

Reactive to Predictive: A Hybrid Artificial Intelligence (AI) Framework for Fault Detection and Productivity Optimisation in Nigerian Biomanufacturing Industries

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Abstract

The inclination toward AI-driven predictive maintenance by biomanufacturing industries universally is profound sequel to multiple benefits availability. These include 80% reduction in false alarms, 80% improvement in failure prediction, and 48 times increment in lead time for preventative actions. However, within Nigerian biomanufacturing industries, reactive maintenance practices are endemic; resulting in unplanned downtime, product quality deviations, and significant economic losses. This study conducts a qualitative analysis of data from relevant sources to develop a hybrid AI framework for transitioning from reactive to predictive maintenance. The adoption of a thematic analytical approach alongside schemas of Technology-Organisation-Environment (TOE) framework, Diffusion of Innovation (DOI) theory, and Technology Acceptance Model (TAM), offered a robust foregrounding. Findings reveal that of the over 150 registered pharmaceutical manufacturers in Nigeria, with key facilities concentrated in major Nigerian cities only. AI adoption is stalled by limited digital infrastructure, inadequate data collection systems, skills shortages, organisational, environmental and financial. This accentuates the timeliness of the introduction of a hybrid AI framework that integrates machine learning techniques for real-time fault detection and predictive modelling. A practical roadmap for practitioners and policymakers, infrastructure development, skills enhancement, and regulatory reform are proffered.

Keywords: artificial intelligence; biomanufacturing industries; fault detection; predictive maintenance; reactive maintenance

1. Background of the Study

The emergence of artificial intelligence (AI) and machine learning as critical enablers of operational excellence has propelled biomanufacturing industry worldwide into Fourth Industrial Revolution (Industry 4.0). In the biotechnology 4.0 paradigm, Tulsyan et al. (2020) assert that process analytical technology (PAT) tools are being progressively deployed to gain improved process insights. This is done through extensive use of advanced and automated sensing techniques. The authors equally noted that critical parameters such as power of Hydrogen (pH), dissolved oxygen, temperature, and metabolite concentrations are routinely measured and controlled in cell culture processes.

Nigeria's biomanufacturing industry is an emerging component of the country's broader biotechnology and pharmaceutical sectors (NBMA, 2026). It involves the application of biological systems and biotechnological processes to produce pharmaceuticals, vaccines, biologics, diagnostics, agricultural inputs, food products, enzymes and other bio-based products. Although Nigeria has substantial scientific capacity and biological resources, the transition from biotechnology research to large-scale commercial manufacturing remains relatively limited (FMIST, 2026).

The sector has developed within a policy and institutional framework established by the Federal Government. The National Biotechnology Development Agency (NABDA), now operating as the National Biotechnology Research and Development Agency (NBRDA), was established following the National Biotechnology Policy approved in 2001. Its mandate covers biotechnology research, product development, commercialisation and industry partnerships across health, agriculture, industry and environmental applications (NBRDA, 2026).

Healthcare is currently one of the most strategically important areas for Nigerian biomanufacturing. The World Health Organization identifies Nigeria as having an emerging ecosystem for the local production of pharmaceuticals, vaccines and biologicals, while emphasising the importance of technology transfer, technical capacity, regulatory strengthening and sustainable investment (WHO, 2024). Nigeria's regulatory framework also accommodates biotechnology-derived products, including biosimilars, vaccines and other biological medicinal products, under the supervision of National Agency for Food and Drug Administration and Control (NAFDAC, 2024).

Government policy has recently placed greater emphasis on domestic production. The 2024 Executive Order on increasing local production of healthcare products introduced fiscal and regulatory measures intended to encourage local pharmaceutical and healthcare manufacturing, including incentives relating to pharmaceutical machinery, active pharmaceutical ingredients and other raw materials. NAFDAC's 2024–2027 strategic plan similarly targets a substantial increase in the proportion of medicines manufactured locally, with a stated objective of reaching 70% local manufacture by 2027 (PIUHVC, 2024).

Apart from healthcare, Nigeria has significant opportunities in agricultural and industrial biomanufacturing. Research institutions such as the National Root Crops Research Institute apply biotechnology to improved crop varieties, disease-free planting materials, seed systems and value addition (Zoominfo, 2026). The Federal Government is also increasingly emphasising the commercialisation of research outputs, recognising that many Nigerian biotechnology innovations have historically remained at the laboratory stage rather than progressing to industrial production.

On the whole, Nigeria possesses considerable biological resources, research institutions, scientific expertise and a growing policy commitment, but its biomanufacturing industry remains at an embryonic stage. Nigerian biomanufacturing industries are grappling with substantial challenges, including ageing equipment, inadequate maintenance practices, and limited adoption of advanced digital technologies. Most facilities continue to rely on reactive maintenance approaches, which is by attending to equipment failures only after they have occurred. This practice only leads to production downtime, quality deviations, and significant revenue losses.

The transition from reactive to predictive maintenance represents innovation and creativity aimed at revolutionising Nigerian biomanufacturing operations. The proposition of this study is the adoption of a hybrid AI framework that integrates machine learning techniques for real-time fault detection and predictive modelling, with a view to optimising productivity and reduce operational costs in Nigerian biomanufacturing industries.

2. Statement of the Problem

Nigerian biomanufacturing industries face persistent operational challenges rooted in outdated maintenance practices and limited technological adoption. The current reactive maintenance culture results in unplanned equipment shutdowns, production delays, product quality issues, and substantial financial losses. Critical biomanufacturing equipment such as bioreactors, centrifuges, chromatography systems, filtration units, water for injection (WFI) pumps, and air handling units (AHUs) are susceptible to failures that can compromise entire production batches (Jubilant HollisterStier, 2025).

