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BLOCKCHAIN FOR DATA INTEGRITY IN PHARMACEUTICAL QUALITY ASSURANCE: CURRENT LANDSCAPE AND FUTURE DIRECTIONS

Thanuja Kilari, Manimaran Vasanthan*

Department of Pharmaceutical Quality Assurance, SRM College of Pharmacy, SRM Institute of Science & Technology. Kattankulathur, Chengalpattu Dt Tamil Nadu – 603203

***Corresponding author**: Dr. V. Manimaran

Associate Professor & Head

Department of Quality Assurance, SRM College of Pharmacy, SRM Institute of Science & Technology. Kattankulathur, Chengalpattu Dt Tamil Nadu – 603203

Email: manimarv@srmist.edu.in

Orchid I.D – 0000-0003-2404-6268

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ABSTRACT

Data integrity is a fundamental rule of Good Manufacturing Practices (GMP) and Quality Assurance (QA) in the pharmaceutical industry which directly affects the level of product quality, safety of the patients, and compliance with the regulations. De-localized data systems that are conventional are prone to breach of regulations and compromise and inefficiency issues which expose them to risk of manipulation and loss of data too. Blockchain technology, and its two key attributes of decentralization, immutability, transparency, and cryptographic security, solutions to these problems are transformative. Blockchain is fully compatible with ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, and extensions) to compose tamper-evident, audit, and real-time records across the pharmaceutical value chain. Its uses include electronic batch records, change control, deviation management, audit trails, CAPA documentation, and supply chain traceability, and regulatory reporting. Moreover, smart contracts can help to adhere to the requirements of GMP automatically and avoid the risk of human error, increasing efficiency in the work. FDA, EMA, and WHO are also starting to appreciate the potential of blockchain, which reveals itself through pilot programs like MediLedger. Although it exists with several challenges like integration with legacy systems, cost, privacy, and a lack of global standardization, blockchain will transform QA systems with the power of predictive, data-driven, and proactive QA systems when combined with other Industry 4.0 technologies, such as IoT and AI. This review investigates the current trend of the blockchain as well as its probable applications, regulatory views, and future paths in pharmaceutical QA.

INTRODUCTION

The pharmaceutical industry is possibly one of the most strictly regulated industries all over the world, due to the vital role of its products on the health of the human population. In connection with this, reliability and accuracy of data generated when developing, manufacturing, testing, storing, and distributing drugs is a crucial aspect(1). In this respect, the principle of data integrity as the soundness, thoroughness, accuracy, and reliability of data in all the aspects of its lifecycle can be used as a critical prime decision stake in issues on product quality, safety, efficacy, and regulatory compliance. The data integrity principles are therefore practically inculcated in the entire landscape of Good Manufacturing Practices (GMP) and Quality Assurance (QA) system(2). The number of data integrity breaches has been on the rise as reported by the regulatory oversight agencies such as the United States Food and Drug Administration (FDA), European Medicines Agency (EMA), World Health Organization (WHO) and Pharmaceutical Inspection Co-operation Scheme (PIC/S)(3). Those breaches include misrepresented data, outdated information, missing raw data, and the inability to maintain electric records or audit parks(4). Punishments of these violations are drastic: regulatory actions, which include warning letters, bans of the import and recall of products, loss of the community trust and increased risks to patient safety. As a result, effective mechanisms of network security and maintenance of data integrity forms not only a compliance obligation, but rather an essentiality (5).

Data integrity is very much embedded into every aspect of GMP including personnel training, manufacturing and environment control, laboratory procedures, documentation and validation(6). Quality Assurance (QA) department plays a central role in the formation, enforcement and monitoring of the procedures which ensures data integrity across these fronts. QA activities cover the confirmation of Standard Operating Procedures (SOPs) compliance, the resolution of the deviation, the accuracy and

completeness of batch records, and showing that all the procedures are auditable and meet the regulatory standards(7).

To achieve a strong data integrity and transparency, new technologies are considered to strengthen the mechanism in QA systems(8). The extreme popularity of blockchain technology among scholars has been associated with its decentralized, immutable, and transparent nature. In technical terms, a blockchain is a distributed online ledger in which data are represented in a network of computers- nodes. All transactions or data entries are packed into a so-called block, which is date-stamped, cryptographically bound to a unique hash, and connected to the previous block in the series, so creating an unchangeable chain of records(9). In the perspective of pharmaceutical QA, blockchain is especially attractive since the data recorded to the ledger cannot be only deleted or altered without affecting all the following blocks and gaining assent of all the concerned nodes(10). The given feature creates an irreplicable audit trail that can be exchanged amongst the QA departments, manufacturing units, regulatory bodies, CRO, suppliers etc. so that every one of the interested parties looks and approves on the same version of the truth. Also, GMP requirements including timelines of addressing the deviations, automated notifications, change control procedures, and approval of the release of batches could be enforced using smart contracts, which, in turn, define automated rules on the blockchain platform. Automation of these QA activities makes blockchain an opportunity to implement compliance programs without the need to resort to human intervention, and manual monitoring(7).

