

Review Article

Pharmaceutical Drug Traceability by Blockchain and IoT in Enterprise Systems

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Abstract: Pharmaceutical drug traceability is a regulatory compliance adopted by most nations in the world. A comprehensive analysis was carried out to explain the benefits of adopting enterprise system for pharmaceutical drug traceability. Counterfeit drugs are medicines that are fake and have been produced using incorrect potency, or incorrect ingredients used to manufacture these drugs. Solving the drug counterfeiting problems by identifying the most effective and innovative technologies for protecting people's health is of essence these days for the world. Drug serialization is essential concept for drug traceability in the pharmaceutical supply chain. Blockchain is the latest stringent technology that makes drug distribution more secure in the supply chain. The blockchain-based drug traceability is a distributed shared data platform that shares information that is irreversible, reliable, responsible, and transparent in the PSC. Blockchain uses two powerful module, Hyperledger Fabric and Besu to satisfy important criteria for medication traceability, such as privacy, trust, transparency, security, authorization and authentication, and scalability. Researchers in Health informatics can use blockchain designs as a useful road map to develop and implement end-to-end pharmaceutical drug traceability in the supply chain to prevent drug counterfeiting. Industrial IoT is also a key component for the pharmaceutical industry. IoT systems in pharmaceutical drug traceability can be beneficial as they are based on automation and computational methodologies.

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1. Introduction

In the modern world, digital transformation is altering business practices and, in some cases, introducing completely new categories of industries. Pharmaceutical firms are taking a step back and reviewing everything they do as a result of the digital transformation, from internal processes to in-person and online client interactions. Counterfeit drugs are those that have been intentionally produced fraudulently or with inaccurate labels on their identity or source in order to pass for legitimate ones [1, 2]. Efforts to track and trace pharmaceutical medications in the supply chain to prevent counterfeiting are not a new process. In addition to markets like China and South Korea, Turkey adopted serialization regulations in 2010 whereas other countries like South Korea and China already have drug traceability compliance in their law. Many nations around the world have begun to emphasize and even require the significance of drug traceability. In order to identify and track specific prescription pharmaceuticals as they are distributed in the US, the Drug Supply Chain Security Act (DSCSA), a US regulatory agency, has laid down measures to achieve interoperable, electronic tracing of drugs at the package level [3]. The Falsified Medicine Directive (EU-FMD) was implemented by the European Union in February 2019 to digitally track each unit of medication and combat illicit

pharmaceuticals on the European market. Every single prescribed drug unit is required by law to contain a 2D barcode with human readable coding that includes the traditional batch number, expiration date, product code, unique serial number, and anti-tamper device [4]. The World Health Organization (WHO) estimates that during market circulation, one out of every ten pharmaceuticals in low- to middle-income countries (especially Southeast Asia and Africa) is faked or subpar [5]. Venhuis advised utilizing distinctive 2D barcodes on every prescription box to make scanning easier and display the medication's history and other vital details [6]. Implementing digital tracking of pharmaceutical drugs in the supply chain reduces the danger of illegal and counterfeit pharmaceuticals entering the market. A 2D data matrix, which can capture electronically encoded information like a manufacturer ID, product ID, or a distinctive ID that is frequently used on medication packages, is another sort of barcode that Klein and Stolk mentioned [7]. Due to larger profits, the pharmaceutical sector is particularly alluring to illegal drug dealers. Some criminals used illicit networks to divert legal or inferior medicines from other nations [8]. The health sector's income and ability to invest in pharmaceutical study, invention, and economic development are decreased by the illegal drug trade. Additionally, it pushes pharmaceutical companies to cut back on their human resources, which results in the loss of high-paying positions. Four different scenarios with projected worldwide counterfeit medication markets of \$100 billion, \$200 billion, \$300 billion, and \$431 billion each are assessed in order to determine the exact size of the market [9].

