AN INVESTIGATION INTO THE IMPLEMENTATION OF AN ELECTRONIC DOCUMENT MANAGEMENT SYSTEM TO AN ORAL SOLID DOSE MANUFACTURING SITE, AN EVALUATION OF SYSTEM PERFORMANCE INDICATORS AND USER PERSPECTIVES.

A Dissertation submitted in partial fulfilment of the requirements for the MSc. in Pharmaceutical Business and Technology

Innopharma Education and Faculty of Science

GRIFFITH COLLEGE DUBLIN

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SUBMISSION DATE: 19TH MAY 2025

Candidate Declaration

I hereby declare that the dissertation entitled “An Investigation into the Implementation of an Electronic Document Management System to an Oral Solid Dose Manufacturing Site, an Evaluation of System Performance Indicators and User Perspectives” submitted in the partial fulfilment of the MSc. In Pharmaceutical Business and Technology is the result of my own work and due acknowledgement given, where reference is made to others work.

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Acknowledgements

I would like to express my sincere gratitude to everyone who has supported me throughout the course of this research. First and foremost, I am deeply thankful to my supervisor, Rex Coughlan, for the invaluable guidance, continuous encouragement, and insightful feedback. I also extend my appreciation to the academic and administrative staff of Griffith College Dublin for providing the resources necessary for the successful completion of this research.

My heartfelt thanks go to my family and friends for their unwavering patience, understanding and motivation during the challenging moments of this journey. Lastly, I am grateful to all participants and contributors who took part in this study. Your input was essential and greatly appreciated.

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List of Abbreviations

GMP	Good Manufacturing Practice
GDP	Good Documentation Practice
DMS	Document Management System
ManualDMS	Manual Document Management System
EDMS	Electronic Document Management System
FDA	Food and Drug Administration
KPI	Key Performance Indicator
OSD	Oral Solid Dose
QMS	Quality Management System

Abstract

This dissertation critically examines the implementation of an Electronic Document Management System (EDMS) on an Oral Solid Dose (OSD) pharmaceutical manufacturing site. The impact of an EDMS and its effects on document performance metrics, as well as user satisfaction and efficiency are investigated.

This study aims to objectively review the introduction of an EDMS in a pharmaceutical manufacturing site in order to support future decision-making in relation to the digital transformation of document management systems to aid overall improved performance, and efficiency on site.

This study adopts a combined quantitative and qualitative research design; where data was gathered from an OSD manufacturing site which had an EDMS deployed in case study style research. Quantitative numerical indicators, including document cycle times, process mapping steps, and time at each stage are collected and analytically reviewed. Further primary data was collected using a questionnaire, which was completed by 40 of the employees of the selected OSD manufacturing site, who are users of the recently implemented EDMS system. The questionnaire results provide further quantitative and qualitative data, as well as unique empirical insights into user satisfaction of the EDMS implemented.

The findings of this research indicate that the implementation of the EDMS enhanced the document management process by streamlining the steps required, which reduced the process steps required from 11 steps to 8 steps. This resulted in a reduction of the average cycle time by 19.6%. This reduction in cycle time was indicative of a significant improvement in the time required for the review and approval stage which decreased by 46%. The key advantages identified through the user perspectives questionnaire included the increased visibility of workflow and document status, improved carbon footprint and access to affiliate and global documents across the organisational network. There were barriers identified including difficulty learning functionality, user resistance and digital literacy challenges which were prevalent in the immediate stage post-implementation. These challenges considerably reduced over time as user familiarity and confidence using the system increased. There were numerous recommendations provided on ways to improve future deployment and overall user satisfaction with an EDMS, which related to training, supporting documents and system interface enhancement.

The research supports the implementation of an EDMS as an approach to enhance the document management process in a pharmaceutical manufacturing site. The adoption of a digitalised system has the potential to streamline document processing, improve document processing cycle time, reduce carbon footprint and allow greater visibility and control over document management tasks. These finding endorse the wider implementation of digitalised DMS and promote the wider digitalization of further systems within the pharmaceutical manufacturing industry.

Chapter 1

Introduction

1.1 Introduction and Background of the Study

Document control is a fundamental element in maintaining compliance with Good Manufacturing Practice (GMP) and ensures traceability throughout the development, production, testing and release activities of a product (Simonovski and Gjorgjeska, 2022). Good manufacturing practice is underpinned by documentation which provides procedural guidance and evidence for managers, quality inspectors and auditors. This allows for rigorous evaluation of the quality of processes involved in the manufacture finished product (Ghante *et al.*, 2024).

Good Documentation Practice (GDP) is an integral part of the collection and reporting of data, product registrations, commercialisation and management of pharmaceuticals across the product lifecycle (Kumar, 2016).

The type of system utilized to manage these documents is referred to as a Document Management System (DMS). A Document Management System (DMS) allows the classification, storage, retrieval, update, approval and archiving of documents, which can be carried out by utilising a paper-based or electronic system (Gandhi *et al.*, 2024). A DMS can be an electronic system which utilises an automated, digitalised system or it can be a Manual Document Management System (ManualDMS) which would include a paper-based, off-line system which must be manually managed.

Importance of the Document Control Management in the Pharmaceutical Industry

In the pharmaceutical industry, the volume of data, documentation, approvals and GMP-controlled information is increasing significantly in line with regulatory requirements (Kulkarni and Kothari, 2024). There is ever-increasing pressure for the pharmaceutical manufacturing industry to streamline processes involved with the management and control of this information, in line with achieving operational excellence (Williamson, 2024).

An effective document management system is imperative for regulatory compliance and quality assurance to maintain accurate records and facilitate audits (Raviteja and Gupta, 2013). Data integrity is essential for regulatory compliance, with the Food and Drug Administration's (FDA) expectations based on the ALCOA principle; Attribute, Long–lasting, Contemporaneous, Original, and Accurate (FDA, 2018).

Emergence of Electronic Document Management Systems

There is a global movement towards digitalisation of processes in pharmaceutical manufacturing. Digital transformation has been an emerging trend across the manufacturing industry, with strong linkages to increasing competitiveness and achieving operational excellence (Pansare *et al.*, 2023). The implementation of an Electronic Document Management System (EDMS) can be utilised to control GMP documents and allow controlled distribution across a global organization network (Höfer *et al.*, 2002). Despite the rise in digital transformation across manufacturing sites, there is limited research examining the effects of transitioning a DMS to an electronic platform in a pharmaceutical industry.

Previous Research and Gaps

Critical analysis of existing literature revealed there have been studies conducted on the implementation of EDMS in various sectors including healthcare, educational, regulatory and corporate institutions. However, there is limited, recent research on the impact of converting to an EDMS on a pharmaceutical manufacturing site. Following an extensive review of the literature, to the best of the author's knowledge, there is no available research on the benefits, limitations, and user perspectives of adapting an EDMS into a pharmaceutical production site. A trend observed which emerged whilst carrying out the review, was that there is a widespread digital transformation across the pharmaceutical industry happening at present, however there is limited research evaluating the practical implications and potential limitations of a digital transformation on a document management system (Colli *et al.*, 2020).

This research will investigate the impact of implementing an EDMS in a pharmaceutical manufacturing site, in replacement of an offline DMS. The effectiveness of the introduction of

the EDMS will be measured by comparing the performance metric data of the document reporting system before and after digital transformation.

The primary research will be centred around an Irish OSD manufacturing site which has transitioned from paper-based DMS to an EDMS.

1.2 Aim and Key Objectives

The aim of this research project is to complete a review on implementing an EDMS on an OSD Manufacturing site including the impact on efficiency of the document control system.

The four key objectives of this research project are:

1. To outline the role and importance of a document management system in the pharmaceutical industry.
2. To establish the relevant performance indicators and methods that can effectively measure the performance of a document management system, facilitating the comprehensive evaluation of its effectiveness and performance.
3. To identify if there are potential benefits or limitations of implementing an EDMS in comparison to a ManualDMS.
4. To explore how the organisation adapts to the new system, including user experience, system implementation, user satisfaction and system improvement recommendations.

1.3 Research Title

An Investigation into the Implementation of an Electronic Document Management System to an Oral Solid Dose Manufacturing Site, an Evaluation of System Performance Indicators and User Perspectives

1.4 Research Hypothesis

The current hypothesis is that the improved functionality of the EDMS, compared to the current ManualDMS, will result in an improvement on the document management system performance indicators. The aim of this research is to critically review the impact of implementing an EDMS adopted by an OSD pharmaceutical site on the document management system performance metrics.

1.5 Scope and Relevance of Study

This study will review the performance indicators of the document control system to assess if there has been a marked increase in efficacy in the EDMS, in comparison to the previous, ManualDMS.

This study is based on the user experience and insights of the pharmaceutical personnel from various departments who have an active involvement in the document control management system in the selected OSD manufacturing site which is being studied. This research aims to evaluate the application and impact of digitalising the DMS and implementing an EDMS. Given the regular and practical involvement these professionals have with using the DMS from various standpoints, their perspectives are essential in evaluating the benefits, limitations and user perception of an EDSM, which may be difficult to identify from performance indicators alone.

1.6 Outline of Thesis

The thesis is structured as follows:

1. **Introduction:** This provides the background, concept, aims, objectives, primary research question, hypothesis, scope and significance of this research.
2. **Literature Review:** Reviews existing research on Document Management System's comparing manual and automated system and identifying gaps in the current knowledge.
3. **Methodology:** Describes the research design, detailing the philosophical approach, data collection systems, study cohort selection, and ethical considerations.
4. **Data Collection and Analysis:** Outlines the collection of quantitative data through semi-structured interviews and the thematic analysis which is used to analyse the data.
5. **Results:** Presents the outcomes of the study, which includes topics linked to efficiency, compliance, and user satisfaction.
6. **Discussion:** Evaluates the findings of the study in respect to existing research, potential applications of this research, the implications for practice, and reviews the research questions, objectives and hypothesis.
7. **Conclusion and Recommendations:** Concludes the key findings, examines the limitations of the research, and outlines recommendations for further research and system use.

This research structure intends to deliver a comprehensive assessment of the effectiveness of automating document management system coding systems in a pharmaceutical manufacturing site context, proposing insights and recommendations for improving system implementation, use and recommendations.

Chapter 2

Literature Review

2.1 An Introduction to the Electronic Document Management System

A document management system is a process used to generate, approve, circulate and archive controlled records during the document life cycle (Ragimova *et al.*, 2020). The aim of a pharmaceutical business organisation is to implement the most efficient, dependable DMS while reducing resource requirements in relation to cost and workforce required (Gokulakrishnan and Venkataraman, 2024). The purpose of documentation within the pharmaceutical industry is to facilitate communication of information across the organisation, to prove compliance with regulatory standards, to encourage knowledge sharing amongst company employees, and preserving experience within the company (EudraLex, 2013; Simonovski and Gjorgjeska, 2022). Many regulatory bodies such as the FDA, advise the use of the ALCOA principles which include Attributable, Legible, Contemporaneous, Original, and Accurate (Ahmad *et al.*, 2019).

The main reason for an organisation automating the DMS system and implementing an EDMS is to identify and remove any problems associated with a ManualDMS. Based on issues identified a target tree for an EDMS was generated by Ragimova et al., which can been seen in Figure 1 below (Ragimova *et al.*, 2020).

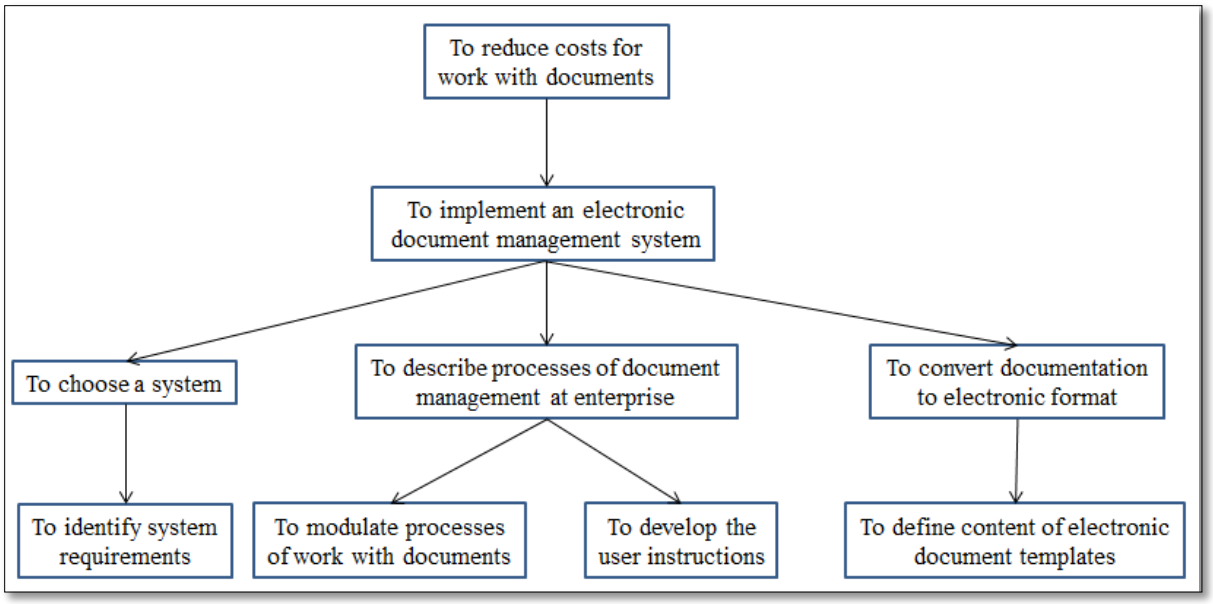

Figure 1 Tree of Targets associated with an Electronic Document Control System (Ragimova et al.*, 2020)*

Electronic document management systems are the cornerstone for many organisations which daily activities are centred around controlled documents. In the pharmaceutical industry, the following four categories of documents are required to be controlled within an DMS: normative legal acts, core manufacturer standards according to GMP, regulatory documents and register documents (Pyatigorskaya *et al.*, 2017). It is to be noted that electronic information includes everything such as emails, adverse event reports, complaints, batch records, quality control records, and any other detail that is stored electronically (Sharma, 2021).

There are six stages in the standard document life cycle which are (Burtylev *et al.*, 2013):

Document is created.

Document is reviewed and corrected, if required.

Document is formally approved.

Document is made effective and published for a wider audience.

Document is stored and made accessible while fulfilling their main purpose.

Document is archived, and if required, retrieved from the archive.

2.2 Issues associated with a Paper-Based Document control system

The digitalisation of document management processes has progressed significantly since the middle of the 20th century to allow the creation, categorisation, update, approval, and storage

of many documents including logbooks, drawings, and specifications. The movement to digitalise the DMS was expedited due to a numerous barriers identified with the ManualDMS. Ragimova et al constructed a Tree of Problems associated with a paper-based document control system which is outlined in Figure 2. The first barrier is although the systems designed to manage these documents have significantly evolved, the documents themselves have not evolved to align with these systems (Orioque *et al.*, 2024). Secondly, the significant issue with a paper-based DMS is that it competes with employees, and equipment for space in an organisational site. A ManualDMS requires more physical space than an EDMS do as these systems are reliant on tangible paper rather than an electronic virtual 'cloud' environment (Ahmad *et al.*, 2024).

When a ManualDMS is in use, there have been increased incidences of variations in formats, document templates, legacy versions, and inaccurate data as a result of human error (Perry, 2007). There is also a lack of visibility along the document update and approval workflow with a manual, paper-based system, with approvals often causing roadblocks and bottlenecks to the process (Das *et al.*, 2024).

Finally, with a ManualDMS the process is often heavily reliant on sourcing, reviewing, and approving hard-copy paper versions of the document which are held on the manufacturing site. This has proved a barrier since the widespread practice of hybrid and remote working patterns which have been escalated by the relatively recent Covid-19 Pandemic (Castaneda *et al.*, 2022).

An electronic document management system has been publicised as the solution to an organisation's paper-associated issues. An electronic platform has potential to offer an increased level of control, in comparison to how paper-based documents are handled.

