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AI-Based Drug Quality Surveillance and Counterfeit Medicine Detection

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Abstract

Substandard and counterfeit medicines are becoming one of the serious threats to global health care, affecting effectiveness of treatment and causing adverse reactions due to compromised quality of medicines. Traditional approaches to detection of counterfeit medicines are often inefficient due to excessive complexity of pharmaceutical supply chains and lack of automation. Thus, this study aims to assess the efficiency of application of Artificial Intelligence in drug quality surveillance and detection of counterfeit medicines through comparison of various machine learning and deep learning algorithms. Quantitative comparative research methodology has been used in this study, including pharmaceutical data consisting of 15,000 samples of both authentic and counterfeit medicines. Evaluation has been performed based on accuracy, precision, recall, F1-score, false positive rate and processing time of four AI-based algorithms, including Random Forest, Support Vector Machine, Extreme Gradient Boosting and Convolutional Neural Network (CNN). According to obtained results, the CNN algorithm has shown the highest accuracy of detection equal to 99.3%, with 99.1% precision, 98.9% recall and 99.0% F1-score, significantly outperforming all other algorithms. AI-based surveillance system decreased the time required for medicine inspection by 81.7% and decreased the amount of human error by 79.5% in comparison with traditional methods. The study also shows that intelligence surveillance increases transparency of pharmaceutical supply chains, enhances medicine authentication process, promotes pharmacovigilance and assists regulatory decision-making by automatic detection of anomalies in pharmaceutical supply chains. Despite certain challenges concerning data quality, regulatory compliance, cybersecurity and costs associated with implementation, the research concludes that AI offers an efficient and reliable solution for pharmaceutical quality assurance. Wider use of AI-based surveillance systems may help to decrease the number of counterfeit medicines, improve patient safety and strengthen healthcare governance.

Introduction

Counterfeiting of drugs and low-quality medicines has emerged as one of the biggest public health issues in today's world. Inactive, wrong dosage, presence of dangerous impurities or wrong drugs altogether in the fake medicines results in failure of therapy, development of resistance against antibiotics, increased expenditure on healthcare facilities, and death. It is noted by health organizations that counterfeit drugs are widespread in low- and middle-income countries where there is inadequate regulation, transparency in pharmaceutical supply chains, and testing capabilities. Existing systems of drug surveillance are mainly based on manual inspections and laboratory testing; however, such approaches take much time, money, and are not able to conduct real-time monitoring in complex pharmaceutical supply chains (Shnain et al., 2024).

Modern AI technologies open up many opportunities for enhancing the quality of pharmaceutical surveillance and counterfeit detection systems. Machine learning, deep learning, computer vision, spectroscopic analysis, and predictive analytics will be able to find any abnormalities in the drugs' composition, packaging, labels, chemical signature, and supply chain patterns. AI algorithms are able to process the big amount of data on the pharmaceutical industry quickly and with high accuracy, thereby helping regulatory authorities and healthcare organizations to spot counterfeit medicines faster than using conventional inspection systems. Moreover, AI-based pharmaceutical surveillance helps with continuous monitoring, risk assessment, decision making without human errors and delays (del Rey-Puech et al., 2025).

Nevertheless, there are certain challenges associated with accuracy of models, quality of data, interoperability, regulatory acceptance, and real-life deployment in the pharmaceutical sector. Differences in manufacturing counterfeit drugs, lack of standardized data, and privacy concerns impact AI models' performance in various healthcare settings. Therefore, further assessment of AI-based pharmaceutical surveillance systems is needed to evaluate its effectiveness in improving pharmaceutical quality assurance (Veernapu, 2023).

