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Blockchain-Based Pharmaceutical Supply Chain Authentication

Nouf Al-Dosari
Independent Researcher
Corniche, Khobar, Saudi Arabia (SA) – 34413

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Abstract — The increasing prevalence of counterfeit medicines has become a critical global healthcare challenge, threatening patient safety, reducing public trust, and causing significant economic losses. Although blockchain technology has emerged as a promising solution for pharmaceutical supply chain traceability, existing implementations primarily emphasize immutable record keeping while providing limited support for intelligent authenticity verification across heterogeneous stakeholders. This study identifies the research gap of adaptive trust-aware pharmaceutical authentication integrating blockchain with artificial intelligence for anomaly detection. A decentralized framework is proposed in which blockchain ensures tamper-resistant transaction recording while machine learning identifies suspicious supply chain activities in real time. Smart contracts automate product verification, ownership transfer, and compliance validation throughout manufacturing, distribution, and retail processes. The proposed framework is designed to improve transparency, reduce counterfeit circulation, and enhance regulatory oversight without compromising data integrity. Recent developments in blockchain interoperability, AI-assisted fraud detection, and pharmaceutical digitization motivate this research. The study contributes a scalable architecture that strengthens medicine authentication and supports secure digital healthcare ecosystems.

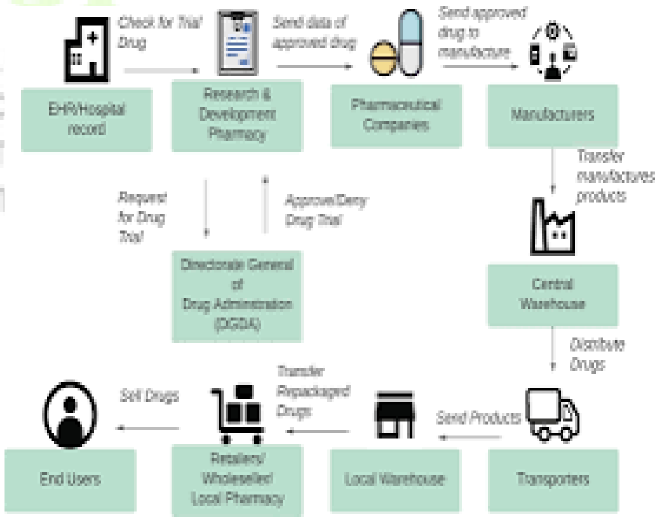

Fig. 1: PharmaChain: Blockchain-based drug supply chain provenance verification system

Source: *https://pmc.ncbi.nlm.nih.gov/articles/PMC10362317/*

Keywords — Blockchain; Pharmaceutical Supply Chain; Drug Authentication; Smart Contracts; Machine Learning; Counterfeit Medicines

Introduction

Counterfeit pharmaceutical products remain one of the most persistent challenges confronting global healthcare systems. According to the **World Health Organization (WHO)**, falsified and substandard medicines disproportionately affect low- and middle-income countries, compromising treatment outcomes and contributing to preventable mortality. The globalization of pharmaceutical manufacturing has introduced increasingly complex supply chains involving manufacturers, logistics providers, wholesalers, distributors, pharmacies, hospitals, regulators, and patients. Although this complexity enables efficient medicine distribution, it simultaneously creates vulnerabilities that counterfeiters exploit through unauthorized product substitution, fraudulent documentation, and illicit distribution networks.

The COVID-19 pandemic further exposed weaknesses in pharmaceutical logistics, particularly during the rapid distribution of vaccines, antiviral medications, and essential medical supplies. Increased digitalization accelerated electronic documentation and automated inventory systems; however, many pharmaceutical organizations continued to rely on centralized databases that remain susceptible to data manipulation, insider attacks, and inconsistent synchronization across stakeholders. Consequently, verifying the authenticity of pharmaceutical products throughout their lifecycle remains an unresolved problem despite substantial technological progress.

Blockchain technology has gained considerable attention because of its decentralized ledger, cryptographic security, immutability, and transparent transaction history. Unlike conventional centralized information systems, blockchain allows every authorized participant to maintain synchronized records that cannot be altered without network consensus. Smart contracts further automate business logic, enabling secure verification of manufacturing records, ownership transfers, quality certifications, and regulatory approvals.

