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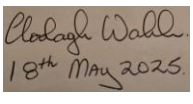
Signed & dated: 

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A Comparative Analysis of Paper-Based vs. Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union: Technological, Regulatory, and Operational Impacts

A dissertation submitted in partial fulfilment of the requirements for MSc in Medical Device Technology & Business

Innopharma Faculty of Pharmaceutical Science

Griffith College Dublin

Clodagh Walsh

2025

Candidate Declaration

I hereby declare that the dissertation titled “A Comparative Analysis of Paper-Based vs. Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union: Technological, Regulatory, and Operational Impacts” submitted for the degree of MSc in Medical Device Technology & Business is the result of my own work and that where reference is made to the work of others, due acknowledgement is given.

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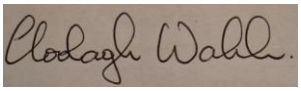
Candidate Signature: 

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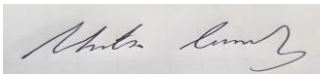
Supervisor Signature: 

Date: 18 May 2025

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This dissertation is dedicated to Fred, my *"Heartbeat"*
Your unconditional love and quiet companionship carried me through every late night of this journey.

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List of Abbreviations

Abbreviations	Definition
EU	European Union
MDR	Medical Device Regulation
EEA	European Economic Area
MRA	Mutual Recognition Agreement
CE	Conformité Européenne
IVDR	In Vitro Diagnostic Regulation
MDD	Medical Device Directive
AIMDD	Active Implantable Medical Devices Directive
IVDD	In Vitro Diagnostic Directive
EEC	European Economic Community
bn	Billion
SMEs	Small and medium-sized enterprises
R&D	Research & Development
AI	Artificial Intelligence
WHO	World Health Organization
3D	3 Dimensional
US	United States
MDCG	Medical Device Coordination Group
QMS	Quality Management System
ISO	International Standards Organisation
GSPRs	General Safety and Performance Requirements
EUDAMED	European Database on Medical Devices
MVP	Master Validation Plan
URS	User Requirement Specification
FDS	Functional Design Specification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification

List of Abbreviations cont'd

Abbreviations	Definition
MVR	Master Validation Report
FDS	Functional Design Specification
FAT	Factory Acceptance Test
SAT	Site Acceptance Test
SME	Subject Matter Expert
RTM	Requirements Traceability Matrix
IMDRF	International Medical Device Regulators Forum
GHTF	Global Harmonisation Task Force
UDI	Unique Device Identification
NSAI	National Standards Authority of Ireland
HPRA	Health Products Regulatory Authority
nIVD ToC	Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents
FDA	Food and Drug Administration
GDPR	General Data Protection Regulation
IoT	Internet of Things
AR	Augmented Reality
ALCOA	Principles of Data Integrity: Attributable, Legible, Contemporaneous, Original, Accurate
GDP	Good Documentation Practices
NIS	Network and Information Security
PIL	Participant Information Leaflet
URL	Uniform Resource Locator
χ^2	Chi-Square
≥	Greater than or equal to
Q1	First Quartile
Q3	Third Quartile
IQR	Interquartile Range
CI	Confidence Interval

Abstract

A Comparative Analysis of Paper-Based vs. Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union: Technological, Regulatory, and Operational Impacts

Clodagh Walsh

The medical device industry is highly regulated, where documented evidence of medical device manufacturing equipment qualification is a critical step to ensuring regulatory compliance, patient safety and device performance.
This study undertook a comprehensive comparative analysis of paper-based and electronic-based equipment qualification (EQ) processes in the manufacturing of implantable orthopedic devices, assessed under the regulatory framework of the European Union Medical Device Regulation (MDR). The study critically evaluated the technological, regulatory, and operational impacts, with a particular emphasis on compliance, operational efficiency, and data integrity.
The research was guided by the hypothesis that electronic-based EQ systems demonstrate superior capability in meeting the stringent regulatory requirements of the MDR, provide enhanced operational efficiencies, improve traceability, and documentation practices compared to traditional paper-based systems.

A positivist philosophy, using a deductive approach, mono-method, quantitative research strategy in the form of a survey with a cross-sectional timeline, supported the aim of this research study. The survey/questionnaire was created using Microsoft Forms. The target audience were eligible participants with experience, either directly or indirectly, of paper-based and/or electronic-based EQ systems within the medical device industry.
The survey was distributed via email and LinkedIn, a shortened URL link to the questionnaire was embedded within the invitation. The survey achieved 187 responses in total. The data was analysed using Minitab software application.

The findings offered critical insights into the advantages and challenges associated with transitioning to or maintaining electronic-based EQ systems in highly regulated medical device manufacturing environments.
Although the implementation of electronic systems requires upfront investment and training which can be seen as time-consuming, electronic systems significantly reduce major challenges such as human error.
The transition from paper-based to electronic-based qualification systems has been overwhelmingly positive from a regulatory, operational, and quality standpoint. 74.43% of the participants agreed that technology has positively influenced the EQ process.
The impact of the MDR has been felt to varying degrees across manufacturing facilities. Approximately 96% of the respondents reported no impact/positive impact on the EQ process since the introduction of the MDR.

The study concluded that electronic-based EQ systems are not only justified but increasingly essential for manufacturers of implantable orthopedic devices within the European Union. Transitioning to electronic-based EQ systems optimises compliance and operational agility.

Keywords: *Comparative Analysis, Paper-based EQ, Electronic-based EQ, Medical Device Manufacturing, Implantable Orthopedic Devices, MDR, Compliance, Operational Efficiency, Data Integrity, Traceability*

Chapter 1: Introduction

1.1 Overview

This research explores the challenges faced by implantable orthopedic device manufacturers operating within the European Union in the context of equipment qualification. As per EU MDR 2017/745, all medical devices intended for the European medical device market (i.e. market includes all EU member states, EEA (Iceland, Liechtenstein, and Norway), Turkey and other countries which have mutual recognition agreements (MRA's) with the EU) must have a CE mark. CE mark can be achieved by following these steps:

1. Device classification
2. Quality Management System
3. Technical File
4. Audit/CE Certification
5. Declaration of Conformity/CE Marking

Equipment qualification is a subset of the Technical File, demonstrating that the equipment is installed according to the manufacturer recommendations, operates according to the manufacturer's specifications, and performs consistently as intended.

Emerging technologies coupled with more stringent EU regulations are making it increasingly difficult for medical device manufacturers to manage equipment qualification data and control documentation using traditional paper-based systems and methods. Equipment qualification systems and methods need to evolve in parallel with emerging technologies to ensure manufacturers remain compliant with the new regulations.

For the purpose of this research, terminology used extensively throughout the study shall be referred to as follows:

Regulations

- **MDR** shall refer to EU MDR 2017/745 – European Union Medical Device Regulation.
- **IVDR** shall refer to EU IVDR 2017/746 – European Union In Vitro Diagnostic Regulation.

Directives

- **MDD** shall refer to MDD 93/42/EEC – Medical Device Directive.
- **AIMDD** shall refer to AIMDD 90/385/EEC – Active Implantable Medical Device Directive.
- **IVDD** shall refer to IVDD 98/79/EC – In Vitro Diagnostic Directive.

1.2 Research Background

The orthopedic device market in Europe is expected to generate a revenue of €12.57bn in 2024. The market is poised for steady growth over the next five years with an expected annual growth rate of 3.53% (Statista, 2024). The growth in the market can be attributed to several factors:

1. Aging population
2. Technological advancements
3. Economic stability
4. Healthcare expenditure
5. Reimbursement policies
6. Market presence

Within the European Union, implantable orthopedics are classified as class III (high risk) medical device (Medical Device Coordination Group, 2021). In the wake of MDR and IVDR enforcement, the industry has been working aggressively to comply. The MDR combines the requirements of the MDD and AIMDD and introduces new requirements. These regulations are now law within the European Union. The new requirements have introduced additional challenges; these challenges are particularly concerning for small and medium-sized enterprises (SMEs) as they struggle to manage large volumes of data from emerging technologies to remain compliant.

In light of Covid-19's global impact; a lack of understanding of the new regulations; the shortage of notified bodies to complete compliance audits on medical device manufacturers; and medical device manufacturer readiness, an amendment to the regulation was necessary. In March 2023, EU 2023/607 amended the MDR and IVDR to extend the transitional period for certain medical devices and *in vitro* diagnostic medical device implementation. As a result of 2023/607 Article 120, the MDR has been amended to extend the transitional period for class III medical device implementation to December 2027 (European Commission, 2023).

The medical device industry is highly regulated, where documented evidence of medical device manufacturing equipment qualification as per MDR Annex II (3) – Technical Documentation – Design and Manufacturing Information (European Commission, 2017a) is a critical step to ensuring regulatory compliance, patient safety and device performance. Equipment qualification is a subset of Technical Documentation which demonstrates, and documents equipment install as per the manufacturer recommendations, operation as per the manufacturer specifications, and consistent performance as per its intended use.

A recent report released by Kneat Solutions revealed (through surveys completed by validation professionals globally, spanning across several industries including the medical device industry) the biggest qualification challenges currently facing the industry are regulatory compliance, audit readiness and data security (Kay, 2024).

To meet these challenges head on, the industry is seeing a shift from the classic paper-based qualification process to a paperless future. The traditional 'paper-based system' standard for qualifying medical device manufacturing equipment is being challenged by the introduction of electronic-based systems.

1.3 Research Significance

The MDR is an unknown entity, with a cutover date from MDD to MDR of the 31 December 2027 fast approaching for all class III devices. The industry is still struggling to understand the new requirements of the regulation and all its nuances in terms of equipment qualifications, data integrity and information security/cybersecurity to remain compliant. The lack of specific guidance and regulation on managing and controlling the quantity of data now being generated by emerging technologies is challenging the industry to revisit the equipment qualification approach.

Equipment qualifications are essential for compliance with the MDR. The outdated paper-based process is now more than ever impacting the medical device approval process due to the increased complexity of the new regulation. Transitioning to more streamlined electronic documentation systems could enhance the overall efficiency in securing approvals.

This study aims to test the theory: Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are more efficient and regulatory compliant than Paper-Based Qualification methods.

1.4 Research Purpose

1.4.1 Hypothesis

It is hypothesised that Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are better equipped to meet the stringent regulatory requirements, offer more efficiencies, have improved traceability and documentation capabilities over Paper-Based Equipment Qualification systems.

1.4.2 Research Objectives

The objectives of this study are as follows:

1. To compare and contrast paper-based and the electronic-based qualification methods.
2. To assess the regulatory, operational, and quality implications of both systems.
3. To evaluate how technology influences the qualification process.
4. To evaluate challenges to equipment qualifications introduced through the MDR.

1.5 Dissertation Structure

The structure of this dissertation is as follows:

- **Chapter 1** – Introduction – This chapter sets the scene for the remainder of the dissertation chapters by providing a brief introduction to the study, the significance of the study, the research aim and research objectives.
- **Chapter 2** – Literature Review – The primary objective of this chapter is to critically review the current literature on the subject matter and to further expand on any gaps identified during the research proposal and in the existing literature.
- **Chapter 3** – Research Methodology – The methodology describes the research design and the rationale for each step in the design process, encompassing the conceptual framework, philosophical approach taken, research choices, research strategy chosen, time horizon, data collection and analysis and the ethical considerations for the research.
- **Chapter 4** – Findings and Analysis – Visual analytics tools are used to represent the findings from the primary research. Results from the primary research are analysed, interpreted, and discussed.
- **Chapter 5** – Conclusions and Recommendations – Analyses, interpretations, and discussions in Chapter 4 are summarised to present the main findings. Based on these findings, the hypothesis is either accepted or rejected. This chapter also presents recommendations, limitations of the study, future research opportunities and the final conclusion.

Chapter 2: Literature Review

2.1 Introduction

Since the introduction of Industry 4.0 in the mid-2010s, a large number of studies have been undertaken regarding advancements in technology within the medical device industry. A study by Lepasepp and Hurst (2021) *'Industry 4.0 Technologies within Medical Device Manufacturing'* concluded that although many of these technologies are still in early R&D phase, are costly to implement, lack necessary security measures and are quite complex due to the complexity of today's manufacturing processes, there are significant gains to be achieved in manufacturing and process optimisation by adopting 4.0 technologies.

A survey conducted by Roy and Srivastava (2024) for their research article *'Role of Artificial Intelligence (AI) In enhancing Operational Efficiency in Manufacturing Medical Devices'* echoed similar concerns to Lepasepp and Hurst regarding the implementation of these complex technologies into the medical device manufacturing environment. The survey concluded that the challenges facing the industry, in terms of cost, regulatory compliance, data security and skills development need to be addressed to realise the full potential of emerging technologies.

In 2017, the core regulatory framework for medical device production and distribution within the EU was revised to align with advancements in technology. The three directives (MDD, AIMDD and IVDD) are in the process of being repealed and two new regulations enacted (MDR and IVDR). The transition from the MDD to the MDR is significantly impacting medical device manufacturers (Brennan, 2024). The introduction of the MDR did not streamline the existing requirements but instead introduced additional ones.

Medical device manufacturing equipment must undergo rigorous qualification to maintain high standards of quality and compliance. The qualification process is integral to ensuring the safety and effectiveness of the devices. Emerging technologies together with more stringent regulations are making it increasingly difficult for medical device manufacturers to manage data and control documentation using traditional equipment qualification methods. Systems and methods need to evolve in parallel with emerging technologies to ensure they are fit for purpose and remain compliant.

The data presented in the *'State of Validation Annual Report 2024 - Validation Industry'* shows that the industry is slowly moving towards electronic equipment qualifications, with the hope of improving efficiencies and data management, by streamlining the documentation process and improving traceability (Kay, 2024).

2.2 Orthopedic Implants & the EU Market

2.2.1 What are Orthopedic Implants

Orthopedic implants fall under the scope of the MDR as medical devices. MDR Article 2 – Definitions, a medical device is defined as *'any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

1. *diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease,*
2. *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability.'* (European Commission, 2017a).

Orthopedic implants are typically manufactured from stainless steel, cobalt chrome or titanium alloy raw material (Quinn *et al.*, 2020), which are surgically implanted into the human body. Such implants are used to support/replace damage to bones/joints caused by trauma or degenerative disease.

2.2.2 The European Market

The European market includes all EU member states (EU27), EEA (Iceland, Liechtenstein, and Norway), Turkey and other countries which have mutual recognition agreements (MRA's) with the EU. Med Tech Europe's annual "Facts and Figures" report identifies Europe as the second largest market for medical devices globally, with a market share of approximately 26.1%, growing on average 5.4% year on year for the last 10 years (MedTech Europe, 2024).

The growth in the market can be attributed to many factors:

1. **Aging Population** – 'Aging of Europe' also called the 'Greying of Europe.' Europe is experiencing a decrease in fertility and mortality rates and an increase in life expectancy. According to the World Health Organization (WHO) the population of over 60s in Europe is projected to reach an astounding 247 million people by 2030, reflecting approximately 14% increase in aging population between 2021 and 2030 (World Health Organisation, 2024). This aging European demographic is putting greater demands on orthopedic interventions.
2. **Technological Advancements** – In a study Kanumilli *et al.* (2024) acknowledged that the continued advancements in 3D printing technology and robotics are transforming how orthopedics was traditionally perceived. Although the technology

has its challenges in terms of accessibility and affordability, it lends to less invasive procedures with better patient outcomes, resulting in faster recovery times thus increasing the demand for these devices.

3. **Economic Stability** – With an expected annual growth rate of 3.33% between 2024 and 2029 (Statista, 2024), the orthopedic device market, demographic trends and the advancements in technology all contribute to the stable economy of the sector within Europe.
4. **Healthcare Expenditure** – With a greater commitment to healthcare spending across Europe through initiatives such as the EU4Health programme 2021-2027 (European Commission, 2024b), budgets are beginning to increase. In the area of orthopedics, Europe and the rest of the world need to invest substantially to meet the future needs of the aging population (Hernigou *et al.*, 2024).
5. **Reimbursement Policies** – Although reimbursement polices differ across EU countries (Health Innovation Hub, 2021), the European market is greatly benefiting from more favourable policies and robust healthcare infrastructure for orthopedic treatments, attracting investment thus enhancing the growth of the sector.
6. **Market Presence** – The European medical device market is the second largest market after the US, harbouring over 37,000 medical device companies, 90% of which are small to medium-sized enterprises (SMEs). This strong presence is driving innovation within the sector (MedTech Europe, 2024).

2.2.3 The Pathway to the European Market

By law, all medical devices intended for the EU market must have a CE mark. Nori et al. (2023) outline the steps to be taken to achieve a CE mark for an orthopedic implant:

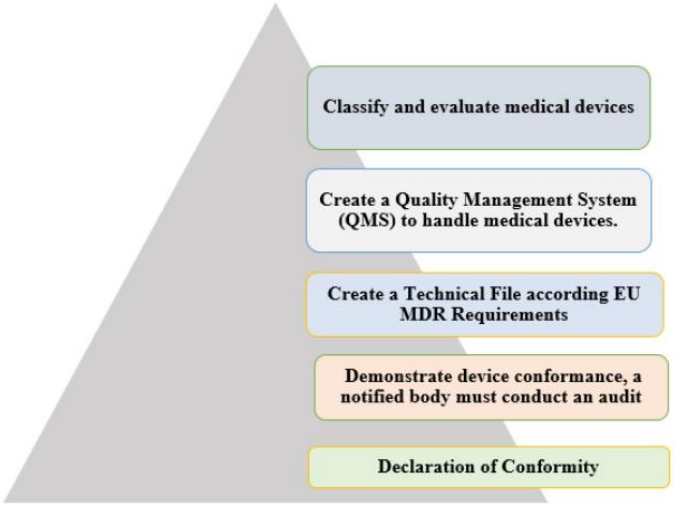

Figure 1 - CE Approval Steps (Nori et al.*, 2023)*

1. **Device Classification** – Device classification is based on the intended use of the device i.e. the risk profile of the device (duration of use, degree of invasiveness, the body parts affected by the device). As outlined in MDCG 2021-24 – Guidance on classification of medical devices, orthopedic Implants fall under Classification Rule 8 – *'Implantable devices and long-term surgically invasive devices (> 30 days). All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: - are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments.'* (Medical Device Coordination Group, 2021). As per Rule 8, orthopedic implants are classified as class III, high risk, medical devices. This classification is also reflected in MDR Annex VIII – Classification Rules.
2. **Quality Management System** – Implementation of a Quality Management System (QMS) that is complaint with the internationally recognised standard ISO 13485-2016 – Medical devices – Quality managements systems – Requirements for regulatory purposes. As mentioned by Mikkola (2019) the adoption of this global standard (ISO 13485) for any medical device manufacturer is voluntary. However, all manufacturers must establish some form of a QMS. Achieving ISO certification proves that the medical device manufacturer complies with the requirements of the standard. This certification is well recognised internationally, demonstrating the organisation's commitment to quality. Being ISO certified provides a faster and efficient route to the medical device market.
3. **Technical File** – To satisfy MDR Annex I – General Safety and Performance Requirements (GSPRs), Annex II – Technical documentation and ISO 13485, Section 7.5.6 – Validation of processes for production and service provision – *'the organisation shall document procedures and validation of processes, including: equipment qualification'*, a medical device technical file shall be compiled by the manufacturer. The technical file shall include the following:
    - Medical Device Description and Specification
    - Manufacturing Processes – Design and Manufacturing Information
    - Risk Management Documentation
    - Clinical Evaluation Data
    - Verification and Validation Reports
    - Labelling and packaging

4. **Audit/CE Certification** – QMS and the medical device technical file shall be submitted for audit to a notified body. Upon successful submission, the notified body issue the manufacturer an ISO 13485 certificate proving compliance with the standard and also issue a CE certificate.
5. **Declaration of Conformity/CE Marking** – As per MDR preamble (40) all medical devices intended for sale within the EU require a CE (European Conformity) mark. This is a legal requirement under the MDR, signifying compliance to safety and regulatory standards. The legal manufacturer shall sign a Declaration of Conformity, stating that the medical device complies with the European regulations. The CE mark and identification number of the auditing notified body can then be applied to the device and device packaging. MDR Article 56 – Certificates of conformity, states the CE certification is valid for up to five years within the EU, after the validity period expires, re-certification shall be sought.

EUDAMED Registration – MDR Article 33 – European database on medical devices. Data for every medical device destined for the EU market shall be entered into the database by Member States, Notified Bodies, Economic Operators and Sponsors of Clinical Investigations. The database is currently available for use on a voluntarily bases, EUDAMED roadmap published December 2024 (European Commission, 2024d) indicates a "go live" date for four of the six modules in Q1 2026.

2.3 Technological Framework for Qualification Systems

Hale (Hale, 2015) outlines the equipment qualification/process validation framework required by a medical device manufacturer to ensure that devices are consistently manufactured to a specified quality. Every equipment qualification starts with a Master Validation Plan (MVP). The MVP is an overarching document outlining the qualification strategy.

2.3.1 Qualification Framework

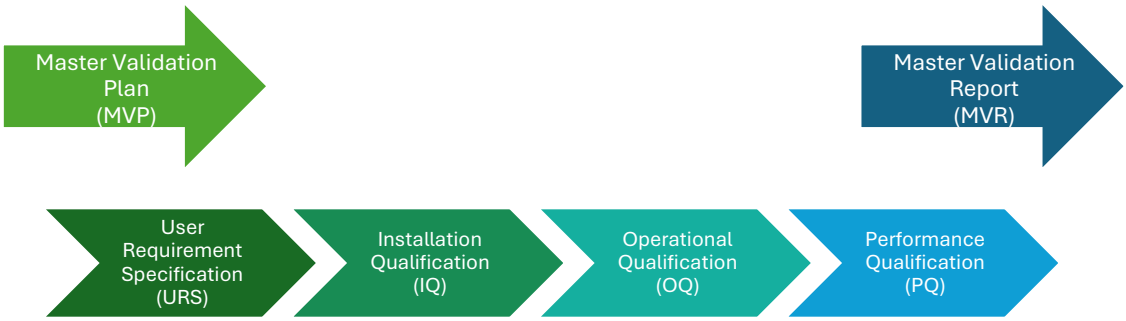

Figure 2 - Qualification Framework - (Author's Own)

The qualification documentation can be divided into three categories:

1. **Specifications:**

   Specifications are generated by a qualified engineer together with manufacturer. All specifications are reviewed/approved at a minimum by Engineering and Quality representatives.

   - **User Requirement Specification (URS)** – Details the customer requirements to the equipment manufacturer for design and build.
   - **Functional Design Specification (FDS)** – Can form part of the URS or be a standalone document. It is the equipment manufacturers response to the URS requirements, confirming the URS requirements can or cannot be met.

2. **Protocols:**

   IQ and OQ Protocols are generated and executed by a qualified engineer. PQ protocols are generated by a qualified engineer and executed by the equipment operators. All protocols/executions are reviewed/approved at a minimum by Engineering and Quality representatives.

   - **Installation Qualification (IQ)** – Establishes through documented evidence that the equipment is installed in accordance with the equipment manufacturer recommendations. IQ testing may include the following:
     - Utility connections
     - Safety features
     - Design features
     - Calibration
     - Preventive maintenance
     - Supplier documentation
     - Spare parts list

     As part of the IQ plan, a Factory Acceptance Test (FAT) (at the equipment manufacturer facility) and/or a Site Acceptance Test (SAT) (at the customers facility) may be performed to ensure that the equipment meets the URS/FDS requirements prior to commencement of IQ.

     FATs and SATs are normally undertaken for more complex pieces of equipment together with the equipment manufacturer Subject Matter Expert (SME) and customer engineer. FATs and SATs provide a high level of confidence that the equipment operates as intended prior to commencing further qualification activities.

- **Operational Qualification (OQ)** – Establishes through documented evidence that the equipment operates as per the manufacturer specifications i.e. the user requirements are being met. OQ testing may include the following:
    - Fail safe – Utility failures
    - Fail safe – Alarms and limits
    - 'Worst case' testing
    - Process parameters
    - Process limit controls
    - Action levels

  OQ can only commence once a successful IQ has been completed and approved.
- **Performance Qualification (PQ)** – Establishes through documented evidence that the equipment consistently performs as per its intended use. PQ testing may include the following:
    - Process capability
    - Process control

  PQ can only commence once a successful OQ has been completed and approved.

3. **Reports:**

   Reports are generated by a qualified engineer. All reports are reviewed/approved at a minimum by Engineering and Quality representatives.

   - **Requirements Traceability Matrix (RTM)** – Maps and traces the requirements of the URS to the test steps in the OQ, ensuring all requirements have been tested.
   - **Master Validation Report** – Summarises the results of the qualification, listing any deviations or open actions. Clearly stating whether all acceptance criteria has been met and states the release of the equipment to production.

2.3.2 Paper-Based versus Electronic-Based Equipment Qualification Systems

Paper-based equipment qualification systems are still widely used and accepted but are becoming more difficult to maintain in light of the increased emphasis on the medical device lifecycle approach and increased documentation requirements stemming from the

introduction of the MDR. Managing paper-based systems is not just time-consuming but also highly susceptible to human error. Specifications, Protocols and Reports must be written and approval signatures obtained. Protocols must be manually executed, reviewed and post-approved. All qualification documentation must be securely stored, readily accessible, and easily searchable.

