



Transparent and Secure Drug Supply Chain using Blockchain

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Abstract: The existence of counterfeit drugs or pharma products in walks of health care services and in the pharmaceutical supply chain has recently become very evident with the increase in serious illness and death from the use of such drugs. Such pharma products can probably contain the wrong dose of the ingredient or be mixed with the wrong composition. Not only are these products useless for treating people, but they can also lead to serious health conditions. With regard to supply chain systems in our country, most of the transfers that take place in the chain are not recorded correctly and transparency is at stake, every stakeholder within the chain has to trust the other person in the chain and proceed with the handovers. Tracking the origin of the falsified drug or any other discrepancy is a difficult task. The main focus of this paper is to discuss the various practices, challenges and existing approaches in digitizing transfers in a supply chain and proposing a solution to ensure security and transparency is achieved by utilizing the technology of blockchain.

Keywords: Blockchain Technology, Supply Chain, Secure, Transparency, Decentralized.

I. INTRODUCTION

Drugs or pharma products are manufactured in bulk for the purpose of distribution to consumers by distributors in the supply chain. During the life cycle of the supply chain, drugs are transferred between different units, beginning with the manufacturer to the consumer as the end users, and the intermediate stakeholders can include distributors, logistics, pharmacies, hospitals, etc. Each transfer can create the opportunity for counterfeit or counterfeit products to penetrate into the drug supply chain and into the healthcare industry or the entire medical network. The role of a manufacturer in the supply chain is to manufacture the pharma products based on predefined standards and ensure they are well packaged and have the relevant manufacture details added to the product. The details like chemical composition of the drug, manufacture date of the pharma product, expiry date of the pharma product and a brief description of the pharma product could be a few examples. The products manufactured would reach the hands of distributors or logistics who will take care of packaging and transportation of the pharma products to retail pharmacies. Consumers will be able to go to purchase the drugs from pharmacies that are available in the locations across the cities and also near clinics or within the hospital's locality.

