A Block Chain-Based Approach for Drug Traceability in Healthcare Supply Chain

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Abstract - Counterfeit drugs pose a significant threat to public health and safety, particularly in complex and opaque pharmaceutical supply chains. This paper proposes a blockchain-based framework designed to enhance traceability, transparency, and accountability across the healthcare supply chain. Leveraging decentralized ledger technology (DLT), smart contracts, and cryptographic primitives, the proposed architecture ensures data immutability, provenance tracking, and efficient recall management. The solution is built on Hyperledger Fabric, a permissioned blockchain framework known for its modularity, privacy features, and scalability. The system's architecture, implementation, performance evaluation, and applicability in real-world scenarios are discussed in detail.
Keywords: Blockchain, Drug Traceability, Hyperledger Fabric, Smart Contracts, Healthcare Supply Chain, Supply Chain Security, Provenance, Distributed Ledger Technology.

1. INTRODUCTION

The global pharmaceutical industry is one of the most critical components of public health infrastructure, yet it remains highly susceptible to fraud, inefficiencies, and data silos. A significant concern is the rampant circulation of counterfeit and substandard medications, which are estimated to account for over 10% of all pharmaceuticals in developing nations. These illicit products not only fail to treat illnesses but may also cause harmful side effects, leading to deteriorated patient outcomes, increased antimicrobial resistance, and loss of trust in healthcare systems.

Traditional pharmaceutical supply chains are typically linear and fragmented, involving a diverse set of stakeholders including raw material suppliers, manufacturers, distributors, repackages, pharmacies, regulatory bodies, and ultimately, patients. Each stakeholder often uses isolated systems for inventory, quality control, and regulatory compliance, leading to a lack of interoperability and real-time visibility[[2]. Consequently, drug provenance and movement data are susceptible to manipulation, data loss, and unauthorized access.

Emerging technologies, particularly blockchain, offer a paradigm shift in how supply chains can be managed and secured. Blockchain's inherent characteristics decentralization, immutability, and consensus-driven validation render it a promising solution for building transparent and tamper-resistant ecosystems. When combined with other digital enablers such as smart contracts, public key infrastructure (PKI), and unique drug identifiers, blockchain can enable real-time auditability, streamline compliance, and automate multi-party workflows. This research presents a blockchain-enabled drug traceability framework implemented using Hyperledger Fabric-a permissioned blockchain platform tailored for enterprise environments. Hyperledger Fabric offers modularity, pluggable consensus protocols, data privacy through private channels, and fine-grained access control, making it an ideal candidate for regulated domains like pharmaceuticals. In this work, we design and evaluate a distributed ledger system that enables seamless collaboration among stakeholders, where every action be it drug manufacturing, transfer, repackaging, or dispensing is cryptographically recorded and verifiable.

We define smart contract logic to enforce compliance with regulatory norms such as FDA approvals and packaging standards. The system not only addresses end-to-end traceability but also supports provenance analytics, anomaly detection, and rapid recall mechanisms.

The remainder of the paper is structured as follows: Section 3 reviews the related literature and current solutions in the domain. Section 4 outlines the system architecture and stakeholder interactions. Section 6 elaborates on the implementation and security mechanisms. Section 7 presents performance metrics and evaluation outcomes Finally, Section 8 concludes the paper with potential directions for future enhancements.

2. SECURITY POLICY

In the proposed blockchain-based drug traceability system for the healthcare supply chain, a robust security policy is implemented to safeguard the integrity, confidentiality, and authenticity of sensitive data. The system leverages a permissioned blockchain architecture (such as Hyperledger Fabric), ensuring that only verified and authorized participants such as manufacturers, distributors, pharmacies, and regulatory authorities can interact with the ledger using role-based access control (RBAC).

Data immutability is achieved through the integration of cryptographic hash functions (e.g., SHA-256), which prevent unauthorized alterations and preserve the verifiability of each transaction. To maintain confidentiality, sensitive data is encrypted using symmetric or asymmetric encryption algorithms and stored off-chain, while only cryptographic hashes are anchored on-chain, minimizing exposure of private information.

