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Drug Traceability - Divine or Challenge for Pharma Sector

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ABSTRACT

Blockchain technology is driving the digital transformation of various industries, and one sector benefiting from this innovation is the pharmaceutical industry. This industry grapples with challenges like a lack of transparency, difficulties in tracking products, a deficit of trust, and issues related to shipping expired products. To address these concerns, blockchain technology has been harnessed as a solution. Notably, counterfeit drug prevention emerged as the most prevalent category, aligning with the pharmaceutical industry's primary objective. Blockchain technology is an emerging innovation that is finding applications in various industries, including healthcare. In the healthcare sector, Blockchain networks are being utilized to securely store and exchange patient data across hospitals, diagnostic laboratories, pharmacies, and medical practitioners. These applications of Blockchain can effectively identify and mitigate critical errors, including potentially hazardous ones within the realm of healthcare. Consequently, this technology holds the promise of enhancing the efficiency, security, and transparency of medical data sharing within the healthcare system. Moreover, it offers valuable tools for medical institutions to gain insights and improve the analysis of medical records. It visually represents the diverse capabilities, enablers, and the unified workflow process of Blockchain technology in supporting healthcare on a global scale. Additionally, the paper presents a thorough discussion of fourteen significant applications of Blockchain in healthcare, underscoring its pivotal role in addressing issues like deception in clinical trials. Blockchain's potential in healthcare lies in improving data efficiency, assuaging concerns about data manipulation, and establishing a robust data storage framework with the highest level of security. It delivers features such as versatility, interconnectivity, accountability, and authentication for data access. The protection and confidentiality of health records are of paramount importance, and Blockchain facilitates decentralized data security in healthcare while mitigating specific threats."

Keywords : Blockchain, Drug Traceability, Pharmaceutical Serialization, Track and Trace System.

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I. INTRODUCTION

Blockchain represents a decentralized and publicly accessible digital ledger, where transactions are recorded on numerous computers, ensuring that no entry can be retroactively altered without necessitating changes to subsequent blocks. This creates a secure, tamper-proof chain of records, with each new entry verified and linked to the previous 'block,' collectively forming the Blockchain. The term 'Blockchain' refers to this entire ledger. Due to the public registration and verification of transactions, Blockchain ensures a high level of accountability [1, 2]. Once data is recorded, it becomes immutable, providing a robust assurance of data authenticity and integrity. Unlike traditional systems relying on a central database, Blockchain distributes data across a network, enhancing stability and reducing susceptibility to hacking. This technology offers an excellent platform for the development and competition of modern and innovative business models, enabling new paradigms in the corporate landscape [3]. 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 [4].

Inferior pharmaceuticals pose significant risks. Counterfeit and substandard medications, which may contain inactive components, incorrect dosages of active ingredients, or potential contaminants, have the potential to be life-threatening [5]. Both popular media often featuring numerous personal accounts, and medical literature [6, 7] have highlighted the perils associated with counterfeit drugs. The utilization of low-quality antimicrobial agents can result in treatment failures, potentially exacerbating antibiotic resistance at both individual and community levels. This, in turn, can lead to elevated mortality rates and the proliferation of highly resistant pathogens on a global scale. The presence of contaminants and impurities in medications may trigger allergic reactions and adverse drug responses. Counterfeit drugs not only deplete individual finances but also place an additional economic burden on governments. Moreover, they can undermine public confidence in the efficacy of genuine pharmaceuticals [8, 9]. Implementing pharmaceutical medication monitoring to enhance transparency throughout the entire pharmaceutical distribution network [10].

An examination of the existing and upcoming technologies aimed at reducing the prevalence of counterfeit pharmaceuticals highlighted the emergence of blockchain technology. This technology offers the potential to facilitate the tracking and tracing of drug products and associated materials, detect counterfeit items by verifying information provided by supply chain participants, and serves as a platform for incorporating anti-counterfeit devices into the Internet of Things, while also enabling compatibility between disparate databases within the supply chain [11]. Furthermore, blockchain technology has the capacity to enhance governance by enabling traceability, establishing ownership of records, encouraging participation through the automation of smart contracts, and promoting policy implementation through multi-sectoral disruption [12].

