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Predictive and adaptive Manufacturing

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Abstract:
This comprehensive analysis explores the integration of digital technologies into the manufacturing industry, with a particular focus on developing and implementing predictive and adaptive frameworks aimed at achieving digital maturity. The study outlines the creation of a Minimum Viable Product (MVP) and its design specifications, primarily intended to enhance digital transformation in manufacturing. The report also emphasises the importance of assessing digital maturity as a prerequisite for implementing predictive systems. It identifies significant gaps in current systems through a thorough literature review. The research highlights the transformative potential of digital technologies in driving digital transformation and streamlining manufacturing processes. By delving into the complexities of implementing predictive and adaptive systems, the study identifies critical gaps in existing frameworks. It emphasises the necessity of structured models, such as the Digital Plant Maturity Model (DPMM), to enhance digital capabilities. Additionally, the role of digital twins is highlighted for their ability to optimise processes and enable real-time monitoring, which significantly improves operational efficiency and product quality in pharmaceutical manufacturing. Furthermore, the research outlines future directions and emerging trends in digital transformation, including the ongoing evolution of digital twins, advanced analytics, and scalable integration solutions. The study encourages the development of a culture centred on continuous improvement, empowering employees to embrace innovation and adapt to dynamic industry standards, thereby ensuring long-term sustainability.
In summary, this research aims to provide a clearer understanding of the transformative impact of digital technologies within the manufacturing sector. By reshaping maintenance practices and optimising operational efficiency, the study seeks to drive the industry towards achieving digital maturity, overcoming challenges associated with legacy systems, and maximising the benefits of advanced digital frameworks. It offers evidence-based recommendations and practical solutions, highlighting the importance of a holistic approach to digital transformation in fostering a sustainable and competitive manufacturing ecosystem

Section I: INTRODUCTION

Batch production is vital in the pharmaceutical industry. Which is impacting product quality and compliance. Failures can arise from human errors, documentation issues, equipment malfunctions, or regulatory non-compliance. Those leading to rejected batches and costly failures(Sharfstein *et al.* 2017). To prevent all these, robust quality control (QC) and quality assurance (QA) systems are inevitable(Denihan *et al.* 2015). QA detects defects during manufacturing, while QC ensures products meet their specifications (Kirwan et al., 2022). Regulatory bodies like the FDA, WHO, and EMA set guidelines to uphold quality standards (Sushma *et al.* 2019).

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Predictive maintenance, using data analytics, anticipates equipment needs. Which helps reduce downtime and failures, hence maintaining product quality and compliance (Vu *et al.* 2021). Without proper implementation of these facilities, companies face fines, suspensions, and reputational damage, risking recalls and financial losses (Sandle 2022).
This research examines batch failure causes and how predictive maintenance, enhanced by AI and big data, can prevent them, ensuring quality and sustainability in the global market.

Section II: LITERATURE REVIEW

Medicine manufacturing is crucial in guaranteeing the safety, quality, and efficacy of medications. However, batch failures, where products fail to meet quality standards, are a significant concern. These failures can result in product rejections, financial losses, delays in distribution, and harm to a company's reputation(Azadeh *et al.* 2019). Common causes of batch failures include human errors, equipment malfunctions, and non-compliance with regulatory standards(Su *et al.* 2019). Regulatory bodies such as the FDA, WHO, and EMA enforce strict guidelines to ensure product quality through quality assurance (QA) and quality control (QC) measures(Sushma *et al.* 2019).
One of the key strategies to reduce batch failures is **predictive maintenance**, which uses technology like AI and Big data to forecast equipment issues before they cause downtime. This approach helps ensure regulatory compliance, minimises costly failures, and improves operational efficiency(Vu *et al.* 2021). Without predictive maintenance, pharmaceutical companies risk penalties, recalls, and severe reputational damage(Sandle 2022; Valjevac 2022). This research highlights the importance of quality control and predictive maintenance in preventing batch failures and promoting long-term sustainability in pharmaceutical manufacturing.

2.1 Common Types of Batch Failures

The pharmaceutical industry heavily relies on batch production, a process that significantly influences both product quality and regulatory compliance. Literature indicates that production failures can arise from various factors, including human errors, inadequate documentation, equipment malfunctions, and non-compliance with regulatory standards, all of which can lead to rejected batches and substantial financial losses (Sharfstein *et al.* 2017). Implementing robust **quality control** (QC) and **quality assurance** (QA) systems is essential to mitigate these risks(Denihan *et al.* 2015). QA is responsible for identifying defects during the manufacturing process, ensuring that potential issues are addressed proactively. In contrast, QC focuses on verifying that the final product meets the necessary specifications before it reaches the market(Kirwan *et al.* 2022).
Regulatory bodies such as the FDA, WHO, and EMA provide guidelines that pharmaceutical companies must follow to uphold high-quality standards throughout production and distribution(Sushma *et al.* 2019). These guidelines ensure that products are consistently safe and effective, thereby protecting consumer health and maintaining public trust in pharmaceutical products.
In recent years, predictive maintenance has emerged as a critical strategy for minimizing batch production failures. By utilizing data analytics, predictive maintenance enables companies to anticipate equipment needs, thereby reducing downtime and preventing unexpected failures. This proactive approach not only ensures the smooth operation of manufacturing processes but also supports compliance with regulatory standards. The absence of predictive maintenance can have severe consequences, including regulatory fines, operational suspensions, and reputational damage, all of which can lead to product recalls and financial losses(Sandle 2022).

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Integrating advanced technologies like artificial intelligence (AI) and big data analytics into predictive maintenance processes further enhances its effectiveness(Vu *et al.* 2021; Kantaros and Ganetsos 2024). These technologies allow for more accurate predictions and timely interventions, which help ensure higher product quality and adherence to regulatory requirements(Nesterov 2023; Gunjal *et al.* 2024). This narrative review explores the causes and consequences of batch failures in the pharmaceutical industry and examines how predictive maintenance, bolstered by AI and big data, can mitigate these issues, ultimately ensuring long-term sustainability in the global pharmaceutical market(Miozza *et al.* 2024).

2.2 Analysis of Batch Failure in the Manufacturing Industry

Batch failures are a significant concern across various industries, including pharmaceuticals, electronics, and automotive sectors. These failures occur when products do not meet established quality and quantity standards, leading to substantial economic and operational challenges. In the pharmaceutical industry, batch failures are often attributed to operational inefficiencies, technological breakdowns, contamination, and human errors, as highlighted by (Pollock *et al.* 2017; Gershwin 2018). Measurement errors and equipment malfunctions are also critical contributors to these failures, as noted by (Diallo *et al.* 2021). Industry 4.0 technologies has introduced improved precision in manufacturing processes; however, it has also increased complexity, emphasising the need for predictive maintenance to prevent failures(Barari *et al.* 2021). Contamination and inadequate maintenance practices frequently result in batch rejections, with human errors, often stemming from insufficient training, exacerbating these issues(Kumar and Jha 2018). Preventive and predictive maintenance, powered by machine learning and IoT, are more effective than traditional methods in reducing batch failures, as demonstrated by (Shamayleh *et al.* 2020; Bouabdallaoui *et al.* 2021)Failure analysis techniques such as **Root Cause Analysis (RCA)**, **Failure Mode and Effects Analysis (FMEA)** and **Fault Tree Analysis (FTA)** are instrumental in identifying the root causes of failures, as explored by (Mokhtarzadeh *et al.* 2024). Batch failures can lead to financial losses, regulatory problems, and disruptions in the supply chain, highlighting the importance of combining advanced maintenance strategies with human expertise to maintain quality control(Ivanov *et al.* 2017; Paul *et al.* 2018).