The existing rules-based monitoring systems in many facilities produce an overwhelming number of false and inadequate alerts. Evidential challenges in biomanufacturing, depicts conventional systems as often generating excessive false alarms, while failing to capture actual failures. This is a pattern that mirrors global industry experiences where rule-based systems captured only 13% of actual failures, while 71% of alerts were false alarms, that provides an average of only 45 minutes of lead time before shutdown (C3 AI, 2025). In the context of WFI pumps and AHUs, which are critical to ensuring sterility in pharmaceutical manufacturing, failing to anticipate an issue could cause batch loss or production shutdowns. The attendant consequences of this include loss of significant material and financial resources. As asserted by HollisterStier, (2025) the situation becomes aggravated when products like biologics that require expensive active pharmaceutical ingredients is manufactured.

Furthermore, Nigerian biomanufacturing industries face unique contextual challenges that include limited digital infrastructure. This is reflected in insufficient data collection systems, unreliable internet connectivity, and inadequate data storage facilities, which ultimately hinder AI implementation. Also, inadequate skilled personnel or limited availability of data scientists, machine learning engineers, and AI specialists with biomanufacturing domain knowledge. AI adoption is equally truncated by high upfront costs of AI technologies and limited access to financing for technology adoption. There are hardly regulatory frameworks in existence that are supportive of policies and standards for AI implementation in biomanufacturing without serious setback. These raise serious concern. To what extent are the industry players equipped with sufficient information, skills and knowledge of AI applications? Lack of this makes AI an exclusive preserve of few, and negates accrued benefits in biomanufacturing contexts.

The absence of a comprehensive framework for AI adoption in Nigerian biomanufacturing industries represents a critical gap in both academic literature and industry practice. While studies have examined technology adoption in Nigerian Small and Medium Enterprises (SMEs), limited research addresses the specific context of AI implementation in biomanufacturing (Eze et al., 2020, 2021). This study addresses this gap by introducing a hybrid AI framework that is tailored to the Nigerian biomanufacturing context.

3. Objectives

To develop a hybrid AI framework for real-time fault detection and predictive maintenance that supports the transition from reactive to predictive maintenance practices in Nigerian biomanufacturing industries.

Specifically, the study is to:

- i. review existing reactive maintenance practices and their operational impact on Nigerian biomanufacturing industries through analysis of secondary data.
- ii. identify the technological, organisational, and environmental factors influencing AI adoption in Nigerian biomanufacturing.
- iii. evaluate the potential benefits of AI-driven predictive maintenance for Nigerian biomanufacturing operations based on available global implementations.
- iv. develop a hybrid AI framework integrating machine learning techniques for fault detection and predictive modelling.
- v. proffer suggestions for implementing the developed framework in Nigerian biomanufacturing contexts.

4. Research Questions

- i. What are the current maintenance practices in Nigerian biomanufacturing industries, and what operational challenges do they present?
- ii. What technological, organisational, and environmental factors influence the adoption of AI for predictive maintenance in Nigerian biomanufacturing?
- iii. What hybrid AI framework components are essential for effective real-time fault detection and predictive modelling in biomanufacturing?
- iv. What potential benefits can AI-driven predictive maintenance offer Nigerian biomanufacturing industries?
- v. What strategies can facilitate the successful implementation of AI-driven predictive maintenance in the Nigerian biomanufacturing context?

5. Significance of the Study

This study contributes to the growing body of literature on AI applications in manufacturing within developing economy contexts. It extends existing technology adoption frameworks by applying them to the unique context of Nigerian biomanufacturing. The hybrid AI framework provides a theoretical contribution that can inform future empirical studies.

There are evidences that suggest that the study offers actionable insights for Nigerian biomanufacturing practitioners seeking to transition from reactive to predictive maintenance. The framework developed in the study provides guidance for technology implementation, while attending to contextual challenges such as infrastructure limitations and skills gaps. As asserted by C3 AI (2025), AI implementations at the global level have led to derivation of over €10 million in

annual economic benefit, 80% reduction in false alarms, and 48-fold increase in lead time. This is a real, quantifiable and compelling evidence from global perspective that can benefit Nigerian industries when hybrid AI framework is adopted.

Findings are expected to inform policymaking by highlighting the need for supportive regulatory frameworks, digital infrastructure investment, and skills development programmes. The study emphasises the importance of government support in facilitating technology adoption in Nigerian manufacturing sectors.

Indeed, improved maintenance practices through AI adoption can reduce production costs, minimise downtime, enhance product quality, and increase competitiveness. This has significant implications for Nigeria's economic development and over all industrial growth.

6. Conceptual Clarifications

6.1 Artificial Intelligence (AI)

AI as applied in the study denotes the simulation of human intelligence processes by computer systems, including learning, reasoning, and self-correction. In biomanufacturing, AI encompasses various techniques for data analysis, pattern recognition, and decision support.

6.2 Machine Learning (ML)

ML is a subset of AI that enables systems to learn and improve from experience without explicit programming. Common ML techniques include supervised learning (classification, regression), unsupervised learning (clustering), and reinforcement learning. In fault detection, ML algorithms learn patterns from historical data to predict future failures (C3 AI, 2025).

6.3 Predictive Maintenance (PdM)

PdM is a maintenance strategy that uses condition-monitoring tools and techniques to predict equipment failures before they occur. This is different and a departure from a reactive maintenance (fixing equipment after failure) or preventive maintenance (scheduled maintenance regardless of condition). PdM enables maintenance activities to be performed based on actual equipment condition and predicted failure probability (Tulshyan et al., 2020; C3 AI, 2025).

