Staying Ahead in Patient Safety and Compliance: Assessing the awareness of Regulatory Requirements in an Irish Medical Devices Distributor

A thesis submitted in partial fulfilment of the requirements form M.Sc. in Medical Devices and Business

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by

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Declaration

“I hereby declare that this dissertation entitled “Staying Ahead in Patient Safety and Compliance: Assessing the awareness of Regulatory Requirements in an Irish Medical Devices Distributor”, submitted in partial fulfilment of the M.Sc. in Medical Devices and Business, is entirely my own, according to my personal study and research, and I acknowledged all material and sources used for the purposes of the study purpose. I also certify that I have not copied in part or whole or otherwise plagiarised the work of anyone else, including other students.”

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Abstract

Staying Ahead in Patient Safety and Compliance: Assessing the awareness of Regulatory Requirements in an Irish Medical Devices Distributor

Safety is paramount in the medical device industry. The main aim of Medical Device Regulation (MDR) is to improve patient safety. The primary aim this study was to investigation the level of awareness and perception of MDR within an Irish Medical Distributor.

A mixed methodology was used in this study. Seventy four surveys and four interviews were completed to obtain qualitative and quantitative data from managers and employees at every level of the organisation.

This study show a significant level of awareness and understanding of MDR among employees, particularly in the areas of adverse event reporting and CE (Conformite Europeenne) marking. However, variations in the perceived importance of MDR across different roles within the organisation suggest the need for tailored training and communication strategies to ensure uniform understanding and compliance. The research also revealed a positive overall perception of MDR among both employees and management.Qualitative findings from interviews with management highlight a positive attitude towards MDR, and recognising the commercial advantages of excellence in MDR awareness.

Based on the findings of this study, several recommendations for future research and practice emerge. Firstly, there is a need for comparative research focusing on non-managerial roles across the spectrum of the medical device industry. Secondly, a longitudinal study could assess the effectiveness of formal training programs over time, tracking knowledge retention and identifying areas for improvement. Additionally, the study could be expanded to examine MDR awareness and perception levels alongside assessment of organisational culture within a company to see if there is correlation. It could also be valuable to assess the level of awareness and perception in MDR among those in the manufacturing sector of medical devices and among healthcare professionals using or implanting medical devices.

In conclusion, this research contributes valuable insights into the level of MDR awareness and perception among employees and manager within an Irish Medical Devices Distributor and highlights the importance of a positive organisational culture and tailored training and communication strategies to ensure regulatory compliance and optimise patient safety.

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To my mother, for giving me my love for education.

Chapter 1: Introduction

1.1 Research topic

The Irish Medical Device market faces unique challenges within the EU, which make awareness of the regulatory landscape both complicated and vital to ensure patient safety, (Hussko et al, 2023). Ireland occupies a unique and challenging position within the framework of Medical Device Regulation. As a country, we are challenged with navigating the regulatory systems of post-Brexit Britain, the European Union, and Northern Ireland.

In their 2023 study, Hussko, Kinnunen, and Saranto underscore the crucial role of familiarity with Medical Device Regulation (MDR) in safeguarding the safety, efficacy, and compliance of the medical device market. Particularly pertinent in the context of the Irish Medical Device market, where unique challenges within the EU necessitate a nuanced understanding of regulatory frameworks, adherence to the EU MDR 2017/745 and 746 emerges not only as a regulatory obligation but as a cornerstone in ensuring patient safety, amid the intricate interplay of regulations such as those set by neighbouring markets like post-Brexit Britain (Han et al, 2022).

In the realm of medical devices, the heartbeat of regulatory compliance and patient safety resonates prominently within the distribution landscape, particularly in the context of Ireland. Amidst the evolving regulatory framework spearheaded by the current European Medical Device Regulation (MDR 2017 145/146), the role of medical device distributors within the Irish market stands as a focal point for ensuring adherence to stringent regulatory standards set forth by the Health Products Regulatory Authority (HPRA), the national regulatory body overseeing medical devices in Ireland. Compliance with appropriate, region specific, MDR is paramount to guarantee the quality, safety, and efficacy of medical devices circulating within a country's healthcare system (Widensohler, 2000).

The evolving regulatory landscape of Europe is centred around the novation of the regulatory legislation from the Medical Device Directive (MDD) to the EU MDR 2017 145/146.

This research endeavours to explore the extent to which the workforce of an Irish Medical Device

Distributor is cognisant of Medical Device Regulation, and highlight any requirements for further training or research into this area. While the scope of this research in the main investigates awareness of the EU MDR 2017/745/746, it is clear that an understanding of the importance of this awareness is only possibly while considering the complex regulatory landscape in which an Irish Medical Device Distributor operates.

1.2 Hypothesis

A proactive strategy aimed at maintaining patient safety and regulatory compliance within an Irish Medical Devices Distributor, including targeted, role specific training and dissemination of information, will lead to increased awareness of Medical Device Regulation (MDR) requirements among employees. Furthermore, individuals in customer-facing roles are anticipated to demonstrate a deeper understanding of MDR due to its potential impact on customer interactions. It is hypothesised that employees directly involved with CE marked medical devices will exhibit heightened awareness of MDR compared to those not engaged in handling such devices. Additionally, the efficacy of internal referral mechanisms for addressing MDR-related inquiries is expected to positively correlate with overall levels of awareness among employees.

1.3 Key objectives of this proposed research

1. To determine the level of awareness and perception of Medical Device Regulation within an Irish Medical Device Distributor.
2. To evaluate if the perceptions and awareness of Medical Device Regulation among the workforce match that deemed desirable by those in management roles within an Irish Medical Device Distributor.
3. To evaluate if an education program in regards to Medical Device Regulation would be useful to improve awareness and perception amongst the workforce of an Irish Medical Device Distributor.

Research questions linked to objectives

• What is the current awareness level among employees regarding the new Medical Device Regulation 2017/745 and 746?

• Is awareness of the current MDR perceived to be necessary for employees in their respective roles? How do employees perceive the importance of compliance with medical devicer regulation in ensuring the safety and efficacy of medical devices distributed by the organisation?

• Do employees regard Medical Device Regulation as a positive or negative thing in relation to their area of work?

• Does awareness of medical device regulation vary across different roles within the distributor, particularly between frontline customer support roles and other positions?

• Does awareness of medical device regulation and appropriate compliance markings vary countrywide, both north and south of the border?

• To what extent are employees familiar with the European Union Medical Device Regulation (MDR), the CE mark, the UKCA, and the CE UKNI created by the unique regulatory arrangement in Northern Ireland post-Northern Ireland Agreement?

• What factors influence awareness of medical device regulation within the distributor, including training, communication channels, and exposure to regulatory standards?

• What level of knowledge of adverse event reporting is present among those working for the Irish Medical Devices Distributor?

• Do employees understand the importance of the CE mark in the context of medical devices?

• Have employees received any formal training on the MDR and if so, how much?

• Does the workforce know who the responsible person in the company is to refer any questions with regards the MDR or regulation in general?

1.4 Scope and limitations of this Study

This study was somewhat geographically limited in scope in that only one Irish Medical Device Distributor is involved in the study.

The study is also limited in the fact that it is a case study by design. This allows for an in-depth study of the organisation in question but generalisability is compromised.

1.5 Overview of this dissertation

This study is composed of five chapters.

Chapter one introduces the topic, purpose, hypothesis and research questions, significance, scope, and structure of this study.

Chapter two includes a review of pertinent literature on the topic of at hand: beginning with a short introduction to the relevant Medical Device Regulations, and then moving towards a discussion of the relevance of the awareness of these regulations. The perception of medical device regulation and its' relation to awareness and education on the topic are also be discussed in the literature review. The gaps in the available literature are identified and the foundational literature for this research is discussed.

Chapter three discusses the research methodology adopted by the study. The research philosophy, design, strategy and approach are discussed. Data collection details are discussed for the collation of primary data and analysis methods thereof are detailed.

Chapter four reports the findings of the primary data collection and the statistical analysis performed on the data.

Chapter five involves a discussion of the findings of the primary research data and provides insights, intellectual analysis and suggestions for further research based on these findings.

1.6 Conclusion

This research embarks on a nuanced exploration of staff knowledge levels, training paradigms, management expectations, and staff perceptions towards medical device regulations within the medical device distributor. It endeavours to shed some light on the interconnected factors that underpin organisational readiness, regulatory compliance, and ethical stewardship within the dynamic landscape of medical device distribution in Ireland. By scrutinising the intricacies of staff expertise, training mechanisms, and perceptual frameworks, this research serves as an insight to guide stakeholders towards a future where knowledge empowerment, training excellence, and regulatory acumen converge to elevate the standards of patient care, organisational excellence, and industry best practices within the medical device distribution ecosystem. The topic of this dissertation is of paramount importance in an evolving regulatory landscape in order to assess and evaluate knowledge and perception of current MDR within the studied population in order to ensure patient safety.

Chapter 2 Literature review

2.1 A brief introduction to the Current Medical Device Regulation 2017/745 and 746 (MDR)

The MDR, enacted by the European Parliament and the Council, represents a fundamental shift in the regulatory landscape for medical devices within the European Union. This legislation replaced the Medical Device Directive (MDD). These regulations, applicable to medical devices and in vitro diagnostic medical devices respectively, aim to establish a robust, transparent, and sustainable regulatory framework. The MDR places a strong emphasis on patient safety, public health, and innovation, necessitating compliance by manufacturers, distributors, and other stakeholders in the medical device industry.

The importance of the MDR lies in its comprehensive approach to ensuring the safety and efficacy of medical devices placed on the market. It introduces stricter requirements for clinical evidence, post-market surveillance, and vigilance, fostering a culture of continuous improvement and accountability. The MDR also incorporates advancements in technology and addresses challenges posed by globalisation, aligning with international standards to facilitate global trade and harmonisation.

(Bretthauer et al., 2023) emphasise the primary goal of the MDR is to balance patient safety and innovation. The recent inquiry into an allegedly non-compliant medical device reportedly implanted in children during spinal deformity surgery underscores the critical need to enhance awareness of accurate compliance markings and adverse event reporting procedures among individuals dealing with medical devices (The Irish Independent, 2023). This is particularly crucial for those involved in the management of implantable medical devices and even more so for those present in the operating theatre when these implants are used.

For those in the Medical Device Industry, awareness of the MDR is paramount. Compliance with the regulation is not only a legal requirement but also a strategic imperative (George et al, 2022). Companies that stay ahead in understanding and implementing the MDR are better positioned to navigate the complexities of the regulatory environment, ensure product quality, and enhance their market competitiveness (Bretthauer et al, 2023). Additionally, heightened awareness enables

stakeholders to proactively address challenges, contribute to regulatory discussions, and adapt to evolving standards.

In summary, the MDR 2017/745 and 746 serve as cornerstones in ensuring the safety and effectiveness of medical devices, shaping the future of the industry. Awareness of these regulations is not only a legal obligation but a strategic advantage for those in the Medical Device Industry, fostering a culture of compliance, innovation, and patient-centricity.

2.2 Key changes between the MDD and the Current MDR 2017/745, 746

The transition from the Medical Device Directive MDD to the MDR 2017 145/146 has introduced significant changes in the regulatory landscape for medical devices within the European Union. A summary of these changes is provided in Table 1:

One notable change is the expansion of the scope of medical devices under the MDR, which now includes products without a medical purpose, such as certain cosmetic implants. Additionally, there have been alterations in the classification criteria for some devices, impacting their regulatory requirements (MDR, no date).

The MDR has implemented a Unique Device Identification (UDI) system to enhance traceability and post-market surveillance. This system involves assigning a unique numeric or alphanumeric code to each medical device.

Stricter requirements have been imposed on Notified Bodies, responsible for assessing the conformity of devices. There is also an increased emphasis on scrutiny and monitoring of Notified Bodies to ensure adherence to higher standards.

Post-market surveillance requirements for manufacturers have been strengthened. The MDR places a greater focus on continuous monitoring and reporting of device performance to ensure ongoing compliance.

The MDR introduces more rigorous requirements for clinical evidence and evaluation, emphasising the importance of clinical investigations in establishing the safety and efficacy of medical devices.

The establishment of the Eudamed database is a key development, aiming to centralise information on medical devices. This database includes registration of economic operators and reporting of serious incidents, contributing to increased transparency in the market.

The MDR aims to improve transparency further by providing public access to certain information. Additionally, market surveillance efforts have been strengthened to ensure ongoing compliance and uphold a high level of safety and efficacy for medical devices in the European market.

These changes collectively represent a shift towards a more stringent and comprehensive regulatory framework under the MDR compared to the previous MDD, all with the primary aim of improving the safety of medical devices. Manufacturers, Notified Bodies, and other stakeholders in the medical device industry are required to adapt to these changes to ensure compliance and maintain the safety and efficacy of medical devices in the European market.

2.3 Awareness and Perception of the Current EU MDR 2017 745/746

In my research, I draw upon the foundational work laid out by Bianchi and Mayer (2022). Their study has provided crucial insights into the landscape of Medical Device Regulation (MDR) awareness, prompting a pivotal suggestion for additional research in the form of surveys. Their encouragement to explore MDR awareness through survey methodologies has served as the primary inspiration for the formulation and focus of my research paper. I aim to build upon their groundwork and contribute to the understanding of MDR awareness in the specific context of an Irish Medical Device Distributor.

Bianchini and Mayer (2022) suggest that assessment of MDR awareness should be examined by surveying those involved at all stages of the medical device lifecycle. Their article serves as a foundational piece for the planning this study. They suggest that the heavy burden of the complex legislation may be born largely in the early stages of development of a device until the point of granting of a CE mark. It is at a later point in the lifecycle of the device, where the device approaches the end-user that an awareness of the MDR, CE marking and intended use that the level of awareness of the MDR among those associated with a medical device is less well known. Given the new and stringent regulations concerning risk management throughout the lifecycle of a device, including managing human risk factors, Bianchini and Mayer (2022), suggest that it is important to assess any gaps in knowledge of those handling or using the device.

Foo and Tan, 2017, also suggest that increased awareness of the MDR and the importance of CE marking is vital. They suggest that while the regulators and medical device manufacturers appreciate the significance and clinical implications of regulation and conformity markings, the significance and understanding of same may not be apparent to the very professionals who are using or maintaining the device, nor indeed to the general public. With digital and portable healthcare devices and mobile applications gaining popularity, better awareness of certification marking will

be needed. Particularly, they suggest, better awareness is required of any deviation from the intended purpose of the medical device.

The article by Wilkinson and Van Boxtel (2020) underscores the heightened focus on evaluating the clinical benefits of medical devices within the European Union's Medical Device Regulation (MDR). This regulatory framework aims to bolster patient safety and efficacy standards through more rigorous requirements. For my research into the awareness and perception of medical device regulation within an Irish Medical Device Distributor, this article is pivotal. It highlights the necessity for distributors to grasp and adhere to the updated regulatory standards outlined in the MDR. Understanding the clinical aspects of the devices they distribute is crucial in meeting these requirements. This article serves as a valuable resource in exploring how distributors perceive and navigate the evolving regulatory landscape, particularly concerning the assessment of clinical benefits mandated by the MDR.

The article by Kearney and McDermott (2023) delves into the challenges faced by manufacturers due to the heightened emphasis on clinical evaluation in the European Medical Device Regulations (MDR). Through a quantitative study, the authors examine the specific hurdles manufacturers encounter in complying with the increased clinical evaluation requirements. For my research on the awareness and perception of medical device regulation within an Irish Medical Device Distributor, this article offers valuable insights. It sheds light on the difficulties manufacturers face in meeting the more stringent clinical evaluation criteria imposed by the MDR. Understanding these challenges is similarly essential for distributors, as it allows us to comprehend the broader regulatory landscape and the potential impact on the devices they distribute. This article serves as a significant resource in exploring how changes in regulatory requirements affect not only manufacturers but also downstream stakeholders like distributors, highlighting the importance of staying informed and adaptable in response to evolving regulations.

Perception of MDR

Little is written in the literature about the perception within the wider Medical Device community in relation to Medical Device Regulation and its' perceived positive or negative effects on the industry. One of the aims of this study is to fill this void in the scholarly literature. Negative perceptions or misconceptions about regulations may impede compliance with regulations and innovation in the adoption of new medical technologies (Maccaro et al, 2022). Thus, addressing and reshaping these perceptions through education and communication strategies is crucial for fostering a culture of compliance and improving regulatory effectiveness (Maccaro et al., 2022). To this end, one of the critical aims of this study is the identification of the existing perceptions of Medical Device Regulation within the industry, and specifically within the Irish Medical Device Distributor that is being examined.

Some might argue that it would be in the best interests of the HPRA to grasp the awareness and perception of Medical Device Regulation within an Irish Medical Device Distributor and the broader Irish Medical Device community both North and South of the border. Such insight at a grassroots level could enable targeted information programs, addressing any identified gaps effectively. This understanding would allow the HPRA to tailor their strategies appropriately, ensuring optimal adoption and adherence to Medical Device Regulation in Ireland. Ultimately, this approach fosters a regulatory environment that is responsive to industry needs and bolsters public confidence in medical device standards.

In examining the perception of Medical Device Regulation (MDR) within an Irish Medical Device Distributor, the systematic review by Polisena et al. (2015), although prior to the adoption of the MDR 2017 145/146, offers valuable insights into factors influencing incident recognition, reporting, and resolution within healthcare settings. The study identifies barriers such as fear of punishment, uncertainty about reporting criteria, and lack of time, which hinder incident reporting among healthcare professionals. These findings are pertinent to understanding the challenges faced by employees within the medical device arena, as they navigate regulatory requirements and safety protocols. For instance, perceptions of punitive measures or ambiguity surrounding reporting guidelines may discourage timely and accurate incident reporting, posing risks to patient safety and regulatory compliance.

Furthermore, the review underscores the importance of organisational culture, feedback mechanisms, and training in fostering a culture of incident reporting and continuous improvement. Similar considerations can be applied to the context of medical device distribution in Ireland, where establishing robust reporting systems and promoting open communication channels are essential for ensuring product safety and regulatory adherence. By aligning with the recommendations proposed in the systematic review, such as implementing accessible electronic reporting systems and providing training on reporting protocols, Irish medical device distributors can enhance awareness and perception of MDR among their workforce.

Incorporating insights from the study by Polisna et al. (2015), enriches the understanding of incident management practices within the medical device industry. By drawing parallels between the findings of Polisena et al. (2015) and the specific challenges faced by Irish medical device distributors in complying with MDR requirements, this study can provide contextually relevant recommendations for improving awareness and more specifically perception of regulatory processes. Moreover, addressing the identified barriers to incident reporting highlighted in the systematic review can inform policy recommendations aimed at strengthening regulatory oversight and promoting patient safety within the Irish medical device distribution sector.

2.4 Organisational Culture and the Effects on Safety and Awareness

The article by Smith-Crowe, Burke, and Landis (2003) delves into the concept of organisational climate as a moderator of the relationship between safety knowledge and safety performance within workplaces. It explores how the prevailing organisational climate influences the effectiveness of safety knowledge on actual safety behaviours and outcomes. This study underscores the importance of considering broader organisational contexts in shaping individual safety-related behaviours and performance. In the context of my research into the awareness and knowledge of Medical Device Regulation within an Irish Medical Device Distributor, this article highlights the significance of organisational factors in influencing employees' understanding and adherence to regulatory requirements. Understanding the organisational climate within the distributor can offer valuable insights into how employees perceive and implement regulatory compliance, thus impacting the company's overall regulatory effectiveness and safety performance.