All transactions undergo consensus validation via Practical Byzantine Fault Tolerance (PBFT) or Raft mechanisms, which ensures distributed agreement and prevents the inclusion of malicious or incorrect entries. The platform also employs smart contracts (chain code) that are rigorously tested and formally verified to mitigate common vulnerabilities such as reentrancy attacks, integer overflows, and unauthorized logic execution. An end-to-end audit trail is inherently supported by the blockchain ledger, enabling real-time tracking of pharmaceutical products and early detection of counterfeit drugs. Furthermore, the system adheres to regulatory standards such as the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR), thereby ensuring legal compliance and ethical management of healthcare data.

3. RELATED WORK

The integration of blockchain technology into the pharmaceutical supply chain has been extensively explored over the past decade. Various studies have proposed distinct frameworks to enhance drug traceability, mitigate counterfeit risks, and improve supply chain transparency. This section discusses the major contributions in this domain and evaluates their strengths, limitations, and gaps to establish the research context of our work.

3.1 Drug Ledger: Blockchain Traceability Model [5]

In 2018, a blockchain-based framework named *Drug ledger* was proposed to record and trace the movement of pharmaceutical products. The system was designed to guarantee **data authenticity** and **privacy preservation** across stakeholders, including manufacturers, regulators, and end consumers. It utilized a private blockchain configuration to restrict unauthorized access while providing cryptographic validation of transactions.

Although the system improved traceability, it lacked effective **storage pruning mechanisms** to manage data growth over time, which is critical for scalability in real-world deployments. Furthermore, the absence of dynamic role management limited its adaptability across diverse pharmaceutical ecosystems.

3.2 Bitcoin UTXO Analysis for Blockchain Traceability [16]

This study conducted an empirical analysis of the Unspent Transaction Output (UTXO) model of Bitcoin to explore its utility in non-financial applications, such as medical traceability. It highlighted how UTXO-based architectures ensure **transaction integrity** and **immutability**.

While the study provided valuable insights into data tracking and flow validation, it concluded that the UTXO model is **ill-suited for healthcare applications** due to its lack of semantic flexibility and inability to model complex, permissioned workflows essential for regulated industries.

3.3 A Medical Blockchain Model Using Hyperledger Fabric [20]

This This model leveraged the **Hyperledger Fabric** platform to implement a blockchain solution specifically aimed at preventing counterfeit drug circulation. Fabric's permissioned nature and modular design were utilized to define **chain code-based smart contracts**, enforce role-based access control (RBAC), and manage private data channels between stakeholders. Despite its security strengths, the model exhibited **low throughput** and **high latency** under load due to consensus and endorsement overhead.

Additionally, the computational complexity of chain code introduced performance bottlenecks when scaled to national-level networks.

3.4 A General Traceability Framework Using Ontologies [19]

This approach introduced the use of **semantic ontologies** to model and standardize data representation across supply chain entities. The ontology framework enabled **interoperability**, **semantic reasoning**, and **automated validation** of compliance rules.

The framework lacked integration with economic and legal mechanisms, making it difficult to enforce accountability in cases of malpractice or data breaches. Also, ontology-based systems, when not coupled with distributed ledger technologies, are vulnerable to centralization risks.

3.5 Blockchain in E-Voting Systems [17]

Although not directly related to drug traceability, this paper analyzed blockchain's performance and privacy trade-offs in the context of **electronic voting systems**. It compared **permissioned** and **permissionless** configurations and evaluated their suitability based on security, scalability, and decentralization metrics. Highlights the need for balancing **performance vs. decentralization. Emphasizes** the impact of consensus algorithms on throughput and fault tolerance.

The findings provide transferable knowledge applicable to pharmaceutical blockchains, particularly the challenges of maintaining trust and confidentiality in decentralized ecosystems.

3.6 Systematic Review of Blockchain in Healthcare [18]

This s A recent study conducted a comprehensive review of blockchain applications in healthcare, identifying key drivers such as **data integrity**, **auditability**, and **trust automation**. It categorized existing works into four domains: drug traceability, clinical trial integrity, patient data management, and insurance processing.