6.4 Fault Detection

Fault detection is the process of identifying abnormal conditions or deviations from normal operation in equipment or processes. In biomanufacturing, fault detection involves monitoring critical parameters such as temperature, pressure, pH, and dissolved oxygen to identify potential failures (Tulshyan et al., 2020).

6.5 Condition-based Maintenance (CbM)

CbM is a maintenance strategy where maintenance decisions are based on the real-time health condition of equipment. CbM deviates from time-based maintenance because it enables maintenance activities to be performed according to need, as a result of monitoring of actual equipment condition (Tulshyan et al., 2020).

6.6 Biomanufacturing

Biomanufacturing has to do with the production of biological products, including pharmaceuticals, vaccines, therapeutic proteins, and other biotechnology products, using living cells or their components. The process involves complex biological and engineering operations requiring strict quality control. The industry is directed by the National Biotechnology Research and Development Agency (NBRDA), NAFDAC provides the necessary regulations. The industry involves specialised areas including healthcare, agriculture and industrial bio-processing.

6.7 Hybrid AI Framework

A hybrid AI framework integrates multiple AI techniques and approaches to achieve improved performance. In this context, the hybrid framework combines different machine learning algorithms for fault detection and predictive modelling, leveraging the strengths of each approach while mitigating limitations.

7. Literature Review

7.1 Global AI Adoption in Biomanufacturing

The biopharmaceutical industry has increasingly embraced AI technologies for predictive maintenance and fault detection. As asserted by C3 AI (2025), a major biopharmaceutical company with over €40 billion in annual revenue implemented AI-driven predictive maintenance across two facilities, developing and evaluating over 200 machine learning models to determine the best-performing approach. Within 12 weeks, the team deployed AI-driven predictive maintenance at two lighthouse facilities in Canada and Belgium, unifying previously siloed data and configuring out-of-the-box machine learning models to predict emerging downtime risks and deliver prioritised, explainable alerts for engineers. The company unified data from over 400 time-series tags integrated across assets and trained 14 users on the AI application. The result of this action was an increment in the revenue profile of the company with over €10 million estimated annual economic benefit per facility (C3 AI, 2025).

in another study conducted at AstraZeneca, Casalini (2025) reports that deep learning models (a one-dimensional convolutional neural network (1D-CNN) and a combined 1D-CNN with bidirectional long short-term memory (1D-CNN-BiLSTM) were developed and evaluated for fault classification in complex industrial packaging machines. The study demonstrated that fault classification in small and complex packaging machines can be achieved with satisfying results by combining vibration sensors and deep learning models. The 1D-CNN-BiLSTM model accurately classified faults under varying speeds and in the presence of Gaussian noise, highlighting the benefits of integrating multiple sensors and incorporating long-term temporal context.

Tulsyan et al. (2020) in their research had proposed a condition-based maintenance (CbM) framework for real-time sensor-health management in biomanufacturing. The framework focuses on fault detection, diagnosis, and prognostics using slow-feature analysis (SFA) for detection and diagnosis, and Gaussian process models for forecasting remaining useful life and probability of failure. This approach fully automates feature selection for different faults and calculates comprehensive health metrics, providing intelligent, flexible maintenance guidance in real time (Tulsyan et al., 2020).

In a practical implementation, Jubilant HollisterStier (JHS) installed 100 wireless vibration sensors with AI features to monitor the health and performance of WFI pumps and AHUs, which are critical to ensuring sterility in pharmaceutical manufacturing (Jubilant HollisterStier, 2025). Using the data collected from the sensors, subject matter experts and AI work together to map each machine's patterns and identify any issues. By analysing deviations from baseline performance, JHS team members can issue a work order before a machine breaks and causes a larger disruption, preventing batch loss and production shutdowns (Jubilant HollisterStier, 2025).

7.2 Nigerian Biomanufacturing Industry Overview

The regulatory reforms and government initiatives have shown that Nigerian biomanufacturing industry has a significant growth potential that can positively affect import dependency. Some of the policies and initiative of the government include the introduction of 5+5 regulatory policy in 2019 by the National Agency for Food and Drug Administration and Control (NAFDAC). The policy was aimed at phasing out the importation of selected medicines that Nigerian manufacturers have the capacity to produce locally (New Telegraph, 2026). According to Guardian Nigeria, (2025) more than 70 per cent of products under the 5+5 initiative and the Ceiling List were now locally manufactured as of October 2025. The import-to-local manufacturing ratio has improved from 70:30 in 2019 to 60:40 in 2025, indicating growing investor confidence and regulatory predictability (Vanguard News, 2026).

The impact of this policy is evident in facility development and regulatory submissions. A total of 161 facility layout reviews with 65 from existing companies and 96 from new entrants have been approved, alongside six new medical device manufacturing companies (New Telegraph, 2026). NAFDAC has reported that as of March 2026, out of 191 applications received, 97% (n=185) have received regulatory approvals, with 58% (n=105) being totally new manufacturers (NAFDAC, 2026). Several established international and local firms have since set up manufacturing operations or entered joint ventures in Nigeria. Notable examples include Finecure of India partnering with Pinnacle Health Pharma, SD Biosensor of South Korea collaborating with Codix Bio, and Turkey's Troment working with NASENI (NASENI, 2024; New Telegraph, 2026). Technology transfer agreements involving GSK and Fidson Healthcare Plc, as well as Innova Pvt India and Fidson, have further strengthened local capacity (New Telegraph, 2026).