In contrast, electronic-based equipment qualification systems allow electronic generation of specifications, protocols, and reports. Workflows are automated with e-signature approvals. Audit trails are automatically generated, time-stamped and support real-time, tamper-evident records linked to each action. Records are maintained in secure, easily searchable databases with automated backups and enhanced data integrity.

Table 1 - Paper-Based vs. Electronic-Based Equipment Qualification Systems (Author's Own)

Aspect	**Paper-Based**	**Electronic-Based**
Efficiency	Low - Time-consuming	High - Automated workflows
Accuracy	Low - Human error	High - Enhanced accuracy
Accessibility	Limited - Difficult to share	High - Easily shared
Compliance	Difficult - More challenging	Better - Easier to maintain
Real-Time Visibility	Limited - No immediate insight	High - Immediate insight
Integration	Limited – Isolated	Simplified – Seamless
Traceability	Difficult - Slow to retrieve	Simplified - Quick to retrieve
Standardisation	Difficult – Difficult to align	Simplified – Becomes the norm

Equipment qualification forms an essential part of the Medical Device Technical Documentation. Before placing a medical device on the EU market, it is the responsibility of the manufacturer to produce technical documentation that proves compliance with the regulatory requirements. According to MDR Article 10 - General Obligations of Manufacturers *'The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed.'* It must be noted that Technical Documentation is also a requirement of the soon to be repealed MDD (1993), MDR has introduced more detailed Technical Documentation requirements and expanded the manufacturers responsibilities, which is proving to be extremely challenging for medical device manufacturers (European Commission, 2017a).

2.4 Regulatory and Compliance Considerations

The IMDRF (International Medical Device Regulators Forum) is the successor organisation of the GHTF (Global Harmonisation Task Force). This global voluntary group of medical

device regulators was launched in 2012. The group is working towards achieving greater uniformity between regulatory authorities (Gallagher, 2019). Whilst the Strategic Plan for 2021 – 2025 is primarily focused on three areas: Innovative Technologies, Post-Market Surveillance and Relationships with Stakeholders, the group provides an international platform for collaboration on all levels of regulatory harmonisation (IMDRF, 2020).

2.4.1 EU MDR Challenges

The MDR is essentially an unknown entity where organisations are finding it particularly difficult to navigate the lengthy 174-page document. The MDR combines the requirements of the MDD and AIMDD and introduces new requirements.

Key changes introduced through MDR (Brennan, 2024):

- Reclassification of devices
- Expanded product scope
- Risk based approach during the entire product lifecycle
- Enhanced role of manufacturers
- New labelling requirements
- Introduction of Unique Device Identification (UDI)
- Introduction of European Database on Medical Devices (EUDAMED)
- More rigorous clinical evidence and post market surveillance
- Involvement of distributors

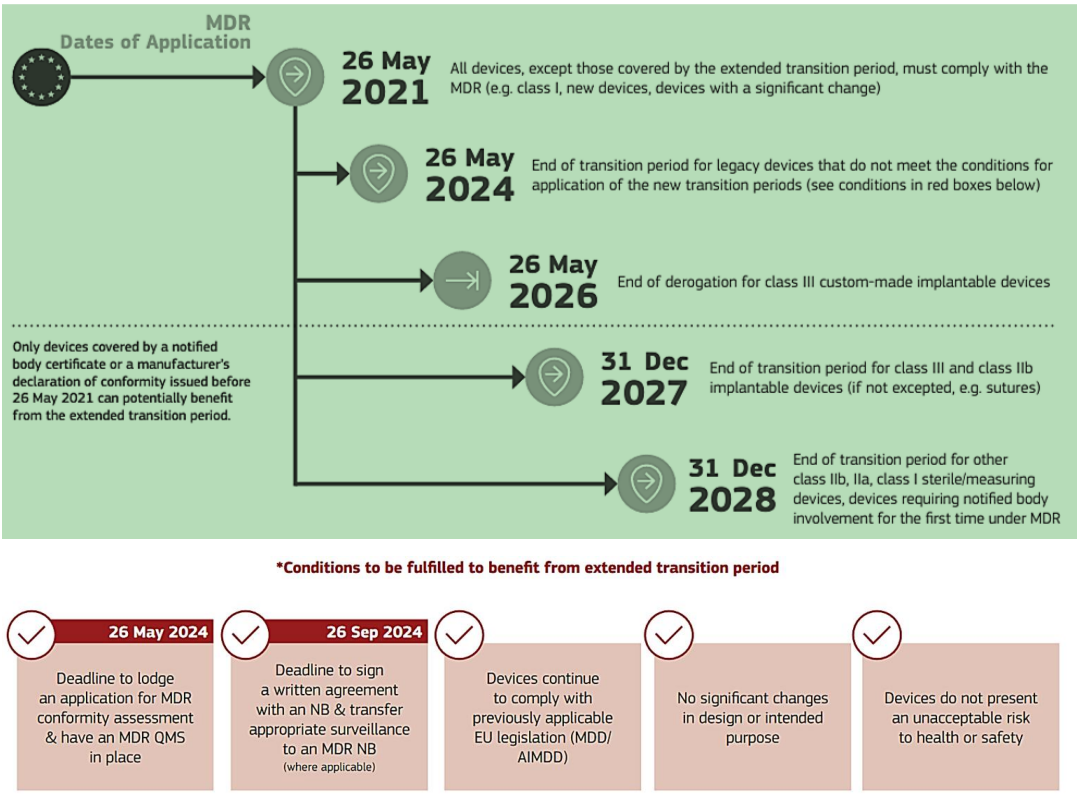

Figure 3 - MDR Dates of Application (European Commission, 2024a)

MDR preamble (51) states that notified bodies are responsible for conducting assessments of the manufacturers' technical documentation e.g. the Irish notified body, the National Standards Authority of Ireland (NSAI) is under the watchful eye of the Irish competent authority, the Health Products Regulatory Authority (HPRA). There is no specific guidance and/or requirement in either ISO 13485 or MDR in relation to the method used to generate/store technical documentation. What the regulation does mandate is comprehensive technical documentation that is '*clear, organised, readily searchable and unambiguous'* (European Commission, 2017b).

The MDR brings with it additional workload, an increase in associated costs, and a lack of clarity across the regulation, which are proving exceptionally challenging for the industry (Brennan, 2024). The industry is witnessing a decrease in product portfolios due to the complexity, cost and fear of the unknown associated with the new regulatory requirements (Carl and Hochmann, 2024). As outlined by Carl and Hochmann *'For some companies, the increased requirements resulting from the MDR are so extensive that it is considered to be an existential threat.'*

Heumesser (2020) in their study *'Proposal for a Harmonised Structure of Technical Documentation and basic Functionalities of a submission Software Tool under EU-MDR'* advocates strongly for the use of nIVD ToC (Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents) created by IMDRF. nIVD ToC is an internationally harmonised structure that can be followed when electronically filing medical device submissions to regulatory authorities (IMDRF, 2024). Heumesser states that the ToC is fairly well aligned with the technical documentation requirements of the MDR, adopting the ToC would streamline existing processes for both manufacturers and regulatory authorities (Heumesser, 2020).

Implementing electronic-based equipment qualifications is expensive in terms of initial setup and training but has the potential to reduce workload in the long run and compliment the nIVD TOC electronic submission software tool.

2.4.2 EUDAMED

The EU MDR introduces a new medical device database EUDAMED – European Database on Medical Devices similar to the FDA (Food and Drug Administration) database in the US. EUDAMED is a central platform, housing living documentation for each device and is aimed at improving transparency, traceability and coordination across all medical devices sold within the European Union. It consists of six interconnected modules (European Commission, 2024c).

1. Actor Registration – **Mandatory: Q1 2026**
2. Unique Device Identification (UDI) and Device Registration – **Mandatory: Q1 2026**
3. Notified Bodies and Certificates – **Mandatory: Q1 2026**
4. Clinical Investigations and Performance Studies – **Under Development**
5. Vigilance and Post-market Surveillance – **Mandatory: Q2 2026**
6. Market Surveillance – **Mandatory: Q1 2026**

The database has two interfaces:

1. Actor interface (Economic operators)
2. Public interface

It is the responsibility of Member States, Notified Bodies, Economic Operators and Sponsors of Clinical Investigations to submit to EUDAMED and maintain medical device information in EUDAMED for each device sold within the EU. Documentation supporting each medical device must be uploaded to the database. As per the functional specifications for EUDAMED, information regarding CE certificates issued/refused will be stored in Module 3 – Notified Bodies and Certificates (European Commission, 2022b). As detailed in section 2.2, the issuance of a CE certificate is partially based on the submission of technical documentation.

Electronically generated supporting documentation would greatly reduce retrieval and scanning efforts for medical device manufacturers.

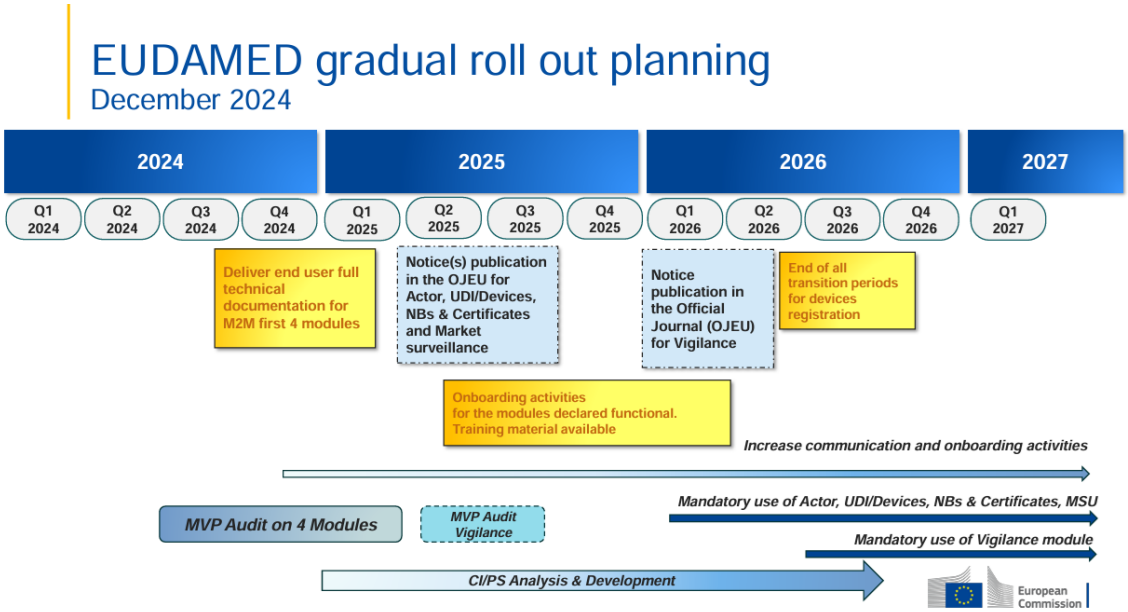

Figure 4 - EUDAMED Roll Out Timeline (European Commission, 2024d)

Modules 1, 2 and 3 are currently available and can be voluntarily used. Some competent authorities are requesting manufacturers avail of these modules to begin registration of their devices (HPRA, 2024). Using the database ahead of the mandatory "go live" date will allow manufacturers resolve any issues early on in the process, as this too is an unknown entity. The mandatory use of each module will commence six months after confirming its functionality through independent audit. Once a successful audit has been completed, the use of the module will be enforced by law, consequently any medical device intended for the EU market must be registered on the database.

2.4.3 Regulatory Audits

As the industry is subject to unannounced audits, a continuous audit readiness strategy is imperative for medical device manufacturers. Since the pandemic, the industry is seeing a trend towards fully remote/hybrid audits (Kay, 2024). Even though Palmarozzo and Toffel (2024) concluded in their study *'Managing Remote Work Quality: Evidence from Auditing Management Systems Standards'* that fully remote audits yielded lower quality audits; in 2024 the FDA released a draft guidance document *'Conducting Remote Regulatory Assessments'* for industry comment. It would appear that the US is leaning towards remote assessments where possible, and the EU towards 'hybrid auditing' (Notified Bodies Coordination Group, 2024) therefore it is becoming increasingly more important to be audit ready. Continuous audit readiness has now become one of the top three challenges facing the medical device manufacturing industry (Kay, 2024). In terms of equipment qualifications, medical device manufacturers are better positioned to meet this challenge by adopting electronic-based systems.

2.5 Technological Impacts on Quality, Safety & Operations

The integration of electronic qualification systems into the quality management framework introduces new risks in terms of compliance, data integrity, information security/cybersecurity and data protection (GDPR). These new risks have the potential to compromise patient safety and device efficacy if not managed effectively.

Leong (2023) advocates strongly for medical device manufacturers to move away from manual based systems in order to stay competitive and compliant. With Industry 4.0 already upon us, through the introduction of emerging technologies such as the Internet of Things (IoT), Artificial Intelligence (AI), Augmented Reality (AR), the industry is seeing the advent of Quality 4.0 i.e. aligning Quality Management with the emerging technologies of

Industry 4.0. The future success of medical device companies is closely linked to the adoption of Quality 4.0.

Leong (2023) highlights several examples of medical device manufacturers where manual systems exposed organisations to compliance risks during audits, through missing documentation and incorrect information. Recovery from audit findings comes at a cost, although this cost was not quantified in any of the examples. Introducing product centric closed loop electronic systems that link Production with Quality makes good business sense, enhancing collaboration between divisions, especially global cross functional teams, reinforcing compliance by reducing errors and strengthening traceability of products to meets the stringent requirements of the MDR.

As with audit findings, the introduction of electronic systems also comes at a cost. The implementation and training costs associated with an electronic system is an on-going industry debate. The slow endorsement of electronic systems by industry is reflected in Kays' Validation Report where less than one-third of the survey respondents have implemented electronic validation systems.

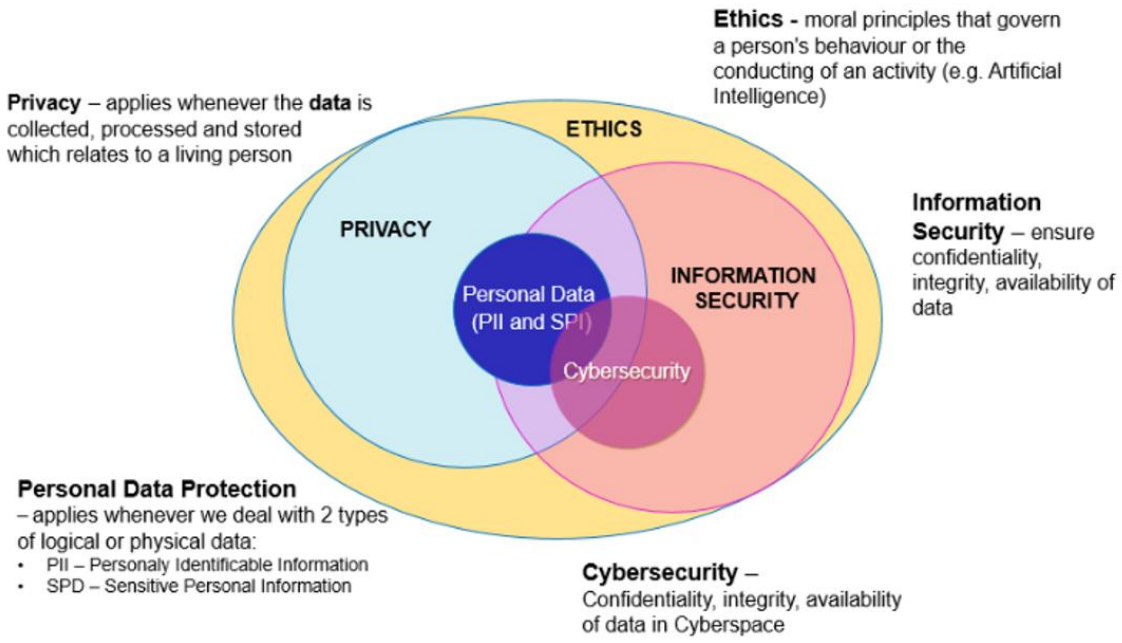

Figure 5 - Data Privacy (Karpowicz, 2019)

2.5.1 Data integrity

According to Rodriguez-Perez (2019) there are four methods of data generation: Paper-based, Electronic-based, Hybrid (Paper and Electronic based) and Photography/Imagery. The integrity of data is an on-going concern for the Life Science industry as Leach (2024) highlighted in their study on *'Enhancing Data Governance Solutions to Optimize ALCOA+*

Compliance for Life Sciences Cloud Service Providers.' With the dawning of the digital era, many industries including the Life Sciences were not adequately equipped to manage and store the large volumes of data that new technologies were producing. Cloud Service Providers (CSP) emerged offering cloud-based services. These providers offer on-demand, scalable resources for storage of data.

As outlined by Müller et al. (2022) the MDR does not specifically address cloud systems or services. To ensure the integrity of data collected and remain GxP compliant, many CSPs and manufacturers have adopted the ALCOA++ framework as best practice: **A**ttributable, **L**egible, **C**ontemporaneous, **O**riginal, **A**ccurate, + (Complete, Consistent, Enduring and Available), ++ (Traceable). The ALCOA principles originated in the pharmaceutical industry around the 1990s and have evolved in parallel with the changing landscape of the Life Science industry (Gleckler, 2023).

Data integrity is a key component of Good Documentation Practices (GDP) and Quality Management Systems (QMS) (Leach, 2024). It is also an essential component of qualification processes to ensure product quality, patient safety and regulatory compliance. As outlined by Rodriguez-Perez (2019) the heightened concern surrounding data integrity is directly related to an increase in observations during regulatory inspections of manufacturing facilities. The increase is attributed to organisations failing to implement robust systems to minimise data risks.

2.5.2 Information Security/Cybersecurity

Within the medical device industry, cybersecurity shall be considered throughout the lifecycle of the device, from design right through to disposal. Cybersecurity is considered a component of Information Security. While Cybersecurity and Information Security are both related to the security of data and are often used interchangeably, they both have very distinct meanings. As outlined by Taherdoost, Cybersecurity is concerned with protection of information in Cyberspace *'the preservation of the confidentiality, integrity, and availability of information in Cyberspace'* whereas Information Security is concerned with the protection of information everywhere *'the preservation of the confidentiality, integrity, and availability of information'* (Taherdoost, 2022). Advancements in digital technologies has brought new levels of connectivity, offering new gateways for attacks on systems.

Within the manufacturing environment, especially for 24/7 operations, unscheduled downtime in the short-term effects productivity, creates potential bottlenecks, leaves employees idle and in the long-term delays patient care, affects company reputation and profitability. To minimise downtime, where equipment has the functionality, equipment

manufacturers connect remotely to troubleshoot issues. Remote access to equipment can introduce information security and compliance risks through unsecure networks, unauthorised access, poor visibility, and insufficient change management processes.

The first EU cybersecurity rules were introduced in 2016 in the form of a Network and Information Security (NIS) Directive, these rules have since been revised to the NIS2 Directive - EU 2022/2555 (European Commission, 2022a). The latest revision expanded the scope to include new sectors and introduced new requirements and obligations for organisations. NIS2 entered into force within the EU on 16 January 2023 with a deadline of 17 October 2024 for transposition into national law by each of the member states (Unikey, 2024).

To comply with the NIS2 directive and further minimise risk to business, organisations are moving away from the traditional 'location centric' security approach and towards a zero-trust 'data centric' approach. Zero trust is based on 'never trust, always verify,' the approach applies within the business and also outside of the business (Yeoh *et al.*, 2023).

2.5.3 GDPR

General Data Protection Regulation (GDPR) came into force on 25 May 2018 with an aim of standardising the collection and processing of EU citizens data. GDPR considers personal data as unique identifiers, online identifiers and other data e.g. physical, cultural, economic (European Commission, 2016). In terms of this study on equipment qualifications there is no collection of any personal data, therefore GDPR is not a consideration.

2.6 Summary

2.6.1 Challenges in Identifying Relevant Literature

Despite employing a wide range of search terms and exploring various databases to ensure comprehensive coverage, identifying specific research material covering paper-based versus electronic-based equipment qualifications in medical device manufacturing of implantable orthopedic devices within the European Union proved challenging. The search criteria were further expanded using alternative keywords and synonyms but there was still limited availability of literature on the topic.

This study aims to bridge the literature gap by performing a comparative analysis of the paper-based versus electronic-based equipment qualifications in terms of the Technological, Regulatory and Operational impacts.

2.6.2 Findings from the Literature Review

The European Union medical device market is the 2nd largest medical device market globally. The EU market continues to see significant growth year on year. The European orthopedic device market is expected to generate a revenue of €12.57bn in 2024. The growth in the market can be attributed to several factors: Aging Demographic, Advancements in Technology, Stable Economy, Favourable Reimbursement Policies and Market Presence.

- In 2017, the core regulatory framework for medical device production and distribution within the EU was revised to align with advancements in technology. The transition from the MDD to the MDR is significantly impacting medical device manufacturers due to additional regulatory requirements.
- Orthopedic implants fall under the scope of MDR as medical devices. Orthopedic implants are classified as high risk, class III medical devices.
- As per MDR, all medical devices intended for the European market must have a CE mark. Even though ISO 13485 certification is not a mandatory requirement, it is often seen as the first step, providing a strong foundation towards achieving a CE mark for a medical device. For an orthopedic implant, class III medical device to achieve a CE mark, several steps must be successfully completed: Device classification, QMS implementation, Technical File submission to a notified body, auditing of QMS and Technical File by a notified body, Declaration of Conformity signed by the manufacturer.
- Equipment qualification is a subset of Technical Documentation which is a requirement under MDR. As orthopedic implants have a high-risk profile, rigorous equipment qualifications are performed to ensure manufacturing equipment can produce implants that are regulatory compliant, ensure patient safety and device performance.
- As new technologies emerge, producing more data than ever before and with the already challenging requirements of the MDR, medical device manufacturers are finding it increasingly difficult to manage equipment qualifications using traditional methods.
- Even though the industry is slow to move towards electronic equipment qualification systems, its hand is being forced, as outdated paper-based systems are impacting the medical device approval process.

- Transitioning to more streamlined electronic documentation systems could enhance the overall efficiency in securing approvals. Electronic qualification systems are better positioned to support the complexities introduced by the MDR and those of emerging technologies.

2.6.3 Potential Gaps in the Literature

A new generation of manufacturing technology has emerged in recent years. The emergence of these new technologies has not changed the equipment qualification framework. Whether the qualification system is paper-based or electronic-based, the framework remains the same. With the increasing complexity of the new generation equipment, qualifications are becoming more complex. Paper-based systems are struggling to keep abreast of these developments. A potential gap from reviewing the current literature is the lack of specific guidance and regulation on managing and controlling the quantity of data now being generated by emerging technologies during medical device manufacturing equipment qualifications.

The MDR cutover date for implantable orthopedic class III medical devices is fast approaching, the mandatory implementation of EUDAMED is looming and remote/hybrid regulatory audits are becoming more commonplace. Although the industry is beginning to understand the benefits associated of having electronic systems in place to manage documentation, not only for regulatory submissions but also for audit purposes, the hand of the industry is also being forced down this path, without due consideration of the associated cost implications especially for small to medium sized enterprises.

Equipment qualifications are not a one-off activity, supporting ongoing compliance through:

- Periodic requalification to ensure continued performance.
- Change control documentation where equipment is modified or upgraded.

It remains unclear from the literature review what is the expectation of EUDAMED in terms of medical device manufacturing equipment qualifications.

Furthermore, even with initiatives such as the introduction by the IMDRF of the nIVD ToC (now in its fourth revision) to help alleviate confusion and standardise the submission approach to notified bodies, it is unknown from the literature review if the ToC is being widely utilised by medical device manufacturers.

The emergence of new technology is bringing unprecedented levels of connectivity, creating new vulnerabilities and new gateways for attacks on data. As the industry moves forward in this connectivity revolution, more medical device manufacturers are moving

from on-site data management technology to Cloud Service Provider data management. There is no specific guidance within the MDR in the context of data integrity. Although data integrity is crucial for compliance, the MDR only implicitly addresses data integrity through the General Safety and Performance Requirements called out in Annex I.

As per NIS2 Annex II, medical device manufacturing is considered a critical sector in regard to cybersecurity (European Commission, 2022a). Each member state was given until 17th October 2024 to enact the directive into national law. As of 28th November 2024, 23 of the member states had not yet fully transposed the NIS2 directive (European Commission, 2024e). Despite reference to the MDR in the NIS2, no mention of the NIS directive appears in the MDR. The literature review has not found any cross reference between the regulation and the directive. In terms of cybersecurity/information security requirements for medical device manufacturing equipment qualifications, neither the regulation nor the directive provide specific guidance. Furthermore, it is unclear what the repercussions are for not having the NIS2 directive fully transposed into national law within each member state.

As a whole, this chapter highlights the challenges that the industry is facing in adopting electronic-based medical device manufacturing equipment qualification systems and its struggles to understand the requirements of the regulation in terms of equipment qualifications.

Chapter 3: Research Methodology

3.1 Introduction

Research methodology is a structured framework that guides researchers in the approach to answering their research questions or hypothesis. The "How" is called the research design and can be approached in a variety of ways using a variety of tools, depending on the research needs and preferences.

As outlined by Mardiana (2020) in their research paper, Saunders research onion is a popular choice for researchers due to its simplicity and adaptability and has therefore been chosen as the tool used to guide decisions to develop the design of this research study.

