# *The Role of Digital Transformation in Pharmaceutical Manufacturing Technology Optimisation With a Focus on Critical Process Parameters (CPP) In India*

GRIFFITH COLLEGE DUBLIN

**A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF**

MSc in Pharmaceutical Business and Technology (QQI)

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# CANDIDATE DECLARATION

I hereby declare that the dissertation entitled: **"THE ROLE OF DIGITAL TRANSFORMATION IN PHARMACEUTICAL MANUFACTURING TECHNOLOGY OPTIMISATION WITH A FOCUS ON CRITICAL PROCESS PARAMETERS (CPP) IN INDIA".**

submitted for the degree of MSc in Pharmaceutical Business and Technology is the result of my own work and where reference is made to the work of others, due acknowledgment is given.

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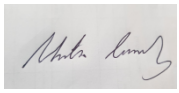
Supervisor signature:  Date: 26/08/2024

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**ASHLY THANKACHAN**

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| | |
|---|---|
| ACTA | Anti-Corruption, Transparency and Accountability |
| AI | Artificial Intelligence |
| AMT | Advanced Manufacturing Technology |
| ANN | Artificial Neural Networks |
| APC | Advanced Process Control |
| API | Active Pharmaceutical Ingredient |
| CADD | Computer Aided Drug Design |
| CDMO | Contract Development Manufacture Organization |
| CFD | Computational Fluid Dynamics |
| CI | Continuous Improvement |
| CMA | Critical Material Attributes |
| COVID 19 | Corona Virus Disease 2019 |
| CPP | Critical Process Parameter |
| CPPS | Cyber-Physical Production Systems |
| CQA | Critical Quality Attributes |
| DAA | Digital Automation Analytics |
| DL | Deep Learning |
| FDA | Food and Drug Administration |
| GCEC | Griffith College Ethics Committee |
| GDPR | General Data Protection Regulation |
| GMP | Good Manufacturing Practices |
| IoT | Internet of Things |
| IT | Information Technology |
| MATLAB | Matrix Laboratory |
| MES | Manufacturing Execution System |
| ML | Machine Learning |
| MPC | Model Predictive Control |
| PAT | Process Analytical Technology |
| PID | Proportional Integral Derivative |
| PSD | Particle Size Distribution |
| QA/QC | Quality Assurance/ Quality Control |
| QbD | Quality by Design |
| QSAR | Quantitative Structure Activity Relationship |
| R&D | Research & Development |
| ReLeaSE | Reinforcement Learning for Structural Evolution |
| RF | Random Forest |
| RFID | Radio-Frequency Identification |
| ROI | Return on Investment |
| RPA | Robotic Process Automation |
| RTR | Real Time Release |
| SME | Small & Medium sized Enterprises |
| SMILES | Simplified Molecular Input Line Entry System |
| TAM | Technology Acceptance Model |
| TPB | Theory of Planned Behaviour |
| US | United States |

| | |
|---|---|
| VR | Virtual Reality |

# Abstract

In this study, the current state of digital transformation in pharmaceutical manufacturing was investigated, focusing on the adoption of advanced digital tools for Critical Process Parameter (CPP) monitoring and control. A qualitative approach using semi-structured interviews with key stakeholders from various pharmaceutical manufacturing organizations, including formulation scientists, regulatory professionals, and digital technology specialists, was employed to gain comprehensive insights into the implementation and impact of these technologies.

Results revealed widespread adoption of digital tools such as Process Analytical Technology (PAT), Artificial Intelligence (AI), Machine Learning (ML), and Internet of Things (IoT) in pharmaceutical manufacturing. These technologies have significantly enhanced real-time monitoring and control of CPPs, improved process efficiency, and strengthened adherence to Quality by Design (QbD) principles. The integration of these advanced technologies has shown promising improvements in product quality and regulatory compliance.

However, the study also identified significant barriers to adoption, including technological challenges, organizational resistance, and regulatory hurdles. These findings highlight the complex landscape of digital transformation in the pharmaceutical industry, where innovation must be balanced with practical implementation challenges and stringent regulatory requirements.

The study emphasizes the need for a strategic approach to digital transformation in pharmaceutical manufacturing. It underscores the importance of addressing technological, organizational, and regulatory barriers to fully realize the benefits of advanced digital tools. These insights provide valuable guidance for pharmaceutical companies, technology providers, and regulators in optimizing the integration of digital technologies to enhance manufacturing processes, ensure product quality, and maintain regulatory compliance in this highly regulated industry.

Keywords: *Digital transformation, CPPs, Artificial Intelligence, Machine learning, pharmaceutical manufacturing*

# 1. Introduction

## 1.1 Introduction to the topic

Digital transformation initiatives have been significantly adopted by global pharmaceutical leaders, considering their potential to streamline and facilitate different operations in the sector, ranging from drug design to commercialisation of the product. The goal of this rapid yet comprehensive shift is to enhance operational efficiency, reduce costs, enhance the quality of the final product, and automate the pre-defined tasks according to the department and the objective of the system being used. The technologies currently used include Artificial Intelligence (AI) and Machine Learning (ML) approaches, cloud computing, Big Data Analytics, Internet of Things (IoT), Virtual Reality (VR), 3D printing technologies, etc, each having the potential to transform operations (Almeman, 2024).

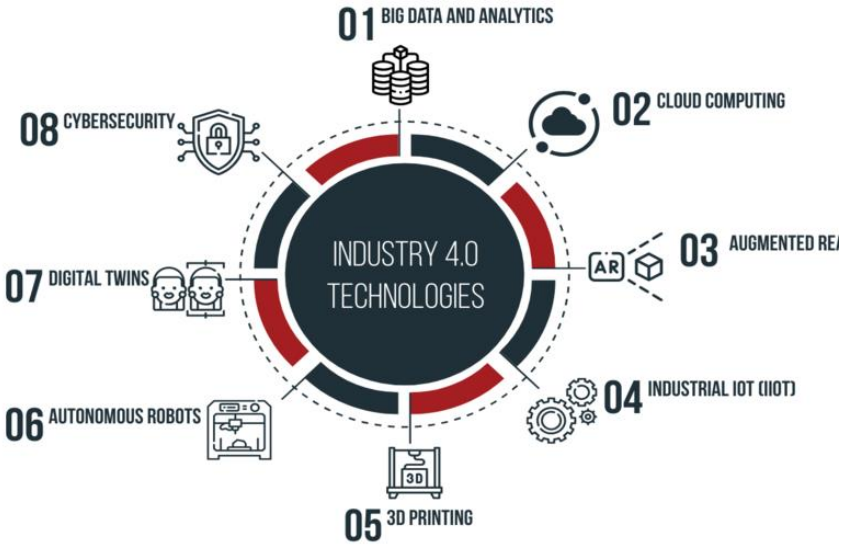


**Figure 1: Industry 4.0 technologies with potential for application in pharmaceutical manufacturing (S-Square, 2023).**

Reports note that the adoption of these technologies can create a 25-40% increase in asset productivity along with a 30-50% increase in labor productivity while bringing down deviations to 40%. For example, Cipla established Digital Automation Analytics (DAA) in 22 sites in India, which has culminated in an increase in data usage to 90% in decision-making, which is a significant shift from the initial values (10%) (Datta, 2023).

Pharmaceutical manufacturing is the central pillar of the pharmaceutical industry and operations, where stringent quality control measures and precise handling of the operations are paramount so as to ensure the quality, safety, and efficacy of the final

drug formulation. Optimising these processes can improve yield while reducing costs and ensuring that precise quality control measures are followed. Critical Process Parameters (CPPs) are process variables that determine the Critical Quality Attributes (CQAs) of the final product and, therefore, vary according to the formulation and manufacturing method used and thus form the deterministic factors in the pharmaceutical formulation (Rantanen and Khinast, 2015).

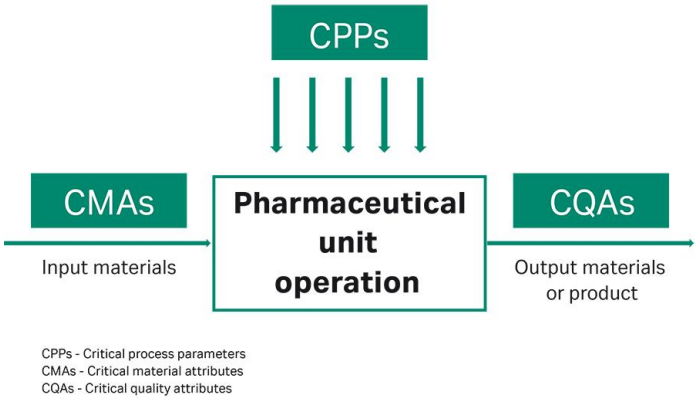


**Figure 2: Relationship between Critical Material Attributes, CPPs and CQAs (Cytiva, 2024).**

Considering the potential of digital technology initiatives such as ML algorithms or predictive analytics, integrating them into the pharmaceutical manufacturing process for optimisation of the same holds prospects. For example, suppose the CPPs are optimised based on the ideal CPP – CQA data, as noted from previous research. In that case, predictive analytics can determine the CQAs beforehand and note down the possibilities of deviations, which can be mitigated accordingly (Vora et al., 2023). AI systems can be used for real-time monitoring, which allows continuous optimisation of the CPPs, while cloud platforms, along with Big Data Analytics, can help with faster data integration and analysis. The benefits include improved process understanding, reduced variability, faster processing, enhanced quality control and regulatory compliance, etc. Thus, digital transformation initiatives can drive continuous innovation and streamline pharmaceutical manufacturing operations (Hole et al., 2021).

## 1.2 Research Issue Definition

The Indian pharmaceutical sector, valued at approximately $50 billion and projected to reach $130 billion by 2030, plays a pivotal role in the global pharmaceutical

landscape (Sengupta, 2024). Known as the "Pharmacy of the World," India significantly contributes to the global supply of generic drugs, exporting 40% of the United States (US) generic demand and supplying 60% of global vaccine production. Despite its robust manufacturing capabilities, with over 670 US Food and Drug Administration (FDA) approved facilities, the sector faces challenges that include regulatory compliance, quality control, and the need for enhanced Research and development investment (Malik, 2024).

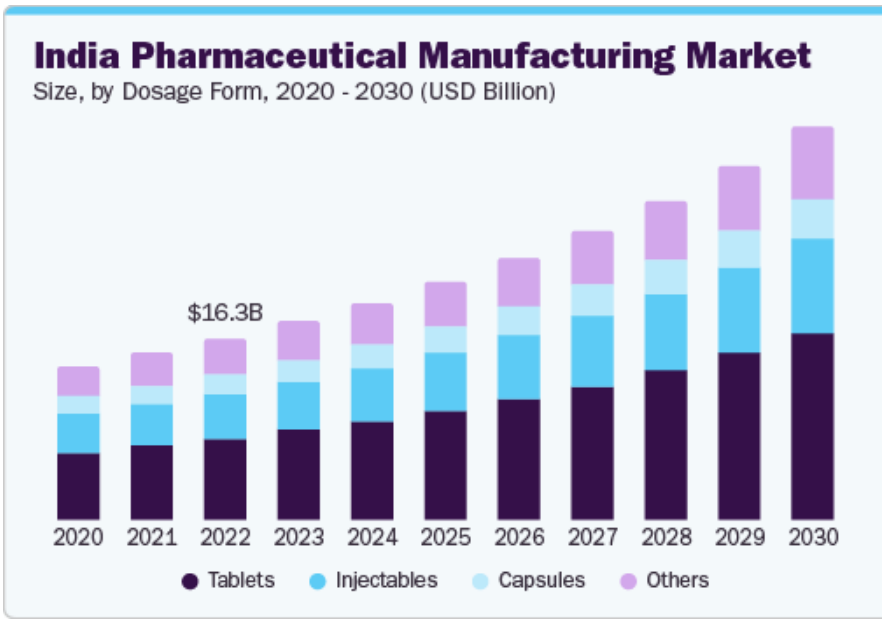


**Figure 3: India Pharmaceutical Manufacturing Market Size, by Dosage Form, 2020 - 2030 (USD Billion)(Grand View Research, 2024)**

CPPs are key variables within pharmaceutical manufacturing processes that, if not properly controlled, can significantly affect the quality of the final product. These parameters, such as temperature, pH, mixing speed, and pressure, are crucial for ensuring consistent product quality, safety, and regulatory compliance. Effective management of CPPs is essential for minimising variability, optimising efficiency, and preventing production failures, which is especially critical in India's high-stakes manufacturing environment (Kim et al., 2021).

The integration of digital technologies holds good opportunities for optimising CPPs in India's pharmaceutical sector. AI and ML technologies analyse vast datasets to optimise manufacturing processes, predict optimal process parameters, and ensure efficient control of CPPs (Cheng et al., 2023). IoT sensors can provide real-time monitoring of CPPs, enhancing the precision of process controls and enabling

immediate adjustments to maintain product standards (Wang et al., 2024). Blockchain Technology offers secure, traceable, and transparent data management systems crucial for regulatory compliance and quality assurance (Afrin and Pathak, 2023). Digital Twin technology utilises virtual replicas of physical manufacturing processes to test and optimise CPP settings in a risk-free environment (Soori et al., 2023).

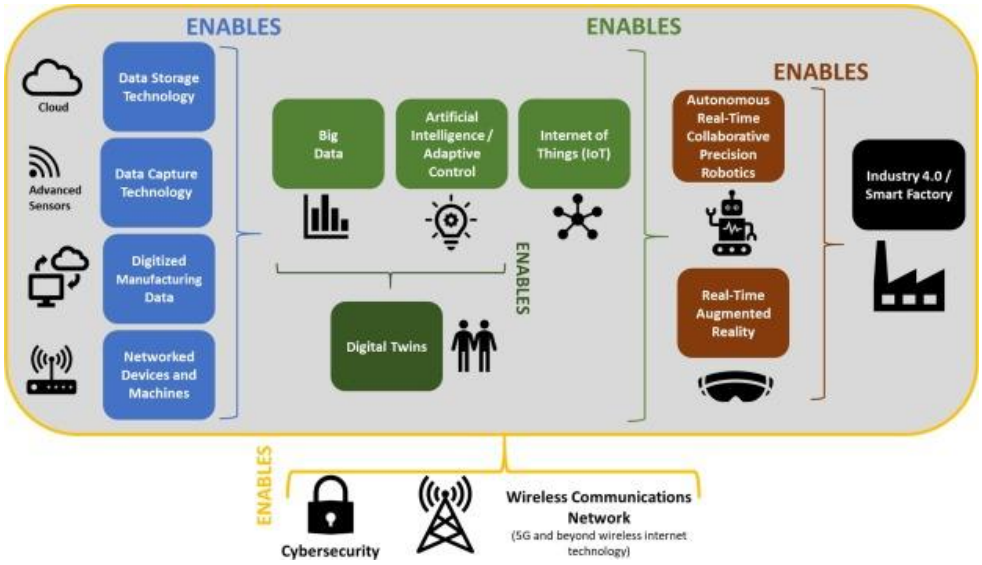


**Figure 4: Application of digital technologies in pharmaceutical manufacturing (Arden et al., 2021).**

## 1.3 Rationale for the Study

Even though the Indian pharmaceutical industry is one of the largest suppliers of generic drugs, the manufacturing sector does hold space for the integration of digital technologies for optimisation. This can help enhance the quality control process and enhance the CQAs to reach the ideal conditions approximately without any deviations in quality and prompt error rectification. Such a proactive advanced step can help pharmaceutical companies stay ahead of the curve and lead amidst the strong competition in the global market. Such an integration can resolve the issues of inefficiencies and variability in manufacturing processes, ruling out the chances of non-compliance and poor product quality. Thus, digital transformation initiatives can play a transformative role by enabling more accurate, consistent, and efficient control of these parameters, thereby addressing the critical need for optimisation of growing domestic and global demands.

The integration of digital technologies such as AI, IoT, and Blockchain into the manufacturing processes, with a particular focus on CPPs, promises substantial improvements across several dimensions. Firstly, **process efficiency** can be

significantly enhanced through the use of AI and machine learning algorithms that predict optimal manufacturing conditions, reduce downtime, and streamline operations. Secondly, **product quality** can see marked improvements due to the precise monitoring and control of CPPs facilitated by IoT technologies, ensuring that each batch meets stringent quality standards. Lastly, **regulatory compliance** is another crucial area that stands to benefit from this research. Blockchain technology, for instance, can provide a robust framework for ensuring data integrity and traceability, which are critical factors in meeting compliance requirements set forth by global and local regulatory bodies.

## 1.4 Purpose and Objectives of the Study

The major purpose of this study is to assess how digital transformation can optimise CPPs in India's pharmaceutical manufacturing, thereby enhancing the industry's global competitiveness and adoption of cutting-edge digital transformation initiatives. The study aims to understand the potential of digital technologies in optimising CPPs, thereby elucidate their role in enhancing quality as well as in increasing process efficiency.

The objectives of the study are as follows:

· To identify and understand the current usage of digital tools and initiatives in the Indian pharmaceutical manufacturing sector focused on optimisation.

· To evaluate the impact of these digital tools on the operational workflows, process efficiency, and final product quality.

· To assess how digital transformation initiatives influence compliance with QbD principles and regulatory standards.

· To identify the challenges faced by the Indian pharmaceutical industries in implementing digitalization, including technological, organizational and regulatory challenges.

Therefore, the significance of this research lies in elucidating insights on the potential benefits and challenges associated with the integration of digital transformation initiatives in optimising CPPs in the pharmaceutical manufacturing process, understanding the fact that optimising CPPs enhances the overall quality and efficiency of the entire scenario, thereby striking the right chord. By addressing these detailed objectives, the study will contribute significantly to the field by proposing

strategies to overcome challenges and by highlighting successful practices that can be adopted more widely, addressing both the technological and commercial perspectives.

## 1.5 Methodological Approach

The study adopts an interpretive approach, employing qualitative methods to explore the impact of digital transformation on CPPs in India's pharmaceutical manufacturing. An inductive approach and exploratory research are used here. Data collection was conducted through structured interviews with professionals from the pharmaceutical industry, such as Pharmaceutical Manufacturing Technologists, Formulation Scientists, Quality Assurance/Quality Control (QA/QC) Experts, Regulatory Professionals, and Digital Technology Specialists. These participants, selected for their expertise and experience, recruited via professional networks like LinkedIn.

