DRUG TRACEABILITY IN SUPPLY CHAIN MANAGEMENT

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ABSTRACT

Healthcare supply chains are complex structures spanning across multiple organizational and geographical boundaries, providing critical backbone to services vital for everyday life. The inherent complexity of such systems can introduce impurities including inaccurate information, lack of transparency and limited data provenance. Counterfeit drugs is one consequence of such limitations within existing supply chains which not only has serious adverse impact on human health but also causes severe economic loss to the healthcare industry. Consequently, existing studies have emphasized the need for a robust, end-to-end track and trace system for pharmaceutical supply chains. Therein, an end-to-end product tracking system across the pharmaceutical supply chain is paramount to ensuring product safety and eliminating counterfeits. Most existing track and trace systems are centralized leading to data privacy, transparency and authenticity issues in healthcare supply chains. In this article, we present an Ethereum blockchain-based approach leveraging smart contracts and decentralized off-chain storage for efficient product traceability in the healthcare supply chain. The smart contract guarantees data provenance, eliminates the need for intermediaries and provides a secure, immutable history of transactions to all stakeholders. We present the system architecture and detailed algorithms that govern the working principles of our proposed solution. We perform testing and validation, and present cost and security analysis of the system to evaluate its effectiveness to enhance traceability within pharmaceutical supply chains.

We propose, discuss, and compare two potential blockchain architectures for drug traceability. We identify and discuss several open research challenges related to the application of blockchain technology for drug

[1].INTRODUCTION

Healthcare supply chain is a complex network of several independent entities that include raw material suppliers, manufacturer, distributor, pharmacies, hospitals and patients. Tracking supplies through this network is non-trivial due to several factors including lack of information, centralized control and competing behaviour among stakeholders. Such complexity not only results in in-efficiencies such as those highlighted through COVID-19 pandemic [1] but can also aggravate the challenge of mitigating against counterfeit drugs as these can easily permeate the healthcare supply chain. Counterfeit drugs are products deliberately and fraudulently produced and/or mislabelled with respect to identity and/or source to make it appear to be a genuine Such drugs can include medications that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferiorquality API, a wrong API, contaminants, or repackaged expired products. Some counterfeit medications may even be incorrectly formulated and produced in substandard conditions. According to the Health Research Funding Organization, up to 30% of the drugs sold in developing countries are counterfeit. Further, a recent study by World Health Organization (WHO) indicated counterfeit drugs as one of the major causes of deaths in developing countries, and in most cases the victims are children. In addition to the adverse impact on human lives, counterfeit drugs also cause significant economic loss to the pharmaceutical industry. In this respect, the annual economic loss to the US pharmaceutical industry due to counterfeit medicine is estimated around $200

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billion. traceability. The proposed blockchain architectures provide a valuable roadmap for Health Informatics researchers to build and deploy an end-to-end solution for the pharmaceutical industry[1-24].

2.PROBLEM STATEMENT

The pharmaceutical industry faces significant challenges in ensuring the traceability of drugs throughout the supply chain, which is crucial for maintaining product quality, consumer safety, and regulatory compliance. The supply chain involves numerous stakeholders, including manufacturers, wholesalers, distributors, and retailers, making it difficult to effectively track and monitor drug products from production to consumption.

One of the primary issues is the proliferation of counterfeit drugs entering the market. These counterfeit or substandard drugs can pose severe health risks, damage public trust, and undermine the integrity of the pharmaceutical industry. Additionally, the problem of product diversion and theft exacerbates this issue, as drugs can be rerouted to unauthorized markets or regions, compromising their quality and safety. Another critical issue is the lack of supply chain transparency. Limited access to real-time data from all supply chain participants reduces visibility, making it difficult to make informed decisions about inventory management and distribution. To address these challenges, a robust drug traceability system is necessary. This system should enable real-time tracking, ensure regulatory compliance, prevent counterfeit drugs, facilitate rapid recalls, and enhance overall transparency. Such a solution would improve drug supply chain security, ensuring both consumer safety and industry efficiency.

3.LITERATURE SURVEY

- **Blockchain for Counterfeit Drug Prevention**

One of the primary applications of blockchain in drug traceability is the prevention of counterfeit drugs. Several studies, such as those by *Zhang et al. (2020)*, highlight the role of blockchain in creating an immutable and transparent record of drug production, distribution, and sales. By providing a secure, tamper-proof ledger, blockchain ensures that the history of a drug can be traced from manufacturing to the end consumer, reducing the risk of counterfeit products entering the market.