The research onion consists of six layers:

1. Research philosophy
2. Research approach
3. Research choices
4. Research strategy
5. Time horizon
6. Techniques and procedures

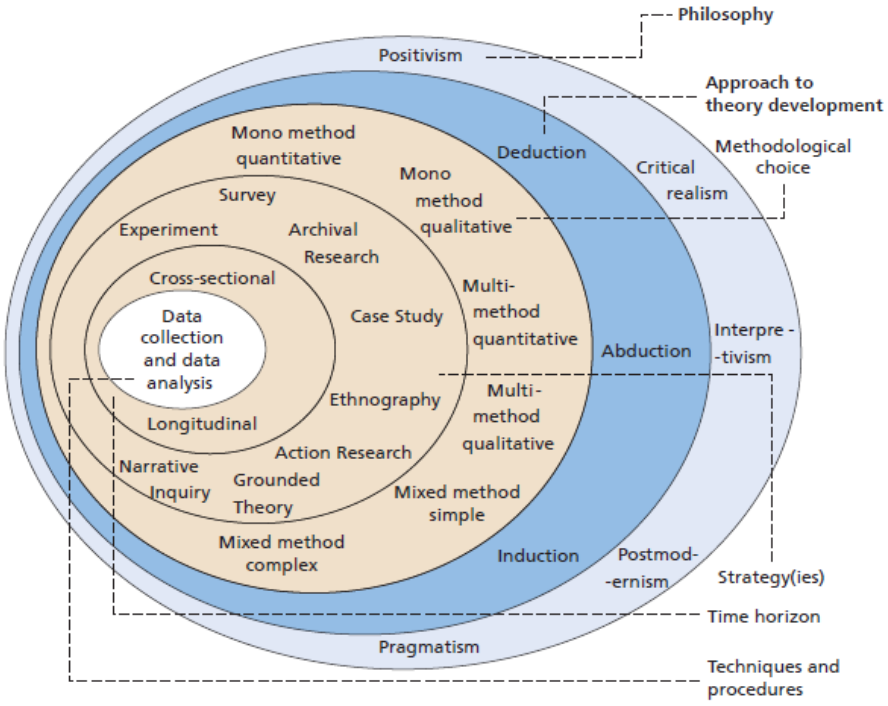

Figure 6 - Research Onion (Saunders et al.*, 2019)*

Despite its inherent strengths, the framework has one flaw, namely, it ignores ethical considerations, which are essential to any research study. Ethical considerations have been addressed as part of this study in section 3.10.

3.2 Conceptual Framework

A conceptual framework can be written, visual or both. For the purpose of this research a hybrid approach was adopted i.e. written and visual.

The framework's key concept is based on the research hypothesis 'Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are better equipped to meet the stringent regulatory requirements, offer more efficiencies, have improved traceability and documentation capabilities over Paper-Based Equipment Qualification systems.'

The secondary research conducted helped identify the independent variables of the study. The concept mapping tool focused the research problem and mapped out specific variables and concepts which were explored during the study. The framework provided a foundation and guide for data collection and analysis.

Dependent variable: Electronic-Based Equipment Qualifications.

Independent variables: Market Growth, Information Security/Cybersecurity, EU MDR, Industry 4.0, Emerging Technologies, Implementation Costs and Data Integrity.

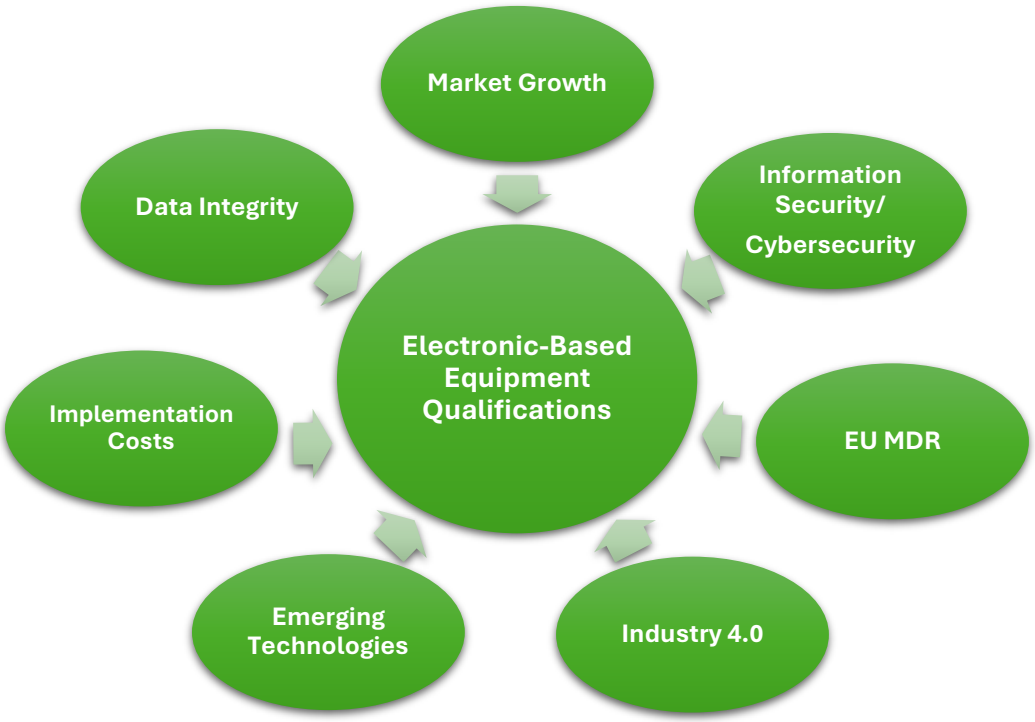

Figure 7 - Conceptual Framework (Author's Own)

- The European orthopedic device market is expected to grow annually by 3.53% over the next five years. Manufacturers need to adopt agile practices to stay competitive and meet the demands of the market.
- By law, medical device manufacturers shall comply with the European Union Medical Device Regulation EU MDR 2017/745. As per the regulation, a technical file for every device going to market shall be complied by the manufacturer, this shall include equipment qualification.
- With the introduction of EUDAMED – European Database on Medical Devices through MDR, the technical file has become an increasingly more important part of medical device reporting for all medical devices being sold inside the European Union.
- The medical device industry is rapidly evolving, Industry 4.0 synonymous with smart manufacturing is causing a paradigm shift within the industry.
- For emerging technologies to reach their full potential, the risks, in terms of cost, regulatory compliance, data security and skills development need to be addressed.
- Emerging technologies along with tighter regulatory requirements are making it increasingly more difficult for medical device manufacturers to manage large quantities of data and control documentation using the traditional methods.
- Outdated traditional paper-based equipment qualification systems need to evolve to ensure continued compliance with the regulatory requirements and industry developments.
- To meet the challenges of data collection and document management, the industry is seeing a slow but gradual shift towards paperless equipment qualifications i.e. electronic systems.
- The introduction of electronic-based equipment qualification systems is seeing its own challenges in terms of implementation costs, training costs, regulatory compliance, data integrity and cybersecurity/information security.

The independent variables identified in this study are causing the industry to move away from the traditional paper-based equipment qualifications and towards electronic-based qualifications, creating a paradigm shift.

3.3 Research Philosophy

The research philosophy is the outermost layer of the research onion framework. It is the first step in the research design and is the foundation of the study. The research onion offers

five philosophical options, each having distinct assumptions about reality, knowledge and research (Jansen, 2023):

1. **Positivism** - knowledge is gained through science e.g. objective observations and measurements (Jansen, 2023).
2. **Critical realism** - knowledge is gained through in-depth historical analysis (Saunders *et al.*, 2019).
3. **Interpretivism** - knowledge is gained through experiences e.g. subjective experiences and viewpoints of people (Jansen, 2023).
4. **Postmodernism** - knowledge is gained through challenging traditional research methods, science and reason are myths and must be deconstructed in order to find the truth (iNtgrty, 2016).
5. **Pragmatism** - knowledge is gained through both science and experiences (Jansen, 2023).

The philosophical approach for this primary research is based on **positivist** philosophy. Positivism was considered the best fit of the five options to test the theory 'Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are more efficient and regulatory compliant than Paper-Based Qualifications.' The positivist philosophy views science as a means of uncovering the truth, relying on scientific evidence to do so e.g. statistics. As detailed by Phoenix et al. (2013) and Park et al. (2020), to avoid bias, a positivist approach should be dualistic and objective. During the data collection process, the researcher maintained an unbiased position by remaining independent and neutral.

3.4 Research Approach

The next step in the research design was to choose the approach. The research onion offers three approach options:

1. **Deduction** - Top-down Approach - Drawing a logical conclusion based on the information. Starting with a theory, developing a hypothesis or statement, collecting data, leading to a conclusion. The truth of the conclusion is guaranteed by the truth of the hypothesis or statement.
2. **Induction** - Bottom-up Approach - Drawing a general conclusion based on the information. Starting with a specific observation, collecting data, developing a theory, leading to a conclusion. The truth of the conclusion is generalised (Saunders *et al.*, 2019).

3. **Abduction** – Neither a top-down nor bottom-up approach. Drawing a probable conclusion based on the information. It is an iterative process, starting with an incomplete observation, developing a theory or hypothesis, leading to a conclusion. The truth of the conclusion is probable.

Table 2 - Research Approach (Author's Own)

Approach	Start	Outcome
Deduction	Theory/Hypothesis	Specific Conclusion
Induction	Specific Data/Observations	General Conclusion
Abduction	Incomplete Observations	Best Explanation

Based on the literature review and research philosophy chosen, a **deductive** approach was deemed the most suitable approach for this primary research. Positivist philosophy tends to use a deductive research approach that can be used to test a hypothesis (Creswell, 2009). Using a top-down approach, the research started with a theory and developed a hypothesis 'Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are more efficient and regulatory compliant than Paper-Based Qualification methods,' explored and tested the validity of the theory and ended with a specific conclusion.

3.5 Research Choices

The research philosophy and approach underpin the research choices. This is the third layer of the research onion and offers six choices:

1. **Mono method quantitative** - Single source data collection, numerical in nature (Quantitative only) e.g. survey.
2. **Mono method qualitative** - Single source data collection, non-numerical in nature (Qualitative only) e.g. interview.
3. **Multi-method quantitative** - Multiple source data collection, numerical in nature (Quantitative only) e.g. survey and experimentation.
4. **Multi-method qualitative** - Multiple source data collection, non-numerical in nature (Qualitative only) e.g. interview and case study.
5. **Mixed method simple** - Combination of both numerical and non-numerical in one study (Quantitative and Qualitative) e.g. survey and interview.
6. **Mixed method complex** - Combination of both numerical and non-numerical in one study (Quantitative and Qualitative) e.g. experiment and case study.

The positivist philosophy with a deductive approach is usually associated with quantitative data collection (Mardiana, 2020). The research choice was a single method of data collection, **mono-method quantitative** in nature. Single source data collection was deemed sufficient to address the research hypothesis.

3.6 Research Strategy

Following on from the research choices, is the research strategy. This is the fourth layer of the research onion and offers eight strategy options:

1. **Experiment**
2. **Survey**
3. **Archival research**
4. **Case study**
5. **Ethnography**
6. **Action research**
7. **Grounded theory**
8. **Narrative inquiry**

The primary research strategy chosen was in the form of a **survey**. Data was collected by means of a survey, using a questionnaire developed with the help of a survey generation tool, Microsoft Forms. The survey consisted of a combination of close ended dichotomous, single choice, multiple-choice and Likert scale type questions. The Likert scale was developed around the 1930s by Rensis Likert as an alternative to the already existing, overly complex, Thurstone scaling technique. The Likert scale is one of the preferred methods in research for measuring opinions, attitudes, behaviours or perceptions (Kempf-Leonard, 2005). The scale can be designed using many different scaling variations, 4-point scales to 7-point scales being the most popular, the 5-point classic model scale is the most commonly used. For the purpose of this research study, a 7-point scale was applied for Likert style questions, this offered the participants seven response options to each survey question, an extreme option at either end of the scale, four intermediate options and a neutral option. The 7-point scale presented participants with more choice and provided the researcher more in-depth feedback. The scale brings with it many advantages:

- Easy to understand and analyse.
- Specific responses are not forced as the scale provides flexibility.
- Participant satisfaction, responses are more meaningful than a ‘Yes’ or ‘No’ answer.

The intended purpose of the survey was to generalise from a sample to an entire population so that conclusions could be drawn from the data collected. Due to its convenience, cost-effectiveness and rapid turnaround time, an online survey was the preferred method for collecting data. A link to the survey was issued via email and distributed via LinkedIn.

3.6.1 Questionnaire Design

The questionnaire was designed using Microsoft forms. It contained 23 close ended questions with predefined response options, divided over six sections:

- **Section 1:** Survey Information & Participant Consent
- **Section 2:** Participant Information
- **Section 3:** Introductory Questions
- **Section 4:** Regulatory, Operational & Quality
- **Section 5:** Technological Influences
- **Section 6**: Medical Device Regulation – EU MDR 2017/745

Prior to distribution, a pilot run of the survey questionnaire was completed. The pilot run was used to inform the researcher of any errors, difficulties in understanding questions, and estimate the time required to complete the survey questionnaire.

Refer to Appendix B - Survey Questionnaire for further information.

3.6.2 Participants

A non-probability sampling method was used to select participants. Non-probability is a non-random selection of participants i.e. participants are selected based on certain criteria. The target audience for the survey/questionnaire was eligible participants working within the medical device manufacturing industry. To qualify for the research survey, the participants needed to be proficient in the English language, fully understand the purpose of the research and had experience, either directly or indirectly with paper-based and/or electronic-based equipment qualification systems. Participants were asked these qualifying questions confirming their eligibility to participate in the research study. Participants who did not meet the eligibility criteria were directed to the end of the study and thanked for their time.

3.6.3 Sample Size Calculation

For research survey purposes a sample of the population i.e. part of a population is used for the following reasons (McMahon, 2023):

1. Normally impossible to survey an entire population.

2. Time constraints.
3. Budget constraints.
4. Quick turnaround of data.

Sampling allows inferences to be made about the entire population.

Terminology explained:

1. **Population Size** - Total population of the study group. Expressed as a whole number.
2. **Confidence Level** - Certainty in the results obtained. Expressed as a percentage.
   e.g. using a 95% confidence level, for a study repeated 100 times, 95 out of 100 times the result falls within a specific range (confidence interval).
3. **Margin of Error** - Reflects the accuracy of the results obtained. Typically expressed as ± value.
4. **Confidence Interval** - Represents the degree of certainty or uncertainty in the estimate, Result ± Margin of Error. Expressed as a whole number and a range.
   e.g. Result = 70%, Margin of Error ±5% therefore the Confidence Interval is 65 – 75.
5. **Sample Size** - Number of survey participants required to obtain a statistical representation of the overall population using a pre-determined population size, confidence level and margin of error. Expressed as a whole number.

As no specific data could be sourced on the number of medical device manufacturing companies of orthopedic implants selling into the European Union market, an assumption was made using the data available. The population size was calculated using data from BoldData and Grand View Research. The 'total number of orthopedic companies in the world is 19,584' (BoldData, 2025), assuming that all sell to the European Union market and the market accounts for 24.5% of the global orthopedic market (Grand View Research, 2025), the population size was calculated at 4,798.

The optimal sample size of 356 was determined using a sample size calculator from the website SurveyMonkey (2025). The sample size is based on a 95% Confidence Level, 5% Margin of Error and a Population Size of 4,798.

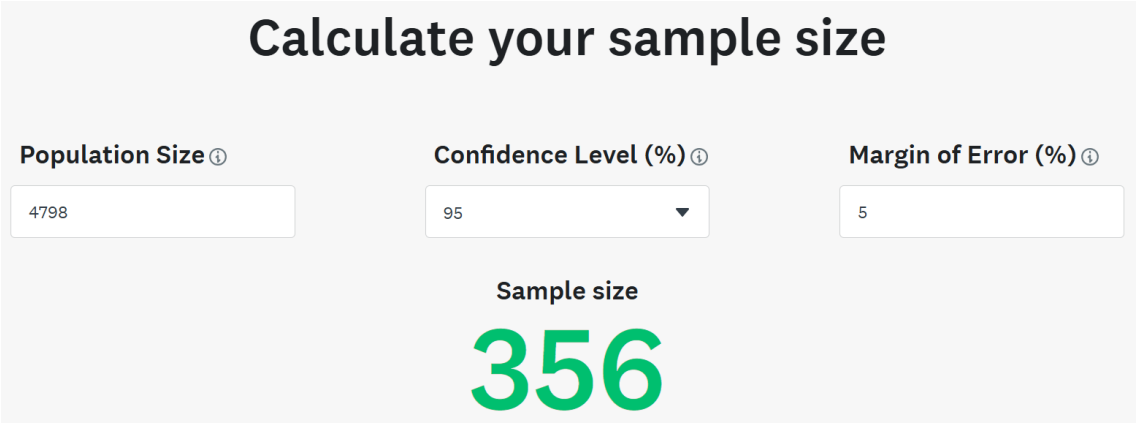

Figure 8 - Sample Size Calculation (SurveyMonkey, 2025)

3.7 Time Horizon

The research onion offers two different time horizon options:

1. **Cross-sectional**
2. **Longitudinal**

A longitudinal time horizon is typically associated with studies where changes over time are necessary to reach a research conclusion. The data is collected at multiple points in time. For the purpose of this research, a **cross-sectional** time horizon was selected. To address the research hypothesis a longitudinal time horizon was not deemed necessary. Data was collected during a specific period of time; representing a moment in time without further follow-up (Jansen, 2023).

3.8 Techniques and Procedures

3.8.1 Data Collection & Analysis

The final layer of the research onion addresses techniques and procedures: data collection and analysis. The survey/questionnaire had a defined start and end date for participant response. As the questionnaires were completed and submitted, the data was reviewed for trends. Once the closing date of the survey elapsed, the survey was closed and removed from the public domain by the researcher. All data received was examined and scrubbed prior to analysis. Data cleansing ensured accuracy, consistency, and uniformity of information.

The research findings were quantifiable in nature. The researcher's role was to analyse the data objectively (Creswell, 2009). To determine whether the hypothesis was supported by the survey responses, a statistical analysis was conducted. A readily available, user-friendly statistical package, Minitab, was used to analyse the survey data. Visual analytics

tools available through Minitab were used to represent the findings of the survey in the form of pie charts, bar charts and boxplots. Based on the data collected and the analysis performed, a conclusion was reached.

Table 3 - Research Methodology - Adapted from 'Modifying Research Onion for Information Systems Research', Mardiana (2020)

Philosophy	Approach	Methods /Choices	Strategy	Time Horizon	Data Collection
Positivism	Deductive	Quantitative	Experiment	• Cross-sectional • Longitudinal	Numerical
Positivism	Deductive	Quantitative	Survey	• Cross-sectional • Longitudinal	Numerical
Interpretivism	Inductive	Qualitative	Archival research	Cross-sectional	Non-numerical
Interpretivism	Inductive	Qualitative	Case study	Cross-sectional	Non-numerical
Interpretivism	Inductive	Qualitative	Ethnography	Cross-sectional	Non-numerical
Interpretivism	Inductive	Qualitative	Action research	Cross-sectional	Non-numerical
• Positivism • Interpretivism • Pragmatism	• Abductive • Deductive	• Quantitative • Qualitative	Design research	• Cross-sectional • Longitudinal	• Numerical • Non-numerical
Interpretivism	Inductive	Qualitative	Grounded theory	Cross-sectional	Non-numerical
Interpretivism	Inductive	Qualitative	Narrative inquiry	Cross-sectional	Non-numerical

3.9 Summary

The positivist philosophy, using a deductive approach, mono-method, quantitative research strategy in the form of a survey with a cross-sectional timeline, supported the aim of this research study. The chosen research design allowed for collection of data, analyses of said data and a conclusion to be reached.

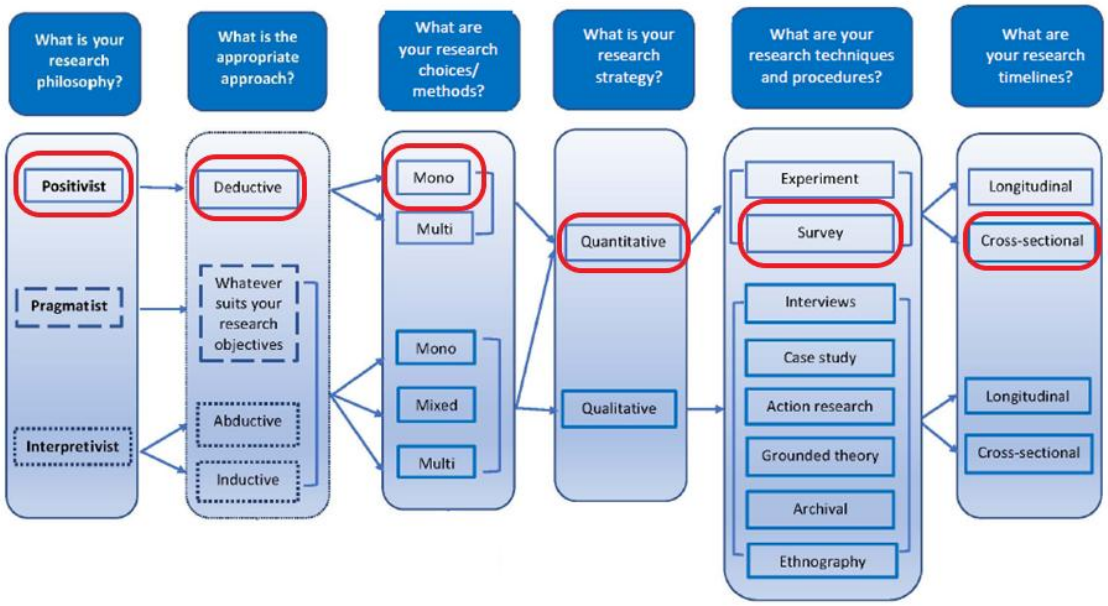

Figure 9 - Graphical Presentation of Research Design - Adapted from 'Musings on the Research Onion', Lawson (2020)

3.10 Ethical Considerations

The researcher has a moral obligation to ensure that the rights, needs, values, and desires of the participants are respected throughout the research study. Ethical concerns are well considered through Griffith College/Innopharma Ethics Application and Declaration Form. Prior to the commencement of the primary research an Ethics Application and Declaration Form was completed and submitted to Griffith College/Innopharma for approval. Refer to Appendix A - Ethics Application and Declaration Form for further information.

As this primary research was conducted using an online survey, the Participant Information Leaflet (PIL) was included in the survey. The PIL took the form of a summary paragraph at the outset of the survey, outlining the clear intent of the research and the rights of the participants. Considering that participation in this research study was entirely voluntary, the participants were asked for consent prior to the commencement of the questionnaire. Anonymity of all survey participants and confidentiality was considered at all times; no identifiable information was collected.

The data collected was only used for the purpose of this particular study and managed in accordance with the General Data Protection Regulation (GDPR) EU 2016/679 (European Commission, 2016). Throughout the research, the data was stored on a password-protected laptop, accessible only to the researcher and shared with the appointed research supervisor for feedback purposes. The primary research raw data will be kept on file for two years as per the approved Ethics Application and Declaration Form and in accordance with Griffith College/Innopharma guidelines and thereafter destroyed.

Chapter 4: Findings and Analysis

4.1 Introduction

The primary data for this study was collected through a survey questionnaire created using Microsoft Forms. The questionnaire consisted of 23 close-ended questions, distributed across six sections. The target audience were eligible participants with experience, either directly or indirectly, of paper-based and/or electronic-based equipment qualification systems within the medical device industry.

The survey was distributed via email and LinkedIn, a shortened URL link to the questionnaire was embedded within the invitation. The invitation also included a brief description of the request. Recipients were encouraged to share the invite with others in their network.

The survey remained open from the 24th February 2025 to the 24th March 2025. During this period, follow-up emails were sent to increase the response rate. The survey sample size was calculated at 356, the final number of responses received was 187.

The survey questions are presented in the following sections, where the findings are analysed and discussed:

- **Section 1** – Survey Information and Participant Consent
- **Section 2** – Participant Information
- **Section 3** – Introductory Questions
- **Section 4** – Regulatory, Operational & Quality
- **Section 5** – Technological Influences
- **Section 6** – Medical Device Regulation – EU MDR 2017/745

4.2 Research Questions

4.2.1 Section 1 - Survey Information and Participant Consent

Section 1 of the survey provided a condensed version of the Participant Information Leaflet (PIL) which summarised the purpose of the research and explained the key points for participation. In addition, this section also included two qualifying questions, both of which required a positive response for participants to continue to Section 2 – Participant Information.

In accordance with the approved Ethics Application and Declaration Form, Section 5 – Information, Consent and Confidentiality, participants must meet the following criteria to proceed to the next section:

- **Survey Purpose:** Participants shall understand the purpose of the survey.
- **Survey Consent:** Participants shall provide their consent to participate in the survey.

Refer to Appendix A - Ethics Application and Declaration Form for further information.

Survey Design:

- **Questions 1 - 2:** All questions in Section 1 were dichotomous in nature, requiring a "Yes" or "No" response.
- Only those who met the eligibility criteria were able to proceed to Section 2 – Participant Information.
- Participants who did not meet the eligibility criteria, were automatically directed to the end of the survey, requested to submit their survey responses by selecting the "Submit" button and thanked for their time.

