Drug Traceability in Healthcare Supply Chain: A Blockchain Solution

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Drug Traceability in Healthcare Supply Chain: A Blockchain Solution

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Abstract— ***This paper offers a blockchain-based solution for improving healthcare supply chain traceability. The suggested method establishes an indelible and unchangeable record of drug transactions using Ethereum, a decentralised blockchain platform, and the proof of stake consensus algorithm. The integrity of the data kept on the blockchain is guaranteed by smart contracts, which are used to enforce traceability. To safeguard the integrity and confidentiality of the data recorded on the blockchain, security measures are put in place. Security, performance, and scalability were used to assess the effectiveness of the proposed system. The evaluation's findings show that the suggested system is efficient at enhancing drug traceability along the supply chain and that it can manage high transaction volumes and speeds while preserving the accuracy and security of the data. According to these findings, blockchain technology has the potential to completely transform the healthcare supply chain by enhancing visibility and traceability.***

Keywords—Traceability, blockchain, supply chain, Ethereum, healthcare.

I. Introduction

In many ways, the healthcare sector is the most important part of any country's economy, and this is because it is an essential part of people's lives, contributing to their health and well-being [1]. The healthcare sector includes a wide range of enterprises, from research to industrial production to facility management. Organisations in the healthcare sector provide medical services, manufacture medical equipment and drugs, and facilitate the delivery of healthcare to patients. The bedrock of healthcare provision is effective supply chain management. This is owing to the fact that the administration of high-quality healthcare depends on the availability of medical consumables to patients at the appropriate times and in the appropriate quantities; otherwise, patients may not receive the quality care they deserve [2]. Effective supply chain management in healthcare will reduce costs, improve efficiency, and in most cases will add agility and resilience to the healthcare value chain.

Due to the growing prevalence of fake and subpar drugs on the global market, the topic of drug traceability has attracted a lot of attention recently. For patient safety and the overall effectiveness of the healthcare system, it is essential to ensure the authenticity and quality of pharmaceuticals [3]. Drug tracking and tracing has proven difficult for conventional supply chain systems, necessitating the use of more sophisticated technologies.

The creation of blockchain-based supply chain platforms for drug traceability is one potential remedy. With its decentralised and secure nature, blockchain technology has the ability to completely change how pharmaceuticals are tracked and traced throughout the supply chain [4]. Blockchain is a technology that combines a special set of properties to guarantee network security, transparency, and visibility, including a decentralised structure, distributed notes and storage mechanism, consensus algorithm, smart contracts, and asymmetric encryption. Furthermore, it has been described as a cutting-edge, decentralised, and distributive technology that upholds the privacy, integrity, and accessibility of all transactions and data. It is a shared, public, distributed ledger that may be used to store/record data and transactions across a peer-to-peer network that are secured by a cryptographic value [5].

In this paper, we propose a blockchain-based solution that will overcome the present issues of traceability in the pharmaceutical supply chain. The rationale for this proposed model is outline below:

- To improve drug authenticity and quality: Blockchain technology enables secure and transparent drug tracking throughout the supply chain, ensuring that patients receive genuine and high-quality medications.
- To improve efficiency and cut costs: A blockchain-based supply chain system can automate supply chain processes and eliminate the need for intermediaries, resulting in more efficient and cost-effective drug tracking and tracing.
- To reduce the risk of counterfeiting: Blockchain-based supply chain systems can help prevent the sale of counterfeit drugs by maintaining a tamper-proof record of each drug's movement and origin.

II. State of the Art

In this section, we give background information on the issues facing the healthcare supply chain today and discuss why implementing blockchain technology is crucial for improving the tracking and traceability of healthcare commodities. We will also highlight previous research on blockchain technology's application in the healthcare supply chain traceability.

A. Background Knowledge

A critical overview and brief background to the healthcare supply chain as it relates to drug traceability and the blockchain technology.