The most basic way of assuring data integrity is by employing strict standards with the major system used throughout the world consisting of the ALCOA+ principles. These principles, which include Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available, are working as an operational checklist ensuring that data will be trustable and usable(11). Any non-adherence to their principles has huge implications on product quality and regulatory compliance.

Blockchain technology, in turn, is a consistent representation of ALCOA+ with time-stamped, unalterable and source-able records that are always stored and can be easily found. Blockchain networks have distributed architecture that guarantees the availability and persistence of data; cryptographic signatures and sequential audit trail guard data integrity as they prove data accuracy, originality, and traceability(12).

The current review looks at blockchain technology potential in strengthening data integrity in pharmaceutical Quality Assurance procedures. Its aims are to describe the fundamentality of blockchain; correlate the properties of blockchain to each of the ALCOA+ functionalities, think through the feasibility of integrating blockchain into the seminal QA functions, namely, batch documentation, audit trail, deviation handling, and supply chain traceability, imagine real-life scenarios, evaluate the potential and pitfalls of adopting blockchain and theorize on the future applications where blockchain can be embedded into the adjacent technologies to develop smart QA ecosystems. It is hoped that, via this review, pharmaceutical scientists, QA professionals, regulatory experts, and technology developers will gain an in-depth perspective on how blockchain can be utilized not only as an impenetrable means to data-store but as a paradigm-shifting framework that has the potential of raising quality, compliance, and trust rates in the pharmaceutical industry as a whole.

ALCOA+ Principle	QA Working	Blockchain working
Attributable	**When and who completed the task?**	To ensure accountability for every action, each entry is timestamped and cryptographically signed.
Legible	**Records need to be comprehensible and readable.**	Over time, formatting and legibility are maintained by immutable, structured data blocks.
Contemporaneous	**Documentation must occur at the time of the event**	The blockchain's real-time entry logging guarantees that actions are recorded immediately and cannot be undone.
Original	**Original document or a confirmed authentic copy.**	The original transaction, which cannot be altered or replaced, is recorded and stored by blockchain technology.
Accurate	**Records need to be trustworthy and free of errors.**	Data is validated through cryptographic checks and consensus; errors in entry or tampering are found.

Table 1: ALCOA+ Principal compliance with Blockchain working(13)

1. Block chain technology working

The blockchain technology rapidly becomes a game-changing paradigm in many areas due to such property characteristics as decentralization, immutability, transparency, and security. These attributes are particularly important in the case of pharmaceutical Quality Assurance (QA)(10) where it enables the promotion of data integrity, regulatory compliance requirements, and the realization of real-time traceability which are the core aspects of Good Manufacturing Practice (GMP)(14). The current summary establishes the workings dynamics behind blockchain and explains its relevance in QA by its main components, which are nodes, blocks, hashing, consensus protocols, blockchain types, smart contracts, cryptographic protection, and digital signatures(15). Traditional QA systems are likely to use the system of centralized databases that are prone to data manipulation, unauthorized modifications, and inefficient tracking(16). Blockchain helps reduce the risks of such vulnerabilities by distributing information on a network of nodes thus making data to have no exclusive control by one actor and making all records transparent, traceable and tamper evident(9). The efficiency of the blockchain in QA of pharmaceuticals can be understood well after analyzing its backend infrastructure and operations. In practical use, a blockchain is viewed as a digital ledger, distributed, some parts of which store transactions with timestamps in a way that prevents alterations later(17). The replicated entries of this ledger are shared on a network of computers, called nodes. The ledger is replicated to every single node with each node having a complete copy of the ledger, thus preventing unilateral control of the information by any individual (17). In a QA environment, nodes may involve a large number of stakeholders- including an internal QA department of a firm, places of manufacturing, outsourced contract manufacturers and regulatory bodies, which may be seeking concurrent access or validation of the quality records(18). Every block is a separate piece of new information, be it a batch-record approval, a deviation investigation clean-up or a change to a cleaning-validation procedure. Each block requires a three-part structure: data payload (i.e. the actual data record), timestamp and cryptographic hash.

