

Review Article

Securing Pharmaceutical Supply chain to Combat Active Pharmaceutical Ingredient Counterfeiting

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Abstract: Pharmaceutical Product serialization aims to assign distinct serial numbers to items within a pharmaceutical supply chain. However, this process faces several security challenges like Theft of valid serial numbers may occur, enabling the labelling of counterfeit products. Therefore, it's essential to ensure the uniqueness of serial numbers can be verified at any point in the product's lifecycle within the supply chain. Intimidatory nodes along the distribution network could corrupt planned changes of custody for products. Ensuring verifiability of compliance with these changes is crucial. Manufacturers and consumers need assurance that perishable goods with expired shelf lives are appropriately discarded. In this paper, we review a product serialization method leveraging blockchain technology to address these security concerns within a multi-party perishable goods supply chain. Blockchains offer potential solutions by providing a secure platform for data sharing in multi-party environments, enhancing security and transparency. Within Blockchain technology, each distribution partner is registered to uphold transparency regarding drug information. The system facilitates real-time transfer of ownership changes, recording them as blocks with date and time stamps. This ensures visibility to all partners in real time, maintaining the authenticity of drugs. This article aims to outline how Blockchain technology benefits the pharmaceutical industry by enhancing traceability and trackability of drugs throughout the entire pharmaceutical supply chain.

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1. Introduction

Pharmaceutical serialization aims to assign unique serial numbers to items within a supply chain. These serial numbers can be generated either by the manufacturer or by a regulatory body authorized to allocate them to manufacturers, who then use them to serialize their products. Serialization is crucial for ensuring the authenticity and safety of products. Despite the existence of interoperable data formats and standards for product serialization, the current state-of-the-art lacks adequate security measures, as evidenced by the prevalence of counterfeit products. Reports indicate substantial financial losses and job displacement due to counterfeiting, with counterfeit medicines alone costing billions annually and leading to significant loss of life [1,2].

Pharmaceuticals multi-party supply chain scenario where no single entity has absolute control. Participants include regulators, manufacturers, intermediaries (such as logistics service providers and cold storage facilities), retailers, and consumers. In such a federated supply chain, trust levels among parties vary, and concerns regarding security challenges differ. For instance, regulators may prioritize preventing counterfeit products, while manufacturers focus on discarding expired perishables, and intermediaries emphasize proper custody changes [3,4]. By leverage blockchain technology to devise a

product serialization approach aimed at addressing the aforementioned security concerns. Blockchains have the potential to transform security and transparency within supply chains by serving as a secure data-sharing platform in multi-party settings. However, the scalability of blockchains becomes problematic when dealing with a high volume of events, such as those encountered in product serialization [5].

Recent developments highlight a shift towards patient-driven interoperability, wherein patients play a central role in exchanging health data. However, the healthcare sector is still in its nascent stages of establishing the requisite infrastructure, software solutions, and strategic frameworks to seamlessly integrate diverse data types in a dependable, secure, and consistent manner [6]. Risk is particularly prevalent among individuals of Hispanic ethnicity who have limited educational opportunities, reside in impoverished conditions, lack citizenship status, are uninsured, and face substantial out-of-pocket healthcare expenses. Concerns regarding traceability within the pharmaceutical supply chain are mounting within the healthcare sector due to efficacy-related issues [7]. The journey of a product from its manufacturer to the end consumer encompasses various stages, including production, distribution, retailing, and eventual consumption. Challenges may arise at any point along this continuum, ranging from minor human errors to the proliferation of counterfeit medications. Within system, pinpointing the exact location of these challenges can be a daunting task. However, it is imperative in the long run to establish a system wherein consumers can trace both the origin and trajectory of a medication within the supply chain. This is crucial to guarantee the authenticity of the medicine they consume [8].

2. Active Pharmaceutical Ingredients

An Active Pharmaceutical Ingredient (API) is the biologically active component of a drug product, which produces the intended therapeutic effect [9]. APIs are typically synthesized through chemical or biotechnological processes and formulated with other substances into pharmaceutical dosage forms, such as tablets, capsules, or injections. APIs must meet stringent quality and safety standards before they can be used in medicinal products [10]. The COVID-19 pandemic highlighted vulnerabilities in global supply chains, including those for APIs. Disruptions in transportation, production, and logistics can lead to shortages of critical medicines [11]. Managing risks associated with Active Pharmaceutical Ingredients (APIs) involves addressing various factors to ensure the safety, efficacy, and regulatory compliance of pharmaceutical products.

