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Detection of Counterfeit Medical Products

Ramya K M[1], Rachana. L [2], Ranjita Kiran Naik[3], Rashmika Satish[4], Saba Naseem[5]
[1]*Assistant Prof,* [2, 3, 4, 5]*Student, Dept of CSE, DSCE Bangalore, India*

Abstract: ***Medical product counterfeiting is one of the many major problems facing the healthcare sector. It is estimated that 10 to 30 percent of medical products sold are fake. Because they do not have access to quality healthcare, these issues are more prevalent in undeveloped and developing nations. As the healthcare supply chain is centralised and the procedure from the product's creation to its delivery to the user is opaque, it is challenging to identify counterfeit goods. As a result, the traceability of medicinal products becomes crucial. In addition to the difficulties of data privacy, data authenticity, and adaptability, traditional methods have not been very effective in resolving these problems. In this study, we reviewed several blockchain-based approaches for detecting fake medical items that employ the Ethereum blockchain, Hyperledger fabric, etc. The adoption of innovative ideas, like the inclusion of a QR code which enables customers to discover more about medical products are also studied. We also discuss the various architectures and techniques that are employed. The key challenges faced, and the research gaps are also analysed.***

I. INTRODUCTION

From the purchase of basic materials toward the distribution of the final item to the clients, the supply chain is an intricate structure composed of various separate businesses. The counterfeiting of medical supplies is just one of the issues that a system this intricate is sure to have. Not only are fake medical items bad for patients, but they also cost the pharmaceutical and healthcare sectors a lot of money. Such problems must be fixed, and measures to boost supply chain system transparency should be done. With the introduction of blockchain inside the supply chain industry, transparency may be addressed. The core concept with a blockchain is similarly to something like a linked list in where both retain a replica of information that had been previously present with in nodes who came before them. Numerous industries have adopted the blockchain. With no need for a centralised authority, a peer-to-peer network was created with the aid of these produced apps. The detection and traceability of medicinal products can be accomplished utilising a variety of blockchain-based solutions. This article also focuses on the obstacles and restrictions associated with applying blockchain technology to the healthcare industry. The stakeholders in a general medical supply chain are Food and Drug Administrator (FDA), the manufacturers, the distributor, the pharmacies and finally the customer.

A. Motivation

A serious threat to society is posed by the counterfeiting of pharmaceuticals. The people's health is adversely affected by the fake medications, and the actual pharmaceutical manufacturing companies suffer financial losses as a result. The pharmaceutical industry's counterfeit medication problem is partly a result of the broken supply chain structure. There have been several anti-counterfeiting strategies proposed up to this point, however most of the existing systems are subpar. When we require both data access and data privacy, blockchain technology is one of the greatest options available. Consequently, we are seeking to use blockchain technology to guarantee the quality of the medicine, the security of the transaction, and the accuracy of the data.

II. LITERATURE SURVEY

A. Traditional Efforts

The capacity to obtain any or all data regarding the entity within investigation across its life cycle using documented identifications is known as traceability. The thing being examined is known as a traceable resource. A unit interaction is any measurable unit inside the logistics network. Tracking the transaction records and the transaction's location in real - time basis are the two objectives of traceability. [1].

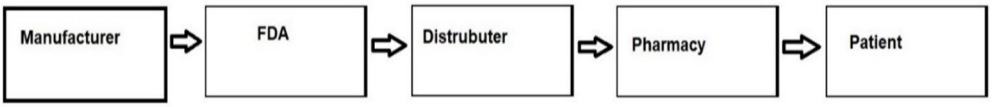


Figure 1. The traditional healthcare supply chain with stakeholders

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In the past, supply - chain services utilise barcode technology and Radio frequency identification as identification techniques, as well as wireless sensor networks (WSN) for gathering information but also electronic product codes (EPC) to acknowledge, gather, and communicate product data in order to support the monitoring of goods through various stages. [2].The GS1 standards barcodes used in this context by Smart-Track [3] contain a unique serialised product identity, a Lot production date, and an expiration date. Various supply chain procedures capture the data found in the GS1 barcode, which is then utilised to keep a running record of ownership transfers.

In [4] Saiyu Qi et al recommended adding the ability for updateable encryption to Ciphertext Policy Attribute Based Encryption (CP-ABE). RFID tags were on the products throughout the supply chain. Despite the fact that attribute data regulations control access to data and RFID tags are scalable, they are expensive and most likely won't function if radio frequency waves collide. There won't be accurate results.

