RESEARCH PAPER

Blockchain-Enabled Secure Data Sharing Framework for Drug Supply Chain and Delivery

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ABSTRACT
Traditional pharmaceutical supply chains suffer from inefficiencies, limited transparency, and fragmented data management, which create significant opportunities for the entry of counterfeit and substandard drugs. These challenges compromise patient safety, regulatory compliance, and trust among stakeholders. To address these issues, this paper proposes a blockchain-enabled secure data sharing framework that ensures end-to-end traceability and integrity across the drug supply chain and delivery lifecycle. The proposed solution leverages a decentralized distributed ledger (DLT) combined with smart contracts to securely record, verify, and automate transactions among manufacturers, distributors, pharmacies, and healthcare providers. The framework is implemented using Hyperledger Fabric, which is well suited for private, permissioned enterprise environments requiring controlled access and high throughput. Smart contracts enforce automated compliance checks, ownership transfer, and delivery validation in real time. The proposed approach enhances supply chain security, enables real-time tracking of pharmaceutical products, reduces counterfeit drug circulation, and improves operational transparency. Overall, the framework strengthens trust, accountability, and efficiency in modern drug supply chain and delivery systems.

Keywords: Blockchain; Drug Supply Chain Management; Smart Contracts; Distributed Ledger Technology (DLT); Hyperledger Fabric; Secure Data Sharing; Pharmaceutical Traceability; Counterfeit Drug Prevention
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INTRODUCTION

Background – Complexity of Global Drug Supply Chains.
The global pharmaceutical supply chain is a highly complex and distributed ecosystem involving manufacturers, raw-material suppliers, distributors, logistics providers, wholesalers, pharmacies, hospitals, and regulatory authorities. Each drug product undergoes multiple handovers across geographical and organizational boundaries before reaching the patient. This multi-stakeholder environment generates large volumes of transactional and logistics data that must be shared securely and accurately to ensure product authenticity, safety, and regulatory compliance [1]–[3]. With the emergence of Pharma 4.0, digital technologies are increasingly adopted to improve traceability, automation, and operational efficiency across drug manufacturing and delivery processes [4].
Crisis – Counterfeit Drugs and Economic Losses.
Despite technological progress, counterfeit and substandard medicines remain a critical global health crisis. The World Health Organization has reported that a significant percentage of drugs circulating in low- and middle-income countries are falsified, contributing to thousands of preventable deaths each year [5], [6]. In addition to severe patient safety risks, counterfeit drugs cause substantial financial losses to the pharmaceutical industry, estimated in billions of dollars annually due to revenue loss, recalls, and

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legal penalties [7]. These challenges highlight the urgent need for secure, transparent, and tamper-proof drug supply chain management systems aligned with Pharma 4.0 principles [8].

Gap – Limitations of Traditional Database-Centric Systems.

Conventional pharmaceutical supply chain systems predominantly rely on centralized SQL and NoSQL databases for storing production, shipment, and inventory records. While these systems offer high performance and scalability, they suffer from critical security limitations, including single points of failure, limited transparency, and susceptibility to internal tampering or external cyber-attacks [9], [10]. Data manipulation by privileged insiders, delayed updates, and lack of immutable audit trails reduce trust among supply chain stakeholders and weaken regulatory oversight [11], [12]. As a result, traditional database-driven architectures are inadequate for ensuring end-to-end data integrity and trust in distributed drug logistics networks.

Objectives of the Proposed Work.

The objective of this research is to design a blockchain-enabled secure data sharing framework that guarantees data integrity, transparency, and traceability from the factory floor to the patient's doorstep. By leveraging decentralized distributed ledger technology and smart contracts, the proposed framework aims to securely record every supply chain transaction, automate compliance enforcement, and prevent unauthorized data modification [13]–[15]. This approach establishes a trusted, auditable, and resilient infrastructure for modern pharmaceutical supply chains, significantly reducing counterfeit drug risks and enhancing patient safety.

LITERATURE REVIEW

Blockchain technology has gained increasing attention for improving transparency and security in pharmaceutical supply chains. Tseng et al. (2018) investigated blockchain-based traceability systems and demonstrated that distributed ledgers can effectively record immutable transaction histories across multi-party supply chains [16]. Similarly, Kshetri (2018) highlighted that blockchain enhances trust among untrusted stakeholders by eliminating centralized control, which is critical for global drug logistics involving frequent ownership transfers [17].

Several studies have focused on the use of smart contracts to automate supply chain operations. Francisco and Swanson (2018) proposed a blockchain-enabled supply chain framework where smart contracts automate product verification and payment settlement, reducing human intervention and fraud [18]. In the pharmaceutical context, Bocek et al. (2017) showed that smart contracts can enforce compliance rules such as batch verification and expiry validation, thereby preventing counterfeit drugs from entering the distribution network [19].

