

REVIEW ARTICLE

Traceability of counterfeit drugs in pharma supply chain through Blockchain Technology - A Systematic Review of the Evidence

**Adithya D. Shetty¹, Sandeep S. Shenoy^{1*}, D. Sreedhar², Ankitha Shetty¹, Rohini Rao³,
Komal Jenifer D'souza¹**

¹Department of Commerce, Manipal Academy of Higher Education,
Manipal – 576104 Dist - Udupi (Karnataka) India.

²Department of Pharmacy Management, Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education, Manipal - 576104 Dist - Udupi (Karnataka) India.

³Department of Data Science and Computer Applications, Manipal Institute of Technology,
Manipal Academy of Higher Education, Manipal – 576104 Dist - Udupi (Karnataka) India.

*Corresponding Author E-mail: sandeep.shenoy@manipal.edu

ABSTRACT:

Effectively managing the pharma supply chain is crucial in order to ensure optimal safety of drugs. Various issues pertained to pharma logistics is evident namely shortage of medicines, fake medicines, vulnerabilities in security, etc., highlights the failures in pharma supply chain and the high stakes involved in this sector in comparison to any other sector. The study incorporates the guidelines of PRISMA in order to synthesize the literature. This paper makes an honest attempt to discuss the glitches in the pharma supply chain due to faulty systems in place. It further deliberates on the need for the implementation of blockchain so as to enable a fool-proof track and trace system which goes on to avoid the occurrence of counterfeit drugs in the supply chain. This perspective highlights the opportunities that blockchain has, in the area of pharma supply chain and how vital it is for future adoption and implementation.

KEYWORDS: Pharma supply chain, Logistics, Counterfeit drugs, Review, Challenges.

INTRODUCTION:

Research and development in the pharmaceutical industry takes several years and is a complex process that begins at discovery of the drug and momentarily pauses at drug development and regulatory approval as the next challenge that poses is to deliver the right drug to the right customer in its original and genuine form manufactured by the legal manufacturer¹. World Health Organization has recently reported that counterfeit drugs are a global problem as an estimated 1 in 10 drugs in low- to middle income countries is falsified or substandard during market circulation².

Due to globalization, while access to information, technology, goods and services from across the world is easier, it also given rise to a self-proliferating and complex work mechanism in the health supply chain sector³. Counterfeit drugs are products from the pharmaceutical industry which are manufactured and sold with the purpose of falsifying information related to origin, authenticity and effective levels of the drug. The paper aims at designing a pharma supply chain based on blockchain technology that will help avoid drug counterfeiting by helping manufacturers and every subsequent link to keep track of their product while the consumers are enabled to trace back the parties involved with the particular drug. Security is the reason for which blockchain is stated as most suitable for pharma supply chain as it prevents any entity from manipulating data.

effectively is critical in order to ensure optimal safety of patients. Problems like shortage of medicines, fake medicines, vulnerabilities in security, etc., highlights the failures in pharma supply chain and the high stakes involved in this sector in comparison to any other sector³.

Blockchain functions as a distributed ledger of transactions that is processed with precision by a distributed network. Transactions made through these networks are called as 'blocks' and ensures all records are secure. The transactions are transmitted through each node of the network. Post this the method of cryptography is implemented automatically in order to validate the transaction after which every 'block' is encoded in a chain of multiple transactions that are stored in each node⁵. Therefore, blockchain in pharma supply chain provides authenticity and security of the drugs to all the stakeholders in the supply chain⁶.

Limited studies have been published with reference to the use of blockchain in pharmaceutical supply chain. Very few pharmaceutical companies across the globe have implemented blockchain technology and experienced decrease in counterfeit of drugs. This paper discusses the problems in the pharma supply chain as bottlenecks keep arising in the network due to faulty systems in place. It further discusses the need for the implementation of blockchain so as to enable a fool-proof track and trace system which goes on to avoid the occurrence of counterfeit drugs in the supply chain. Apart from tracking, tracing and avoidance of counterfeit, blockchain offers an array of advantages to companies who implement the technology. This perspective highlights the opportunities that blockchain has, in the area of pharma supply chain and how crucial it is for future adoption and implementation.

Impact of blockchain in pharmaceutical supply chain:

Substandard and falsified (SF) medicines are one of the biggest threats in pharma supply chain. These SF drugs are also known as counterfeit drugs that are manifested due to infiltration of fake or poor-quality products via illegitimate marketing and distribution channels, importing inferior quality drugs without proper regulatory approval, poor monitoring of manufacturing and storing methods and theft of drugs⁷. According to a report from the World Health Organization, the market for counterfeit drugs is estimated at a range of \$75 to \$200 Billion per year⁸.

