e-ISJN: A4372-3114
p-ISJN: A4372-3115

ISSN: 2321-7782 (Online)
ISSN: 2347-1778 (Print)
Impact Factor: 7.529

Volume 10, Issue 11, November 2022

International Journal of Advance Research in Computer Science and Management Studies

Research Article / Survey Paper / Case Study

Available online at: www.ijarcsms.com

Critical Success Factors of the Blockchain in the Pharmaceutical Enterprise Business

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DOI: https://doi.org/10.61161/ijarcsms.v10i11.16

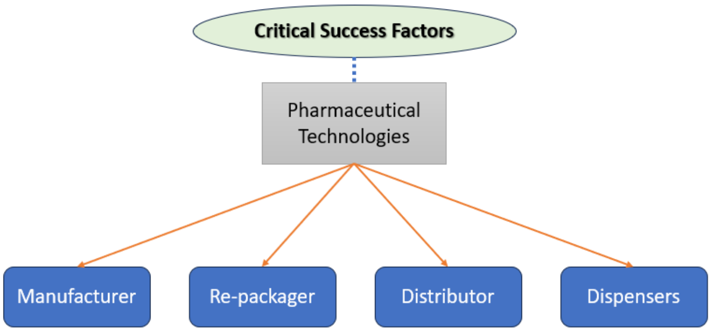
Abstract: Pharmaceutical Drug counterfeiting has been a global problem for nearly 20 years, and the most recent data indicates that phony drugs will keep finding their way into the supply chains of real pharmaceutical companies. At order to tackle the issue of counterfeit drugs, it is imperative to recognize the challenges that the pharmaceutical supply chain faces. This will necessitate the use of technology at various phases of the supply chain to improve visibility. To achieve the following goals, a review of the literature was done in this regard: examine how traceability technologies have been applied in different PSC phases to identify counterfeits; assess the various obstacles preventing the creation of a safe supply chain and the crucial success factors that have been employed to overcome those obstacles; and create a conceptual framework and set of guidelines to illustrate how traceability technologies and success factors have an impact on overcoming the various obstacles in various supply chain phases. This review's main conclusion was that constructing a secure supply chain can be facilitated by leveraging traceability technologies and crucial success elements

Keywords: Enterprise Resource Planning, Digital Supply Chain, Big Data, SAP, Enterprise Business Application, IoT.

I. INTRODUCTION

The development of supply chain management involves a number of management tasks, including sourcing, conventions, manufacturing operations, marketing, product design, financing, procurement, and all logistics-related activities. Pharmaceutical companies can experience problems with their business processes as a result of their wide range of activities. These problems include those related to supplier selection, purchasing, warehousing, data accuracy, and the increased complexity and distribution of operations because of their complex context. The creation and distribution of fake medications has presented difficulties for pharmaceutical businesses recently, which has had a big impact on the sector. Fake medications that mimic real medications and endanger a patient's health are known as counterfeit drugs. Due to manufacturers' and distributors' poor supply chain management, counterfeiters and smugglers have developed quickly, become extremely skilled at creating fake medications, and are now proficient at smuggling them into genuine supply chains. As a result, many fake medications go undetected [1]. Global agencies including the World Health Organization (WHO), the European Union (EU), and the US Food and Drug Administration (FDA) collaborate to stop the spread of this horrifying crime in order to safeguard patient security and safety [2]. Compared to other kinds of supply chains, pharmaceutical supply chains are more intricate. The primary cause of this is the frequent transfers of ownership of pharmaceuticals between raw material suppliers and patients. Businesses are at risk when manufacturers and distributors are unable to provide a sufficient supply. For example, mistakes in drug distribution, storage, temperature, composition, and manufacturing methods can result in drugs that are not effective or that have fatal side effects. Drugs that are counterfeit may contain hazardous substances that become dangerous when taken by humans, or they may contain no active ingredients at all. Due to the pharmaceutical companies' missteps, people are forced to pay for goods that have little to no medicinal benefit, which leads to a host of other problems [3]. The pharmaceutical sector has implemented strategies to address the issue as a result of the problem's growing intensity over time and growing competitiveness. The pharmaceutical industry has therefore adopted a number of potential solutions, including tightening laws, keeping an eye on cold-chain shipments, controlling prescription drug prices, improving supply chain visibility, and offering a variety of serialized mandates [4]. This review conducts a thorough and methodical assessment of the literature on traceability technologies for the purpose of identifying counterfeit medications and guaranteeing a safe pharmaceutical supply chain, given the significance of applying novel technology to overcome supply chain difficulties in the pharmaceutical business. In order to achieve a safe PSC and identify counterfeits, it evaluates the use of traceability technologies, obstacles to their implementation, and crucial success elements in different PSC phases. This evaluation is important for the industry since it addresses supply chain system development requirements and technologies for traceability.

