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A Secure Blockchain-based Pharmaceutical Supply Chain Management System: Traceability and Detection of Counterfeit Covid-19 Vaccines

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***Abstract*—Despite the network and internet technologies development, cases of counterfeit medicine still exist and an unreliable pharmaceutical supply chain infrastructure is one of the key factors behind drug counterfeiting. Before reaching the patient, medicines are transferred from suppliers to wholesalers, distributors, and pharmacists. Currently, information is not exchanged between supply chain management systems. Therefore, there is no visibility on the drug supply chain. Drug counterfeiting issue has become more important during the side spread of coronavirus disease due to the high popularity of this disease's vaccine. Even though this vaccine can help millions of people to eliminate coronavirus, the fake vaccine might be killable for them. This paper is proposing a solution by using blockchain technology for developing a secure pharmaceutical supply chain management system. This technology can add visibility, traceability, security, and transparency to the supply chain system. It is considered that to store the transactions, a permissioned blockchain will be used for this system, and only trusted parties will be permissioned to push data to the blockchain. By the end of this paper, a secure blockchain-based drug supply chain management system will be proposed by the researcher.**

Keywords—Blockchain, Information security, Pharmaceutical supply chain, Counterfeiting, Traceability, Counterfeit, COVID-1.

I. Introduction

Product counterfeiting is growing globally, both in terms of scale, degree of complexity, and in both developed and developing countries. The pharmaceutical industry's primary aim is to find, grow, manufacture, and sell medications. Pharmaceutical firms struggle with many challenges during the production, shipping, and sale of these products.

There are various aspects of the increase in the market of fake medications Some of these aspects include high demand, high prices, lack of legislation, weak penalty and drug regulations. It is considered that one of the most important reasons behind drug counterfeiting can be mentioned as owning an imperfect pharmaceutical supply chain system [1].

There are many problems available within the current supply chain management system for pharmaceutical industries. The most important available issues are:

1. The lack of information visibility
2. Inability to precisely track medicine movement within the supply chain.
3. Lack of traceability
4. Absence of trust and transparency
5. Lack of unified identification and labelling standard
6. Low security of these systems [2]

A successful supply chain management framework will offer much more benefits to the pharmaceutical sector as well as to patients and healthcare systems [3].

As a result, the developer will a pharmaceutical management system with the main aim of traceability and detection of counterfeit medicines especially covid-19 vaccines by using blockchain technology. The main objectives of the proposed system are to increase trust and transparency, to design a unique labelling and identification system, to have extended security, and to evaluate information visibility and traceability. In this paper, the researcher will provide blockchain's explanation, classification, and benefits in the literature review section. Furthermore, blockchain's essential components and general application and use cases will be provided in the methodology section. Lastly, a solution for pharmaceutical industries will be proposed using blockchain technology.

II. Literature Review

A. Blockchain

Blockchain technology can be defined as a shared database technology administered by multiple nodes on a peer-to-peer platform [4]. This technology functions without any central administrator or centralized database management. Each block plays an essential role in linking to the previous block and the next block as soon as it joins the chain to be part of the system [5], [6]

The planet has been exposed to a new paradigm with the invention of Bitcoin in 2008, which will revolutionize the entire civilization. It guarantees to affect each sector, containing but not restricted to the financial system, economy, media, legislation, and healthcare [7], [8]. Further development is supposed to continue along with adaptation and greater blockchain technology's maturity. Eventually, in 2025, the technology is predicted to be advanced enough for day-to-day usages [9], [10] as shown in fig. 1.

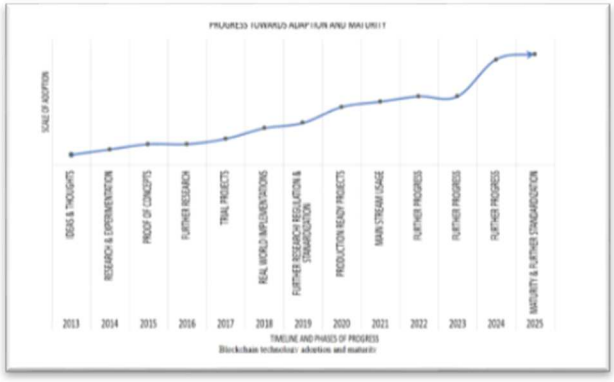

Fig. 1. Blockchain technology adoption and maturity [5]