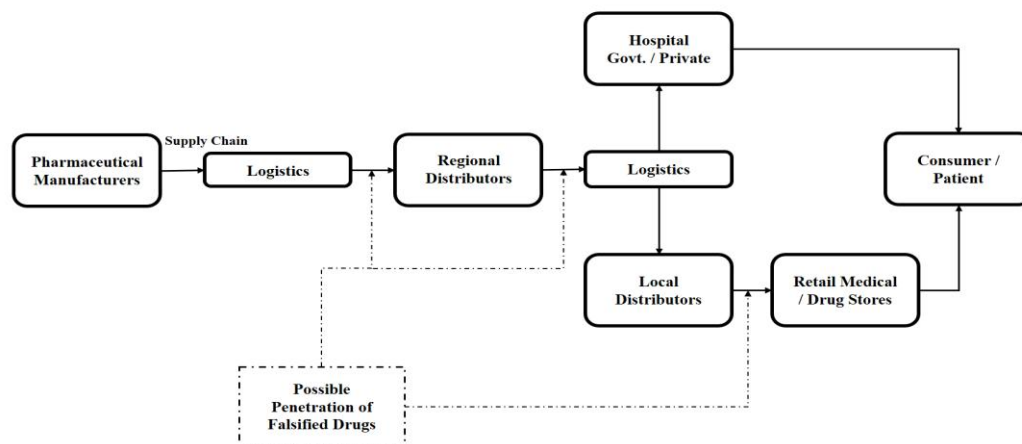


Figure 1.1 Possible introduction of falsified drug in a Supply Chain Lifecycle



Figure 1.1 depicts all the possible intrusion of counterfeit drugs into a typical supply chain system which can usually include manufacturers, distributors/logistics, pharmacies and consumers. The intrusion of fake drugs happens mostly during the handover between the stakeholders in the supply chain and this is due no proper tracking or monitoring system to take care of this. In order to overcome such a drawback this paper discusses about a model that will help resolve the counterfeit problem by leverage the blockchain technology. Blockchain technology offers a quick tracking approach of supply chain information because the information will be stored in the same order of the transactions as it arises. Therefore, it provide a functionality more like a database that can only be appended and each and every transaction is recorded. Blockchain will act as the data pool from which the data can be queried and tracked and it does provide a decentralized way of storage so it is very much fault tolerant and reliable, and therefore there is no dispute or fight over and handover that was done. The proposed digital supply chain network considers the users - manufacturer, distributor, pharmacy and consumer as the possible stakeholders. Transfers are recorded and they are stored into the ledger based on the sale that is performed. Figure 1.2 give a high level block diagram of the proposed model. The physical flow depicts the flow between the users that act as stakeholders in the pharmaceutical supply chain network. When these users interact with the blockchain network which is leveraged using the hyperledger fabric framework in order to perform a particular transaction or handover and then query the recorded transactions to ensure transparency exists in the network. The architecture of the proposed system is shown in Figure 1.3. Unique identifiers are associated with each of the stakeholders that will be registered into the network. Similarly, the pharma products that will be added by the manufacturers also will have a unique identifier associated and recorded in the blockchain network. Based on the handovers performed the relevant transaction data will be added into the ledger. This project work also ensures not only transparency and security but also considers validations for the life cycle of the pharma product. The validations that are considered is for the expiry of the pharma product and also to ensure resale of pharma product transactions would not be supported or enabled in the proposed system.

II. LITERATURE SURVEY

L. Ganapathy, [1] discusses areas of affliction that can be observed in the supply chain to improve transparency. End-to-end accountability and transparency in any supply chain is a very crucial factor these days with the recent cases of counterfeit in the country now. The supply chain networks have become very intricate and sophisticated with the growing number of stakeholders and the amount of products being manufactured.

Athul Jayaram [2] projected a Global Logistics IIoT Industry 4.0 Model to govern the global supply chain. The recommended model encompass, Logistics Sensors, Inbuilt Equipment, Package Score Vehicle Sensors, Product Sensors and Black Box. The Lean Six Sigma methodology in the global supply chain method which uses Industry 4.0 and IIoT will produce an ideal process flow that will highly be optimal and also ideal and free from any defects or wastage.

H. Delalin [3] suggested a Product Traceability Systems (PTS) which can provide assurance on the product legitimacy to be envisioned throughout its complete lifecycle, and thus it reduces the possibility for bad publicity and reducing the recall costs avoiding the circulation of any unsafe or non-genuine products. The system which is proposed consists of mainly four components that is Mobile Application, Web-Service, Cluster cloud system and an HTTP Server which are used for data visualization on the web application.

Jaswinder Kaur[4] advises the use of IoT in pharmaceutical manufacturing, supply chain management and warehousing to increase the quality of the product, Error reduction and productivity increase during the multiple stages that are involved in pharmaceutical product.

Toru Nakamura [5] presents a review on trust problems and the security and of a digital supply chain management system with applied technologies, like Cloud Computing and IOT,. The study aims on discussing the current status, challenges, etc., specifically in direction of security and trust problems, to improve various system properties and performance, i.e. visibility, accountability, reliability, transparency, and traceability.

Andrejs Romanovs[6] studies the idea of Sustainable Supply Chain Management (SSCM), the main drivers, and the inspirations for having a more sustainable drill. The main effects of the study were related to Internet of Things (IoT) in, Big Data and Predictive Analytics, Blockchain technologies, Supply Chain, Artificial Intelligence(AI) and Design for Environment(DfE).

Toru Takahashi [7] advises a technique for verifying distinct tablets by matching the images of printed characters on the tablets with the protected images in the dataset. The printed characters look alike to the human senses, but each is diverse by exceptional variances. The contributions of the paper are to disclose the individuality of the characters published by an authentic pharmaceutical manufacturing unit machine and to advise a practical system to recognize the individual tablets using design matching on the tablets.