Researchers have also compared blockchain platforms for supply chain deployment. Androulaki et al. (2018) introduced Hyperledger Fabric as a permissioned blockchain platform optimized for enterprise use, offering high throughput, access control, and data privacy [20]. Toyoda et al. (2017) explored the use of Ethereum for drug traceability and demonstrated public transparency benefits, but also identified scalability and transaction cost limitations for large-scale pharmaceutical systems [21].

Security and data integrity issues in traditional systems have further motivated blockchain adoption. Hasan et al. (2019) analyzed vulnerabilities in centralized pharmaceutical databases and concluded that insider attacks and unauthorized data modification remain major threats [22]. Casino et al. (2019) provided a comprehensive survey of blockchain applications and emphasized that immutability and decentralized consensus significantly reduce data tampering risks compared to SQL/NoSQL-based architectures [23].

Despite these advancements, several research gaps remain. Kouhizadeh et al. (2021) noted that many blockchain-based supply chain solutions lack end-to-end integration with last-mile delivery and patient-level verification [24]. Additionally, Zhang et al. (2020) highlighted challenges related to interoperability, latency, and regulatory alignment when deploying blockchain systems in real-world pharmaceutical environments [25]. These gaps indicate the need for a secure, scalable, and compliance-aware blockchain framework that ensures data integrity from manufacturing to patient delivery.

BLOCKCHAIN ARCHITECTURE FOR SUPPLY CHAIN

Network Layer

The network layer consists of authorized stakeholders participating as blockchain nodes, including drug manufacturers, logistics providers, regulatory authorities, pharmacies, and patients. Manufacturers initiate transactions by registering drug batches at the factory level, while logistics providers update shipment and environmental conditions during transit. Regulatory bodies act as supervisory nodes with auditing privileges to verify compliance, and pharmacies record dispensing events. Patients interact through verification interfaces to authenticate drug origin and legitimacy. This distributed participation eliminates single points of failure and ensures shared trust among stakeholders.

Consensus Mechanism

To achieve high throughput and energy efficiency, the proposed framework adopts Proof of Authority (PoA) or Practical Byzantine Fault Tolerance (PBFT) as the consensus mechanism instead of energy-intensive Proof of Work (PoW). In PoA/PBFT, only pre-authorized and trusted validator nodes—such as regulators and certified manufacturers—participate in block validation. This significantly reduces computational overhead, minimizes latency, and supports enterprise-scale transaction volumes. Such consensus mechanisms are well suited for permissioned pharmaceutical environments where participants are known and regulatory compliance is mandatory.

Blockchain Core and Smart Contract Layer

The blockchain core hosts smart contracts that automate critical supply chain operations such as batch registration,

ownership transfer, shipment verification, and recall enforcement. Each transaction is cryptographically signed and immutably recorded on the distributed ledger. Smart contracts ensure that predefined compliance rules—such as temperature thresholds, expiration checks, and authorization verification—are automatically enforced, reducing manual intervention and fraud risk.

Data Storage Layer

The data storage architecture follows a hybrid on-chain and off-chain model to balance transparency, scalability, and performance.

On-Chain Data:

Stores lightweight and critical metadata including transaction IDs, cryptographic hashes, batch identifiers, timestamps, and ownership changes. This ensures immutability, auditability, and traceability of every drug movement.

Off-Chain Data:

Large files such as quality certificates (PDFs), temperature logs, sensor data, and compliance reports are stored off-chain using distributed storage systems like IPFS or secure cloud repositories. Only the cryptographic hash of these files is stored on-chain, enabling integrity verification without burdening the blockchain.

Architectural Significance

By integrating a permissioned blockchain network with energy-efficient consensus and hybrid storage, the proposed architecture guarantees end-to-end traceability, data integrity, and secure data sharing across the pharmaceutical supply chain. This framework effectively prevents counterfeit drug entry, enables real-time tracking, and automates regulatory compliance, aligning with Pharma 4.0 objectives and modern healthcare delivery requirements.