Issues in Conventional Drug Supply Chain:

Drug supply chain encompasses the entire process, starting from the cultivation of medicinal materials to the delivery of medicines to consumers. This process covers a vast spatial expanse and unfolds over an extended period, making effective supervision challenging. Consequently, Pharmaceuticals sector often encounters safety issues, such as the presence of excessive levels of harmful heavy metals in Drug products and incidents involving fatalities related to injections. These problems erode public trust. After conducting comprehensive market research, it became evident that the challenges associated with tracing the drug supply chain data stem from the difficulty in

ensuring the accuracy of traceability data and the absence of a trust consensus widely accepted by the public. Traceability can be seen as an integral part of quality management. The pursuit of enhancing data collection, plant control, and quality assurance efficiency can serve as a catalyst for the creation of a more sophisticated internal traceability system [13]. Ensuring drug safety is fundamental to the well-being of individuals, and the Drug supply chain is confronted with several key issues.

- Numerous Nodes and Numerous Unpredictable Variables Exist in the Supply Chain: Drug supply chain encompasses a broad spectrum of stages, including cultivation, production, processing, transportation, marketing, pharmacy distribution, hospital delivery, and various other components. Throughout this complex process, each segment of the supply chain is susceptible to unpredictable variables. The ultimate quality of Drug products can be influenced by a multitude of factors, including the natural environment, processing conditions, human-operated procedures, storage circumstances, and logistics. The entire supply chain harbours a plethora of concealed risks. Any alteration in a specific link within this chain has a high probability of impacting the ultimate drug quality and consequently affecting the overall stability of the entire supply chain.
- The trustworthiness of information is limited: Drug supply chain involves numerous participants, each of whom enters into contractual agreements to establish mutual constraints. However, various factors impede the effectiveness of these contracts in regulating all parties involved. Firstly, there is a substantial likelihood of contract breaches. Drug's market equilibrium is influenced by both environmental elements and market dynamics, leading to considerable fluctuations in supply and demand, and consequently, significant price variations. These fluctuations in market dynamics can incentivize parties to breach their agreements to secure their interests, thereby elevating the overall breach risk within the Drug supply chain. The effectiveness of solely relying on contracts to regulate each facet of the supply and marketing of Drug products is suboptimal.
- Online medicine purchases attract individuals for various reasons, such as geographical limitations, cost savings, faster market access, direct customer targeting, and broader customer reach [14]. Another noteworthy obstacle to implementing pharmaceutical serialization is the necessity for manufacturers and supply chain participants to generate, document, and communicate serialized event data to both clients and regulatory bodies [15]. This data sharing must ultimately occur within a restricted and secure network [16].
- The information is unclear: In the current Drug supply chain, a variety of factors, such as differing qualifications and asymmetric information among enterprises at various positions within the supply chain, make it challenging for both parties to engage in trade based on the actual market value of Drug products.
- Challenge in Supervising, managing, and tracing accountability: Given the complexity of the Drug supply chain with its numerous links and limited transparency in information, tracing responsibility becomes challenging when issues arise with the final product. The Drug supply chain model should possess the capability to adapt, function efficiently, ensure fairness, maintain oversight, establish stability, and manage risks.
- Conducting an audit of supply chain: The current Drug supply chain comprises various stages, including cultivation, research and

development, manufacturing, sales, and logistics. Each stage's data and information are managed by the respective enterprises. The challenge of conducting audits significantly escalates due to the lack of cooperation from certain enterprises and the incomplete, irregular accounting records maintained by some of them.

II. Blockchain Technology

At its core, a blockchain is a decentralized, peer-to-peer database, continually expanding to store information, which includes distributed applications known as smart contracts, all shared among the involved parties. It enables systems and applications to operate autonomously, without the need for third-party intermediaries or trust authorities [17]. Whether a distributed ledger is public or private, its underlying data structure resembles a linked list of blocks that contain transactions. Each entry in the list is connected to the preceding block, and each block's reference includes the hash of the preceding one. The fundamental aspect of blockchain security is this hash. In fact, any attempt to alter the content can be easily detected by calculating a block's hash and comparing it with the hash recorded in the subsequent block to check for discrepancies. An adversary could endeavour to modify all the hashes from the tampered block up to the most recent block to avoid detection. Consequently, altering the content of a block on public chains becomes an infeasible task. In contrast, participants in private chains have the flexibility to reach consensus offline and modify the content of data [18].

Blockchain technology is not only a widely discussed subject but is also extensively embraced across various sectors and domains [19]. This technology represents a distributed storage database system [20, 21], characterized by decentralization, immutability, traceability, transparency, openness, security, and credibility [22]. It functions as a distributed ledger, fusing elements of cryptography, mathematics, hash functions, and computer network technologies [23]. Data within the blockchain is disseminated across the entire network and is structured by multiple hubs to establish a shared online database, with nodes throughout the network collectively maintaining blockchain data [24]. This data remains transparent and impervious to forgery. In blockchain technology, data blocks are organized in a chain-like structure, storage nodes are spread throughout the network, and information within the nodes is updated through a consensus algorithm. Cryptography plays a pivotal role in safeguarding the storage and transmission of blockchain data, making it a cutting-edge distributed database technology [25].