Karan Bhavsar [8] suggested a model to identify counterfeit medicines using a fast and modest method using hyperspectral sensing. Spectral signatures that were captured are from the initial stage to all stages of contaminations of the medicine and analysed using machine learning skill which is multilayer perceptron (MLP) classifier.



Nirupama Bulusu [9] proposed a fresh Tag Reapplication Detection (TRD) system to identify the reapplication outbreaks that are witnessed, using NFC tags and public key cryptography. The TRD tracks how many times a tag has been recited in the supply chain using a virtual validation protocol.

Srimathi C [10] converses the applications of Blockchain and IoT towards the Pharmaceutical Industry. The authors implement an analysis of the progress in pharmaceutical industry by the methodology of implementation of Blockchain and IoT.

Daniel Tse [11] discusses the severe problem of food safety in China, which jeopardizes the people's wellbeing directly or indirectly, quality of life and security of life is also at stake. Thus, the paper presents the Blockchain technology concept in such a situation.

Feng Tian [12] debates a study on the utilization of RFID and blockchain technology first in a food traceability supply chain, and then an exploration of the merits and demerits of the use of RFID and blockchain technology in constructing the agri-food supply chain traceability system is completed.

Xiaodong Lin [13] discusses how assimilating the Industrial Internet of Things (IIoT) into supply chain management facilitates a flexible and proficient on-demand exchange of the product between the merchants and the suppliers. The recommended system will take benefit of blockchain technology in terms of its tamper-proof nature and its transparency. Also the decentralization delivered by blockchain will help inhibit any attacks at a single source. The proposed system was prototyped using Ethereum and the demonstrations were done to test its practicality.

Adrian E. Coronado Mondragon[14] inspects the applications of blockchain technology in the supply chain of composite materials/carbon fibre, that is the engineering of structures and components relying on semi-finished materials such as prepregs (preimpregnated) which would need temperature-controlled transportation and storage settings. Blockchain technology is utilized for the purpose of damage resistant history of product manufacturing, provenance, transportation, handling and storage.

Siya Agarwal [15] tries to combine both physical and digital worlds, where the dairy products journey from the production to the consumption tracked and managed. Supply chain sector areas like fraudulent activities elimination, better customer trust, error reduction, delays in product, management improvement etc. can be achieved with blockchain technology. In the cases where transparency is lacking, recorded information is provided by blockchain on transactions of the supply chain that is tracked and recorded in real-time.

N. Karthikeyan P [16] discusses blockchain advantages in supply chain management in the areas of sea food. The authors, with the help of blockchain technology make use of unique tags to get complete details from manufactures like date of manufacture, date of expiry etc., as there is no possibility of altering the details by anyone; therefore it builds trustworthiness with the wholesalers. Consumers make use of these special tags.

Ujjwal Guin [17] proposed a novel framework which is based on blockchain to provide traceability of the hardware. Each IoT device is unique identified using a concept called physically unclonable function (PUF). The verification of these devices are ensured by blockchain by comparing the unique IDs that are assigned to it. HyperLedger was given importance in implementation of the blockchain-based framework, performance is also being evaluated and analysed in this work.

Pavle Skoir [18] proposed a DL-Tags solution which includes an analysis on cost for all transactions that is implemented on the blockchain of Ethereum. It also provides an evidence of the product's origin and its journey throughout its lifecycle in the supply chain avoiding tag duplication and manipulation.

Bidi Ying [19] proposed an architecture which provides prescription of drug supply using blockchain. This architecture includes efficient authentication to prevent an illegal agents among un-trusted people from get to know sensitive drug transactions.

Rakesh Tripathi [20] discusses the issues on drug safety, and also proposes a model using blockchain technology. Advanced features in blockchain makes it capable of providing complete traceability of drugs reaching to final customers from manufacturers, and also it has the ability to identify fake drugs.

