

The Impact of Working Irregular Hours on Quality and Human Resources in the Irish Pharmaceutical Industry

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

Innopharma Labs Faculty of Science

Griffith College

MAY 2023

[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: Charlotte Lucas

Dated: 13May2023

Acknowledgements

I would like to express a sincere thank you to my project supervisor Susanna Coghlan. Without her preparation and organisation from the outset, the project would not have come to fruition. I really appreciate her consistent support, feedback and guidance throughout the project. I would also like to express thanks to the lecturers and module coordinators at Griffith College and Innopharma for presenting interesting and relevant concepts related to the pharmaceutical industry, some of which have inspired the research behind this thesis. Things I have learned in this course have and will continue to prove invaluable to me in my future career progression within the pharmaceutical industry.

Dedications

As this is potentially the last large piece of academic writing that I will submit to cap of my formal education I would like to dedicate it to my parents: David and Lorna Lucas. They were my earliest educators and have not only supported me through formal education in the last 21 years but have also taught me important life lessons that you just can't learn in school. They raised me to be (what I would consider) a good person and I would not be where I am today without their constant support through life's little challenges and victories.

~For inspiring me to be inquisitive, daring me to dream and encouraging me to excel, thank from the bottom of my heart~

Table of Contents

Candidate Declaration.....	i
Acknowledgements.....	iii
Dedications	iii
Table of Contents.....	iv
List of Figures.....	vii
List of Abbreviations	viii
Abstract.....	x
Chapter One: Introduction	1
1.1 Research Topic.....	1
1.2 Ireland as a Pharmaceutical Hub.....	1
1.3 Objectives	2
1.4 Scope and Layout.....	2
1.5 Introduction to Quality in Manufacturing	3
1.5.1 Quality: RFT Manufacturing	3
1.5.2 Quality: Quality Assurance.....	3
1.6 Human Resources in Manufacturing.....	4
1.6.1 HR: Staff Turnover	4
1.6.2 HR: Staff Morale.....	4
Chapter Two: Literature Review.....	6
2.1 Introduction.....	6
2.1.1 Evolution of Research.....	6
2.2 Personal Level Impact of Irregular Working Hours	7
2.2.1 Disruption of Circadian Rhythm.....	7
2.2.2 Immune and Inflammatory Responses.....	8
2.2.3 Metabolic and Cardiovascular Disorders	8
2.2.4 Sleep Disorders & Link with Quality.....	9
2.2.5 Mood Disorders & Link with Human Resources.....	9
2.3 Pharmaceutical Manufacturing	10
2.3.1 Irish Landscape for Pharmaceutical Manufacturing	10
2.3.2 Why is Ireland a Hub for Pharmaceutical Manufacturing?.....	11
2.4 Current Quality Practices in Pharmaceutical Manufacturing.....	12
2.4.1 HPRA in Ireland	12
2.4.2 Quality Legislations Within the EudraLex	12

2.4.3 ISO & ICH Quality Guidelines.....	13
2.5 Quality: RFT Manufacturing	14
2.5.1 Most Fatal Quality/ RFT Errors	14
2.5.2 RFT in Manufacturing Industry	15
2.5.3 RFT with Shift Work in the Healthcare Industry.....	15
2.6 Quality: Quality Assurance.....	17
2.6.1 Quality Assurance in Manufacturing	17
2.6.2 Fatigue and Levels of Quality	17
2.7 HR: Staff Turnover Intention.....	18
2.7.1 Staff Turnover Intention & Manufacturing.....	18
2.7.2 Staff Turnover & Shift Work	19
2.8 Human Resources: Staff Morale	20
2.8.1 Staff Morale and Manufacturing.....	20
2.8.2 Staff Morale and Poor Work/Life Balance with Shift Work	21
2.9 Conclusion	21
Chapter Three: Methodology	23
3.1 Introduction.....	23
3.1.1 Logic of Enquiry	24
3.1.2 Research Settings and Participants	24
3.2 Methods and Procedures for Data Collection	25
3.2.1 Interviews.....	25
3.2.2 Surveys.....	26
3.2.3 Justifications	27
3.3 Methods and Procedures for Data Analysis.....	27
3.3.1 Interview Analysis	27
3.3.2 Survey Analysis	28
3.4 Access and Ethical Considerations	30
3.4.1 Access Considerations	30
3.4.2 Ethical Considerations	30
3.5 Method Limitations.....	31
3.5.1 Interviews.....	31
3.5.2 Surveys.....	31
Chapter Four: Analysis and Findings.....	33
4.1 Introduction.....	33
4.2 Quality Interviews.....	33
4.2.1 Background Findings	33

4.2.2 QA Interview Findings.....	35
4.2.3 RFT Interview Findings.....	37
4.3.4 Quality Issue Impact Findings	38
4.3 Human Resource Surveys	39
4.3.1 Staff Moral Survey Findings.....	39
4.3.2 Turnover Intention Survey Findings	44
Chapter Five: Conclusion	49
5.1 Conclusions Summarised.....	49
5.1.1 Objective 1	49
5.1.2 Objective 2	50
5.2 Study Limitations.....	51
5.3 Future Work and Recommendations.....	52
5.4 Dissertation Reflection.....	52
Bibliography	54
Appendices.....	61
Appendix A- Interview Questions	61
Appendix B- Survey Questions.....	64

List of Figures

Figure 1. Circadian Rhythm (Waters, 2021).....	7
Figure 2. Potential shift work induced pathways to disease (Rajaratnam et al., 2013).....	9
Figure 3. Pharmaceutical Manufacturers in Ireland (LSC, 2018).....	11
Figure 4. Running a Chi Square Test on Minitab®.....	28
Figure 5. Options Selected for Chi Square Test on Minitab®.....	29
Figure 6. A Bar Chart Showing Responses for Good Staff Morale Within an Organisation.....	40
Figure 7. Pie Charts Representing Responses Related to Impact Work on Personal Well-Being.....	41
Figure 8. A Bar Chart Showing Responses for Feeling Tired During the Workday.....	42
Figure 9. Bar Chart Showing Responses for Feeling too Tired to do Anything Else After Returning Home from Work.....	42
Figure 10. Staff Turnover Intention Over Time for Participants Working in the Pharmaceutical Industry.....	45
Figure 11. Bar Chart Showing Responses for Benefits Associated with Job Prevent Participants from Quitting.....	46
Figure 12. Pie Charts Representing Responses Related to the Primary Reason for Quitting.....	47

List of Abbreviations

ANOVA	Analysis of Variance
CAPA	Corrective Action & Preventative Action
CFT	Cross Functional Team
CIPD	Chartered Institute of Personnel and Development
CQA	Critical Quality Attributes
EMA	European Medicines Agency
E.U.	European Union
FDA	Federal Drugs Agency
GDP	Good Documentation Practise
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practise
GMP	Good Manufacturing Practise
HIQA	Health Information & Quality Authority
HPRA	Health Products Regulatory Agency
HR	Human Resources
ICF	Informed Consent Forms
ICH	International Council for Harmonisation
IDA	Industrial Development Agency
ISO	International Organisation for Standardisation
NDA	Non-Disclosure Agreement
NIBRT	National Institute for Bioprocessing Research & Training
NOR	Normal Operating Range
NSW	Non-Shift Worker

PAR	Proven Acceptable Range
PIL	Participant Information Leaflet
RFT	Right First Time
SFI	Science Foundation Ireland
SME	Subject Matter Expert
SOP	Standard Operating Procedure
SW	Shift Worker
SWD	Shift Work Disorder/ Sleep Wake Disorder
TIS	Turnover Intention Survey
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person

Abstract

INTRODUCTION. Ireland is a hub for pharmaceutical manufacturing activity. Due to business demands and/or nature of products being manufactured some pharmaceutical manufacturers have no other option but to manufacture 24/7. This research aimed to investigate the potential impacts of working irregular hours on human resources and quality in the Irish pharmaceutical industry. This research is important as it investigated factors influencing a pharmaceutical organisation's operational excellence and quality management systems.

OBJECTIVES. This research consisted of two primary objectives. The first was to determine if working irregular hours has any effect in the area of human resources (namely staff morale and staff turnover intention) by surveying both employees that work regular hours and those that work irregular hours in the pharmaceutical industry. The second was to determine if working irregular hours has any effect in the area of quality (namely quality assurance (QA) and right first time (RFT) manufacturing) by interviewing key subject matter experts working in the pharmaceutical industry.

METHODS. To address the objective focusing on human resources quantitative research was used in the form of surveys. 84 people were surveyed: 44 shift workers (SWs) and 40 non-shift workers (NSWs). Questions were focused on areas of staff morale and turnover intention. Raw data from survey respondents were analysed using Chi Square Tests of Independence to determine whether difference between group were independent of each other. The objective regarding quality within manufacturing was addressed through using qualitative research in the form of interviews. SMEs were interviewed with questions focusing on QA and RFT manufacturing. Thematic analysis was carried out on interviews which involved open coding followed by axial coding.

RESULTS. There was no significant difference between the groups for self-perceived levels of staff morale. There were however significant differences between groups when it came to other negative impacts associated with shift work. SWs were more likely to feel fatigued both during and after work, feel that their work negatively impacts their personal well-being,

frequently feel under pressure in their role and feel emotionally agitated upon arriving home from work. It is possible that these negative implications of shift work may gradually impact employee morale over time by wearing people down. There were no significant differences between the groups and turnover intention. SWs were significantly more likely to admit that benefits associated with their job (i.e., compressed work week and financial bonus allowance) prevented them from quitting. An overall pattern was highlighted among the two groups that the rate of turnover intention increased over time.

The majority of interviewees believed that irregular working hours had no impact on QA. Interviewees emphasised that quality errors can occur at any time of day and stated that there are many possible factors at play when looking at quality errors with human root causes rather than fatigue alone. These can include but aren't limited to; operator competency, complacency, mindfulness for task at hand and diligence to work. Similarly, the majority of interviewees believed that working shift work had no impact on the rate of RFT manufacturing. The general consensus of interviewees was that systems should be in place in order to catch mistakes before they occur and therefore set operators up for success.

CONCLUSION. Maintaining positive staff morale, low staff turnover, QA and RFT manufacturing are all important factors in ensuring operational excellence, productivity and products are produced to meet regulatory quality standards. This is why investigating potential factors which may impact these is important. Although some findings for this research thesis were insignificant, it helped highlight potential research areas for the future. These may include the impact of shift work on productivity or employee absenteeism all of which effect business functions. Looking closer at costs involved in investigating quality deviations would also be a worthwhile research topic.

Chapter One: Introduction

1.1 Research Topic

The research topic of this dissertation involved looking at the impact shift work has in the areas of quality (Quality Assurance (QA) and Right First Time (RFT) Manufacturing) and human resources (staff turnover intention and staff morale) within the Irish pharmaceutical industry. Irregular working patterns are necessary in certain lines of work in order to maintain business demands and functions. This research project aimed to investigate the potential impacts caused by irregular working hours in the business level areas mentioned above, quality and human resources. There is an abundance of literature about the business levels effects of unsociable hours in the healthcare, hospitality and aviation industries however there is currently very little published about the pharmaceutical industry, despite many manufacturing plants working continuously (24/7). Both areas of quality and human resources are important in operational excellence, productivity and products are produced to meet regulatory quality standards.

The terms ‘shift work’ and ‘irregular working hours’ can be used interchangeably to describe working hours which are outside the standard working hours of 7am to 6pm (Caruso and Rosa, 2007). According to the U.S. Bureau of Labor Statistics 13.6% of full-time employees are involved in shift work at some capacity (U.S, Bureau of Labor Statistics, 2019). Industries where shiftwork is common include: Aviation, healthcare, manufacturing, emergency services, telecommunications and hospitality (Folkard and Tucker, 2003). The impacts of shift work on a personal level are widely known. People that do shift work are considerably more likely to develop cardiovascular diseases, have gastrointestinal problems, hormonal imbalances and sleep-wake disorders (SWD) (Moore-Ede and Richardson, 1985, James et al., 2017, Buja et al., 2013). There is less information publicly available about the impact of shift work at a business level.

1.2 Ireland as a Pharmaceutical Hub

Ireland is seen as a global hub for businesses in the pharmaceutical manufacturing sector. Nine out of ten of the largest pharmaceutical companies in the world have established facilities within Ireland (O'Connor, 2021, Burke, 2021). Examples of pharmaceutical manufacturing companies which have facilities in Ireland include Pfizer, MSD, Johnson and Johnson, Bristol-

Myers Squibb, Biogen, Stryker and Regeneron Pharmaceuticals, to name but a few (LSC, 2018). The pharmaceutical industry in Ireland employs approximately 27297 people (Fitzgerald and Wilson, 2022b). Ireland is the third largest exporter of medicinal products in the E.U., exporting 42 billion worth of medicines to E.U. markets in 2022 (Healy, 2023). Being a world player in pharmaceutical manufacturing contributes positively to the Irish economy with pharmaceutical product account for over 50% of all exports within the country (IPHA, 2022).

1.3 Objectives

The following were set as the objectives of this research project:

1. To determine if working irregular hours has any effect in the area of quality (namely QA and RFT manufacturing) by interviewing key subject matter experts working in the pharmaceutical industry.
2. To determine if working irregular hours has any effect in the area of human resources (namely staff morale and staff turnover intention) by surveying both employees that work regular hours and those that work irregular hours in the pharmaceutical industry.

1.4 Scope and Layout

This chapter is designed to set the scene for the research project. Its intention is to provide a high-level overview of the topic's background, importance and how it addresses research gaps in the area. The overall aims and objectives are also discussed in this introductory section. Chapter two focuses in on an in-depth review of literature in the area. This chapter is separated into sections: QA, RFT manufacturing, staff turnover intention and staff morale. Acting as secondary research, relevant papers, reviews and studies will be discussed in detail. Links are formed between what has previously been carried out and research still to be done in the area. Chapter three then looks at the methodology followed through the dissertation process. This chapter describes the approach taken in the research design process including how the data was to be collected, analysed and presented. Justifications will be given based on chosen methodology used. Other areas covered under the methodology chapter include a description of target participants, conceptual framework used and potential ethical and/or access issues. Chapter four involves the presentation, discussion and analysis of results obtained from the

primary research. This penultimate chapter includes a statistical analysis of relevant data as well as graphical representatives of data collected. Chapter five concludes the dissertation. In this section conclusions will be summarised and practical recommendations will be made based on research findings. Study limitations will be discussed as well as suggestions made to help improve any future research in the area. This section ends with a small piece reflecting on the dissertation process.

1.5 Introduction to Quality in Manufacturing

1.5.1 Quality: RFT Manufacturing

RFT manufacturing is a concept that originates from six sigma which encourages procedures being carried out correctly the first time (Bruce et al., 2005). This reduces deviations and the need for re-work. Fatigue, as a result from working irregular hours has contributed to many serious quality disasters by incorrectly performing tasks for the first time. The most famous being the disasters associated with Chernobyl, the Space Shuttle Challenger and Three Mile Island (Keller et al., 2009, Sadeghniaat-Haghighi and Yazdi, 2015). The most common fatigue-driven mistakes today are medical errors and automobile crashes (Caruso, 2006). Although studies show a correlation between human error and fatigue, particularly in the healthcare industry, there is a gap in the research showing the link between shift work and RFT manufacturing in the pharmaceutical industry.

1.5.2 Quality: Quality Assurance

Quality assurance (QA) is a term used to describe the systematic efforts taken to ensure a product or service meets predefined quality standards as set out by law, standards and customer expectations (Elassy, 2015). QA is hugely important in the pharmaceutical industry as it ensures the drug being manufactured has no contaminants present and will elicit its intended effect while contemporaneously meeting quality and regulatory requirements. Linked with the topic above of RFT manufacturing, fatigue plays a role in QA. Poor quality assurance can impact a business negatively as it means a loss of customer trust, increased costs, reduced efficiency which in turn can slow business growth (Elassy, 2015). Although there is an evident link between fatigue related human error and decreased quality assurance as well as an increased level of fatigue in employees doing shift work, there is a gap in the research showing a direct relationship between QA levels and shift workers in the pharmaceutical sector.

1.6 Human Resources in Manufacturing

1.6.1 HR: Staff Turnover

As outlined by the Chartered Institute of Personnel and Development (CIPD) staff turnover is the number of employees that quit working for an organisation as a proportion of total workforce over a set timescale (i.e. yearly) (CIPD, 2021). Common causes for high staff turnover are poor compensation packages, poor management, lack of opportunities for career development, toxic work culture, poor work/life balance and boredom (Shimp, 2017). In recent years employee turnover has been at an all-time high and this period has since been labelled: ‘The Great Resignation’ (Sheather and Slattery, 2021, Serenko, 2022). Companies are increasing their efforts to explore the reasoning behind high turnover with the intention of increasing staff retention. High employee turnover is costly to an employer, with higher positions associated with higher turnover costs (Guilding et al., 2014).

Conflicting evidence has been published when assessing the impact of shift work on staff turnover. Some research suggests that there is no link between shift work and increased staff turnover (Shen and Dicker, 2008) and other papers suggest a positive correlation between problems associated with working irregular hours (i.e. shift work disorder (SWD) and poor work-life balance) and increased staff turnover intention (Blytt et al., 2022, Jagun, 2015). Given the variation in the published results and the lack of results representing the direct link between staff turnover and shift work in the pharmaceutical industry it is worthwhile delving into primary research to get a deeper understanding of the topic.

1.6.2 HR: Staff Morale

Staff morale is defined as the satisfaction of staff within an organisation. Good staff morale is important as it has been shown to be linked with reducing the aforementioned topic of staff turnover while increasing productivity, overall job satisfaction and employee engagement (Jackson and Cooper, 1997). Poor work/life balance has been repeatedly shown to correlate with low staff morale (Lockwood, 2003, Fleetwood, 2007, Dhas and Karthikeyan, 2015). With good staff morale being the glue that holds an organisation together, it's important to maintain it. There is a plethora of literature looking at the different shift patterns and their effect on

work/life balance and staff morale. This will be discussed in more detail in the literature review in chapter two. There is however a gap in research focusing on the topic of work/life balance and morale among shift workers specifically in the pharmaceutical sector.