It also holds the hash of the previous block thus connecting the previous block to the new one. This block chain forms a chronological record whose integrity is hard to tamper with. When one or more characters in the content of a block are altered the hash is altered completely thus breaking the chain and alerting that some form of unauthorized change is being attempted(19). The agenda of such structure, of course, corresponds to that of ALCOA+, especially accuracy, consistency, and integrity(11). Hashing involves cryptographic algorithm which is helpful in providing an identity (unique number) to each block by looking at its contents. In QA, this will make every document or digital

signature have its personal fingerprint. In case a QA auditor accesses a deviation report on the block chain, and he wishes to see whether it is authentic, then he just needs to rework on its hash and match it with what was stored. A difference implies a shift. This is needed in ensuring data precision and reliability(7). This cryptographic connection keeps intact the authenticity of each block. Prior to the addition of a block to the blockchain, the network has to be validated through the employment of a consensus mechanism. Consensus protocols are protocols to guarantee the concurrence among the spread nodes(20). The well-known mechanism is Proof of Work (PoW), Proof of Stake (PoS), and Practical Byzantine Fault Tolerance (PBFT). PBFT or Proof of Authority (PoA) are best applied in pharmaceutical QA systems where the stakeholders are known and access can be limited, in the PBFT method, a subset of trusted nodes agrees in the correctness of a transaction whereas in PoA, only authorized nodes can create new blocks, this is more secure but at the same time fast and scalable(19). This is to guarantee that any update like document update or authorization is checked and approved before being made as permanent records. It also enables regulatory expectations of traceable, auditable and attributable data flows(18).

According to the degree of decentralization and control of access to them, the blockchain networks can be divided and there are three big kinds of the blockchain network Public, Private and Consortium. Public Blockchains are transparent and open and hence all the participants can read and write to the blockchain(19). They are the common tools used on a cryptocurrency such as Bitcoin or Ethereum, but since there is no confidentiality and regulatory control, they cannot be applied in pharma QA. Private Blockchains are controlled by one organization. They are faster in the processing of transactions and provide an improved level of data control, although they can present centralization risks, which hamper transparency. Consortium Blockchains are kind of decentralized given the fact that it is run by a consortium of legitimate participants. The pharmaceutical QA systems would be most appropriate under this model where various departments, external partners and regulators need to share access to validated and quality data without affecting security or ownership. The consortium blockchains promise regulation of access, amplified information honesty, and shared duty of care organization(20). The use of smart contracts- digital rules that are automatically followed in case of certain, predetermined conditions is one of the strongest features of blockchain technology(21). GMP rules can be enforced into the QA system with the help of smart contracts. As an example, an alert feature can be integrated in the smart contract whereby a notification will automatically be issued to the QA department in case the variance is not eliminated within a confined period of time. It may deny the release of batches till the end of the checking of quality control outcomes by QA employees. A possible application is change controls, i.e. making sure that no unauthorized change is applied to a validated system. The fact that one can encode compliance logic into blockchain does not only make QA processes efficient but reduces human error, provides audit readiness, and improves a continuous verification of the process(22).

The use of complex cryptography in data security and user authentication makes blockchain very safe. cryptography enables blockchain to guarantee data confidentiality and transparency at the same time(23). Although the information can be viewed by authorized users, it is still encrypted to avoid interference or unauthorized viewing. The feature helps to directly comply with regulation needs, including the 21 CFR Part 11 regulation of electronic records and electronic signatures(24). The regulation provides that electronic records must be trustworthy, reliable and are the same as paper records. These Digital signatures on blockchain meet these requirements in the sense that they allow each record to be Attributable by the person who created it, Time-stamped and immutable, Verifiable using audit trails. Due to the shift toward digital transformation in the pharmaceutical industry, the usage of the blockchain and building it into the existing Quality Management Systems (or QMS) provide a unique approach to solving enduring problems with data management (17)t. Additional benefits associated with Blockchain are its synergy with Internet of Things (IoT) and Artificial Intelligence (AI)(9). As an example, the information about the cleaning state of equipment or environmental monitoring provided by sensors can be written directly to blockchain and can be checked that some validated state is followed. AI may then be used to interpret this permanent data to forecast deviations or quality trends in aid of proactive QA.