Question 1 - Do you understand the purpose of this research?

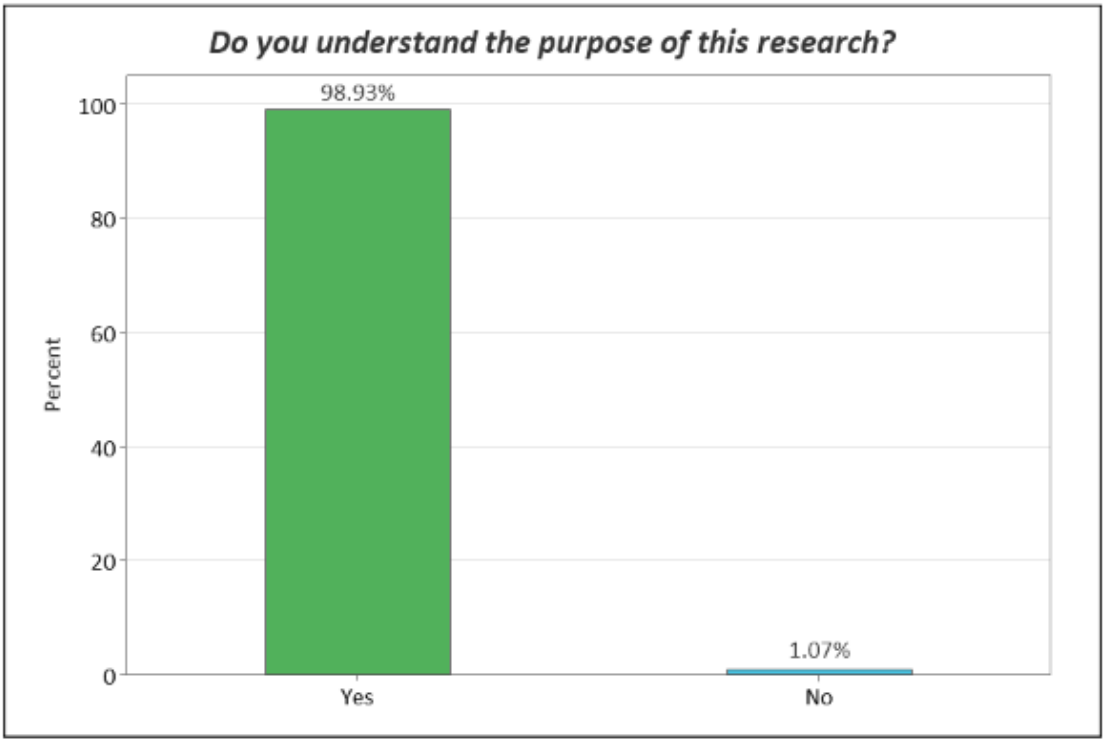

Figure 10 - Survey Question 1 Response - (Minitab)

Analysis:

Participants to Question 1: 187 participants

Question 1: *'Do you understand the purpose of the research?'*

- **Positive responses (Yes):** 185 participants (98.93%)
- **Negative responses (No):** 2 participants (1.07%)

Outcome:

- **Positive responses (185 participants):** Progressed to Question 2.
- **Negative responses (29 participants):** Directed to the end of the survey and thanked for their time.

Discussion:

The high percentage of positive responses indicates that the majority of the participants clearly understood the purpose of the research as explained in the introductory paragraph. The small proportion who did not understand suggests that while the introductory paragraph was effective for most participants, there was room for minor adjustments to ensure better clarity.

Question 2 - Do you agree to participate in this survey?

Analysis:

Participants progressing from Question 1 to Question 2: 185 participants

Question 2: *'Do you agree to participate in this survey?'*

- **Positive responses (Yes):** 185 participants (100%)
- **Negative responses (No):** 0 participants (0%)

Outcome:

- **Positive responses (185 participants):** Progressed to Section 2 – Participant Information– Question 3.
- **Negative responses (0 participants):** A negative response to Question 2 would have automatically directed the participant to the end of the survey and thanked for their time.

Discussion:

Full participation and agreement was reached on this survey question.

4.2.2 Section 2 - Participant Information

Section 2 of the survey aimed to gather essential information regarding participant eligibility. It included two further qualifying questions that required a positive response for participants to continue to Section 3, the Introductory Questions.

According to the approved Ethics Application and Declaration Form, Section 2 – Possible Ethical Issues and Section 4 – About Your Participants, participants must meet the following criteria to proceed to the next section:

- **Fluency in English:** Participants must be fluent in English, as specified in Section 2 of the Ethics Application.
- **Experience with Equipment Qualification Systems:** Participants must have direct or indirect experience with either paper-based or electronic-based equipment qualification systems, as outlined in Section 4 of the Ethics Application.

Refer to Appendix A - Ethics Application and Declaration Form for further information.

Survey Design:

- **Questions 3 - 4:** All questions in Section 2 were dichotomous in nature, requiring a "Yes" or "No" response.
- Only those who met the eligibility criteria were able to proceed to Section 3 – Introductory Questions.
- Participants who did not meet the eligibility criteria, were automatically directed to the end of the survey, requested to submit their survey responses by selecting the "Submit" button and thanked for their time.

Question 3 - Are you proficient in the English language?

Analysis:

Participants progressing from Question 2 to Question 3: 185 participants

Question 3: *'Are you proficient in the English language?'*

- **Positive responses (Yes):** 185 participants (100%)
- **Negative responses (No):** 0 participants (0%)

Outcome:

- **Positive responses (185 participants):** Progressed to Question 4.
- **Negative responses (0 participants):** A negative response to Question 3 would have automatically directed the participant to the end of the survey and thanked for their time.

Discussion:

Full participation and agreement was reached on this survey question.

Question 4 - Have you experience either directly or indirectly with Paper-Based and/or Electronic-Based equipment qualification systems within the medical device industry?

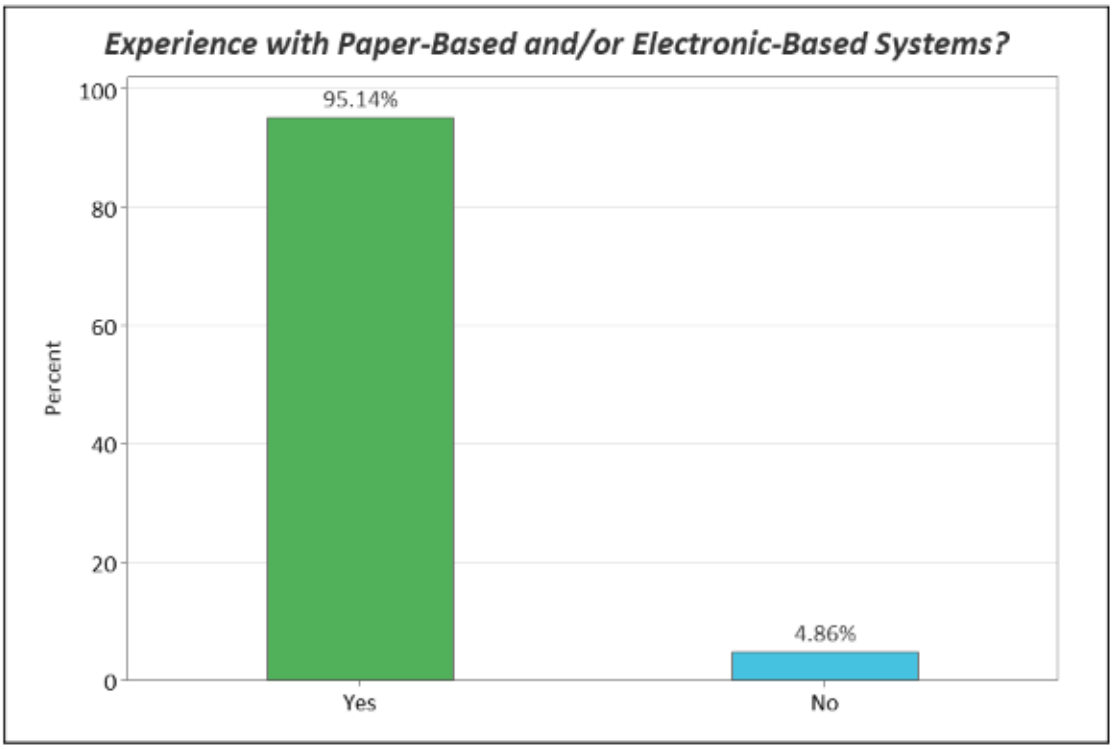

Figure 11 - Survey Question 4 Response - (Minitab)

Analysis:

Participants progressing from Question 3 to Question 4: 185 participants

Question 4: *'Have you experience either directly or indirectly with Paper-Based and/or Electronic-Based equipment qualification systems within the medical device industry?'*

- **Positive responses (Yes):** 176 participants (95.14%)
- **Negative responses (No):** 9 participants (4.86%)

Outcome:

- **Positive responses (176 participants):** Progressed to Section 3 – Introductory Questions – Question 5.
- **Negative responses (9 participants):** Directed to the end of the survey and thanked for their time.

Discussion:

A total of 187 participants initially commenced the survey questionnaire. Following the completion of the four qualifying questions, 94.12% of participants (176 out of 187) were eligible and proceeded to the main survey, while 5.88% (11 out of 187) did not meet the eligibility criteria and were excluded.

4.2.3 Section 3 - Introductory Questions

Section 3 of the survey contained three questions aimed at gathering information about the participants' background within the medical device industry. Specifically, these questions sought to determine the sector participants represented, whether their company was classified as a Small to Medium-Sized Enterprise (SME), and which equipment qualification system their company used.

Survey Design:

- **Questions 5 - 7:** The questions contained within Section 3 were a combination of single choice and multiple-choice formats, helping to collect specific data on the participants' roles and organisational characteristics.
- Participants were able to proceed to Section 4 – Regulatory, Operational & Quality regardless of their responses in Section 3.

Question 5 - Which category best describes your job role?

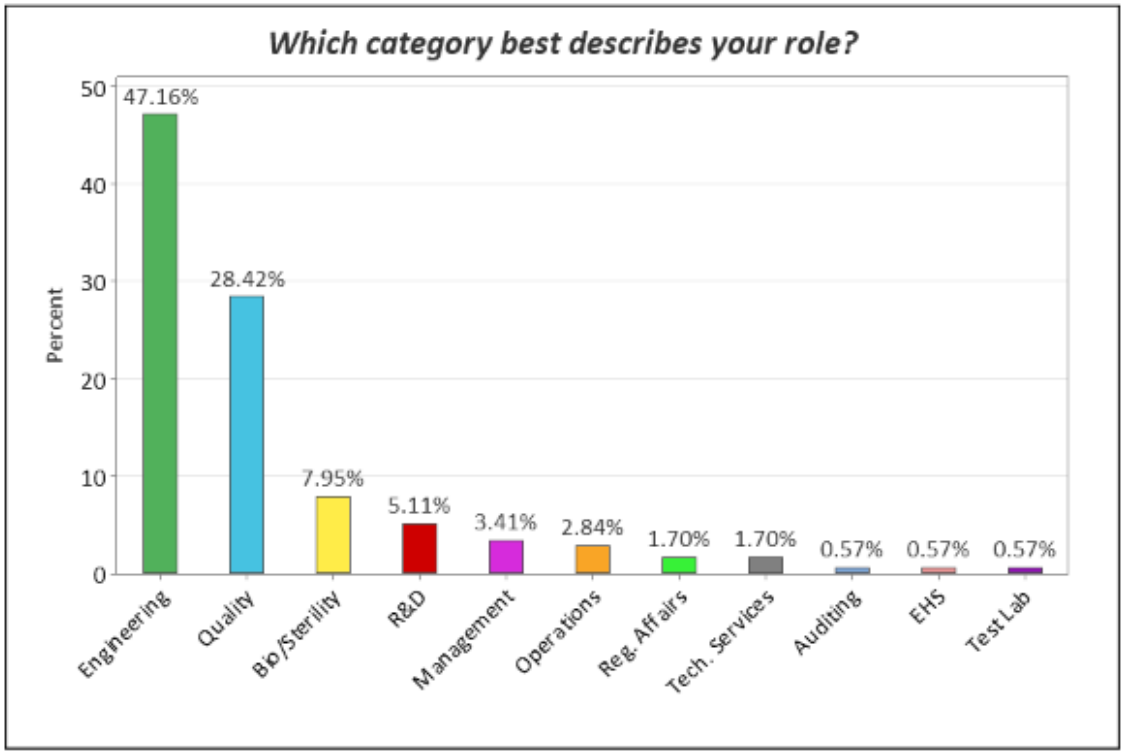

Figure 12 - Survey Question 5 Response - (Minitab)

Analysis:

Participants progressing from Question 4 to Question 5: 176 participants

Question 5: *'Which category best describes your job role?'*

Most of the respondents to this survey had either an Engineering or Quality background within the medical device industry.

- **47.16%** of the respondents had a background in Engineering.
- **28.42%** had a background in Quality.

Indicating that both engineering and quality hold significant roles in terms of equipment qualifications.

The remaining **24.42%** represented a diverse set of backgrounds within the medical device industry including:

- Biological Sciences/Sterility
- Research & Development
- Management, Operations
- Technical Services
- Regulatory Affairs
- Test Laboratory
- Environmental, Health & Safety

- Auditing

Irrespective of role, all respondents from Question 5 progressed to Question 6.

Discussion:

The qualifying questions for this survey were designed to ensure that participants were professionals working within the medical device manufacturing industry, with direct or indirect experience in paper-based and/or electronic-based equipment qualification systems.

Secondary research identified Engineering and Quality departments as the primary users of such systems within the industry, a finding that is echoed in the primary research data collected through the survey.

The Equipment Qualification framework discussed in Section 2.3.1 emphasises the critical role of both Engineering and Quality departments in the review and approval of protocols.

The Engineering department is primarily responsible for the technical aspects of the qualification i.e. the equipment meets the user requirements and operates as per the manufacturer's specification.

The Quality department is primarily focused on compliance i.e. the equipment meets the standards and specifications.

Both departments work collaboratively to ensure equipment readiness and compliance.

Question 6 - Is your company classed as a small to medium-sized enterprise (SME) i.e. 250 employees or less?

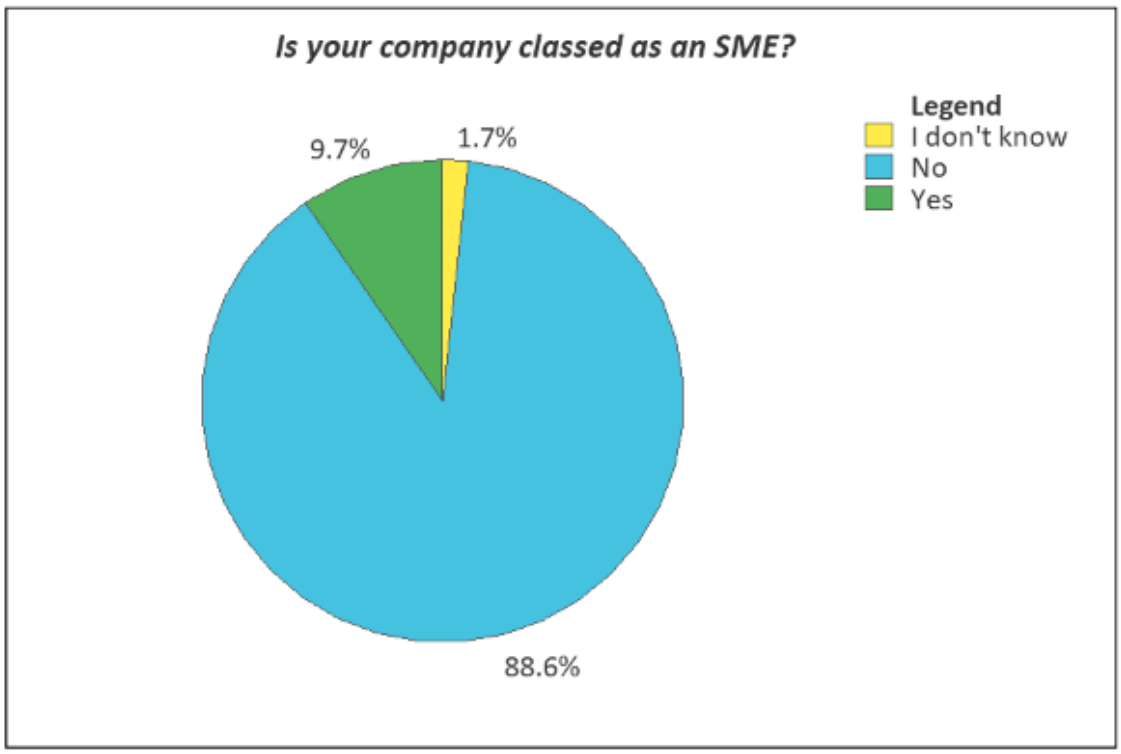

Figure 13 - Survey Question 6 Response - (Minitab)

Analysis:

Participants progressing from Question 5 to Question 6: 176 participants

Question 6: *'Is your company classed as a small to medium-sized enterprise (SME) i.e. 250 employees or less?'*

- **9.7%** of the respondents were from SMEs.
- **88.6%** came from large-sized enterprises.
- **1.7%** did not know if their organisation was classed as an SME.

Irrespective of company size, all respondents from Question 6 progressed to Question 7.

Discussion:

17 respondents identified as working within small to medium-sized enterprises (SMEs). Analysis of the primary research data revealed that 4 of the 17 respondents were still utilising paper-based equipment qualification systems. All 4 respondents reported that the paper-based approach was inefficient, and susceptible to human error. Notably, 2 of the 4 respondents had prior experience with electronic-based systems and noted significant improvements in data integrity and audit readiness when using electronic systems.

Question 7 - Which equipment qualification system does your company primarily use?

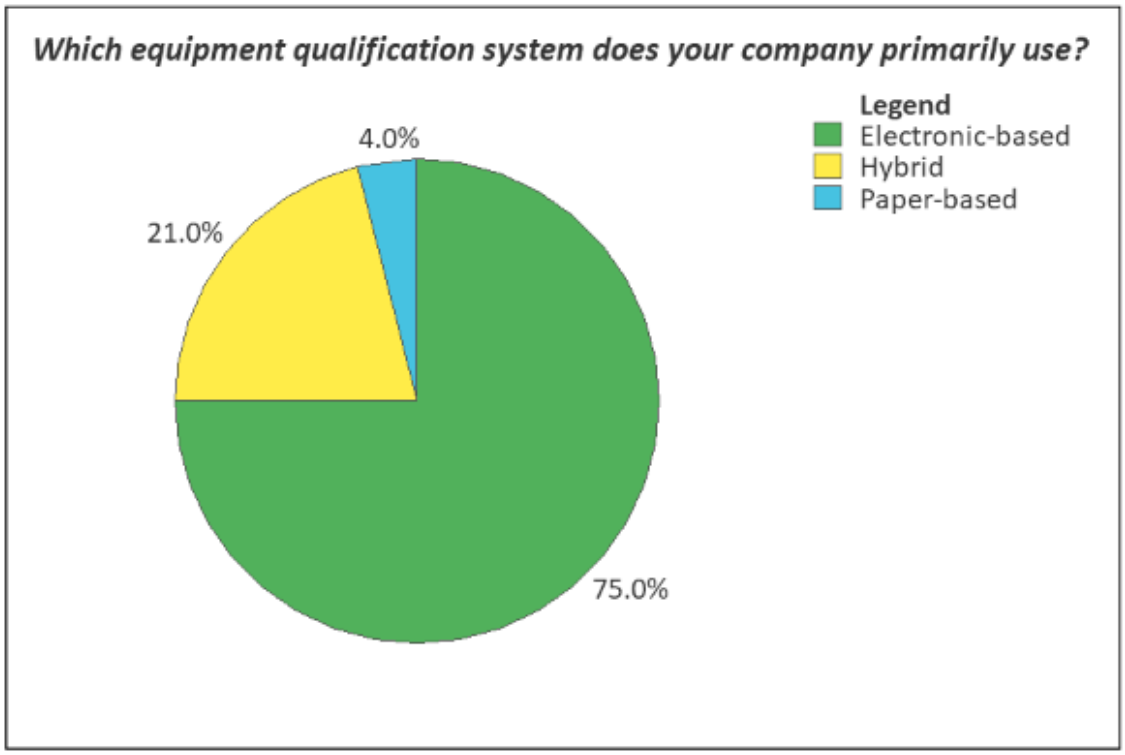

Figure 14 - Survey Question 7 Response - (Minitab)

Analysis:

Participants progressing from Question 6 to Question 7: 176 participants

Question 7: *'Which equipment qualification system does your company primarily use?'*

- **75.0%** of the respondents used electronic-based equipment qualification systems, indicating a strong preference for digital solutions.
- **21.0%** used a hybrid option, combining electronic and paper-based systems, balancing traditional methods with technological advancements.
- **4.0%** relied solely on paper-based systems, representing a small minority still using traditional methods.

Irrespective of the response to Question 7, all respondents from Question 7 progressed to Section 4 – Regulatory, Operational & Quality – Question 8.

Discussion:

According to a 2024 report on the "State of Validation" (Kay, 2024), based on a survey launched March 2024 and published in August 2024, 30% of respondents had already implemented electronic systems. The report also indicated that an additional 14% planned

to adopt electronic systems with the year, with a further 26% expected to do so within one to two years.

In comparison, this survey conducted in March 2025 found that 75% of respondents' organisations had implemented electronic-based equipment qualification systems. This represents a slightly higher adoption rate than previously projected in the 2024 report, suggesting an accelerated industry shift towards digital transformation.

Several challenges identified in Kay's report may explain the accelerated adoption rate: compliance burdens, audit readiness and data security concerns, motivating organisations to prioritise implementation of electronic systems to remain competitive and compliant.

4.2.4 Section 4 - Regulatory, Operational & Quality

Section 4 of the survey focused on gathering insights into the participants' experiences and practices related to regulatory, operational, and quality aspects, with a particular emphasis on the transition from paper-based to electronic-based systems for equipment qualifications. This section contained 11 questions in total, Questions 8 through 18.

Survey Design:

- **Questions 8 - 13:** All participants who progressed to Section 4 answered these, covering topics related to regulatory, operational, and quality factors.
- **Questions 14 - 18:** Only those who answered "Yes" to Question 13 ('*Have you transitioned from paper-based to electronic-based equipment qualification methods during your career?',* indicating the transition from paper-based to electronic-based systems) answered these additional questions.
- Participants who responded "No" to Question 13 were automatically directed to Section 5 – Technological Influences – Question 19.
- The questions contained within Section 4 were a combination of single choice, multiple-choice, Likert scale and dichotomous formats.
- Participants were able to proceed to Section 5 – Technological Influences regardless of their responses in Section 4.

Question 8 - How would you rate the efficiency of your current equipment qualification system?