Chapter Two: Literature Review

2.1 Introduction

As mentioned in chapter one the terms 'shift work' and 'irregular working hours' can be used interchangeably to describe working hours which are outside the standard working hours of 7am to 6pm (Caruso and Rosa, 2007). The concepts of quality (QA and RFT manufacturing) and HR (staff morale and staff turnover) have also been introduced in chapter one. This review chapter will act as secondary research for this research project. It will involve referring to and discussing published literature in the area of irregular working hours and its impact on both quality and HR. Background information will also be provided on the personal level impact of irregular working hours, presence of pharmaceutical manufacturers in Ireland as well as current regulations in the pharmaceutical manufacturing sphere with the aim of giving a more holistic view of the topic.

2.1.1 Evolution of Research

The earliest recorded evidence of shift work was in a cotton spinning mill in the late 18th century. This was driven by capitalism and involved making the most out of production in each 24 hour day during the industrial revolution (Cooper, 1983). Shortly after that shift work became common practice in large manufacturing companies with high customer demands. Research in the area of shift work started out looking at its potential impacts on a personal level and how employees working shift are impacted from a health perspective (Snell, 1895, Seeherunwong et al., 1837). Since then, a plethora of research studies, articles and reviews have been published investigating this impact and are discussed in more detail in the following section (2.2). It is an area in which research is constantly evolving and making novel discoveries. Research looking into the business level impacts of working shift work have been considerably less popular with lower volumes of published research in that area compared to their personal level impact counterparts. More recently in the 20th century, concepts such as lean manufacturing, operational excellence and kaizen have emerged which has reflected in an increase in popularity of relevant research in the area of business operations, maximizing efficiency, highlighting problematic areas which may need addressing to provide continuous improvement in a business. Shift work and its potential impact on a business level have been researched but not to the same degree as personal level impacts. Business level impacts that

have been researched in the past include fatigue related errors (Lockley et al., 2007, Keller et al., 2009), staff morale (Lockwood, 2003, Williams, 2008), turnover intention (Blytt et al., 2022, Jagun, 2015), absenteeism (Shen and Dicker, 2008), work quality (Yung et al., 2020, Kazemi et al., 2016) and productivity (Wang et al., 2021a, García Alcaraz et al., 2021). It's evident however that further research needs to be carried out in this area to bring clarity to the potential business level impacts that result from having employees that work irregular hours.

2.2 Personal Level Impact of Irregular Working Hours

2.2.1 Disruption of Circadian Rhythm

There is an abundance of literature published showing the negative impact that shift work has on the body at a personal level. This knowledge is widely known among shift workers and non-shift workers alike. Working irregular hours has been shown to impact cardiovascular, immune, metabolic and hormonal health as well as evoking a variety of mood and sleep disorders (Ferri et al., 2016, Matheson et al., 2014, Griffin, 2010). The primary contribution towards the increase in these problems experienced by shift workers over time is the desynchronization of their circadian rhythm. A circadian rhythm is an internal 24-hour clock which regulates bodily processes such as hormone production, the sleep-wake cycle, body temperature and digestion (Vitaterna et al., 2001, Waters, 2021). An example of activities that occur as part of a normal circadian rhythm can be seen in the figure below.

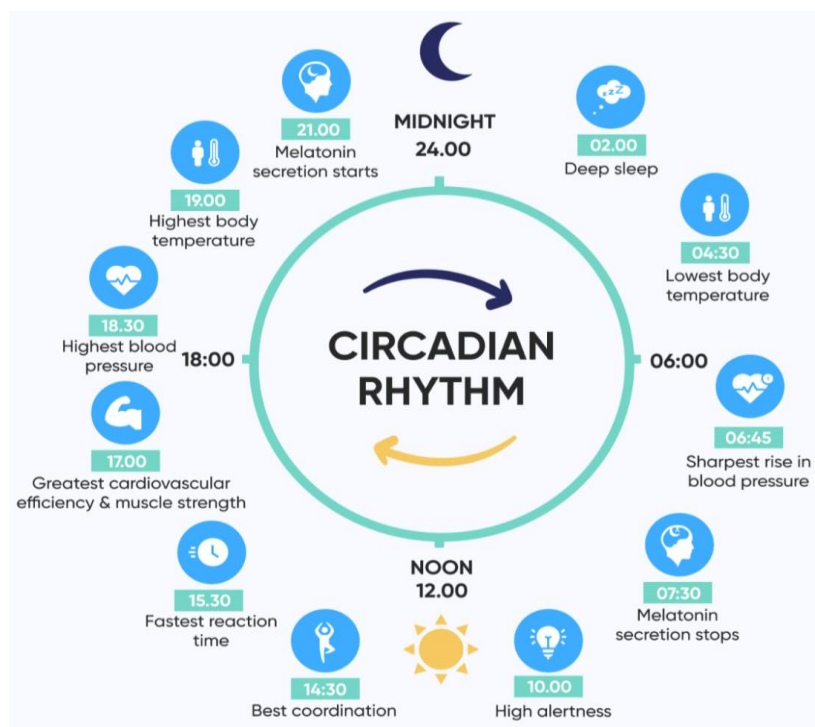


Figure 1. Circadian Rhythm (Waters, 2021).

The daylight during the day and darkness at night helps regulate this cycle. A person that works irregular hours would have a circadian rhythm which is disrupted from normal functioning due to being awake at times when the body expects to be asleep (Knutsson, 2003).

2.2.2 Immune and Inflammatory Responses

A recent systematic review by Fatima and colleagues (2022) looks at 49 studies investigating the impact of shift work on the immune system. The review identifies the mechanism involved in the deregulation of both immune and inflammatory responses. Immuno-related analytes were reduced in those that do shift work which disrupts normal immune responses (Fatima et al., 2022). A study by Harding and colleagues (2021) showed that shift workers in the car manufacturing industry had a decrease in immune markers and cytokines which are necessary for effective immune response (Harding et al., 2021).

2.2.3 Metabolic and Cardiovascular Disorders

This dysregulation of the circadian rhythm as a result of shift work is also known to contribute to metabolic disorders. Metabolic syndrome is an umbrella term used to describe the combination of obesity, diabetes and high blood pressure. Multiple studies have shown an increased incidence of metabolic syndrome among night-shift workers in healthcare (D'ettore et al., 2019, Pietroiusti et al., 2010) and transport (Dong et al., 2022) industries when compared to people working regular hours. Linking with metabolic disorders, it has also been discovered that there is an increased likelihood that shift workers will develop cardiovascular problems such as heart attacks, strokes and heart disease. A review by Bøggild and Knutsson (1999) summarized 17 studies and subsequently showed that on average shift workers were 40% more likely to develop cardiovascular problems (Bøggild and Knutsson, 1999). The review discusses the multifactorial aspects contributing to the increased risk. It highlights topics such as the circadian rhythm, biochemical changes, behaviors and socio-temporal patterns. More recent papers have similarly shown the causal relationship between irregular working patterns and increase cardiovascular problems (Kervezee et al., 2020, Torquati et al., 2018, Wang et al., 2021b). The implications of a dysregulated circadian rhythm and potential pathways linking to increased likelihood of different disease states can be seen in the summary figure below taken from a supplementary review by Rajaratnam and colleagues (2013).

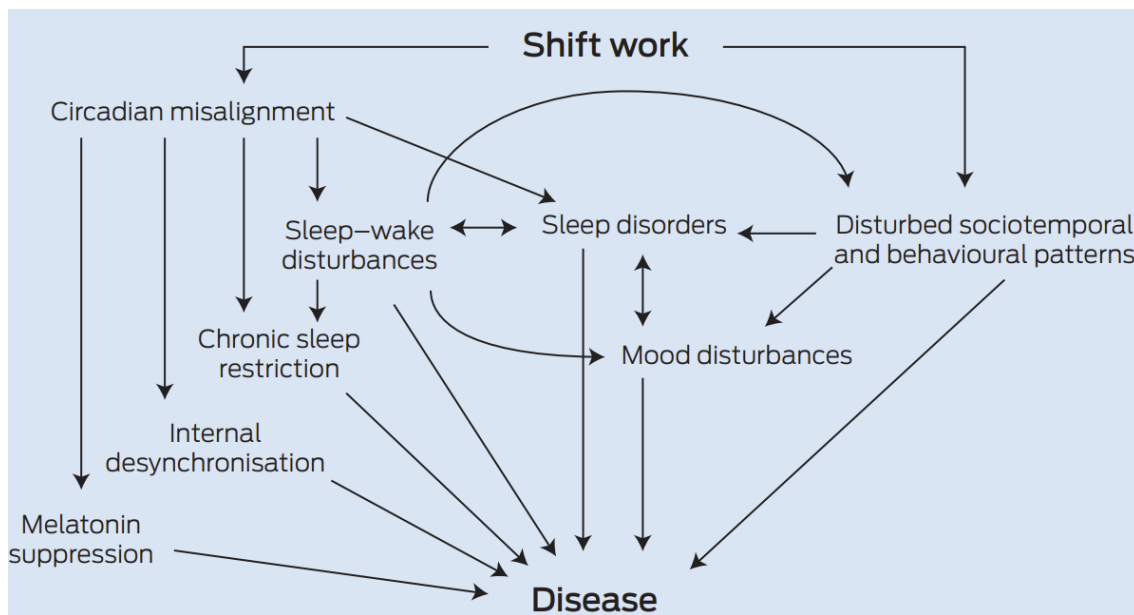


Figure 2. Potential shift work induced pathways to disease (Rajaratnam et al., 2013).

2.2.4 Sleep Disorders & Link with Quality

Sleep disorders such as insomnia and shift work disorder (SWD) are common among SWs. A study carried out by Drake and colleagues (2004) showed there to be prevalence of SWD in approximately 10% of the shift working population in a community (Drake et al., 2004). This increase in prevalence of SWD has been seen in both night shift (Blask, 2009) and rotating shift (Ohayon et al., 2002) workers alike. Sleep disturbances subsequently lead to employees feeling fatigued at work which increases the likelihood of work-related errors and accidents. Excessive employee tiredness has provenly led to lower productivity, decreased resilience to stress, lower cognitive function, increased work related injuries, higher levels of absenteeism and depleted energy levels (FatigueScience, 2020). Although sleep disorders, as a result of working irregular hours, have huge implications at a personal level they evidently cause implications to the business too. This will be discussed in more detail in the QA and RFT manufacturing sections of this review.

2.2.5 Mood Disorders & Link with Human Resources

The perceived general feeling of being unwell, decreased quality of life and poor work-life balance associated with working unsocial hours alongside hormonal disruption can contribute

to mood disorders (Angerer et al., 2017). A cross sectional study by Shehata and colleagues (2021) showed that shift workers in a healthcare setting had altered brain chemistry when compared to their counterparts working regular hours. People working shift work had significantly lower levels of serotonin, more commonly referred to as the ‘happiness hormone’ versus day workers (Shehata et al., 2021, Sookoian et al., 2007). Similarly, other studies and reviews showed that people working irregular hours were more likely to have higher levels of depression (Angerer et al., 2017, Lee et al., 2017) and anxiety (Juliana et al., 2022, Almondes and Araújo, 2009). In addition to that, a study by Booker and colleagues (2020) showed that those working shift work were more likely to use a greater amount of sick leave due to mood disorders (Booker et al., 2020). These mood disorders can have a wider impact on human resources by decreasing an individual’s and/or team’s morale and subsequently lead to an increase in staff turnover within an organisation. Staff morale and turnover intention from shift work will be discussed in more detail below as potential business level impacts of working irregular hours.

In conclusion, the implications of shift work on a personal level are well researched, documented and summarised in published research papers and reviews. There is considerably less information available in the area of potential business level impacts, notably in the areas of human resources and quality. This is the main focus of this literature review and subsequent primary research.

2.3 Pharmaceutical Manufacturing

2.3.1 Irish Landscape for Pharmaceutical Manufacturing

A pharmaceutical is a substance that can promote well-being by preventing, curing, or treating a disease. Pharmaceutical manufacturing can be split into two main categories, both of which are manufactured in Ireland: Chemical (i.e. solid oral dose, powders, topical creams) and Biological (i.e. biologics/ monoclonal antibody injectables) (Crommelin et al., 2005). Examples of pharmaceutical manufacturing companies which have facilities in Ireland include Pfizer, MSD, Johnson and Johnson, Bristol-Myers Squibb, Biogen, Stryker and Regeneron Pharmaceuticals, to name but a few (LSC, 2018). Pharmaceutical manufacturing companies and their locations within Ireland can be seen in the figure below.



Figure 3. Pharmaceutical Manufacturers in Ireland (LSC, 2018).

2.3.2 Why is Ireland a Hub for Pharmaceutical Manufacturing?

These multinationals are attracted to Ireland for many reasons. Firstly, Ireland has a corporation tax of 12.5%. This tax rate is lower than the E.U. average of 20.3% (OECD.Stat, 2022). In the E.U., Ireland has the third smallest rate of statutory corporation tax in Europe with only Bulgaria and Hungary having lower rates. This incentivises companies to come and set up manufacturing facilities in Ireland as it means less tax is to be paid on profits (Stewart, 2011). This equates to huge savings when talking about multi-billion-dollar corporations and is undoubtedly important in the attraction and retention of foreign direct investment. Secondly, Ireland has a large workforce of young and highly educated people (Burke, 2021). This English-speaking, rich talent pool offers highly trained people with both technical and managerial experience. Some pharmaceutical manufacturers have been involved with university courses offering internships and joint research projects. Ireland also has a track record when it comes to research and development with funding being funneled towards the work of Science Foundation Ireland (SFI), Industrial Development Agency (IDA) and the National Institute for Bioprocess Research and Training (NIBRT) (Van Egeraat, 2010, Niamh Miller, 2019). As an E.U. state, Ireland's accessibility to E.U. markets is also an attractive element for multinationals, especially companies that may be based in outside Europe (i.e., America or Canada) and wouldn't have the same access. These points collectively make Ireland

an attractive option for foreign direct investment particularly in the pharmaceutical manufacturing industry.

2.4 Current Quality Practices in Pharmaceutical Manufacturing

Quality is very important in the pharmaceutical manufacturing industry as it ensures that the pharmaceutical being manufactured meets pre-defined standards and elicits desired therapeutic effects to patients taking them (Dubey et al., 2011). Quality management in the pharmaceutical industry is the practice of overseeing all tasks and activities associated with maintaining quality levels. It encompasses areas including good manufacturing practice (GMP) compliance, quality control testing, quality assurance, risk management, auditing, standard operating procedure (SOP) development, staff training and quality system design (Dubey et al., 2011).

2.4.1 HPRA in Ireland

The Health Products Regulatory Authority (HPRA) is the Irish regulatory authority governing regulation in the manufacturing of pharmaceuticals and medical devices. The HPRA regularly carries out audits in the pharmaceutical manufacturing industry to ensure regulatory compliance as well as appropriate quality management (HPRA, 2022). As Ireland is an E.U. state, European laws in the remit of pharmaceutical manufacturing must be followed by Irish companies. European laws pertaining to pharmaceutical manufacturing are outlined in the EudraLex.

2.4.2 Quality Legislations Within the EudraLex

The EudraLex is a body of E.U. legislation which is easily accessible online. It has 10 volumes, each volume dealing with a separate topic (Eudralex, 2022a). The most relevant volume related to quality within pharmaceutical manufacturing is volume four: “Guidelines for good manufacturing practices for medicinal products for human and veterinary use” (Eudralex, 2022b). Directive 2003/94/EC lays down good manufacturing practice (GMP) principles specifically for medicinal products. The first chapter in volume four states the basic regulatory requirements of having a pharmaceutical quality system in place (Eudralex, 2012). It states that the marketing authorization holder must manufacture products that are adequately safe and do not put patients at risk, are compliant with marketing authorization requirements and are fit for

their intended use. Chapter one states that senior management is responsible for manufacturing products to meet the regulatory quality objectives above. This requires a well-designed, robust and correctly implemented pharmaceutical quality system in place. Aspects outlined in this regulatory document include quality risk management, quality control, product quality review and good manufacturing practice. Chapter six then outlays the basic regulatory requirement of having sufficient quality control in place (Eudralex, 2014). Chapter six focuses in on legal requirements in all-encompassing areas to assure quality is upheld from good laboratory practice (GLP), production, review and storage of documentation, sampling methods, testing methods, long-term ongoing stability programs to technical transfers of methods across manufacturing plants (Eudralex, 2014).

2.4.3 ISO & ICH Quality Guidelines

There are International Organisation for Standardisation (ISO) standards and International Council for Harmonisation (ICH) guidelines also available to provide guidance to pharmaceutical manufacturers in the area of quality management and are referenced in volume 4 under the part three heading: ‘GMP related documents’. ICH guidelines are produced by the European Medicines Agency (EMA). ICH Q10 offers additional guidance on the topic mentioned above of pharmaceutical quality systems (EMA, 2015b). ICH Q10 discusses management’s responsibility in the planning of quality policies, their communications and resource management to ensure quality is maintained as well as the importance of continuous improvements in manufacturing processes. ICH 9 offers guidance in the area of quality risk management (EMA, 2015a). It provides guidelines for the risk management process and helps with the integration of said methodology to meet regulatory requirements in the industry. Another document that’s important to note in the area of quality management in the pharmaceutical industry is the ISO 9001 (ISO, 2015). The ISO 9001 defines criteria for a successful quality management system and has a focus on end-users (i.e., patients in the case of pharmaceuticals). The ISO 9001 promotes leadership, engagement of stakeholders and continuous improvement in the quality sector. It is evident that quality plays a huge role in the manufacturing of pharmaceuticals and this research focuses in on QA and RFT manufacturing in the Irish pharmaceutical industry and will be discussed in more detail below.

2.5 Quality: RFT Manufacturing

As mentioned in chapter one, RFT manufacturing can be defined as a concept which encourages manufacturing processes to be carried out correctly the first time (Bruce et al., 2005). The benefits associated with this quality concept involves reducing the need for deviations and re-work which reduces wastage of both time and resources. This, in turn, increases quality and reputation of a company. Although RFT is a quality term referred to mostly in relation to the manufacturing industry the quality concept itself is often applied to everyday life and service providing industries. That point being made, the literature in this section comes from a mixture of manufacturing and healthcare service environments.

2.5.1 Most Fatal Quality/ RFT Errors

Fatigue, as a result of working irregular hours has contributed to many serious quality disasters in industry by incorrectly performing tasks for the first time. The most famous being the disasters associated with Chernobyl, the Space Shuttle Challenger and Three Mile Island (Keller et al., 2009, Sadeghniat-Haghighi and Yazdi, 2015).

