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## Blockchain technology in drug traceability

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### Abstract

Currently, Drug Counterfeiting is biggest challenge pharma industry is encountering as high market demand of the drugs and due to high profit margin. The lack of data transparency and lack of traceability also lured black market for the counterfeiting which impact Pharma organization and putting the life of the patient in danger. Through the Drug Supply chain substantial portion of the counterfeit drug are getting injected and distributed through healthcare supply chain network, so supply chain is playing vital role in the drug distribution and impact the patient life. Through digitalization in the healthcare sector, Blockchain technology give platform with groundbreaking results via providing the system for the drug traceability with consideration of the critical requirement of transparency, privacy, authenticity with involving any third party. In Blockchain technology, each distribution partner registered to maintain transparency with the drug information. Real time transfer the information about the change of ownership with date and time in forms of blocks giving the visibility to all the partners real time with authenticity of drugs. This article will give the information about the use of the block chain technology benefit to the pharmaceuticals industry and traceability and trackability information of drugs from end-to-end of the pharmaceutical supply chain.

**Keywords:** Drug Traceability; Pharmaceutical Serialization; Supply chain; Blockchain; Enterprise System; Digital Technologies

### 1. Introduction

World Health Organization (WHO) define counterfeits drugs. Which are mislabelled to hide the source or its identity by a unregulated organization. These drugs can be with wrong active ingredients or with wrong quantity of the ingredients. Counterfeit products can include drugs with no active ingredient, drugs that are super potent, and drugs with dangerous impurities.

The Centre for Medicine in the Public Interest reports that the sales of counterfeit drugs are on the rise worldwide, increasing annually at approximately 13%, which is nearly double the growth rate of genuine pharmaceuticals. Primary responsibility is to assign the authority to make medicines in accordance with national standards and to regulate the flow of all manufactured items [1]. As a consequence, regulators and pharmaceutical companies are under pressure to take action to curb the escalating trade in counterfeit medicines. These fake medications can either be camouflaged or misrepresented. [2]. Product serialization is still a major factor behind packaging reform in the pharmaceutical industry as it fights against fraud, duplication, deviation, and false returns to manufacturers. In order to decrease the supply of counterfeit drugs, serialization necessitates a sophisticated program to monitor and regulate the flow of prescription medications throughout the whole supply chain. Direct printing of 2D barcodes onto the prescription medications, packets, and cartons is a requirement for serialization and labelling. Manufacturers, pharmacies, and hospitals use it to monitor their pharmaceutical products. Automatic Identification allows a customer to check the authenticity of a product by using labels. In addition, vision identification is used for real-time barcode recognition that can be applied to products in accordance with the FDA's specific product recognition requirements. Radiofrequency Identification

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(RFID) is another sophisticated serialization technology used [3]. The advancement of technology and the growing interconnectedness of the pharmaceutical trade have brought significant advantages to the global healthcare sector. As a result, individuals now enjoy increased access to essential medications from reputable sources. Nevertheless, this change has also created opportunities for counterfeiters and illegal drug sellers to utilize social media platforms and dark web websites for selling medicines. Several factors motivate individuals to buy medication online, such as overcoming geographical constraints, reduced costs, quicker market access, targeted customer engagement, and wider audience reach [4].

A recent development emphasizes patient-driven interoperability, where patients take a pivotal role in exchanging health data [5]. Nevertheless, the healthcare sector is still in its early stages of building the necessary infrastructure, software solutions, and strategic approaches to effectively integrate diverse data types in a reliable, secure, and consistent manner [6]. Risk is especially common among people of Hispanic ethnicity with limited educational opportunities, living in impoverished conditions, lacking citizenship status, lacking health insurance, and facing significant out-of-pocket healthcare costs [7]. Concerns regarding the traceability of the pharmaceutical supply chain within healthcare are mounting due to issues related to effectiveness. The journey of a product from its manufacturer to the end consumer involves multiple stages, including production, wholesaling, retailing, and eventual consumption. Complications can arise at any point along this chain, ranging from minor human errors to the circulation of counterfeit medications. In our traditional system, pinpointing the precise location of these issues can be a challenging endeavour. In the long term, it is imperative to establish a system in which consumers can track both the source and the route of a medication within the supply chain. This is essential to ensure the authenticity of the medicine they have ingested.

