

Harnessing Artificial Intelligence for Improved Quality Assurance in the Pharmaceutical Sector: Opportunities and Barriers

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Abstract

The pharmaceutical sector plays a critical role in safeguarding public health and supporting economic development. However, challenges such as substandard drug quality, counterfeit medications, and regulatory lapses continue to undermine its effectiveness in Nigeria. This study, therefore, explored the transformative potential of Artificial Intelligence (AI) in enhancing quality assurance across the pharmaceutical value chain. The study adopted literature review approach. Drawing on extensive literature, the research highlighted how AI applications ranging from predictive maintenance and real-time defect detection to pharmacovigilance and supply chain optimization can significantly improve the safety, accuracy, and efficiency of pharmaceutical operations. Despite these promising benefits, the study identified several barriers to AI adoption. These include data quality issues, regulatory uncertainty, algorithmic bias, ethical concerns, lack of skilled personnel, high deployment costs, and cybersecurity risks. The findings suggested that while AI is not a panacea, its proper integration into pharmaceutical quality assurance systems can drastically reduce human error, ensure compliance with regulatory standards, and enhance patient safety. The study concluded that adopting AI is not just an innovation but a strategic imperative for transforming Nigeria's pharmaceutical sector and ensuring global competitiveness. Sequel to this, strategic collaboration among stakeholders such as government regulators, pharmaceutical firms, academia, and technology providers, to create an enabling environment for AI deployment was recommended.

Keywords: Artificial Intelligence, Pharmaceutical Sector, Quality Assurance, Nigeria, Drug Safety, Predictive Maintenance, Regulatory Compliance.

Introduction

The health and life expectancy of people depend on many things, but one of the most critical things relevant to the determination of these is the pharmaceutical sector. Obukohwo, Olele and Buzugbe (2018) in supporting this position posit that the pharmaceutical industry in any economy plays a prominent role in the general health of citizens residing in the country. Similarly, Sadiku, Adekunle and Sadiku (2024) state that the pharmaceutical industry is a critical field that plays a vital role in saving lives. Being one

of the industrial sectors, the pharmaceutical sector also plays its fair share of role in the economic development of nations. Ojo-Emmanuel, Ayanlade and Jegede (2023) assert that the industrial sector is one of the major contributors to Nigeria's economic growth as they contributed 27.38% to the country's GDP.

To perform well, the pharmaceutical industry relies heavily on innovation and creativity as stated by Sadiku, Adekunle, and Sadiku (2024) who posit that in the pharmaceutical industry, innovation is key, and it is typically predicated on extensive research and development across various domains. Hence, the adoption and application of Artificial Intelligence (AI) in the various processes of their operations across the globe.

Artificial Intelligence (AI) is at the forefront of technological adoptions in many sectors (Ebuka, et al., 2023). Huanbutta et al., (2024) posit that AI is rapidly transforming numerous industries in different countries. The pharmaceutical industry is not left out in the transformation capabilities of AI, as Huanbutta et al., (2024) state that AI assist the industry in offering advanced techniques for data analysis and decision-making. The application of AI in the operation of the pharmaceutical sector is wide, covering areas such as drug discovery, clinical trials, precision medicine, personalized medicine, and supply chain optimization (Sadiku, Adekunle, Sadiku, 2024). However, for the purpose of this study, the focus is on AI applications for quality control and assurance.

Quality control or regulatory control, refers to the processes and systems implemented by governments, regulatory agencies or organizations as it were to ensure the safety, efficacy, and quality of products available to consumers (Orikpete et al., 2023), and in this case, quality of pharmaceutical products. Quality assurance and control have posed significant threats to the Nigerian economy, especially in the area of drug production, leading to counterfeit, fake and expired products. In alignment with this, Ebugosi and Olaboye (2024) assert that many developing nations, including Nigeria, grapple with significant challenges in ensuring the quality control of both food and medication (Oweibia et al., 2024). The country faces a multitude of issues ranging from contamination and adulteration in food products to the proliferation of counterfeit drugs in the pharmaceutical market (Ebugosi & Olaboye, 2024). Poor storage conditions further compound medication quality control challenges in Nigeria. Inadequate infrastructure, unreliable electricity supply, and lack of temperature control systems contribute to the degradation of pharmaceutical products, reducing their potency and efficacy (Chukwu and Adibe, 2022).