Upon carrying out a root cause analysis, the cause outlined for the Chernobyl disaster was a mixture of improbable chain-events involving reactor design flaws and human error. The human error aspect involved two employees that didn't follow limits outlined in operating procedures and therefore not being RFT (Stang, 1996). This disaster ultimately led to nearby livestock being deformed, people suffering with long-term negative effects as a result of radiation sickness and contamination of forests and farmland (Yablokov et al., 2010). The Space Shuttle Challenger disaster was physically caused by a misplaced 'O' ring. Engineers pointed this out and showed that the ring wasn't doing its job correctly and was out of specifications. The human error in this case was the decision made by NASA program managers to fly despite the issue being flagged (Altabbakh et al., 2013). The consequence of this RFT error was that the challenger exploded 73 seconds into the spacecrafts flight and all seven crew member on board were killed (Kramer, 1992). Similar to the Chernobyl disaster, the Three Mile Island accident was a consequence of a chain-events involving equipment failure and operator error. The operator error being miscommunication and not noticing that the pilot-operated relief valve had stayed open (Le Bot, 2004). Although the consequence of this RFT accident didn't lead to long-term radiation-induced health defects for people in the

surrounding areas, the clean-up took approximately 14 years and cost over one billion (Talbot et al., 2003).

In today's world automobile crashes and medical-related errors are the most common fatigue-driven mistakes (Caruso, 2006). According to a report published in the Irish Times (2022) 130 people died in 119 fatal collisions in 2021 on Irish roads as a result of crashes (Wilson, 2022). The Health Information and Quality Authority (HIQA) estimated that one medication error occurs per hospital patient per day in Ireland. This estimation means there are approximately three million medication errors annually in Irish hospitals (HIQA, 2018).

2.5.2 RFT in Manufacturing Industry

A study by García Alcaraz and colleagues (2021) on Mexican automotive and medical manufacturing plants looked at RFT manufacturing as a quality lean manufacturing tool for commercial benefits. It was discovered that there was a positive correlation between RFT manufacturing and commercial benefits. By decreasing defects, adhering to standards and providing sufficient employee training there was a decrease in material and energy wastage as well as an increase in sales (García Alcaraz et al., 2021). Another study by Wang and colleagues (2021) looked at RFT in pharmaceutical manufacturing. They showed a correlation between RFT rate and decreased level of deviations and CAPAs (corrective and preventative actions). Decreased levels of deviations were shown to impact and decrease levels of customer complaints and amount of foreign inspections (Wang et al., 2021a). An article published by Scott and Migliaccio (2009) discusses culture in Pfizer with lean manufacturing and continuous improvements. Pfizer sites around the world have since started implementing the RFT manufacturing concept. Benefits seen already in Pfizer include reduced inventory, enhanced efficiency and cycle times (Scott and Migliaccio, 2009).

2.5.3 RFT with Shift Work in the Healthcare Industry

A study by Lockley and colleagues (2007) showed that physicians working shifts greater than or equal to 24 hours were 36% more likely to commit a serious medical error (Lockley et al., 2007). The methodology used in this study consisted of healthcare workers filling out monthly diary-like reports containing approximately 60 questions including working hours, sleep,

occupational injuries and self-reported medical errors over a 9-month period. Bolstering these findings, a review by Keller and colleagues (2009) discussed doctors who recurrently work 24 hour shifts and said that they were more likely to make diagnostic errors, medication errors, fatigue-induced errors leading to patient death as well as having attentional failures and decreased levels of productivity (Keller et al., 2009). A more recent systematic review carried out by De Cordova and colleagues (2016) highlighted nine studies with robust methodology showing a positive relationship between night shift workers and increased error rate (De Cordova et al., 2016). The methodology here involved using specific and relevant search terms in electronic databases and then abstracting data from chosen studies and assessing the quality by looking at the research's design and reliability of both quantitative and qualitative based studies. This systematic review showed that both quantitative and qualitative research has been successfully carried out in this area. A study by Cappadona and colleagues (2020) showed that younger midwives working shiftwork with lower levels of experience and intermediate chronotype (i.e. body clocks which tend to follow the sun) were more likely to make RFT errors with medications (Cappadona et al., 2020). The methodology used in this study involved midwives taking an online questionnaire to determine their working schedule, demographic, chronotype and self-perception of their risk of medication error. A paper by Ker and colleagues (2010) looked at shift workers with a disrupted circadian rhythm and deteriorated performance due to sleepiness. This paper focused mainly on the role of external stimulants in the promotion of alertness and reduced RFT errors. Caffeine was shown to reduce the number of errors as well as improve cognitive performance in people working irregular hours. Other interventions such as brief naps, bright lights and Modafil (a stimulant designed to decrease sleepiness for sleep disorders such as narcolepsy) had no significant impact in reducing errors among the shift working population studied (Ker et al., 2010).

There are evidently both significant personal and economic consequences due to human error as a result of fatigue-induced performance deficits. Although studies show a correlation between human error and fatigue, particularly in the healthcare industry there is a gap in the research showing the link between shift work and RFT manufacturing specifically in the pharmaceutical industry.

2.6 Quality: Quality Assurance

Linked with the topic above of RFT manufacturing, fatigue plays a role in QA. QA ensures that a product or service meets predefined quality standards as outlined by law, standards and customer expectations (Elassy, 2015).

2.6.1 Quality Assurance in Manufacturing

QA is a regulatory requirement in the pharmaceutical manufacturing industry and legislations governing QA have been discussed in more detail above in section 2.4. While the QA department's job is to ensure that process parameters are within specification and are compliant with procedures and regulations, it is also their job to record and investigate any process parameters which deviate from the norm (deviations). When a deviation occurs it is also QA personnel's responsibility to carry out root cause analysis and implement corrective and preventative actions (CAPAs) to prevent said deviation from reoccurring (WHO, 2007). A compendium of published guidelines by the World Health Organisation (WHO) highlights roles and responsibilities of QA (Ajit et al., 2021). A study by Boltic and colleagues (2010) looked into deviation management and the implementation of CAPAs and discovered that implementing corrective actions decreased number of deviations by greater than 50% in any given deviation category (Boltic et al., 2010). It is evident that the work carried out by QA is essential and highly regulated in the pharmaceutical manufacturing industry as it is required for obtaining and maintaining marketing authorization to manufacture and market pharmaceuticals.

2.6.2 Fatigue and Levels of Quality

A study published by Åhsberg and colleagues (2000) looked at the fatigue levels of shift workers after working day, evening and night shifts. Levels of fatigue were significantly higher after a night shift (Åhsberg et al., 2000). Fatigue was qualitatively assessed here and involved a questionnaire which measured perceived fatigue and accumulated time with sleepiness. A review by Yung and colleagues (2020) accumulated and reviewed 26 relevant studies examining the relationship between quality and fatigue in employees. They discovered that employee fatigue accounted for 42% of quality defect variance in a manufacturing environment (Yung et al., 2020). Similarly, a more recent systematic review by Yung and colleagues (2022) highlighted the link between the two in first aid responders (Yung et al., 2022). Kazemi and

colleagues (2016) carried out a study on petrochemical operators working shift work. They discovered that shift workers working long shifts (i.e., 12 hours) had a decline in cognitive performance and were fatigued towards the end of the shift. They also showed that those working night shifts had significantly lower levels of quality sleep and higher levels of perceived sleepiness, reducing quality performance further (Kazemi et al., 2016). The methodology used in this paper involved measuring cognitive performance and sleepiness. Cognitive performance was measured objectively using a reaction time test, n-back test and continuous performance test. Sleepiness was measured subjectively using the Karolinska Sleepiness Scale in which study participants answered questions on how they felt. A book by Carling and colleagues (2016) details research insights in the area of shift work offers a myriad of well-referenced information. The book states the most common cognitive deficits in shift workers include; decreased vigilance, processing speed, logical reasoning, creativity, psychomotor functioning, social functioning and increased errors which combined together impacts work quality (Barling et al., 2016). Although there is an evident link between fatigue related human error and decreased quality assurance and there is also an increased level of fatigue in employees doing shift work, there is little research showing a direct relationship between QA levels and shift workers in the pharmaceutical sector. Therefore, gaining perspectives from those working in the pharmaceutical industry sheds light in the area.

2.7 HR: Staff Turnover Intention

As mentioned in chapter one staff turnover is the number of employees that quit working for an organisation as a proportion of total workforce over a set timescale (i.e. yearly) (CIPD, 2021).

2.7.1 Staff Turnover Intention & Manufacturing

The manufacturing industry is known for having a high turnover. This can be mainly attributed to lack of job security, lack of career growth, repetitive nature of manufacturing and mismanaged candidate expectations of day-to-day activities (Harver.com, 2021). Staff turnover intention is defined as the willingness of an employee to leave an organisation at any given time (Lazzari et al., 2022). The measurement of turnover intention is important as a review by Hom and colleagues (2017) showed it was the best predictor of actual staff turnover (Hom et al., 2017). Staff turnover intention has been measured across multiple industries in published

literature (Lazzari et al., 2022). Approaches for measuring turnover intention can range from a simplistic 1-question (Spector et al., 1988) , 2-question (Metcalf et al., 2015) or 3-question (Lawler et al., 1979) scale or can be longer surveys with 15 questions and ranges for responses (Roodt, 2004). A simplistic scale would involve asking one to three questions to ascertain an employee's turnover intention. They would be direct in nature and easy for employees to take part in. A larger survey would involve Likert scales and would be more time-consuming, more in-depth and would capture more information including the motivations behind people leaving and staying. A midsize scale called TIS-6 as devised by Bothma and Roodt. The TIS-6 has been proven on multiple occasions to be a valid scale at predicting staff turnover (Bothma and Roodt, 2013, Su, 2021). Measuring staff turnover intention is evidently important and is shown to be an accurate estimation of actual turnover.

2.7.2 Staff Turnover & Shift Work

Conflicting evidence has been published when assessing the impact of shift work on staff turnover. Research conducted by Shen and Dicker (2008) suggested that there is no link between shift work and increased staff turnover. They did however discover that employees carrying out shift work tended to retire earlier compared to counterparts working regular hour jobs. They also identified a correlation between higher levels of absenteeism and shift work (Shen and Dicker, 2008). A recent study by Blytt and colleagues (2022) looked at nurses carrying out shift work and looked at their turnover intention. This study concluded that there was a trend towards increased turnover intention with nurses that suffered from shift work disorder (SWD) (Blytt et al., 2022). In this study by Blytt and colleagues (2022), turnover intention was measured in a group of Norwegian nurses using 3 question turnover intention scale (TIS-3). A 3-question questionnaire was also used to determine whether participants had SWD. This research was very quantitatively driven. A study by Jagun (2015) showed that in the hospitality industry in Ireland high levels of staff turnover were due to poor work-life balance associated with unsocial working hours (Jagun, 2015). The methodology used here for data collection comprised of a quantitative survey. This survey contained 10 questions and covered turnover intention and retention factors such as the job itself, the company, the compensation package and management. Multiple studies have been published investigating staff turnover in the pharmaceutical industry internationally but focused on employee reward programs, staff retention strategies (i.e. exit interviews) and poor work environments rather than unsocial working hours (Guyo et al., 2011, Kumari and Pandey, 2021). In a 24/7

manufacturing plants unsocial working hours cannot be changed, which might explain why research tends to investigate and alter things that can be changed i.e., retention strategies and employee total rewards. Given the variation in the published results mentioned above (i.e. some papers showing a correlation and some showing no correlation) and the lack of results representing the link between staff turnover and shift work in the pharmaceutical industry it is worthwhile taking a deeper look into the topic.

2.8 Human Resources: Staff Morale

As previously mentioned in chapter one, staff morale is defined as the satisfaction of staff working within an organisation. Maintaining good staff morale is crucial for businesses to maintain high levels of productivity and positive levels of employee engagement (Jackson and Cooper, 1997, Neely, 1999). Good staff morale has also been shown to reduce levels of staff turnover, which has been discussed in more detail in the section above.

2.8.1 Staff Morale and Manufacturing

Manufacturing is a fast-paced industry. The physically demanding and repetitive nature of the work can often take its toll on staff and their morale (Gesrepair.com, 2022). For companies manufacturing at a 24/7 capacity, some employees are required to work irregular hours. Some working irregular hours report to have a poor work/life balance due to being asleep during the day or having to work weekends which in turn impacts staff morale negatively (Williams, 2008). Staff morale can be measured in a variety of different ways including check-in meetings, anonymous surveys, observing employee behavior and studying turnover rates and exit interviews (Bowles and Cooper, 2009). An article published by Power (2016) in Harvard Business Review showed that John Deere carry out pulse surveys to monitor staff moral biweekly (Power, 2016). They believe these regular check-ins to be the reason behind maintaining their productivity and competitiveness. Ways which have been proven to boost morale in a manufacturing setting include; showing appreciation by providing positive feedback, providing a variety of jobs where possible, providing opportunities for continuing education, being flexible with vacation schedules, ensuring sufficient breaks are provided as well as offering incentives which are meaningful (Gesrepair.com, 2022).

2.8.2 Staff Morale and Poor Work/Life Balance with Shift Work

Poor work/life balance has been repeatedly shown to correlate with low staff morale (Lockwood, 2003, Fleetwood, 2007, Dhas and Karthikeyan, 2015). An article written by Williams (2008) showed that work/life balance varied among shift workers and was dependent on the type of shift pattern worked. People working standard daytime hours perceived a significantly higher quality in their work/life balance. Those employees who worked shift work with a regular schedule (i.e., always evenings shifts/ night shifts) had the next highest rating of their work life balance. The group of shift workers that were least satisfied with their work/life balance were employees that had the least amount of control over their schedules: this included people working irregular shifts, split shifts or 'on call' (Williams, 2008). Specific data was collected and analysed for this article through the General Social Survey (GSS) which is a Canadian based interview which covers a wide range of issues with Canadians over the age of 15 in each Canadian province. The time data was collected in a 24-hour diary format. Multiple intervention studies have shown that allowing employees that work irregular shifts to self-scheduled working hours significantly increased work/life balance and morale (Bambra et al., 2008b, Albertsen et al., 2014). The methodology used in the studies involved interviews with both employees and managers at baseline and then a follow-up after the intervention (a self-rostering IT system was used). Many factors were investigated including work-life conflicts, time with children, marital conflicts and work-life facilitation. A systematic review carried out by Bambra and colleagues (2008a) concluded that working longer shifts (i.e. >8 hours) as part of a compressed working week correlated with an improved work/life balance (Bambra et al., 2008a). There was a gap in research focusing on the topic of work/life balance and staff morale among shift workers in the pharmaceutical sector.

2.9 Conclusion

Upon carrying out this literature review there is evidently a requirement for more research in the area of human resources (more specifically staff morale and turnover intention) as well as the area of quality (more specifically quality assurance and right-first-time manufacturing) in the Irish pharmaceutical industry. Both human resources and quality play important roles in the operational excellence of an organization. Although there is research in the aforementioned areas of human resources and quality, this research tends to be focused on the healthcare and hospitality sector. The little research that is published in this area for manufacturing is in the medical device and automobile industries which are different to pharmaceuticals in their own

respect. There therefore is a research ‘niche’ looking at the potential business level impacts of shift work on both human resources and quality in the pharmaceutical industry and more specifically the Irish pharmaceutical industry. It is hoped that this research sheds light on the topic.

Chapter Three: Methodology

3.1 Introduction

This chapter describes the methodology used to carry out this primary research. The following conceptual framework was used as part of this dissertation research project and will be discussed in more detail within this chapter.

- Introduced the topic by giving background information about relevant areas (i.e., shift work, quality and human resources)
- Carried out secondary research and presenting findings in the form of an in-depth literature review
- Designed appropriate interview questions and surveys for research participants
- Submitted all ethics related forms prior to carrying out primary research
- Conducted 8 interviews with experienced professionals working in manufacturing (4) and quality assurance (4) in the pharmaceutical industry
- Conducted 84 surveys with employees working irregular hours (44) and regular hours (40) in the pharmaceutical industry
- Generated, analysed and documented data and findings in a clear, accessible and ethical manner
- Drew a conclusion from findings achieved and making recommendations for future research

Due to the mix of quantitative and qualitative research there are a mixture of research paradigms (mixed-mode research). The research paradigm that will be used for the surveys producing quantitative data is positivism. Its aim is to discover rules that govern human behaviour and believes certain behaviour is based on social norms. The research paradigm that will be used for the interviews producing qualitative data is interpretivism. Interpretivism identifies the importance of understanding actions, motives, and beliefs of others to help understand human behaviour.

3.1.1 Logic of Enquiry

A mixture of both quantitative and qualitative data was collected and analysed. Research that was qualitative in nature was used to gain perspectives about how professionals working in the pharmaceutical industry think and feel about the potential impacts of shift work on the quality of pharmaceutical manufacturing. Qualitative data in the form of interviews were used to obtain the following research objective:

‘‘Determine if working irregular hours has any effect in the area of quality (namely QA and RFT manufacturing) by interviewing key subject matter experts working in the pharmaceutical industry.’’

Qualitative data was used here to gain opinions from relevant SMEs when it comes to quality in the pharmaceutical manufacturing industry.

Research that was quantitative in nature was used to obtain numerical data and subsequent statistics on the potential impact of shift work in the areas of staff morale and turnover intention from an employee perspective. Quantitative data in the form of surveys were used to obtain the following research objective:

‘‘Determine if working irregular hours has any effect in the area of human resources (namely staff morale and staff turnover intention) by surveying both employees that work regular hours and those that work irregular hours in the pharmaceutical industry.’’

Quantitative data was used here to get an insight into the morale and turnover of participants working in the pharmaceutical industry. Quantitative data made comparing differences between groups more clearcut. Different methodologies were used here to capture information in different ways and although the areas of human resources and quality seem sectioned from each other they both have a hand in operational excellence and an organisations quality system as a whole.

3.1.2 Research Settings and Participants

As mentioned above two methods were used to achieve the objectives of the research: interviews (qualitative) and surveys (quantitative). The interviews were completed with people

working in the pharmaceutical manufacturing industry. The interview was designed to be more specific when looking for participants. Participants required in this section were those with at least three years' experience in a pharmaceutical manufacturing plant working in either the manufacturing or QA department. All participants were based in Ireland. Participants were not excluded based on gender or age. Interviews were confidential with participants being referred to solely by their position and relevant years' experience in the pharmaceutical landscape, all identifying information about them were removed. 8 people were interviewed in total, 4 people worked in manufacturing and 4 worked in QA. Interviewees level of professional working experience ranged from 3 years to 28 years. All interviews were carried out face-to-face.