- **Supply Chain Transparency**

Research by *Mougayar (2016)* and *Kshetri (2018)* discusses how blockchain can provide end-to-end visibility in the pharmaceutical supply chain. The ability to track and verify the movement of drugs in real-time across multiple stakeholders helps reduce inefficiencies and errors. Blockchain's distributed ledger ensures that all parties in the supply chain, from manufacturers to wholesalers to retailers, can access the same transparent and up-to-date data, reducing fraud and increasing accountability.

- **Regulatory Compliance and Smart Contracts**

Blockchain can also facilitate compliance with regulatory standards such as the U.S. *Drug Supply Chain Security Act (DSCSA)*. Studies by *Patel et al. (2020)* explore the use of smart contracts on blockchain platforms to automatically execute and enforce regulations, such as verifying drug authenticity, monitoring expiry dates, and triggering recalls. These features ensure that drug distributors and retailers remain compliant with regulatory requirements and industry standards.

- **Drug Recall Efficiency**

A major advantage of blockchain is its ability to speed up drug recalls. Research by *Franco et al. (2019)* indicates that blockchain can significantly reduce the time it takes to trace and recall drugs in the event of safety concerns. The real-time, tamper-proof nature of the blockchain ledger allows for rapid identification of affected batches, ensuring patient safety and reducing the costs associated with widespread recalls.

- **Challengesand Limitations**

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While blockchain presents promising solutions for drug traceability, several challenges need to be addressed. *Hileman and Rauchs (2017)* point out the scalability and interoperability issues between different blockchain platforms. Moreover, the integration of blockchain with existing supply chain systems, especially for smaller manufacturers or distributors, can be a costly and technically complex process. There are also concerns regarding data privacy, as sharing sensitive drug information across a decentralized network may expose trade secrets or other confidential data.

• **Case Studies and Implementations**
Several pharmaceutical companies and organizations have started pilot projects exploring blockchain technology for drug traceability. For instance, *Pfizer* and *IBM* have partnered to create a blockchain-based system aimed at improving the visibility and security of the global pharmaceutical supply chain. Similarly, *Medi Ledger*, a blockchain-based platform for pharmaceutical supply chains, aims to address regulatory compliance and secure data exchange between stakeholders.

4.EXISTING SYSTEM

Existing Systems for Drug Traceability

- **Manual and Paper-Based Systems**
  Traditionally, many pharmaceutical companies relied on paper-based documentation to track drug movement through the supply chain. These systems involved manual records of drug production, transportation, and distribution, often requiring physical forms and signatures at each stage.

- **Barcode and RFID-Based Systems**
  Barcodes and RFID (Radio Frequency Identification) technologies are commonly used in pharmaceutical supply chains for tracking drugs. Barcodes and RFID tags are applied to drug packaging, which contain unique identifiers scanned at various stages such as manufacturing, warehousing, and retailing. These technologies allow for better inventory management and product identification throughout the supply chain.

- **Centralized Database Systems**
  Many pharmaceutical companies use centralized database systems (e.g., ERP systems such as SAP or Oracle) to store and manage data about drug production, shipment, batch numbers, and expiration dates. These platforms provide a unified interface for all stakeholders in the supply chain to input, update, and access relevant drug information. • **Serialized Tracking Systems**

  Serialized tracking assigns unique serial numbers to each drug unit, allowing for precise tracking from production to delivery. This system ensures that each drug unit is identified and traced at each step in the supply chain. Serialization is mandated in several countries as part of regulatory compliance, such as under the U.S. *Drug Supply Chain Security Act (DSCSA)*.

- **Third-Party Drug Tracking Solutions**
  Some pharmaceutical companies use third-party platforms that integrate RFID, barcodes, and cloud technology to improve drug traceability. Platforms like *MediLedger* and *IBM's Blockchain-based supply chain solutions* connect manufacturers, wholesalers, and retailers to share and access real-time traceability data securely.
- **Blockchain-Based Systems**
  Blockchain technology is an emerging solution for drug traceability, offering decentralized, transparent, and tamper-proof record-keeping. Each transaction related to drug movement is securely logged in a blockchain ledger, ensuring that all stakeholders can track and verify drug histories in real-time across the supply chain.

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5.PROPOSED SYSTEM

Proposed System for Drug Traceability Using Blockchain Technology

To address the growing challenges in drug traceability, we propose the implementation of a **blockchain-based drug traceability system** that will revolutionize the way drugs are tracked throughout the supply chain. This system aims to provide real-time visibility, enhanced security, and absolute transparency from manufacturing to the end consumer, ensuring that all parties involved can access and verify drug information accurately.