Interviews were prepared according to a structured questionnaire (data collection tool) tailored to align with the research objectives, ensuring relevance and depth in the responses collected. Ethical considerations were deemed paramount, with strict adherence to confidentiality and data protection standards under General Data Protection Regulation (GDPR) guidelines. The research will handle participant data sensitively, maintaining anonymity and securing informed consent.

Data in the form of text responses transcribed after the interview will be analyzed through thematic analysis to identify and interpret patterns within the qualitative data.

## 1.6 Outline of the Study

**Chapter 1: Introduction** introduces the scope and significance of the study, explaining why digital transformation in the optimisation of CPPs is crucial for the pharmaceutical industry in India. It presents the research objectives, outlines the research questions, and discusses the background leading to this research.

**Chapter 2: Literature Review** reviews existing literature related to digital transformation in pharmaceutical manufacturing, focusing particularly on the application and impact on CPPs. The literature review identifies gaps in current research and justifies the necessity of this study, setting a theoretical foundation for the methodology and analysis that follow.

**Chapter 3: Research Methodology** describes the qualitative approach used to gather data, detailing the interpretivist philosophical stance used in the study. This chapter outlines the inductive research strategy, participant selection criteria, data collection via structured interviews, and ethical considerations involved in the research.

**Chapter 4: Findings and Analysis p**resents the primary research data collected through interviews with industry professionals. This chapter employs thematic analysis to interpret the data, highlighting key findings, which are then discussed with respect to theoretical frameworks.

**Chapter 5: Conclusions and Recommendations** summarizes the findings of the research, offers practical recommendations for pharmaceutical manufacturers, and suggests areas for further research based on identified limitations.

# 2. Literature Review

## 2.1 Introduction

Digital transformation initiatives hold large potential to transform the pharmaceutical manufacturing process in terms of increasing efficiency and streamlining processes. This literature review explores the integration of digital technologies in pharmaceutical manufacturing, particularly focusing on CPP optimization and regulatory compliance. As the industry strives to enhance efficiency, ensure product quality, and meet stringent global regulations, the adoption of digital tools has become indispensable.

This review is structured around several key themes that capture the essence of digital transformation in the pharmaceutical sector. First, it reviews the application of AI in drug formulation development, highlighting how AI optimizes formulation parameters and maintains quality control, thus revolutionizing traditional methodologies. The discussion extends to real-time CPP monitoring through the utilization of the IoT and sensors, demonstrating their pivotal role in enhancing process control and product consistency.

Furthermore, the review addresses predictive analytics, highlighting its role in forecasting and mitigating risks associated with CPP variability. This is followed by an examination of automation technologies that dynamically adjust CPPs, ensuring optimal process conditions are maintained. Each of these technological advancements is discussed in the context of their ability to meet regulatory requirements and improve manufacturing outcomes.

Finally, the review tackles the challenges hindering technology adoption, such as regulatory hurdles, skill gaps, high costs associated with implementing advanced

digital solutions and the potential of these tools to ensure regulatory compliance within the pharmaceutical industry. Through a thorough exploration of current literature, this review provides a comprehensive overview of the state of digital transformation in pharmaceutical manufacturing, offering insights into how these technologies are shaping the future of the industry.

## 2.2 Application of AI in Formulation Development

### 2.2.1 AI in Drug Discovery and Preformulation

The application of AI in drug discovery and preformulation is reshaping the landscape of pharmaceutical research, offering innovative solutions to enhance efficiency and effectiveness in drug development. AI technologies, particularly ML and deep learning (DL), are being utilized to predict drug behaviour, optimize drug design, and streamline preformulation processes.

Gupta *et al.* (2021) highlight AI's role in enhancing computer-aided drug design (CADD), demonstrating its capability to refine predictions in chemical structure-activity relationships. AI's ability to integrate historical computational methods with modern algorithms enables more precise forecasting of compound behaviours, aiding in the rapid development of effective drugs.

Merk *et al.* (2018) showcase the prospective application of generative AI in molecular design. Their use of recurrent neural networks trained on Simplified Molecular Input Line Entry System (SMILES) strings to design new compounds emphasizes AI's potential to significantly accelerate the drug discovery process and enhance the specificity of drug actions through transfer learning.

Popova *et al.* (2018) introduce the novel Reinforcement Learning for Structural Evolution (ReLeaSE) method, which combines deep and reinforcement learning to generate compounds optimized for specific properties. This approach marks a significant advancement in de novo drug design and illustrates how AI can produce targeted chemical libraries more efficiently.

Dhamodharan and Mohan (2021) focus on multi-target directed ligands using AI to predict inhibitory activities. Their development of Quantitative Structure Activity Relationship models (QSAR) using ML techniques showcases AI's effectiveness in

identifying potential drug candidates and emphasizes the importance of accurate molecular descriptors in enhancing the predictability of inhibitory activity.

The reviewed studies collectively illustrate the transformative potential of AI in the realm of drug discovery and preformulation. AI's integration into pharmaceutical research not only streamlines the drug development process but also enhances the accuracy and efficacy of new drug candidates. While the promise of AI is vast, challenges such as data dependency, computational resource requirements, and model transparency must be addressed to fully realize its potential. Ongoing advancements in AI technology, coupled with improvements in algorithmic clarity and data quality, are crucial for solidifying AI's role in the future of pharmaceutical development.

### 2.2.2 Application of AI in Formulation Development

Advancements in AI have significantly impacted pharmaceutical formulation development, providing innovative solutions for optimizing various formulation parameters. AI algorithms have been effectively applied to enhance the efficiency and predictability of pharmaceutical formulations, including nanoparticles, solid dispersions, and controlled-release tablets.

Ganju and Gupta (2023) highlight the application of AI in optimizing the nanoparticle formulation process using Matrix Laboratory (MATLAB) and Jupyter Notebook to analyze data from Box-Behnken designs. The models predict critical parameters like particle size and entrapment efficiency, demonstrating AI's precision in handling complex, multi-variable formulation challenges. The use of simulation studies to visualize the interaction effects provides a deep understanding of the formulation dynamics, enhancing the predictability and efficiency of the development process.

Dong *et al.* (2023) developed "FormulationAI," a comprehensive web-based AI platform that revolutionizes in silico formulation design. By integrating extensive datasets and employing various AI algorithms, this platform facilitates the prediction and evaluation of key properties across multiple formulation systems. This tool exemplifies the transition from traditional empirical methods to data-driven, intelligent formulation strategies, significantly reducing time and cost while increasing the robustness of the design process.

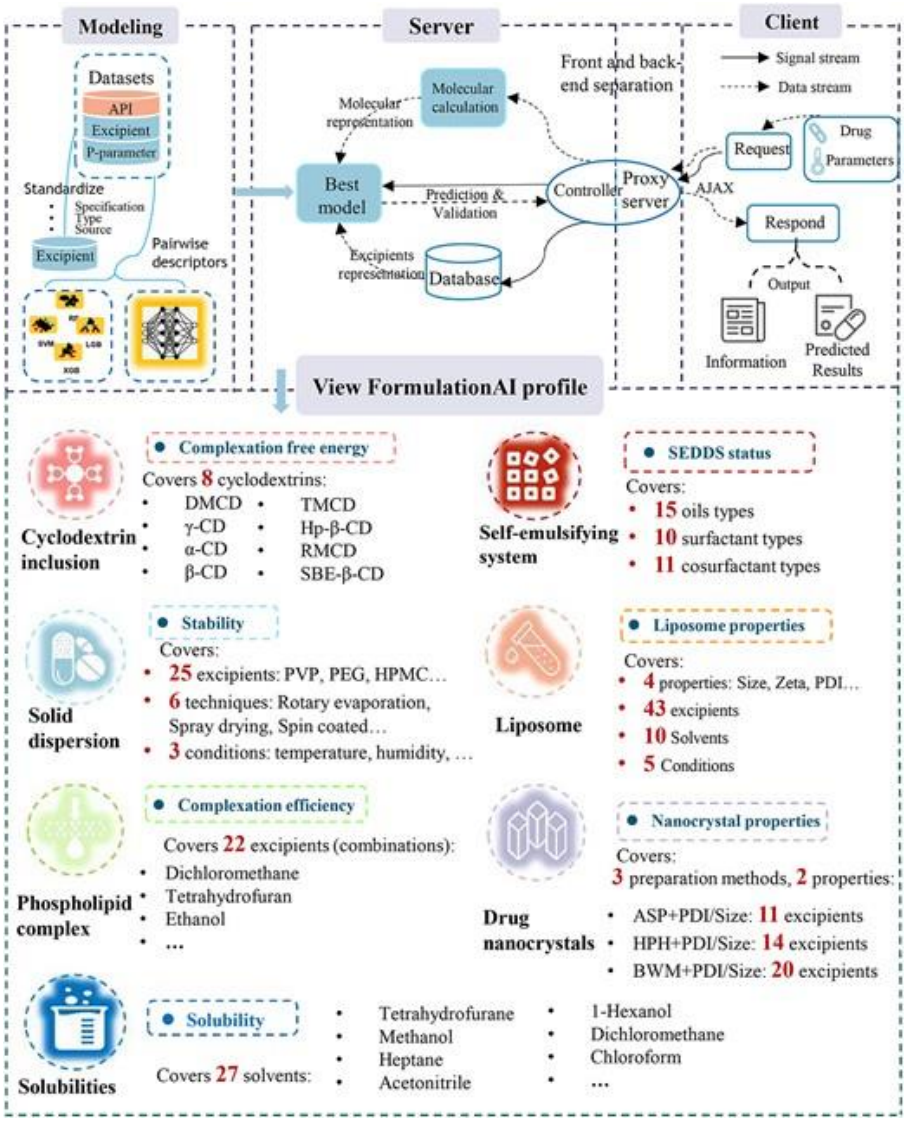


**Figure 5: Workflow process in Formulation AI, a novel platform for formulation design as noted by Dong et al. (2023).**

Ali *et al.* (2024) discuss the broad applications of AI in optimizing formulations of complex systems like solid dispersions and liposomes. Their work focuses on AI's capability to address issues related to the solubility and stability of active pharmaceutical ingredients (APIs), which are critical factors that affect the efficacy of drug products. This study showcases AI's potential to enhance traditional pharmaceutical formulations through advanced problem-solving approaches.

Hamet and Tremblay (2017) explore the use of pharmacokinetic simulations coupled with Artificial Neural Networks (ANN) to develop controlled-release formulations. By predicting optimal drug release profiles, AI proves to be an invaluable tool in

designing formulations that require precise control over drug release kinetics, thus ensuring therapeutic efficacy and patient compliance.

Yüksel *et al.* (2000) highlight the application of neural networks, demonstrating their superiority over traditional statistical methods in formulating immediate-release tablets. The study shows AI's effectiveness in optimizing disintegration and durability parameters, which are critical for ensuring the immediate release and absorption of the drug.

The integration of AI into pharmaceutical formulation development has brought about significant enhancements in both traditional and novel formulation techniques. Across the studies reviewed, AI has shown a remarkable capacity to streamline processes, reduce reliance on trial-and-error methods, and improve the predictability of formulation outcomes. These advancements not only save valuable resources but also pave the way for more sophisticated and patient-centric drug delivery systems.

### 2.2.3 – AI in Quality Control of Formulations

Artificial Intelligence has a significant role in enhancing quality control within pharmaceutical formulation development.

Simões *et al.* (2020) illustrate the use of ANNs within a QbD framework for developing a test drug product, focusing on optimizing drug particle size distribution (PSD) as a critical quality attribute. The ANN model demonstrated high predictive accuracy ($R2 > 0.94$) for in vitro dissolution rates, which was validated in industrial-scale production and subsequent clinical studies. The integration of ANNs enabled precise control over formulation parameters, directly correlating with successful clinical outcomes and demonstrating the model's efficacy in bridging in vitro and in vivo performance.

Dawoud *et al.* (2023) explored AI’s potential in formulating nanoparticles for carcinoma treatment using a QbD approach. Their study utilized ANN models to predict the release profiles of silymarin from lecithin/chitosan nanoparticles, achieving an entrapment efficiency of 97%. This approach not only optimized the formulation parameters but also enhanced the cytotoxic effects of silymarin, showcasing AI’s capability to predict and optimize nanoparticle characteristics effectively for targeted drug delivery.

Aksu *et al.* (2012) focusses on the formulation of ramipril tablets, Aksu et al. employed ANNs alongside traditional experimental designs to define a multidimensional design space that ensures consistent product quality. By leveraging AI to analyze and interpret complex datasets, the study established robust quality parameters that enhance the predictability and reliability of pharmaceutical products.

Kavasidis *et al.* (2023) demonstrated how supervised learning could be applied in pharmaceutical manufacturing for predictive maintenance and quality control. Their approach used data from manufacturing processes and equipment sensors to anticipate failures and deviations, emphasizing AI's utility in maintaining operational efficiency and product quality consistency.

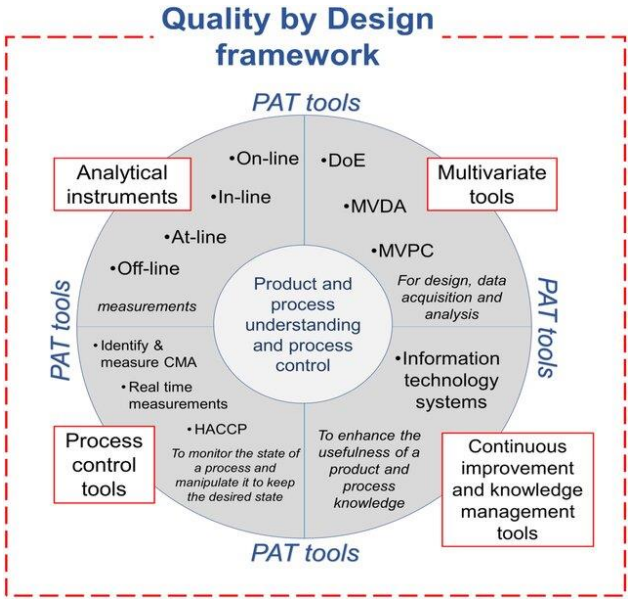


**Figure 6: The QbD framework for pharmaceutical manufacturing and its components (Pérez-Beltrán et al., 2022).**

By integrating AI tools like ANNs within QbD frameworks, these studies achieve significant advancements in automating and enhancing the precision of quality assessments. AI's capability to process complex datasets and predict outcomes with high accuracy ensures that pharmaceutical products are not only effective but also meet stringent quality standards. This integration of AI in quality control processes marks a significant shift towards more dynamic, responsive, and efficient pharmaceutical manufacturing practices.

## 2.3 Current Usage of Digital Transformation Initiatives in CPP Optimization

### 2.3.1 Digital Tools for Real-time Monitoring of CPPs

The real-time monitoring of CPPs is crucial for ensuring the quality and efficiency of pharmaceutical manufacturing.

Han *et al.* (2019) developed a machine-learning model to predict the physical stability of amorphous solid dispersions, a key CPP in pharmaceutical formulations. By using over 646 stability data points and a Random Forest (RF) algorithm, they achieved an accuracy of 82.5% in their predictions. This study demonstrates how ML can be utilized to reduce the time traditionally required for stability testing from months to a predictive instant assessment, thus significantly accelerating the formulation development process.

Bannigan *et al.* (2021) discuss the transformative impact of ML in drug formulation development. By incorporating ML workflows, pharmaceutical scientists are able to expedite the formulation process, enhance bioavailability, and optimize targeted delivery of new medicines. The study highlights the application of AI technologies like generative models and reinforcement learning, showcasing their potential to not only streamline formulation development but also innovate new material discovery.

Rantanen and Khinast (2015) explore the use of computational fluid dynamics (CFD) integrated with Reynolds-Averaged Navier-Stokes solvers technology to monitor CPPs such as agitation and stress levels within manufacturing equipment. By automating these analyses, the pharmaceutical industry can achieve more precise control over manufacturing processes, enhancing both product consistency and production efficiency.

Wasalathanthri *et al.* (2020) review the implementation of PAT tools in real-time monitoring of bioprocesses. They propose a comprehensive PAT roadmap that includes the integration of various analytical technologies and advanced data analytics. This approach not only enables real-time monitoring but also facilitates the smart utilization of data for process optimization, demonstrating a significant advancement towards QbD manufacturing and real-time release (RTR) testing.

Through the adoption of digital tools such as machine learning algorithms, IoT sensors, and PAT, the industry can achieve more dynamic and responsive manufacturing processes. These technologies enable pharmaceutical companies to

maintain high standards of product quality while optimizing manufacturing efficiency and reducing costs. The continuous evolution of these digital tools is set to further revolutionize CPP monitoring, paving the way for more innovative and effective pharmaceutical production methods.

### 2.3.2 Predictive Analytics in CPP Management

By forecasting and mitigating risks associated with CPP variability, predictive analytics enhances both the efficiency and reliability of production processes.

Wang *et al.* (2017) Wang and colleagues propose a comprehensive framework utilizing flowsheet models to optimize continuous pharmaceutical manufacturing processes. By performing sensitivity and feasibility analyses, they identify influential input factors and characterize the design space, leading to optimized operational conditions with minimized costs. This approach demonstrates how predictive analytics can streamline process adjustments and enhance product quality through precise model-based predictions.

Hernandez and Zhang (2017) review the application of predictive analytics in healthcare, particularly for medication management in population health interventions. They highlight how predictive models use large datasets to identify patients at risk of medication noncompliance or adverse effects, enabling pharmacists to tailor interventions. This study underscores the broader implications of predictive analytics in enhancing patient-specific outcomes and optimizing treatment efficacy.

Jelsch *et al.* (2021) discuss the application of Model Predictive Control (MPC) in pharmaceutical continuous manufacturing. MPC uses real-time data and predictive models to make informed decisions about future plant outputs, optimizing the manufacturing process dynamically. Their approach allows for anticipatory adjustments, ensuring that the manufacturing process remains within desired operational thresholds and continuously aligns with quality standards.