Blockchain Technology for Preventing Drug Counterfeiting

Blockchain, a relatively recent and emerging technology, exhibits innovative applications in the healthcare sector. Its effective facilitation of seamless and efficient data exchange among key network participants and healthcare providers contributes to the development of cost-effective therapies and advanced treatments for various medical conditions. This is poised to propel the growth of healthcare in the years ahead. The logistics industry has only recently begun to explore the potentials of Blockchain technology, which has also demonstrated its advantages within the healthcare sector. Given the direct impact on the quality of life, healthcare is among the forefront domains experiencing improvements and innovations through digital transformation. Concurrently, Blockchain technology is gaining prominence, particularly in the financial sector, and it offers numerous significant and promising opportunities for the healthcare industry, spanning aspects from scientific advancements and logistical enhancements to interactions between healthcare professionals and patients [26].

Explores the noteworthy uses of Blockchain technology in the healthcare sector:

- In a Blockchain, transactions undergo validation through algorithms before they become linked to the chain. The data's integrity is confirmed through encryption, digital signatures, and secure storage [27].
- Blockchain technology can serve as an ideal solution for maintaining records in the healthcare field. Its potential applications encompass sharing medical data, managing electronic health records, overseeing insurance matters, and handling administrative functions [28].
- The Blockchain system will provide information regarding the source of the medication, ensuring its high quality and verifying that it originates from an authorized pharmaceutical manufacturer. Track and trace and/or authentication smart technology integration into databases will also prevent counterfeiting [29].
- Researchers can conduct thorough analyses of specific medical procedures across a significant portion of the patient population by securely accessing their data [30].
- Blockchain decreases unnecessary overhead costs, facilitating the efficient utilization of health records. Furthermore, this technology will alleviate the necessity for multiple intermediaries overseeing the exchange of vital health information [31].
- Maintaining precise financial records is of paramount importance in the bookkeeping procedure, particularly when it comes to the seamless operation and evaluation of clinical trials. In this context, Blockchain firms have introduced techniques for optimizing the accounting and reporting procedures [32].
- It offers outstanding security and transparency, freeing up physicians to allocate more of their time to patient care. Additionally, it facilitates support for clinical trials and treatments of rare disorders [33].

III.CONCLUSION

Within a blockchain framework, blockchain technology, with a focus on cost-efficiency and security, has the potential to enhance the pharmaceutical cold chain and combat counterfeit medicines. This study outlines the utility of a blockchain-based system in tracking drugs and identifying counterfeit medications at every stage of the supply chain. To address data storage concerns, blockchain platforms can integrate with cloud storage components. Blockchain possesses the capacity to amalgamate diverse data from multiple sources, enabling efficient tracking of medication authenticity. This technology enables the real-time tracking of various elements, including medical supplies, prescriptions, and temperature monitoring within the pharmaceutical supply chain.

IV. REFERENCES

[1]. S. Khezr, M. Moniruzzaman, A. Yassine, R. Benlamri, Blockchain technology in healthcare: a comprehensive review and directions for future research, Appl. Sci. 9 (9) (2019) 1736.

[2]. T. Kumar, V. Ramani, I. Ahmad, A. Braeken, E. Harjula, M. Ylianttila, Blockchain utilisation in healthcare: key requirements and challenges, in: In2018 IEEE 20th International Conference on E-Health Networking, Applications and Services (Healthcom), IEEE, 2018 Sep 17, pp. 1–7.

[3]. Moona, Girija, Mukesh Jewariya, and Rina Sharma. "Relevance of dimensional metrology in manufacturing industries." Mapan 34 (2019): 97-104.

[4]. Kumar, Gaurav. "Optimizing pharmaceutical supply chain with digital technologies."

International Journal of Science and Research Archive 9.02 (2023): 727-731.

[5]. World Health Organization. "A study on the public health and socioeconomic impact of substandard and falsified medical products." (2017).

[6]. Blackstone, Erwin A., Joseph P. Fuhr Jr, and Steve Pociask. "The health and economic effects of counterfeit drugs." American health & drug benefits 7.4 (2014): 216.

[7]. Sugita, Minoru, and Michiko Miyakawa. "Economic analysis of use of counterfeit drugs: health impairment risk of counterfeit phosphodiesterase type 5 inhibitor taken as an example." Environmental health and preventive medicine 15.4 (2010): 244-251.

[8]. Johnston, Atholl, and David W. Holt. "Substandard drugs: a potential crisis for public health." British journal of clinical pharmacology 78.2 (2014): 218-243.