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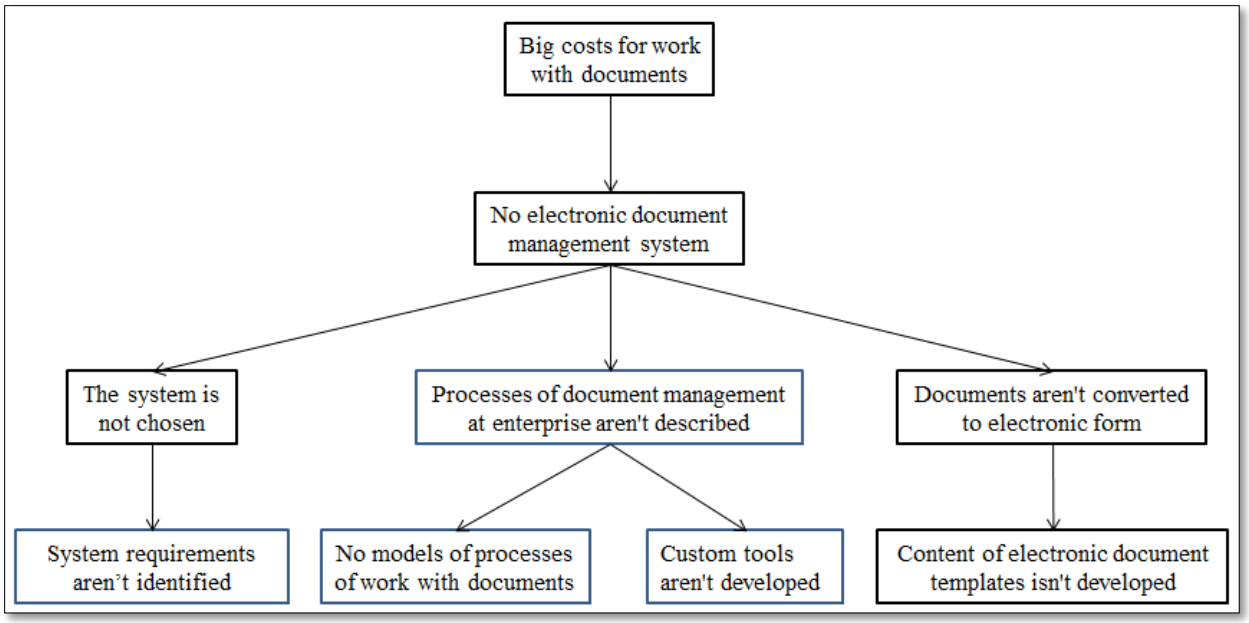

Figure 2 Tree of Problems associated with a paper-based document control systems (Ragimova et al.*, 2020)*

2.3 Current Research relating to Digitalisation of the Documentation Management System across all Industries

There is an increasing volume of information supporting the migration to an online, automated DMS in the pharmaceutical industry. In 2017, a study completed on the 'Automated document management system (ADMS) of pharmaceutical manufacturer's quality management system in accordance with requirements of GMP' found that employing an ADMS significantly increased the compliance and productivity of the manufacturer's Quality Management System (QMS) in respect to GMP guidelines (Pyatigorskaya *et al.*, 2017). Key findings of the research were increased compliance due to reduced levels of human error, greater traceability due to the availability of detailed audit trails, cost savings due to reduced document control resources required, and lastly, scalability to meet the ever-changing requirements of the pharmaceutical landscape.

In a recent research paper 'Electronic document management systems implementation across industries: systematic analysis' a detailed systematic review to evaluate the roll out and performance of EDMS's across various industries was completed (Anggraini *et al.*, 2024). The research highlighted the significant link where a well-designed EDMS resulted in accurate document handling which resulted in a significant reduction in project budget overruns. The cost

overspends had been previously linked to inaccurate documents when being handled with a ManualDMS. A significant strength which increased the reliability of this study was that over 30, peer-reviewed articles and scholarly sources were analyzed in this review. A notable finding from the research was the impact of employee perspectives towards the system, and its potential impact on the success of the implementation. These factors were characterized by the users' personal characteristics, technical factors, business factors, and trust within the organization, which were found to be equally weighted in importance. Interpreting and offsetting these factors are key to ensuring smooth implementation of the system and guaranteeing user acceptance. This systematic analysis presents evidence-based perceptions for future researchers, policymakers and professionals deploying EDMSs. This places emphasis on, not only the technical aspects, but the investment in system users in order to gain trust, improve technical skills, and foster employee commitment.

Since the relatively recent global pandemic, there has been a global movement across the pharmaceutical industry, to facilitate working from home or from other hybrid locations (Castaneda *et al.*, 2022). Therefore, a system which removes the need to be physically on site to view, review, or generate a document would support and align with these work patterns. The implementation of an EDMS offers flexibility in employee location which allows all documents and tasks to be accessed remotely once an employee has an internet connection. This way of working aligns with the shift towards remote or hybrid employment (Burtylev *et al.*, 2013).

A previous two-part study was carried out on a pharmaceutical site which specialised in suppository development, in which the document flow was analysed using the methodology of content analysis, system analysis, survey method, and a SWOT analysis. The document flow of the quality systems was analysed and Smekhova *et al.*, concluded in this study that clarity on the documentation process and the range of documents required was obtained (Smekhova *et al.*, 2021).

2.4 The key benefits of an Electronic Document Management System

The key benefits and modern requirements of an EDSM were defined in a recent literature review entitled 'Analysis of Main Requirements for Electronic Document Management Systems'

(Ragimova *et al.*, 2020). There were numerous advantages highlighted in connection to EDMS usage. The initial benefit outlined was the improvement in time efficiency associated with daily documentation tasks when using the EDMS. The increased effectiveness of digitalising a paper based system was also seen in a case study carried out within a Logistic company (Kuzmina *et al.*, 2021). This research showed a trend that there was a significant decrease in the time required for each of the lifecycle stages of the document process including information population, verification, duplication, sorting, access, routing, and storage, due to these properties becoming an automated function of the system (Burtylev *et al.*, 2013). It was identified that there was a significant reduction in the time required for each stage of the workflow when the paper-based system was replaced and compared with a digitalised system (Dolin, 2006). As outlined in Figure 3 below, there was a significant reduction in the time required to enter information, verification, sorting, access, routing, and storage during the document life cycle. This resulted in a greater proportion of time available for working on content to improve detail and accuracy of the documents.

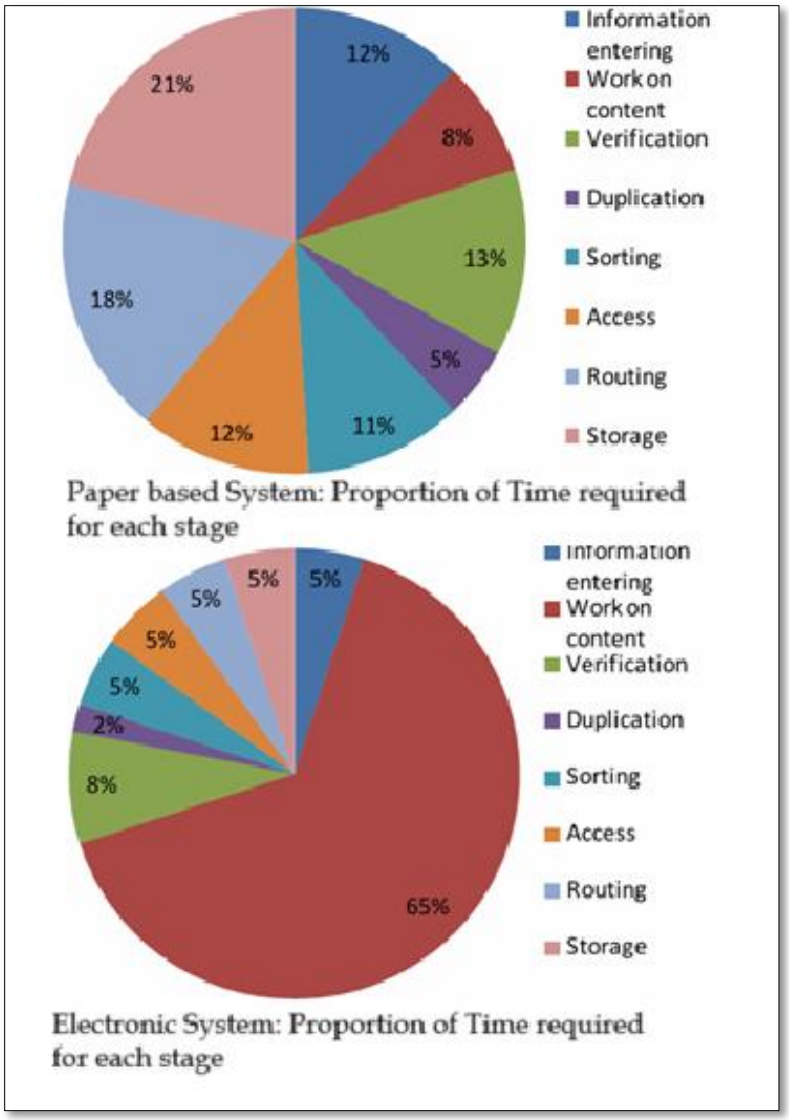

Figure 3 Proportion of Time required for each stage of work in the document life cycle; in comparing the paper based and electronic document management system (Dolin, 2006)

Optimised Physical Storage was also an advantage identified by Ragimova et al, due to the digitalisation of documents. This is extremely advantageous for manufacturing sites who can repurpose these areas for a more productive use (Ragimova *et al.*, 2020).

Enhanced transparency by providing clear visibility to all internal processes relating to document management including update, review, approval, previous versions, and protected audit trails. This allows increased accountability, and workflow oversight across the document management process, which leads to the identification and removal of bottlenecks within the process (Burtylev *et al.*, 2013; Ragimova *et al.*, 2020).

There is an increased level of security with electronic systems due to the advancement of security features, which protects unauthorized access to sensitive information (Ragimova *et al.*, 2020). Documents are protected from a significant event which may cause damage or loss of documents stored in a paper-based system (Das *et al.*, 2024). All actions are tracked in an audit history trail, which also allows a greater level of accountability within the system. It is not possible to track such activities within a paper-based system.

Although it was highlighted by Burtylev et al., that a significant financial investment is required to deploy an EDMS, there is cost savings associated in the long term with removing a paper based system which were called out by Ragimova et al. (Burtylev *et al.*, 2013 Ragimova *et al.*, 2020). The reduction in printing, postage, physical archiving storage costs and document forwarding transport costs are a long-term benefit associated with an EDMS.

Similar benefits were also concluded in a study by Burtylev et al. entitled 'Development of Electronic Document Management Systems: Advantage and Efficiency'(Burtylev *et al.*, 2013). The primary benefits concluded in this previous research are better usage of physical space onsite, increased efficiency, more transparency of document through workflow, greater flexibility with physical work location of employees, increased document security, and decreased printing costs. The main requirements customers need from a EDSM are continuous document availability, document integrity, confidentiality, reliable archiving and hardware infrastructure. Further evidence in relation to the process of developing an EDMS was outlined in this study in 2013, examining a variety of industries and applications. The versatility of an EDMS was outlined by a review of its application in the environmental, trade, housing, and inventory sectors (Burtylev *et al.*, 2013).

The research carried out by Ragimova et al. entitled 'Analysis of the Main Requirements for Electronic Document Management System' was a qualitative analysis which analysed existing information available on EDMS to identify the main benefits and advantages of this system (Ragimova *et al.*, 2020). A particular strength of this overview was that this was a comprehensive investigation which offers a detailed examination which included valuable insights. This study has a customer-centric approach which prioritises the practical organisational and user requirements

of this system. There were limitations of this previous study including a lack of empirical data or primary research to support its findings. khe investment made in the system. Therefore, with time an EDMS must financially pay itself off overtime, but there is increasing pressure for the implementation of these systems to result in a cost saving in the long term (Pyatigorskaya *et al.*, 2017).

In the pharmaceutical industry, the regulatory requirements are underpinned by specific regulatory expectations. The Eudralex Guidelines has an entire chapter to outlining the Documentation Standards (EudraLex, 2011). The guidelines encompass the use of either a paper based or an electronic based system and was last updated in January of 2011 considering the increased use of electronic documents and management systems within the GMP environment. Electronic documents such as templates, logbooks and master documents are to be controlled to prevent modification. A document should be controlled during storage, throughout the retention period. There should be function in place to allow working documents to be replicated from master documents. Documents should undergo a formal review process, with the signature and date present on the documents (Segalstad, 2008).

2.5 Barriers associated with an Electronic Document Management System

Although there is an array of benefits associated with deploying an EDMS system, there are a number of barriers which may impede an organisation from implementing an EDMS in replacement of a paper-based system. As highlighted in research completed by Burtylev et al., in order to implement and maintain an EDSM the customer must generate significant financial investment, in order to finance the roll-out and maintenance of this system (Burtylev *et al.*, 2013).

There has been an array of problems identified with implementing an EDMS system which can impede the smooth and efficient roll out of this. Burtylev *et al.* outlines some of these in their qualitative research. This included staff resistance which may be due to limited IT literacy which results in resistance to training and an unwillingness to access and edit document's using the new system on the computer. This issue required additional time and resources to provide reassurance on the system. Another disadvantage is that occasionally managers can resist the change as they don't want the increased level of transparency to their task and turnaround times.

There has been specific research into this exact issue completed with Dykman and Davis completing a study entitled 'Addressing Resistance to Workflow Automation' (Dykman and Davis, 2012). Findings of this study highlighted that a variable such as system cost is a relatively simple factor to calculate, however determining employee cooperation is a more difficult factor to foresee, and factors should be taken to alleviate any issues in advance. A case study completed in an accounting and tax office concluded that, careful consideration to identify system advocates from the offset were required and other employees who required additional support and reassurance should be provided with this (Bratarchuk and Milkina, 2021).

The cost of implementation is a significant barrier which may prevent an organisation implementing an EDMS. In the review completed by Raviteja et al., a survey concluded that companies invest 6% to 15% of its revenue in its DMS. Therefore, with this level of investment there is the expectation and pressure for a highly functioning EDMS (Raviteja and Gupta, 2013).

An EDMS is not used to its full advantage if there are other branches, affiliate sites, or entities which are still using a paper-based system. This results in duplication of work trying to merge the two systems, particularly if access, review and approvals are required from these parallel bodies which are still utilising a paper-based system. Ideally, an EDMS is most effective when all entities are digitalised and using the same system (Burtylev *et al.*, 2013). It is important to call out that most of these disadvantages and barriers are experienced within the immediate hypercare stage after implementation.

The availability of internet connection across all areas of the manufacturing site and remote employee locations can be a barrier to EDMS implementation and usage (Das *et al.*, 2024).

To help reduce the barriers and disadvantages the following approaches can be adapted. The deployment of an EDMS can be completed gradually, perhaps department by department instead of a specific "go-live" date. This may help to identify and resolve issues which arise during the implementation with the initial departments (Dykman and Davis, 2012). A second approach could be to identify system supporters and enthusiasts who champion the system. These system champions can assist employees who may have reservations or need extra support with the initial stages of use (Dykman and Davis, 2012). The next technique which can be used to remove

barriers is to explain the benefits of the EDMS to managers, including how it will help them, their team and potentially the wider business. Although system experts may assume that the benefits are widely known, it is important to inform managers and leaders within an organisation to ensure system support.

2.6 Performance indicators and methods used to effectively measure the performance of a document management system

A review of the methods used to collect data in order to evaluate and compare document management systems was completed. A study carried out which compared a paper-based and electronic DMS system by analysing and defining the process stages and evaluating what percentage of time was spent at each stage (Dolin, 2006). The results were presented by Dolin in two separate pie charts.

A case study entitled 'Implementing & Customising Document Management & Archiving System' identified the following key performance indicators (KPI) in Figure 4 suitable for evaluating an EDMS (Macaraeg, 2022).

Key Performance Indicator	Type of KPI Impact
Average service turn-around time (2 days to complete a service)	Reduce errors, efforts, costs and time
Average percentage of re-print service	Reduce errors, efforts, costs and time
Compliance with the service requirements	Reduce errors, efforts, costs and time
Average to access documents	Reduce efforts, costs and time

Figure 4 Key Performance Indicators Identified to evaluate an EDMS (Macaraeg, 2022).

Another study involved a cross-sectional investigation of electronic health record system compared against a manual system in healthcare environment utilised the use of tangible system performance metrics to collect quantitative information and user feedback also collected qualitative information. A time based analysis was performed through a statistical process control charts and interviews with employees were completed to gain feedback on the issue was utilised (Slyngstad and Helgheim, 2022)

Survey Questionnaires were the methodological tool of choice. There was 60 statement link questions and the user had to select a score on a 7-point Likert scale which ranged from strongly disagree to strongly agree (Gani, 2024)

The use of a survey questionnaire has been commonly observed as a collection tool to gather information on a digitalised systems alongside gathering user insights in existing literature. The user questionnaire was utilised to collect all primary data for the evaluation of effectiveness of an automated coding system (Dominic, 2024). Descriptive statistics was then used to evaluate and interpret the findings from the questionnaire.

