

Impact of Blockchain in Drug Traceability in Healthcare Supply Chain

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3.1 INTRODUCTION

Counterfeit drugs are fraudulently produced, mislabelled and prescribed with respect to identity/brand similar to a genuine product [1] [2] to permeate the healthcare supply chain quickly. The supply chain of the healthcare is one of the most complex networks of independent bodies, unlike other supply chains which contain semi-independent entities, such as raw material suppliers, drug scientists or labs, manufacturers, distributors, hospitals, patients, pharmacies. Tracking drug supply in such a complex network may not be feasible since the scope for counterfeit drugs to permeate the healthcare supply chain is huge. Some of the potential inefficiencies are largely highlighted during the COVID-19 pandemic [3]. The independence of individual entities in the supply chain aggravates the challenge of mitigating against counterfeit drugs.

Counterfeit drugs are a class of drugs in medicine which are fake in nature and sometimes are harmful to human health, also leading to economic loss. drugs with an improper amount of active pharmaceutical ingredient (API) or no API, contamination, incorrect API, low-quality API, and repackaged expired products, or produced under substandard conditions [4] are generally considered to be counterfeit drugs [5]. Mitigating counterfeit drugs in the healthcare supply chain is essential to prevent economical loss. Counterfeit drugs lead to heavy annual economic loss in the pharmaceutical industry along with adverse human life loss. The US pharmaceutical industry had faced a \$200 billion annual economic loss due to counterfeit medicines [6] [7]. According to the World Health Organisation (WHO), the inefficiency to trace counterfeit medicines is the major causes of death in developing nations, and most of the victims are children [8] [9].

A healthcare supply chain, or more precisely a drug supply chain, consists of individual entities such as an API supplier who is in charge of supplying the raw materials, a producer who has been given the go-ahead by a governing authority like the US Food and Drug Administration (US FDA) responsible for packing drugs into a Lot or sending drugs for packaging, and transport to primary distributors. The primary distributor is responsible to distribute the lots to pharmacies or secondary distributors based on the demand and size of the lots. The secondary distributors, in the case of large lots, transfer lots to the pharmacies. At last, the pharmacies dispense the medicines to patients [10] based on doctor's prescription. In some cases, the transportation of lots or drugs between the individual entities of the supply chain is carried out by a third-party logistics service providers like FedEx, otherwise, distributors carry lots using only their own vehicles.

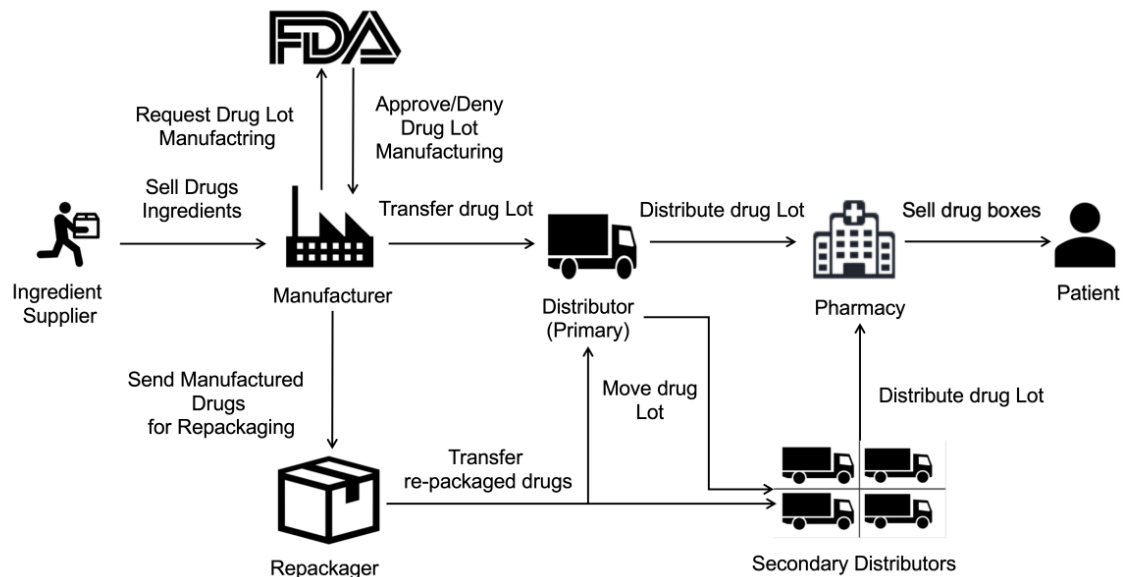


Figure 1.1: Healthcare supply chain [5]