The Association of Community Pharmacists of Nigeria (ACPN) reports over 150 registered pharmaceutical manufacturers, with at least five certified by the World Health Organization (WHO) for Good Manufacturing Practice (GMP) (Voice of Nigeria, 2025). NAFDAC has also achieved broader regulatory milestones, including ISO 9001 certification, WHO Maturity Level 3 benchmarking and re-benchmarking in 2025, and Nigeria's admission into the International Council for Harmonisation (ICH) has positioned Nigeria as a regional and global regulatory leader (New Telegraph, 2026). NAFDAC has confirmed that locally manufactured medical products have attained WHO-Prequalification. These include Paediatric Zinc Sulphate tablets and Sulphadoxine/Pyrimethamine tablets manufactured by Swiss Pharma Limited, and 0.5ml auto-disabled vaccine needle and syringe manufactured by Afrimedical Manufacturing Company (NAFDAC, 2026).

These milestones notwithstanding, challenges persist. This is reflected in the continuous importation of over 70 per cent of medicines, while overdependence on imported Active Pharmaceutical

Ingredients (APIs) is estimated at between 70 and 80 per cent (The Guardian Nigeria, 2026). The Nigerian pharmaceutical sector faces severe foreign exchange volatility, escalating production costs, and rising API prices, all of which continue to weaken domestic manufacturing capacity (The Guardian Nigeria, 2026). See Table 1 for some metrics of some industries in Nigeria.

7.3 Technology Adoption in Nigerian Context

Research on technology adoption in Nigeria has primarily focused on SMEs and information technology contexts. Eze et al. (2020) explored factors shaping technology adoption in Nigerian SMEs, and were able to develop an extended Technology-Organization-Environment (TOE) framework that incorporate communication context to identify key success factors. The study highlighted challenges including limited infrastructure, financial constraints, and skills gaps.

The adoption of emerging information communication technology (EICT) in Nigerian SMEs is critically shaped by perceived information need, information sources selection, and factors determining information source selection (Eze et al., 2021). The TOE framework has been extended to explain technology adoption decisions in Nigerian contexts, identifying technological, organisational, and environmental factors (Eze et al., 2021).

Adeosun and Owolabi (2021) examined factors influencing technology adoption in Nigerian business contexts, identifying workplace factors, geographical factors, and employee benefits as prominent considerations. The study highlighted challenges with infrastructure, skills, and regulatory compliance (Adeosun & Owolabi, 2021).

7.4 Fault Detection and Predictive Maintenance

Recent research has explored various AI approaches for fault detection and predictive maintenance. Wadel et al. (2024) analysed models for IoT-driven (Internet of Things) predictive maintenance under constraints in the biopharmaceutical industry, emphasising the importance of data quality and algorithm selection. Aghaee et al. (2024) reviewed AI applications for fault detection and diagnosis in pharmaceutical bioprocesses, highlighting the growing body of evidence supporting AI effectiveness.

Rojek et al. (2023) demonstrated that even relatively simple AI solutions can offer high efficiency at low implementation costs, suggesting that developing countries can benefit from AI adoption without massive investments. The study emphasised that effective use of preventive maintenance requires large amounts of reliable annotated sensor data and well-trained machine-learning algorithms (Rojek et al., 2023).

A comprehensive solution based on industrial big data for probiotic activity monitoring and predictive maintenance is vital according to Xu (2025). This suggestion depicts AI as an essential device that can significantly improve monitoring accuracy and reduce equipment failure rates.

7.5 Predictive Maintenance in Emerging Economies

Research on predictive maintenance in emerging economies has highlighted specific challenges and opportunities. The integration of wireless vibration sensors with AI features, as demonstrated by Jubilant HollisterStier, represents a scalable approach that could be adapted to Nigerian contexts (Jubilant HollisterStier, 2025). The key insight is that preventive maintenance using sensors and AI

to monitor equipment health can prevent batch loss and production shutdowns, which are critical concerns in pharmaceutical manufacturing (Jubilant HollisterStier, 2025).

The 12-week deployment timeline achieved by the major biopharmaceutical company demonstrates that AI-driven predictive maintenance can be implemented relatively quickly, even in complex manufacturing environments (C3 AI, 2025). The key success factors included unified data access, out-of-the-box machine learning models, and user training, suggesting a model that could be adapted for Nigerian contexts.

7.6 Gaps in Literature

Although the literature has shown massive growing evidence of AI effectiveness in biomanufacturing ecosystem, however, sufficient vacuum is obvious, which include:

- Limited research on AI adoption in developing country biomanufacturing contexts.
- Absence of comprehensive frameworks for AI implementation in Nigerian industries.
- Limited understanding of contextual factors affecting AI adoption.
- Lack of practical guidance for transitioning from reactive to predictive maintenance.
- Insufficient attention to the unique challenges of Nigerian biomanufacturing.

This study addresses these gaps by developing a hybrid AI framework tailored to Nigerian biomanufacturing contexts.

8. Theoretical Framework with Relevance to the Study

8.1 Technology-Organisation-Environment (TOE) Framework

The TOE framework, developed by Tornatzky and Fleischer, provides a comprehensive lens for understanding technology adoption decisions in organisations (Eze et al., 2020, 2021). The framework identifies three contextual factors influencing technology adoption:

Technological Context: This encompasses the characteristics of the technology itself, including relative advantage, compatibility, complexity, trialability, and observability. In this study, the technological context includes the capabilities of AI for fault detection, data requirements, integration challenges, and perceived benefits. Global evidence demonstrates that AI technologies for predictive maintenance offer significant advantages, but their compatibility with existing Nigerian systems and complexity of implementation may affect adoption decisions (C3 AI, 2025; Jubilant HollisterStier, 2025).