4. PROPOSED SYSTEM

The proposed system introduces a blockchain-based architecture to enhance traceability, transparency, and data integrity within the pharmaceutical supply chain. This system addresses the critical issues of counterfeit drugs, data tampering, and lack of accountability by utilizing decentralized ledger technology and smart contracts.

A. System Architecture

The architecture comprises four key stakeholders: manufacturers, distributors, pharmacies, and consumers. Each stakeholder interacts with the system through a role-based interface that enables authorized access and transaction execution. The Ethereum blockchain is utilized as the core platform to ensure immutability of records, while the Interplanetary File System (IPFS) is integrated for decentralized storage of drug-related documents and metadata.

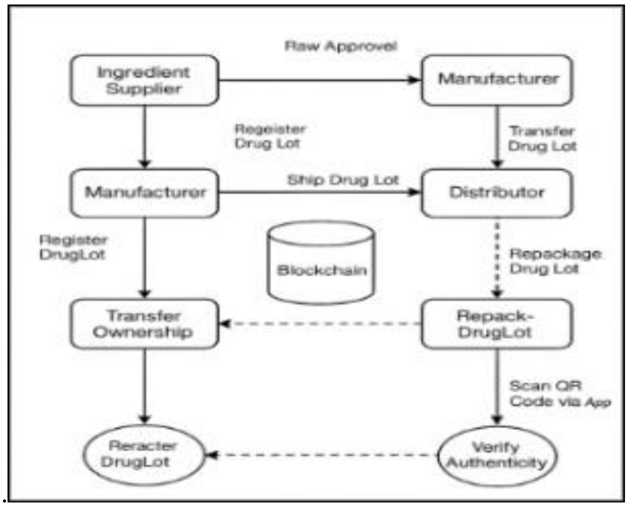

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Fig.4.1 System Architecture of Blockchain Drug Traceability

B. Smart Contract Design

Smart contracts are employed to automate and secure interactions among stakeholders.

The contract defines essential functions including addDrug(), transferDrug(), verifyDrug(), and getDrugDetails(), each associated with specific access control mechanisms.

These contracts ensure that only authorized entities can perform designated actions, thus enforcing security and trust.

C. Workflow

The drug traceability process begins at the manufacturer, where drug batch details are recorded and uploaded to IPFS. The corresponding hash is then stored on the blockchain via a smart contract invocation.

Subsequent stakeholders between distributor and pharmacy validate the batch and update the transaction status on the blockchain. Finally, consumers can trace the complete history of a drug using a unique identifier or QR code through a web interface.

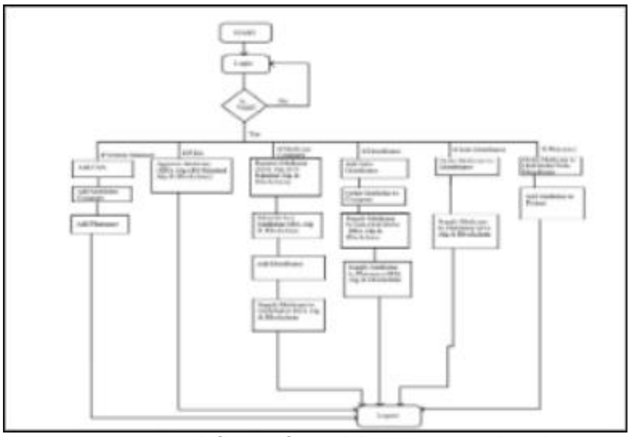

Fig.4.2 Workflow of HealthCare Supply Chain

D. Security and Data Integrity

All data interactions are recorded as immutable transactions on the blockchain, which provides auditability and tamper resistance. The integration of IPFS ensures that drug metadata and compliance documents remain securely stored off-chain, while still being verifiable on-chain through cryptographic hashing.