2.5 The Effects of MDR of the Workforce and Wider Healthcare Community

Promoting positive perception and evaluating awareness regarding Medical Device Regulation (MDR) and patient safety within the medical device industry is of paramount importance for several reasons. Firstly, while any MDR aims to ensure the safety and efficacy of medical devices, fostering a positive perception among stakeholders such as healthcare professionals, distributors, and patients is crucial for building trust in these devices (Maccaro et al, 2022). Positive perceptions can lead to increased adoption rates and compliance with regulatory standards, ultimately enhancing patient safety (Maccaro et al,, 2022). Moreover, evaluating awareness levels helps identify potential gaps in understanding or implementation of regulatory requirements, allowing for targeted education and training initiatives (Hill, 2009). Clearly identifying individuals or departments responsible for promoting positive perceptions and ensuring awareness facilitates accountability and streamlines communication channels, enabling swift response to emerging issues or concerns. By proactively addressing perception and awareness within the medical device industry, this study aims to promote stakeholders to work collaboratively towards safer and more effective healthcare outcomes, reinforcing trust and confidence in medical devices.

2.6 Importance of Awareness of the Current EU MDR 2017 145/146 in an Irish Medical Distributor

The awareness of the MDR across the workforce of an Irish Medical Devices Distributor is indispensable for multiple reasons, encompassing regulatory compliance, quality assurance, and overall business sustainability. In terms of regulatory compliance, it is not only advisable but also a legal obligation for the workforce to be well-versed in the MDR. The regulations outlined in the MDR form the basis for ensuring the safety and performance of medical devices, and non-compliance can result in severe consequences, including legal repercussions and issues with market access (Vasljeva, Van Duren and Prandt, 2020).

Quality assurance and patient safety are paramount considerations, with the MDR placing a strong emphasis on these aspects. Workforce awareness is essential to guarantee that all processes, spanning from manufacturing to distribution, align with regulatory standards, contributing to the production of high-quality and safe medical devices (Bianchini and Mayer, 2022). A proactive approach to regulatory changes is facilitated by awareness, allowing the workforce to stay ahead of

significant changes introduced by the MDR. This proactive stance is crucial for maintaining business continuity and preventing disruptions in the supply chain (Sen, 2021).

Efficient internal processes are another outcome of workforce awareness, as it ensures that employees are well-informed about MDR requirements and internal procedures related to compliance. This awareness facilitates efficient communication channels within the organisation, reducing the likelihood of misunderstandings and ensuring alignment with regulatory expectations (Bianchini and Mayer, 2022). Customer confidence and market competitiveness are also positively influenced by a workforce that is aware of and adheres to MDR standards (Carden and Oldapo, 2021). Such awareness contributes to the overall reputation of the company, enhancing customer confidence in the quality and safety of distributed medical devices, which is particularly valuable in the competitive medical devices industry (Wicks, 2013).

In terms of risk mitigation, awareness of the MDR enables the workforce to identify potential risks and challenges related to regulatory compliance (Bretthauer et al, 2023). This understanding empowers employees to contribute to risk mitigation strategies and the development of effective quality management systems (Carden and Oldapo, 2021). Lastly, fostering a culture of continuous improvement and compliance within the organisation is facilitated by building awareness. This culture not only benefits meeting regulatory requirements but also drives overall operational excellence (Jiang et al, 2023).

The recent study conducted by Maccaro et al. (2022) on the universality of medical device regulations, specifically focusing on Benin, provides significant insights into the importance of awareness and perception of Medical Device Regulation. Maccaro et al. (2022) highlight how inadequate awareness and understanding of medical device regulations can hinder regulatory compliance, potentially compromising patient safety and quality of care. This underscores the critical need to enhance awareness among healthcare professionals, regulatory bodies, and medical device distributors to ensure adherence to regulatory standards (Maccaro et al., 2022).

Moreover, the research illuminates how perceptions of Medical Device Regulation can impact behaviour and decision-making within healthcare settings. Negative perceptions or misconceptions about regulations may impede compliance and innovation in the adoption of new medical technologies. Thus, addressing and reshaping these perceptions through education and communication strategies is crucial for fostering a culture of compliance and improving regulatory

effectiveness (Maccaro et al., 2022). The findings from Maccaro et al.'s (2022) study emphasise the interconnected nature of awareness, perception, and regulatory compliance in the domain of medical device regulations. By addressing awareness gaps and promoting positive perceptions, stakeholders can contribute to a safer and more efficient healthcare environment that upholds regulatory standards (Maccaro et al., 2022).

The study conducted by McDermott and Kearney (2024) investigates the significance of real-world evidence (RWE) within the context of European medical device regulations, particularly regarding its role in providing clinical evidence. Through a mixed-methods approach, the authors explore how the integration of RWE impacts stakeholders' awareness and perception of medical device regulation. This research is pertinent to my investigation into the awareness and perception of medical device regulation within an Irish Medical Device Distributor. It highlights the evolving regulatory landscape and the growing importance of alternative sources of evidence, such as RWE, in demonstrating the safety and effectiveness of medical devices. As distributors, understanding the role and implications of RWE in regulatory compliance is crucial for shaping our awareness and perception of medical device regulation. This study serves as a valuable resource in exploring how the integration of RWE influences stakeholders' perceptions, attitudes, and practices related to medical device regulation, thus informing strategies for navigating the regulatory environment effectively.

An Irish Medical Devices Distributor operating across the border faces a unique set of challenges due to the regulatory differences between Northern Ireland and the Republic of Ireland (Regulating medical devices in the UK, 2024). A thorough search of the available academic literature yields nothing in regard to these unique challenges. With the EU Medical Device Regulation (MDR) 2017/745 governing devices south of the border, necessitating the CE compliance marking, and the compliance mark in Northern Ireland being either the CE UKNI or the CE mark, navigating these distinctions becomes critical. This creates complexity in ensuring that devices meet the necessary regulatory standards for both territories, as well as in managing the logistics of distribution. Moreover, the Northern Ireland Protocol further complicates matters by introducing separate regulations governing medical devices in Northern Ireland compared to Great Britain (Han et al, 2022). Therefore, an Irish Medical Devices Distributor must carefully navigate these regulatory nuances to ensure compliance and seamless distribution of medical devices across both sides of the Irish border.

In summary, awareness of the MDR across the workforce of an Irish Medical Devices Distributor is vital for ensuring compliance, maintaining product quality, and fostering a culture of continuous improvement. It is a strategic imperative that contributes to the long-term success and sustainability of the organisation in a highly regulated and competitive industry.

The awareness of Medical Device Regulation (MDR) and whether a medical device being implanted bears the correct compliance marking is crucial for all employees within a medical devices distributor, but customer-facing employees play a particularly vital role in ensuring patient safety and regulatory compliance.

Importance of MDR Awareness for Customer-Facing Employees:

Customer-facing employees, including sales representatives and customer service personnel, play a pivotal role as frontline communicators between the medical device company and its clients. These employees engage directly with healthcare professionals, clinicians, and end-users, making their understanding of Medical Device Regulation (MDR) crucial. This comprehension enables them to effectively address customer queries, provide accurate information regarding regulatory compliance, and instil confidence in the quality and safety of the distributed medical devices (Bianchini and Mayer, 2022).

In the healthcare sector, customer trust holds significant value, and customer-facing employees contribute to building this trust. A comprehensive knowledge of MDR allows these employees to convey the company's commitment to regulatory compliance, fostering a positive perception of the organisation and its dedication to quality and safety, which is especially important in the healthcare industry (Hendy and Barlow, 2012).

Customer-facing employees may encounter regulatory inquiries or requests for documentation from customers. A profound understanding of MDR equips these employees to respond effectively, ensuring that necessary information is provided promptly and accurately. This proficiency contributes to the overall efficiency of the organisation's response to regulatory-related matters (George et al, 2022).

Compliance with regulatory standards is a shared responsibility across the organisation, and customer-facing employees, through their awareness of MDR, align their interactions with customers according to regulatory expectations. This proactive approach helps prevent potential

regulatory issues and fosters a culture of compliance throughout the company (Hendy and Barlow, 2012).

Moreover, customer-facing employees who possess knowledge about MDR contribute valuable insights to the company's continuous improvement efforts. Their direct interactions with customers reveal areas where the organisation can enhance its processes or better meet customer expectations regarding regulatory compliance, thus contributing to the company's overall development (Hendy and Barlow, 2012).

In the dynamic medical device industry, sales representatives serve as frontline ambassadors for the organisation, establishing crucial connections with hospital staff and stakeholders. Their awareness of the MDR is not only a regulatory obligation but a strategic imperative. It underscores the company's commitment to delivering products of the highest quality and safety, positioning sales representatives as key contributors to the success of the organisation in the competitive and regulated healthcare environment.

In conclusion, while MDR awareness is vital across the entire workforce, its particular significance for customer-facing employees cannot be overstated. Their understanding of regulatory requirements ensures compliance, builds customer trust, facilitates regulatory inquiries, and contributes to the overall success and reputation of the medical devices distributor.

2.7 Who is responsible for increasing awareness of the MDR?

The responsibility for informing organisations, individuals, and stakeholders about the MDR primarily lies with regulatory authorities and governing bodies involved in medical devices. These entities take the lead in disseminating information, providing guidance, and ensuring that relevant parties are aware of the regulatory requirements. While regulatory authorities take the lead, a collaborative effort involving various stakeholders ensures that information about the MDR is effectively communicated throughout the medical devices industry. It is essential for organisations and individuals to actively seek and engage with official channels and resources to stay informed about regulatory requirements.

Stakeholders in the medical devices industry play distinct roles in promoting awareness and compliance with regulatory requirements. Regulatory authorities, such as the European Medicines Agency (EMA) at the EU level and national health authorities within member states, are pivotal in disseminating information about the Medical Device Regulation and offering guidance on

compliance. Medical device manufacturers bear the responsibility of staying informed about regulatory changes, including the MDR, and communicating these changes to employees, distributors, and other relevant parties (Herman and Goossens, 2019). They are instrumental in ensuring that their devices align with regulatory requirements.

Similarly, medical device distributors have the responsibility of understanding and adhering to the MDR, especially when involved in the distribution of medical devices within the EU. Their role is crucial in guaranteeing that the devices they handle comply with regulatory standards (Widensohler, 2000). Healthcare professionals, working in hospitals, clinics, and healthcare facilities, need to be aware of the regulatory landscape. Training programs and educational initiatives within healthcare institutions contribute significantly to the awareness of MDR requirements (Foo and Tan, 2017).

Educational institutions and certification bodies, as training and certification organisations, also contribute to disseminating knowledge about regulatory requirements. Courses and certification programs should frequently incorporate information on MDR compliance (Foo and Tan, 2017). Industry associations, operating at national and international levels, play a role in distributing information about regulatory changes. They may organise workshops, conferences, and provide resources to enhance awareness among their members (Foo and Tan, 2017).

Regulatory consultants and advisors, specialising in regulatory affairs and compliance consulting, assist companies in understanding and implementing MDR requirements. They offer guidance on navigating the complexities of the regulatory landscape (Fudim et al, 2021). In conclusion, the responsibility for creating a culture of awareness and compliance with the MDR is shared among these stakeholders. Effective communication, training programs, and collaboration among these entities are essential to ensuring that all relevant parties throughout the life-cycle of the medical device are well-informed about regulatory requirements.

2.8 **Conclusion**

The literature review chapter outlines the critical aspects of the current Medical Device Regulation (MDR) 2017/745 and 746, highlighting the significant changes from the previous Medical Device Directive (MDD) and the subsequent implications for the medical device industry. The introduction of stricter requirements for clinical evidence, post-market surveillance, and vigilance aims to enhance patient safety and public health while fostering innovation. Key differences between the MDD and MDR, such as expanded device scope, unique device identification systems, and

strengthened post-market surveillance, underscore the shift towards a more stringent regulatory framework aimed at ensuring the safety and efficacy of medical devices in the European market.

The review also emphasises the importance of MDR awareness across all stakeholders, in this case, within an Irish Medical Device Distributor, to ensure compliance, safety, and enhance market competitiveness. Studies by Bianchini and Mayer (2022), Foo and Tan (2017), and others highlight the need for comprehensive understanding and adherence to the MDR throughout the device lifecycle, from development to end-user application. Organisational culture, as discussed by Smith-Crowe et al (2003), plays a vital role in shaping safety behaviours and regulatory compliance. Additionally, the review identifies gaps in knowledge of awareness and perception of the MDR within the medical device community, suggesting the need for targeted education and communication strategies to foster a culture of compliance and continuous improvement. Overall, this chapter concludes that heightened awareness and proactive engagement with MDR requirements are strategic imperatives for ensuring regulatory compliance, maintaining product quality, and ultimately safeguarding patient safety.

2.9 Table 1 Literature Review Table:

Author	Study Description	Sample Size	Key Points	Conclusion
Bretthauer et al (2023)	This study examines balancing the challenges of innovation versus safety in regards MDR	Discussion and literature review. No primary research.	Innovation and safety must be balanced when considering legislation	The authors underscore the importance of balancing innovation and safety in terms of MDR
Huusko et al (2023)	The authors investigate the perspectives of managers and regulatory professionals in relation to MDR	74 respondents were surveyed, all managerial level in Finland. 74 respondents out of 405	This study explores perceptions of managers and compliance professionals in relation to MDR	Managers and compliance professionals understood the role of MDR but found it a burden and found a gap in information quality

Author	Study Description	Sample Size	Key Points	Conclusion
Kearney and McDermot (2023)	This study aims to qualitatively assess the challenges resulting from complying with tightened clinical evidence requirements mandated but the MDR	68 respondents to a questionnaire. All respondents at a managerial level or higher	Companies manufacturing high-risk devices are relying on internal knowledge transfer rather than external training. Whereas manufacturers of medium-risk devices rely more on external training as a knowledge source.	The study concludes that there is the need for strategising to identify means to help organisations deal with the significant burden posed by the new requirements for clinical evidence posed by the MDR
George et al (2022)	George et al examine healthcare “champions” through a mixed method approach.	Health care champions = 30 Colleagues = 58	This study examines health care “champions” and their role in implementation	The authors emphasise the role of healthcare “champions” in implementing change in a healthcare setting
Han et al (2022)	This study explores opportunities and risks associate with UK Medical Device reform	32 stakeholders, mixed method survey and interview	This study examines the benefits and challenges of Medical Device Reform in the UK	The authors highlight the need for careful consideration of the opportunities and risks associate with MDR reform to ensure safety, efficacy and accessibility of medical devices in the UK.
Bianchini et al (2022)	Overview of key aspects of EU MDR 2017 145/146	Discussion and literature review. No primary research.	The authors question the importance of MDR and its’ impact	The study highlights the necessity to evaluate the awareness and perception of MDR
McKernan and McDermott (2022)	This study describes the evolution of Irelands Medical Device Cluster	Literature Review	Authors identify vulnerabilities and opportunities within the MedTech Cluster in Ireland	The disruption of the fast-track approval channel for medical devices in Europe with the current MDR is an impediment to innovation

Author	Study Description	Sample Size	Key Points	Conclusion
Maccaro et al (2022)	The author describes the challenges of MDR in a remote location	Conceptual study	The author examines the applicability and effectiveness of MDR in a remote location to assess universality and adaptability of regulations	The author provides insight into he challenges of MDR in remote healthcare systems, highlighting the importance of context-specific approaches to healthcare regulations
Carden et al (2021)	The study proposes an ethical rip management approach for medical devices	Conceptual framework applied. No primary research.	The study outlines an ethical framework for managing risks associated with Medical Devices	The authors advocate the adoption of ethical risk management strategies to enhance safety and efficacy in the use of medical devices
Fudim et al (2021)	This study examines the risk versus innovation aspect of critical medical devices	Literature Review. No primary research	The study emphasises the critical need for fluent approval pathways for vital medical devices	Critical medical devices in the USA can gain 510 K approval in a timely fashion, this is significantly more difficult in Europe
Vasiljeva et al (2020)	This study investigates how evolving MRR in Europe affects innovation, research and clinical practices in the othopaedic field	Review of EU directives and published literature	Authors highlight the need for post-market surveillance, clinical trial and data transparency under the new MDR	The authors highlight the need for adaptation and compliance in a twinned fashion to continue progressions in patient care
Wilkinson and Boxtel (2020)	This study examines how the MDR intensifies focus on the clinical benefits of devices	A discussion of MDR and available literature	There is an increased emphasis of clinical benefits under the MDR	The authors highlight the importance, under the MDR, for manufacturers to provide robust evidence of the clinical benefits of their devices

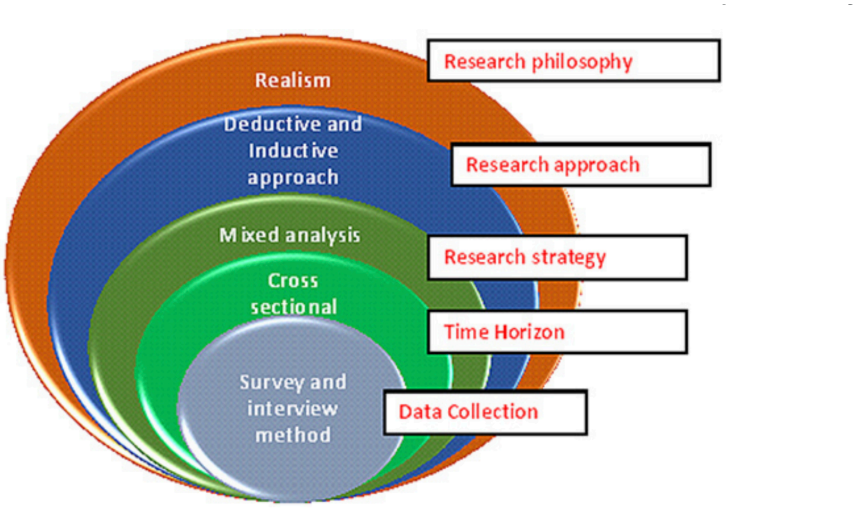
Author	Study Description	Sample Size	Key Points	Conclusion
Herman and Goossens (2019)	The authors discuss the importance of disclosing the composition of medical devices at a European Level	Literature review and discussion	The study highlights the importance of transparency of the composition of medical devices to ensure patient safety and informed decision making	The authors advocate for enhanced regulations mandating the disclosure of medical device composition a the EU level to decrease risks and improve patent safety
Foo et al (2017)	Foo and Tan investigate the limited awareness of certification markings on medical devices	Discussion of literature and MDR. No primary research	This study highlights the lack of awareness of the significance of compliance markings on medical devices among users and medical professionals	The authors emphasise the importance of raising awareness and improving education on certification and compliance markings to ensure safe and appropriate use of medical devices
Galgon (2016)	This study is designed to provide a structural and functional understanding of systems used for the regulation of medical devices in the EU and the USA	Discussion of professional observation and literature, no primary data	This study discusses the complexities of medical device regulations in both the USA and the EU	The authors propose a low level of knowledge of their colleague anaesthetists in relation to MDR and emphasise the importance of familiarisation
Henry et al (2012)	This study examines the role of the health care “champion” in achieving health system change	Three identified organisational “champions” in the UK	Health care “champions” are significant in the early stages of driving system change and implementation of innovations	Organisational champions are key in the early stages of adopting change, but can be detrimental to the later stages of the process.
Hill (2010)	Hill explores awareness dynamics in the context of philosophical logic	Philosophical Analysis	The author delves into the intricacies of awareness dynamics, examining how awareness evolves and influences logical reasoning processes	Hill’s work contributes to the understanding of awareness dynamics, shedding light on its complexities and implications for philosophical logic

Author	Study Description	Sample Size	Key Points	Conclusion
Smith et al (2003)	The authors investigate the organisational climate and the affect of knowledge-safety performance	Conceptual study	The authors found that positive climates promoted improved knowledge-safety performance	The authors highlight the importance of the organisational climate a creating a positive climate to enhance knowledge transfer and safety performance among employees

Chapter 3 Methodology

3.1 The Research Onion

This research an be comprehensively analysed using the research onion model from Saunders et al (2009). Each layer of the onion guides specific aspects of this research methodology, ensuring a structured and robust approach.



