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Short Review: A new promising technology to ensure drug safety

Emine Dilek Ozyilmaz

Eastern Mediterranean University, Faculty of Pharmacy, Famagusta, T.R North Cyprus, Mersin 10 Turkey.

Abstract

With the recent technological developments and the declaration of an individual or a community known as Satoshi Nakamoto in 2008, it can be assumed that the blockchain technology is mainly used for cryptocurrency, and it is the beginning of a disruptive transition in every area of existence. However, this technology has attracted attention towards providing security in the pharmaceutical supply chain in recent years as well.

Benefits and drawbacks of good manufacturing practies (GMP) and supply chain tracking in pharmaceutical manufacturing can be determined via blockchain and sensor (Radio Frequency Identification Technology) technologies and these technologies can ensure the protection and health of the chain all the way up to the patients.

Furthermore, the capacity can be tracked back to the raw material and pharmaceutical supply chain, which essentially ensures the drug's protection by gathering, transferring, and exchanging drug data in the manufacturing, storage, delivery, and sales connections. After a precise study conducted by the experts in this particular area, it was determined that the concept of counterfeit drugs can be fully eliminated.

Keywords

Blockchain technology, counterfeit drugs, drug safety, good manufacturing practices (GMP).

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***Corresponding author:** Emine Dilek Ozyilmaz **email:** emine.ozyilmaz@emu.edu.tr

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INTRODUCTION

Drug formulations are used to treat common illnesses such as headaches, colds, coughs, and runny noses, as well as more severe conditions such as stomach ulcers, cardiovascular disorders, infection removal, and even life-threatening diseases. However, if drug formulations are not produced, stored, and distributed on a regular basis under adequate manufacturing, storage, and distribution conditions, they may pose a threat to life. As a result, pharmaceutical manufacturers must be able to ensure that drug formulations are tested using validated testing methods and that calibration, equipment, and instruments are carried out in accordance with regulations and laws. Furthermore, the quality control and quality assurance departments in the facilities should provide appropriate quality under predetermined parameters (Bocek *et al.*, 2017).

Furthermore, it is the responsibility of the drug company to ensure that each drug product is faultlessly produced and delivered to the patients. Many of these commitments have been expressly stated by the authorities in the standards of GMP. In this case, GMP, which is essential in drug production, can be interpreted as a set of rules that ensures safe and efficient production in the pharmaceutical industry (Rabah, 2017). Nonetheless, counterfeit drugs continue to be a major problem in drug markets around the world, resulting in the deaths of nearly one million people per year.

Despite the fact that the drug manufacturing is strictly regulated by authorities, the prevalence of counterfeit products demonstrates that transparency, identity authentication, and visibility which play essential roles in the drug supply chain, are not entirely feasible under the current system (Sadouskaya, 2017). It is unknown whether the required conditions are established or not in the drug storage and shipping conditions that should be used in the current drug tracking systems, especially in cold chain conditions. As a consequence of this scenario, the safety of vaccines and protein-based drugs has been jeopardized. (Nugent *et al.,* 2016). Because of the complexities of traditional systems and fragmented technical solutions, it is becoming increasingly difficult to monitor a single drug package from point of development to point of consumption, and it is much more difficult for parties to account for it when the issues occur (Sadouskaya, 2017; Rabah, 2017). Exploration of these new technologies to eradicate all of these negative circumstances and protect human health is

as inevitable as the generation of creativity in the drug formulation production and distribution processes (Roberts *et al.,* 2018). The present review article point out that the blockchain technology, which has developed rapidly, can be used to resolve the problem of confidence in the pharmaceutical supply chain.

Blockchain technology

In the early 1990s, the concept of blockchain was debated. However, this technology became more relevant after a paper posted on a website (metzdowd.com) by an individual or a group known as Satoshi Nakamoto in October, 2008. The first sign of blockchain technology was the Bitcoin: A Peer-to-Peer Electronic Cash System. This technology saves records as thousands of data on the server, and the blocks form a structure (Bocek *et al.,* 2017). There is not a way to alter any documents in this manner. Since each record has a timestamp, when it wishes to update a record, the records on thousands of servers must be updated entirely (Peters and Panayi, 2019).

As a result, blockchain technology can be described as a highly reliable infrastructure technology in which encrypted records in the system can be controlled by a stable, distributed structure and the approved individuals can track all of the movements.