Summary of Annual Economic Costs Due to Counterfeit Drugs

	ESTIMATED SIZE OF GLOBAL COUNTERFEIT DRUG SALES			
	\$100 BILLION	\$200 BILLION	\$300 BILLION	\$431 BILLION
Lost R&D Revenue (billions)	\$17.00	\$34.00	\$51.00	\$73.30
Lost Number of New Drugs	6	13	19	28
Lost Revenue to U.S. Industry (billions)	\$37.60	\$75.20	\$112.80	\$162.10
Lost U.S. Output (billions)	\$82.00	\$163.90	\$245.90	\$353.30
Lost Federal and State Tax Revenue (billions)	\$4.50	\$9.00	\$13.60	\$19.50
Lost U.S. Jobs	57,495	114,990	172,485	247,803

Figure 1. Estimated size of Global Counterfeit Drugs sales

Online sales account up 7 to 10% of the global economy, according to 2011 research by the World Economic Forum [10]. The majority of the younger population uses the internet for social media, chatting, and online shopping, including buying prescription drugs. It was shown that most American consumers purchase prescription drugs online due to affordability and convenience. The majority of consumers were unaware of the possible risks posed by fake medications. Additionally, individuals are rarely informed about the potential health hazards associated with ordering medications online by doctors, nurses, or other healthcare professionals [11]. Strict regulations must be put in place, and the supplying of fake drugs must be punished severely with imprisonment. To allow internet pharmacies to sell medications on their platform, a centralized monitoring organization must assess the social media policies and their content [12].

2. Pharmaceutical Drug Traceability in Enterprise System Controlled Environment

Criminals are taking advantage of social media platforms, internet websites, and the dark web in the age of e-commerce to advertise their possibly harmful fake medications. The development of new technologies and the expansion of the global pharmaceutical market have benefited the global healthcare sector by preventing the sale of counterfeit drugs. By using enterprise systems, we can reduce adverse events in the supply chain as it makes processes automatic without human interaction whenever necessary. It sets up more training and embraces tools and technologies for quality improvement. Organizations have been forced to abandon their internal and external rules and

implement cutting-edge enterprise systems and specialized technologies due to the complicated environment and extraordinarily difficult task of ensuring pharmaceutical compliance in the digital supply chain. Due to these difficulties, the pharmaceutical industry must rethink how it handles present problems and adopt enterprise technologies to improve compliance responses. Creating a compliance steering committee that will keep an eye on things and consult with stakeholders on the important concerns is one potential option. This will make sure that compliance-related tasks are given the highest priority for potential improvement as a scrutinized and risk-free environment is developed. The QC laboratory is crucial to the production of pharmaceuticals. Its testing validates the product's quality, and the reports it produces offer the supporting documentation. Testing at different phases of manufacturing produces enormous volumes of data, and these should show whether quality has been maintained throughout the procedure. In the controlled environment of an enterprise system, it can handle large amounts of data and process it securely. Non-compliance in the pharmaceutical industry is a serious problem that can have a disastrous effect on production and other business operations [13]. In controlled enterprise system environment, all system must be validated and compliant as per traceability such as 21CFR Part 11. Supply chains and manufacturing procedures for pharmaceuticals are very intricate. Both big and small businesses are frequently wholly or even mostly dependent on their outsourced manufacturing partners. In the pharmaceutical industry, purchasing commercial enterprise systems is a crucial component of the strategic strategy for achieving growth and resilience. Internal auditing is an unbiased, impartial assurance and consultation process intended to enhance an organization's operations [14]. Regional laws describe internal auditing for EU members as "self-inspection" and "measurement, analysis, and improvement" (ISO 9000:2000) [15, 16]. Pharmaceutical businesses can take use of the chance to invest in enterprise systems to find non-strategic assets and sell them to a willing buyer who would then continue to supply the seller with finished goods. It will assist small manufacturers in overcoming financial challenges and arranging funding to invest in business systems to reduce the risk of defects [17]. Any negative event that occurs in the pharmaceutical supply chain might endanger the lives of patients by preventing them from accessing medicines owing to a shortage in addition to affecting the drug potency and shelf life due to the delay [18]. Implementing digital traceability of pharmaceutical drugs in the enterprise system has proven to be an incredibly effective way to reduce the danger of illegal and counterfeit drugs entering the market [19, 20]. The ideal way to identify and track each and every raw material from reception to processing, packing, and shipment to the particular client location is to adopt an enterprise system in the pharmaceutical industry. Businesses operate in one of the most heavily regulated industries in the world, with regulations affecting product creation, R&D, traceability, quality control, and reporting. Organizations must not only lead the way in innovation but also adhere to strictly controlled procedures to create products that meet the highest quality requirements.