As each stakeholder acknowledges having the product in their possession, an end user (patient) may verify validity over a single point of contact organised like Global Synchronization Network (GDSN) via using a smartphone app. To verify the items and their specifications, pharmaceutical as well as healthcare departments would scan the barcode inside the production flow at the warehouse. The Data-Matrix monitoring system [5] creates a Data-Matrix for each drug that includes the producer ID, product ID, id Number of the packaging, identification code, and extra meta-data. The patient may confirm under which item was created by using the connected Data-Matrix.



Figure 2. Data Matrix

NFC tags have recently been proposed as a technique to improve authenticity and visibility along the whole pharmaceutical supply chain. Regarding this, [6] details an initiative to develop an NFC-based system that permits visibility throughout all stages of the pharmaceutical manufacturing process. Each pill has an NFC label attached to it that is used for authentication and registration. Similar to the first available methods, the user or patient may verify the validity or country of origin of the medicine by scanning the associated NFC tag with a smartphone application.



Figure 3. NFC and RFID tags

The systems for traceability in [9] use centralised databases, which make it very simple to tamper with products information and challenging to spot. In addition, the utilisation of many centralised databases may leave the proposed solutions with limited scalability and interoperability.

B. Blockchain Based Approach

In addition to all the previously stated conventional approaches, Ilhaam A. Omar et al [10] suggest a private blockchain-based solution that makes use of decentralised storage and Ethereum smart contracts to enable inventory sharing among supply chain participants. Through thorough testing of numerous situations and system functionalities, the proposed solution is validated.

They have analysed the costs and security to show that the plan can be implemented. However, it failed to validate the stakeholders.

In [11] Pinchen Cui et al introduce a novel method to trace the electronic components in the supply chain, they used a permissioned (consortium) blockchain in their suggested system. They choose whether to include the transaction in blocks using miners. This technology is inexpensive and may be applied both on chain and off-chain. It stops unlawful transfers and fault transfers, as well as illegal device registration. Due to the lack of PUF and other distinctive identifiers, the device is vulnerable to manipulation within the network.

Blockchain networks rely on consensus algorithms to reach an agreement among various distributed nodes. One such algorithm proposed by Yash Madhwal in [12] is the Proof of Delivery (PoD) algorithm.It supports real-time information visibility but has lengthy verification of compliance with the delivery terms. [11] discusses the Proof of Work algorithm, a consensus mechanism that includes solving difficult computational challenges to produce new blocks.

[13] puts forward the Proof of Authority (PoA) consensus mechanism. it is used in a private Ethereum Blockchain, which has three smart contracts to control registration, production,and consumption. The front end of the blockchain is built using Dapps and web3.js libraries.

[14] Adopted the Delegated Proof of Stake (DPoS) consensus algorithm, whose delegates are chosen based on their standing and perceived reliability. Delegates are rewarded for excellent behaviour, as according DPoS proponents, since the members has the rights to elect them out and substitute them at any moment. They organised the pharmaceutical companies employing DPoS onto branch chains, in which the main chain's structure and the branch chains' structure were helpful for departmental regulatory review and it would also dramatically cut the amount it required for medication data to be detectable. With a larger transaction rate per second than blockchains powered by PoW and PoS systems, DPoS systems are often speedier. But because DPoS is still relatively new, it is not usually seen as being safe enough to serve as the foundation for blockchains that conduct financial transactions.

In 2009, Satoshi Nakamoto released bitcoin, which served as the first use of the blockchain concept [15]. It had a concept of conditional transactions which was later introduced as a smart contract in Ethereum Blockchain. The drug ledger employs a UTXO-based transaction model to show the full workflow of the supply chain from start to finish. It includes packaging and repackaging processes, which are crucial to drug traceability. The service provider has been divided into three distinct elements, namely the Certificate Service Provider, the Query Service Provider, and the Anti-Attack Service Provider, according to a different architecture. The drug ledger's construction is done in a way that it can fend off Sybil attacks. To ensure system security, a certificate service provider is employed. The medication ledger is effective at resolving packaging, unpackaging, and repackaging issues. Recent research has revealed that using UTXO for programming, together with its high storage cost and low state space utilisation, is not very successful when used in drug traceability systems [16].

