INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Article

Drug Recall Management for Pharmaceutical Industry from Blockchain Perspective

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ARTICLE INFO

Published: 12 Aug 2025
Keywords:
Blockchain technology, Drug recall supply chain management, CAPA, OOS/OOT
DOI:
10.5281/zenodo.16812751

ABSTRACT

In the pharmaceutical industry, drug recalls are critical events that can significantly impact public health, company reputation, and financial stability. This study investigates how blockchain technology, which offers a decentralised, transparent, and unchangeable ledger for tracking medications over their whole lifecycle, can improve drug recall management. We examine the limitations of traditional recall systems, including inefficiencies in traceability, communication breakdowns, and delays in response time. By implementing blockchain solutions, stakeholders can achieve real-time visibility of drug products, streamline communication across the supply chain, and facilitate rapid identification and retrieval of affected batches. The paper further discusses the implications of smart contracts in automating recall processes and ensuring compliance with regulatory requirements. Case studies illustrate successful blockchain applications in drug recall scenarios, highlighting improvements in safety, efficiency, and accountability. Ultimately, we propose a framework for integrating blockchain into existing recall management systems, aiming to enhance the overall resilience and reliability of the pharmaceutical supply chain.

INTRODUCTION

The process of developing new drugs and getting them approved by regulators is called pharmaceutical research and development, and it can take several years. After the process is finished and a standard product is developed, the next task for manufacturers is to deliver the finished product to the intended customer in its original form and ensure that the customer receives the authentic product, created by the authorised manufacturer and not by a counterfeiter. However, the pharmaceutical industry's present supply chain management (SCM) system is antiquated and lacks regulatory authority over the distribution of medications as well as visibility and control for

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

producers [1]. The procedure of recovering defective and possibly dangerous products from customers and giving them compensation is known as a product recall. Even though a product recall might be viewed as a business' worst nightmare and has a clear short-term financial impact on shareholders [2]. corporations can lessen the negative effects of product dangers by implementing voluntary recalls. They demonstrate their social responsibility in this way as well [3]. We propose a system that will increase transparency throughout the product recall process and shorten the time frame for recalls after the first signs of potential harm. This framework has three layers, as seen in figure [4]. Blockchain is a platform for architecture and technology that was initially made public in 2009 by Nakamoto (2008). A decentralised distributed infrastructure made up of computing equipment that are a part of the blockchain architecture is created by collapsing peer-to-peer recording ledgers, which store data. Blockchain is defined as a distributed database that functions as a peer-to-peer network. Every asset transaction on the network is verified by cryptography and subject to rules outlined in smart contracts between its members before being added to a permanent record (or "ledger") that documents any violations and builds a chronological timeline of events [5]. Drug recalls can be costly for businesses since they have to replace recalled goods or cover lost revenue [6]. Certain health-related transactions, such as the procurement and delivery of pharmaceuticals and medical supplies through supply chains, as well as the management of staff access privileges and authorisations to facilities, patient information, and medical records, may also require transparent and unchangeable record keeping [7]. The medication supply chain is an intricate web of exchanges that needs careful
the strict compliance with laws at all times. The present issue with manufacturers' lack of transparency on the supply chain process utilised to confirm authenticity [8].

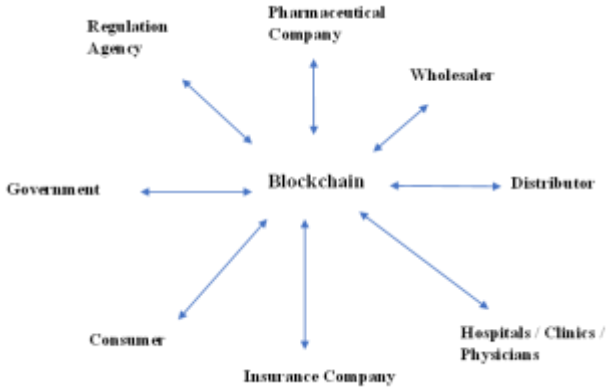

Figure 1. Blockchain-based medical supply chain [9]