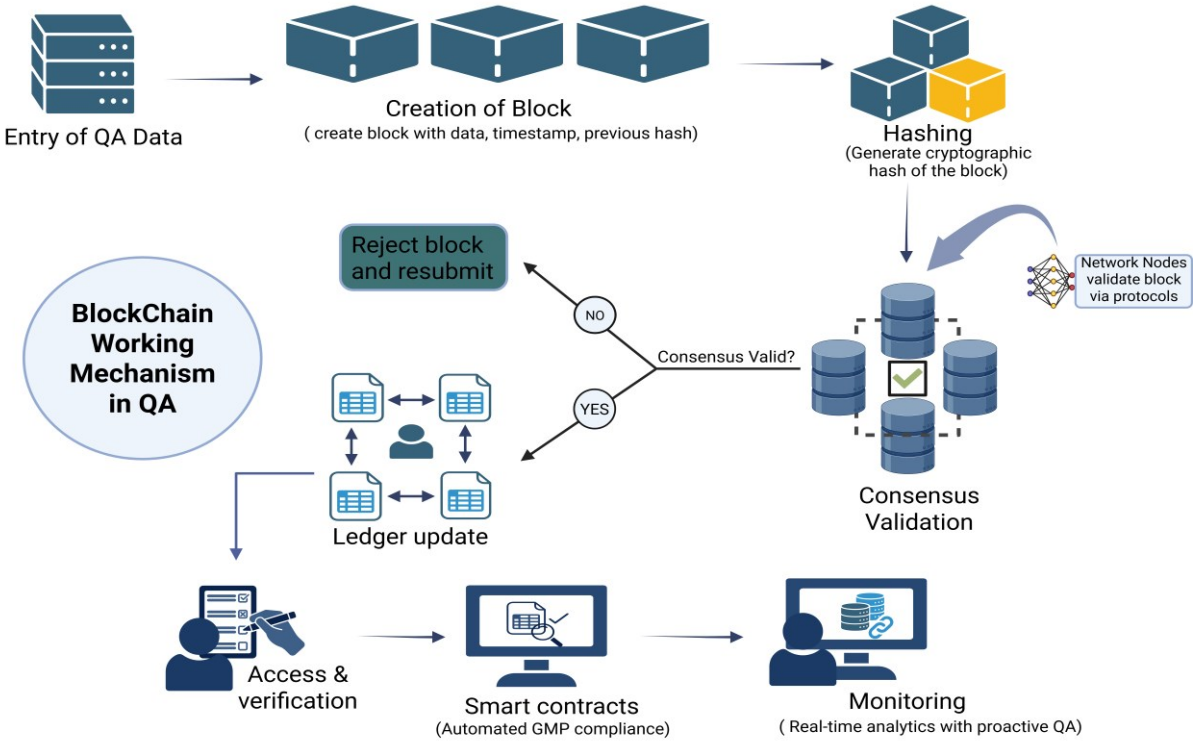

Figure 1: Blockchain working Mechanism in Pharmaceutical Quality Assurance

2. Application of block chain in pharmaceutical quality assurance

Blockchain technology can revolutionize the approach to managing pharmaceutical quality systems by establishing a traceable and transparent infrastructure and maintaining data in pharmaceutical quality systems at all times, enabling safe collaboration and higher regulatory compliance. Throughout fundamental quality assurance (QA) areas. here are few the applications where blockchain serve as digital backbone to assurance, traceability, and accountability. Blockchain curbs the vulnerabilities that have always been present with traditional and centralized forms of data due to their overwritable, or even loss through abuse of the distributed, cryptography-secured, and consensus reached state that blockchain entails, especially within multi-stakeholder pharmaceutical systems.

a) Electronic batch records and GMP documentation

Batch Manufacturing Records (BMRs) and Electronic Batch Records (EBRs) are a part of the pharmaceutical industry that are fundamental documents in the drug production process and what guarantees that every batch of drug product reaches a drug warehouse and ends up in the hands of consumers with no deviations by being produced and regulated by predetermined specifications. The blockchain technology brings a disruptive solution because it allows storing data in decentralized immutable, time-stamped entries that can only be accessed by authorized entities which guarantee the maximum data integrity and security. Through blockchain, each event including an operator sign-off, an environmental parameter record, and a deviation will be reflected instantly across a shared ledger in form of a transaction. The transactions are cryptographically chained, i.e., a subsequent alteration of a prior record would tamper with the chain, thereby indicating any tampering of the chain of records instantly. This secured architecture promotes Good Manufacturing Practice (GMP) and contributes a lot as far as regulatory checks by regulatory bodies like FDA and EMA are concerned. In audits, inspectors have access to complete, chronological, and unaltered records, cutting significantly the time spent on the authenticity of the information. Prevention of overwriting capability not only maintains integrity of the data but also instills the culture of accountability in the manufacturing spaces. Further, blockchain enables interaction with the Internet of Things (IoT) devices and digital sensors. As an example, environmental parameters such as temperature, humidity and the pressure inside cleanrooms could automatically record the data in the blockchain in real-time. This integration provides true, tamper-resistant records of the critical quality attributes (CQAs), critical process parameters (CPPs) that are the further guarantee of the compliance with the requirements of the 21 CFR Part 11 and Annex 11. Finally, this system creates efficiencies within the operation, minimizes the load of manual records and increases the pharmaceutical manufacturing credibility (16,25).

