

Enhancing Security, Transparency, and Efficiency of Blockchain Technology in Pharmaceutical Supply Chain

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ABSTRACT

Blockchain technology has emerged as a promising solution to address persistent challenges like lack of transparency, inefficient tracking, and counterfeiting issues in pharmaceutical supply chains. However, there are still limitations in integrating blockchain with existing legacy systems, lack of common standards, scalability concerns due to its decentralized architecture, and lack of regulatory clarity that need to be addressed before successful implementation in the pharmaceutical industry is feasible. This review explores the potential benefits and current use cases of blockchain in enabling drug traceability, establishing authenticity and integrity of data, facilitating smart contracts for seamless financial transactions, and optimizing overall supply chain operations. The current blockchain-based solutions employed by various stakeholders like drug manufacturers, wholesalers, distributors, retailers, hospitals, and regulators across the different stages of the pharmaceutical value chain are reviewed in this article. Recent research efforts to mitigate the key challenges are discussed, including technical improvements in blockchain architecture for increased security and privacy, the use of permissioned blockchains, innovative consensus protocols to improve scalability, and growing regulatory guidance. The future outlook highlights the tremendous opportunities for blockchain to enable end-to-end visibility, accountability, automation, real-time monitoring and combating counterfeiting in pharmaceutical supply chains through collaborative efforts among stakeholders.

Keywords: Blockchain, Pharmaceutical industry, Supply chain, drug traceability, Transparency, Security.

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INTRODUCTION

The pharmaceutical industry plays a pivotal role in healthcare systems around the world. However, complex pharmaceutical supply chains have been plagued by issues like lack of transparency, inefficient tracking of drugs, medication errors, and rampant counterfeit drug distribution that compromise patient safety.¹⁻³ Blockchain technology has emerged as a promising solution to transform traditional pharmaceutical supply chain models by enhancing security, transparency, and efficiency.⁴ Blockchain is a distributed digital ledger technology that enables decentralized, immutable, and secure storage of transactional records on a peer-to-peer network. It eliminates the need for third-party intermediaries by enabling a single source of truth through consensus mechanisms. The pharmaceutical supply chain involves several stakeholders,

including drug manufacturers, wholesale distributors, pharmacies, hospitals, and regulators.⁵ Blockchain can transform this complex network by allowing seamless information sharing and collaboration among entities in a highly secure and transparent manner.

The global pharmaceutical supply chain is a complex network involving numerous entities working together to ensure patients receive life-saving and life-improving medications. However, this vast system faces significant challenges that impact the security of the supply chain and quality of products, increase costs, and potentially compromise patient safety.⁶ Some of the major issues plaguing pharmaceutical supply chains include the proliferation of counterfeit drugs, undefined visibility into drug diversions and unauthorized flows through the grey market, lack of transparency between supply chain

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Figure 1: Pharmaceutical supply chain workflow and areas impacted by blockchain

participants, which can create gaps, and inefficient tracking of shipments as they traverse the globe leading to stockouts or expiration.⁷ Additionally, the immense amounts of sensitive commercial and patient-level data generated lacks robust security controls and privacy protections. These challenges have real-world consequences. Counterfeit medications can endanger patients by including incorrect active ingredients, dosages, or no active ingredient at all. Product diversion strips authorized channels of supply while also enabling counterfeits to enter through the back door.⁸ Lack of transparency and inefficient tracking systems hinder recalls and exacerbate issues when they do arise. Insufficient data security breeds distrust and leaves valuable intellectual property vulnerable to theft. The overall effect is increased costs, reduced availability of authentic medicines, and compromised care- a situation in dire need of modernization.⁹ Several proof-of-concept studies and pilots over the past few years have demonstrated how blockchain technology can help address long-standing supply chain issues through decentralized networks, transparency, immutable record-keeping, and smart contract automation. Key application areas explored with promising early results include drug traceability spanning the complete journey from manufacturers to end consumers, authenticity verification through drug pedigree verification preventing counterfeits, blockchain-enabled smart contracts for processing transactions like payments and orders in a transparent yet private manner, and supply chain optimization unlocking inventory visibility and real-time adjustments.¹⁰ Beyond specific use cases, blockchain also offers broader potential transformational impacts. Distributed ledgers establish a single shared version of supply chain events visible to all authenticated parties, resolving long-time issues around information fragmentation between entities. Cryptographic protection of data enhances privacy and security over sensitive commercial assets, intellectual property, and patient medical records.¹¹ The pharmaceutical supply chain workflow is illustrated in Figure 1.