The use of lean six sigma techniques to improve the document process has been adapted. A recent case study carried out on the 'Application of Lean Techniques to Eliminate Waste from Delays in Document Management Process through EDMS' involved the review of the document process in respect to lean techniques combined with the transition to an electronic system (Wiwattanakornwong, 2024a). This resulted in the process steps required go from thirteen to seven steps, which was a 46.15% reduction of process steps. The time per document transaction also significantly reduced verifying the increased efficiency.

An earlier study carried out in the construction industry entitled 'Implementing electronic document management system for the Lean design process' completed shadowed similar findings. The lean outcomes were elimination of non-value-add activities, increased document consistency, cycle time improvement, minimise process steps required and increased process transparency (Giandon *et al.*, 2002).

The emphasis of operational excellence tools being used as performance metrics for pharmaceutical sites has been ever increasing. A study was carried out entitled 'Critical Success Factors for Operational Excellence in the Pharmaceutical Industry: Insights from a Qualitative Study'(O'Callaghan *et al.*, 2023). This study aimed to determine the levels of Operation Excellence understanding and utilisation within the pharmaceutical industry, by interviewing 28 Pharmaceutical Manufacturing Operational Excellence personnel. A key strength of this study which makes the finding particularly relevant to the proposed research is that it is based on the pharmaceutical manufacturing industry in Ireland. This methodology used was an open-ended

qualitative interview which consisted of nine questions. The responses from the interviews were presented in a verbatim quote format to allow clear insights into the OpEx function. Participant anonymity was maintained by using a P number, as pseudo names.

There is a reasonable level of research carried out on the implementation of an EDMS and specific document control indicators, however there is limited, current investigations carried out on the specific effects of an EDMS on the performance of a OSD manufacturing site.

2.7 Case study Research carried out on the Implementation of an Electronic Document Management Systems

A case study was carried on a company, named JJJ Company, in Thailand who moved from a paper-based document management system to an electronic system (Wiwattanakornwong, 2024b). The category of organisation was not confirmed in this study. The methodology used to collect qualitative information involved carrying out in-depth interviews and questionnaires with 38 employees. The sample population as part of this research was a significant strength which added to the reliability of its findings. The sample population of 38 is large which is proportionally divided across seniority levels and departments, with 3 executives, 10 supply chain, and 25 operational personnel completing the questionnaire or interview.

This case study is comparable to the proposed research into the implementation of an EDMS to an OSD manufacturing site, therefore the methodology was evaluated (Wiwattanakornwong, 2024b). Data was collected by structured interviews and questionnaires, analysing paper and electronic system process flows, and reviewing electronic system testing information. This study had several findings including that paper-based document management systems required the storage of physical documents and paper supplies, resulting in increased paper costs and decreased work efficiency. The implementation of an EDMS was economically warranted by using the benefit-cost analysis theory. This resulted in a benefit-cost ratio of 1.874 in the company, with nett financial returns of 167,935 baht, which shows that an EDMS has financial benefits also. When paper usage was analysed pre and post EDMS implementation, there was 3,659 sheets per month to 58 sheets per month, respectively, which resulted in a 98.84% reduction, saving 4,681.3 THB monthly. The User perspective questionnaires confirmed that an

EDMS improved the document management efficiency by 49.70% in processing time, 67.13% in convenience, 54.77% in responsiveness, 44.17% in data accuracy, and 52.73% in overall satisfaction. (Wiwattanakornwong, 2024b)

A second case study was completed in Bangkok by the same researcher Kunakorn Wiwattanakornwong in a study entitled 'Application of Lean Technique to Eliminate Waste from Delays in Document Management Process Through Electronic Document Management System: Case Study of AAA Company, Bangkok' (Wiwattanakornwong, 2024a). For this case study thirty transactions completed within the electronic document management system were studied using lean Techniques tools. The methodology included the use of multiple lean tools including cause & effect diagram, value stream diagram, waste reduction technique with ECRS, information flow diagram, and information relationship diagram. Time for each process step was a key indicator taken to quantify the results. Machine was identified as the primary root cause as a paper-based system was used and the centralised management system was not used at this time. The secondary cause is method which as there was redundant steps identified. The root cause category of Man was responsible for miscellaneous errors which can occur with physical document delays, loss, and printing errors. The initial assessment stated there was a delay of up to 351 minutes a month. The review concluded that the initial process had 13 steps, and after the improvement was completed, the process was simplified to seven steps which was a 46.15 % improvement. The results were statistically assessed using a P-Value to confirm if the improvements and results were statistically significant, which was a key strength of this study. There were key recommendations resulting from this study including the principle that a system should not just be implemented, but new tools or frameworks should be used to improve the process even after implementation to ensure its constantly meeting customer needs.

2.8 Current Gaps in Research

Having reviewed the current research on EDMS implementation in an Oral Solid Dose (OSD) manufacturing site, reveals a number of critical gaps that require additional investigation. To start, there is an evident lack of robust metrics to facilitate the measurement for an precise assessment between a paper-based DMS and an Electronic DMS. The majority of the existing research carried out on the pharmaceutical industry, place particularly emphasis on broader

benefits of the EDMS, with lack of true measurable outcomes. The research which has based their methodology on measuring a performance indicator of a process, were not based on the pharmaceutical industry, but instead a comparable industry which utilises an EDMS. Moreover, there is a gap in recent case studies that provide a comprehensive insight into the practical application and barriers of automatic, electronic systems in real-world pharmaceutical site.

In addition, while it has been found that an EDMS has resulted in higher levels of efficiency, there is a deficiency of thorough data regarding the results of these time-saving benefits on the various performance outputs.

User perspectives and recommendations for improvement signify another area which require further research. Current studies largely suggest positive feedback among users regarding EDMS's, however additional in-depth exploration is required to assess user perspectives across all levels of personnel on an OSD manufacturing Site. This may include examining the system implementation supports which are intended to facilitate the transition to an EDMS. The effect of time on the system usability, user acceptance and performance would also be investigated. The effectiveness and modes of training programmes involved in the implementation also need to be investigated further. The relationship with training and system deployment, with overall user acceptance and performance required investigation.

Furthermore, the lasting effects of digitalising an EDMS on document standards, and its implications for the performance of the site remain poorly understood. Further studies into these systems could uncover whether digitalising an DMS results in improved document quality, information accuracy and improved timeliness in the document process, therefore improving the sites performance comprehensively.

As there is a lack of case study style research into OSD Manufacturing sites, there is a lack of understanding of the practical obstacles, such as integration with legacy processes, and adaptation of training programme to meet training needs. Have a well-rounded understanding of these barriers are essential to understanding how best to implement an EDMS into a pharmaceutical manufacturing site.

Addressing these gaps in future research studies would significantly advance knowledge of electronic document management systems in the pharmaceutical sector, particularly a manufacturing site. It would also give rise to providing potential recommendations to enhance implementation and overall use in the pharmaceutical manufacturing sector.

2.9Literature Review Conclusion

In review, the accuracy and efficiency of a document management system within the pharmaceutical industry is fundamental for documenting and recording all processes which occur during drug manufacture. The digitalisation of processes by implementing an EDMS offer substantial advantages including greater control of documents, increased accessibility, removing workflow delays associated with remote working and decreased demand on physical storage. A paper-based document management system has limited process visibility, restricted document accessibility, consumes physical space, and requires an onsite presence to complete tasks. Furthermore, a successful EDMS implementation can be enhanced by a comprehensive training programme, and working to meet end-users needs. Additional investigation to close the existing research gaps to better understand the EDMS implementation in a pharmaceutical manufacturing site, combatting implementation challenges and exploring the wider impact on the site performance. By advancing EDMS in the pharmaceutical industry, we can enhance compliance, have more robust procedures and facilitate the progressive hybrid work environment in the pharmaceutical sector.

Chapter 3

Methodology

3.1 Introduction

This chapter details the research methodology used to evaluate the effectiveness, impact and user perspectives of EDMS in a pharmaceutical manufacturing site. The methodology of this study is based on a positivist approach, which uses a quantitative measure to assess without bias the main elements such as efficiency, user satisfaction and overall impact to site. This methodology section additionally summarises the participant selection, data collection techniques and ethical factors, which ensured a comprehensive and ethically compliant research protocol. Finally, the limitations of the research process are confronted, addressing how this impacted result interpretation.

3.2 Conceptual Framework of the study

The conceptual framework for this research is designed around the elements of electronic systems, user needs and the increasing demands of the pharmaceutical manufacturing industry. The framework is made up of three main elements: efficiency, overall impact to site and user satisfaction.

The efficiency of an EDMS system is a crucial element to gauge its success. Efficiency can be a strong indicator of how an EDMS system can handle the operational demands of a document management system on a pharmaceutical manufacturing site, who manage a large volume of documents. In theory, an EDMS will expedite the document management process, allowing for quicker retrieval, update and approvals of key documentation. This study evaluates whether key performance metrics of the document control system were improved on the implementation of an electronic system, compared to a paper-based system. This may possibly release resources to be used on other duties, which may reflect an improvement in the operational efficiency of the department.

The overall impact to site will be evaluated to assess if the management of documentation has a wider impact on site operations. As documentation underpins all site operations on a pharmaceutical manufacturing site, the link between the system to which all these documents are managed and the wider site operations will be evaluated. This will encompass if the accuracy of the documentation, the ease of access and simplified document workflow has a beneficial impact on the site.

User satisfaction embodies the human aspect of the conceptual framework. This reviews and encompasses the practical element of the how the users experienced the implementation and operation of the system. These elements included user-friendliness, benefits, barriers and impact on daily tasks. By system users completing a survey, this research aims to provide insights to the user response and suggest recommendations to improve the implementation and operational experience of an EDMS.

Simultaneously, these elements form a comprehensive framework to which evaluated both the operational performance of an EDMS, and the practical transition and application from a paper-based document system to an electronic document management system in an actual pharmaceutical manufacturing site in Ireland.

3.3 Philosophical approach to primary research

This research study utilises a positivist research philosophical approach. This centres around a non-biased standpoint, measurement and the utilisation of quantitative data to measure the EDMS system performance in the pharmaceutical industry.

Positive research philosophy is when the researcher is objective with the primary purpose being to collect data through quantifiable observations which can be statistically analysed (Park *et al.*, 2019) . As the methodology utilises Positivism, the data collection will include the analysis of a large proportion of the of the performance metrics which are objective, quantitative research. The positivism theorises that the status of a situation is objective and can be interpreted by the use of empirical reflection alongside rational exploration. Therefore, the primary philosophical approach also includes elements of empiricism while designing the data collection methods, and

the analysis of data. In other words, the data collection is based on the principle of direct experience and observation within that field also, rather than from abstract principles or theory.

The empiricism method is utilised in a select number of objectives defined for this study. Empiricism indicates that concepts can originates from direct involvement and that rationally acceptable theories are acquired through experience. The empirical physiological approach will be used to interpret data through system understanding and familiarity with the system. This will be particularly useful when gauge process mapping, satisfaction levels, and challenges relating to the use of the new system.

This study is based on the hypothesis that there is a demonstrable association between the performance of an electronic document control system and a paper-based manual document control system. The objective reality can be evaluated using identifiable values such as efficiency, impact to wider site metrics and user satisfaction. In reviewing these markers, the purpose of the research is to identify evident correlations between the data and the document system type, which can be compared with the wider pharmaceutical sector. These measurable outcomes will be supported with the data and feedback collected by the users through the questionnaire which will offer further context.

The selected methodology highlights that expertise is optimal when obtained through methodical surveillance and analysis. To strengthen the research findings, a systematised questionnaire with a combination of closed and opened-ended questions was created. As a result of this questionnaire, both objective, quantifiable data and qualitative, perspective-based data. The information collected is then assessed to ensure that all findings and associated conclusions are solid, reproducible and widely relevant across the industry. The questionnaire will support in providing further context on user perspectives in relation the system performance.

This study prioritises accuracy and reliability. As the study is centred on a positivism approach, the study aims to provide robust findings in relation to EDMS implementation, role and impact. As an empiricism approach is also used to interpret open-ended feedback, the aim is to provide further context and recommendations in relation to the user perspectives on the system.

3.4 Research Onion

Philosophy: *Positivism*

The positivist paradigm is deemed appropriate for this study, as it underscores the importance of objectivity, empirical measurement, and the application of quantitative methodologies in the investigation of observable phenomena. This philosophical stance aligns with the research aim of systematically evaluating the performance of EDMS, utilizing quantifiable metrics such as efficiency metrics, overall impact to site and user satisfaction to ensure rigorous analysis.

Approach: *Deductive*

This study adopts a deductive research approach, beginning with predefined hypotheses based on established theories related to system implementation and performance outcomes. By applying this top-down methodology, the research seeks to test whether the introduction of an EDMS leads to measurable improvements in operational efficiency, document accessibility, and user satisfaction. Quantitative data collected before and after the system implementation are used to validate or refute these hypotheses, ensuring a structured and objective assessment aligned with a positivist research philosophy. This approach is particularly valuable in this study where a hypothesis in relation to an EDMS is formed, and this requires objective assessment and data-driven insights, with the support of empirical viewpoints.

Methods (Mixed): *Quantitative and Qualitative*

The research primarily utilised quantitative methods to gather primary data, by collecting key performance metrics, and through a questionnaire with close-ended questions. However, there was also qualitative methods used to collect qualitative data via open-ended questions which gathered user perspectives in the questionnaire. This technique authenticates the evaluation of objective data and data analysis which results in the recognition of correlations in the data elements which can be applied across the pharmaceutical sector.

Strategy: *Case Study and Survey*

Numerical data was collected in a case study format by obtaining selected system and site performance metric data over a two-month period before electronic system implementation, i.e., during the use of a paper-based system, and after the implementation of an EDMS.

Numerical indicators which track document processing efficiency, retrieval time, and document related actions are collected.

The use of questionnaire was chosen as it represents a robust strategy to obtain data from a select cohort of system users, which is a critical requirement for rigorous analysis within a positivist research framework. This methodology approach facilitates the systematic collection of quantitative and qualitative data related to multiple dimensions of both electronic and paper-based document control systems, including efficiency, site impact and user satisfaction.

Time-Horizon: Longitudinal (Numerical Data Collection) and Cross-Sectional (Questionnaire)

This study employs a longitudinal time horizon, allowing for the collection and comparison of data at two distinct points: prior to and following the implementation of an EDMS. By capturing data both before and after the system's deployment, this approach facilitates the assessment of changes in KPI such as document processing efficiency, retrieval time and document related actions. The longitudinal design enables a more accurate evaluation of the EDMS's impact over time, aligning with the study's objective to measure system effectiveness through observable and quantifiable outcomes.

The questionnaire was circulated at a cross-sectional time point which gauged the users' perspective of an EDMS after the implementation had occurred. This method is successful in capturing the current performance, and user satisfaction in relation to the EDMS, compared to the paper-based DMS, which allows a snapshot of its impact. While collecting the post-implementation numerical data, and the circulation of the questionnaires, it was important to note that the hypercare phase had passed. The hypercare stage is a stage after the implementation of a system where heighted support is needed, increased issues are raised, and the users are adjusting to the new system. The collection of data occurred 10-12 months after system implementation to ensure the hypercare period was concluded and data which accurately represented EDMS implementation was collected.

Techniques and Procedures: Data Collection and Analysis

Data Collection: Structured questionnaires distributed to professionals from different departments within an OSD manufacturing site, aimed at their experience and perceptions with an EDMS.

Data Analysis: Techniques including descriptive statistics to assess the impact and user satisfaction with the EDMS. This technique reveals relationships and insights which contribute towards future use, system implementation, and best practices in relation to EDMS's.