A. Causes of Batch Failure

Inadequate maintenance is identified as a primary cause of batch failures across industries, with the selection of suitable machine-learning applications for predictive maintenance playing a crucial role in mitigating these issues(Carvalho *et al.* 2019). The failure to detect equipment faults can lead to breakdowns and shutdowns, particularly in automated environments reliant on Industry 4.0 technologies (Sang *et al.* 2021). While Industry 4.0 enhances manufacturing through connectivity, an inappropriate approach heightens the risk of equipment failures and prolonged downtimes. Poor maintenance decisions and external interference further contribute to batch failures, as noted by (Zhong *et al.* 2023). In bioprocessing, inadequate training and poor working conditions result in errors, with skill shortages aggravated by insufficient human resource investment(Ranck 2022). Substandard equipment, untrained personnel, and poor production planning lead to products falling short of specifications, necessitating quality control measures and failure mode analysis to mitigate these risks and ensure product consistency(Wu and Lin 2019; Satzer *et al.* 2022).

B. Impact of Component Faults

Component faults are a significant cause of batch failures in pharmaceutical manufacturing, affecting both product quality and regulatory compliance. Key failure types include raw material contamination,

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calibration issues, packaging defects, and cross-contamination. Improper handling, environmental exposure, or microbial contamination can degrade active pharmaceutical ingredients (APIs), compromising potency and safety, as noted by (Dispas *et al.* 2018; Boukoufi *et al.* 2022). Variability in particle size can also affect dissolution rates, leading to quality issues(Markl and Zeitler 2017). Inaccurate calibration of equipment can lead to unstable conditions, such as incorrect humidity or pressure levels, resulting in defective products(Sangshetti *et al.* 2017; Park *et al.* 2022; Zhang *et al.* 2022). Packaging defects, such as poor sealing or exposure to oxygen, moisture, or light, can degrade drug stability and increase contamination risks(Rather *et al.* 2017; Janga *et al.* 2018; Ling *et al.* 2018). Insufficient cleaning procedures can transfer drug traces between batches, leading to incorrect dosages or adverse reactions(Dahiya *et al.* 2022).

C. Role of Human Error

Human error remains a critical challenge in pharmaceutical manufacturing, affecting batch quality despite automation. Key human errors contributing to batch failures include poor record-keeping, miscommunication, inadequate training, failure to follow standard operating procedures (SOPs), and fatigue. Inaccurate documentation of raw materials, operational processes, or storage conditions can cause deviations, leading to batch rejection(Gomez Mulero 2022; Moorkoth *et al.* 2024). Lack of clear communication between departments can result in missed instructions, incorrect formulations, or quality control lapses(Del Giorgio Solfa 2022). Insufficient staff training in handling sensitive materials and operating complex equipment increases contamination risks(Li 2022; Nguyen *et al.* 2023). Non-adherence to standard procedures leads to cross-contamination, improper mixing, and regulatory non-compliance(Chryssolouris *et al.* 2023). Overworked staff are prone to errors, particularly in high-pressure situations like the COVID-19 pandemic(Wouters *et al.* 2021).

D. Other Contributing Factors

Variability in manufacturing processes can cause batch failures, impacting quality, production, and public health. Problems with fermentation, reactor designs, and rigid batch processes have made continuous manufacturing more appealing(Kumar *et al.* 2020; Grahn and Sjödin 2021; Hu 2021). Inaccurate calibration leads to flawed measurements, affecting product quality, while environmental fluctuations such as temperature and humidity changes degrade products, causing rejections. Poor documentation exacerbates operational inconsistencies, as highlighted by (Sandle 2022).

2.3 Adverse Effects of Batch Failures

A. Economic Impacts

Batch failures in pharmaceutical production result in significant financial losses, such as wasted raw materials, labour costs, equipment downtime, and penalties(Sardella *et al.* 2021). Stopping production is costly because specialised equipment still incurs high maintenance costs(Vlasov and Lapteva 2022). Wasting expensive materials, especially in biologics, increases these losses(Alshemari *et al.* 2020)). Failing to meet regulations can lead to fines and delays in market entry, further harming revenue('iSpeak' 2023). Supply chain problems also cause contract breaches, lost sales, and damaged relationships with distributors, which negatively affect future revenue(Sardella *et al.* 2021).

Case Study: Johnson & Johnson's COVID-19 Vaccine Contamination

In 2021, a contamination of 15 million doses of the Johnson & Johnson COVID-19 vaccine at a Baltimore facility caused significant financial losses(CRANE 2021). This included the immediate destruction of the affected doses, the cost of delayed shipments, increased regulatory oversight, and the re-investigation of

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production processes(LaFraniere and Weiland 2021). This incident shows how complex pharmaceutical supply chains can make the economic impact of batch failure even worse.

B. Operational Downtime

Batch failures in pharmaceutical manufacturing cause major disruptions, requiring investigations and equipment adjustments, which lead to longer downtime(Ganesh *et al.* 2020). Specialised machinery also needs revalidation after failures, further delaying production(Azab *et al.* 2021). Continuous production systems are especially at risk, as failures can stop entire production lines and disrupt supply chains(Ganesh *et al.* 2020). Delays in getting Active pharmaceutical ingredients (API) affect suppliers, logistics, and contracts. Additionally, long downtime reduces employee productivity and morale, increasing retraining costs and operational expenses.

Case Study: Global Pharma Healthcare Pvt Ltd Indian Pharmaceutical Company

Global Pharma Healthcare Pvt Ltd, an Indian pharmaceutical company, experienced an operational shutdown of over two months due to a sterilisation equipment failure. This prolonged downtime caused significant disruptions in production schedules, leading to the eventual loss of key supply contracts with distributors. Unlike larger multinational firms that may have contingency plans and financial buffers, smaller companies are more vulnerable to the operational impacts of batch failures, which can threaten their viability and survival(Opinion 2023).

C. Reputational Damage

Pharmaceutical companies rely on their reputation for producing safe and effective products, and batch failures can damage trust among healthcare professionals, regulators, and consumers(Pollock *et al.* 2017). Publicised failures, especially those causing recalls, are made worse by media coverage, requiring costly public relations efforts and quality improvements to rebuild confidence(Sardella *et al.* 2021). For companies making critical medications, this damage can lead to consumer boycotts, loss of market share, and reduced trust from healthcare providers. Frequent batch failures can also lower investor confidence, causing stock prices to drop, especially for smaller firms that depend on external funding.

D. Customer Dissatisfaction

Pharmaceutical companies rely on delivering high-quality, safe, and effective products consistently, and batch failures can damage customer trust, especially when they cause recalls or delays in life-saving drugs. Healthcare providers may switch suppliers to ensure reliable access, leading to lost business and more customer scrutiny(Dubin *et al.* 2021)). Batch failures also increase production costs, which may result in higher prices for customers, causing dissatisfaction and reduced loyalty, particularly in competitive markets(Dubin *et al.* 2021).

Further supporting examples can be found in the case studies in Appendix 2

2.4 Drawbacks of Current Maintenance Practices

Maintenance management faces challenges like budget constraints, aging infrastructure, technological advancements, and regulatory compliance. These issues can lead to higher costs and operational disruptions.