1) Blockchain Classification: Blockchain networks can be classified according to their model of authorization, which specifies who can manage them. If anyone is allowed to publish a new block, this is named as the permission-less or public blockchain. However, if only specific users are permitted to publish blocks, this blockchain is a private or permissioned blockchain. These two classifications are explained below [11].

a) Public or permission-less blockchain: A public blockchain can be described as a database without any authorization that is available to everyone. Within this Blockchain, everyone can publish blocks without any need for approval from any regulator. To avoid this, blockchain networks without authorization often use a multiparty contract forcing users to expand or preserve resources while trying to publish a block [12].

b) Private or permissioned Blockchain: Private blockchain networks are those where individuals must be authorized first to publish blocks by some authorities. Because these blockchains are maintained only by approved users, it is possible to limit read access and to control who can make transactions [13].

2) Benefits of Blockchain

a) Decentralization: This is a central principle and the advantage of the blockchain. A trustworthy third party or broker is not required to verify transactions.

b) Transparency and trust: Since blockchains are distributed, and anyone can see what is on database, this helps the system to be transparent. Consequently, trust is generated.

c) Immutability: If the information has been published to the blockchain, it is incredibly impossible to modify it again.

d) High availability: Since this system is based on millions of peer-to-peer network's nodes, and the data from each node is distributed and reviewed, the system becomes highly accessible.

e) Highly secure: Due to the fact that all block's data and headers are cryptographically hashed, the blockchain networks can be considered as the secure network.

f) Faster dealings: Blockchain can play a crucial role in the financial sector, especially in post-trade settlement functions, by allowing the fast settlement of transactions.

g) Cost saving: Since the blockchain model does not need a trustworthy third party or clearing house, overhead expenditures may be significantly reduced in form of the fees charged to these parties [14].

III. Materials and Methods

A. Blockchain's Essential Components

1) Cryptography: In simple terms, cryptography can be defined as the technique of creating strategies and protocols to prohibit a third party from viewing and acquiring knowledge of data from a private message throughout a communication. Finally, Key is a minimal amount of information needed to conduct the encryption and decryption. There are mostly three distinct kinds of cryptography that are symmetric-key cryptography, asymmetric-key cryptography, and hash functions. Blockchain technology uses two types of cryptographic algorithms that are discussed below.

2) Asymmetric-key Cryptography: Despite Symmetric-Key Cryptography, asymmetric-Key Cryptography uses a pair of keys for encryption or decryption procedure named as a private key and public key which are mathematically connected. Asymmetric-key cryptography helps people who do not trust or know each other to provide a bond of trust by offering a system to check the validity and legitimacy of transactions while allowing transactions to remain public. Alternatively, information might be encrypted with the public key of a user to be decrypted only by people who have access to the private key [6].

3) Cryptographic Hash functions: The cryptographic hash function is an essential element of blockchain technology. Hashing can be defined as a process of applying a cryptographic hash function to data that computes a unified output for any input of any size. Cryptographic hash functions are used for several roles within blockchain networks. The primary objective of hashing within blockchain technology is to secure block data [6].

4) Transactions: A transaction constitutes an interchange between entities on a blockchain network. For instance, with the cryptocurrencies scenario, a transaction represents the transition of cryptocurrencies among two entities of the blockchain network. A transaction's authenticity is also essential, as it specifies that the recipient of digital assets has ownership of those digital content [6].

5) Blocks: Firstly, through the system, a blockchain network user sends the required transaction to the blockchain. Later on, inside the blockchain network, the system sends this transaction to all nodes. This allows altered blocks to be readily identified and discarded. A collective chain of blocks within a blockchain as shown in fig. 2[6].

6) Smart Contracts: These programs work over the blockchain and encapsulate the organization's rationale to be carried out in some circumstances. There are several use cases for smart contracts, including but not restricted to, financial markets, identity management, commercial finance, insurance, data management, and e-governance [15].