At the core of the proposed system is blockchain technology, which will serve as a decentralized, tamper-proof ledger to securely record every transaction and movement of drugs across the supply chain. Each drug unit will be assigned a unique identifier, and all data related to its production, storage, transport, and sale will be securely logged on the blockchain. This means that every stakeholder in the supply chain, including manufacturers, wholesalers, distributors, and retailers, will have access to a single, transparent record of each drug's journey.

Furthermore, real-time tracking of drugs will become seamless, as the blockchain system will allow for instant updates on the movement of drugs across various touchpoints. This means that if a recall is issued due to safety concerns, affected batches can be quickly identified and removed from shelves, ensuring patient safety and minimizing harm.

Overall, the proposed blockchain-based drug traceability system will drastically reduce the risks of counterfeit drugs, improve regulatory compliance, streamline supply chain operations, and ensure that consumers receive safe, high-quality medications. By integrating blockchain, we are moving toward a future where the integrity and transparency of the pharmaceutical supply chain are guaranteed.

6.WORKING PROCESS

1.Working Process of the Blockchain-Based Drug Traceability System

The working process of the proposed blockchain-based drug traceability system involves several key stages, from drug production to delivery, ensuring transparency, security, and real-time tracking at each point in the supply chain. Here's how it operates step-by-step:

1. Drug Manufacturing

- **Drug Production Data Entry**: At the start of the supply chain, the manufacturer inputs critical information about the drug, such as its unique identifier (serial number), batch number, expiration date, and manufacturing details (e.g., production date, manufacturing site) into the blockchain. This data is encrypted and added as a new block in the blockchain ledger.

- **Smart Contracts for Compliance**: Smart contracts are used to automatically check compliance with regulatory requirements, ensuring the drug meets safety and quality standards before moving forward in the supply chain.

2. Drug Packaging and Serialization

- **Serialization and Barcode Assignment**: Each unit or batch of drugs is given a unique identifier (serial number) and labeled with a barcode or RFID tag. This identifier is linked to the blockchain, ensuring each drug can be traced individually or as part of a batch.

- **Blockchain Entry**: Information about the serialized product (e.g., serial number, packaging details) is added to the blockchain, where it becomes part of the immutable ledger that will track the drug's journey through the supply chain.

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3. Drug Distribution and Transportation

- **Real-Time Tracking**: As the drugs move through various stages of the supply chain (e.g., warehouse storage, transportation), each handover or location change is recorded on the blockchain in real-time. Each event is time-stamped and encrypted, ensuring that all data remains secure and tamper-proof.

- **Visibility for All Stakeholders**: Stakeholders, such as wholesalers, distributors, and even regulators, can access the blockchain ledger to view the status and location of drugs, allowing for full transparency and trust throughout the supply chain.

4. Retail and Sale

- **Verification at Point of Sale**: When the drug reaches the retail point (e.g., pharmacy or hospital), its barcode or RFID tag is scanned, and the drug's information is verified against the blockchain. This ensures the product is legitimate, has not been tampered with, and is compliant with regulatory standards.

- **Consumer Access to Data**: Consumers can use an app or platform to scan the drug's barcode to check its full traceability history. This empowers them to verify the authenticity of the product, increasing trust in the drug's safety and quality.

5. Drug Recall (if necessary)

- **Instant Notification**: If a drug recall is issued due to safety concerns, the blockchain allows for instant identification of affected batches. The unique identifiers on the blockchain ensure that every unit of the recalled drug can be quickly traced, even down to individual pills if necessary.

- **Swift Action and Transparency**: As soon as the recall is initiated, the blockchain system triggers notifications across the supply chain, informing all stakeholders and facilitating the rapid removal of the affected drugs from shelves. The recall process becomes more efficient and transparent, ensuring minimal harm to consumers.

6. Regulatory Reporting and Audits

- **Automatic Reports**: The blockchain system generates automatic compliance reports for regulators, providing real-time data about the movement and status of drugs. This ensures adherence to regulatory standards like the *Drug Supply Chain Security Act (DSCSA)* in the U.S.

- **Audit Trail**: Blockchain provides an immutable audit trail, allowing regulators or auditors to trace the history of a drug from manufacturing to delivery. This audit trail helps ensure ongoing compliance and supports the fight against counterfeit drugs.