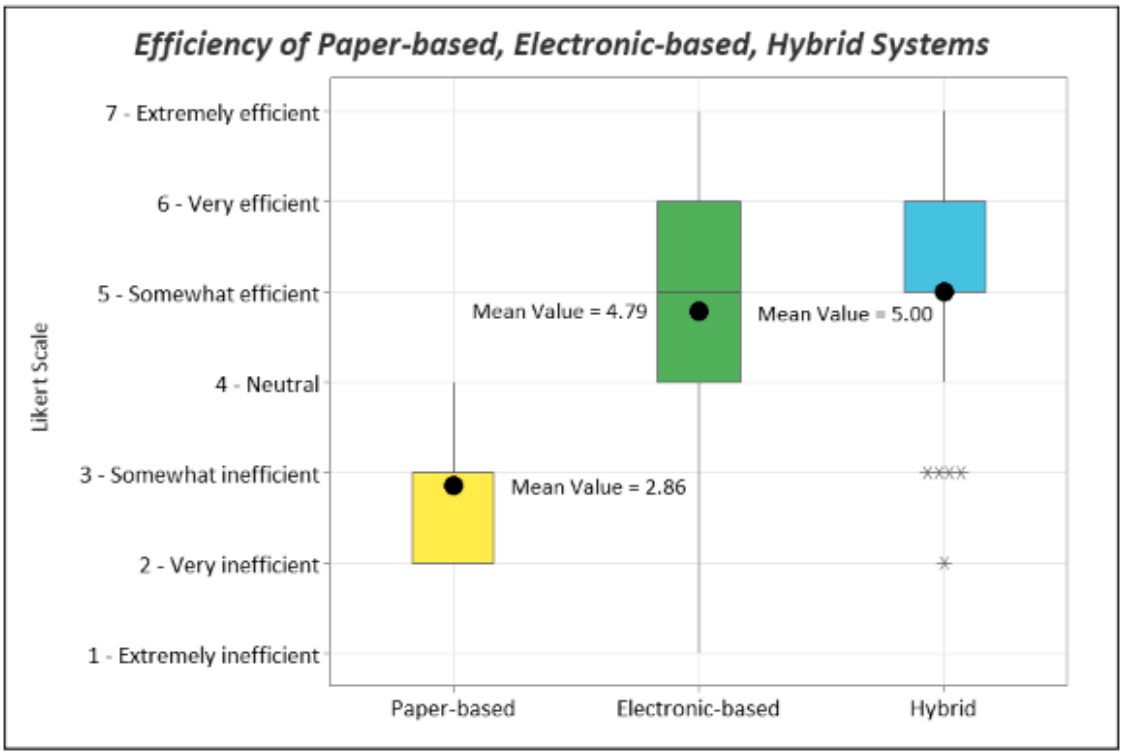

Figure 15a - Survey Question 8 Response - (Minitab)

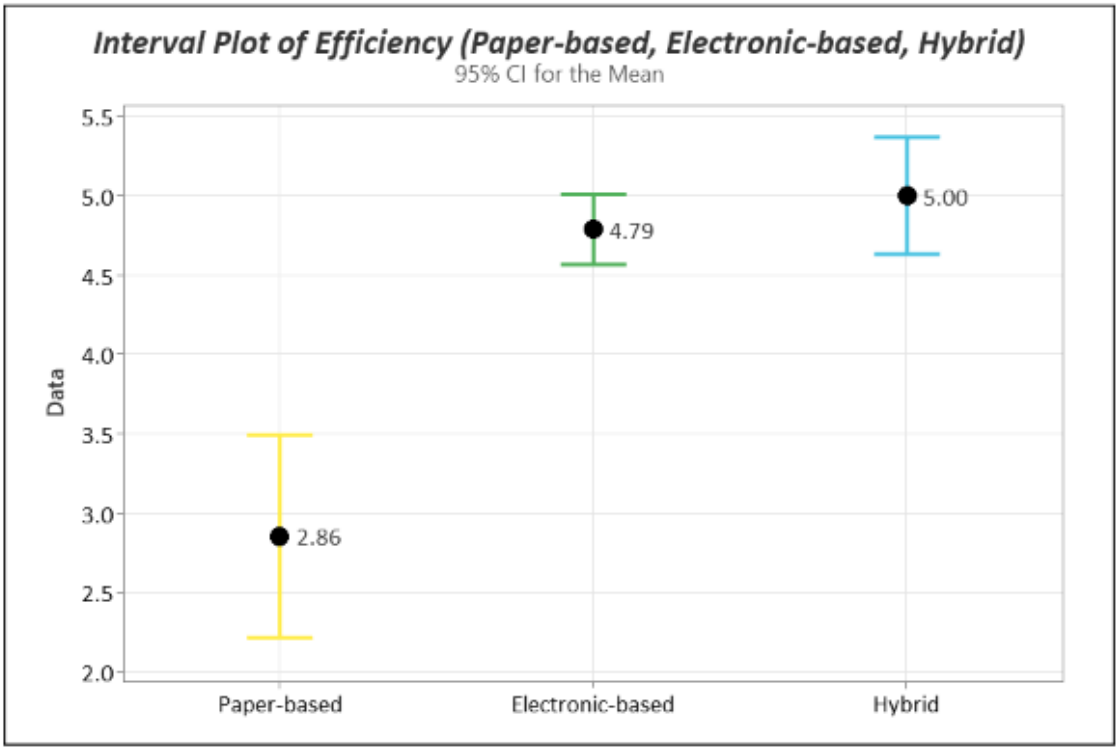

Figure 16b - Survey Question 8 Response - (Minitab)

Analysis:

Participants progressing from Question 7 to Question 8: 176 participants

Question 8: *'How would you rate the efficiency of your current equipment qualification system?'*

Table 4 - Survey Question 8 Statistical Analysis (Author's Own)

Analysis / System	Q1	Median	Q3	Interquartile Range (IQR)	Whiskers	Mean
Paper-based	2	3	3	1	2, 4	2.86
Electronic-based	4	5	6	2	1, 7	4.79
Hybrid	5	5	6	1	4, 7	5.00

χ^2 test (Chi-square Test) could not be performed for this question as not all typical sampling conditions could be met i.e. the expected value ≥ 5 (Davis, 2025). Refer to Appendix C - Statistical Analysis for further information.

Irrespective of the response to Question 8, all respondents from Question 8 progressed to Question 9.

Discussion:

Table 5 - Survey Question 8 Statistical Discussion (Author's Own)

Analysis / System	Mean (95% CI)	Interpretation	Variability in responses	Outliers
Paper-based	2.86	Very inefficient to Somewhat inefficient	Low	None
Electronic-based	4.79	Neutral to somewhat efficient	Moderate	None
Hybrid	5.00	Somewhat efficient	Moderate	Yes (inefficient)

Most respondents viewed paper-based systems as inefficient. A low variability across the responses indicates a resounding consensus of paper-based system inefficiency.

Electronic-based systems show improved efficiency over paper-based systems, within the range Neutral to Somewhat efficient but a greater spread in responses reveals that the data is less consistent when compared to paper or hybrid systems.

Hybrid systems rated the highest mean efficiency. The presence of outliers suggests that while most users found the hybrid system efficient, a minority of users expressed some dissatisfaction.

The secondary research highlighted that the growing complexity of equipment qualifications due to technological advancements underscores the need for efficient qualification systems, to remain both competitive and compliant. Paper-based systems are struggling to keep abreast of these developments whilst remaining efficient and compliant. Transitioning from paper-based to electronic or hybrid is beneficial, even though the secondary research does not specifically review hybrid equipment qualification systems, the combination appears to offer a practical balance, leveraging the strengths of both systems.

Question 9 - How confident are you in the integrity of data of your current equipment qualification system?

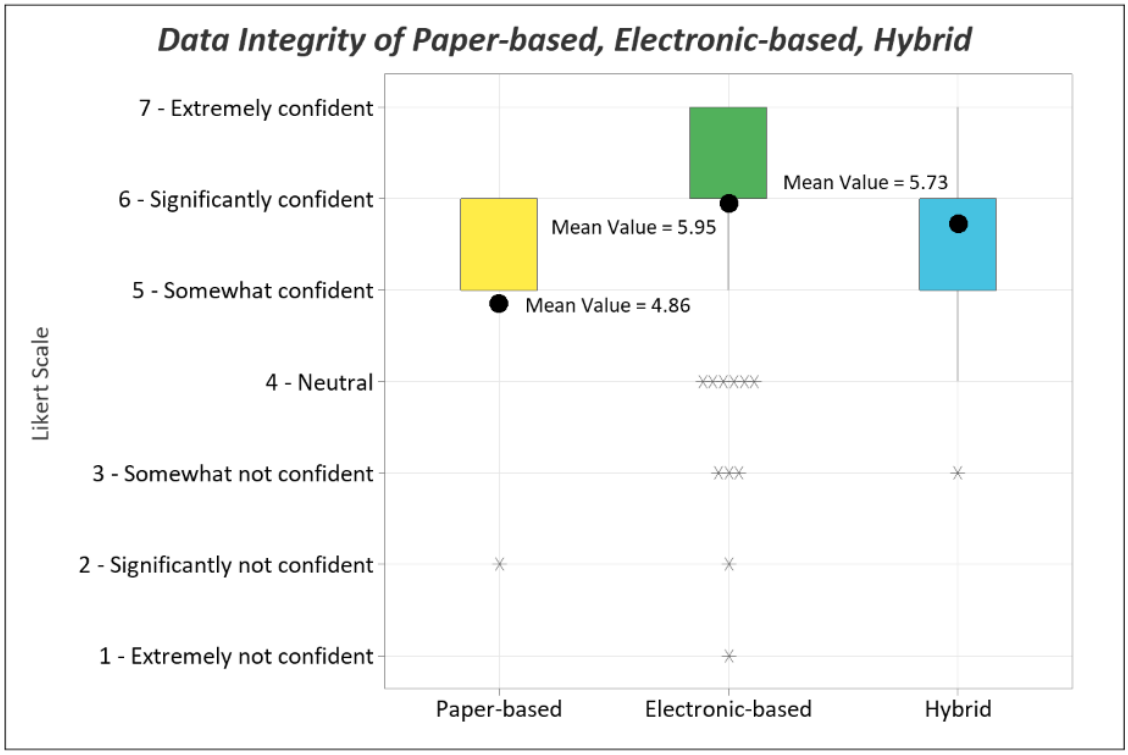

Figure 17a - Survey Question 9 Response - (Minitab)

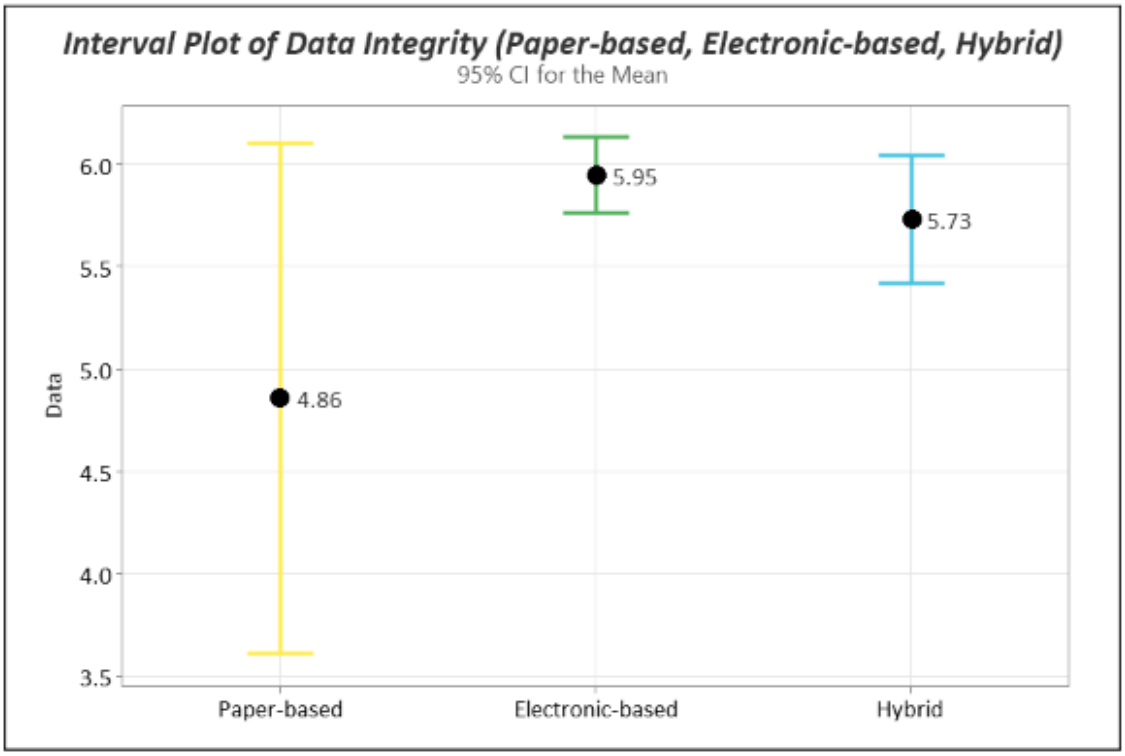

Figure 18b - Survey Question 9 Response - (Minitab)

Analysis:

Participants progressing from Question 8 to Question 9: 176 participants

Question 9: *'How confident are you in the integrity of data of your current equipment qualification system?'*

Table 6 - Survey Question 9 Statistical Analysis (Author's Own)

Analysis / System	Q1	Median	Q3	Interquartile Range (IQR)	Whiskers	Mean
Paper-based	5	5	6	1	5, 6	4.86
Electronic-based	6	6	7	1	5, 7	5.95
Hybrid	5	6	6	1	4, 7	5.73

χ^2 test (Chi-square Test) could not be performed for this question as not all typical sampling conditions could be met i.e. the expected value ≥ 5 (Davis, 2025). Refer to Appendix C - Statistical Analysis for further information.

Irrespective of the response to Question 9, all respondents from Question 9 progressed to Question 10.

Discussion:

Table 7 - Survey Question 9 Statistical Discussion (Author's Own)

Analysis / System	Mean (95% CI)	Interpretation	Variability in responses	Outliers
Paper-based	4.86	Neutral to Somewhat confident	Low	Yes (not confident)
Electronic-based	5.95	Significantly confident	Moderate	Yes (neutral/not confident)
Hybrid	5.73	Somewhat confident to Significantly confident	Moderate	Yes (not confident)

The majority of the respondents expressed some level of confidence in the integrity of data across all three systems.

The paper-based system had the lowest average confidence value and the electronic-based system the highest average value.

Outliers were identified across all three systems, but more notably with the electronic-based system, which suggests that while many respondents trust electronic systems, a subset has significant concerns about their data integrity.

Despite the presence of outliers, data integrity did not seem to be a real concern for the majority of the respondents.

Although the secondary research findings in Section 2.5.1 highlighted data integrity as an on-going concern for the Life Science industry, as organisations failed to implement robust systems to manage and store the large volumes of data that new technologies were producing. With the emergence of Cloud Service Providers (CSPs) over the last number of years, adopting the ALCOA++ framework, risks have been minimised and with that the level of confidence in the integrity of data increased.

Question 10 - What do you perceive as the biggest advantage of electronic-based equipment qualification systems?

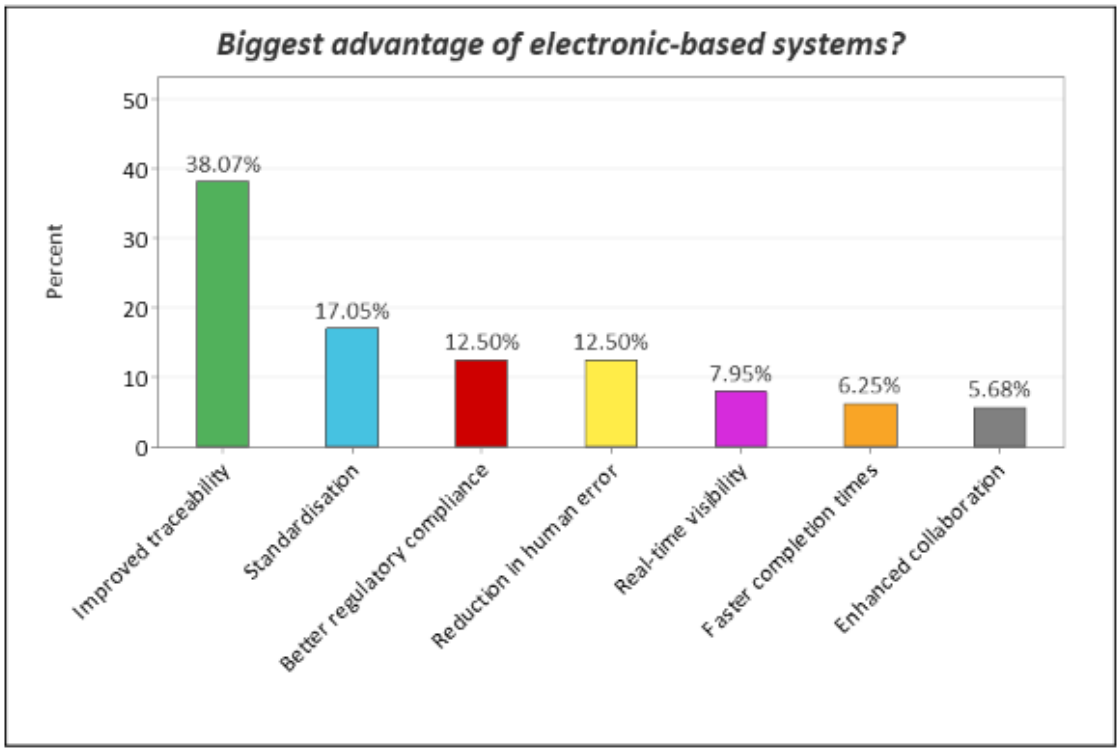

Figure 19 - Survey Question 10 Response - (Minitab)

Analysis:

Participants progressing from Question 9 to Question 10: 176 participants

Question 10: '*What do you perceive as the biggest advantage of electronic-based equipment qualification systems?'*

- **38.07%** of the respondents identified *"Improved Traceability"* as the most significant advantage of electronic-based equipment qualification systems.
- Other significant advantages included:
    - Standardisation
    - Reduction in human error
    - Better regulatory compliance
    - Real-time visibility
    - Faster completion times
    - Enhanced collaboration

Additionally, an "Other" option was available, and chosen by 7 participants. However, after data cleansing, these responses were categorised under existing pre-determined options.

For example: *“Less GDPR mistakes for poor writing or wrong dates”* was reclassified under *“Reduction in human error.”*

Irrespective of the response to Question 14, all respondents from Question 14 progressed to Question 15.

Discussion:

The secondary research findings are further reinforced by the survey data. As detailed in Section 2.3.2 - Paper-Based versus Electronic-Based Equipment Qualifications, Table 1, “Traceability” was identified as a key advantage of transitioning from paper-based to electronic-based systems.

Under the MDR, rigorous tracking of production equipment used in the manufacturing of medical devices is required. Electronic-based systems support compliance by offering a centralised, easily searchable database for qualification documentation. In addition, they provide robust audit trails, enable automated periodic reviews, enforce standardised workflows, and ensure each piece of equipment is directly linked to its qualification records. This leads to significantly enhanced traceability compared to traditional paper-based or hybrid systems.

Question 11 - How would you rate the ease of maintaining regulatory compliance with your current system?

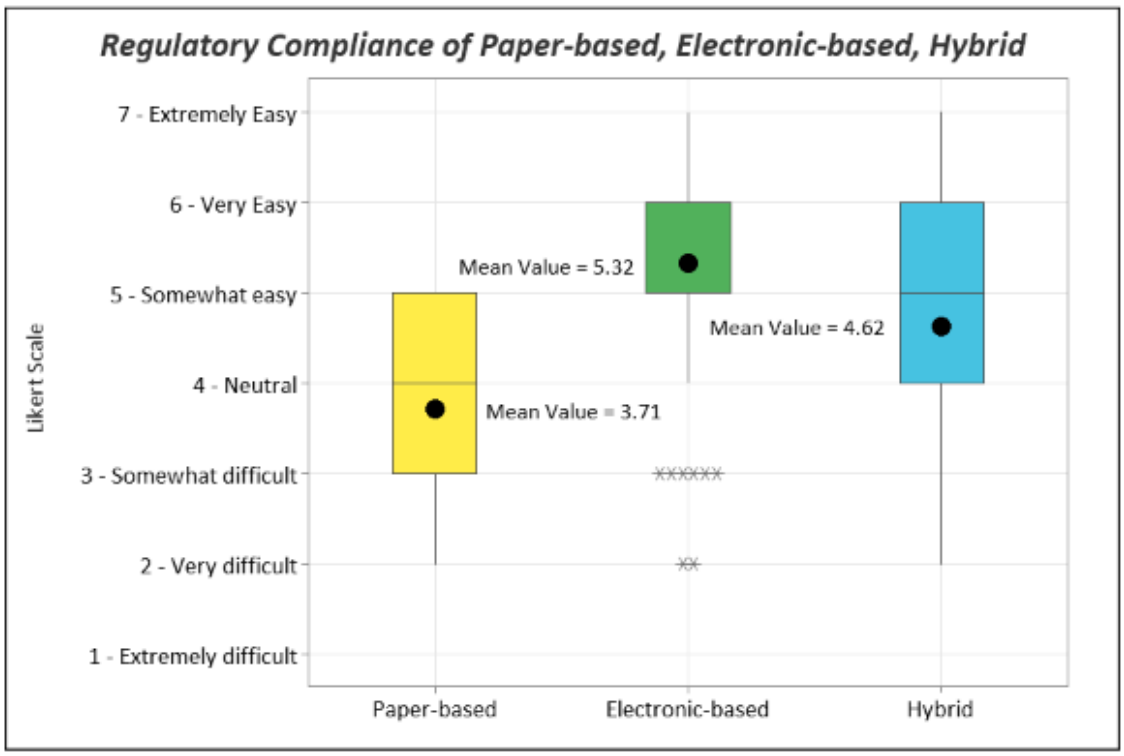

Figure 20a - Survey Question 11 Response - (Minitab)

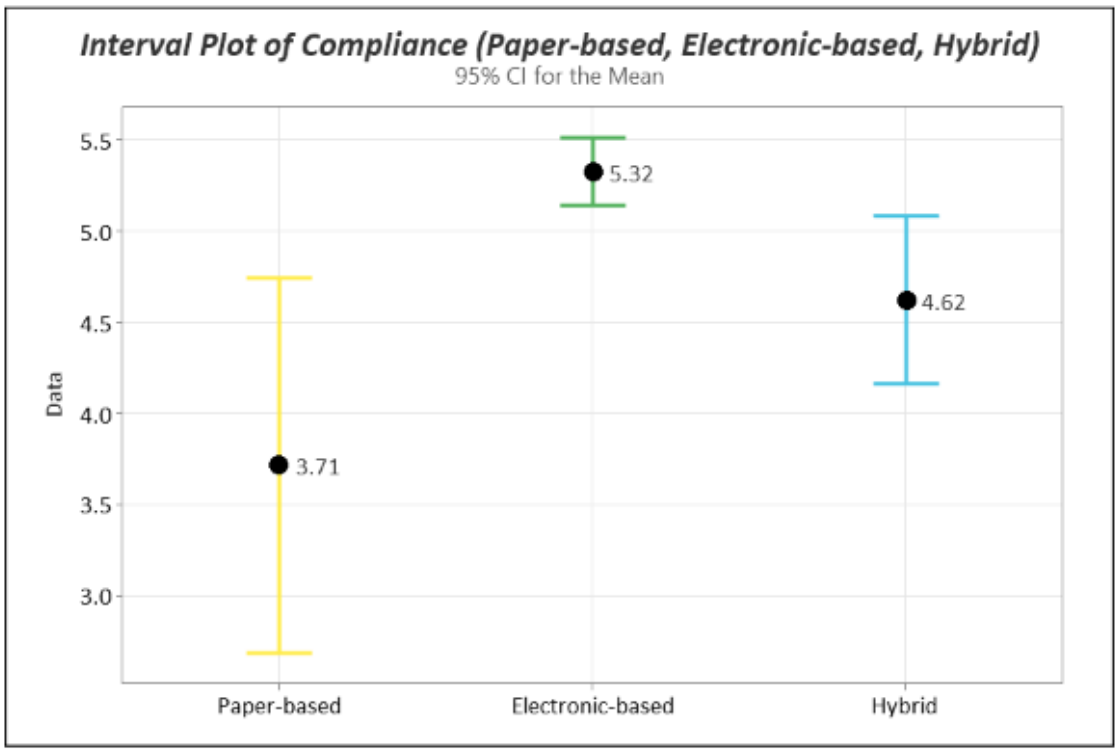

Figure 21b - Survey Question 11 Response - (Minitab)

Analysis:

Participants progressing from Question 10 to Question 11: 176 participants

Question 11: *'How would you rate the ease of maintaining regulatory compliance with your current system?'*

Table 8 - Survey Question 11 Statistical Analysis (Author's Own)

Analysis / System	Q1	Median	Q3	Interquartile Range (IQR)	Whiskers	Mean
Paper-based	3	4	5	2	2, 5	3.71
Electronic-based	5	5	6	1	4, 7	5.32
Hybrid	4	5	6	2	2, 7	4.62

χ^2 test (Chi-square Test) could not be performed for this question as not all typical sampling conditions could be met i.e. the expected value ≥ 5 (Davis, 2025). Refer to Appendix C - Statistical Analysis for further information.

Irrespective of the response to Question 11, all respondents from Question 11 progressed to Question 12.

Discussion:

Table 9 - Survey Question 11 Statistical Discussion (Author's Own)

Analysis / System	Mean (95% CI)	Interpretation	Variability in responses	Outliers
Paper-based	3.71	Somewhat difficult to neutral	Moderate	None
Electronic-based	5.32	Somewhat easy to very easy	Low	Yes (difficult)
Hybrid	4.62	Neutral to somewhat easy	Moderate	None

With the lowest mean value of 3.71, paper-based systems are perceived to be the most difficult in the context of regulatory compliance. The lower whisker indicates that some respondents found maintaining compliance using paper-based systems very difficult.

Electronic-based systems have the highest mean compliance, suggesting that on average, respondents found electronic-based systems easier in terms of compliance than both other systems. The presence of outliers suggests that while most users found the electronic-based system easier, there are exceptions.

Hybrid systems showed better compliance than paper-based systems. The spread in the responses suggests some respondents found it easier and some more difficult.

As detailed in Section 2.1 of the secondary research, medical device manufacturing equipment must undergo rigorous qualification activity to maintain a high standard of compliance, it is integral to ensuring the safety and effectiveness of devices.

The risk of human error and missing information is more prevalent with the use of paper-based systems, posing significant challenges for maintaining regulatory compliance.

Electronic-based systems offer features such as audit trails, version control and easy retrieval of documentation, making them better placed to support compliance as detailed in Section 2.6 Technological Framework for qualification Systems, Table 1 – Paper-Based vs. Electronic-Based Equipment Qualification Systems.

