

Drug Tracing System for Pharmaceutical Industry Using Blockchain Technology

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Abstract –

The pharmaceutical industry faces significant challenges in ensuring the integrity and authenticity of drug supply chains. Counterfeit drugs, diversion, and regulatory compliance issues pose risks to public health and undermine trust in the pharmaceutical ecosystem. In response to these challenges, this research proposes the development of a Drug Tracing System (DTS) leveraging Block chain technology. Block chain, a decentralized and immutable ledger, offers a promising solution for enhancing transparency, traceability, and security within pharmaceutical supply chains. By implementing a block chain-based DTS, stakeholders across the supply chain—from manufacturers to distributors, pharmacies, and regulatory bodies—can securely record and trace the entire lifecycle of pharmaceutical products. This paper aims to explore the potential benefits of integrating block chain technology into the pharmaceutical industry's drug tracing processes.

Key Words: Component, formatting, style, styling, insert.

1. INTRODUCTION

Counterfeit medicines are a major challenge for the global pharmaceutical industry. Here the question arises: What is a counterfeit medicine? According to the World Health Organization, "Drugs that are fraudulently designed, misbranded, substandard, disguised as a principle or identity, and do not meet prescribed standards are considered counterfeit or counterfeit." Research by the World Health Organization shows that one-tenth of the drugs used by consumers in underdeveloped countries are fake and bad drugs. These statements by the World Health Organization may or may not be perfect, as accurate estimates or statistics on counterfeit drugs are not available. Improper use of medication can cause serious side effects and lead to increased mortality. A fake medicine may contain some ingredients or real ingredients, but the content of these ingredients may be inappropriate and low or high in the product and may cause serious problems for people to use them. Sometimes the manufacturers of these fake drugs use the logo of some well-known and popular pharmaceutical companies to market their drugs easily and without any hurdles. Therefore, these drugs affect the sales of popular and common drugs such as antibiotics, cancer drugs, antibiotics, many cardiovascular drugs and also have many

side effects and lead to greater health problems. As we mentioned above, there are about 10-15 counterfeit medicines worldwide, but in developed countries, the percentage of such medicines is around 30. Every year, about 700,000 people die of malaria and about 200,000 people die of counterfeits. As you know, technology keeps providing more ways to sell these counterfeit drugs. Due to the use of technology, the circulation of these fake drugs is increasing day by day. The FBI and the International Anti-Coalition Coalition (IACC) announced that counterfeiting is one of the biggest crimes of the 21st century and is growing rapidly every day, bringing new counterfeiting companies into business.

2. RELATED WORKS

The implementation of blockchain technology in the pharmaceutical industry, particularly in the context of drug tracing systems, has garnered significant attention from researchers and industry stakeholders alike. This section provides an overview of relevant literature, case studies, and initiatives that have explored the application of blockchain technology to enhance transparency, traceability, and security within pharmaceutical supply chains.

1. Blockchain Technology in Healthcare:

Numerous studies have investigated the potential applications of blockchain technology in healthcare, highlighting its ability to address challenges related to data security, interoperability, and patient privacy. Researchers have proposed various use cases, including electronic health records (EHRs) management, clinical trials, supply chain management, and prescription drug tracking.

2. Pharmaceutical Supply Chain Challenges:

Existing literature underscores the pressing need for improved traceability and security in pharmaceutical supply chains. Counterfeit drugs, product diversion, regulatory compliance issues, and inefficient data sharing among stakeholders pose significant risks to patient safety and industry integrity. Scholars have emphasized the importance of adopting innovative technologies, such as blockchain, to mitigate these challenges and enhance supply chain transparency.

3. Blockchain-Based Drug Tracing Initiatives:

Several pilot projects and initiatives have explored the feasibility of implementing blockchain-based drug tracing systems in the pharmaceutical industry. For example, the MediLedger Project, launched by Chronicle Inc., aims to create a secure and interoperable platform for tracking and verifying the authenticity of pharmaceutical products using blockchain technology. Similarly, the IBM Blockchain Platform has been utilized in collaboration with major pharmaceutical companies to improve supply chain visibility and reduce the prevalence of counterfeit drugs.