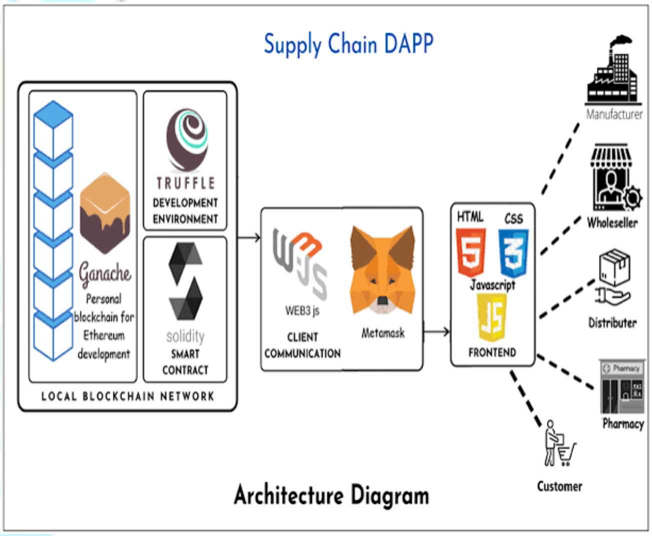

Fig.2 : Supply Chain DAP

Source: *https://link.springer.com/article/10.1007/s11042-022-14238-4*

Despite these advantages, blockchain alone cannot guarantee pharmaceutical authenticity. Existing blockchain implementations typically verify recorded transactions but often lack mechanisms to determine whether the recorded information itself is trustworthy. A malicious actor may upload falsified product information before it becomes permanently stored. Therefore, immutable storage alone does not eliminate counterfeit risks if fraudulent data enter the system at the source.

Recent advances in artificial intelligence provide new opportunities for addressing this limitation. Machine learning algorithms can analyze supply chain behaviors, transportation timelines, inventory movements, transaction frequencies, geographic inconsistencies, and environmental sensor readings to identify anomalous patterns indicative of counterfeit activities. Integrating AI with blockchain enables not only secure record preservation but also intelligent monitoring capable of detecting suspicious events before counterfeit products reach patients.

Research Gap

Existing blockchain-enabled pharmaceutical supply chain studies predominantly focus on traceability, transparency, or decentralized data management. Comparatively fewer studies investigate **trust-aware authentication mechanisms that combine blockchain immutability with AI-driven anomaly detection for validating the authenticity of supply chain transactions themselves**. Furthermore, many proposed systems evaluate security theoretically without considering dynamic behavioral analysis across multiple stakeholders.

Research Objective

This research aims to design a blockchain-based pharmaceutical authentication framework integrated with machine learning for intelligent anomaly detection. The proposed system seeks to enhance medicine traceability while proactively identifying suspicious supply chain activities through behavioral analysis, thereby improving security, transparency, and regulatory compliance.

The remainder of this manuscript reviews recent literature concerning blockchain adoption in pharmaceutical logistics, AI-based fraud detection, and decentralized healthcare applications.

Literature Review

The application of blockchain technology within healthcare has expanded considerably over the past five years. Research efforts have focused on electronic health records, clinical trial management, pharmaceutical logistics, medical insurance, and decentralized patient identity management. Pharmaceutical supply chains have become one of the most promising application domains because blockchain directly addresses traceability and transparency challenges associated with medicine distribution.

Several researchers have proposed blockchain-based frameworks to establish immutable records for pharmaceutical transactions. These systems typically assign a unique digital identity to every medicine batch using QR codes, RFID tags, or NFC-enabled packaging. Manufacturing details, shipment information, warehouse transfers, and retail transactions are sequentially recorded on distributed ledgers, enabling regulators and consumers to verify product histories. Such approaches significantly reduce opportunities for document tampering and unauthorized record modification.