Component	Function
Peer Nodes	Maintain the ledger and execute Chain code
Certificate Authority	Issues cryptographic identities (X.509 certificates)
Ordering Service	Packages transactions into blocks using consensus (e.g., Raft)
Chain code	Encodes business logic for validation and transaction handling
Ledger	Immutable, append-only database of all validated transactions

Table. 4.3 Components of Hyperledger Fabric

E. Benefits

This system significantly reduces the risk of counterfeit drugs entering the supply chain and enhances stakeholder trust by ensuring data provenance. Furthermore, the elimination of centralized intermediaries reduces operational costs and improves process efficiency.

5. METHODOLOGIES

The proposed methodology employs a decentralized approach using blockchain and smart contracts to achieve secure, transparent, and traceable drug movement within the pharmaceutical supply chain. The system is designed to involve all stakeholders, manufacturers, distributors, pharmacies, and consumers to ensure end-to-end visibility and integrity of drug data.

5.1 System Components

Blockchain Platform

The system is implemented on the Ethereum blockchain due to its support for smart contracts and decentralized application (Dapp) development. Ethereum provides a tamper-proof ledger to record drug transactions with timestamps and cryptographic integrity.

Smart Contract:

Smart contracts are deployed to automate and govern transactions between stakeholders. Functions include adding drug details, updating location status, verifying authenticity, and transferring ownership across the supply chain. These contracts enforce role-based access control to prevent unauthorized actions.

IPFS Integration

The Interplanetary File System (IPFS) is used to store documents and metadata (e.g., manufacturing certificates, quality control reports) off-chain. The content-addressed hashes of these files are stored on the blockchain for reference, ensuring secure and decentralized storage.

5.2 PROCESS

Drug Registration

The manufacturer initiates the process by registering a drug batch on the platform, including details such as batch number, manufacturing date, and composition. A unique ID is generated, and associated documents are uploaded to IPFS.

Supply Chain Transactions

As the drug moves through the supply chain, each participant updates the status and ownership on the blockchain using smart contract functions. This ensures a traceable record of each handover.

Verification

Pharmacies and end-users can scan the drug's QR code to verify its origin and transaction history via the blockchain. The immutability of records ensures that authenticity cannot be falsified.

Security Enforcement

All transactions are validated and recorded in blocks, which are cryptographically linked to previous records. Unauthorized modifications are prevented by the consensus mechanism inherent in the Ethereum blockchain.

6. MODULE DESCRIPTION

The proposed system is divided into several interconnected modules that ensure secure, traceable, and tamper-proof drug movement throughout the pharmaceutical supply chain. Each module corresponds to a key entity in the system and performs specific operations through blockchain and smart contracts.

6.1 Manufacturer Module

This module is responsible for initiating the drug traceability process. Manufacturers enter details such as drug name, batch number, composition, date of manufacture, and expiry date. These details, along with relevant documents like quality certificates, are uploaded to the Interplanetary File System (IPFS) for decentralized storage. The corresponding hash is stored on the Ethereum blockchain using a smart contract, ensuring that the data is both verifiable and immutable.
This step also generates a unique drug ID, marking the beginning of the supply chain tracking.

6.2 Distributor Module

After manufacturing, the drug is transferred to authorized distributors. In this module, distributors can view and verify drug data using blockchain records. Once verification is complete, they confirm receipt and update the current location and condition of the drug. Ownership is then transferred through a blockchain transaction, and the handover is recorded immutably. This module ensures that only validated drugs progress to the next stage in the supply chain.

6.3 Pharmacy Module

Pharmacies receive drug batches from distributors. The pharmacy module allows pharmacists to confirm drug authenticity by checking blockchain records. Upon verification, they update the transaction history to reflect successful delivery and stock the drug for public access. This module ensures that only verified drugs are made available to consumers and helps prevent counterfeit products from reaching the market.

