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Review Article

Blockchain Technology – A Algorithm for Drug Serialization

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Abstract: The Blockchain technology uses different type of database that transact data in blocks and then chained each data blocks. When data fills one block, it is chained the same data onto previous block therefore, all the data blocks are stored in chronological order. The blockchain technology can help to ensure that data in supply chain is reliable, accurate and can be shared with all stakeholders without any manipulation. It makes supply chain more transparent and end-to-end digital visibility of data source. Blockchain is stringent technology which fill the gap between stakeholders by providing transparent unmanipulated and truthful data in supply chain. There are many initiatives has been taken by multiple regulatory bodies with partnering with supply chain stakeholders including pharmaceutical manufacturer, distributors and dispensers. In USA, Food and Drug Administration's regulatory body Drug Supply Chain Security Act (DSCSA) initiated pilot program in 2019 with the partnership of leading pharmaceuticals distributors to authenticating saleable returns to distributor from supply chain partners. DSCSA used MediLedger blockchain interoperable technology for process evaluation and it robustness for mitigating risk of drug counterfeiting possibilities in supply chain. The DSCSA found that pilot project was successful and results were astonishing. Later it was declared that blockchain technology can also be used for meeting DSCSA's 2023 Act for unit level traceability.

Keywords: History of Pharmaceutical Industry, Pharmaceutical Barcode, Pharmaceutical Serialization, Digital Drug Traceability

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1. Introduction

As technology is evolving, it is bringing more secure methods of technical architecture and technology such as Artificial Intelligence (AI) Machine Learning (ML) and Blockchain. These technologies are helping organization to develop stringent and secure processes, transparency in supply chain and unmanipulated data distributions to stokeholds.

Blockchain is not very new and initially was developed for cryptocurrency platforms. Gradually industry understood its significant benefits which also can be utilized in other industries such as pharmaceutical and clinical research and development. Statista estimated that global spending on blockchain solutions is projected to reach 6.6 billion dollars. Forecasts suggest that spending on blockchain solutions will continue to grow in the coming years, reaching almost 19 billion U.S. dollars by 2024 [1]. In 2020, Deloitte conducted survey and observed that 83% responders accepted that they will lose their business due to technological backwardness if they do not adopt block chain technology [2]

UNICEF has developed a blockchain solution in 2020 for detecting COVID-19 vaccine in supply chain. In this process manufacturer encode unique serial number in COVID-19 vaccine and same serial number transferred to blockchain network. In supply chain stakeholder has to be scanned serial number of physical product and compared with blockchain network for product authenticity and verification [3].

Blockchain technology is secure, decentralized and set of public ledgers that stores every single transaction, event and data exchange as record in verifiable data blocks in chronological manner which is always linked to its previous data block with actual timestamp of transaction. Once data block is been recorded it is visible to all users and it cannot be edited, deleted or manipulated. Data can only be stored and linked to previous blocks when majority of stakeholder validate its authenticity. Blockchain technology is very robust and secure which allow to share information in safest manner among connected users in organization. In pharmaceutical supply chain it provides complete transparency between stakeholders from drug manufacturing to final dispensing to patients. The nature of blockchain technology provide a strict mechanism to improve the drug authentication and traceability by providing end-to-end visibility. All connected users in blockchain network can validate the authenticity of data as it has advantage of not having single centralized owner of all information recorded in network. Organizations connected to blockchain network need not to share information with their internal system or data attributes as only shared data which needs to verify is only required. DSCSA is also evaluating Blockchain based traceability system for its Verification Router Services (VRS) regulatory compliance where if Wholesaler / Distributor determines that medicine can be resell again in supply chain then he must verify the individual medicines packets authenticity with medicine manufacturer [4].