These and more critical challenges in healthcare could be solved by the development and application of sophisticated supply chain management methods like blockchain technology³. While conducting a detailed

study of the role of blockchain in the efficient and effective management of pharmaceutical products, there are questions that need to be addressed in order to justify the adoption of blockchain. The reasons for the of blockchain technology in the field of pharmaceutical supply chain are illustrated in Table 1 and Figure 1.

Table 1: Application of blockchain technology in the field of pharmaceutical supply chain

| Function | Blockchain applicability |
|-------------------------|---|
| Information | A shared ledger of information like source, product license and transactional data related to the drug is stored |
| Identification | Blockchain identifies the product based on the holistic information contributed to the database stored in secure blocks |
| Tracking and tracing | Manufacturers, wholesalers, distributors and retailers will have round the clock information on the location of the product as the information is provided on the shared ledger while important information is automatically verified |
| Verification | The origin, authenticity and legitimacy of the product is verified as the information once stored in the blocks cannot be tampered |
| Detection and reporting | The participants of the block chain transactions have the liberty to report drugs that are identified or suspected to be counterfeit. |
| Securing IoT | IoT devices are used in supply chain for tracking and tracing to offer real-time updates of the product. These devices can assist blockchain while its security can be provided for by blockchain technology |

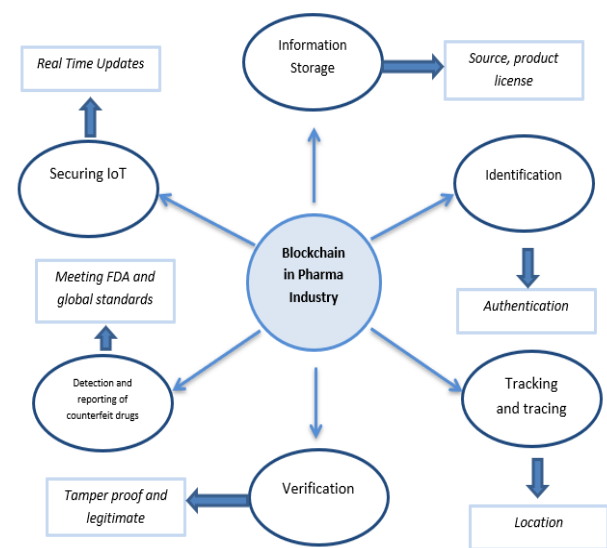


Figure 1: Blockchain Operations in Pharma Supply Industry

In a holistic view, assessing the credibility of blockchain technology can help the pharma supply chain to combat long prevailing challenges like SF medicines. Blockchain offers to better the industry through improved care and reduced via by increasing the efficiency of pharma supply chain³.

REVIEW OF LITERATURE:

Management of supply chain involves many phases within which the data flows forward as well reverse i.e., to/from suppliers, manufacturers, distributors, wholesalers, retailers, end users and all the other middlemen involved that go into fulfilling the requirement of the market. It includes supplying the goods to the market here the demand arises and this process occurs through the different phases in the supply chain⁹. Through the years, the pharma industry has seen tremendous growth and development. It plays a decisive role in the availability of drugs by manufacturing and selectively distributing them so that they meet the needs of community and market¹⁰.

The pharma industry provides all round health care services to the citizens of the world. Critical health care service is provided by means of supplying life-saving drugs to the people. In spite of stringent laws and vigilance by various boards, recently there has been a surge in counterfeit drug supply in the market and this has raised concerns, issues of mistrust and alarms among the people. The presence of counterfeit drugs not just poses a threat to the economy but a dire one on the society as one wrong medicine can affect the health and treatment of the end customer¹¹. Reports indicate that developing countries show significant rise in counterfeit of drugs¹². Counterfeiting of pharma drugs is a serious threat to people, governments and society in general as it causes a negative effect on the health of the consumers while also causing loss of revenue to manufacturers and government. Over the years, many techniques have been proposed to overcome counterfeiting of pharma drugs but most of the techniques, technologies and schemes crumble as they are not secured or are prone to hacking or are incompetent in nature⁶. So as to counter the problems of counterfeit pharma drugs, various regulatory authorities like FDA has made it mandatory for companies to implement a fool-proof trace and track system into their respective supply chain¹⁰.

