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Review Article

# Blockchain technology for enhancing supply chain integrity in the pharmaceutical industry

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## Abstract

Pharmacies have to effectively oversee their data. Blockchain is a cutting-edge technology that could improve safety and transparency for a range of pharmaceutical activities. Blockchain technology is a solution to the Drug Supply Chain Security Act (DSCSA), which was passed by the US Congress in 2013 to forestall drugs that are stolen, tainted, or counterfeit. Blockchain technology is a decentralized distributed ledger that secures a peer-to-peer network of transactions leveraging cryptographic techniques. These ensure that a product is safe and appropriate for sale to consumers. Blockchain offers solutions to increase the validity, reliability, and efficiency of drug production by ensuring that laws are easily followed. It also offers an opportunity to address one of the primary problems, which is the increase of counterfeit drugs entering the market and ending up in the hands of consumers or patients. The pharmaceutical industry claims that imitation pharmaceuticals pose a severe threat to society. False prescription drugs can have a direct or indirect detrimental effect on a patient's health, occasionally resulting in serious issues or even death. This counterfeiting, which puts patient safety at risk and harms the manufacturer's reputation, is the result of the pharmaceutical industry's poor supply chain management. By offering visibility and immutability of every point in the chain, blockchain technology can be used in supply chain management to provide assurance, security, traceability, and transparency. Blockchain, a relatively new electronic data management system, holds promise for accountability and transparency. All users of a computer network can examine a blockchain, which is a ledger of transactions, as well as each user has an identical copy of the ledger.

**Keywords:** Pharmacy, Cryptographic techniques, Drug supply chain

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## 1. Introduction

Blockchain is a decentralized, digital, and computerized public ledger in which transactions are chronologically stored into "blocks." A blockchain network is governed by a global network of devices. Due to the decentralized nature of the system, a transaction between two parties is recorded on the blockchain and cannot be changed without also changing all following blocks. Blockchain is a platform for innovation and architecture that was first revealed by Nakamoto in 2008.[1] Blockchain works by allowing peers to construct distributed ledgers, which store data in a decentralized manner among computer systems that are a part of the blockchain architecture. Peers build distributed ledgers, which store data in a decentralized manner across computer systems that are a part of the blockchain infrastructure, this is how blockchain works.[4]

Blockchain was first developed for cryptocurrencies to combat the high risk of fraud and theft and to lessen the need for intermediaries like banks. It may also be necessary to maintain transparent and unalterable records for certain health-related transactions, such as the purchase and transportation of medications and medical equipment in supply chains, as well as the tracking of employee access rights and permissions to facilities, medical records, and other health data. Blockchain is the best answer for cybersecurity in the twenty-first century, and to yet, no flaws have been found in it. Blockchain may increase trust and help eliminate bias in traditional supply chain systems since it is designed to make it difficult for one individual to change transactions or data.[2,3]

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## 2. Block chain

A blockchain is a kind of database or storage system that stores data using blocks and chaining. When fresh information is received, it is first added to a new block and then linked to the earlier Blockchain. A data chain known as a "Blockchain" is created when blocks with certain storage capacities are filled and connected to the block that came before it. In 1991, studies conducted the first research on the concept of blockchain.[5] Their goal was to create a system that made it illegal to change the timestamps on documents. In 2008, a group of mysterious people called Satoshi Nakamoto created the Blockchain, a peer-to-peer network that addressed the double-spending issue. A BC is a kind of distributed ledger in computing that creates an immutable ledger of data cryptographically using a special technological idea. It is managed by a decentralized network where all records are approved by a certain consensus method. Because BC is a distributed ledger, network supervision and control don't need a centralized entity or an administrator.[1,6]

To put it simply, BC is defined as a collection of blocks that include information in the form of transactions that are publicly and chronologically recorded and that are not subject to backdating or manipulation. A consensus mechanism is used by the decentralized nodes to validate the transactions (user systems). Instead of being overseen by a single entity, the ledgers are dispersed across all participants. Once information has been recorded on a BC, it is very hard to alter. A BC is a kind of database that only permits data addition and reading.[7]

### *2.1. Blockchain network types*

There are several methods for creating a BC network. They may be authorized or created by a consortium of people, or they may be private or public.

Public BC Networks: Anyone can sign up for and take part in a public BC, like Bitcoin. Significant processing power is needed in this kind of BC, and transactions are conducted with little to no privacy and inadequate security.