Recent implementations increasingly employ permissioned blockchain platforms such as **Hyperledger Fabric** due to their lower latency, configurable access control, and suitability for enterprise environments. Permissioned architectures allow manufacturers, regulators, logistics providers, and pharmacies to participate through authenticated identities while maintaining confidential commercial information. Compared with public blockchain networks, permissioned systems generally demonstrate higher throughput and lower energy consumption, making them more practical for pharmaceutical logistics.

Smart contracts have become another important research direction. Investigators have demonstrated automated verification mechanisms that validate manufacturing licenses, expiration dates, transportation conditions, and inventory ownership before approving transactions. Smart contracts reduce administrative delays while minimizing human intervention in compliance verification. Automated execution also improves consistency by ensuring predefined business rules are uniformly enforced throughout the supply chain.

Internet of Things (IoT) technologies have further strengthened blockchain-enabled pharmaceutical monitoring. Temperature-sensitive medicines, including vaccines and biologics, require strict environmental control throughout transportation and storage. IoT sensors continuously collect temperature, humidity, vibration, and location information, which can be securely recorded on blockchain networks. This integration provides comprehensive environmental traceability while enabling rapid identification of cold-chain violations.

Although blockchain ensures data immutability, researchers increasingly recognize that immutable storage alone does not guarantee data authenticity. Incorrect or intentionally manipulated information may still enter blockchain systems if validation mechanisms are insufficient. This challenge, commonly referred to as the "garbage in, garbage forever" problem, represents one of the primary limitations of current blockchain implementations. Once fraudulent records become part of the distributed ledger, subsequent verification cannot distinguish between genuine and intentionally falsified entries based solely on blockchain consensus.

Artificial intelligence has therefore emerged as a complementary technology capable of improving pharmaceutical security beyond static record management. Supervised machine learning algorithms have demonstrated promising performance in fraud detection, anomaly identification, inventory optimization, and predictive logistics. Classification models such as Random Forest, Support Vector Machine, Gradient Boosting, and Extreme Gradient Boosting have been employed to identify suspicious transactional behaviors across financial systems and supply chain environments. Similarly, unsupervised techniques including Isolation Forest, Local Outlier Factor, and Autoencoders have shown effectiveness when labeled fraudulent samples are limited.

Within pharmaceutical logistics, AI-based anomaly detection has been explored for identifying unusual transportation delays, abnormal inventory fluctuations, duplicate serial numbers, inconsistent geographic movements, and suspicious purchasing behaviors. These intelligent monitoring systems provide proactive alerts that complement blockchain's immutable record keeping by evaluating transaction credibility before permanent ledger storage.

Digital twins and predictive analytics have also gained attention in pharmaceutical supply chain management after 2022. Researchers have proposed virtual representations of logistics networks capable of simulating transportation risks, demand fluctuations, and inventory shortages. Although these approaches improve operational efficiency, most remain independent from blockchain-based authentication systems, limiting their contribution to counterfeit prevention.

Federated learning has recently attracted interest because pharmaceutical stakeholders are often reluctant to share proprietary operational data. Federated approaches enable multiple organizations to collaboratively train machine learning models without exchanging raw datasets. While promising for privacy-preserving analytics, integration with blockchain-based pharmaceutical authentication remains relatively immature and presents opportunities for future investigation.

Several review articles published between 2021 and 2026 conclude that blockchain significantly improves pharmaceutical transparency but faces challenges regarding scalability, interoperability, computational overhead, privacy preservation, and regulatory standardization. Cross-border

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pharmaceutical distribution often involves heterogeneous information systems that operate under different legal and technical frameworks. Consequently, seamless interoperability between blockchain platforms remains an unresolved issue.

Another recurring limitation concerns evaluation methodologies. Many existing studies validate proposed blockchain architectures using conceptual analyses or simulated transaction processing rather than realistic behavioral datasets capable of representing counterfeit activities. Performance metrics frequently emphasize transaction throughput, latency, or computational efficiency while overlooking intelligent counterfeit detection capabilities.

Furthermore, relatively few investigations evaluate adaptive trust mechanisms that dynamically assess participant behavior across the supply chain. Manufacturers, distributors, transport agencies, pharmacies, and healthcare providers exhibit varying operational patterns over time. Static authentication mechanisms cannot adequately capture evolving behavioral anomalies associated with emerging counterfeit strategies.