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## 2. Blockchain Technology Overview

Blockchain technology stands out as a paramount innovation of our century. It not only offers improvements in operational and regulatory verification but also elevates the traceability and transparency of supply chains across various industries [8]. The concept of Distributed Ledger Technology (DLT), often referred to as 'blockchain,' has ignited the interest and investments of financial services institutions [9]. Blockchain operates as a decentralized and distributed system, where data is recorded, stored, and managed by a peer-to-peer network of individual computers referred to as nodes. It comprises a series of unchangeable blocks, each bearing a timestamp and connected using cryptographic hashes. When a new block is appended to the end of the chain, it includes a distinct code or reference (referred to as a hash value) to the information appended in a preceding block. This specific hash value is generated by a one-way encrypted hash function [10]. Wholesalers and distributors are tasked with using the cloud-based database hub to authenticate medications at different stages within the supply chain, an essential aspect of the supply chain operation [11]. It enables systems and applications to operate autonomously, free from reliance on third parties and trusted authorities [12]. After the blockchain has completed its information processing, all computers within the network simultaneously establish a permanent, unchangeable digital record. Each blockchain system defines the process and permissions for adding new blocks to the chain [13]. The unique advantages of blockchain technology stem from its ability to enable data and transaction sharing across an unchangeable peer-to-peer network, thus enhancing transparency and security [14]. Although blockchain has primarily found use in cryptocurrency and financial transactions, other sectors like entertainment, manufacturing, and healthcare are increasingly incorporating blockchain technology to harness its enhanced security and privacy advantages [15].

### Core characteristics of blockchain technology

- **Decentralization:** A digital public ledger accessible to all network users, with data distributed across multiple systems. Blockchain technology is well-suited for any digital data that requires authentication and consensus on data integrity, and when shared write access is essential. It can effectively safeguard critical medical information [16].
- **Traceability:** Offers a comprehensive audit trail at every point in the supply chain, including historical records, ensuring the verification of drug authenticity. Enhancing the flow of health data would facilitate remote monitoring and telemedicine consultations by doctors. This, in turn, empowers patients to maintain open communication with their healthcare providers regarding their medical history [17].
- **Immutability:** Data remains securely preserved and is challenging to alter without full access from a node. As reported by the global cybersecurity insurance company Beazley, healthcare organizations were the focus of 45 percent of ransomware attacks in 2017 [18].
- **Autonomy:** Each node operates independently within the blockchain network, ensuring reliability and freedom from external interference.

- **Transparency:** This exceptional feature allows public access to every network node, enabling anyone to verify and track asset information.

The healthcare sector places great significance on blockchain technology due to its role as a public ledger featuring continually updated and strongly encrypted cryptographic records that are unchangeable [19].

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### 3. Need for Blockchain Technology in Pharma Sector

Like all major and minor sectors, the pharmaceutical industry is undergoing substantial transformations to align with the evolving times [20]. Utilizing blockchain technology for tracking and tracing has the capacity to revolutionize the pharmaceutical supply chain. Research has shown that blockchain has the capability to significantly enhance transparency, efficiency, and the trustworthiness of transactions within the pharmaceutical sector, which often lacks stringent regulation. Through blockchain, manufacturers and other stakeholders in the supply chain can achieve real-time data access and improved visibility at every stage, commencing from the manufacturing point.

Major Highlights are [21]

- Enhance the transparency of drug or medication movement across all stages and stakeholders in the value chain. This heightened traceability supports the optimization of drug distribution and a more efficient inventory management system, resulting in significant enhancements in stock planning.
- The drug in transit can be monitored along the entire supply chain, ensuring visibility at every ownership juncture. Moreover, the transparent ledger simplifies the process of tracing the participants or entities engaged in the shipping process. Blockchain possesses the ability to pinpoint the origins of issues that might surface during the drug or medicine supply process.
- Entries are added to the distributed ledger gradually in an incremental manner. This ledger is stored within a peer-to-peer network, guaranteeing that all participants consistently possess identical copies of the ledger.
- Blocks are generated exclusively after all network peers have validated and verified the transactions. This consensus mechanism ensures the accuracy of the information stored in the ledger.
- Pharmaceutical drug origins can be readily traced with the help of blockchain, as ownership transfers are permanently recorded in real-time on the immutable ledger.