Private BC Networks: A private BC network administered by an organization is one that is managed by a single firm for its clients. This company also decides who is allowed to participate, conducts a consensus process, and keeps track of the shared ledger. This can entail using a BC inside the business's firewall. A permissioned BC network is typically set up by a company looking to create a private network.

Notably, public BC networks can also have permissions configured. All users can see the public, permissioned BC network validation of blocks by pre-selected nodes. In private permissioned BC, an organization controls the block's validation, meaning it is fully centralized.[8]

Consortium BC: By working together, multiple businesses can keep a BC. All transactions and data access in this kind of BC are managed by pre-selected companies. When all members need permits and share responsibility for the BC, a consortium BC is suitable.

### *2.2. Blockchain Development*

Decentralization, distribution, encryption, and immutability are the five elements that make up a real BC, according to research and consultancy firm Gartner. Provides a model based on the development and maturity of BC systems based on these five factors:

#### *2.2.1. Phase 1: Solutions Inspired by BC (2012-2020)*

The solutions only include three of the five elements: immutability, encryption, and dissemination. With the goal of increasing efficiency by streamlining current processes, the majority of these services are experimental and not yet fully implemented.

#### *2.2.2. Phase 2: BC-Complete Solutions*

In order to spread the full BC value offer, this phase's solutions incorporate all five components. However, according to Gartner, only startups will be developing solutions at this stage of development by 2023.

#### *2.2.3. Phase 3: Improved-BC solutions*

In the third phase of BC, complete solutions will be integrated with related technologies, such as decentralized self-sovereign identity (SSI) systems, artificial intelligence (AI), and the Internet of Things (IoT).

### *2.3. Why Is BC Necessary?*

1. Unchangeable transactions: By recording transactions in chronological order, BC ensures that all activities are unchangeable. A new block cannot be removed or altered after it has been added to the current BC. This promotes transparency and guarantees the permanence of every transaction.
2. Fraud prevention: The concepts of agreement and shared information aid in lowering losses from embezzlement and fraud. Using BC as a monitoring tool lowers costs for businesses that rely on logistics.
3. Reliability: The distributed ledger (DLT) technology remains functional even in the event that a significant number of other nodes fail since each participant has access to a copy of the original BC.
4. Time reduction: Because all parties have access to a single version of the agreed-upon data from the shared ledger, BC can play a crucial role in facilitating speedier trade resolution by doing away with the need for a

drawn-out verification, settlement, and clearing procedure.

5. Collaboration: Enables parties to communicate directly with one another without the use of an intermediary. Security: BC certifies and validates the interested parties' identity. This speeds up transactions, reduces charges, and gets rid of duplicate records.
6. Transparency: All transactions are final and the BC offers greater transparency. With a BC network, we can track orders, payments, accounting, and manufacturing. We can thus view all aspect of a transaction from start to finish when we look at the BC, which gives us more assurance as well as more opportunities and efficiency.

### *2.4. Blockchain technology*

A blockchain is a distributed database that is impenetrable and uses peer-to-peer networks to store blocks of data for transactions that are cryptographically bonded. Users may exchange verified and updated ledgers for each transaction thanks to a blockchain's design. Copies of every transaction are sent to nodes, who verify them and synchronize the data across the network. Therefore, there is no longer a requirement for a central validating authority. The word "blockchain" originated from the linkages between transactions in distinct blocks.

Ensuring quick, safe transactions and supply chain integrity are key priorities for the pharmaceutical sector. Due to inadequate monitoring and tracing, stakeholders in the pharmaceutical business regularly lose money to theft and product loss. Authorities in charge of regulating drugs and medicine have also found inferior and fake goods on the market. Because of malpractice and dysfunctional supply chains, some pharmaceutical companies have attempted to use blockchain technology to improve operations and expedite patient safety, medical transactions, and tracing and monitoring.

#### *2.4.1. Blockchain technology in the pharmaceutical sector*

The pharmaceutical business uses blockchains for a variety of reasons. The application of cryptographic methods that validate transaction blocks addresses security, a significant concern. various paradigms give rise to various aspects of security. Serialization has been used to combat the security issue posed by counterfeit drugs. This technique incorporates verification tests that confirm serial numbers across the supply chain system. In order to avoid theft, drug traceability has also been improved. Digital signatures are used to provide quality control, and blockchain chain codes, health data, and data miners are used from the producer to the pharmacy to ensure constant quality.[8,9]