I. Healthcare Supply Chain Traceability

As already discussed above, a supply chain system is made up of a variety of components, including individuals, groups, resources, and actions like management and planning. These factors combine to transport a good or service from the producer to the consumer; doing so requires collaboration and coordination with numerous parties, including suppliers, shippers, distributors, and wholesalers (Fig.1).

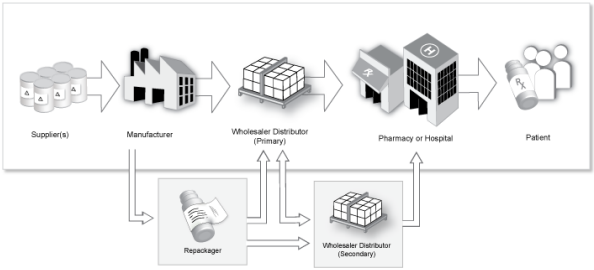

Fig. 1. Drug supply chain system showing the interaction with various stakeholders (https://www.fda.gov/drugs/drug-shortages/graphic-drug-supply-chain-example).

This process is often not straightforward and comes with a lot of challenges, especially in developing countries, as the majority of healthcare commodities are manufactured in developed countries [6]. These challenges range from sudden shortages, hoarding, and counterfeiting, which have been linked to traceability. Traditionally, drug traceability has been achieved through the use of serialisation, which involves assigning unique identifying codes to each drug unit that can be traced throughout the supply chain [7]. However, this system relies on manual data entry and is prone to errors and tampering.

Track and trace systems are thought to be a useful tool for reducing the risk of shortages and combating the production and marketing of counterfeit medicines. They provide real-time visibility into the pharmaceutical supply chain but have been plagued with poor implementation [8]. Digital Pharmaceutical serialisation has also proven to be a successful method for digitally tracing prescribed medications and reducing the risk of fake medications in the supply chain. Traceability regulations necessitate additional space in manufacturing facilities for specialised packaging equipment required for serialisation, which have proven to be challenges for most manufacturers, especially the small-scale manufacturers [9].

II. Blockchain- A distributed Ledger Technology

Known approaches to achieving traceability in the pharmaceutical supply chain are frequently centralised and lack openness among supply chain partners, allowing the central authority to change information without informing other parties [10]. A blockchain-based system, on the other hand, delivers transaction records with verified authenticity, immutability, provenance, and data security.

Blockchain is an immutable ledger that records data entries in a decentralised manner. It allows entities to interact without the need for a trusted third party. The blockchain keeps a constantly growing set of data entries bundled together into data blocks. The so-called hash, which is produced via a cryptographic one-way hash function, connects each block in the blockchain (e.g., SHA256).

The controlling infrastructure of a blockchain is a node, which replaces the need for a central authority to validate and store data (Fig.2). Connecting to the blockchain network, storing an up-to-date ledger, listening for transactions, passing on valid transactions into the network, listening for newly sealed blocks, validating newly sealed blocks—confirming transactions, creating and passing on new blocks are the basic tasks of a blockchain node [11].

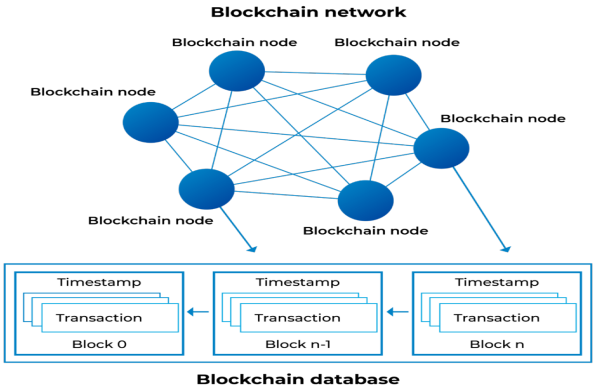

Fig. 2. Description of the blockchain with its node (https://unova.io/blockchain/)

There are three types of blockchains based on the managed data, the availability of such data, and the actions that the user can perform—public permissionless, consortium (public permissioned), and private. Blockchain technology allows for the creation of a private permissioned network to trace and track events in the pharmaceutical supply chain, as well as providing time-stamped records of each transaction completed [12]. Examples of events include ownership, timing, location, and the parties involved in the transaction.