7. Consumer Safety and Trust

- **End-Consumer Verification**: With the integration of blockchain, consumers can scan drug packaging to access its entire traceability history, giving them the confidence that the product they are purchasing is authentic and safe. This promotes trust in the pharmaceutical system and reduces concerns about counterfeit or substandard drugs.

- The working process of the blockchain-based drug traceability system ensures that every step, from production to consumption, is transparent, secure, and verifiable. By leveraging blockchain's

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decentralized, immutable ledger and integrating smart contracts, this system guarantees the integrity chain.

7.ADVANTAGES

1.Advantages of the Blockchain-Based Drug Traceability System

- **Enhanced Security and Fraud Prevention**
- Blockchain's decentralized, immutable ledger ensures that once information is recorded, it cannot be altered or tampered with. This makes it highly resistant to fraud and counterfeit drugs entering the supply chain. Each drug unit's unique identifier is securely stored, reducing the risk of fraud and ensuring that only legitimate products reach consumers.
- **Transparency and Accountability**
- All participants in the supply chain—manufacturers, wholesalers, distributors, and retailers—have access to a transparent, shared ledger of drug transactions. This transparency ensures that every transaction is visible to all stakeholders, increasing accountability and trust across the entire supply chain.
- **Real-Time Tracking**
- Blockchain enables real-time tracking of drugs as they move through various stages of the supply chain. Each change in location, ownership, or status is immediately recorded on the blockchain, giving stakeholders up-to-date information about the drug's journey. This reduces the chance of errors and delays while providing clear visibility.
- **Efficient Drug Recalls**
- In the event of a safety issue or regulatory concern, blockchain facilitates faster and more accurate drug recalls. By using the unique identifiers of drugs, affected batches or individual products can be traced and removed from the supply chain almost instantly. This ensures that harmful drugs are removed quickly, minimizing potential harm to patients.
- **Improved Regulatory Compliance**
- Blockchain can automatically capture and store data required by regulatory bodies, ensuring that the pharmaceutical supply chain complies with laws such as the U.S. *Drug Supply Chain Security Act (DSCSA)*. It also generates real-time compliance reports, making it easier for pharmaceutical companies to adhere to stringent regulations and avoid fines or penalties.
- **Consumer Confidence and Safety**
- By providing a transparent, accessible traceability system, consumers can easily verify the authenticity and safety of the drugs they purchase. Scanning a drug's barcode or RFID tag can provide consumers with a detailed history of the product, which helps build trust and confidence in the pharmaceutical industry.
- **Reduced Operational Costs**
- By automating processes such as compliance checks and regulatory reporting, blockchain reduces the need for manual oversight and data management. This results in lower administrative and operational costs for pharmaceutical companies, allowing them to operate more efficiently.

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- **Streamlined Supply Chain Operations**
- Blockchain enables seamless communication and data sharing between stakeholders in the supply chain. This improved coordination helps prevent delays, errors, and inventory discrepancies, leading to a more efficient and reliable supply chain overall.
- **Improved Data Integrity**
- Blockchain's immutable nature ensures that once data is entered, it remains accurate and tamperproof. This integrity is critical for tracking drugs throughout the supply chain and ensures that accurate, up-to-date information is available to all parties involved.
- **Faster Dispute Resolution**
- The transparent nature of blockchain makes it easier to resolve disputes within the supply chain. Since all data is recorded and accessible, parties can quickly refer to the blockchain to verify claims, reducing the time and cost associated with resolving conflicts.

- By implementing a blockchain-based drug traceability system, the pharmaceutical industry can improve security, compliance, efficiency, and consumer trust while simultaneously reducing fraud, operational costs, and the risk of counterfeit drugs. .

8.LIMITATIONS

1. **Scalability Issues**
    - Blockchain technology, especially public blockchains, can struggle with scalability when handling a large volume of transactions. As the pharmaceutical supply chain grows and more data points are added, blockchain systems may face challenges in maintaining performance and speed, especially when processing vast amounts of real-time data across many participants.
2. **Integration with Legacy Systems**
    - Pharmaceutical companies often rely on legacy systems for managing inventory, compliance, and logistics. Integrating blockchain into these existing systems can be complex and costly. There may be a need for significant updates or entirely new software solutions to ensure compatibility with blockchain-based traceability platforms.
3. **Initial Implementation Costs**
    - Implementing a blockchain-based traceability system can involve high initial setup costs, including technology infrastructure, training for stakeholders, and the development of custom solutions. Smaller companies, especially in developing countries, may find these costs prohibitive, limiting the adoption of blockchain in the global pharmaceutical supply chain.
4. **Data Privacy Concerns**

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- Blockchain's transparency, while beneficial for traceability, could also raise concerns regarding data privacy. Sensitive information, such as drug formulations, pricing, and proprietary manufacturing processes, may need to be shared across the blockchain. Securing private data while maintaining transparency is a key challenge that must be addressed to prevent exposure of confidential business information.