Blockchain refers to the continuous chain of blocks that contain information built according to requirements by adhering to strict governing rules. More often, multiple copies of block chains are stored on many different computer systems that are independent of each other¹³. Scores of industries in the global market have taken a technologically advanced step by adopting and implementing blockchain for the purpose of transparency and traceability. Food industry is considered as one of the closest to the pharmaceutical industry. Food producers and retailers have incorporated blockchain technology to ensure food safety by means of tracing sources in the supply chain network of the product that are contaminated. Blockchain, given its sophisticated structure is considered as an ideal solution

for tracking and tracing through the secure blocks as it creates a trusted environment for every transaction made. Relevant parties are given access to the blocks so that the occurrence of any sort of discrepancy can be alerted downstream¹⁴.

Blockchain is cited as an emerging technology based on detailed review of existing and upcoming technologies that help in mitigating the occurrence of counterfeit drugs or fake drugs. Blockchain has the potential to track and trace drug reagents and products and detect counterfeit activities through a systematic verification of information related to the various participants in the supply chain¹⁵. It functions as a distributed ledger of transactions at various levels of the supply chain which are further processed by a distributed network. The transactions are known as 'blocks' within which are secure records created by the system that are transmitted to each and every node within the network. By making use of cryptography, upon proper scrutiny, the node validates the transaction by approving it and then encodes multiple transactions stored by each node in a block¹⁶. Within the pharma supply chain, there are many processing units like manufacturing, storage, packing and distribution, etc., that transform the input in the form raw materials to output in the form of medical equipment and medicines for further distribution in the market. In each of these various units, there are chances and reports of substandard or counterfeit drugs as companies do not take it seriously to follow proper storage/manufacturing techniques, compromise on quality, manipulate market price through practices of hoarding, etc.¹⁰.

Through blockchain, every time the product changes ownership, a new transaction will be pushed to the blockchain. Storing the history of a product makes it easy to reveal its actual origin and designated destination. This will dramatically bring down delay in time, human error, and cost that frequently occur in various transactions. For instance, when a manufacturer produces a drug, it will be registered on the network of blockchain which makes it a digital asset, and this very digital asset can be transferred to other participants (device, entity or person) just like crypto currency¹⁷. Every digital record is joined into blocks as and when the product changes hands throughout its supply chain. These blocks are later cryptographically and chronologically chained using a set of algorithms as each block that surfaces in the system is joined with the previous block while also creating a reference to the previous block. As the data is systematically encrypted, it offers a platform for users to change only those blocks to which they have been given access by using private codes and keys¹. With the help of blockchain, there exists a transparency of all the financial transactions and drug quantity supply information and its quality. Once

relevant information is stored in a block, the various participants in the supply chain network of the product can gain only read access to this information. The information stored is available all the time for further analysis due to the existence of feature known as immutability¹⁸. As the data is systematically encrypted, it offers a platform for users to change only those blocks to which they have been given access by using private codes and keys¹.

With reference to the pharma industry, its supply chain can be efficiently managed through blockchain technology as it helps in achieving tracking and auditability of manufactured drugs. Apart from this, it helps to maintain the privacy of users that function at various stages of the supply network, details on availability of drug and the security of information as the transactions recorded within the blocks are cryptic which is accessible to designated personnel only. Due to the decentralized nature of blockchain, trust among the various participants in the pharma supply chain can be significantly achieved¹⁹. As the pharma industry has consistently shifted to going digital over the years, it has found reflection in the digitization of particular processes that are related to its supply chain network. Blockchain technology has shown promising results in various industries which makes the pharma industry to expect from benefiting not only its end consumers but also agencies, governments and organizations as it helps ensure transparency of processes, save tremendous material resources, completely avoid counterfeit drug and time and promote fair competition across every process in the pharma products' supply network¹.

Proposed Architecture:

The purpose of this study is to provide a reliable and durable blockchain model to overcome the challenges like counterfeit, tracking, tracing, etc., that are faced by the pharma industry. *Figure 2* shows the link between the various components of the blockchain system in order to understand the basic functioning of the technology. Every participant in the network, based on given authority can feed information into the system which is stored in a cryptic format that can be retrieved only by authorized personnel/individual.