Currently Pharmacy supply chains are series of linked but separate events. Stakeholders are often buying back data to access the overview of their product history and consumption record. Blockchain basically a network solution and developing blockchain is very complex and costly process. Companies do not buy blockchain but they join the network as participants and build a solution acceptable by all stakeholders in network. Unlike other solutions, stakeholders in blockchain network control their own data and decide who will have ability to access their data. Supply chain partners in network can share data for completing transactions while keeping other data confidential and hidden from others visibility. Blockchain technology allow pharmaceutical industry to streamline their supply chain process by controlling drug manufacturing, packaging, distribution and digitally data interoperability between stakeholders. It provides highly efficient decentralized network structure that provides high transactional output and programmability of complex relationships between large numbers of users, and therefore can handle a large volume of transaction data. The blockchain solution is distinguished based on different system configurations, ranging from public to private, open-source system to private which needs special permission to access and modify data.

2. Blockchain technology: a future basic need of pharmaceutical industries

Blockchain technology follow stringent method for data visibility hence it has potential to transform entire pharmaceutical and healthcare industries. Blockchain uses distributed ledger technology which can be used for legislative, product digital visibility, transparency, logistical and patient safety benefits for pharmaceutical supply chain management. The DSCSA, regulatory body of United States, in 2019 took initiative to run blockchain based pilot project on Verification Router Services for saleable return with pharmaceutical leaders. Under this pilot project DSCSA in partnership with MediLedgerTracelink and UCLA-Ledger domain evaluated product track, trace, and verification technologies in the pharmaceutical supply chain in interoperable manner. This pilot project is also developing an industry owned permissioned blockchain network for the pharmaceutical sector based on open standards and specifications. DSCSA observed that results of pilot project were very promising and positive therefore accepted that blockchain based technology on pharmaceutical processes will be very helpful for patient safety and product traceability.

DSCSA drafted a 10-year timeframe where it will include blockchain technology in pharmaceuticals drugs traceability, product authenticity, verification in supply chain and

notifying supply chain stakeholders about illegitimate drugs. Blockchain technology uses shared ledger of information that enable visibility in supply chain and create trust between stakeholders. As per Kevin Clouson, Associate Professor of Collage of Pharmacy and Health Science at Lipscomb University. "One of the most promising benefits of blockchain from a patient safety perspective is to help stem the tide of the so-called SSFFC medicines – substandard, spurious, falsely labeled, falsified and counterfeit – that continue to plague the pharmaceutical supply chain."

Pharmaceutical and healthcare industry is very discreet and complex which continues to grow due to its nature demand in supply chain. It needs to improve digital drug traceability mechanism to mitigate the risk of counterfeit drugs in supply chain, end to end visibility of drugs, coupled with regulatory authority such as DSCSA for 2023-unit level traceability compliance. DSCSA also required to maintain data as per General Data Protection Regulations (GDPR), "these personal data which is obtained from patients during treatment of clinical trials must managed by pharmaceutical companies in appropriate way and every access from stakeholders must have digital record. Blockchain-based electronic medical inserts are expected to allow pharmaceutical companies to provide secure and accurate updates directly to patients in near real-time. The patients will have ability to use mobile based app to scan the drug information encoded in barcode from product package, this will allow patient to validate the product authenticity of drug and access useful information of product safety and transparency in supply chain. Blockchain based technology can be used to validate packaging and labelled and can reduce the risk of mislabeling or incorrect information printing on label which can cause costly confusion in supply chain and create unnecessary delay of drug circulation in market. There are some other benefits of using blockchain based technology by inserting medical record in data blocks for verification which can reduce mislabeling issues from incorrect paper inserts and improve production and disbursement efficiency in supply chain. Pharmaceutical industry is growing aggressively and becoming more technology driven industry so acceptability and adoptability of blockchain based technology in pharmaceutical processes is very positive among pharmaceutical manufacturer, wholesalers, dispensers and research & development (R&D) companies.