Figure 1. Critical success factor of the pharmaceutical supply chain



II. Pharmaceutical Supply Chain

The chain that carries genuine APIs to manufacturers for use in manufacturing and delivers completed medications to patients is known as the pharmaceutical supply chain. Therefore, a good supply chain can meet safety and quality requirements, provide the necessary amount of medication on time, and keep costs down for as many patients as feasible. This section examines the problems associated with the existence of fake medications in genuine supply chains, the use of traceability technology at various stages of supply chain obstacles, and essential success elements for setting up a secure supply chain. In the PSC, where these pharmaceuticals are typically replicated and sold in the black market, counterfeit drugs can be found anywhere. The disruption that COVID-19 has caused to all supply chains, the lack of corporate resilience, and the rapid development of technology have all contributed to an increase in the rate of manufacture of counterfeit drugs [5]. The presence of fake pharmaceuticals in the authorized pharmaceutical supply chain infringes upon the intellectual property and trademark rights of the actual brand's makers and reduces sales. Potential customers stop trusting the brand, which has a negative impact on its value and profitability. The majority of fake medications hit the market during product demand's peak seasons. Drugs that are counterfeited are frequently the priciest medications, including chemotherapy. When medicine producers' products were found to be counterfeited and marketed in gray markets, the WHO launched its campaign against fake drugs in 1980 [6]. One in ten medications that are offered legally, especially in developing or middle-income nations, are thought to be fake [7]. According to a recent assessment from US pharmaceutical companies, the legal PSC experienced annual revenue losses of over USD 200 billion as a result of counterfeit medications [8]. The huge profit margins from illicit trafficking make the pharmaceutical business a desirable target for adulteration and counterfeiting activities [29]. Theyel [30] talked on the significance of tracking medications through the PSC at every stage, from the stage of raw materials to the stage of patient consumption in his study. Drug fraud can happen at any stage of the PSC. However, by offering item-level tracking systems, technologies like traceability can help pharmaceutical companies improve the robustness of their supply chains [9] and benefit all parties involved. Additional studies in this field have demonstrated that traceable techniques, like the application of RFID, electronic product codes (EPCs), and business-to-business (B2B) tactics, can guarantee that the goods are traceable on an individual basis, enabling businesses to fight [10]. There are numerous traceability systems available in a range of sizes, forms, costs, and degrees of complexity. The customer base will suffer fewer fatal effects the earlier counterfeit pharmaceuticals are detected [11]. Current research summarizes the primary applications of traceability technologies.

III. Blockchain Technology in Business Enterprise System

Employing cutting-edge technology to keep operations running smoothly is acceptable, but businesses must first ensure that their backbone of systems is strong enough to support any new technology [12]. Blockchain is one sophisticated emergent technology. The goals of various technologies vary. Blockchain technology is more suited for exchanging private data. A blockchain is essentially a time-stamped collection of immutable and unchangeable data that is not held by a single entity and is recorded and managed by a collection of decentralized computers. Up until 2014, the most well-known uses of blockchain technology were in Bitcoin and electronic transactions. However, experts soon began to find more practical uses for blockchain [13]. Blockchain technology has already shown benefits in the healthcare industry, however before utilizing its applications, one must first grasp blockchain technology [14]. Information can be shared on a blockchain in a way that makes information tampering difficult [15]. This technological feature can assist in overcoming the shortcomings and difficulties of different systems, such as those pertaining to information accessibility, consistency, and safety. Because all parties involved in a supply chain share this information, the structure of blockchain technology makes it difficult to make modifications to the data without being detected. As a result, data exchanged by authorized parties is protected. Furthermore, a blockchain can guarantee the accuracy and consistency of the data in a PSC management system. The fact that information on blockchain is instantly accessible from anywhere in the globe is another important feature. It does not, however, imply that information is readily accessible to all. Blockchain security is strong enough that access to it is restricted to approved parties only. Using blockchain technology, fake medical supplies can be stopped from spreading [16]. Because traceability techniques are quite effective when combined with blockchain technology, PSCs can employ them to carefully monitor the chains' interconnectivity. This makes it easier to combat any fault that would enable the use of fake medications. In their review of the potential applications of blockchain technology, Glover and Hermans [17] demonstrated how they were able to enhance clinical trials by making sure that enough APIs were obtained from several trustworthy suppliers for the raw materials and that all involved PSC partners recorded important information about their prescriptions in the shared network. Blockchain has the potential to significantly improve data security, interoperability, and data and information traceability in the healthcare industry.