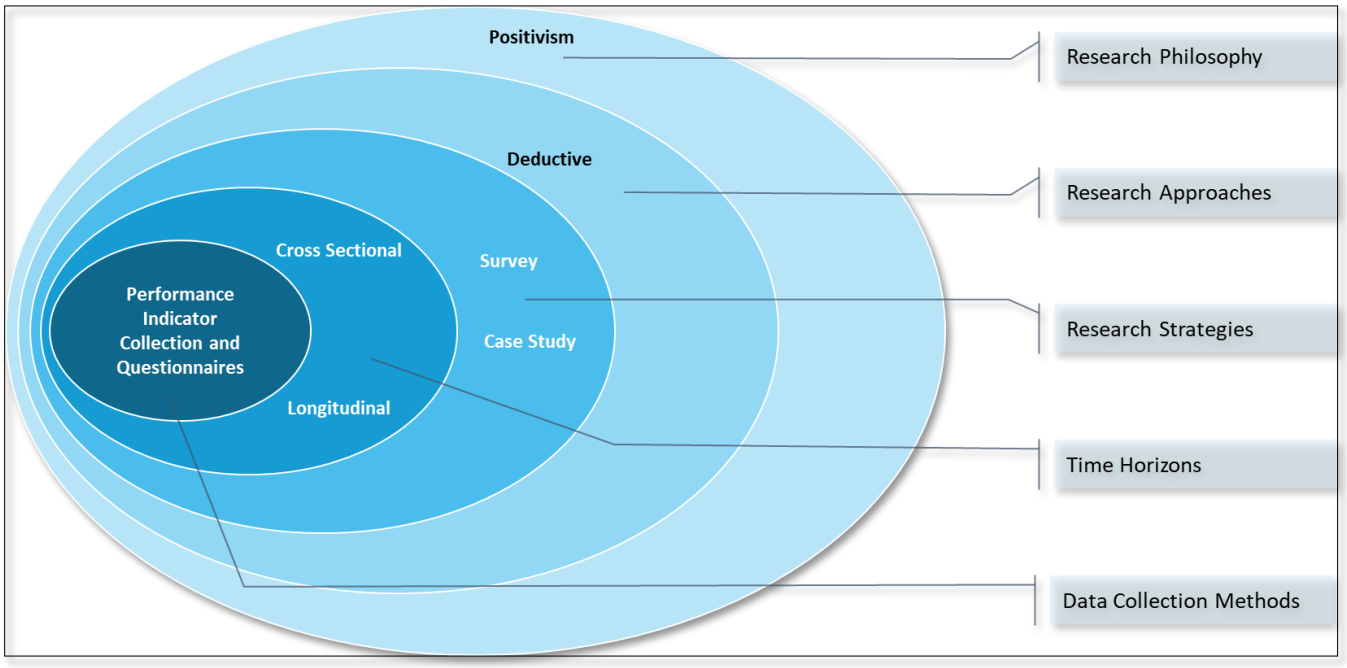

Figure 5 Research Philosophy for this study using the research onion framework as adapted from (Seuring et al.*, 2021)*

3.5 Study Participants

In alignment with the objective of evaluating the performance and user perspectives of an EDMS within the pharmaceutical industry, the selection of study contributors was precisely controlled to ensure the assembly of valid and reliable data. The questionnaire respondents were personnel employed at the selected oral solid dosage (OSD) pharmaceutical manufacturing site which the case study was completed on. Participants are from a range of departments representative of the site which utilise the EDMS including quality assurance, quality control, production, technical, validation, regulatory, supply chain, facilities and maintenance.

Participant Selection Criteria:

EDMS Usage Requirements

Users must have an electronic document management system (EDMS) account. As part of their role, they must use the EDMS for any of the following tasks including accessing documents, reviewing or approving documents during update, withdrawing documents, retrieving logbooks or forms, report approval, and to view global or affiliate site a SOPs.

EDMS Experience

There is no minimum experience which a user is required to have as data collection is required from less experienced users up to users with greater levels of experience. Once a user meets the usage requirements as outlined above, they can complete the questionnaire.

Participant Exclusion Criteria

Participants with limited EDMS Exposure as part of their role were excluded from completing the survey.

3.6 Sample Size Calculation and Sampling Strategy

For this selection of sample size for the distribution of questionnaires the industry standard of a 95% confidence level and a 5% margin of error was selected and the formula outlined in Figure 6 was utilised (Sample Size Calculator, 2025). There were 44 active users identified using the system as of the January 2025. Therefore, a sample size of 40 was concluded, by using the below formulation.

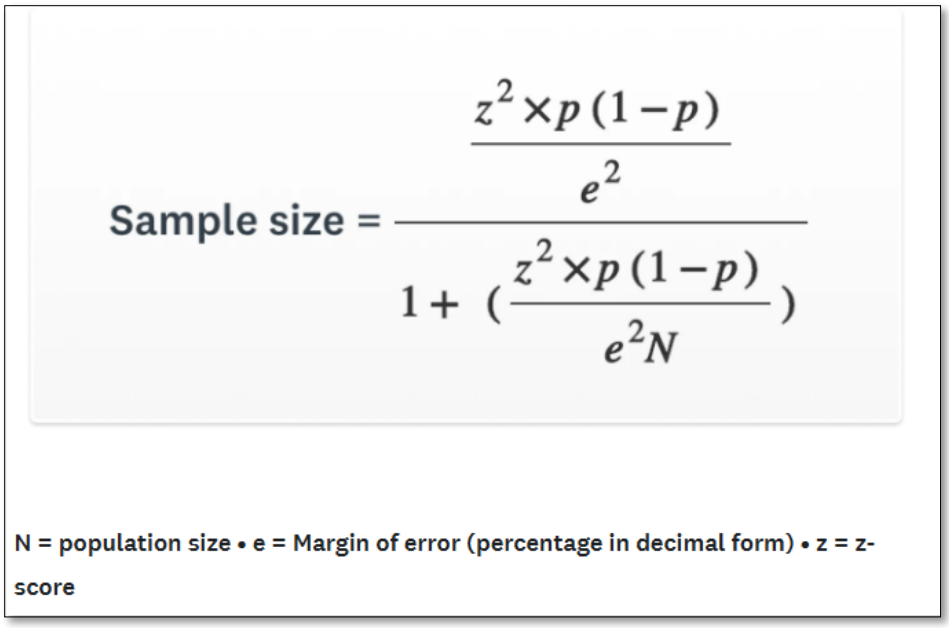

Figure 6 Sample Size Calculation Formula (Sample Size Calculator, 2025)

Previous studies which captured qualitative and quantitative data via a survey questionnaire in case study research had sample sizes ranging from 20-38 participants(Raviteja and Gupta, 2013; Smekhova *et al.*, 2021; Wiwattanakornwong, 2024b).

The sample size priority was participant diversity and representation across all departments and role requirements; therefore depth, saturation and purposive sampling was a priority. This was similar to the methods employed by previous case study research on EDMS (Wiwattanakornwong, 2024b).

3.7 Ethical Implications

This study was carried out in strict accordance with published ethical standards to protect the rights, privacy, and confidentiality of all contributors throughout the study process. In advance of completing the questionnaire the respondents reviewed a Participant Information Leaflet (PIL) and signed the Informed Consent Form (ICF). The PIL contained a thorough overview outlining the study's objectives, scope, and procedural framework, guaranteeing that respondents were fully informed in advance of confirming their consent. The ICF required participants to confirm both their understanding and voluntary consent before proceeding. Involvement in the research was completely voluntary, in which individuals were advised they could withdraw at any point

without consequence. This ensured that all contributors were genuinely informed and willing to take part in the research.

To maintain participant confidentiality, only necessary characteristic information was retrieved, and no personally identifiable data were associated with individual responses. Survey responses were anonymized, and responses were managed using secure practices to protect data confidentiality. Contributors were guaranteed that all data would be used exclusively for research purposes and treated with strict confidentiality.

The survey was administered via Google Forms, to enhance data integrity. Ethics approval was obtained from the college institutional review board before data collection started, ensuring the study's accordance with ethical guidelines.

With these ethical guidelines, the research retained a high standard of ethical integrity, guaranteeing user confidentiality, voluntary participation, and responsible data handling throughout the research process.

3.8 Data Collection

For this research, a two-part primary data collection strategy was implemented to collect primary data, to evaluate the implementation of an EDMS, similar to the combination technique observed in previous research (Slyngstad and Helgheim, 2022). The first part involved collecting empirical data to evaluate and compare the efficiency of the EDMS system, against the ManualDMS system. To review the process involved and collect the information required to compile the process maps, the primary researcher reviewed the steps involved in the standard document update process by reviewing SOPs, job aids and assessing the performance metrics for the system.

To assess the performance and efficiency for both systems, the document performance data was collected for a two-month period both pre-EDMS implementation (1st January to 28th February 2024) and post-EDMS implementation (1st January to 28th February 2025). The EDMS was deployed on the 8th of April 2024. It was important when selecting the representative period pre- and post-implementation, that the same period across the annual calendar was selected to

remove any variances in trends associated to the time of year. It was also important to note that the post-implementation representative period allowed enough time to pass after implementation to allow users the opportunity to adjust to the system and the challenges to stabilize. The metric data collected included a log of documents processed and dates of each stage. The pre-implementation data had been recorded on an excel spreadsheet by the site document controller while the ManualDMS system was in place. The post-implementation data was exported from the EDMS system for the representative period.

The second element of the primary data collection is the user questionnaire which was completed by the system users. The questionnaire was developed after an extensive review of previous research to gain detailed insights into questionnaire development. Part 1 of the questionnaire focused on user demographic including department, experience, and exposure to electronic and manual DMSs. Part 2 of the questionnaire gathered further information on EDMS frequency of use, EDMS activities, and user role.

Part 3 of the questionnaire collected information the users' perceived barriers and benefits of the EDMS. The questionnaire collected information on the barriers experienced across the 13 months period post implementation, as existing literature hypothesized that the barriers may only be transient and alleviate as time progresses post-implementation of the EDMS.

Part 4 of the questionnaire collected information in relation to the users' opinions on perceived system usability, ease of navigation, document retrieval, user efficiency and overall satisfaction.

Part 5 of the questionnaire collected recommendations from the user in relation to rollout and implementation improvements and overall improvements to improve satisfaction.

Prior to officially launching the survey questionnaire, a trial questionnaire was completed by one user who confirmed that all questions were easily interpreted, and no adjustments were required. The survey was launched on 7th of May and remained open until the 10th of May. The questionnaire was circulated to 40 users on site, and all users completed the questionnaire.

3.9 Data Visualisation and Data Analysis

As utilised by Slyngstad and Helgheim, both DMSs were evaluated and a process map created illustrating the steps involved in each stage of a standard document update (Slyngstad and Helgheim, 2022). A comparative analysis was completed on the process maps to assess the number and criticality of the steps involved.

In relation to the document performance metric data gathered, the first output analysed was the volume of documents processed, and the associated outcome. The process maps will be visually represented as process flow charts with numbered steps.

Secondly, the total cycle time from start to finish of the document lifecycle was calculated using integrated formulas on the excel sheet. The document lifecycle was categorized into the four document lifecycle stages as outlined in Table 1. The total document lifecycle pre- and post-implementation will be represented in a bar chart. The document lifecycle stage analysis will be represented in two separate pie charts, pre- and post-implementation.

Table 1 Stage categorisation to analyse the document management system cycle time

	Stage Description
Stage 1	Update Request Creation, Submission and Approval by Document Co-ordinator
Stage 2	Document Review and Edit
Stage 3	Document Submitted for Review, Approval and Feedback
Stage 4	Document Approved and Document Issued with Effective Date

The data collected from the survey questionnaires was analysed and visually represented. The demographic information in relation to user experience and department was visually represented in a pie chart and bar chart, respectively. For the close-ended survey questions the results were statistically analysed and visually represented on a bar chart. For the open-ended questions, a qualitative thematic analysis to assess the qualitative data using the data keyword context to code the data was employed. This allowed the prevalence of a particular insight to be analysed.

3.10 Limitations of the Methodology

Although the methodology adopted in this research offers meaningful perceptions into the effectiveness of an EDMS, certain limitations must be acknowledged.

Selection Bias: One notable limitation pertains to the size and representativeness of the sample. As this is case study style research, there is only information and sample population from one OSD manufacturing site analysed. This may result in the experience of this one site impacting the results. Furthermore, eligibility criteria requiring prior experience with the EDMS system may have limited participant diversity, potentially narrowing the range of perspectives captured.

Self-Reported Data: The survey questionnaire is based on self-reported survey responses, which inherently carry certain limitations. Biases such as personal opinions or inaccuracies in self-assessment may affect the reliability of the data, as participants might overstate or underreport their challenges, or positive experiences encountered while using the EDMS system.

Collectively, these limitations emphasize the importance of interpreting the results with appropriate attention. They also point to potential directions for future research, such as expanding the sample size across multiple sites, and employing more diverse recruitment strategies.

3.11 Conclusion

In conclusion, the methodological framework selected for this research project provides a systematic approach to critically analysing the effectiveness of an EDMS on a pharmaceutical manufacturing site. Based on a positivist research philosophy and by applying quantitative and qualitative practices, the report aims to conclude both objective and tangible insights in relation to document processing efficiency, cycle times, system advantages and disadvantages and user satisfaction. The analysis of performance metrics and the feedback received via the structured questionnaire, resulted in a comprehensive appraisal of an EDMS System. Although certain limitations—such as possible selection bias and the inherent constraints of self-reported data—are recognized, the methodology has been meticulously assembled to collect important insights to the progression of the digital systems in the pharmaceutical industry. The results are projected

to support the development of best practices and serve as a foundation for future investigations aimed at optimizing EDMS's.

Chapter 4

Findings and Analysis

4.1 Data analysis and Discussion

The analytical phase of this study was divided into two elements. The first element was collection and analysis of performance indicators in relation to the document management system. These numerical indicators which track document processing efficiency, retrieval time, and document related actions were collected over two representative time points, both pre- and post- EDMS implementation. Descriptive statistics were utilised to compare the two datasets in order to assess if the EMDS resulted in any objective improvement in document management efficiency.

The second element of the data analysis for this study was for the document control system users within the manufacturing site to complete a survey questionnaire. A sample population of 40 participants were selected across all departments on site, in which all 40 questionnaire responses were completed and received back. This final dataset of 40 questionnaires were used to perform a detailed data analysis which focused on user perspectives in relation to system implementation and performance of the EDMS on an OSD manufacturing site. The evaluation and review were designed to draw useful insights which meet the objectives of the research, while maintain the results are representative and provide an accurate evaluation the implementation, use and performance of an EDMS.

4.2 Document Management System Process Map Comparison

To gain a fundamental understanding into the operational process and the impact of migrating from a manual DMS to an EDMS, a comparative review was completed comparing the process map between the manual DMS and the EDMS. This review assisted in visually assessing the procedural variations, which may highlight any improvements when the EDMS was implemented. The manual process flow outlined in Figure 7 illustrates a manual, paper-based workflow, which relied on email communication, physical document circulation, multiple task transfers and lengthy approval periods. As can be seen in the manual process map has a total of 11 steps in the

standard process, which doesn't include if a step has to be repeated to correct errors. Many of these steps are heavily reliant on manual involvement, therefore this can lead to extended delays from moving from step to step, and breakdowns in the process which prevent the process progressing any further. This is outlined further in the time-based metric analysis of the process below. By comparison, the EDMS process map outlined in Figure 8, outlines a considerably more simplified workflow which is embedded in author-lead processes, automated routing, collaborative digital review and enhanced traceability.

Figure 7 Process mapping of Manual Document Management System

Figure 8 Process mapping of Electronic Document Management System

To review the process steps of the manual DMS, the first step is retrieving the document information, including the number, title and document itself. This step is comparative between both processes outlined in Figure 7 and Figure 8. Once it is opted that the document will be updated, the author sends the request to the document controller to release the document for update via email. The issue with the manual DMS at this step is that the author has no visibility if the document is out of update with another user, which leads to an increased level of document

processing and communication with no output, as if this is the case the update cannot progress. The second issue with this step is that this can be a bottle neck in the system where all these requests await action by the one user, the document controller. This leads to step 3, where the document controller releases the document for update. As part of this step, there are several tasks to complete in the background to action to release of the document for update, which means this is a resource-intensive step for the document controller. A problem with this step in the manual DMS, is that the editable document version for update is sent back via email therefore there can introduce a breakdown in the process where the author may neglect this email due to other priorities, and the document update isn't progressed.

The EMDS process has exchanged these two steps for a controlled, openly viewable two step alternative. This involves the author raising a change request document on the system, which outlines what documents are to be amended and the details of the amendment. Although this doesn't reduce the number of steps, the system prevents an author from raising a change request for a document which is already being updated which reduced the unintentional duplication of work on behalf of the author and document controller which is a common occurrence by the author and document controller as outlined in the data analysis below. Similar in Step 3 of the EDMS process, once the author approved the change request, the system controls the document status which is openly visible to all users, which reduced the workload required by the document controller.