The distributed ledger's state and the method for putting data into blocks must both be agreed upon by the peers of the blockchain network in order for the blockchain to remain functional and this agreement is a consensus protocol. Different consensus protocols have been proposed and implemented in various blockchain projects such as Proof of Work (PoW), Proof of Stake (PoS), Delegated Proof of Stake (DPoS), and Practical Byzantine Fault Tolerance (PBFT). The choice of one of these protocols will rely on the particular specifications and features of the blockchain network and its intended usage [13].

B. Related Work

There have been several pilot projects and initiatives aimed at using blockchain technology for drug traceability. For example, the U.S. Food and Drug Administration has launched a pilot program called the Drug Supply Chain Security Act (DSCSA) which aims to improve the traceability of prescription drugs through the use of blockchain technology. Similarly, the EU has launched a pilot project called the EU Blockchain Observatory and Forum, which aims to explore the potential use of blockchain for traceability in the pharmaceutical supply chain.

Furthermore, there are several existing approaches to the use of blockchain to create a decentralised, verifiable track and trace system for pharmaceutical drugs. Huang [14], proposed Drug Ledger, a drug traceability system that takes into account workable drug transaction logic in the distribution chain and provides both integrity and confidentiality of stakeholders' traceability information while maintaining system resilience. Drugledger completes its workflow using the expanded UTXO data structure, particularly the package, repackage, and unpackage operations. However, concerns have been raised about the use of the UTXO data structure due to its lack of programmability, high storage cost, and low state space utilisation.

A Hyperledger-based solution for drug traceability in the pharmaceutical supply chain was put forth by Jamil [15]. The authors claim that the proposed system performs better in terms of throughput and minimises delay while using fewer resources, but their method was not thoroughly evaluated and was only used in a small network. A traceability system using Ethereum for anticounterfeiting was suggested by Muniandy [16]. Smart contracts are used in the suggested solution, however there is no implementation or evaluation, which makes it difficult to comprehend how it contributes.

III. The Proposed Solution

A. System Model

We suggest a blockchain-based drug traceability solution that links suppliers, producers, distributors, healthcare providers and patients inside the same decentralised Ethereum network, as shown in Fig. 3.

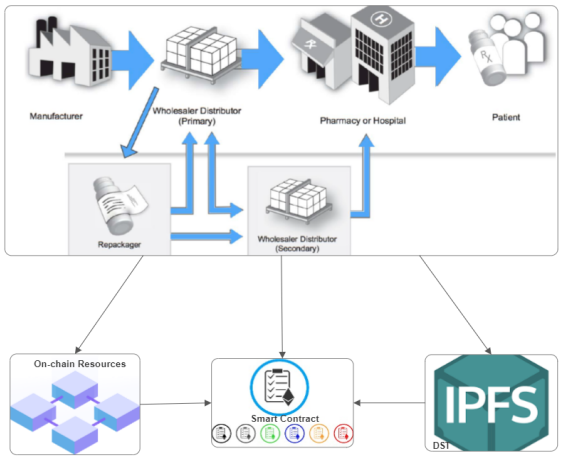

Fig.3. System architecture of the proposed blockchain solution for healthcare supply chain traceability.