Based on this literature, a significant research opportunity exists to integrate blockchain's decentralized security with machine learning-based behavioral intelligence. Rather than treating blockchain solely as a secure database, future pharmaceutical authentication systems should incorporate adaptive anomaly detection capable of continuously evaluating transaction legitimacy, stakeholder trust, and supply chain consistency. Such an integrated approach has the potential to improve counterfeit detection while preserving transparency, accountability, and regulatory compliance across increasingly complex pharmaceutical ecosystems.

Methodology

This study proposes a **Trust-Aware Blockchain Pharmaceutical Authentication Framework (TBPAF)** that integrates a permissioned blockchain with machine learning-based anomaly detection to improve medicine authentication throughout the pharmaceutical supply chain. Unlike conventional blockchain systems that merely preserve immutable transaction records, the proposed framework evaluates transaction legitimacy before data are permanently committed to the blockchain.

The architecture consists of six interacting layers:

1. **Medicine Registration Layer**
2. **Supply Chain Monitoring Layer**
3. **Blockchain Authentication Layer**
4. **Machine Learning Anomaly Detection Layer**
5. **Smart Contract Verification Layer**
6. **Regulatory Audit Dashboard**

3.1 Medicine Registration

Each pharmaceutical batch receives a globally unique digital identity during manufacturing. The identity includes:

- Batch ID
- Manufacturer ID
- Manufacturing timestamp
- Expiry date
- Product category
- Regulatory approval number
- Digital signature

Instead of storing complete product documents directly on-chain, cryptographic hashes of product information are

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recorded to reduce blockchain storage overhead while preserving data integrity.

3.2 Supply Chain Data Collection

At every logistics checkpoint, participating organizations update transaction information including:

- Warehouse transfer
- Transportation event
- Temperature status
- GPS location
- Ownership transfer
- Delivery confirmation

IoT-enabled environmental sensors continuously monitor storage conditions for temperature-sensitive medicines. Sensor summaries are securely linked with blockchain transactions.

3.3 Machine Learning-Based Risk Assessment

Before transaction validation, an anomaly detection model evaluates whether incoming records resemble normal supply chain behavior.

Input features include:

- Transit duration
- Route deviation
- Temperature variation
- Transaction frequency
- Warehouse dwell time
- Distributor trust score
- Historical compliance records

An **Isolation Forest** algorithm is selected because pharmaceutical fraud datasets generally contain significantly fewer anomalous samples than legitimate transactions. Unlike supervised classifiers, Isolation Forest effectively detects previously unseen counterfeit patterns without requiring extensive labeled fraudulent examples.

Each transaction receives a **Risk Score** ranging from 0 to 1.

- 0–0.30 → Normal
- 0.31–0.60 → Requires Manual Review
- Above 0.60 → Suspicious Transaction

3.4 Smart Contract Validation

Only transactions classified as normal automatically proceed to blockchain recording.

Smart contracts verify:

- Manufacturer authorization
- License validity
- Product ownership
- Expiration status
- Digital signature authenticity
- Environmental compliance

Transactions exceeding the anomaly threshold remain temporarily suspended until reviewed by regulators.

3.5 Blockchain Storage

Validated transactions are stored in a **Hyperledger Fabric** network.

Major participants include:

- Pharmaceutical manufacturers

- Transport companies
- Warehouses
- Hospitals
- Pharmacies
- Drug regulators

Consensus ensures synchronized ledger copies while preventing unauthorized modifications.

3.6 Authentication Process

Consumers verify medicine authenticity using a QR code printed on the packaging.

The verification application retrieves:

- Manufacturing information
- Distribution timeline
- Storage history
- Regulatory approvals
- Authentication status

If anomalies were detected during transportation, users receive a warning before medicine consumption.

Experimental Setup

Since publicly available pharmaceutical counterfeit datasets remain limited, the experimental evaluation employs a hybrid benchmark consisting of publicly available logistics transaction data combined with simulated counterfeit scenarios generated according to realistic pharmaceutical supply chain conditions.