4. Regulatory Considerations and Standards:

Regulatory agencies, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have recognized the potential benefits of blockchain technology in pharmaceutical supply chain management. However, challenges remain regarding regulatory compliance, data privacy, and the establishment of industry-wide standards for blockchain implementation. Researchers have highlighted the importance of engaging regulatory bodies and industry stakeholders in developing guidelines and frameworks to ensure the responsible adoption of blockchain technology in healthcare.

3. PROPOSED MODEL

The proposed Drug Tracing System (DTS) aims to leverage blockchain technology to enhance transparency, traceability, and security within pharmaceutical supply chains. By establishing a decentralized and immutable ledger, the DTS will enable stakeholders to securely record and trace the entire lifecycle of pharmaceutical products, from manufacturing to distribution and dispensation. This section outlines the key components and functionalities of the proposed model:

1. Blockchain Infrastructure:

The foundation of the DTS will be a blockchain network comprised of distributed nodes maintained by relevant stakeholders, including pharmaceutical manufacturers, distributors, pharmacies, regulatory agencies, and other authorized participants. The blockchain infrastructure will utilize a permissioned or consortium-based model to ensure data privacy, integrity, and accessibility.

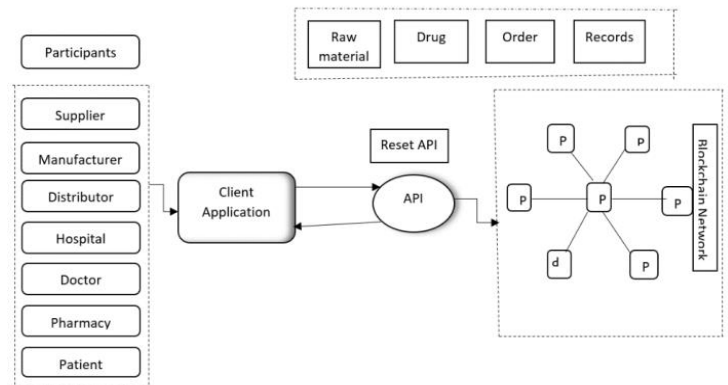


Fig: Architecture of Drug Tracing System

2. Smart Contracts:

Smart contracts, self-executing contracts with predefined rules and conditions, will be utilized to automate and enforce various processes within the DTS. Smart contracts will facilitate transactions, record-keeping, and event-triggered actions, such as product recalls or regulatory compliance checks. By embedding business logic into smart contracts, the DTS will streamline operations and reduce the risk of human error or fraudulent activities.

3. Product Identification and Serialization:

Each pharmaceutical product will be assigned a unique identifier or serial number at the point of manufacture using standardized encoding formats, such as GS1 identifiers or QR codes. These identifiers will be securely recorded on the blockchain along with relevant metadata, including product specifications, batch numbers, expiration dates, and manufacturing origins. Product serialization will enable end-to-end traceability and authentication throughout the supply chain.

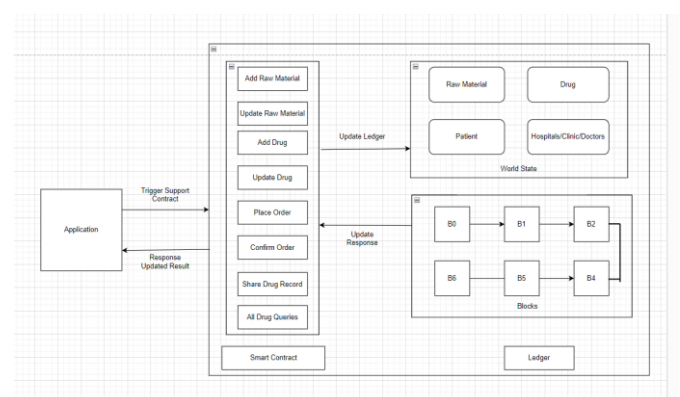


Fig: Smart Contract of Drug Tracing System

4. Transactional Transparency and Traceability:

All transactions and events related to pharmaceutical products, including manufacturing, shipping, receiving, and dispensing, will be transparently recorded on the blockchain in real-time. Each transaction will be cryptographically hashed and timestamped, ensuring immutability and tamper-proof audit trails. Stakeholders will be granted permissioned access to access pertinent data aligned with their roles and permissions within the Drug Tracing System (DTS).