In our proposed approach, we use blockchain technology to promote transparency, data integrity, and data immutability. Additionally, we explain the role of each stakeholder and component in our solution below:

- Manufacturer: Produces goods like pharmaceuticals or medical supplies utilising raw materials obtained from manufacturing facilities and research labs. A manufacturer also does market research, picks out the required goods, buys the raw materials, and calculates the quantity needed to meet client demand while guaranteeing that the goods fit regulatory requirements. A manufacturer must also be able to anticipate situations that could lead to shortages, such as production interruptions brought on by pandemics or natural catastrophes that affect raw materials.
- Distributor: they acquire medical equipment and supplies from manufacturers and deliver them to hospitals or clinics or distribute them to wholesalers. In order to ensure that medical products are handled with extra care, the distributor may repackage or re-label them along the process. Distributors serve as go-betweens in the supply chain, connecting the producer and suppliers.
- Healthcare Provider: Healthcare providers, such as hospitals and pharmacies, typically purchase products from distributors or directly from manufacturers, rather than through distributors as intermediaries. They ensure that the patients who in this case are the consumers get safe, affordable and quality products.
- Patient: In the supply chain, the patient is the person who receives healthcare services or products, which includes prescription medications, medical devices, and other supplies required for treatment and care. The patient can contribute to the supply chain process by sharing their wants and preferences, offering feedback, and taking part in activities where they get the finest care possible by working with healthcare providers and other stakeholders.

- Regulatory Agency: they are accountable for registering participants in the blockchain network and keeping track of the entire supply chain process. Additionally, it makes sure that any healthcare commodities, medical devices, or medications made available in the nation adhere to the laws and guidelines established by authorities like the US Food and Drug Administration to guarantee their efficacy, quality, and safety. Only drugs that have received FDA approval can be traced and tracked under this proposed approach.
- Blockchain (Ethereum smart contract): Smart contracts can be written in code on second-generation blockchain platforms like Ethereum. The code and the agreements contained within it are stored on the blockchain, ensuring their transparency, immutability, and security. It functions as a software agent, verifying transactions without the intervention of third parties. Our proposed solution consists of various smart contracts, each specialised in a specific task.
- On-Chain Resources: Resources that are kept on a blockchain are referred to as on-chain resources. These resources could include things like information that is recorded and saved directly on the blockchain itself, such as data, transactions, and smart contracts. The decentralised network of computers that makes up the blockchain stores and manages on-chain resources, which are often impervious to hacking and censorship. They enable the safe and transparent management of data and other resources, making them a crucial component of many blockchain-based systems including this proposed system.
- Decentralised Storage Technology: A peer-to-peer distributed file system such as Interplanetary File System (IPFS) and Filecoin, that aids in linking the same file system to each network node. They offer an affordable off-chain storage to store supply chain transactions data, which guarantees the dependability, accessibility, and integrity of the stored data. Large amounts of data can be stored in IPFS by authorised users on the network, and the immutable IPFS links can be stored in blockchain transactions that are time-stamped and encrypted using cryptographic techniques.

This proposed solution will function fully on smart contracts. In order to create smart contracts, Solidity, the programming language built on Ethereum, will be used. These smart contracts will outline the procedures and logic for tracking the movement of pharmaceuticals along the supply chain and capturing and updating data about the drugs themselves. The Ethereum network will then deploy nodes to host the smart contracts and take part in the proof of stake consensus procedure, confirming transactions and preserving the accuracy of the medication traceability information. For transparency and traceability, this data will be accessible to authorised parties and immutably kept on the Ethereum blockchain.

As shown in Fig. 4, the proposed supply chain system is portrayed as a collection of activities and events in a sequence diagram that capture the interactions between each stakeholder and contracts.

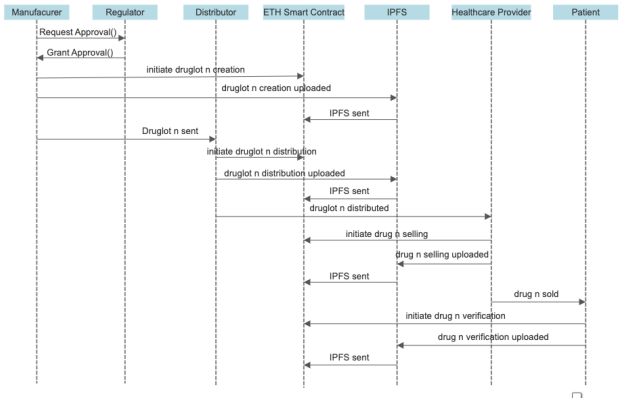

Fig. 4. The interactions between each stakeholder and contracts in the proposed supply chain system.