In [17] Claudia Antal et al propose a smart contract-based monitor and tracking system for the management of COVID-19 vaccination supply on the ropsten network. It improves the COVID-19 vaccine distribution process' efficiency and transparency by ensuring traceability and conducting a thorough audit of the conditions for storage and delivery. It also ensures accuracy and openness in the registration process as well as the administration of the vaccination waiting list. It offers a framework for openly reporting potential negative consequences. Because DApps have not been implemented in the author's system, digital apps must rely on a single machine to function.

In [18] Rohit Raj et al, have used Proof of Ownership in their paper. The proposed model is continuous, decentralised, and digital. To improve system performance and decrease latency, very few resources were utilised. In order to create transparent and traceable system, the authors used. Logistical businesses are given access to real-time surveillance of pharmaceuticals being carried out. Ethereum just needs 10 to15 seconds to process a transaction compared to Bitcoin's 10 to 12 minutes.

The proposed solution in [19] makes use of the Ethereum blockchain. Additionally, there is a website that uses JavaScript, HTML, CSS, and Solidity for smart contracts. Due to the inclusion of blockchain technology, the programme is helpful in tracking down medications. In terms of security and increased openness in identifying the many parties, from the producer to the supplier of a particular drug, it also demonstrated excellent results. The proposed system makes use of smart contracts, but there hasn't been any implementation, which makes it difficult to comprehend the full scope of the suggested fix since testing was limited to their local host.

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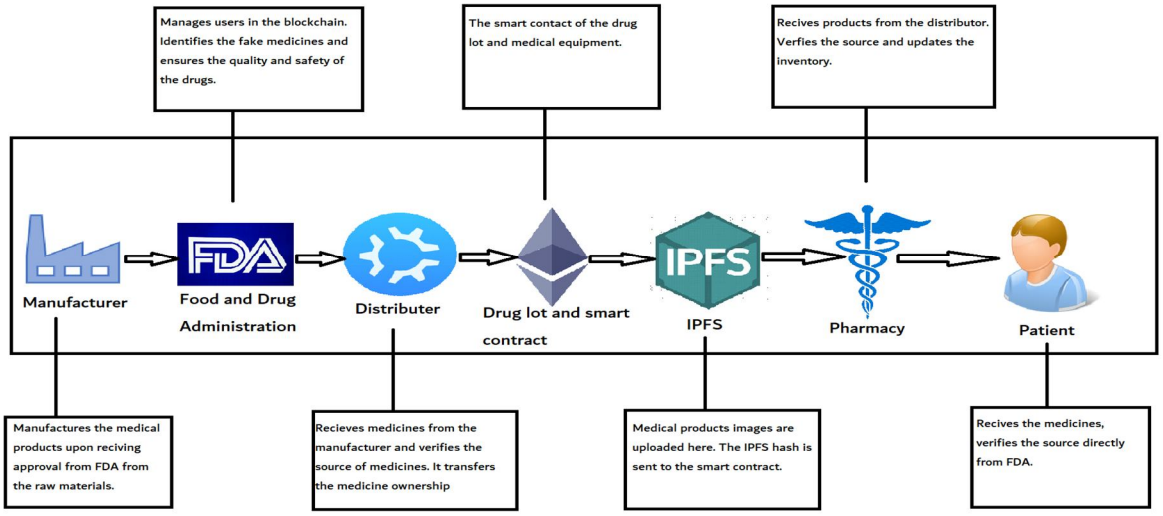


Figure 4. Blockchain based solution for healthcare supply chain

[20] combines the blockchain with the Interplanetary File System (IPF), a protocol, hypermedia, and peer-to-peer network for file sharing that is used to store and share data in a distributed file system. Each file in a global namespace connecting IPFS servers is uniquely identified via content-addressing, which is used by IPFS. The technology is quite effective at thwarting Sybil assaults and can be quickly set up as either a permissioned blockchain or a permissionless blockchain, depending on the need. Furthermore, because the algorithms don't use loops or arrays, they are cheaper than other alternatives that have been suggested. For massive data storage, it is typically paired with other cloud storage platforms because it is expensive for storage.

[21] does a rough examination of the application of blockchain inside the supply chain to address the problem within the Indian merchandise for fake medications. In Hyperledger Fabric v1.0, a blockchain is established and used to launch this research. Second, in allocating identity and privileges via digital certificates and maintain network transactions, a design of the drug distribution system is developed.