Advantages of Blockchain technology

Blockchain technology has many features that can be useful in different areas. Moreover, it can bring benefits for all of the components that takes place in production, especially for customers. Such benefits and key factors have been listed in the following:

1- *Compliance and transparency*. These are the most important advantages of blockchain. These properties will aid in the elimination of organizational silos within current sections of the supply chain, as well as the leadership's understanding of how to make the supply chain more competitive on various levels.

2- *Tracking and Tracing.* Companies can obtain and provide better knowledge about the product life cycle as a result of these features, which provide all forms of detailed information.

3- *Reduction of errors in auditing.* Because of this blockchain function, auditing reports can be submitted to the digital ledger and easily reviewed and confirmed.

4- *Fraud security.* Blockchain technology is “unhackable.” It reduces the likelihood of some kind of fraud. Furthermore, it does not depend on patches, making blockchain the most stable cybersecurity project in the market.

5- *Increase of customers' trust*. Blockchain allows patient to find all necessary information about the origins of the products, way of transportation and packaging, which consequently increases their trust to the company. Even only this feature demonstrates the necessity of using blockchain in drug production.

6- *Real-time feedback from consumers.* Patients may react in real time to items they have received. It will assist different parties in the supply chain in analyzing their work and avoiding many mistakes (Sadouskaya, 2017; Nugent, 2016; Prisco, 2019).

GMP and Blockchain technologies in drug safety

GMP covers all stages of production in pharmaceutical production which includes starting materials, production site, equipment, training and hygiene of each personnel. Detailed procedures for each process that may affect the quality of the complete product in GMP are essential. There should be systems that provide documented evidence that the correct procedures are followed consistently in every step of the production process. Nowadays, to ensure this, manufacturers provide records by keeping standart operation procedure (SOP) documents (Peters and Panayi, 2019). However, there are many drawbacks to it. In this system, the fact that these records reflect the truth when it is the human factor is a condition of the record holder. At this point, blockchain technology, which is an unchangeable recording system, finds solutions to the problems that will arise from the human factor. However, it will provide a database that auditors can rely on when reviewing all these records. In addition, the manufacturing companies will be able to review their production records in an instant. Thus, they will play an important role in increasing their quality and saving time (Li *et al.,* 2006; Apte and Petrovsky, 2016).

GMP- Blockchain and sensor technologies in drug safety

All of the digital records created with the sensors has no possibility to change after these records registered on blockchain basis. This will show whether the products are in compliance with the SOP standards. Thus, whether or not the manufacturer makes production in accordance with GMP standards, the quality of pharmaceutical production will be able to monitored and checked. In addition to all of these, auditors will be able to make continuous follow-up. Thus, it will be an important step in securing human health (Radanović and Likić, 2018; Bocek *et al.*, 2017)

The utility of blockchain technology in the safe drug supply system has been shown in detail (Figure 1).