Additionally, Fig. 5 describes the data model used in the proposed system, including the types of data that are stored on the blockchain, how they are organised, and how they support traceability. It aids in comprehending the system's functionality and structure and offers a visual depiction of the object-oriented architecture of the system [17].

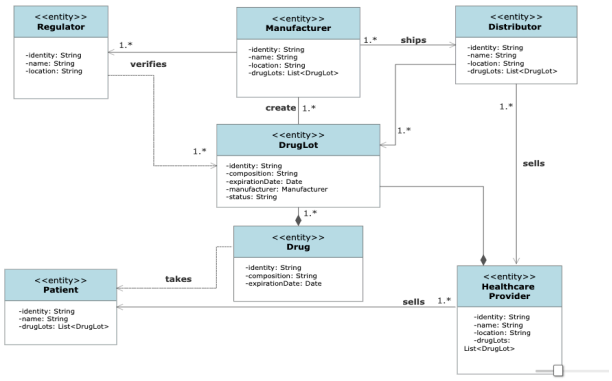

Fig. 5 Description of the data model used in the proposed supply chain system.

B. Justification of the Proposed Approach

This proposed blockchain-based supply chain system components are designed to work together to track the history of the drug under consideration and verify its authenticity. Compared to Bitcoin or Hyperledger, using Ethereum as the blockchain platform for this proposed supply chain system has some benefits as seen in Fig. 3. The ability of Ethereum's built-in smart contracts to execute specific operations, such as tracing the authenticity of a drug, automatically makes it valuable in supply chain management [18]. In addition, Ethereum enables the development of personalised tokens and decentralised applications. Subsequently, it has a sizable developer community and ecosystem, which can be useful for locating resources, obtaining support, and forming alliances.

Hyperledger, a private blockchain platform that is mostly used for enterprise, consortium, and permissioned blockchain will not be a good fit for a decentralised, public supply chain solution as proposed in this paper.

Due to its many benefits, proof-of-stake (PoS) was chosen over proof-of-work (PoW) as the consensus protocol for this proposed blockchain-based supply chain system. Firstly, PoS uses fewer resources and is more energy-efficient, which helps save costs. Furthermore, it is more scalable since it can handle more transactions per second (TPS) and is less vulnerable to centralization by a limited number of validators. Finally, PoS offers a higher level of security and is better suited for use with sharding and other scalability methods.

IV. Evaluation

In this section, we briefly examine the security and technical evaluation of the proposed blockchain-based solution for healthcare supply chain traceability. The smart contract was written via Ethereum using Remix IDE because it has the capacity to build security, performance, and scalability with contract code into the system (Fig. 6).

```
pragma solidity ^0.8.0;

contract SupplyChain {
    struct DrugBatch {
        address manufacturer;
        address verifier;
        bool isVerified;
    }
    mapping(bytes32 => DrugBatch) public batches;
    event LogBatchAdded(bytes32 indexed batchId);
    event LogBatchVerified(bytes32 indexed batchId);

    function addBatch(bytes32 _batchId, address _manufacturer) public {
        require(msg.sender == _manufacturer, "Only the manufacturer can add a new batch.");
        batches[_batchId] = DrugBatch(_manufacturer, address(0), false);
        emit LogBatchAdded(_batchId);
    }

    function verifyBatch(bytes32 _batchId, address _verifier) public {
        require(msg.sender == _verifier, "Only the verifier can verify the batch.");
        DrugBatch storage batch = batches[_batchId];
        require(batch.isVerified == false, "Batch has already been verified.");
        batch.isVerified = true;
        batch.verifier = _verifier;
        emit LogBatchVerified(_batchId);
    }

    function getBatchInfo(bytes32 _batchId) public view returns (address, address, bool) {
        DrugBatch storage batch = batches[_batchId];
        return (batch.manufacturer, batch.verifier, batch.isVerified);
    }
}
```

Fig. 6. The proposed supply chain system smart contract.