Organisational Context: This includes organisational characteristics such as top management support, organisational readiness, resources, size, and structure. Nigerian biomanufacturing facilities vary significantly in these characteristics, influencing their readiness for AI adoption. The success of AI implementation at major biopharmaceutical companies demonstrates that organisational commitment, resource allocation, and user training are critical success factors (C3 AI, 2025).

Environmental Context: This includes external factors such as competitive pressure, regulatory environment, government support, and market conditions. The Nigerian biomanufacturing environment presents unique challenges and opportunities for AI adoption, including the presence

of WHO-GMP (World Health Organization for Good Manufacturing Practice) certified manufacturers and government support through agencies like NASENI (NASENI, 2024).

The TOE framework is particularly relevant to this study because it

- Provides a comprehensive view of technology adoption factors
- Acknowledges the bidirectional relationships among factors
- Allows for contextual adaptation
- Has been validated in various technology adoption studies

8.2 Diffusion of Innovation (DOI) Theory

Diffusion of Innovation theory by Rogers (2023) describes how, why, and at what rate new ideas and technology spread through social systems. The theory categorises adopters into five groups: innovators, early adopters, early majority, late majority, and laggards.

In the Nigerian biomanufacturing context, the innovation-decision process for AI adoption involves five stages: knowledge (learning about AI capabilities), persuasion (being convinced of benefits), decision (choosing to adopt), implementation (utilising the technology), and confirmation (validating worth). The documented success of early adopters like major biopharmaceutical companies provides evidence that can influence the persuasion and decision stages (C3 AI, 2025; Jubilant HollisterStier, 2025).

The DOI theory complements the TOE framework by explaining the process of technology spread and the characteristics of different adopter categories. This is relevant for understanding the likely adoption patterns in Nigerian biomanufacturing industries.

8.3 Technology Acceptance Model (TAM)

The Technology Acceptance Model, developed by Davis (1989), identifies perceived usefulness and perceived ease of use as primary determinants of technology acceptance (Venkatesh & Davis, 2000). In this study, TAM helps explain how Nigerian biomanufacturing practitioners perceive AI technologies.

- **Perceived usefulness:** This details the degree to which users believe AI will improve their job performance, for example, reducing downtime, improving quality, and reducing costs. This is where result of the study by C3 AI, (2025) is instructive because as found out in the study there are benefits from AI implementations, including over €10 million annual economic benefit, 80% reduction in false alarms, and 48-fold increase in lead time. indeed, perceived usefulness is strongly supported here.
- **Perceived ease of use:** It denotes the degree to which users believe AI systems will be free of effort, including ease of learning, operation, and integration with existing systems. The 12-week deployment timeline achieved by the major biopharmaceutical company suggests that AI systems can be relatively easy to implement with appropriate support and training (C3 AI, 2025).

8.4 Relevance of the Theories

This study integrates these theoretical frameworks to provide a comprehensive understanding of AI adoption in Nigerian biomanufacturing. The TOE framework identifies contextual factors, DOI

explains the adoption process, and TAM addresses individual perceptions. This integrated approach is essential for understanding both organisational and individual factors affecting AI adoption.

9. Methods and Materials

9.1 Research Philosophy

This study adopts an interpretivist research philosophy. This is recognition of the fact that technology adoption is entirely different from innovation, design and manufacturing. Technological adoption and application are rather shaped by social, cultural, and contextual factors that require understanding from the participants' or end-users' perspectives.

9.2 Research Approach

A qualitative research approach is adopted to explore the complexities of AI adoption in Nigerian biomanufacturing. This approach allows for in-depth understanding of participants' experiences, perceptions, and challenges (Awak, 2022).

9.3 Research Design

The study employs a case study design, focusing on selected Nigerian biomanufacturing facilities. The case study approach is appropriate for exploring complex phenomena in real-life contexts (Awak, 2022; Yin, 2014). A secondary qualitative data analysis approach is used, which dwelt on publicly available data from industry reports, government publications, and professional association documents.

9.4 Data Sources

Data for this study are collected from multiple secondary sources including reports and statements from the Association of Community Pharmacists of Nigeria (ACPN), publications from the National Agency for Science and Engineering Infrastructure (NASENI), industry case studies and results of some empirical studies.

9.5 Data Collection Procedure

The data collection procedure followed Awak (2022); Cheong et al. (2023) and Sage (2026) methodology for qualitative research, which include definition of research questions, data sources, quality assessment, data collection, categorisation, thematic discourse analysis and reporting of findings.

9.6 Artificial Intelligence Use Disclosure

ChatGPT (GPT-5.6 Luna), and DeepSeek were used as parts of the research team, serving as research-assistance tools during this study. However, they were not listed as co-authors. Their usage included support for conceptual and literature search, and the generation of some data related materials. AI generated outputs were not accepted in their raw forms and uncritically. All materials were reviewed, evaluated, revised, and where applicable, independently verified by the authors. All intellectual contributions, conclusion, and recommendations are the sole responsibility of the authors.

10. Findings, Results, and Discussions

10.1 Profile of Nigerian Biomanufacturing Industries

Analysis of secondary data reveals a growing Nigerian biomanufacturing sector with significant potential for AI adoption. The Association of Community Pharmacists of Nigeria (ACPN) reports over 150 registered pharmaceutical manufacturers, with at least five certified by the World Health Organization for Good Manufacturing Practice.