Question 12 - Which of the following challenges do you encounter with your current equipment qualification system? (Select all that apply)

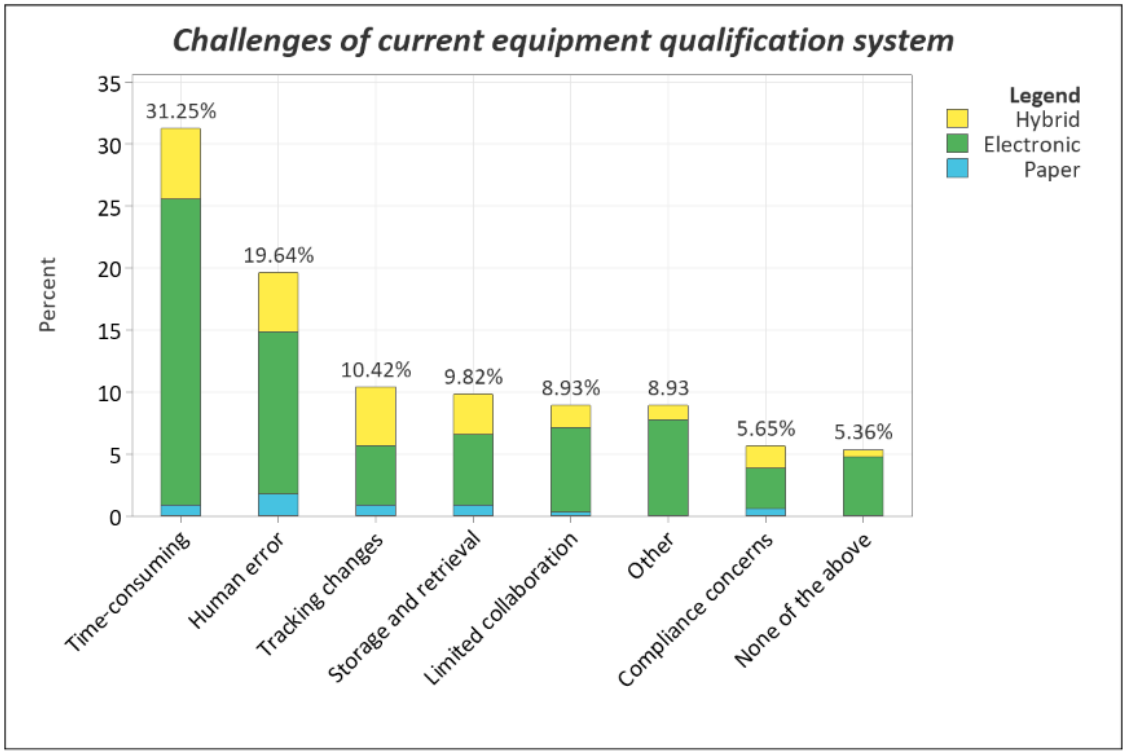

Figure 22 - Survey Question 12 Response - (Minitab)

Analysis:

Participants progressing from Question 11 to Question 12: 176 participants

Question 12: *'Which of the following challenges do you encounter with your current equipment qualification system?'*

- *"Time consumption"* **(31.25%)** was the most common challenge reported by the respondents. The majority of the responses are from electronic systems.
- The second most common challenge was identified as *"Human Error"* **(19.64%).** The majority of the responses are again from electronic systems.

  Other challenges included:
  - Tracking Changes
  - Storage and Retrieval
  - Limited Collaboration
  - Compliance Concerns

Additionally, an "Other" option was available, 8.93% choose this option. Some examples included:

- Training to electronic systems

- Electronic system architecture, poor interface, not so intuitive
- Lengthy approval times in electronic systems

"None of the above" 5.36% felt that none of the pre-determined options challenged their equipment qualification system.

Irrespective of the response to Question 12, all respondents from Question 12 progressed to Question 13.

Discussion:

The primary research data reveals that although time consumption was seen as the biggest challenge of equipment qualification systems collectively, human error was identified as the most critical challenge of the paper-based system. While change tracking, documentation management, collaboration and compliance were seen as lesser issues, they continue to affect the effectiveness of equipment qualification systems.

Electronic systems appear significantly in all challenge categories. Section 2.5 - Technological Impacts on Quality, Safety & Operations highlights that electronic systems come with their own set of challenges in terms of implementation and training, regulatory compliance, data integrity and cybersecurity/information security.

With regard to human error, both Leong (2023) and Rodriguez-Perez (2019) emphasise the need for medical device manufacturers to move away from manual based systems in order to stay competitive and compliant. Manual systems have exposed organisations to compliance risks during audits, through missing documentation and incorrect information. These insights reinforce the need for a well-supported transition from manual to electronic systems to ensure operational efficiency, regulatory compliance, and competitiveness within the market.

Question 13 - Have you transitioned from paper-based to electronic-based equipment qualification methods during your career?

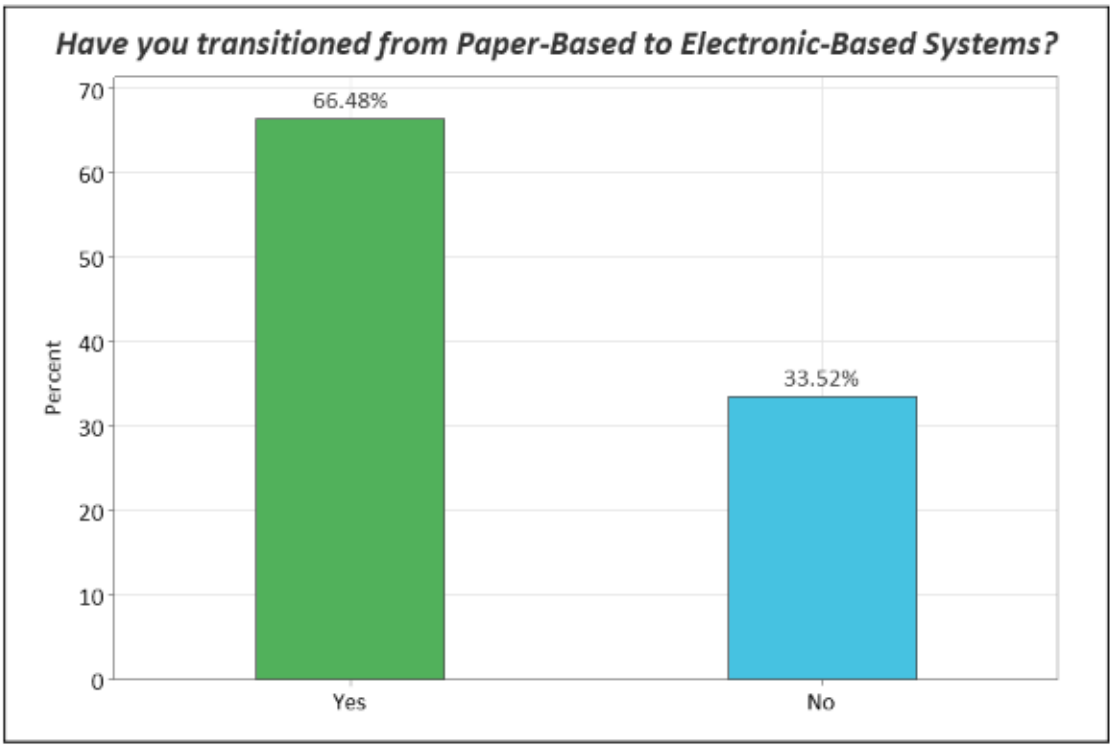

Figure 23 - Survey Question 13 Response - (Minitab)

Analysis:

Participants progressing from Question 12 to Question 13: 176 participants

Question 13: *'Have you transitioned from paper-based to electronic-based equipment qualification methods during your career?'*

- **Positive responses (Yes):** 117 participants (66.48%)
- **Negative responses (No):** 59 participants (33.52%)

Outcome:

- **Positive responses (117 participants):** Progressed to Question 14.
- **Negative responses (59 participants):** Skipped Question 14, 15, 16, 17, 18 and automatically directed the participants to Section 5 - Technological Influences – Question 19.

Discussion:

A total of 117 participants remained eligible to proceed to Question 14, offering a deeper insight into how the transition to electronic-based systems has impacted specific aspects of the equipment qualification process. In contrast, 59 participants had not transitioned to electronic systems during their career and therefore skipped ahead to Question 19.

Question 14 - How has the transition affected data integrity?

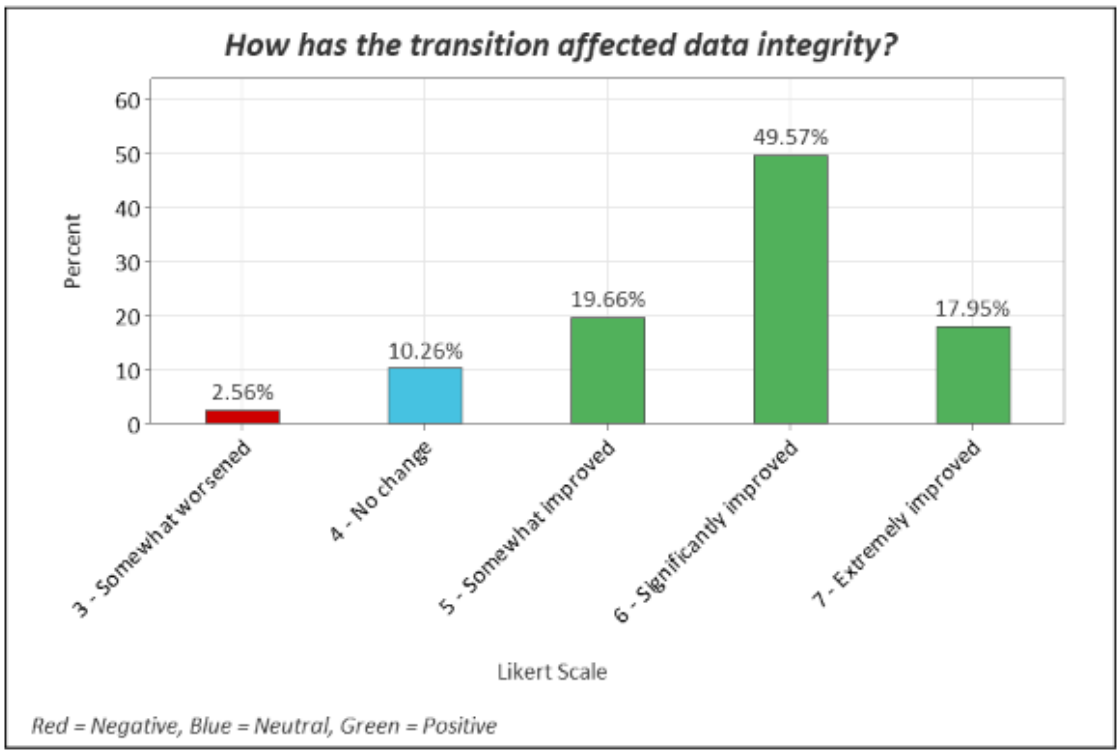

Figure 24 - Survey Question 14 Response - (Minitab)

Analysis:

Participants progressing from Question 13 to Question 14: 117 participants

Question 14: '*How has the transition affected data integrity?'*

- **87.20%** of the respondents felt data integrity had improved to some degree with the transition from paper-based to electronic-based equipment qualification systems:
    - Extremely improved, significantly improved, or somewhat improved
- **10.26%** felt data integrity had not been impacted.
- **2.56%** felt data integrity had somewhat worsened.

Irrespective of the response to Question 14, all respondents from Question 14 progressed to Question 15.

Discussion:

Regardless of the system in use, "Data Integrity" remains a significant concern across the medical device industry. It is a fundamental aspect of Good Documentation Practices (GDP), an essential element of Quality Management Systems (QMS) and a critical requirement for regulatory compliance.

According to Rodriguez-Perez (2019) in the secondary research, as new technologies have emerged and the volume of generated data has grown, many organisations found

themselves unprepared to manage and store such large quantities of data. This gap led to an increase in regulatory observations during inspections of manufacturing facilities, as organisations had failed to implement robust systems to minimise data risks.

The survey results indicated improved data integrity among respondents who had transitioned from paper-based to electronic-based equipment qualification methods over the course of their career. While electronic systems do not entirely eradicate all data integrity concerns, the secondary research supports the view that they help mitigate these risks, especially if the ALCOA++ principles are also adopted (Gleckler, 2023).

Question 15 - How has the transition affected audit readiness?

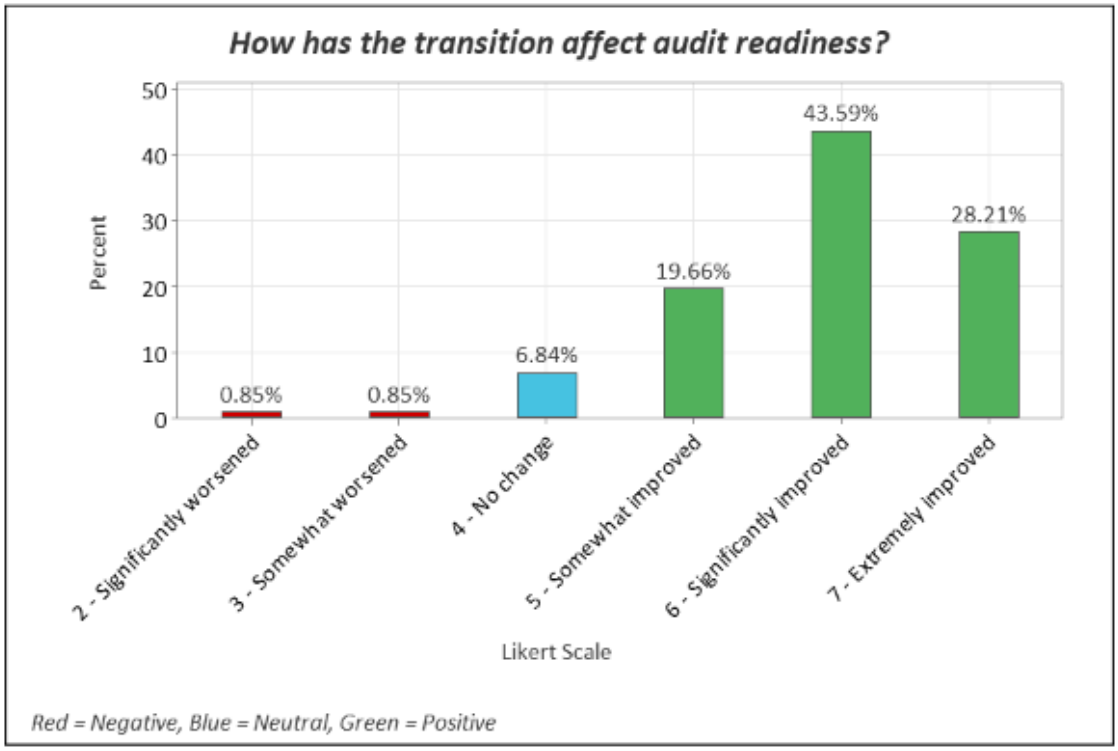

Figure 25 - Survey Question 15 Response - (Minitab)

Analysis:

Participants progressing from Question 14 to Question 15: 117 participants

Question 15: '*How has the transition affected audit readiness?'*

- **91.46%** of the respondents felt audit readiness had improved to some degree with the transition from paper-based to electronic-based equipment qualification systems:
    - Extremely improved, significantly improved, or somewhat improved
- **6.84%** felt audit readiness had not been impacted.
- **1.70%** felt audit readiness had worsened to some degree:
    - Significantly worsened, or somewhat worsened

Irrespective of the response to Question 15, all respondents from Question 15 progressed to Question 16.

Discussion:

As highlighted in the secondary research findings, continuous audit readiness has emerged as one of the top three challenges facing the medical device manufacturing industry. Accelerated by the COVID-19 pandemic, the landscape of auditing practices has been transformed. In both the US and EU, remote and hybrid audits are becoming increasingly

prevalent, prompting organisations to adopt strategies that support continuous audit readiness (Kay, 2024).

These new trend audits rely heavily on digital technologies to ensure a seamless process. Electronic-based systems offer a reliable, efficient, and easily accessible platform that enables organisations to meet the demands of continuous audit readiness.

The primary research data reinforces these findings, with over 90% of respondents reporting that the transition from paper-based to electronic-based systems has led to improved audit readiness.

Question 16 - How has the transition affected cost effectiveness (Effort/Benefit)?

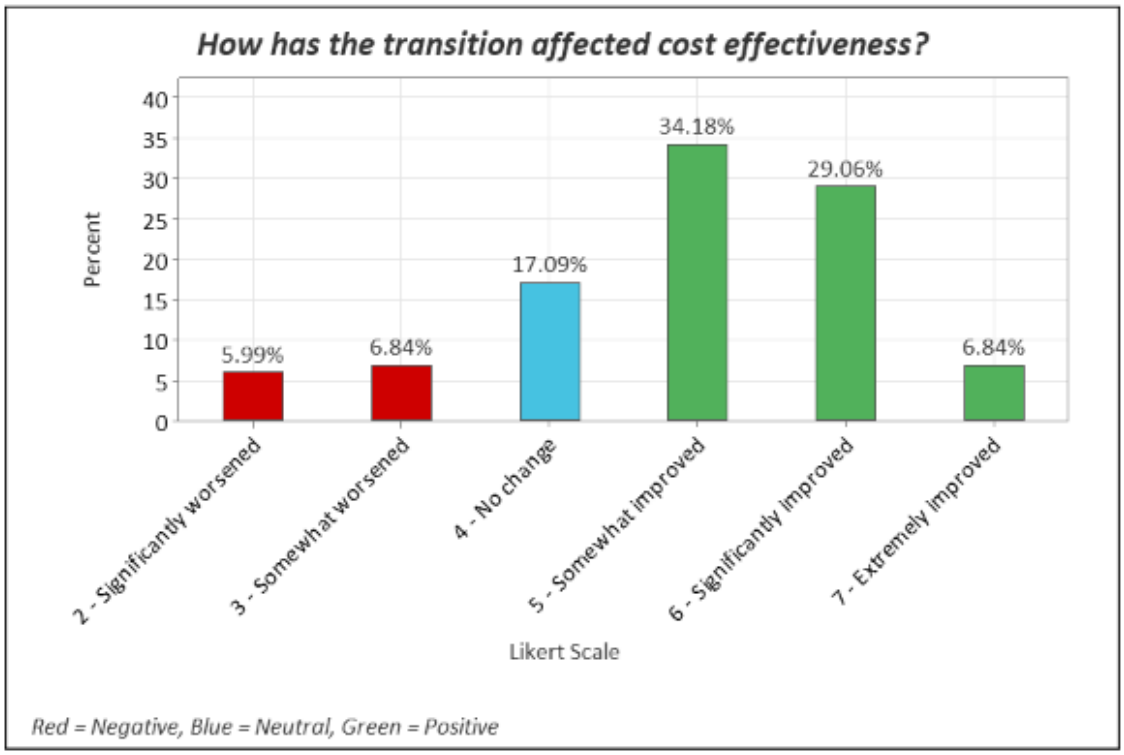

Figure 26 - Survey Question 16 Response - (Minitab)

Analysis:

Participants progressing from Question 15 to Question 16: 117 participants

Question 16: '*How has the transition affected cost effectiveness (Effort/Benefit)?'*

- **70.08%** of the respondents felt cost effectiveness had improved to some degree with the transition from paper-based to electronic-based equipment qualification systems:
    - Extremely improved, significantly improved, or somewhat improved
- **17.09%** felt cost effectiveness had not been impacted.
- **12.83%** felt cost effectiveness had worsened to some degree:
    - Significantly worsened, or somewhat worsened

Irrespective of the response to Question 16, all respondents from Question 16 progressed to Question 17.

Discussion:

The implementation and training costs associated with an electronic system is an on-going industry debate. The initial effort and set-up costs of such systems is significant, particularly for Small to Medium Sized Enterprises (SMEs), these costs must be carefully

balanced against the potential cost of an audit finding. As highlighted by Leong (2023) in the secondary research findings, the risks and consequences of a non-compliance can outweigh the upfront cost of an electronic-based system.

Furthermore, the primary research data indicates that 70% of the respondents recognised cost-related benefits when implementing electronic-based system.

Question 17 - How has the transition affected time efficiency?

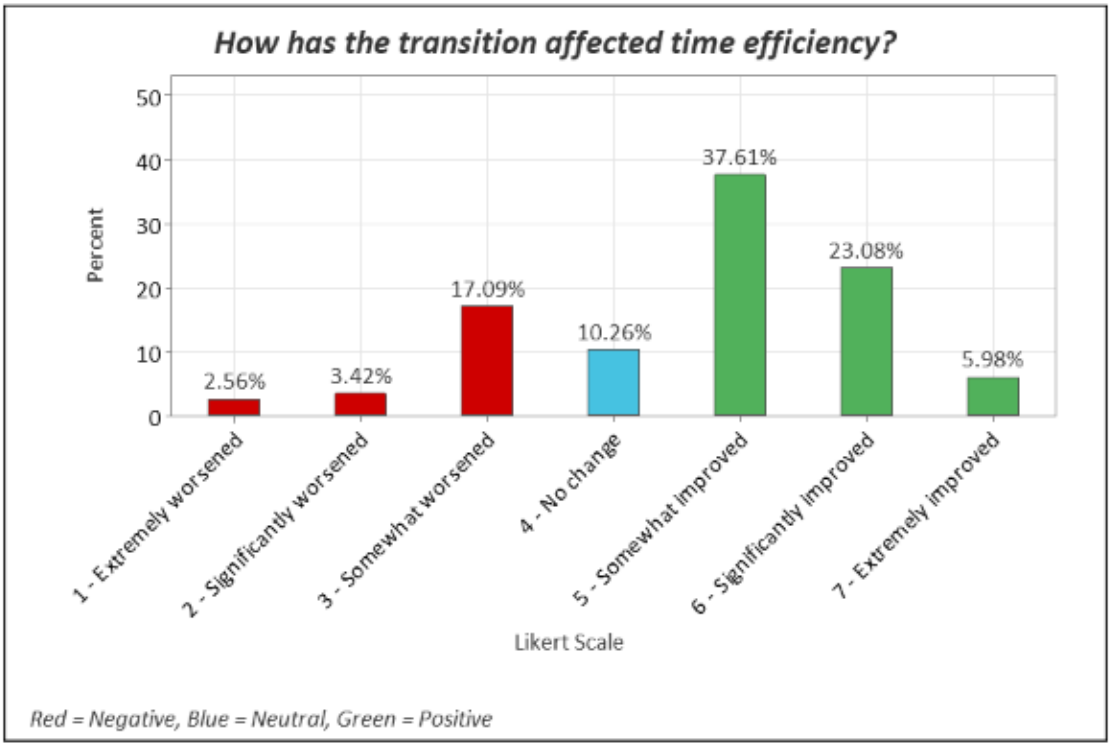

Figure 27 - Survey Question 17 Response - (Minitab)

Analysis:

Participants progressing from Question 16 to Question 17: 117 participants

Question 17: '*How has the transition affected time efficiency?'*

- **66.67%** of the respondents felt time efficiency had improved to some degree with the transition from paper-based to electronic-based equipment qualification systems:
    - Extremely improved, significantly improved, or somewhat improved
- **23.07%** felt time efficiency had worsened to some degree:
    - Extremely worsened, significantly worsened, or somewhat worsened
- **10.26%** felt time efficiency had not been impacted.

Irrespective of the response to Question 17, all respondents from Question 17 progressed to Question 18.

Discussion:

One of the key advantages of transitioning from paper-based to electronic-based systems is the significant increase in efficiency. As discussed in Section 2.3.2. Paper-Based versus Electronic-Based Equipment Qualification Systems, while paper-based systems are still

widely used and accepted, they are becoming increasingly difficult to maintain, especially in light of the growing documentation demands imposed by the MDR.

Electronic-based systems offer enhanced efficiency through standardisation, digital approvals, automated workflows, real-time visibility, and ease of documentation retrieval. Tasks that consumed considerable time, such as:

- Generating protocols
- Collecting wet signatures
- Scanning and filing qualification documentation
- Retrieving archived records

have been streamlined or entirely eliminated with the use of electronic-based systems. Furthermore, regulatory submissions are now more efficient, given that all the necessary equipment qualification documentation is readily available in digital format.

Notably, over two-thirds of respondents reported a measurable increase in efficiency following the adoption of electronic-based systems.

Question 18 - How has the transition affected collaboration?