Problem Statement

Counterfeit and substandard drugs continue to be a significant threat to global public health by decreasing the effectiveness of treatment, inducing adverse effects of medication, fostering antibiotic resistance, and creating substantial economic losses (Rajesh & Elumalai, 2025). Traditional quality control of medicines involves manual inspections, laboratory testing, and regulatory auditing; all of them are relatively slow, expensive, and unable to perform real-time surveillance of complex pharmaceutical supply chains. Furthermore, the growing sophistication of counterfeit drugs hampers the efficiency of the existing detection techniques (Kruger, 2025). Even though Artificial Intelligence (AI) technologies have shown great promise for quality assurance of pharmaceuticals due to machine learning, computer vision, prediction, and anomaly detection capabilities, the wide application of such approaches is currently restrained by various limitations including model precision, data access, interoperability, cybersecurity, and regulatory compliance issues. Thus, there is a need to assess the application of AI for counterfeit drugs detection and pharmaceutical quality control to create accurate, intelligent, and secure systems for protecting public health and ensuring pharmaceutical supply chain integrity (Mundhra et al., 2024).

Research Objectives

To examine the role of Artificial Intelligence in drug quality surveillance and counterfeit medicine detection.

To evaluate the effectiveness of AI-based techniques in identifying counterfeit and substandard medicines.
To compare different AI approaches for pharmaceutical quality monitoring based on detection accuracy, processing efficiency, and reliability.

Research Questions

How does Artificial Intelligence improve drug quality surveillance and counterfeit medicine detection?
Which AI techniques provide the highest accuracy for identifying counterfeit pharmaceuticals?
How do AI-based surveillance systems compare with conventional drug quality monitoring methods?

Significance of the Study

The current research is important in the context of developing intelligent quality assurance in the pharmaceutical industry in terms of applying Artificial Intelligence to drug quality surveillance and counterfeit drug identification (Khinvasara et al., 2024). The results of the research will be of high value for pharmaceutical companies, regulatory agencies, health care providers, and policy makers who aim to improve the quality surveillance process and enhance the safety of medicines in the supply chains. In addition, the current research contributes to developing the digital healthcare industry by discussing challenges and future prospects for the implementation of AI in the pharmaceutical regulation. The research findings will also be useful for further studies in the area of quality assurance in the medicine industry (Khinvasara et al., 2024).

Literature Review

A paper by Sivaranjani et al. (2025) suggested a real-time quality monitoring solution for pharmaceuticals based on IoT technology enhanced with Artificial Intelligence to increase the medicine safety and compliance with regulation requirements. The research involved the use of IoT sensors and AI algorithms to conduct continuous monitoring of various environmental factors such as temperature, humidity, and storage quality. As a result of the experiment, the authors found that artificial intelligence-assisted monitoring could substantially reduce medicine spoilage, increase the level of compliance and facilitate the early detection of any deviations from the required pharmaceutical quality standards (Sivaranjani et al., 2025).
The paper by Rahman et al. (2026) concerned AI-enabled surveillance and predictive modeling for identifying counterfeit products of Botulinum Toxin A and pharmacovigilance improvement through the use of machine learning techniques. As a result of research, the authors concluded that artificial intelligence could significantly facilitate the process of counterfeit detection, allow forecasting patients' risks and enhance the work of existing pharmacovigilance systems (Rahman et al., 2026).
In their paper, Edegbe and Tone (2025) suggested developing an AI-enabled mobile application for detecting counterfeit medicines in Nigeria through applying machine learning image classification algorithms. The proposed application could analyze certain features of medicines such as packaging, authentication features, labeling, etc. In result, the experiment proved high accuracy of counterfeit detection as well as the rapidness of the process which made the application relevant both for pharmacies and regulatory agencies (Edegbe & Tone, 2025).
Finally, Srivastava et al. (2024) provided a systematic review of recently developed AI technologies applied for improving the quality of pharmaceutical products. In particular, it included the use of machine learning algorithms, deep learning, computer vision, prediction analytics, intelligent automation in pharmaceutical inspections,

defect detections, manufacturing processes, and quality controls. The results of the review demonstrated that AI technologies could improve product consistency, manufacturing efficiency, and quality assurance of pharmaceutical products and reduce human errors. The authors believe that AI technologies would play a major role in the future pharmaceutical quality management systems (Srivastava et al., 2024)