In the manual DMS, steps 4 involve the author updating the document offline. The following 5 steps (Step 5 to 9) depict the review and approval process which involve a review on SharePoint, a secondary review via email by the document controller and followed by being printed on Ivory Paper, to be circulated for hardcopy signature approval. The issue with this manual review and approval process is that the corrections and feedback given are not recorded, as once the document is removed from SharePoint the feedback is removed. Similarly, if there is feedback provided by the document controller, this is sent via email. The approval section of this process is also paper based which results in the requirement for the document controller, and approvers to be onsite to facilitate their tasks. This does not support the hybrid wok patterns which is evident in the pharmaceutical industry. There have also been incidences of the hardcopy version

of the document getting misplaced, this requires a reprint by the document controller which is additional workload.

In the EDMS, the step 4 involves the author editing a draft of the document, which is controlled by minor versions, which allows an author to make updates, save the document and continue at a later stage if required. The review and approval are simplified into a three-step process (Step 5 to 7) which involve the document being routed into an automated review and approval workflow. Step 6 and 7 of the EDMS process, include the major benefit of the automated workflow which allows multiple stakeholders to review the document at once, which will inherently positively impact the time required to complete the document review and approval steps. At this stage any feedback, comments, or notes recorded for the author will be logged as part of the document history. The review and approval tasks also sit as a task in the system task inbox which allows users to easily manage tasks and priorities.

When comparing the phase of issuing and making the updated document effective, in both cases this is the responsibility of the document controller. With the manual system this is a time-consuming step which involves the completion of many tasks by the document controller to execute this. Once issued for training, a manual reminder must be set to make the document effective. On the effective date the document controller, will complete another suite of tasks on the offline system and will notify the site that a new version is now effective. This step has been simplified in the EDMS in which the document can be issued by the document controller relatively quickly, and the effective date is set at this point. The document automatically is made effective by the system and the new effective version is renewed on the system.

This was also found in previous literature that the EDMS resulted in a more streamlined process. A case study completed by Wiwattanakornwong, concluded that the initial process had 13 steps, and after the improvement was completed, the process was simplified to seven steps which was a 46.15 % improvement (Wiwattanakornwong, 2024a).

In conclusion, there is a simplification of the process which resulted in a decrease in the number of process steps from 11 steps to 8 steps. During the analysis of each of the steps it is evident

that there is an elimination in the level of manual work required for each step. This worked towards supporting system performance metrics of shorter document update cycle time.

4.3 Document Control Metric Analysis

The document control performance metrics were analysed both pre and post implementation of the EDMS. The results were statistically reviewed to assess significance and then compared with the findings from the user survey.

Total documents processed pre-implementation and post-implementation of the EDMS

Table 2 represents the analysis of the number of documents processed within a representative two-month period, both prior to and after the implementation of the EDMS. From initial review of the figures, it would appear that there was a significant decrease in the document requests submitted since transferring to the EDMS. Pre-implementation there was a total of 140 requests submitted to the document controller to release a document for update, however this decreased to 92 documents which were requested for update post-implementation. This revealed a marked decrease of 34.29%. However, when the document outputs were scrutinised, it was revealed that there were a significant number of duplicate requests made for the same documents with the ManualDMS system. As when using the manual DMS, a user has no visibility of a document status, and the requests for update are made via email which are difficult to track. Therefore, there can be incidences where a document can be request is made twice for the same document which is evident in the figures outlined in Table 2. 9.29% (13 requests) of the document requests made were for a document which was already being updated by a different user, and a further 7.14% (10 requests) of document requests made were for a document which had already been issued to that same user. The EDMS automatically protects this situation from occurring therefore there was no incidence of this occurring post-implementation, which was a 100% decrease in occurrence in both categories. Furthermore, the pre-implementation figures showed there was 38 document requests made for documents which were not returned to QA for update. This is symptomatic of an offline system which makes it difficult to track workload, and in progress document tasks. These 38 documents made up 27.14% of all document requests made. There were also 6 documents which were categorised as in progress as the update was still in progress at point of migration to the EDMS system. The EDMS system had a much smaller proportion of

documents in which the update hadn't progressed with a total of 9 documents (9.78 %). There were 11 documents still in progress (11.96 %). These figures indicate a more streamlined workflow, with reduced process breakdowns and increased visibility.

This concluded a total of 73 documents (52.14%) of the total document requests which were successfully updated and issued by the document controller. When compared to the post EDMS implementation data, a much higher percentage of 78.26 % of documents were updated successfully. With a significantly higher percentage of documents reaching final update successfully with eliminated duplicated requests due to system visibility, results in reduced administrative overhead as a result of EDMS implementation.

Table 2 Number of documents processed Pre and Post Implementation of the EDMS system

	Total Documents Requested for Update		Repeat Document Request- Different User	Repeat Document Request- Same User	Document Update not Progressed	Document Update Still in Progress	Document Updates Completed by QA
Pre-EDMS	140	Number of Documents	13	10	38	6	73
		Percentage of Total	9.29 %	7.14 %	27.14 %	4.29 %	52.14 %
Post-EDMS	92	Number of Documents	0	0	9	11	72
		Percentage of Total	0 %	0 %	9.78 %	11.96 %	78.26 %

Document Processing Cycle Time

The average document processing cycle time for both pre and post implementation of the EDMS was evaluated and is represented below in Figure 9. This cycle time calculated from the initial request to update the document to issuing the final approved document to be made effective. Prior to the EDMS deployment the average document processing time was 39.37days, whereas this significantly reduced to 31.67 days post-implementation which corresponded to a 19.6% decrease in average cycle time. This equates to a reduced document update cycle time of over one week (7.7 days) on average for a document update, which would have a substantial impact

to site resources if processing approximately 35 documents per month. This decrease in average cycle time identified could be as a result of the elimination of three steps once required as part of the ManualDMS process. This suggests an improvement in workflow efficiency, aligning with the more streamlined and automated functionality of the EDMS process. This finding of a reduced cycle time and increased time efficiency aligns with conclusions of the secondary research completed on existing literature (Burtylev *et al.*, 2013; Dzikria *et al.*, 2022). These results also compared with the findings from a case study based on a logistic company, which also reported increased efficiency (Kuzmina *et al.*, 2021).

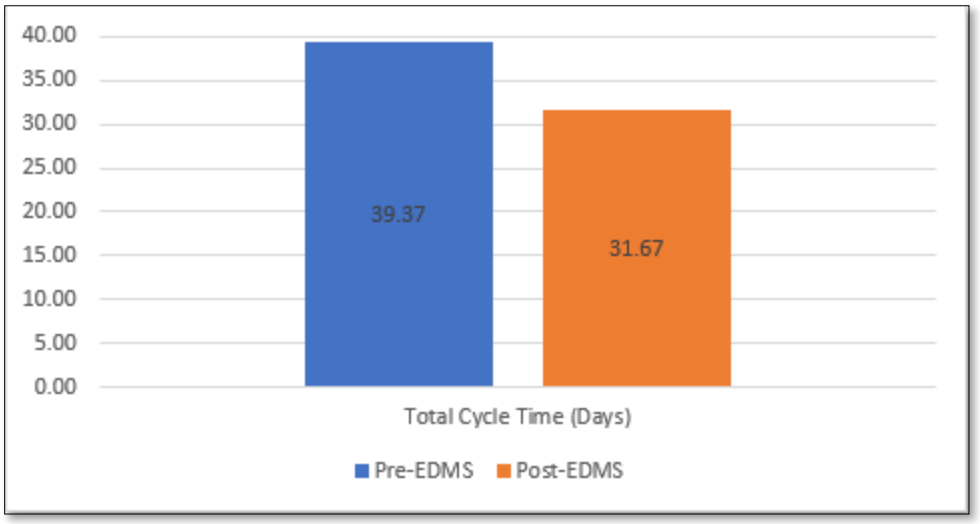

Figure 9 Total Document Processing Cycle Time in Days for the Pre-Implementation of the EDMS and Post-Implementation of the EDMS

Document Processing Stage Cycle Time

To further understand the impact of the digitalisation of the DMS, the stages of the document control process were evaluated and are represented in Figure 10 and Figure 11. There were significant shifts across the different stages of the document lifecycle. The initial stage 1 which is involves the update request creation, submission and approval actually increased from an average of 1.78 days to 2.67 days with the EDMS system. When evaluated it was concluded that this may be as the EDMS, requires an official 'Change Request' form rather than the former email request. Therefore, the compilation and approval of this form suggests marginally more time is required at this stage. There was additional time spent at stage 2 at the post-implementation EDMS stage, which increased from 10.14 days to 14.48 days. This was also identified in existing

research, where the proportion of time spent 'working on the contents' of the documents increased from 8% to 65% due to revised reduction in time required for the other stages as part of an EDMS introduction (Burtylev *et al.*, 2013). This was identified as a major advantage by Burtyleev, as an author can spend additional time refining and eliminating errors within documents, while continuing to meet tight deadlines with the improved EDMS document lifecycle. Stage 3, review and approval phase presented the most substantial change which almost certainly impacted the overall document cycle time. The review and approval phase significantly decreased from 23.71 days to 12.79 days, yielding a 46 % (10.92 day) reduction. This considerable efficiency improvements at this stage are likely owing to the automated workflows, programmed notifications, collaborative capabilities and digital sign-off for reviewers and approvers facilitated by the EDMS. The ManualDMS system review and approval stage, has been recognised as a bottleneck in the document lifecycle by Das et al., and the 23.71 day average review and approval stage identified in this research completely aligns with existing findings (Das *et al.*, 2024). The final stage 4, involving the issuing of the approved document reduced from 4.00 days to 2.37 days, which is likely due to the capability to issue a document remotely, which previously was heavily reliant on processing and storing paper-based documents.

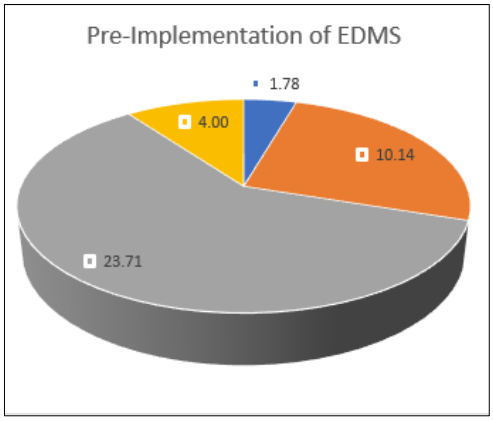

Figure 10 Pie Chart outlining the time in Days for each stage of the Document Management Process Pre-Implementation of the EDMS

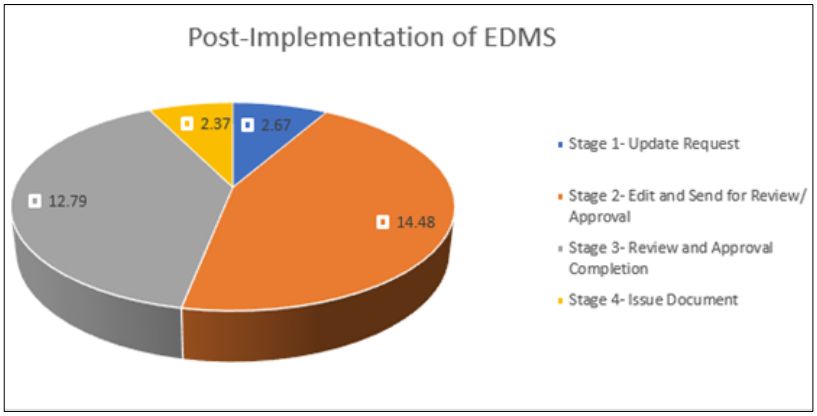

Figure 11 Pie Chart outlining the time in Days for each stage of the Document Management Process Post-Implementation of the EDMS

4.4 User Questionnaire Results and Analysis

Experience and Department of Respondents

The data received from the questionnaires was reviewed and analysed. As per Figure 12, the data confirms what 20% of respondents had over two years' experience, and the majority of respondents had four plus years' experience.

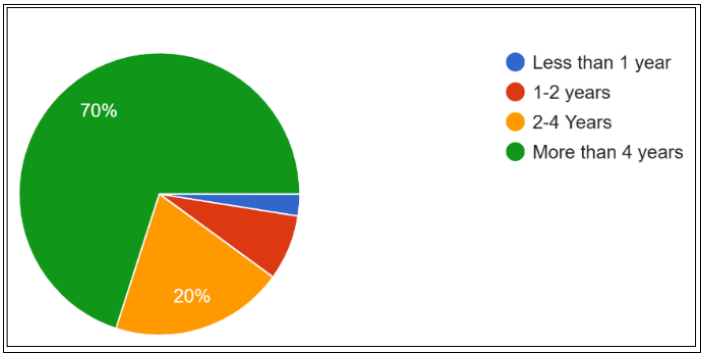

Figure 12 Experience in Document Management System Process

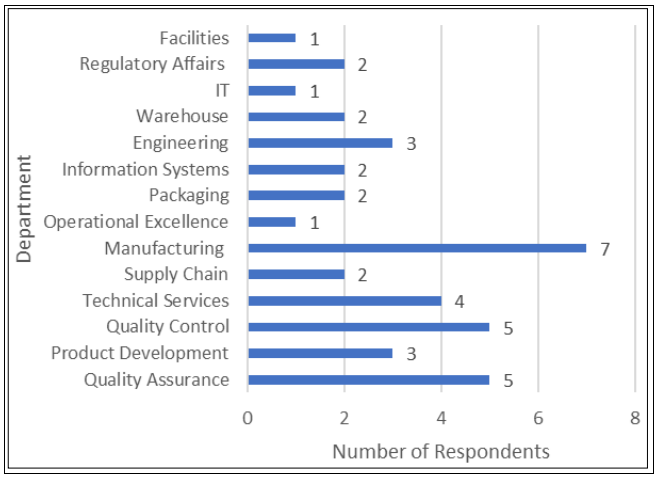

Figure 13 Number of Respondents per Department

This confirms that the majority of respondents involved in the survey have a high level of expertise in relation to the complexities of the document management process. This directly links to the aims of this research study, to assess how users adapt to the EDMS, including the overall user experience, implementation, and user satisfaction. Figure 13 outlines the wide representation of the 40 respondents across fourteen departments. Given the extensive experience and wide-ranging background and perspectives, the respondents are ideal to provide beneficial insights into the advantages, barriers and recommendations of the EDMS system. The responses received will most likely represent the day-to-day interactions alongside the ongoing system indications. 38 out of the 40 respondents (95%), utilised the manual DMS system prior to the transition to the EDMS which provides a reliable comparative baseline for users to provide feedback. Currently, an electronic document management system has been widely implemented in the practice of tax authorities, which allows you to reduce time and labor costs for processing and preparing documents; to provide operational services to the population; to ensure the availability and openness of information to the public about the activities of tax authorities, as

well as services provided by tax authorities; to reduce the cost of interaction between the population and tax authorities. However, despite the automation of office work, a number of unresolved problems remains in the field of document management of tax authorities.\nThe relevance of this study is that the main problems of the tax authorities are a large number of routine manual operations performed by employees, as well as a large volume of incoming documents that are received by the tax authorities. The creation of documents, as well as their storage, transmission and search for such documents require significant labor, time and financial costs. That is why recently tax inspections have been working on a comprehensive automation of the inspection's activities by introducing a system for processing and accounting documents, which will allow you after a while to abandon documents and information presented on paper.\nThe study analyses the electronic document management systems used in the practice of public administration, describes the advantages and disadvantages of each system. The paper also analyses the features of the document management process in the tax authorities. Based on the conducted research, the authors propose the introduction of a modern domestic system built on the "Logic of SED"-platform. This system is aimed at improving the efficiency of work in various areas of joint activity of employees of the organization in terms of automation of project document flow and the possibility of collective work.

Barriers associated with the EDMS

The survey questionnaire collected information in relation to barriers experienced with the EDMS, in relation to the various time points. A comparative analysis was completed of these user-reported barriers which they experienced during implementation or continued use of the EDMS. The two time points of 0-3 months post implementation, which occurred in April to June 2024, and the most recent period of 9-13 months post implementation, January to present, were analysed. These findings are displayed in Figure 14. In the initial post implementation stage, more commonly referred to as the hypercare phase, the most commonly reported challenges included difficulty learning the functionality of the new system (n=37), user resistance either directly or from other team members (n=26), and digital literacy challenges for personnel with limited IT skills (n=21). These three barriers aligned with the difficulties raised by Burtylev et al in his research entitled 'Development of Electronic Document Management Systems: Advantage and

Efficiency'(Burtylev *et al.*, 2013). The user resistance was a significant barrier in the hypercare stage which 65% of users reported experiencing directly or from other members within team, which was emphasised during the literature review (Dykman and Davis, 2012). Technical issues with the system were also reported including system buffering which resulted in workflow delays (n=15), and system downtime to perform updates (n=11), and restricted system access due to network or device availability (n= 10 and n=9, respectively). Integrations problems such as difficulty merging the EDMS with legacy systems was also reported (n=16) which emphasises the comprehensive approach required when reviewing system requirements. These barriers indicate that the immediate period of system implementation were primarily user-related and system-related challenges, which stresses the requirement for intensive training and technical guidance.