The backend, which serves as an API for the front end, and the application were both launched as in cloud provider in [22]. The IBM Blockchain service, which is built in Hyperledger Fabric which is private permission and ensures an extra security model, has replaced the creation of the blockchain. It provides both qualitative and quantitative validation.

First one gives customers a sense experience, and it asked individuals whether they would be open to using an app to confirm the medications they had brought. It was accepted 92% of the time. The second one concentrated on the system's performance once many people entered it, however it resulted in time-out issues. Additionally, the authentication component validates the user's credentials to ensure their identity before granting access to the system in accordance with their assigned role.

[23] makes use of the Ethereum blockchain which is created using AWS. Each and every transaction in the medical supply chain is recorded and timestamped. It has smart contracts that control the creation and transfer of goods. In comparison to Huang et al.'s Drugledger, the PharmaCrypt approach is more user-friendly because it eliminates concepts like query service provider and certification service provider. PharmaCrypt uses bar code scanning technology, so it doesn't need sensors. The implementation process is expensive. To make the proposed solution more practical, it needs to take less time to complete the transaction. Because it relies on the AWS service and is based on the AWS blockchain, barcode scanning is not a very effective solution.

Utilising the Blockchain technology The goal of [24] is to prevent drug fraud and enhance the transparency, integrity, and accessibility of the healthcare supply chain utilizing Blockchain technology and indeed the AWS S3 service. Only individuals who are the owners of those assets have the choice to transfer their authority to other stakeholders. For the prompt settlement of any conflicts in the drug supply chain, the suggested system offers a non-repudiation technique that identifies the collection of knowledge, offers proof of its integrity, and exhibits traceability. It aids in identifying medications that lack intended active components. The device is able to produce foolproof logs, which aid in locating fake medicines.

The suggested approach uses Blockchain technology's cryptographic underpinnings to protect logs of occurrences across the supply chain, ensuring drug safety and eradicating counterfeits. One of the drawbacks of utilizing this method is that AWS limits resources by default. Hence the complete utilisation
cannot be made.

[25] presents a trustworthy blockchain-based platform for healthcare chain supply across stakeholders. The storage of transactional information is what makes it similar to bitcoin transactional information. With the use of digital signatures and PKI, the system is protected against man-in-the-middle and replay attacks. Data given by the stakeholders is shown as encoded QR codes. The author has not fully decentralised the system, and there is a lack of transparency in the supply chain. PKI and digital signatures are used in the offered method to protect against man-in-the-middle as well as replay attacks. During the performance analysis, the Caliper evaluation tool showed a decline in performance and latency.

In Addition to the techniques used in [25], [26] made use of google Geolocation API to get real-time location of the delivery of the product. Along with that it also removed information of the expired products, thereby optimizing the data storage. For block generation, which is encrypted using CRC-32 hashing, the
medication labels, ingredients, manufacturing expiration date, and amount are extracted from the drug packaging. Its sole flaw is that the medication administrator represents one system failure.

TABLE 1. Table showing various consensus algorithm

Features	Proof of Work	Proof of Stake	Proof of Authority	Delegated Proof of Stake
Blockchain type	Permissionless	Permissionless	Permissioned	Permissionless
Network type	Decentralized	Decentralized	Centralized	Less centralized
Speed	Low	Normal	High	Normal
Tolerated power od adversary	Less than 25% computing power	Less than 51% stake	Less than 51% nodes can act maliciously	Less than 51% validators
Verification of block	Mining	Minting	Private administrators	Authenticators who are voted in
Year	Firstly in 1993, reintroduced in 2008	2012	2017	2014
Example	Bitcoin, Litcoin	Peercoin, Casper	Microsoft Azure, Vechain, Xodex	Bitshares

[27] presents a novel blockchain framework which is the New Economy Movement (NEM). It offers templates for smart contracts that are executed outside of the blockchain, which makes them quick and free of the need for programming. A smart contract can easily be included in apps by developers using an API. As a result, it is quicker and safer. But because NEM lacks a scripting framework, the developer is only able to use the available resources and cannot create their own smart contracts using NEM.