The pharmaceutical sector has the potential to be a leading sector in Nigeria, sadly, they still grapple with issues of quality, hence, calling into question their quality assurance processes. One of the tools they could use to enhance this aspect of their operations is AI, but sadly, this seems not to be the case for them. Gonesh, et al., (2023) posit that AI's potential to enhance efficiency, accuracy, and decision-making has ignited a revolution that promises to reshape the landscape of drug production, quality control, and overall operational excellence. AI, a branch of computer science that simulates human intelligence processes using machines, is harnessing data-driven insights and computational power to

optimize various stages of pharmaceutical manufacturing. From drug discovery and development to quality control and supply chain management, AI is demonstrating its ability to revolutionize the industry's core functions (Gonesh, et al., 2023). Pharma companies that adopt and utilize AI across their operations have the potential to double their operating profit (Sadiku, Adekunle & Sadiku, 2024). Quality assurance protocols in manufacturing processes improve production efficiency by lowering expenses. Strict quality standards help manufacturers cut waste and prevent the need for reworks or product recalls (Priyankumar, 2014). The deployment of techniques that could reduce the error rate and improve both effectiveness and efficiency is paramount (Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023), which is where AI comes in. It is against this backdrop that this study seeks to examine how the pharmaceutical sector in Nigeria can harness AI to improve its quality assurance processes.

Review of Related Literature

Artificial Intelligence

The origins of AI research can be traced back to a 1956 workshop at Dartmouth College, where participants conceived the idea of developing a machine with human-level intelligence (Kaplan and Haenlein, 2019; Newquist, 1994 cited in Huanbutta et al., 2024). Therefore, AI is structured to think and act like humans. It is the ability of machines to do what intelligent humans do (Ebuka, Emmanuel and Idigo, 2023). Hence, Arachie, Nwosu, Ugwuanyi and Ibrahim (2025) posit that AI is in action when machines, applications and software are deployed and structured in a way that enables them to reason like humans, making intelligent decisions and taking the burdens from humans so that they can face more complex tasks. Artificial intelligence refers to the various processes involved in the programming of machines that enable them to act like humans and mimic their actions (Adigwe, Onavbavba & Sanyaolu, 2024). These activities may include carrying out tasks, processing information, and making decisions based on past events (Mahomed, 2018).

The endpoint or the most significant part of AI is to solve complex problems quicker so as to make the best decisions all the time. The objective of AI is to solve problems that otherwise would require a lot of brainwork to arrive at a decision (Arachie, Nwosu, Ugwuanyi & Ibrahim, 2025). Typically, AI systems demonstrate at least some of the following human behaviours: planning, learning, reasoning, problem-solving, knowledge representation, perception, speech recognition, decision-making, language translation, motion, manipulation, intelligence, and creativity (Sadiku, Adekunle & Sadiku, 2024).

McCarthy, Minsky, Rochester and Shannon (2006) coins AI as "the science and engineering of making intelligent machines, this was borrowed from emeritus Stanford Professor John McCarthy in 1955. It is a cross-disciplinary method for comprehending, modelling, and producing intelligence in many forms (Frankish & Ramsey, 2014). Therefore, the adoption and application of AI cuts across different fields, including medicine, applied sciences, social sciences, industry etc. Today, AI is transforming a vast number of businesses. First, AI frees

human resources for better use by automating repetitive tasks. For instance, in the factories, AI-enabled robots can perform tasks reliably and accurately (Huang, Shen, Li, Fey & Brecher, 2021, cited in Priyankkumar, 2024).

Artificial Intelligence (AI) includes diverse methodologies, such as natural language processing (Fanni et al., 2023), computer vision (Kakani et al., 2020), and robotics (Van Roy et al., 2020), whereas Machine Learning (ML) is primarily concerned with creating algorithms that learn from data to provide predictions without direct programming. In machine learning, deep learning is a sub-field that uses artificial neural networks to replicate the structure of the human brain, enabling the identification of intricate patterns and relationships within extensive datasets. These technologies have attained advanced outcomes in areas such as picture recognition (Lee et al., 2017), natural language comprehension (Liu et al., 2019), and speech recognition (Badjatiya et al., 2017).

AI in the Pharmaceutical Sector and Quality Assurance

The adoption of AI in different fields has been on for many years. For instance, Yang, Wang, Byrne, Schneider and Yang (2019); Burton, Albur, Eberl and Cuff (2019) aver that AI has been involved in medicine since as early as the 1950s when physicians made the first attempts to improve their diagnoses using computer-aided programs. Meskò, Drobni, Bényei, Gergely and Gyorffy (2017) state that interest and advances in medical AI applications have surged in recent years due to the substantially enhanced computing power of modern computers and the vast amount of digital data available for collection and utilisation.

