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# Blockchain in Enterprise Application for Pharmaceutical Drug Traceability

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**Abstract:** ***A promising approach to building a distributed platform for shared data that is unchangeable, trustworthy, dependable, and accessible is blockchain - based drug traceability. The Hyperledger fabric and Hyperledger Besu methodologies are used in this article to provide a complete study and summary of the present state of drug traceability distribution research on the blockchain technology in enterprise platform. The Hyperledger Fabric and Besu blockchain - based platforms satisfy critical requirements for medication traceability, including privacy, reliability, transparency, security, authorisation, authentication, and scalability. Drug supply chain transactions are carried out skill fully and securely by the Hyperledger Fabric blockchain platform among a dispersed network of stakeholders. Various pharmaceutical stakeholder groups comprise this fabric - enabled private, permissioned distributed network, which supports the efficient and secure execution of medication in supply chain transactions in enterprise system. This study also explains how blockchain technology is benefiting the healthcare industry while showcasing some of its disruptive aspects that have the potential to alter current enterprise application in drug tracking procedures.***

**Keywords:** Drug Traceability, Drug Counterfeit, Pharmaceutical Serialization, Supply chain, Blockchain, Track and Trace System, Enterprise System

## 1. Introduction

The World Health Organization (WHO) classifies fake medications as unregulated, wrongly labelled products whose identity and source are concealed or fraudulently portrayed on purpose as counterfeit drugs. Fake medications can be either disguised or falsely represented [1].

Since a substantial portion of these counterfeit pharmaceuticals are produced and distributed through healthcare supply networks, they have extremely negative side effects on the patient's life. Unsecure supply chains frequently lead to serious issues like safety, security, authenticity, and traceability issues. New secure, accessible, and decentralized drug tracing systems must be created in order to address the problem of counterfeit medicines. Up to this point, various approaches and techniques have been proposed and put into use, including mobile technology - based approaches, serial numbers and QR codes, RFID tags, potent computational approaches (machine learning), and serialization solutions that validate drugs at the point of sale. Although medicine may continue to be an art, the success of, for instance, the "human genome" project to take into account genetic variations and provide tailored medical options ushers in a new era of optimism [2]. Creating compounds that target particular patient subgroups based on pharmacogenomics is one component of personalized therapy, as was previously discussed. Customizing the dose, dosage form, and drug release kinetics to each patient's needs, as well as the severity and stage of their disease, is the other component of personalized medicine [3]. Evolution of technologies and increased globalization of pharmaceuticals trade benefited global healthcare industries. Now people have greater accessibility of critical medicine and can buy them from trusted source. It is also giving an opportunity to counterfeiters and illegal drug traders to sell medicine through social media platforms and dark - web sites. There are multiple factors which attract people towards online medicine purchase such as geographical limitations, lower cost, fast go - to - market time, target direct customers, and wider reachability to customers [4]

**Digital Drug Traceability**

By gradually incorporating linked computing platforms and diagnostic point - of - care sensors into patients' daily routines, the healthcare sector is rapidly going digital [5]. Some emerging technologies such as, Internet of Things (IoT) of today's personal mobile and wearable sensors may detect a variety of things, including functionality, breathing, biomarkers from sweat, and even a person's mental state [6, 7] DSCSA 2023 Act defines that all trading partners in supply chain including dispenser and pharmacy must be able to verify suspected or illegitimate product identifier based on request made by trading partner, regulatory agency, or any state agency. DSCSA 2023 compliance recommend having traceability at unit level instead of lot level so healthcare industry must adopt a robust system which should have highest levels of scalable solution [8]. New drug serialization and traceability mechanisms were evaluated at the joint initiative of drug manufacturers, wholesale distributors and community pharmacists. Pharmaceutical industry is further trying to adopt new secure technologies like block chain in interoperable digital communications [9]. By establishing digital traceability in the supply chain and accelerating the regulatory and investigative processes within a given time frame, the primary goal of pharmaceutical traceability regulation is to assure patient safety [10]. As there was no regulatory compliance provision to encode a unique product identity at the level of the medication package, the initial requirement was to track the pharmaceutical product at the lot level (US DSCSA 2015) [11]. Pharmaceutical medication tracking to increase visibility across the whole pharmaceutical supply chain. With the printing of a unique identity on each individual medicine unit, Turkey adopted serialization requirements in 2010. Other markets, including China and South Korea, already have legislation in place [12]. Since the turn of the

century, China has mandated that all supply chain participants in the distribution of medicines record data about individual drug units in a traceability system. Many nations around the world have begun to emphasize and even require the significance of drug traceability [13]. 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 products at the package level [14].

