(REVIEW ARTICLE)

Optimizing pharmaceutical supply chain with digital technologies

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Abstract

The pharmaceutical supply chain environment has undergone tremendous change in recent decades due to technology, and this shift is intensifying. One of the main concerns of business practitioners is how to cost-effectively integrate, implement, and manage technologies across the supply chain of an organization. Pharmaceutical organizations that produce, ship, and supply goods have trouble tracking their goods, which makes it easier for counterfeiters to get fake medications into the system. The creation and implementation of a stringent technological system might be a significant step in the arduous battle against the prevalence of fake medications and other healthcare items. In supply chain management, digital technologies have a number of potential advantages. The usage of the Internet of Things in supply chains can make every component visible and create a visible supply chain, making it possible to identify the position and specifications of all the components and materials in the supply chain at any given time.

Keywords: Pharmaceutical Supply Chain; Drug Traceability; Drug Counterfeit; Pharmaceutical Serialization; Track and Trace System; Enterprise System; Blockchain; IoT

1. Introduction

A supply chain with numerous members is used to move medicines. The manufacturer, wholesaler, and retailer are typically among them. They are involved in the manufacture, distribution, and sale of these goods. Another important player in these systems is the regulating body in charge of overseeing each phase of the flow of product batches throughout the chain. This participant may specifically be a state-level authorized state apparatus body, such as a special agency for the control of pharmaceutical product turnover. Its 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]. The creation of inter-organizational networks that enable the processing and exchange of information in real time has been made possible by the development of modern information technology (IT) solutions. This has allowed for numerous controls, including traceability in supply chains [2, 3]. In several businesses, traceability has emerged as a differentiation factor. Due to stricter supervision by governments and international organizations, the pharmaceutical sector, along with the food industry has been attracting academics' attention more than other industries, while safety and quality in the industry have captured the attention of the entire globe [4]. The deployment of efficient drug traceability systems is fraught with difficulties, so it's crucial to pinpoint the CSFs for these systems. There are theoretical gaps in the research on the deployment of traceability systems and the production of value in various pharmaceutical supply chains [5, 6]. Pharmaceutical supply chains are affected by counterfeiting and theft problems, which risk not only the earnings and brands of producers, distributors, drug stores, and hospitals but also public well-being and consumer safety [7, 8]. Traceability is crucial in a variety of contexts, but it is especially important in supply chains with many partners involved and strict requirements for success [9]. The wholesalers and distributors should be in charge of using the cloud-based database hub to check the validity of medications all along the supply chain as part of the supply chain process. Before delivering medications to patients, dispensers and pharmacies connected to a cloud-based database hub must authenticate the unique product identity, the lot number, and the expiration date with the database [10].

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2. Digital Drug Traceability in The Supply Chain

Systems created to track the flow of products or product attributes via the production process or supply chain are referred to as pharmaceutical medication traceability systems. By enabling flexible production, automation, and the use of sensors to track the location, quality, and authenticity of products, digital technologies are, in this context, revolutionizing supply chains [11]. Requirements for traceability generally change based on the situation. Based on the fundamental requirements and goals of any organization, the information that must be gathered is decided. The best strategy for preventing illegal commerce and dealing with smuggling in general is to provide traceability [12]. The deployment of traceability systems by the pharmaceutical sector is a challenging and frequently expensive task. Government rules have improved the safety of the pharmaceutical product distribution process. United States of America Many nations around the world are adopting regulatory frameworks and their mandatory requirements, which increases some operational challenges for multinational manufacturing and distribution and forces producers and distributors to develop adaptable systems to serialize goods shipped to various markets in accordance with regional regulatory standards [13, 14, 15]. In a traceability system, managerial choices about the value chain extend beyond crisis-related product substitution and falsification avoidance. Traceability is frequently valued differently by supply chain actors, including for improving risk management and management process effectiveness. This provides consumers with added value that is mostly linked to quality and safety. In addition to making sure that the necessary regulations are followed, this is a tool that producers may use to prevent an interruption in market supply that could damage their brand [16]. In essence, traceability is a component of quality management. The effort to enhance and boost the effectiveness of data collection, plant control, and quality assurance can also serve as a catalyst for the development of a cutting-edge internal traceability system. Additionally, according to Moe (1998), a data model must be developed in order to track the variation in the amount of unit-traceable resources over time or the history of process activity [17]. Since data flow happens across several firms, traceability systems demand the sharing of information and the usage of a common language. In the United States, Digital data interoperability is main attribute of FDA's Enhanced Drug Distribution Security (EDDS) project. According to FDA regulations, trading partners and federal, state, and local authorities are required to monitor the quality of prescription pharmaceuticals and safeguard the supply chain's integrity [18]. The main goal of implementing a traceability system is to reevaluate the duties and goals of the entire supply chain management. In a traceability system, managerial choices about the value chain extend beyond crisis-related product substitution and falsification avoidance. Traceability is frequently valued differently by supply chain actors, including improving risk management and management process effectiveness. This provides consumers with added value that is mostly linked to quality and safety. In addition to making sure that the necessary regulations are followed, this is a tool that producers may use to prevent an interruption in the market supply that could damage their brand [19]. The control of serialization has shown to be quite effective in preventing the sale of counterfeit medications. By using improved tamper-proof packaging techniques, GS1 2D Barcodes on labels, and interoperable digital data interchange for drug tracking and verifications, new secure technologies introduce new ways to identify and assure the safety of pharmaceuticals [20].