Manufacturing and quality control are essential to the pharmaceutical and medical device industries. They both significantly impact a product's safety, effectiveness, and compliance with strict regulations (Priyankkumar, 2014). Traditional quality control procedures, while effective, can be arduous and prone to human mistakes. The integration of AI technologies, particularly in machine learning and computer vision, has instigated a significant transformation in quality control (Huanbutta et al., 2024). In post-market surveillance, AI analyzes real-world data to detect adverse drug reactions, maintaining the safety of pharmaceutical products throughout their lifecycle (Zinchenko et al., 2022). AI also improves final product quality assurance by detecting defects and ensuring safety and efficacy (Prajwala, 2018). AI technologies are also transforming product or quality control, an essential aspect of pharmaceutical manufacturing in the pharmaceutical industry (Huanbutta et al., 2024). AI systems can quickly and accurately detect flaws, irregularities, and deviations from established standards in pharmaceutical production and packaging (Saha et al., 2023). The incorporation of AI has accelerated the inspection procedure and minimized errors. Thus, AI has enhanced the safety and reputation of products being introduced to the market while safeguarding patients' well-being (Huanbutta et al., 2024).

Challenges of AI Integration in the Pharmaceutical Sector

Just like it is in different fields, the adoption and deployment of AI in the pharmaceutical sector is not devoid of its challenges as captured by Gonesh, et al. (2023) who aver that the integration of AI in pharmaceutical manufacturing is not devoid of challenges. Similarly, Adekunle and Sadiku (2024) opine that as with any new and revolutionary technology, the potential benefits of AI in the pharmaceutical industry come with significant challenges and considerations

Ensuring data integrity and availability, while adhering to strict regulatory compliance, poses a significant hurdle. The interpretability of AI decisions also remains a concern, as pharmaceutical manufacturing demands transparency and accountability (Gonesh, et al., 2023). Challenges like data privacy, biases, regulatory issues, and ethical concerns about decision-making need addressing (Sadiku, Adekunle & Sadiku, 2024). There are also issues of ethical concerns about AI deployment in the pharmaceutical sector (Mottaghi-Dastjerdi & Soltan y-Rezaee-Rad, 2024; Ajalkar, Sharma, Shinde & Nayak, 2024). Regulatory compliance issues are also raised while contemplating deployment of AI in the sector (Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023; Mottaghi-Dastjerdi & Soltan y-Rezaee-Rad, 2024; Ranjan & Singh, 2024).

The efficacy and precision of AI models are contingent upon the quality of the data utilized for their training, hence, the issue of biases comes into play when it comes to challenges of AI deployment (Sadiku, Adekunle & Sadiku, 2024). AI systems can perpetuate existing disparities if trained on biased data, leading to unequal treatment in drug development and patient care (Mottaghi-Dastjerdi & Soltany-Rezaee-Rad, 2024; Vyas, Eisenstein & Jones, 2020). Skills gap also limits the deployment speed of AI in the pharmaceutical sector. Successful implementation and management of AI systems require a skilled workforce. Acquiring a proficient workforce is a prerequisite in all sectors to leverage their expertise, proficiency, and aptitude in product innovation. Data scientists, AI specialists, and other professionals with AI and machine learning expertise are essential for developing, interpreting, and managing these technologies (Sadiku, Adekunle & Sadiku, 2024, Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023).

The threat of security breaches and loss of sensitive data to attacks also present a considerable amount of albatross to AI deployment in all fields, including in the pharmaceutical sector (Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023). Data Privacy and Security: Handling sensitive patient and proprietary data requires robust security measures to prevent breaches and ensure compliance with data protection regulations (Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023). AI models use complex algorithms and are often referred to as "black boxes" because it is difficult to understand how the model arrives at its predictions, hence bringing the issue of lack of transparency to the front burner (Sadiku, Adekunle & Sadiku, 2024). Transparency and explainability are critical, especially for deep learning models often regarded as 'black boxes' due to their complexity (Mottaghi-Dastjerdi & Soltan y-Rezaee-Rad, 2024; Zahoor,

Bawany & Ghani, 2023). There is the existential threat of breaches of the intellectual property rights of the deployment and the whole process (Groper, 2023). Additionally, the high cost of integrating AI solutions may limit accessibility, particularly in low-resource settings, potentially widening global healthcare disparities (Khanna, Maindarkar, Viswanathan, Fernandes, Paul, Bhagawati, et al, 2022).