#### *2.4.2. Preventing counterfeiting*

Pharmaceutical items are given security features and serial numbers so that customers may verify them and distinguish them from fakes. Transparent and chain code-based transactions are another way that the blockchain system improves security. The pharmaceutical industry depends on trust and openness since, in the absence of trust, the counterfeiting sector flourishes and the public is put at risk of receiving subpar or low-quality medications. Blockchain technology improves safety and saves lives when used in quality control and medicine counterfeiting detection. The Anti-Counterfeit Medicine System (ACMS) is one of several strategies that may be employed to stop counterfeiting.[10]

The Ethereum blockchain and Interplanetary File System (IPFS) networks are used by ACMS in the following ways:

Create Ethereum smart contracts for useful ACMS administration by utilizing IPFS networks and the Ethereum blockchain; implement the program for small businesses; and set ownership rules for retail and non-retail medications to avoid cloning.

Analyze and assess the suggested system.

Fraud is successfully prevented by the ACMS. When a transaction is started, clients create a chain codes. The endorsements are gathered and forwarded to the ordering services, where transaction confirmation is the final stage, after the signature has been confirmed by endorsing peers.[11]

### *2.5. Distribution of products*

The effectiveness of the supply chain is threatened by malpractice when there are several dealers and middlemen. Blockchain technology has been praised for stopping the spread of subpar medications. Inadequate medications are isolated and their introduction into the pharmaceutical supply chain is examined. Pharmaceutical distribution is facilitated by ledger systems, chain codes, and serialization—the process of assigning pharmaceutical items serial numbers to allow for identification and distinction. To prevent unwanted access that can compromise security systems, blockchain data is strictly managed. The pharmaceutical delivery system is more efficient because to the Internet of Things (IoT).[12]

### *2.6. Monitoring and tracing*

It goes without saying that items in transportation should be monitored and traceable from point of departure to point of arrival. Delivery delays impair company operations generally, but in the pharmaceutical and medical sectors, issues can result in fatalities or worsening of illnesses. The pharmaceutical supply chain has seen the implementation of blockchain technology. Regulatory compliance, patient health, and corporate operations all depend on drug monitoring and traceability. Pharmaceutical business and patient management are made possible by the timely delivery of commodities in transit to their intended locations thanks to sophisticated and secure tracking and tracing systems. To

help with the worldwide delivery of medications, a safe international register was established. Smaller businesses could gain from the technology as well, even if it offers huge prospects for big pharmaceutical companies.

### *2.7. Security and safety*

Security is required to protect pharmaceuticals since they are valuable commodities. The pharmaceutical industry's safety and security are based on the cryptographic properties of blockchain technology. Cryptographic technology improves medication security, and monitoring and tracing capabilities meet regulatory standards. Security is strengthened against the introduction of fake medications and theft. Additionally, unauthorized drug changes are reduced, preventing shady pharmaceutical companies from altering medications and compromising their quality. Strict safety and security protocols that sound an alert in the event of a breach underpin supply chain systems.[13]

## 3. Manufacturing of pharmaceutical chains

Monitoring and optimizing the production and distribution of a business's goods and services is known as supply chain management, or SCM. In order to transform raw materials and components into finished goods and deliver them to the final consumer, it aims to enhance and increase the efficiency of every process. A firm may gain a competitive edge in the market, enhance consumer value, and decrease waste by streamlining its operations with the aid of effective supply chain management.

### *3.1. Important takeaways*

All of the procedures involved in turning raw materials and component parts into finished items are included in supply chain management (SCM), which is the centralized control of the movement of goods and services to and from a business.

1. Businesses may reduce unnecessary expenses and provide goods to customers more quickly and effectively by using supply chain management (SCM).
2. Costly product recalls, legal action, and negative publicity may all be avoided with effective supply chain management.
   Planning, sourcing, manufacturing, distribution, and returns are the five most important stages of supply chain management (SCM). A supply chain manager's duties include cost control and reduction as well as preventing supply shortages.

From production to distribution to providing medications and vaccines to customers, a pharmaceutical supply chain is a collection of different activities that take place within a pharmaceutical organization. Numerous procedures, including medication delivery, inventory control, pharmaceutical logistics, and supply chain management, make up a pharmaceutical supply chain. In addition to procedures, it involves a number of organizations, including distributors, manufacturers, suppliers, multimodal shippers, pharmaceutical logistics partners, and retailers. The pharmaceutical sector, which generated over $1.27 trillion worldwide in 2020, is constantly impacted by the supply chain. Because it guarantees that the products are transported effectively, punctually, and with the utmost quality, the pharmaceutical supply chain plays a critical role in the entire performance of the sector. As a result, the pharmaceutical industry's bottom lines are strongly impacted by how well a supply chain operates.[14]

The pharmaceutical supply chain techniques and network have been developed over decades of trial and error by pharmaceutical businesses, regulatory agencies, and leaders. There is still much space for improvement, though, particularly in terms of eliminating inefficiencies. The pharmaceutical supply chain is currently about to undergo yet another overhaul brought about by Industry 4.0.