A significant obstacle confronting the healthcare sector is the absence of dependable and safe techniques for data storage and retrieval. Blockchain technology provides an answer by enabling the safe sharing and storing of data in a decentralized database, making it more difficult for unauthorized parties to access or modify the data.

Furthermore, blockchain can promote interoperability across various healthcare organizations and systems, enabling more smooth data flow and communication. Many healthcare systems today are technologically incompatible and compartmentalized, which makes it challenging for various providers to access and share patient data. Healthcare practitioners can more readily access and share pertinent information by utilizing a shared, decentralized database, which improves care coordination and results. The capability of blockchain technology to track the provenance and history of pharmaceuticals and medical equipment is another potential advantage for the healthcare industry. As a result, blockchain has been extensively used in the healthcare industry [18–19], and it may potentially be able to assist in resolving issues in the supply chain [20]. These distributed systems have the essential benefit of resolving issues with responsibility and disclosure amongst entities and individuals whose interests may not coincide [21]. As a result, blockchain technology may improve the openness, accountability, integrity, secrecy, and dependability of SCs. Manufacturers, distributors, and dispensers can record traceability information in a distributed ledger that automatically verifies critical data through product tracing with blockchain technology. Through notifications from both public and private actors, this establishes a framework for product verification and, if needed, can be utilized to identify, and report pharmaceuticals that are not authorized or counterfeit [22].

IV. Hyperledger Fabric Architecture

A modular architecture that offers high levels of confidentiality, resilience, flexibility, and scalability supports the distributed ledger solutions offered by the Hyperledger Fabric platform. It is an enterprise-grade DLT built on blockchain technology that enforces mutual trust between parties via the use of smart contracts [23]. The idea of mining is removed by Hyperledger Fabric, but it retains all of the positive aspects of a standard cryptocurrency blockchain, like block immutability, determinism in the order of events, avoidance of double spending, etc. It has been verified that Hyperledger Fabric provides higher transaction throughput—up to several thousand transactions per second.31 These features, along with some more that will be covered later, make Hyperledger Fabric an ideal choice for intricate supply chain systems with numerous logical and physical participants and processes. The adoption barrier for smart contract technology is lower than for other technologies that use specialized programming languages (like Solidity in Ethereum) because general purpose programming languages (like Java, Go, and NodeJS) are used to create them. This review paper presents the Hyperledger Fabric drug traceability architecture, which offers a preliminary design for an enterprise-level blockchain-based supply chain system. This system identifies the various stakeholders in the pharmaceutical supply chain and establishes their relationships through various channels to ensure optimal privacy, confidentiality, and data security. Hyperledger Fabric is unusual in that it uses a channel notion [24]. Channels allow many stakeholders using the same system to clearly separate their data privacy standards and business logic. Among a collection of untrusted stakeholders, Hyperledger Fabric by default offers a transparent and safe crash-fault tolerant transaction ordering that guarantees deterministic event recording, secure communication, and dependable exchange of medication-related transactions. By utilizing the membership service provider (MSP) component of Hyperledger Fabric, the Health Authority is able to identify and register all participating organizations (pharmaceutical stakeholders) and their end-users on a permissioned private blockchain network.