**Existing Issues in Digital Drug Traceability in the Supply Chain**

Due to geopolitics, market accessibility issues, and political unpredictability, major pharmaceutical companies do not invest in or set up production facilities in poor nations. Some other conditions such as, high per capita income and price monopoly in industrialized nations like the USA and Europe, they are more concentrated on producing and distributing branded medications. Because of inadequate infrastructure and a lack of government funding for research and infrastructure improvements, developing countries face significant obstacles when it comes to pharmaceutical industry investment. Existing pharmaceutical facilities struggle to reach international standards because they must make significant expenditures in new production and packaging equipment. The traceability requirements for digital pharmaceutical items necessitate additional room in the manufacturing units for specialist packaging equipment, label grading systems, barcode printers, and vision systems that print the unique identifier on every level of packaging. For producers, this system requires a large financial commitment. Additionally, wholesalers and dispensers must spend money on sophisticated software and drug scanners that connect to centralized databases for verification. Implementing digital drug traceability is problematic because developing nations lack enough infrastructure [15]. The majority of pharmaceutical producers view this traceability requirement as an additional investment that could raise drug prices. The printing of a unique identification on a drug package has been found to be insufficient for determining the legitimacy and traceability of the drug [16]. All stakeholder systems should be linked to one another via a centralized cloud system (EU - FMD model for Europe) for real - time traceability and authenticating content. Because there is no technical system integration for digitally verifying the authenticity of medications, counterfeit makers or criminals can readily reproduce the product's unique identity and supply it to marketplaces [17]

India is a major producer and exporter of generic medications [18]. The Directorate General of Foreign Trade (DGFT) published a public notice on January 10, 2011, requiring all pharmaceutical drug exporters to create a track and trace system for serialization in accordance with GS1 standards [19]. All export pharmaceutical consignments are required by this notice to be serialized using GS1 barcode standards at various packaging levels. [20]. The lack of preparedness of traceability systems that complied with DGFT criteria, drug producers in India encountered significant difficulties implementing track and trace solutions. Many manufacturers used outdated packaging tools that couldn't encode serialization data in packaging hierarchies [21]. Generic and prescription medications are frequently imported into the United States. The DSCSA requires in 2018 that pharma makers serialize all prescribed medications sold in the US market [22]. Despite their best efforts, regulatory authorities in the US market continue to face difficulties with drug counterfeiting [23]. The FDA and DSCSA have worked hard to develop stronger regulations and sanctions throughout the supply chain in an effort to address this problem. However, through smuggling or other illicit means, criminals and counterfeiters can enter the supply chain and provide phony or illegal pharmaceuticals. Finally, drug authenticity [24].

**What is Enterprise Resource Planning (ERP) Applications.**

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 [25]. 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. ERP is a collection of distinct but related modules that may be applied as a whole by any company [26] Contrarily, the pharmaceutical industries could be threatened by the sale of counterfeit drugs. Instead of focusing on technical system implementation techniques, key success criteria for adopting ERP for drug counterfeiting encourage highly effective enterprise system implementations for drug traceability and assist the business in concentrating on the most crucial elements. In order to achieve the essential requirements of a medication traceability system, acceptable functionality must be developed. This functionality can be evaluated by looking at the success factors of systems that have already been successfully implemented and how they interact [27].

**What is Blockchain Technology**

A blockchain, in essence, is a decentralized, peer - to - peer, constantly expanding database (or ledger) of information, including distributed applications (or smart contracts), that have been run and distributed among the involved parties. It makes it possible for systems and apps to function entirely independently of third parties and trust authorities [28] Whether a distributed ledger is public or private, its data structure corresponds to a linked list of blocks containing transactions. Each item on the list is linked to the block before it. Additionally, every block's pointer includes the hash of the block before it. The foundation of blockchain security is this hash. In fact, anyone can identify an attempt at content modification by computing a block's hash and comparing it to the hash stored in the following block to look for discrepancies. The adversary could attempt to modify all the hashes from the tampered block to the most recent block in an effort to prevent this detection. Therefore, on public chains, it is impossible to change the content of a block. On the other hand, participants of private chains can quickly agree offline and change the substance of data. [29].