Benefits of Artificial Intelligence Deployment

Artificial Intelligence (AI) has proven over the years to have a significant impact on the pharmaceutical industry (Sadiku, Adekunle & Sadiku, 2024). It is revolutionizing the pharmaceutical industry and drug development process by enhancing the speed, efficiency, and success rates of drug discovery (Sadiku, Adekunle & Sadiku, 2024). With AI, the pharmaceutical industry can now predict the machines that would need maintenance before they get bad; it helps them anticipate problems before they occur. Predictive maintenance algorithms can anticipate equipment breakdowns, reducing downtime and ensuring uninterrupted production operations. Predictive maintenance algorithms can predict when equipment may go down, which reduces downtime and keeps production running smoothly. Predictive maintenance uses AI to keep an eye on how well the equipment is working and make sure that products are of high quality (Sadiku, Adekunle, & Sadiku, 2024). AI-powered predictive maintenance helps keep equipment from breaking down by predicting when it will need repair, cutting down on downtime, and making everything work better (Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023). Similarly, the predictive forecasting capability of AI also aids pharmaceutical firms to be able to tell what the future outlook of the business will be in terms of sales volume, profitability and customer needs. Using a predictive forecast, pharmaceutical firms can plan their supply chain to ensure the appropriate quantity and timing of inventory is available (Sadiku, Adekunle & Sadiku, 2024).

Automation is another area pharmaceutical firms can benefit from AI deployment in their businesses. To keep up with expansion, businesses are using more efficient and automated processes to make decisions based on data, and AI helps immensely in this aspect (Sadiku, Adekunle & Sadiku, 2024; Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023). In the past, people used manual algorithms to do things that needed artificial intelligence. It is very important to check that raw materials, parts, and finished goods all meet the criteria. But there are limits to repeated manual checks. AI, on the other hand, checks everything, making sure every checks out properly (Sadiku, Adekunle & Sadiku, 2024). Data management is an area AI also plays a role in also. AI significantly benefits the pharmaceutical business by accelerating medication research and development. Historically, the process of introducing a novel pharmaceutical to the market may require years, even decades, and incurs costs up to billions of dollars. AI is significantly transforming this by optimizing the process. AI-driven platforms can forecast the behaviour of novel substances, simulate chemical interactions, and detect potential negative effects before

the commencement of human testing (Sadiku, Adekunle & Sadiku, 2024; Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023).

Artificial intelligence also has a cost reduction significance to pharmaceutical firms over a long period. The adoption of AI in the pharmaceutical sector leads to substantial cost savings in various operational domains. It enables firms to enhance operational efficiency by automating mundane processes and streamlining resource management. It can automate data entry, manage extensive datasets, and optimize administrative operations, hence diminishing the necessity for manual labour and decreasing the likelihood of human error (Sadiku, Adekunle & Sadiku, 2024). Pharmacovigilance, or drug safety surveillance, is a vital domain in which AI is exerting a substantial influence on pharmaceutical firms. AI systems can evaluate extensive quantities of real-time data from clinical trials, patient records, and social media to identify hazardous medication reactions (Sadiku, Adekunle & Sadiku, 2024). Similarly, AI provides data-driven insights that facilitate informed decision-making across all stages of pharmaceutical manufacturing, from drug development to distribution (Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023). AI helps ensure adherence to regulatory standards by automating documentation, reporting, and quality control processes (Gonesh, Lima, Hasi, Prasanta, Ravichandaran, Sanjiv & Barun, 2023).

Methodology

An interpretivism research philosophy was adopted for this study, given that it focuses on comprehending the subjective meanings and experiences of social actors; no quantitative analysis will be carried out. Therefore, an exploratory research design was deployed, because of the nature and characteristics of the study. Secondary qualitative data was collected for the study. The databases used for this include Google Scholar, ScienceDirect, Semantic Scholar, SpringerLink, Emerald and ResearchGate. Keywords such as AI in the manufacturing sector and the pharmaceutical sector, challenges to the adoption AI, prospects and challenges of AI adoption. To be able to select only relevant articles, inclusion and exclusion criteria were employed. The inclusion criteria were to include only peer-reviewed articles, articles between 2020-2025, articles written in English, and articles with available full versions. Any article that fell short of these were excluded.