III.SYSTEM ARCHITECTURE

Figure 1.2 depicts a higher level block diagram of the system that is designed to be implemented. The Physical flow involves all the stakeholders like Pharmaceutical Manufacturer, Distributor, Pharmacy and Consumer. The Network that the users interact with is composed using the hyperledger fabric framework. So, whenever a proposal is made by the above mentioned stakeholders they are evaluated and the transaction is approved or denied based on the chaincode that is written. The chaincode is the business logic involved in the project. CouchDB is used to record the current state of the contract data.

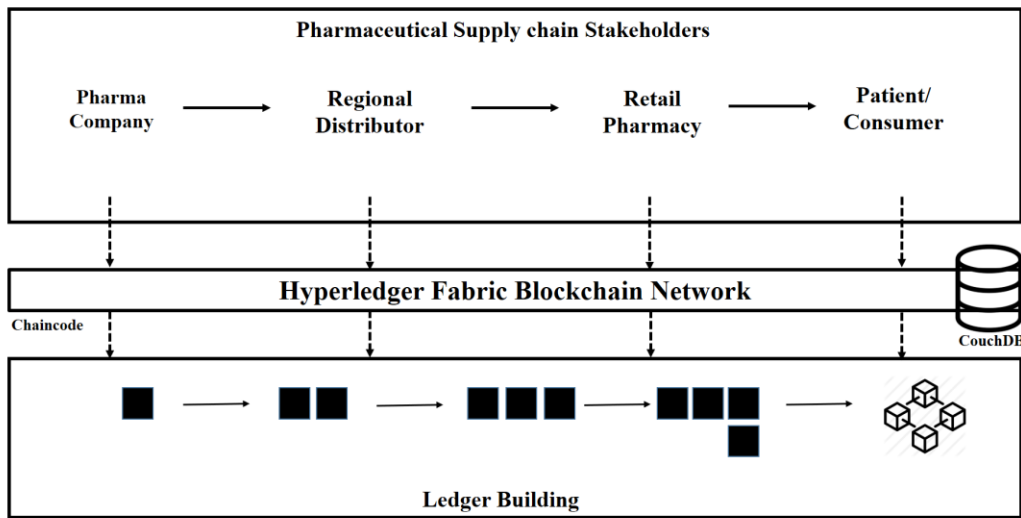


Figure 1.2 Block Diagram of Transparent and Secure Drug Supply Chain using Blockchain

A detailed diagram of the architecture of the project can be seen below in Figure 1.3.

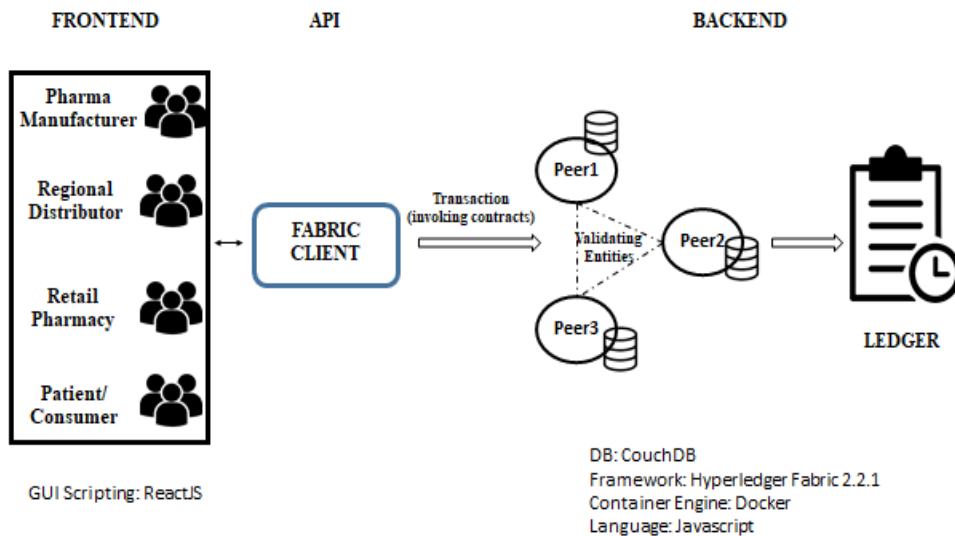


Figure 1.3 Detailed Architecture Diagram of Transparent and Secure Drug Supply Chain using Blockchain