3. Blockchain Technology Overview

The API (Active Pharmaceutical Ingredient) supply chain involves the process of sourcing, manufacturing, and distributing the biologically active components of pharmaceutical products [12]. The supply chain begins with the sourcing of raw materials needed for the synthesis of APIs. These raw materials can include chemicals, biological materials, or intermediates required for the manufacturing process. APIs must adhere to regulatory requirements set by health authorities in different countries. This includes Good Manufacturing Practices (GMP), which ensure consistent production quality and safety. Given the critical nature of APIs in healthcare, ensuring safety and security throughout the supply chain is paramount. This includes protecting against contamination, theft, or counterfeit products.

Blockchain technology has the potential to revolutionize Enterprise Resource Planning (ERP) systems by enhancing transparency, security, and efficiency in various aspects of business operations [13]. Here's how blockchain could impact ERP systems: Blockchain can provide an immutable and transparent ledger of transactions across the supply chain. This capability ensures that ERP systems can track the movement of goods and raw materials from their origin to the final product. It helps in verifying authenticity,

preventing counterfeit goods, and improving overall supply chain transparency [14, 15]. Blockchain's decentralized and cryptographic nature ensures that data stored on the blockchain is tamper-proof and secure. In ERP systems, this can enhance data integrity across various modules such as finance, inventory management, and customer relationship management (CRM). It reduces the risk of data manipulation and unauthorized access. By automating processes through smart contracts and providing real-time data transparency, blockchain can streamline operations within ERP systems. This leads to faster transaction processing, reduced paperwork, and improved overall efficiency in supply chain management, financial operations, and other business functions. Over time, implementing blockchain in ERP systems can lead to cost savings by eliminating intermediaries, reducing administrative costs, improving inventory management efficiency, and minimizing the risk of fraud and errors.

Blockchain technology emerges as a pivotal innovation of the current era, offering enhancements not only in operational and regulatory verification but also in bolstering the traceability and transparency of supply chains across diverse industries [16]. The concept of Distributed Ledger Technology (DLT), commonly known as 'blockchain,' has spurred the interest and investments of financial services institutions. Operating as a decentralized and distributed system, blockchain records, stores, and manages data through a peer-to-peer network of individual computers known as nodes. It consists of a chain of immutable blocks, each timestamped and interconnected via cryptographic hashes [17, 18]. When a new block is appended, it includes a unique code or reference (hash value) to the information in the preceding block, generated by a one-way encrypted hash function. Wholesalers and distributors utilize a cloud-based database hub to authenticate medications at various stages within the supply chain, a crucial aspect of supply chain operations. This framework enables systems and applications to function autonomously, without reliance on third parties or trusted authorities. Once the blockchain completes its information processing, all network computers simultaneously establish a permanent, unalterable digital record. The distinct advantages of blockchain technology stem from its ability to facilitate data and transaction sharing across an immutable peer-to-peer network, thereby enhancing transparency and security. While blockchain initially found prominence in cryptocurrency and financial transactions, sectors such as entertainment, manufacturing, and healthcare increasingly integrate blockchain technology to leverage its enhanced security and privacy benefits [19, 20].

Key characteristics of blockchain technology include:

- **Decentralization:** A digital public ledger accessible to all network users, with data distributed across multiple systems, making it suitable for authenticating digital data, ensuring consensus on data integrity, and enabling shared write access, particularly valuable in safeguarding critical medical information [21].
- **Traceability:** Offers a comprehensive audit trail at every stage of the supply chain, including historical records, ensuring the verification of drug authenticity, and facilitating the flow of health data for remote monitoring and telemedicine consultations, empowering patients to communicate openly with healthcare providers regarding their medical history [22, 23, 24].
- **Immutability:** Data remains securely preserved and challenging to alter without full access from a node, crucial in light of cybersecurity threats targeting healthcare organizations.
- **Autonomy:** Each node operates independently within the blockchain network, ensuring reliability and freedom from external interference.

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

Given its role as a public ledger featuring continually updated and strongly encrypted cryptographic records that are immutable, the healthcare sector places significant emphasis on blockchain technology [25].

