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Review Article

Blockchain technologies in pharmaceutical industry: A comprehensive overview

Manasi S. Zade[1], Firoj A. Tamboli[2]*, Apurva A. Salunkhe[1], Monali D. Kore[3], Dipali S. Bhusnar[4], Komal M. Dikole[5], Dnyaneshwar M. Mane[6]

[1]*Dept. of Pharmaceutical Quality Assurance, Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra, India*
[2]*Dept. of Pharmacognosy, Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra, India*
[3]*Dept. of Pharmaceutical Chemistry, Dattakala College of Pharmacy, Maharashtra, India*
[4]*Dept. of Pharmaceutics, SVERI's college of Pharmacy, Pandharpur, Maharashtra, India*
[5]*Dept. of Pharmacology, Loknete Shri Dadasaheb Pharate College of Pharmacy, Mandavgan, Maharashtra, India*
[6]*Dept. of Pharmaceutics, Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra, India*

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ABSTRACT

Pharmacies need to manage their data effectively. A novel technology known as blockchain holds the potential to enhance transparency and safety for various pharmaceutical operations. The Drug Supply Chain Security Act (DSCSA), which was passed by the US Congress in 2013 to stop pharmaceuticals that are stolen, tainted, or counterfeit, has a response provided by blockchain technology. Blockchain technology is a decentralized distributed ledger that uses cryptographic techniques to provide security to a peer-to-peer network of transactions. These guarantee that a product is secure and suitable for consumer sale. By making sure laws are readily followed, blockchain provides solutions to improve the validity, reliability, and efficiency of medicine production. It also presents a chance to address one of the main issues, which is the surge of fake medications getting into the system and into the hands of patients or customers. According to the pharmaceutical industry, society is seriously threatened by fake medications. False medications have a direct or indirect negative impact on patients health, sometimes leading to major problems and even death. The pharmaceutical industry's inadequate supply chain management is the cause of this counterfeiting, which jeopardizes patient safety and damages the reputation of the manufacturer. Blockchain technology can be applied to supply chain management to provide assurance, security, traceability, and openness to the chain by providing visibility and immutability of each stage in the chain. A relatively new electronic data management technology called blockchain has promise for transparency and accountability. A blockchain is a ledger of transactions that is viewable by all users of a computer network, each with an identical copy of the ledger.

1. Introduction

Blockchain is a computerized public ledger that is decentralized and digital, where transactions are recorded chronologically into "blocks." Around the world, a network of devices governs a blockchain network. A transaction between two parties is stored on the blockchain and cannot be modified because of the decentralized structure of the system without also altering all subsequent blocks[1–3] In First disclosed by Nakamoto in 2008, blockchain is an innovation and architecture platform that was introduced in 2009. The way that blockchain operates is by having peers create distributed ledgers where information is stored in a decentralized fashion across computing machines that are

* *Corresponding author*.
E-mail address: drfatamboli@gmail.com (F. A. Tamboli).

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part of the blockchain infrastructure.[3] In order to reduce the need for middlemen like banks and safeguard against a high risk of fraud and theft, blockchain was first created for cryptocurrencies. Certain transactions in the health sector, like the buying and shipping of pharmaceuticals and medical equipment in supply chains, as well as the monitoring of staff access rights and permissions to facilities, medical records, and other health data, may also require transparent and unchangeable record keeping.[4] The tracking and supply of medicinal products could be reliably protected legally through the application of blockchain technology in pharmacy. A system like this may greatly simplify pharmaceutical product audits and controls, even for specifically designated entities. The greatest solution for 21st-century cybersecurity is blockchain, and as of right now, no vulnerabilities have been discovered in it. Because it is made to make it impossible for a single person to alter transactions or data, blockchain can boost confidence and aid in the eradication of bias present in conventional supply chain systems.[5]

2. Block Chain and Supply Chain

Following tight laws is crucial at every stage of the medication supply chain, which is a very complex operation with numerous transactions. There is a problem with manufacturerscurrent lack of transparency on the supply chain procedure used to verify authenticity.[6] With the implementation of the Drug Supply Chain Security Act (DSCSA) in the United States, supply chain security has gained prominence recently. The Act has been put into effect, among other things, to combat the issue of counterfeit drugs. Medication that is counterfeit is defined as having less active chemicals than it should, which can be harmful to patients.The pharmaceutical supply chain is a complicated one, with medications passing via distributors, repackagers, wholesalers, and manufacturers before they are delivered to a patient. Manufacturers can trace authenticity with minimal to no visibility across the supply chain.[7]