The project has been developed using hyperledger fabric framework to leverage blockchain technology. The details on hyperledger fabric are discussed in the next section. The project work is designed such that the peer nodes, orderer nodes and couchDB that stores the ledger data at each of the peer node is hosted and running on different docker containers. The flow of execution works as follows, the stakeholders register to the network by providing personal details and have unique identifiers assigned to them post registration and a type value such as ‘Manufacturer’, ‘Distributor’, ‘Pharmacy’, and ‘Consumer’ are assigned to them and stored in the ledger. Once the users are registered to the network they will be able to access their respective dashboard and perform the functionalities which are the major features of this project work. The Manufacturer is provided with a capability to add a new pharma product. The Manufacturer, Distributor and Pharmacy will be able to sell the pharma product to another stakeholder considering the constraints of validating the expiry of the pharma product as well the validation that check if the pharma product is already sold. In these two cases, the transaction proposal will be rejected, otherwise, the transaction is approved and added to the ledger with relevant information.



IV. METHODOLOGY & IMPLEMENTATION

Hyperledger Fabric:

Hyperledger Fabric is a blockchain platform for distributed ledger solutions underpinned by a modular architecture delivering high degrees of confidentiality, resiliency, flexibility, and scalability. It is designed to support pluggable implementations of different components and accommodate the complexity and intricacies that exists across the economic ecosystem.

Hyperledger Fabric Framework mainly consists of certain components that are required to host a Blockchain network which includes a Ledger, Membership Service Provider (MSP), Smart Contract, Peers, Ordering Services, Channel, Certification Authority and Organizations.

A ledger majorly consists of two parts which is the blockchain itself and the state database, which is otherwise known as state database. Ledgers are immutable when it comes to blockchain and hence only append operations are enabled. The Membership Service refers to an abstract component of the system that provides credentials to clients, and peers for them to participate in a Hyperledger Fabric network transactions. The smart contract or chaincode is the main business logic that is involved in the project that is developed. The network entities that maintains the ledger and the transactions are known as peers. Ordering services orders transactions into a block and are independent of the peer processes and orders transactions on a first-come-first-serve basis for all the channels that are active. Channel is a private blockchain overlay which allows for data isolation and confidentiality. A channel-specific ledger is shared across the peers in the channel, and transacting parties must be properly authenticated to a channel in order to interact with it.

Certificate Authority issues PKI-based certificates to network member organizations and their users. Organizations are invited to join the blockchain network by a blockchain service provider. An organization is joined to a network by adding its Membership Service Provider to the network.

Modules:

1. Blockchain Network setup leveraging Hyperledger Fabric

Hyperledger fabric version 2.2.1 is used to setup the blockchain network. It required docker engine to run the required entities to setup the network. The images of hyperledger, couchDB and other components are pulled from the hub and built to run them as containers in the system.

2. Identity Management and Role based Access Management

This module includes the development of user registration, user login and dashboard setup for each user type.

Algorithm:

Step 1: Launch the drug supply chain web application.

Step 2: Select the user role on the home page, the users defined in the system include Pharma Manufacturer, Regional Distributor, Retail Pharmacy and Consumer.

Step 3: The stakeholder is taken to the Signup Page to enter their details like Name, Registration ID (if applicable), Phone Number, Gender (if applicable), Location and also a unique Username and Password for the user to access the application, the user information is tagged to the user role they select before sign up.

Step 4: If the sign up is already done, an alert appears to the user and the user can navigate to the Sign In Page to login to the dashboard for that user.

Step 5: The username, password and registration id (if applicable) are entered in the login page and if the provided details are valid and is verified the user will have role based access to the relevant dashboard.

3. Traceability and Transparency

This module focuses on providing traceability and transparency to the users in the blockchain network.

