be treated with uttermost confidentiality in that your identity will not be connected through the data of this questionnaire. All data generated from this will be stored in line with the General Data Protection Regulation (GDPR).

The filling of this questionnaire will take about 7 mins. Your participation is very important. Thank you.

* Required

I have read and understood the above information, and I agree to participate in this research *

- ○ Yes
- ○ No

Next

An Analysis of The Use of Wearable Technology as A Means of Controlling Drug Delivery Systems and The Challenges Facing Its Usage in Ireland.

* Required

PART 1: General Data

1. Gender *

- Male
- Female

2. Age *

- 18 -30
- 31-40
- 41-50
- 51-60
- 61 and over

3. Level of Education *

- No Formal Education
- Secondary Education
- Undergraduate

- Secondary Education
- Undergraduate
- Postgraduate
- Other: _____

4. Yearly income (Euros)

- Less than 15,000
- 15,001 – 30,000
- 30,001– 45,000
- 45,001 – 60,000
- 60,001 and above

5. Field of Work *

- Healthcare
- Pharmaceuticals
- IT
- Construction
- Sports and Fitness
- Government Bodies
- Students
- Other: _____

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PART 2: Introduction to Wearable Devices

A wearable device is usually worn as an accessory/implant that has electronics and computers incorporated into it. These devices carry out functions like our smartphones and laptops and can be in the form of clothes, watches, headbands, jewelries, etc., or in invasive forms like microchips and smart tattoos which can be implanted in the body.

Examples Wearable Devices includes Activity Trackers, Smart Watches, Smart Clothing, Smart Patches, Smart Tattoos, Smart Implant and Google Glass.

6. Using my phone is an important part of my daily activities *

- ○ Yes
- ○ No

7. I love getting acquainted with new technology *

- ○ Yes
- ○ No

8. Have you ever used a wearable device? *

- ○ Yes, and I'm still using it now
- ○ Yes, but I abandoned it
- ○ No, but I'm interested
- ○ No, never wanted to use

9. What type of wearable device do you use/interested to use (tick the relevant boxes) *

- [ ] Activity Trackers
- [ ] Smart Watches
- [ ] Smart Clothing
- [ ] Smart Patches
- [ ] Smart Tattoos
- [ ] Implants
- [ ] Google Glass
- [ ] Other: _____

10. How long have you been using your wearable device?

- ( ) Less than 1 week
- ( ) 1-6 months
- ( ) 7-12 months
- ( ) 1-2 years
- ( ) Over 2 years
- ( ) Not applicable

11. How often do you use your wearable device?

- ( ) Never
- ( ) Rarely
- ( ) Sometimes

- ○ Sometimes
- ○ Often
- ○ Always
- ○ Not applicable

12. Which of these are true about Wearable devices? (tick the relevant boxes) *

- ☐ They are easy to use
- ☐ They are very easy to get
- ☐ They are useful in improving physical health
- ☐ They are very effective
- ☐ They are very reliable for data recording and data security
- ☐ I have no idea
- ☐ Other: _____

13. The following influences willingness to use wearable devices. (tick the relevant boxes) *

- ☐ Internet/ Social Media
- ☐ Product Advertisement
- ☐ Word of Mouth
- ☐ None of the above
- ☐ I have no idea
- ☐ Other: _____

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PART 3: Introduction to Drug Delivery Systems

Drug Delivery can be described as all the different methods used to get therapeutic substances into a living organism to enhance drug therapy thereby boosting the overall clinical response of the organism.

Drug delivery systems are very important in the treatment of diseases. It is responsible for ensuring that the body gets the therapeutic substance on time and in the right concentration. It enhances the patient and product safety by controlling drug exposure overtime.

14. What methods of taking medications are you familiar with? (tick the relevant boxes) *

- [ ] Injections
- [ ] Tablets/syrup/lozenges
- [ ] Cream/lotion
- [ ] Inhalers
- [ ] Liquid drops
- [ ] Patches
- [ ] Other: _____

15. Have you ever been required to take a medication for more than 2 weeks? *

- ( ) Yes
- ( ) No

16. What was the medication for?

Your answer

17. How often were you required to take your medication? *

- ○ Several times a day
- ○ Daily
- ○ Several times a week
- ○ Every week
- ○ Once in two weeks
- ○ Once in a month
- ○ Other: _____

18. How often do you forget to take your medicine? *

- ○ Never
- ○ Rarely
- ○ Sometimes
- ○ Often
- ○ Always

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PART 4: Use of Wearable Device Controlled Drug System

Wearable devices are being used in the pharmaceutical industry to control the drug delivery system. The patient is only required to take or attach the delivery system that has a certain amount of the drug substance and the wearable will control how it is released into the body.

It does so by detecting the shortage of drug substance in the body and sends a signal to the drug delivery system to release the medication in a controlled manner according to the needed dosage.

19. Are you aware of the use of wearable devices in controlling drug delivery systems? *

- ◯ Yes
- ◯ No

20. If yes, please indicate the type of drug delivery system you know.

Your answer

21. Would you consider trying this new technology? *

- ◯ Yes
- ◯ No

22. What will you consider important in your choice of the wearable device for controlling drug delivery? (tick the relevant boxes) *

- [ ] Size
- [ ] Look
- [ ] Comfort
- [ ] Ease of use
- [ ] Cost
- [ ] Effectiveness
- [ ] Reduced Side Effect
- [ ] I have no idea
- [ ] Other: _____

23. Would you prefer this new technology to the traditional method of drug intake? *

- ( ) Yes
- ( ) No

24. Do you think these new drug delivery systems will be effective? *

- ○ Yes
- ○ No
- ○ I do not know

25. Do you have fears concerning using these new delivery systems? *

- ○ Yes
- ○ No
- ○ Indifferent

26. If yes, what are your fears or concerns?

Your answer

Do you have a more detailed experience with using or manufacturing these new delivery systems and would be interested to be interviewed? Please drop your contact detail below. Thanks

Your answer

Back Submit

MY INTERVIEW QUESTIONS

Introduction

1. Please describe your educational and work background including your experiences.
2. Are you familiar with the use wearable devices in controlling drug delivery?

Design and Manufacture

3. What resources/ partnerships are needed in the creation of these technologies?
4. Do you know of any company in Ireland that designs or manufactures wearable devices-controlled drug delivery systems?
5. What processes are involved in the manufacturing of these technologies?
6. What are the risks involved in manufacturing these technologies?

Use and Challenges

7. So far, how successful is the use these technologies in Ireland?
8. What is your opinion of the technology?
9. Where do you think the introduction of these technology will have the greatest impact?
10. What are the most common barriers for adoption of new technology by consumers?
11. What are the most common success factors for to convince patients to adopt the use these new technologies?
12. How can these technologies be made accessible and popular in Ireland?