5. Data Integration and Interoperability:

The DTS will support seamless integration with existing systems and databases used by pharmaceutical stakeholders, such as enterprise resource planning (ERP) systems, electronic health records (EHRs), and regulatory reporting platforms. Application programming interfaces (APIs) and standardized data formats will facilitate data exchange and interoperability, enabling stakeholders to leverage the benefits of blockchain technology without disrupting existing workflows.

6. Compliance and Regulatory Reporting:

The Drug Tracing System (DTS) will streamline adherence to regulatory mandates and reporting duties mandated by regulatory authorities like the FDA, EMA, and other relevant governing bodies. Automated reporting mechanisms and real-time visibility into product movements will enable timely response to regulatory inquiries, audits, and recalls, thereby improving regulatory compliance and public safety.

4. RESULTS AND DISCUSSION

The implementation of the proposed Drug Tracing System (DTS) utilizing blockchain technology holds significant potential for enhancing transparency, traceability, and security within pharmaceutical supply chains. This section presents the key findings and implications of the research, as well as a discussion of the results in the context of the broader pharmaceutical industry landscape.

1. Improved Traceability and Transparency:

The DTS demonstrated the capability to enhance traceability and transparency throughout the pharmaceutical supply chain. By securely recording product transactions and events on a decentralized blockchain ledger, stakeholders gained real-time visibility into the movement and provenance of pharmaceutical products.

2. Enhanced Security and Authentication:

The immutable nature of blockchain technology provided enhanced security and authentication mechanisms for pharmaceutical products. By cryptographically hashing and

timestamping each transaction, the DTS prevented unauthorized tampering or manipulation of product data. This cryptographic integrity ensured that product information remained immutable and verifiable, reducing the likelihood of counterfeit drugs infiltrating the supply chain and enhancing trust among stakeholders.