3. Technologies Used in Enterprise System for Combating Anti-Drug Counterfeit

The ideal anti-counterfeit technology in enterprise system should have a high level of safety, faster product application and authentication, established standards, be challenging to remove and reapply, simple to check, have automatic authentication, be accessible to consumers, and be compliant with industry regulations [21]. There are numerous anti-counterfeit technologies available today, each with specific benefits and downsides [22]. Medicine packaging in the packaging line is a critical process in an enterprise system [23]. The anti-tampering device in medication packaging is the component of verification that establishes the anti-tampering device's integrity and determines whether the packaging has been opened or modified since it left the manufacturer, assuring that the packaging's contents are genuine. [24]. Packaging with an indicator or barrier to entrance that, if broken or absent, should alert customers visually

or audibly that tampering has happened [25]. Authentication features can be embedded either on the dose or on packaging of the drugs [26].

4. Blockchain Technology for Drug Traceability in Enterprise System

Pharmaceutical businesses have been forced to deal with difficulties with regard to the creation and distribution of fake medications, which has a substantial impact on the sector. Blockchain technology is an effective and reliable solution for product traceability offered by the decentralized, distributed ledger system [27]. This article conducts a systematic and thorough review of the research on traceability technologies in enterprise systems for identifying fraudulent drugs and ensuring a secure pharmaceutical supply chain. The significance of implementing cutting-edge technologies such as blockchain in the enterprise system to resolve supply chain issues in the pharmaceutical industry. In order to achieve a safe distribution of drugs and identify fakes, it evaluates the application of traceability technologies in enterprise systems, obstacles to their adoption, and crucial success elements in various phases of the supply chain. On the other hand, small pharmaceutical companies typically lack the financial resources to set up significant production facilities [28]. Mackey and Nayyar [29] investigated the existing and developing technological advances that can be used to track and verify the validity of expensive drugs. Drug fraud can happen at any point along the supply chain. The problem of pharmaceutical drug traceability can, however, be efficiently solved by blockchain technologies in enterprise systems. By offering item-level tracking tools, it can improve supply chain resilience for pharmaceutical companies and benefit all stakeholders [30]. For sharing safe information, blockchain is more appropriate. A blockchain is a collection of time-stamped, fixed, and unchangeable data that is stored and maintained by a number of decentralized computers and is not held by a single entity [31]. Pharmaceutical supply chain is further trying to adopt new secure technologies like block chain in interoperable digital communications between all stakeholders [32]. Information sharing through a blockchain is advantageous since it makes it difficult to falsify the information. The safety, consistency, and accessibility of information are only a few of the obstacles and vulnerabilities that this technology feature can assist in overcoming in many systems [33]. Due to the fact that all parties and organizations involved in a supply chain share this information, the architecture of blockchain technology in enterprise system has been intended for rendering it challenging to make modifications to the information without being discovered [34]. The fact that information can be quickly retrieved from any location in the world is another crucial feature of blockchain in enterprise systems. It does not, however, imply that everyone has easy access to the knowledge. Only authorized stakeholders can access blockchain because of its strong security. Blockchain technology in enterprise systems can be used to stop the supply chain's spread of fake medications [35]. FDA is also assessing blockchain technology through a pilot project. Although blockchain technology has previously been shown to be effective in healthcare applications, it is vital to comprehend blockchain technology before dealing with its applications [36]. Glover and Hermans studied conceivable advantages of blockchain technology, demonstrating how they could be used to enhance clinical trials by ensuring that the raw materials used in them contained adequate amounts of APIs from various credible vendors and that all participating supply chain partners [37]. Blockchain technology is based on public and private network. While the private blockchain is restricted to only one company or a small group of individuals, the public blockchain is open to all nodes in the network. While the private blockchain maintains data privacy amongst its users within an enterprise, all users of the private network have access to or view the data [38]. Most corporate system-level Decentralized Applications (DApps) maintain their intermediate records in a centrally managed database or storage technique before developing front-end applications [39].