A. Budget Constraints

Budget limitations are a pervasive issue in maintenance management. Insufficient financial resources can lead to deferred maintenance, which increases equipment failure rates and operational disruptions. Studies show that equipment failure rates rise by 25% due to deferred maintenance(Le *et al.* 2018). Organisations

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with limited budgets may adopt reactive maintenance, addressing issues only after they occur, leading to higher long-term costs and extended downtime. Research indicates that reactive maintenance can increase maintenance costs by 30% compared to preventive maintenance schedules(Palange and Dhatrak 2021). Proper budgeting is essential to maintain equipment reliability and efficiency.

B. Ageing Infrastructure

Ageing infrastructure poses significant challenges for maintenance management. As equipment and systems age, they require more frequent maintenance and replacements, leading to higher costs. Companies with older infrastructure spend 40% more on maintenance than those with newer systems(Capacci *et al.* 2022). Additionally, maintaining ageing infrastructure requires specialised skills and knowledge, as technicians must be familiar with outdated equipment and technologies. The shortage of skilled maintenance workers for ageing infrastructure can result in longer downtime and reduced maintenance efficiency(Lee 2020)

C. Technology Migration

The steep rise of technological growth offer both opportunities and challenges for maintenance management(The4 2024). While new technologies, such as the machine learning, Internet of Things (IoT), and predictive analytics, can improve maintenance precision and efficiency, adopting these technologies can be costly(Jerez-Jerez *et al.* 2025). (Alam *et al.* 2021) found that the huge cost of the latest technology migration is a major barrier to its adoption. Moreover, implementing these technologies requires significant investments in new tools, training, and process changes. Maintenance personnel must be adequately trained, and existing workflows must be adapted to integrate these new technologies.

D. Regulatory Compliance

Regulatory compliance adds complexity to maintenance management. Organisations must maintain, document, and report according to industry regulations. Compliance activities require additional inspections, documentation, and reporting, which can be time-consuming and costly. A study published in 2023 found that 15% of organisations' maintenance budgets are devoted to compliance activities, including inspections and reporting(Trebbi *et al.* 2023). Non-compliance can result in significant penalties, highlighting the importance of staying up to date with regulatory changes and integrating compliance into maintenance planning.

2.5 Drawbacks of Current Quality Practices

A. Cost Implications

The Cost of Quality (CoQ) in manufacturing is divided into four categories: prevention costs, appraisal costs, internal failure costs, and external failure costs(Vakilifard and Khozein 2012). Prevention costs involve investments in training and quality systems to avoid defects, offering long-term savings despite initial high costs. Appraisal costs relate to monitoring quality through inspections and testing, balancing necessary assessments with operational efficiency. Internal failure costs are incurred due to defects identified before a product is delivered, causing rework and downtime. In contrast, external failure costs emerge when defects are detected after delivery, leading to product recalls and harm to the company's reputation(Vakilifard and Khozein 2012). Balancing these costs is crucial for effective quality management, with companies needing to allocate resources strategically to improve product quality and maintain financial efficiency(Trebbi *et al.* 2023).

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B. Inefficiencies in Time Management

Inefficiencies in time management can affect production schedules and profitability in manufacturing. Key factors include inadequate equipment management, lack of standard operating procedures (SOPs), poor communication, production bottlenecks, and the absence of real-time data analytics. Equipment downtime from unplanned breakdowns can be reduced with predictive maintenance. The absence of SOPs causes variability and longer cycle times, while standardised procedures streamline operations. Poor communication can delay processes, but integrated systems improve coordination. Bottlenecks can be identified through value stream mapping, and real-time data helps address inefficiencies swiftly. Addressing these issues leads to improved operations, reduced lead times, and enhanced competitiveness(Boya and Rao 2019)).

C. Resource Allocation Issues

Resource allocation is critical for quality management in manufacturing, ensuring efficient production through effective distribution of personnel, equipment, and materials. Challenges such as outdated resource allocation systems and conflicting goals hinder this process. Siloed departments and a lack of integration cause inefficiencies, which can be addressed by fostering collaboration and implementing integrated management systems(Cheng *et al.* 2019). Legacy systems hinder resource allocation, but modern solutions like ERP systems provide real-time data and improve management. Conflicting goals, such as production prioritising output and quality control focusing on defects, can be resolved by aligning objectives and using balanced scorecards. Inefficient resource allocation leads to defects, delays, and customer dissatisfaction. Regular resource assessments, capacity planning, and continuous improvement initiatives help optimise allocation and improve operational efficiency(Cheng *et al.* 2019).

D. Lack of Proactive Measures

Proactive quality management in manufacturing is a strategic approach that aims to prevent problems, reduce costs, and improve customer satisfaction by identifying potential issues early and implementing preventive measures. Unlike reactive management, which addresses problems after they occur, proactive quality management seeks to enhance efficiency and minimise defects from the outset. (Wu and Lin 2019) highlights that reactive management often leads to higher costs and delays due to expensive rework and warranty claims. In contrast, (Salonen and Gopalakrishnan 2021) emphasizes that proactive management focuses on prevention, thereby improving efficiency and reducing defects.

Supplier quality management is a critical component of proactive quality management. Neglecting supplier quality can significantly affect production outcomes. (Obaidat and Liao 2021) suggests that proactive management involves regular audits and collaboration with suppliers to ensure they meet quality standards. This collaborative approach helps maintain a consistent level of quality across the production process, thereby reducing the likelihood of defects and enhancing overall product quality.

Training programs are another essential element of proactive quality management. (McIlwraith 2021) argues that proper employee training enables early identification of potential issues. Without adequate training, employees may struggle to address problems before they escalate, leading to increased costs and reduced quality. Effective training programs equip employees with the skills necessary to maintain high standards of quality and prevent defects.

Lean, Six Sigma, and TQM are the key continuous improvement methods for proactive quality management. (Hussain and Mackie 2024) discuss how these methods help improve processes and reduce costs by systematically identifying and eliminating sources of waste and inefficiency. By adopting these

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methodologies, companies can continuously enhance their processes, resulting in higher quality outcomes and greater customer satisfaction.
The adoption of proactive quality management practices allows companies to avoid problems, improve supplier relationships, train employees effectively, and enhance processes for better results. This approach reduces costs and improves customer satisfaction by delivering higher-quality products consistently.

2.6 Drawback of Manufacturing Excellence.

A. In-line Process Monitoring and Control

In-line process monitoring ensures real-time assessment of production parameters, enabling immediate adjustments for quality and efficiency(Smith and Hawkins 2019). By reducing manual inspections, it minimizes errors and enhances consistency(Chukwunweike *et al.* 2024). While implementation can be costly and complex, requiring integration and maintenance(Sardella *et al.* 2021), its accuracy and operational benefits make it essential in modern manufacturing.