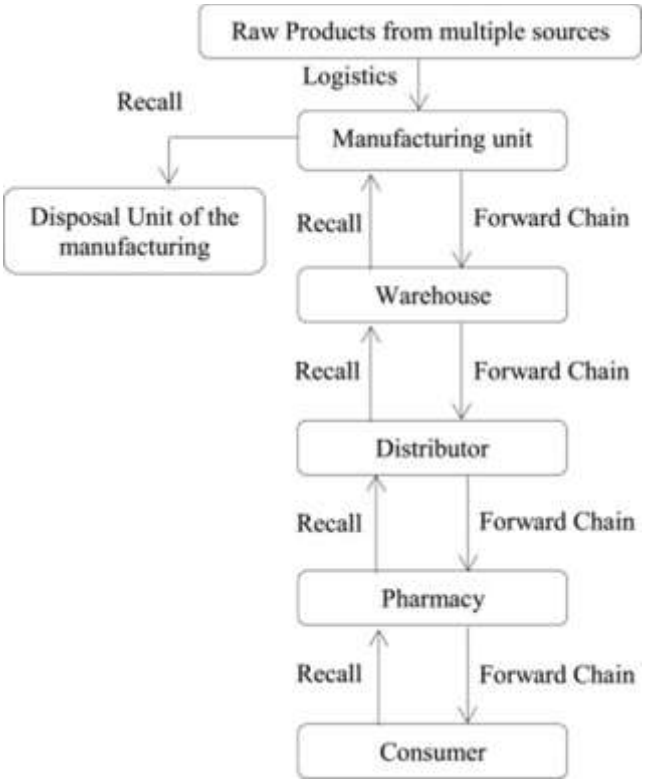

Figure 2. Drug recall supply chain management [10]

With the US enacting the Drug Supply Chain Security Act (DSCSA), supply chain security is growing in popularity. The Act has been put into effect in order to combat the issue of counterfeit pharmaceuticals, among other things. The hallmark of counterfeit medication is a lower concentration of active chemicals than is advised, which puts patients at danger. Drugs must first pass via a complex supply chain that includes

producers, wholesalers, distributors, and repackagers before they are administered to a patient. Manufacturers can confirm authenticity even in situations where they have little to no supply chain visibility [9].

Table 1: The Blockchain technology principally contains six key elements: Decentralized, transparent, immutable, autonomy, open-source, and anonymity [11].

Key Elements	Functional Description
Decentralized	A database that is open to all network users with unrestricted access. The information is available for viewing, tracking, storing, and updating across several platforms.
Transparent	The recorded and stored data on the blockchain is easily updated by potential users, allowing others to see it. The transparency of blockchain technology may effectively prevent data theft and alteration.
Immutable	Once saved, the records become permanently reserved and are difficult to edit without simultaneously controlling more than 51% of the node.
Autonomy	Due to the blockchain's independence and autonomy, data may be safely accessed, transferred, stored, and updated by any node on the system, making it reliable and unaffected by outside interference.
Open Source	Every network member has open-source access because to the way the blockchain technology is designed. Anyone has the right to create a variety of future applications in addition to being able to view the records openly thanks to its unique versatility.
Anonymity	The system is more dependable and safer since nodes send data while maintaining the anonymity of the individual.

Three steps are used by blockchain technology to improve the security of certain data: 1) Data 2) Hash 3) Hash of the Previous Block (HOPB). The security key connects these three phases [12].

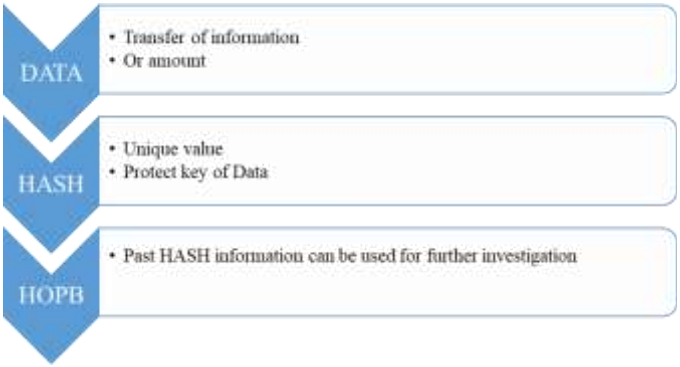

Figure 3. The working principle of blockchain

2. Types of block-chain technology [13]

Blockchain technology is classified based on three types of concepts that are:

1) Based on data accessibility,
2) Based on authorization to participate, and
3) Based on core functionality and smart contract.