7) Address: Addresses can be defined as specific identifiers used in a blockchain transaction to indicate sender and the receiver. Inside blockchain networks, users of the blockchain network may not be the only source of addresses. [6]

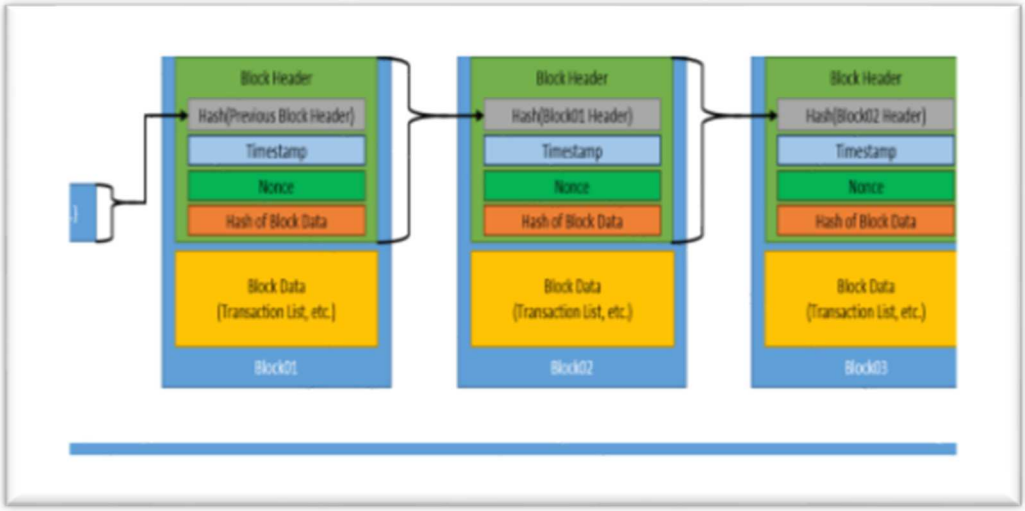

Fig. 2. Blocks structure in a blockchain [6]

B. *Blockchain General Applications*

Blockchain was proposed for use in various implementations and use cases following the successful introduction of bitcoin because of its silent functionality. Different blockchain use cases in various sectors accompanied by some appliers that have used this technology for developing their system are listed in the below table. However, since healthcare is one of the world's essential markets and is the focus section of this project, the healthcare use cases will be explained in depth [7].

TABLE I. BLOCKCHAIN APPLICATIONS [7]

Category	Use cases	Appliers
Data Management	Data Monitoring	Modum.io
	Identity data management	UniqueID, OneName, IBM
Data Verification	Photo and video proofing	Uproov
	Product quality proofing	Everledger, Verisart
Financial	P2P Payments	BitBond, Codius, BTCjam
	Value transfer and leading	Ripple, Monero, Bitcoin
Others	Voting System	ThanksCoin, Ballotchain
	Gaming	PlayCoin, Deckbound

C. *Blockchain use cases in Healthcare*

1) Electronic medical records: The administration of electronic medical records is one of the common scenarios of blockchain uses in healthcare. Guardtime is an example of an organization that uses a blockchain-based network to protect more than 1 million patient data in Estonia, as it is reported. Another example is the medrec initiative, which seeks to provide patients with their records [8].

2) Biomedical Research and Education: In pharmaceutical research and education, Blockchain has fascinating attributes for being deployed. A prototype of the system implementation for clinical consent traceability using the blockchain protocol is provided in this report [8].

3) Remote Patient Monitoring: The process of remote patient monitoring includes gathering biomedical data using body area sensors, IoT devices or mobile devices to remotely track the patient's status. As it is reported, there are some examples of remote patient monitoring system which illustrate how smart contracts can help a patient tracking program in real-time that can deliver automatic treatments in a protected environment [8].

4) Drug/Pharmaceutical Supply chain: Another defined blockchain application is in the management of the health supply chain, especially in the pharmaceutical or drug industries. This startup uses blockchain to create immutability by providing public exposure to temperature records for pharmaceutical supply chain management [8].

IV. PROPOSED SOLUTION

For stakeholders such as suppliers, patients, distributors, pharmacists, etc., the Blockchain technology offers a secure platform. The flow of medications on the blockchain is recorded at any phase throughout the supply chain management system. The manufacturer produces medications and assigns them to a generic QR code. The distributor is the second component of this supply chain. First, wholesalers verify the source and legality of drugs and then store the transaction on the blockchain network. The drug is then forwarded to the pharmacist. This process is continuous in the supply chain from companies to end-patients to validate the originality of medications and to store transactions on blockchains as shown in fig. 3.