B. Manual Recipe Adjustments

Manual adjustments in manufacturing processes can lead to inefficiencies and errors. These adjustments are often time-consuming and prone to human error, which can result in inconsistent product quality and increased operational costs(Adrita *et al.* 2021). The reliance on manual processes can be a significant bottleneck in production

C. Lack of Fully Automated Execution

The absence of full automation in manufacturing processes limits scalability and efficiency. Manual processes still dominate many areas, leading to delays and increased labor costs(Vlachos *et al.* 2023). Automation can streamline operations, reduce errors, and enhance productivity, but its implementation requires significant investment and a shift in workforce skills

D. Data Flow and Integration

Effective data flow and integration are crucial for seamless manufacturing operations(Guo *et al.* 2021). Many manufacturers struggle with disparate systems that do not communicate efficiently, leading to data silos and inefficiencies. Integrating data across various platforms can improve decision-making and operational efficiency but often requires significant technological upgrades(Chinta and Chhapola 2024).

E. Operator Involvement

While operator involvement is essential for oversight and quality control, excessive reliance on human intervention can introduce variability and errors. Automation can reduce the need for constant human monitoring, allowing operators to focus on more strategic tasks. However, this transition requires retraining and a cultural shift within the organisation(Sharma *et al.* 2024).

F. Vendor Independence

Vendor dependence can limit flexibility and responsiveness in manufacturing operations(Jiang *et al.* 2023). Relying heavily on specific vendors for equipment or software can lead to challenges if those vendors change terms or go out of business. Achieving vendor independence requires strategic planning and often involves adopting open standards or multi-vendor strategies

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2.7 ADMA TranS4mers & DPMM Recommendations

The ADMA TranS4MErs project indeed plays a crucial role in aiding small and medium-sized enterprises (SMEs) in their journey toward digital transformation in the manufacturing sector across Europe. It focuses on helping these enterprises become more sustainable and competitive by adopting advanced digital technologies. The Change Platform is a key component of this initiative, serving as a collaborative space where SMEs can connect with digital service providers to customize their transformation journeys(IMR 2024). This platform offers various tools and resources to guide companies through the digital transformation process, addressing challenges related to ecological sustainability, digital integration, and societal impacts. Table 1 explains the level of plant maturity.

Name	Characteristics
Pre-Digital	Paper-based processes, Manual processes, Basic PLC controls, Low level automation
Digital Silos	Siloed automation system, Semi-automated batch records, Local batch recipes, Analytics on Demand
Connected Plant	Vertical integration ERP, LES, MES and automation, Electronic BR, S88 / S95 adoption, Analytics that are semi-automated
Predictive Plant	Enterprise integration - IT/OT integration, Product development and manufacturing integration, Supply chain visibility, Pro-active analytics across plants
Adaptive Plant	Full integration - Supplier to patient, Modular, mobile and collaborative manufacturing, Plug & Play - From line to instrument, Zero system downtime, "Self-aware", adaptive, autonomous plant

Table 1: DPMM Level of plant maturity

On the other hand, BioPhorum is an industry consortium that provides valuable data and insights specifically for the biopharmaceutical sector. It facilitates collaboration among industry leaders, helping them share best practices and leverage digital technologies to improve operational efficiency and product quality. Biophorum's resources can be particularly beneficial for companies looking to understand the impact of digital tools on manufacturing processes and to benchmark their progress against industry standards(BioPhorum 2024).

Both platforms emphasize the importance of collaboration and data-driven decision-making in achieving successful digital transformations. They provide frameworks and support systems that enable companies to navigate the complexities of integrating digital technologies into their operations.

2.8 Refined Research Question

How can the Digital Plant Maturity Model be implemented, and what potential solutions can improve operational excellence to reduce batch failures and enhance quality control for better product quality in the pharmaceutical industry?

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Section III: IDENTIFICATION/REFINEMENT OF RESEARCH-PRACTICE GAPS

The implementation of the 'Connected plant' or Smart Plant(Xia *et al.* 2021) as per DPMM concept has emerged as a key innovation in several industries, particularly in manufacturing and healthcare, offering significant opportunities to improve operational performance, efficiency, and decision-making through the creation of virtual models of physical systems(BioPhorum 2024). However, despite the growing interest and the availability of cutting-edge technologies to support the deployment of 'Digitally Connected plant', a significant gap exists between research and practical implementation. This section explores the key research-practice gaps that hinder the adoption of Digital Twin technology(O'Connell *et al.* 2023), which is a cornerstone of 'Digitally connected plant' and also serves as a foundation for predictive and adaptive plants according to DPMM concepts and Pharma 4.0 concepts, particularly in manufacturing and healthcare, and outlines areas where future research is needed to refine these practices.

3.1 Data Ownership and Collection Issues

One of the primary road blockers in the deployment of Digital Twins is the lack of data ownership and the incomplete collection of data from production environments. Studies by (Chen *et al.* 2020) indicate that, as per Figure 1, up to 70% of data generated in manufacturing settings is not captured, and crucially, it lacks clear ownership. Without accurate, real-time data, the creation of a Digital Twin is severely limited, as the digital replica depends on continuous data flow from sensors, machines, and processes on the production floor(Babu *et al.* 2024). The challenge of data capture and ownership stems from a mix of technical limitations, such as the absence of digital devices capable of collecting the data, and organisational hurdles, such as unclear data governance structures(Xia *et al.* 2021). To overcome this gap, research is needed on establishing data ownership models and frameworks for better data governance in industries, particularly those with large-scale operations, such as pharmaceutical manufacturing. Investigating effective methods for integrating data from disparate sources into a unified hub could significantly improve the accuracy and efficiency of Digital Twin systems.

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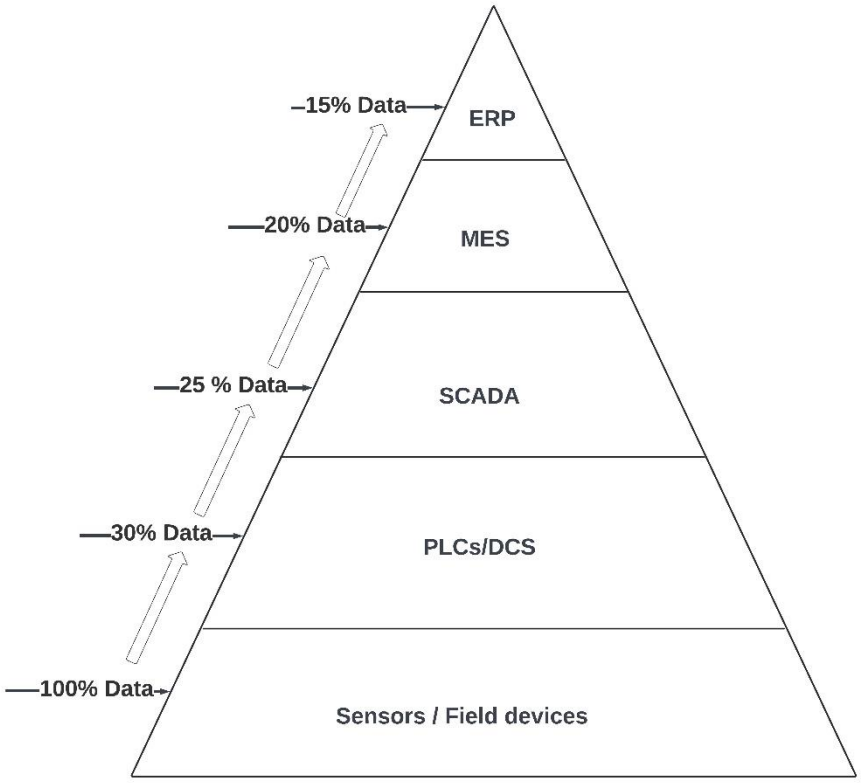

Figure 1: Data flow in the plant Hierarchy

3.2 Complexity of Point-to-Point System Integration

In many industries, point-to-point integration remains a significant challenge(Federico *et al.* 2021). This refers to the difficulty of integrating various legacy and modern systems across the production floor into a cohesive, real-time data flow suitable for creating Digital Twins. Manufacturing environments typically rely on a mix of legacy software, machine controllers, and Iot devices, which are often incompatible with each other. This integration complexity is a substantial barrier to implementing the Digital Twin effectively.