**Blockchain Technology for Preventing Drug Counterfeiting**

We can make sure that genuine drugs are delivered to a valid stakeholder at every transfer point and that verified and authenticated transactions continue to be accessible in

Medledger by using blockchain technology. This technology creates an impermeable decentralized drug tracing system, lowers barriers in the drug supply chain, and promotes collaboration across pharmaceutical stakeholders with varying levels of trust. Blockchain technology ensures the legitimacy of every drug in the supply chain by providing both privacy and transparency for each drug transaction in a distributed, decentralized ledger of cryptographically protected timestamped data. [30].

The blockchain - enabled supply chain method discussed in this article offers a dependable and proactive means to find fake and fraudulent drugs by tracking and documenting transaction activity more securely and transparently through the shared ledger. Additionally, the blockchain - enabled cold chain enhances and revolutionizes the safety of pharmaceuticals by actively detecting risks and the events they are connected with, monitoring the temperature of drugs using sensors, and serving as a shared ledger for post - transaction monitoring. It is extremely difficult for medicine counterfeiters to supply fake drugs through illicit channels in a supply chain that uses blockchain technology, which may raise patients' confidence that their meds are genuine and increase their willingness to purchase. By measuring the temperature of medications at every stage of the supply chain, the use of blockchain technologies in pharmaceutical data integration gives firms a competitive edge, safeguards information from being stolen or changed, and prevents resource waste.

By utilizing blockchain technology for medicine traceability and cold chain transportation as well as by distributing medications between different businesses using IoT - enabled cars, the problem of drug counterfeiting in the supply chain can be reduced. In this essay, we'll go through two technological architectural platforms for digital drug tracing that are built on blockchain technology. Because they provide a higher level of installation, adaptability, expansion, security, privacy, and data trustworthiness than other blockchain platforms, we will mainly concentrate on the Hyperledger Fabric and Hyperledger Besu platforms as the foundation of architectures. Basic pharmaceutical design concepts may be crucial building blocks for creating private permissioned blockchain ecosystems where pharmaceutical stakeholders and their end consumers are registered, monitored, and regulated by a regulatory body, group of authorities, or stakeholders. Chain codes are designed, programmed, and implemented utilizing sequence maps in the drug supply chain environment to control and regulate interactions between the parties involved [31].

Hyperledger Fabric is a structure for the regulation of pharmaceutical drug delivery techniques, quality assurance measures, risk assessment components, and temperature monitoring. The creation of this temperature and humidity monitoring system is crucial for preserving the potency of biopharmaceutical medications. [32] Identity service modules, interoperability modules, consensus layers, connectivity layers, contract layers, storage of data modules, policy service modules, encrypted components, and APIs are among the nine parts of a hyperledger system [33, 34].

**Challenges in Blockchain Technology**

To fully realize the enormous potential of blockchains, a number of issues will need to be solved, especially before this paradigm change becomes technically, commercially, and legally feasible in commercial settings. The technical characteristics of blockchains, such as their governance (i. e., open, private, or consortium), scalability, data privacy, and the validity of smart contracts, fall under the first group of these difficulties. The second set of difficulties surrounds the creation of workable underlying business models and incentive systems. At the very least, the legal implications of blockchains visible a challenge, particularly in France and Europe, where this technology should be evaluated in light of upcoming new regulations, like the General Data Protection Regulation (GDPR), whose goal is to improve users' privacy and security of their data within the European Union. [35]

In the study, we found that compared to other fields of research, the pace of blockchain research for pharmaceutical medication counterfeiting is quite moderate. The implementation of blockchain technology in pharmaceutical drug traceability is fraught with difficulties, including those related to technical adaptability, interoperability, trade partner resistance, uniform data practices, regulatory restrictions, readiness for transparency, and difficulties from competing developing technologies. IoT networks are already very big, and as more businesses and other entities start using them, their size will only increase significantly. One of the most well - known drawbacks of blockchain technology is the network's scalability. Scalability has been viewed as one of the most significant concerns with the blockchain technology since the inception of the blockchain community. Many blockchains take a long time to load due to block size limitations [36].