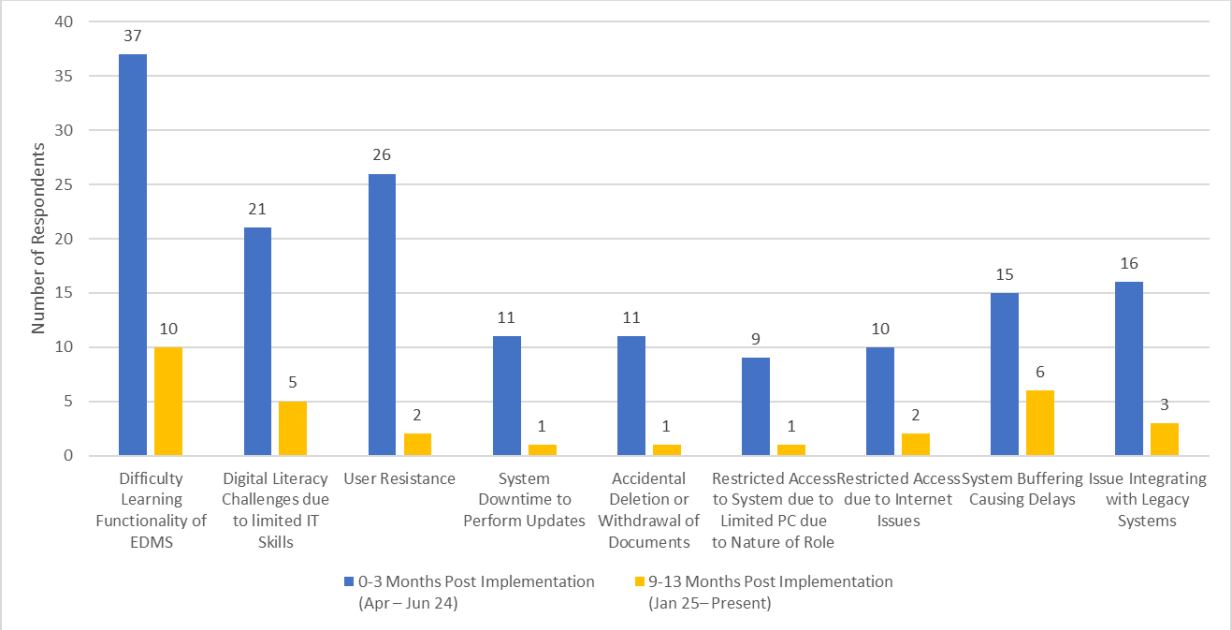

Figure 14 Barriers reported by number of users at both 0-3 months and 9-13 months post implementation

The barriers reported 9-13 months post implementation, conveyed a significant regression in all barriers and disadvantages reported. The three highest reported barriers all reduced significantly with difficulty learning functionality of the new system (72.97% reduction), digital literacy challenges (76.19 % reduction) and most significantly user resistance with a 92.31 % reduction. There was no existing literature which examined the barriers at several timepoints post implementation, instead at one post implementation timepoint. Bratarchuk and Milkina did indicate that user resistance does alleviate particularly with continued support and system

advocates(Bratarchuk and Milkina, 2021). However, it is important to be aware that many barriers may be encountered in the hypercare stage and will eventually subside as time progressed and users build familiarity with the system. Despite the continued infrastructure maintenance and improvements, system buffering and integration with legacy system challenges still remains at 6 and 3 users reporting issues 9-13 months post implementation. Although the system downtime preventing system access reduced by 90.91 %. This data indicates that user knowledge and system familiarisation increase significantly over time as a result of targeted training, supported troubleshooting and procedural guidance. However, technical enhancement remains a critical field to be improved upon. Continued technical support is essential to utilise the EDMS to its greatest potential, and to realise all intended system advantages.

The users also had the opportunity to provide further information on barriers which they were experiencing, in which clear patterns emerged in relation to barriers which were being reported from multiple users. The system interface was reported as 'not user-friendly' in many incidences and reported as difficult to navigate. Users reported having difficulties utilising and scheduling the 'automated review and approval workflows'. Finally, users reporting the documents changing naming convention from an alpha-numeric coding based on department and function, to a completely numerical naming as a barrier to finding documents.

Benefits Associated with the EDMS

There was an analysis completed on the user-reported advantages of the EDMS, which uncovered various key findings related to increased efficiency, accessibility, and workflow transparency and accountability, which is represented in Figure 15. The top two reported advantages identified were increased visibility of a document status within a document workflow, and the reduction of paper required resulting in an improved carbon footprint, which were both reported by 80% of users. Enhanced visibility which reduced bottlenecks was a key finding in the previous literature reviewed (Burtylev *et al.*, 2013; Ragimova *et al.*, 2020; Das *et al.*, 2024).

A new and useful advantage of adopting a EDMS was access to global or affiliate SOPs which was reported by 72.5% of users (n=29). The quick search and instant document retrieval (70%) was

also highly esteemed by 27 users, indicating that the EDMS supported information retrieval and promoted document access across user levels. The ability to access documents and tasks remotely was acknowledged by 60% (n=24) of users, indicating a positive impact on operational flexibility and decentralized work environments. Over half of the participants also acknowledged the reduced usage and storage of paper and physical document storage (52.5%) and automated version tracking and compliance improvements (50%) as promising outcomes, signifying the EDMS's role in streamlining regulatory compliance and document control.

There were additional benefits listed which were less frequently cited, but still important, were benefits such as automated audit trails (n=17/ 42.5%), error reduction and reduced level of unauthorized changes (n=14/ 35%), and increased collaboration (n=14/ 35%). These findings imply that while technical traceability and collaborative functionality are operational, they are either underutilised or not detectable to system users. Controlled access by user permissions (27.5%) and enhanced backup and disaster preparedness (22.5%) received the lowest ratings being reported by 11 and 9 users respectively, possibly signalling that these benefits would not be recognised by certain departments or levels, or that back-end system advantages are not directly visible to users. Overall, the user reported data emphasised that the EDMS has promoted considerable practical and fundamental improvements, particularly in document visibility, accessibility, and sustainability. The insights propose a high level of user-perceived value in functionalities that directly impact daily operational efficiency, while also highlighting areas that may benefit from further user engagement or system refinement.

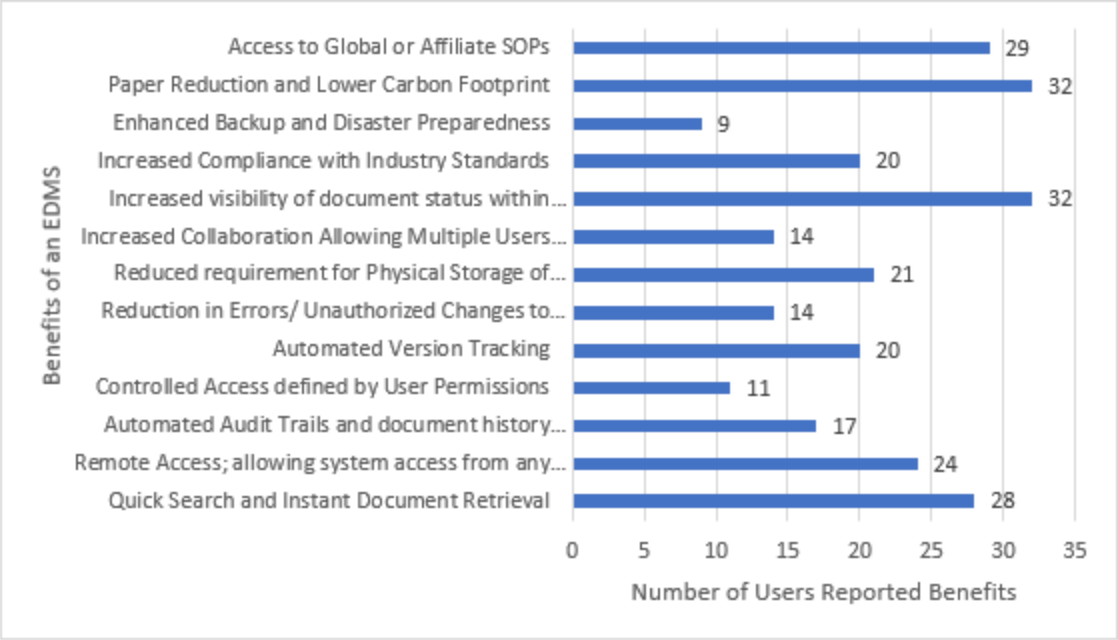

Figure 15 Benefits reported by users of the EDMS

Satisfaction with Ease of Use and System Navigation of the EDMS

There was an evaluation on the user perception in relation to how easy the EDMS system was to use and navigate once trained, which was collected on a five-point Likert scale. The results are displayed below in Figure 16. The results are right skewed in a normal distribution, which reveals that the majority of users held a neutral or moderately positively viewpoint on how easy the system is to use and navigate. 19 respondents (47.5%) selected 3 indicating a neutral view, while 13 respondents (32.5%) selected 4 on the 5-point scale indicating they found it somewhat easy. This finding shadows the information reported in the perceived barriers, stating that the system interface isn't user-friendly, and documents can be difficult to locate. A small proportion (7.5 %, n= 3) selected the prime selection of 5, demonstrating that don't find the system challenging to navigate. In the other hand, a section of respondents reported a more difficult (10%, n= 4) to very difficult (2.5%, n= 1) user experience when navigating the system. This implies that the EDMS, was not found to be fundamentally challenging however there is certainly the opportunity to improve the system interface and increase system training and support to elevate users' satisfaction and achieve increased usability reports. The neutrally skewed data may suggest a level of transitional uncertainty in fully adjusting to the electronic system, and the digitalised workflows.

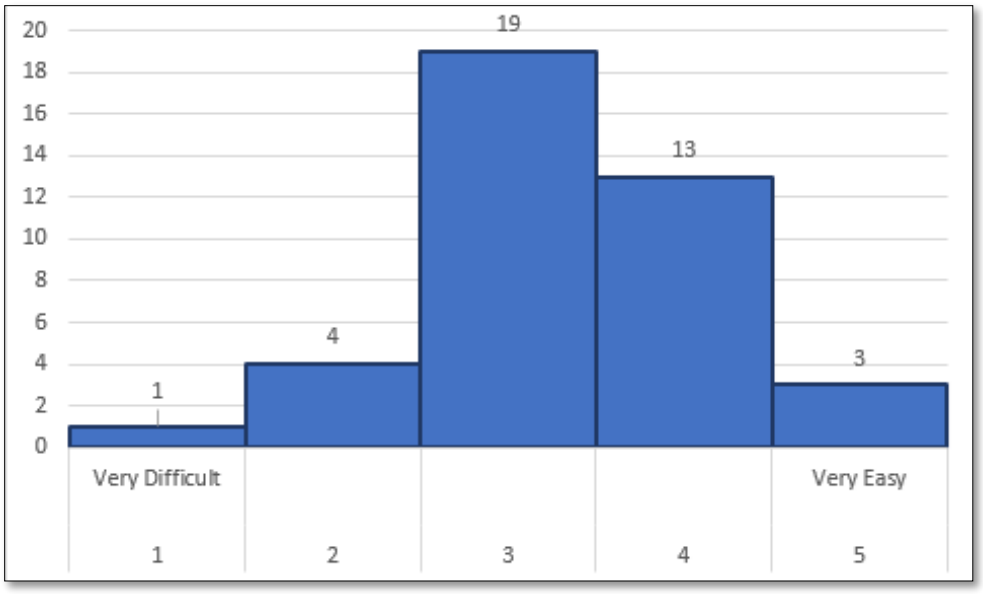

Figure 16 Chart displaying user perspective on how easy the EDMS system is to use and navigate

Perceived User Efficiency of the EDMS

The efficiency was queried in order to obtain the user-perceived efficiency outcomes, following the switch to the EDMS. As per Figure 17, the results confirm that there was a positive trend in this data. Out of the sample size of 40, 65% reported an increase in efficiency with the implementation of the new system with 47.5% (n=19) indicating slightly increased efficiency, and 17.5% reporting a significant increase. On the contrary, only 8 users (20%) stated a decrease in efficiency, with a large proportion of this 15% (n=6) claiming a slightly reduced efficiency. The remaining 15% (n=6) of users felt the system had no impact on efficiency. These finding suggest that the response to the implementation of the EDMS in the main, has been favourable, with an overall positive return on efficiency levels. The impact could certainly not be defined as transformative, but a moderate positive shift has definitely been identified. The data outlined in Figure 17, highlights the users' recognition that this system can increase efficiency, but further enhancements is required to achieve more significant efficacy level payoffs.

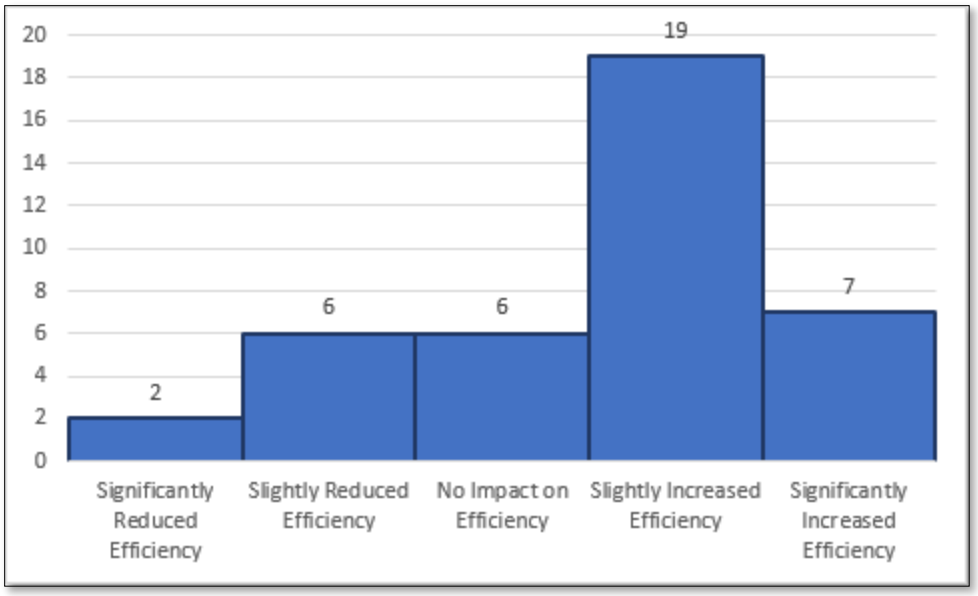

Figure 17 Bar Chart outlining the perceived user efficiency of the EDMS

Overall Satisfaction of the EDMS

The overall satisfaction appraisal perceived by users is represented in Figure 18, which was based on the overall combination of efficiency, advantages, function and improvements required. This trend represents a primarily optimistic trend in relation to overall satisfaction levels. 65% of the 40 respondents reported satisfaction with the EDMS system, which comprised if the majority (60%, n= 24) of respondents confirming they were somewhat satisfied, and 5% (n=2) confirming they were very satisfied. This above average skewed data is a common trend across the user-perceived data reported. This indicates that the system has promising functionality, however users require continued support, alongside system interface improvements to progress user experience to optimal levels.