Existing research by (Federico *et al.* 2021)highlights the critical need for interoperability frameworks that can seamlessly connect these disparate systems and provide real-time data to the Digital Twin. Developing unified communication protocols and open-source platforms that facilitate interoperability between old and new technologies will be essential to overcoming this barrier. Further studies on how to standardise communication protocols across industries could significantly impact the successful adoption of Digital Twins(Chen *et al.* 2020).

3.3 Lack of a Comprehensive Digital Strategy

A widespread gap exists in many organisations where digital strategy is either poorly defined or completely absent(Hanelt *et al.* 2021). In order to implement a successful Digital Twin system, companies need a clear, strategic framework that identifies key data sources, integrates new technologies with existing systems, and aligns with business objectives. Many organisations do not have a comprehensive digital transformation plan, leading to fragmented, disjointed efforts that fail to leverage the full potential of Digital Twin technology(O'Connell *et al.* 2023).

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(Rogers *et al.* 2018)suggest that having a comprehensive digital strategy is essential to guiding the transformation and ensuring successful implementation. Future research should focus on frameworks for building these digital strategies in industrial contexts, especially in healthcare and pharmaceutical industries, which are highly regulated and require careful planning for digital integration.

3.4 Legacy Plant Structures and Outdated Equipment

Many manufacturing plants are hindered by outdated infrastructure and legacy equipment that is not designed to support modern digital technologies. Older machines and plant structures often lack the sensors and communication capabilities required to feed data into a Digital Twin system. Retrofitting these systems to support new technologies can be costly and technically challenging(Chen *et al.* 2020).

Research on hybrid solutions or retrofit strategies could be essential for bridging this gap. Exploring low-cost and scalable solutions to upgrade older systems without overhauling entire plant infrastructures could be key to ensuring broader adoption of Digital Twin technologies (Xia *et al.* 2021)

3.5 Change Management in Digital Twin Implementation

The implementation of Digital Twins requires significant organisational change. Employees may resist new technologies, and organisations often lack sufficient plans for staff training and process updates(Haber and Carmeli 2023). Successful implementation hinges on ensuring that personnel are trained to work with the new systems and that the company's processes are adjusted to accommodate the Digital Twin framework.

As highlighted by (Hanelt *et al.* 2021), change management is pivotal in in the successful deployment of Digital Twin technology. Research is needed on best practices for managing this change, particularly in complex environments like manufacturing plants or healthcare settings, where systems are often complex, and employees are accustomed to traditional methods of working.

3.6 Data Security and Privacy Concerns

Digital Twin systems rely heavily on real-time data, which may include sensitive information regarding processes, equipment performance, and proprietary details. As such, data security and privacy concerns are paramount, especially in industries such as healthcare and pharmaceuticals, where patient confidentiality and intellectual property protection are critical(Lee and Ahmed 2021).

The integration of Digital Twin technology opens up several cybersecurity vulnerabilities, particularly with the proliferation of connected devices and IoT technologies. Studies such as those by (Lee and Ahmed 2021) emphasize the importance of developing robust security frameworks and encryption protocols to safeguard sensitive data within Digital Twin systems. More research is needed on how to implement secure data-sharing mechanisms and ensure the privacy of critical information during the Digital Twin lifecycle.

3.7 Scalability and Future Growth

As industries grow and technological advancements continue, the scalability of Digital Twin systems remains a significant concern(O'Connell *et al.* 2023). Many existing systems are not designed to handle the increasing volume of data that will arise from the integration of new devices, sensors, and production equipment over time. Scalable solutions that can accommodate future technological advancements without becoming obsolete are necessary for ensuring long-term success.

Research on designing scalable architecture for Digital Twin systems, particularly in large-scale manufacturing and healthcare systems, is crucial. Solutions must be able to grow and evolve in line with future developments in artificial intelligence, machine learning, and Internet of things technologies (Li *et al.* 2023)

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Section IV: Initial Research Methodologies / Constructs / Concepts Identified

2.9 4.1. Research Methodologies

This study will use a mixed-methods approach to implement the Digital Plant Maturity Model (DPMM) in the pharmaceutical industry, aiming to improve operations and product quality. This methodology integrates qualitative and quantitative research methods to provide a comprehensive perspective on the digital transformation processes within the manufacturing sector(Wolf 2024).

A. Qualitative Methods

Interviews: Semi-structured interviews will be held with key stakeholders, including plant managers, quality control experts, IT specialists, and operations managers. These interviews will focus on three areas: Current Digital Maturity, Challenges and Barriers, and Digital Solutions(Janssens *et al.* 2019). The interviews will be flexible yet structured, allowing participants to share their views openly and providing detailed and valuable insights.

Focus Groups: Cross-functional teams, including representatives from operations, IT, quality control, and management, will be brought together in focus groups to discuss their perspectives on digital maturity and operational challenges.

B. Quantitative Methods

Surveys: A structured survey will be developed and distributed to a larger sample of employees across various plants. The survey will be designed to assess the current state of digital maturity across different plants by evaluating the following dimensions: **Technology Integration**, **Process Optimisation**, and **Cultural Readiness**(Davis 2004)**.** The data gathered from the surveys will allow for statistical analysis of trends, such as correlations between digital maturity levels and other operational metrics, including batch failure rates, production efficiency, and quality control outcomes.

Experiments: Pilot digital solutions will be implemented in test rigs to test the effectiveness of these interventions. These experiments will focus on implementing specific digital solutions, such as predictive maintenance systems, real-time quality control monitoring, or automated reporting tools. Also monitor the impact of digital tools on operational performance, focusing on batch failure rates, product quality, and process efficiency. The experiments will involve collecting baseline data before the implementation of digital tools and then comparing this data to post-implementation results.

C. Rationale for Mixed-Methods Approach

The mixed-methods approach is well-suited for this study because it enables data triangulation, which enhances the credibility and dependability of the findings. By combining qualitative methods such as interviews and focus groups with quantitative techniques like surveys and experiments, researchers can achieve a more comprehensive and nuanced understanding of the topic. The study can capture both the subjective perspectives of key stakeholders and objective, measurable data on digital maturity and operational performance. This approach provides a thorough understanding of the problem and supports evidence-based recommendations for digital transformation in the pharmaceutical industry(Janssens *et al.* 2019).

Moreover, the mixed-methods approach enables the exploration of complex relationships between digital maturity and operational outcomes, which would be challenging to capture with only one method fully. Integrating both types of data offers a more nuanced and well-rounded view of how digital technologies impact pharmaceutical manufacturing processes.

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2.10 4.2. Construct

The key constructs central to this research on implementing the Digital Plant Maturity Model (DPMM)(BioPhorum 2024) in the pharmaceutical industry, to enhance operational excellence and product quality, include digital maturity, operational excellence, batch failure rate, and quality control. These constructs are essential for understanding how digital transformation can enhance manufacturing efficiency and the quality of product.