Source: Adopted from Saunders et al. (2009)

Figure 1 The Research Onion

3.1.1 Layer 1: Research Philosophy

Philosophies: Combining Positivism and Interpretivism

- Positivism: This approach is reflected in the use of structured surveys with closed-ended questions and quantitative data analysis methods. This allows for objective measurement and analysis of MDR awareness levels.

- Interpretivism: This perspective is evident in the inclusion of open-ended questions and qualitative data analysis methods, such as thematic analysis, to understand the subjective experiences and perceptions of employees regarding MDR awareness.

Research Philosophy

The philosophical approach guiding the proposed primary research on the level of MDR awareness in an Irish Medical Devices Distributor is a critical aspect that shapes the research design and methodology.

Two main philosophical approaches, positivism and interpretivism, were considered in research. Positivism, grounded in the belief in an objective reality that can be measured and studied, assumes a detached observer role and aims to discover universal laws (Ryan and Rutty, 2019). This approach was suitable for research intending to quantify the level of MDR awareness using structured surveys with closed-ended questions.

3.1.2 Layer 2: Research Approach

Approaches: Deductive and Inductive

- Deductive Approach: Employed in the structured surveys to test hypotheses about MDR awareness using predefined questions and statistical analysis.
- Inductive Approach: Used in the thematic analysis of interview data to explore and develop deeper insights into the factors influencing MDR awareness.

Table 2: Deductive vs. Inductive Approaches

Aspect	Deductive Approach	Inductive Approach
Hypothesis Testing	Structured surveys with closed-ended questions	Thematic analysis of open-ended interviews
Data Analysis	Quantitative techniques((e.g. statistics)	Qualitative techniques (thematic analysis)
Research Focus	Objective measurement	Subjective interpretation

3.1.3 Layer 3: Research Strategy

A mixed research strategy was adopted for this study. Data was collected by structured surveys and interviews with key management personnel within the company. A mixed method research strategy was chosen to provide a deeper insight into the research questions that that offered by surveys alone.

Choices: Qualitative and quantitative methods

Qualitative methods used in interviews and open-ended survey questions to gain insights into employee perceptions and experiences.

Quantitative methods applied in structured surveys and statistical analysis to objectively measure MDR awareness levels.

Structured surveys were distributed to employees within the organisation. The survey consisted of closed and open ended questions with predefined response options, enabling the collection of standardised and quantifiable data. This deductive approach reflects a positivist approach. This method ensured efficiency in gathering information from a large sample, providing a statistical overview of MDR awareness levels.

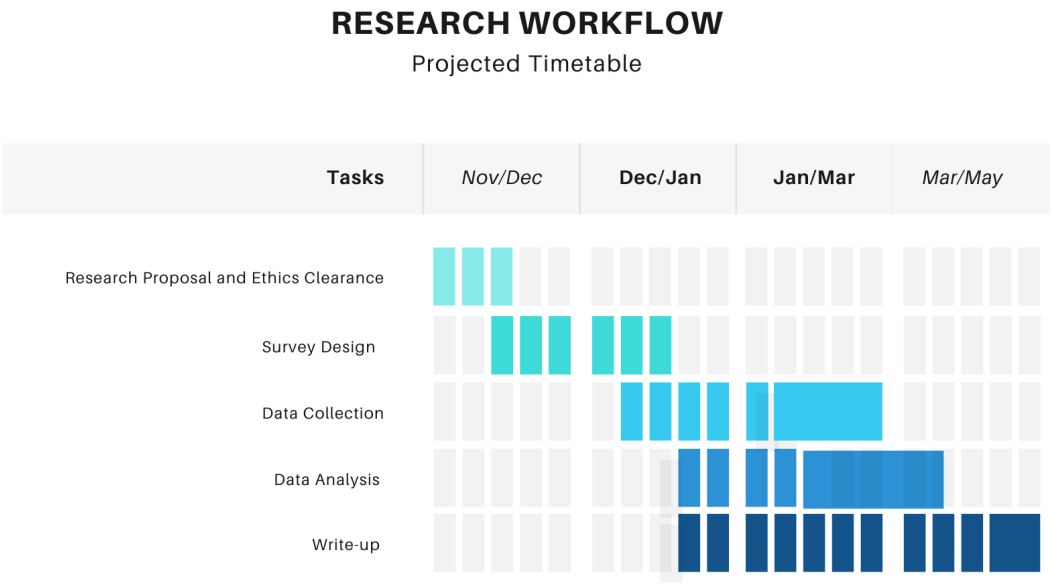
Interviews were conducted with four managers in the sample population. The interviews conducted reflect an inductive approach are are representative of an interpretivist research philosophy.

Table 3: Qualitative and quantitative methods

Method	Qualitative	Quantitative
Data collection	Interviews, open-ended survey questions	Structured surveys, closed-ended questions
Data analysis	Thematic analysis	Descriptive analysis

3.1.4 Layer 4: Time Horizons

Cross-sectional design captures a snapshot of the current state of MDR awareness within the distributor at a specific point in time. This design is effective for identifying immediate areas for improvement and provides a foundation for future longitudinal studies.



3.1.5 Layer 5: Data Collection and Analysis

Data collection involved structured surveys distributed via Microsoft Forms and interviews with key management personnel. The use of Microsoft Teams ensures accessibility and anonymity for participants.

Data Collection

The questionnaire was distributed to employees across different roles within the distributor. Participants were asked to complete the questionnaire anonymously.

Interviews were also scheduled with four individuals in management roles within the organisation to provide some context and further insights into the findings of the survey.

Data analysis:

Quantitative analysis; descriptive statistics (mean, median, mode), inferential statistics (chi-squared test, Student t-test), and correlation analysis.

Statistical Analysis

Data analysis involved both quantitative and qualitative techniques.

Initially, descriptive statistics were used to ascertain the frequencies and percentages of responses to each MCQ survey question option, offering an overview of response distributions. Measures of central tendency such as mean, median, and mode, along with measures of dispersion like standard deviation and range, were used to summarise the data effectively.

In order to analyse quantitative data obtained from surveys, inferential statistical techniques were applied to assess relationships or correlations between different variables. For instance, statistical tests such as chi-square tests, Student t-tests and Correlation Analysis were utilised to determine if there are significant differences in awareness levels among various employee groups.

The Chi-square test was used to determine if there were significant links between respondents' characteristics—such as demographics or professional experience—and their survey responses, shedding light on any disparities in awareness or perception across different groups.

The Student t-test was used in order to determine whether the difference between responses of the groups involved in the study were statistically significant or not.

Correlation analysis was performed to see if there was any correlation between quantitative factors investigated in the survey.

Qualitative analysis: thematic analysis to identify recurring themes and patterns in interview responses. Initially, the responses of open-ended interview questions were carefully reviewed multiple times to gain familiarity with the content. As the answers are examined, significant themes, recurring patterns, and noteworthy points were identified and noted.

Subsequently, a coding process was undertaken to systematically categorise segments of text representing key concepts or ideas. Once the data was coded, themes are developed by grouping related codes and identifying overarching patterns within the data. Analysing data from interviews involved several key steps to derive meaningful insights and actionable conclusions.A thematic analysis to identify common themes and patterns was conducted, using focused coding to organise the data.

Table 4 Data collection and analysis techniques

Technique	Description
Data Collection	Surveys via Microsoft Forms, interviews with key management personnel
Quantitative Analysis	Descriptive statistics (mean, median, mode), inferential statistics (Chi-squared, Student T-test) and correlation analysis.
Qualitative Analysis	Thematic analysis of interview questions

Integration of data

Both qualitative and quantitative data were integrated to provide a comprehensive understanding of MDR awareness and the factors influencing it. This integration offers a holistic view, allowing for the identification of variations in awareness levels across different segments of the organisation.

By aligning the study with the Research Onion Model (Sunders et al 2009), each critical aspect of the research process is addressed, providing valuable insights into MDR awareness within the Irish Medical Device Distributor context.

3.1.6 Ethical Considerations

An ethics application was submitted to Griffith College Dublin and Innopharma for approval in advance of any data being collected. This application detailed all ethical considerations and included a copy of the PIL and ICF (Appendix 1).

In conducting research on the awareness of the MDR among employees of an Irish Medical Devices Distributor through surveys, a comprehensive approach to ethical considerations was crucial, especially concerning participant confidentiality and the company involved. Informed consent was

paramount, requiring a transparent explanation of the research's purpose, potential risks, benefits, and the voluntary nature of participation. An explicit assurance of confidentiality was essential, emphasising the protection of participant data and ensuring anonymity. This commitment to confidentiality extends to organisational information, acknowledging that the sensitive nature of the study may involve proprietary details about the company.

Voluntary participation is a central ethical concern, and participants understood that their decision to participate or withdraw would not adversely affect their employment or relationships within the organisation. Clear communication regarding data security measures was important to prevent unauthorised access and maintain the integrity of both individual and company information. The survey content's sensitivity was communicated in advance of any data collection with senior directors to ensure that they were comfortable with the data being collected.

In the context of the company's confidentiality, a commitment was made to protect proprietary information and preventing any inadvertent disclosure of trade secrets or sensitive company data. Safeguards such as restricted access to survey results was implemented in order to ensure confidentiality and data protection. Seeking approval from Griffith College’s ethics committee, with a clear understanding of the dual commitment to participant and company confidentiality, reinforces the ethical foundation of the study.

In regard to any interviews conducted, a participant information leaflet was distributed, detailing the methods and purpose of the research. An informed consent form was also signed in advance of any interviews being conducted.

3.1.7 Summary

This research strategy allowed for a thorough investigation of awareness of medical device regulation within the Irish Medical Device Distributor, providing insights and opportunities for enhancing regulatory compliance and safety standards within the organisation. In addition, the qualitative information provided by interviews with key management personnel allowed the comparison of the perception of the level of awareness and attitudes of MDR within the company, with the reality of the knowledge and perceptions of the workforce, allowing for any gaps in knowledge of or considerations with regards the perception of Medical Device Regulation, to be addressed in the form of a targeted educational program.

Chapter 4 Findings and Analysis

4.1 Overview of Survey

At the outset of this study, the aim was to assess the level of awareness and perception of Medical Device Regulations among employees in all areas of an Irish Medical Device Distributor. The survey that was distributed had seventeen questions, These questions were divided into four sections; demographic, knowledge, perception and satisfaction. One hundred and twelve people were contacted and seventy four responded yielding a response rate of 66.1%, with a 95% confidence interval and a 7% margin of error.

The questions and answers are discussed and analysed below under sections that each relate back to the research questions in Chapter 1. The research questions were focused on achieving the primary three objectives of this dissertation.

1. To determine the level of awareness and perception of Medical Device Regulation within an Irish Medical Device Distributor.
2. To evaluate if the perceptions and awareness of Medical Device Regulation among the workforce aligned with those supposed and expected by those in management roles within an Irish Medical Device Distributor.
3. To evaluate if further education in regards to Medical Device Regulation would be useful to improve awareness and perception amongst the workforce of an Irish Medical Device Distributor.

4.2 Informed consent and Qualifying Question

The first two questions in the survey were used to determine if the respondents were qualified persons to engage in this survey. The criterion applied for a qualifying person for participation in this study was that the individuals involved consented to participation and worked for an Irish Medical Device Distributor.

Qualifying Questions

The criterion applied for a qualifying person for participation in this study was that the individuals involved consented to participation and worked for an Irish Medical Device Distributor.

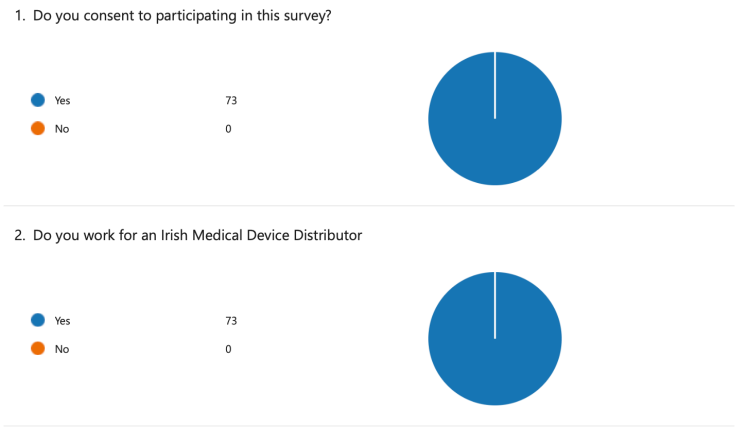


Figure 2 Qualifying Questions

4.3 Thematic Analysis of Survey Question Results

Based on the survey results presented in this study, a thematic analysis reveals several key themes related to the research topic:

Theme 1	Overall MDR Awareness	Research Question 1, 4, 5,7,8
Theme 2	MDR Perception	Research Question 2 and 3
Theme 3	MDR Training	Research Question 6
Theme 4	Commercial advantages of Compliance	Research Question

4.3.1 Theme 1 Overall MDR Awareness and Understanding

The survey results indicate a significant level of awareness and understanding of MDR among employees within the organisation studied. Participants demonstrated a solid understanding of crucial aspects of MDR, such as adverse event reporting and CE marking.

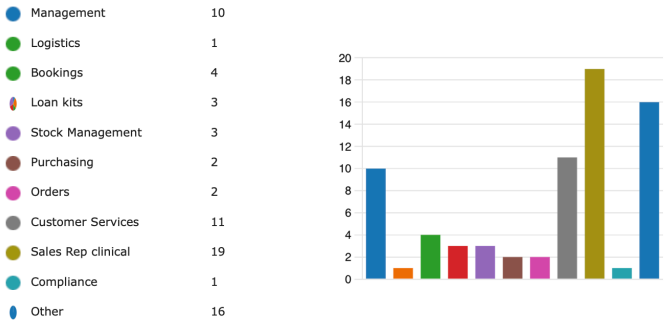


Figure 3 Role Profile of Respondents

13. What does the CE mark signify in relation to Medical Device Regulation in Europe?

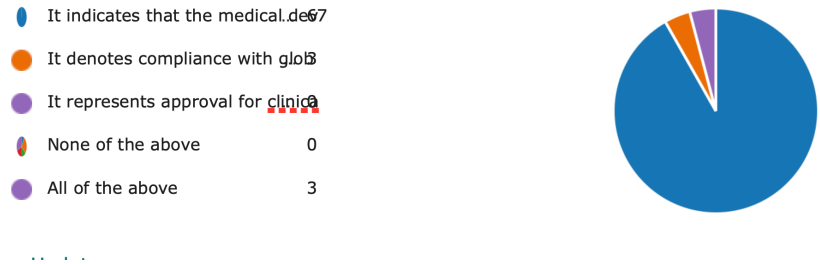


Figure 4

Research Question 1 Awareness of MDR

The findings indicate a generally high level of awareness among employees regarding the examined aspects of Medical Device Regulation. Most notably, the majority of employees demonstrate awareness of the primary legislation in the EU; MDR 2017 745/746. Awareness is demonstrated in key areas such as adverse event reporting, CE marking significance, and implant card concepts. However, there are areas, particularly regarding implant cards where awareness could be improved.

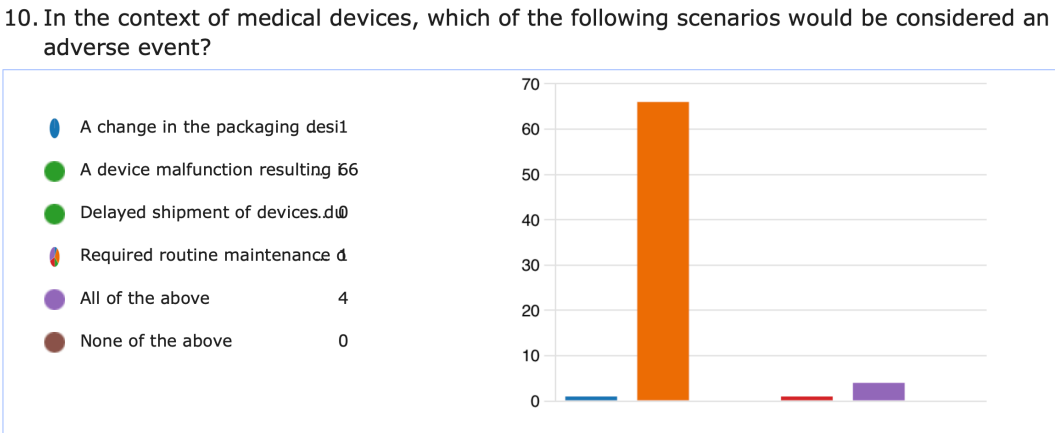


Figure 5

Statistical Analysis of Research Question 1

Table 5

		Frequency	Percent
In the European Union, what is the current, primary legislation governing Medical Device Regulation?	Not Aware	11	15.1
	Aware	61	83.6
What is the primary purpose of adverse event reporting under Medical Device Regulation?	Not aware	17	23.3
	Aware	55	75.3
In the context of medical devices, which of the following scenarios would be considered an adverse event?	Not Aware	6	8.2
	Aware	65	89
Which of the following steps best describes the process involved in reporting adverse events related to medical devices	Not Aware	3	4.1
	Aware	69	94.5
According to statutory requirements, what is the appropriate timeframe for reporting an adverse event related to a medical device?	Not Aware	17	23.3
	Aware	53	72.6
What does the CE mark signify in relation to Medical Device Regulation in Europe?	Not Aware	6	8.2
	Aware	66	90.4
What is an implant card according to Medical Device Regulation within the EU?	Not Aware	32	43.8
	Aware	37	50.7
Implant cards are not a regulatory requirement for orthopedic or spinal implants	Not Aware	31	42.5
	Aware	38	52.1

What is the current awareness level among employees regarding the new Medical Device Regulation 2017/745 and 746?

The current awareness level among employees regarding the new Medical Device Regulation 2017/745 and 746 was assessed by examining several key aspects related to medical device regulation. Findings reveal that the majority of employees are aware of the primary legislation governing Medical Device Regulation in the European Union (83.6%). Additionally, a significant portion of employees demonstrate awareness of the primary purpose of adverse event reporting (75.3%), scenarios considered as adverse events in the context of medical devices (89%), the

process involved in reporting adverse events (94.5%), the appropriate timeframe for reporting adverse events (72.6%), the significance of the CE mark in relation to Medical Device Regulation (90.4%), and the concept of an implant card within the EU regulations (50.7%). Notably, while a substantial proportion of employees show awareness across these aspects, there are still some areas where awareness levels could be improved, such as understanding the concept of implant cards and the regulatory requirements for orthopaedic or spinal implants.

Theme 1 - MDR Awareness

Research Question 4 - Variation Across Roles

While awareness of medical device regulation appears consistent across different roles within the distributor there are no significant differences between frontline customer service support roles and other positions.This suggests a uniform level of awareness and understanding across various job functions.

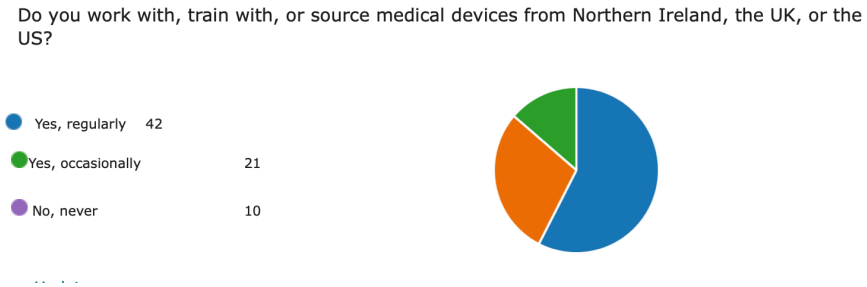


Figure 6

Data Analysis of Research Question 4

Does awareness of medical device regulation vary across different roles within the distributor, particularly between frontline customer support roles and other positions?