[9]. Kelesidis, Theodoros, and Matthew E. Falagas. "Substandard/counterfeit antimicrobial drugs." Clinical microbiology reviews 28.2 (2015): 443-464.

[10]. Kumar, Gaurav. "Blockchain in Enterprise Application for Pharmaceutical Drug Traceability." International Journal of Science and Research 12.8 (2023): 130-134.

[11]. Mackey, Tim K., and Gaurvika Nayyar. "A review of existing and emerging digital technologies to combat the global trade in fake medicines." Expert opinion on drug safety 16.5 (2017): 587-602.

[12]. Chapron, Guillaume. "The environment needs cryptogovernance." Nature 545.7655 (2017): 403-405.

[13]. Kumar, Gaurav. "Critical Success Factors of Adopting an Enterprise System for Pharmaceutical Drug Traceability." Universal Journal of Pharmacy and Pharmacology (2023): 3-10.

[14]. Arden, N. S., Fisher, A. C., Tyner, K., Yu, L. X., Lee, S. L., & Kopcha, M. (2021). Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future. International Journal of Pharmaceutics, 602, 120554.

[15]. Hole, G., Hole, A. S., & McFalone-Shaw, I. (2021). Digitalization in pharmaceutical industry: What to focus on under the digital implementation process?. International Journal of Pharmaceutics: X, 3, 100095.

[16]. Kumar, Gaurav. "Securing pharmaceutical supply chain using digital drug serialization." World Journal of Advanced Engineering Technology and Sciences 10.01 (2023): 015-020.

[17]. Hamida, Elyes Ben, et al. "Blockchain for enterprise: overview, opportunities and challenges." The Thirteenth International Conference on Wireless and Mobile Communications (ICWMC 2017). 2017.

[18]. Zheng, Zibin, et al. "Blockchain challenges and opportunities: A survey." International journal of web and grid services 14.4 (2018): 352-375.

[19]. V. Chang, S. Gagnon, R. Valverde, and M. Ramachandran, “Guest editorial,” Journal of Enterprise Information Management, vol. 34, no. 5, pp. 1277–1286, 2021.

[20]. Sung, Chang Soo, and Joo Yeon Park. "Understanding of blockchain-based identity management system adoption in the public sector." Journal of Enterprise Information Management 34.5 (2021): 1481-1505.

[21]. Yi, Haibo. "A secure logistics model based on blockchain." Enterprise Information Systems 15.7 (2021): 1002-1018.

[22]. Yang, Bingqing. "Prevention of business risks of internet information security platforms based on blockchain technology." Computational Intelligence and Neuroscience 2022 (2022).

[23]. Hughes, Alex, et al. "Beyond Bitcoin: What blockchain and distributed ledger technologies mean for firms." Business Horizons 62.3 (2019): 273-281.

[24]. Fusco, Antonio, et al. "Blockchain in healthcare: Insights on COVID-19." International Journal of

Environmental Research and Public Health 17.19 (2020): 7167.

[25].Song, Yuchen, and Yun Shen. "System design for online foreign language education based on blockchain technology." Computational Intelligence and Neuroscience 2022 (2022).

[26].Fu, Junsong, Na Wang, and Yuanyuan Cai. "Privacy-preserving in healthcare blockchain systems based on lightweight message sharing." Sensors 20.7 (2020): 1898.

[27].Reddy, Bhuvana, and P. S. Aithal. "Blockchain as a disruptive technology in healthcare and financial services-A review based analysis on current implementations." (2020).

[28].Berdik, David, et al. "A survey on blockchain for information systems management and security." Information Processing & Management 58.1 (2021): 102397.

[29].Kumar, Gaurav. "Pharmaceutical Drug Packaging and Traceability: A Comprehensive Review." Universal Journal of Pharmacy and Pharmacology (2023): 19-25.

[30].Khatoon, Asma. "A blockchain-based smart contract system for healthcare management." Electronics 9.1 (2020): 94.

[31].Tandon, Anushree, et al. "Blockchain in healthcare: A systematic literature review, synthesizing framework and future research agenda." Computers in Industry 122 (2020): 103290.

[32].Al Omar, Abdullah, et al. "Medibchain: A blockchain based privacy preserving platform for healthcare data." Security, Privacy, and Anonymity in Computation, Communication, and Storage: SpaCCS 2017 International Workshops, Guangzhou, China, December 12-15, 2017, Proceedings 10. Springer International Publishing, 2017.

[33].Wang, Shuai, et al. "Blockchain-powered parallel healthcare systems based on the ACP approach." IEEE Transactions on Computational Social Systems 5.4 (2018): 942-950.

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