In Retailers, Manufacturers, and Drugstores Within the supply chain, the manufacturers job is to make sure their medicine inventory is ready for distribution to wholesalers. Manufacturers ship their items to distributors warehouses so they can be stored after receiving orders from distributors or wholesalers. Distributors will give manufacturers reports on inventory data in order to keep things transparent all the way through. The purpose of wholesalers is to streamline and expedite the process of buying prescription medications. Thousands of dispensers and pharmacies are served by wholesalers who link with them. Manufacturers can send big batches of medications to a comparatively smaller number of wholesalers, saving them the trouble of sending drugs to pharmacies one at a time. After the product is in the wholesaler's possession, they offer a variety of services, such as repackaging, electronic order services, and drug delivery. Hospitals and pharmacies are the last participants in the supply chain. Roughly 75% of the prescription medicine market is made up of pharmacies, with the remaining 25% coming from non-retail sources including hospitals. Products are bought by pharmacies and hospitals from wholesalers and subsequently sold to patients.[8]

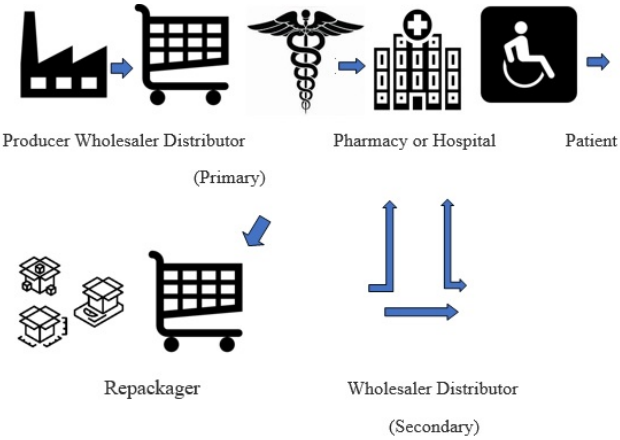

Figure 1: Chain of pharmaceutical supplies

3. Blockchain Networks

3.1. Blockchain technology

A blockchain is an ongoing series of blocks with data constructed in accordance with predetermined guidelines. Block chain copies are typically kept separate and unrelated on numerous computers.[9,10]

These devices, which are linked together by a common protocol and are used to carry out transactions and append new blocks to the chain, make up a Blockchain network[11]. The Blockchain network thus serves as a distributed information system that contains records of each and every transaction that has ever been finished in the past. It also runs on a predetermined protocol that defines the guidelines for carrying out and verifying transactions as well as the behaviors of network users.[12] Furthermore, this network is also occasionally referred to as a distributed registry since data regarding each transaction on the network is stored on each node that takes part in it.

There are three types of blockchain systems:

1. Public Blockchain (Permissionless Blockchain)
2. Consortium Blockchain
3. Private Blockchain

Any user can view and validate any transaction occurring on the network and take part in the consensus-building process on the public blockchain. The public blockchain operates without an administrator node to verify transactions; instead, participant consensus ensures that transactions are

genuine[13,14] Two well-known examples of these kinds of networks are Ethereum and Bitcoin. Permissionless and non-restrictive public blockchain allows anyone with internet access to register as an authorized node on a blockchain network. This user has access to both historical and current records and can perform mining operations, which are intricate calculations required to validate transactions before adding them to the ledger.[15]

An administrative node exists in the consortium blockchain. It is first chosen by the network's members based on the best means of achieving their respective business objectives, such as in the case of a collaboration. These kinds of networks can be thought of as somewhat decentralized since the data within them might be private as well as public (for instance, secret information). The Hyperledger platform is one instance of such a network.When a company needs a combination of private and public blockchain characteristics, a consortium blockchain—also referred to as a federated blockchain—is an innovative solution. A consortium blockchain allows for the public sharing of certain organizational details while keeping others confidential.[16]

There's one difference between a public blockchain and a private one. The public cannot access any of the data in a distributed register of this kind. Blockchain data is only accessible to members who have been granted permission by the administrative node. The development of such solutions can be done using Multichain or Hyperledger platforms. A private blockchain is a blockchain network that operates within administrative control or in a restricted setting, such as a closed network. In terms of peer-to-peer connectivity and decentralization, this kind of blockchain functions similarly to a public blockchain network, although it is significantly more limited in scope.