A specialised drug tracking and tracing mechanism are essential to mitigate counterfeit drugs permeating the healthcare blockchain. Many public healthcare organisations, and drug regulatory bodies such as DSCSA, and WHO have emphasised building IT solutions to track and trace drugs, whenever the position or environment of the drug changes in the supply chain, as an integral system or mechanism of the pharmaceutical supply chain that ensures quality, and authenticity of drug supply tracking. In recent times, the Chinese and US governments are mandated to enhance the tracking and tracing of drugs in the supply chain.

The fundamental concept of blockchain technology is an architecture for a blockchain [11] resembling a linked list (unlike a linked list, the nodes are blocked and mutable only forward in chronological order) where each node has its own set of the local copy of the nodes/data blocks in the chain, blocks of the longest chain, starting from the genesis block, called the distributed ledger technology [12]. Blockchain, in simple terms, is a novel model of application development for tracking and tracing any virtual asset that has value. Each transaction on the virtual asset such as a change of ownership or/and change of value is stored as a new block that's chained to the existing blockchain network [13]. After the successful implementation of the data structure within the Bitcoin application, many real-world applications have been developed in diverse domains, such as the IoT [14], e-Government [15] like Digi-locker, and e-document management like LaTeX[16][17]. These applications are heavily benefited by the key ideas of blockchain such as distributed ledger technology, self-cryptographic validations structure among the transactions, through hashes, i.e. smart contracts that validate a transaction before adding a new transaction block to the chain. The open availability of distributed ledger or database of transaction records and blocks of connected cryptographic hashes makes it robust to tampering. Tampering any transaction in the blockchain would need to be reworked from the genesis to the latest transaction which needs huge compute cost hence it's difficult to tamper.

The [18] and [5] are some of the early works on the application of blockchain specifically to the complex supply chain network of health care. The [5] has proposed some of the additional mechanisms that generalise to the complete supply chain whereas [18] addressed a few among all the plausible problems in the supply chain. The [18] concentrated more on supplier, manufacturer, and wholesaler as being the stakeholders whereas [5] identified and prioritised every individual entity of the supply chain including the pharmacies as stakeholders unlike those considered in the work [18]. The primary contributions of [5] are, the work proposed a new design of smart contracts or hashes that can handle transactions between participants in the pharmaceutical supply chain was proposed as part of a blockchain-based solution for the industry. This solution offers accessibility, immutability, traceability, and security of data provenance for drugs., presented a

tested smart contracts with defined principles and analysed the performance of proposed blockchain solution feasibility.

3.2 OVERVIEW OF BLOCKCHAIN

Some of the early literature on blockchain defined the technology behind the bitcoin as a data structure similar to a linked list where nodes are self-cryptographically linked through hashes i.e. “chain of blocks” [11]. Blockchain was introduced as a peer-to-peer version of maintaining any virtual asset that has value and under transactions such as change of ownership or state.

Blockchain technology is based on a distributed ledger system of database that stores blocks chained chronologically. These blocks store information regarding any transaction on the virtual asset. As mentioned in the Introduction, these blocks are chained or linked through hashing (cryptographically) [19] that ensuring the immutability of transactions and the distributed ledger technology enables participants to have a local copy of the database of transactions making blockchain a hash-based proof-of-work [20][21].

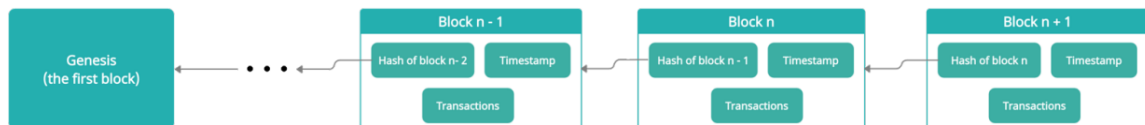


FIGURE 2: Blockchain data structure [21]

Blockchain technology has developed in the last decades and almost exploding. The evolution of blockchain with its wide range of application domains can categorise its development into four key stages [22]:

Blockchain 1.0: 1.0 is the initial stage of blockchain introduced in 2008 by [11]. The first stage majorly focused on applications of blockchain in digital currencies maintained and validated using cryptographic hashes or contracts. Blockchain 1.0 was mainly introduced to reduce the cost of intermediaries [22] [23] and improve security.