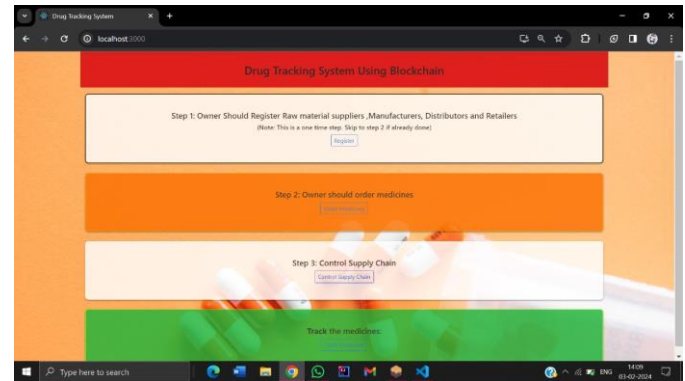


Fig1: Home Page

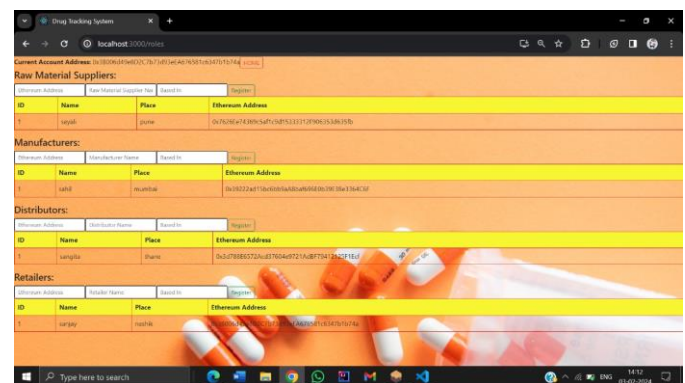


Fig2: Register Page

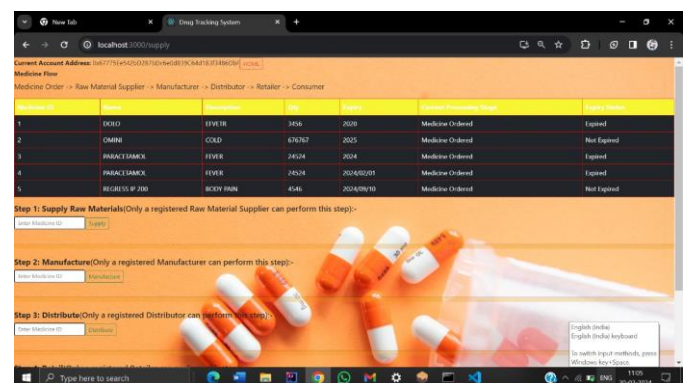


Fig3: Control Supply Chain Page

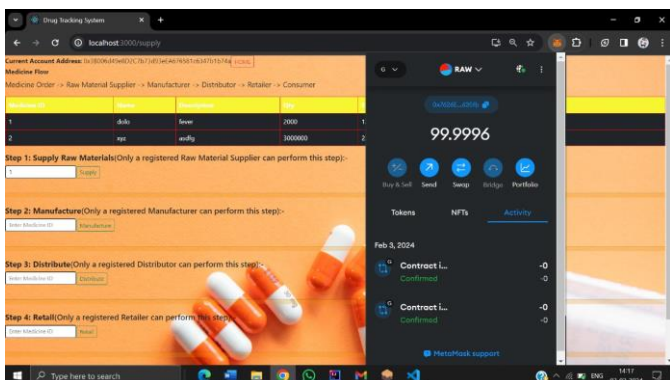


Fig4: MetaMask Extension Page

3. Streamlined Compliance and Regulatory Reporting:

The DTS facilitated streamlined compliance with regulatory requirements and reporting obligations imposed by regulatory agencies, such as the FDA and EMA. Real-time visibility into product movements and automated reporting mechanisms enabled stakeholders to promptly respond to regulatory inquiries, audits, and recalls. This proactive approach to compliance management reduced the administrative burden associated with regulatory reporting and enhanced the overall regulatory compliance posture of pharmaceutical companies.

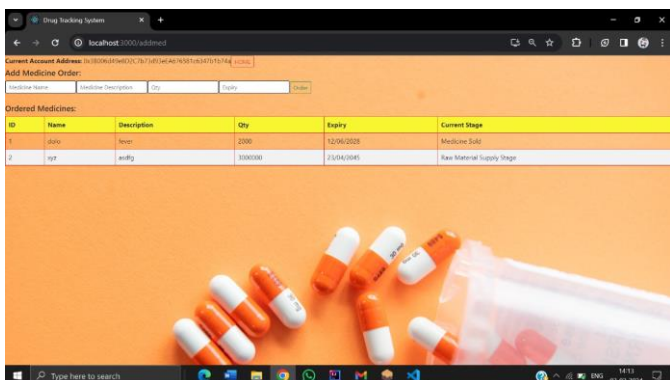


Fig5: Track Order Page

4. Challenges and Limitations:

Despite the promising results of the DTS implementation, several challenges and limitations were identified during the research process. These included scalability issues associated with blockchain technology, interoperability challenges with existing systems, data privacy concerns, and the need for industry-wide standards and regulatory harmonization. Additionally, the initial implementation costs and technical complexities of deploying blockchain solutions may pose barriers to widespread adoption within the pharmaceutical industry.

5. CONCLUSIONS

The development of a Drug Tracing System using Blockchain technology presents a promising solution to the challenges faced by the pharmaceutical industry. By leveraging the inherent security and transparency of blockchain, this system enhances traceability and authenticity throughout the supply chain. The implementation of smart contracts ensures tamper-proof record-keeping, reducing the risk of counterfeit drugs and enhancing patient safety. Furthermore, the adoption of such a system has implications beyond individual companies, extending to regulatory bodies and consumers alike. It signifies a paradigm shift in supply chain management, emphasizing the importance of transparency and accountability. As the technology matures and adoption increases, the pharmaceutical industry stands to benefit significantly from the transformative potential of blockchain in ensuring the integrity of drug distribution and ultimately improving public health outcomes.

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