The surveys were also looking for people working in the manufacturing pharmaceutical industry. Professionals were required to work in the pharmaceutical industry to meet the focus areas needs of this research. As the body of research is focused on this industry, this was the sole inclusion criteria. A dichotomous question in the introductory section ensured this was the case. Furthermore, the participants were then split into two groups: Shift workers (SWs) and non-shift workers (NSWs). Having similar amounts of professionals working regular and irregular hours ensured that each side was represented equally. This was ascertained by another dichotomous question in the introductory session. All participants were based in Ireland. Participants were not excluded based on gender, age or industry experience. Surveys were also anonymous, to protect the privacy of those taking them. The anonymity of the surveys helped foster a sense of trust encouraging honest answers from survey participants. 84 people were surveyed in total; 44 were SWs and 40 were NSWs in the pharmaceutical industry.

3.2 Methods and Procedures for Data Collection

3.2.1 Interviews

Interview questions were designed to determine the potential impact of shift work on quality namely QA and RFT manufacturing. The interview consisted of 15 questions and each participant was asked the same questions. Questions involved looking at a general overview of QA responsibilities, quality errors, human level root causes, 24/7 shift work, RFT manufacturing and impact of quality errors on a business. The template used for interview questions can be seen below in appendix A. Potential candidates were approached and were

given background information about the research project. If interest was displayed, the participant information leaflet (PIL), informed consent form (ICF) and interview questions were sent to them via email. If potential participants were still interested, then a meeting would be set up and a room would be booked for the interview to take place. At the start of the interview the participant and researcher signed the ICF. It was ensured that the participant had sufficient knowledge of what the interview and project entailed and they agreed to both being recorded and how data was going to be stored. Once signed, interview questions were asked and the interview was recorded. A transcript was written up retrospectively and each participant received a copy of their transcript via email. All transcripts were merged into one document for data analysis.

3.2.2 Surveys

Survey questions were designed to investigate the potential impact working irregular hours has on human resources namely staff morale and turnover intention. Different survey sites were explored as potential mediums to design, distribute and store research information. QuestionPro was the site selected as it was free, offered the option to export survey data, had no questions or response limitations and had an easy-to-use interface for designing questions and analysing responses. Screenshots, questions and a link for the survey can be found in appendix B. Section one contained 16 questions about staff morale. Questions covered topics of staff morale, job fulfilment, work-life balance, job security, professional relationships, fatigue, stress and personal well-being. Section two contained 11 questions about staff turnover intention. Questions covered topics of turnover intention, job benefits, personal and professional needs. A bulk email was sent to work colleagues within my organisation. A link was also shared to my professional network via a LinkedIn post. Responses were reviewed and separated based on introductory responses. If respondents said no to any of the introductory questions their survey response was discounted; 'I understand what this survey is about', 'I consent to taking part in this survey' or 'I work in the pharmaceutical industry'. When respondents said that they did shift work their responses were compiled into an excel sheet under the SW group and respondents that said that they didn't do shift work their responses were compiled into the NSW group. Once all data was compiled into an excel sheet they were then analysed.

3.2.3 Justifications

Interview questions were designed to investigate the potential impact of shift work on QA and RFT manufacturing. A template was designed as it was important to have standardised questions. Having standardised questions for the interviews helped avoid bias as each participant had the same questions and responses could therefore be easily compared. This qualitative data collection method was used because key SMEs could be chosen directly allowing them to give their nuanced opinions on the topics of QA and RFT manufacturing based on their expertise. Interviews allowed the researcher to probe for more detail and seek further clarity about certain points made in real time which can't be captured in surveys. As interviews were conducted face to face this allowed the researcher to work with more context by not only examining what was said but how it was said and body language used.

Surveys were used to investigate the potential impact of shift work on staff turnover intention and staff morale. From secondary research carried out in the previous section staff turnover intention was mostly measured using surveys. Also, from the secondary research carried out in the previous section staff morale was most commonly measured using surveys and regular employee check-in meetings. There is a large body of successful research already published in the area using surveys as the primary research tool for measuring staff morale and turnover intention (e.g. (Blytt et al., 2022), (Bowles and Cooper, 2009), (Jagun, 2015), (Lazzari et al., 2022), (Power, 2016)). These have each been discussed in the relevant literature review sections. Surveys were advantageous for these sections as they could capture large amounts of information. The confidential nature of surveys used, helped to avoid any potential bias and encourages honest responses from participants. Survey responses were also easy to analyse for significant difference between groups in statistical software and therefore were easy to interpret.

3.3 Methods and Procedures for Data Analysis

3.3.1 Interview Analysis

Thematic analysis was performed to determine common themes among interviewees' responses. Interview transcripts were merged into one document and important points and key phrases/codes were highlighted for each interview question. An excel sheet was opened and

each question was entered into a row and different key words from each interviewee's responses were entered into their respective columns. This open coding allowed for initial organisation of raw data. Axial coding then occurred which involved interconnecting common themes and key ideas from interviewees for each question. Patterns and relationships were then identified by looking at repeated words, phrases, ideas and concepts. If a pattern in response was identified across participants, it was noted in the excel sheet in a final column. Quotations from transcripts that were noteworthy were also included in the excel sheet under whoever said them. Once all themes were summarised in the excel sheet, they were then linked to the objective associated with the interviews. The thematic analysis for the interviews involving open coding followed by axial coding was the best way for raw data to be organised initially and then linked to allow for the identification of themes and relationships. This form of analysis allowed for a more in-depth analysis and interpretation for the research objective of investigating the potential impact of shift work on QA and RFT manufacturing.

3.3.2 Survey Analysis

A Chi square test of independence was used to ascertain if there were any statistical differences between survey responses from SW and NSW. A Chi square test of independence was performed for each question in the survey in a statistical software package called Minitab®. To analyse data and perform chi square tests Minitab® was opened. Data for each question was entered in a tabular fashion with groups (SW and NSW) in the column and number of survey responses for each heading (i.e., strongly agree, agree, neutral, disagree, strongly disagree) were recorded in the rows. Once data was entered statistical analysis took place. To run a chi square test the stat tab was clicked, in the drop down the tables tab was clicked and the cross tabulation and chi square option was selected. This can be seen in the image below.

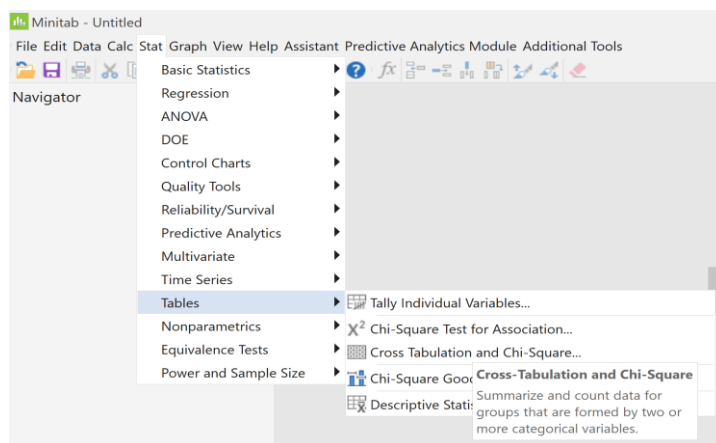


Figure 4. Running a Chi Square Test on Minitab®.

On the next box that popped up an option containing: ‘‘Summarized data in a two-way table’’ was selected, groups were selected for the rows box and for the columns box each Likert scale response was selected (i.e., strongly agree, agree, neutral, disagree, strongly disagree). A box was ticked to display counts. Chi-square box was clicked into and expected cell counts box was ticked. Once that was done, ok was pressed and the results were statistically analysed. The screengrabs below show this option entered into Minitab®.

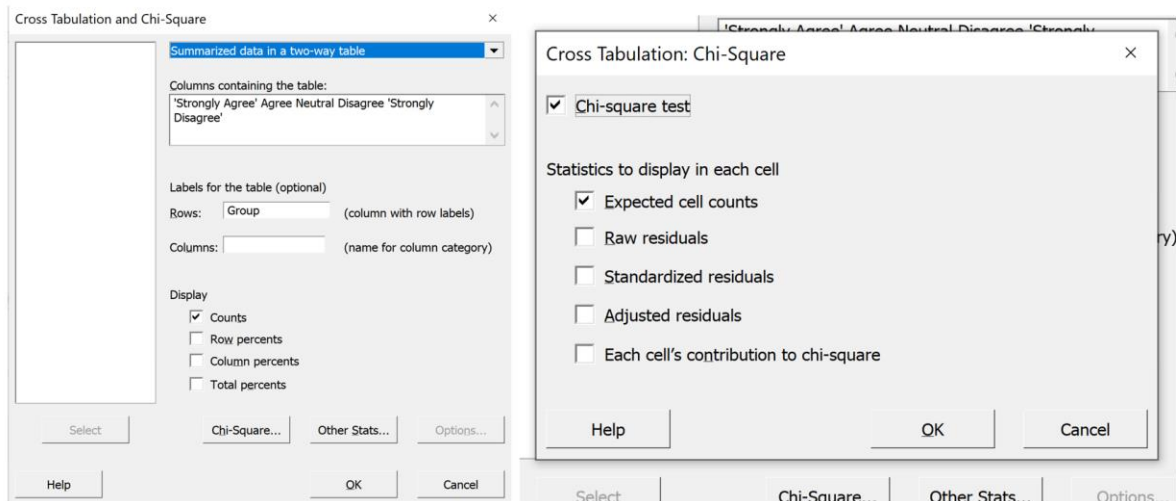


Figure 5. Options Selected for Chi Square Test on Minitab®.

The Pearson P-Value produced was then analysed. A value of <0.05 determined there to be a statistically significant difference between the two groups for a given question. If the expected counts for any of the survey responses was less than one than the software wouldn't assign a P-value. In that case survey responses for strongly agree and agree were merged together and responses for strongly disagree and disagree were merged together. Statistical analysis was then repeated and because expected cell counts were higher, overall P-values were given. A chi square test of independence was used to determine the difference between the two groups as the two variables in this case are forms of categorical data. The first variable (nominal) was the worker group (i.e., SW vs. NSW) the second variable (ordinal) was the question's responses which were Likert scale responses: Strongly agree, agree, neutral, disagree, strongly disagree. Due to the nature of the variables, the chi square test of independence was more fitting for this survey compared to other forms of statistical analysis such as ANOVA and regression. These types of tests required at least one variable to be numerical and for that variable to have a

normal distribution. This test gave a P-value which can then be used to determine whether the difference between the variable is independent of each other.

3.4 Access and Ethical Considerations

3.4.1 Access Considerations

As the researcher works in a large-scale manufacturing plant in the pharmaceutical industry and having studied a life science degree in college a large pool of potential participants for the surveys and interviews were available.

3.4.2 Ethical Considerations

Ethical application forms were completed and approval was granted prior to carrying out primary research described above. The ethics application form consisted of the following sections:

- Description of research study: This section detailed the research's purpose and objectives as well as a high-level overview of the methodology used.
- Possible ethical issues: This section highlighted potential ethical issues related to subject matter, research procedure and research participants.
- About your participants: This section detailed information about participant's profile, justification for their selection as well as plan for approaching/accessing potential participants.
- Information, consent and confidentiality: This section ensured a relevant participant information leaflet (PIL), and Informed consent form (ICF) was drafted and attached to the end of the ethics application. The PIL was designed specifically for the interviews to provide information in layman's terms to potential participants. It contained a description of the research topic and method, details of what participation will involve, a description about information retrieval and access including their right to anonymity, confidentiality and withdrawal. The ICF was designed to ensure participants consented to taking part in interviews.
- Storage of Data: This section outlined how data would be stored and for what length of time. Research data is currently stored on researcher's personal laptop which is password protected. Raw was submitted alongside this dissertation and will be stored

for no more than 2 years from the date of collection. References to participant's place of work and specific names will be avoided to evade GDPR breaches.

The remaining sections covered the need of NDAs for industry-based research, consent from students to publish work, record project's *viva* as well as a document checklist for relevant attachments related to ethical approval. There were no ethical implications highlighted and therefore there was no requirement to send the ethics form to the ethics committee. Upon reviewing the ethics approval form, interview questions, survey questions, ICFs and PILs ethical approval was granted by the researcher's supervisor.

3.5 Method Limitations

3.5.1 Interviews

Interview participants were working in two organisations and as Ireland is a hub for pharmaceuticals this may have led to a skewed response by not being more inclusive of perspectives from other organisations. I think widening participation from SMEs across more organisations would provide a more holistic view of the pharmaceutical sector in Ireland. Another limitation of the interviews was that personal bias of interview subjects can creep in due to the subjective nature of the data. Interviewees could have been presenting inaccurate or incorrect information unbeknownst to themselves. Another limitation of the interviews was that the quality of the data achieved from each interview was very much dependent on the participant's ability to communicate ideas, opinions and answers effectively. There were 8 participants in total which is a small sample size but was realistic for the time and resources available to the researcher.

3.5.2 Surveys

There currently are approximately 27297 employees in the pharmaceutical sector in Ireland (Fitzgerald and Wilson, 2022b) approximately 50% of those work in the manufacturing department (i.e. ~13649) (Fitzgerald and Wilson, 2022a). Using a sample size calculator and based on the number of responses achieved (84) we were able to report results with a 95% confidence interval and a 10.7% margin of error. This was quite a large margin of error and a figure closer to a 5% margin of error would have been more accepted across research bodies. To have a 5% margin of error 374 survey responses would have been required. Considering

the duality of the data collected for this thesis (both quantitative and qualitative) aiming for 374 respondents seemed unrealistic and would be more aligned with the scope of a larger more focused project. Some responses had to be discounted due to the participants not fully engaging with the survey by either stopping early or skipping questions. More survey respondents would have led to a greater confidence in reported results. Other limitations associated with the surveys included the possibility of people misunderstanding a question or interpreting a question differently than intended.

Chapter Four: Analysis and Findings

4.1 Introduction

In this section the findings from the analysed data will be presented and discussed. In the quality section data findings will be discussed and presented by providing context of common themes through the use of written descriptions and illustrative quotes/ phrases taken directly from interviews. In the human resource section data findings will be discussed and presented using a mixture of descriptive statistics, inferential statistics based on P-values produced from chi square tests of independence and graphs for visualisation. Once findings have been discussed the results achieved from primary research were then compared and contrasted to research discussed in the literature review obtained from the secondary research stage. Positive staff morale, low turnover intention, good QA systems and high rates of RFT manufacturing each play a role in ensuring an organisation's operational excellence and top-quality management systems that work.

4.2 Quality Interviews

There were eight participants in the interviews which were used to investigate the potential impact of shift work on QA and RFT manufacturing. There was a mixture of participants with backgrounds in manufacturing (four) and QA (four). Thematic analysis was carried out to determine patterns in responses to interview questions, the findings are presented below.

4.2.1 Background Findings

Participants were asked to provide a general overview of what is done in the QA department from when an issue is identified, to how it's escalated and managed, to how it's investigated, recorded and eventually closed out. This background information was important as it helps to set the scene giving information to those reading the dissertation that may not be familiar with the role of QA. It also ensured that interview participants had sufficient knowledge in the area of QA operations to be considered a SME in the area. The process descriptions were common between all interview participants therefore it can be inferred that the general process is standard across pharmaceutical manufacturing plants in Ireland. This standardisation is due to the highly regulated nature of the department within the pharmaceutical landscape.

Quality issues otherwise known as deviations can vary in seriousness from a small, good documentation practise (GDP) error which have no/ very little product impact, to breaching a critical quality attribute (CQA) which means the product can no longer continue through supply chain and must be dumped. The first step in dealing with quality-based issues is identification. Some quality issues are identified as they occur while manufacturing and other quality issues are identified after the fact when either manufacturing or QA are reviewing manufacturing records. Once identified, the issue is then escalated as appropriate. If an issue is discovered in the process area, the issue will be escalated to shift lead and area management. If an issue is discovered after the fact, then it will be escalated through appropriate chains within QA and manufacturing. If necessary, a cross functional team (CFT) meeting will be held which involves different stakeholder groups who all have input into the decision-making process e.g., manufacturing, maintenance, QA, QC, microbiology and engineering. Actions taken in response to identified quality issues are dependent on severity (i.e., batch vs. non-batch impact) and frequency of deviation occurrence.

Based on interviewee responses pharmaceutical organisations have a three-tiered hierarchy of deviation management within their systems. A deviation is first raised in the lowest tier of deviation and a risk assessment is done. If it is a small issue with minimal impact to product quality, then it remains in this level. If it is a high frequency deviation or one that is more serious with more potential to impact product quality, then it would go up to the second tier. This tier generally has a longer time to close and more stringent investigational requirements before it can be closed out. The third tier is the most serious and could involve the product being outside regulatory filings or breaching CQAs. These are potential batch-killer situations. Essentially the level of deviation correlates with seriousness of the issue identified and the subsequent extent of its investigation. For more severe issues impacting product quality more investigations will be done and the qualified person (QP), which is an external person who ultimately decides whether to disposition batches or not, will make their decision on whether the batch is released into supply chain or not.

Each deviation is assigned a number and details linked with the deviation are all recorded in an organisation's compliance and deviation management system and linked with a relevant batch number. Deviation numbers are cross-referenced with annotations being attached to

relevant steps in manufacturing records to ensure full traceability. Full risk assessment and investigations are carried out before a deviation can be closed out. Investigations could involve additional process samples, CFT meetings and/ or leveraging normal operating range (NOR) and proven acceptable range (PAR) ranges from process science. For deviations in the second tier or higher, corrective and preventative actions (CAPAs) must be implemented. These are designed to try and eliminate causes for deviations and aims to improve the process as a whole.

The most common quality issues in the pharmaceutical industry as identified by interviewees were GDP errors (such as omitted initials and dates for tasks performed, incorrect calculations, mis-verifications, incorrect transcriptions), leaks and readings/ results which are out of specifications. The most common causes highlighted for these errors include standard operating procedures (SOPs) being unclear, type of plant (i.e., mostly automated vs mostly manual-manual plants lend to manual errors), operators not following proper aseptic technique, layout of manufacturing record documentation and sometimes just oversight by an individual. The most common quality issues associated with human errors are GDP errors mentioned above, operators not reading SOPs while doing tasks and leaks from not setting up equipment or tightening clamps correctly. The majority of quality issues identified have minimal impact to product quality.