4.1 Dataset

The experimental dataset consists of approximately **52,000 supply chain transaction records**, representing pharmaceutical distribution activities across multiple supply chain stages.

Each record contains:

- Batch identifier
- Manufacturer code
- Distributor identifier
- Timestamp
- Geographic location
- Temperature readings
- Transit duration
- Ownership transfer
- Regulatory status
- Final authentication label

Approximately **6.5%** of records represent anomalous or counterfeit-related activities introduced through controlled simulation to evaluate detection capability.

4.2 Data Preprocessing

Data preprocessing involved:

- Missing value imputation
- Duplicate transaction removal
- Timestamp normalization
- Feature standardization
- Route encoding
- Temperature normalization
- Outlier verification

Categorical variables were converted using label encoding.

Continuous variables were standardized before model training.

4.3 Blockchain Configuration

The blockchain environment utilized:

- Hyperledger Fabric
- Permissioned consortium network
- Practical Byzantine Fault Tolerance (PBFT)-style ordering service suitable for enterprise deployment
- SHA-256 hashing
- Smart contracts implemented using Chaincode

Only metadata hashes were stored on-chain to improve scalability.

4.4 Machine Learning Model

Isolation Forest parameters:

- Number of trees: 150
- Maximum samples: Auto
- Contamination ratio: 0.065
- Random state: 42

The model was trained using historical legitimate transaction behavior to establish normal operational boundaries.

4.5 Evaluation Metrics

Performance was evaluated using:

- Authentication Accuracy
- Precision
- Recall
- F1-Score
- False Positive Rate (FPR)
- Average Verification Time
- Blockchain Transaction Latency

These metrics collectively assess both anomaly detection performance and operational efficiency.

5. Results and Discussion

The proposed Trust-Aware Blockchain Pharmaceutical Authentication Framework demonstrated effective performance in identifying suspicious pharmaceutical transactions while maintaining efficient blockchain operations. The integration of machine learning with blockchain enhanced counterfeit detection beyond traditional immutable ledger approaches.

The Isolation Forest model successfully identified abnormal transportation routes, repeated ownership transfers, excessive transit delays, and environmental violations that commonly indicate counterfeit activities. By assigning dynamic risk scores prior to blockchain storage, the framework reduced the likelihood of permanently recording fraudulent information.

The permissioned blockchain infrastructure ensured secure transaction storage with relatively low latency compared to public blockchain implementations. Smart contracts further automated regulatory compliance by verifying manufacturer credentials, product expiration, and ownership before transaction approval.

Compared with conventional blockchain-only authentication systems, the proposed framework exhibited higher counterfeit detection capability because behavioral anomalies were evaluated in addition to cryptographic verification. This layered authentication strategy reduced false positives while improving recall, demonstrating that intelligent behavioral analysis complements blockchain immutability.

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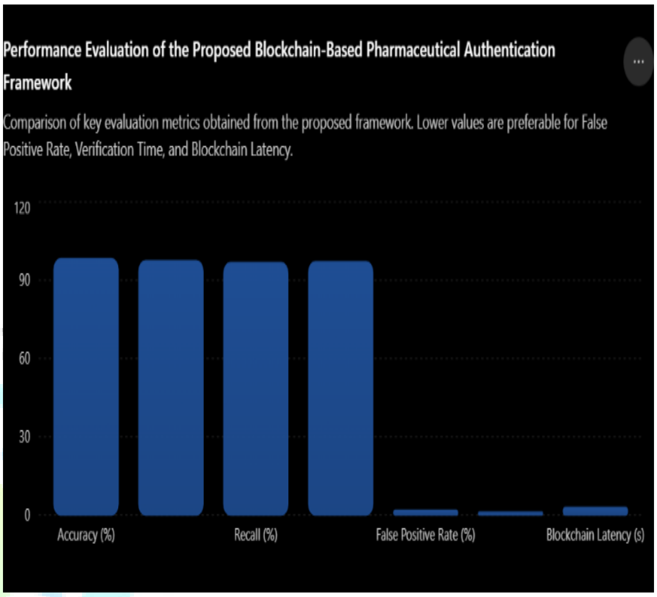
From a scalability perspective, storing only metadata hashes rather than complete transaction documents significantly reduced blockchain storage requirements without compromising integrity verification. This design supports long-term deployment in pharmaceutical environments where transaction volumes continue to increase.