The analysis aimed to investigate whether awareness of medical device regulation varies across different roles within the distributor, specifically between frontline customer support roles and other positions. The frequencies indicate that employees who work with Northern Ireland, the UK, and the US exhibit awareness of medical device regulation across all levels of engagement, whether they work with those regions never (Not Aware: 1, Aware: 9), occasionally (Not Aware: 3, Aware: 17), or regularly (Not Aware: 7, Aware: 35). However, a chi-square test revealed a non-significant association between awareness and the frequency of engagement with these regions, χ^2 (2, N = 71) = 0.302, p = 0.860. The findings suggest that awareness of medical device regulation does not significantly vary across different roles within the distributor, including between frontline customer support roles and other positions.

Table 5: Awareness across different distributors

Work with Northern Ireland UK, and US	Not Aware	Aware	χ2	p-value
No, never	1	9	0.302	0.86
Yes, occasionally	3	17		
Yes, regularly	7	35		

Theme 1 - MDR Awareness

Research Question 5 - Countrywide Variation

The finding suggests that awareness of MDR legislation does not significantly differ between regions north and south of the border. Both areas exhibit high levels of awareness, indicating a consistent understanding of regulatory standards regardless of geographic location.

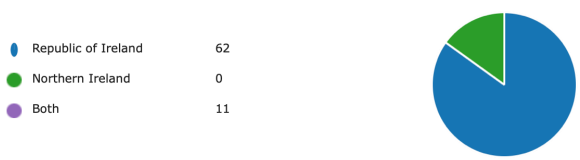


Figure 7 Area of Ireland in which Respondents Work

Data Analysis of Research Question 5

Does awareness of medical device regulation and appropriate compliance markings vary countrywide, both north and south of the border?

The examination aimed to determine if awareness of medical device regulation and appropriate compliance markings varies countrywide, encompassing both regions north and south of the border. Frequencies indicate that within the Republic of Ireland, a majority of respondents are aware of MDR legislation (Republic of Ireland: 52) compared to those who are not aware (Republic of Ireland: 9). Similarly, in both regions (north and south of the border), the majority of respondents are aware of MDR legislation (Both: 9) compared to those who are not aware (Both: 2). However, a chi-square test revealed no significant difference in awareness levels between the Republic of Ireland and both regions (χ^2 (1, N = 71) = 0.081, p = 0.776).

Table 7: Cross tabulation for awareness of MDR primary legislation in Europe and job location

Awareness of MDR legislation	Republic of Ireland	Both	χ	p-value
Not Aware	9	2	0.081	0.776
Aware	52	9		

Theme 1 MDR Awareness

Research Question 7 - Factors influencing Awareness

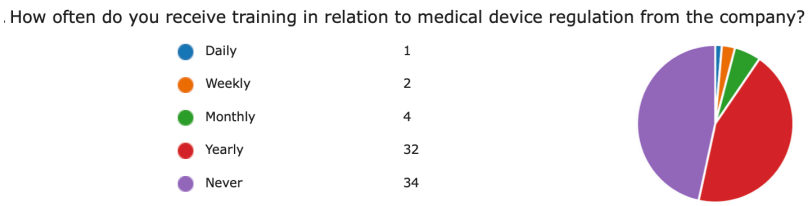


Figure 8

Several factors were found to influence awareness of MDR, including familiarity with specific regulatory requirements for medical devices in Northern Ireland, the effectiveness of training programs provided by the company, and the satisfaction with communication channels used for regulatory information dissemination.

Data Analysis of Research Question 7

What factors influence awareness of medical device regulation within the distributor, including training, communication channels, and exposure to regulatory standards?

The investigation sought to identify factors influencing awareness of medical device regulation within the distributor, encompassing training, communication channels, and exposure to regulatory standards. Correlation analysis revealed several significant relationships. Specifically, familiarity with specific regulatory requirements for medical devices in Northern Ireland under the Northern Ireland Protocol exhibited a significant positive correlation with the perception of compliance importance in one's role ($r = 0.415^{**}$, $p < .01$) and the effectiveness of training programs provided by the company ($r = 0.476^{**}$, $p < .01$). Additionally, the effectiveness of training programs correlated significantly with the frequency of receiving training ($r = 0.667^{**}$, $p < .01$) and satisfaction with communication channels used for regulatory information dissemination ($r = 0.668^{**}$, $p < .01$). Moreover, satisfaction with communication channels correlated significantly with feeling supported by management in efforts to stay informed and compliant ($r = 0.767^{**}$, $p < .01$).

Table 7: Factors influencing awareness of medical device regulation

	1	2	3	4	5	6	7	8
1. How familiar are you with the specific regulatory requirements for medical devices in Northern Ireland under the Northern Ireland Protocol?	1	0.213	.415**	.414**	.476**	.240*	.482**	.530**
2. Are you familiar with the appropriate department or contact person within the company to address compliance related queries or concerns?	0.213	1	0.155	.321**	.398**	0.02	.406**	.476**
3. How important do you perceive compliance with Medical Device Regulation to be in your specific role?	.415**	0.155	1	.271*	.445**	.437**	.443**	.387**

4. How often do you receive training in relation to medical device regulation from the company?	.414**	.321**	.271*	1	.667**	0.156	.526**	.527**
5. How effective do you find the current training programs provided by the company in enhancing your understanding of medical device regulations and CE marking?	.476**	.398**	.445**	.667**	1	0.222	.668**	.642**
6. Do you view Medical Device Regulation as beneficial or detrimental to the company?	.240*	0.02	.437**	0.156	0.222	1	0.175	0.135
7. How satisfied are you with the communication channels used by the company to disseminate information about changes in medical device regulation?	.482**	.406**	.443**	.526**	.668**	0.175	1	.767**
8. To what extent to you feel supported by management in your efforts to stay informed about and compliant with medical device regulations and CE marking requirements?	.530**	.476**	.387**	.527**	.642**	0.135	.767**	1

Theme 1 MDR Awareness

Research Question 8 - Knowledge of Adverse Event Reporting

The majority of respondents demonstrated awareness of adverse events, this suggests a solid basis for ensuring safety and efficacy in handling medical devices within the organisation.

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Data Analysis of Research Question 8

To establish the knowledge of adverse event reporting among those working for the Irish Medical Devices Distributor.

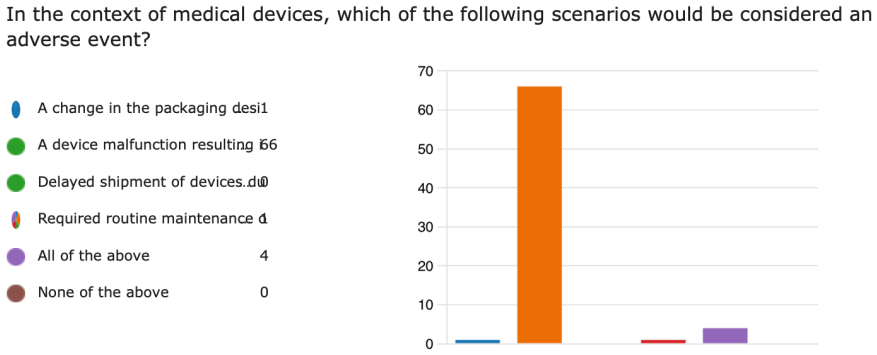

Figure 9

The investigation aimed to establish the knowledge of adverse event reporting among those working for the Irish Medical Devices Distributor. Analysis of the data revealed that the majority of respondents in the Republic of Ireland are aware of adverse events (Republic of Ireland: 54), while only a few are not aware (Republic of Ireland: 6). Similarly, in both regions, a majority of respondents are aware of adverse events (Both: 11), with none indicating being not aware. However, a chi-square test yielded a non-significant p-value of 0.145 at the 0.05 level of significance (χ^2 (1, N = 71) = 2.119).

Table 9: Awareness of adverse events across location of work

Awareness of adverse events	Republic of Ireland	Both	$\chi 2$	p-value
Not Aware	6	0	2.119	0.145
Aware	54	11		

Theme 1 MDR Awareness

Research Question 9 - Understanding of CE Marking

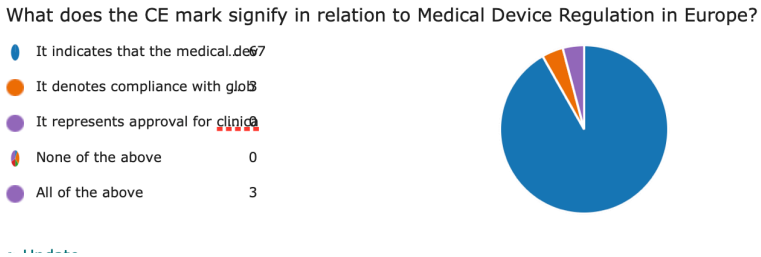

Figure 4

The findings indicate a high level of awareness regarding the CE mark among employees. This suggests a strong understanding of the importance of compliance with regulatory standards in ensuring the safety and effectiveness of medical devices.

Data Analysis of Research Question 9

Do employees understand the importance of the CE mark in the context of medical devices?

The investigation aimed to determine whether employees understand the importance of the CE mark in the context of medical devices. Analysis of the data revealed that the majority of respondents in the Republic of Ireland are aware of the CE mark (Republic of Ireland: 56), while only a small proportion are not aware (Republic of Ireland: 5). Similarly, in both regions, the

majority of respondents are aware of the CE mark (Both: 10), with only one indicating not being aware. However, a chi-square test yielded a non-significant p-value of 0.922 at the 0.05 level of significance (χ^2 (1, N = 71) = 0.01).

Table 10: Awareness of the CE mark across location of work

Awareness of the CE mark	Republic of Ireland	Both	$\chi 2$	p-value
Not Aware	5	1	0.01	0.922
Aware	56	10		

Theme 1 - MDR Awareness

Theme 1 MDR Awareness

Research Question 11 - Awareness of Responsible Personnel

The majority of employees demonstrate familiarity with the responsible person within the company for addressing MDR-related queries, indicating clear communication channels for regulatory concerns within the organisation.

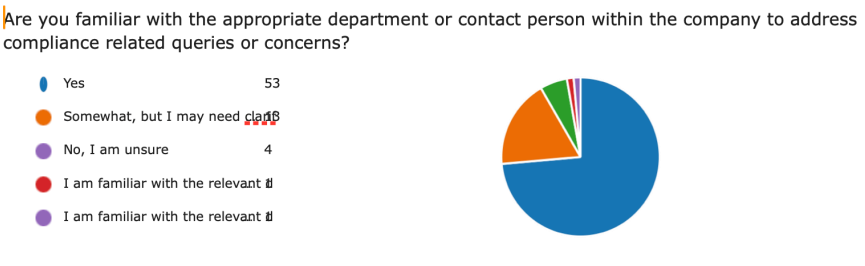

Figure 12

Data Analysis of Research Question 11

Does the workforce know who the responsible person in the company is to refer any questions with regards the MDR or regulation in general?

The investigation sought to determine if the workforce knows the responsible person in the company to refer any questions regarding the Medical Device Regulation (MDR) or regulation in general. Analysis of the data revealed varying levels of familiarity with the appropriate department or contact among respondents in the Republic of Ireland and both regions. A majority of respondents in the Republic of Ireland reported being familiar with the responsible person (Republic of Ireland: 43), while smaller proportions indicated being unsure (Republic of Ireland: 4), needing clarification (Republic of Ireland: 11), being hesitant to contact them (Republic of Ireland: 1), or being unsure of the queries to address (Republic of Ireland: 1). Similarly, in both regions, a majority of respondents reported being familiar with the responsible person (Both: 10), with only a few indicating uncertainty or needing clarification. However, a chi-square test yielded a non-significant p-value of 0.557 at the 0.05 level of significance (χ^2 (4, N = 71) = 3.005).

Table 11: Familiarity with the appropriate department or contact to address compliance across location of work

Familiar with the appropriate department or contact to address compliance	Republic of Ireland	Both	χ2	p-value
No, I am unsure	4	0	3.005	0.557
Somewhat, but I may need clarification	11	1		
I am familiar with the relevant department but I am unsure what queries are to be addressed to them	1	0		
I am familiar with the relevant department but I am hesitant to contact them	1	0		
Yes	43	10		

In summary, analysis of data grouped under this theme enables us to answer one of the primary research questions asked in Chapter 1 of this thesis; the findings of this study show a high level of awareness of critical areas of MDR among the employees of an Irish Medical Device Distributor.

2. Theme 2 Perceived Importance of MDR

Research Question 2 - Importance of Awareness and Compliance

Perceptions regarding the importance of MDR awareness vary across different roles within the organisation. While roles like Sales Rep and Management perceive awareness as highly important, other roles, such as Bookings and Customer Services, view it with less significance. This highlights the need for tailored training and communication strategies based on employees roles and responsibilities.

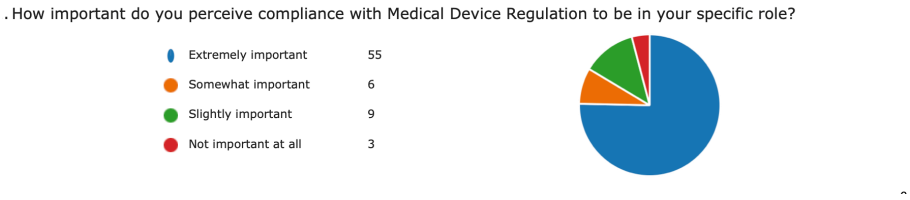

Figure 10

Data Analysis of Research Question 2

Is awareness of the new MDR perceived to be necessary for employees in their respective roles? How do employees perceive the importance of compliance with medical device regulation in ensuring the safety and efficacy of medical devices distributed by the organisation?

The perception of the importance of awareness regarding the new Medical Device Regulation (MDR) varies among employees in different roles within the organisation. Analysis of the data reveals that employees across various areas of work, such as Sales Rep clinical, Customer Services, Management, and others, demonstrate varying degrees of perception regarding the importance of MDR awareness in their respective roles. For instance, a substantial number of employees, particularly those in roles such as Sales Rep clinical and Management, perceive awareness of the MDR as extremely important. Conversely, some employees, particularly in areas like Bookings and Customer Services, indicate lower levels of perceived importance.

Table 12: Cross tabulation for perceived importance of compliance with medical device regulation and role at work

Area of work	Not important at all	Slightly important	Somewhat important	Extremely important	χ	p-value
Bookings	0	1	0	3	44.662	0.995
Business Unit Manager	0	0	0	1		

Compliance	0	0	0	1
Customer Services	2	2	1	6
Engineering	0	0	0	1
Engineering and Project Manage	0	0	0	1
Inventory Control	0	1	0	0
Loan kits	0	0	0	3
Logistics	0	0	0	1
Management	0	0	0	10
Marketing & Sales Support	0	0	1	0
Orders	0	0	0	2
Product and Clinical Training	0	0	0	1
Purchasing	0	0	0	2
QCRS	0	0	0	1
Sales & Management	0	0	0	1
Sales Rep and Customer Service	0	0	0	1
Sales Rep clinical	0	4	2	13
Service	0	0	0	1
Service Support	0	0	0	1
Stock Management	0	1	0	2
Tech services and clinical sup	0	0	0	1
Technical Services	0	0	0	1
warehouse	1	0	1	0

4.4 Theme 2 -MDR Perception

Research Question 3 - Perception of MDR

Overall, a majority of employees perceive the MDR as beneficial to their area of work. This sentiment is consistent across different job locations, indicating a general positive outlook toward regulatory standards within the organisation.

Data Analysis of Research Question 3

Do employees regard Medical Device Regulation as a positive or negative thing in relation to their area of work?

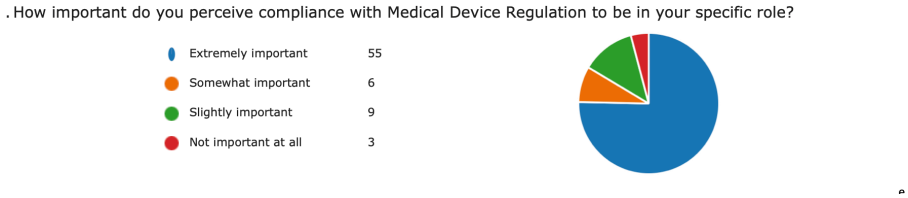

Figure 11

Employees' perceptions of Medical Device Regulation (MDR) in relation to their area of work were examined, revealing varied viewpoints. A chi-square test was conducted to compare the distributions of perceptions between employees based solely in the Republic of Ireland and those who work in both the Republic of Ireland and another location. Results indicate a non-significant difference in perceptions between the two groups (χ^2 (2, N = 71) = 4.056, p = 0.132). In both groups, a significant majority of employees regard MDR as beneficial (Republic of Ireland: 49, Both: 11) rather than detrimental (Republic of Ireland: 6, Both: 0) to their area of work. Additionally, some employee's express neutrality, neither considering MDR as beneficial nor detrimental (Republic of Ireland: 5, Both: 0).

Table 13: Cross tabulation regard Medical Device Regulation as a positive or negative and job location

Perception of MDR	Republic of Ireland	Both	χ	p-value
Neither	5	0	4.056	0.132
Detrimental	6	0		
Beneficial	49	11		

In summary, analysis of data grouped under this Theme, allow us to answer on of the primary research questions asked in Chapter 1 of this dissertation. The survey reveals that the perceived importance of MDR varies among employees. While some recognise its significance in ensuring patient safety and regulatory compliance, others may not fully appreciate its importance in their roles. Data suggests a positive correlation between those who had received training and a positive

perception of MDR. This highlights the need for tailored training and communication strategies to address the varying perception and awareness of MDR among employees of the organisation.

While there was a positive perception of MDR among employees and management, variations were observed in the importance of MDR across different roles within the organisation. Employees directly involved with medical devices exhibited heightened awareness of MDR compared to those not engaged in handling such devices. This discrepancy suggests that certain job functions may require more targeted training to ensure uniform understanding of MDR.

Theme 3 - MDR Training

Research Question 6 - Familiarity with Regulatory Requirements

Employees familiarity with specific regulatory requirements varies, with respondents from both regions generally expressing higher levels of familiarity compared to those solely in the Republic of Ireland. While there is a notable trend in familiarity levels between regions, it falls just short of statistical significance.

Data Analysis of Research Question 6

To what extent are employees familiar with the European Union Medical Device Regulation (MDR), the CE mark, the UKCA, and the CE UKNI created by the unique regulatory arrangement in Northern Ireland post-Northern Ireland Agreement?

The investigation sought to determine the extent to which employees are familiar with the European Union Medical Device Regulation (MDR), the CE mark, the UKCA, and the CE UKNI, as

established by the unique regulatory arrangement in Northern Ireland post-Northern Ireland Agreement. Frequencies illustrate varying levels of familiarity among respondents in the Republic of Ireland and both regions. The majority of respondents in the Republic of Ireland perceive these regulations as not relevant to their role (Republic of Ireland: 20), while a smaller proportion indicate being not familiar at all (Republic of Ireland: 17). Conversely, respondents in both regions generally express higher levels of familiarity, with some indicating they are somewhat familiar (Both: 5) or very familiar (Both: 0). However, a chi-square test yielded a marginally significant p-value of 0.062 at the 0.05 level of significance (χ^2 (5, N = 71) = 10.504). Although the p-value slightly exceeds the conventional threshold for statistical significance, it indicates a notable trend in familiarity levels between the Republic of Ireland and both regions.

Table 14: Familiarity with the specific regulatory requirements for MDR and location of work

Familiarity with the specific regulatory requirements for MDR	Republic of Ireland	Both	χ2	p-value
Not relevant to my role as I don't work in NI	20	0	10.504	0.062
Not relevant to my role	2	0		
Not familiar at all	17	4		
Not very familiar	8	2		
Somewhat familiar	12	5		
Very familiar	2	0		

Theme 3 -MDR Training

Theme 3 -Need for MDR Training

Research Question 10 - Formal Training on MDR

While there is a variation in the frequency of formal training on the MDR, the majority of respondents reported never receiving formal training. This suggests a potential area for improvement in providing educational resources on regulatory compliance.