4.2.2 QA Interview Findings

Upon completing eight interviews with SMEs there was very little evidence between them to suggest that working shift work had any significant impact on the QA of a product. When asked if working irregular hours in a 24/7 shift pattern had any impact on product quality the majority of interviewees didn't think it would be a huge factor. Interviewee #3, who had 28 years' experience in multiple different types of pharmaceutical companies stated that 'in my time there's no evidence to suggest that there are an inordinate number of errors towards the end of shifts or shift blocks'. Many emphasised that errors can occur at any time of day and don't necessarily occur in the middle of night shifts or towards the end of a shift or shift block. Interviewee #4 made the point saying: 'Do things happen at 3am in the morning? Yes. But things happen at 3pm in the afternoon as well'. For human root causes time is not something that is looked at, a larger picture is looked at and all human elements are considered.

Interviewee #5 said 'I don't think there's impaired quality with shift work because we have such stringent and robust quality systems that everything is identified and dealt with properly'. The interview participants stated that their organisations don't look at or record times in deviation systems for when quality issues occur. As this isn't measured by QA, we are unable to infer whether there are more deviations at a particular time of day. A couple of interviewees suggested that different shift patterns have the potential to impact the number of quality issues caused by human error because of fatigue. Talking about shift patterns interviewee #2 stated: 'For some that have a short turnaround there would be a lot of commentary in people saying that they're tired, feeling like they could make more mistakes because of the tiredness associated with turning around their shift from nights to days'. However, this point reflects comments made by operators on the floor and is not backed up with sufficient evidence to support the commentary.

Contrasting what the majority of interviewees were saying, interviewee #1 thought that shift work would have a negative impact on product quality. They stated that 'at night even we see people are quite tired' and 'they aren't going to be as likely to read their procedure when they're tired and that's what leads to mistakes'. However, this subjective opinion was not backed up by facts as they had no evidence that they experienced an increase in deviations at certain times in the day.

The majority of interviewees stated that fatigue rarely comes up as a root cause for human level errors and have stated that there could be a multitude of reasons behind humans not carrying out tasks correctly. The most common highlighted include but aren't limited to a person's mental health or mindset on the day, distraction or lack of mindfulness for the task at hand, level of competence or training received, complacency, an individual's diligence to work or could be just plain oversight by the individual. Interviewee #7 explained that interviews are carried out with operators involved in tier two deviations or higher where the issue is investigated further to determine the human error root cause and fatigue or tiredness rarely comes up.

A common theme between interviewees showed that pharmaceutical companies are moving away from having human error as a root cause. Interviewee #1 stated that 'in industry they try

not to put things down to human error because often there is an underlying reason why someone hasn't done something'. They take a more holistic approach and look at how systems and processes external to operators can be improved to set those working in manufacturing up for success rather than playing the blame game. As mentioned in my secondary research there was actually very little research that showed a direct linkage between shift work and quality assurance. Research that was found showed a linkage between fatigue and decreased cognitive performance (Åhsberg et al., 2000) as well as fatigue and increase quality defect variance (Yung et al., 2022, Yung et al., 2020) but didn't actually look at shift work and quality assurance. This means that although results show insignificance that the primary research conducted as part of this thesis is original and pioneers new information in the area nonetheless.

4.2.3 RFT Interview Findings

Upon completing eight interviews with SMEs there was very little evidence between them to suggest that working shift work had any significant impact on the rate of RFT manufacturing. Interviewee #1 and interviewee #6 believed that shift work would impact the rate of RFT manufacturing negatively. Interviewee #6 admitted that 'I would think it does, on paper it shouldn't but tiredness takes over'. Similarly, interviewee #1 who worked shift work in the past described the fatigue felt working shift work as a 'different type of tiredness' and stated, 'there's more of a risk of not doing something correctly RFT when you're tired from shift work'. The remaining interviewees are of the belief that despite procedures being in place that should be followed, mistakes can occur at any time of day and systems should be in place to ensure RFT manufacturing is followed. This could involve having a second person verification in real time or a system which might alarm or catch potential errors before they occur. Interviewee #3 stated 'it's about setting people up for success, acknowledging people are working shift and not removing the thought process entirely but certainly making it easier for them'. If systems aren't in place to catch potential mistakes before they occur then it is likely that shift work might negatively impact the rate of RFT however as pharmaceutical companies know their operators work shift, they have systems in place to promote RFT manufacturing. Interviewee #8 said 'you have to assume that someone at some point is going to make a mistake and you have to do everything you can to prevent it'. Therefore because of these systems in place, there's little evidence to show that shift work impacts the rate of RFT manufacturing currently in the pharmaceutical industry. There's a pattern here about leveraging systems to set people up for success. Saying that there is no evidence that shift work is linked with decreased

quality assurance or decreased rates of RFT manufacturing doesn't mean it doesn't happen ever.

An interesting thing to note here about interviewees profiles that were of the opinion that shift work may negatively impact RFT manufacturing were both at the lower end of the range for professional experience. The lack of industry experience compared to other interviewees may be linked with a narrower mindset when determining human root causes for things. Information published in this area largely focuses on the impact of shift work on RFT activities in the healthcare industry. Many research papers concluded that fatigue associated with shift work negatively impacts the rate of RFT (Lockley et al., 2007, Keller et al., 2009, De Cordova et al., 2016). This primary research for the dissertation suggests otherwise. Of the eight participants interviewed, six expressed opinions that shift work doesn't impact the rate of RFT manufacturing in the pharmaceutical industry due to the safeguards in place to catch potential mistakes before they occur. The next section will look at the impacts of quality issues associated with human error.

4.3.4 Quality Issue Impact Findings

The point was also made that some pharmaceutical companies have no other choice but to manufacture 24/7. This could be due to business demand, the nature of the product (i.e., biologics are living organisms that need constant monitoring) and to meet specific hold times as recorded in regulatory filings. The consensus was that the benefits and profits made by pharmaceutical companies by working 24/7 far outweigh the potential costs of quality issues. Interviewee #6 stated that if you 'weigh up the issues with the amount of work that is covered then you would still get a lot more work covered'. Quality issue impacts can vary greatly and largely depend on the severity of the issue. The most common impacts of quality issues in a business involve the manhours from multiple functions gone into investigations and costs in terms of loss of profits. In more serious cases the manufacturer could have reputational impact, you may have to do a product recall which could lead to potential impact to supply chain and subsequent large-scale re-planning. Quality issues have the potential to impact a batch's disposition as no batch is dispositioned without all deviations being risk assessed and investigated appropriately to ensure full due diligence is done, 'nothing goes out this door that isn't fully signed off and we're comfortable to stand over'. Interviewees explained that

deviations are generally closed within 30 days, but they have seen deviations that require extension requests and have remained open for up to three months. When asked if this would then impact the accessibility of the drug to patients the majority said no providing that there are sufficient safety stocks in place. Manufacturers which run at a just-in-time capacity are more likely to have accessibility impacted by quality issues. Every interviewee agreed that once all deviations are investigated, reviewed, and closed out satisfactorily and all CQA are met that an organisation will have confidence to stand over their product. When it comes to deviation investigations pharmaceutical companies would always 'err on the side of caution' and would 'have confidence in the quality systems in place'. The public's perception is only impacted by public issues i.e., product recall situations, however the general consensus among interviewees was that 'the public are unaware of what happens in a pharma company in terms of quality systems, management structures, regulatory filings'. In summary the impact of quality issues extends mostly to affect the batch's disposition and costs companies a lot internally in terms of man hours and profits however the external impacts are minimal due to regulations and the number of safeguards in place to protect the public ensuring the product produced is 100%.

4.3 Human Resource Surveys

There were 84 participants in the survey which was used to investigate the potential impact of shift work on staff morale and staff turnover intention. Out of those 84, 44 were SW and 40 were NSW. Statistical analysis was carried out to determine if there were any significant differences between the two groups, the findings are presented below.

4.3.1 Staff Moral Survey Findings

In terms of the self-perceived level of staff morale in the participant's current position, there were no significant difference between the two groups ($P=0.791$). A large proportion of survey participants agreed that they had good staff morale with 82% of SWs either strongly agreeing or agreeing and 86% of NSWs either strongly agreeing or agreeing. Participants were then asked another question about how they perceived overall staff morale among employees within their organisation. The participant's perception of staff morale as a whole within an organisation was significantly different between the SW and NSW groups ($P=0.002$). NSWs tended to view staff morale within an organisation to be more positive compared to their shift working counterparts. 93% of NSWs believed there to be good staff morale in their

organisation, 3% were neutral and 5% disagreed. This number was decreased in the SW group, 64% believed there to be good staff morale within the organisation, 25% were neutral and 11% disagreed. This significant difference is interesting as there was no significant difference between the groups for levels of self-perceived morale. Although SWs have high levels of self-perceived staff morale it is possible that they assume staff morale within an organisation is lower based on interactions with their work colleagues and discussing negative associations with shift work like fatigue, well-being, and work-life balance with their colleagues. These significantly difference responses can be seen in the bar chart below.

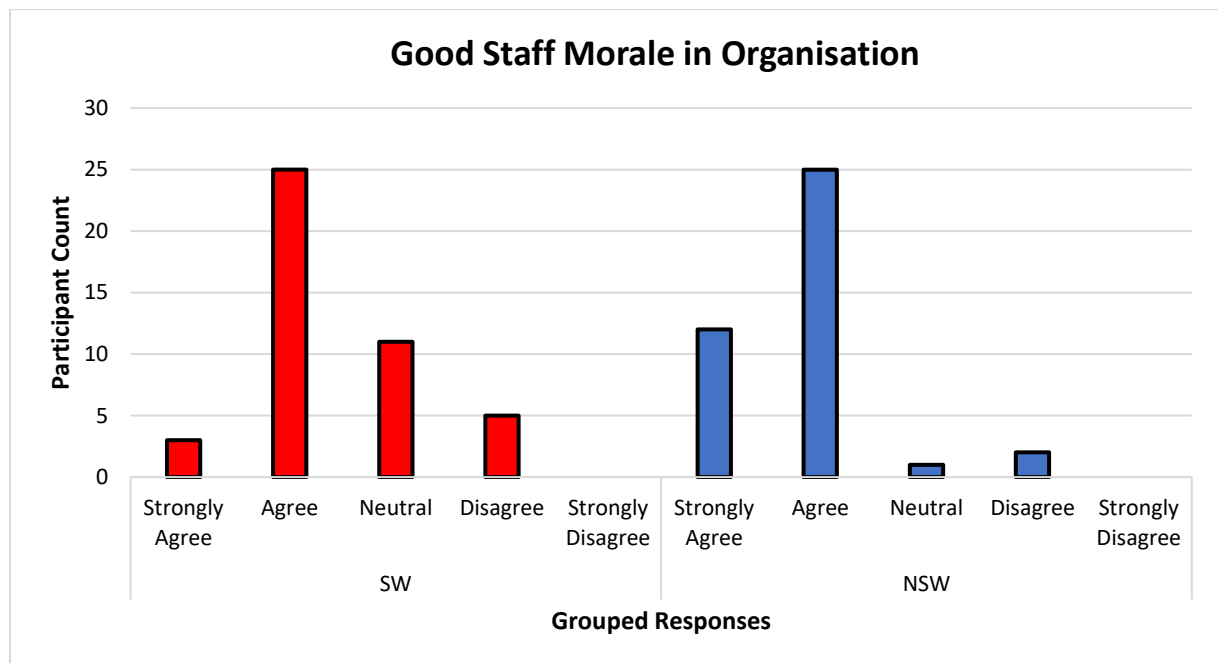


Figure 6. A Bar Chart Showing Responses for Good Staff Morale Within an Organisation.

Despite the irregular hours involved with working shift work the majority of both groups claimed to be happy with the hours they work. In the SW group, 62% agreed to enjoying the hours that they worked, 20% were neutral and 18% disagreed with the statement. In the NSW group 78% agreed to enjoying the hours that they worked, 8% were neutral and 15% disagreed. Although there was a tendency for SWs to be less likely to agree and be more indifferent towards the statement this difference wasn't statistically significant ($P=0.337$). Branching from this point, the majority of participants from both groups agreed that working hours are an important aspect of a job with 93% of SWs and 88% of NSWs agreeing with the statement.

While survey participants reflected on their personal well-being, SWs were significantly more likely to agree that their current working pattern negatively impacts their well-being ($P=0.006$). In the SW group 34% agreed that their current job impacted their personal wellbeing negatively, 11% were indifferent and 55% disagreed. Contrasting this, in the NSW group 5% agreed, 13% were indifferent and 83% disagreed. The spread of results for this question showing significant difference between groups can be seen below represented with two pie charts.

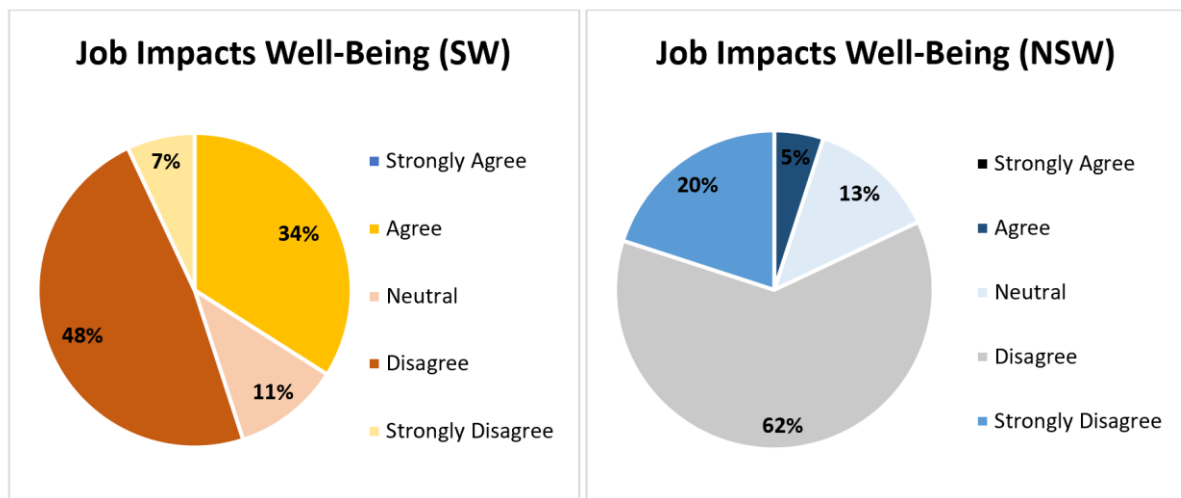


Figure 7. Pie Charts Representing Responses Related to Impact Work on Personal Well-Being.

Following on from perceived impact of work on personal well-being, SWs were significantly more likely to feel emotionally agitated upon arriving home from work ($P=0.004$). 21% of SWs reported to frequently feeling emotionally agitated when arriving home from work compared to 5% of NSWs. SWs were also more likely to claim to feeling frequently under pressure in their current role compared to their NSW counterparts ($P=0.040$). 70% of NSWs disagreed to feeling under pressure in their current role whereas only 44% disagreed in the SW group. Despite the majority of SW participants feeling pressure during the workday the majority of survey respondents from both groups felt that workplace stress did not affect their lives outside of work with 90% of NSW and 73% of SW disagreeing with the statement that workplace stress impacts their lives outside of work. There was no significant difference between the groups here ($P=0.128$).

There was a significant difference between the two groups when looking at levels of fatigue both inside and outside work. SWs were significantly more likely to feel tired while working ($P < 0.001$). 70% of SWs agreed to frequently feeling tired when working whereas this figure was 23% for the NSW group. Outside of work, SWs were significantly more likely to be too fatigued to do anything else upon returning home from work ($P < 0.001$). The majority of SWs (52%) agreed to being too tired to do anything else when coming home from work. In comparison, only 3% of participants in the NSW group agreed to the statement. This may be a result of SWs working longer shifts (i.e., >8hrs). 12 hr shifts are common in the pharmaceutical manufacturing industry, being in work for longer periods of time may cause excessive fatigue by the time they return from work. The visualisation of data for differences in levels of fatigue between the two groups can be seen below.

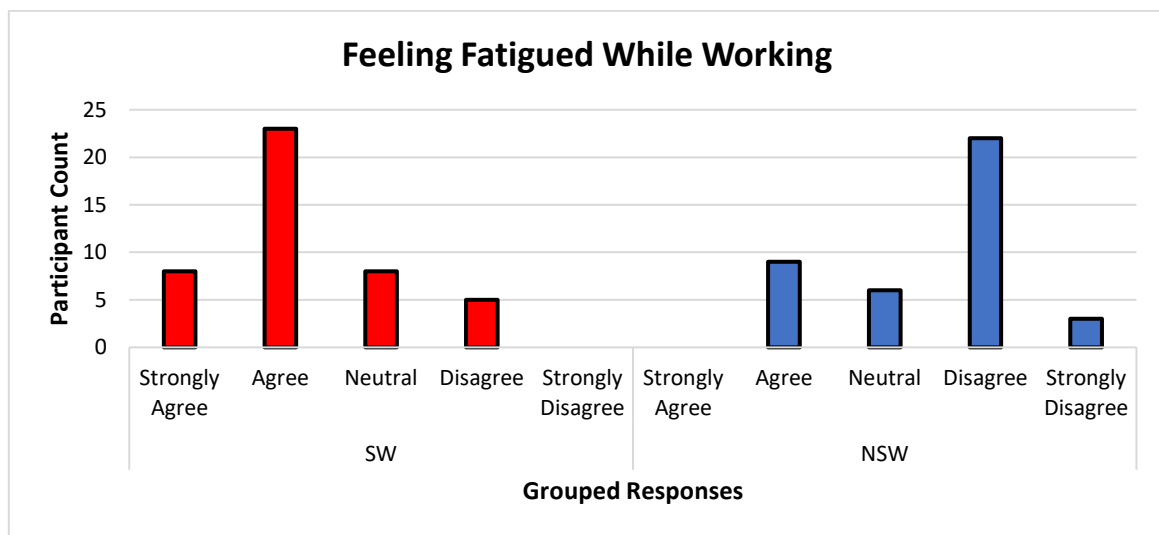


Figure 8. A Bar Chart Showing Responses for Feeling Tired During the Workday.