Blockchain, an electronic cryptographic ledger, operates on a decentralized network model where data is shared and synchronized across all network nodes [22]. The system utilizes a consensus mechanism to avoid duplicate transactions, enabling nodes to verify data accuracy before promptly appending it to the ledger [23]. Blockchain represents a decentralized architecture for distributed ledger technology, comprised of a series of blocks, each containing transaction data [24]. A meticulously designed blockchain-based system has the potential to greatly streamline the oversight of pharmaceutical turnover for authorized government agencies. In contrast to centralized alternatives, a decentralized approach offers numerous advantages that enhance the security of information in these systems. A blockchain network comprises multiple computers collaborating under a shared protocol to process transactions and append new blocks to the chain. Every user within the public blockchain ecosystem has the capability to observe and scrutinize every transaction transpiring on the network, as well as participate in the consensus-building process [25].

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### 4. Digital Drug Traceability in The Supply Chain

Pharmaceutical medication traceability systems refer to the systems designed to monitor the movement of products or product characteristics throughout the production process or supply chain. In this context, digital technologies are bringing about a transformation in supply chains by enabling adaptable production, automation, and the implementation of sensors to monitor the whereabouts, quality, and authenticity of products [26]. Traceability requirements typically adapt to particular circumstances. The data collection criteria are established according to the fundamental needs and objectives of each organization. The most effective approach to combat illicit trade and address smuggling, in general, involves implementing robust traceability measures [27]. Introducing traceability systems in the pharmaceutical industry is a challenging and frequently expensive undertaking. Government regulations have bolstered the safety of pharmaceutical product distribution, with numerous countries, such as the United States, adopting regulatory frameworks and obligatory standards. This situation has brought about increased operational difficulties for multinational manufacturers and distributors, requiring the creation of adaptable systems to serialize products for various markets in accordance with regional regulatory standards. [28]. In a traceability system, managerial decisions go beyond merely preventing product substitution and falsification during crises. Different stakeholders within the supply chain often place varying degrees of importance on traceability, whether for enhancing risk management or streamlining operational processes. As a result, consumers gain an extra level of value primarily linked to product

quality and safety. Beyond ensuring regulatory compliance, traceability serves as a tool producers can leverage to avert disruptions in market supply that might harm their brand reputation [29]. Essentially, traceability is a crucial component of quality management. Striving to improve and enhance data collection, plant control, and quality assurance can also act as a driving force for the creation of a state-of-the-art internal traceability system. Furthermore, as outlined by Moe (1998), the development of a data model is imperative for monitoring fluctuations in the quantity of unit-traceable resources over time or the historical record of process activity [30]. Implementing, coordinating, and managing serialization demands substantial financial investment and a deep comprehension of pertinent regulations [31]. The main goal of establishing a traceability system is to reevaluate responsibilities and objectives throughout the entire domain of supply chain management. Within a traceability system, managerial decisions encompass more than just crisis-related actions like preventing product substitution and falsification. Traceability often holds varying degrees of importance among different supply chain participants, serving purposes such as enhancing risk management and streamlining management processes. In the end, this provides consumers with increased value, primarily concerning product quality and safety. Beyond ensuring regulatory compliance, this tool enables producers to proactively avert disruptions in market supply that might harm their brand reputation [32].

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## 5. Conclusion

Within a blockchain platform, blockchain technology, with a strong focus on cost-efficiency and safety, holds the potential to enhance pharmaceutical cold chains and combat the counterfeiting of medicines. This research outlines how a blockchain-based system can be beneficial for tracking drugs and identifying counterfeit medications throughout the supply chain. To tackle data storage challenges, blockchain platforms can integrate with cloud storage components. Blockchain possesses the capability to integrate vast and diverse data from multiple sources, effectively enabling the tracking of medication fraud. This technology empowers the tracking of various elements within the pharmaceutical supply chain, including medical supplies, prescriptions, and even temperature monitoring, at any given time. Achieving the right blend of technologies for the redesign of an end-to-end channel design that aligns with the organization's strategic plan requires increased coordination and collaboration between engineering and technology experts and key business decision-makers.

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