V. Hyperledger Besu Architecture

For businesses searching for blockchain architectures that are Ethereum-compatible, the Hyperledger Besu drug traceability architecture offers an open-source distributed ledger solution that is completely compatible. Because Hyperledger Besu allows for the construction of networks that enable high transaction throughput and architectural flexibility while facilitating both private transaction processing and interaction with public blockchains (such as Ethereum), it is becoming more and more popular among organizations [25]. By bridging the gap between private and public blockchains, the proposed Hyperledger Besu architecture assists pharmaceutical supply chain companies in developing high-performance, scalable applications on peer-to-peer private networks that fully support sophisticated permissioning management and data privacy. Hyperledger Besu can use Ethereum cryptocurrencies and ERC20 tokens, and it enables business logic via Solidity smart contracts. Another open-source Ethereum client is called Hyperledger Besu. It offers a basic JSON-RPC API for controlling and operating Hyperledger Besu nodes as well as carrying out transaction processing. medication transaction execution data, both private and public, can be stored using the proposed Hyperledger Besu architecture. This is necessary to provide effective medication traceability across various stakeholders throughout the pharmaceutical supply chain. The two main components of Hyperledger Besu architecture are privacy and permissioning, despite its focus on a public blockchain. Hyperledger Besu enables the creation of particular companies (stakeholders) and their users (nodes) with their associated network accounts (wallets/addresses) in order to construct a permissioned private blockchain for the pharmaceutical supply chain. Hyperledger Besu uses the address of each node as a unique identifier and the built-in Public Key Infrastructure (nodes are assigned a private/public key pair) to sign and validate transactions. As an external wallet service provider, EthSigner is advised to be used in conjunction with Hyperledger Besu to isolate business logic from crucial storage/management procedures. One such PTM is Orion, which is built into Hyperledger Besu. For every Hyperledger Besu node, an Orion node must be started in order to configure a network that enables private transactions. Finally, Hyperledger Besu provides both on-chain (via smart contracts) and off-chain permissioning (through configuration files) for granting access rights to various organizational users and their accounts. Node and account permissioning is made possible by a permissioned network, which limits network access to just designated nodes and accounts. In addition, Hyperledger Besu's permissioning features enable actions to be restricted based on account or organization details, refuse access to smart contracts that break, and suspend accounts in real time. This facilitates safe and open communication over the network by making access control administration easier. Nevertheless, more investigation into practical implementations is required to offer a more definitive assessment of the functions and outcomes of blockchain in healthcare supply chains. Both Besu and Hyperledger Fabric are intended to be utilized as private, permissioned Business-2-Business networks, in contrast to Ethereum. With its emphasis on business-to-customer interactions, Ethereum lacks built-in support for privacy groups and private information. Better transaction execution speed and better state reconciliation are provided by Belu and Hyperledger Fabric. Because Hyperledger Fabric smart contracts use general-purpose programming languages rather than the domain-specific languages used by Besu and Ethereum, they may be simpler to create. But Hyperledger Fabric doesn't have a sufficient framework for developing smart contracts like Truffle, which is available in Ethereum and Besu. Hyperledger Fabric requires more network configuration, setup, and deployment work, but because every component is Dockerized, it is simpler to manage, update, and upgrade. Although using Hyperledger Fabric gives the client more control, it also raises the responsibility for client applications. Because Hyperledger Fabric has both physical (channels) and logical (chain codes, certificate characteristics) capabilities to manage identification and access control, it outperforms both Ethereum and Besu. The greatest options and features for an efficient trace and trace solution are offered by Hyperledger Fabric and Besu for the pharmaceutical traceability application.

VI. Challenges

The current efforts of researchers worldwide to utilize this cutting-edge technology were highlighted by this systematic literature review on the use of blockchain technology to support SCs in healthcare. This is especially true for industry-derived products like drugs and medical devices as well as patient-derived products like blood, organs, and tissues. The results of this systematic review, despite its shortcomings, show that there is a substantial but still developing interest in this subject in the literature that is currently available, despite its varied concepts and approaches as well as its dearth of useful real-world applications. In blockchain networks, smart contracts have been shown to be a practical method for automating peer-to-peer transactions upon the fulfillment of predetermined criteria. The implementation of blockchain technology in the healthcare industry has promised for enhancing patient outcomes and the system as a whole.