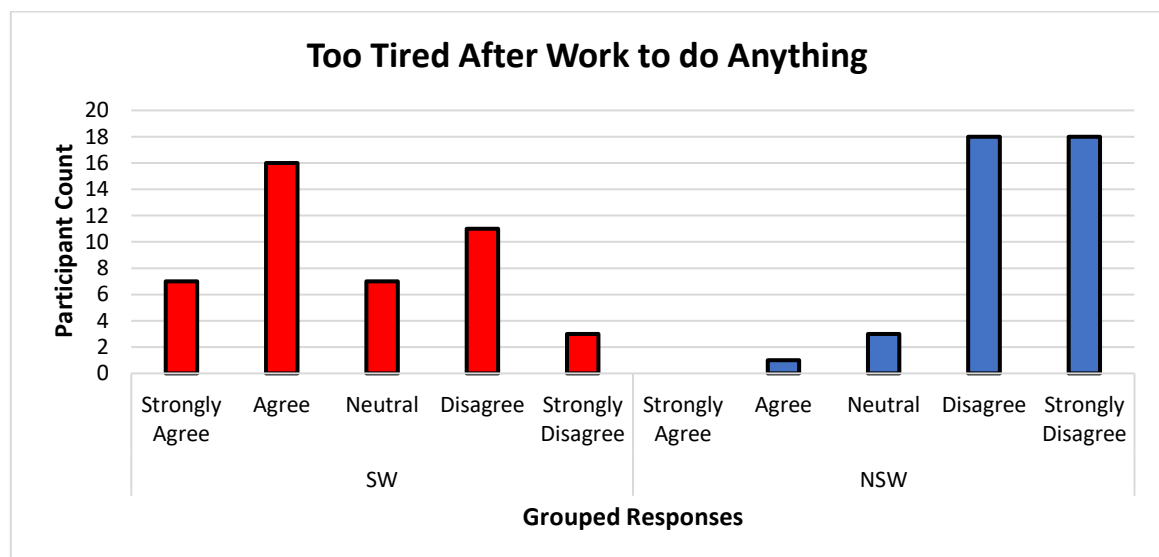


Figure 9. Bar Chart Showing Responses for Feeling too Tired to do Anything Else After Returning Home from Work.

Another area showing significant difference between the two groups involved missing personal events because of work ($P < 0.001$). 100% of NSWs disagreed that they frequently missed personal events as a result of work. In the case of SWs, 36% disagreed, 14% were indifferent and the remaining 50% agreed that they frequently missed personal events. The nature of shift work involves working evenings, nights and weekends which are prime times for social events and interactions. Missing events involving friends and families can result in being withdrawn and out of phase with society which in turn can impact work-life balance.

The majority of workers from both groups agreed that they often looked forward to another day at work. Among SWs, 64% agreed with the statement and 73% agreed in the NSW group. The difference between groups here was insignificant ($P = 0.152$). There was a high rate of perceived level of job security between the two groups with 95% of SW and 90% of NSW either strongly agreeing or agreeing that they felt secure within their jobs. The pharmaceutical manufacturing industry is one that is constantly growing and manufacturing medicines is seen as an essential service which translates to the high job security which many feel. There was also a high rate of job fulfilment across the two groups with the majority of participants in each group stating they felt fulfilled in their current position. 68% of SWs and 73% of NSWs reported positive fulfilment. There was no significant difference between the groups in this area ($P = 0.432$). Both groups reported a largely positive relationship with their work colleagues with 100% either agreeing or strongly agreeing in both groups, there was no significant difference here ($P = 0.691$).

There was very little secondary research which showed a direct linkage between shift work and staff morale. Multiple studies did however show that there was a correlation between poor work-life balance and negative staff morale within an organisation (Lockwood, 2003, Fleetwood, 2007, Dhas and Karthikeyan, 2015, Williams, 2008). In this research there was no suggestions that there was a correlation between the poor work-life balance and negative staff moral. Similarly, when asked directly about self-perceived work-life balance, there was no significant difference in self-perceived level of work-life balance which suggests shift work doesn't negatively impact either, which contrasts what was discovered in the aforementioned studies. Although there was insignificant difference between the two groups for self-perceived level of work-life balance SWs were significantly more likely to admit to missing personal

events due to working irregular hours. It is likely here that although personal events are missed SWs feel that it doesn't impact their overall work-life balance and manage to plan and attend events that are on when they aren't scheduled to work. Although rates of self-perceived staff morale were similar between groups there was a significant difference in how participants thought staff morale was in the organisation as a whole, SWs were significantly more likely to rank staff morale as being lower than NSWs. It is likely here that because SWs spend so much time together (with up to 12 hours shifts) that they become closer and more vulnerable, open and honest with each other about how they are feeling and things they are going through. Other questions in the staff morale section of the survey showed there to be significant difference in certain things linked with morale with SWs having increased levels of fatigue both inside and outside work, workplace stress and emotional agitation and decreased levels of personal well-being which may be why they believe that the organisation's morale as a whole is lower compared to the NSWs.

4.3.2 Turnover Intention Survey Findings

Staff turnover intention was gauged by asking participants if they envisioned themselves within the company in the next one year, two years and three years' time periods. In the SW group 63% of participants agreed that they believed they would be in the same position this time next year, 14% responded neutrally and 23% disagreed with the statement. In the NSW group 73% agreed, 7% were neutral and 20% disagreed. The difference between the two groups for this question was insignificant ($P=0.591$). In the SW group 43% of participants agreed that they believed they would be in the same position in two years' time, 16% were neutral and 11% disagreed. In the NSW group 33% agreed, 28% took a neutral stance and 40% disagreed. The difference between the two groups here was again insignificant ($P=0.088$). Although insignificant, it is very close to the level of marginal significance ($P<0.05$) which could suggest there is potential trending difference and if the sample size were greater, the data would have been more representative of the sample population and it's possible that the difference would have been significant. The trend in this case is that shift workers were more likely to agree than disagree that they would be in their current position in two years compared to NSWs. Similarly, when looking at whether participants envisioned themselves within their current position in three years the differences between groups was insignificant but trending towards significance ($P=0.085$). 25% of SWs felt confident that they would be in the same position in in three years' time, 16% were neutral and 54% believed they would be in a different position, among the

NSW group 11% agreed that they would be in the same position in three years, 30% were had a neutral stance and 61% disagreed. Again, there is a trend here for SWs to be more likely to agree than disagree to keeping their role for up to three years into the future compared to their NSW counterparts. The percentage of respondents agreeing to statements where they would remain in their position decreased as the timeframe got longer which reflects the ongoing economic trend known as ‘The Great Resignation’. This is a trend mostly driven by the younger workforce of millennials and Gen Zs since the onset of Covid which has involved people with short tenures (i.e. 1-3 years) resigning in order to get a job with better perks, be it higher compensation package, more job flexibility or more opportunities for growth (Jiskrova, 2022, Serenko, 2022, Liang et al., 2023). As there were insignificant differences between the two groups in terms of staff turnover, data was merged for the purpose of visualising staff turnover intention over time.

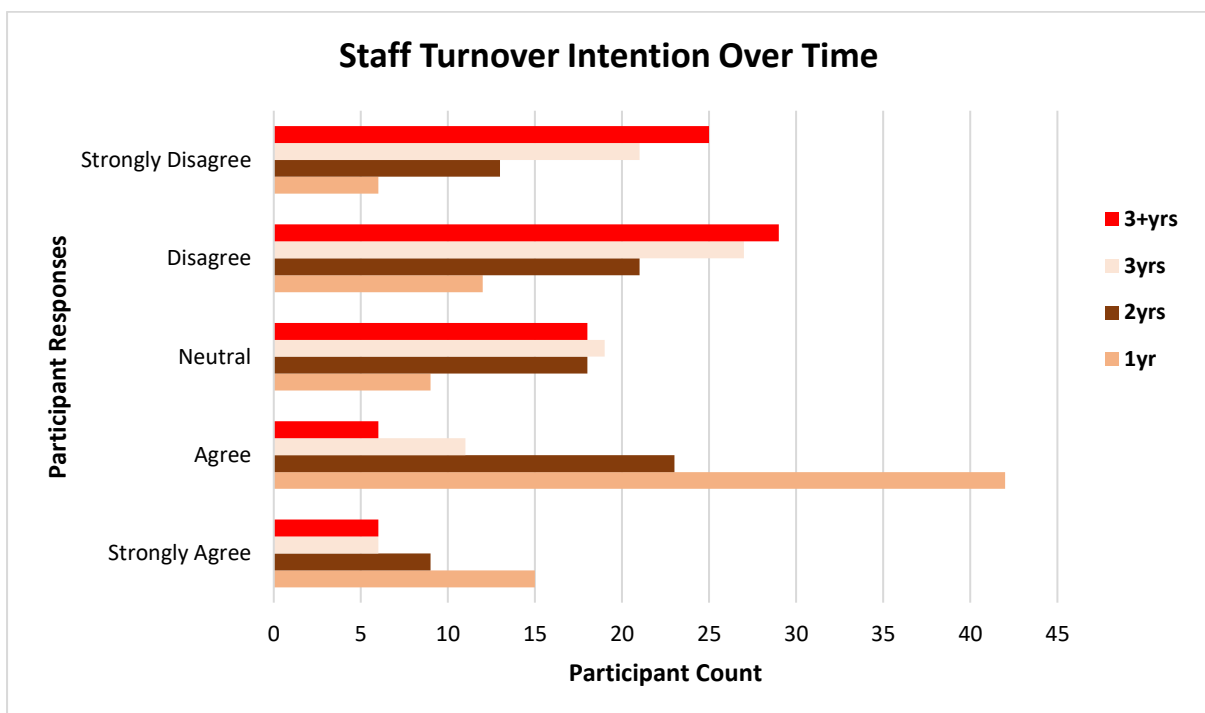


Figure 10. Staff Turnover Intention Over Time for Participants Working in the Pharmaceutical Industry.

In terms of current turnover intention, 12% of SWs and 18% of NSWs agreed to having current intentions to quit their job meaning the majority in both groups didn’t have any immediate intentions to quit. There were no significant differences between groups for this question (P=0.153). Similarly, the majority of both SWs (62%) and NSWs (70%) disagreed that they would accept another job offer today if given one. Again, the difference here between groups

was insignificant ($P=0.704$). When asked if participants had taken part in an interview for an external organisation in the last 3 months the majority in both SW and NSW groups denied it. There was no significant difference between groups for this aspect either ($P=0.882$).

There was a significant difference between groups when looking at the benefits associated with their jobs. SWs were significantly more likely to agree with the fact that benefits associated with their job prevented them from quitting compared to their NSW counterparts ($P<0.001$). 89% of SWs agreed with the statement, 2% were neutral and 9% disagreed. This is hugely different when 18% of NSW group agreed, 18% took a neutral stance and 66% disagreed. Benefits associated with shift work which regular hour workers don't receive include shift allowance, options for overtime and more days off due to working longer shifts. The financial incentives involved with working unsociable hours are percentage increases on top of base salary, these percentage increases can range from 20-33% depending on where you work and type of shift pattern. These benefits make working irregular hours worthwhile for certain individuals. The significant difference between the two groups can be seen in the bar chart below.

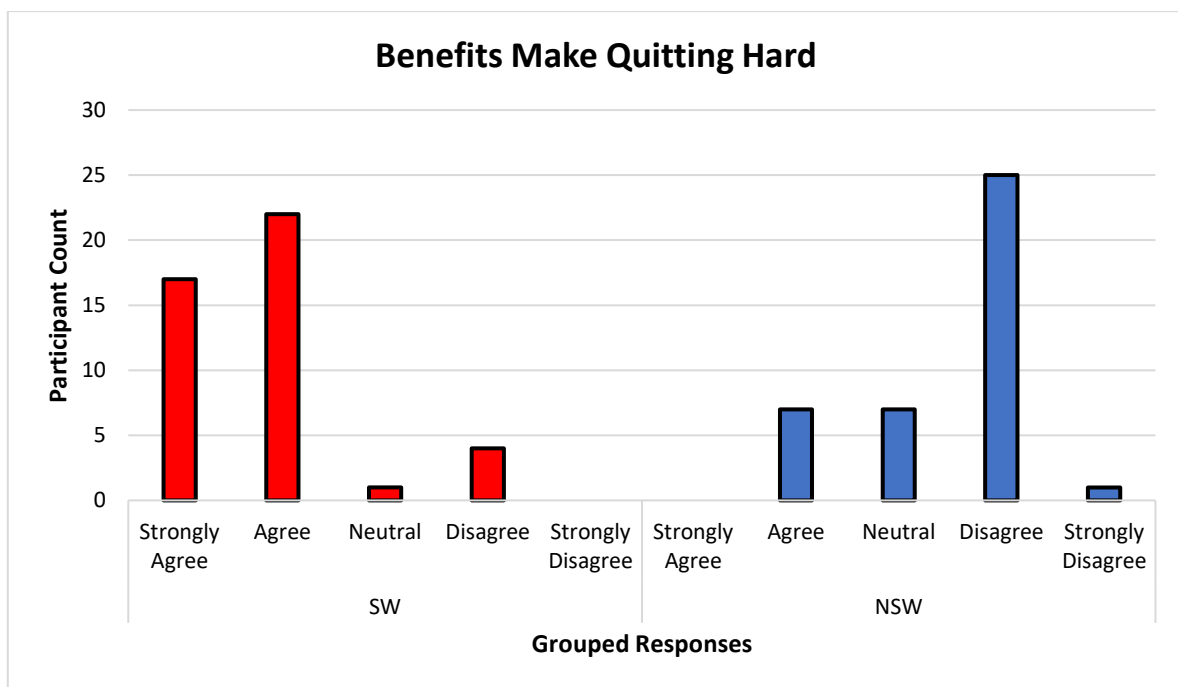


Figure 11. Bar Chart Showing Responses for Benefits Associated with Job Prevent Participants from Quitting.

When participants were questioned about whether they dreamed of getting a job which suited their personal needs better 43% of the SW group agreed and 45% of the NSW group agreed. There was no significant difference between the groups here ($P=0.208$). These percentages infer that people are often dreaming of other roles without actively applying for other roles (i.e., current turnover intention). This is akin to the ‘grass is always greener on the other side’ analogy. When looking at whether participants frequently scanned internet to search for alternative job opportunities the majority disagreed with the statement. 56% of SWs disagreed and 73% of NSWs disagreed. Again, there was no significant differences in responses between the groups here ($P=0.116$).

When survey participants were asked to give a primary reason for why they would leave their career their responses focused on different areas. The SW group claimed to be more likely to leave for more opportunities for growth and better work-life balance whereas NSWs claimed to be more likely to leave for greater job flexibility and better total compensation packages. All responses for each group can be seen in the pie charts below.

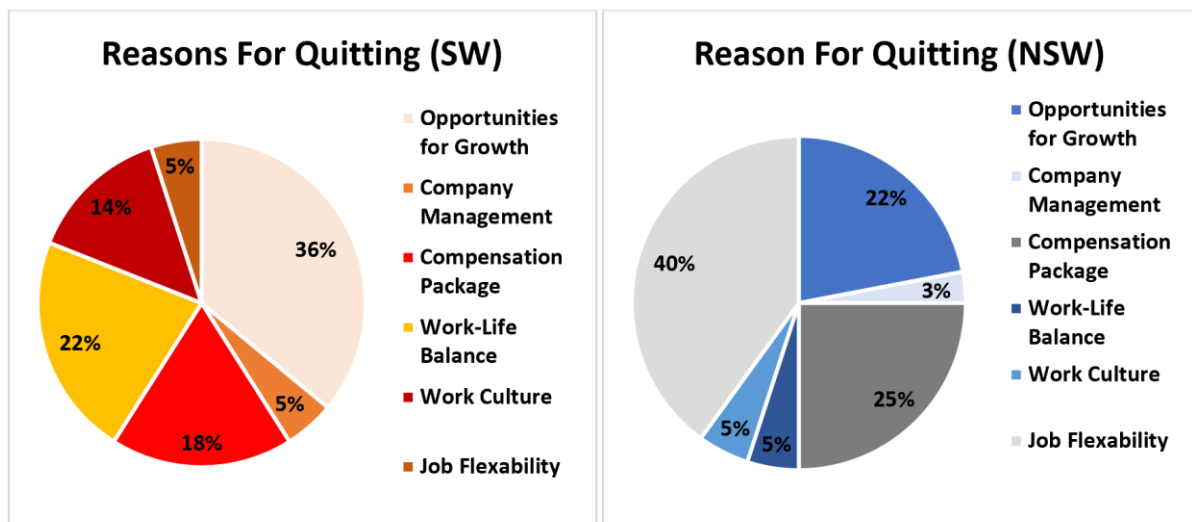


Figure 12. Pie Charts Representing Responses Related to the Primary Reason for Quitting.

These research findings support those findings from Shen and Dicker (2008) which looked at the potential impacts of shift work on employees in the areas of human resources. Their research also showed there to be no significant correlation between staff turnover intention and shift workers. They did however find that those working shift work had higher levels of absenteeism and were more likely to retire early (Shen and Dicker, 2008). This research in the

area of human resources didn't explore topics such as retirement and absenteeism. More recent studies which were reviewed as part of the secondary research by Blytt and colleagues (2022) and Jagun (2015) had conflicting evidence compared to this primary research as they found there to be a positive correlation between shift work and increased staff turnover intention (Blytt et al., 2022, Jagun, 2015). In conclusion there was no significant difference between groups in terms of current turnover intention, turnover intention in the future and interest in alternative job opportunities. The only area of significant difference between the two groups here was the fact that SW were more likely to feel that the benefits associated with their job prevented them from quitting their current job compared to their NSW counterparts.

Chapter Five: Conclusion

5.1 Conclusions Summarised

The conclusions summarised will be discussed based on the two objectives highlighted from the outset in the project's proposal:

5.1.1 Objective 1

Objective 1: Determine if working irregular hours has any effect in the area of quality (namely QA and RFT manufacturing) by interviewing key subject matter experts working in the pharmaceutical industry.

In terms of QA there wasn't significant evidence to suggest a correlation between QA of a product with employees working shift work. The majority of interview participants emphasised that errors could occur at any time of day and had no evidence to suggest that an inordinate number of errors occur in the middle of the night or at end of shifts or shift blocks. Quality issues are raised as deviations and QA don't record times when deviations occur. The majority of interviewees made the comment that fatigue rarely comes up as a root cause for human level errors. The most common reasons highlighted for human error range from mindset, distraction, competency to level of training, complacency to just plain oversight by an individual. A theme which was common across all interviews was stating the fact that pharmaceutical manufacturers are wary about putting things down as human error root cause and are trying to take a more holistic approach to look at how systems and processes external to operators can be improved to set operators up for success, preventing human error root causes. Examples of these mistake-proofing (poka-yoke) type of responses involve including dashes, so operators transcribe lot numbers correctly into manufacturing records or not allowing automation prompts to be acknowledged until tasks are complete.