Fig. 3. Blockchain-based drug traceability [9]

A. Proposed system's security

Since the proposed system is based on blockchain technology, all security features will be like blockchain technology's security features. Blockchain technology is a recent development in secure networking without centralized control in a distributed networked environment. Blockchain technology includes three important security features, including the ledger, block chaining, and a decentralized structure. The Blockchain network's ledger must monitor each transaction. Furthermore, nobody can access the transaction or confidential data since this database is decentralized. Since any block contains a hash value and is related by its previous hash, block chaining is a significant aspect of the blockchain. This attribute would not allow any block to be changed by the attacker because it would affect the total chain [7].

Blockchain Certificate Distribution System is a web application that aims to provide a platform for the university to upload their certificates onto the blockchain and allows the recipient to search through the blockchain for their certification. According to [11], development of web application can be categorized into two major tiers, which are Client-side Scripting and Server-side scripting. Client-side scripting represent the front end of the web application that is visible to the user, in which the user will perform all kind of operations through the UI. Some of the famous languages that are used for client-side scripting are JavaScript, HTML, CSS, jQuery, Ajax, and others. Server-side scripting on the other hand, represents the back end of the web application, where it is not viewable by the user. Server-side languages such as PHP, ASP.NET, Ruby on Rails, Python are commonly used, each have their own pros and cons when they are utilized for the development.

For the front-end development of the Blockchain Certificate Distribution System, authors recommend utilizing HTML, CSS, JavaScript, and React. HTML allows us to build the basic structure for the web application; CSS provides us a way to modify and beautify the presentation of the HTML page; On the other hand, JavaScript is used to control the behavior of the elements, which improve the dynamicity and interactivity of the HTML pages. React is a framework that can be utilized throughout the development. Authors recommend utilizing JavaScript and Solidity as backend languages, and they can be hosted with Nodejs as the server-side scripting for the Blockchain Certificate Distribution System. Implementing JavaScript language into the system provides several advantages that can improve the overall performance and efficiency for the Blockchain Certificate Distribution System. JavaScript is a statically typed language, in which the code is verified and validated for any errors before it is compiled into the web application. Moreover, JavaScript supports object-oriented programming, which is recommended to be utilized throughout the development of the Blockchain Certificate Distribution System. Solidity is used for developing the smart contract which is necessary for the web application to connect with the blockchain.

Agile software development is a modern development framework that makes use of the idea of continuous iterative development and testing throughout system development life cycle. This system development methodology allows collaborative team to achieve faster deliverables, produce higher quality of deliverables, and improve the flexibility of the system towards the changes. Extreme programming is a type of agile software methodology, where it aims to provide frequent support release. This allows the product to be able to adjust to the changing requirement of the vendors, as well as improving the quality of the product while delivering frequent release of bug fixing and enhancement patches.

By utilizing extreme programming, all major tasks are broken down into smaller components, where these can be accomplished by the team members in a short time. Daily stand-up meetings allow the team members to keep track with the current progress of the project, as well as providing the opportunities to address the problems and concerns faced during the development. Moreover, the developing product will be present for the vendors from time to time, and feedback is collected for identifying any necessary changes

V. CONCLUSIONS

In conclusion, the main goal of this research is to develop a secure blockchain-based supply chain management system for the pharmaceutical industry for detecting counterfeit medicines especially covid-19 vaccines. It is reported by the

world health organization that the drug counterfeiting issue has become more crucial with the widespread of coronavirus disease since people have a high demand for personal protective equipment (PPE) and vaccines. Despite the enhancement of the pharmaceutical supply chain management systems, there are still many issues within this sector such as lack of trust and transparency, lack of unified identification and labeling, the security of the system. The researcher has gone through many articles, books, and journals to deeply explain the chosen topic. This paper explained the blockchain concept, its classification, essential components, its benefits, and its general application in different industries. In the end, a proposed solution for the pharmaceutical management system has been presented by using blockchain technology which will add extended security to the system. Lastly, although much care was taken while proposing this supply chain management system, it is considered that this proposed system needs to be developed by a future developer. Furthermore, besides the mentioned functionalities, future developers can add more operations to the system. As a result, once a patient checks the supply chain of a particular medicine, he will be also able to view his past medical records and decide whether this medicine is sufficient for him or not.

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