Bhaskar *et al.* (2017) introduced an advanced MPC system integrated with real-time tablet weight measurement in a continuous manufacturing setting. Bhaskar et al.'s control system effectively manages tablet weight and breaking force, demonstrating superior performance to traditional Proportional Integral Derivative (PID) controllers. This predictive control system not only ensures consistent quality but also adapts to

real-time process variations, illustrating the effectiveness of predictive analytics in maintaining rigorous quality standards.

Haas *et al.* (2017) developed a sophisticated control system for tablet pressing operations, incorporating MPC and PID strategies. By simulating different control systems, they determine that a hybrid MPC-PID strategy, augmented by a feedforward controller, provides optimal control over tablet weight and hardness. This study highlights the potential of predictive analytics to enhance control strategies, leading to improved product consistency and manufacturing efficiency.

The integration of predictive analytics in CPP management has shown significant potential in enhancing the precision and reliability of pharmaceutical manufacturing. The reviewed studies illustrate various applications of predictive analytics, from optimizing tablet production to improving process stability and reducing variability. By leveraging real-time data and predictive models, manufacturers can ensure that products consistently meet quality standards.

### 2.3.3 Automation and CPP Optimization

The integration of automation technologies in the adjustment of CPP is vital for optimizing pharmaceutical manufacturing processes. This includes application of robotic process automation (RPA), cyber-physical production systems (CPPS), and advanced PAT in dynamically adjusting CPPs to maintain optimal process conditions.

Bhatnagar (2019) discusses the transformative potential of RPA in the pharmaceutical sector, particularly in data-heavy contexts such as drug discovery and quality control. RPA, combined with machine learning, facilitates the automation of repetitive tasks, enhancing efficiency and accuracy in data analysis and CPP management. The paper emphasizes RPA's role in standardizing traditional medicine production, illustrating its capability to ensure consistent product quality through automated data handling and process standardization.

Coito *et al.* (2022) explores the application of CPPS in pharmaceutical Quality Control (QC) laboratories to improve workflow efficiency. They utilize a simulation model to assess the impact of introducing automation on workflow parameters such as throughput and resource occupation. Their findings demonstrate that automation

significantly increases equipment and analyst availability, thereby optimizing the overall QC process and ensuring consistent monitoring of CPPs.

Unnikrishnan *et al.* (2019) investigates the use of machine vision and machine learning for automating the quality assessment of pharmaceutical emulsions. Their study demonstrates that an automated classification system outperforms manual assessments in accuracy, speed, and repeatability. By integrating real-time image acquisition, the automated system offers a robust method for in situ monitoring of CPPs, significantly enhancing process control and reducing variability in product quality.

Liu *et al.* (2024) address the slow adoption of automated continuous manufacturing in China, emphasizing the crucial role of PAT and self-optimizing algorithms in enhancing process efficiency. The study highlights recent advances in PAT tools that enable real-time CPP monitoring and adjustments, facilitating a transition towards more automated and reliable manufacturing processes.

From RPA's enhancement of data processing to CPPS's optimization of QC workflows and PAT's real-time process adjustments, these technologies collectively drive the industry towards more efficient and consistent manufacturing conditions. As automation technologies continue to evolve, their integration into pharmaceutical production is expected to further enhance the precision, efficiency, and reliability of drug manufacturing processes, ultimately ensuring higher standards of product quality and safety

## 2.4 Challenges in Technology Adoption

### 2.4.1 Regulatory Challenges

Navigating regulatory challenges is crucial for the successful adoption of new technologies in the pharmaceutical industry.

Hilliard (2006) explores the interaction between regulatory requirements and the adoption of cleaner technologies in the pharmaceutical industry. His analysis indicates that despite regulatory intentions to promote technological advancements, the actual uptake is mediated by the firms' managerial and organizational capabilities. This study reveals that merely imposing regulatory requirements is insufficient without considering the firm-specific factors that influence the ability to adopt new

technologies. Hilliard's findings suggest a need for more supportive regulatory frameworks that better align with the capabilities and operational realities of pharmaceutical companies.

O'Connor *et al.* (2016) discuss the constraints imposed by the regulatory framework on pharmaceutical manufacturing advancements. The paper highlights how rigid regulatory processes can slow down the implementation of manufacturing improvements, leading to inefficiencies and increased costs. The study underscores the need for a more flexible regulatory approach that allows for continuous process optimization without the burdensome requirement of frequent regulatory submissions, which can stifle innovation and delay the adoption of new technologies.

Coustasse *et al.* (2016) address the challenges related to the implementation of Radio-Frequency Identification (RFID) technology in tracking and securing the pharmaceutical supply chain. The study focuses on the complexities of existing regulatory environments and the transition to a more standardized federal system under the Drug Quality and Security Act. This transition is presented as a critical step towards reducing counterfeiting and ensuring the integrity of pharmaceutical products, showcasing how regulatory evolution can facilitate technological adoption by creating a more cohesive framework.

Cauchon *et al*. (2019) provides an in-depth analysis of the regulatory challenges associated with novel therapeutic modalities, such as cell and gene therapies. The paper discusses the difficulties in applying traditional regulatory frameworks to these complex products and the necessity for regulatory bodies to adapt to technological advancements. The authors argue for the development of more flexible and nuanced regulatory approaches that can accommodate the unique characteristics of these therapies while still ensuring patient safety and product efficacy.

The reviewed papers emphasize the need for regulatory bodies to evolve and adapt in response to technological advancements to facilitate innovation while ensuring safety and efficacy. Streamlining regulatory processes and embracing more adaptive frameworks could significantly enhance the industry's capacity to integrate new technologies, ultimately leading to better patient outcomes and more efficient manufacturing processes.

### 2.4.2 Employee Up skilling and Change Management

As industries transition to more technologically advanced operations, significant challenges arise concerning human resource capabilities and the need for extensive training in digital tools.

Cetindamar *et al.* (2021) this study emphasizes the critical role of digital literacy in leveraging cloud technologies within organizations. By applying the Theory of Planned Behaviour, the authors convincingly demonstrate that enhanced digital literacy significantly boosts employees' ability to utilize technological tools effectively. The findings suggest that fostering digital literacy is crucial for employees to capitalize fully on the benefits of digital transformation, highlighting the need for tailored educational programs that enhance cognitive behaviours towards technology use.

Li (2022) focuses on the reskilling and up skilling demands posed by Industry 4.0. With a projection that 50% of all employees will require reskilling by 2025, the study provides a comprehensive blueprint for addressing future skill requirements. The emphasis on lifelong learning as part of organizational strategy underlines the ongoing need for adaptive skills development in response to evolving technological landscapes, suggesting that continuous education is essential for workforce preparedness in the digital era.

Chaudhuri *et al.* (2023) explore resistance to digital technology adoption within the hospitality industry, specifically examining how employees' reluctance to change impacts their willingness to upgrade skills. By employing dynamic capability view and status quo bias theories, the findings indicate that enhancing employees' dynamic capabilities significantly fosters their acceptance of digital tools. This study underscores the importance of managerial strategies aimed at reducing resistance to change and encouraging skill advancement to ensure smooth digital transitions.

Mutambik and Almuqrin (2024) examine the factors influencing employees' acceptance of digital transformation. The study identifies management support and perceived benefits as key to encouraging positive attitudes towards digital changes while highlighting how process complexity and inertia can impede acceptance. These insights are crucial for organizations aiming to foster a digitally adept workforce,

suggesting that comprehensive support structures and clear benefits communication are pivotal in overcoming barriers to digital adoption.

Ensuring employees are well-prepared and receptive to new technologies not only facilitates smoother transitions but also enhances operational efficiency and innovation. Organizations must prioritize continuous learning and supportive management practices to bridge the skill gaps and fully harness the potential of digital tools in the workplace.

### 2.4.3 High Costs and ROI Uncertainty

The adoption of advanced technologies in pharmaceutical manufacturing is fundamentally transforming industrial operations. However, the significant costs and uncertainties regarding return on investment (ROI) pose substantial challenges.

Hynek *et al.* (2009) explores managers' hesitation to invest in advanced manufacturing technologies within Czech manufacturing firms. Despite recognizing the potential benefits, such as cost reduction and enhanced competitiveness, managers are often reluctant due to the high costs and risks associated with these investments. The findings from surveys conducted in the Czech Republic, juxtaposed with similar studies globally, underscore a universal caution among managers about the substantial financial commitments required and the uncertain economic outcomes of such investments.

Small (2006) delves into the justification processes used by manufacturing plants when investing in Advanced Manufacturing Technology (AMT). The study highlights that while more complex technology portfolios often adopt hybrid (economic and strategic) justification approaches, the underlying economic assessments tend to rely heavily on traditional financial metrics such as discounted cash flows. This approach indicates an underlying uncertainty about the direct ROI, prompting firms to consider broader strategic benefits alongside immediate economic gains.

Trakadas *et al.* (2020) reported the industry pressure to adopt AI and ML technologies, emphasizing the lack of preparedness and strategic planning in many firms. This pressure leads to investments in technology that may not be fully integrated or utilized to their potential, contributing further to uncertainties about their economic justification and long-term value.

Babina *et al.* (2024) present a novel approach by measuring AI investments through employee resumes and linking these investments to firm performance. Their findings suggest that while AI investments correlate with increased sales, employment, and market valuations, particularly through product innovation, these benefits are more pronounced in larger firms. This disparity raises concerns about the equitable distribution of AI's economic benefits and the broader implications for industry concentration and competition.

While potential benefits such as increased efficiency, market growth, and innovation are clear, the high initial costs and ongoing uncertainties regarding the tangible returns on these investments make decision-making complex. The studies underscore the need for a balanced approach that considers both economic and strategic factors in technology adoption strategies, with a particular emphasis on developing clear, measurable objectives to guide investment decisions and manage ROI uncertainties effectively.

### 2.4.4 Lack of Standardization

The lack of standardization in technological adoption poses significant barriers to innovation and efficient implementation of new technologies.

Zoo *et al.* (2017) explores the dynamic between innovation and standardization within developing countries, a topic that has received less attention compared to developed nations. The study reveals that standardization can significantly support innovation by providing scaling, proving, and coordinating mechanisms. However, the paper points out that in developing countries, the focus tends to skew more towards the adoption rather than the creation of standards. This can lead to a gap where standardization does not fully catalyse innovation due to the predominant focus on simply meeting existing standards rather than developing new ones. The study notes the crucial role of governmental and technology support organizations in bridging this gap due to the general technological under-preparedness of the private sector in these regions.

McDermott *et al.* (2021) discuss the specific challenges faced in the pharmaceutical industry due to the lack of standardized continuous improvement (CI) processes under stringent regulatory frameworks. The fear of additional validation requirements and a culture that prioritizes compliance over quality innovation are highlighted as

significant barriers. This study underscores the necessity for standardizing CI processes to better integrate quality and regulatory compliance, which could enhance operational efficiency without compromising safety.

Chaturvedi *et al.* (2017) examines the Indian pharmaceutical sector, noting a substantial variance in how sustainability is adopted, largely driven by the absence of standardized guidelines across the industry. The lack of commitment to sustainability research & development (R&D) and involvement from top management are identified as critical issues. The absence of a standardized approach hinders the comprehensive adoption of sustainable practices, reflecting a broader problem of fragmented standards in emerging markets.

Engineering National Academies of Sciences et al. (2021) report highlights the broader implications of the lack of standardization across industries. It outlines the challenges in technology integration due to different vendors' incompatible technologies, difficulties in data sharing, and the lack of interoperability. The need for common frameworks and protocols is emphasized as essential for fostering effective technology adoption and operational integration across sectors.

The absence of standardization emerges as a profound barrier to technological adoption, significantly affecting sectors from pharmaceuticals to broader manufacturing and service industries. The reviewed literature collectively calls for the development and implementation of universal standards that can support innovation, ensure interoperability, and streamline regulatory processes. Such efforts are crucial for enabling more effective and widespread adoption of advanced technologies, ultimately enhancing industry efficiency and sustainability.

### 2.4.5 Cultural and Organizational Barriers

Cultural and organizational barriers significantly impede the adoption of new technologies within various industries. This review examines scholarly insights on how entrenched cultural norms and organizational structures act as obstacles to technological integration, focusing on diverse industries and regions.

Riedel (2024) discusses the impact of organizational culture on technology adoption, emphasizing resistance to change, siloed structures, and risk aversion within highly regulated industries. The study highlights how traditional manufacturing methods and

organizational inertia prevent the seamless integration of new technologies, underscoring the need for cultural flexibility and cross-functional collaboration to foster innovation.

CHOUKI *et al.* (2018) focus on the barriers faced by Moroccan small and medium-sized enterprises (SMEs) regarding information technology adoption. Their research model identifies organizational culture, specifically informalization, resistance from technology stakeholders, and centralized decision-making, as significant impediments. This qualitative study enriches understanding by showcasing how organizational culture directly affects technological adoption in SMEs, suggesting that decentralized governance and stakeholder engagement are critical for overcoming these barriers.

Bozkus (2023) explores the relationship between technological adoption and organizational culture change, presenting a comprehensive framework that examines the stages of digital transformation. The study emphasizes the role of leadership in managing cultural shifts and the human aspects of digital transitions. It argues for a balanced approach that addresses both technological needs and the ethical implications of new technologies, promoting a responsible and inclusive organizational culture that can adapt to ongoing changes.

Aquilani *et al.* (2017) delve into the cultural barriers that hinder Open Innovation processes, with a particular focus on how Open Innovation Intermediaries can facilitate overcoming these obstacles. The paper identifies specific cultural impediments, such as a lack of openness and aversion to risk-taking, that can stifle innovation. By outlining the roles of different intermediaries, the study provides practical insights for organizations aiming to embrace Open Innovation by adjusting their cultural norms and embracing external collaborations.

The studies highlight various cultural barriers, from resistance to change and fear of risk to poor cross-functional communication, which can derail technological initiatives. Addressing these barriers requires a multifaceted approach that includes leadership commitment, structural adjustments, and continuous learning environments. By fostering a culture that embraces change and innovation, organizations can better position themselves to capitalize on the benefits of new technologies, enhancing their competitive edge in an increasingly digital world.

## 2.5 Ensuring regulatory compliance through digital tools in pharmaceutical manufacturing

The digital tools when integrated with pharmaceutical manufacturing has the potential to enhance regulatory compliance, driven by the need to maintain data integrity and improve operational efficiency.

Ullagaddi (2024) delves into the digital transformation challenges in the pharmaceutical sector, emphasizing data integrity as a pivotal element. The discussion addresses issues like outdated legacy systems, data silos, and cybersecurity risks, which impede data integrity. The article underscores the advantages of embracing digital transformation, such as enhanced product quality, operational efficiency, and regulatory compliance, contributing to improved patient safety and brand trust. Strategic recommendations include adopting a comprehensive digital roadmap, investing in modern Information Technology (IT) infrastructure, and fostering continuous improvement cultures.

Hole *et al.* (2021) explores the resistance to digitalization within the pharmaceutical industry, attributed to the complexity of its processes and the stringent requirements of Good Manufacturing Practice (GMP). The paper highlights the unique digitalization challenges faced by Contract Development Manufacture Organizations (CDMO), stressing the importance of maintaining GMP compliance during digital transitions. It calls for close collaboration with stakeholders and constant focus on regulatory standards as critical to successful digital implementation in pharmaceutical manufacturing.

Saeed *et al.* (2022) focus on the role of digital tools in mitigating corruption risks within the pharmaceutical supply chain, especially highlighted during the Corona Virus Disease 2019 (COVID-19) pandemic. The study reviews various digital solutions, including e-procurement, track-and-trace, anti-counterfeiting, and blockchain technologies, and their effectiveness in enhancing anti-corruption, transparency and accountability (ACTA). While these technologies offer potential improvements in supply chain governance, the study finds that their deployment often lacks direct alignment with ACTA objectives, suggesting a need for more targeted policy development to fully realize their benefits.

The reviewed literature notes the critical role of digital tools in supporting regulatory compliance in the pharmaceutical industry. The challenges of adopting these technologies—ranging from overcoming internal resistance and managing data integrity to aligning with strict regulatory frameworks—are significant yet surmountable with strategic planning and stakeholder collaboration. As digital tools continue to evolve, their integration into pharmaceutical manufacturing promises substantial compliance benefits.

## 2.6 Conceptual Framework

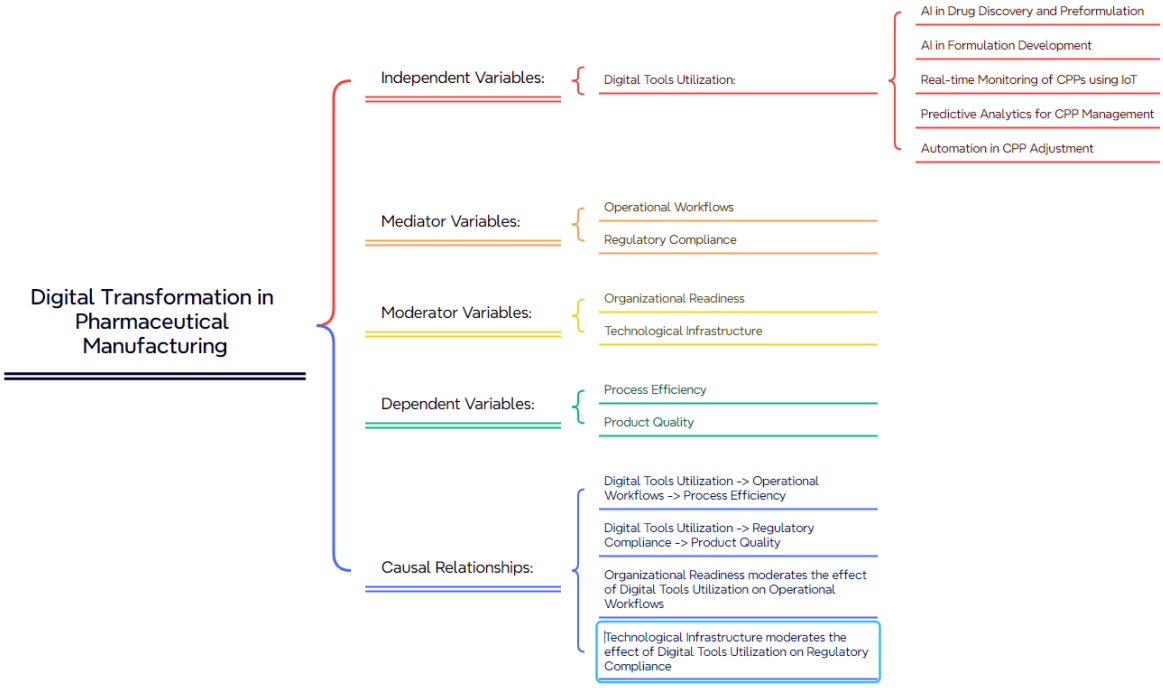


**Figure 7: Conceptual Framework**

The conceptual framework for this study on digital transformation in pharmaceutical manufacturing outlines the relationships between the deployment of digital tools and their impacts on process efficiency and product quality. Central to this framework are various independent variables, including the utilization of digital tools such as AI in drug discovery and formulation, real-time monitoring of CPPs via the IoT, predictive analytics, and automation technologies. These tools are posited to influence the dependent variables—process efficiency and product quality—through specific mediating and moderating variables.