Blockchain 2.0: 2.0 was majorly focused on designing smart contracts, introduced in 2013. A smart contract is a set of instructions that are automatically executed to validate any transaction chaining the information of the transaction as a block into the chain [24] [25]. These smart contracts are used as agreements between the participants of the transactions in the network

blockchain. Through smart contracts, the networks of blockchain enable the idea of a decentralized system requiring no third party to monitor the transactions except the participants in the blockchain network, who monitor the transactions through smart contracts and distributed-cum-centralized ledger. Smart contracts improve the automation of validating transactions, reducing human error or third-party security vulnerabilities [22]. One of the most famous practical examples of blockchain implementing smart contracts is Ethereum [26].

Blockchain 3.0: 3.0 was introduced in 2015, mainly focusing on the application in the development of decentralized web applications and computing services [27]. The applications are developed on a decentralized system on an open-source platform [28]. 3.0 has introduced the notion of cryptographic tokens, which are valued assets [29], that each participant holds to perform transactions in the network.

Blockchain 4.0: 4.0 is the convergence of blockchain systems and artificial intelligence [13]. Blockchain technology ensures the security and flow of data while AI utilises the data to draw intelligent conclusions or decision-making. The convergence of these two hyped technologies unveils the idea of Trustworthy AI and Intelligent Distributed systems. Blockchain and AI are very complementing technologies that boost the efficacy of one another. In other words, blockchain ensure secure data making the AI system's predictions trustworthy since blockchain brings trust in data [30].

Based on the characteristics of blockchain applications, the major types are [13] [31]:

A public blockchain or open blockchain [32] is a permission-less blockchain [33] network that allows everyone to take part in transactions. All the participants in the open blockchain are anonymous and are permitted to view the transaction log prior to their first transaction. All the open blockchain networks are operated at a cost of privacy. Some of the popular examples of public blockchain are Bitcoin, Litecoin, and Ethereum [32]. The privacy blockchain is confined to authenticated participants who are permitted to make transactions. The permissioned blockchain are closed network, allowing authenticated individuals or groups to join and make transactions. The very popular example of privacy blockchains is Hyperledger Fabric [32], Ripple [33] and other business blockchain platforms of software companies. A few partially defined fundamental

types of blockchain technology are consortium and permissioned blockchains. Permissioned blockchains are partially public blockchain networks in which authorized individuals are invited to make or monitor the transactions in the network. These networks are restricted to participants who are invited by the organization monitoring the network. Consortium blockchains are semi-centralized blockchain networks that are controlled by a small group of validation nodes with pre-defined features as smart contracts. According to IBM [13], Consortium based blockchains are a class of blockchain-based applications managed by organizations internally with customers or confined/authorised users who share the responsibility. The participants could be other organizations or direct customers with shared responsibility as hosts.

The smart contracts or agreements in blockchain technology which validate the new transactions before adding the data blocks into the chain are designed based on a consensus algorithm among the community of blockchain. The consensus algorithm is defined to represent the state of a distributed ledger. Consensus ensures the standard of a block before adding new transaction data into the networks while also preserving the character of the chain to be compatible and extensible. The features such as proof-of-work (PoW) (introduced in 2008 [11]), proof-of-importance (PoI), proof-of-stake (PoS), delegated-proof-of-state (DPoS), proof-of-activity (PoA), proof-of-burn (PoB), and proof-of-deposit (PoD) [27] are the ideal features of consensus algorithm.

3.2 Related Work

In this section, we cover a complete overview of efforts which were focused on addressing the problem of traceability in the supply chain, especially in the healthcare system. The efforts made in the field of drug traceability are briefly explained, categorizing the efforts into blockchain-based and non-blockchain-based

3.2.1 Non-blockchain-based works

In a supply chain, the product or component considered to be tracked and recorded timely are generally attributed as Traceable Resource Unit (TRUs). TRUs are generally the main product/service in a supply chain and sometimes the intermediate stages and their states are also

considered for tracking to ensure the efficient tracking of the main TRU. Fundamentally, the TRUs are tracked in multiple phases, mainly there are two folds involved, one is to maintain the history transaction and the other is to track the product or TRU in real-time. In order to track and understand the transaction that happens in the supply chain over time during the lifetime of TRU, some of the published and followed mechanism has already been proved to be effective to mitigate the challenge of counterfeit drugs permeating the supply chain. Various techniques leveraged and designed to track the real-time position of the TRU were effective in identifying and distinguishing TRUs. Most of the mechanisms followed are designed to record the transactions and attributes.