In terms of RFT manufacturing there wasn't significant evidence to suggest a correlation between the rate of RFT manufacturing and those working shift work. Similar to what was mentioned above, interviewees believed that errors could occur at any time of day and systems should be in place in order to catch mistakes before they happen. These systems which catch

errors before they occur could involve having a system or machine which will alarm to catch potential errors before they occur or having steps which involve second person verification where a second operator verifies a task is being done correctly contemporaneously. The theme of avoiding the blame game is repeated here and underlines the importance of having systems in place to ensure RFT manufacturing occurs as mistakes have the potential to occur at any time of day and not necessarily as a result of working shift work.

5.1.2 Objective 2

Objective 2: Determine if working irregular hours has any effect in the area of human resources (namely staff morale and staff turnover intention) by surveying both employees that work regular hours and those that work irregular hours in the pharmaceutical industry.

In terms of staff morale there was no significant difference between SWs and NSWs in terms of the level of self-perceived staff morale. When questioned about overall staff morale within the organisation SW were significantly more likely to believe that there was a decreased level of staff morale within an organisation compared to their NSW counterparts. It's possible that SWs assume staff morale within their organisations is lower from interactions with their work colleagues discussing the negative effects of shift work. From the survey responses SWs were significantly more likely to be fatigued both during and after the workday, feel that their job negatively impacted their personal well-being, feel workplace stress, feel emotionally agitated after a workday and feel more likely to miss personal events in comparison to the NSW group. So, although there was no significant difference in self-perceived levels of staff morale there were some significant differences in areas which may impact morale over time.

In terms of staff turnover intention there was no significant difference between SWs and NSWs in terms of current turnover intention and turnover intention in the future. A trend was seen in the two groups displaying an increase in staff turnover intention over time. There was however a significant difference when participants were asked whether the benefits associated with their jobs prevented them from quitting. SW were significantly more likely to agree to that statement. This may be down to the significant financial incentives that SW get for working irregular hours. When looking at reasons why participants would quit their current job the

responses also varied between groups. In the SW group, the top three reasons were classed as opportunities for growth, work-life balance and compensation package. In the NSW group the top three reasons were job flexibility, compensation package and opportunities for growth.

5.2 Study Limitations

The limitations associated with this study are largely linked with methodology used as well as participants involved in both the surveys and the interviews. One specific limitation associated with the interviews would be the lack of representation of more organisations. The interview participants were only working in 2 organisations and this may have potentially meant that responses could have been skewed as there are far more than 2 pharmaceutical manufacturing companies in Ireland. To get a more representative view of the pharmaceutical hub Ireland is would have required a greater participation from SMEs with varied backgrounds. More general limitations associated with interviews themselves would include biases involved with qualitative data. With the nature of interviews being so subjective, biases have the potential to emerge. In addition to that interviewees have the potential to provide information which is either inaccurate or incorrect unbeknownst to themselves. Another generalised limitation associated with interviews is that the quality of data achieved from each interview was completely dependent on the SME's ability to communicate their ideas, opinions, and answers effectively. In the interviews some participants were more willing to share their point of view compared to others and their responses in their transcripts made this apparent.

As discussed in chapter 3, based on the 84 survey respondents we are only able to report results with a 95% confidence interval using a 10.7% margin of error. This margin of error is quite large and wouldn't be as widely accepted across research like a 5% margin of error. This is due to the fact that there is a lower likelihood that the results could be relied on with confidence for the sample population. Based on the data discussed above in the methodology section with ~13649 people working manufacturing jobs in the pharmaceutical industry, 374 survey responses would have been required to have responses converted to data with a 5% margin of error. Considering the duality of the data collected for this thesis (both quantitative and qualitative) aiming for 374 respondents seemed unrealistic and would be more aligned with the scope of a larger more focused project. Another limitation associated with choosing surveys is that participants didn't fully engage with the questions whether it was from lack of

understanding or lack of interest. Some responses had to be discounted due to surveys not being completed in its entirety. Another limitation with the survey is that there was no guarantee that participants involved interpreted and understood the questions as intended, it's possible that they had their own interpretation for each question.

5.3 Future Work and Recommendations

Due to the duality of the study containing aspects of both quantitative and qualitative data collection methods, sample sizes for both the interviews and the surveys were quite small. This meant that there's less confidence in the responses received being an accurate representation of the sample population. If there was more time and resources available to the researcher, I would recommend looking into similar topics but increasing sample sizes so they would be more representative of the sample population. This would decrease the margin of error and therefore confidence in reported results will be greater. As discussed above when summarising the studies weaknesses, having a greater variety of interviewees from different pharmaceutical companies may have impacted results giving a more representative view in the area of quality. The topic itself was one that was original in terms of the mixture of methodologies used, topics of quality and human resources looked at as well as business area focused on (i.e., the pharmaceutical industry). Other topics of research that may be worthwhile looking at in the future as an extension of work carried out from this research could be looking into the impact of shift work on more hidden business level costs such as employees' mental health, their productivity while working and absenteeism. A lot of the interviewees said that times aren't recorded as part of their deviation management system so in the future it may be worthwhile doing research into when deviations occur or carry out more specific case studies which look at fatigue-related quality issues and the factors interplaying there.

5.4 Dissertation Reflection

Based on my own personal interest and experience I would have expected working irregular hours to have negative impacts on both human resources and quality. I was therefore surprised to find that a lot of the findings were insignificant and there was little evidence to suggest that there was any correlation at all. Although the research was largely insignificant, it doesn't equate to lack of importance. Research is still research as long as new information is uncovered regardless of significance or lack of evidence-based opinions. One lesson I learned is the

importance of putting time into the planning stage by putting together a clear proposal alongside SMART (specific, measurable, achievable, relevant and timely) objectives. I was a little bit naive at the start as I rushed my first proposal draft without thinking about it too much as I was eager to get into my primary research. The planning stage really helped set me up for success and made carrying out the research a lot easier. Another lesson I learned is that what you find in research might not be what you expected to find. I believe the research carried out as part of this thesis module is relevant to the MSc in 'Pharmaceutical Business and Technology' as topics covered relate to overall quality managements systems and operational excellence in the pharmaceutical industry.

Balancing a dissertation module from a part-time course with a full-time job proved to be quite challenging. A lot of sacrifices had to be made in order to complete this dissertation and involved becoming a semi-recluse. I am looking forward to re-integrating into society on completion of my *viva*. Overall, I am both happy and proud that I completed this module, I learned a lot and strongly believe I'll be able to apply it to my career into the future.

Bibliography

- ÅHSBERG, E., KECKLUND, G., ÅKERSTEDT, T. & GAMBERALE, F. 2000. Shiftwork and different dimensions of fatigue. *International journal of industrial ergonomics*, 26, 457-465.
- AJIT, C. P., BHAGWAT, A. M. & CHAUDHARI, A. P. 2021. CAPA: An important concept of Quality Assurance in Pharmaceutical Industry. *Asian Journal of Research in Chemistry*, 14, 357-362.
- ALBERTSEN, K., GARDE, A. H., NABE-NIELSEN, K., HANSEN, Å. M., LUND, H. & HVID, H. 2014. Work-life balance among shift workers: results from an intervention study about self-rostering. *International Archives of Occupational and Environmental Health*, 87, 265-274.
- ALMONDES, K. M. D. & ARAÚJO, J. F. 2009. The impact of different shift work schedules on the levels of anxiety and stress in workers in a petrochemicals company. *Estudos de Psicologia (Campinas)*, 26, 15-23.
- ALTABBAKH, H., MURRAY, S., GRANTHAM, K. & DAMLE, S. 2013. Variations in risk management models: a comparative study of the space shuttle challenger disasters. *Engineering Management Journal*, 25, 13-24.
- ANGERER, P., SCHMOOK, R., ELFANTELE, I. & LI, J. 2017. Night work and the risk of depression: a systematic review. *Deutsches Ärzteblatt International*, 114, 404.
- BAMBRA, C., WHITEHEAD, M., SOWDEN, A., AKERS, J. & PETTICREW, M. 2008a. "A hard day's night?" The effects of Compressed Working Week interventions on the health and work-life balance of shift workers: a systematic review. *Journal of Epidemiology & Community Health*, 62, 764-777.
- BAMBRA, C. L., WHITEHEAD, M. M., SOWDEN, A. J., AKERS, J. & PETTICREW, M. P. 2008b. Shifting schedules: the health effects of reorganizing shift work. *American journal of preventive medicine*, 34, 427-434. e30.
- BARLING, J., BARNES, C. M., CARLETON, E. & WAGNER, D. T. 2016. *Work and sleep: Research insights for the workplace*, Oxford University Press.
- BLASK, D. E. 2009. Melatonin, sleep disturbance and cancer risk. *Sleep medicine reviews*, 13, 257-264.
- BLYTT, K. M., BJORVATN, B., MOEN, B. E., PALLESEN, S., HARRIS, A. & WAAGE, S. 2022. The association between shift work disorder and turnover intention among nurses. *BMC nursing*, 21, 1-8.
- BØGGILD, H. & KNUTSSON, A. 1999. Shift work, risk factors and cardiovascular disease. *Scandinavian journal of work, environment & health*, 85-99.
- BOLTIC, Z., RUZIC, N., JOVANOVIĆ, M. & PETROVIĆ, S. 2010. Measuring the performance of quality assurance processes: pharmaceutical industry deviation management case study. *Accreditation and quality assurance*, 15, 629-636.
- BOOKER, L. A., SLETTEN, T. L., ALVARO, P. K., BARNES, M., COLLINS, A., CHAI-COETZER, C. L., NAQVI, A., MCMAHON, M., LOCKLEY, S. W. & RAJARATNAM, S. M. 2020. Exploring the associations between shift work disorder, depression, anxiety and sick leave taken amongst nurses. *Journal of sleep research*, 29, e12872.
- BOTHMA, C. F. & ROODT, G. 2013. The validation of the turnover intention scale. *SA journal of human resource management*, 11, 1-12.
- BOWLES, D. & COOPER, C. 2009. *Employee morale: Driving performance in challenging times*, Springer.
- BRUCE, J. A., CONRAD, E. W., DICK, G. J., NICKEL, D. J. & SMOLINSKI, J. G. Model-based verification for first time right manufacturing. *Design and Process Integration for Microelectronic Manufacturing III*, 2005. SPIE, 198-207.
- BUJA, A., ZAMPIERON, A., MASTRANGELO, G., PETEAN, M., VINELLI, A., CERNE, D. & BALDO, V. 2013. Strain and health implications of nurses' shift work. *International journal of occupational medicine and environmental health*, 26, 511-521.

- BURKE, C. 2021. 5 reasons why Ireland attracts some of the world's leading Pharmaceutical Companies. Available at: <https://blog.frsrecruitment.com/articles/ireland-attracts-some-of-the-worlds-leading-medical-pharma-companies-why>. (Accessed: 27 December 2022). .
- CAPPADONA, R., DI SIMONE, E., DE GIORGI, A., BOARI, B., DI MUZIO, M., GRECO, P., MANFREDINI, R., RODRÍGUEZ-BORREGO, M. A., FABBIAN, F. & LÓPEZ-SOTO, P. J. 2020. Individual circadian preference, shift work, and risk of medication errors: A cross-sectional web survey among Italian midwives. *International Journal of Environmental Research and Public Health*, 17, 5810.
- CARUSO, C. & ROSA, R. 2007. Shift work and long work hours. *Environmental and Occupational Medicine*, 4, 1359-64.
- CARUSO, C. C. 2006. Possible broad impacts of long work hours. *Industrial health*, 44, 531-536.
- CIPD 2021. Employee turnover and retention. *Learn how to measure turnover and retention, and understand why people leave organisations*, Available at: <https://www.cipd.ie/news-resources/practical-guidance/factsheets/turnover-retention#7169> (Accessed: 02 November 2022).
- COOPER, B. 1983. *Transformation of a valley: the Derbyshire Derwent*, Heinemann Educational Publishers.
- CROMMELIN, D., BERMEJO, T., BISSIG, M., DAMIAANS, J., KRÄMER, I. & RAMBOURG, P. 2005. Pharmaceutical evaluation of biosimilars: important differences from generic low-molecular-weight pharmaceuticals. *Eur J Hosp Pharm Sci*, 11, 11-7.
- D'ETTORRE, G., PELLICANI, V., GRECO, M., CAROLI, A. & MAZZOTTA, M. 2019. Metabolic syndrome in shift healthcare workers. *La Medicina del Lavoro*, 110, 285.
- DE CORDOVA, P. B., BRADFORD, M. A. & STONE, P. W. 2016. Increased errors and decreased performance at night: A systematic review of the evidence concerning shift work and quality. *Work*, 53, 825-834.
- DHAS, M. D. B. & KARTHIKEYAN, D. P. 2015. Work-life balance challenges and solutions: overview. *International Journal of Research in Humanities and Social Studies*, 12.
- DONG, C., ZENG, H., YANG, B., ZHANG, Y. & LI, Z. 2022. The association between long-term night shift work and metabolic syndrome: a cross-sectional study of male railway workers in southwest China. *BMC Cardiovascular Disorders*, 22, 1-7.
- DRAKE, C. L., ROEHRS, T., RICHARDSON, G., WALSH, J. K. & ROTH, T. 2004. Shift work sleep disorder: prevalence and consequences beyond that of symptomatic day workers. *Sleep*, 27, 1453-1462.
- DUBEY, N., GUPTA, H., SHARMA, R., DUBEY, N. & DUBEY, N. 2011. Pharmaceutical quality management system: Current concept. *Journal of Advanced Pharmacy Education & Research*, 2, 120-124.
- ELASSY, N. 2015. The concepts of quality, quality assurance and quality enhancement. *Quality Assurance in Education*.
- EMA 2015a. ICH guideline Q9 on quality risk management. *Committee for Human Medicinal Products*.
- EMA 2015b. ICH guideline Q10 on pharmaceutical quality system. *Committee for Human Medicinal Products*.
- EUDRALEX 2012. Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Chapter 1: Pharmaceutical Quality System. *EudraLex. The Rules Governing Medicinal Products in the European Union*
- EUDRALEX 2014. Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Chapter 6: Quality Control. *EudraLex. The Rules Governing Medicinal Products in the European Union*
- EUDRALEX 2022a. EudraLex - EU Legislation. Available: https://health.ec.europa.eu/medicinal-products/eudralex_en. (Accessed: 27 December 2022).

- EUDRALEX 2022b. EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines. Available from: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en. (Accessed: 27 December 2022).
- FATIGUESCIENCE 2020. How fatigued employees affect your business. Online Source: <https://fatiguescience.com/blog/fatigued-employees-affect-business-infographic/>. (Accessed: 24 December 2022).
- FATIMA, N., SONKAR, G. K. & SINGH, S. 2022. Circadian mechanism disruption is associated with dysregulation of inflammatory and immune responses: a systematic review. *Beni-Suef University Journal of Basic and Applied Sciences*, 11, 1-12.
- FERRI, P., GUADI, M., MARCHESELLI, L., BALDUZZI, S., MAGNANI, D. & DI LORENZO, R. 2016. The impact of shift work on the psychological and physical health of nurses in a general hospital: a comparison between rotating night shifts and day shifts. *Risk management and healthcare policy*, 9, 203.
- FITZGERALD, D. & WILSON, C. 2022a. Table of 212 Pharmaceutical and Medical Device Factories in Ireland Organised by County. Available at: <https://www.getreskilled.com/pharmaceutical-jobs/ireland-factory-table/>. (Accessed: 14Feb2023).
- FITZGERALD, D. & WILSON, C. 2022b. What Types of Jobs are there in the Pharmaceutical and Medical Device Industry? Available at: <https://www.getreskilled.com/types-of-pharma-jobs/>. (Accessed: 14Feb2023).
- FLEETWOOD, S. 2007. Why work–life balance now? *The international journal of human resource management*, 18, 387-400.
- FOLKARD, S. & TUCKER, P. 2003. Shift work, safety and productivity. *Occupational medicine*, 53, 95-101.
- GARCÍA ALCARAZ, J. L., MARTÍNEZ HERNÁNDEZ, F. A., OLGUÍN TIZNADO, J. E., REALYVÁSQUEZ VARGAS, A., JIMÉNEZ MACÍAS, E. & JAVIERRE LARDIES, C. 2021. Effect of quality lean manufacturing tools on commercial benefits gained by Mexican maquiladoras. *Mathematics*, 9, 971.
- GESREPAIR.COM 2022. 10 Ways to Foster Employee Morale at a Manufacturing Company. Available at: <https://gesrepair.com/10-ways-foster-employee-morale-manufacturing-company/>. (Accessed: 07 January 2023).
- GRIFFIN, M. 2010. The Health Risks of Shift Work. Available at: <https://www.webmd.com/sleep-disorders/features/shift-work>. (Accessed: 21 December 2022).
- GUILDING, C., LAMMINMAKI, D. & MCMANUS, L. 2014. Staff turnover costs: In search of accountability. *International Journal of Hospitality Management*, 36, 231-243.
- GUYO, W., GAKURE, R. & MWANGI, B. factors contributing to the employee turnover in pharmaceutical companies in Kenya: a case study of Ranbaxy Laboratories limited. PROCEEDINGS OF 2011 KABARAK UNIVERISTY 1 ST ANNUAL INTERNATIONAL RESEARCH CONFERENCE, 2011. 298.
- HARDING, B., AGUILAR, R., MONCUNILL, G., DOBAÑO, C., VINYALS, G. C., ESPINOSA, A., PAPANTONIOU, K. & KOGEVINAS, M. 2021. O-198 Altered levels of immune markers among male rotating night shift workers in Spain—the HORMONIT study. BMJ Publishing Group Ltd.
- HARVER.COM 2021. 10 Tactics to Reduce Employee Turnover in Manufacturing. Available at: <https://harver.com/blog/reduce-employee-turnover-manufacturing/>. (Accessed: 05 January 2023).
- HEALY, A. 2023. Ireland is one of EU's largest exporters of medicines. Available at: <https://www.irishexaminer.com/business/economy/arid-41124529.html#:~:text=New%20figures%20from%20the%20EU's,Netherlands%20on%20%E2%82%AC22bn%20each>. (Accessed: 01May2023).
- HIQA 2018. HIQA recommends promoting a national strategic approach to reduce the amount of medication errors in public acute hospitals. *HIQA News Updates*, Available at: <https://www.hiqa.ie/hiqa-news-updates/hiqa-recommends-promoting-national-strategic->