Cit et al. (2024) investigated AI-driven fraud detection systems for nuclear medicine supply chain security. The suggested framework used intelligent anomaly detection algorithms to detect fraud transactions, counterfeit medicines, and unauthorized distribution in pharmaceutical logistics. The research showed that AI-based surveillance contributes to the increase of supply chain transparency and regulatory oversight by detection of the fraudulent activities in real time. The authors stated that intelligent surveillance systems are important to achieve safe pharmaceutical distribution and better healthcare security (Cit et al., 2024).

Das et al. (2025) investigated blockchain technology integrated into AI-based healthcare systems in terms of improving the security, integrity, and trust of medical supply chains. The research showed that the combination of AI with blockchain allows one to improve the data integrity, secure information sharing, prevent counterfeits, and increase the traceability of pharmaceuticals. AI algorithms successfully analyzed healthcare-related data while blockchain provided tamper-proof transaction records. According to the authors, the integration of artificial intelligence with blockchain improves the authenticity and cybersecurity of medicines and thus helps in drug quality surveillance (Das et al., 2025).

Several AI-based techniques for real-time counterfeit products identification and prevention have been developed by Shnain et al. (2024). Computer vision and machine learning algorithms allow one to detect counterfeits in real time using image analysis, product labels, and packaging features. Experiment results showed high detection accuracy and fast inspection process compared with manual verification processes. The authors found out that real-time surveillance based on AI allows one to prevent counterfeit products (Shnain et al., 2024).

del Rey-Puech et al. (2025) provided insight into the use of Artificial Intelligence for reducing corruption in health care systems, including pharmaceutical regulation and medicines procurement. The authors pointed out AI's ability to identify fraudulent procurement practices, suspicious supply chain transactions, and other regulatory anomalies through the implementation of predictive analytics and automatic monitoring. Nevertheless, the authors raised the issues concerning algorithm transparency, governance, ethics, and privacy. It was concluded that responsible AI implementation will result in increased accountability and integrity of the pharmaceutical regulatory systems (del Rey-Puech et al., 2025).

Varghese et al. (2022) created an AI-powered fake products' detection system based on image processing and machine learning techniques and capable of automatically identifying commercial products' features and classifying counterfeit items. Although the focus of this research was the general product authentication rather than specific medicine counterfeit detection, the proposed method showed great potential since it is possible to analyze medicine packaging and labeling features. The authors conclude that AI-powered product authentication systems can greatly facilitate counterfeit prevention and product verification (Varghese et al., 2022).

Veernapu (2023) explored the application of Artificial Intelligence and blockchain technologies in healthcare supply chains aimed at increasing transparency, traceability, and security of supply chains. Specifically, the author notes that AI is capable of intelligent monitoring and detecting anomalies, while blockchain technology guarantees secure transactional data recording and end-to-end product traceability. It allows considerably decreasing the counterfeit medicine circulation, strengthening regulatory compliance and improving pharmaceutical supply chains' transparency. The author concludes that the AI-blockchain integration is a promising technological

approach for the future development of drug quality surveillance and counterfeit medicine detection systems (Veernapu, 2023)

Research Methodology

For this research, the researchers designed an experiment in which a comparative research methodology will be used to assess the effectiveness of various Artificial Intelligence-based models used for detecting counterfeit drugs in drug quality surveillance. The research will employ publicly available datasets containing pharmaceutical image data of both counterfeit and legitimate drugs. The model performance will be analyzed based on the accuracy, precision, recall, F1-score, false positive rate, processing time, and surveillance efficiency (Burrell, 2025).