A. Digital maturity

Digital maturity refers to the extent of integration of digital technologies (e.g., automation, IoT, AI) into plant operations(Gökalp and Martinez 2022). It signifies a plant's ability to adopt and leverage technologies to optimize production processes. Digital maturity will be assessed using tools like the Digital Maturity Assessment Model, evaluating dimensions like technology integration and process optimisation. This construct helps determine how digital tools impact operational and quality improvements, laying the groundwork for operational excellence(BioPhorum 2024).

B. Operational excellence

Operational excellence focuses on optimizing plant performance through efficiency and reduced waste(Vlachos *et al.* 2023). It includes metrics such as production cycle time and resource utilisation. Operational excellence will be measured through KPIs like production cycle time and resource utilisation. Achieving operational excellence is a primary goal of digital transformation, aligning digital maturity with better performance.

C. Batch failure rate

The batch failure rate refers to the proportion of production batches that do not conform to established quality standards, impacting product quality and operational efficiency. It will be calculated as the percentage of failed batches per total produced batches, helping assess the effectiveness of digital solutions in reducing quality issues. Reducing batch failure rates is directly tied to improvements in digital maturity and operational excellence, enhancing product quality and compliance(Ranck 2022).

D. Quality control

Quality control refers to systematic measures to ensure product quality through inspections, testing, and compliance with regulatory standards. Quality control will be assessed through defect rates and compliance with GMP standards. This construct directly relates to maintaining product quality, which is enhanced through the application of digital tools like real-time monitoring and predictive analytics(Sardella *et al.* 2021).

This study will measure specific factors to determine how digital transformation affects pharmaceutical manufacturing, focusing on improvements in product quality and reductions in production inefficiencies(Navabhatra 2025). The results are expected to offer significant insights into the effectiveness of the Digital Plant Maturity Model (DPMM) in the pharmaceutical industry(Gökalp and Martinez 2022; BioPhorum 2024).

2.11 4.3. Concepts

The ideas from ADMA TranS4MErs project(IMR 2024), Digital Plant Maturity Model (DPMM)(BioPhorum 2024), Unified Namespace (UNS)(Péter and Werner 2024), and Digital Twin technologies(O'Connell *et al.* 2023) provides a comprehensive framework for digital transformation in

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pharmaceutical manufacturing. These concepts are crucial for understanding how digital maturity influences operational excellence and product quality.

A. Digital Transformation Theory

Digital transformation theory examines how digital technologies like IoT, AI, and machine learning can reshape organisational processes, enhance efficiency, and drive innovation(Hanelt *et al.* 2021). The ADMA TranS4MErs project supports SMEs in their digital transformation journey, focusing on integrating these technologies to enhance efficiency and innovation(IMR 2024). This theory provides a foundation for understanding how digital maturity contributes to improving plant operations, reducing batch failures, and enhancing product quality

B. Lean Manufacturing Principles

Lean manufacturing principles focus on minimising waste and optimising processes. Digital concepts, such as data analytics and automation, enhance lean practices by integrating with frameworks like DPMM. The Unified Namespace facilitates real-time data flow and process efficiency, supporting lean practices in pharmaceutical manufacturing(Palange and Dhatrak 2021; Péter and Werner 2024)

C. Quality Management Theories

Quality management principles from Six Sigma and Total Quality Management (TQM) guide the exploration of digital tools in quality improvement(Alzoubi *et al.* 2022). Digital Twins, integrated with AI, support these theories by enabling predictive maintenance and real-time quality control, thus reducing defects and variability. The Unified Namespace ensures data integrity and interoperability, crucial for maintaining quality standards.

Together, these concepts underpin the research into digital transformation's impact on operational and quality outcomes in pharmaceutical manufacturing. They align with the research exploring the effectiveness of the DPMM in enhancing digital maturity, operational efficiency, and product quality(Chen *et al.* 2020; Alzoubi *et al.* 2022).

2.12 4.4. Preliminary Findings

In the early stages of the research, several preliminary findings have emerged, providing valuable insights into the role of digital maturity in enhancing operational performance within pharmaceutical manufacturing plants(Gökalp and Martinez 2022). These early observations suggest a notable relationship between the extent of digital technology adoption and key operational metrics such as batch failure rates and quality control(Sangshetti *et al.* 2017).

One significant trend identified is that plants with higher levels of digital maturity, where digital technologies are more deeply integrated into daily operations, report consistently lower batch failure rates(Xia *et al.* 2021). This suggests that the implementation of digital solutions, such as advanced process control systems, predictive analytics, and real-time monitoring, plays a critical role in mitigating risks associated with product quality failures. The capability to gather and analyse live data from production processes allows operators to detect anomalies, deviations, and potential issues much earlier, which helps prevent these issues from developing into larger, costly failures(Gökalp and Martinez 2022).

For instance, predictive analytics is used to forecast potential risks in the manufacturing process based on historical data patterns(Shamayleh *et al.* 2020). This enables plant managers to anticipate quality issues and implement preventive measures before production batches fail to meet quality standards. Early warning systems that trigger alerts based on real-time data further enhance the ability to take corrective

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actions promptly, preventing minor issues from escalating into batch failure(Azab *et al.* 2021; Sang *et al.* 2021).
Moreover, these plants have leveraged real-time monitoring to improve quality control. By using digital tools such as sensors and automated inspection systems, plants can continuously monitor critical quality parameters throughout the production process. This real-time visibility ensures that any deviations from the desired product specifications are detected and addressed immediately, resulting in fewer defects and ensuring adherence to regulatory standards(Sardella *et al.* 2021).
The initial findings point to the importance of having integrated digital systems that support decision-making with accurate, timely information. These systems not only help in ensuring compliance with regulatory requirements but also enable plants to streamline their operations, reduce waste, and improve overall production efficiency.

A. Current Challenges in Asset Management & Maintenance Systems
Modern production lines and asset-heavy industries face numerous systemic and technological challenges. The lack of real-time visibility and integration is a significant issue, as process data often remains isolated in SCADA systems, while maintenance logs reside separately in CMMS(Parlikad and Jafari 2016). This fragmentation leads to delayed insights, allowing anomalies to go undetected and necessitating reactive firefighting.
High downtime costs and inefficient predictive maintenance further complicate operations. Unscheduled stoppages can be extremely costly, especially in high-value sectors such as pharmaceuticals, semiconductors, and heavy machinery(Alam *et al.* 2023). Many plants adhere to overly conservative maintenance schedules to avoid risks, inadvertently increasing labour and part usage(Dittrich 1990).
The scattering of data silos across corporate software ecosystems adds to the complexity. Facilities may employ legacy PLCS with outdated communication protocols, while others use advanced edge computing solutions, resulting in minimal cross-system communication(Margaria and Steffen 2024). Mergers, acquisitions, or expansions often create "islands of automation" without a unified data architecture.
Outdated legacy corporate solutions fail to adapt to the rapid sensor updates or AI-based analytics demanded by Industry 4.0(Margaria and Steffen 2024). Traditional EAM or CMMS solutions lack flexibility, making modifications or expansions resource-intensive and prompting organisations to seek next-generation alternatives.
These challenges highlight the need for more integrated, flexible, and innovative asset management and maintenance systems that can adapt to the demands of modern industrial environments.