As a solution for product traceability data, [28] presented a permissioned blockchain including double structure. A base layer and a secondary layer make up the system. The Permissioned type of blockchain is built on the top layer. A private type of blockchain is built inside the sublayer. To increase efficiency and scalability, operations like data entry and reading are segregated. The double layer considerably boosts system performance and is comparable to multi-layer architecture. Resources are typically used up quickly during data storage processes. In a two-layer system, the sub-layer is responsible for data entry and storage while the main layer manages query activities. As a result, the performance is enhanced. The scalability is significantly enhanced by the double layer. Additionally, it enhances overall performance and promotes customer utility. The suggested solution makes full use of blockchain. It offers a practical approach to enhancing product traceability and preventing data manipulation.

[29] have proposed two workable blockchain-based distributed structures, Hyperledger Fabric and Besu, that address key requirements for drug tracing, including confidentiality, trust, integrity, security, authorization and authentication, and scalability. Hyperledger Fabric is a framework for distributed ledger applications, and its modular design provides high levels of security, dependability, adaptability, and scalability. The Health Authority uses the membership service provider (MSP) element of the suggested Hyperledger Fabric architecture to identify and register all medical stakeholder and their end customers, creating a permissioned private type of blockchain network. The suggested Hyperledger Besu drug tracking design is an open - sourced distributed ledger approach that is completely compatible with Ethereum and may be used by businesses looking for blockchain architectures that are compatible with it. Unlike Ethereum, Besu and Hyperledger Fabric are designed to be used as private and permissioned B2B structure. Besu plus Hyperledger Fabric enable faster state to reconcile and activity processing. On the downside, neither the system's core components nor the proposed designs' user interface DApps have indeed been developed or put into use.

[30] has enhanced the blockchain's traditional usage by involving a novel Practical Byzantine Fault Tolerance (PBFT) consensus technique to increase system performance during the traceability of medical supplies. This is one of the essential steps to ensure anticounterfeiting as it involves the consensus of all the nodes to support the veracity of the drug information. The number of honest nodes is gradually due to the enhanced PBFT algorithm. Since the proportion of corrupt nodes to authentic nodes would be so much lower than the threshold for a successful attack, the recommended technique is therefore assured to be exceedingly difficult to attack. Their approach uses less energy, which increases the acceptability of blockchain technology for medical traceability and anti-counterfeiting. The recommended method defends against single-point assaults by utilising a distributed P2P architecture. The disadvantage of this method is that, instead of employing a clustered deployment, just one PC was used for operation and testing, and memory usage was not mentioned.

[31] utilizes a new CSC framework to avoid the issues seen in the conventional supply chain. A construction supply chain using blockchain is called the CSC framework. They also used private key distribution protocols, which have 10 sub-protocols, to implement the recovery of private keys and a consensus algorithm is used. It guards against attacks on network protocols as well as secret-sharing techniques. The transmission expenses, additional delays, and information loss are addressed and are considered in traditional CSC. However, the mechanisms for distributing private keys do not guard against attacks like history analysis and collusion assaults. Time costs arise due to communication delays.

[32] created the BIOT3 system for supply chain monitoring and tracing, which includes of five layers combining blockchain and the IOT (Internet Of Things). The platform is verified using the Hyperledger Fabric Blockchain. It allows multilayer monitoring and visibility of medicinal products as well as integrity inside this supply chain paradigm. Smart contract-based alert mechanisms are used to verify information regarding fake medication goods. O n and off-chain storage are provided in the implementation. The supply chain in real-time is more complicated. Therefore, firms are responsible for the actual implementation of this one.

[33] engages the FDA in every step of the supply chain, whereas the conventional supply chain approach did not. Therefore, this leads to the verification of the stakeholders but also the products and the processes. It also outlines potential disadvantages of utilising blockchain to find counterfeit medical products. Firstly, it will be very challenging to make blockchain based solutions used by healthcare organisations that choose to use various platforms interoperable. Second, the efficacy of the blockchain solution depends on both the coding of the smart contract and the consensus technique used to validate and approve a transaction.