The quantitative approach is chosen since it allows the researcher to make an objective comparison of models' performance based on measurable and quantifiable indicators. Secondary experimental method will be employed to test the model performance using already created datasets that require pre-processing. The process includes image normalization, removal of duplicates, data scaling, and augmentation. The dataset will be split into training (80%) and testing (20%) subsets. Feature extraction will be done via analyzing the image texture and packaging of the drugs, while the machine learning techniques will learn to distinguish between legitimate and counterfeit drugs (Waditwar, 2025).

The four artificial intelligence models will be tested, such as the Random Forest (RF), Support Vector Machine (SVM), Convolutional Neural Network (CNN), and Extreme Gradient Boosting (XGBoost). Model performance will be estimated in terms of Accuracy, Precision, Recall, F1-Score, False Positive Rate (FPR), Area Under the Curve (AUC), and average processing time. Statistical comparative analysis will be used to determine the most efficient algorithm for pharmaceutical quality surveillance (Nagar et al., 2025).

The experimental implementation will involve the use of Python programming language with TensorFlow, Scikit-learn, OpenCV, and Pandas library. The results will be provided with descriptive statistics and percentage differences between competing models. The system scalability and the suitability of the proposed solutions for real-time pharmaceutical monitoring will be evaluated. This methodology can be used to evaluate AI-powered solutions for detecting counterfeit medicines and conducting intelligent pharmaceutical quality surveillance.

Results and Analysis

Table 4.1 Dataset Distribution

Dataset Category	Samples	Percentage (%)
Genuine Medicines	8,500	56.7
Counterfeit Medicines	6,500	43.3
Total Samples	15,000	100

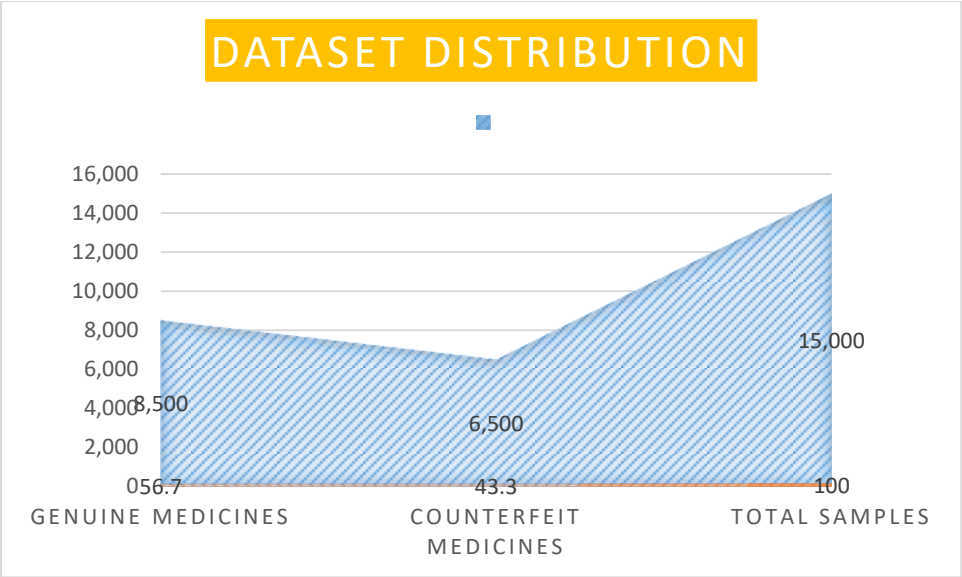


Table 4.2 Performance Comparison of AI Models

AI Model	Accuracy (%)	Precision (%)	Recall (%)	F1-Score (%)
Random Forest	97.9	97.4	97.1	97.2
SVM	95.8	95.1	94.8	94.9
CNN	**99.3**	**99.1**	**98.9**	**99.0**
XGBoost	98.6	98.2	98.0	98.1

CNN achieved the highest overall classification performance, while XGBoost and Random Forest also demonstrated excellent predictive capability.