Additionally, substandard and counterfeit products have been found on the market by drug and medical regulatory bodies. In order to optimize operations and expedite medical transactions, patient safety, and tracing and tracking, many businesses in the pharmaceutical sector have looked to implement blockchain technology as a result of misconduct and malfunctioning supply chains.[1]

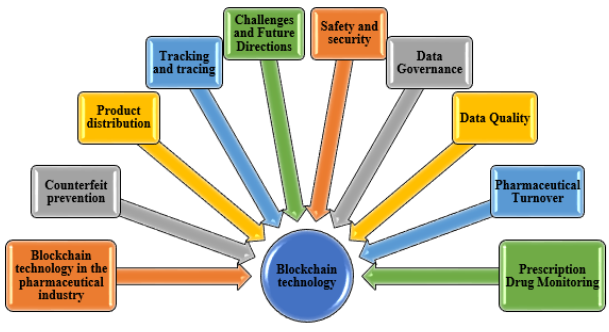

Figure 2: Blockchain technology

3.2. *Blockchain applications in the medical field*

Blockchains are employed in the pharmaceutical sector for a variety of reasons. Cryptographic methods are utilized to validate blocks of transactional data, thereby addressing a significant difficulty in security.[17,18] In order to combat theft, drug traceability has also been improved. Digital signatures are used for quality control, and data miners, blockchain chaincodes, and health information are used from the producer to the pharmacy to ensure consistent quality.[19] Before a medication's final formula is created, its ingredients are often obtained from a number of sources. The medication can be supplied once the ideal recipe has been established. The drug will move between numerous parties over its life cycle in the supply chain, most notably between the patient and the producer.[8]

3.3. *Counterfeit prevention*

Security elements that allow consumers to verify the authenticity of pharmaceutical items and distinguish them from counterfeits are applied to them through serialization. Fake medications are extremely risky and put consumers lives at risk due to either a lack of active components or the presence of hazardous substances.[20] Additional ways that the blockchain technology enhances security are through transparent and chaincode-based transactions. The pharmaceutical industry depends on transparency and trust to operate. Lack of trust fosters the growth of the counterfeiting sector, endangering the public with shoddy or subpar medications. The application of blockchain technology improves quality control, helps identify counterfeit drugs, and saves lives.[17,21] The Anti-Counterfeit Medicine System (ACMS) is one instrument that can be used to prevent counterfeiting. ACMS makes advantage of the Interplanetary File System (IPFS) networks and the Ethereum blockchain in the following ways:

1. Launch the small business initiative.
2. Create Ethereum smart contracts using the Ethereum blockchain and IPFS networks for useful ACMS management.
3. To stop cloning, establish ownership guidelines for both retail and non-retail pharmaceuticals.
4. Evaluate and evaluate the proposed fix.

3.4. *Product distribution*

The existence of numerous dealers and middlemen creates a chance for dishonesty that reduces the effectiveness of the supply chain. Blockchain is praised for its ability to stop the distribution of subpar medications.[22] Blockchain technology is a good fit for addressing issues with distribution processes, like the spread of illicit or counterfeit drugs.[23] Reconstructing the product history and packaging

hierarchy is possible with serialization.[24] Four nodes were identified in one prototype: the FDA, the manufacturer, the distributor, and the retailer.[25]

Within the supply chain, the Manufacturers job is to make sure their medicine inventory is ready for distribution to wholesalers. After manufacturers receive orders from distributors or wholesalers, they ship the goods to the distributors warehouses, where they are stored. To ensure openness throughout the process, distributors will give manufacturers reports on inventory data.

Wholesalers job is to streamline and expedite the process of buying prescription medications. Thousands of pharmacies and dispensers are served by wholesalers who link and deliver to them. This allows manufacturers to distribute big batches of medications to a comparatively smaller number of wholesalers, saving them the trouble of sending drugs to pharmacies one at a time. After the product is in the wholesaler's possession, they offer a variety of services, such as repackaging, electronic order services, and drug delivery.[8]

3.5. Tracking and tracing

It makes sense that from the point of dispatch to the destination, commodities in transit should be monitored and traceable. In general, delivery delays cause problems for businesses, but in the pharmaceutical and health sectors, they can cause fatalities or worsen existing illnesses. Pharmaceutical supply chains have begun using blockchain technology.[26] There are new potential offered by blockchain to guarantee pharmaceutical traceability. Drug tracking, user privacy, quality control, non-repudiation, drug transparency, and demand-supply management are all facilitated by this architecture, which also fosters consumer trust.[27] To describe important blockchain features including responsibilities, authenticity, and the capacity to track pharmacological information, a quantitative investigation was conducted in India.[28] At any time and location, IoT devices have also been used to verify the legitimacy of data sources and evaluate the state of pharmaceutical products. Data transparency and traceability are ensured by blockchain's role as a mediator in data storage and sharing.[29] Crucial information regarding the origin, date, and storage methods of supplies can be viewed by key players throughout the supply chain thanks to blockchain-based track and trace. In addition, their ability to observe possible issues like delays or improper handling helps to reduce risk when working with expensive and highly sensitive materials.[30]