Tamper-proof tracking establishes new standards of accountability across multi-partner networks. Streamlined workflows through smart contract automation yield cost and time savings. However, widespread adoption also faces barriers. Integrating blockchain platforms seamlessly into legacy IT infrastructures already entrenched across this industry proves challenging. Achieving true interoperability is

hampered without standardized frameworks to bridge differing blockchain protocols. Performance and scalability become pressing issues as networks expand globally with billions of stock-keeping units (SKUs) in motion concurrently.¹² Ensuring privacy and confidentiality of sensitive data on transparent distributed ledgers requires continual innovation. Regulatory and legal clarity around blockchain applications also lags the pace of emerging technology.

In spite of these limitations, blockchain's potential remains highly compelling in finally transforming traditional pharmaceutical warehousing, distribution, reimbursement, and logistics streams into connected digital supply networks.¹³ This review aims to explore the current landscape of blockchain for pharmaceutical supply chains with a focus on real or pilot-ready applications, key benefits realized thus far, lingering challenges, and recommendations to maximize blockchain's advantages of trust, visibility and security for supply chain processes going forward. The goal is to evaluate blockchain's current role and future trajectory toward empowering smarter, more efficient and patient-centric approaches to global drug delivery.

Benefits of Blockchain for Pharmaceutical Supply Chains

Enhanced traceability and drug provenance

One of the major pain points in pharmaceutical supply chains is the lack of traceability and transparency regarding the origin and journey of drug products. Companies have limited visibility beyond their immediate upstream or downstream partners. This makes it difficult to track incidents such as diversion, grey market distribution, introduction of counterfeits, temperature deviations, etc.¹⁴ Blockchain brings an opportunity to establish end-to-end traceability across multiple entities in the supply network. Each drug packet can have a unique identity that provides its manufacturing and ownership provenance as it moves through the ecosystem.¹⁵

Some examples of how blockchain improves traceability are:

- Detailed logging of batch numbers, manufacturing sites, dates, shipping details, distributors, warehouses, etc., which allows tracing drugs back to the origin.¹⁶
- Seamless tracking as custody changes from manufacturer to contract packagers, wholesalers, distributors, and retailers. Automated verification of transactions and partners.¹⁷

- Sensors can record environmental conditions such as temperature and location in transit, while IoT integrations can transmit the data seamlessly to the blockchain.¹⁸
- If quality issues or adverse events arise, the manufacturer can quickly trace back to determine affected batches, distribution sites, etc., to contain the problem.
- Any attempts to introduce counterfeits can be detected early by tracing anomalies in the provenance trail. All actors in the ecosystem get alerted.¹⁹
- Diversion of drugs to unintended markets can be prevented as blockchain only allows legitimate partners to accept custody transfers.

Improved transparency and visibility

Pharmaceutical supply chains typically suffer from information silos and opacity. Companies have limited visibility beyond their tier 1 suppliers and customers. This allows gaps to develop where issues may go undetected. Blockchain establishes a single shared ledger that brings common visibility to all permitted participants in the network. Some examples include:

- All transactions, such as sales orders, purchase orders, invoices, and delivery acknowledgments between trading partners, get recorded chronologically, providing end-to-end visibility.²⁰
- The ledger is immutable and tamper-proof, so data cannot be changed without consensus from the network. This improves confidence and trust.²¹
- Data like manufacturing certificates, clinical reports, licenses, and shipping documents is securely shared, leading to transparency.²²
- Automated chain of custody handovers based on fulfillment of contractual terms enhanced visibility into ownership changes.
- Sensor data seamlessly integrated from IoT devices provides real-time visibility into environmental conditions.²³
- Regulators can also access supply chain data, improving compliance, oversight, and accuracy of interventions.