The pharmaceutical supply chain must implement the most cutting-edge future technological solutions in order to deliver timely and high-quality medications and vaccines to patients. Given the excessive complexity of the pharmaceutical supply chain, the solutions must be able to keep up with the rate of interruptions, and visibility is crucial in this situation.
The pharmaceutical supply chain functions as a symbiotic relationship between several entities and activities.[15]

The following key phases are encountered when the supply chain strives to provide value to the final customers:

#### *3.1.1. Manufacturing*

Depending on patient demand, pharmaceutical companies manufacture medications and vaccines in different parts of the world. Purchasing the chemical components needed to make the medications is another aspect of this procedure. Pharmaceutical logistics, which are essential at every stage, are frequently used to convey the raw components to the production site. Additionally, manufacturers must label medications and vaccines in accordance with regulatory bodies such as the Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in Europe, the Central Drugs Standard Control Organization (CDSCO) in India, or the Therapeutic Goods Administration (TGA) in Australia.

#### *3.1.2. Storage*

To preserve the required quality after manufacturing, medications and vaccines require specialized storage facilities. When it comes to pharmaceutical cold chain-specific medications and vaccinations, it becomes even more crucial.

*3.1.3. Distribution*

Pharmaceutical logistics, which are often hired by pharmaceutical firms or distributors, assist in the distribution of the medications and vaccines.

*3.1.4. Retail*

After being replenished at retail establishments, the pharmaceutical items are sent to different pharmacies or patients.

*3.1.5. Compliance screenings*

At different points in a pharmaceutical supply chain, the pharmaceutical business is subject to many compliance screenings. Customs inspections at ports, airports, or borders are examples of these nodes. Additionally, the pharmaceutical compliance screening aids businesses in identifying inferior or fake medications.

These five key components are intertwined throughout the pharmaceutical supply chain manufacturers sell pharmaceutical medicines to distributors, who subsequently ship them to different retail outlets. Delivery to the final customer, made possible by pharmaceutical logistics partners, is the most important stage in the lifecycle of a medication, vaccination, or other medical product once it has been introduced. Pharma supply chain leaders must acquire and comprehend cutting-edge technologies that help businesses adapt to disturbances in order to guarantee that all the components operate together flawlessly.[16]

Drug distributors play a crucial role in the pharmaceutical distribution system by ensuring that patients receive high-quality, transparent, and timely medications. Pharmaceutical distributors oversee and facilitate 92% of pharmaceutical sales in the US (United States), according a Deloitte report. As a result, a medication distribution system becomes vital and they form an integral part of the pharmaceutical supply chain.[17,18]

The following duties are within the purview of the pharmaceutical distribution system

Ensuring a consistent flow of medications and vaccines: The optimal drug distribution system adjusts the supply to meet changing patient needs. This entails forecasting an impending surge in consumption and addressing all last-minute demand gaps.

Taking ownership of pharmaceutical products: The medicine distribution system not only acts as a middleman between pharmacies and pharmaceutical producers, but it also legally owns the medications and vaccines.

Increasing value in the pharmaceutical ecosystem: Optimal medication distribution systems lower capital and operating costs by delivering operational efficiency throughout the entire supply chain. Pharmaceutical distribution networks are still developing and contributing to the broader supply chain framework. Clean data and timely awareness of disruptive pharmacological events are increasingly essential components of an effective pharmaceutical distribution system in the present environment. It adds to the broader field of supply chain management for pharmaceuticals.[19]

A pharmaceutical supply chain differs significantly from a typical supply chain. First of all, compared to a typical supply chain, the pharmaceutical supply chain is somewhat more complicated. The pharmaceutical supply chain has a direct influence on people's lives and is governed by stringent government compliance standards.

The safe and prompt delivery of generics, prescription medications, over-the-counter (OTC) medications, biologics, and many more items—all of which have unique handling and storage requirements and hazards—is another duty of the pharmaceutical supply chain.