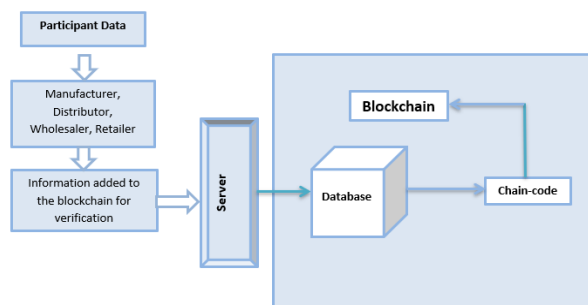


Figure 1: Blockchain Architecture for Pharma Supply Chain

IMPLICATIONS:

Traceability:

Over the recent years, the regulatory bodies around the world are focusing on serialization of pharma drugs⁵. Blockchain helps pharmaceutical companies to adhere to world regulations and achieve a high level of product traceability²⁰. It provides a secure IT system that originates from the famous decentralized cryptocurrency of Bitcoin²¹ which makes it interoperable in nature where the distributed ledger can enable all the stakeholders involved in the transaction to collaborate⁵. Transactions that occur within the blockchain are verified, cleared and stored continuously by the network on every node in the digital blocks that are connected to the previous blocks. The technology provides the most effective and efficient solution for sharing data securely in the supply chain network throughout the life cycle of the product. As the physical ownership of the drug changes from one entity to another, the ownership will be transferred accordingly on the blockchain network as well. Therefore, it makes it possible to minimize corruption to a large extent as the company can trace its product as it moves from one point to another in the supply chain.

Transparency in transactions:

Application of blockchain technology can help mitigate counterfeit drugs²² as long proper predefined guidelines are adhered to²³. The transparent nature of blockchain technology enables manufacturers and customers to track their products from source to destination and vice versa. The manufacturers can ensure that their product has reached the client safely and with authenticity-from-source while the client/customer can know for sure that the procured product is from a legitimate manufacturer with the product received in its original form.

Avoid counterfeiting:

Once a block has been registered in the system, it is non-susceptible to change which makes it extremely difficult for anyone to change its tracks, details or any information whatsoever. It makes it possible for the product to move from source to destination in its original form and avoid counterfeit. If at any point of time, the supply chain has any trace of a counterfeit product, it can be recognized and discarded easily from the supply chain. The ability of the technology to detect any counterfeit product and the inability to change or tamper with data because of full transparency makes blockchain reliable⁵.

Security:

The use of IoT devices have been increasing tremendously²⁴ and the most interesting use of these devices are considered to be in the area of supply chain for the purpose of tracking and tracing⁵. Among all the technologies that fall under Internet of Things (IoT),

blockchain is considered as one of the most secure and safe systems of ledger in the world. Information once stored cannot be easily deleted or modified as it is highly cryptic in nature as only legitimately permitted participants will be given privileges to push data into the supply chain network of the product²⁵⁻²⁶.

Privacy protection:

On the one hand, blockchain is by far the best technology that guarantees to verify the authenticity of the product, the information of which is available to all the participants in the supply chain who are granted access to it. On the other hand, no information regarding the medical records of the patient or manufacturer's secret techniques will be accessible to the participants in the supply chain¹⁷.

Inventory management:

Inventory at any firm needs constant monitoring to avoid surplus or deficit levels so that there is neither wastage due to the former nor bottlenecks in manufacturing due to the latter. Blockchain provides a platform to keep updated information on the stock and movement of drugs throughout the supply chain which makes it easier for every level in the supply chain to keep sufficient inventory so that no client or patient suffers from non-availability of drug.

CONCLUSION:

The research shows that pharma companies can implement blockchain technology to ensure effective management of products throughout a product's journey in the supply chain by adhering to the industry's track and trace regulations. The issues and challenges faced by the pharma industry are highlighted and a roadmap is provided so as to prevent the presence and movement of counterfeit medicines in the pharma supply chain. As the transactions are transparent in nature, there is no need for a supervisor or a central authority to man the operations. Blockchain is a niche and young technology which has tremendous potential to not just combat counterfeit drugs but to help build efficiency in every industry.

REFERENCES:

1. Garankina, R. Y., Zakharochkina, E. R., Samoshchenkova, I. F., Lebedeva, N. Y., and Lebedev, A. V. Blockchain Technology and its Use in the Area of Circulation of Pharmaceuticals. *Journal of Pharmaceutical Sciences and Research*. (2018); 10(11): 2715-2717.
2. Bagozzi D, Lindmeier C. World Health Organization. 1 in 10 medical products in developing countries is substandard or falsified: WHO Urges Governments to take action. 2018; (11).
3. Clauson, K. A., Breeden, E. A., Davidson, C., and 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 in Healthcare Today*. (2018); 1(3): 1-12.
4. Sylim, P., Liu, F., Marcelo, A., and Fontelo, P. Blockchain technology for detecting falsified and substandard drugs in distribution: pharmaceutical supply chain intervention. *JMIR Research Protocols*. (2018); 7(9): e10163.