2.13 4.5. Challenges and Considerations
Several challenges and considerations for this research could affect the data collection process and the overall validity of the study. These challenges include data access, ethical concerns, and limitations in applying findings across industries.
A. Data Collection Challenges
A major challenge is gaining access to reliable data from different pharmaceutical plants. Some companies may be hesitant to share sensitive information like batch failure rates or digital maturity levels due to privacy and competitive concerns. To address this, data will be anonymised, and efforts will be made to gain the trust of stakeholders, ensuring confidentiality and encouraging participation.

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B. Ethical Considerations

Ethical concerns include ensuring that participants' rights are protected throughout the study. This means obtaining informed consent from participants before interviews or surveys, ensuring they understand their voluntary participation and the right to withdraw at any time. Confidentiality is also a priority, and any identifying details from participants will be kept anonymous.

Section V: DISCUSSION

5.1 The Technological Gap in Current Market Solutions

In the rapidly evolving landscape of Industry 4.0, many established corporate solutions, including those from giants like SAP PM, IBM Maximo, Aveva, and Bentley, are increasingly showing their age. These systems, while robust in their time, are now facing significant challenges in meeting the dynamic demands of modern industrial environments(Lee and Ahmed 2021). A primary issue is their inadequate handling of real-time data. Many existing solutions are designed to poll data at intervals ranging from five to fifteen minutes, which means they can miss crucial micro-trends or early signs of faults that could be detected with more frequent data collection(Babu *et al.* 2024).

Furthermore, the integration of artificial intelligence and analytics in these systems is often limited. Although some solutions offer basic predictive modules, they typically lack the advanced deep learning capabilities, anomaly detection, and prescriptive analytics that are becoming essential for proactive maintenance and operational efficiency(Azab *et al.* 2021). The deployment of these large enterprise suites is another hurdle, often requiring years to fully implement, alongside specialised staff and resulting in a high total cost of ownership(Alzoubi *et al.* 2022).

Visualisation capabilities in traditional solutions are also lacking, primarily relying on textual data, basic 2D schematics, or partial CAD linkups, which fall short of the immersive experiences offered by augmented reality (AR) and virtual reality (VR). These gaps highlight the need for more agile and comprehensive solutions that can meet the demands of modern industrial environments(Denny *et al.* 2011).

5.2 Adma TranS4mers Outcome

In the ever-evolving digital transformation landscape, the ADMA TranS4MErs Digital Maturity Assessment program stands as a beacon for manufacturing SMES striving to enhance their digital capabilities. This narrative unfolds the journey and learnings from this pivotal program(IMR 2024).

The program commenced with the introduction of the ADMA TranS4MErs Scan, a comprehensive tool crafted to evaluate digital maturity across seven key transformation areas. These areas, namely Advanced Manufacturing Technologies, Digital Factory, ECO Factory, End-to-End Customer Focused Engineering, Human-Centred Organisation, Smart Manufacturing, and Value Chain Oriented Open Factory, form the backbone of the assessment. The tool, comprising a mix of multiple-choice and open-ended questions, was met with diverse feedback(Interregeurope.eu 2025). While some participants appreciated its depth, others preferred a more concise version, highlighting the need to balance thoroughness with user-friendliness(IMR 2024).

As the programme unfolded, it became evident that manufacturing SMEs were particularly drawn to services related to Digital Factory and Smart Manufacturing. This preference was reflected in the high volume of service requests—474 in total—with an impressive completion rate of 91%. However, the path was not without its hurdles(Interregeurope.eu 2025). The programme faced stiff competition from other EU initiatives, language barriers in communication, and onboarding delays. These challenges underscored the necessity for clearer communication strategies, national representation, and structured funding(IMR 2024).

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Feedback from SMEs was invaluable, pointing out the need for increased cash funding to bolster infrastructure. To remain relevant and adaptable in a dynamic market, the programme was urged to incorporate Points of Differentiation and flexible Key Performance Indicators. These insights informed recommendations for the programme's design, emphasising the creation of shared visions, market-driven KPIS, and enhanced communication plans to better engage SMEs(IMR 2024).
In essence, the ADMA TranS4MErs programme illuminated the critical importance of aligning digital transformation initiatives with the nuanced needs of SMEs. Through adaptability, clear communication, and a focus on market relevance, the program not only assessed digital maturity but also paved the way for meaningful advancements in the manufacturing sector.

5.3 DPMM Outcome

When embarking on a Digital Plant Maturity Model assessment, it is crucial to set appropriate expectations with stakeholders regarding the likely maturity rating. According to industry standards, most plants typically fall between levels 2 and 3(Level details added in Table 1). This context helps in framing the assessment process and aligning expectations from the outset(BioPhorum 2024).
The assessment, like many similar models, is inherently subjective. It relies heavily on stakeholder discussions and the normalisation of scores to ensure alignment. During this process, some individuals may overrate or underrate the organisation's capabilities. Therefore, it is vital to engage in thorough discussions to reach a consensus that accurately reflects the plant's maturity level.
To maintain consistency across sites, it is advisable to have a single team conduct the assessments, even if the workload is distributed among different teams. This approach ensures that the outcomes are uniform and comparable. Additionally, the assessment serves as a valuable tool for identifying process improvement opportunities. These insights can be communicated to stakeholders, highlighting areas where enhancements can be made(BioPhorum 2024).
Documenting valuable data in the 'Comments' section of the assessment report can provide additional context, aiding teams in better understanding the ratings. This qualitative data enriches the quantitative scores and offers deeper insights into the plant's digital maturity.
It is important for assessment leaders and teams to recognize the significant time and effort required to adequately prepare for and conduct the assessment. Proper preparation is essential for obtaining accurate and meaningful results. The outcome of the assessment can also serve as a benchmark for informal comparisons with other companies, providing a broader perspective on the plant's digital maturity relative to industry peers. Overall, the assessment process is a comprehensive exercise that not only evaluates current capabilities but also reveals potential areas for growth and improvement(Markarian 2019).

5.4 Gaps in Manufacturing Digitisation

The manufacturing sector has witnessed a significant push towards digitisation, with many companies claiming to have completed this transformation(Markarian 2019). However, the reality is that achieving true digital maturity remains elusive for most organisations. The vision of a smart plant, where interconnected systems seamlessly operate to optimize production, is still a distant goal for most manufacturers(Li *et al.* 2023).
One of the pioneering advancements in manufacturing technology was the development of predictive systems and algorithms over 15 years ago(Canito *et al.* 2022). These systems promised to revolutionize manufacturing by providing insights into equipment maintenance needs and production efficiencies. Despite their potential, full implementation of these predictive systems has not been realized. The barriers to their complete integration are multifaceted(Zhong *et al.* 2023).

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Similarly, the idea of digital twins has been discussed for over a decade. This provide a virtual version of physical assets to improve decision-making and how efficiently things run. (Zafar *et al.* 2024). But, manufacturing companies find it difficult to effectively implement these frameworks (Jerez-Jerez *et al.* 2025). The challenges are not rooted in the technology itself but rather in the foundational data infrastructure required to support such innovations(Xia *et al.* 2021).

The primary obstacle is the lack of comprehensive data and a coherent data collection strategy. Manufacturing environments often consist of legacy systems that were not designed with modern digital capabilities in mind(Babu *et al.* 2024). Extracting data from these systems is a complex task, further complicated by the need for point-to-point integration. The diversity of communication protocols and the variations in data sampling times add layers of complexity to data management(Alqoud *et al.* 2022).