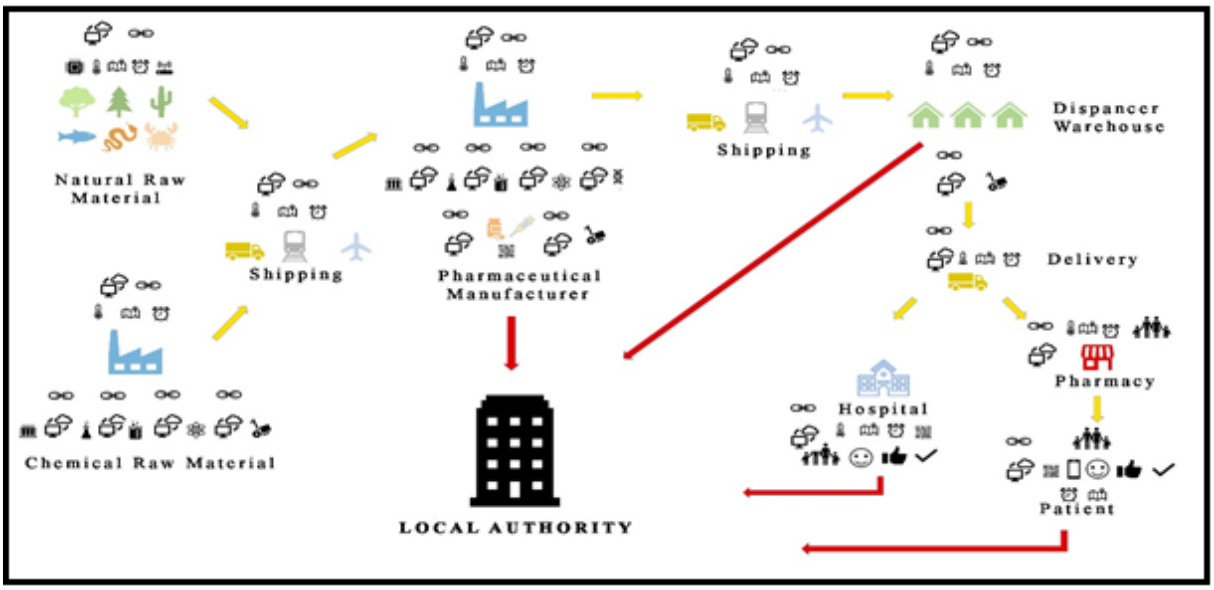

Figure 1: Original and safe drug supply system with blockchain technology.

CONCLUSION

Except drug manufacturing technology, there are various applications of blockchain technology for example, smart contracts, operational risks in financial markets and payment systems. However, pharmaceutical production is the most important area for safe production. Drug formulations should be produced within appropriate and safe conditions and delivered to the patients.

Drug packages are authenticated, timestamped and placed on the blockchain at each delivery point through the drug production process. Therefore, the drug packages can be tracked. Blockchain makes the distribution of medicines transparent and secure, so it can prevent the drugs from thefts and reduce the possibility of price manipulation and delivery of expired drugs. In addition to the use of the blockchain to ensure the transparent safety of pharmaceutical production, sensor technology is also needed to assist it. Moreover, with all these technologies available, GMP rules should be strictly apply in pharmaceutical production. Another advantage of this technology is that the problems in process such as shipment are detected immediately and these problems are solved at the beginning of the process to prevent time and labor losses.

In addition, it will be possible to eliminate the market shortages of drugs by providing communication between independent points such as social security institution, retail point of sale, warehouses and producer. Furthermore, the blockchain technology will allow the fight against counterfeit drugs. Thus, social security institutions will not reimburse the price of

counterfeit drugs. In addition to the important advantages of blockchain in the drug supply chain, it is inevitable that sensor technology should be used with the blockchain in order to make the pharmaceutical production completely transparent.

In conclusion, considering all of the advantages and disadvantages of this new technology, which has been used in many fields in the recent years, has to be accepted as a promising technology in the production of safe drugs.

REFERENCES

Apte S, Petrovsky N (2016). Will blockchain technology revolutionize excipient supply chain management? *J Excip and Food Chem* **3**:910.

Bocek T, Rodrigues BB, Strasser T, Stiller B (2017). Blockchains everywhere-a use-case of blockchains in the pharma supply-chain. In Integrated Network and Service Management IFIP/IEEE Symposium on:772-777.

Li D, Kehoe D, Drake P (2019). Dynamic planning with a wireless product identification technology in food supply chains. *Int J of Adv ManufacTech* **30**:938-44.

Nugent T, Upton D, Cimpoesu, M (2016). Improving data transparency in clinical trials using blockchain smart contracts. F1000 Research Oct;5.

Peters G, Panayi E (2019). Understanding Modern Banking Ledgers through Blockchain Technologies: Future of Transaction Processing and Smart Contracts on the Internet of Money. Available at: https://arxiv.org/pdf/1511.05740v1.pdf Accessed 13 Feb.

Prisco, G. Walmart (2019). Testing Blockchain Technology for Supply Chain Management. online Bitcoinmagazine. Available at: https://bitcoinmagazine.com/articles/ Accessed 13 Feb.

Rabah K (2017). Challenges, Opportunities for Blockchain Powered Healthcare Systems: A Review. Mara *Research Journal of Medicine and Health Sciences* **1**:45-52.

Radanović I, Likić R (2018). Opportunities for Use of Blockchain Technology in Medicine. *App health eco and health policy* **5**:583-90.

Roberts J (2018). Big Pharma Turns to Blockchain to Track Meds. online Fortune. Available at: http://fortune.com/2017/09/21/pharma-blockchain/ Accessed 26 Jan..

Sadouskaya K (2017). Adoption of Blockchain Technology in Supply Chain and Logistics. Bachelor's Thesis.