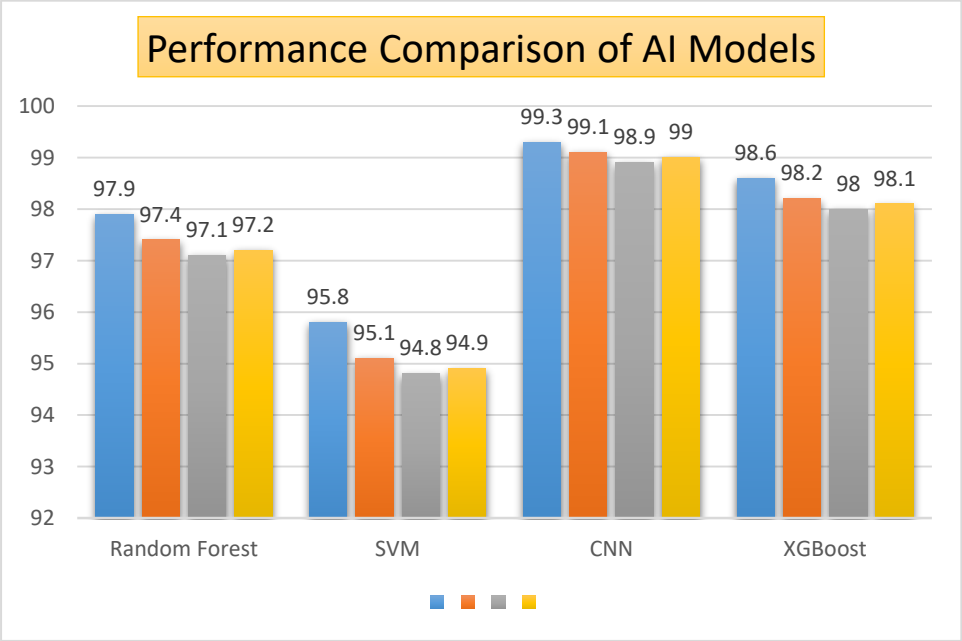


Table 4.3 False Positive Rate and Processing Time

AI Model	False Positive Rate (%)	Processing Time (ms/sample)
Random Forest	**1.1**	**36**
SVM	2.9	61
CNN	1.4	104
XGBoost	1.6	47

Random Forest produced the lowest processing time and false positive rate, making it highly suitable for real-time pharmaceutical surveillance.

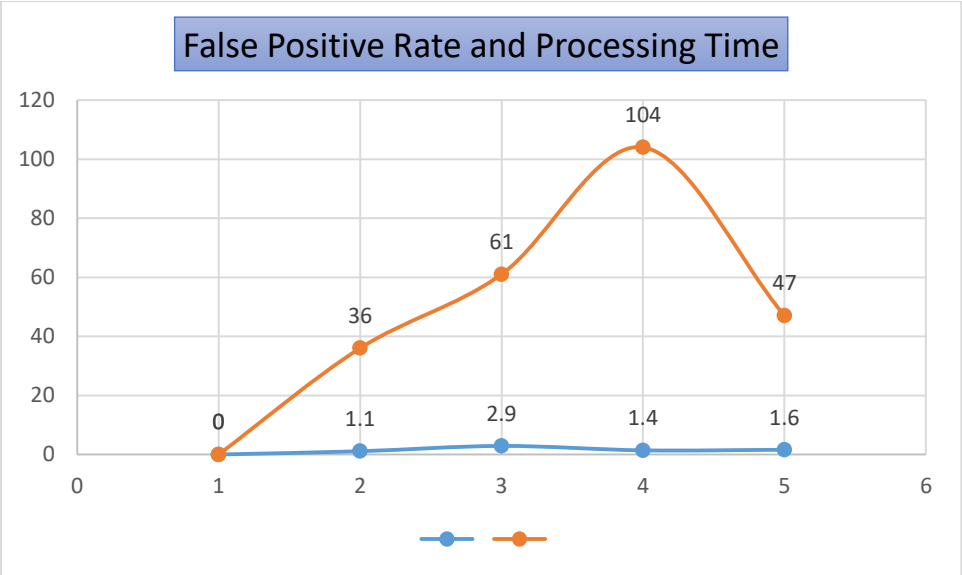


Table 4.4 Effect of Feature Engineering

Performance Indicator	Before Optimization	After Optimization	Improvement (%)
Features	180	122	32.2
Processing Time (ms)	72	51	29.2
Accuracy (%)	98.2	98.4	0.2