Some of the current and recent advancements in approaching the problem of mitigating counterfeit drugs are initially, the identifying technologies of barcodes and RFID tags. Data is collected using Wireless Sensor Networks (WSN), and product information is collected using Electronic Product Codes (EPC) that enhances the mechanism of real-time tracking of TRUs [35]. GS1 standard barcodes containing unique serialized product identifier is used for smart-tracking along with lot production and expiration details. Each individual entity or stakeholder poses a unique record of TRU's possession, which an end customer can verify authenticity through a centralized database in a real-time synchronized data network or (GDSN) through a web app or mobile app. In general, these products or TRUs can be tracked using a barcode that encodes the data regarding the authenticity at warehouses, pharmacies or others. Data-Matrix tracking systems [28] are one of the recent ideas to track the product in a supply chain by maintaining a data matrix that stores the details of each drug including the stakeholders and their unique IDs. This system of tracking enables users to monitor or understand the complete details of the drug in the market.

NFC (Near Field Communication) product tags, which were proposed in the recent past, have achieved high standards of tracking in terms of visibility and authenticity across the pharmaceutical supply chain. Much like the earlier methods, NFC-based tags allow users to access the complete details of a drug through a mobile application but NFC tags also enhance the visibility, authenticity and reliability of drug tracking through a key-value registered to the drug in addition to the tag on the drug or product. A few other methods have also been proposed [36] [37]

[38] which were based on maintaining a centralized database which had a vulnerability to being tampered and a few other methods had issues in scalability and interpretability.

3.2.2 Blockchain-based methods for drug tracing and tracking

Since most of the traditional methods proposed had a serious vulnerability of security and tampering of the data due to centralized maintenance of data. In contrast, all the blockchain-based product traceability mechanism guarantees security, transparency, verifiable and traceability. Blockchain is a distributed ledger technology, that uses the complex ideas of distributed databases or computing to effectively enhance security by reducing the control to intermediaries that prevent the data from tampering.

Oftentimes, the transparency in the supply chain is misunderstood as the traceability of the drug or product. Understanding the transparency in the network reveals that transparency refers to how open the network between the participants is. In other words, transparency refers to how well the stakeholders such as pharmacies, and manufacturers know the other participants at various stages. While traceability deals with the minute level of information on the drugs and their position in the supply chain and how timely the changes are being updated to the participants on the network.

3.3 Application of Blockchain in Drug Traceability

According to JP Morgan chase and EY [34], In the long-run, blockchain enables a transformation of operating models across industries, it also mentions “Just as the internet upended how we share information, blockchain has the potential to revolutionize how we exchange value, transfer ownership and verify transactions.”

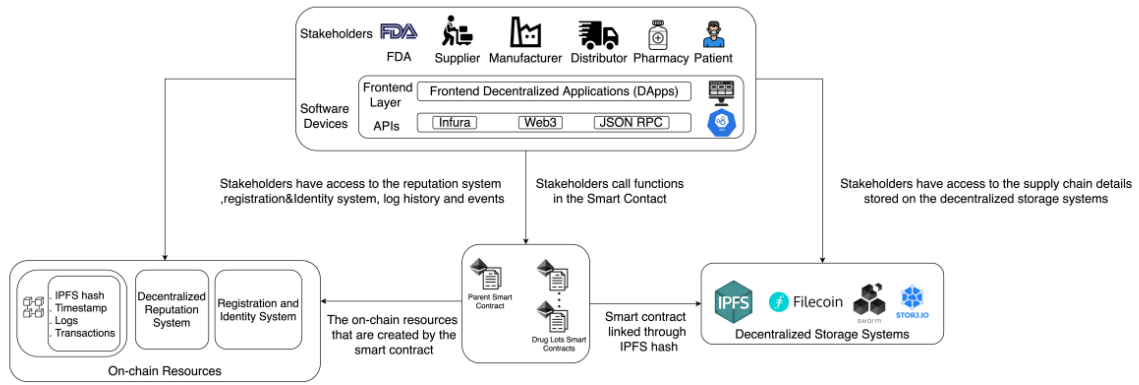


FIGURE 3: Blockchain architecture for drug traceability [5]