Key security challenges in product serialization include:

- **Security of serial numbers:** Valid serial numbers can be stolen and used for counterfeit labelling, highlighting the need for verifiability of serial number uniqueness throughout the supply chain lifecycle.
- **Secure Change of Custody:** Planned changes in product custody during distribution can be compromised by certain nodes, necessitating verifiable compliance with custody changes by consumers [26].
- **Control over serial numbers for perishable food:** Manufacturers must ensure proper disposal of perishable goods with expired shelf lives.
- **Secure Serialization:** A serialization method that prevents counterfeiters from duplicating genuine serial numbers to label counterfeit products. Existing traceability solutions, proactively prevents the replication of genuine serial numbers [27].
- **Trust in Multi-party Supply Chains:** In multi-party supply chains, trust issues abound as each party seeks assurance regarding the authenticity of shipped products and the absence of expired goods. Existing blockchain-based supply chain management solutions do not effectively resolve these trust concerns.
- **Control for Perishable Goods:** It ensures that products with expired shelf lives are not distributed. Existing blockchain-based supply chain management solutions do not adequately prevent the distribution of expired products.
- **Secure Change of Custody:** Serialization solution guarantees adherence to a predefined distribution path for products. While existing blockchain-based traceability solutions can verify the execution of such paths, they fall short in enforcing them.
- **Scalability:** Serialization Traceability scalability by employing offline channels within the blockchain. existing solutions, except for Hyperledger-based approaches, thereby minimizing the need for trust among parties acting as transaction validators [28, 29].

4. Supply Chain with Digital Serialization

Pharmaceutical medication traceability systems encompass the mechanisms devised to oversee the movement of products or their attributes throughout the production process or supply chain [30]. In the contemporary landscape, digital technologies are revolutionizing supply chains by facilitating adaptable production, automation, and the integration of sensors to monitor product whereabouts, quality, and authenticity [31, 32]. The requisites for traceability are often tailored to specific circumstances, with data collection criteria established based on the unique needs and objectives of each organization. The most effective strategy against illicit trade and smuggling typically involves the implementation of robust traceability measures [33, 34].

Introducing traceability systems in the pharmaceutical sector presents notable challenges and often entails significant expenses. Government regulations have

heightened the safety standards for pharmaceutical distribution, with many countries, including the United States, adopting regulatory frameworks and mandatory standards. Consequently, multinational manufacturers and distributors face increased operational complexities, necessitating the development of adaptable systems to serialize products for different markets in compliance with regional regulatory norms [35, 36, 37].

In a traceability system, managerial decisions extend beyond mere prevention of product substitution and falsification during crises. Various stakeholders within the supply chain assign differing levels of importance to traceability, whether for enhancing risk management or streamlining operational processes [38]. Consequently, consumers derive added value primarily linked to product quality and safety. Traceability, beyond ensuring regulatory adherence, serves as a tool for producers to mitigate disruptions in market supply that could tarnish their brand reputation [39, 40].

Essentially, traceability constitutes a critical component of quality management. The pursuit of improving data collection, plant control, and quality assurance can serve as a driving force for establishing a cutting-edge internal traceability system. Furthermore, as emphasized by Moe (1998), the development of a data model is essential for monitoring fluctuations in the quantity of unit-traceable resources over time or maintaining a historical record of process activity [41, 42, 43].

5. Conclusion

The utilization of blockchain within the healthcare domain plays a pivotal role in the market landscape. Pharmaceuticals Supply Chain presents a distinctive approach to implementing a traceability system, which can be utilized by auditing agencies and consumers alike to verify the authenticity of pharmaceutical drugs. Embedded within a blockchain platform, this technology, with a strong emphasis on cost-efficiency and safety, holds significant promise in enhancing pharmaceutical cold chains and combating the proliferation of counterfeit medicines. This study delineates how a blockchain-based system can offer advantages in tracking drugs and detecting counterfeit medications across the supply chain.

To address challenges associated with data storage, blockchain platforms can seamlessly integrate with cloud storage components. Moreover, blockchain demonstrates the capability to amalgamate extensive and varied data from numerous sources, facilitating effective tracking of medication fraud. This technology empowers the monitoring of various facets within the pharmaceutical supply chain, encompassing medical supplies, prescriptions, and even temperature monitoring, at any given moment. The attainment of an optimal amalgamation of technologies for the reconfiguration of an end-to-end channel design, aligning with the organization's strategic objectives, necessitates heightened coordination and collaboration between engineering and technology experts alongside key business decision-makers.

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