5. **Interoperability Challenges**

   - Many different stakeholders (manufacturers, distributors, retailers, regulators) are involved in the pharmaceutical supply chain, and these entities may use different technologies or platforms. Ensuring that various blockchain systems can communicate and share data seamlessly (interoperability) across diverse systems is a significant challenge, and without it, the full benefits of blockchain cannot be realized.

6. **Regulatory Uncertainty**

   - While blockchain has the potential to improve regulatory compliance, regulatory frameworks for blockchain technology in the pharmaceutical industry are still developing. Governments and health authorities have yet to fully standardize and regulate blockchain usage in pharmaceutical traceability, which could delay the widespread adoption and implementation of blockchain systems.

7. **Lack of Industry-Wide Adoption**

   - For blockchain-based drug traceability to work effectively, it requires widespread industry participation. However, the pharmaceutical industry consists of many fragmented players, including manufacturers, wholesalers, regulators, and retailers. Convincing all stakeholders to adopt and integrate blockchain can be a lengthy and challenging process, especially when some companies may be resistant to new technologies.

8. **Energy Consumption**

   - Public blockchains, especially those that use proof-of-work consensus mechanisms (e.g., Bitcoin), can be highly energy-intensive. Although blockchain platforms like Ethereum are moving towards more energy-efficient models (proof-of-stake), high energy consumption can still be a concern, particularly when considering large-scale implementation in industries like pharmaceuticals.

9.FUTURE WORK

The future of blockchain in drug traceability holds tremendous potential to transform the pharmaceutical industry. As the technology evolves, key advancements are expected in scalability, security, and integration with other systems. One major area of focus is improving blockchain's ability to handle a growing number of transactions efficiently. By adopting Layer-2 solutions or hybrid blockchain models, performance can be optimized, allowing real-time updates without compromising security.

Another important development will be the integration of Internet of Things (IoT) devices, such as smart sensors and GPS trackers, which can work in tandem with blockchain to provide real-time updates on a drug's journey. This integration will ensure accurate tracking, particularly for sensitive products like vaccines, where

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environmental conditions are critical. IoT devices could automate data entry, reducing errors and ensuring seamless traceability.

Blockchain's role in ensuring privacy and data security will also continue to evolve. Advanced encryption methods and privacy-preserving technologies like zero-knowledge proofs will enable companies to maintain confidentiality while still providing transparency and traceability. This will be crucial for safeguarding sensitive information such as pricing and production details.

Blockchain's potential to empower consumers will also grow. With the ability to scan barcodes or QR codes, consumers could instantly verify the authenticity and traceability of the drugs they purchase, fostering trust and reducing counterfeit risks.

Furthermore, blockchain will help streamline regulatory compliance by automating checks and providing real-time updates to authorities. This will reduce administrative burdens while ensuring adherence to stringent regulations.Finally, blockchain will support global adoption, making traceability systems more accessible to smaller companies and developing countries, helping to create a more transparent, secure, and efficient global pharmaceutical supply chain

10.CONCLUSION

In this article, we have investigated the challenge of drug traceability within pharmaceutical supply chains highlighting its significance especially to protect against counterfeit drugs. We have developed and evaluated a blockchain-based 9740 VOLUME 9, 2021: Blockchain-Based Approach for Drug Traceability in Healthcare Supply Chain solution for the pharmaceutical supply chain to track and trace drugs in a decentralized manner. Specifically, our proposed solution leverages cryptographic fundamentals underlying blockchain technology to achieve tamper-proof logs of events within the supply chain and utilizes smart contracts within Ethereum blockchain to achieve automated recording of events that are accessible to all participating stakeholders. We have demonstrated that our proposed solution is cost efficient in terms of the amount of gas spent in executing the different functions that are triggered within the smart contract. Moreover, the conducted security analysis has shown that our proposed solution achieves protection against malicious attempts targeting is integrity, availability and non-repudiation of transaction data which is critical in a complex multi-party settings such as the pharmaceutical supply chain. We continue our efforts to enhance the efficiency of pharmaceutical supply chains and envision to focus on extending the proposed system to achieve end to end transparency and verifiability of drugs use as future work.