Table 1

Selected Biomanufacturing Industries in Nigeria

Company name	Location	Revenue in billion (#)	Employee count	Key products/ specialisation
Fidson Healthcare Plc	Lagos & Ogun	50-65b	450-600	Ciprotab, Astymin, feroglobin, intravenous fluids, Anti-malarials, anti-retroviral drugs.
May & Baker Nigeria Plc	Lagos & Ogun	20-30b	400 – 500	M&B paracetamol, artesunate, Subacell, herbal supplements.
Elbe Pharma Nigeria Ltd.	Lagos	50.2	150-300	Amalar, softgel antimalarials, antibiotics, nutraceuticals.
Marleyshree Pharmaceutical Ltd.		45.6	50-150	Generic solid dosage forms, essential antimalarials and anti-infectives.
Jawa International Limited	Lagos	10-20b	400+	Jawaron Tonic, Jawasil antacid, Jawaclox, antibiotics, liquid OTC formulations.
Emzor Pharmaceutical Industries Ltd.	Lagos & Ogun	40-60b	1000+	Emzor paracetamol, Zolon, Anti-malarials, pediatrics, active APIs.
Neimeth International Pharmaceuticals Plc	Lagos	3-6b	200-300	Cik lavit, Pyrantrin, Normaten, disinfectants
Swiss Pharma Nigeria Ltd. (Swipha)	Lagos	10-20b	300-450	Anti-infectives, ARVs, CNS medications, maternal health products.
Chi Pharmaceuticals Ltd.	Lagos	Na	300+	Antiretrovirals (ARVs) antimalarials, zinc /ORS

Codex Bio (Codix Pharma)	Lagos	15-25b	150-250	Diagnostics, cardiometabolic therapeutics, antimalarials, specialty care.
NASENI-TROMENT Biotech Factory	Abuja	Na	200+	Rapid Diagnostic Test kits (RDT)

Note. Data from NASENI and NAFDAC (2026); Neimeth Interim and Annual Financial Reports (2024 & 2025); May & Baker Audited Financial Statements & AGM Disclosures (2024 & 2025); Fidson Audited Annual Financial Statements (2024 & 2025), NBMA (2026); NBRDA (2026)

10.2 Current Maintenance Practices in Nigerian Biomanufacturing

Nigerian biomanufacturing industries predominantly rely on reactive maintenance practices. Equipment failures are addressed after they occur, and this has led to:

- **Unplanned Downtime:** This connected with production interruptions when equipment suddenly and unexpectedly fails. According to Jubilant HollisterStier (2025), failing to anticipate issues with critical equipment such as WFI pumps and AHUs can cause batch loss or production shutdowns.
- **Product Quality Deviations:** Equipment failures can compromise product quality, particularly in biologics manufacturing especially as expensive active pharmaceutical ingredients are usually at stake. To Jubilant HollisterStier, (2025) this connotes batch losses that cost significant time and money, especially when manufacturing processes involve products with expensive APIs.
- **Financial Losses:** Production disruptions result in revenue losses. As noted by C3 AI, (2025), a major biopharmaceutical company implemented AI-driven predictive maintenance and realised over €10 million in estimated annual economic benefit per facility, which means if there were no such measure, that amount would have been lost.
- **Excessive Interventions:** As noted by C3 AI, (2025) time-based maintenance strategies lead to excessive interventions, extended turnaround times, and difficulties in scaling production efficiently.

10.3 Factors Influencing AI Adoption in Nigerian Biomanufacturing

Analysing secondary data within TOE framework reveals that the following factors affect AI adoption in Nigerian biomanufacturing industries:

10.3.1 Technological Factors

- **Data quality and availability:** Effective AI implementation requires large amounts of reliable sensor data (Rojek et al.,2023). The major biopharmaceutical company that achieved over €10 million in annual benefit unified previously siloed data from over 400 time-series tags across assets (C3 AI, 2025). The implications of these findings on Nigerian manufacturers rest on a dainty scenario laced with challenges of data quality and limited data collection infrastructures.
- **Integration capabilities:** The global success of AI implementation depended on integrating previously siloed data (C3 AI, 2025). Nigerian manufacturers may face challenges with legacy systems and limited data integration capabilities.

- **Infrastructure requirements:** The 100 wireless vibration sensors installed by Jubilant HollisterStier represent a scalable approach that requires reliable sensor networks and connectivity (Jubilant HollisterStier, 2025). Nigerian facilities are fronted by limited digital infrastructure.