- [approach-reduce-amount-medication#:~:text=The%20Institute%20of%20Medicine%20estimated,year%20Irish%20Medication%20Safety%20Network](#)). (Accessed: 29 December 2022).
- HOM, P. W., LEE, T. W., SHAW, J. D. & HAUSKNECHT, J. P. 2017. One hundred years of employee turnover theory and research. *Journal of applied psychology*, 102, 530.
- HPRA 2022. About Us. Accessed from: <http://www.hpra.ie/homepage/about-us>. (Accessed: 27 December 2022).
- IPHA 2022. Contribution to the Irish Economy. Available at: <https://www.ipha.ie/about-us/contribution-to-the-irish-economy/>. (Accessed:01May2023).
- ISO 2015. Quality management principles. *International Organization for Standardization*.
- JACKSON, S. E. & COOPER, C. L. 1997. *Creating tomorrow's organizations: a handbook for future research in organizational behavior*, Wiley.
- JAGUN, V. 2015. An investigation into the high turnover of employees within the Irish hospitality sector, identifying what methods of retention should be adopted.
- JAMES, S. M., HONN, K. A., GADDAMEEDHI, S. & VAN DONGEN, H. 2017. Shift work: disrupted circadian rhythms and sleep—implications for health and well-being. *Current sleep medicine reports*, 3, 104-112.
- JISKROVA, G. K. 2022. Impact of COVID-19 pandemic on the workforce: from psychological distress to the Great Resignation. *J Epidemiol Community Health*, 76, 525-526.
- JULIANA, N., MOHD AZMI, N. A. S., EFFENDY, N., MOHD FAHMI TENG, N. I., AZMANI, S., BAHAROM, N., MOHAMAD YUSUFF, A. S. & ABU, I. F. 2022. Exploring the Associated Factors of Depression, Anxiety, and Stress among Healthcare Shift Workers during the COVID-19 Pandemic. *International Journal of Environmental Research and Public Health*, 19, 9420.
- KAZEMI, R., HAIDARIMOGHADAM, R., MOTAMEDZADEH, M., GOLMOHAMADI, R., SOLTANIAN, A. & ZOGHIPAYDAR, M. R. 2016. Effects of shift work on cognitive performance, sleep quality, and sleepiness among petrochemical control room operators. *Journal of circadian rhythms*, 14.
- KELLER, S. M., BERRYMAN, P. & LUKES, E. 2009. Effects of extended work shifts and shift work on patient safety, productivity, and employee health. *Aaohn Journal*, 57, 497-504.
- KER, K., EDWARDS, P. J., FELIX, L. M., BLACKHALL, K. & ROBERTS, I. 2010. Caffeine for the prevention of injuries and errors in shift workers. *Cochrane Database of Systematic Reviews*.
- KERVEZEE, L., KOSMADOPOULOS, A. & BOIVIN, D. B. 2020. Metabolic and cardiovascular consequences of shift work: The role of circadian disruption and sleep disturbances. *European Journal of Neuroscience*, 51, 396-412.
- KNUTSSON, A. 2003. Health disorders of shift workers. *Occupational medicine*, 53, 103-108.
- KRAMER, R. C. 1992. The space shuttle challenger explosion. *White collar crime reconsidered*, 214-243.
- KUMARI, G. & PANDEY, K. M. Factors influencing employees turnover and measuring its impact in pharmaceutical industry: an analytical analysis with SPSS method. Proceedings of International Conference on Communication and Computational Technologies, 2021. Springer, 519-539.
- LAWLER, E., CAMMANN, C., NADLER, D. & JENKINS, D. 1979. Michigan organizational assessment questionnaire. *Journal of Vocational Behavior*.
- LAZZARI, M., ALVAREZ, J. M. & RUGGIERI, S. 2022. Predicting and explaining employee turnover intention. *International Journal of Data Science and Analytics*, 1-14.
- LE BOT, P. 2004. Human reliability data, human error and accident models—illustration through the Three Mile Island accident analysis. *Reliability Engineering & system safety*, 83, 153-167.
- LEE, A., MYUNG, S.-K., CHO, J. J., JUNG, Y.-J., YOON, J. L. & KIM, M. Y. 2017. Night shift work and risk of depression: meta-analysis of observational studies. *Journal of Korean Medical Science*, 32, 1091-1096.
- LIANG, B., LINCOLN, B. & LAI, B. S. 2023. Generation Z Leading the Great Resignation Movement. *Rethinking Work: Essays on Building a Better Workplace*, 6.

- LOCKLEY, S. W., BARGER, L. K., AYAS, N. T., ROTHSCHILD, J. M., CZEISLER, C. A. & LANDRIGAN, C. P. 2007. Effects of health care provider work hours and sleep deprivation on safety and performance. *The Joint Commission Journal on Quality and Patient Safety*, 33, 7-18.
- LOCKWOOD, N. R. 2003. Work/life balance. *Challenges and Solutions, SHRM Research, USA*, 2.
- LSC 2018. Ireland's Biotech Boom. Available at: <https://lscconnect.com/irelands-biotech-boom/>. (Accessed: 27 December 2022).
- MATHESON, A., O'BRIEN, L. & REID, J. A. 2014. The impact of shiftwork on health: a literature review. *Journal of Clinical Nursing*, 23, 3309-3320.
- METCALF, A. Y., STOLLER, J. K., HABERMANN, M. & FRY, T. D. 2015. Respiratory therapist job perceptions: the impact of protocol use. *Respiratory care*, 60, 1556-1559.
- MOORE-EDE, M. C. & RICHARDSON, G. S. 1985. Medical implications of shift-work. *Annual review of medicine*, 36, 607-617.
- NEELY, G. H. 1999. *The relationship between employee morale and employee productivity*, Citeseer.
- NIAMH MILLER, L. H., DOROTHEE FOUCHIER, CATHERINE PARKER, REBECCA TRAPPE 2019. Ireland's Ambitions and Innovation for Drug and Research Development. *Regulatory Rapporteur - Vol. 16, N. 9*.
- O'CONNOR, F. 2021. Focus on pharmaceuticals: Ireland a global hub for pharma and medtech. Available at: <https://www.independent.ie/business/irelands-best-employers/focus-on-pharmaceuticals-ireland-a-global-hub-for-pharma-and-medtech-40451474.html>. (Accessed: 27 December 2022).
- OECD.STAT 2022. Statutory Corporate Income Tax Rates. Available at: https://stats.oecd.org/Index.aspx?DataSetCode=CTS_CIT&ga=2.68693137.1448497614.1621943646-903265589.1617788975. (Accessed: 27 December 2022).
- OHAYON, M. M., LEMOINE, P., ARNAUD-BRIANT, V. & DREYFUS, M. 2002. Prevalence and consequences of sleep disorders in a shift worker population. *Journal of psychosomatic research*, 53, 577-583.
- PIETROIUSTI, A., NERI, A., SOMMA, G., COPPETA, L., IAVICOLI, I., BERGAMASCHI, A. & MAGRINI, A. 2010. Incidence of metabolic syndrome among night-shift healthcare workers. *Occupational and environmental medicine*, 67, 54-57.
- POWER, B. 2016. Why John Deere measures employee morale every two weeks. *Harvard Business Review*, 24, 05-16.
- RAJARATNAM, S. M., HOWARD, M. E. & GRUNSTEIN, R. R. 2013. Sleep loss and circadian disruption in shift work: health burden and management. *Medical Journal of Australia*, 199, S11-S15.
- ROODT, G. 2004. Turnover Intention Scale (TIS-15). *Unpublished Document. Copyright © 2004, G. Roodt*. Available at: https://www.researchgate.net/profile/Petrus-Albertus-Botha/post/What_are_the_Turnover_Intention_Scale_TIS-6_questions/attachment/5b86e15c3843b0067536d7f8/AS%3A665026880880640%401535566172561/download/Turnover+intentions+questionnaire+-+v4.docx. (Accessed: 07 January 2023).
- SADEGHNIAT-HAGHIGHI, K. & YAZDI, Z. 2015. Fatigue management in the workplace. *Industrial psychiatry journal*, 24, 12.
- SCOTT, J. & MIGLIACCIO, G. 2009. Embedding a Culture of Continuous Improvement & Lean Manufacturing Across Pfizer Global Manufacturing.
- SEEHERUNWONG, A., CHAIEAR, N., KHUNTIKEO, N. & EKPANYASKUL, C. 1837. Cholangiocarcinoma Attributed to Occupation: A Systematic. *Asian Pacific Journal of Cancer Prevention*, 23.
- SERENKO, A. 2022. The Great Resignation: the great knowledge exodus or the onset of the Great Knowledge Revolution? *Journal of Knowledge Management*.
- SHEATHER, J. & SLATTERY, D. 2021. The great resignation—how do we support and retain staff already stretched to their limit? *bmj*, 375.

- SHEHATA, R. S. A., MOHAMED NOUR, Z. A., ABDELRAHIM BADR, A. M. & KHALIFA, E. M. 2021. Serotonin variations and sleep disorders among shift workers. A cross-sectional study. *Toxicology and Industrial Health*, 37, 603-609.
- SHEN, J. & DICKER, B. 2008. The impacts of shiftwork on employees. *The International Journal of Human Resource Management*, 19, 392-405.
- SHIMP, K. M. 2017. Systematic review of turnover/retention and staff perception of staffing and resource adequacy related to staffing. *Nursing Economics*, 35, 239-266A.
- SNELL, S. 1895. Coal Mining, and the Health of Colliers. *Journal of the Sanitary Institute*, 16, 105-124.
- SOOKOIAN, S., GEMMA, C., GIANOTTI, T. F., BURGUEÑO, A., ALVAREZ, A., GONZÁLEZ, C. D. & PIROLA, C. J. 2007. Serotonin and serotonin transporter gene variant in rotating shift workers. *Sleep*, 30, 1049-1053.
- SPECTOR, P. E., DWYER, D. J. & JEX, S. M. 1988. Relation of job stressors to affective, health, and performance outcomes: a comparison of multiple data sources. *Journal of Applied Psychology*, 73, 11.
- STANG, E. 1996. Chernobyl-System accident or human error? *Radiation protection dosimetry*, 68, 197-201.
- STEWART, J. 2011. Corporation tax: How important is the 12.5% corporate tax rate in Ireland? *Financial Times*, 8, 12.
- SU, X. 2021. Validation of the Chinese version of the turnover intention scale in social workers. *Journal of Social Service Research*, 47, 207-218.
- TALBOTT, E. O., YOUK, A. O., MCHUGH-PEMU, K. P. & ZBOROWSKI, J. V. 2003. Long-term follow-up of the residents of the Three Mile Island accident area: 1979-1998. *Environmental Health Perspectives*, 111, 341-348.
- TORQUATI, L., MIELKE, G. I., BROWN, W. J. & KOLBE-ALEXANDER, T. 2018. Shift work and the risk of cardiovascular disease. A systematic review and meta-analysis including dose-response relationship. *Scandinavian journal of work, environment & health*, 44, 229-238.
- U.S Bureau of Labor Statistics, 2019. Economic News Release. *Table 7. Workers by shift usually worked and selected characteristics, averages for the period 2017-2018*, Available at: <https://www.bls.gov/news.release/flex2.t07.htm> (Accessed: 01 November 2022).
- VAN EGERAAT, C. 2010. The scale and scope of process R&D in the Irish pharmaceutical industry. *Irish Geography*, 43, 35-58.
- VITATERNA, M. H., TAKAHASHI, J. S. & TUREK, F. W. 2001. Overview of circadian rhythms. *Alcohol research & health*, 25, 85.
- WANG, G., WANG, W. & ZHENG, Q. 2021a. Quantitative Analysis of the QMS for Pharmaceutical Manufacturing. *Journal of Pharmaceutical Innovation*, 1-18.
- WANG, N., SUN, Y., ZHANG, H., WANG, B., CHEN, C., WANG, Y., CHEN, J., TAN, X., ZHANG, J. & XIA, F. 2021b. Long-term night shift work is associated with the risk of atrial fibrillation and coronary heart disease. *European Heart Journal*, 42, 4180-4188.
- WATERS, S. 2021. How not to lose sleep over your circadian rhythms. Available at: <https://www.betterup.com/blog/circadian-rhythms>. (Accessed on: 21 December 2022).
- WHO 2007. *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection*, World Health Organization.
- WILLIAMS, C. 2008. *Work-life balance of shift workers*, Statistics Canada Ottawa, Ontario, Canada.
- WILSON, J. 2022. Road deaths in Ireland drop to record low in 2021. *The Irish Times*, Available at: <https://www.irishtimes.com/news/ireland/irish-news/road-deaths-in-ireland-drop-to-record-low-in-2021-1.4766748>. (Accessed: 29 December 2022).
- YABLOKOV, A. V., NESTERENKO, V. B., NESTERENKO, A. V. & SHERMAN-NEVINGER, J. D. 2010. *Chernobyl: Consequences of the Catastrophe for People and the Environment*, John Wiley & Sons.

- YUNG, M., DU, B., GRUBER, J., HACKNEY, A. & YAZDANI, A. 2022. Fatigue measures and risk assessment tools for first responder fatigue risk management: A scoping review with considerations of the multidimensionality of fatigue. *Safety Science*, 154, 105839.
- YUNG, M., KOLUS, A., WELLS, R. & NEUMANN, W. P. 2020. Examining the fatigue-quality relationship in manufacturing. *Applied Ergonomics*, 82, 102919.

Appendices

Appendix A- Interview Questions

I would like to know how quality assurance performed in the company. So, what is done when a quality issue is identified? How is the issue investigated? How is it recorded and/or reported? How are the impacts managed?

Listen to answer and get them to expand on points if necessary

Would the overall process you've described be common practise in other companies within the pharmaceutical manufacturing industry?

Listen to answer and get them to expand on points if necessary

What are the most common quality issues? Are there any specific causes which can be attributed to those common quality issues?

Listen to answer and get them to expand on points if necessary

What is the most common quality issue associated with human error?

Listen to answer and get them to expand on points if necessary

Some pharmaceutical manufacturing plants have to work 24/7 to meet business demand. Do you believe there are any negative effects of shift work on product quality?

Listen to answer and get them to expand on points if necessary

Do you think that there are any other human contributory factors other than sleep deprivation associated with quality assurance?

Listen to answer and get them to expand on points if necessary

Do you think that people working in the quality assurance department notice an increase in quality issues during different times in the day like more deviations during a night shift versus a day shift?

Listen to answer and get them to expand on points if necessary

Can you think of anything that is currently being done in an attempt to decrease quality assurance issues related to working irregular hours?

Listen to answer and get them to expand on points if necessary

Are you aware of the term right first-time manufacturing? Do you believe that irregular working hours has any impact on the rate of right first-time manufacturing?

Listen to answer and get them to expand on points if necessary

Again, why do you think that is? Do you think there is anything else contributing to decreased right first-time manufacturing?

Listen to answer and get them to expand on points if necessary

Do you think that decreased quality as a result of irregular working hours costs much to the company? Would you be able to make an estimate at all? (Or even a recorded cost if documented) How much do you think a right first-time error would cost?

Listen to answer and get them to expand on points if necessary

What are the most common impacts from quality issues? Is this formally measured or your own perception?

Listen to answer and get them to expand on points if necessary

Do you think the costs and impacts associated with decreased quality assurance make manufacturing 24/7 worthwhile?

Listen to answer and get them to expand on points if necessary

Do you think an organisation can confidently stand over a product which may have impaired quality due to employees manufacturing it working irregular hours?

Listen to answer and get them to expand on points if necessary

Do you think quality errors have any impact on the public's perception of drug safety?

Listen to answer and get them to expand on points if necessary

Do you think quality errors impact a batch's disposition and therefore impact the accessibility of the medicine to the public?

Listen to answer and get them to expand on points if necessary

Is there anything else that you would like to discuss in the area of quality and shift work which you think is important that we missed earlier during this interview before we close out?

Listen to answer and get them to expand on points if necessary

Appendix B- Survey Questions

Available at: <https://www.questionpro.com/a/TakeSurvey?tt=hcbMOujkLXMECHrPeIW9eQ%3D%3D>

Hello,

You are invited to participate in my survey investigating the impact of shift work on human resources. In this survey, approximately 50 people will be asked to complete a survey that asks questions about staff turnover intention and staff morale. This survey will investigate responses from both people that do shift work and those that don't in the pharmaceutical industry. It will take approximately 15 minutes to complete the questionnaire.

Your participation in this study is completely voluntary. There are no foreseeable risks associated with this project. However, if you feel uncomfortable answering any questions, you can withdraw from the survey at any point.

It is very important to learn your opinions. Your survey responses will be strictly confidential and data from this research will be reported only in the aggregate. Your information will be coded and will remain confidential. If you have questions at any time about the survey or the procedures, you may contact Charlotte Lucas at charlotte.lucas97@hotmail.com. Thank you very much for your time and support. Please start with the survey now by clicking on the **Start** button below.

Introduction Section

I understand what this survey is about	Yes No
I consent to taking part in this survey	Yes No
I work in the pharmaceutical industry	Yes No
I work shift work	Yes No

Section 1: Staff Morale

Read the following statements and answer truthfully:

I often look forward to another day at work.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe that I have a good work/life balance.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I find my current job to be fulfilling.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I enjoy the hours that I work.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe that there is a good staff morale in my organisation.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I have a positive relationship with my work colleagues.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I feel secure in this job.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe working hours are an important aspect of a job.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I feel my current job negatively effects my personal well-being.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I frequently feel emotionally agitated when I arrive home from work.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I frequently feel under pressure in my current role.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

Workplace stress affects my life outside of work.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I often feel tired when I am working.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

When I get home from work, I am too tired to do anything else.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I frequently miss personal events because of work.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

Overall, I feel like I have good staff morale in my current position.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

Section 2: Turnover Intention

Read the following statements and answer truthfully:

I believe that I will be in the job I'm currently doing this time next year.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe that I will be in the job I'm currently doing in two years' time.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe that I will be in the job I'm currently doing in three years' time.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe that I will be in the job I'm currently doing in over three years' time.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I currently have intentions to quit my current job.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe benefits associated with my current job prevent me from quitting.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I believe that I would accept another job offer today if I received it.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I have interviewed for another organisation in the last 3 months.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I often dream about getting another job that will suit my personal needs better.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

I frequently scan the internet in search of alternative job opportunities.

Strongly Agree Agree Unsure/ Neutral Disagree Strongly Disagree

If you were to give notice to leave your job what would the primary reason be?

Compensation Package

Opportunities for Growth

Work Culture

Work-Life Balance

Job flexibility

Company Management

Other: _____