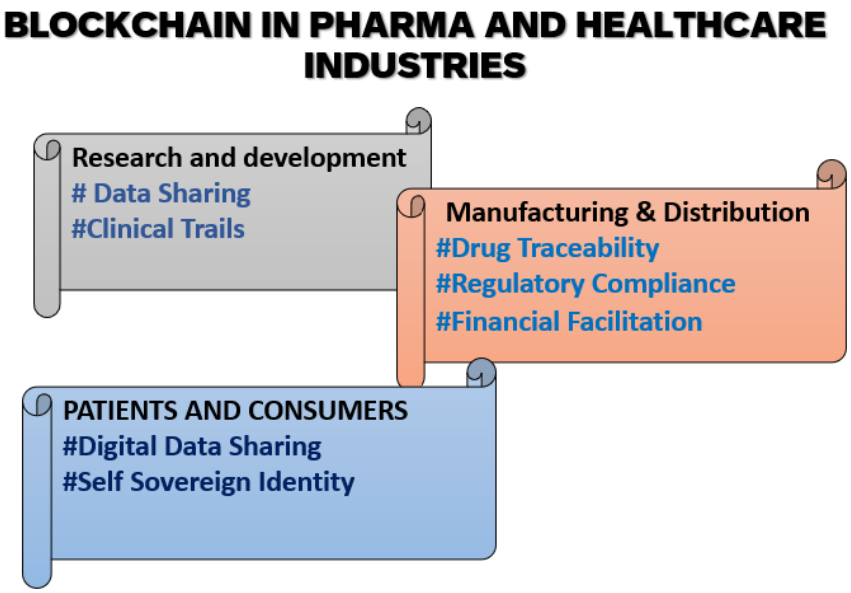

Figure 1. Blockchain in Pharma and Healthcare Industries

Since biological therapies such as cell and plasma is required regression and complex manufacturing and supply chain processes compare to small molecule drugs

manufacturing and developments so blockchain technology can establish end to end standardized process for needle to needle delivery of autologous cell and gene therapies.

Blockchain technology in pharmaceutical industry can be an advantage in new drug discovery process in many ways. Block chain provide data visibility, transparency in supply chain and digital authentication and verification in real time across globally dispersed teams. Many other technologies are also evolving with blockchain technology such as Machine Learning (ML) Artificial Intelligence (AI) and these technologies altogether can provide robust mechanism to improve data mining and analytical of information.

Ten major pharmaceutical companies, academic researchers, data scientists, and a major Artificial Intelligence company have been running a three-year public-private joint pilot project "The Machine Learning Ledger Orchestration for Drug Discovery" to combine machine learning with blockchain technology to improve drug development. The aim of project was to share huge amount of data on biological effects of billions of different small molecules. Under this project, companies were responsible for maintaining their own data but sensitive information which would be processing by machine learning algorithms. Clinical trial and pharma industries are hoping that this pilot project will give companies a much larger set of molecules to explore for new treatments.

Clinical trial is another promising area where blockchain technology can increase trust between patient and service provider by securing patient data. In clinical trial patient data are stored at different stages for sample management. Pharmaceutical industries run these and publish clinical trials result for commercialized products in market and approval from regulatory bodies. Patients also participate in clinical trials to gain early access of new medicine and therapies that are still under observation and investigated for efficacy and patient safety. Patients basically cares about protecting their health records, authentic clinic trail data, safety and outcome of experimental verified result.

Pharmaceutical companies are also putting their best effort to use proven technology such as blockchain to improve data transparency and visibility in supply chain.

2.1. Blockchain architectures for drug authentication and traceability for serialization.

Pharmaceutical industry can utilize following two blockchain based architecture for drug traceability and other global serialization compliance.

2.2. Hyperledger Fabric Architecture

Hyperledger Fabric platform is based on distributed ledger technology (DTL) Platform. It uses open-source enterprise contexts, which is responsible to delivers advance capabilities over other popular distributed ledger platform.