Operational workflows and regulatory compliance serve as the primary mediators in this framework. The adoption of digital tools is expected to transform operational workflows, thereby enhancing process efficiency. Simultaneously, these tools aid in meeting regulatory compliance, which is crucial for maintaining and improving product quality within the highly regulated pharmaceutical industry.

The framework also incorporates two key moderators: organizational readiness and technological infrastructure. Organizational readiness reflects the capacity of a company to adopt and integrate new technologies, potentially influencing how effectively digital tools can improve operational workflows. Similarly, the existing technological infrastructure of a company may affect how well these tools support regulatory compliance efforts.

By mapping out these relationships, the framework suggests that the successful integration of digital technologies into pharmaceutical manufacturing can lead to significant improvements in efficiency and quality. However, the extent of these benefits is also contingent upon the company's readiness and its technological capabilities, which can either enhance or hinder the effective use of digital tools. This comprehensive view allows for a deeper understanding of the multifaceted impacts of digital transformation initiatives in the pharmaceutical sector.

## 2.7 Conclusion

This literature review on digital transformation initiatives and their potential to optimize CPPs notes a significant shift towards more integrated, intelligent, and efficient production processes. Through the adoption of advanced technologies such as artificial intelligence, IoT, predictive analytics, and automation, the industry aims to overcome traditional barriers, enhancing both productivity and compliance with regulatory standards.

AI, with its emergence has been a significant component in the transformation, with applications in drug formulation optimization and quality control, where it offers optimized precision and efficiency. AI's ability to predict drug behaviours and optimize formulation parameters not only speeds up the drug development process but also enhances the quality and efficacy of pharmaceutical products. Moreover, the integration of IoT devices for real-time monitoring of CPPs exemplifies how

continuous data collection and analysis can lead to more responsive and adaptable manufacturing environments.

Predictive analytics further contribute by enabling foresight into process variabilities, allowing manufacturers to pre-emptively adjust conditions to maintain product quality and consistency. Similarly, automation technologies are instrumental in dynamically adjusting CPPs, which ensures that manufacturing processes remain within optimal parameters without constant human oversight, thereby reducing errors and increasing efficiency.

However, the review also highlights significant challenges that need to be addressed to realize the potential of these technologies fully. Regulatory complexities, skill gaps within the workforce, and the high costs of technology adoption are substantial barriers. Organizations must navigate these challenges through strategic planning, investment in workforce training, and active engagement with regulatory bodies to shape policies that support innovation while ensuring safety and compliance.

To conclude, while the path forward involves considerable challenges, the strategic implementation of digital technologies holds the promise of transforming pharmaceutical manufacturing into a more agile, efficient, and compliant industry. This transition not only supports the industry's growth but also enhances its capability to meet the evolving healthcare demands.

# 3. Methodology and Research Design

## 3.1 Overview

The methodology for this research is designed to comprehensively explore the research topic and the devised objectives. Utilizing a qualitative approach, the study employs structured interviews to gather in-depth insights from various professionals, including pharmaceutical manufacturing technologists, formulation scientists, QA/QC experts, regulatory professionals, and digital technology specialists. An overview of the research methodology is detailed in Table 1.

| | |
|---|---|
| Research Philosophy | Interpretivism |
| Research Approach | Inductive Approach |
| Research Strategy | Primary Method (Interview ) |
| Research Design | Qualitative Design |
| Participant Profile | ● QA/QC Experts<br>● Regulatory Professionals |

| | |
|---|---|
| | • Pharmaceutical Manufacturing Technologists<br>• Digital Technology Experts<br>• Formulation Scientists. |
| Data Analysis | Thematic Analysis |

**Table 1: Overview of the Research Methodology**

## 3.1 Research Philosophy and Approach

The philosophical stance of the research study was based on interpretivism, which emphasised understanding social phenomena from the perspectives of those involved. Interpretivism argues that reality is subjective and can be explained in relation to the situational context, thereby grouping together diverse approaches. Here, it was pertinent for the researcher to understand the differences and social differences between individuals. This philosophical stance was particularly pertinent to qualitative research, where the subjective experiences and insights of participants are important to the investigation (Chowdhury, 2018).

For this study, interpretivism was chosen because it aligned with the qualitative nature of the research and the methodological approach of conducting semi-structured interviews. This philosophy supports the exploration of complex human perceptions and interactions with the research topic, which can help deduce practical world scenarios and implications of the topic, solely relying on the experiences of the professionals selected during the study. By focusing on interpretivism, the research could explore deeply how professionals perceive and integrate these digital technologies into their practices, providing a nuanced understanding that purely quantitative data might overlook (Priya, 2021).

The research approach employed was inductive, which is characterised by the generation of new theories or explanations through the observation of empirical phenomena without the constraint of testing pre-existing hypotheses. This approach was suitable for the study as it allows for the emergence of insights and patterns directly from the data collected during interviews. By using a bottom-up approach, the study not only aimed to document specific instances of digital tool integration but also sought to generalise findings to develop broader theoretical contributions (Dudovskiy, 2021). The process was based on the concept of learning from experiences so as to generate theories or concepts that facilitate the resulting development.

The exploratory research methodology uses approaches that are best suited for research questions or topics that have not been studied, thereby addressing the novelty of the research topic. It adapts to the unfolding nature of data and phenomena encountered (Chigbu et al., 2023). The inductive method enables a flexible framework that adjusts to the richness of qualitative data, thereby enhancing the depth and breadth of understanding concerning the nuances of the research topic. The exploratory research methodology was, therefore, often primary and qualitative in nature, best suitable for the research. The end goal is to construct a meaningful narrative that not only reflects the practical implications and challenges faced in the field but also contributes actionable insights for further research and practical application in the industry.

## 3.2 Research Approach

The research strategy adopted for this study was a qualitative methodology, specifically chosen for its strength in exploring complex phenomena within their situational context, allowing for an in-depth examination facilitated by the perceptions and experiences of the pharmaceutical professionals in line with the objectives. Employing semi-structured interviews facilitated a nuanced exploration of professional perspectives, enabling the collection of rich, detailed data that quantitative methods might not capture (Barroga and Matanguihan, 2022).

Semi-structured interviews are utilised as the primary data collection tool, designed to align with the specific objectives of the study. This ensures that each question directly contributes to addressing the research questions, minimising data redundancy, and enhancing the relevance of the information gathered (George, 2022). The interviews are tailored to accommodate the unique roles and responsibilities of different professional groups within the pharmaceutical sector, such as technicians, managers, and policy-makers. This customisation is crucial for eliciting specific insights related to each participant's interaction with digital transformation initiatives in their workflow.

The choice of qualitative research is particularly suitable given the exploratory nature of the study. It allows for the identification of patterns, themes, and insights that are grounded in the empirical data collected from real-world settings. This method is

advantageous in studies like this, where the aim is to understand 'how' and 'why' digital tools are integrated and the impact they have on CPP optimisation.

To guide the research process, the study employs a framework based on the Technology Acceptance Model (TAM) and the Theory of Planned Behavior (TPB), which are instrumental in understanding the factors influencing the adoption and effective use of technology in organisational contexts. These frameworks helped analyse how beliefs, attitudes, and external factors influence the behavioural intentions and actual usage of digital technologies among pharmaceutical professionals (Cheng, 2019).

The qualitative strategy with its structured yet flexible approach to data collection through interviews is adept at capturing the complexities and dynamics of digital tool integration in pharmaceutical manufacturing. This strategy not only aligns with the research objectives but also helped build a wide knowledge on the practical exploration of the research topic, which can indeed potentiate the research significance.

## 3.3 Primary Data Collection

### 3.3.1 Sources

The primary sources of data for this study were semi-structured interviews conducted with pharmaceutical professionals. These interviews utilised a structured questionnaire carefully designed to align with the research objectives. The questionnaire is used in Appendix

Participants included Pharmaceutical Manufacturing Technologists, Formulation Scientists, QA/QC Experts, Regulatory Professionals, and Digital Technology Specialists. The participants were selected through purposive sampling, where participants will be selected based on specific characteristics, traits, knowledge of the field, etc. Each participant was selected based on specific criteria that matched their expertise to the study’s needs, such as a minimum of three years of relevant experience and a profound understanding of manufacturing technologies, regulatory standards, and digital transformation impacts in their respective areas.

The selection of these sources was aimed at capturing a comprehensive view of the research topic, adhering to practical scenarios and concepts in the pharmaceutical

industry, as the interviews captured the perceptions of the participants. To ensure a diverse and knowledgeable participant pool, recruitment was conducted through professional networks such as LinkedIn and academic networks such as Research Gate. An initial contact email was followed by a detailed Participant Information Letter that included the study details, along with the plain language statement and informed consent, emphasising the voluntary nature of participation. Further, informed consent was also sent to the interviewees, citing their willingness to participate,

Each interview was conducted via Zoom, lasting approximately 20 minutes, and was audio-recorded with the consent of the participants. The structured nature of the interviews allowed for consistency across sessions while providing the flexibility to explore individual experiences and insights deeply. After the interviews, the responses were collected and meticulously analysed to deduce the study's results, deducing insights on the topic.

### 3.3.2 Ethical Considerations

As mentioned earlier, participants were recruited via professional networks such as LinkedIn and academic platforms like Research Gate. An initial contact was made through the same platforms regarding the participation in the study. Further, a participant information letter was sent to the focal participants explaining about the study details, ethical considerations and data storage implications and seeking their willingness. An informed consent was also attached for them to read and acknowledge, thereby marking their willingness to participate.

The study adhered to the strict ethical guidelines outlined by the Griffith College Ethics Committee (GCEC), ensuring the maintenance of confidentiality and anonymity for all participants. This involved coding participant information in the presentation of results to prevent identification. Participants had the freedom to withdraw from the study at any time without any repercussions.

Data protection was rigorously enforced in line with the GDPR and the ethical standards prescribed by Griffith College. All collected data, including audio recordings and signed consent forms, were securely stored on a password-protected institutional OneDrive accessible only to the researcher and the supervisor. Plans were

in place for the secure destruction of all data within five days post-research completion to further protect participant privacy.

The research also anticipated potential challenges, such as the availability of participants and the validity of subjective responses. To address these, ethical approval forms were meticulously prepared and submitted for review to the GCEC before commencing data collection. Flexible scheduling according to participants' convenience and the option for remote interviews via online platforms were implemented to accommodate participant availability. Additionally, to enhance data validity, a triangulation method was employed, where a thorough data fact check was done to cross-verify the information provided.

## 3.4 Data Analysis

The research employs a thematic analysis approach, which is ideally suited for qualitative data derived from structured interviews. This method involves identifying, analysing, and reporting patterns (themes) within the data. It allows for the depth, complexity, and richness of the data to be preserved, making it a powerful tool for obtaining nuanced insights into the subtleties of the data.

Given the interpretivism philosophical stance used in this study, thematic analysis is particularly appropriate. It aligns with the inductive approach of the research, where themes identified are strongly linked to the data themselves rather than being driven by the researcher’s preconceived ideas or theoretical preoccupations. This method allows for the flexibility to explore the perceptions and experiences of pharmaceutical professionals regarding the use of digital tools in optimising pharmaceutical manufacturing operations without being constrained by rigid hypotheses.

Interviews conducted via Zoom were transcribed verbatim using Transkriptor to allow an immersive engagement with the data. The researcher read through the transcripts multiple times to gain a deep understanding of the content, noting initial ideas and potential patterns that relate to the utilisation and impact of digital tools in CPP optimisation. The transcribed data was systematically coded. This involved identifying significant statements and expressions related to the research objectives—such as mentions of specific digital tools, descriptions of process changes, and reflections on the challenges and benefits of these tools. Each code encapsulated core ideas found in the data, facilitating the organisation and grouping of similar data

points. Codes were collated into potential themes that represented broader patterns across the dataset. These themes reflected major insights about digital transformation in CPP optimisation, such as adaptation processes, effectiveness, and integration challenges. This step ensured that themes were relevant to the research questions and provided a comprehensive understanding of the data. Each theme was reviewed to ensure it accurately reflected the corresponding coded data and maintained relevance across the entire dataset. This may have involved refining, combining, or separating themes to better capture the nuances of the data related to digital tool adoption and its impact on CPP optimisation. Detailed analysis of each theme was undertaken to define and articulate the essence of what each theme was about and how it contributed to understanding the broader research topic. Names for each theme were carefully chosen to reflect their core essence and ensure clarity for the subsequent reporting of the findings. The final report integrated the thematic analysis results, presenting a clear narrative that linked the themes with the research questions and existing literature.

The application of thematic analysis in this research provided a detailed and nuanced understanding of how pharmaceutical professionals perceive and interact with digital tools in their workflow, aligning with the study's goals to enhance practical applications and build future recommendations and practice for application in industry and pharmaceutical manufacturing (Villegas, 2024).

# 4. Findings and Analysis

## 4.1 Overview

The results reveal a comprehensive adoption of technologies such as PAT, Advanced Process Control (APC) systems, Manufacturing Execution Systems (MES), digital twins, and IoT sensors. These innovations have significantly impacted manufacturing processes, product quality, and regulatory compliance. The findings demonstrate both the substantial benefits of digital adoption and the challenges faced during implementation, providing valuable insights into the current state of digital transformation in the pharmaceutical industry. The codes are explained in Table 1.

| Occupation | Occupation Code | Participant Codes |
|---|---|---|
| Pharmaceutical | OCC-1 | P1.1 |

| | | |
|---|---|---|
| Manufacturing Technologist | | |
| Formulation Scientists | OCC-2 | P2.1, P2.2 |
| QA/QC Experts | OCC-3 | P3.1 |
| Regulatory Professional | OCC-4 | P4.1 |
| Digital Technology Specialist | OCC-5 | P5.1 |

**Table 2: Codes used in this research and their interpretations.**

## 4.2 Theme 1: Integration of Advanced Digital Tools for CPP Monitoring and Control

### 4.2.1 Sub-theme 1.1: Process Analytical Technology (PAT)

PAT has emerged as a critical tool for real-time monitoring and control of CPP within the pharmaceutical manufacturing sector. By enabling continuous measurement of key variables during the production process, PAT facilitates the early detection of deviations, ensuring that corrective actions can be taken promptly to maintain product quality and consistency.

OCC-1 P1.1 emphasized:

*"PAT has become an integral part of our manufacturing process. We use it to monitor variables such as temperature, pressure, and moisture levels in real-time. This real-time data helps us to adjust the process instantly if something goes wrong, ensuring that the product remains within the required specifications."*

This response highlights the role of PAT in ensuring real-time control of critical parameters, helping the organization avoid deviations that could compromise product quality.

Similarly, **OCC-3 P3.1** noted:

*"With PAT, we're able to maintain a much tighter control over the production process. It not only ensures that our products meet the required standards but also helps us to comply with regulatory requirements for continuous process verification.*

*The data collected from PAT is crucial for reporting and demonstrating compliance during audits."*

This response underscores the dual benefit of PAT: improving product quality and ensuring compliance with regulatory standards, particularly under the QbD framework.

Furthermore, **OCC-5 P5.1**, remarked:

*"PAT has streamlined our operations by reducing the time needed for post-production testing. Because we're monitoring in real-time, there's no need for long delays while waiting for lab results. This has significantly shortened our production cycle times, allowing us to get products to market faster."*

This response highlights how PAT improves operational efficiency by eliminating the need for offline testing, thereby reducing delays and improving overall production timelines.

As noted by the responses, PAT plays a critical role in modern pharmaceutical manufacturing by enabling real-time monitoring and control of CPPs, which aligns with the findings of Wasalathanthri et al. (2020) who discuss the implementation of PAT tools for real-time monitoring of bioprocesses. Its ability to enhance product quality, ensure regulatory compliance, and improve operational efficiency makes it a vital component of digital transformation in the industry, echoing the benefits of digital tools highlighted by Ullagaddi (2024) in improving product quality and regulatory compliance.

### 4.2.2 Sub-theme 1.2: Artificial Intelligence (AI) and Machine Learning (ML)

AI and ML have emerged as critical tools in optimizing CPP in pharmaceutical manufacturing, allowing for better predictive capabilities and process efficiency.

**OCC-1 P1.1** shared the application of AI and ML within their organization, stating:
*"We use AI to identify potential deviations in our processes before they happen. By analyzing historical data, AI can predict when certain parameters like temperature or pressure are likely to deviate from their set points. This gives us time to make the necessary adjustments and avoid any disruptions."*

This highlights the predictive capabilities of AI, which helps prevent deviations and ensures continuous process control.

**OCC-5 P5.1** emphasized the role of AI and ML in handling large volumes of data for process optimization:
*"AI allows us to process vast amounts of data quickly and find patterns that a human might miss. It has significantly improved our ability to optimize processes in real-time, which has led to a marked improvement in our overall product quality."*
This response demonstrates how AI's data processing capabilities provide deeper insights into optimizing processes and improving product quality.