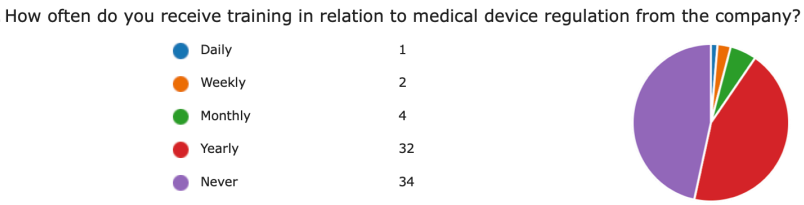

Figure 15

Data Analysis on Research Question 10

Have employees received any formal training on the MDR and if so, how much?

The investigation aimed to determine if employees have received any formal training on the Medical Device Regulation (MDR) and, if so, the frequency of such training. Analysis of the data revealed varying frequencies of training among respondents in the Republic of Ireland and both regions. A majority of respondents in the Republic of Ireland reported never receiving formal training on the MDR (Republic of Ireland: 30), whereas a smaller proportion reported receiving training yearly (Republic of Ireland: 24), monthly (Republic of Ireland: 4), weekly (Republic of Ireland: 2), or daily (Republic of Ireland: 1). Similarly, in both regions, the majority of respondents reported never receiving formal training on the MDR (Both: 4), with smaller proportions reporting training yearly (Both: 7). However, a chi-square test yielded a non-significant p-value of 0.432 at the 0.05 level of significance (χ^2 (4, N = 71) = 3.811).

Table 13: Training across location of work

Frequency of training	Republic of Ireland	Both	$\chi 2$	p-value
Never	30	4	3.811	0.432
Yearly	24	7		

Monthly	4	0
Weekly	2	0
Daily	1	0

In summary, analysis of data grouped under this theme allows us to address one of the primary research questions asked in Chapter 1 of this study, which was to determine the level of training given to employees in regards to MDR within the Irish Medical Device Distributor. Despite the overall positive outlook on MDR, challenges in formal training were evident. A significant portion of employees reported never receiving formal MDR training.

4.4 Overall Implications of the Survey Findings in the Context of Examined Literature

The findings suggest a generally positive level of awareness and perception regarding MDR among employees within the distributor. However, there are areas, such as understanding specific regulatory requirements and the need for formal training, where improvements could be made to enhance compliance and ensure the continued safety and efficacy of distributed medical devices.

Perceptions regarding the importance of MDR awareness vary across different roles within the organisation. While roles like Sales Rep and Management perceive awareness as highly important, other roles, such as Bookings and Customer Services, view it with less significance. This highlights the need for tailored training and communication strategies based on employees roles and responsibilities.

One significant, and apparently contradictory finding of the survey is the high level of MDR within the organisation alongside the reporting that the majority of employees have never received formal training. This may be explained by examining the organisational culture within the distributor. The article by Smith-Crowe, Burke, and Landis (2003) delves into the concept of organisational climate as a moderator of the relationship between safety knowledge and safety performance within workplaces. It explores how the prevailing organisational climate influences the effectiveness of

safety knowledge on actual safety behaviours and outcomes. This study underscores the importance of considering broader organisational contexts in shaping individual safety-related behaviours, knowledge dissemination and performance. In the context of my research into the awareness and knowledge of Medical Device Regulation within an Irish Medical Device Distributor, this article highlights the significance of organisational factors in influencing employees' understanding and adherence to regulatory requirements. Understanding the organisational climate within the distributor can offer valuable insights into how employees perceive and implement regulatory compliance, thus impacting the company's overall regulatory effectiveness and safety performance. The findings of this survey indicate a positive organisational climate within the organisation, resulting in informal knowledge dissemination among employees.

As there is an absence of comparative, primary, research available in regard to MDR perception and awareness among employees in non-managerial roles, no comparison is possible in this population from examination of the literature. This warrants further study.

The only comparative study involving primary research available at the time of this study examined aspects of MDR perceptions of those in a management role (Hussko et al 2023). The study by Hussko et al (2023), concluded that respondents in management roles in medical device companies in Finland regarded MDR as a burden. The findings of this study show positive perceptions towards MDR among those in management roles within the Medical Device Distributor examined. There are some considerations to regard in relation to this; the study by Hussko et al (2023) examined a broad spectrum of respondents in management roles in the medical device industry, rather than just those in a medical device distributor as are examined in this study. There may conceptually be an increased MDR burden on those in the manufacturing industry, rather than those involved in distribution. This warrants further study.

The findings from Maccaro et al.’s (2022) study emphasise the interconnected nature of awareness, perception, and regulatory compliance in the domain of medical device regulations. The good level of awareness and positive perception of MDR demonstrated by the findings of this study bode well for compliance within the organisation when examined in the context of the findings of Maccaro et al (2022)

4.5 Qualitative Findings from Interviews

To add a layer of perceptive knowledge to the quantitive findings of this study, interviews were also carried out with those in management positions.

4.6 The Interview Process

Four interviewees participated in this process. The approximate duration of the interviews were 10 minutes, during which, selected questions were asked of each of the interviewees. The research questions all stemmed from the three primary research objectives set forwards in Chapter 1 of this dissertation.

Table 12 summarises the profile of each of the interviewees and Table 13 summarises answers to questions during the interview. Of note is that Respondent 4 was new to the role and in middle management, in contrast to Respondent 1,2 and 3, who were highly experienced directors in the organisation.

4.7 Analysis of Qualitative Data From Interview

Data collected from the interview process was examined in relation to thematic analysis..

Theme 1 - MDR Awareness

Theme 2 - MDR Perception

Theme 3 - MDR Perception

Theme 4 - Commercial Affects on Economic Opportunity

Table 14 Profiling Themes

Interview Question Theme	Main Theme	Sub-Theme
MDR awareness	Theme 1: MDR awareness	A broad awareness of MDR within the role Variance of awareness across roles
MDR perception	Theme 2: Perception of Regulations	Variance across roles and training level

Interview Question Theme	Main Theme	Sub-Theme
Training in MDR	Theme 3: MDR training	Lack of formal training Training only provided to managers Those with training had a more positive perception of MDR
Commercial affects	Theme 4 Commercial advantages of compliance	The affects of positive perception and high levels of awareness on commercial outcomes.

Table 15 Profiling Interviewees

Interview ID	Area of Management	Years of Experience
Respondent 1	General Manager	14 years
Respondent 2	Sales Director	33 years
Respondent 3	Compliance Director	15 years
Respondent 4	Business Unit Lead	3 months

Table 16 Table Summarising Interview Answers

Question	Theme	Respondent 1	Respondent 2	Respondent 3	Respondent 4
Does managerial role extend to Northern Ireland?	NA	Yes	Yes	Yes	Yes
Sufficiently familiar with EU MDR?	Awareness Theme 1	Yes	Yes	Yes	Not familiar
Aware of Northern Ireland Regs?	Awareness Theme 1	Limited	Yes	Yes	Not familiar
Any formal, internal training?	Training Theme 3	Yes	No	Yes	Yes
Provided any formal training to staff?	Training Theme 3	No	No	Yes	No
Basic Level of Knowledge necessary for all roles?	Awareness Theme 1	Yes	Yes	Yes	Yes

Question	Theme	Respondent 1	Respondent 2	Respondent 3	Respondent 4
Expectations of greater knowledge in customer facing roles?	Awareness Theme 1	No	No	No	No
Challenges in relation to MDR?	Perceptions Theme 2	Master data load CE cert reference number, expiry date,	None current	Transactions and volume numbers	Timelines and awareness in relation to reporting adverser events.
Perception of MDR?	Perceptions Theme 2	Positive	Positive	Positive	Postitive
Sufficient resources for compliance dept?	NA	No-under-resourced	Yes	No	Yes

4.7.1 Thematic Analysis 1 - MDR Awareness

Both respondent 1 and 2 felt that their own knowledge was sufficient in relation to MDR for their role within the company in the context that they have a robust Compliance Department to use as a reference centre. Respondent 3 was very confident in all aspects of the regulation in their role as Compliance and Quality Director. Respondent 4 was new to the role and unfamiliar with MDR.

In relation to MDR awareness of non-managerial roles, all Respondents felt that a tailored awareness depending on the role of the individual in the organisation was necessary.

Respondent one felt that staff should possess the “Requisite level to understand context and level of significance of MDR in relation to their role”.

Respondent 2, commented in relation to the level of necessary awareness of MDR that a “Minimum level depending on the role of the person but less relevant for customer service” Respondent 2 also commented that “Customer facing need the dos and don’t and confidence that the company is compliant”. They continued to emphasise the importance of “Due process when we take a new product in that due diligence has been done by our Compliance Department”

Respondent 3 again, notes the importance of role specific knowledge: “Understanding the level to which people need to be made aware so that it makes sense and it’s relevant to them”, “Awareness of specifically for them, what it would mean”.

All Respondents were correct in asserting that those who they managed had not received MDR training.

Of note is that Respondent 4 was only 3 months into their managerial role, in stark contrast to the other, highly experienced respondents. This may account for their lack of familiarity with MDR>

4.7.2 Thematic Analysis 2 - MDR Perception

The over-arching view of those interviewed in management positions was positive in relation to MDR. Despite the significant extra administrative and regulatory load, it was understood to be in both the companies and ultimately the patients best interests to be compliant with MDR.

Respondent 3 commented: “I think it's a real positive in terms of making sure the standards of what we are responsible for placing on the market are tightened up. I think the benefit for us as a distributor has been the introduction of the economic operators being called out under MDR where it wouldn't have been under the previous legislation and so if it's been put into practice the way we expect it should be, it should really weed out any operators who don't meet the highest standards in relation to medical devices”.

Respondent 1 said “it that can only be good. And then I also think then, I think we have taken a very responsible and serious view of it. We've resourced up, I think we have a good QCRS department and that, albeit as I said we might be tight on resources in other areas, but I think we've overall embraced it properly.”

Referring to MDR, Respondent 2 noted “it’s positive. Ultimately our purpose, I view it as, we're here to serve the healthcare professional and their patient. And the regulations, as I understand them or interpret them, are designed ultimately to protect the patient.”

4.7.3 Thematic Analysis 3 - MDR Training

Of note is that all of those in managerial roles who were interviewed had personally received some training in regard to MDR, in contrast to non-managerial staff that they manage as we see from our survey results. All of those in managerial roles were aware of the lack of training in relation to MDR among their employees.

In relation to the training of staff, Respondent 2 expressed an opinion that training should be relevant and manageable for staff: “I think a little education is good you know but realising that identifying the people you're going to teach and what's the basic information they need. Yeah target. You know we're in a world of soundbites what are the soundbites what are the things they remember and something that's not too onerous on our staff.”

This opinion was echoed in the comments of Respondent 3, noting that some roles require further training; “ I think in the transactional requirements of what we need to do under the regulations, we have to have roles that have an in depth understanding”.

In summary, data from the interview process indicates that those in Managerial roles within the organisation had a positive attitude towards the MDR, a confidence in the compliance of their organisation and an optimism in relation to the commercial advantage that excellence in the area of MDR awareness could bring.

4.7.4 Thematic Analysis 3 - Implications of Awareness and Perception Economically

Respondent 1, when referring to the choice to make investment in Compliance and Quality in the company, Respondent one noted; “It’s almost like a competitive advantage relative to other businesses that may not have invested and things may not be as robust and compliant”.

Respondent 2 commented that MDR awareness was “Crucial with regards the success and function of the company”.

Respondent 3 observed that “The benefit for us as a distributor has been the economic operators being called out under the MDR whereas they wouldn’t have been under the previous legislation and so of it is put into practice as it should be it should weed out the operators who don’t meet the highest standards in relation to medical devices and that, for any of us in the industry is what we’re looking for”.

4.8 Results Versus Hypothesis

At the outset of this study, it was hypothesised that a proactive strategy aimed at maintaining patient safety and regulatory compliance within an Irish Medical Devices Distributor, including targeted training and dissemination of information, will lead to increased awareness of MDR requirements among employees. Furthermore, individuals in customer-facing roles are anticipated to demonstrate a deeper understanding of MDR due to its potential impact on customer interactions. It is hypothesised that employees directly involved with compliance marked medical devices will exhibit heightened awareness of MDR compared to those not engaged in handling such devices.

The findings of the study largely support the original hypothesis regarding the effectiveness of a proactive strategy aimed at maintaining patient safety and regulatory compliance. Firstly, the study revealed a significant level of understanding of MDR among employees within the organisation, This was evidenced by employees’ familiarity with crucial aspects of the primary legislation such as adverse event reporting and CE marking. Additionally, qualitative findings from interviews with management indicated a positive attitude towards MDR, demonstrating confidence in compliance within the organisation and recognising the commercial advantages of excellence in MDR awareness. This aligns with the hypothesis that a proactive strategy would lead to increased awareness of MDR requirements among employees. The proactive strategy would appear to be found within the positive organisational culture of the organisation, rather than in any formal training programs.

Chapter 5

5.1 Findings and Conclusions

Several key conclusions emerge from this study. Firstly, this study found a significant level of awareness and understanding of MDR among employees within the Irish Medical Devices Distributor. Employees demonstrate familiarity with crucial aspects of the primary legislation, such as adverse event reporting and CE marking. However, variations in the perceived importance of MDR across different roles within the organisation suggest the necessity for tailored training and communications strategies to ensure uniform understanding and compliance.

The investigation sought to identify factors influencing awareness of medical device regulation within the distributor, encompassing training, communication channels, and exposure to regulatory standards. Correlation analysis revealed several statistically significant relationships. Specifically, there was a positive correlation between those that had received training felt that the training they had received was effective. Those who were familiar with the nuances of the MDR North and South of the border exhibited a greater appreciation for the importance of MDR within their role. It was also seen that those who felt supported by management felt more satisfied by the communication channels within the company.

The overall perception of MDR is positive among employees and management. Despite this positive outlook, challenges in formal training are evident, as a significant proportion of employees reported never receiving formal MDR training.

Crucially, this study highlights the influence of the organisational climate on knowledge dissemination and specifically in this case, on MDR awareness. Qualitative finding from interviews with management reveal a positive attitude towards MDR, indicating confidence in compliance within the organisation and recognising the commercial advantages of excellence in MDR awareness.

In light of these findings, it is evident that the initial hypothesis regarding the positive level of awareness and perception of MDR among employees within the Medical Device Distributor has been largely supported.

5.2 Limitations of this Study

The fact that this study was conducted as a case study within a single medical device distributor presents both strengths and limitations from scientific and contextual perspectives.

Scientifically, focusing on a single case allows for in-depth exploration and detailed analysis of specific factors relevant to the organisation, such as organisational culture, communication channels, and compliance strategies. This depth of investigation can provide valuable insights into the complexities of MDR perception, awareness, and compliance within a real-world context. Furthermore, by studying a specific case, through both survey and interviews, one can closely examine the interactions between various variables and their impact on regulatory practices, offering rich qualitative and quantitive data for interpretation.

However, from a scientific standpoint, the generalisability of findings may be limited due to the specificity of the case. Since the study focuses on a single medical device distributor, the findings may not be broadly applicable to other organisations with differing organisational culture within the industry. As such, caution should be exercised when extrapolating the results of this study across different contexts or populations. Additionally, the lack of comparative data from multiple organisations may limit the ability to identify industry-wide trends or benchmarks for MDR awareness or compliance.

In the context of this study, there are underlying assumptions. Firstly, it is assumed that the distributor's workforce possesses a foundational understanding of regulatory frameworks, though this understanding may vary among individuals. This aligns with an inductive approach, where general conclusions are drawn from specific observations. Secondly, it is assumed that regulatory awareness correlates directly with compliance and adherence to standards. This assumption reflects a deductive approach. Additionally, it is assumed that the findings from this study can be generalised to other similar distributors, indicating a claim to generalisability. However, it must be recognised that the limitations of this generalisability are significant due to the unique contexts of individual distributors. Moreover, it is assumed that the chosen research methods of surveys and

interview accurately assess regulatory awareness. Recognising these assumptions informs the design of the research methodology and guides the selection of appropriate data analysis techniques. This study aimed for a larger sample size and quantitative analysis methods to address the limitations of generalisability . Conversely, when seeking a deeper understanding of individual perspectives, qualitative methods such as open ended questions and interviews were employed. Overall, acknowledging and understanding these assumptions contextualises my research within the broader philosophical and methodological framework, ensuring the validity and relevance of this study.

Contextually, conducting the study within a single medical device distributor allows for a comprehensive understanding of the organisations unique challenges, strengths, and opportunities related to MDR. This context-specific approach enables tailored recommendations and interventions to address the specific needs of the organisation, potentially leading to more effective strategies to improve regulatory compliance.

It is important to acknowledge, however, that the findings of this study may be influenced by the specific characteristics and circumstances of the organisation under study. Factors such as company size, location, industry sector and organisations structure can all shape the implementation and perception of MDR (Smith et al 2003). Therefore, while the insights of this case study are valuable for the organisation in question, they may not necessarily be transferable to other settings without careful consideration.

The restricted timespan of this study also proved to be a limiting factor in regards to the number of completed surveys obtained and number of interview conducted.

5.3 Recommendations for the Company

From a company perspective, the results of this study would suggest a tailored approach to further education in relation to MDR, which is role specific within the organisation. Further education in relation to Implant Cards would also be helpful to ensure optimal patient safety. In addition, some areas of the company, such as Bookings, may need greater attention due to the poor perception and training levels involved in this section of the company The apparently positive organisational

culture of the company could be further encouraged, supported, measured, and utilised as a further commercial and cultural advantage.

5.4 Wider Recommendations for Research

Based on the results of this study, several potential avenues for further study emerge. Firstly, there is a need for comparative research focusing on non-managerial roles across the spectrum of medical device industry.

Secondly, a longitudinal study could assess the effectiveness of formal training programs over time, tracking knowledge retention and identifying areas for training improvement. Moreover, expanding the study to include cross-cultural comparative analysis could shed light on how cultural factors may influence compliance behaviours and regulatory attitudes.

Additionally, researchers could explore the specific organisational climate factors contributing to the positive perception of MDR observed within the medical device distributor examined in this study, utilising qualitative methods to examine employee perceptions of organisational culture and leadership.

Further research into the level of awareness, perception and difficulties faced by organisations working in medical devices in Northern Ireland could allow for an insightful study into a globally unique regulatory micro-climate.

Lastly, examining MDR awareness and perception of those within the medical profession who are using or implanting medical devices as a form of treatment may provide valuable insights.

5.5 Final Reflections

This study has demonstrated a significant level of awareness and positive perceptions of MDR among employees of a medical device distributor in Ireland. These findings are despite limited formal training programs in this regard and suggest a positive organisational culture.

On reflection, it may have been useful to try to obtain interviews from all Business Unit Leads in middle management and compare the qualitative information of these interviews with those of higher level managers in Director roles within the organisation. It could also have prove useful to investigate further into whether employees of the organisation have ever had to report an adverse event, and question further in regard to their experience of the process. It could be suggested that putting a time limit on survey completion could have provided a more authentic set of responses, although this researcher appreciates that circumstances may interfere with the timely completion of surveys. The average time to complete this short survey was 16.28 minutes, the estimated time at the outset of the study was 5 minutes. A longer period of primary data collection could have also yielded a greater response rate to both surveys and interviews.