In [5], the standard architecture of employing the blockchain networks in drug tracking and tracing was explained by various internal mechanisms followed by the systems i.e. interactions between the stakeholders and the smart contracts, which are crucial to validate any transaction in the chain. In [5], DApp (Decentralized Application) was proposed to leverage the advantages of blockchain into the application and use the resources including smart contracts and decentralized storage by users to perform tasks. The DApp was deployed using an API (application programming interface) which are as Infura, JSON RPC, and Web3. The participants initiate the transaction through pre-authorized protocols or functions to use resources such as smart contracts, and decentralized databases to effectively track and trace the drugs in the blockchain. The transactions are stored in time-stamped logs, and IPFS hashes

The key ideas in the DApp architecture proposed in the paper consist of the following terminologies:

- *Stakeholders or participants* include regulatory agencies such as US FDA, and other direct participants such as API providers, manufacturers, pharmacies, distributors and patients. The direct participants and regulatory bodies are responsible to carry out particular tasks and are provided with access to use the on-chain resources including decentralized storage, time-stamped history of logs of transactions, and smart contractions. Additionally, the stakeholders also possess access to view the IPFS details of drug lots, images and other fine details recorded in the decentralized database.
- *Decentralized Storage System* (IPFS [39]) offers an off-chain storage for supplying or aiding chain transactions data that guarantees security, and integrity of the stored data with

reduced vulnerabilities to tampering with the data. The integrity of the data that can be stored can be assured by maintaining unique hashes to every file uploaded on the decentralized storage. Each unique hash of files is recorded as a transaction between the stakeholder or product and the DDB (Decentralized Database). The unique hashes recorded on the DDB to every transaction or modification in the files ensure the security of files and modifications since any changes through tampering produces a hash deviating from the recorded.

- *Ethereum Smart Contract*: Smart contracts are a set of virtual agreements that participants abide by while performing transactions on the blockchain network that automatically validates any new transaction on the chain and registers the data to the corresponding transaction on to the chain resources. Smart contracts employ strict restriction and verifications functions to carry out decentralized authenticity of every transaction. Generally, a few of them are assigned to particular participants of the blockchain network, especially these specific functions are modified via decorators to add or avoid any new features/rules that facilitate or enhance the outcomes.
- *On-chain resources*: The resources employed over the blockchain, common to all the participants, to record the logs of transactions, and details of assets, or TRU (in the case of drug traceability) such as storage, and computational resources to run and validate new transactions using smart contracts. Compute and storage is also utilized to deploy an identification system to link the Ethereum address of the participants to human interpretable form and for hashing the participant's credentials

The system proposed [5] is a blockchain-based solution to tackle the counterfeit drug preventing the supply chain. The proposed system was efficient enough in mitigating the counterfeit drugs in the market, however, the proposed method doesn't claim it efficient to track the TRU or drug throughout the supply chain. For the same, various ideas were drafted with the necessary equipment such as GPS, temperature sensors, and other barcodes.

3.4 Implementation of the Proposed Method

The method proposed in [5] was implemented using Ethereum, ethers being the currency of transactions in the blockchain. The smart contracts are coded up in Solidity language, which is compiled and tested in Remix web IDE. The code is publicly open source on the GitHub repository <https://github.com/DrugTraceability/DrugTraceability/blob/master/Code>.

The flow of the method starts from the manufacturer when he requests the FDA for initiating the manufacturing process of the drug lot and updates the details about the drug lot over the blockchain decentralized ledger open to all the participants. Using the IPFS, the images and details of the manufactured and packaged drug lot are updated on the ledger and communicated between the participants. The updates via hashes enable the participants to timely track the history of the drug. However, as discussed earlier, real-time tracking is not proposed. The images of packaged lots are updated and left to distributors. The relationship and the guidelines of the interaction are maintained through the Ethereum smart contracts. The interaction is briefly conveyed in Figure 4.