11. SYSTEM REQUIREMENTS

Category	Hardware Tools	Software Tools
Frontend Development	Computer/PC with internet access	Next.js (React Framework)
		Tailwind CSS (for UI design)
		JavaScript, HTML5, CSS3

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		Shadan UI (for reusable components)
Backend Development	Server with at least 4GB RAM and 100GB storage	Node.js (version 14 or higher)
		Prisma (ORM for database interaction)
Authentication	Server with secure storage	Clerk (Authentication service)
Database	Server with SSD storage for fast access	Neon DB (PostgreSQL Database)
API Integration	Reliable network connection	RESTful API (if applicable)
Hosting & Deployment	Cloud server or dedicated hosting service	Vercel (Recommended for deployment)
Version Control	Computer with Git installed	Git, GitHub (for repository management)
Security	Secure physical server environment	Encryption protocols (SSL/TLS)
		Access control features via Clerk
Performance Monitoring	Monitoring hardware (optional)	Performance monitoring tools (e.g., Ingest)
User Interface	Responsive displays for testing	Responsive design frameworks (Tailwind CSS)
		Browser compatibility tools

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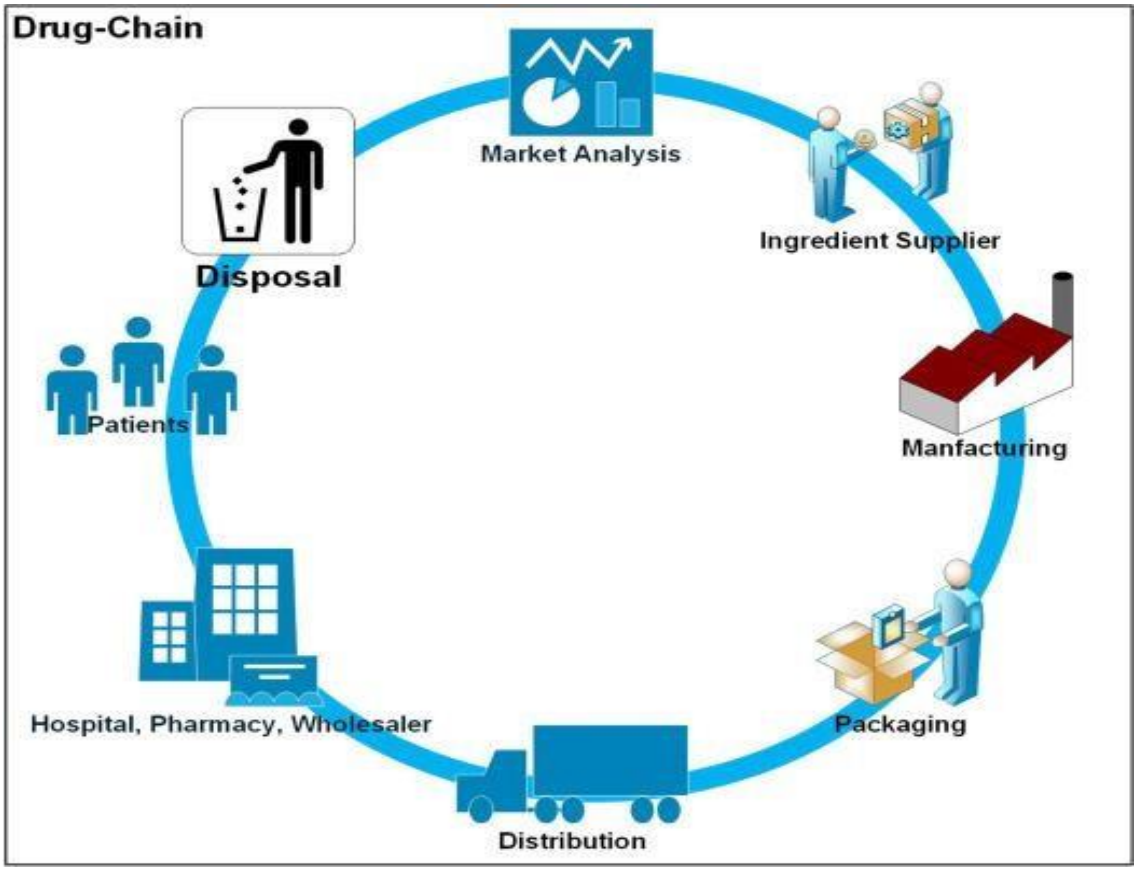

Figure no.1(block chain)

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