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Appendices

1. Ethics Application

Ethics Application & Declaration Form

DISSERTATION TITLE: Staying Ahead in Patient Safety: Assessing the Awareness and Perception of Regulatory Requirements in an Irish Medical Devices Distributor

RESEARCHER'S NAME: Cathy Tyndall

PROGRAMME OF STUDY: M.Sc. (Medical Devices and Business)

SUPERVISOR'S NAME: Dr. Gillian McMahon

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

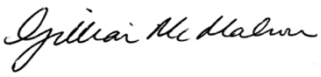
For Student:
STUDENT SIGNATURE: Cathy Tyndall

DATE: 09/03/2024

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required: ☐ Yes ☑ No

SUPERVISOR SIGNATURE: 

DATE: 13/03/24

For Ethics Committee (if required):

Ethics Committee Approval Given: ☐ Yes ☐ No

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research The research endeavours to gauge the level of awareness and understanding of Medical Device Regulation among employees within an Irish Medical Devices Distributor. Its principal objectives are twofold: firstly, to quantify the extent of MDR awareness among the workforce using structured surveys and interviews; and secondly, to identify the factors that influence this awareness. By examining both quantitative data, such as survey responses, and qualitative insights garnered from interviews with key management personnel, the study aims to provide a comprehensive assessment of regulatory comprehension within the organisation. Furthermore, the research seeks to explore employee perceptions of MDR and its implications for organisational compliance and patient safety. Ethical considerations are paramount throughout the research process, ensuring participant confidentiality, informed consent, and the responsible handling of sensitive organisational information. The conceptual framework establishes a structured understanding of how regulatory awareness relates to compliance and patient safety within the organisation, while also accounting for contextual factors such as industry standards and organisational culture. Ultimately, the research aims to offer valuable insights that can inform decision-making processes and facilitate improvements in regulatory compliance and safety standards within the medical device industry.

1.2 Research methodology: The primary data collection for the research on MDR awareness within the Irish Medical Devices Distributor will be executed through a mixed-methods approach, incorporating structured surveys and interviews. Structured surveys will be disseminated to all relevant employees, encompassing closed and open-ended questions to gather both quantitative and

qualitative data. These surveys will be administered online to ensure accessibility and anonymity for participants, covering aspects such as awareness levels and perceived challenges regarding MDR compliance. Concurrently, interviews with key management personnel will provide qualitative insights into organisational perspectives and expectations regarding MDR awareness. Through this comprehensive data collection strategy, the research aims to obtain a holistic understanding of MDR awareness within the organisation, facilitating the identification of influencing factors and areas for improvement. The integration of both quantitative and qualitative data analysis methods will enable the generation of nuanced insights, enhancing the validity and reliability of the findings. Ethical considerations, including informed consent and participant confidentiality, will be meticulously adhered to throughout the data collection process, ensuring the responsible conduct of research. The research methodology aligns with the overarching objectives of assessing MDR awareness levels, identifying influencing factors, and providing actionable recommendations for enhancing regulatory compliance and patient safety within the medical device industry.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:	
Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:	
Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:	
People who are not competent and/or fluent in English	**No**
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.
If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.

3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study The participant profile for this study encompasses employees of an Irish Medical Devices Distributor, spanning various departments and roles within the organisation. This comprehensive approach aims to capture diverse perspectives and experiences related to MDR awareness within the company. Employees from departments such as sales, marketing, regulatory affairs, quality assurance, logistics, and customer service will be included in the study. Additionally, key management personnel, including executives and department heads, will be interviewed to provide insights into the organisational perspective on MDR awareness and compliance. The participant selection covers individuals with a range of roles and experience levels, from entry-level staff to seasoned professionals. This diversity allows for a comprehensive examination of MDR awareness across different job functions and tenure within the company. By involving employees from various departments and roles, the study seeks to understand how MDR awareness varies across different segments of the organisation and how factors such as job responsibilities and organisational culture may influence awareness levels.

Moreover, by including key management personnel in the study, the research aims to compare the expectations and perceptions of MDR awareness held by management with the actual results obtained from the survey of employees. This comparison will provide valuable insights into any gaps between the anticipated level of awareness and the reality within the workforce. By

juxtaposing management's expectations with employees' responses, the study will shed light on potential discrepancies and areas for improvement in communication, training, and organisational practices regarding MDR awareness. Overall, the chosen participant profile facilitates a comprehensive exploration of MDR awareness and its determinants within the Irish Medical Devices Distributor, offering insights for enhancing regulatory compliance and aligning organisational expectations with the reality of employee awareness.

4.2 How do you plan to gain access to/contact/approach your participant(s). To access participants for this study, I plan to collaborate closely with the management team of the Irish Medical Devices Distributor. Initial contact will be established through formal communication channels, such as email or official announcements within the company. A detailed explanation of the research objectives, methodology, and ethical considerations will be provided to the management team to gain their support and endorsement for the study. Once approval is obtained, I will work with the Human Resources & Compliance department or relevant personnel to identify and recruit participants from various departments and roles within the organisation. Employees will be invited to participate in the study through internal communication channels, such as company newsletters, intranet announcements, or direct emails. Participation will be voluntary, and individuals will have the option to opt-in or opt-out without any adverse consequences to their employment or relationships within the organisation. Additionally, I will coordinate with key management personnel to schedule interviews with executives and department heads, ensuring their availability and willingness to participate in the study. Throughout the recruitment process, confidentiality and data security measures will be emphasised to reassure participants about the protection of their personal information. Overall, accessing participants will involve a collaborative effort with the management team, Compliance Dept and HR department to ensure the recruitment of a diverse and representative sample of employees and key management personnel from the Irish Medical Devices Distributor.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2 **Informed Consent Form (ICF) for participants**

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.

SECTION 6: STORAGE OF DATA

6.1. How will you store the research data and for how long? How will you manage data protection issues? I, Cathy Tyndall, will be the primary data controller. Data will be stored for two years on the secure Griffith College electronic research platform. The only people with access to the data are myself, the researcher, my supervisor and other relevant College staff. At all times, the identity and privacy of the participants will be maintained.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**

If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**

The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	Yes
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: Cathy Tyndall

DATE: 09/03/2024

SECTION 10: APPENDIX

Participant Information Letter

Staying Ahead in Patient Safety: Assessing the Awareness and Perception of Regulatory Requirements in an Irish Medical Devices Distributor

Dear Participant,

You are invited to participate in a research study aimed at understanding the awareness of medical device regulation among employees in a medical device distribution company. The study is being conducted as part of a research project to fulfil academic requirements.

Your participation in this study involves completing an interview or survey that will assess your level of awareness of medical device regulation. The survey will consist of both closed-ended and open-ended questions and it will be distributed electronically for your convenience. The interview will take place in person or using an online platform e.g. zoom. All responses will be anonymised and treated confidentially.

You have been invited to participate because you are employed by a medical device distribution company and your insights are valuable for understanding the level of awareness among employees.

Participation in this study is completely voluntary, and you have the right to refuse participation, decline to answer any question, or withdraw at any time without facing any consequences. Your decision to participate or not will not affect your employment or relationship with the company in any way.

There are no direct benefits to you for participating in this study. However, your input will contribute to research aimed at improving awareness and compliance with medical device regulation, informing future knowledge, which may ultimately enhance patient safety.

All information provided by you will be kept strictly confidential. Any identifiable information will be removed from the data collected to ensure anonymity. Data will be stored securely and only accessible to the researcher and relevant College staff. In the event that confidentiality needs to be breached due to concerns about harm or criminal activity, appropriate action will be taken.

The results of this study will be used for academic purposes and may be disseminated through conferences, publications, or teaching materials. However, your data will remain confidential.

If you require further information or have any questions about the study, please feel free to contact Cathy Tyndall at Griffith College Dublin via cathy.tyndall@student.griffith.ie

Thank you for considering participation in this study.

Sincerely,
Cathy Tyndall
Griffith College Dublin
cathy.tyndall@student.griffith.ie

Informed Consent Form

Staying Ahead in Patient Safety: Assessing the Awareness and Perception of Regulatory Requirements in an Irish Medical Devices Distributor

- I _____ voluntarily agree to participate in this research study
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind
- I understand that I can withdraw permission to use data within two weeks following the survey or interview, in which case the material will be deleted
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study
- I understand that participation involves assessing perception and awareness of Medical Device Regulation within the company
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I agree to my interview being recorded.
- I understand that disguised extracts from my interview may be quoted in a Masters Dissertation, without my identity being revealed in any way.
- I understand that I will adhere to all the codes of conduct and employee confidentiality for my company and there is no expectation to breach these by partaking in this research.
- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission.
- I understand that signed consent forms and original video/audio recordings will be retained electronically for a period of two years.

- I understand that a transcript of my interview in which all identifying information has been removed will be retained for a period of two years from the date of the exam board.
- I understand that under freedom of information legislation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

Name	Cathy Tyndall
Degree Programme;	M.Sc. (Medical Devices and Business)
College Details	Griffith College Dublin
Contact number	0872444231
Contact mail	**cathy.tyndall@student.griffith.ie**

Signature of participant

---------- Date ----------

Signature of researcher

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

---------- Date ----------

3. Draft Interview Questions

Suggested Interview Questions for those in Managerial Roles:

Demographics

1. How long have you been in your current managerial role?

2. How long have you worked in the Medical Devices industry?

3. What area of the company do you manage?

4 Does your managerial role extend to Northern Ireland?

Knowledge:

5. How familiar are you with the European Union Medical Device Regulation (MDR), and are you aware of any differences in regulations between the North and South of Ireland, the UK, and the US?

6. Have you received any formal training in regards to Medical Device Regulation?

7. Have you provided or are you aware of any formal training or education on medical device regulation that has been provided to employees of the company?

8. Has this training been provided to all employees of the company?

11. What strategies do you employ to ensure that employees are aware of and compliant with MDR, considering the differences in regulations across different regions?

Expectations:

12. What are your perceptions of the current level of awareness of MDR among employees in non-management roles, considering the variations in regulations across different regions?

13. What expectations do you have regarding the level of awareness and compliance with MDR among employees, considering the regulatory differences between regions?

Challenges

14. Can you describe any specific challenges or difficulties the organisation faces in ensuring compliance with medical device regulations, particularly with respect to differences between the North and South of Ireland, the UK, and the US?

Suggestions

15. How do you believe the company could improve its communication regarding regulatory updates and requirements, taking into account the variations in regulations across different regions?

Perception

16. How do you perceive the impact of awareness of MDR on the overall success and reputation of the company, considering the regulatory variations?

17. Do you believe there are sufficient resources allocated for regulatory compliance within the organisation, accounting for differences in regulations between regions?

4. Draft Survey Questions:

Participant introduction:

Dear Participants,

Thank you for considering taking part in this research study. This short survey aims to assess your awareness and perception of medical device regulations (MDR) within our company, particularly focusing on your understanding of the Medical Device Regulation (MDR) and the importance of CE marking for regulatory compliance. Your participation will help us understand the level of regulatory awareness among employees and identify areas for improvement in our training and communication strategies. Your responses will remain confidential, and your feedback will be invaluable in shaping our efforts to ensure compliance with medical device regulations. The survey should only take 10 minutes of your time. Thank you for your time and contribution to this important research endeavour.

Demographics:

1. How long have you been employed by the company?

- Less than 1 year
- 1-3 years
- 4-6 years
- 7-10 years
- More than 10 years

2. Do you or your department ever work with or train with medical devices outside the Republic of Ireland or the EU?

- Yes, regularly
- Yes, occasionally
- No, never
- Not applicable to my role

3. Do you or your department ever work with or source medical devices from the North of Ireland, the UK, or the US?

- Yes, regularly
- Yes, occasionally
- No, never
- Not applicable to my role

Knowledge

4. How familiar are you with the European Union Medical Device Regulation (MDR 2017 145/146), including requirements for CE marking?

- Very familiar
- Somewhat familiar
- Not very familiar
- Not familiar at all

5. To what extent do you feel adequately informed about the specific regulatory requirements for medical devices distributed by our company?

- Completely informed
- Moderately informed
- Slightly informed
- Not informed at all

6. How confident are you in your ability to ensure compliance with medical device regulations while carrying out your role within the company?

- Very confident
- Moderately confident
- Slightly confident
- Not confident at all

7. How familiar are you with the specific regulatory requirements for medical devices in Northern Ireland under the Northern Ireland Protocol?

- Very familiar
- Somewhat familiar
- Not very familiar
- Not familiar at all

8. How knowledgeable do you feel about the differences between medical device regulations in Britain and the European Union, particularly in light of Brexit?

- Very knowledgeable
- Moderately knowledgeable
- Slightly knowledgeable
- Not knowledgeable at all

9. How often do you receive training or updates on changes to medical device regulations from the company?

- Regularly
- Occasionally
- Rarely
- Never

10. Are you familiar with the appropriate department or contact person within the company to address compliance-related queries or concerns?

- Yes, I am familiar with the relevant department/contact person

- Somewhat, but I may need clarification
- No, I am unsure
- Not applicable to my role

Perception:

11. How do you perceive the importance of compliance with the Medical Device Regulation (MDR) in your specific role within the company?

- Extremely important
- Very important
- Moderately important
- Slightly important
- Not important at all

12. How important do you consider CE marking for medical devices distributed by our company in ensuring compliance with EU regulations?

- Extremely important
- Very important
- Moderately important
- Slightly important
- Not important at all

13. To what extent do you believe that awareness of and compliance with medical device regulations contributes to the overall success and reputation of the company?

- Strongly contributes
- Moderately contributes
- Slightly contributes
- Does not contribute

14. How effective do you find the current training programs provided by the company in enhancing your understanding of medical device regulations and CE marking?

- Very effective
- Moderately effective
- Slightly effective
- Not effective at all

15. How well do you think the company adheres to medical device regulations in comparison to other organisations in the industry?

- Much better
- Somewhat better
- About the same
- Worse
- Much worse

Satisfaction

16. How satisfied are you with the communication channels used by the company to disseminate information about changes in medical device regulations?

- Very satisfied
- Moderately satisfied
- Slightly satisfied
- Not satisfied at all

17. To what extent do you feel supported by management in your efforts to stay informed about and compliant with medical device regulations and CE marking requirements?

- Strongly supported
- Moderately supported
- Slightly supported
- Not supported at all

Interview Transcripts

Transcript of Interview with Respondent 1

0:00:00

So the date is the 5th of April.

0:00:03

Yeah. It should have started to record.

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I should have pressed that.

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That's great.

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Wonderful.

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So it's the 5th of April and I'm talking to Tom O'Connell. And so Tom, can I just ask you how long have you been working in the area of medical devices?

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I'm in my 14th year. I came into the industry when I joined what was previously Cisco Healthcare, now Unifar MedTech. I joined in 2010, so I've been involved since then. OK, and that which led me to the second question, which is

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how long have you been in the current role? Yeah, my current role in Techno as General Manager, just over two years. Wonderful. And with regards to your current role, do you feel that you have a sufficient level of awareness of the EUMD or TEPES and N17?

0:01:06

Probably the requisite knowledge to understand context, right? And it's significant and why it's so important and that, right? But as we get down into maybe next layers of technicality and that, I wouldn't proclaim to be an expert on that, but that's where we'd rely on Vicky's team would have reported into me in my previous role, so we would have kind of recognised the emergence, I suppose, of the

0:01:54

industry becoming more regulated, and that's why we invested in that quality and regulatory and compliance team. We built that up into a stronger team than over over the years, you know, so just knowing the industry, the direction of the industry and that.

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Yeah, and with regards your managerial role, does it extend to north and south of Ireland?

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It does. The majority of technology businesses are in the Republic, but certainly we have some in Northern Ireland. And as part of our strategy, our intent would be to kind of deepen penetration there in Northern Ireland from a business perspective. So it will become more and more relevant.

0:02:42

Okay. And in that regard, how familiar do you feel with the regulations governing the north of Ireland and the UK? I would say limited. I suppose during the Brexit period and everything that was there

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you know that we were we were there was there was probably a lot of information and grappling to try and understand the nuances and the differences and everything like that so I I wouldn't have a sufficient level of expertise and knowledge on that, Cathy.

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And I suppose obviously the regulatory department, that's where they kick in. Obviously that presents a unique set of challenges.

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There might be an opportunity and I think there's probably a need for a next layer of knowledge, right, that the management team in general should should have, right, while not trying to get to the level of expertise that a Lauren or QCRS might have, but I do think there's probably we need to go down another layer of knowledge. You know, and equip management team and the leadership with that, and when I mean leadership I mean even first line managers, team leaders and so on down to that level you know.

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And to that point have you received any formal training in medical device regulation either in the EU or in relation to the north of Ireland or the UK?

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Now when you say formal Cathy so I think from time to time we would have probably got some internal training or pass downs from the quality QCRS team, Vicky's team. But you know, nothing of a more formal nature beyond that.

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Yes, yes. And with regards those working for you and whom you're managing, are you aware that whether they have received any training in regards to medical device regulation?

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I'm pretty certain they haven't. I don't think they would have received anything beyond what I might have received. So it would be some internal training and then probably learning on the job by engaging with QCRS on a less required basis. I think it would be more like that. opinion is there a basic level of medical device regulation that anyone working in

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a medical device distributor should have or do you think there's some roles that could do without any knowledge of it? I think given that we're I suppose given

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the the ultimate purpose of the regulation right which which I guess is ultimately geared towards patient safety and given that we're now in that industry I think every employee should have kind of the requisite level of knowledge, right? That may be deeper for different roles but I think everybody should have a degree of awareness and I suppose understand it in the context of their role and their responsibilities. You don't know if you are somebody taking product and sending it in a warehouse and shipping it to a customer. There's things you have to understand if you're receiving

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product, if you're setting up master data, you know, all those roles permeate through the organisation need a certain level of awareness.

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And to that point, would you expect those in customer facing roles to have a greater or lesser knowledge than those outside the compliance department within the operational aspect of the company. Now when we say customer facing, Kathy, can you say a little bit more?

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Are you referring to the field sales people or the field service or are you referring to

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the functions and like customer care? So I suppose customer facing largely being if we refer to the customer largely in this case as in a healthcare setting, potentially the hospitals or the surgeons, so largely the sales reps who are probably out on the ground. Would you predict that they would have a greater or lesser knowledge than those who are potentially office-based but outside the compliance department? I hope that's more clear.

0:07:31

Good question.

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I probably need to reflect on that one a bit more right I think they would they would certainly need a certain level but I would also see that you know the all the different operations or enabling functions outside of QCRS you know play a very important part right because there are many stages in the value chain up to the point where say even like yourself as a in your role the product eventually arrives to the hospital and then you're ready to support the case right.

0:08:16

Everything along the value chain we've got to ensure that you know once we Once we reach that point of providing an implantable device that could be used in a case, everything's got to be right to that point. So I think everybody plays a role along the value chain. I can't readily see a dramatic difference to say, well, the field needs to be all over this but it's kind of less so in other areas.

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areas you know. I see there's a role for, there's a level of knowledge and

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there's a responsibility right through the value chain. And would you like those in customer facing roles let's say in this case out in the hospital setting and health care setting to be able to answer basic customer questions in relation to the medical device that is about to be

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Yes, I would. I think definitely. Plus I think it would be helpful as well, with the right level of knowledge, it would give the field-based people context for some of the procedures and processes that have to be adhered to upstream in order that we ensure we're compliant with the regulation. So, let me give you an example, right? The salesperson, maybe, you know, with a business development focus and they have identified some new supplier,

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new product, and say, I'd love to get samples of those to show to the professor or whatever, right? And you can't readily do that.

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Of course.

0:10:03

You know, there's protocols that have to be followed, right? So without maybe the understanding the context, then they might feel and get very frustrated that the process isn't happening fast enough and I don't understand why I'm just ordering a sample, take it out, it's not going to be implanted in a...

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I'm just going to show it to somebody, you know? Just an example, you know, that's why I think

everybody needs to be knowledgeable and then they have a better understanding of why the process needs to be the way it is.

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Yes, yes. And final question Tom is do you believe that the Compliance Department has sufficient resources?