**OCC-3 P3.1** added how ML continuously improves the accuracy of control parameters:
*"With machine learning, each batch we produce helps to refine the model we use for controlling CPPs. The more data the system collects, the better it gets at predicting the right conditions, which reduces variability and increases the consistency of our products."*
This showcases the adaptive nature of ML, where the system learns and improves over time, leading to more consistent outcomes in production.

Thus, AI and ML are transforming CPP monitoring in pharmaceutical manufacturing by offering predictive insights, optimizing processes in real-time, and improving product consistency, which aligns with the findings of Han et al. (2019). The participants' experiences demonstrate how these tools have significantly enhanced operational efficiency and product quality, resonating with the potential benefits of AI in pharmaceutical manufacturing highlighted by Bannigan et al. (2021), who discuss how ML can improve the formulation process.

### 4.2.3 Sub-theme 1.3: Internet of Things (IoT)

The integration of IoT in pharmaceutical manufacturing plays a pivotal role in real-time monitoring and automation of CPP. IoT-enabled devices provide continuous data collection, enabling a proactive approach to process control and optimization.

**OCC-1 P1.1** discussed the value of IoT in enhancing data collection and monitoring by stating:

*"Using IoT devices, we can continuously monitor equipment performance, environmental conditions like humidity and temperature, and even track the movement of materials within the plant. This constant stream of data allows us to make quicker decisions and avoid any delays in production that might arise from equipment failure or process deviations."*

This highlights how IoT facilitates real-time monitoring, allowing pharmaceutical companies to react swiftly to potential issues before they escalate.

Additionally, **OCC-2 P2.1** noted:

*"IoT has been a game-changer for us, especially in connecting all our machines and systems together. Now, we don't have to manually check each machine for issues. If something starts to go wrong, the system alerts us immediately, and we can step in to fix the problem without disrupting the entire production line."*

This response underscores the role of IoT in automating the detection of equipment malfunctions, ensuring a more efficient and streamlined production process.

**OCC-5 P5.1** further emphasized the benefits of IoT by adding:

*"We've deployed IoT sensors across our facilities that not only monitor the CPPs but also give us predictive maintenance insights. This has reduced our downtime significantly because we can address maintenance issues before they cause any disruptions."*

This points to the value of predictive maintenance, enabled by IoT, in reducing operational downtime and improving the overall efficiency of manufacturing processes.

IoT has transformed pharmaceutical manufacturing by enabling continuous monitoring, predictive maintenance, and real-time decision-making, which aligns with the findings of Rantanen and Khinast (2015) who explored the use of computational fluid dynamics integrated with Reynolds-Averaged Navier-Stokes solvers technology to monitor CPPs. The insights from the participants highlight the significant improvements IoT has brought to CPP monitoring, operational efficiency, and overall production reliability, aligning with the benefits of IoT in pharmaceutical manufacturing discussed by Kavasidis et al. (2023).

### 4.2.4 Sub-theme 1.4: Digital Twins

The adoption of digital twins in pharmaceutical manufacturing has allowed companies to create virtual replicas of physical processes and systems. These virtual models help in optimizing CPPs by enabling real-time simulations and predictions of outcomes without disrupting actual production.

**OCC-1 P1.1** discussed the role of digital twins in their organization, stating:
*"Digital twins give us the ability to simulate changes in the manufacturing process before implementing them on the actual production line. We can adjust parameters in the virtual environment and see how it impacts the final product, all without risking any disruptions to ongoing production."*
This highlights the use of digital twins in risk-free testing of process changes, allowing for more precise control over CPPs.

**OCC-2 P2.2** elaborated on the predictive capabilities of digital twins, noting:
*"We use digital twins to predict potential bottlenecks in the production process. By simulating different scenarios, we can identify points of failure before they occur and make adjustments to ensure that production continues smoothly."*
This illustrates how digital twins allow manufacturers to foresee and resolve issues before they affect the actual production process.

**OCC-5 P5.1** emphasized the cost-saving potential of digital twins, sharing:
*"The ability to simulate production processes virtually has saved us a lot of time and resources. Instead of running physical tests that could halt production, we can do it all digitally and only implement changes once we know they will work."*
This points to the efficiency and cost-saving advantages of digital twins, enabling manufacturers to optimize processes without costly interruptions.

Digital twins significantly enhances operational efficiency, reduces risk, and provides cost-effective solutions for process optimization, echoing the benefits of model-based predictions discussed by Wang et al. (2017) in optimizing continuous pharmaceutical manufacturing processes. The identified capabilities align with the advanced process control strategies described by Jelsch et al. (2021) and Haas et al. (2017).

## 4.3 Theme 2: Enhancing Efficiency and Quality in Manufacturing

### 4.3.1 Sub-theme 2.1: Process Efficiency

Digital transformation initiatives have significantly improved process efficiency in pharmaceutical manufacturing by streamlining operations, reducing cycle times, and enabling real-time monitoring and optimization of CPPs.

**OCC-1 P1.1** shared how digital tools have improved process efficiency in their organization:
*"With the integration of real-time monitoring systems, we've seen a reduction in production cycle times. We no longer need to stop and manually inspect processes because the systems alert us to any deviations immediately. This has cut down on delays and improved our overall output."*
This highlights how digital tools have reduced the need for manual inspections and contributed to more streamlined operations, resulting in faster production cycles.

Similarly, **OCC-2 P2.1** emphasized the impact of automation on process efficiency:
*"Automation has really helped us cut down on errors and speed up the process. Now, with advanced monitoring and control systems in place, we can ensure that the processes run smoothly without frequent interruptions for quality checks."*
This illustrates how automation and advanced monitoring systems have not only reduced errors but also improved the speed and consistency of manufacturing processes.

**OCC-2 P2.2** emphasized the positive effect on production consistency:
*"Automation and advanced digital controls have streamlined our operations significantly. We now have fewer stops in production and much better consistency in terms of output. It's a far cry from the old way of stopping the line for quality checks every few hours."*
This shows how digital tools have minimized disruptions, allowing for continuous production without the frequent pauses needed for manual inspections.

**OCC-5 P5.1** added:
*"Predictive analytics and machine learning have allowed us to anticipate potential issues before they occur, meaning we can address them proactively rather than reactively. This has greatly reduced downtime and increased the efficiency of our production lines."*
This response underscores how predictive analytics and machine learning have

contributed to proactive management of processes, minimizing downtime and enhancing operational efficiency.

*Digital transformation, particularly through real-time monitoring, automation, and predictive analytics, has greatly enhanced process efficiency in pharmaceutical manufacturing, which aligns with the findings of Wasalathanthri et al. (2020) These tools have allowed companies to minimize delays, reduce errors, and ensure smooth operations, similr to the benefits highlighted by Bhaskar et al. (2017) in their study of advanced MPC systems and Coito et al. (2022) in their exploration of CPPS.*

### 4.3.2 Sub-theme 2.2: Product Quality

The integration of digital tools in pharmaceutical manufacturing has significantly improved product quality by enabling more precise control over production parameters, reducing variability, and ensuring consistency across batches.

**OCC-2 P2.1** shared how digital transformation has enhanced product quality:
*"The use of real-time monitoring systems has allowed us to detect deviations from product quality standards much earlier in the process. This means that we can adjust the parameters before the product is compromised, leading to fewer rejected batches and more consistent product quality."*
This response highlights the role of real-time monitoring in maintaining product quality and reducing waste.

**OCC-1 P1.1** emphasized the impact of automation on product consistency, stating:
*"Automation has ensured that every batch is produced under the exact same conditions, which has greatly reduced variability. With digital tools monitoring every step, we now have greater control over the manufacturing process, and that has directly improved the quality of our final products."*
Automation allows for precise, repeatable processes, leading to more consistent product outcomes.

**OCC-3 P3.1** added that data integration across systems plays a crucial role in maintaining quality:
*"By integrating data from different stages of production, we can track how CPPs affect product quality in real-time. This enables us to make informed decisions that*

*maintain quality from start to finish, ensuring that every product meets the required specifications."*
This notes how data integration facilitates better decision-making and helps maintain product quality throughout the entire manufacturing process.

**OCC-5 P5.1** further noted the importance of predictive analytics:
*"Predictive analytics help us foresee potential quality issues before they arise. This proactive approach has led to improved consistency in our products because we can adjust the process in advance to maintain high standards."*
Predictive analytics enable preemptive adjustments, ensuring that product quality is consistently maintained.

The adoption of digital tools such as real-time monitoring, automation, data integration, and predictive analytics has led to significant improvements in product quality. These technologies have allowed pharmaceutical manufacturers to maintain consistent standards, reduce variability, and proactively address potential quality issues before they affect the final product.

### 4.3.3 Sub-theme 2.3: Cost Reduction

The integration of digital tools in pharmaceutical manufacturing has led to significant cost reductions, primarily through increased process efficiency, reduced downtime, and more accurate resource utilization.

**OCC-1 P1.1** shared the cost-saving impact of digital transformation in their operations:
*"With the implementation of digital monitoring systems, we've been able to reduce the number of rejected batches, which has significantly lowered our production costs. By catching deviations early, we don't waste resources on batches that fail quality control."*
This demonstrates how real-time monitoring prevents costly rework and material waste, resulting in substantial cost savings.

**OCC-2 P2.2** highlighted how automation contributes to cost efficiency:
*"Automation has cut down on the labor costs associated with manual checks and adjustments. With fewer human interventions needed, we've streamlined our labor*

*force, and the savings are evident in our operational budgets."*
This response underscores how automation has reduced labor costs by minimizing the need for manual oversight and adjustments during production.

**OCC-5 P5.1** emphasized the role of predictive maintenance in reducing costs:
*"One of the biggest cost-saving benefits we've seen is through predictive maintenance. By identifying equipment issues before they cause breakdowns, we've drastically reduced unplanned downtime and the expensive repairs that come with it."*
Predictive maintenance, enabled by digital tools, has helped reduce costly disruptions and repairs, thereby improving overall operational efficiency and cutting costs.

Digital transformation has contributed significantly to cost reduction in pharmaceutical manufacturing, aligning with the broader benefits of digital tools discussed by Ullagaddi (2024) in enhancing operational efficiency. Real-time monitoring, automation, and predictive maintenance have enabled companies to reduce waste, lower labor costs, and prevent expensive equipment failures, as with the potential of predictive analytics highlighted by Kavasidis et al. (2023). This cost reduction through digital means reflects the economic benefits of advanced manufacturing technologies discussed by Small (2006).

### 4.3.4 Sub-theme 2.4: Continuity of Operations

Digital tools have played a critical role in ensuring the continuity of operations within pharmaceutical manufacturing, particularly during periods of disruption, such as the COVID-19 pandemic, and by providing real-time data to mitigate risks and maintain smooth operations.

**OCC-1 P1.1** explained how digital monitoring systems helped maintain operations during disruptions:
*"With real-time monitoring in place, we didn't need to have all the staff physically present on-site to keep operations running. The systems alerted us remotely to any deviations, allowing us to respond quickly without stopping production. This was especially important during the pandemic when we had limited access to the plant."*
This highlights the role of real-time monitoring in maintaining operations even when access to the physical plant was restricted, ensuring that production could continue smoothly.

**OCC-2 P2.1** noted how digital tools ensured continuous production:
*"The integration of digital tools allowed us to maintain production even when our workforce was reduced. Automated systems continued to monitor and adjust the processes, reducing the need for manual intervention and ensuring that operations remained uninterrupted."*
This response emphasizes how automation played a key role in maintaining continuity of operations by minimizing the reliance on manual intervention during periods of reduced staffing.

**OCC-3 P3.1** shared how cloud-based systems contributed to operational continuity:
*"Cloud-based data management and process control allowed us to continue operations remotely. Even when key staff couldn't be on-site, we could still monitor and adjust processes from anywhere, ensuring that production wasn't affected by personnel shortages."*
This highlights the advantage of cloud-based technologies in providing remote oversight, enabling key staff to manage operations without being physically present.

**OCC-5 P5.1** discussed the role of predictive analytics in preventing operational disruptions:
*"Predictive analytics have helped us ensure continuity by identifying potential issues before they cause downtime. By addressing problems proactively, we've managed to prevent production halts and keep the manufacturing line running smoothly."*
This underscores the importance of predictive analytics in maintaining continuous operations by addressing issues before they escalate into disruptions.

Digital tools such as real-time monitoring, automation, cloud-based systems, and predictive analytics have been instrumental in ensuring the continuity of operations in pharmaceutical manufacturing, similar to the potential of digital tools highlighted by Ullagaddi (2024) in enhancing operational efficiency and product quality. However, the ability to minimize reliance on manual labor through these digital tools contrasts somewhat with the findings of Chaturvedi et al. (2017), who noted a lack of commitment to sustainability R&D and involvement from top management in adopting new technologies in the Indian pharmaceutical sector.

## 4.4 Theme 3: Digital Transformation in Support of Regulatory Compliance and Quality by Design (QbD)

### 4.4.1 Sub-theme 3.1: Quality by Design (QbD)

Digital transformation has significantly enhanced the implementation of QbD principles in pharmaceutical manufacturing. By embedding quality into every stage of the manufacturing process through advanced digital tools, companies can ensure that products consistently meet regulatory and quality standards from the outset.

**OCC-1 P1.1** emphasized how digital tools have supported QbD in their operations:
*"With the implementation of digital monitoring and control systems, we are able to apply QbD principles more effectively. We monitor critical parameters in real-time, which allows us to make adjustments on the fly and ensure that quality is built into the product at every stage of production. This has reduced the number of deviations we experience, and our products consistently meet the required specifications."*
This highlights the role of real-time monitoring in embedding quality into the process by ensuring that critical parameters remain within the specified limits, thus maintaining consistency and minimizing deviations.

**OCC-3 P3.1** explained how data integration and analytics contribute to QbD:
*"Data integration across different manufacturing stages has been key in applying QbD. By having access to comprehensive data on critical process parameters, we can identify trends and correlations that help us understand how these parameters influence product quality. This allows us to design more robust processes that ensure quality from the very beginning."*
This reflects the value of integrated data systems in implementing QbD principles, enabling better process understanding and control.

**OCC-2 P2.2** further elaborated on the role of QbD in regulatory compliance:
*"QbD principles, when supported by digital tools, help us meet regulatory requirements more easily. By designing our processes with quality in mind from the start, we can demonstrate to regulators that our manufacturing processes are robust and capable of consistently producing high-quality products. This has simplified the compliance process during regulatory inspections."*
This shows how the adoption of QbD through digital tools strengthens compliance

with regulatory standards, making regulatory submissions and inspections more straightforward and efficient.

**OCC-5 P5.1** noted the importance of predictive analytics in QbD:
*"Predictive analytics are essential to QbD because they allow us to predict how changes in process parameters will impact the final product. We can simulate different scenarios and adjust our processes to ensure that quality is maintained without the need for extensive trial and error."*
This demonstrates how predictive analytics support QbD by enabling manufacturers to anticipate the effects of process changes and optimize quality outcomes before implementing adjustments on the production line.

The emphasis on ensuring consistent product quality while facilitating regulatory compliance aligns with the benefits of digital tools discussed by Ullagaddi (2024), who highlighted their potential to enhance product quality and regulatory compliance. The use of these digital advancements to design robust processes that adhere to QbD standards reflects the advanced process control strategies described by Jelsch et al. (2021) and Haas et al. (2017) in their discussions of Model Predictive Control in pharmaceutical manufacturing.

### 4.4.2 Sub-theme 3.2: Regulatory Compliance

Digital transformation has revolutionized regulatory compliance within pharmaceutical manufacturing by enabling more efficient documentation, real-time tracking of processes, and improved alignment with regulatory standards. Advanced digital tools have streamlined compliance efforts, ensuring that manufacturers can meet strict regulatory requirements with greater ease and accuracy.

**OCC-1 P1.1** discussed how digital systems have improved compliance processes:
"By using electronic documentation systems, we can ensure that every step of the manufacturing process is recorded accurately and in real-time. This has made regulatory compliance much easier because we always have up-to-date records that we can provide to regulators when needed. There's no need to dig through paper files or manually compile reports."
This illustrates how electronic documentation has simplified compliance by ensuring that accurate, real-time data is always available for regulatory purposes.

**OCC-3 P3.1** highlighted the role of automated systems in maintaining compliance:
"Our automated systems continuously monitor critical process parameters, which means we can detect any deviations from regulatory standards immediately and take corrective action. This real-time monitoring has reduced the number of compliance issues we face and ensures that we remain in line with regulatory requirements."
This underscores the importance of automation in maintaining continuous compliance by providing real-time data that allows for immediate corrective actions.

**OCC-4 P4.1** added a regulatory perspective, noting how digital tools have streamlined audits and inspections:
"Digital systems have transformed the way we prepare for regulatory audits. We can quickly generate the reports and data needed by regulators, and everything is traceable, which reduces the time spent on inspections. These systems ensure that we are always ready for an audit without last-minute scrambling."
This highlights how digital tools improve audit readiness and streamline the inspection process by providing traceable and easily accessible data.

The use of electronic documentation, real-time monitoring, and automated systems has ensured that manufacturers can more easily adhere to regulatory standards, minimize compliance issues, and remain audit-ready, which aligns with the discussion by Ullagaddi (2024) on the advantages of digital transformation. The emphasis on reducing the burden on manufacturers while ensuring consistent compliance with stringent industry standards reflects the broader themes discussed by Hole et al. (2021), who stressed the importance of maintaining GMP. Interestingly, while the conclusion presents a positive view of digital tools in easing regulatory compliance, it contrasts somewhat with the findings of O'Connor et al. (2016), who discussed how rigid regulatory processes can slow down the implementation of manufacturing improvements.

## 4.5 Theme 4: Barriers to Digital Transformation in the Pharmaceutical Sector

### 4.5.1 Sub-theme 4.1: Technological Barriers

Despite the numerous benefits of digital transformation, pharmaceutical manufacturers face significant technological barriers in adopting and integrating

advanced digital tools. These challenges range from outdated legacy systems, difficulties in data integration, and a lack of infrastructure to support new technologies.