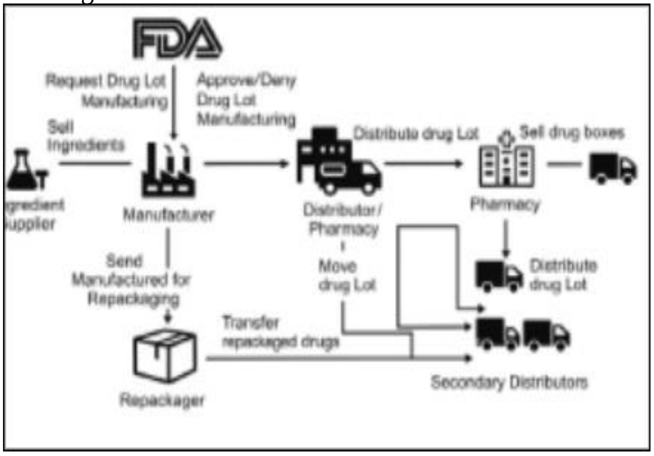

Fig.6.1 Modules of Drug Traceability.

6.4 Consumer Module

The consumer module offers an interface for end-users to verify the authenticity of the drugs they purchase. By scanning a QR code on the drug package, consumers can access blockchain-based details such as manufacturing history, distribution trail, and validity. This fosters transparency, consumer trust, and awareness by allowing real-time verification directly through the web interface.

6.5 Smart Contract Module

At the core of the system lies the smart contract module, which manages all transactions and enforces the rules of interaction among stakeholders. It includes functions such as addDrug(), transferDrug(), verifyDrug(), and getDrugDetails(), with access control mechanisms based on stakeholder roles. This contract ensures secure, automated, and tamper-proof execution of supply chain events.

Function	Purpose
AddDrug()	Initializes a drug batch with metadata and unique identifier
VerifyDrugLot()	Confirms FDA approval and checks digital signatures
TransferDrugLot()	Transfers drug custody between entities and logs provenance
RepackageDrug()	Ensures compliance with packaging regulations during repackaging
DispenseDrug()	Records the dispensing of drugs to the end-user or pharmacy
RecallDrug()	Triggers recall events and flags affected batch numbers

Table 6.2 Components of Smart Contract

6.6 IPFS Storage Module

Since storing large documents directly on the blockchain is expensive and inefficient, the IPFS(Interplanetary File System) storage module handles off-chain storage of drug-related documents. Files are uploaded to IPFS, and only their content-addressable hashes are stored on-chain. This ensures data integrity and availability while reducing on-chain storage costs. It also provides decentralized and secure access to drug compliance documents and certificates.

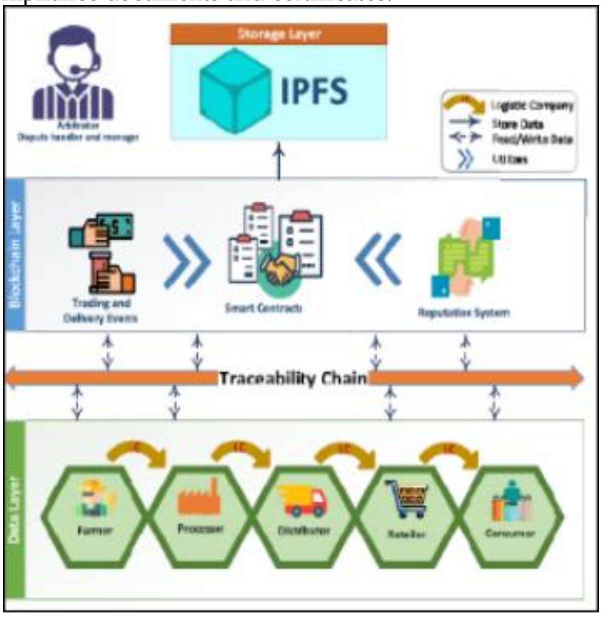

Fig.6.3 Traceability chain using IPFS Storage

7. EXPERIMENTAL RESULTS

The proposed blockchain-based drug traceability system was developed and tested on a local Ethereum network using tools such as Ganache, Remix IDE, MetaMask, and Web3.js. Fig.

7.1, titled **"Drug Batch Registration by Manufacturer,"** demonstrates the initial stage where the manufacturer enters critical drug batch details including drug ID, composition, manufacturing and expiry dates, and uploads related certification documents to IPFS.