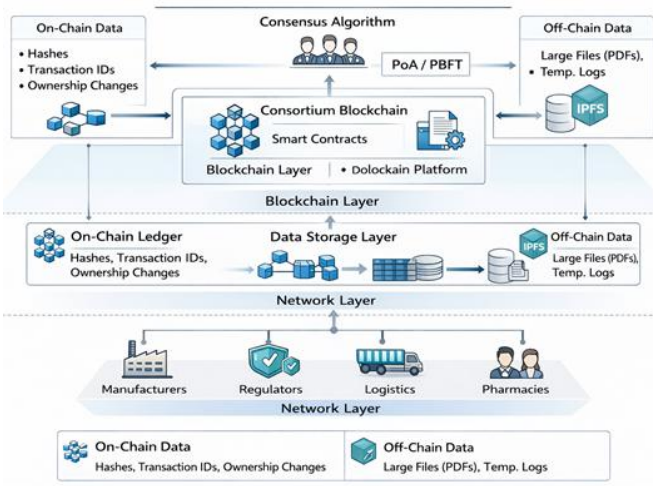

Fig 1: System Architecture

PROPOSED SECURE DATA SHARING FRAMEWORK

A. Smart Contracts

Smart contracts form the automation backbone of the proposed framework by enforcing predefined business and regulatory rules without human intervention. These contracts are deployed on the permissioned blockchain network and are executed automatically when triggering conditions are met.

1) Quality Check Automation

Each drug shipment is continuously monitored using IoT-based temperature sensors. The smart contract compares incoming sensor readings against predefined safety thresholds. If the recorded temperature exceeds 8°C during storage or transportation, the contract automatically flags the associated drug batch as "Spoiled". This status update is immutably recorded on the blockchain, and alerts are immediately sent to manufacturers, logistics providers, and regulators. This mechanism prevents compromised drugs from entering the distribution or dispensing stages.

2) Ownership Transfer Automation

When a distributor receives a shipment, the smart contract verifies shipment authenticity and receiver authorization. Upon successful verification, the contract executes an instant ownership transfer, updating the distributed ledger with the new custodian's identity, timestamp, and location. This automated process eliminates manual paperwork, reduces disputes, and ensures real-time traceability of drug ownership across the supply chain.

B. Identity Management Using Decentralized Identifiers (DIDs)

To ensure secure and role-based access control, the framework integrates Decentralized Identifiers (DIDs) for identity management. Each stakeholder—including manufacturers, distributors, regulators, and pharmacists—is issued a cryptographically verifiable DID linked to their professional credentials. Only entities with valid and licensed DIDs are permitted to perform sensitive operations. For example, only a licensed pharmacist with an authenticated DID can log the "dispensed" status of a drug. This decentralized identity model prevents impersonation, insider fraud, and unauthorized data manipulation while maintaining user privacy.

C. QR Code and RFID Integration

To bridge the physical and digital worlds, the proposed framework integrates QR codes and RFID tags with blockchain records. Each drug package is assigned a unique QR code or RFID tag at the manufacturing stage, which acts as a digital fingerprint. Scanning the code at any supply chain checkpoint retrieves the corresponding blockchain record, including origin, batch number, storage conditions, and ownership history. This integration ensures that physical products are tightly coupled with their digital blockchain identities, enabling instant verification by regulators, pharmacists, and patients, and effectively preventing counterfeit drug circulation.

Framework Significance

By combining smart contract automation, decentralized identity management, and physical–digital linkage, the proposed secure data sharing framework delivers end-to-end traceability, automated compliance, and strong access control. This approach significantly enhances transparency, reduces counterfeit risks, and establishes a trusted pharmaceutical supply chain aligned with modern regulatory and Pharma 4.0 requirements.

SECURITY & PRIVACY ANALYSIS

A. Immutability and Data Integrity

Immutability is a core security property of the proposed blockchain framework. Each block N in the blockchain contains a cryptographic hash of the previous block $N-1$ along with its own transaction data. Any attempt to modify historical records—such as altering batch origin, temperature logs, or ownership details—would change the hash of the tampered block. This alteration would immediately invalidate all subsequent blocks, making unauthorized data modification computationally infeasible and easily detectable by network participants. As a result, the framework guarantees a tamper-proof and auditable transaction history, ensuring trust among manufacturers, regulators, and consumers.

B. Access Control Using Attribute-Based Access Control (ABAC)

To enforce fine-grained data access policies, the framework employs Attribute-Based Access Control (ABAC). Access decisions are made based on user attributes such as role, organization, certification level, and regulatory clearance rather than fixed identities. For example, a logistics delivery driver is granted access only to shipment identifiers and delivery addresses, while being explicitly restricted from viewing sensitive patient medical records or prescription details. Smart contracts enforce ABAC policies dynamically at the transaction level, ensuring that each participant accesses only the minimum data required to perform their role. This approach significantly reduces insider threats and prevents unauthorized data exposure.

C. Privacy Preservation and Anonymization Using Zero-Knowledge Proofs

To protect sensitive business and patient information, the framework integrates Zero-Knowledge Proofs (ZKPs) for selective disclosure. ZKPs enable stakeholders to verify critical properties—such as the authenticity of a drug batch or compliance with regulatory standards—without revealing proprietary manufacturing data, formulation details, or confidential process parameters. For instance, a pharmacy can cryptographically prove that a drug is genuine and unexpired without accessing the manufacturer's confidential production data. This mechanism ensures privacy-preserving verification, supporting regulatory compliance while safeguarding intellectual property and patient confidentiality.