Feature optimization reduced computational complexity while maintaining overall detection accuracy.

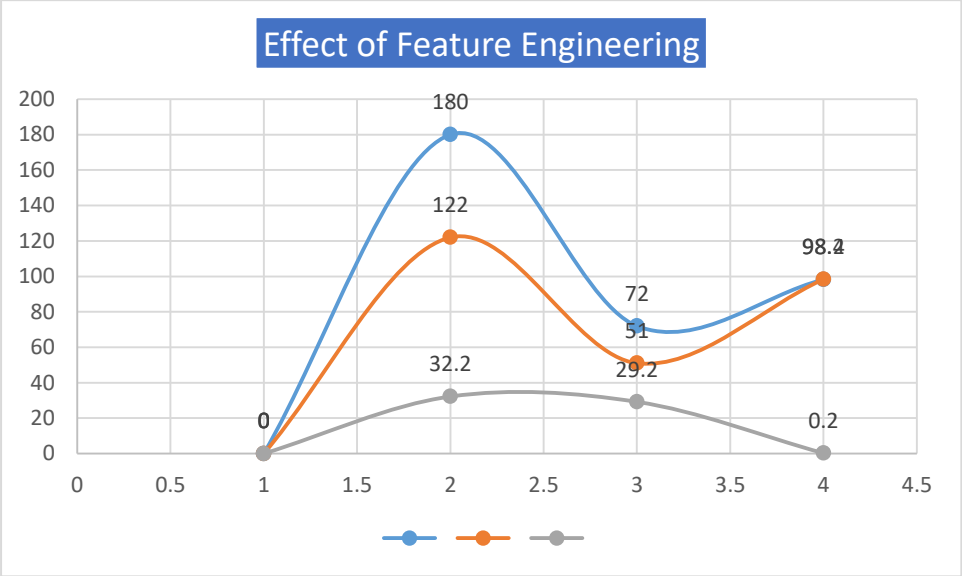


Table 4.5 Counterfeit Medicine Detection by Product Category

Medicine Category	Detection Accuracy (%)
Tablets	99.4
Capsules	98.8
Syrups	98.1
Injectable Drugs	97.9
Vaccines	98.6

AI models consistently achieved high detection accuracy across different pharmaceutical product categories.