3.6. Safety and security

Traditional drug supply chain management's design features make it difficult to transmit essential information in a safe and reliable manner. Data can often be readily altered, deleted, and tampered with. Cryptography technology enhances drug security, while tracing and tracking capabilities satisfy regulatory standards.[31] Protection from theft and the introduction of fake medications is increased. Additionally, unapproved drug modifications are lessened, which stops shrewd pharmaceutical stakeholders from changing medications and compromising their quality.[14]

4. Data Governance

Blockchain technology provides delicate, transactional systems that need completely auditable, tamper-proof tracking mechanisms with data-centered security. Thus, despite preserving separate application domains and operational philosophies, blockchain and data governance (DG) complement each other in many ways. Supply chains and data governance have benefited from the application of blockchain and IoT technology.[32] IoT has also been utilized to guarantee regulatory compliance for medical products.[33]

5. Data Quality

The Internet of Things (IoT) has been utilized to meet GDP rules and guarantee quality during the transportation of medical supplies (e.g., temperature control) by using sensor devices in each package.[17] By guaranteeing the high quality of all data, blockchain technology can help overcome these difficulties. The new block is approved once it has been confirmed by all nodes that the data is genuine. Blocks with low quality scores, however, won't be added. Every transaction a user completes on a blockchain requires the network to carry out a number of specialized, monitored tasks. These are intended to make sure that the transaction is legitimate. This transaction is broadcast to all other nodes on the blockchain, which updates them instantly.

6. Pharmaceutical Turnover

By enhancing supply chain procedures, cutting waste, and guaranteeing that goods are dispersed effectively, blockchain can assist in lowering pharmaceutical turnover. Pharmaceutical firms are able to save money as a result, and patients can obtain medications on schedule.[34]

7. Prescription Drug Monitoring

Blockchain technology provides a transparent, safe, and decentralized answer to the problems that conventional PDMPs are facing. This is how blockchain technology can transform the monitoring of prescription drugs:

1. ***Decentralized Data Sharing:*** Blockchain makes it possible for states, pharmacies, and healthcare providers to securely share data in real-time, guaranteeing that authorized parties have access to the most recent patient prescription information. This stops patients from using data silos to their

advantage by requesting several medications from several places.

2. ***Immutable Records:*** Every prescription and patient interaction is documented on the blockchain as an unchangeable transaction. This lowers the possibility of fraudulent activity by guaranteeing the accuracy of prescription data.
3. ***Increased Privacy:*** Patient privacy can be given top priority in blockchain design. To improve confidentiality, patients can explicitly consent to the use of their data, and access can be restricted to licensed healthcare providers only.
4. ***Interconnection:*** The capacity of blockchain technology to facilitate seamless connections between various states and healthcare systems promotes cooperation in the monitoring and control of prescriptions.
5. ***Smart Agreements:*** Before writing a new prescription, a smart contract can automate a procedure like checking a patient's past prescription history. This improves accuracy and lessens the workload for healthcare professionals.
6. ***Real-time notifications:*** When healthcare professionals come across patients with questionable prescription histories, blockchain-based systems can send out real-time notifications to them, allowing for early intervention and reducing over prescribing.[35]

8. Blockchain: Distributed Ledger Technology

By means of the so-called hash, which is produced by a cryptographic one-way hash function (such as SHA256), every block in the blockchain is connected. Additionally, it guarantees the block's tightness, immutability, and anonymity.[36,37] Every transaction that a node completes is signed before it is broadcast to the network for a subsequent confirmation. The digital signature applied to a transaction using the private key ensures the transaction's authenticity and integrity. Two reasons exist for this: first, only a user with a certain private key can sign the transaction; second, a data transmission error stops decryption (i.e., digital signature verification). When a network employs a certain consensus mechanism, such as proof-of-work or proof-of-stake, a subset of nodes, referred to as miners, gather and group the transactions that are dispersed over the network and approved by the network into blocks that are timestamped. The validation nodes examine the blocks once they are broadcast to the network. They do this by using the hash that goes with the block to verify that the block they have received contains valid transactions and references the block that came before it in the chain. The nodes add the block to the blockchain when both requirements are satisfied. If the requirements are not fulfilled, the barrier is taken down.