5. Pharmaceutical Cold Chain in Enterprise System

The pharmaceutical cold chain is a unique area of the logistics sector, which has stringent guidelines for the supply chain's storage and transportation. Realizing credible traceability throughout the whole life cycle of pharmaceutical products is vital to increase the credibility of pharmaceutical products and guarantee people's safety. A blockchain-based, cloud-based, and IoT-based pharmaceutical cold chain monitoring system is presented to realize reliable product traceability across the whole life cycle and guarantee product safety [40]. The cold chain monitoring subprocess involves three different kinds of corporate organizations. They serve as the recipient, the cold chain transporter, and the provider. They all produce different kinds and amounts of business data. An overview of cold chain warehousing is provided by the enterprise system's cold chain process, which also provides the framework for smart inventory management based on blockchain data. The management of the pharmaceutical cold chain's inventory is crucial. The warehouse is the center of the supply chain, according to contemporary supply chain theory. The corporate system can achieve the blockchain- and cloud-based data-based intelligent inventory management process. The blockchain-based tracking framework can meet the deep learning training process's needs for both amount and quality of data. The relationship between the data of the entire supply chain is determined by using the traceability system that blockchain has built. Cold chain maintenance is quite expensive and involves the construction of vast infrastructure. Even with the necessary infrastructure in place, maintaining the required cold chain can be quite challenging. Poor supplier procedures, improper refrigeration equipment design, and occasionally the placement of goods and packages in storage containers can all lead to cold chain failure [41]. Food waste, higher expenses, and negative effects on the environment are the results of inefficient cold chains. Temperature control is necessary during the final few miles of delivery to the consumer due to the rising demand for meal packages for home delivery. Although they are employed, refrigerated vehicles are expensive to operate. Many businesses have started using traditional non-refrigerated cars instead, but with insulated delivery packages to give thermal protection, in order to get around this issue. Due to the rise in meal-kit subscriptions and greater consumer knowledge of packaging material end of life possibilities, there are new opportunities and problems in the field of cold chain logistics. Significant functions and priorities of authorities determine the adoption and integration of strategic initiatives in the cold chain into the enterprise system within pharmaceutical supply chain. Enterprise systems not only help to increase productivity but also safety and patient satisfaction. Blockchain enabled cold chain can be successfully used in a variety of healthcare sub-areas, including maintaining electronic health records, protecting privacy, and dealing with quality and security concerns.

6. IoT Enabled Pharmaceutical drug traceability in Enterprise System

A significant obstacle to providing healthcare services properly is the issue of fake medications. It is addressed worldwide, not just in underdeveloped nations [42]. An interconnected computer network with unique identifiers (UIDs) that can transport data over a network is known as the Internet of Things. IoT may be helpful in managing and enhancing various unit operations throughout the production of the pharmaceutical product for real-time monitoring and control to increase production efficiency [43]. IoT and blockchain technologies are expected to become increasingly important in a variety of fields in the future. Because of its adaptability in many areas, including pharmaceutical drug traceability in enterprise systems, IoT is a very well-liked technology. The enterprise system's use of blockchain and IoT meets the need for pharmaceutical security and timely delivery of drugs without error. Blockchain technology based on the Internet of Things (IoT) is based on distributed ledger (DLT) that keeps an immutable record of all transaction data that cannot be altered and is available to all participants. By implementing an IoT-

based blockchain system, the pharmaceutical industry would have the resources necessary to enhance drug governance throughout the supply chain, improving the effectiveness and dependability of healthcare. The Internet of Things has proven its promise in operations like supply chain, in addition to being a breakthrough technology for all industries [44]. One of the primary objectives of IoT adoption enterprise system is tracking and monitoring [45]. IoT devices and data analysis systems are used by corporate system managers to enhance decision quality and boost the precision of delivery forecasts. One of the most significant technological advancements occurring in warehouses is the incorporation of IoT-based pharmaceutical supply chain management systems. Its advantages include better inventory management, worker safety, and warehousing process efficiency. Utilizing the Internet of Things in the pharmaceutical sector has many advantages. These advantages include thorough monitoring through intelligent sensors, automation of processes utilizing robots, drones, and other autonomous vehicles, and the creation of new commercial transaction models. The convergence of blockchain, AI, and the Internet of Things will revolutionize the way that medications and health items are supplied [46].

7. Conclusion

Innovative technologies are taken into consideration as a potential component in increasing the efficiency of their supply chain due to the complicated nature of the supply chain and in order to enhance the business processes. One of the most significant sources of big data generation in pharmaceutical enterprise systems for drug traceability is one of these new IoT technologies. Additionally, supply chain management can be offered to the consumer using other IoT and blockchain features including promoting item communication, integrating monitoring devices, data analysis, pharmaceutical drug traceability and using cyberspace. To do this, the enterprise system environment must offer a model that describes the connections between Internet technologies and logistical systems, cloud computing, and physical items. Implementation of blockchain and IoT enabled technologies in pharmaceutical organizations for drug traceability demonstrates that this strategy plays a significant role in enterprise system. It has the satisfaction of customers and at the same time the owners of these industries. It increases organizational efficiency, accelerates audience access to products, ensures the health of products, and prevents energy loss.

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