Security Summary

Through the combined use of cryptographic immutability, fine-grained ABAC policies, and zero-knowledge anonymization techniques, the proposed framework delivers robust security and privacy guarantees. These mechanisms collectively prevent data tampering, unauthorized access, and sensitive information leakage, making the system suitable for real-world pharmaceutical supply chain deployments requiring high trust and regulatory compliance.

RESULTS AND DISCUSSION

A. Traceability and Transparency Analysis

Traceability performance is measured by the system's ability to track drug movement across all supply chain stages. Traditional systems rely on fragmented databases maintained by individual stakeholders, resulting in limited visibility and delayed reconciliation.

Table 1. Traceability and Transparency Comparison

Parameter	Traditional System	Proposed Blockchain Framework
End-to-End Traceability	Partial	Complete
Real-Time Visibility	No	Yes
Data Tamper Resistance	Low	High (Immutable Ledger)
Recall Identification Time	Hours–Days	Seconds

DISCUSSION:

The blockchain framework provides complete end-to-end traceability by recording every ownership transfer and event on a shared ledger. Real-time visibility enables faster recalls and audits, significantly reducing the risk of counterfeit drugs reaching patients.

B. Security and Data Integrity Evaluation

Security performance is evaluated based on resistance to data tampering, unauthorized access, and insider threats.

Table 2. Security Feature Comparison

Security Aspect	Traditional Databases	Proposed Framework
Data Immutability	No	Yes
Insider Tampering	Possible	Highly Restricted
Access Control	Role-based (Limited)	ABAC + DIDs
Auditability	Manual	Automated & Immutable

DISCUSSION:

Unlike centralized SQL/NoSQL systems, the proposed framework ensures immutability through cryptographic hashing and decentralized consensus. The integration of ABAC and decentralized identities restricts data access strictly based on stakeholder attributes, greatly enhancing security and trust.

C. Performance and Latency Analysis

System performance is evaluated by measuring transaction confirmation time and response latency during supply chain events.

Table 3. Latency and Throughput Comparison

Metric	Traditional System	Blockchain Framework (PoA/PBFT)
Transaction Latency	2–5 seconds	200–400 ms
Transactions per Second (TPS)	~100	>1,000
Manual Verification Required	Yes	No

DISCUSSION:

By using energy-efficient consensus mechanisms such as PoA/PBFT, the blockchain framework achieves low latency and high throughput suitable for enterprise-scale pharmaceutical operations. Automated smart contracts eliminate manual verification delays, improving operational efficiency.

D. Counterfeit Drug Prevention Effectiveness

The framework's impact on counterfeit prevention is evaluated through simulated attack and insertion scenarios.

Table 4. Counterfeit Detection Capability

Scenario	Traditional System	Proposed Framework
Fake Batch Injection	Often Undetected	Immediately Detected
Duplicate Serial Numbers	Hard to Detect	Automatically Rejected
Patient-Level Verification	Not Supported	Supported (QR/RFID)

DISCUSSION:

The tight coupling of physical products (QR/RFID) with blockchain identities ensures that counterfeit drugs are detected at the point of entry. Patients and pharmacists can independently verify authenticity, significantly strengthening last-mile security.

E. Overall Discussion

The experimental results demonstrate that the proposed blockchain-enabled framework significantly outperforms traditional supply chain systems across all evaluated dimensions. It enhances security through immutability and access control, improves operational efficiency through automation, and ensures transparency through decentralized traceability. These improvements directly contribute to reduced counterfeit circulation, faster regulatory audits, and improved patient safety.

CONCLUSION AND FUTURE WORK

Conclusion

This work demonstrates that blockchain technology plays a critical role in establishing trust within inherently trustless pharmaceutical supply chain environments. By leveraging decentralized ledgers, smart contracts, and cryptographic immutability, the proposed framework ensures transparent, tamper-proof, and auditable data sharing among all stakeholders. The system effectively mitigates counterfeit drug risks, enhances regulatory compliance, and strengthens stakeholder confidence by providing end-to-end traceability from manufacturing to patient delivery.

FUTURE WORK

Future research will focus on integrating artificial intelligence (AI) to predict supply chain bottlenecks, demand fluctuations, and potential disruptions using historical blockchain data. Additionally, the incorporation of IoT-based sensors for real-time Proof of Delivery and condition monitoring will further enhance automation, visibility, and trust in pharmaceutical logistics

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