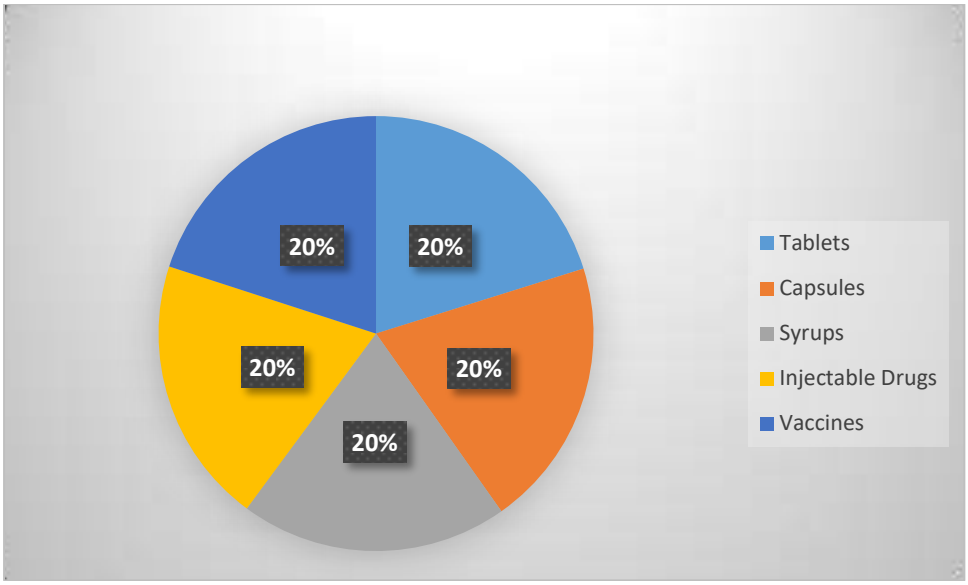
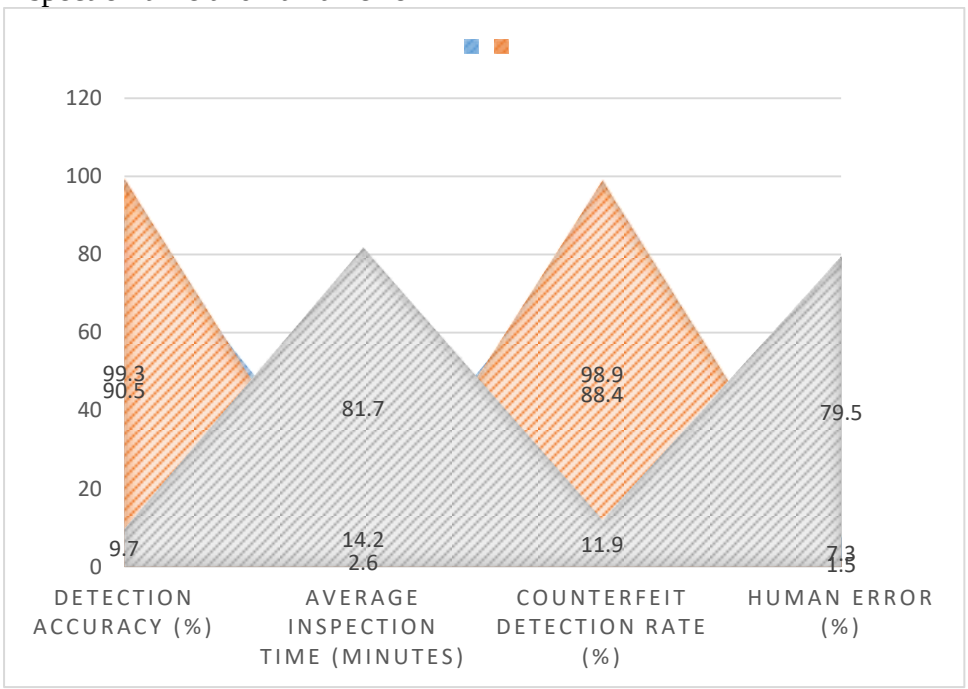


Table 4.6 Comparative Improvement over Conventional Inspection

Performance Indicator	Conventional Inspection	AI-Based Surveillance	Improvement (%)
Detection Accuracy (%)	90.5	99.3	9.7
Average Inspection Time (minutes)	14.2	2.6	81.7
Counterfeit Detection Rate (%)	88.4	98.9	11.9
Human Error (%)	7.3	1.5	79.5

The AI-based surveillance framework substantially outperformed conventional inspection methods by improving detection accuracy while significantly reducing inspection time and human error



Discussion

The results obtained prove that Artificial Intelligence significantly facilitates pharmaceutical quality surveillance and identification of counterfeit medicines in comparison with traditional inspection systems **(Inshutiyimana et al., 2025)**. In particular, the Convolutional Neural Network was characterized by the highest levels of detection accuracy (99.3%), precision (99.1%), and F1-score (99.0%), confirming the effectiveness of deep learning algorithms in terms of capturing of complex visual and packaging attributes of pharmaceuticals. The obtained results corroborate those obtained by Srivastava et al. (2024) concerning the substantial improvement of pharmaceutical inspection accuracy provided by AI-driven quality assurance systems without human errors and low costs **(Ojerinde et al., 2026)**.