3. Blockchain Technology Securing Pharmaceutical Supply Chain

An electronic cryptographic registry known as blockchain is built on a decentralized network concept in which data is disseminated and synchronized among all network nodes [21]. A consensus technique used in the system to prevent repeated transactions offers this functionality, enabling nodes to confirm the accuracy of data before it is immediately recorded to the registry [22]. For authorized governmental agencies, a well-designed blockchain-based system can greatly ease the task of controlling drug turnover. In contrast to centralized equivalents, a decentralized method has a variety of benefits that raise the information security of such systems. A blockchain network is made up of a collection of these computers that work together as a network under a common protocol to perform transactions and add new blocks to the chain. Every user of the public blockchain has the ability to view and examine every transaction occurring on the network, as well as take part in consensus building [23]. The authenticity of transactions on the public blockchain is established by participant consensus; there is no administrative node that verifies them. With one exception, a private blockchain is comparable to the preceding variety. Such a distributed register completely prohibits the public from accessing any of its data. The data kept on blockchain can only be accessed by members who have been given permission by the administrative node. Such systems can be developed using platforms like Hyperledger or Multichain [24]. Blockchain technology is increasingly becoming relevant in the context of a global supply chain. Although blockchain technology was initially launched within the bitcoin framework as a platform for digital currency, its applicability has quickly expanded into several industries, including supply chains for agriculture, prescription drugs, and transportation [25]. Blockchain technology is being used by pharmaceutical supply chains to protect international trade against fake medications that might damage sales and injure unwary consumers. Blockchain technology is being used in physical distribution and transportation systems to track shipments and improve supply chain visibility [26]. Blockchain

technology can also be used to offer security in the IoT and machine learning contexts of smart factories. Blockchains can improve upstream and downstream visibility for all linked supply chain participants in a global supply chain. As a result, trading partners may become more trustworthy because each member has a better understanding of the operations of several other partners [27]. Through shorter lead times and better response, this increased degree of transparency can help all participants in the supply chain, and there is also an underlying link to sustainability. Through a secure blockchain, upstream partners may be sure that the materials used in their processes were procured sustainably, with no harm done to the environment or the workers, and no child labor or forced labor. Blockchain technology can safeguard the reputations of numerous consumer product companies as well as the brands they sell. However, the problem still exists because a trade partner within a global supply chain could criticize what a partner is doing in terms of sustainability standards. Due to the increased degrees of sustainability that customers, governments, and nongovernmental organizations are demanding from businesses and their supply chains, not all of these groups can be satisfied. To prove that the beans were cultivated sustainably and the employees were treated decently, a blockchain network is being created to trace coffee from the farmer to the customer. To enable consumers to trace the origin of the coffee and follow its path through the supply chain of dealers, roasters, manufacturers, and distributors, a smartphone app named "Thank My Farmer" is scheduled for release in March 2020. Farmer product tracking projects from farm to retailer are being developed by IBM, Microsoft, and SAP. [28]