10.3.2 Organisational Factors

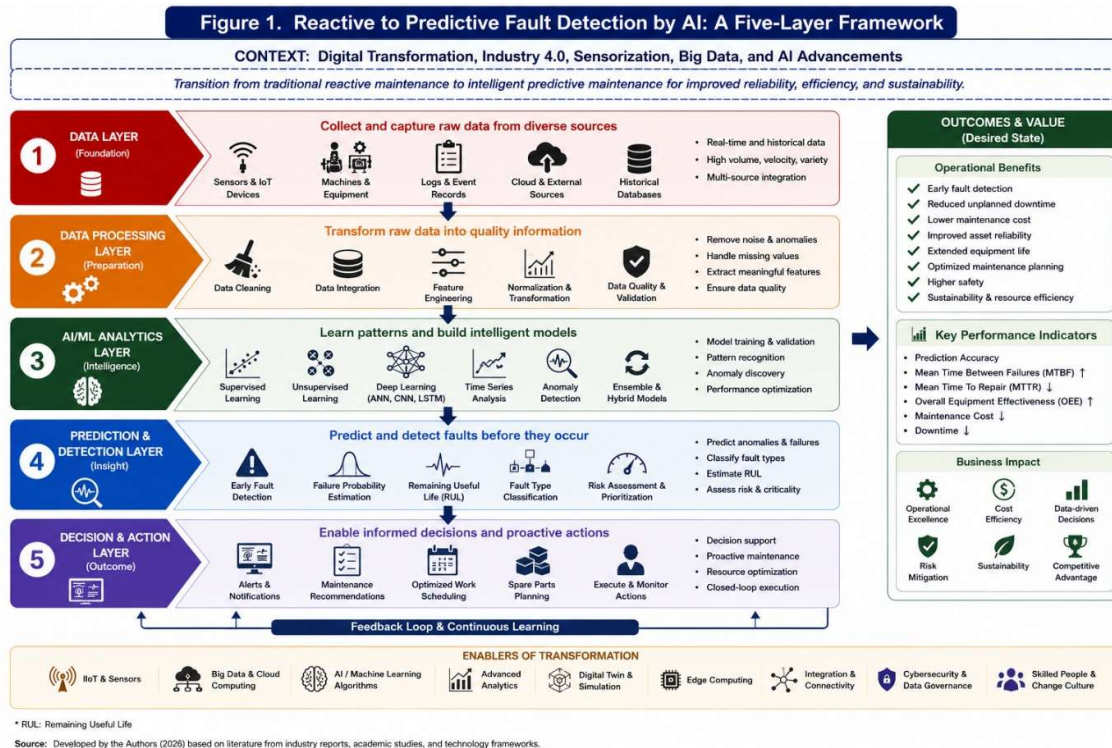
- **Organisational readiness:** The major biopharmaceutical company's success was facilitated by organisational commitment, resource allocation, and user training (C3 AI, 2025). Nigerian manufacturers may face varying levels of organisational readiness.
- **Skills and expertise:** The development and evaluation of over 200 machine learning models required significant AI expertise (C3 AI, 2025). Nigerian manufacturers are being challenged by skills gaps in data science and AI.
- **Management support:** The 12-week deployment timeline at two facilities required strong management commitment (C3 AI, 2025). Nigerian manufacturers are confronted by varying levels of management support for AI adoption.

10.3.3 Environmental Factors

- **Competitive pressure:** Global competition in the pharmaceutical industry is driving AI adoption. The company that implemented AI-driven predictive maintenance serves 170+ countries and produces 4.8+ billion units of medicine annually (C3 AI, 2025). Nigerian manufacturers face competitive pressure to improve efficiency.
- **Regulatory environment:** WHO-GMP certification is a key regulatory requirement for Nigerian manufacturers. Regulatory frameworks supporting AI adoption may be limited.
- **Government support:** Government agencies such as NASENI are supporting biotechnology development, including the NASENI-TROMENT biotechnology facility in Abuja (NASENI, 2024). However, AI-specific support seems be limited.

10.4 The Hybrid AI Framework

The hybrid AI framework as depicted by figure 1 is introduced for Nigerian biomanufacturing.



The developed hybrid AI framework consists of five layers presented as a progressive AI-enabled fault-management chain:

- Data Layer:** Captures raw real-time and historical data on critical parameters including vibration, temperature, pressure, pH, dissolved oxygen, and flow rate from sensors, equipment, logs, databases and external sources. This layer addresses the challenge of limited data collection in Nigerian contexts by providing a structured approach.
- Data Processing Layer:** Cleans, integrates, transforms and validates the raw data, including feature engineering. It takes care of historical maintenance records, and quality control data. This layer addresses the challenge of siloed data common in Nigerian manufacturing contexts.
- AI/ML Analytics Layer:** Applies machine-learning and analytical techniques to recognise patterns, detect anomalies and build intelligent predictive models. These make use of slow-feature analysis (SFA) and 1D-CNN; SFA and 1D-CNN-BiLSTM, Gaussian process models, Random Forest, and XGBoost.
- Prediction and Detection Layer:** Converts model outputs into early fault detection, failure-probability estimates, RUL, fault classification and risk prioritisation.
- Decision and Action Layer:** Translates predictions into alerts, maintenance, risk assessment, actionable insights, scheduling, spare-parts planning that are delivered to engineers, thereby enabling proactive intervention.

The layers therefore, move logically from **data** → **preparation** → **intelligence** → **prediction** → **action** with the **feedback loop** enabling **continuous learning and improvement** (DeepSeek, 2026; OpenAI, 2026).

10.5 Potential Benefits for Nigerian Biomanufacturing

Nigerian biomanufacturing industries can expect significant benefits from implementing the hybrid AI framework developed in this study as follows:

- **Economic benefits:** The major biopharmaceutical company that implemented AI-driven predictive maintenance realised over €10 million in estimated annual economic benefit per facility as reported by C3 AI (2025). No matter the scales of Nigerian facilities, proportional benefits could be substantial if this is implemented.
- **Reduced false alarms:** 80% reduction in false alarms was found by C3 AI (2025), which translates to reduction in unnecessary interventions. This could mean more efficient maintenance operations for Nigerian manufacturers.
- **Improved failure prediction:** The major biopharmaceutical company achieved 80% improvement in failure prediction (C3 AI, 2025). For Nigerian manufacturers, this means reduced unplanned downtime and fewer batch losses.
Increased lead time: The lead time for preventative actions increased from 45 minutes to more than 2 days (C3 AI, 2025). For Nigerian manufacturers, this provides significantly more time for planned maintenance and parts procurement.
- **Prevention of batch loss:** AI monitoring of critical equipment such as WFI pumps and AHUs can prevent batch loss and production shutdowns. These are costly in biologics manufacturing with expensive application programming interfaces (APIs) that could be prevented through AI adoption (Jubilant HollisterStier, 2025).
- **Knowledge transfer:** The 14 users trained at the major biopharmaceutical company represent knowledge transfer and capacity building (C3 AI, 2025). Nigerian manufacturers can similarly build local AI capabilities by adopting this model.