5. Jochumsen, M. L., and Chaudhuri, A. Blockchain's impact on supply chain of a pharmaceutical company. In *EUROMA Conference 2018*; (6).
6. Kumar, R., and Tripathi, R. Traceability of counterfeit medicine supply chain through Blockchain. In *2019 11th International Conference on Communication Systems and Networks (COMSNETS)*. 2019; (1): 568-570.
7. Brechtelsbauer, E. D., Pennell, B., Durham, M., Hertig, J. B., and Weber, R. J. Review of the 2015 Drug Supply Chain Security. (2016); 51(6): 493-500.
8. World Health Organization. 1 in 10 medical products in developing countries is substandard or falsified. 2017; (11). Available URL: <https://www.who.int/en/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>
9. Wu, H., Li, Z., King, B., Ben Miled, Z., Wassick, J., and Tazelaar, J. A distributed ledger for supply chain physical distribution visibility. *Information*. (2017); 8(4): 137.
10. Alangot, B., and Achuthan, K. Trace and track: Enhanced pharma supply chain infrastructure to prevent fraud. In *International Conference on Ubiquitous Communications and Network Computing*. 2017; 218(8): 189-195.
11. Soundarya, K., Pandey, P., and Dhanalakshmi, R. A Counterfeit Solution for Pharma Supply Chain. *EAI Endorsed Transactions on Cloud Systems*. 2018; 3(11): e5.
12. Cockburn, R., Newton, P. N., Agyarko, E. K., Akunyili, D., and White, N. J. The global threat of counterfeit drugs: why industry and governments must communicate the dangers. *PLoS Med*. 2005; 2(4): e100.
13. Kim, H. M., and Laskowski, M. Toward an ontology-driven blockchain design for supply-chain provenance. *Intelligent Systems in Accounting, Finance and Management*. 2018; 25(1): 18-27.
14. Abeyratne, S. A., and Monfared, R. P. Blockchain ready manufacturing supply chain using distributed ledger. *International Journal of Research in Engineering and Technology*. 2016; 5(9): 1-10.
15. Mackey, T. K., and Nayyar, G. A review of existing and emerging digital technologies to combat the global trade in fake medicines. *Expert Opinion on Drug Safety*. 2017; 16(5): 587-602.
16. Forbes - Stephanie Overby. Transforming Transaction Processing for the Digital Economy. *Forbes*. 2016; 11: 1-9.
17. Haq, I., and Esuka, O. M. Blockchain technology in pharmaceutical industry to prevent counterfeit drugs. *Int. J. Comput. Appl*. 2018; 180(25): 8-12.
18. Jangir, S., Muzumdar, A., Jaiswal, A., Modi, C. N., Chandel, S., and Vyjayanthi, C. A Novel Framework for Pharmaceutical Supply Chain Management using Distributed Ledger and Smart Contracts. In *2019 10th International Conference on Computing, Communication and Networking Technologies (ICCCNT)*. 2019; 7: 1-7.
19. Vujičić, D., Jagodić, D., and Randić, S. Blockchain technology, bitcoin, and Ethereum: A brief overview. In *2018 17th International Symposium Infoteh-Jahorina (infoteh)*. 2018; 3: 1-6.
20. Shanley, A. Could Blockchain improve pharmaceutical supply chain security. *Pharmaceutical Technology*. 2017; 41(8): 34-39.
21. Nakamoto, S. Bitcoin: A peer-to-peer electronic cash system. *Manubot*. 2019.
22. Mettler, M. Blockchain technology in healthcare: The revolution starts here. In *2016 IEEE 18th International Conference on e-Health Networking, Applications and Services (Healthcom)*. 2016; 9: 1-3.
23. Kurki, J. Benefits and guidelines for utilizing blockchain technology in Pharmaceutical supply chains: case Bayer Pharmaceuticals. 2016.
24. van der Meulen, R. Gartner Says 6.4 Billion Connected "Things" Will Be in Use in 2016, Up 30 Percent From 2015. 2015. 2016. Available URL: <https://www.gartner.com/newsroom/id/3165317> (visited on 05/23/2016).
25. Brechtelsbauer, E. D., Pennell, B., Durham, M., Hertig, J. B., and Weber, R. J. Review of the 2015 Drug Supply Chain Security. 2016.
26. European Medicines Agency, "Falsified Medicines Directive". 2018; 25(1). Available URL: <https://ec.europa.eu/health/human-se/falsifiedmedicines-en>