## 2. Conclusion

On a blockchain platform, blockchain technology, with an emphasis on cost and safety, may help pharmaceutical cold chains and fight medicine counterfeiting. This study describes how a blockchain - based system may be useful for drug tracking and the identification of counterfeit medications throughout the supply chain. To address the issue of data storage, blockchain platforms can interact with cloud storage components. Blockchain has the ability to combine massive heterogeneous data generated from several sources in order to effectively track medication fraud. The ability to trace down anything at any time, including medical supplies, prescriptions, and even the monitoring of temperature in the pharmaceutical supply chain, is made possible by blockchain technology.

## Reference

[1] Sarkar, S. (2022). Digital Traceability of pharmaceutical drugs in supply chain. International Journal of Advance Research in Computer Science and Management Studies, 10 (2), 39–44.
[2] Issa, A. M. (2007). Personalized medicine and the practice of medicine in the 21st century. McGill Journal of Medicine: MJM, 10 (1), 53.

[3] Goole, J., & Amighi, K. (2016).3D printing in pharmaceutics: A new tool for designing customized drug delivery systems. International journal of pharmaceutics, 499 (1 - 2), 376 - 394.
[4] Sarkar, S. (2022). Online Drug trade a threat to pharmaceutical industry. International Journal of Advance Research in Computer Science and Management Studies, 10 (5), 15–20.
[5] Ballard, Z. S. (2020). Deep learning - enabled point - of - care sensing using multiplexed paper - based sensors. npj Digital Med.3.
[6] Li, Y., Chen, W., & Lu, L. (2020). Wearable and biodegradable sensors for human health monitoring. *ACS Applied Bio Materials*, *4* (1), 122 - 139.
[7] Sempionatto, J. R., Jeerapan, I., Krishnan, S., & Wang, J. (2019). Wearable chemical sensors: emerging systems for on - body analytical chemistry. *Analytical chemistry*, *92* (1), 378 - 396.
[8] Sarkar, S. (2022). Drug Supply Chain Security Act 2023: Interoperable Data Exchange for Drug Traceability. International Journal of Scientific Research in Computer Science, Engineering and Information Technology, 8 (3), 471–477.
[9] Drug Supply Chain Security Act Implementation: https: //www.fda. gov/media/88790/download
[10] Sarkar, S. (2023). Blockchain for Combating Pharmaceutical Drug Counterfeiting and Cold Chain Distribution. Asian Journal of Research in Computer Science, 16 (3), 156–166.
[11] Raijada, D., Wac, K., Greisen, E., Rantanen, J., & Genina, N. (2021). Integration of personalized drug delivery systems into digital health. Advanced drug delivery reviews, 176, 113857.
[12] 'Hagan A, Garlington A. Counterfeit drugs and the online pharmaceutical trade, a threat to public safety. Forensic Research & Criminology International Journal.2018; 6 (3): 151 - 158
[13] Sarkar, S. (2022). Pharmaceutical serialization: Impact on drug packaging. International Journal of Advance Research in Computer Science and Management Studies, 10 (3), 21–26.
[14] Azzi R, Chamoun RK, Sokhn M. The power of a blockchain - based supply chain. Computers & Industrial Engineering.2019; 135: 582 - 592.
[15] Sarkar, S. (2022). Challenges for Implementing Digital Drug Traceability in Developing Countries. International Journal of Research Publications, 103 (1), 760–766. https: //doi. org/10.47119/IJRP1001031620223477
[16] Human regulatory Falsified medicines: reporting obligations | European Medicines Agency (europa. eu) https: //www.ema. europa. eu/en/human - regulatory/post - authorisation/compliance/falsified - medicines reporting - obligations.