Increased efficiency and cost reduction

Pharmaceutical supply chains involve complex logistics, paper-based manual processes, duplication of efforts, and lack of transparency between siloed entities. Pharmaceutical supply chains involve complex logistics, paper-based manual processes, duplication of efforts, and lack of transparency between siloed entities. This increases costs and inefficiencies in various ways.²⁴ There can be excess inventory buffers and stockouts due to the lack of visibility into real-time demand and supply. Significant overhead costs arise from reconciliation and audits to reduce errors from manual processes. Delays and extra steps get added to payment processing, document sharing, and obtaining approvals. Contract disputes occur due to ambiguity and errors in order execution and fulfillment. However, blockchain can enhance efficiency and reduce costs for pharmaceutical companies in several key ways. It allows automating processes for order placement, execution, shipment, verification, invoicing, and payment through

smart contracts, reducing overhead and eliminating delays. Real-time inventory tracking enabled by blockchain prevents stockouts or losses and improves planning and logistics for all stakeholders.²⁵ Timestamped paperwork and digital signatures on the blockchain eliminate reconciliation efforts and disputes. Payments get processed faster through cryptocurrencies or digital tokens, leading to improved cash flows. Regulatory reporting and audits are simplified due to the easily accessible and tamper-proof records. Lower risks of counterfeits, diversions, and defects reaching customers reduce potential costs associated with recalls and settlements. According to estimates, global adoption of blockchain in pharmaceutical supply chains could yield cost savings of \$100 billion to \$150 billion on an annual basis by 2025.²⁶

Enhanced security and prevention of counterfeiting

Pharmaceutical supply chains face major threats from counterfeiting and the introduction of fake or substandard drugs that put patient health at risk. Blockchain significantly enhances security in pharmaceutical supply chains in several key ways.²⁷ The cryptographic hashes unique to each drug packet make tampering almost impossible without detection, preventing alteration of expiration dates or replacement with counterfeits. The complete provenance trail enabled by blockchain makes the infiltration of fake products difficult since new actors cannot join the ecosystem without permission. Any party attempting to alter the drug or introduce fakes would need consensus from the entire peer network, which is virtually unattainable.²⁸ Attempts to divert drugs into unintended markets get instantly flagged through the transparency of all custody transfers and parties involved on the blockchain. Patients can also independently verify drug authenticity through mobile apps by scanning unique identifiers on the packaging, closing the loop by enabling end-customer verification. Additionally, machine learning algorithms applied to the blockchain data can identify patterns, anomalies, and high-risk transactions indicative of potential fraud and proactively flag them for intervention.²⁹ Taken together, these capabilities make blockchain a robust solution to prevent leakage of substandard, expired, or fake drugs into pharmaceutical supply networks, thereby enhancing patient safety.

Better integrity and trust in data

Pharmaceutical operations generate massive amounts of sensitive data related to proprietary formulas, clinical trials, adverse events, supplier audits, contracts, forecasts, inventory, delivery records, etc. However, current systems for data management are fragmented, opaque, and prone to errors or falsification.³⁰ Blockchain establishes common facts, transparency, and trust in data sharing across entities in the pharmaceutical supply chain. Distributed ledgers eliminate single points of failure by providing redundancy and making data tampering infeasible. Another key capability is that blockchain data is append-only, which provides an immutable audit trail and longitudinal data integrity. All transactions are cryptographically signed and timestamped

Table 1: Benefits, use cases and challenges of blockchain in pharmaceutical supply chains

<i>Benefits</i>	<i>Use cases</i>	<i>Challenges</i>
Enhanced traceability and drug provenance	- Drug traceability systems	- Legacy systems integration
Improved transparency and visibility	- Counterfeit prevention	- Lack of standards
Increased efficiency and cost reduction	- Clinical trials data integrity	- Scalability limitations
Enhanced security and counterfeiting prevention	- Drug authenticity and smart packaging	- Data privacy concerns
Better data integrity and trust	- Payments and contract management - Inventory management and logistics	- Regulatory uncertainty

on the blockchain, providing non-repudiation. Consensus mechanisms additionally ensure any modifications are cross-validated before being added, enabling trust. Smart contracts automate data exchange only between permissioned parties, reducing the potential for leaks.³¹ An important aspect is that data visibility in blockchain is granular with different access policies enabling confidentiality alongside transparency. Taken together, these blockchain capabilities enable multiple parties to share data seamlessly with an unprecedented degree of accuracy, security, privacy and accountability. The benefits of blockchain in pharmaceutical supply chains are summarized in Table 1.