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I think from a resourcing standpoint, the way I would look at it is, Cathy, I think

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that, and I look at it from the business overall, right, there's a level of expertise that's required to understand and interpret the regulations and have that technical knowledge on all of and it does feel like the QCRS department have the capacity for that. I think the likes of Lorne and all that. Now, I don't know, Vicky would know best if there needs to be a Lorne number too because of we're now 10 businesses across the MedTech group.

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But by and large I think we're about right there. There's a second level of activity then which is a lot of execution type activity that's there to I suppose ensure we implement everything that we should implement regarding the regulations and it's in that area throughout the business that I think we are under resource in that regard. I think as a business we've probably ended up taking on a lot of, well it's not taking on, but the industry has

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moved this way, right, so we're now in a different environment but we probably assessed what that additional load is and made sure we've resourced it accordingly. We might be in a spot, but we're generally squeezed there so we find then that we might have a certain amount of building somewhere but not enough, right? It's not complete enough and I even think about maybe all of our master data that needs to be on our system. We're trying to be in catch up now to get that populated, to get that cleansed and that

0:13:02

right. And that things like making sure on our system we have the correct information about a CE CERT, we have the CE CERT reference number, the expiry date and you know and there's definitely resource that's required to properly manage all that and I think in execution realm I don't think we're

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resourced enough. To your point do you believe that then medical regulation in general is a positive or a negative thing to the company? I think it's positive. Okay, despite the extra load.

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Yeah, it's positive. Ultimately our purpose, I view it as, we're here to serve the healthcare professional and their patient. And the regulations, as I understand them or interpret them, are designed ultimately to protect the patient.

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And that can only be good. And then I also think then, I think we have taken a very responsible and serious view of it. We've resourced up, I think we have a good QCRS department and that, albeit as I said we might be tight on resources in other areas, but I think we've overall embraced it properly.

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And I think that that gives us a, as a business, it's a very important kind of, it's almost like a competitive advantage relative to potentially other organizations that may not have invested and may not be as,

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but things may not be as robust and compliant and everything like that, you know? Yeah, that's wonderful. Listen, Tom, thank you so much.

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I'm gonna stop the recording now, if that's okay. Yeah, that's wonderful. Tom, thank you so much. I'm going to stop the recording now if that's okay.

0:14:55

Okay. I'm going to put the camera on the table. What is that? What is that? You know what makes it so special, Brica? It's like the future we've been living in

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but then you were in it now. I'm going to try to be in the chair until I make it. Oh well. Is that you? Yeah. I'm going to put it in the middle.

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I'm going to put it in the middle.

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I'm going to put it in the middle. I'm going to put it in the middle.

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Thank you.

Transcript of Interview with Respondent 2

0:00:00

So I'm just asking questions today of Brendan Murray, Sales Director. And the first question would be how long have you been in your current managerial role?

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17 years.

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Okay, and how long have you worked in the area of medical devices?

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Since 1991.

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Okay. What area of the company do you manage?

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All sales and marketing.

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Does your managerial role extend to Northern Ireland?

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Yes.

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And how familiar are you with the EUMD or 2017 145, 146?

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At a high level, the basics.

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Do you feel that you could benefit from further guidance from the regulatory department to this end?

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To a certain degree, yes.

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And are you aware of the differences between the regulations in the Republic of Ireland, Northern Ireland, the UK and the US? At a high level, yes. Okay, and do you feel you could benefit from any further guidance in this regard from the Regulation Department?

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I think for the need to know information, yes.

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Okay, so have you received any formal training in regards to medical device regulation?

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No. Okay. Have you provided, are you aware of any formal training having been provided

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with regards medical device regulation to those that you manage? No. Okay. Do you perceive medical device regulation as a positive or negative aspect for the company? It's crucial. Yeah, it's a crucial part. Okay. And crucial with regards to the success of the

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company or the functioning of the company? So, yeah, to all of those things, yeah. And being compliant, right, it's obviously crucial that you're compliant with all regulations for bringing products into the Irish market.

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Do you believe there's a minimum level of medical device regulation awareness that every employee in the company should possess?

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I think, yeah, I think a minimum level, I think the Bluffer's Guide. Okay, okay. It depends on the role of the person. Okay, and to that

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end, which specific roles do you believe can function effectively without much knowledge of medical device regulation or compliance? I think anyone

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who is perhaps maybe not directly involved with the actual medical device device from a selling or surgery presence customer facing role. I think people like customer services, people like that, probably not that relevant to them.

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Okay, and from your perspective do you believe there are certain roles within the medical device distribution company that require a deeper understanding of medical device regulation compared to others? And if so, what roles do you think would benefit most from the

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awareness? Well it would be part of our regulatory team. Okay. Obviously they yeah they take ownership of that and then I think you know obviously senior management probably would need to know more than the people on the ground but the people on the ground need a basic information on the do's and don'ts. Okay

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and what are your perceptions of the current level of medical device regulation awareness among those in

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non-management roles in the company? Probably not very strong. I would assume they assume that anything that the company asks them to sell is compliant with all regulations. They would expect that the company

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oversees that. Okay and slightly repetitious here but do you expect those in customer facing roles that they will have a greater similar or lesser awareness of medical device regulation than those in non-customer facing roles?

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That's a bit broad on the non-customer facing role side. I think obviously people customer facing

need the basic information, the do's and don'ts and confidence that the company is being compliant. So they're really important. For the people non-facing, average office people doing clerical work or whatever, customer services, it's not really key to them.

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So can you describe any specific challenges the organisation faces in ensuring compliance with MDR, particularly in respect to the differences between the Republic of Ireland, Northern Ireland, the UK and the US?

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Repeat that question again.

0:04:35

So can you describe any specific challenges the organisation faces that you're dealing with currently in ensuring compliance with MDR, particularly in respect to the differences between the Republic of Ireland, Northern Ireland, the UK and the US? Is there any current issue you're dealing with or facing?

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Not dealing with anything currently but the fact that we look after Northern Ireland and the Republic of Ireland, you know, we have to have our due diligence done on what we can sell in the Republic versus what we can sell in Northern Ireland because the regulations are different. Again, this is part of our due process when we take a new product in to the company, that all the due diligence is done by our regulatory team and our senior management team and make it clear to our staff what we can sell on both sides of the border. And also getting

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product in for samples or to show surgeons or to do first surgeries it's important that regulatory are involved in this so that they can do the checks and balances to make sure we can actually sell it and bring it into the Irish market.

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So how do you believe it can

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could improve its communication? I think a little education is good you know but realizing that

identifying the people you're going to teach and what's the basic information they need. Yeah target. You know we're in a world of soundbites what are the soundbites what are the things they remember and something that's not too onerous on our staff.

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No problem. Okay.

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Do you believe that there's sufficient resources allocated for regulatory compliance within the organisation?

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Yes.

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Thanks very much, Brendan. Thanks very much, Brendan.

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Thank you.

Transcript of Interview with Respondent 3

2

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Okay, so I'm speaking with Vicky O'Reilly and it is the 28th of March. So the first question is what area of the company do you manage Vicky?

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So I'm responsible for the Quality, Compliance, Regulatory and Sustainability Department. Okay and how long have you worked in the area of medical devices now. Okay, and does your managerial role extend to Northern Ireland? Yes, yes. Okay, so are you familiar with the EUMD or 2017 145, 146 and if so how familiar would you regard yourself as being? Yes, I'd be very familiar with it in my role. Yeah. Great. And are you familiar with the differences between

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the regulations of the Republic of Ireland, Northern Ireland and the UK in your role? Yes. Yeah.

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Super. And have you provided or are you aware of any formal training having been provided in regards to medical device regulation to those which you manage? Yes. Yeah. So as a team we would have to be quite aware of it and then we would also provide training out to the wider organisation. And do you perceive medical device regulation as a positive or negative aspect for the company?

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I think it's a real positive in terms of making sure the standards of what we are responsible for placing on the market are tightened up. I think the benefit for us as a distributor has been the introduction of the economic operators being called out under MDR where it wouldn't have been under the previous legislation and so if it's been put into practice the way we expect it should be, it should really weed out any operators who don't meet the highest standards in relation to medical devices and that really for any of us in the industry is what we're

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looking for. Okay, do you believe there's a minimum level of medical device regulation and awareness with every employee the company should possess? Yes, I think everybody's role has something to do with it. So it's just understanding, I suppose, the level that people need to be made aware so that it makes sense and it's relevant to them. Yeah, so in essence that kind of negates my next question was going to be, if not, what

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specific roles do you feel can function effectively without any knowledge of it but you do believe that some basic level. Yes and an awareness of kind of specificity for them what it might mean. Okay and again to that from your perspective do you believe that certain roles within medical device distribution require a deeper understanding of medical device regulation compared to others and if so what roles do you feel benefit most from the awareness? I think

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in a couple of ways in the transactional requirements of what we need to do under the regulations we have to have roles who have in-depth understanding of that so for example my department have

to have an in-depth understanding because we offer that business partner support and that consulting support across all the businesses. And then within the businesses, again,

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depending on the roles, you've got people working in the likes of purchasing or looking at tenders in the likes of purchasing or looking at tenders and contracts who need to know.

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So with regards, if I can go back to that one, sorry now Vicky. So are there any yeah are there any communication channels or mechanisms in place for employees to express their concerns, ask questions or provide feedback related to medical device regulation? Yes, yeah so we'd get feedback in a number of different ways. We've really, I suppose,

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set ourselves up as a centre of knowledge and a centre of excellence. So, anybody that we would deal with in relation to this, we would say, come to us, ask us, let us find out for you. And there's mechanisms whereby, you know, people will ask formally through. We have a regulatory inbox set up for queries to come through. We've got people who might contact us on Teams just to ask a quick question. And then formally where we've had different work streams and different projects set up when we were earlier in the implementation of MDR, we'd focus groups around different

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areas and we were able to gather feedback through that. But at the moment on the day-to-day, now that it's kind of in play, now we're dealing with it all the time, it would be very much that people would come to us directly as a team. So either to, if they're used to dealing with myself or to Lauren or to the Regulatory Inbox, to say, you've come across this, what do you think? So we've done a lot of work of moving the doing into the business units, so people in

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purchasing, people in incoming sampling, people in vendor approval, and people in business services, check and search. What they'll do is, if it looks and feels normal, they're good to go. When they come across something that they think just doesn't feel right or the supplier has provided us with something we've never seen before, they'll use us then as an escalation method to come and ask us, can we check or can we give our own guidance or

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advice on it? And, you know, products will be held until that conversation happens and until we're okay to release it then. Okay. Are there any initiatives or strategies in place to encourage open dialogue and communication between employees and the compliance department and address any barriers that employees feel that they may have or concerns in reaching out to compliance with questions about MDR? Yeah, I don't think, I suppose the strategies we've had in place around have been very much

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to be very open about it and to put ourselves forward as I say as that department say, the earlier you come to us and engage with us, the easier it will be or, you know, the more support we can give you. Where we find there can be a little bit of difficulty is where people either go outside of processes or don't have an awareness and product turns up somewhere in the supply chain that everybody's going, how did it happen and where did it get here? And what you can sometimes face in organizations, and we've seen it a little bit ourselves

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is that there becomes a little bit of a, but it wasn't my job and I didn't know and it wasn't my fault or I was just doing it because somebody else told me to do it. So we very much have another strategy, I suppose, that backs that up then of when something does happen,

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how can we use it as a learning? How can we bring it back to the business to say, this happened and we think it fell down at this point and this is why it was important that we picked it up. So how do we make sure that that doesn't happen again?

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So how do we put a preventive measure in so that this issue that we've now come across doesn't come up again within the whole supply chain? Yes. And last question, do you believe there's sufficient resources allocated for regulatory compliance within the organization? I'm going to say no. I like your question. I think that we've made huge progress from where we were. Like when I think of starting this department as a department of one, it's still not huge relative to the size of

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the organization. Relative to the size of the people, numbers we have of employees, it probably is a

good size but it's the transactions and the throughput. When you multiply it out by the numbers of suppliers and the numbers of products and the numbers of geographies, it's probably not enough and I think as we move into resource planning for 25, it will definitely be something that will be on the radar because everybody is looking for support in this area

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and for us to be able to do two things, for us to be business partners to the organization and say, this is our guidance, we need time to research that, we need time to take a position on something, we need time to consider how will it impact all those different roles and different departments and to your earlier questions, how will we maybe do communication out to the warehouse? That needs to be different to the field.

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That needs to be a couple of training sessions. And then you layer that on top of, we've also got the transactional stuff that has to happen every day. So how do we do all of those things? And when you take it wider than just this business unit,

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how do you do it for 10 business units that are all looking for your support at the same time. So I think I would say no, I don't think we're probably a million miles away from where what we could achieve with probably another couple of heads. Like we don't need to double the department, but I think we are aware, I think the wider senior management team would be aware that there probably is a need to go a couple more in terms of strengthening it. And how many do you currently have working in the department? In the department all together

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we would have including myself seven. Okay and that's not just for this particular medical device distributor that's for the bigger parents company? That's across the medtech group. Okay and the bigger group yeah. No that's fine and that's wonderful thanks so much Vicky I'll just stop the recording there if that's okay.

Transcript of Interview with Respondent 4

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So, how long have you been in your current managerial role?

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Current role, what's that, three months now?

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Thank you, and what area of the company do you manage?

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Head and neck. Head and neck and spine.

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There we go, sorry, I should say that.

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Does your managerial role extend to Northern Ireland?

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It does. How familiar are you with the EU MDR 2017, 145 and 146? I've heard of them, I'm familiar, I know they exist basically. Do you feel you could benefit from further guidance from the Regulation Department in this regard? Yes. Are you aware of the differences between the regulations in the Republic of Ireland, Northern Ireland, the UK and the US?

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Broadly as in the regulatory bodies that look after them and so on and the UKCAC, EFPA, the rest of it, but beyond that I don't know the details.

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Okay and do you feel you could benefit from further guidance from the regulations to that end as

well. So have you received any formal training in regards to medical device regulation from the company?

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Yes, I think I have had a presentation.

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Okay. Have you provided or are you aware of any formal training having been provided in regards to medical device regulation to those that you manage?

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I'm aware that they probably would have received the same training that I did, but I haven't been responsible for them getting that training.

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Do you perceive medical device regulation as a positive or negative aspect to the company? Positive. Do you believe there's a minimum level of medical device regulation awareness that every employee in the company should possess? Yes. Okay, from your perspective do you believe that certain roles within medical device distribution

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require a deeper understanding of medical device regulation compared to others?

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Absolutely yes.

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And if so, what roles do you think would benefit most from this awareness and why? Compliance

and regulatory because they would ultimately be responsible for ensuring that what we sell meets the standard required and that all certification is in place before we would sell it in our market.

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And what are your perceptions of the level of awareness of medical device regulation among those in non-management roles within the company.

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Would that be non-management, would that include regulatory or would that be just non-management?

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Excluding I suppose because we've already kind of touched on regulatory so I suppose. Yeah, I would say

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there is an awareness that is there, but just and in fairness, I would presume that all of that was in place before it would get into my hands and put it to the customer. So the actual nuts and bolts of the legislation, I think there is a minimum level of understanding and knowledge that it needs to be there, but the actual detail, I'm not so sure.

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That's no problem. Do you expect that those in customer facing roles will have a greater, similar or lesser awareness of MDR than those in non-customer facing roles?

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I would say they would have... Similar or lesser? I would say similar.

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Okay, okay.

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I'm sort of, I know this is being recorded, I'm kind of debating whether it would be similar or whether it would be to a lesser degree. Because, I mean, it would come off the back of my previous answer, which would be that if they know it exists, they know it's in place. perhaps a customer-facing member of staff would go, right, well, someone else has done all of the work, so if it's made it as far as me, then everything must be in order. So perhaps a lesser extent.

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And do you think those in customer-facing roles should be able to answer basic questions from customers with regards to medical device regulation?

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Yeah.

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Okay. Okay.

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Can you describe any specific challenges that you're aware of that the organisation faces in ensuring compliance with MDO or particularly in respect of the differences between the Republic, Northern Ireland, the UK and the US? I think it is probably the timelines for reporting what are clear adverse events. Okay, okay. So I would say, pardon? Do you think they're tight timelines or you know do you think in relation to why you think that's an issue is it just difficult to get all the reporting done on time or?

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I think it is a clear understanding of what an adverse event is and also what our actions need to be off the back of that as the seller of those items.

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Okay, and do you think it would be helpful for those in the customer facing roles who are most likely to be, I shouldn't say most likely, but are likely to be present during an adverse event, do you think it's important that they're aware and very familiar with exactly how to trigger

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that kind of reporting?

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Yeah.

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Okay, okay.

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Do you believe the company could improve its communication with regards to regulatory updates and requirements? Yeah.

3

0:06:05

Okay.

1

0:06:07

And do you believe there's sufficient resources allocated for regulatory compliance within the organization?

113

3

0:06:18

I think there is, but they're not publicized enough.

2

0:06:20

I don't think it is made visible enough to people. I don't think it is made visible enough to people.

1

0:06:24

Yeah, yeah. Okay, that's wonderful, Damien. Thanks a million.

Raw Data

Microsoft Forms Data Visualisation

Data Visualisation

Survey data Collected

Staying Ahead in Patient Safety

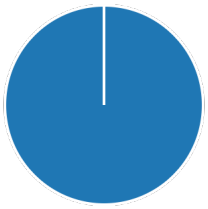
74 Responses 16:28 Average time to complete Closed Status

1. Do you consent to participating in this survey?

Yes	73
No	0

2. Do you work for an Irish Medical Device Distributor

Yes	73
No	0



3. How long have you been employed by the company?

Less than a year	6
1-3years	21
4-6years	9
7-10years	14
More than 10 years	23

4. How long have you worked in the area of Medical Devices?

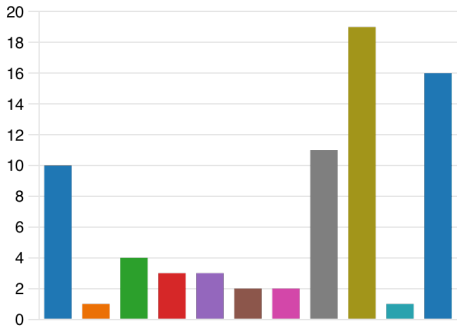
Less than a year	4
1-3 years	16
4-6 years	8

115

7-10 years	8
More than 10 years	36

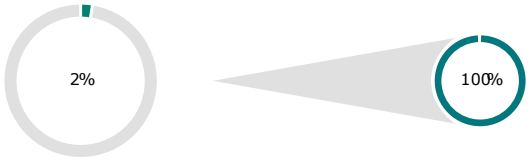
5. What area of the company do you work in?

Management	10
Logistics	1
Bookings	4
Loan kits	3
Stock Management	3
Purchasing	2
Orders	2
Customer Services	11
Sales Rep clinical	19
Compliance	1
Other	16



Update

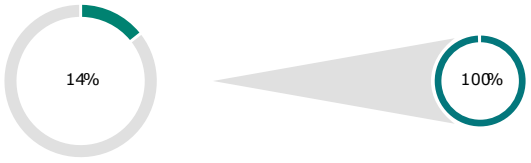
2% of people answered **Service Support** for this question, and the majority answered **Very dissatisfied** for Question 24.



2% people answered "Service Support " for question 5

100% of them answered "Very dissatisfied" for question 24

14% of people answered **Management** for this question, and the majority answered **Extremely important** for Question 21.

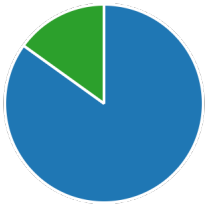


14% people answered "Management" fcquestion 5

100% of them answered "Extremely important" for question 21

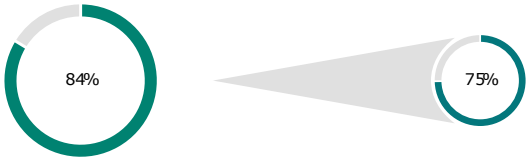
6. What area of Ireland do you work in?