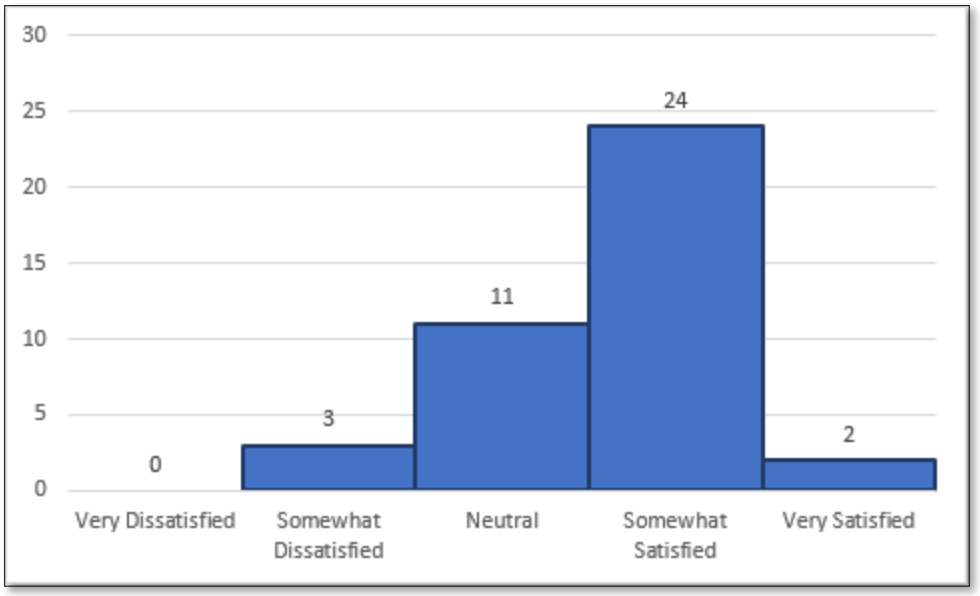

Figure 18 Overall satisfaction reported by users of the EDMS

4.5 Recommendations for Improving the Implementation and User Experience of the EDMS

As with the transfer to any new digitalised system, it is imperative to have robust supports in place to ensure the transition is a smooth as possible. Users were asked to confirm improvements required and provide further suggested improvements on how to enhance the roll-out process. Overall, 39 users (97.5%) selected improvements required, with only one user citing that there were no improvements required as the implementation went smoothy.

As displayed in Figure 19, the most common improvement required was more comprehensive training for users with 75% of users (n=30) citing this, which stresses the requirement for a structured, and comprehensible training programme which tailors to the needs of all users. This was perhaps linked with the second improvement required, which was clearer documentation and user guides (n=21, 52.5%) to support the training plan, and system usage in the long-term. Improved technical support during the roll-out was reported by 19 users (47.5%). Other improvements required relate to implementation preparation with improved customization to better fit work processes, increased system testing prior to launch and increased communication relating to the deployment were cited by 16, 15 and 13 users respectively. These items replicate

the importance of system readiness, and flexibility to integrate with existing processes and documents in use on site in the real-world operational setting.

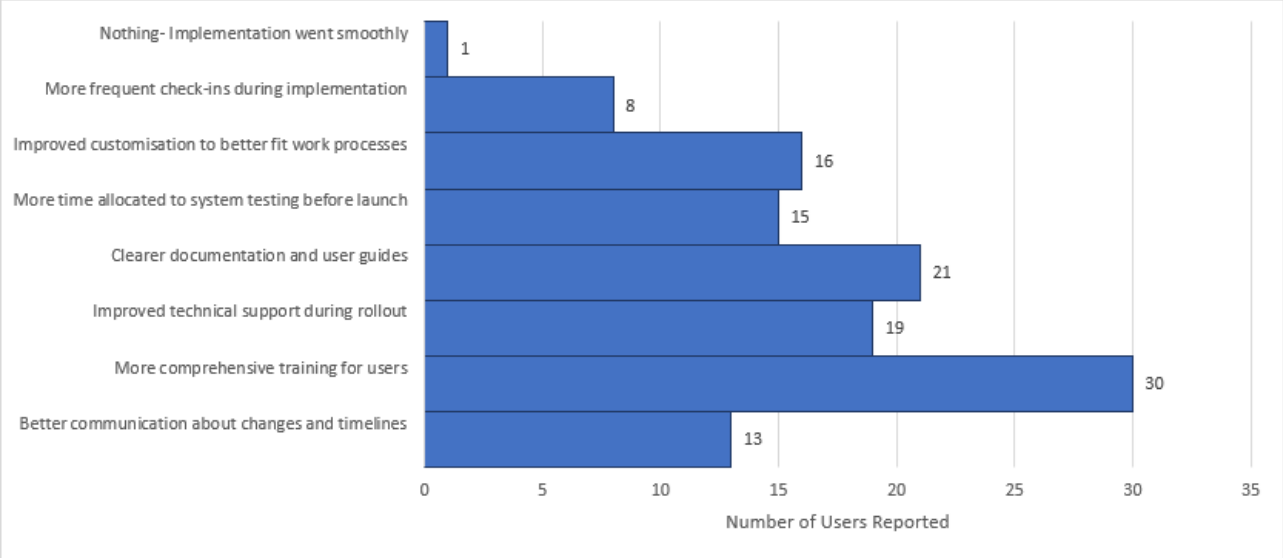

Figure 19 Improvements suggested by users during the roll-out and implementation of the EDMS

Respondents were provided with the opportunity to give open-ended feedback on how to improve the EDMS system overall, in which 36 users provided actionable guidance, and 1 user provided a positive statement expressing satisfaction with the system. The user which provided the positive commendation of the system uses it on a 'daily basis' and feels the EDMS is 'much more efficient than the old SOP update process'.

After a qualitative thematic analysis was performed there was 57 evident enhancements identified, as reported by the 40 users, which were coded and categorised as outlined below. Training and onboarding were the most common recommendation raised, which was cited by 42.5% (n=17) respondents. The need for more simplified, task specific training was highlighted, with the addition of the following aids as called out by respondents: 'Step-by-step guides', 'Interactive Role-Based Training Modules' and 'increased 1:1 support for initial tasks'. This finding aligns with the existing literature reviewed which underscored the importance of tailored training in the successful integration of EDMS in industry (Sternad *et al.*, 2023).

It was recognised that the system usability and design were not user-friendly by 13 users (32.5%), causing issues while users were navigating the system. The specific issues raised was an excess

of widget dashboard views, inconsistent workflows, difficulty accessing user feedback, and workflow challenges. 8 respondents highlighted technical and performance issues which included extended system loading time, and errors in document formatting and appearance when viewing on the platform. This can increase user frustration with the EDMS and create a barrier of trust with the system. Improved job aids were called out by 7 users to be improved to align with the enhanced training approach. Document Search and classification was highlighted as an area of improvement by improving document numbering and classification, only displaying the effective version of a document when searching and improve search functionality to improve document retrieval.

These insights provide numerous actionable proposals to improve system deployment, which not only apply to EDMS systems, but also the digitalisation of other systems across manufacturing industries. User Training Enhancement would be a primary recommendation which could include a training course which includes task-based training as the user needs of the EDMS are so varied. An interactive learning platform would be invaluable, and continued refresher training sessions post-implementation to further system knowledge as familiarity increases. Enhanced continued support and simplified task specific step action guides would be a valuable tool to support users during EDMS implementation. To address the system usability challenges and to improve the interface design it is recommended to complete user-centred design enhancements.

4.6 Discussion Conclusion

In conclusion, the findings of the discussion based on the literature review and data obtained satisfies all study objectives and the primary research question. The existing literature suggests that an EDMS is a more efficient system, which carries many benefits compared to a manual or paper-based alternative, in both the pharmaceutical industry and broader industry research. As per the data analysis completed in this study the adoption of and EDMS is likely to increase efficiency, simplify the document lifecycle and increase overall control and visibility of documents across the document process lifecycle. These findings were also reflected in the user perspective questionnaire, which users also highlighted many benefits of the system. There were also significant barriers identified which were most prevalent during the immediate stage after EDMS deployment, however they did subside as time progressed. There was associated

recommendations raised by the users for implementation and overall system usage which, if adopted, would further strengthen an EDMS's efficiencies and advantages. In summary, the findings conclude that an EDMS can be extremely advantageous for an organisation to adopt to maximise efficiency of all document management resources, however continued work is required to enhance the system and support users to ensure all needs are met.

Chapter 5

Conclusion and Recommendations

5.1 Research Summary

This research aimed to investigate of the implementation of an EDMS on an Oral Solid Dose Manufacturing Site in Ireland and its effect on system performance indicators and user perspectives. All four objectives of this research were met. Objective one was to outline the role and importance of a document management system in the pharmaceutical industry, which was extensively detailed during the secondary research in chapter 2. Objective two was to establish the relevant performance indicators and methods that can effectively measure the performance of a document management system, was explored through the existing literature completed and is detailed throughout chapter 2. Suitable methods and indicators were utilised in the methodology of this research. Objective three to identify the potential benefits or limitations of implementing an EDMS in comparison to a ManualDMS, were detailed in the primary data analysis and discussion of this research and aligned with the secondary research completed. Objective four to explore how the organisation adapts to the new system, including user experience, system implementation, user satisfaction and system improvement recommendations, was answered by the primary data collected in the user perspective study. The research hypothesis statement that 'that the improved functionality of the EDMS, compared to the a ManualDMS, will result in an improvement on the document management system performance indicators' was confirmed to be true as document cycle time decreased, and the DMS process was streamlined.

To collect primary data, a dual approach was adopted to collect empirical system performance data and secondly, a survey questionnaire was utilised to collect user perspectives and insights. Collecting both quantitative and qualitative information, the survey questionnaire was completed by 40 OSD manufacturing site employees, selected to offer perspectives and insights from those who utilise the EDMS system daily. The key findings from this research included, that the implementation of the EDMS considerably streamlined the document management process

by removing non-value add steps and duplication of work. The average document cycle time reduced by 19.6% post-implementation of the EMDS when compared to the ManualDMS. This improvement in total cycle time, is coupled with the 46% (10.92 day) reduction in time required to review and approve documentation.

The user perspectives questionnaire demonstrated a keen inclination towards the EDMS due to the perceived advantages, efficiency and overall autonomy of tasks; however, the opportunity to further improve EDMS implementation and overall system still remain. The data analysis from the questionnaire highlighted some key advantages of the EDMS reported by users, which included increased visibility of document and workflow status (80%), reduce carbon footprint by reduction of paper (80%), and access to affiliate documents from across the organisational network (72.5%). The perceived efficiency of the EDMS system was positively skewed which aligned with the empirical data analysis, and previous research completed.

However, the questionnaire confirmed that the EDMS implementation involved significant barriers, including difficulty learning new system (92.5%), user resistance (65%) and digital literacy challenges (52.5%). Therefore, insightful recommendations were provided relating to approaches to improve the future deployment and overall user satisfaction with EDMSs, which related to training, supporting documents and system interface enhancement.

5.2 Relevance of the Study

The relevance of this study is based on the case study investigation on an operational OSD manufacturing site, which experienced the deployment of an EDMS in relatively recent period. Having reviewed existing literature, there was limited research on EDMS implementation in the pharmaceutical industry. Therefore, this research study performed on an operational manufacturing site would provide invaluable findings to the industry. As lean processing techniques are being applied across all pharmaceutical processes, the findings related to system efficiency, process stages and process mapping provide will be invaluable for experts in this field.

As this research investigation was case study investigation, a comprehensive investigation was designed as the researcher had access to information, participants and system knowledge. A

strength in this research remains in the review of the combination of numerical system performance indicators alongside the user perspective survey questionnaire insights.

The respondents involved in this research, are active users of the EDMS system, and utilise it regularly to complete documentation tasks. The collection of the user insights provides vital real-world insights on the EDMS system performance and useability. The omissions and recommendations from previous literature was reviewed rigorously and applied within the methodology of this research.

The EDMS enhancement recommendations from this research have the capability to advise pharmaceutical companies, and system developers in relation to the current user experience and potential recommendations and improvements, which would ultimately enhance the EDMS system implementation and process. In emphasizing the practical impacts of an EDMS, this research not only develops current literature available, but also extends actionable insights which can influence regulation, strength industry norms, elevate system enhancements and EDMS deployment practices.

5.3 Limitations of the Study

Although this study raises valuable observations into the into the system performance and user perspectives of the EDMS, within an OSD manufacturing site in Ireland, there are several limitations which must be noted.

To start, the research study was centred on the EDMS implementation on one manufacturing site, which allowed great depth in analysis however it may restrict the ability to generalise the conclusions across the wider pharmaceutical network. The user perspectives of the EDMS implementation and performance at this manufacturing site may have been prejudiced, due to the specific deployment experience. It is difficult to conclude that that findings are exactly representative of the experiences of all organizations, although all findings did align with existing literature.

In addition, although empirical quantitative data and metrics was collected focusing on effectiveness, cycle time and process streamline. However, other data categories could have

been evaluated. To authenticate more tangible outcomes of the EDMS such as cost and paper usage.

The research did assess data at two time points while allowing sufficient time for EDMS familiarisation before collecting post-implementation data. However, the long-term impact and performance of these systems on a document management process, suggesting the need for a longitudinal study in the future. The limitations outlined the importance of deciphering results in relation to the scope of the study and highlight opportunities for future research to reinforce findings and insights from this research.

5.4 Recommendations for Future Research

For further research into the area of EDMS deployment and performance, it would strengthen findings to broaden the scope of the sample population. A suggested approach would be to encompass multiple pharmaceutical organisations to assess system performance, user experience and perspectives. The sample size could include all categories of pharmaceutical organizations including research and development facilities, quality laboratories, distribution centres and administration offices. This increase in diversity could extend across geographical regions.

Operating a longitudinal study design to monitor and assess the progressive nature of the EDMS and continued system enhancements. Longitudinal data collected across multiple timepoints, proposing a comprehensive outlook on trends, system and process advancements, and potential declines in certain aspects of performance or satisfaction.

Lastly, given the widespread evolution of artificial intelligence, further investigation could include how emerging technologies could be adapted to improve system functionality.

The adoption of these valued recommendations, prospective studies can more systematically address the current thesis study ‘s limitations and offer valued findings and insights to support Electronic Document Management System implementation and performance within the pharmaceutical industry.

Chapter 6

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Appendices

Appendix A

Questionnaire: Survey

* This indicates a required question

1. Please enter your first name.

   Your answer

   _____

2. What department are you a member of? *

   Your answer

   _____

3. How many years' experience do you have in the document control process in any capacity? *

   ◯ Less than 1 year
   ◯ 1-2 years
   ◯ 2-4 Years
   ◯ More than 4 years

4. Have you been involved in a manual document control process, in any capacity, before the electronic system implementation of the D2 Documentum system in April 2024? *

   ◯ Yes
   ◯ No

5. How often do you utilize the D2 Documentum or Reader System for any document related activities? *

   ◯ Multiple times a day
   ◯ Once a day
   ◯ A few times a week
   ◯ Once a week
   ◯ A few times a month
   ◯ Rarely (less than once a month)

○ Never

6. What tasks do you use the D2 Documentum system or Reader system for? (please tick all that apply) *

- ◯ Accessing/ reading documents
- ◯ Raising change requests and updating documents
- ◯ Reviewing documents during update
- ◯ Approving documents during update
- ◯ Withdrawing documents
- ◯ Accessing document templates
- ◯ Document co-ordinator tasks
- ◯ Retrieving logbooks, forms or BMRs
- ◯ Technical Report Review and Approval (Not SOP or Form Documents)
- ◯ To view global or affiliate site SOPs
- ◯ To generate reports or metrics on document related activities
- ◯ Other: _____

7. Within the D2 Documentum System, what user role best describes your most frequent roles within the system? Click all that apply. *

- ◯ Document System Co-ordinator
- ◯ Read Access Only
- ◯ Document Creator/ Author (SOP and Form Update Only)
- ◯ Report Creator/ Author (APQR/ Technical/ Validation/ Regulatory)
- ◯ Reviewer
- ◯ Approver
- ◯ Other: _____

8. Please tick any barriers or disadvantages you may have experienced personally, while using the new D2 Documentum system? Tick any barrier experienced and the time period at which they were experienced. (please tick barriers that apply)

	0-3 Months Post Implementation (Apr – Jun 24)	3-6 Months Post Implementation (Jul – Sep 24)	6-9 Months Post Implementation (Oct – Dec 24)	9-13 Months Post Implementation (Jan 25– Present)
Difficulty Learning Functionality of the New System	☐	☐	☐	☐
Digital Literacy Challenges for personnel with limited IT Skills	☐	☐	☐	☐
User Resistance Directly or from Other Team Members	☐	☐	☐	☐
System Downtime to Perform Updates	☐	☐	☐	☐
Accidental Deletion or Withdrawal of Documents	☐	☐	☐	☐
Restricted Access to System due to Limited PC/ Internet Access- Nature of Role	☐	☐	☐	☐
Restricted Access to System due to Internet Access Issues	☐	☐	☐	☐
System Buffering Causing Workflow Delays	☐	☐	☐	☐
Issue Integrating with Legacy Systems	☐	☐	☐	☐

9. Was there any additional barriers, challenges or disadvantages which you or someone on your team experienced using the new D2 Documentum system, which wasn't mentioned above? Please outline below.