Table 2: Types of Blockchain Technology Based on Data Accessibility

Public blockchain technology	Private Blockchain Technology	Community/Consorti um blockchain technology	Hybrid Blockchain Technology
Anyone can read and contribute transactions using public blockchain technology.	One company may employ private blockchain technology, or all of the subsidiary companies in the same group may be able to view and submit transactions.	Combining elements of both public and private blockchain technology, consortium blockchain technology is more like private blockchain technology in terms of functionality and proportions.	In this novel concept, transactions can be facilitated or secured by combining any three types of blockchain technology: Public, Private, Community/Consortium. Hybrid Blockchain technology allows a Blockchain platform to be secured and configured in several modes.

Table 3: Types of blockchain Technology Based on Authorization

Permission Less blockchain technology	Permissioned blockchain technology
Without requiring prior authorisation to use this type of blockchain technology, anyone can utilise their computer resources to join the Blockchain technology network and participate in the verification process. For example, Ethereum and Bitcoin	Participation in this type of Blockchain technology necessitates prior approval. In the Blockchain technology network, nodes are used to validate transactions and can only be operated by authorised persons.

Table 4: Types of blockchain Technology Based on Core Functionality and Smart Contracts

Stateless blockchain technology	Stately blockchain technology
Systems using stateless blockchain technology only concentrate on transaction optimisation and chain functionality, such as hash computation for transaction verification. This kind of Blockchain technology requires permission in advance.	This type of blockchain technology enables smart contracts and transaction computing. It preserves the logic states and facilitates the optimisation of intricate business logic.

3. Functioning of Blockchain Systems-Consensus Mechanisms:

The consensus is nothing more than the kinds of algorithms that are employed to correctly apply blockchain technology for a given transaction or task [14]. Consensus in a blockchain network is the process of coming to an agreement on what is believed to be the present state of the blockchain, which is considered to be its trustworthy reality. A consensus protocol specifies the procedures for validating transactions, adding a new block to the chain, and choosing which fork or partition to use in the event that a network split. The necessity and prerequisite for the consensus may vary based on the use case and the surrounding circumstances. Global and local consensus mechanisms can be roughly categorised. According to the global consensus model, each node in the network agrees on the same network state and stores the entire chain to validate any transaction. This first block of the chain, known as the genesis block, is shared by all nodes in the network. Blockchains with global consensus that are most frequently used are Ethereum and Bitcoin. Compared to global consensus equivalents, this local consensus is typically more scalable and lowers the storage needs on individual nodes. Examples of blockchains are Nano and Trust Chain [15].

4. Blockchain technology

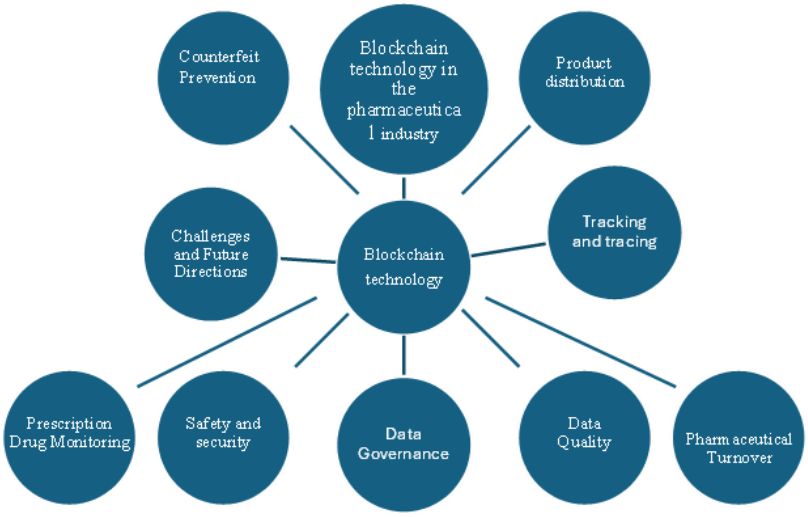

Figure 4. Blockchain Technology

1. Blockchain technology in the pharmaceutical industry: The pharmaceutical industry uses blockchain technology for a number of purposes. One of the primary issues is security, which is resolved by validating transactional data blocks using cryptographic technology [16]. To further discourage theft, drug traceability has been improved. Digital signatures are used for quality control from the manufacturer to the pharmacy, and data miners, blockchain chaincodes, and medical records are utilised to ensure consistent quality [17]. Press Atlantis. By using this method, verification checks that are placed across the supply chain system authenticate serial numbers [18].