b) Change control and deviation

Blockchain pioneers a new level of transparency as all changes are stored in the form of unique, unalterable transactions with metadata, including the name of the initiator, time stamp, reason, and evaluation. Change control and deviation resolution steps can be coded and enforced by smart contracts, i.e. self-executing contracts encoded in blockchain. To take an example, once the request of change has been triggered, the smart contract can respectively direct the request to the relevant quality, validation or regulatory departments to review the request and approve it. They can be able to automatically remind or escalate approvals when they have not been conferred within a specified time. This prevents the possibility of the unapproved or undocumented changes that might leak through the system. Since all the activities are time marked and interconnected in chronological order, any activity diversion or modification can be tracked back to its source point clearly with full transparency(25).

c) Audit trials and regulatory compliance

The decentralized structure and cryptographical security of Blockchain allow a secure audit path, which cannot be tampered or edited after the fact. Every transaction in a blockchain network is encrypted with cryptographic hash functions and gets time-stamped which leaves an immutable ledger. Such entries cannot be deleted or altered without approval of the whole network which is also not practically possible in permissioned enterprise blockchain applications. Such immutability provides assurance of authenticity and reliability of audit trails during regulation inspection especially when done under regulative guides (e.g., such as 21 CFR Part 11 FDA, Annex 11 EU-EMA, and Good Documentation Practices (GDP) WHO). The records that regulators need to access can be accessed with assurance that no data is fabricated or concealed. Remote inspections and digital audit are another occurrence that blockchain can enable and are made even more relevant in the post-pandemic world. The application of blockchain-based audit trails is in line with data integrity principles of ALCOA + (Attributable, Legible, Contemporaneous, Original, Accurate) and therefore reinforces the confidence in pharmaceutical records(16,26).

d) Corrective and Preventive Actions (CAPA) & Quality Management System (QMS) Documentation

Effective CAPA system relies on proper documentation, immediate response and traceable follow up. Blockchain and its capability to deliver unchangeable documents and workflow trigger automation can contribute to the improvement of CAPA management to a great extent. In a blockchain-based QMS the creation of a CAPA, all related investigation and root cause work, corrective action planning and follow through all become entries in the block chain, making them time and date stamped verifications, that cannot be altered or changed. As an example, in the event that a deviation arises during the production process and a corrective and preventive action (CAPA) is raised, the blockchain charts not only the deviation report but also the investigation process details, interview records, corrective action plan and validation results. Data can be transferred between departments and between companies to third-party auditors or even the regulators without loss of data integrity. The end product is a traceable, auditable closed-loop CAPA system which complies with global standards such as ICH Q10, ISO 9001 and with the FDA requirements. Moreover, blockchain can be combined with such other QMS components as training records, SOP management, and risk assessments. The integration also results in a single quality ecosystem with all the components visual, responsible, and connected together- enhancing the quality culture and culture overall but not only in terms of compliance(25,27).

e) Supply Chain Quality Control and Traceability

blockchain, each transaction (hand- off) in the supply chain, that is, the raw materials, the API-manufacturer, formulation plant, packaging unit, wholesaler, and the pharmacy retain a verifiable transaction. This track-and-trace traceability makes origin, passage, and custody of any given batch visible and un hackable. The blockchain can be connected to digital tagging technologies, e.g. QR-codes, RFID or NFC chips to provide autonomous digital identity to each and every unit of product. These tags can be scanned by consumers, pharmacists and regulators to ensure goods are the real thing and to know the complete history of the product. Not only does this strategy meet the current worldwide traceability requirements like the U.S. Drug Supply Chain Security Act (DSCSA), the EU Falsified Medicines Directive (FMD) and the WHO Traceability Framework, but it also has the ability to deliver the supply chain with real-time intelligence. As an example, when a temperature sensitive vaccine goes off track in transit, the blockchain record will document both time and place of deviation, allowing faster reaction and quarantining of possibly damaged products. Blockchain can also be used to qualify suppliers, manage the release of batches and conduct supplier compliance checks throughout the supply chain due to a shared, immutable record of certificates, audit reports and quality agreements. Such openness encourages trust and cooperation among manufacturers, regulators and consumers and ends up enhancing patient safety and the overall health of the population