Your answer

_____

10. What benefits have you experienced using the new D2 system? (tick all that apply) *

- ◯ Quick Search and Instant Document Retrieval
- ◯ Remote Access; allowing system access from any location
- ◯ Automated Audit Trails and document history tracking
- ◯ Controlled Access defined by User Permissions
- ◯ Automated Version Tracking
- ◯ Reduction in Errors/ Unauthorized Changes to documents
- ◯ Reduced requirement for Physical Storage of Documents
- ◯ Increased Collaboration Allowing Multiple Users to Work On Documents Simultaneously
- ◯ Increased visibility of document status within workflow
- ◯ Increased Compliance with Industry Standards
- ◯ Enhanced Backup and Disaster Preparedness
- ◯ Paper Reduction and Lower Carbon Footprint
- ◯ Access to Global or Affiliate SOPs
- ◯ Other: _____

11. Were there any additional benefits which you or someone on your team experienced using the new D2 Documentum system, which wasn't mentioned above? Please outline below.

Your answer

_____

12. On a scale of 1 to 5, how easy is the D2 documentum system to use and navigate, once trained? *

Very Difficult	1	2	3	4	5	Very Easy
	◯	◯	◯	◯	◯	

13. On a scale of 1 to 5, how easy is it to find the documents you need within the D2 documentum system?

Very Difficult	1	2	3	4	5	Very Easy
	◯	◯	◯	◯	◯	

14. How would you rate that the D2 documentum system has affected your efficiency in relation to document management tasks? *

- ◯ Significantly Reduced Efficiency
- ◯ Slightly Reduced Efficiency
- ◯ No Impact on Efficiency
- ◯ Slightly Increased Efficiency
- ◯ Significantly Increased Efficiency

15. Overall, how satisfied are you with the D2 documentum system? *

- ◯ Very Dissatisfied
- ◯ Somewhat Dissatisfied
- ◯ Neutral
- ◯ Somewhat Satisfied
- ◯ Very Satisfied

16. Overall, what improvements could be made during the roll-out and implementation of the D2 documentum system? *

- ◯ Better communication about changes and timelines
- ◯ More comprehensive training for users
- ◯ Improved technical support during rollout
- ◯ Clearer documentation and user guides
- ◯ More time allocated to system testing before launch
- ◯ Improved customisation to better fit work processes
- ◯ More frequent check-ins during implementation
- ◯ Nothing- Implementation went smoothly
- ◯ Other:

17. Overall, what improvements could be made to the D2 documentum system to improve user experience? *

Your answer

_____

Appendix B

Ethics Application and Declaration Form

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: An investigation of the introduction of an Electronic Document Management System (EDMS) to an OSD manufacturing site, its impact on site performance indicators and user perspectives.

RESEARCHER'S NAME: Amie Lynch

PROGRAMME OF STUDY: Masters (MSc) in Pharmaceutical Business and Technology

SUPERVISOR'S NAME: Rex Coghlan

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: Amie Lynch

DATE: 04/03/2025

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

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☑

SUPERVISOR SIGNATURE: R Coghlan

DATE: 31/03/2025

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

The aim of this research project is to evaluate the impact of implementing an Electronic Document Management System (EDMS) on key performance indicators and site functionality including document control efficiency, CAPA implementation and APQR completion. This is a case study in an oral solid dose manufacturing site, to assess the impact of changing the paper-based document control system to an electronic document control system. There is a shift in the pharmaceutical industry, towards digitalisation of processed, to enable greater visibility and accessibility however there is limited research to assess the wider impact of this and the user perspectives.

The four key objectives of this research project are:

1. To outline the role and importance of a document management system in the pharmaceutical industry.
2. To establish the relevant Key Performance Indicators that can effectively measure the performance of the business before and after the implementation of the EDMS, facilitating the comprehensive evaluation of its impact.
3. To identify if there are potential benefits of implementing an Electronic Document Management System (EDMS) in comparison to an off-line hardcopy document management system.
4. To explore how the organisation adapts to the new system, including user experience, training, and user satisfaction.

The primary research question of this research is does the type of document management system in place, which can be identified as variable Y, have any effect on the performance of the site, referred to as variable X.

1.2 Research methodology

3-b Primary Research Strategy

The research will be completed in the form of a case study. Key Performance Indicators which can be used to assess the functionality and effectiveness of the site will be compiled and reviewed. This data will be collected in a case study for a representative period of three months before the EDMS was implementation and after the implementation. The document management system is a categorical variable, and the site metric influential factor is a numerical variable.

To evaluate the user perspectives, there will also be a questionnaire which will consist of primarily closed-ended questions but will also contain open-ended questions which will facilitate the collection of both quantitative and qualitative data. The questionnaire process will be completed utilising an online platform, which will ensure anonymity and accessibility for all contributors. All active users of the document system will be approached to complete the questionnaire, to ensure a representative cohort from each department contribute. This inclusive invitation ensures a representative cohort of the workforce, which allows for a comprehensive analysis of user experience with the EDMS, across the various disciplines on site.

The quantitative data obtained from the KPI information will be statistically analysed to assess for correlation to the type of document system in place. There will also be analysis conducted to establish the mean; median and standard deviation for each metric to compare and contrast the two time periods to assess if the document system in place had any effect.

Data analysis will be completed using both quantitative and qualitative methods. For closed-ended questions used in the questionnaire a Likert Scale will be used to obtain quantitative data. This will be statistically analysed using descriptive statistics. This will result in measures such as mean; median and standard deviation being calculated to conclude a result for each question. The open-ended questions will be analysed using thematic analysis to evaluate the qualitative data. The answer provided to the open-ended questions will be coded and grouped into themes.

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	Yes/ No	
Research into politically and/or racially/ethnically and/or commercially sensitive areas	Yes No	
Sensitive, personal, professional or corporate issues	Yes No	

RESEARCH PROCEDURES

Does the research proposal involve:

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

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English Yes No

Does your research group include any of the following vulnerable groups Yes 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

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

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

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study

The participant profile of the cohort of personnel who will be offered the opportunity to complete the user perspectives questionnaire, are the group of personnel which have a user role within the Documentum D2 system. This may include a role in accessing, coordinating, reviewing, approving, or controlling documents within the document management system.

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

The primary researcher is currently working in the identified OSD manufacturing site. The subject participants will be contacted via email, from the email mailbox of the student email of the primary researcher.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

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

The PIL is attached.

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**

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

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

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/).

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

Signed consent forms, participant information leaflets and completed interview questionnaires will be retained on a password-protected, desktop hard drive to which only the primary researcher, Amie Lynch, has access to. Any non-anonymised data in the form of the signed consent form and participant information leaflet will be stored on a password-protected, desktop hard drive to which only the primary researcher has access. This will be held until the exam board confirms the results of this dissertation project until after my degree has been conferred. After such date, this information will be erased. Under freedom of information legalisation, you are entitled to access the information you have provided at any time.

It will be required for the anonymised questionnaires to be submitted in the primary research raw data section of the final research submission. This will be viewed as required for the purpose of research project grading by the research supervisor and a secondary result verifier.

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?

Yes (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 No

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**

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

SECTION 9: DOCUMENT CHECKLIST

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

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

9.1 Participant Information Letter (PIL) for participant (Yes) N/A

9.2 Informed Consent Form (ICF) for participant (Yes) N/A

9.3 Interview Questionnaire/survey for interviewees/focus groups etc *(can be in draft form)* (Yes) N/A

9.4 Any other documents e.g. Non-Disclosure Agreement Yes (N/A)

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

For Student:

STUDENT SIGNATURE: *Amie Lynch*

DATE: 04/03/2025

SECTION 10: APPENDIX

Appendix 1: Participant Information Leaflet (PIL)

PARTICIPANT INFORMATION LETTER

RESEARCH TITLE: An Investigation into the Introduction of an EDMS to an OSD Manufacturing Site, an Evaluation of System Performance Indicators and User Perspectives.

I would like to invite you to take part in a research study. Before you decide to participate you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

I am Amie Lynch, and I am a master's student in the course Masters (MSc) in Pharmaceutical Business and Technology with Griffith College Dublin. I am completing a research project as part of my completion of the level 9 master's degree. The aim of this research project is to evaluate the impact of implementing an Electronic Document Management System (EDMS) on key performance indicators and to gain user perspectives on the system.

The document control system, Documentum D2, has been implemented on a OSD manufacturing site. There has been an increased movement across the pharmaceutical industry to transition to electronic online systems, rather than paper-based systems. This study is being completed to evaluate the impact, potential benefits and user perspectives of implementing an Electronic Document Management System (EDMS) on an Oral Solid Dose manufacturing site. The research

project is a 40-credit requirement of the Level 9 master's course (100 credit total) which I am completing.

WHAT WOULD TAKING PART INVOLVE?

If you choose to participate in this research project, there will be an interview questionnaire you will be asked to complete. This interview questionnaire will collect a range of information in relation to the use of the Documentum D2 system, in comparison to the previous offline paper-based system. The questionnaire will collect information in relation to potential benefits, barriers, and user perspectives from using the Documentum D2 system. As part of this questionnaire, your identity will be completely anonymous. The company which you work for will be kept completely anonymous, and no company sensitive information will be collected as part of this questionnaire.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

If you have been asked to take part in this interview questionnaire, you have been identified as part of a cohort of personnel which have a specialised role within the Documentum D2 system. This may include your role in accessing, coordinating, reviewing, approving, and controlling the document management system.

DO YOU HAVE TO TAKE PART?

Participation in this research project by completing this interview questionnaire is completely voluntary. The decision not to participate will have no adverse consequences and consent can be withdrawn at any time. If you need to withdraw consent or participation at any time, please contact Amie Lynch via email *amie.lynch@student.griffith.ie* .

POSSIBLE RISKS AND BENEFITS OF TAKING PART.

There have been no identified risks or benefits of completing this questionnaire.

WILL TAKING PART BE CONFIDENTIAL?

Confidentiality and anonymity for all participants will be of the highest priority throughout the research project. As a participant you will be labelled using a numerical identifier, to which only the primary researcher will have the identifying information. The company to which you work for will be kept completely anonymous throughout this research project, and the research project will not be publicly published after completion. Permission and authorisation from the relevant company officials has been sought prior to collecting any primary data.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms, participant information leaflets and completed interview questionnaires will be retained on a password-protected, desktop hard drive to which only the primary researcher, Amie Lynch, has access to. Any non-anonymised data in the form of the signed consent form and participant information leaflet will be stored on a password-protected, desktop hard drive to which only the primary researcher has access. This will be held until the exam board confirms the results of this dissertation project until after my degree has been conferred. After such date, this information will be erased. Under freedom of information legalisation, you are entitled to access the information you have provided at any time.'

It will be required for the anonymised questionnaires to be submitted in the primary research raw data section of the final research submission. This will be viewed as required for the purpose of research project grading by the research supervisor and a secondary result verifier.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

This research project is being carried out for the purpose of the fulfilling the requirements of the Masters (MSc) in Pharmaceutical Business and Technology degree with Griffith College Dublin. The research will be submitted to Griffith College Dublin exam board for evaluation and appraisal for the purpose of grading. Griffith College Dublin may upload this dissertation research projects in the college library, at their discretion.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Please contact the Primary Researcher if you have any further questions.

Name: Amie Lynch

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SECTION 10: APPENDIX

Appendix 2: Questionnaire

* This indicates a required question

1. Please enter your first name.

   Your answer

   _____

2. What department are you a member of? *

   Your answer

   _____

3. How many years' experience do you have in the document control process in any capacity? *

   - ◯ Less than 1 year
   - ◯ 1-2 years
   - ◯ 2-4 Years
   - ◯ More than 4 years

4. Have you been involved in a manual document control process, in any capacity, before the electronic system implementation of the D2 Documentum system in April 2024? *

   - ◯ Yes
   - ◯ No

5. How often do you utilize the D2 Documentum or Reader System for any document related activities? *

   - ◯ Multiple times a day
   - ◯ Once a day
   - ◯ A few times a week
   - ◯ Once a week
   - ◯ A few times a month
   - ◯ Rarely (less than once a month)
   - ◯ Never

6. What tasks do you use the D2 Documentum system or Reader system for? (please tick all that apply) *

- ◯ Accessing/ reading documents
- ◯ Raising change requests and updating documents
- ◯ Reviewing documents during update
- ◯ Approving documents during update
- ◯ Withdrawing documents
- ◯ Accessing document templates
- ◯ Document co-ordinator tasks
- ◯ Retrieving logbooks, forms or BMRs
- ◯ Technical Report Review and Approval (Not SOP or Form Documents)
- ◯ To view global or affiliate site SOPs
- ◯ To generate reports or metrics on document related activities
- ◯ Other: _____

7. Within the D2 Documentum System, what user role best describes your most frequent roles within the system? Click all that apply. *

- ◯ Document System Co-ordinator
- ◯ Read Access Only
- ◯ Document Creator/ Author (SOP and Form Update Only)
- ◯ Report Creator/ Author (APQR/ Technical/ Validation/ Regulatory)
- ◯ Reviewer
- ◯ Approver
- ◯ Other: _____

8. Please tick any barriers or disadvantages you may have experienced personally, while using the new D2 Documentum system? Tick any barrier experienced and the time period at which they were experienced. (please tick barriers that apply)

	0-3 Months Post Implementation (Apr – Jun 24)	3-6 Months Post Implementation (Jul – Sep 24)	6-9 Months Post Implementation (Oct – Dec 24)	9-13 Months Post Implementation (Jan 25– Present)
Difficulty Learning Functionality of the New System	☐	☐	☐	☐
Digital Literacy Challenges for personnel with limited IT Skills	☐	☐	☐	☐
User Resistance Directly or from Other Team Members	☐	☐	☐	☐
System Downtime to Perform Updates	☐	☐	☐	☐
Accidental Deletion or Withdrawal of Documents	☐	☐	☐	☐
Restricted Access to System due to Limited PC/ Internet Access- Nature of Role	☐	☐	☐	☐
Restricted Access to System due to Internet Access Issues	☐	☐	☐	☐
System Buffering Causing Workflow Delays	☐	☐	☐	☐
Issue Integrating with Legacy Systems	☐	☐	☐	☐

9. Was there any additional barriers, challenges or disadvantages which you or someone on your team experienced using the new D2 Documentum system, which wasn't mentioned above? Please outline below.

Your answer

_____

10. What benefits have you experienced using the new D2 system? (tick all that apply) *

- ◯ Quick Search and Instant Document Retrieval
- ◯ Remote Access; allowing system access from any location
- ◯ Automated Audit Trails and document history tracking
- ◯ Controlled Access defined by User Permissions
- ◯ Automated Version Tracking
- ◯ Reduction in Errors/ Unauthorized Changes to documents
- ◯ Reduced requirement for Physical Storage of Documents
- ◯ Increased Collaboration Allowing Multiple Users to Work On Documents Simultaneously
- ◯ Increased visibility of document status within workflow
- ◯ Increased Compliance with Industry Standards
- ◯ Enhanced Backup and Disaster Preparedness
- ◯ Paper Reduction and Lower Carbon Footprint
- ◯ Access to Global or Affiliate SOPs
- ◯ Other: _____

11. Were there any additional benefits which you or someone on your team experienced using the new D2 Documentum system, which wasn't mentioned above? Please outline below.

Your answer

_____

12. On a scale of 1 to 5, how easy is the D2 documentum system to use and navigate, once trained? *

Very Difficult	1	2	3	4	5	Very Easy
	◯	◯	◯	◯	◯	

13. On a scale of 1 to 5, how easy is it to find the documents you need within the D2 documentum system?

Very Difficult	1	2	3	4	5	Very Easy
	◯	◯	◯	◯	◯	

14. How would you rate that the D2 documentum system has affected your efficiency in relation to document management tasks? *

- ◯ Significantly Reduced Efficiency
- ◯ Slightly Reduced Efficiency
- ◯ No Impact on Efficiency
- ◯ Slightly Increased Efficiency
- ◯ Significantly Increased Efficiency

15. Overall, how satisfied are you with the D2 documentum system? *

- ◯ Very Dissatisfied
- ◯ Somewhat Dissatisfied
- ◯ Neutral
- ◯ Somewhat Satisfied
- ◯ Very Satisfied

16. Overall, what improvements could be made during the roll-out and implementation of the D2 documentum system? *

- ◯ Better communication about changes and timelines
- ◯ More comprehensive training for users
- ◯ Improved technical support during rollout
- ◯ Clearer documentation and user guides
- ◯ More time allocated to system testing before launch
- ◯ Improved customisation to better fit work processes
- ◯ More frequent check-ins during implementation
- ◯ Nothing- Implementation went smoothly
- ◯ Other:

17. Overall, what improvements could be made to the D2 documentum system to improve user experience? *

Your answer

_____