**OCC-1 P1.1** highlighted the difficulty of integrating digital tools with existing legacy systems:
*"We've faced a lot of challenges trying to integrate new digital technologies with our existing systems. Many of our legacy systems weren't designed to handle the kind of real-time data we need for modern manufacturing processes, and upgrading them has been both time-consuming and expensive."*
This response illustrates how older legacy systems, which were not built to support the vast amounts of data required by modern digital tools, present significant barriers to full digital adoption.

**OCC-5 P5.1** emphasized the complexity of data integration:
*"One of the biggest technological challenges we've encountered is integrating data from different systems. We have multiple platforms handling various parts of the manufacturing process, and getting them all to communicate effectively has been a real struggle. Data often gets stuck in silos, and without proper integration, we're unable to make the most of the insights these systems offer."*
This highlights the struggle with data silos and the difficulty in creating a seamless flow of information across different systems, a common technological barrier faced during digital transformation.

**OCC-2 P2.2** pointed out the infrastructure limitations that hamper digital adoption:
*"Many of the digital tools require significant investments in infrastructure, like high-speed internet and cloud-based storage solutions. In some of our facilities, especially in more remote areas, the infrastructure simply isn't there to support these technologies. This has delayed our ability to fully implement digital transformation across all of our plants."*
This response sheds light on how inadequate infrastructure, particularly in remote locations, can be a major roadblock to the implementation of digital tools.

**OCC-3 P3.1** added that technological barriers also include the need for continuous updates and maintenance:

*"Keeping up with the rapid pace of technological advancements is another challenge. Even after adopting new systems, they require regular updates and maintenance to stay current, which is a costly and resource-intensive process. Without ongoing investment in technology, we risk falling behind."*
This highlights the ongoing cost and complexity associated with maintaining and updating digital tools, adding another layer of difficulty to the adoption of new technologies.

The pharmaceutical sector faces several technological barriers to digital transformation, including the integration of modern tools with legacy systems, data integration challenges, infrastructure limitations, and the need for continuous updates and maintenance aligning with the challenges discussed by Ullagaddi (2024), who highlighted issues like outdated legacy systems and data silos.

### 4.5.2 Sub-theme 4.2: Organisational Barriers

Organizational barriers present significant challenges to the adoption of digital transformation in the pharmaceutical sector. These barriers include resistance to change, lack of digital skills within the workforce, and difficulties in aligning digital transformation initiatives with traditional corporate cultures.

**OCC-1 P1.1** pointed out the resistance to change within the organization:
*"One of the biggest challenges we've faced is the resistance from staff who are used to the old ways of doing things. There's a lot of hesitation to adopt new digital tools, especially from employees who have been working here for decades. They feel that these changes complicate their work rather than simplify it."*
This highlights the internal resistance that often arises when new technologies disrupt long-standing processes and routines.

**OCC-3 P3.1** also commented on the skills gap as a major organizational barrier:
*"Many of our employees simply do not have the digital literacy needed to work with the new systems. We've had to invest heavily in training programs to get our workforce up to speed, but it's been a slow process. The lack of digital skills is definitely slowing down the adoption of these technologies."*
This response underscores the importance of digital literacy and the need for

extensive training to bridge the skills gap, which delays the implementation of digital initiatives.

**OCC-2 P2.1** added that aligning digital transformation with traditional corporate structures poses another challenge:
*"Digital transformation requires a shift in mindset, and that's difficult when the company has operated in the same way for years. It's not just about adopting new tools but about changing the way we think about processes and efficiency. This cultural shift has been hard to achieve, especially in an industry as regulated and process-driven as pharmaceuticals."*
This illustrates the deep-rooted cultural and structural challenges that complicate the integration of digital technologies within traditional organizations.

**OCC-5 P5.1** stated similar statements:
*"The biggest issue isn't always the technology itself but the way the organization adapts to it. We've encountered a lot of internal friction from departments that feel their workflows are being disrupted. It takes time and effort to align everyone with the new way of operating."*
This emphasizes how organizational friction can hinder the smooth adoption of digital tools, often requiring significant effort to foster acceptance and alignment.

Organizational barriers such as resistance to change, the digital skills gap, and challenges in aligning digital transformation initiatives with existing corporate cultures significantly impact the adoption aligning with the cultural and organizational barriers discussed by Riedel (2024).

The digital skills gap reflects the findings of Li (2022), who highlighted the significant reskilling and upskilling demands posed by Industry 4.0, projecting that 50% of all employees will require reskilling by 2025. The need for strong leadership and a shift in mindset across the organization aligns with the insights from Bozkus (2023).

### 4.5.3 Sub-theme 4.3: Regulatory Barriers

Regulatory barriers present significant challenges to the adoption of digital transformation in the pharmaceutical sector. Strict regulatory standards, the slow pace

of regulatory adaptation to new technologies, and complex approval processes for digital tools often hinder progress.

**OCC-1 P1.1** emphasized the difficulty of aligning digital transformation with regulatory expectations:
*"One of the biggest barriers we've encountered is the lack of clear regulatory guidance on how to implement digital tools in our processes. The regulations often lag behind the technology, and we're sometimes unsure of how to stay compliant while adopting these new systems."*
This highlights how outdated or unclear regulations can create uncertainty for pharmaceutical companies trying to innovate while remaining compliant.

**OCC-4 P4.1** echoed this sentiment, pointing out the slow pace of regulatory adaptation:
*"Regulatory bodies are still catching up with the pace of digital transformation. We need clear frameworks that explain how to validate and qualify digital tools like AI and machine learning in the context of pharmaceutical manufacturing. Until then, we're hesitant to fully adopt these technologies because of the risk of non-compliance."*
This response demonstrates how regulatory uncertainty regarding the use of advanced digital technologies like AI and machine learning slows down their adoption in pharmaceutical manufacturing.

**OCC-2 P2.1** discussed the complexity of approval processes:
*"The approval process for any new digital technology is incredibly complex and time-consuming. We need to provide a lot of documentation to prove that these tools meet regulatory standards, and the process is not always straightforward. It's a major barrier to implementing new systems quickly."*
This highlights how the extensive and often unclear regulatory approval process can delay the integration of new digital technologies.

**OCC-3 P3.1** added that the validation requirements for digital tools create significant challenges:
*"Regulatory authorities require extensive validation for any new system we implement, which can be a long and costly process. We understand the need for*

*validation, but the lack of streamlined processes for digital tools adds complexity and slows down our ability to innovate."*
This shows how the validation process, while necessary for ensuring compliance, becomes a significant barrier when it comes to adopting new digital tools.

**OCC-5 P5.1** also noted the challenges of data security and privacy regulations:
*"With digital tools, especially those that involve cloud storage or data analytics, there are additional concerns about data security and privacy regulations. Ensuring that we're compliant with both local and international standards adds another layer of complexity to the adoption process."*
This highlights the regulatory challenges around data security and privacy that accompany the implementation of digital technologies.

Regulatory barriers such as unclear guidelines, slow adaptation of regulations to digital technologies, complex approval processes, and stringent validation requirements significantly hinder the adoption of digital transformation as noted by O'Connor et al. (2016), who highlighted how rigid regulatory processes can slow down the implementation of manufacturing improvements. The conclusion's emphasis on these regulatory hurdles delaying innovation and adding complexity to the implementation of advanced digital tools reflects the concerns raised by Hilliard (2006).

# 5. Conclusions and Recommendations

## 5.1 Summary of findings and their implications

The research findings highlight the transformative impact of digital technologies on pharmaceutical manufacturing. PAT has emerged as a critical tool for real-time monitoring and control of CPPs, significantly enhancing product quality and regulatory compliance. AI and ML have revolutionized CPP monitoring by offering predictive insights, optimizing processes in real-time, and improving product consistency. The IoT has enabled continuous monitoring, predictive maintenance, and real-time decision-making, leading to substantial improvements in operational efficiency and reliability.

Digital twins have proven to be powerful tools for optimizing CPPs, predicting potential issues, and testing process changes in a virtual environment, thereby reducing risks and costs associated with physical trials. These digital advancements have collectively enhanced process efficiency by minimizing delays, reducing errors, and ensuring smooth operations. Product quality has improved through more precise control over production parameters, reducing variability, and ensuring consistency across batches.

Significant cost reductions have been achieved through increased process efficiency, reduced downtime, and more accurate resource utilization. Moreover, digital tools have been instrumental in ensuring continuity of operations, particularly during disruptions such as the COVID-19 pandemic. QbD principles have been strengthened through digital tools, embedding quality into every stage of production and facilitating regulatory compliance. Regulatory compliance processes have been streamlined through electronic documentation, real-time tracking, and improved alignment with regulatory standards.

These findings have significant implications for the pharmaceutical manufacturing sector. They suggest that digital transformation is no longer just an option but a necessity for manufacturers to remain competitive, ensure product quality, and meet increasingly stringent regulatory standards. The adoption of these technologies can lead to more agile, efficient, and reliable manufacturing processes. However, the successful implementation of digital transformation requires addressing several challenges, including technological barriers, organizational resistance, and regulatory hurdles. Manufacturers must invest in infrastructure, workforce training, and change management strategies to fully realize the benefits of digital transformation.

## 5.2 Summary of differences between findings and literature

The summary of differences between the findings and that in the literature review are as follows:

- While the literature review focused on theoretical benefits, the findings provide concrete examples of how digital tools are being applied in real-world pharmaceutical manufacturing settings.

- The findings suggest a more widespread adoption of digital tools than implied in the literature review, particularly in areas like PAT and IoT implementation.
- The findings highlight the role of digital tools in ensuring operational continuity during disruptions, an aspect not prominently featured in the literature review.
- The findings reveal more specific challenges in integrating new technologies with legacy systems, a point not extensively covered in the literature review.
- The findings suggest that digital tools have made regulatory compliance easier in some aspects, contrasting with the literature review's emphasis on regulatory hurdles.
- The findings provide more detailed insights into organizational resistance and the digital skills gap, expanding on the broader discussions in the literature review.
- The findings offer more specific examples of cost reductions achieved through digital transformation, providing practical context to the economic benefits discussed in the literature.
- The findings demonstrate a stronger link between digital tools and QbD implementation than was evident in the literature review.
- The findings highlight data integration as a significant challenge, an aspect not prominently featured in the literature review.
- The findings emphasize the role of predictive maintenance in improving efficiency and reducing costs, a specific benefit not extensively discussed in the literature review.

These differences suggest that while the literature provides a strong theoretical foundation, the practical implementation of digital transformation in pharmaceutical manufacturing presents both additional challenges and benefits not fully captured in existing research.

## 5.3 Recommendations

Practical recommendations for pharmaceutical manufacturers include prioritizing digital literacy programs to address the skills gap and foster a culture of innovation. Companies should develop comprehensive digital transformation strategies that align with their specific operational needs and regulatory requirements. Collaboration with technology providers and regulatory bodies is crucial to develop tailored solutions and influence future guidelines. Manufacturers should also consider creating cross-

functional teams to oversee digital transformation initiatives, ensuring seamless integration across departments.

For academics, there's a need to focus research on the long-term impacts of digital transformation in pharmaceutical manufacturing, particularly on product quality, cost-effectiveness, and regulatory compliance. Studies should explore the integration of emerging technologies like Blockchain and advanced robotics in pharmaceutical production. Research on developing standardized frameworks for validating AI and ML models in pharmaceutical manufacturing could address regulatory uncertainties. Additionally, academics should investigate the environmental impacts of digital transformation in this sector, aligning with growing sustainability concerns.

Both industry and academia should prioritize research on cyber security measures specific to digitalized pharmaceutical manufacturing, addressing the unique challenges of maintaining data integrity in a highly regulated environment. Collaborative research initiatives between industry and academia could bridge the gap between theoretical advancements and practical implementation, accelerating the adoption of innovative digital solutions in pharmaceutical manufacturing.

## 5.4 Limitations

This study's primary limitation is its focus on a specific subset of pharmaceutical manufacturers, potentially limiting the generalisability of findings to the entire industry. The reliance on interview data, while providing rich insights, may be subject to individual biases and may not capture the full spectrum of experiences across different organizational levels. Additionally, the rapid pace of technological advancement means that some findings may become outdated quickly.

Despite these limitations, the research makes significant contributions. It provides a comprehensive, real-world perspective on the implementation of digital transformation in pharmaceutical manufacturing, bridging the gap between theoretical benefits and practical challenges. The study offers valuable insights into the interplay between technological advancements, regulatory requirements, and organizational dynamics in the context of digital transformation.

## 5.5 Suggestions for further research

The research contributes to the growing body of knowledge on QbD implementation, highlighting how digital tools enhance this approach. It also sheds light on the evolving role of regulatory compliance in a digitalised manufacturing environment, providing a foundation for future discussions on adapting regulatory frameworks.

Furthermore, the study's exploration of barriers to digital transformation offers a nuanced understanding of the challenges faced by pharmaceutical manufacturers, contributing to both academic discussion and practical problem-solving in the industry. The findings on operational continuity during disruptions like the COVID-19 pandemic provide timely insights into the resilience of digitalised manufacturing processes. Future research should expand on this study's findings by conducting longitudinal studies to track the long-term impacts of digital transformation on pharmaceutical manufacturing. This could include measuring changes in product quality, operational efficiency, and regulatory compliance over time as digital tools become more integrated into manufacturing processes. Researchers should investigate the potential of emerging technologies not covered in this study, such as blockchain for supply chain transparency or advanced robotics for manufacturing processes. Studies focusing on the application of digital twins in drug discovery and development could provide valuable insights into expanding the use of this technology beyond manufacturing.

There's a need for in-depth research on the cybersecurity implications of increased digitalization in pharmaceutical manufacturing. This should include developing industry-specific best practices and exploring the balance between data accessibility and security in a highly regulated environment.

Future studies should also examine the environmental impact of digital transformation in pharmaceutical manufacturing, aligning with growing concerns about sustainability in the industry. This could include assessing the carbon footprint of digital tools versus traditional manufacturing methods.

Comparative studies across different regions or between large pharmaceutical companies and smaller manufacturers could provide insights into how digital transformation varies based on company size, resources, and regulatory environments.

Lastly, research into effective change management strategies specifically tailored for digital transformation in pharmaceutical manufacturing could address the organizational barriers identified in this study, providing practical guidance for companies embarking on digital initiatives.

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# APPENDICES

## Appendix A - Interview Questions

1. Can you describe the digital tools currently utilized in your pharmaceutical manufacturing processes, specifically for CPP optimization?
2. How do these digital tools integrate into your daily manufacturing operations?
3. What specific benefits or improvements have you observed from using these digital tools in CPP optimization?
4. Could you discuss any noticeable changes in process efficiency since the implementation of digital tools for CPP optimization?
5. What impact have digital tools had on the quality of your final pharmaceutical products?
6. Can you provide examples or metrics that demonstrate how digital tools have transformed your operational workflows?
7. How have digital transformation initiatives facilitated your organization's alignment with Quality by Design (QbD) principles?
8. In what ways have digital tools helped or hindered your compliance with regulatory standards?
9. Could you describe any challenges or obstacles you've faced in maintaining compliance with regulatory standards while implementing digital tools?
10. What technological challenges have you faced while adopting digital tools for CPP optimization?
11. From an organizational perspective, what barriers have impacted the adoption of digital tools in your manufacturing processes?
12. How have regulatory requirements affected your approach to digital transformation in pharmaceutical manufacturing?

# Appendix B - Sample Interview Transcript and Translation

Date: 08/08/2024
Interview method: Online Zoom meeting
SPK_1 is the interviewer and SPK_2 is the interviewee
**Transcript:**
00:00:02 SPK_1
Hi, good evening.

00:00:05 SPK_2
Good evening Ashley. So you have mailed me regarding the interview.

00:00:10 SPK_1
Yeah, so it's about my dissertation interview. Like I think being working in a pharmaceutical manufacturing area, you will be quite familiar with these questions. So I will be asking my questions throughout my interview. Yeah. So let me start the interview.

00:00:29 SPK_2
Sure, sure.

00:00:30 SPK_1
Yeah. So my first question is like can you describe the digital tools actually utilised in your pharmaceutical manufacturing process, especially for CPP optimization?

00:00:43 SPK_2
Okay. So for continuous process parameters, we use as in part of the industry 4.0 evolution, we always use this artificial intelligence and machine learning based platforms to, for the management analysis of these data sets. And they are also useful for integrating automating CPB's by this predicting process outcomes and also in identifying any deviations in the, you know, the pharmaceutical processes in. We can have a real time analysis of if there are any deviations so that we can adjust our things accordingly so that with the final output is very much ideal to what we recur and also for the prediction of anomalies. And it can help have this swift corrective action so that the product quality essentially it helps us act very fastly. For example, in case of a driven predictive analytics. And all we can foresee, like we can run a simulation process or we can run process and see what are the process deviations and adjust the cpps accordingly so that we can, we can have an in back proactive control over this production process and ensure that these regulatory requirements are met. And also use of like NLP tools for. We can set the, you know, the clinical data will be a lot more structured and a whole lot effort is required to make it structured and ready for analytics. In case of manufacturing to, for example, we will have, we will have a row set of data which we need to automate it into or we need to feed it into the process stuff for the, for its execution. And if we use NLP based tools and also a based tools, it, it can help us, as I earlier said in the analysis part and also making it ready for analytics. You know, the prior effort is not much needed when you have an, have a digital tool here like extraction of any insights. We recur from last assets. You know how it is difficult to analyse large data sets and all right, so we can, for example, me being a regulatory professional, I can give an example like we need compliance reports and all for income to make it to see that the product manufacturing and consistent with GMB practises, you

know what GMP, right. So GMP as well as for the main regulatory bodies like FDA and DMA, and also with the local regulatory bodies, we need to be complained since we are working on numerous projects. So in that case, this works big time. And also in case of real world data. And, you know, ideality is not achievable. Right? So we can only have, we can, we can always have standard deviations where real world data is very important on how much we can improve on product quality or improve on these cpps. And therefore extracting data from prior clinical trials and also real world manufacturing settings can help. In this case. We can, we can have a better understanding of this process dynamics as well as we can have, you know, that, that fine tuning this manufacturing parameters to ensure a consistent quality, like for example, identify the correlation between product quality. And then, you know, like we, the basic thing is we adopt a proactive approach in case of regulatory requirements as well as process requirements, so that we can detect any deviations, make the necessary adjustments and all that stuff.