Republic of Ireland	62
Northern Ireland	0
Both	11



Update

84% of people answered **Republic of Ireland** for this question, and the majority answered **Extremely important** for Question 21.

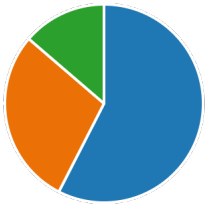


84% people answered "Republic of Ireland" for question 6

75% of them answered "Extremely important" for question 21

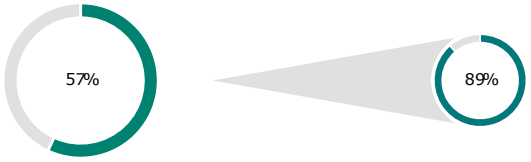
7. Do you work with, train with, or source medical devices from Northern Ireland, the UK, or the US?

Yes, regularly	42
Yes, occasionally	21
No, never	10



Update

57% of people answered **Yes, regularly** for this question, and the majority answered **Extremely important** for Question 21.

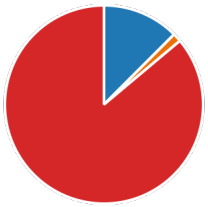


57% people answered "Yes, regularly" fcquestion 7

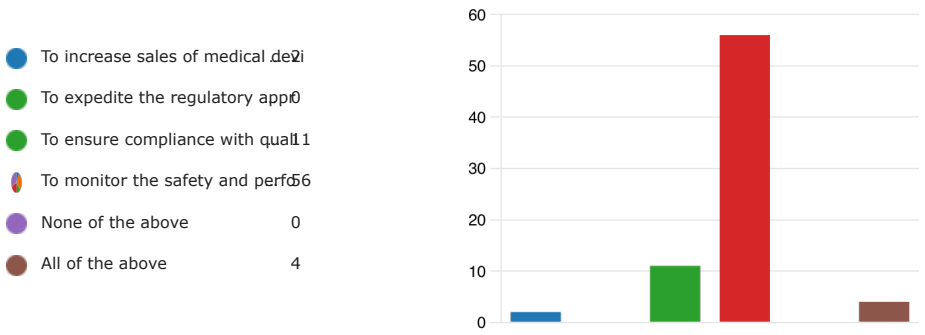
89% of them answered "Extremely important" for question 21

8. In the European Union, what is the current, primary legislation governing Medical Device Regulation?

Medical Device Directive (MDD)	9
General Data Protection Regulat	1
Food and Drug Administration (	0
Medical Device Regulation (MDR)	62
None of the above	0

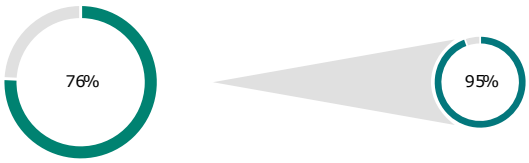


9. What is the primary purpose of adverse event reporting under Medical Device Regulation?



Update

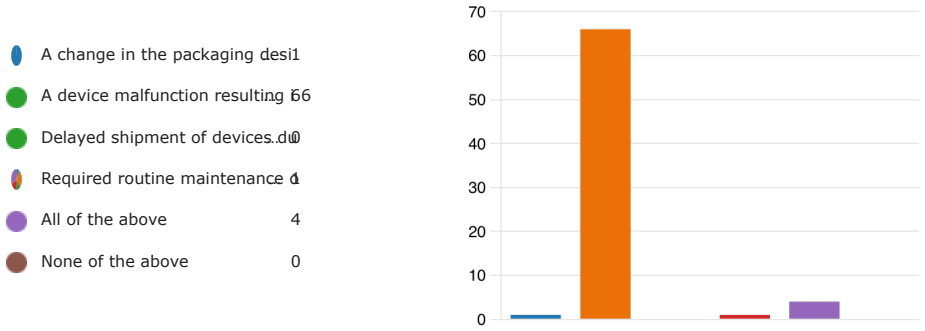
76% of people answered **To monitor the safety and performance of medical devices** for question, and the majority answered **A device malfunction resulting in patient injury or death** for Question 10.



76% people answered "To monitor the safety and performance of medical devices" foquestion 9

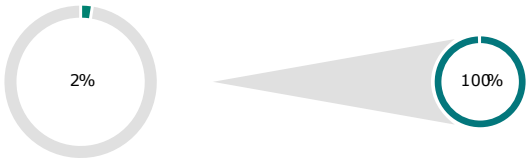
95% of them answered "A device malfunction resulting in patient injury or death" for question 10

10. In the context of medical devices, which of the following scenarios would be considered an adverse event?



Update

2% of people answered **A change in the packaging design for a device** for question, and the majority answered **Less than a year** for Question 3.

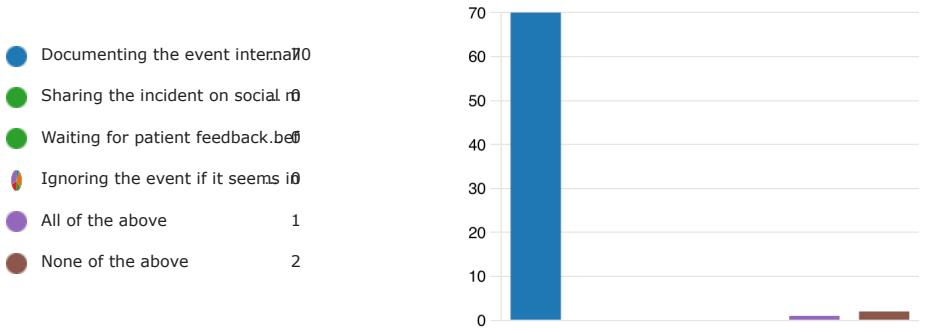


2% people answered "A change in the packaging design for a device" for question 10

100% of them answered "Less than a year" for question 3

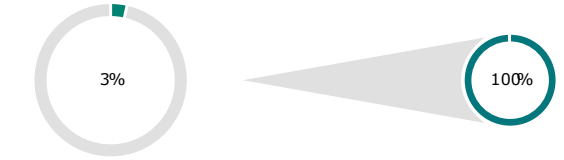
11. Which of the following steps best describes the process involved in reporting adverse events related to medical devices

118



Update

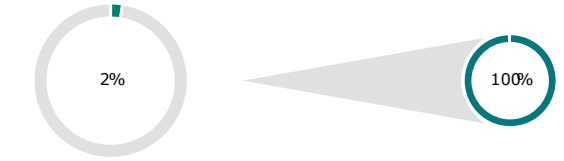
3% of people answered **None of the above** for this question, and the majority answered **"I have not received any training"** for Question 22.



3% people answered "None of the above" for question 11

100% of them answered "I have not received any training" for question 22

2% of people answered **All of the above** for this question, and the majority answered **"1-3 years"** for Question 3.

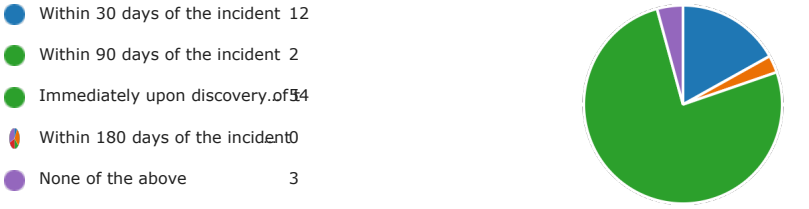


2% people answered "All of the above" for question 11

100% of them answered "1-3 years" for question 3

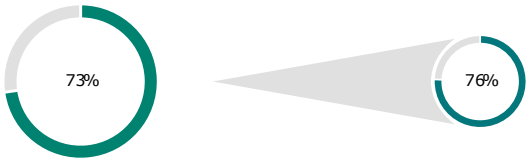
12. According to statutory requirements, what is the appropriate timeframe for reporting an adverse event related to a medical device?

119



Update

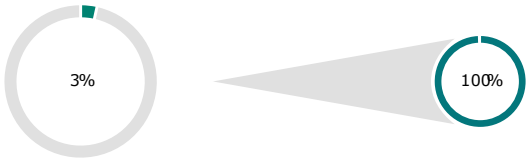
73% of people answered **Immediately upon discovery of the incident** for this question, and the majority answered "**Extremely important**" for Question 21.



73% people answered "Immediately upon discovery of the incident" for question 12

76% of them answered "Extremely important" for question 21

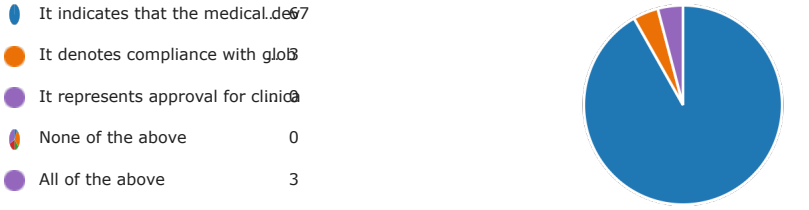
3% of people answered **Within 90 days of the incident** for this question, and the majority answered **1-3 years** for Question 3.



3% people answered "Within 90 days of the incident" for question 12

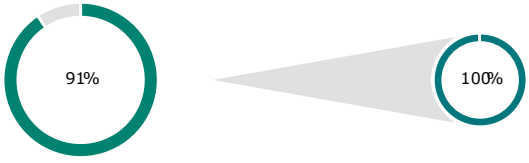
100% of them answered "1-3 years" for question 3

13. What does the CE mark signify in relation to Medical Device Regulation in Europe?



Update

91% of people answered **It indicates that the medical device meets quality standards set by the European Union** for this question, and the majority answered **Yes** for Question 2.



91% people answered "It indicates that the medical device meets quality standards set by the European Union" for question 13

100% of them answered "Yes" for question 2

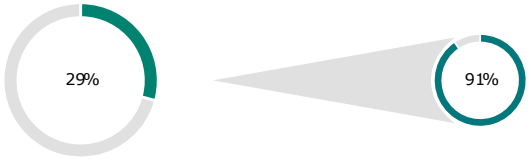
120

14. To what extent do you believe that you are adequately informed about the specific regulatory requirements for medical devices distributed by our company?

Completely informed	21
Moderately informed	23
Slightly informed	24
Not informed at all	5

Update

29% of people answered **Completely informed** for this question, and the majority answered **Extremely important** for Question 21.

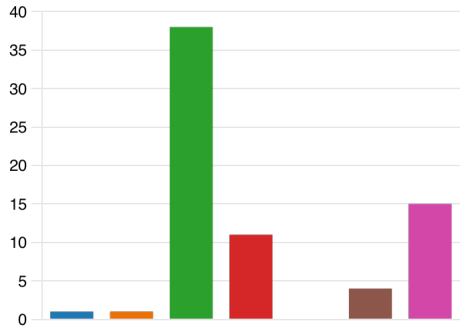


29% people answered "Completely informed " for question 14

91% of them answered "Extremely important" for question 21

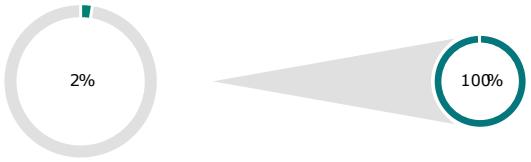
15. What is an implant card according to Medical Device Regulation within the EU?

A card used by healthcare provi	1
A card provided by manufacture	4
A card designed for patients wi	38
A card designed for healthcare	11
None of the above	0
All of the above	4
I don't kmow	15



Update

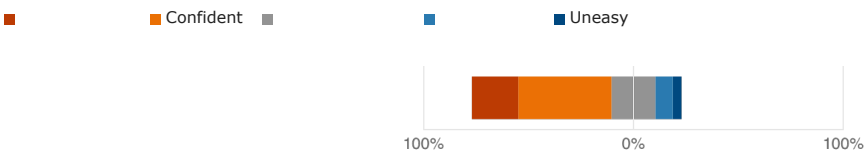
2% of people answered **A card used by healthcare providers to track device sales** for this question, and the majority answered **Less than a year** for Question 4.



2% people answered "A card used by healthcare providers to track device sales " for question 15

100% of them answered "Less than a year" for question 4

16. Implant cards are not a regulatory requirement for orthopaedic or spinal implants



True	6
False	38
I don't know	26

Update

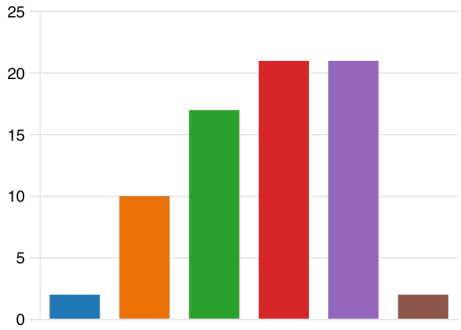
9% of people answered **True** for this question, and the majority answered **Extremely important** for Question 21.

9% people answered "True" for question 16

100% of them answered "Extremely important" for question 21

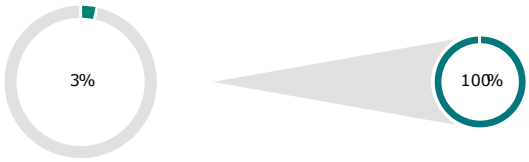
17. How confident are you in your ability to ensure compliance with medical device regulations while carrying out your role within the company?
18. How familiar are you with the specific regulatory requirements for medical devices in Northern Ireland under the Northern Ireland Protocol?

Very familiar	2
Somewhat familiar	10
Not very familiar	17
Not familiar at all	21
Not relevant to my role as I don't	21
Other	2



Update

3% of people answered **Very familiar** for this question, and the majority answered **Very effective** for Question 22.

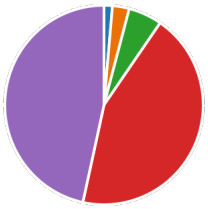


3% people answered "Very familiar" fquestion 18

100% of them answered "Very effective" fquestion 22

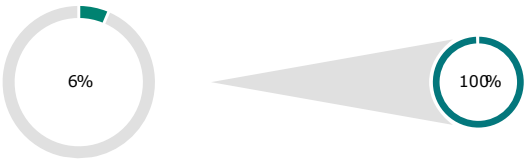
19. How often do you receive training in relation to medical device regulation from the company?

Daily	1
Weekly	2
Monthly	4
Yearly	32
Never	34



Update

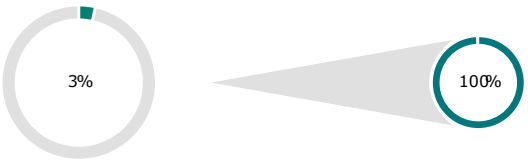
6% of people answered **Monthly** for this question, and the majority answered **Extremely important** for Question 21.



6% people answered "Monthly" foquestion 19

100% of them answered "Extremely important" for question 21

3% of people answered **Weekly** for this question, and the majority answered **Very effective** for Question 22.

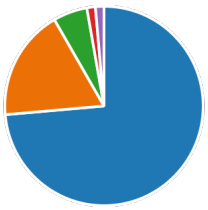


3% people answered "Weekly" foquestion 19

100% of them answered "Very effective" fquestion 22

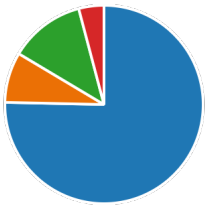
Are you familiar with the appropriate department or contact person within the company to address compliance related queries or concerns?

Yes	53
Somewhat, but I may need clari	18
No, I am unsure	4
I am familiar with the relevant d	1
I am familiar with the relevant d	1



20. How important do you perceive compliance with Medical Device Regulation to be in your specific role?

Extremely important	55
Somewhat important	6
Slightly important	9
Not important at all	3

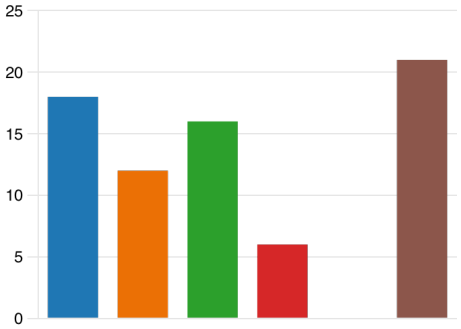


e

123

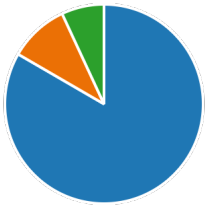
21. How effective do you find the current training programs provided by the company in enhancing your understanding of medical device regulations and CE marking?

Very effective	18
Somewhat effective	12
Neither effective nor ineffective	16
Not effective at all	6
Very ineffective	0
I have not received any training	21



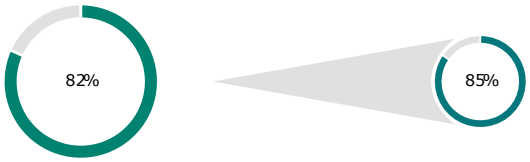
22. Do you view Medical Device Regulation as beneficial or detrimental to the company?

Beneficial	60
Detrimental	7
Neither	5



Update

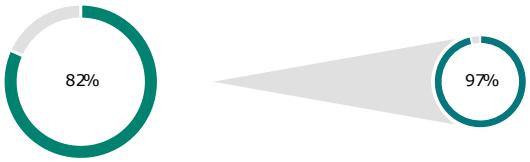
82% of people answered **Beneficial** for this question, and the majority answered **Extremely important** for Question 21.



82% people answered "Beneficial" for question 23

85% of them answered "Extremely important" for question 21

82% of people answered **Beneficial** for this question, and the majority answered **Documenting the event internally and notifying the manufacturer immediately** for Question 11.



82% people answered "Beneficial" for question 23

97% of them answered "Documenting the event internally and notifying the manufacturer immediately" for question 11

23. How satisfied are you with the communication channels used by the company to disseminate information about changes in medical device regulation?

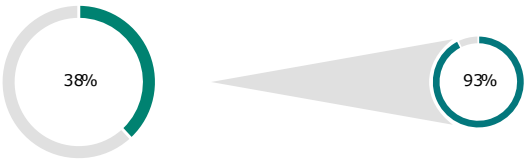
Very satisfied	20
Somewhat satisfied	9
Neither satisfied nor dissatisfied	38
Somewhat dissatisfied	3
Very dissatisfied	3

24. To what extent to you feel supported by management in your efforts to stay informed about and compliant with medical device regulations and CE marking requirements?

Strongly supported	28
Moderately supported	19
Slightly supported	13
Not supported at all	12

Update

38% of people answered **Strongly supported** for this question, and the majority answered **Extremely important** for Question 21.



38% people answered "Strongly supported" for question 25

93% of them answered "Extremely important" for question 21

18% of people answered **Slightly supported** for this question, and the majority answered **Neither satisfied nor dissatisfied** for Question 24.

18% people answered "Slightly supported" for question 25

93% of them answered "Neither satisfied nor dissatisfied" for question 24

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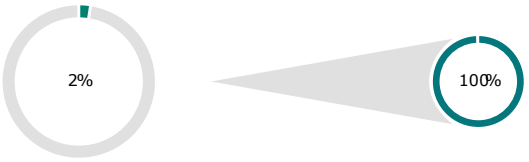
25. Would you be happy to participate in further, relevant training in this area?

Yes	50
No	1
Maybe	20

Update

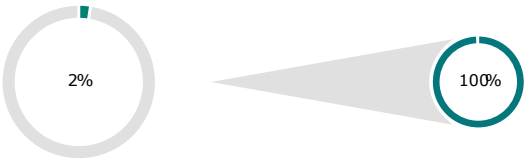
2% of people answered **No** for this question, and the majority answered **More than 10 years** for Question 3.



2% people answered "No" for question 26

100% of them answered "More than 10 years" for question 3

2% of people answered **No** for this question, and the majority answered **Very effective** for Question 22.



2% people answered "No" for question 26

100% of them answered "Very effective" fquestion 22