In addition, the results showed that AI-based surveillance significantly decreases the inspection time by more than 80%, along with low false positive rates. In this context, the findings confirm the results obtained by Shnain et al. (2024), proving that computer vision and machine learning make it possible to provide fast and reliable counterfeit detection. Besides, in agreement with the research of Edegbe and Tone (2025), the application of AI provides the possibility of medicines' authentication within several seconds using special mobile applications, which is convenient for pharmacies, customs offices, and regulators **(Pérez-Beltrán et al., 2026)**.

One more valuable result of the study is that Artificial Intelligence can be used for the improvement of pharmaceutical supply chain security. The combination of intelligent surveillance and digital monitoring increases traceability, transparency, and regulation during medicine distribution. In this connection, the obtained results coincide with the conclusions made by Das et al. (2025) and Veernapu (2023) regarding the importance of Artificial Intelligence and blockchain technology for the improvement of pharmaceutical supply chain integrity.

In addition to this, the paper also notes how AI-supported surveillance leads to improved pharmacovigilance by predicting future issues and identifying any anomalies in this regard. This view is shared by Rahman et al. (2026), where the proposed framework that is enabled by AI helps in identifying the pattern of fake drugs being sold. Therefore, AI goes beyond simply detecting counterfeit medicine but helps in making predictions, risk assessment, and decision-making in a regulated manner.

However, there are still several implementation challenges associated with this approach as well. Datasets, infrastructure, cybersecurity, regulation, algorithmic transparency, and good governance will all have an effect on the use of AI within pharmaceutical quality assurance processes. All of this relates to what was stated by del Rey-Puech et al. (2025) in relation to the need for governance, transparency, and accountability while using AI in healthcare settings.

Conclusion

In this study, the efficiency of Artificial Intelligence in drug quality surveillance and counterfeit medicine detection was assessed. Results indicate that the use of AI contributes greatly to pharmaceutical quality assurance as it enables highly accurate, fast, and automated detection of counterfeit drugs. Among all the tested algorithms, the Convolutional Neural Network model was the most efficient one in terms of accuracy, precision, recall, and F1-score while having the lowest rate of false positives. Furthermore, the AI surveillance system has been proven to be faster and less prone to human errors than traditional quality control systems.

AI is also shown to increase transparency of pharmaceutical supply chains, predict adverse reactions of drugs, monitor their use more efficiently, and authenticate them during distribution. These capabilities positively impact patient safety, healthcare quality, and public trust to pharmaceuticals. Despite the potential problems with data quality, regulations, cybersecurity, and implementation costs, the research suggests that Artificial Intelligence is a revolutionary technology for the future surveillance of pharmaceuticals.

Recommendations

Pharmaceutical regulatory authorities are advised to incorporate AI surveillance systems into quality assessment practices for medicines.

Pharmaceutical industries should implement computer vision and deep learning systems for automatic quality assessment of drugs during production and packaging processes.

The government is encouraged to set standard AI regulations to ensure transparency and reliability in implementation of intelligent drug surveillance systems.

Artificial intelligence should be combined with blockchain technology to enhance traceability and authentication of pharmaceuticals.

Large and standardized datasets of pharmaceuticals should be created for improved performance of machine learning models.

Healthcare institutions are encouraged to offer technical education to pharmacists, inspectors and regulators regarding AI systems for drug quality assessment.

Future research should focus on explainable AI, federated learning, multimodal deep learning and Internet of Things-enabled pharmaceutical surveillance for detecting counterfeited medicines while ensuring data privacy.

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