00:04:32 SPK_1
Okay, yeah, that sounds good. So my second question is like, how do these digital tools actually integrate into your manufacturing or daily operations? Right?

00:04:44 SPK_2
Okay, so about this daily operational integration, mainly we, in case of workflow integration, those digital tools can be integrated into, as I said earlier, for mainly through data collection, analysis and reporting, I can. Our team uses a and ML algorithms such as to ensure that CPP's are within the acceptable range is the ideal values are made. They are within the regulatory, they have complained with the regulatory requirements of each local body as well as the regulate national bodies as well as international bodies. They are in range within the ICH value. They are in range in the GMB value. So we can create a single data set, for example. That's what I'm saying. We can create a single data set to ensure that. What if we have a tabular form for every a column and we can see if they are complying to this and that instead of having a lot of manpower on this, we can execute this with single use of digital tools and all. And also in case of we, automation is the main thing for artificial intelligence and machine learning, obviously. So we can generate like real time compliance reports because, which is obviously needed because in case of our medical writing team, they work with the regulatory submissions and all that stuff. So they only create the template, but we need to put in the data. So rather than sitting around one table and discussing things and taking this on, you know, there's huge lot of effort and stuff. We can you, if we can create compliance reports and all in line with the manufacturing processes, then we can, it will be easy for the regulatory submissions and the team to work on that. And it will be also helpful for the audience and stuff, which will be happening in a monthly basis for which we will be also be a part. Since my role confines to the regulatory, my thing will be like regulatory compliance checking, so that I can completely look into how all the processes are dealt with in accordance with the regulations and close deviations and all that stuff, so I can go through it and analyse.

00:07:02 SPK_1
Right.

00:07:02 SPK_2
So digital tools help in that. Yeah, it's a successful integration example.

00:07:08 SPK_1
Exactly. So my third question is, like, what specific benefits or improvements have you observed from using these digital tools in CVP optimization?

00:07:18 SPK_2
Okay, so the first one I would say is like, like improvement in accuracy and real time monitoring, because like, if there are any deviations, I can work with the manufacturing scientist or the formulation technologist. And obviously we'll be working as a team, but different stakeholders need to be present at the site for the same. So if we have a, you know, an editor tool approach, then I can also closely monitor, have a real time monitoring, and different stakeholders can come together and contribute from their departments. For example, me being a regulatory professional, I can assure that the data we use is correct and manufacturing process are within the regulatory sensor. The compliance issues are met and up to date data things are used, and regulatory audits are done, and regulatory audits and inspections. The process is ready for regulatory audits and inspections, and I can perform the audits and inspections real time, you know, rather than spending more expenses on it on a different level, so that external audit channel inspections come, we can be more compliant and more advanced to that stuff. So, like that we can, we can manage with it. And also the decision making, I think you have improved much because we have an assistant now, we have, we have a digital tool now whom we can use for, you know, uh, understanding the deviations and all that stuff and making. And we, we can have a proactive risk management approach, uh, by that. And also we can have insights on how process variability and what, what are the root causes of deviations. And it will, it will be things that we have adopted through this whole lot here. But, uh, you see, uh, if we can have an idea on this, it's always so I can also document the process and I can ensure that this doesn't happen in the future thing. And things are optimised at a better scale in terms of regulatory compliance and all. And also cause I've been cut down apart from the implementation process, which obviously the company as a whole will be taking care of it. The corporate as always be taking care of it. But in terms of specific manufacturing processes, for example, you can see how much efficient the process is doing. Like the human labour as well as the QC processes are associated with the same can be reduced once we can we train them algorithm on the same. Right. So that is a major thing we have achieved.

00:10:06 SPK_1
Yeah.

00:10:08 SPK_2
And also regarding continuous process verification is another thing like that ensure that this CPPs and CQ, as you know, like the critical quality attributes we need to achieve through optimization of CPP's. That's the main ideology by the main, the basic principle behind it. So this helps that, this helps assure that the quality and the standards are really met and the compliance with regulatory standards are met. And, and also this, and as I was speaking earlier about the cost cutting and all resource allocation is a major thing. Like we don't have our employees to have downtime, obviously. So in case of we can have like, you know, an efficient resource allocation so that every employee can bring over maximum productivity not only in the, but also in manufacturing process in QC and all that stuff. So that resource allocation is optimised identifying trends and patterns from real world data offering and all. So they can strengthen regulatory submissions by

providing robust data to support planes and also in whether the document management process are streamlined and there is submissions are completed in a timely manner, alert systems are kept so that there are no delays in product approval and. Or like that.

00:11:30 SPK_1
Yeah. So my next question is like, could you discuss any noticeable changes in process efficiency since the implementation of digital tools for CPP optimization?

00:11:42 SPK_2
Yeah, so as I said earlier, benefits are profound, to be honest. For example, we'll start from the basics. Error, innumerable errors being reduced, to be honest, that especially human errors. Yeah, to erase human. But when an digital tool comes into play, the continuous monitoring minimises human errors and ensures that the products are, product quality is completely consistent or what we want to achieve is achieved. It is not a dream anymore, to be honest. So we can, as I said earlier, the immediate detection of issues are facilitated so that we can have a, you know, swift response and give corrective actions to marine. And also we can also, with these actions corrected. We can also note this in our sops, the standard operating procedure, so that this is followed through the, you know, the further processes or next level process or for different products and, or, and also this allows or even spaces for advanced optimization process. Like it's always what is ahead. So it also helps us plan what is ahead, what can be improved, what can be what deviations can be mitigated or whatever else can be mitigated and thereby leading to these, all are collected. You know, if errors come down and the response time is high, the efficiency is always high. So those automated data collection analysis reduce time and effort, which is always the main idea of digital tools. The time and effort is reduced and efficiency is always increased and decision making is improved. And of course, consistent work is maintained through the continuous process verification and all of, so that high standards of working compliance are maintained and resource allocation is improved. As I said earlier, better resource management can of course lead to increased productivity and faster time to market for new products. And manual effort is reduced, accuracy is improved and of course technology transfer, when in some cases, this is very important point in case of digital integration and also in case of manufacturing, as well as regulatory approaches. Because in some cases we will be outsourcing the supply chain processes as well as in some cases we will be manifest outsourcing the quality. It depends upon the project, on the companies we are working with. In some cases, some cases we outsource the quality infrastructure and or with them. So while this technology transfer is happening, it is very much uh, obvious that lack of regulatory knowledge and all can cause the employees to, you know, cause a glitch. You know, like there a glitch in the regulatory compliance of and all, or in case of transfer and, or if. Suppose my supply chain things are in Belgium or Ireland, I need to follow a certain set of regulations, you know, is to, in logistics and as well as, and all that. So if there is a. No, if it's a teamwork, ultimately, but if there is a lack of regulatory knowledge or if there is a. If there are inaccuracies, it can always lead to inconsistencies. So if we have a, you know, digital tool to scale up the production and all, it can mitigate these glitches and it can make the process more consistent and smooth. So these are the benefits I have seen.

00:15:21 SPK_1
Yeah. So my next question is like what impact actually a digital on the quality of your final pharmaceutical products?

00:15:32 SPK_2
Okay. On the quality basis, yeah, I can, working along with the QC department, I can provide some details on that. Yeah, sure. So it will be like, as I said earlier, data accuracy and consistency are the major key things that we aim to achieve, like real time monitoring and compliance with IC quality standards. Like ics Q ten and Q twelve. Quality assurance are completely meant these the products consistently meet this predefined quality attributes of cQas, which is of course essential. For, apart from that, when we branch into the different aspects of the process. So how I look more closely into this, we can, we can see that the traceability and transparency has improved a lot, to be honest. Like improved traceability can ensure that the old steps in the manufacturing process are very documented and easily auditable. Suppose, for example, if I need to go into the site and look in response, it is also even that I can also make others right. Or there will be some things that it will be specific to the manufacturing department's area of concern, which I won't be able to handle. So if there is a uniform traceability, there is an, if there is a good amount of traceability working within the processes, and I can also identify bottlenecks from my perspectives and experience and improve, which is obviously crucial for regulatory inspection, so that we can avoid further, uh, you know, complexities related to the same, uh, and as I said earlier, proactive preventive quality management is the thing we are aiming for. Uh, like, uh, emphasising, emphasising only risk based approaches to quality management such as, uh, QBD principles. Like QBD, aligning the QBD principles is our main aim, to be honest. So we aim to come up with, you know, this timely intervention so that every real time issues are, and products are compliant with the regulatory standards. And so, and finally, as things come into paper, efficient data management and documentation and automation of this data can reduce a whole lot of work from my side in putting all this data into paper and documenting what if I can have a like tools to get this data and just take a printout and combine this together, then also I can also have that assure that these regulatory, I mean, these regulations, I mean, process do meet GMP practiceology and ich loss. So it will be like, it is an easy to go task. What you call it, regulatory readiness, we can call it, it is ready to go into the regulatory department. Once I have correctly inspected and seen that like every regulatory requirements are met, so that the compliance process is, and ultimately it's all about reducing human errors, you know, like how much how we can improve safety and efficacy with that, which is obviously a primary concern for us. So, yeah, these are the impacts I have seen.

00:19:02 SPK_1
Yeah. So my next question is like, can you provide some examples of metrics that actually demonstrate how digital tools have transformed your operational workflows?

00:19:14 SPK_2
Okay, in terms of my operation, I think I would speak, I mean, I would bring some broader insights in this and being specific, like as the corporate as a whole, to be honest. So in case of streamlining our global content operations, you know, indigenous in terms of content operations was considered the global top ten pharmaceutical company and with respect to its improvements in efficiency and scalability, and the transformations we marked in that case were streamlining workflows, upgrading technology architecture, implementing robust change management mechanisms, etcetera. Metrics we use obviously is like reduction in time to market. You know, you know that it is a very complex. It takes a lot of time for the truck to reach the market. With the regulatory

approvals and with the introduction of digital tools and the streamlining of operation, we were able to reduce the time to market by 35 percentage and also cost savings. We were able to achieve a large number of cost savings, approximately counting to 45% in the last financial year and 60% asset reuse in the digital asset, so that redundancy is reduced and efficiency is enhanced. And digital asset management, for example, the company is pro. It's a. The company offers solutions on the same and centralised storage and management of digital content, leading to better organisation, kuka access and improved life cycle management. It has provided, as you know, a centralised hub for managing digital content, enabling global to local marketing and Q go to market strategies and improvement in efficiency leading to. Although specific percentage improvements are not disclosable, the overall impact includes reduced cross functional efforts and faster life cycle management. And automation has already helped a lot in manual errors. We can see that clearly in the audits we do that errors have been brought down to a large pattern. We have this real time monitoring alert systems. As I already said, these digital systems provide real time monitoring, regulatory benchmarks and all, ensuring that it is like the provost, compliance is completely met. And you know, in case of pharmacovigilance operation, we have seen that there is a 40 percentage increase in compliance and also case processings where 25 percentage of the case processings were done through, achieved through automation and with, you know, ideality was achieved up to 60 percentage. And I. In the future, in the next twelve months, we see a clear trend, very clearly increased trend. And as part of the. To be very specific, as part of regulatory is concerned, we have already discussed about the increased transparency and traceability, like how much we can improve the traceability and ensuring that the manufacturing process well documented, easily auditable and all that. And there is this proactive preventive complaint management and timely interventions. Regulatory submissions are achieved through NLP tools and automations so that timeliness as well as compliance is achieved on both scenarios. So that.

00:22:45 SPK_1
Yeah, so my next question is like how have digital transformation initiative actually facilitated your organisation alignment with quality by design principle QPD.

00:22:59 SPK_2
Okay, so yeah, QBD is one of our main aims and it comes to it covers both the regulatory as well as QC perspective to be honest. So I have given my perspective on same. Of course it is about PET mainly for use of like process analytical technology and advanced data analytics and they provide real time data and insights into the CPP's and CQAs and all. So it helps like, you know, more process design and understanding ensure that manufacturing process consistently produces high quality products and also real time monitoring and control align with the regulatory expectations for continuous process verification, proactive quality management and also in as part as far as QBD is concerned, risk management or applying risk based risk management approaches are greater concerns and we use this Monte Carlo simulations and FMEA processes for, you know, the risk management approaches in a large scale, to be honest. So digital rules facilitate this comprehensive risk assessments like helping to identify potential failure points and implement mitigation strategies in line with the ICH Q nine guidelines and I in line with this, identifying this bottleneck. We can also ensure that the documentation is properly done so that understanding as well as it means. Yeah, as I said, automations can be achieved and efficiency in documentation and of course the, you know, the main aim is on, you know, improving regulatory compliance as well as improving efficiencies

in lifecycle management and so that continuous monitoring and data analytics can enable ongoing process optimization and adaptation in accordance with the ICHQ ten and Q twelve guidelines. And DOE is concerned like design of experiments like these have enhanced the design and execution of experiments, allowing for more robust process development and optimization. So they help in systematically exploring the design space and identifying optimal process conditions, ensuring product development works at the most robust scenarios.

00:25:20 SPK_1
Okay. Yeah, so my next question is like in what are these, the digital tools helped your compliance with regulatory standards.

00:25:32 SPK_2
Okay. So yeah, so in case of regulatory compliance, as I said, the data management has significantly taken a whole new path to be host, ensuring that vast amounts of data which we had been generated during this doking processes and you know, simulation draws and all, and are completely met in case of production and that quality controls are systematically organised and analysed and retrieved. Timely submissions are, as I said earlier, are a key stone that we, a key cornerstone that we have achieved. And there is the risk of non compliance as with the metrics that we have discussed earlier, has reduced ways and because we are now focusing on systematic data organisation completely. So the non compliance is now a past story and in future it's going to be a myth. To be honest. The automation technologies such as robotic process automation which we are using have streamlined repetitive tasks like data entry, report generation and follow up submission. This, like, you know, like as, as far our metrics are concerned, like it minimises a lot of human errors and improved efficiency. As we have seen, we have quantitative data for that. And also it identify potential areas of non compliance, helping us for continuous improvement and proactive compliance management. And also, as I said earlier, real time monitoring alerts can help us have jump in at the right time and have this immediate corrective actions and continuous monitoring. And of course, by improving traceability and transparency, I can have something called this regulatory confidence. You know, it can be said amongst our team that we, it can boost our confidence among regulators that no discrepancies can be, are left unaddressed and the documents management are done more efficiently. The electronic document management systems can be, are linked with the digital rules so that documentations are proper and every process is ready for an audit.

00:27:53 SPK_1
Yeah, exactly. So, yeah, so my next question is like, could you describe any challenges or like obstacles you have actually faced in maintaining compliance regulatory standards like implementing such digital tools?

00:28:10 SPK_2
Yeah, challenges has been there down the road, to be very honest. Like it is, it is, it's a new system to be like bringing all the. Even though the discovery has been, it's been a few years, but the integration and of course, the cultural management and our adapting people into this using these flows and all, it's a bit of a thing. And of course, challenges are obviously there. So the primarily, as I said, as I said now this complexity is the main concern. Implementation. When complexity in the implementation process leads to delays in achieving full compliance, especially during the initial phases, we had to

perform this workshops and training stuff and our a long time, to be honest, and assessments to. For the. So that the employees are well, you know, well curated with this process and for the same significant resources are required to implement and maintain these digital tools which may divert attention from other compliance activities. You know, there are data security and privacy concerns too. Like the use of digital tools raise concerns about data for security and privacy. Like what is the, I mean, how is it ensured that this data security, I mean, their data feeder to the system are, you know, secure or it is not lost. You, you may know about like cyber security risk can breach, like how data is lost from the companies and all and how it can have a significant impact on the negative impact on the company. Right. Yeah. Like for example, if we have a pipeline, we have the $10 stored in a cyber, I mean, in a digital tool system. You know, you know, the cyber security concerns associated with it, like breach issues and all can significantly impact. Right. So we need to ensure that the compliance is completely done with GDPR, you know, by general data production regulation and, or. And any breeds can. No, no breaches are done. That. That is my major concern over there. Like I need to ensure that the regulatory compliance is in case of, I need to work in hand with the cybersecurity team. You see that regulatory compliance are completely met and there is no cyber attacks happening within the systems. And integration with legacy systems, like new duel digital rules are completely new. Right. So when, when it is coupled with the existing systems, like there are manual systems too. Now, we can't completely avoid or throw away the manual system just because these new tools came in. They formed the basis, to be honest. And if you even ask a manufacturing technologist or a formulation scientist, it is very evident that there are. They are like, you know, they form the basics, they form the way these missionaries form the basics. So we can only integrate these digital tools into these systems so that bottlenecks are identified, mitigated issues are resolved. Efficiency is increased, operational efficiency is increased. Right. So when it comes to regulatory process too, this incompatibility between new and legacy systems can lead to data inconsistencies and gaps in compliance. Also, more of the employees will prefer legacy systems, existing systems, and we need to push them to use this thing so it can also create operational disruptions impacting compliance loss and time like that.

00:31:54 SPK_1
Yeah.

00:31:55 SPK_2
So that is with the challenges we have seen.

00:31:58 SPK_1
Yeah. So my next question is, like, what are the technology challenges have you faced while adopting digital tools for CPP optimization?