3. Regulatory perspective

The use of blockchain technology in the quality system in a pharmaceutical is rapidly getting considered and even being promoted with limited caution by the regulatory bodies all over the world. Regulators have understood that blockchain can facilitate the current long-standing standards regarding data integrity, electronic records, audit trail, traceability, and supply chain safety(28). These features are suitable with the current international regulatory practices such as the U.S. FDA 21 CFR Part

11, ICH Q9 and Q10 (29), WHO TRS 996(24) Annex 5 (28), and the GAMP 5 Second Edition. In these documents, traceability, validation, real-time monitoring, and transparency are highlighted, and the blockchain technology practices these philosophies by nature. Along with the Drug Supply Chain Security Act (DSCSA), the U.S. Food and Drug Administration (FDA) initiated a special Pilot Project Program in order to define the potential of blockchain to enhance the traceability of pharmaceuticals(24,29). Among the most noticeable projects in this program was the MediLedger Project which was a consortium consisting of large pharmaceutical manufacturers and distributors. The project has managed to prove that a permissioned blockchain network can reliably verify authenticity of drug products, trace the movement of items between partners, and interoperate without central control. These attributes make blockchain a perfect solution to DSCSA-2024 requirement of an interoperable electronic system. Serialisation, product verification, and supply chain transparency are the focal points of the European context in the field of investigation, to be precise during the European Medicines Agency (EMA) and the EU Falsified Medicines Directive (FMD). Despite the effort to meet FMD requirements through centralized repositories that EU has already applied, both regulators and industry consortia have acknowledged the benefits of blockchain as drivers of drug authenticity verification as well as ensuring cross-border data sharing lapses. Blockchain has already been piloted to improve compliance reporting as well as verification of serializations in real time in a number of EU member states and thus demonstrates a potential to help implement the FMD objectives in a broader context(30,31).

Internationally, the World Health Organization (WHO) has recognized the importance of improvement and documentation systems, essential regarding the lower-and middle-income economies in terms of infrastructure and regulatory maturity. WHO, in its Traceability of Medical Products framework and guidelines (including TRS 996 Annex 5) points out that records should be attributable, legible, contemporaneous, original and accurate, which are reflected in the ALCOA+(24) data integrity standard. Blockchain naturally fulfills these requirements in the form of a decentralized, un-tamperable, ledger that makes tampering-with-data near-nearly impossible, and the ledger is still auditable in the future. Regulators still keep a close eye on blockchain implementations within the pharma environment, and pilot programs, such as the MediLedger Consortium are critical to the process. These consortia, which include stakeholders in the drug value chain (manufacturers, distributors, pharmacies, and regulators) are formulating block chain protocols to verify the product, charge back transactions, and share serialized data(28). Through close collaboration with regulators, such efforts are doing much to influence the standards, validation standards, and audit expectations that will become characteristic of how blockchain is implemented at scale tomorrow. Although the blockchain has not yet been officially imposed by any significant regulator, evidence of increased acceptance and positive involvement can be seen. The next evolution of regulation is to shift the pilot programs into reality with regulators then jumping to formal recommendations which will help blockchain emerge as a central pillar of next-generation innovation(28,30).

4. Advantages and Limitation of Blockchain implementation in QA

The blockchain technology is regarded as a disruptive enabler in the pharmaceutical quality assurance (QA) developments as it has emerged as the tool that can address the strict regulatory demands as well as simplifies documentation, compliance, and oversight tasks. Here, some of the advantages(32,33)