Current Applications of Blockchain in Pharmaceutical Supply Chains

Blockchain technology is rapidly moving from proof-of-concept studies to pilot deployments and production systems in the pharmaceutical industry. Various stakeholders across the pharmaceutical value chain are exploring blockchain to improve drug traceability, prevent counterfeiting, and ensure data integrity.

Drug traceability systems

Several companies are piloting blockchain-based solutions to track drugs across multiple legs of the supply chain to improve provenance, prevent diversion, and enable recalls.

For example, The MediLedger Project, launched in 2017, involves a consortium of over two dozen pharma companies focused on implementing a decentralized network based on chronicle’s ethereum blockchain.³² It assigns unique identities to saleable units, which are then tracked as ownership changes hands among verified participants across manufacturing, warehousing, and distribution channels down to the dispensary. This gives end-to-end visibility in near real-time to improve authentication and prevent counterfeiting. Sanofi partnered with SAP in 2018 to build a proof of concept for a blockchain-based serialization system.³³ It focuses on serialization data sharing, authentication, and automatic booking of sales orders across the supply chain from distributors to pharmacies in real time. This improves compliance, security, and supply chain efficiency. McKesson, the largest North American pharmaceutical distributor, launched its McKesson Distributed ledger technology in 2019 to offer blockchain-enabled solutions for drug traceability from manufacturer to patient.³⁴ It allows verifying authenticity by sharing product and transaction data across multiple tiers of the supply chain.

Counterfeit prevention

Blockchain’s ability to provide tamper-proof drug provenance is also being leveraged for protecting product authenticity and preventing counterfeiting. FarmaTrust uses artificial intelligence and blockchain to secure pharmaceutical supply chains for clients like Uganda’s National Drug Authority.³⁵ Each packet has a unique cryptographic hash on the blockchain, which patients can verify *via* text messages to prevent counterfeit drugs. Pharmeum has built a blockchain ecosystem for registration, cold-chain monitoring, and authentication of pharmaceutical assets.³⁶ Their crypto-anchors attached to drug packages link the physical product to its supply chain record on the permissioned blockchain network to enable reliable product provenance across multiple entities.

Clinical trials data integrity

Blockchain brings opportunities to improve security, provenance tracking, and integrity management for clinical trial data. IrisGuard uses blockchain to ensure the integrity of clinical trial photography data used for the approval of new ophthalmic drugs.³⁷ Photographs are uploaded by investigator sites globally and blockchain is leveraged to evidence the exact origin, time, and completeness of the entire data package. ClinTex combines blockchain, machine learning and big data analytics to improve clinical trials supply chain monitoring, gain insights, and streamline operations. This improves compliance, optimizes costs, and provides high-quality data.

Blockpharma, built by Amgen, Pfizer and other pharma firms, uses blockchain and smart contracts to enable secure, near real-time data collection from study sites and sharing with sponsors and regulators.³⁸ This automates site payments and improves overall efficiency and transparency. Thus, blockchain is already being integrated into live pharmaceutical systems to deliver enhanced security, traceability, integrity, and efficiency across the drug development and market delivery value chain through collaborative ecosystems and innovative use cases

Drug authenticity and smart packaging

Blockchain technology is being combined with smart packaging solutions and IoT sensors to establish tamper-proof drug authenticity and prevent counterfeiting. The Aitheon platform uses integrated printers to imprint unique QR codes on each drug package, which are linked to the item’s digital identity on their blockchain network.³⁹ Real-time sensors can monitor location and environmental conditions like temperature and transmit data to the blockchain throughout the

supply chain. This makes counterfeiting virtually impossible as any disruption in the expected conditions gets immediately flagged. Chronicled has developed a solution where a unique cryptographic seal is attached to each drug package at the point of manufacturing and the corresponding digital identity is immutably logged on a blockchain ledger. As the product moves through different locations, the seal gets automatically scanned and verified against the blockchain record, enabling reliable authentication. Any tampering attempts get instantly detected.