A pharmaceutical product encounters a variety of goals and limitations once it leaves the warehouse, which adds complexity to the supply chain process. Supply networks for pharmaceuticals must manage a number of stakeholders. Medical research groups, hospitals, clinics, and government agencies are also involved in addition to producers and distributors. In contrast, the standards of a typical supply chain are considerably easier.[20]

Compared to a standard supply chain, the complexity and cost of a pharmaceutical cold chain increase dramatically. Strict temperature control, which is required by the authorities, is a component of the pharmaceutical cold chain that helps to preserve the quality of the medications and vaccines. If pharmaceutical businesses lack adequate cold chain visibility, temperature-sensitive vaccines, medications, or biologics deteriorate. It may jeopardize the pharmaceutical supply chain's quality compliance component, putting patients' health at risk.

The way a pharmaceutical supply chain is managed is determined by its compliance component. Because there is no risk of product spoiling or temperature regulation, activities are far more relaxed in a typical supply chain. Dealing with insurance companies, healthcare management organizations, and other entities adds to the complexity. All of this adds to the difficulty of a pharmaceutical supply chain or cold chain logistics professional's work. Compared to managing a typical supply chain, managing a pharmaceutical supply chain is far more difficult.

The following are the top five roles that pharmaceutical supply chain management plays:

1. Planning: This entails developing a comprehensive supply chain plan for pharmaceuticals.

2. Sourcing: acquiring supplies, logistical partners for pharmaceuticals, storage facilities, etc.
3. Producing: Making medications and immunizations.
4. Delivering: Giving the patients their purchases.
5. Returning: Relocating medications to new markets with higher demand or returning or discarding spoiled drugs.

Supply chain management tasks vary from sector to industry and are approached differently by various firms. Other aspects of pharmaceutical supply chain management that businesses must consider include compliance.[21]

The absence of real-time visibility in pharmaceutical supply chains compensates for a number of friction points that prevent businesses from reaching their maximum potential. When combined, these friction points have a more significant detrimental effect on the entire revenue bottom lines. Let's examine the three main issues facing the pharmaceutical supply chain. The management of pharmaceutical cold chains differs greatly from that of a standard supply chain. Having a passive datalogger report alone is not enough to provide a complete picture of pharmaceutical cold chain monitoring; there are numerous levels involved. Leaders in the pharmaceutical supply chain may cause disruptions beyond compliance problems if they fail to respond promptly. Due to product rejection, it may also result in problems for the pharmaceutical supply chain in the medication distribution system. Pharma supply networks have started using active or passive data recorders lately to get accurate information about the conditions of cold chains.[22]

However, these are insufficient to stop compliance problems from leading to interruptions in the pharmaceutical supply chain. They are Compliance-related disruptions: A significant portion of the worldwide vaccine supply degradation is caused by incorrect shipment, which poses problems for the pharmaceutical supply chain. If there is a scarcity of a product because of damage or spoiling, the pharmaceutical business or the distributors are responsible for reshipping appropriate quality items.

Difficulty identifying disruptions: Because of the vast scope of a big pharmaceutical supply chain, it is challenging to identify certain occurrences in terms of time, place, or cause. Only a few times a year is it possible to conduct periodic audits, which are costly and time-consuming activities.

Overspending: Pharmaceutical executives need to budget for last-minute fulfillment orders to guarantee product availability in the event of damaged or non-compliant items. Using backup forwarders to cover these voids results in excessive labor, packing, and shipping costs.[23]

*3.1.6. Demand-Supply Fluctuations*

It works responding promptly to changes in supply and demand due to the characteristics of the pharmaceutical supply chain. Your rivals may gain an edge if you are unable to adequately adjust to changes in supply and demand. Products in the pharmaceutical sector are unavailable due to expiry, delays in transit and overstocking, which ensures that a certain product is never out of stock. This results in a high cost of working capital. Additionally, problems including product deterioration, theft, loss, and recalls necessitate that you enhance and optimize your supply chain's competitiveness, to beat the competition, think about overstocking, establish and adhere to stringent compliance standards.[24]

The following demand-supply fluctuations-related pharmaceutical supply chain issues are caused by the three issues mentioned:

1. Expiring products: In order to accommodate variations in supply and demand, overstocking is inevitable, which leads to product expiry. Pharmaceutical supply chains must therefore optimize their inventories in order to maximize stock availability.
2. Addressing the bullwhip effect: As the pharmaceutical product advances upstream in the supply chain, the likelihood of overstocking rises when accurate data on product demand is lacking. As we go up the pharmaceutical supply chain, the prediction efficiency declines because of the effect.
3. FIFO Management Challenges: Optimizing the pharmaceutical inventory is challenging due to the lack of good inventory data and forecast information.
4. On-time but incomplete: In the pharmaceutical sector, a partial delivery to patients is equivalent to no delivery at all. To fulfill the strict SLAs (Service Level Agreements), pharmaceutical teams must dispatch the remaining inventory as soon as possible. It exacerbates the problems with the pharmaceutical supply chain by increasing spending on the same number of goods that are associated with pharmaceutical logistics.
5. Complete Load Rejection Could Result from Part-load Damage: Part-load might result in needless waste of the remaining excellent packages and additional costs associated with a fresh JIT (Just in Time) full-load and on-time consignment.

*3.1.7. How can data-driven supply chains help you get the most out of your investment?*

Theft and counterfeiting of drugs among the most significant supply chain issues facing the pharmaceutical business are drug theft and counterfeiting. Pharmaceutical supply chain executives currently face three primary issues: Drug identification: It is fairly difficult to separate legitimate drugs from bogus ones, especially without a laboratory.

1. Tracing: Finding the good batch or shipment containing the counterfeit medications is crucial to stopping the medications from getting to consumers; knowing about a counterfeiting incidence alone is insufficient.

2. Locating breaches: It is challenging to identify the contaminated pharmaceutical product or products when there is no real-time awareness at the package level. Pharmaceutical firms require real-time package-level visibility in order to detect and address contamination.

To combat these issues with the pharmaceutical supply chain, real-time visibility is crucial. In a pharmaceutical corporation, from production to distribution to customer delivery of medications and vaccines. Numerous procedures, including medication delivery, inventory control, pharmaceutical logistics, and supply chain management, make up a pharmaceutical supply chain. In addition to procedures, it involves a number of organizations, including distributors, manufacturers, suppliers, multimodal shippers, pharmaceutical logistics partners, and retailers.[25]

The pharmaceutical sector, which generated over $1.27 trillion worldwide in 2020, is constantly impacted by the supply chain. Because it guarantees that the products are transported effectively, punctually, and with the utmost quality, the pharmaceutical supply chain plays a critical role in the entire performance of the sector. As a result, the pharmaceutical industry's bottom lines are strongly impacted by how well a supply chain operates.

The pharmaceutical supply chain techniques and network have been developed over decades of trial and error by pharmaceutical businesses, regulatory agencies, and leaders. There is still much space for improvement, though, particularly in terms of eliminating inefficiencies. The pharmaceutical supply chain is currently about to undergo yet another overhaul brought about by Industry 4.0.

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distributors oversee and facilitate 92% of pharmaceutical sales in the US (United States), according a Deloitte report. As a result, a medication distribution system becomes vital and they form an integral part of the pharmaceutical supply chain.[26]

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A pharmaceutical product encounters a variety of goals and limitations once it leaves the warehouse, which adds complexity to the supply chain process. Supply networks for pharmaceuticals must manage a number of stakeholders. Medical research groups, hospitals, clinics, and government agencies are also involved in addition to producers and distributors. In contrast, the standards of a typical supply chain are considerably easier.[22]

Compared to a standard supply chain, the complexity and cost of a pharmaceutical cold chain increase dramatically. Strict temperature control, which is required by the authorities, is a component of the pharmaceutical cold chain that helps to preserve the quality of the medications and vaccines. If pharmaceutical businesses lack adequate cold chain visibility, temperature-sensitive vaccines, medications, or biologics deteriorate. It may jeopardize the pharmaceutical supply chain's quality compliance component, putting patients' health at risk.

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Supply chain management tasks vary from sector to industry and are approached differently by various firms. Other aspects of pharmaceutical supply chain management that businesses must consider include compliance.[23]

The absence of real-time visibility in pharmaceutical supply chains compensates for a number of friction points that prevent businesses from reaching their maximum potential. When combined, these friction points have a more significant detrimental effect on the entire revenue bottom lines. Let's examine the three main issues facing the pharmaceutical supply chain.

## 4. Observance

Numerous life-saving medications are handled by the pharmaceutical supply chain. Leaders in pharmaceutical supply chains must thus design their pharma cold chain operations with compliance in mind. The management of pharmaceutical cold chains differs greatly from that of a standard supply chain. An estimated $35 billion has been lost by pharmaceutical corporations, according to research from the IQVIA Institute for Human Data Science.