Algorithm:

Step 1: Launch the drug supply chain web application.

Step 2: The users Manufacturer, Distributor, Pharmacy and Consumer login to their dashboards using their username, password and Registration id (if applicable).

Step 3: The Manufacturer begins to add the pharma product with details like pharma product name, pharma product id, expiry date, chemical composition, description and the manufacture date in the Add Pharma Product tab in the manufacturer dashboard.



Step 4: The manufacturer initiates a sale transaction in the Sell to Distributor tab in the dashboard by selecting the pharma product and registered distributor available in the list as desired.

Step 5: The distributor initiates a sale to a registered pharmacy that appears on the list as desired in the Sell to Pharmacy tab in the dashboard.

Step 6: The pharmacy initiates a sale to the desired consumer from the list and sells the pharma product that is under the control of the pharmacy.

Step 7: The users can navigate to their view audit tab in their respective dashboards to trace and track the location of the asset.

4. Pharma Product Lifecycle Validation

This module focuses on validations with respect to adding the pharma product to the system and selling them to the other stakeholders within the system. The scenarios that are validated during the addition of a pharma product are, if the pharma product is added such that the expiry date is prior to the manufacture date or expiry date is prior to local time then the proposal will be rejected. The scenarios that are validated during the selling of a pharma product are, if the pharma product has expired or if the product is already sold and recorded in the ledger, in such cases the proposal is rejected.

Implementation Details:

To setup the network to host the ledger enabled by blockchain, the framework used is hyperledger fabric. The setup uses orderer and peer nodes and they are hosted in docker containers as running instances. CouchDB is hosted for each of the peers available in the network setup and they are also hosted on docker containers to have the ledger updated at each peer node's end. Docker images for these entities are used from the hub and then built to run them as containers using docker commands. The server that helps to enable the transactions using the chaincode is written using javascript. The code helps with process of registering the stakeholders into the system, the verification of user logins based on username, password and registration id (if applicable) and also the transactions for adding the pharma product by the manufacturer and also the handovers between the stakeholders. The code also considers the validations during the addition of the pharma product to the system based on expiry date of the pharma product and also duplicate addition of the pharma product. The validations to ensure reselling of the same pharma product to a stake holder is not possible. The web application is developed using ReactJS and the Material-UI library is used to implement the react components. The homepage consists of four options which showcase the user roles that the system supports and they include Pharmaceutical Manufacturer, Distributor, Pharmacy and Consumer. When the user tries to click on these options the control is taken to the sign up page where the users can provide their details to register themselves to the system. Once the registration is complete, the user can navigate to the sign in page from the sign up page. The sign in page provides the user the capability to enter the username, password and registration id (if applicable) to login to the user's dashboard. The dashboard are designed to ensure role based access control is enabled so only the manufacturer can add a pharma product, the manufacturer, distributor and pharmacy can only sell the pharma product to a stakeholder. All the user have the feature of viewing the transactions for the pharma product they have come in contact with.

V. CONCLUSIONS & FUTURE ENHANCEMENT

The paper has discussed various practices, challenges and approaches that exists in digitizing the supply chain system and has also proposed a new model to over the drawbacks in the conventional pharmaceutical supply chain system by digitizing them using the blockchain technology which would ensure security and transparency among the users involved in the supply chain. Hyperledger fabric framework is considered for the implementation of this blockchain project as it is a framework that would support a permissioned network setup as all the stakeholders will possess unique identities. Such a system is required when it comes to a supply chain system implementation as creating awareness of who is a part of the supply chain is very important. It also enabled to have access control based on the role that a particular user possess and hence it helps with protection of data and confidentiality. Since it creates a distributed environment setup, the system is reliable and available at all times. Blockchain technology is of great use as it makes the drug trade transparent and secure. The future enhancements to this project would be to avail the option for return option by the users as it is currently not considered during the design of the project work. The project can also be stretched further to integrate payment solutions during the handovers so the payments also can be traced for a particular transaction.

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