Hyperledger Fabric has a highly segmented and configurable architecture, enabling innovation, flexibility, transparency, versatility and optimization for a broad range of industry use cases including banking, finance, insurance, healthcare, human resources, supply chain and even digital music delivery. Hyperledger Fabric Architecture is based on Java SDK and also hoping to utilized Python based REST. Fabric has a highly modular and configurable architecture, enabling innovation, versatility and optimization for a broad range of industry use cases including banking, finance, insurance, healthcare, human resources, supply chain delivery. Fabric is the first distributed ledger platform to support smart contracts authored in general-purpose programming languages such as Java, Go and Node.js, rather than constrained domain-specific languages (DSL). This means that most enterprises already have the skill set needed to develop smart contracts, and no additional training to learn a new language or DSL is needed [4]. Hyperledger is comprised pluggable modular component which has pluggable Ordering service, membership service, peer-to-peer gossip services. It uses environment like Docker and configured to support a verity of DBMS. It can also be used in permissioned blockchain network which provide secure interaction between stakeholders that have common goals

but don't each other in network. Permissioned blockchain are traditional way of Crash Fault Tolerance (CFT) or Byzantine Fault Tolerant (BFT) consensus protocol which do not require costly mining. There will be multiple procedural steps are involved for drug traceability as per Hyperledger Fabric blockchain platform. Registered users in network will send drug authentication information as transactional proposal (Step 1) Transactional proposal will request a chaincode function execution with some of product attributes for reading and updating data-block in ledger (Step 2). This activity will invoke a proposal which will submit to all stakeholder (node) in network as per chaincode endorsement policy (Step 3) Required node, peers must sign/check every transaction as per endorsement policy defined in chaincode (Step 4) All endorsement decisions will be recoded encrypted with endorsing peers and nodes as "Cryptographic Signature" and information sent back to client app (Step 5)

Authenticated result will be encrypted and recorded with endorsing peers and nodes. After encryption, client app determines if it received sufficient endorsement, it also validates if chaincode ledger was not updated in-between proposal to endorsement time period (Step 6) Client app accumulate all information and broadcast the transaction proposal and acknowledgement within Ordering services (Step 7) Broadcasted information contain endorsing peers signature and channel identifier. Now decentralized Ordering service calculate execution order of all submitted channel based on pluggable consensus protocol. Finally order will be placed chronologically for multiple drugs (Step 8). Broadcasted information is formed as blocks by Ordering system in Hyperledger Fabric Network (Step 9) Blocks exchange between leading peers using gossip protocol (Step 10) Peer now validate endorsement according to chaincode policy and confirm no violation since last check (Step 11) Any invalid endorsement make transaction also invalid. Subsequently all peers in network append with results, valid endorsement are updated as world state whereas invalid endorsement remain in ledger but does not update in world state (Step 13) [5, 11].

2.3. Hyperledger Besu Architecture

Hyperledger Besu is an open-source Ethereum client developed under the Apache 2.0 license and written in Java. It runs on Ethereum Mainnet, private networks, and test networks such as Rinkeby, Ropsten, Goerli, and the Merge testnet. Besu serves as an execution client on Ethereum Mainnet and the Merge testnet. Besu implements proof of authority (QBFT, IBFT 2.0, and Clique) and proof of work (Ethash) consensus mechanisms. Besu implements the QBFT, IBFT 2.0, and Clique proof of authority (PoA) consensus protocols. PoA consensus protocols work when participants know each other and there is a level of trust between them. For example, in a permissioned consortium network. PoA consensus protocols have faster block times and a much greater transaction throughput than the Ethash proof of work consensus protocol used on the Ethereum Mainnet. In QBFT, IBFT 2.0, or Clique, a group of nodes in the network act as validators (QBFT and IBFT 2.0) or signers (Clique). The existing nodes in the signer/validator pool vote to add nodes to or remove nodes from the pool [6].