TABLE 2. Comparison of various blockchain types

Features	Bitcoin	Ethereum	Hyperledger
Cryptocurrency	Bitcoin	Ether	No
Consensus	• Proof of Work	• Proof of Work • Proof of Stake	• PBFT • Kafka
Type	• Public	• Public • Private • Permissioned	• Private • Permissioned
Smart Contract	No	Solidity and others	Chain node
Scalability	3 to 7 transactions per second	15 to 30 transactions per second	Scalable

III. CONCLUSION

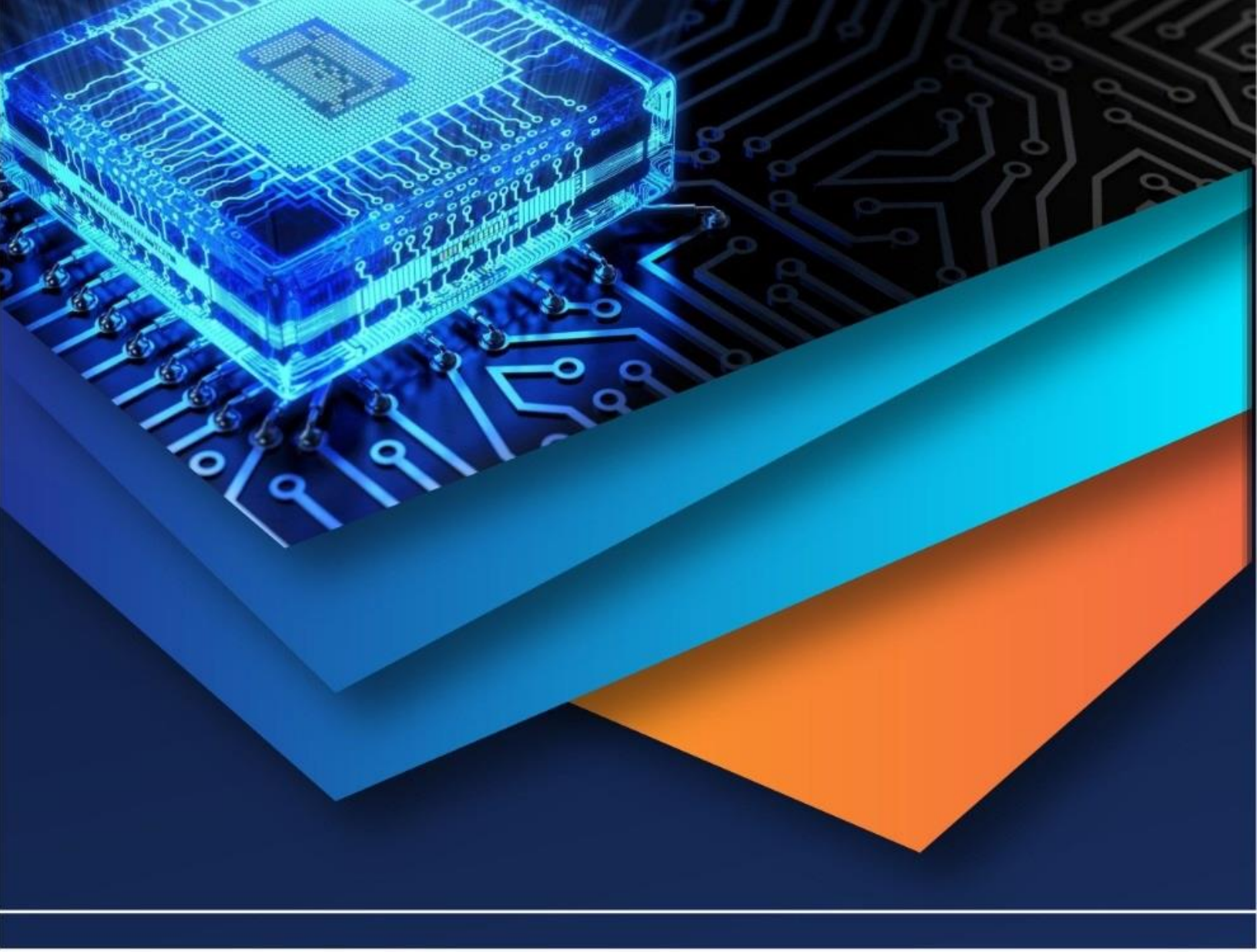
To counteract the sale of fake medicines, this article examines the issue of medication tracing within pharmaceutical supply chains. We looked into a number of conventional and blockchain-based approaches for distributed drug monitoring and tracing in the healthcare supply chain. We have also investigated several blockchain networks like Ethereum, Hyperledger, and others, as well as different consensus algorithms like Proof - Of - work, Proof - Of - stake, and others. We considered the advantages and disadvantages of these strategies and came up with added features like Google's Geolocation API enabling real-time monitoring, QR codes allowing product authentication, including FDA participation throughout each step of the medical supply chain.

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