Having a passive data logger report alone is not enough to provide a complete picture of pharmaceutical cold chain monitoring; there are numerous levels involved. Leaders in the pharmaceutical supply chain may cause disruptions beyond compliance problems if they fail to respond promptly. Due to product rejection, it may also result in problems for the pharmaceutical supply chain in the medication distribution system.

Pharma supply networks have started using active or passive data recorders lately to get accurate information about the conditions of cold chains. However, these are insufficient to stop compliance problems from leading to interruptions in the pharmaceutical supply chain.

1. Compliance-related disruptions: A significant portion of the worldwide vaccine supply degradation is caused by incorrect shipment, which poses problems for the pharmaceutical supply chain. If there is a scarcity of a product because of damage or spoiling, the pharmaceutical business or the distributors are responsible for reshipping appropriate quality items.

2. Difficulty identifying disruptions: Because of the vast scope of a big pharmaceutical supply chain, it is challenging to identify certain occurrences in terms of time, place, or cause. Only a few times a year is it possible to conduct periodic audits, which are costly and time-consuming activities.

3. Overspending: Pharmaceutical executives need to budget for last-minute fulfilment orders to guarantee product availability in the event of damaged or non-compliant items. Using backup forwarders to cover these voids results in excessive labour, packing, and shipping costs.

4. Demand-Supply Variability: responding promptly to changes in supply and demand due to the characteristics of the pharmaceutical supply chain. Your rivals may gain an edge if you are unable to adequately adjust to changes in supply and demand. Products in the pharmaceutical sector are unavailable due to expiry, delays in transit, and overstocking, which ensures that a certain product is never out of stock.

This results in a high cost of working capital. Additionally, problems including product deterioration, theft, loss, and recalls necessitate that you enhance and optimize your supply chain's competitiveness, To beat the competition, think about overstocking, Establish and adhere to stringent compliance standards. The following demand-supply fluctuations-related pharmaceutical supply chain issues are caused by the three issues mentioned above:

1. Expiring products: In order to accommodate variations in supply and demand, overstocking is inevitable, which leads to product expiry. Pharmaceutical supply chains must therefore optimize their inventories in order to maximize stock availability.

2. Addressing the bullwhip effect: As the pharmaceutical product advances upstream in the supply chain, the likelihood of overstocking rises when accurate data on product demand is lacking. As we go up the pharmaceutical supply chain, the prediction efficiency declines because of the bullwhip effect.

3. FIFO management challenges: Optimizing the pharmaceutical inventory is challenging due to the lack of good inventory data and forecast information.

4. On-time but incomplete: In the pharmaceutical sector, a partial delivery to patients is equivalent to no delivery at all. To fulfil the strict SLAs (Service Level Agreements), pharmaceutical teams must dispatch the remaining inventory as soon as possible. It exacerbates the problems with the pharmaceutical supply chain by increasing spending on the same number of goods that are associated with pharmaceutical logistics.

5. Complete load rejection could result from part-load damage: Part-load might result in needless waste of the remaining excellent packages and additional costs associated with a fresh JIT (Just in Time) full-load and on-time consignment.

### *4.1. How can data-driven supply chains help you get the most out of your investment?*

Theft and counterfeiting of drugs among the most significant supply chain issues facing the pharmaceutical business are drug theft and counterfeiting. Pharmaceutical supply chain executives currently face three primary issues:

Drug identification: Without a laboratory, it might be challenging to distinguish between genuine and counterfeit medications.

Tracing: Finding the good batch or shipment containing the counterfeit medications is crucial to stopping the medications from getting to consumers; knowing about a counterfeiting incidence alone is insufficient.

Locating breaches: It is challenging to identify the contaminated pharmaceutical product or products when there is no real-time awareness at the package level. Pharmaceutical firms require real-time package-level visibility in order to detect and address contamination. To combat these issues with the pharmaceutical supply chain, real-time visibility is crucial Specialized impediments are sometimes associated with specialized procedures. The majority of pharmaceutical supply chain problems fall into one of the following categories:

1. Regulatory compliance: Any business that operates in a highly regulated sector must abide by all rules and regulations set out by appropriate authorities.

2. Cold chain management: Since practically all medications and pharmaceuticals need extremely precise temperature-controlled conditions during storage and transit, maintaining a dependable "cold chain" is a significant problem in pharmaceutical supply chain warehouse logistics.