2. Counterfeit prevention: Pharmaceutical products are given security characteristics through serialisation, allowing consumers to verify their legitimacy and distinguish them from fakes. Because fake pharmaceuticals either contain dangerous compounds or have no active ingredients, they are quite dangerous and endanger the lives of their users [19]. The pharmaceutical industry relies on transparency and trust since, in the absence of these attributes, the counterfeiting industry thrives and puts the public at danger of receiving mediocre or low-quality pharmaceuticals [20]. Several tactics, like the Anti-Counterfeit Medicine System (ACMS)validity and separating them from counterfeits, can be used to curb counterfeiting [21]. Fraud is successfully prevented by the ACMS. When a transaction starts, clients create a chaincode. Peer endorsements are used to validate the signature. Once the endorsements are gathered, they are forwarded to ordering services, where transaction validation completes the process [22].

3. Product distribution: The probability of deceit stemming from the existence of several vendors and intermediaries reduces the effectiveness of the supply chain. We applaud blockchain for its ability to stop the proliferation of subpar medications [23]. Four nodes were discovered in one prototype: the distributor, the manufacturer, the retailer, and the FDA[24]. Along the supply chain, it is the manufacturers' duty to make sure that their stock of pharmaceuticals is ready for delivery to wholesalers. After receiving orders from wholesalers or distributors, manufacturers ship their goods to distributors' warehouses, where they are stored. Distributors will provide reports on inventory data to manufacturers in order to ensure transparency at every stage of the process. Wholesalers are in charge of streamlining and expediting the prescription medication procurement process. Connecting with thousands of pharmacies and dispensers, wholesalers deliver their goods. This allows producers to distribute big batches of goods to a relatively small number of wholesalers, relieving them of the load of having to transport pharmaceuticals to pharmacies one at a time. The wholesaler offers a variety of services after gaining custody of the items, such as computerised order services, drug delivery, and repackaging [21].

4. Tracking and tracing: It seems sense that from the point of dispatch to the final destination, commodities in transit should be able to be tracked and traced. Delivery delays typically cause problems for businesses, but in the pharmaceutical and medical sectors, they can worsen preexisting diseases or even be fatal [9]. Drug traceability and tracking are essential for company operations, patient safety, and regulatory compliance. Precise and safe tracking and tracing technologies enable the prompt delivery of goods in transit to their designated destinations, facilitating pharmaceutical trade and patient management [25]. Key players in the supply chain may now review crucial information on the provenance, date, and storage methods of goods thanks to blockchain-

based track and trace. Additionally, its ability to identify possible issues like as delays or improper handling reduces risk when handling expensive and particularly delicate objects [9].

5. Safety and security*:* Transmission of critical information in a reliable and secure manner is a challenge posed by the design components of traditional medication supply chain management. Tracing and tracking capabilities help meet regulatory standards, while encryption technology improves drug security [26]. Pharmacogenomics data may now be efficiently stored and queried on the Ethereum blockchain thanks to a proprietary smart contract that was developed using an index-based, multi-map methodology. Because each genomic note—three genetic drugs with results—is stored in a searchable mapping by a unique identity, the nodes offer efficient storage and query time and space [27].

6. Data Governance: Blockchain technology enables complex, transactional systems that call for data-centered security and completely auditable, tamper-proof tracking techniques. Data governance and supply chains have improved thanks to blockchain and Internet of Things applications. The use of blockchain and Internet of Things technology has improved supply chains and data governance [28]. IoT has also been used to make sure that laws governing medicinal items are followed [29].

7. Data Quality: The Internet of Things (IoT) has been utilised to ensure quality during the transit of medical supplies (e.g., temperature control) and follow GDP laws by utilising sensor devices in each package [9]. Similarly, IoT can be used to monitor the temperature of pharmaceuticals as they are being distributed, alerting all parties to take appropriate action [30]. In addition to preserving the veracity of product recall data, recall management can increase accountability and efficiency. However, stochastic simulations have been utilised to protect drug supplies against theft and temperature aberrations even in markets where open management and tamper resistance are not very common [31].

8. Pharmaceutical Turnover: The Internet of Things (IoT) has been utilised to ensure quality during the transit of medical supplies (e.g., temperature control) and follow GDP laws by utilising sensor devices in each package [32]**.** Pharmaceutical turnover has been managed using blockchain technology, in this case Hyperledger Fabric, however it is unclear how useful this technology will be in the future because it is so new [33]**.**

9. Prescription Drug Monitoring: This is how blockchain technology can transform the monitoring of prescription drugs are Decentralized Data Sharing, Immutable Records, Increased Privacy, Interconnection, Smart Agreements and Real-time notifications. The RxCoin smart contract, which uses Ethereum blockchain technology and a type of digital currency to electronically represent medications, was implemented to address the opioid issue [34]**.** RxCoin contracts do not take into account HIPAA privacy standards for personal health information kept on the blockchain, nor do they demonstrate how the blockchain may be utilised to supply the functionality of a prescription drug monitoring system (PDMP).