To test and validate various functions, the Remix IDE in-browser development and testing environment was used as seen below (Fig. 7).

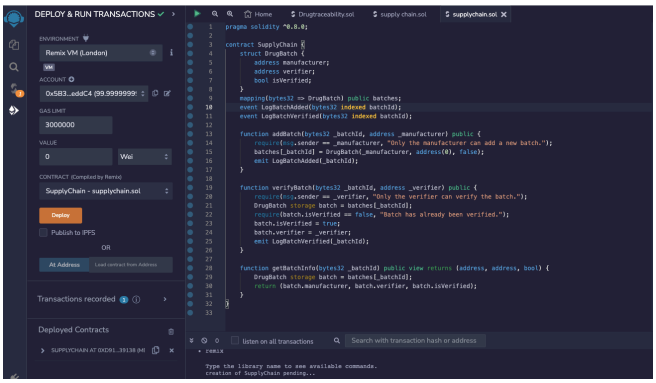

Fig. 7. Remix IDE in-browser development and testing environment

A. Security Evaluation

For the security evaluation, the following was considered key objectives:

- Data Integrity: The main goal of the suggested blockchain solution is to record every transaction that takes place across the healthcare supply chain, ensuring the history of the Lots, ownership transfers, and their accompanying boxes can be traced. This was done by securing the data by making use of IPFS and using cryptographic methods like hashing and digital signatures.
- Access control: In the proposed solution, only verified manufacturers can produce drug lots and only verified healthcare providers can sell drugs. This was accomplished by using smart contracts, which permit only authorised stakeholders to read and write data on the blockchain.
- Concurrent access: For the proposed solution, it was critical to ensure the system's ability to handle concurrent access from multiple users, such as manufacturers, distributors, and regulators, and ensure that data consistency and accuracy are maintained.

B. Technical Evaluation

For the technical evaluation, the following were considered key objectives:

- Scalability: it was to ensure that the proposed blockchain system can fulfil the needs of drug traceability, while handling a large number of transactions.
- Performance: It's critical to make sure the blockchain is effective and capable of meeting the supply chain's requirements for speed and dependability. This is to avoid operational issues that lead to run-time problems.

These are based on the presumption that the smart contract is not intentionally written to be malevolent, with the capability of Remix IDE to ensure a highly scalable, secure and efficient contract. There are other automatic tools such as Smartcheck, a static analysis tool for Ethereum smart contracts which was developed by the European Medicines Agency (EMA) for evaluating the technical and operational aspects of blockchain-based drug traceability systems. It offers a methodical and structured way to assess the capability of various blockchain technologies for drug traceability applications in terms of security, interoperability, scalability, and performance [19].

V. Conclusion

In conclusion, a blockchain-based supply chain system for drug traceability has the potential to greatly raise the legitimacy and calibre of medicines sold on the international market. Such a system might offer an effective and dependable way of tracking and tracing medications along the supply chain thanks to the decentralised and secure nature of blockchain technology. But there are obstacles that must be overcome for a blockchain-based supply chain system for drug traceability to be adopted and implemented successfully. Various stakeholders, including manufacturers, regulatory agencies, and distributors, will need to work together and support this. It will also need the creation of reliable and established methods for data management and entry.

Overall, the process of proposing and evaluating a blockchain-based supply chain system for drug traceability has provided valuable lessons on the potential benefits and challenges of such a system. Further research and development will be necessary to fully realise the potential of blockchain technology in the healthcare industry.

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