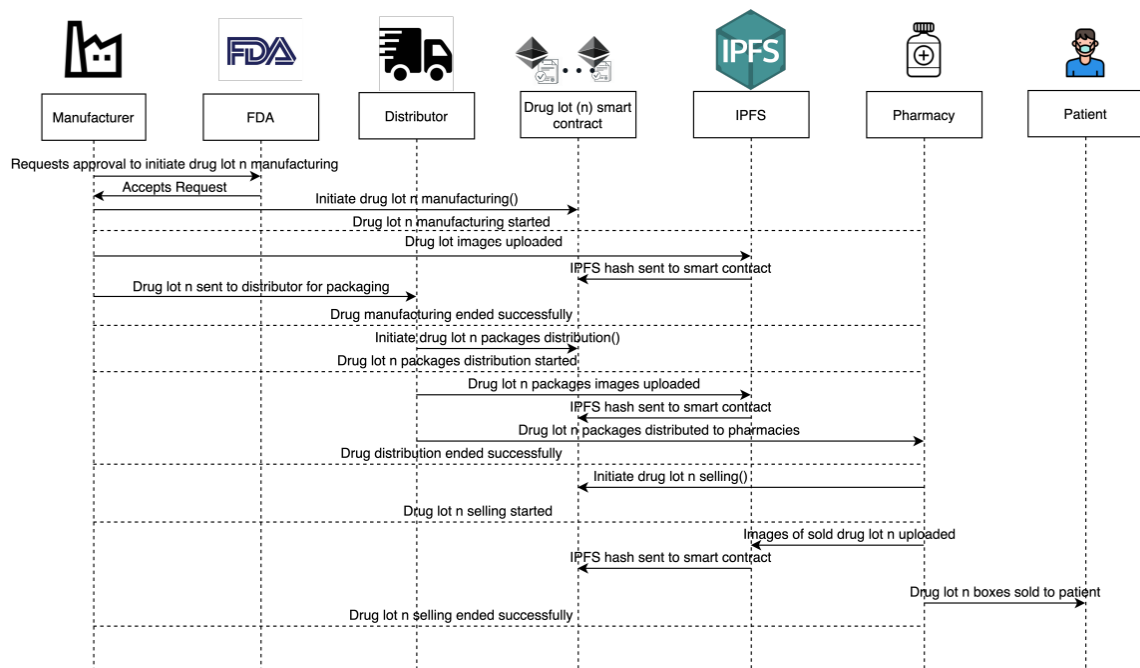


FIGURE 4: Interaction between the participants in the method proposed by [5]

The first verified participant of the network i.e., the manufacturer deploys the smart contract with all the details of the drug lot. In the proposed method [5], the approval of the FDA for initiating the manufacturing of the drug lot is not authorised through smart contracts with assumed to be done through the manual process. Whenever a drug lot is manufactured, an event is triggered to all the participants on the blockchain, however, the primary distributed will get access to some special

functions to initiate or transact with the manufacturer to buy the lot and distribute to the secondary distributors or pharmacies. Additionally, the drug lot image can be uploaded to IPFS by the manufacturer for the participants to access after the manufacturing. After a newly manufactured lot is announced for sale by the manufacturer to the primary distributor, through a set of functions, the primary distributor can place or request the order of a drug lot, which the manufacturer can accept and initiate the sale. Any processed change of ownership is tracked and logged in the list of transactions. All the details of the lot are synchronized into the ledger. The details of the drug lot are mostly mapped to an encrypted code while few other details such as the owner's name are not hashed since the owner of the drug lot is a single entity. The functions that any participant can access at any point in time are accessed through the smart contracts based on the position, owner, and state of the drug lot. Details of the drug lot are uploaded into the IPFS in hashed code in a one-on-one relationship. Functions like `lotDetails` are accessed by the buyers on the blockchain and functions like `grantSale` are accessed by the sellers by the smart contract to perform a transaction by initiating functions. Some of the functions build to execute the transaction by the participants on the blockchain :

- **Creating a Lot:** Used to initiate the lot after FDA approval to the manufacturer.
- **Grant Lot Sale:** Used to raise a event to notify and sell the lot available for sale.
- **Buying Lot:** A function to buy the lot from the seller, executed to record the buy transaction.
- **Buying Lot Boxes:** A function to buy the boxes, if in case, the buyers request for part of the drug lot to sell.