5. The architecture of the pharmaceutical recall management system based on blockchain [4]

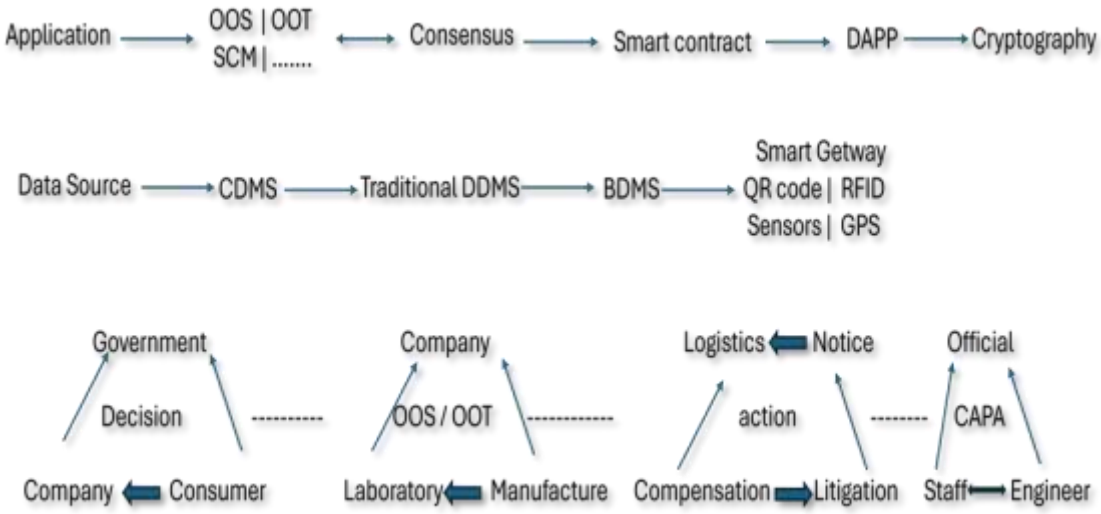

Figure 5. The architecture of the pharmaceutical recall management system based on blockchain

Our proposal aims to improve transparency throughout the product recall process and reduce the amount of time it takes to initiate the recall following the primary indications of potential damage. This architecture, as seen in figure 1, has three layers. A product recall often entails a number of decision-making processes, recall activities, and Corrective and Preventative Action (CAPA) measures.

There are four sources of data in the blockchain network: real-time data collected, the Blockchain Database Management Systems (BDMS), the Centralised Database Management Systems (CDMS), and the classic Distributed Database Management Systems (DDMS). The final source is made up of a variety of smart assets, such as sensors, GPS, RFID tags and readers, and QR codes [35].

The component based on smart contract (CBSC) for producing the blocks will receive the data and information provided by the perception layer. It offers the Component Based on Smart Contract (CBSC), which serves as a single party (node) for the integration and transmission of information. These consist of numerous proprietary software and systems, such as the Out of Specification (OOS) and Out of Trend (OOT) management systems, Supply Chain Management Systems (SCMS), Logistics Management Systems (LMS), and Enterprise Resource Planning (ERP) software. Through the CBSC, the application layer collaborates closely with the blockchain network.

5.1 Essential steps for a product recall

1. Synergistic decision: There are two types of product recalls: proactive recalls and passive recalls. Pharmaceutical businesses acquire and analyse information, carry out investigations, and assess goods that might be a safety issue in a proactive recall before it is mandated by law. In a passive recall, the government's regulatory agencies order pharmaceutical companies to recall any products that may pose a risk to public health through analysis and inquiry. A product can be recalled at three different levels. Recalling goods that pose a substantial risk to health is the first step. Recalling products that pose a short-term or short-term risk to health is the second step. The second stage is to recall products that present a short-term or short-term health risk. The third level involves recalling products that, for the most part, do not

present a health danger but need to be recalled for other reasons. In general, the level will affect the recall metrics. We help the service analyse the data it has collected in order to determine the recall threshold. Recall decisions can result from a variety of quality issues, including bias, investigating out of specification (OOS), investigating out of trend (OOT), complaints, adverse medication reactions, and more. The gathered data is analysed to determine the recall level.