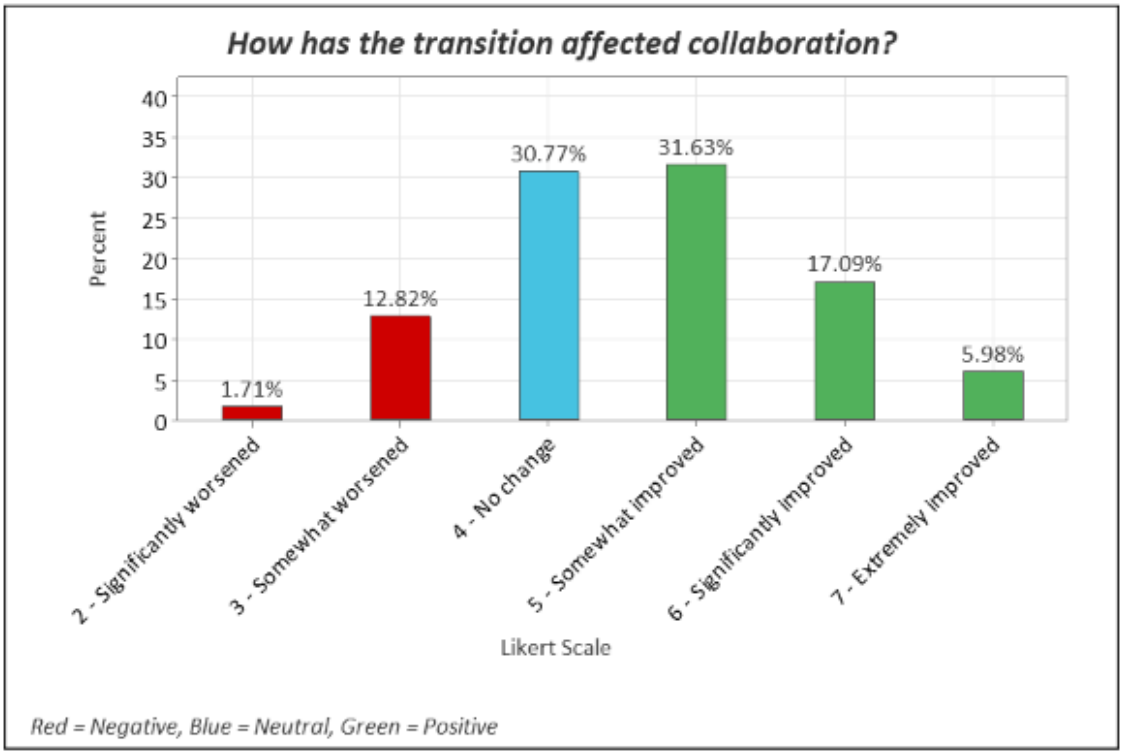

Figure 28 - Survey Question 18 Response - (Minitab)

Analysis:

Participants progressing from Question 17 to Question 18: 117 participants

Question 18: '*How has the transition affected collaboration?'*

- **54.70%** of the respondents felt that collaboration had improved to some degree with the transition from paper-based to electronic-based equipment qualification systems:
    - Extremely improved, significantly improved, or somewhat improved.
- **30.77%** felt collaboration had not been impacted.
- **4.53%** felt collaboration had worsened to some degree:
    - Significantly worsened or somewhat worsened

Irrespective of the response to Question 18, all respondents from Question 18 progressed to Section 5 – Technological Influences - Question 19.

Discussion:

Another of the key advantages of transitioning from paper-based to electronic-based equipment qualifications is accessibility, highlighted in *Table 1 – Paper-based vs. Electronic-based Equipment Qualification Systems*. Electronic systems have broken down silos between departments. Accessibility to information through centralised platforms has

enhanced collaboration. Departments can access and perform work on equipment qualifications in parallel and regardless of location.

In addition, cloud-based platforms further facilitate real-time collaboration, support remote work, eliminate inefficiencies and delays associated with managing physical documentation in a paper-based environment, especially across global functional teams.

Supporting this transformation, the primary research data indicates 54.70% of respondents observed an improvement in collaboration following a transition to electronic systems, underscoring the positive impact on operational efficiency.

4.2.5 Section 5 - Technological Influences

Section 5 of the survey contained three questions focused on understanding the role of technology in equipment qualification, specifically examining the adoption of the electronic systems and the challenges associated with their implementation and maintenance.

Survey Design:

- **Questions 19 - 21:** The questions contained within Section 5 were a combination of single choice, multiple-choice, Likert scale formats.
- Participants were able to proceed to Section 6 – Medical Device Regulation – EU MDR 2017/745 regardless of their responses in Section 5.

Question 19 - How has technology influenced your equipment qualification process over the past number of years?

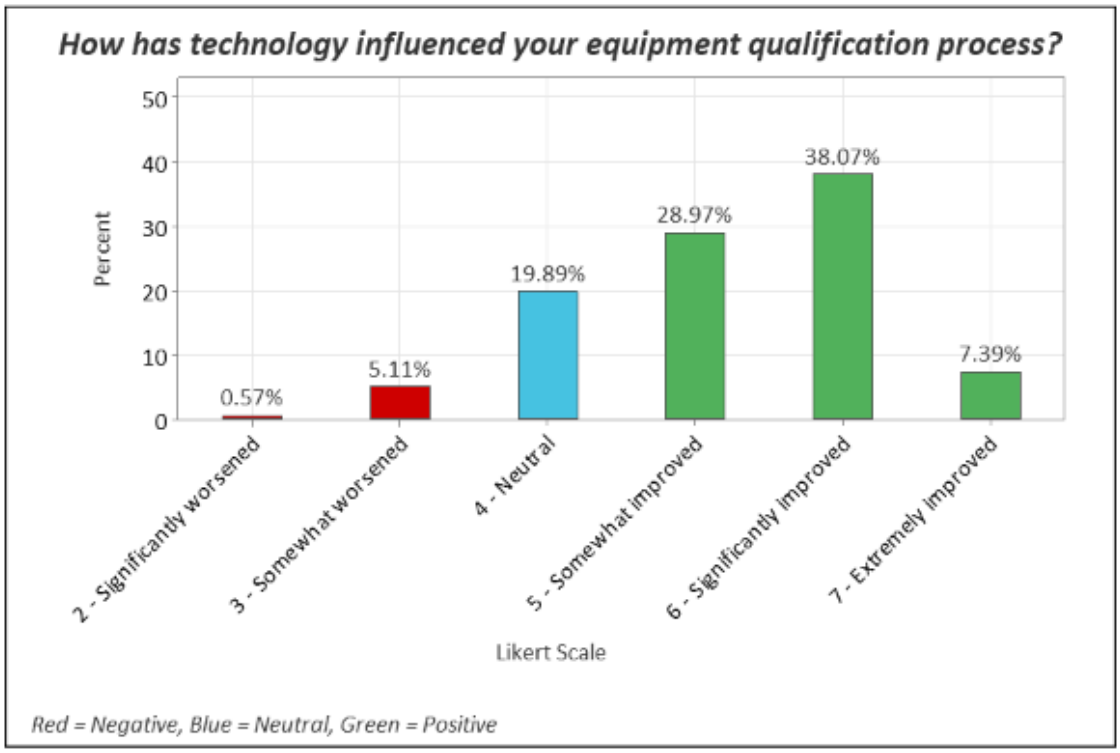

Figure 29 - Survey Question 19 Response - (Minitab)

Analysis:

Participants progressing from Question 13 (59) & Question 18 (117) to Question 19: 176 participants

Question 19: '*How has technology influenced your equipment qualification process over the past number of years?'*

- **74.43%** of the respondents felt technology had improved the equipment qualification process to some degree:
    - Extremely improved, significantly improved, or somewhat improved
- **19.89%** felt technology had no influence on the process.
- **5.68%** felt technology had adversely impacted the process to some degree:
    - Significantly worsened or somewhat worsened

Irrespective of the response to Question 18, all respondents from Question 18 progressed to Section 5 – Technological Influences - Question 19.

Discussion:

In 2017, the core regulatory framework for medical device production and distribution underwent a significant transformation with the introduction of the MDR. This regulation

replaces the previous MDD and aims to strengthen safety, performance, and post-market surveillance requirements across the European Union while aligning with advancements in technology.

As highlighted by Kanumilli *et al.* (2024) in the secondary research, even though technology has its challenges in terms of accessibility, affordability and sometimes complexity, it has positively transformed equipment qualifications in recent years.

Digital transformation (automation, machine learning, artificial intelligence, real-time monitoring, digital signatures, electronic systems) have increased efficiencies, improved accuracy, enhanced compliance, all resulting in better product quality. These findings are supported by the primary research data, where 74.43% of respondents felt that technology has positively influenced the equipment qualification process over the past number of years.

Question 20 - Which of the following technologies have you implemented in your equipment qualification process? (Select all that apply)

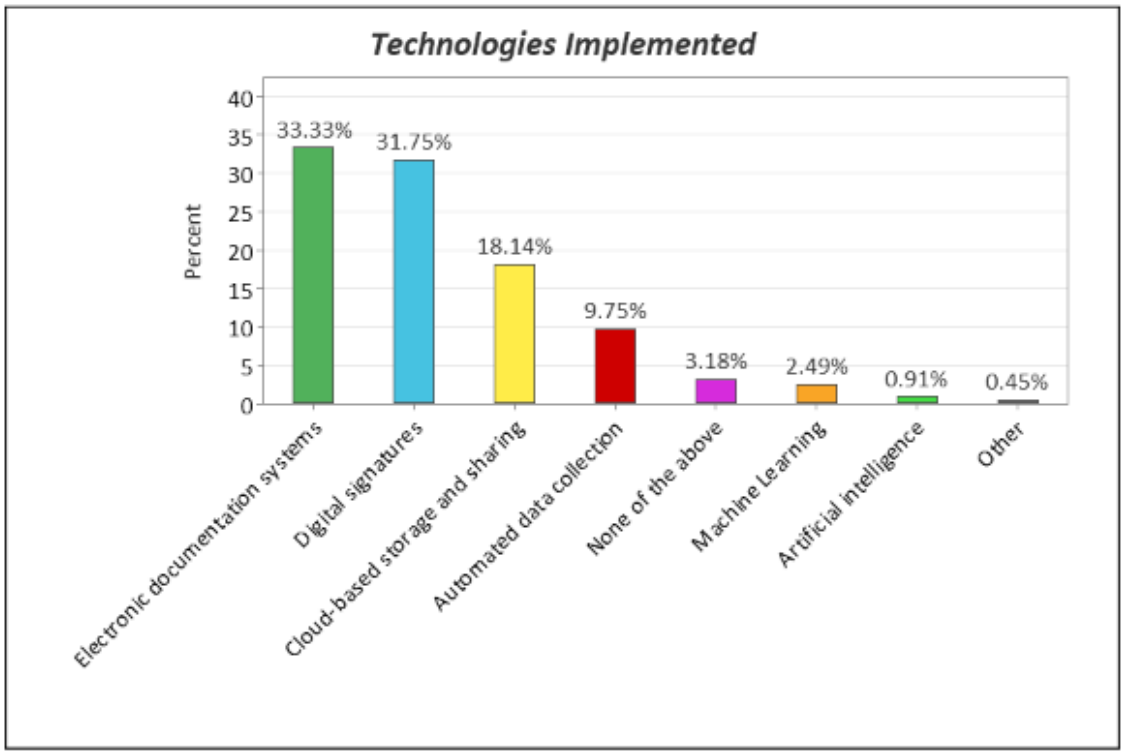

Figure 30 - Survey Question 20 Response - (Minitab)

Analysis:

Participants progressing from Question 19 to Question 20: 176 participants

Question 20: '*Which of the following technologies have you implemented in your equipment qualification process?*'

- **33.33%** of the respondents had implemented *"Electronic Documentation Systems"* into their equipment qualification process.
- Other technologies implemented included:
    - Digital signatures
    - Cloud-based Storage and Sharing
    - Automated Data Collection
    - Machine Learning
    - Artificial Intelligence

Additionally, an "Other" option was available, and chosen by 2 participants, who implemented Minitab (Statistical software package).

"None of the above" 3.18% had not implemented any of the pre-determined technologies.

Irrespective of the response to Question 20, all respondents from Question 20 progressed to Question 21.

Discussion:

Electronic documentation systems and digital signatures are very much intertwined in terms of equipment qualifications as is evident in the primary research data. There is a definitive shift away from manual systems and towards electronic-based systems within the industry as it begins to understand the benefits of having electronic-based systems in place. It is an investment for those that can afford it, in terms of continuous audit readiness, documentation management and regulatory submissions.

As highlighted in the secondary research, technologies like machine learning and artificial intelligence are still evolving. In some cases, widespread implementation is hindered by high costs and security concerns. Despite their complexity and the complexity of today's manufacturing processes, there are significant gains to be achieved in manufacturing and process optimisation by adopting 4.0 technologies.

Question 21 - What do you perceive as the biggest challenge in transitioning to or maintaining an electronic-based equipment qualification system?

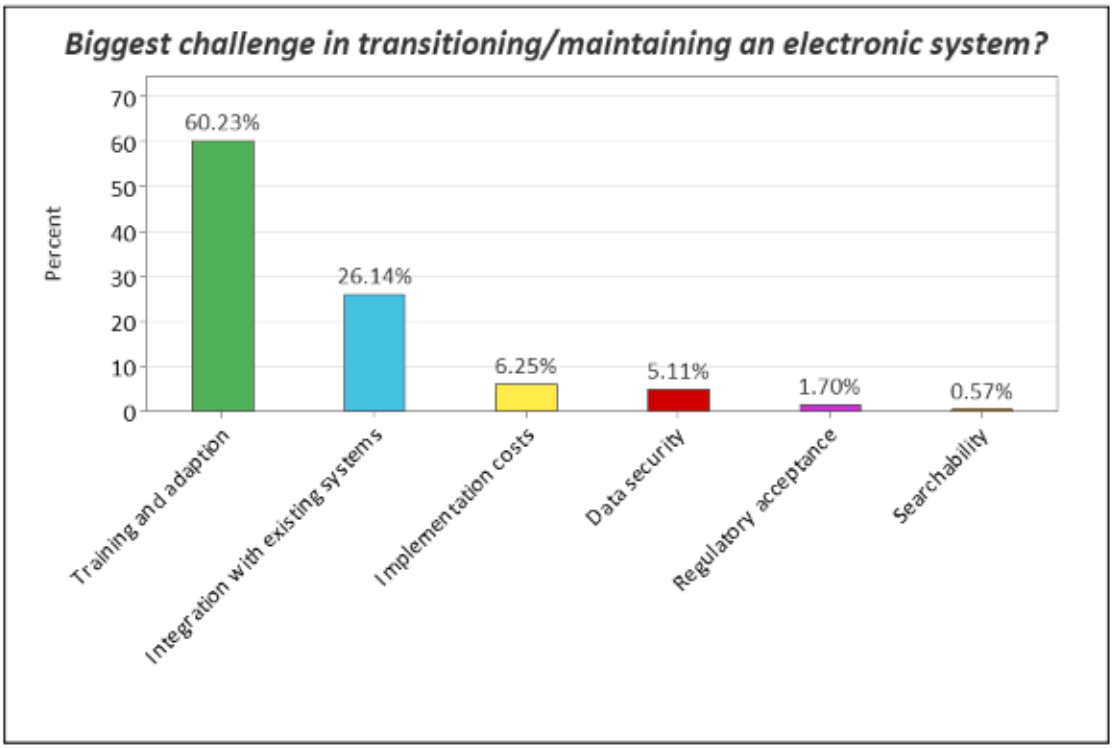

Figure 31 - Survey Question 21 Response - (Minitab)

Analysis:

Participants progressing from Question 20 to Question 21: 176 participants

Question 21: '*What do you perceive as the biggest challenge in transitioning to or maintaining an electronic-based equipment qualification system?'*

- **60.23%** of the respondents identified "Training and adaption" as the most significant challenge in transitioning to or maintaining an electronic-based equipment qualification system.
- Other challenges included:
    - Integration with existing systems
    - Implementation costs
    - Data security
    - Regulatory acceptance
    - Searchability

Additionally, an "Other" option was available, and chosen by 4 participants. However, after data cleansing, all but 1 of these responses "Searchability" were categorised under existing pre-determined options. 1 respondent believed that searchability had worsened with the

transition to electronic-based system, this has been included in the bar chart above for completeness.

Irrespective of the response to Question 21, all respondents from Question 21 progressed to Question 22.

Discussion:

The implementation of electronic-based systems is a real concern for the industry. This is reflected not only in the primary data but also in the secondary research.

The secondary research emphasises the financial implications, particularly the cost associated with training and adaptation. In contrast, the primary data emphasises training and adaptation in terms of user experience, the practical obstacles that must be overcome when adopting an electronic system.

The hand of the industry is being forced down the electronic path to remain competitive and compliant. Transitioning from manual to electronic processes involves a cultural shift.

As technologies rapidly evolve, steep learning curves must be overcome, training becomes a lifelong activity. This path must be carefully navigated to achieve a successful outcome.

It is important to note that implementation costs may be underrepresented in the survey data. The majority of respondents were end-users rather than individuals in managerial or decision-making roles. As a result, their perspectives may focus more on the day-to-day use and benefits.

4.2.6 Section 6 - Medical Device Regulation – EU MDR 2017/745

Section 6 was the final section of the survey and contained two questions, focused on evaluating the impact of the Medical Device Regulation on the equipment qualification process.

Survey Design:

- **Questions 22 - 23:** The questions contained within Section 6 were a combination of multiple-choice and Likert scale formats.
- Participants were requested to submit all survey responses by selecting the "Submit" button and thanked for their time.

Question 22 - How would you rate the impact of the Medical Device Regulation EU MDR 2017/745 on your equipment qualification process?

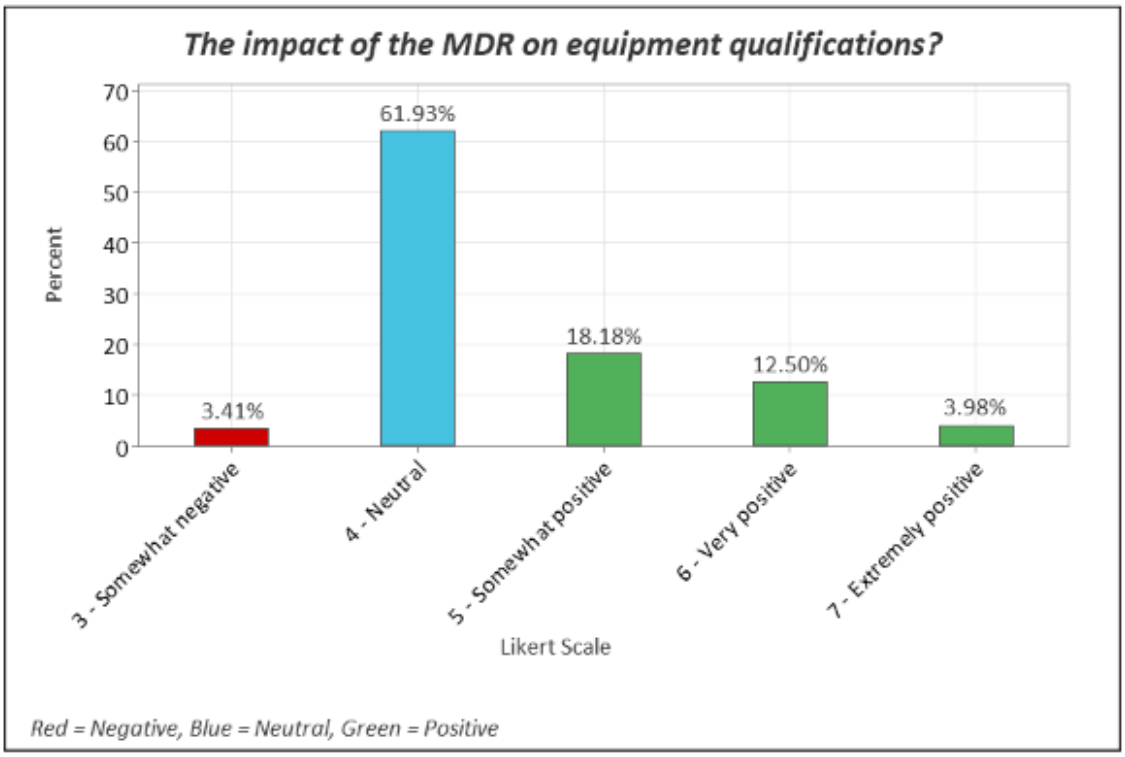

Figure 32 - Survey Question 22 Response - (Minitab)

Analysis:

Participants progressing from Question 21 to Question 22: 176 participants

Question 22: '*How would you rate the impact of the Medical Device Regulation EU MDR 2017/745 on your equipment qualification process?'*

- **61.93%** of the respondents felt the MDR had no impact on the equipment qualification process.
- **34.66%** felt the MDR had to some degree made a positive impact:
    - Extremely positive, very positive, or somewhat positive
- **3.41%** felt the MDR had somewhat negatively impacted the equipment qualification process.

Irrespective of the response to Question 22, all respondents from Question 22 progressed to Question 23.

Discussion:

Three-fifths of the respondents felt that the MDR had no impact on the equipment qualification process. In contrast, the secondary research findings highlighted the broader challenges faced by medical device manufactures since the introduction of the MDR.

With respect to equipment qualification, the most notable impact is related to the technical file requirements. However, the adoption of electronic systems alleviates some of the compliance burden, particularly during the submission process.

The disparity between the primary data and secondary research findings may be attributed to the following:

- The majority of the respondents had already transitioned to electronic-based qualification systems.

According to the secondary research, electronic-based qualification systems are better positioned to support the complexities introduced by the MDR and those of emerging technologies. This may explain why those who have adopted electronic systems to manage equipment qualifications have experienced minimal disruption since the introduction of the MDR.

Question 23 - Which aspects of the MDR significantly challenge your equipment qualification process? (Select all that apply)

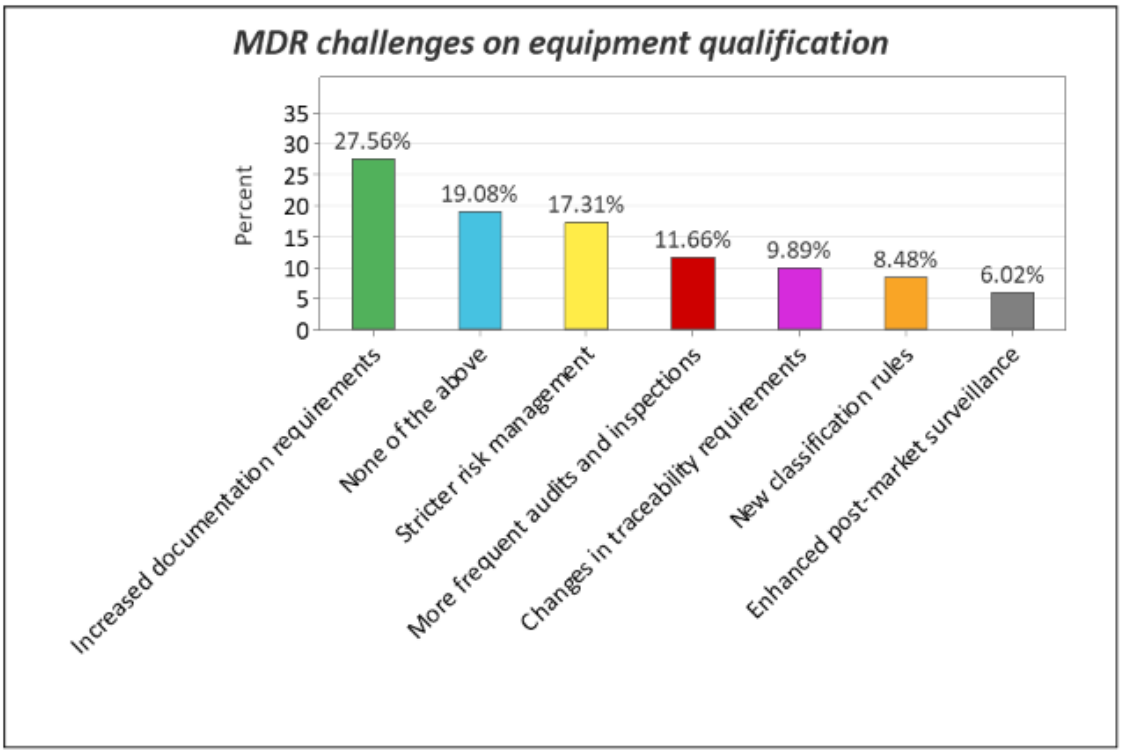

Figure 33 - Survey Question 23 Response - (Minitab)

Analysis:

Participants progressing from Question 22 to Question 23: 176 participants

Question 23: **'***Which aspects of the MDR significantly challenge your equipment qualification process?'*

- **27.56%** of the respondents identified *"Increased documentation requirements"* as the most significant challenge posed by the MDR on the equipment qualification process.
- Other challenges included:
    - Stricter Risk Management
    - More Frequent Audits and Inspections
    - Changes in Traceability Requirements
    - New Classification Rules
    - Enhanced Post-Market Surveillance

Additionally, an "Other" option was available, and chosen by 11 participants. However, after data cleansing, these responses were categorised under existing pre-determined

options. For example: *"I haven't seen any direct changes"* was included within the pre-determined option *"None of the above."*

*"*None of the above*"* 19.08% felt that none of the pre-determined options challenged the equipment qualification process.

Question 23 was the final question in the survey and the participants were then requested to submit their responses by selecting the "Submit" button and thanked for their time.

Discussion:

The MDR has imposed stricter requirements on medical device manufacturers. As highlighted in the secondary research, equipment qualification documentation is a subset of the comprehensive technical file mandated by the MDR. The technical file shall be '*clear, organised, readily searchable and unambiguous'* (European Commission, 2017b). There is an increased burden on manufacturers to ensure that the technical file is thoroughly prepared to avoid rejections and or/and delays when submitting to notified bodies for certification or recertification.

Transitioning from MDD to MDR certification for legacy devices has been particularly onerous for manufacturers as submissions shall include historical changes and supporting data.

Chapter 5: Conclusions & Recommendations

5.1 Summary of Main Findings

This study aimed to test the theory: Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are more efficient and regulatory compliant than Paper-Based Qualification methods.

The key objectives linked to the study were as follows:

1. To compare and contrast paper-based and the electronic-based qualification methods.
2. To assess the regulatory, operational, and quality implications of both systems.
3. To evaluate how technology influences the qualification process.
4. To evaluate challenges to equipment qualifications introduced through the MDR.

Objective 1:

To compare and contrast paper-based and the electronic-based qualification methods.