References

1. Ghadge, A.; Duck, A.; Er, M.; Caldwell, N. Deceptive counterfeit risk in global supply chains. Supply Chain Forum Int. J. 2021, 22, 87–99.
2. Venhuis, B.J.; Oostlander, A.E.; Di Giorgio, D.; Mosimann, R.; du Plessis, I. Oncology drugs in the crosshairs of pharmaceutical crime. Lancet Oncol. 2018, 19, e209–e217.
3. Singh, R.; Dwivedi, A.D.; Srivastava, G. Internet of Things Based Blockchain for Temperature Monitoring and Counterfeit Pharmaceutical Prevention. Sensors 2020, 20, 3951.
4. Bansal, D.; Malla, S.; Gudala, K.; Tiwari, P. Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective. Sci. Pharm. 2013, 81, 1–13.
5. Zhang, H.; Hua, D.; Huang, C.; Samal, S.K.; Xiong, R.; Sauvage, F.; Braeckmans, K.; Remaut, K.; De Smedt, S. Materials and Technologies to Combat Counterfeiting of Pharmaceuticals: Current and Future Problem Tackling. Adv. Mater. 2020, 32, e1905486.
6. Burns, W. WHO launches taskforce to fight counterfeit drugs. Bull. World Health Organ. 2006, 84, 689–690.
7. Bryatov, S.R.; Borodinov, A.A. Blockchain technology in the pharmaceutical supply chain: Researching a business model based on Hyperledger Fabric. In Proceedings of the International Conference on Information Technology and Nanotechnology (ITNT), Samara, Russia, 21–24 May 2019.
8. Abbas, K.; Afaq, M.; Khan, T.A.; Song,W.-C. A Blockchain and Machine Learning-Based Drug Supply Chain Management and Recommendation System for Smart Pharmaceutical Industry. Electronics 2020, 9, 852.
9. Kovacs, S.; Hawes, S.E.; Maley, S.N.; Mosites, E.;Wong, L.; Stergachis, A. Technologies for Detecting Falsified and Substandard Drugs in Low and Middle-Income Countries. PLoS ONE 2014, 9, e90601.

10. Ab Talib, M.S.; Hamid, A.B.A.; Thoo, A.C. Critical success factors of supply chain management: A literature survey and Pareto analysis. EuroMed J. Bus. 2015, 10, 234–263.
11. Modgil, S.; Sonwaney, V. Planning the application of blockchain technology in identification of counterfeit products: Sectorial prioritization. IFAC-PapersOnLine 2019, 52, 1–5.
12. Haji, M.; Kerbache, L.; Muhammad, M.; Al-Ansari, T. Roles of Technology in Improving Perishable Food Supply Chains. Logistics 2020, 4, 33.
13. Jamil, F.; Ahmad, S.; Iqbal, N.; Kim, D.-H. Towards a Remote Monitoring of Patient Vital Signs Based on IoT-Based Blockchain Integrity Management Platforms in Smart Hospitals. Sensors 2020, 20, 2195.
14. Iqbal, N.; Jamil, F.; Ahmad, S.; Kim, D. A Novel Blockchain-Based Integrity and Reliable Veterinary Clinic Information Management System Using Predictive Analytics for Provisioning of Quality Health Services. IEEE Access 2021, 9, 8069–8098
15. Ding, B. Pharma Industry 4.0: Literature review and research opportunities in sustainable pharmaceutical supply chains. Process. Saf. Environ. Prot. 2018, 119, 115–130.
16. Shahbazi, Z.; Byun, Y.-C. A Procedure for Tracing Supply Chains for Perishable Food Based on Blockchain, Machine Learning and Fuzzy Logic. Electronics 2020, 10, 41.
17. Sanmarchi, F.; Toscano, F.; Fattorini, M.; Bucci, A.; Golinelli, D. Distributed Solutions for a Reliable Data-Driven Transformation of Healthcare Management and Research. Front. Public Health 2021, 9, 710462.
18. Clauson, K.A.; Breeden, E.A.; Davidson, C.; Mackey, T.K. Leveraging Blockchain Technology to Enhance Supply Chain Management in Healthcare: An exploration of challenges and opportunities in the health supply chain. Blockchain Healthc. Today 2018, 1.
19. Longo, F.; Nicoletti, L.; Padovano, A.; d'Atri, G.; Forte, M. Blockchain-enabled supply chain: An experimental study. Comput. Ind. Eng. 2019, 136, 57–69.
20. Page, M.J.; McKenzie, J.E.; Bossuyt, P.M.; Boutron, I.; Hoffmann, T.C.; Mulrow, C.D.; Shamseer, L.; Tetzlaff, J.M.; Akl, E.A.; Brennan, S.E.; et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. BMJ 2021, 372, n71. Hyperledger. Hyperledger/fabric. GitHub, 21 January 2020.
21. Hyperledger Besu. Besu Enterprise Ethereum client, besu.hyperledger.org/en/stable/ (2020, accessed 15 January 2020).