Moreover, the absence of digital silos and inconsistent data logging methods contribute to the difficulty in establishing a unified digital framework. Without consistent and reliable data, the potential benefits of advanced technologies like predictive systems and digital twins remain untapped. Manufacturers must address these data-related challenges to move closer to the vision of a fully digitized and smart manufacturing landscape(Alqoud *et al.* 2022).

Section VI: REQUIRED SOLUTION

The system must provide high-frequency real-time data streaming to support industrial operations, ensuring that advanced machine learning analytics deliver predictive maintenance insights and prescriptive guidance(Mohammadi *et al.* 2021). It should offer comprehensive digital twin support, creating immersive, photogrammetric 3D models of assets for remote inspection and real-time defect marking(Yiğit and Uysal 2024). Utilizing a modern cloud-edge architecture, the solution must ensure quick adaptability and cost-effective scaling. The tiered SaaS revenue model should accommodate both small factories and large, multi-site organisations.

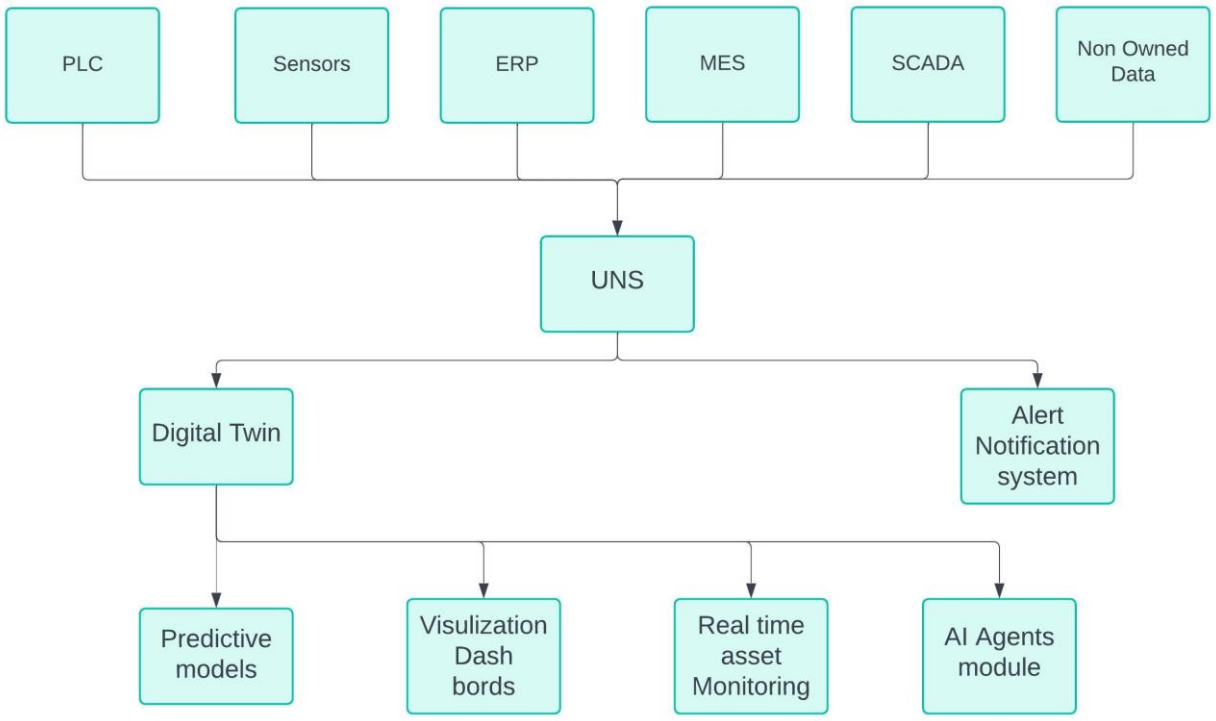

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Figure 2: Proposed Architecture of Smart plan
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Integration services are essential for specialized deployments, including pharmaceutical compliance and food and beverage hygiene tracking('Gazer 3D' 2024). IoT and sensor integration must be ensured for granular visibility into machine health. A unified namespace is required to facilitate real-time data exchange and eliminate data silos. AR/VR capabilities should be incorporated to enhance on-site troubleshooting, remote collaboration, and training(Muhammed *et al.* 2024).

AI agents and conversational interfaces are needed to simplify user engagement in large-scale facilities or remote operations(Alam *et al.* 2023). Asset management must merge 3D scanned site data with CAD schematics for precise equipment replicas, particularly important for high-risk industries(Coimbatore E Boxall and Boxtail 2021; Muhammed *et al.* 2024). Predictive and prescriptive maintenance features must include advanced scheduling and optimisation to minimize downtime and operational disruptions(Parlikad and Jafari 2016). Real-time monitoring and sensor data analysis are required for dynamic anomaly detection and live KPI dashboards(Akano *et al.* 2024).

Enterprise integration capabilities must ensure seamless synchronisation with existing ERP, SCADA, and MES systems for consolidated work orders and inventory management(Emma 2024; Lanzini *et al.* 2024). Bidirectional communication capabilities should enable real-time synergy between equipment operational status and external scheduling logic. Finally, the solution must adapt to the evolving demands of Industry 4.0, as traditional corporate solutions become increasingly obsolete(Manditereza 2022).

Figure 2 illustrates a proposed new architecture of UNS integrated Smart plant. This UNS acts as a central hub, data collection from diverse operational technology (OT) and information technology (IT) systems(Manditereza 2022). This consolidated data within the UNS then feeds into several key downstream components. A Digital Twin, virtual representation of physical assets and processes, utilizes this unified data for Predictive Models. Visualisation Dashboards provide a user-friendly interface to monitor key performance indicators and gain insights('Gazer 3D' 2024). Real-time Asset Monitoring offers immediate visibility into the status and performance of equipment. The AI Agents Module will assist manufacturing by providing support within the manufacturing environment('Gazer 3D' 2024). Overall, architecture proposes a highly integrated system where data from diverse sources converges in a central namespace, empowering advanced analytics, visualisation, and intelligent alerting for improved operational efficiency and decision-making(Muhammed *et al.* 2024).

Developed and tested concept outcomes are written as article manuscripts and published in Preprints. The links can be found in Appendix 3

Section VII: CONCLUSION

The study underscores the critical need for a holistic approach to addressing batch failures and quality challenges in the manufacturing industry. By integrating advanced technologies, improving maintenance practices, and continuous improvement, firms can enhance operational efficiency, minimise waste, and ensure consistent product quality.

Implementing predictive analytics and real-time monitoring can help manufacturers identify potential quality issues before they escalate into batch failures, reducing production downtime and financial losses. Proactive maintenance strategies, such as condition-based and preventive maintenance, ensure that equipment operates optimally, preventing unexpected breakdowns and minimising variability in production processes.

A strong digital transformation strategy is essential for streamlining data collection, analysis, and decision-making. Leveraging data-driven insights enables organisations to improve process control, enhance

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traceability, and comply with stringent regulatory requirements. Additionally, creating a culture of continuous improvement where employees are trained and encouraged to embrace innovation ensures long-term sustainability and adaptability to evolving industry standards.

By adopting these measures, manufacturing firms, particularly in the pharmaceutical sector, can enhance product reliability, optimise resource utilisation, and maintain a competitive edge in an increasingly digital and quality-driven landscape.

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