3.5 Traceability Analysis of The Proposed Solutions

In order to use and leverage the advantages of the blockchain in efficiently tracing the drugs i.e., authenticity of the drug lot, any change in the state, or ownership should trigger a event that's is stored in the ledger. A QR code is used to replace the hash or more specifically the ethereum address of the drug log to simplify the method of scanning and verifying the authenticity of the drug. The DApp interacts with nodes of Ethereum using a local node or remote node using `web3j`. The JSON-RPC is used i.e., `infura` or Ethereum node to map hashes of the lot encoded or

encrypted. The mappings of the different drug lots, functions and the events are stored in the ledger for future reference.

The functions such as lotSold, imageuploaded, lotManufactured and newOwner are made accessed and initiated by the smart contracts based on the transactions that happen to allow the participants to perform the actions to proceed in the blockchain.

The Ethereum network distributes the information among the participating entities. Each entity in the network will have a its own duplicate copy of the ledger that is immutable and is synchronized to all the entities in subject to any change in the details or ownership of the drug lot. The methods since ensures security through immutability, decentralized security system and sophisticated smart contracts that turns out to be effective in the healthcare applications, especially the drug traceability through the use of Infura or Ethereum node, web3j interface, and FSON-RPC for mapping of the hashes.

The cost analysis of the method concluded that the method has estimated expenditure of 2.8 GWEI based on the ETH or Ethereum gas station [40]. The table below presents the cost analysis of the method below

TABLE 1: Table comparing the resource cost of the method in Eth gas and US dollars

Function Caller	Function Name	Transaction Gas	Execution Gas	Cost in USD
SC Owner	grantSale	29745	8473	0.00845
Buyer	buyBox	62305	40841	0.0228
Buyer	buyLot	40845	19573	0.01334
SC Owner	IoT Details	107356	83844	0.04226

Based on the security analysis of the method, it is concluded that, integrity of the data and transaction is maintained due to the immutable ledger technology that only register the logs of transactions in one way. The accountability of the transaction is possible since the functions are stored using the Ethereum address. Authorization, availability and non-reproduction of transaction (due to cryptographic encryption). MITM attacks are prevented due to assigned private key to the original data and which need to be confirmed via signing though the key. However, the standard of

security received by using the features of Remix online editor to test and debug. Additionally, the SmartCheck is used to further enhance the bug-free report in validation. Oyente tool was used using Linux that analysed the code to rule out the hidden vulnerabilities.

3.6 Limitation of the Method

Immutability, being a advantage of blockchain also has some negative challenges such as inability to change or modify any transaction that was recorded incorrectly due to human error. The immutability can be addressed to an extent using the simulated annealing. The idea of simulated annealing can allow the change of a block for stipulated time period with high rate of ease and on the course of increments of blocks in the blockchain, the rate of ease to change the registered block or log of transaction is decreased. This is hypothesis that would work effectively to problem based on the nature of the solutoin and its promising results from other problems.

Data Privacy is both the strength and the weakness of the method. A few participants would like to erase their data from the permanent storage in the blockchain on-chain resource. To an extent the problem can also be solved using the idea of simulated annealing i.e., allow the deletion of data for a stipulated time period and restrict the action of deletion later on.

Scalability, Another important issue of the blockchain-based solution for supply chain including the method of [5] is scalability. The major drawback is the huge compute demand by the method to the participants. The cost of executing function or the smart contracts requires various Ethereum nodes as analysed in the [41]. The only solution to reduce the compute cost is again implement the method with a centralized storage and compute services on-chain, making the method a semi-centralized but fully-immutable ledger technology.

Interoperability and Efficiency, The development of smart contracts has a significant impact on the blockchain solution's effectiveness. The consensus algorithm also impacts the efficiency of whole blockchain-based solution since the 90% of the compute power and storage required in the solution via blockchain is to execute the smart contracts, and storing the transaction log on the decentralized ledger.

3.7 Conclusion

The research in the domain of application of blockchain to the supply chain especially to try to mitigate the fake products into the market is at the stage of exploding and with the introduction of robust mechanism and application, the ability of blockchain is advancing towards solving the drawbacks.

Some of the possible areas of research to eliminate the drawbacks mentioned in [5] and in this paper would be to introduce a new state variable mechanism, when the drug's value changes, notify the participants through observer pattern. Aid smart contract validation using A.I systems to automate the process of validating a transaction before adding it into the ledger of the blockchain (IBM's research on intelligent contracts replacing the smart contracts). AI can also be employed to generate the novel hash function that usually take long years to hand design the state-of-art bug free and secure functions.

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