4. Internet of Things (IoT) and Machine Learning (ML) Enhancing Drug Traceability

Health-related data, such as electronic health records and traceability, have created new difficulties for data administration, processing, and storage in recent years. However, the management of health information in cyber-physical systems (CPS) can be improved with the use of technologies like Cloud Computing and Big Data. Multiple connected devices with the ability to turn on and off the internet so they may use software and automated procedures for smart applications are known as the Internet of Things (IoT) [29]. The Internet of Things (IoT) is a system that operates across a network with individually identified machines, devices, animals, items, and people that are connected and have the capability of exchanging data without interacting with one another [30]. Research on IoT has quickly expanded with a surge of studies addressing cutting-edge applications in SCM and logistics as supply chains have grown smarter, more technologically driven, and more interwoven. RFID tags connected to a network, for instance, can establish communication to convey identifying data [31]. The IoT integrated blockchain system essentially offers enough advantages, such as connecting the flow links in the supply chain to increase the efficiency of the supply chain network, making the system transparent to reduce code of conduct violations across the supply chain networks, and the immutable properties aiding the stakeholders in tracking the products throughout the networks [32]. Global supply chain networks are becoming more automated thanks to developments in big data, analytics, and computing power. Big data and sophisticated analytical tools can be utilized to develop more accurate predictive models that could be applied to global supply chain coordination [33]. As with the installation of any technology, the success of AI implementation depends on upper management support and a distinct focus on business strategy. Massive volumes of data are gathered by businesses to fuel technologies like AI, but this data must be sifted for the technology's commercial applications. For the adoption of AI to be successful, interdisciplinary teams made up of technical and data specialists will be needed to guide users in understanding the value and application of the technology [34].

5. Emerging Enterprise Technologies in Pharmaceutical Supply Chain

The qualities of the technological environment are referred to as technological factors, and they might affect how widely used drug traceability systems are within an organization. These elements, which promote the adoption of information technology within the company, include a variety of technological aspects, such as the relative benefit of the system's information quality. The environmental dimension refers to the framework in which a business develops its industry, competitors, and government interactions, whereas organizational factors allude to the scope, resources, and scale of an organization [35]. Manufacturing and, ultimately, the organization and management of global supply chains have undergone some extremely notable advancements. The fourth phase of the industrial revolution is now underway. Each era has had shocks that have caused the restructuring of social norms, global economies, and industrial management [36]. A higher degree of business intelligence will be gathered more quickly thanks to the emergence of big data and sophisticated analytical methodologies. The smart factories of Industry 4.0 will also be built in part by new types of human-machine interactions (like touch interfaces and other biometric authentication) and advancements in digital transfers (such as improved robotics and 3-D printing). Illegal online stores are a prime source of counterfeit drugs in the supply chain [37]. Adopting new technologies such as enhanced VPN and blockchain in digital networks can reduce illegal online stores presence on social media and the dark web. An ERP system is a computer system designed to bring together the components and operations of each department into a single, all-encompassing computer system. In actuality, the main goal of ERP is to improve information flow throughout all areas of a company's internal operations

while managing the business. Pharmaceutical companies handle daily corporate operations, distribution, manufacturing, and accounting more easily using a computer platform called enterprise resource planning for "drug traceability requirements". It helps you coordinate your efforts to more effectively manage your daily operations while streamlining procedures. Both small and large businesses consider ERP to be crucial. ERP software enhances efficiency and accuracy to reduce costly errors and delays and is a critical component of everyday operations, productivity, and record-keeping. A single source of truth provided by ERP systems can provide data integrity and eliminate redundant data. With the capabilities of this program, you can increase data visibility and process efficiency [38]

6. Conclusion

Adoption of the new technology can help the global supply chain operate better for upstream and/or downstream applications. While the downstream applications concentrate on the fulfilment applications and refer to the replenishment system upstream, they both place a strong emphasis on the channel design for speed and efficiency. To ensure that they implement and manage the proper mix of technologies in the redesign of end-to-end channel design that supports the objectives of the organization's strategic plan, this will necessitate a higher level of coordination and collaboration between engineering and technology professionals and business decision-makers. IoT enables devices to connect with other objects for better decision-making with advanced business analytics and AI aimed toward targeted business results thanks to developing technologies and the convergence of sensors.

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