- **ALCOA+ principles:** The most significant solution blockchain has to offer is that its functionality suits well the ALCOA+ principles which are Attributable, Legible, Contemporaneous, Original, and Accurate with extensions of completeness, consistency, endurance, and availability. GxP-compliant documentation is dependent on these principles being met, and with blockchain, the immutable, time-stamped, and digitally signed entries associated with blockchain are by their nature able to meet these principles without requiring further controls or undertaking an overlay into the system.
- **Data transparency and traceability:** Blockchain provides a distributed ledger which is updated simultaneously on all nodes in the system, which makes it possible to synchronize in real time QA records between stakeholders. Each single step undertaken, starting with active pharmaceutical ingredient (API) sourcing and formulation, through to final release and logistics, is indelibly and directly documented, resulting in a chain of uninterrupted custody. This is especially useful in the course of an audit, recall, or investigation when it is vital to have valid data quickly available.
- **Automated workflows:** Blockchain can help simplify this challenge by automating specialized workflows to digitize forms and smart contracts, which enable the self-enforcement of QA policies, automatic review introduction, and overdue work escalation. This does not only decrease the chance but also increases the procedural screening and audit readiness. Auditors will have access to the entire, uninterrupted sequence of events that will automatically be validated and chronologically arranged with a reduced time and cost to verify compliance.
- **real-time quality monitoring:** blockchain also allows in-time quality control and data analytics. Live logging their environment conditions, equipment behavior, and operator activities is possible in the live logging through integration with IoT sensors and manufacturing execution systems (MES) and all elements are recorded to the blockchain. The Quality Assurance teams will be able to monitor the trends, detect deviations at their early stages, and take corrective actions in time. This functionality facilitates direct support of real-time release testing (RTRT), continuous manufacturing and, principles of continuous improvement and knowledge management outlined in ICH Q10.
- **security and auditability:** The capacity to include verifiable documentation that cannot be altered and which depicts operations as they occur in real-time, boosts the reliability of QA information in case of regulatory inspections. The FDA, EMA, and WHO among others are becoming more aware of the opportunities that blockchain has of improving the compliance aspects and data validity in the global supply chain. Decentralization of the technology also implies that data access may be highly permissioned, this means that only their trusted users (including regulators) can view or validate specific records with zero risk of data compromise, or system configurations.

  Though the potential of incorporating blockchain in pharmaceutical Quality Assurance is tremendous, the process does not come without some key challenges(34).
- **Conformity with Quality Management System (QMS):** Most of the existing GxP-compliant platforms deployed in pharmaceutical plants have not been developed with a blockchain architecture, which causes an incompatibility problem. To replace these systems is expensive and very disruptive. A more practical solution is to implement middleware or APIs that will connect both existing systems to blockchain networks so that synching data with real-time delay is possible without entirely restructuring the system.
- **Data privacy:** When handling sensitive patient data at the clinical QA environment, the process of having a transparent environment that upholds the confidentiality of data becomes confusing. This may best be solved by using permissioned or private blockchains where roles are defined and access to certain data will be controlled at a granular level without undermining compliance.
- **cost and complexity:** Building and sustaining the infrastructure of blockchain, educating the personnel,

and ensuring the system is regulated by GxP demands significant resources. A way to overcome it is to use a pilot based implementation plan, and implement a single QA area at a time, e.g. deviation logging or electronic batch record control, gradually scaling up. This enables the phased and performance based validation efforts and cost allocation.

- **lack of standardized protocols:** Each of the implementations can vary extremely in its scope and reliability without the common framework. These standards are being determined by industry-wide cooperation through projects such as consortia such as the MediLedger Project.