3. Supply chain transparency: Ensuring patient safety and drug efficacy requires inventory traceability. Supply chain transparency can aid in the prompt detection of possible instances of medicine expiration, counterfeiting, or delays in transportation.

4. Disruption preparation – Among the disruptions that important participants in the pharmaceutical supply chain must foresee and be ready for are delays, power outages, and problems with insufficient packaging. Unquestionably, the global scope of the supply chain has benefits, but it also presents unique risks. Natural catastrophes, changes in raw material availability, and geopolitical events can all have an almost instantaneous impact on the pharmaceutical supply chain.

5. Cost management: This is an almost continuous problem that affects the whole chain: striking a balance between the demands of innovation and the requirement of customer affordability. Although there is no place for shortcuts due to the demands of innovation and production, end users cannot afford to bear any amount of expense.

### *4.2. System of regulation*

The medical regulatory system in India is governed by a federal structure that separates national and state entities. The following organizations are the main regulatory agencies in charge of approving, manufacturing, and distributing high-quality medications in India [10]:

Central Drug Standards and Control Organization (CDSCO): This organization establishes guidelines to guarantee the quality and safety of medications, gadgets, cosmetics, diagnostics, and drug import oversight.

The National Pharmaceutical Pricing Authority (NPPA): It is responsible for setting or updating the costs of deregulated bulk medications.

Ministry of Chemicals and Petrochemicals: This agency oversees the planning, development, policy, and regulatory activities related to chemicals and petrochemicals in the pharmaceutical industry (Figure 3).

While some studies adopt a more comprehensive approach, others concentrate on particular nations and sectors. As a result, while implementing block chain technology, there may be obstacles unique to a certain sector or nation, such as particular rules and regulations, in addition to issues that are generally relevant, including knowledge and comprehension. However, there is still a lack of actual research on the difficulties in implementing block chain technology to increase sustainability in the pharmaceutical sector.[25,26]

This study intends to identify the unique obstacles relevant to the pharmaceutical business in order to improve sustainability performance and comprehend the interdependencies among these challenges, building upon earlier theoretical frameworks that address the difficulties of using blockchain technology. Thus, two research topics are addressed in this study:

RQ1: What obstacles must blockchain technology overcome in order to improve sustainability performance in the pharmaceutical sector?

RQ2: How do the issues surrounding the use of blockchain technology to improve sustainability performance in the pharmaceutical sector relate to one another?

With a three-phase decision framework, the research technique mostly employs a two-step strategy. First, a literature analysis was conducted to compile a list of obstacles to blockchain adoption in the pharmaceutical sector. Expert comments were then used to reduce the list of problems, and each challenge's relevance was assessed using a Likert scale. A statistical test within the Statistical Package for the Social Sciences software version 28 was used to verify the reliability of the chosen challenges by computing the importance index and the correlation index modified to test consistency (CIMTC). This was done in order to finalize the list. The FISM and MICMAC approaches were ultimately used to determine the connection of these completed problems.

## 5. Conclusion

The study's findings highlight the obstacles that prevent blockchain technology from being widely used to improve sustainability performance. Among the many difficulties, those that are important in this situation are noted. Furthermore, several issues that are connected both directly and indirectly are organized into a thorough, methodical model. This final model uses a well thought-out pattern to show the structure of the problem. A more accurate depiction of the issue is possible thanks to this method, which finds connections between particular difficulties rather of taking into account each one separately. As a result, an organized framework is offered for deciphering the many linkages and

dependencies inside a system, improving the processes of strategic planning and decision-making.

## 6. Future Aspects

The study fills a gap in the literature by shedding light on the specific obstacles that pharmaceutical companies face when attempting to use blockchain technology to improve their sustainability performance. It is also the first attempt to describe the elements that influence and are influenced by the difficulties in implementing blockchain technology to increase sustainability in the pharmaceutical industry.

Ensuring the accuracy of the data entering the chain, connecting and adhering to blockchain standards, verifying the relationship between individuals and businesses, Overseeing security and compliance standards, Dealing with interoperability, Dealing with governance, Guaranteeing the accuracy of the data that enters the chain, Connecting and conforming to blockchain standards, Verifying the existence and formation of the relationship, Overseeing security and compliance standards, Talking about interoperability, Educating and increasing the awareness of the stakeholders concerned, Having difficulties bringing together the required stakeholders, Non-supervisory implicit counter charges.

## 7. Conflict of Interest

None.

## 8. Source of Funding

None.

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