8.1. Blockchain node's fundamental responsibilities are:[38,39]

1. Establishing a connection to the blockchain network,
2. Maintaining an accurate ledger,
3. Listening to transactions,
4. Forwarding legitimate transactions to the network,
5. Keeping an eye out for freshly sealed blocks,
6. Validating recently sealed blocks by verifying transactions,
7. Generating and forwarding new blocks.

8.2. Advantages[40,41]

1. (a) Available: Since it's available to everyone, anyone can contribute to the development of blockchain technology.
   (b) Endless: Since blockchain technology creates a decentralized network with multitudinous dependable bumps, multiple clones of data are kept at each original knot, making records and information stored with it noway need to be bothered about being lost.
   (c) Uncensored: The agreement process of blockchain technology, which uses smart contracts to validate deals, permits deals to be approved without the intervention of a single party. This makes blockchain technology uncensored.
   (d) Empirical: Using zero- knowledge evidence, which allows one party to demonstrate to another party the delicacy of data without telling any information about the data, blockchain technology is used to keep information in a decentralized way, enabling everyone to confirm the delicacy of the data.

8.3. Challenges

The following are the main obstacles to blockchain deployment:[42,43]

1. (a) Assuring the integrity of the data entering the chain;
   (b) relating and aligning on blockchain norms;
   (c) Authenticating individual and firm relating;
   (d) Managing compliance and security norms;
   (e) Addressing interoperability;
   (f) Addressing governance;
   (g) Ensuring the integrity of the data entering the chain;
   (h) relating and aligning on blockchain norms;
   (i) Authenticating existent and establishment relating;
   (j) Managing compliance and security norms;
   (k) Addressing interoperability;

(l) Educating and raising mindfulness of the involved stakeholders;
(m) Having trouble assembling the necessary stakeholders;
(n) Implicit non supervisory counter accusations

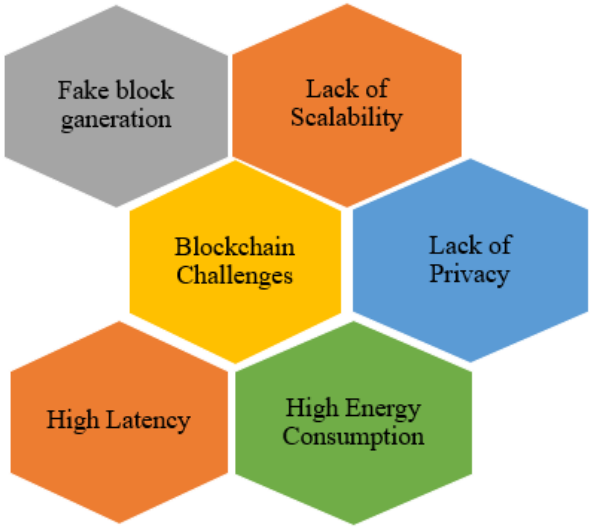

Figure 3: Blockchain challenges[44]

9. Conclusion

New technology like blockchain is predicted to provide a bright future for a number of different businesses. Blockchain research in healthcare is now trending toward being mostly utilized for data exchange, access control, and health records; it is seldom employed for other purposes, such as supply chain management or medication prescription administration. As a result, blockchain has a lot of untapped potential. Smart healthcare systems with IoT capabilities are vulnerable to serious security risks and difficulties. It is necessary to comprehend the security requirements of such systems in order to reduce these threats and obstacles. Because of the single-point-of-failure, greater cost, limited scalability, and resource-constrained nature of IoT devices, standard security procedures are unable to fully address the security needs of the IoT-enabled smart healthcare system. Additionally, blockchain has its limitations. Scalability is a problem with blockchain technology. Deploying a Blockchain solution to every supply chain participant would be challenging at this point. Much more thorough testing would be necessary to guarantee the success of large-scale deployments involving numerous clients.

10. Sources of Funding

None.

11. Conflict of Interest

None.

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Author biography

Manasi S. Zade, PG Student

Firoj A. Tamboli, HOD

Apurva A. Salunkhe, PG Student

Monali D. Kore, PG Student

Dipali S. Bhusnar, PG Student

Komal M. Dikole, PG Student

Dnyaneshwar M. Mane, PG Student

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