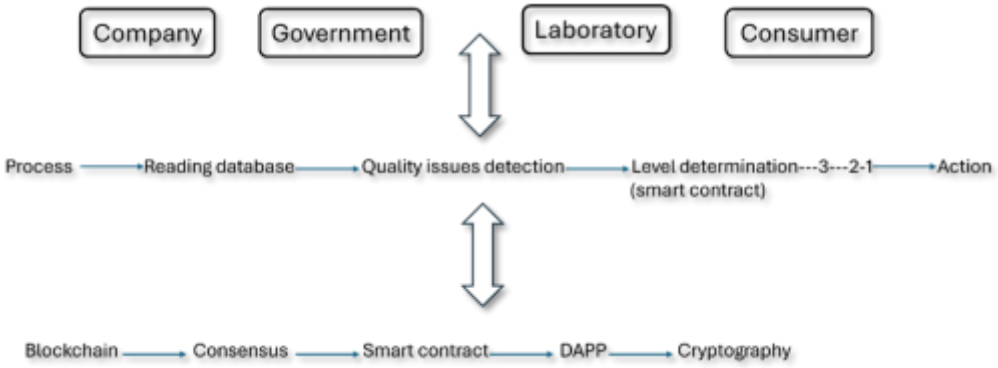

Figure 6. Synergistic decision making

2. Quality issues detection: In order to determine the deviation, the complaint rate, and the adverse events, we have developed an analytical model. The smart contract will then decide what happens. The smart contract will direct the government or a related commercial laboratory to finish the OOS/OOT investigation once the results satisfy the recall requirements. Each record that is produced in this manner needs to be added to the blockchain network.

3. The OOS/OOT investigation: In Figure, the OOS/OOT query is visible. After deciding to move forward with the OOS/OOT study, laboratory analysis must be finished in order to receive the OOS/OOT outcome. The smart contract will decide whether to proceed to the next phase of the inquiry based on this result. The OOS survey will be divided into multiple phases, each overseen by a smart contract.

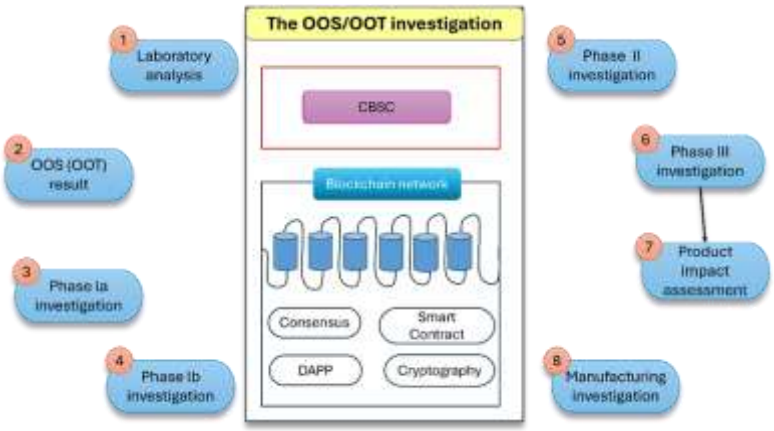

Figure 7. OOS/OOT investigation

6. Challenges of blockchain [36]

- Fake block generation
- Lack of scalability
- Lack of privacy
- High latency
- High energy consumption

7. Advantages of Drug recall management from blockchain [37]

- Traceability
- Enhanced Security
- Faster Response Times
- Improved Communication
- Regulatory Compliance
- Consumer Confidence
- Cost Efficiency

8. Disadvantages of Drug recall management from blockchain perspective

- High Implementation Costs
- Complexity of Integration
- Scalability Issues
- Regulatory Uncertainty
- Data Privacy Concerns
- Technological Immaturity

AUTHORS' CONTRIBUTIONS: All authors contributed equally

FUNDING: The author did not receive any financial aid.

CONFLICTS OF INTEREST: The authors have declared that no competing interests exist.

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HOW TO CITE: Khyati Shah, Dhara Patel, Grishma Patel, Dhananjay Meshram, Drug Recall Management for Pharmaceutical Industry from Blockchain Perspective, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 8, 1276-1287. https://doi.org/10.5281/zenodo.16812751