00:32:09 SPK_2
Yeah, technological challenges and say some of what we have discussed in the regulatory area also comes here, like the data security and privacy concerns, as we all, like the digital tools, have like, you know, vast amount of sensitive data, including patient information, proprietary research data, in terms of manufacturing stuff and all, there are a lot of cybersecurity threats in there, to be honest. Like the main, which we can make the organisation like, more vulnerable to cyber attacks and, or we need in, when the digital tools are implemented, we need a very robust, high end cybersecurity

system so that no breach can happen with it. That is very important. And also in case of upskilling and change management has been a major concern. I have given you a hint about this in the last question. So we, as we, as we said earlier, like training programmes were extensively required to train these employees and all into these, about these new processes and all. So see, for them, it's a, it's an. It's an extra effort. They will be thinking like, we already know about these manufacturing laws and already we know about these regulatory submissions and we have ample knowledge from our experience, real world experience, matching this real world experience, and digital rules as well, experience them, because most of the works happen under experience, you know. Right. So when these digital tools come into contact, they focus more on the ideality. So the thin line between theory and practises, you know, very, very much long, to be honest, we need to have, we need to have a very careful conservation about this. So we, this, this has created a large impact, especially on conflicts, to be honest. And so therefore, effective change management strategies were required to minimise this resistance and ensure that technologies are adapted smoothly. And as I said earlier, even though course cuttings do happen, like, these technologies are very complex, these systems are very complex and sophisticated. So high implementation courses are required for the same in terms of budget allocation and all in return of investment and all, we really recover this, you know, allocating sufficient budget for digital transformation while ensuring that compliance is maintained. We need to ensure that this was not underfunded and also demonstrating our digital transformation initiatives were very essential to justify the investment and ensure continuous support from stakeholders. And also in case of data validation, continuous monitoring with respect to regulatory submissions and standards and or like challenges we faced in terms of technological challenges, to be the rest of the things we have mentioned in the regulator, I think.

00:35:18 SPK_1
I covered standards and hurdles. Yeah, exactly. So my next question is, like, from an organisational perspective, what are the barriers actually impacted, the adoption of digital tools in your manufacturing process.

00:35:35 SPK_2
In case of organisational change, I would focus on. These are similar to what we have discussed earlier, but in from an organisational, organisational perspective, I would say consider data security and privacy are a concern. The organisation need to implement significant changes or improve efficiency in the cybersecurity and as well as the learning and management team, so that employees are trained well, employees are trained efficiently on this. And the, you know, the cybersecurity teams systems are well equipped to identify any kind of incoming breach and all. So the organisation needs to ensure that. So organisation needs to be equipped with that sort of systems and all to ensure this, to prevent this, to be honest, and also in case of implementation course I have, as I have discussed earlier, the organisation should not face any budget constraints regarding the same. So as we are, we are going to achieve operational efficiency and we are going to take the next step or the next higher thought. We should be able to, there should be a significant amount of budget that the organisation should put in so that the digital tools are efficiently managed. And in terms of upskilling and change management, as I said earlier, employees will show resistance to the new changes. Some employees who lack knowledge on the same or who lack adapting and adapting skills may fall out in the process. To be honest, the organisation needs to manage that along with the human resource as well as learning and management team, so that things

are pretty well smooth and things don't take a long turn and that employees are addressed properly. They are there. The challenges and kind of, you know, what would you say the challenges and thoughts of the employees are properly met and their thoughts and attitudes are also considered in the long run because obviously they form the pillars of the organisation. So there both physical and mental considerations are to be well addressed by the organisation rather than taking it on a hinge note to be asked.

00:37:52 SPK_1
Yeah, exactly. So my last question is like how have regulatory requirements affected your approach to digital transformation in pharmaceutical manufacturing sector?

00:38:04 SPK_2
Okay. So in regulatory requirement, okay, regulate the current regulatory requirements, right. These regulatory requirements. Now currently we have the regulatory bodies such as the FD and EMAb, like we show, like universal complaints, like the, they have, they have the regulations for data integrity and security to protect the manufacturing process information and ensure that the data reliability is methadone. And now the company has implemented advanced data management robust data management system to ensure data integrity and security. And also we need to take in consideration GDPR and HIPAA to see that robust cyber security measures are taken and sensitive data is protected against breaches and cyber attacks. And also, as I said earlier, QBD is the major cornerstone. Quality wide design principles are a major, you know, pillars of regulatory as well as quality control. So the integration of this advanced analytics and real time monitoring tools in optimising CPP's can ensure that quality is built. Quality is the main thing from initial raw material uptake to the final product building. Adoption of CPV also aligns with QBD principles by continuously monitoring and verifying processes to ensure consistent product quality and compliance with regulatory standards. And also there we also use regulatory information management system, that's my in our department, which we use to centralise and manage all regulatory data and streamline the approval process and reduce any risk of human error in line with the automation tools we use so that accurate, up to date and compliant compliance. And also like, as we said earlier, that in regards to the ICS Q and A and guidelines in case of risk management in product lifecycle, we automate the FMEA and the simulation processes with you. And we also use advanced risk assessment tools to identify potential failure points and thereby adopting a very proactive goal. I mean quality management and finally traceability and transparency. As we have said earlier in the manufacturing browser we have a hand with the automation process happening. Every stakeholder can come in and put in their contributions and regulatory obviously so that we can ensure that things are in line with in within the manufacturing process in planning and execution so that audits are completely achieved 100% compliance. So basic idea is achieving 100% regulatory compliance with this automation, automation and digital tools and all and also to reduce human errors and to improve efficiency in terms of audits and inspections and also compliance in audits and inspections so that we can move to higher, higher levels with all these tools.

00:41:14 SPK_1
And so that's it, that's end of the interview. Thank you so much. Thank you for your time and patience.

00:41:22 SPK_2

No issues, no hope. I was able to contribute something for you.

00:41:29 SPK_1
Thank you, bye.

## Appendix C: Ethics Form


# Ethics Application & Declaration Form

DISSERTATION TITLE: The Role of Digital Transformation in Pharmaceutical Manufacturing Technology Optimization with a focus on Critical Process Parameters (CPP) in India.

RESEARCHER'S NAME: Ashly Thankachan

PROGRAMME OF STUDY: MSc Pharmaceutical Business and Technology

SUPERVISOR'S NAME: Martin Conneely

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE: Ashly Thankachan

DATE: 07/07/2024

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

For Supervisor:
Ethics Committee Approval Required: Yes [ ] No [X]

SUPERVISOR SIGNATURE: 

DATE: 07 July 2024

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 purpose of this study is to examine the role of digital transformation in optimizing Critical Process Parameters (CPPs) within the Indian pharmaceutical manufacturing sector. It aims to identify and evaluate the current digital tools and initiatives employed, assess their impact on operational efficiencies, product quality, and regulatory compliance. Additionally, the study seeks to uncover the challenges faced by the industry in adopting these digital technologies, including technological, organizational, and regulatory obstacles. This research will provide valuable insights into the integration of digital transformation initiatives in enhancing pharmaceutical manufacturing processes in India.

The objectives of the research are as follows:

· To identify and understand the current usage of digital tools and initiatives in the Indian pharmaceutical manufacturing sector focused on the optimisation of CPPs.

· To evaluate the impact of these digital tools on the operational workflows, process efficiency, and final product quality.

· To assess how digital transformation initiatives influence compliance with Quality by Design (QbD) principles and regulatory standards.

· To identify the challenges faced by the Indian pharmaceutical industries in implementing digitalisation initiatives, including technological, organisational, and regulatory challenges.

1.2 Research methodology:

The research methodology for this study is primarily qualitative, focusing on gathering in-depth insights through structured interviews with industry professionals in the Indian pharmaceutical sector. This

approach allows for a detailed exploration of personal experiences and perspectives regarding the adoption and impact of digital transformation initiatives on Critical Process Parameters (CPPs).
The primary data will be collected through one-on-one interviews conducted via Microsoft Teams or Zoom. Each interview will last approximately 30-35 minutes. The participants will include pharmaceutical manufacturing technologists, formulation scientists, quality assurance/control experts, regulatory professionals, and digital technology specialists. These professionals will be selected based on their direct involvement with digital transformation projects focusing on CPPs in their respective organizations.
Participants will be recruited using purposive sampling to ensure that they possess relevant experience and knowledge about the digital transformation in CPP optimization. The selection criteria will include professionals with at least three years of experience in their fields and active involvement in projects related to digital transformation in pharmaceutical manufacturing.
The interviews will be semi-structured, allowing for flexibility in responses while ensuring that all relevant topics are covered. The interview guide will be developed to explore three main areas: the current usage of digital tools in CPP optimization, the impact of these tools on manufacturing processes and product quality, and the challenges faced in implementing these technologies.
The audio-recorded interviews will be transcribed verbatim. Thematic analysis will be employed to analyse the data, where themes and patterns regarding the use of digital technologies in CPP optimization and the associated challenges will be identified and interpreted.

## SECTION 2: POSSIBLE ETHICAL ISSUES

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

### SUBJECT MATTER

**Does the research proposal involve:**

| | |
|---|---|
| Research into specific company activities that would be deemed sensitive or confidential | No |
| Research into politically and/or racially/ethnically and/or commercially sensitive areas | No |
| Sensitive, personal, professional or corporate issues | No |

### RESEARCH PROCEDURES

**Does the research proposal involve:**

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

### PARTICIPANTS

**Does the research proposal involve:**

| | |
|---|---|
| People who are not competent and/or fluent in English | No |
| Does your research group include any of the following vulnerable groups | No |

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

**<u>If you have answered NO to ALL questions, please go straight to Section 4.</u>**

**<u>If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.</u>**

## 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.

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## SECTION 4: ABOUT YOUR PARTICIPANTS

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

*Pharmaceutical Manufacturing Technologists*

- Master's degree in Pharmaceutics
- Minimum of 3 years working in Indian pharmaceutical manufacturing sector, with hands-on experience in operating and managing manufacturing processes.
- Deep understanding of manufacturing technologies, process automation, and familiarity with the latest trends.

*Formulation Scientists*

- Master's degree or Ph.D. in Pharmaceutics
- At least 3 years of experience in pharmaceutical formulation development in India, including working with novel delivery systems.
- Extensive knowledge of formulation principles, process development, scale-up challenges, and the integration of new technologies into formulation processes.

*QA/QC Experts*

- Master's degree in Pharmaceutical Quality Assurance.
- Minimum experience of 5 years in quality assurance or quality control within the Indian pharmaceutical sector.
- Proficient in quality standards, regulatory compliance, quality control processes and current digital techniques employed in the sector.

*Regulatory Professionals*

- Master's degree in Regulatory Affairs.
- At least 5 years of experience working in regulatory affairs.
- Deep knowledge of pharmaceutical legislation, regulatory requirements across different regions, especially India, and the impact of digital transformation on regulatory strategies.

*Digital Technology Specialists*

- Master's degree in Information Technology, Computer Science, or related fields with specialisation in digital technologies.
- Minimum of 3 years in developing or implementing digital solutions in a healthcare or pharmaceutical manufacturing environment.
- Proficiency in the implementation of AI and ML algorithms, IoT, etc.

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

The participants will be recruited through professional networks such as Linked In or academic networks such as Research Gate. An initial mail will be sent to them, followed by a detailed participant recruitment mail with the study details, along with the plain language statement and informed consent, notifying them of the voluntariness in participation. Once their consent is obtained, a 30–35-minute interview will be set up through Microsoft Teams or Zoom. The interview will be conducted based on the prepared questionnaires. Once the interview is completed, the responses will be collected and further analysed to deduce the results of the study.

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## SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

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

**Please confirm below that your information letter covers:**

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

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

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

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

---

## SECTION 6: STORAGE OF DATA

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

Signed consent forms, audio recordings, and text transcripts will be stored securely on the Griffith College authorized OneDrive platform. Access will be restricted to the principal investigator and supervisor. The data will be retained for one year after my graduation, from September 2024 to September 2025. After this period, all data will be completely destroyed to ensure your privacy is maintained.

Upon completion of the research, all primary data, including audio recordings, transcripts, and signed consent forms, will be handed over to the college in an electronic format as part of the thesis submission. This data will be uploaded to the primary data folder on Moodle.

The research will strictly adhere to the General Data Protection Regulation (GDPR) and the national data protection laws. This includes obtaining explicit consent from participants for data collection, storage, and usage.

Participants will be fully informed about the purpose of the study, the nature of their participation, and how their data will be used. Informed consent will be obtained before any data collection begins.

All personal identifying information will be removed from the transcripts to ensure anonymity. Participants and their occupations will be coded and presented in the reporting of results to prevent any identification.

The data will be stored on a secure, password-protected Griffith College authorized OneDrive platform, with access limited to the principal investigator and supervisor. Non-anonymized data, such as signed consent forms and audio recordings, will be kept in a locked cabinet and on a secure server.

Signed consent forms and original audio recordings will be retained until after the degree has been conferred. An anonymized transcript of the interviews will be retained for one year after graduation (September 2024 to September 2025).

After the retention period, all data will be securely destroyed to ensure the privacy and confidentiality of participants. Confidentiality may be breached only if the researcher believes there is a serious risk of harm to the participant or others, or if a serious crime has been committed. In such cases, the relevant authorities will be notified, and participants will be informed of this action.

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## SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

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

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

No

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

Yes

## SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

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

## SECTION 9: DOCUMENT CHECKLIST

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

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

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

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

For Student:

STUDENT SIGNATURE: Ashly Thankachan

DATE: 07/07/2024

## SECTION 10: APPENDIX


Participant Information Letter

'The Role of Digital Transformation in Pharmaceutical Manufacturing Technology Optimization with a focus on Critical Process Parameters (CPP) in India.'

I would like to invite you to take part in a research study aimed at understanding the impact of digital technologies on pharmaceutical manufacturing processes in India with particular focus on Critical Process Parameters (CPPs). Before you decide 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.

My name is Ashly Thankachan, and I am conducting this study as part of the completion of my Master's degree in Pharmaceutical Business and Technology at Griffith College, Dublin. The purpose of this study is to explore how digital tools such as IoT, AI, and machine learning are used to optimize Critical Process Parameters (CPPs) in the pharmaceutical industry in India. This research aims to provide insights that could potentially enhance operational efficiencies and compliance within the industry.

Participation in this study involves taking part in an online interview lasting approximately 30-35 minutes. During the interview, you will be asked about your experiences and opinions regarding the use of digital technologies in pharmaceutical manufacturing. The interview may be audio-recorded for transcription purposes, ensuring accuracy in capturing your responses.

You have been selected to participate in this study because of your expertise and experience in the pharmaceutical manufacturing sector in India. Your insights will be invaluable in understanding the practical implications of digital transformation in this field and their application in streamlining processes and enhancing operational efficiency

Please note that the participation is entirely voluntary. You can decide not to participate, refuse any question, or withdraw at any time without any consequences. If you choose to withdraw anytime from the study, please contact me at ashlythankachan2017@gmail.com

There are minimal risks associated with your participation in this study. The potential benefits include contributing to a better understanding of the research topic, fulfilling the objectives of the research and contribute to the research on digital transformation initiatives in the pharmaceutical manufacturing sector. All personal information will be handled with strict confidentiality.

Your participation will be confidential. No personal identifiers will be used in any reports or publications resulting from this study. Any confidential company data used will be with proper authorization, and all data will be stored securely. Identifiable data such as consent forms and audio recordings will be kept until the completion of my degree, after which they will be securely destroyed, except for anonymized transcripts retained for a further two years.

Your privacy and data security are of utmost importance in this study and will be managed in compliance with the General Data Protection Regulation (GDPR) and national data protection laws. All collected data, including signed consent forms, audio recordings, and transcripts, will be securely stored on Griffith College's authorized OneDrive platform, which is password-protected and accessible only to the principal investigator and the supervising faculty member.

Upon the completion of my research, all primary data will be digitally transferred to Griffith College as part of my thesis submission, and stored securely on Moodle. Any personal identifying information will be carefully removed or anonymized from the transcripts to ensure participant anonymity. This data, including any physical copies, will be retained until one-year post-graduation, September 2025, after which it will be securely destroyed to prevent any potential misuse.

Confidentiality will be strictly maintained; however, it may be breached if there is a credible risk of harm to you or others, or if a serious crime has been committed. In such cases, only the necessary authorities will be notified, and you will be informed about this action. These precautions are in place to ensure the integrity of the research process while protecting the privacy and security of all participants.

The results of this study will be used for my dissertation and may be presented at academic conferences or published in academic journals. The findings will also be accessible in the college library and may be included in online repositories.

If you have any concerns of queries regarding your participation, please contact:

Principal Investigator: Ashly Thankachan

Mail: ashlythankachan2017@gmail.com

Supervisor: Martin Conneely

Mail: martin.conneely@griffith.ie

Thank you for considering participation in this study. Your input is incredibly valuable and much appreciated.

Sincerely,

Ashly Thankachan


**Consent to take part in research**

**Research Title:** The Role of Digital Transformation in Pharmaceutical Manufacturing Technology Optimization with a focus on Critical Process Parameters (CPP) in India.'

The researcher retains one copy signed by both themselves and the participant. The participant should also receive a copy of consent form as a record of what they have signed up to.

- I [*insert participant name*] voluntarily agree to participate in this research study
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study
- I understand that participation involves completing a series of questionnaires about my experiences with digital tools in the workplace and participating in a one-on-one interview that will be recorded for further analysis. The interview will take approximately 30-35 minutes and will cover topics related to the adoption of digital technologies, challenges faced, and personal views on digital transformation used in the pharmaceutical manufacturing processes.
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.

- I agree to my interview being audio-recorded over Microsoft TEAMS/Zoom.
- I understand that disguised extracts from my interview may be quoted in my dissertation, conference presentations, published papers, electronic journals, and potentially included in the Griffith College library.
- I understand that I will adhere to all of the codes of conduct and employee confidentiality for company I belong to and there is no expectation to breach these by partaking in this research. A signed confidentiality statement between the researcher and the company will be included if deemed necessary.
- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission
- I understand that signed consent forms and original audio recordings will be retained securely on the Griffith College authorized OneDrive platform, accessible only to the principal investigator and supervisor, until the exam board confirms the results of my dissertation.
- I understand that a transcript of my interview, from which all identifying information has been removed, will be retained for two years from the date of the exam board confirmation.
- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

**Researcher Details**

Name: Ashly Thankachan

Degree Programme: MSc in Pharmaceutical Business and Technology

College Details: Griffith College, Dublin

Contact number: 0892460046

Contact mail: ashlythankachan2017@gmail.com

***Signature of participant***

Signature of research participant

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-- Date

***Signature of researcher***

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

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--- Date

Signature of researcher

**ASHLY THANKACHAN**