PharmaLogika provides smart tags enabled with blockchain-based software to secure packaging and verify authenticity.⁴⁰ They have ultra-low power requirements, allowing integration into packaging of any drug type. The tamper evidence capability makes counterfeiting and grey market distribution highly unlikely.

Payments and contract management

The transparency, automation and security capabilities of blockchain platforms are also being leveraged for payments, invoicing and contract management use cases. Modum's pharma supply chain solution uses blockchain and smart contracts to automatically execute and settle payments between supply chain stakeholders upon delivery and verifying receipt of shipments.⁴¹ This improves cash flows by eliminating delays and errors in invoicing and payment processes. Doc.ai developed the Nebula genomics platform, which enables blockchain-based automated payments to be integrated into smart contracts governing genomic data sharing agreements and transactions. This brings greater accountability and efficiency to such data-sharing networks.

Medicalchain enables healthcare organizations to build and access patient medical records using blockchain. They facilitate automated payments for record access using MedTokens which enables patient ownership and control over their own data.⁴²

Inventory management and logistics

Blockchain also offers the potential to transform inventory management by enabling real-time visibility and improving expiration management across the ecosystem. Saphala uses blockchain to improve last mile delivery and availability of medicines in remote rural regions in India. Their mobile app seamlessly integrates distributors, field agents, and pharmacies onto a common ledger, providing real-time visibility into stock levels. This has helped optimize inventory and reduce stockouts in remote regions.

McKesson and Chronicled collaborated to explore blockchain's potential in hospital inventory management, including expiration tracing to avoid losses and improve inventory turns.⁴³ Chronicled's system can automate expiration date tracking on medicine packaging *via* scanning and integrate with blockchain-based inventory systems.

Challenges in the Adoption of Blockchain Technology

While blockchain holds great potential for transforming pharmaceutical supply chains, there are notable challenges to be addressed surrounding integration with legacy systems,

lack of standards, scalability, privacy and regulations. A key challenge is developing interoperability between blockchain platforms and the existing legacy systems used by pharmaceutical companies for ERP, inventory management, distribution, claims processing and other functions. Blockchain applications cannot exist in isolation and need seamless integration with ancillary systems used across the healthcare value chain. This requires building standardized interfaces and ensuring data synchronization across disparate systems.⁴⁴ The transition also needs to minimize disruption to existing processes and workflows.

The absence of common standards is another hurdle, as multiple blockchain platforms and protocols promoted by technology vendors have fragmented the marketplace. For example, solutions may be built on public blockchains like Ethereum or private blockchains from IBM, SAP, Microsoft and others.⁴⁵ Managing interoperability across diverse technology stacks with varying cryptographic algorithms, consensus rules, programming languages, etc., is challenging. A shared framework and common standards for permissions, identities, data formats, and APIs are essential to avoid siloed platforms. Scalability is another concern, given the massive transaction volumes and data assets involved in pharmaceutical operations. Public blockchains may present bottlenecks at scale and private blockchains also have limitations in the number of nodes supported. Current infrastructure may require significant upgrades to match the performance demands and achieve quick transaction finality. Solutions exploring alternative consensus models, sharding, sidechains, state channels and other innovations are needed. Privacy and security considerations arise due to blockchain's transparent ledger, where critical IP, customer data and sensitive transactions are visible to multiple entities. Private data may need to be stored off-chain or emerging encryption techniques leveraged to ensure confidentiality. Stringent access policies are required to prevent unauthorized use of data. Patient groups also have concerns regarding the storage of personal medical data on blockchains.

Regulatory uncertainty poses another barrier as current legislative and compliance frameworks have not kept pace.⁴⁶ The legal status and norms around cryptographic proof, smart contracts, tokenized incentives, data sharing, and blockchain-generated digital evidence are still evolving. Policy guidance for blockchain-based identity, insurance claims, medical records, e-clinical data, and pharmacovigilance systems needs development. Close collaboration between regulators, industry groups and technology firms is critical to shape the right governance frameworks and ease of adoption.