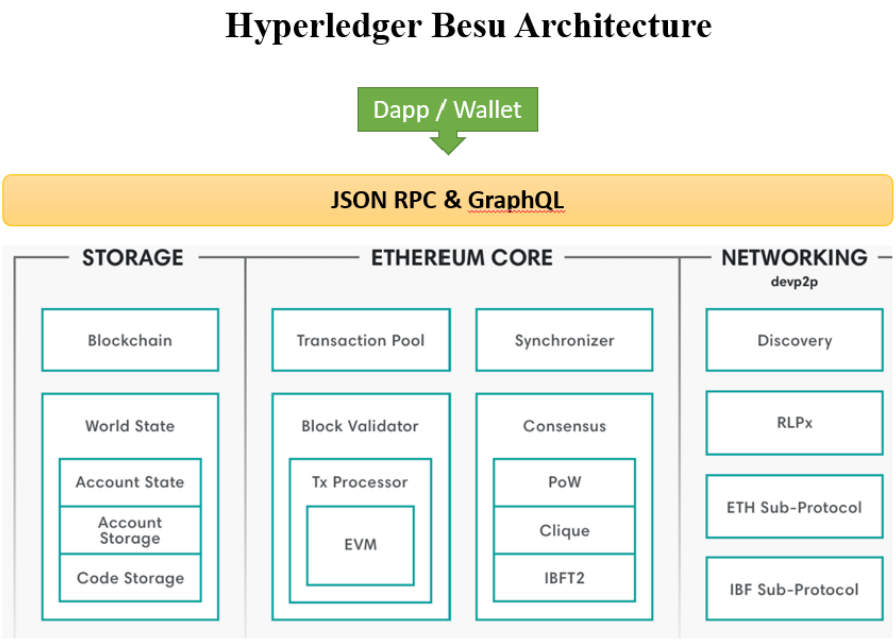

Figure 2. Hyperledger Besu Architecture

3. Benefits of Blockchain in healthcare

Implementing blockchain in healthcare and pharmaceuticals industries have multiple benefit as it provide digital transparency and resilient end-to-end digital traceability through the supply chain. It can be potentially useful by assigning GS1 standard barcodes in all levels of packaging units where unique identifier of product with other critical attribute can be scan and send to block chain network for authentication and send updated data blocks to all peer nodes. [7] (Sarkar, 2022). The distributor receives the physical product packages from manufacturers and scans Product identifier barcodes to validate physical product with digital data received from manufacturer or supply chain partner. The system then validate barcode information matches with shipping pedigree received in the DApp inbox. The wholesaler or distributor then verifies that the manufacturing EPCIS information referenced in the shipping events EPCIS information exist and matches with physical drug products. The recipient then creates a receiving event with the crypted hash valuesof the manufacturing EPCIS file of drug products actually. [8] (Sylim et al., n.d.). Now a daysonline medicine sales has given a perfect opportunity to counterfeiter for supplying illicit drugs in supply chain. Blockchain based technology will control the fake drug circulation in supply chain as Authorized Trading Partner (ATP) will only be register and communicate transaction to other peer nodes. [9].

4. Conclusion

In recent years pharmaceutical industries observed that the process of digital traceability in supply chain life cycle becomes very complex. It is very difficult to know the source of medicine component and its authenticity. Due to lack of transparency patient does not know the source medicine and which channel defective drugs have been dispensed, and it may give an opportunity to drug counterfeiter to introduce fake drug in market [10] (Ouf, 2021). Some of the biggest use of blockchain in pharma is the improvement in returned drug authenticity, better compliance when it comes to sensitive drugs, automation, and better clinical trials. The last two improvements will be inventory management and clinical trial data. Blockchain technology is still a new technology that

has not been widely implemented in the health care sector [11]. One of the main use cases of Blockchain technology is Drug or pharmaceutical supply chains. There are many complex scenarios where pharmaceutical industry needs digital transparency of drug between supply chain stakeholders. It generally starts with drug manufacturing at manufacturers end to final dispensing to patients or consumers. Blockchain technology provide safety, security, transparency and trust between patients and supply chain partners. Blockchain may mitigate the risk of counterfeiting in pharmaceutical industry, such as delivery of substandard or counterfeit medication, which may have a negative impact on patients [12] (Elangovan et al., 2022). Blockchain technology can be replaced to basic distributed database management system, which have generally been designed with structured query language or similar input. Traditional distributed method is already established in healthcare industry but they have significant limitations. Traditional database management system are unable to support peer to peer data sharing susceptibility to external adversaries such as hacking. It also does not have immutable audit trail which create higher risk of data manipulation. Immutable blockchain technology can easily address these issues and allow peer and stakeholders to use utmost benefit of blockchain technology [13].

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Conflicts of Interest: The authors declare no conflict of interest

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