10.6 Discussion

The findings reveal both the potential and challenges for AI adoption in Nigerian biomanufacturing. The concentration of pharmaceutical manufacturers in Lagos, Ogun, and Abuja suggests that initial implementation efforts could focus on these areas, so as to leverage existing infrastructure and industry networks.

The TOE framework highlights significant challenges across all three contexts. Technological challenges include limited data collection infrastructure, data quality issues, and integration capabilities. Organisational challenges include varying levels of readiness, skills gaps, and the need for management support. Just as environmental challenges include competitive pressure, regulatory frameworks, and government support. These corroborate C3 AI (2025) and NASENI (2024).

The hybrid AI framework addresses these challenges by providing a structured approach that Nigerian manufacturers can adapt to their contexts. The framework's focus on data collection, integration, analytics, and decision support aligns with the layers of global AI implementations as observed by Tulsyan et al. (2020); C3 AI (2025); Jubilant HollisterStier (2025) and Casalini (2025).

The benefits from global implementations provide compelling evidence for Nigerian manufacturers considering AI adoption. The major biopharmaceutical company's achievements with the record of over €10 million annual economic benefit, 80% reduction in false alarms, 80% improvement in

failure prediction, and 48-fold increase in lead time illustrate the transformative potential of AI-driven predictive maintenance.

The successful deployment at the biopharmaceutical company and at Jubilant HollisterStier suggests that Nigerian manufacturers can expect positive returns on AI investment. However, the contextual challenges identified in this study including limited infrastructure, skills gaps, and financial constraints must be tackled head-on through targeted interventions by industry, government, and academia.

The role of government support is particularly important. The establishment of the NASENI-TROMENT biotechnology facility in Abuja represents a positive example of government support for biotechnology development (NASENI, 2024). Similar support for AI adoption in biomanufacturing could accelerate the transition from reactive to predictive maintenance.

11. Conclusion

This study has conducted a qualitative analysis of data from Nigerian biomanufacturing industries, government agencies, and professional associations to develop a hybrid AI framework for transitioning from reactive to predictive maintenance. The findings reveal that Nigeria has over 150 registered pharmaceutical manufacturers, with key facilities concentrated in Lagos, Ogun, Abuja, and Kano, representing significant potential for AI adoption.

The hybrid AI framework developed in this study is grounded in the TOE framework, DOI theory, and TAM, which have explicated how technological, organisational, and environmental factors affecting AI adoption in Nigerian contexts could be tackled. The framework's five layers provide a structured approach that Nigerian manufacturers can adapt to their contexts.

The transition from reactive to predictive maintenance is a conscionable action to innovate biomanufacturing industries in developed climes. The prototype can transform Nigerian biomanufacturing operations, thereby improving productivity, quality, and competitiveness. However, successful implementation requires confronting contextual challenges, including infrastructure deficit, skills gaps, and financial constraints. The involvement of government agencies like NASENI, NAFDAC, NBRDA and the presence of WHO-GMP certified manufacturers can provide a foundation and smoothen the process for AI adoption.

12. Recommendations

12.1 For Biomanufacturing Practitioners

- **Begin with data collection:** Establish comprehensive data collection systems to capture equipment performance, maintenance history, and quality data essential for AI implementation.
- **Start with pilot projects:** Implement AI-driven predictive maintenance in targeted areas with high failure rates to demonstrate benefits before broader deployment.
- **Invest in skills development:** Develop capabilities in data science, machine learning, and AI to support implementation and maintenance of AI systems.

- **Foster a data-driven culture:** Cultivate appreciation for data-driven decision-making among staff at all levels. The success of AI implementation depends on cultural acceptance and usage.
- **Engage technology partners:** Collaborate with technology providers who have acquired robust with experience in biomanufacturing contexts.

12.2 For Policymakers

- **Develop regulatory frameworks:** Create supportive regulatory frameworks for AI adoption in manufacturing, addressing data governance, privacy, and quality requirements. The presence of WHO-GMP certified manufacturers in Nigeria provides a regulatory foundation that could be extended to AI.
- **Invest in infrastructure:** Support digital infrastructure development, including reliable internet connectivity and data storage facilities.
- **Provide financial incentives:** Offer tax incentives, grants, and subsidised loans for technology adoption.
- **Establish training programmes:** Support skills development programmes for AI and digital technologies.
- **Promote research and development:** Fund research on AI applications in Nigerian manufacturing contexts. The National Biotechnology Research and Development Agency (NBRDA), National Biosafety Management Agency (NBMA) and other institutions have capacity for biomanufacturing research that could be extended to AI adoption and application.

12.3 For Future Research

- **Empirical validation:** Conduct quantitative studies to validate the introduced framework using primary data from Nigerian biomanufacturing facilities.
- **Comparative studies:** Compare AI adoption across different Nigerian manufacturing sectors to identify sector-specific challenges and opportunities.
- **Implementation studies:** A study should be conducted to focus on AI implementation processes in Nigerian organisations to understand success factors and barriers.
- **Technology transfer studies:** Investigate the transfer and adaptation of AI technologies from developed to developing country contexts.
- **Impact Studies:** These should be directed at evaluating the economic impact of AI-driven predictive maintenance in Nigerian contexts.

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Appendix

Table 2

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