Table 10 - Objective 1 - Primary Data Conclusions (Author's Own)

Question	Paper-Based	Electronic-Based
Q8 - How would you rate the efficiency of your current equipment qualification system?	Very inefficient to Somewhat inefficient (**Mean Value** = 2.86)	Neutral to Very efficient (**Mean Value** = 4.79)
Q9 - How confident are you in the integrity of data of your current equipment qualification system?	Somewhat confident to Significantly confident (**Mean Value** = 4.86)	Significantly confident to Extremely confident (**Mean Value** = 5.95)
Q11 - How would you rate the ease of maintaining regulatory compliance with your current system?	Somewhat difficult to Somewhat easy (**Mean Value** = 3.71)	Somewhat easy to very easy (**Mean Value** = 5.32)
Q12 - Which of the following challenges do you encounter with your current equipment qualification system?	Human error	Time consuming

Main Finding:

The shift towards electronic-based qualification methods is becoming widely recognised as best practice for organisations to enhance operational efficiency, ensure integrity of data and reduce compliance risks. The industry trend shows a rapid move to electronic methods, much faster than originally anticipated. This is driven by the need for greater compliance under the new MDR regulation and also by the need for greater operational efficiency across organisations.

Paper-based qualification methods are labour intensive, prone to documentation errors and present difficulties in documentation management and traceability. In contrast, electronic-based qualification methods offer substantial benefits in efficiency, data integrity and compliance through real-time visibility, traceability, accuracy, standardisation, and accessibility. While implementing electronic systems requires upfront investment and training, which can be seen as time-consuming, these systems significantly reduce major challenges such as human error.

Objective 2:

To assess the regulatory, operational, and quality implications of both systems.

Table 11 - Objective 2 - Primary Data Conclusions (Author's Own)

Question	Overall Conclusion
Q13 - Have you transitioned from paper-based to electronic-based equipment qualification methods during your career?	**Yes** = 66.48%
Q14 - How has the transition affected data integrity?	**Improved** = 87.20%
Q15 - How has the transition affected audit readiness?	**Improved** = 91.46%
Q16 - How has the transition affected cost effectiveness (Effort/Benefit)?	**Improved** = 70.08%
Q17 - How has the transition affected time efficiency?	**Improved** = 66.67%
Q18 - How has the transition affected collaboration?	**Improved** = 54.70%

Main Finding:

The transition from paper-based to electronic-based qualification systems delivers substantial benefits across regulatory, operational, and quality arenas. The impact from the transition has been overwhelmingly positive.

Regulatory

Maintaining MDR compliance is more challenging with paper-based systems. Manual processes are labour intensive, increase the risk of documentation errors, data loss and difficulties in ensuring traceability for audit readiness. Audits on paper-based systems are more timing consuming, not only for the organisation but also for the auditors. Electronic-based systems facilitate compliance, designed to be in a state of audit readiness at all times, through standardisation of documentation, automated workflows, and audit trails.

Operational

Operations relying on a paper-based system are slower, less efficient, time-consuming, resource intensive and hinder collaboration, especially across global teams, which can often hamper decision making. Physical documentation requires significant storage space, complicates documentation retrieval, causing delays and increasing operational costs. Electronic-based systems improve operational efficiency by streamlining collaboration, reducing administration and physical storage costs, and automating workflows and approvals.

Quality

Quality management is vulnerable when using paper-based systems. Errors, inconsistent documentation, data loss, traceability, efficiency, documentation retrieval and cost, make it difficult to ensure consistent quality outcomes. Electronic-based systems support higher quality standards with more robust data management practices and standardised processes. Improved traceability helps to identify issues as they arise so they can be addressed without delay.

Electronic-based systems enhance data integrity, audit readiness, efficiency, and collaboration, while reducing operational costs.

Objective 3:

To evaluate how technology influences the qualification process.

Table 12 - Objective 3 - Primary Data Conclusions (Author's Own)

Question	Overall Conclusion
Q19 - How has technology influenced your equipment qualification process over the past number of years?	**Improved** = 74.43%
Q20 - Which of the following technologies have you implemented in your equipment qualification process?	**Most common:** Electronic Documentation Systems & Digital signatures
Q21 - What do you perceive as the biggest challenge in transitioning to or maintaining an electronic-based equipment qualification system?	Training and adaption

Main Finding:

Technology, particularly electronic documentation systems and digital signatures, have significantly improved equipment qualification processes within the medical device industry by boosting efficiency, accuracy, and regulatory compliance.

However, it must be noted that the integration of electronic qualification systems into the quality management framework introduces its own set of compliance, data integrity, information security/cybersecurity risks. Therefore, it is imperative that the implementation is managed effectively to mitigate these risks and maintain regulatory compliance.

Despite the clear advantages, the transition to or maintaining of electronic-based equipment qualification systems is not without its challenges. The most significant challenge is ensuring that end-users are adequately trained. Organisations must invest in robust on-going training that supports every stage of the transition and continued use, in order to realise the full benefits that electronic systems have to offer.

Objective 4:

To evaluate challenges to equipment qualifications introduced through the MDR.

Table 13 - Objective 4 - Primary Data Conclusions (Author's Own)

Question	Overall Conclusion
Q22 - How would you rate the impact of the Medical Device Regulation EU MDR 2017/745 on your equipment qualification process?	**No impact** = 61.93% **Positive Impact** = 34.66%
Q23 - Which aspects of the MDR significantly challenge your equipment qualification process?	Increased documentation requirements

Main Finding:

The introduction of the MDR in 2017 marked a significant overhaul of the regulatory landscape for medical device manufacturers within the European Union. The MDR introduction has faced significant challenges:

- Resource constraints: Reduction in designated notified bodies
- Infrastructure issues: EUDAMED partially operational
- Regulatory support: Lack of clear guidance
- Manufacturer readiness: Increased responsibilities

The amendment to the MDR in 2023, extending the transitional period for certain medical devices, further underscores that both the industry and regulatory infrastructures were not fully prepared for the scale of the change required by the MDR. The impact has been felt to varying degrees across manufacturing facilities. In the context of the equipment qualification process, the MDR did not alter the traditional equipment qualification framework. Approximately 96% of the respondents reported no impact/positive impact since the introduction of the MDR. The impact has been uneven across functions, with the greatest burdens falling on the introduction of UDI, labelling, registration to EUDAMED, clinical evidence, post market surveillance and reclassification of devices, while equipment qualification processes have largely remained stable. The MDR increased responsibilities for manufacturers. One of these responsibilities is comprehensive technical documentation. This has increased the burden on manufacturers to ensure that the technical file is thoroughly prepared, 'right first time' to avoid delays at regulatory submission. In terms of legacy device recertification, compiling and submitting supporting documentation has been particularly cumbersome for manufacturers. The adoption of electronic equipment qualifications systems is helping to alleviate some of the documentation burden, as electronic submissions rapidly become the industry norm.

5.2 Summary of Differences

- **Level of integrity of data** - Surprisingly higher than anticipated level of integrity of data experienced by users of paper-based systems.
- **Time-consumption** - Unexpectedly, one of the biggest challenges of electronic-based systems was time-consumption.
- **Impact of MDR** – Interestingly, the introduction of the MDR has had no impact/positive impact on the equipment qualification process.

5.3 Recommendations

5.3.1 Accelerate Adoption of Electronic Qualification Systems

There is an opportunity for organisations to improve audit readiness and reduce documentation errors (approx. 91% reported improved compliance) by implementing electronic qualification systems with automated audit trails and digital signatures. Electronic qualification systems also support standardised MVP, URS, IQ, OQ, PQ, MVR templates, which could potentially help to address some of the training-related challenges seen when adopting electronic qualification systems.

5.3.2 Hybrid Approach for Transition Management

A recommended dual approach during the transition period from a paper-based system to an electronic-based system to help support organisational goals. The hybrid approach does not eliminate paper immediately but takes a phase out/phase in approach with the aim of creating a seamless, efficient, and compliant structure where both systems coexist for a pre-determined period. Organisations should adopt risk-based prioritisation to determine which records transition first.

5.4 Limitations of the Study

As detailed by Ross & Bibler (2019) in their study 'Limited by our limitations', research limitations are inevitable. They are an inherent part of every study. Simply put, a perfect research study does not exist. Furthermore, acknowledging these limitations is not only expected but is crucial for the integrity and credibility of the research findings.

The following limitation has been identified as part of this study:

5.4.1 Sample Size

Due to a lack of specific population data, the population size used in the sample size calculation was assumed. This assumption could have overestimated or underestimated the population size and thus impacted the sample size of the survey.

Based on the assumption, a sample size of 356 was determined for this study. The sample size achieved was 187. A lower-than-expected response rate may be attributed to several factors:

- Survey fatigue - has been commonly reported, especially since the Covid-19 pandemic as outlined by Creedon (2024) in their study '*Comparative Analysis of Global Access to Computed Tomography (CT) Services: Radiographers' Experiences in Ireland and Sub-Saharan Africa'*.
- Voluntary participation - there was no obligation to participate in the survey.
- No incentive - there was no incentive to participate in the survey.
- Survey time - the survey statistics reported the survey took on average 23 minutes to complete, in the demanding work environment of a medical device manufacturing facility, eligible participants may not have been able to fully complete and submit the survey due to time constraints.

As a result, while the study maintained a 95% confidence level, the reduced sample size increased the margin of error of the study from the intended 5% to approximately 7%.

The combination of assumed population size, lower than expected sample size achieved and increased margin of error suggests that some caution must be applied when generalising the findings to the broader population.

5.5 Future Research Opportunities

The study presents several opportunities for future research:

- **IMDRF (International Medical Device Regulators Forum) Electronic Submission Systems** - There is significant scope to investigate the impact on electronic submissions to regulatory authorities, when an electronic-based qualification system is used in conjunction with the IMDRF's Non-In Vitro Diagnostic (nIVD) Table of Contents (ToC) framework. Future studies could assess how this integration influences the efficiency, consistency, and acceptance of electronic regulatory submissions.
- **EUDAMED (European Database on Medical Devices) Centralised Platform** - Once all EUDAMED modules are fully operational, there is potential for a future

study to explore the efficiencies (faster registration), transparency (public access to device data), traceability (product lifecycle monitoring) and coordination amongst stakeholders (manufacturers, notified bodies and regulators) of the centralised platform.

- **Remote/Hybrid Auditing** - Additional research could examine the effectiveness of remote or hybrid auditing models compared to traditional in-person audits, evaluating audit thoroughness, regulatory compliance, cost-effectiveness, and stakeholder satisfaction.
- **Cybersecurity Implications** - There is an opportunity to further explore cybersecurity challenges associated with electronic validation systems in GxP-regulated environments. In particular, future research could explore the implications of the evolving NIS2 (Network and Information Security) directive in terms of implementation and compliance with these systems.

5.6 Final Conclusion

This research set out to prove or disprove the hypothesis that *'Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are better equipped to meet the stringent regulatory requirements, offer more efficiencies, have improved traceability and documentation capabilities over Paper-Based Equipment Qualification systems.'*

Through a comprehensive analysis of regulatory and qualification frameworks, audit processes, workflow efficiency, data integrity and information/cybersecurity, the findings strongly support the validity of the hypothesis.

Electronic-based systems demonstrate clear advantages in ensuring regulatory compliance with the EU's MDR and ISO 13485 through automated workflows and audit trails, enhanced accuracy and accessibility, simplified integration and traceability, real-time visibility, and standardisation of documentation.

As regulatory frameworks continue to evolve, electronic-based equipment qualification systems are not only justified but increasingly essential for manufacturers of implantable orthopedic devices within the European Union. By enhancing reliability, operational efficiency, and regulatory alignment, these systems are well-positioned to become the industry standard in the medical device sector within the European Union in the near future.

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Appendices

Appendix A - Ethics Application and Declaration Form

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: A Comparative Analysis of Paper-Based vs. Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union: Technological, Regulatory, and Operational Impacts.

RESEARCHER'S NAME: Clodagh Walsh

PROGRAMME OF STUDY: MSc in Medical Device Technology & Business

SUPERVISOR'S NAME: Martin Conneely

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: Clodagh Walsh.
DATE: 24 FEB 2025

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

For Supervisor:
Ethics Committee Approval Required: Yes ☐ No ☒
SUPERVISOR SIGNATURE:
DATE: 24 Feb 2025

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

It is hypothesised that Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are better equipped to meet the stringent regulatory requirements, offer more efficiencies, have improved traceability and documentation capabilities over Paper-Based Equipment Qualification systems.

EU MDR is an unknown entity, with a cutover date from MDD to EU MDR of the 31 December 2027 fast approaching for all class III devices, the industry is still struggling to understand the new requirements of the regulation and all its nuances in terms of equipment qualifications, data integrity and information security/cybersecurity to remain compliant. The lack of specific guidance and regulation on managing and controlling the quantity of data now being generated through emerging technologies is challenging the industry to restructure the equipment qualification approach.

Equipment qualifications are essential for compliance with the EU MDR. The outdated paper-based process is now more than ever impacting the medical device approval process due to the increased complexity of the new regulation. Transitioning to more streamlined electronic documentation systems could enhance the overall efficiency in securing approvals.

This study aims to test the theory: Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are more efficient and regulatory compliant than Paper-Based Qualification methods.

The objectives of this study are as follows:

1. To compare and contrast the paper-based and the electronic-based qualification methods.
2. To assess the regulatory, operational, and quality implications of both systems.
3. To evaluate how technology influences the qualification process.
4. To evaluate challenges to equipment qualifications introduced through EU MDR 2017/745.

1.2 Research methodology:

The philosophical approach for the proposed primary research is based on **positivist** philosophy with a **deductive** approach to test the theory 'Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are more efficient and regulatory compliant than Paper-Based Qualifications'.

The research choices/methods will be a single method of data collection i.e. **Mono-Method**. The primary research strategy will be **quantitative** in nature, in the form of a **survey** with a **cross-sectional** timeline. Data will be collected by means of a survey, using a questionnaire developed with the help of a survey generation tool, Microsoft Forms. The survey questionnaire will consist of a mix of close ended multiple choice and Likert scale type questions. For the purpose of this research study, a 7-point Likert scale will be used where deemed necessary, offering the participants seven response options to each survey question, an extreme option at either end of the scale, four intermediate options and a neutral option. The 7-point scale will offer participants more choice and provides the researcher more in-depth feedback.

Refer to Section 10, Appendix A for survey questionnaire.

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 2. 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 target audience for the survey/questionnaire will be eligible participants working within the medical device manufacturing industry. To qualify for the research survey, participants shall have experience either directly or indirectly with paper-based and/or electronic-based equipment qualification systems. Participants will be asked a qualifying question confirming their eligibility to participate in the research study.

4.2 How do you plan to gain access to/contact/approach your participant(s).

Data will be collected by means of a survey, using a questionnaire developed with the help of a survey generation tool Microsoft Forms. A link to the online survey will be issued via email and distributed via LinkedIn to industry experts.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants – N/A**

[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 No
Details of what participation will involve	Yes No
Rights to anonymity	Yes No
Confidentiality	Yes No
Rights to withdraw from the research	Yes No
The contact details of the researcher and supervisor (if necessary)	Yes No

5.2 **Informed Consent Form (ICF) for participants – N/A**

[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:

No: my research study involves an online survey only and/or does not require signed consent.

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

*The student is responsible for storage of data, and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Research data collected will be stored on a password-protected laptop, accessible only to the researcher. Throughout the research, the data will be shared with the appointed research supervisor for feedback purposes only. The raw data will be retained for two years on the secure Griffith College electronic research platform after qualification.

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	**N/A**
9.2 Informed Consent Form (ICF) for participant	**N/A**
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: Rodayl Wahl
DATE: 24 Feb 2025

Appendix B - Survey Questionnaire

Section 1

Survey Information and Participant Consent

The survey will take approximately **5 minutes** to complete. This survey forms part of my dissertation for a Master of Science in Medical Device Technology & Business. It is hypothesised that Electronic-Based Equipment Qualifications in Medical Device Manufacturing of Implantable Orthopedic Devices within the European Union are better equipped to meet the stringent regulatory requirements, offer more efficiencies, have improved traceability and documentation capabilities over Paper-Based Equipment Qualification systems. The purpose of this survey is to test the theory by collecting your feedback/experience of Paper-Based and/or Electronic-Based equipment qualification systems within the medical device industry. Your information is highly confidential and is for research purposes only. Any identifiable information will be removed from the data collected to ensure anonymity.

1. Do you understand the purpose of the research? *

- ◯ Yes
- ◯ No

2. Do you agree to participate in this survey? *

- ◯ Yes
- ◯ No

Section 2 ...

Participant Information

3. Are you proficient in the English language? *

- ◯ Yes
- ◯ No

4. Have you experience either directly or indirectly with Paper-Based and/or Electronic-Based equipment qualification systems within the medical device industry? *

- ◯ Yes
- ◯ No

Section 3 ...

Introductory Questions

5. Which category best describes your job role? *

- ◯ Engineering
- ◯ Quality
- ◯ Regulatory Affairs (RA)
- ◯ Research & Development (R&D)
- ◯ Biological Sciences/Sterility
- ◯ Operations
- ◯ Documentation Control
- ◯ Technical Services
- ◯ Management
- ◯ Other

6. Is your company classed as a small to medium-sized enterprise (SME) i.e. 250 employees or less? *

- ◯ Yes
- ◯ No
- ◯ I don't know

7. Which equipment qualification system does your company primarily use? *

- ◯ Paper-based
- ◯ Electronic-based
- ◯ Hybrid (combination of paper and electronic)

Section 4 ...

Regulatory, Operational & Quality

8. How would you rate the **efficiency** of your current equipment qualification system? *

- ◯ 1 - Extremely inefficient
- ◯ 2 - Very inefficient
- ◯ 3 - Somewhat inefficient
- ◯ 4 - Neutral
- ◯ 5 - Somewhat efficient
- ◯ 6- Very efficient
- ◯ 7 - Extremely efficient

9. How confident are you in the **integrity of data** of your current equipment qualification system? *

- ◯ 1 - Extremely not confident
- ◯ 2 - Significantly not confident
- ◯ 3 - Somewhat not confident
- ◯ 4 - Neutral
- ◯ 5 - Somewhat confident
- ◯ 6 - Significantly confident
- ◯ 7 - Extremely confident

10. What do you perceive as the **biggest advantage** of electronic-based equipment qualification systems? *

- ◯ Improved traceability
- ◯ Enhanced collaboration
- ◯ Faster completion times
- ◯ Reduction in human error
- ◯ Better regulatory compliance
- ◯ Real-time visibility
- ◯ Standardisation
- ◯ Other

11. How would you rate the ease of maintaining **regulatory compliance** with your current system? *

- ◯ 1 - Extremely difficult
- ◯ 2 - Very difficult
- ◯ 3 - Somewhat difficult
- ◯ 4 - Neutral
- ◯ 5 - Somewhat easy
- ◯ 6 - Very easy
- ◯ 7 - Extremely easy

12. Which of the following **challenges** do you encounter with your current equipment qualification system? (Select all that apply) *

- [ ] Time-consuming
- [ ] Human error
- [ ] Tracking changes
- [ ] Limited collaboration
- [ ] Storage and retrieval
- [ ] Compliance concerns
- [ ] None of the above
- [ ] Other

13. Have you transitioned from paper-based to electronic-based equipment qualification methods during your career? *

- ◯ No
- ◯ Yes

14. How has the transition affected **data integrity**? *

- ◯ 1 - Extremely worsened
- ◯ 2 - Significantly worsened
- ◯ 3 - Somewhat worsened
- ◯ 4 - No change
- ◯ 5 - Somewhat improved
- ◯ 6 - Significantly improved
- ◯ 7 - Extremely improved

15. How has the transition affected **audit readiness**? *

- ◯ 1 - Extremely worsened
- ◯ 2 - Significantly worsened
- ◯ 3 - Somewhat worsened
- ◯ 4 - No change
- ◯ 5 - Somewhat improved
- ◯ 6 - Significantly improved
- ◯ 7 - Extremely improved

16. How has the transition affected **cost effectiveness (Effort/Benefit)**? *

- ◯ 1 - Extremely worsened
- ◯ 2 - Significantly worsened
- ◯ 3 - Somewhat worsened
- ◯ 4 - No change
- ◯ 5 - Somewhat improved
- ◯ 6 - Significantly improved
- ◯ 7 - Extremely improved

17. How has the transition affected **time efficiency**? *

- ◯ 1 - Extremely worsened
- ◯ 2 - Significantly worsened
- ◯ 3 - Somewhat worsened
- ◯ 4 - No change
- ◯ 5 - Somewhat improved
- ◯ 6 - Significantly improved
- ◯ 7 - Extremely improved

18. How has the transition affected **collaboration**? *

- ◯ 1 - Extremely worsened
- ◯ 2 - Significantly worsened
- ◯ 3 - Somewhat worsened
- ◯ 4 - No change
- ◯ 5 - Somewhat improved
- ◯ 6 - Significantly improved
- ◯ 7 - Extremely improved

Section 5 ...

Technological Influences

19. How has technology **influenced** your equipment qualification process over the past number of years? *

- ◯ 1 - Extremely worsened
- ◯ 2 - Significantly worsened
- ◯ 3 - Somewhat worsened
- ◯ 4 - Neutral
- ◯ 5 - Somewhat improved
- ◯ 6 - Significantly improved
- ◯ 7 - Extremely improved

20. Which of the following technologies have you **implemented** in your equipment qualification process? (Select all that apply) *

- ☐ Electronic documentation systems
- ☐ Automated data collection
- ☐ Cloud-based storage and sharing
- ☐ Digital signatures
- ☐ Artificial intelligence
- ☐ Machine learning
- ☐ None of the above
- ☐ Other

21. What do you perceive as the biggest challenge in **transitioning to or maintaining** an electronic-based equipment qualification system? *

- ◯ Implementation costs
- ◯ Training and adaption
- ◯ Integration with existing systems
- ◯ Data security
- ◯ Regulatory acceptance
- ◯ Other

Section 6 ...

Medical Device Regulation - EU MDR 2017/745

22. How would you rate the **impact** of the Medical Device Regulation EU MDR 2017/745 on your equipment qualification process? *

- ◯ 1 - Extremely negative
- ◯ 2 - Very negative
- ◯ 3 - Somewhat negative
- ◯ 4 - Neutral
- ◯ 5 - Somewhat positive
- ◯ 6 - Very positive
- ◯ 7 - Extremely positive

23. Which aspects of the MDR **significantly challenge** your equipment qualification process? (Select all that apply) *

- ☐ Increased documentation requirements
- ☐ Stricter risk management
- ☐ Enhanced post-market surveillance
- ☐ New classification rules
- ☐ More frequent audits and inspections
- ☐ Changes in traceability requirements
- ☐ None of the above
- ☐ Other

Appendix C - Statistical Analysis - Minitab

Question 8 - How would you rate the efficiency of your current equipment qualification system?

Q8 - SYSTEM VS. EFFICIENCY

Chi-Square Test for Association: Qualification System, Efficiency

Rows: Qualification System Columns: Efficiency

	Efficient	Inefficient	Neutral	All
Electronic	97	29	6	132
	95.250	30.000	6.750	
	0.0322	0.0333	0.0833	
Hybrid	30	5	2	37
	26.699	8.409	1.892	
	0.4082	1.3821	0.0062	
Paper	0	6	1	7
	5.051	1.591	0.358	
	5.0511	12.2195	1.1516	
All	127	40	9	176

Cell Contents
Count
Expected count
Contribution to Chi-square

Chi-Square Test

	Chi-Square	DF
Pearson	20.367	4
Likelihood Ratio	20.154	4

1 cell(s) with expected counts less than 1.
Chi-Square approximation probably invalid.
3 cell(s) with expected counts less than 5.

Question 9 - How confident are you in the integrity of data of your current equipment qualification system?

Q9 - SYSTEM VS. DATA INTEGRITY

Chi-Square Test for Association: Qualification System, Data Integrity

Rows: Qualification System Columns: Data Integrity

	Confident	Neutral	Not Confident	All
Electronic	121	6	5	132
	120.000	6.750	5.250	
	0.00833	0.08333	0.01190	
Hybrid	33	3	1	37
	33.636	1.892	1.472	
	0.01204	0.64880	0.15113	
Paper	6	0	1	7
	6.364	0.358	0.278	
	0.02078	0.35795	1.87025	
All	160	9	7	176

Cell Contents
Count
Expected count
Contribution to Chi-square

Chi-Square Test

	Chi-Square	DF
Pearson	3.165	4
Likelihood Ratio	2.691	4

2 cell(s) with expected counts less than 1.
Chi-Square approximation probably invalid.
4 cell(s) with expected counts less than 5.

Question 11 - How would you rate the ease of maintaining regulatory compliance with your current system?

Q11 - SYSTEM VS. REGULATORY COMPLIANCE

Chi-Square Test for Association: Qualification System, Regulatory Compliance

Rows: Qualification System Columns: Regulatory Compliance

	Difficult	Easy	Neutral	All
Electronic	8	108	16	132
	14.250	97.500	20.250	
	2.741	1.131	0.892	
Hybrid	8	20	9	37
	3.994	27.330	5.676	
	4.017	1.966	1.946	
Paper	3	2	2	7
	0.756	5.170	1.074	
	6.665	1.944	0.799	
All	19	130	27	176

Cell Contents
Count
Expected count
Contribution to Chi-square

Chi-Square Test

	Chi-Square	DF
Pearson	22.101	4
Likelihood Ratio	19.199	4

1 cell(s) with expected counts less than 1.
Chi-Square approximation probably invalid.
3 cell(s) with expected counts less than 5.