[17] Sarkar, S. (2022). Pharmaceutical Serialization: A Challenge for Small Manufacturers. International Journal of Scientific Research in Computer Science, Engineering and Information Technology, 8 (4), 174 - 181. https: //ijsrcseit. com/CSEIT228428
[18] Goldhammer A, Scott ML. Pharmaceutical Supply Chain Security: a view from the pharmaceutical research and manufacturers of America. J Pharm Pract 2006; 19: 239–243. http: //dx. doi. org/10.1177/0897190006293514
[19] C. Uleanya, B. T. Gamede, Technology: Solution to Quality Rural University Education. International Journal of Interdisciplinary Educational Studies, vol.13, No.2
[20] Government of India. Directorate of Foreign Trade. "Implementation of the Track and Trace System for Export of Pharmaceutical and Drug Consignments. http: //dava. gov. in/davahq/files/DGFT_Drug_Track_N_Trace_Implementation_Manual. pdf
[21] Sarkar, S. (2023). Why Pharmaceuticals Serialization is a Fairytale for Third World. Novel Aspects on Pharmaceutical Research, 5, 155 - 162.
[22] Gutorova N, Zhytnyi O, Soloviov O. Falsification of Medical Products: Criminal Law Mechanism Combating Threats to Public Health. Wiad Lek.2019; 72: 856 - 861.
[23] Fayzrakhmanov NF. Fighting Trafficking of Falsified and Substandard Medicinal Products in Russia. Int J Risk Saf Med.2015; 27: 37 - 40.
[24] Sarkar, S. (2023). Why Pharmaceutical Drug Traceability in the US Needs a Centralized Cloud - Based Platform. Current Journal of Applied Science and Technology, 42 (21), 1 - 11.
[25] Ogechi, Anyanwu, (2018). The Role of Enterprise Resource Planning Systems in Continuous Auditing of A Selected Organization in the Western. Unpublished Master Thesis in Technology in Business Information Systems in the Faculty of Business and Management Science, University of Technology.
[26] Khan, S.; Haleem, A.; Khan, M. I.; Abidi, M. H.; Al - Ahmari, A. Implementing traceability systems in specific supply chain management (SCM) through critical success factors (CSFs). Sustainability 2018, 10, 204
[27] Kumar, G. (2023). Critical Success Factors of Adopting an Enterprise System for Pharmaceutical Drug Traceability. Universal Journal of Pharmacy and Pharmacology, 2 (1), 3–10.
[28] Hamida, E. B., Brousmiche, K. L., Levard, H., & Thea, E. (2017, July). Blockchain for enterprise: overview, opportunities and challenges. In The Thirteenth International Conference on Wireless and Mobile Communications (ICWMC 2017).
[29] Z. Zheng, S. Xie, H. - N. Dai, and H. Wang, "Blockchain challenges and opportunities: A survey, " International Journal of Web and Grid Services, 2017, pp.1–23.
[30] Roman - Belmonte JM, De la Corte Rodriguez H, Rodriguez - Merchan EC. How blockchain technology can change medicine. Postgraduate Medicine.2018; 130 (4): 420 - 427.
[31] Uddin M. Blockchain Medledger: Hyperledger fabric enabled drug traceability system for counterfeit drugs in pharmaceutical industry. International Journal of Pharmaceutics.2021; 597: 120235.
[32] Bishara RH. Cold chain management—An essential component of the global pharmaceutical supply chain. Am. Pharm. Rev.2006; 9: 105–109.
[33] Blummer M, Sean C Cachin. An introduction to Hyperledger. Linux Found; 2018. [Online]. Available: https: //www.Hyperledger. org/wpc

ontent/uploads/2018/08/HL_Whitepaper_In troductiontoHyperledger. pdf
[34] Fan C, Lin C, Khazaei H, Musilek P. Performance Analysis of Hyperledger Besu in Private Blockchain. In 2022 IEEE International Conference on Decentralized Applications and Infrastructures (DAPPS). IEEE.2022; 64 - 73.
[35] "Regulation (eu) 2016/679 of the european parliament and of the council of 27 april 2016, " accessed: 2017 - 07 - 01. [Online]. Available: http: //eur - lex. europa. eu/eli/reg/2016/679/oj
[36] Jamil F, Hang L, Kim K, Kim D. A novel medical blockchain model for drug supply chain integrity management in a smart hospital. Electronics.2019; 8 (5): 505.