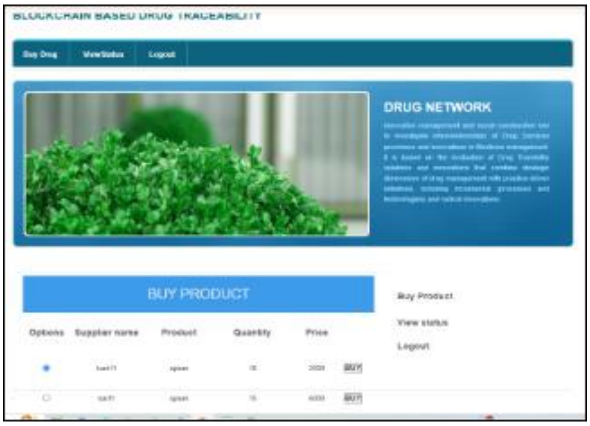

Fig.7.1 Drug Batch Registration by Manufacturer

Upon registration, the drug is assigned a unique identifier, and the data is stored immutably on the blockchain. In the next phase, Fig.7.2, **"Drug Data Access and Validation by Processing Entity,"** shows how a processing stakeholder can securely access and verify the drug's metadata from the blockchain to ensure its authenticity before passing it along the supply chain.

Fig.7.2 Drug Data Access and Validation by Processing Entity

Authorized distributor retrieves drug details, confirms their validity, and initiates a secure transfer transaction that updates the drug's ownership and status on-chain.

Following this, Fig. 7.3, **"Pharmaceutical Verification Interface for Retailers,"** depicts how pharmacies access the blockchain to verify the legitimacy of drug batches before stocking them, ensuring that only authenticated drugs reach consumers.

Counterfeiting is not the main issue itself, but, rather, the fact that, as compared to traditional drugs, these counterfeit drugs produce different side effects to human health. According to WHO, around 30% of the total medicine sold in Africa, Asia, and Latin America is counterfeit

Fig.7.3 Pharmaceutical Verification Interface for Retailers

Lastly, Fig. 7.4, **"Patient-Side Drug Traceability Confirmation,"** demonstrates how end-users or patients can view the historical records of the drug by accessing its ID through the system interface, providing transparency and confidence in the drug's origin and handling. These results confirm that the proposed system ensures end-to-end traceability, tamper-resistance, and secure interactions between all stakeholders in the pharmaceutical supply chain.

Fig.7.4 Patient-Side Drug Traceability Confirmation

8. CONCLUSION AND FUTURE WORK

This paper presents a blockchain-based system tailored for **end-to-end drug traceability** in healthcare supply chains. By leveraging **Hyperledger Fabric**, the proposed architecture provides:

- **Secure, permissioned participation** across the supply chain.
- **Immutable records** for traceability and accountability.
- **Resilience and auditability** under real-world conditions.

Our system has demonstrated significant improvements in **traceability resolution**, **transaction transparency**, and **operational efficiency**, compared to traditional systems.

Future Directions:

- **AI-Driven Anomaly Detection**: Use ML models to detect fraudulent activity (e.g., batch duplication, identity spoofing).
- **Cross-Border Interoperability**: Adopt **GS1 and HL7 standards** to enable global data sharing and regulatory compliance.
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- **IoT Sensor Network Expansion:** Integrate real-time telemetry for cold chain monitoring using blockchain oracles.
- **Zero-Knowledge Proofs**: Implement ZKPs to validate data authenticity without revealing sensitive patient or supplier data.
- **Mobile App for Patients**: Launch a lightweight mobile app for end-users to verify drug authenticity and report anomalies instantly.

By creating a tamper-proof, transparent, and scalable digital backbone, this approach can help transform pharmaceutical supply chains into **secure, trustworthy ecosystems ultimately** protecting patients and upholding regulatory integrity. As the healthcare industry continues to digitize, the adoption of such blockchain-enabled traceability systems stands to revolutionize supply chain integrity, offering a promising step toward a safer and more accountable pharmaceutical ecosystem.

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