5. Future Directions

With the digitalization of the pharmaceutical sector, the application of the blockchain technology in combination with other, complementary solution including such innovations as artificial intelligence (AI), the Internet of Things (IoT), and smart contracts is paving the way to completely new paradigms of quality assurance (QA)(35–37).The combination of these technologies go beyond the classic blockchain advantages of immutability, transparency, and decentralization but open the possibilities of proactive compliance, real-time monitoring, and forecasted quality control(35,38). The convergence of the blockchain and AI-based predictive quality assurance is one of the most promising. Pharmaceutical companies can use blockchain ledgers to record the equipment logs, batch data, operator entries, and environmental data so securely and feed high-quality and trusted data into AI models. Such models then have ability to establish emerging trends or patterns which present a higher likelihood of deviation or non-compliance(37,39–41). This ecosystem can be boosted by integration with the IoT. The IoT sensors on manufacturing apparatus, cleanrooms facilities, and shipping containers can produce real-time data continuously. This data is then tamper-proof and audit according to block chain linking, this enhances credibility and acceptance under regulation(42–45). As an example, the calibration status, the history of maintenance, and the deviations of run-time may automatically be logged on blockchain under the parameters of equipment qualification. This makes use of a safe operating and real-time audit path that enables preventive maintenance, assists in ensuring equipment is kept within validated conditions and provides direct QA intervention in the event of any anomalies, making it easier to comply with GMP and lowers the likelihood of failures occurring during manufacturing processes(35,46,47). The next frontier is on the development of Quality Management Systems (QMS) using blockchain technology that combines dynamic dashboards. Older QMS platforms can be characterized by non-unified source of information and slow observation of quality concerns. Deviation tracking, CAPA (Corrective and Preventive Actions), document control, and training records are examples of quality processes that must be centralized in blockchain-enabled QMS(38,47), therefore taking several valuable quality processes and placing them under one common platform. Smart dashboards developed using this as foundation may give real-time information on quality performance measures and automatically point out non-conformance and monitor the corrective actions. Users can immediately see the status of open deviations, CAPAs overdue, and history of document revision, as well as the scores of audit readiness, all on the basis of reliable and time-stamped data(47,48). Such integration minimizes the amount of manual reconciliation between different systems and makes sure that the latest and verified data is available at any point when internal reviews are done or external inspection is provided(38,47). In addition, role-based access to the blockchain-based QMS can be secure role, so that a particular staff member in QA, the auditor, or the regulator might be shown only data to which they have security access, but full traceability can be maintained of everyone who has the access and what changes(36,47). Blockchain is also in the process of transforming clinical quality assurance. Consent management is also a special zone, in which privacy and transparency of data, as well as traceability, are the most important issues. Blockchain is able to produce time stamped, non-repudiable records of informed consent of version-controlled protocol documentation and the digital signature of participants(36,43). Moreover, protocol violations in real-time will be recorded and become visible to all authorized stakeholders without the need to report manually and record delays. The effectiveness of smart contracts to automate the compliance processes is growing. These run-time scripts have flexible capabilities to employ the SOPs (Standard Operating Procedures), start escalations automatically in case of timeline violations or lock down the processes until they complete sign-offs(38,45). As an example, QA leads might want to get a notification and set up a CAPA workflow in case a deviation investigation takes more than its established time to complete by using a smart contract. Equally, release of products through the production line becomes gated by smart contracts that not only follow the completion of all necessary quality checks, training validations and environmental monitoring records, but also enabling the clearance of the batches(38,47); because every mortal compliance check serves as a gate check that no essential risk control step has been skipped and the likelihood of human error or malpractice is greatly diminished. All these innovations can all be considered a digital evolution of the pharmaceutical Quality Management System (QMS). QMS is no longer a document-driven reactive process but a real-time, predictive and data-driven role. Blockchain is the basis on which AI, IoT and smart automation can be driven with trust, accountability and regulatory confidence. Pharmaceutical companies that embrace these bundled systems not only improve their efficiency with respect to operations but also increase their competitive edge as well as their compliance posture(35–38,48).

CONCLUSION

Data integrity has always been at the forefront of Good Manufacturing Practices (GMP) and regulatory compliance in the pharmaceutical sector which forms the basis of quality assurance (qA) systems and finally, patient safety. The blockchain technology is a persuasive paradigm shift in this context because it provides a secure data infrastructure having transparent usage and tamper-evidence that is inherently compliant with the ALCOA+ principles. Blockchain solves the most fundamental problems of data integrity: The data on its read-only ledger is attributable, readable, timely, authentic, correct, complete, consistent, durable and its authenticity is easy to verify. To have pharmaceutical QA practices transformed, there are a few practical approaches, as this review has pointed out, in which blockchain can be useful. Electronic batch records (EBR), audit trails, change control documentation, CAPA systems, quality management systems (QMS), and supply chain traceability are some of the applications that can be facilitated by increased transparency, traceability and fraud prevention. Projects such as MediLedger, a developing interest among regulators (such as the FDA, EMA, and WHO), and a more general cautious acceptance of distributed ledger technologies to exist even within validated environments are yet more promising. Though the application of regulatory frameworks remains in development, the ability of blockchain functions to morph with the existing demands in terms of data integrity and GMP compliance opens possibilities. Again, however, the switch to the blockchain-enabled QA systems is not flawless. The obstacles are that its implementation is complex, it is expensive to implement infrastructure, it poses privacy concerns over data, has interoperability problems, and has no harmonized standards in different parts of the globe. In addition, the pharmaceutical bodies need to find a way of blending blockchain technology with their legacy systems and determine the applicability of its use as per the regulatory requirements and guarantee secure protection of good cybersecurity governance. In prospect, blockchain could interact with additional technologies of Industry 4.0 AI - like the Internet of Things (IoT) and smart contracts. This could continue developing QA frameworks further. The use of predictive analytics, automated decision making, and quality monitoring in real time can potentially transform the quality systems to proactive, intelligent, and data driven systems over time. Ultimately, blockchain is not only an instrument of data security but also of a complete revolution in meeting pharmaceutical quality assurance with its roots in trust, transparency, and accountability. Strengthening the trust radius of each activity and transaction along the entire drug lifecycle,

blockchain may be able to up the levels of regulatory compliance, operational performance, and consumer confidence in a major way. Wisdom applied to it under the prism of scientific, regulatory knowledge, and ethical insight can strengthen, make it dynamic, and more believable pharmaceutical industry in the digital age.

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