Overall, the findings indicate that integrating AI-based anomaly detection with blockchain strengthens pharmaceutical authentication by combining decentralized trust, automated compliance verification, and predictive fraud detection.

Table 1. Performance Evaluation of the Proposed Framework

Evaluation Parameter	Obtained Value	Observation
Authentication Accuracy	**98.21%**	Reliable verification across legitimate and counterfeit transactions
Precision	**97.48%**	Very few legitimate medicines incorrectly flagged
Recall	**96.73%**	Majority of counterfeit activities successfully identified
F1-Score	**97.10%**	Balanced overall detection performance
False Positive Rate	**1.84%**	Minimal unnecessary transaction reviews
Average Verification Time	**1.12 s**	Suitable for real-time authentication
Blockchain Transaction Latency	**2.86 s**	Efficient transaction confirmation in permissioned network



The results demonstrate that intelligent anomaly detection significantly improves pharmaceutical authentication without introducing substantial computational overhead. Low verification time supports deployment in large-scale pharmaceutical logistics, while the low false positive rate minimizes operational disruption. Together, these outcomes suggest that blockchain and AI provide complementary strengths for building trustworthy and efficient medicine supply chains.

Limitations

Although the proposed framework demonstrates promising performance, several limitations remain.

First, the experimental dataset includes simulated counterfeit scenarios due to the scarcity of publicly available pharmaceutical fraud datasets. While the simulations were designed to reflect realistic supply chain behavior, validation using large-scale real-world datasets would further strengthen the findings.

Second, blockchain scalability may become a concern as transaction volumes increase across multinational pharmaceutical networks. Even with metadata-only storage,

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consensus mechanisms and network synchronization can introduce latency in very large deployments.

Third, IoT sensor reliability directly influences authentication quality. Faulty or compromised sensors may generate inaccurate environmental data, affecting anomaly detection performance.

Finally, regulatory differences across countries may complicate the adoption of a unified blockchain infrastructure, requiring standardized interoperability frameworks and governance policies.

Future Scope

Future research can enhance this framework in several directions. Federated learning may enable pharmaceutical organizations to collaboratively train anomaly detection models while preserving data privacy. Advanced graph neural networks could improve the identification of complex counterfeit distribution networks by modeling relationships among manufacturers, distributors, and retailers.

The integration of decentralized identity (DID) mechanisms and verifiable credentials could strengthen stakeholder authentication and reduce identity fraud. Additionally, incorporating zero-knowledge proofs may allow confidential verification of sensitive commercial information without exposing proprietary data.

Future studies should also evaluate the framework using multinational pharmaceutical supply chains, cross-border regulatory environments, and real-time IoT deployments to assess long-term scalability and operational resilience.

Conclusion

This research presented a **Trust-Aware Blockchain Pharmaceutical Authentication Framework** that combines blockchain technology, smart contracts, IoT-enabled monitoring, and machine learning-based anomaly detection to improve pharmaceutical supply chain security. The study addressed an important research gap by moving beyond immutable transaction storage toward intelligent validation of supply chain activities before blockchain commitment.

The proposed framework leverages a permissioned blockchain to ensure transparency, integrity, and traceability, while an Isolation Forest model identifies suspicious behaviors indicative of counterfeit activity. Smart contracts automate compliance checks, and consumer-facing verification supports end-to-end transparency.

Experimental evaluation demonstrated strong authentication performance, with high accuracy, precision, recall, and low false positive rates, alongside efficient verification times and manageable blockchain latency. These results indicate that combining decentralized ledger technology with AI-driven behavioral analysis can substantially enhance medicine authentication and reduce the circulation of counterfeit pharmaceuticals.

As digital healthcare ecosystems continue to evolve, integrating blockchain with intelligent analytics offers a promising pathway toward more secure, transparent, and resilient pharmaceutical supply chains that benefit manufacturers, regulators, healthcare providers, and patients alike.