Key Findings

The following are the key findings:

- a) Artificial intelligence improves the precision, efficiency, and reliability of quality control (Huanbutta et al., 2024). AI-driven technologies, such as machine learning algorithms and automated inspection tools, enable companies and institutions to identify issues with greater precision than manual methods.
- b) The implementation of AI in Nigeria's pharmaceutical industry can enhance AI-driven discovery and development, intelligent manufacturing and predictive

maintenance, as well as predictive forecasting and supply chain management, among other applications. AI possesses significant potential in pharmacovigilance, drug safety monitoring, quality assurance, regulatory compliance, workforce training, and skill development within Nigeria's pharmaceutical industry (Sadiku et al., 2024; Gonesh et al., 2023; Huanbutta et al., 2024).

- c) Artificial intelligence possesses numerous advantages yet encounters significant barriers to widespread implementation. The primary obstacles included the expenses associated with AI adoption, shortages of experienced personnel (Gonesh et al. 2023; Sadiku et al. 2024; Ojediran et al. 2014), and the inadequate comprehension of pharmaceutical firm proprietors. Numerous individuals find it challenging to finance AI infrastructure, and the scarcity of AI-trained personnel impedes their capacity to utilize AI technology. Employee opposition to change and concerns around job displacement hinder AI adoption (Gonesh et al. 2023; Adigwe 2021).

Conclusion

This study has examined the transformative capacity of Artificial Intelligence (AI) in improving quality assurance in Nigeria's pharmaceutical industry. Amid escalating apprehensions over counterfeit pharmaceuticals, inadequate storage, and regulatory deficiencies, the incorporation of AI presents a timely and unique remedy to enduring difficulties. AI applications—ranging from real-time quality control, predictive maintenance, and supply chain optimization to defect detection and pharmacovigilance—present a compelling case for its adoption across all phases of pharmaceutical production and distribution. Nonetheless, despite the tremendous advantages, the path to AI integration is fraught with considerable challenges. Challenges including data integrity, regulatory compliance, insufficient skilled personnel, algorithmic bias, and elevated implementation costs hinder adoption. Ethical issues around transparency, data privacy, and intellectual property exacerbate the process, particularly in a resource-limited context such as Nigeria.

Notwithstanding these challenges, AI continues to be an effective and potent instrument for enhancing the quality assurance processes of pharmaceutical companies. Its capacity to automate monotonous tasks, reduce human error, and facilitate data-informed decision-making establishes it as an essential catalyst for operational efficiency and patient safety. A concerted effort among industry players, regulatory authorities, and politicians is essential to properly exploit these potentials. Enhancing infrastructure, developing local AI capabilities, and advocating for ethical standards will be crucial for facilitating sustainable AI integration. Ultimately, adopting AI is not merely an option but a strategic necessity for enhancing public health outcomes and securing the worldwide competitiveness of Nigeria's pharmaceutical sector.

Recommendation

The study makes the following recommendations:

- a. The pharmaceutical firms in Nigeria should prioritize investment in AI-driven tools and infrastructure, particularly in areas like machine learning, computer vision, and predictive analytics. These technologies can significantly improve real-time quality assurance, defect detection, and compliance with manufacturing standards.
- b. To overcome the skill gap, firms and stakeholders should invest in training programs and partnerships with academic institutions to develop local expertise in data science, AI, and pharmaceutical informatics. This will ensure the availability of qualified professionals to manage and sustain AI systems.
- c. Regulatory agencies like the National Agency for Food and Drug Administration and Control (NAFDAC) should work closely with pharmaceutical companies and technology providers to develop clear, flexible, and AI-inclusive regulatory guidelines. This will reduce ambiguity and build trust in AI-supported quality assurance processes.
- d. High-quality and unbiased data are essential for AI accuracy. Companies should adopt strict data governance policies to ensure data integrity, avoid algorithmic bias, and maintain patient confidentiality, in line with global best practices on data protection.
- e. Pharmaceutical firms should begin with small-scale AI pilot programs in areas such as inventory quality checks or equipment monitoring. This will allow them to test the feasibility, measure Return on Investment (ROI), and scale up gradually based on real-world insights and outcomes.

Limitations of the Study

This study, just like every other study, has some limitations, including the use of only secondary qualitative data, which may have limited the generalizability of the study. This study, because of lack of quantitative data and analysis lacks empiricism also. The exclusion criteria used in the study may have also prevented some very salient studies from being included in the study. Against this backdrop, the study recommend that other researchers may do well to add some level of quantitative statistics so as to improve on the generalization of the findings. Other studies could also widen the scope of the inclusion criteria to make provisions for some studies to be added to the data to be used.

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