While blockchain pilots show promise, these technology, security, privacy, regulatory and governance-related challenges must be addressed through collective action by regulators, technology vendors, healthcare providers and pharmaceutical companies to fully harness blockchain's advantages at an industry-wide level.⁴⁷ Continued technology innovation and appropriate legislative changes are integral to accelerate

Table 2: Different consortiums and their role in blockchain standards development

Consortium	Participants	Role
MediLedger	Pfizer, McKesson, AmerisourceBergen, Merck, Genentech, Walmart, Walgreens	Standards for pharma supply chain blockchain implementation
Pharmaceutical Supply Chain Consortium	Merck, Pfizer, McKesson, Walmart, Amerisource Bergen	Framework for serialization, traceability, blockchain adoption
BlockRx Consortium	SAP, Pharmaceutical industry leaders	Standards for security, supply chain
Institute of Electrical and Electronics Engineers (IEEE)	Academic, industry and tech experts	Blockchain healthcare standards development
DIN (German Institute for Standardization)	Industry associations, companies, regulators	Blockchain standardization including ISO focus group

maturity and encourage adoption. But the prospects remain highly compelling given the huge potential benefits for patients, manufacturers, distributors, insurers, and healthcare systems. Blockchain can profoundly re-engineer pharma supply chains to be more transparent, resilient, agile and efficient.

Recent Advances and Developments for Widespread Adoption

In response to the challenges surrounding blockchain adoption, significant progress has been made recently across areas like standards development, IoT integration, new architectures, privacy techniques and regulatory guidance.⁴⁸ The evolution of blockchain technology and its key aspects in every stage are discussed in Figure 2.

Consortia have emerged to promote common standards and interoperability. The MediLedger consortium with over two dozen Biopharma companies, published guidelines for the implementation of blockchain networks based on principles like openness, global applicability, flexibility, scalability and validation. The Pharmaceutical Supply Chain Consortium, including major firms like Pfizer, McKesson and Walmart, is defining frameworks for serialization, traceability and blockchain adoption across the industry.⁴⁹ Such collaborative initiatives are laying the groundwork for standardization. Integration with IoT sensors and infrastructure is also accelerating. Chronicled’s MediLedger network combines EPCIS and IoT telemetry data from packages with blockchain to establish a verifiable chain of custody audit trail. Software AG’s Pharma Supply Track taps near real-time data from IoT devices monitoring location and condition to provide end-to-end supply chain visibility. IoT integration unlocks new use cases around smart warehousing, delivery, and tracking.⁵⁰

Hybrid blockchain architectures are emerging that leverage both permissionless and permissioned blockchain properties. For instance, Factom’s approach uses a permissioned network for pharma enterprises to manage access and conduct transactions while simultaneously anchoring encrypted data summaries onto the Bitcoin blockchain for immutable record-keeping. Hybrid models balance access control with openness.

Consortium blockchains like MediLedger allow only certified participants to join the peer network, overcoming some scalability and privacy aspects of public blockchains. Galileo’s NetsTok permissioned network uses Hyperledger

to provide a secure and compliant blockchain platform for transparent biopharma supply chain flows.⁵¹ Permissioned blockchains promote scalability. Different consortiums and their role are listed in Table 2.

Advances in consensus protocols like Tendermint, Hashgraph and Corda enable high throughput processing while maintaining distributed trust. PharmaLedger uses Hyperledger with the Raft consensus protocol to achieve performance at scale for tracing pharmaceutical pedigrees. New algorithms overcome previous limits like Blockchain 1.0’s energy intensive proof of work. Emerging zero-knowledge proof and homomorphic encryption techniques enable the analysis of encrypted data without exposing underlying confidential information. Researchers are also exploring secure multi-party computation, ring signatures, zk-SNARKs and other methods to reconcile transparency with privacy.⁵² Such advances will be integral for compliance in the pharma domain.

Regulatory guidance is gradually developing around blockchain adoption and use cases. The FDA has released guidelines for blockchain-enabled medical product traceability, highlighting the potential benefits and suggesting voluntary pilot projects for the industry to pursue.⁵³ The EU and China have also published recommendations regarding blockchain integration in clinical trial data management to improve integrity while ensuring compliance with data privacy regulations. Increased policy clarity and direction will only further spur adoption.⁵⁴

These advances indicate the maturing ecosystem, the growing sophistication of technology capabilities, collaborative alignment across players, and increasing regulatory receptivity for blockchain in pharma. Widespread

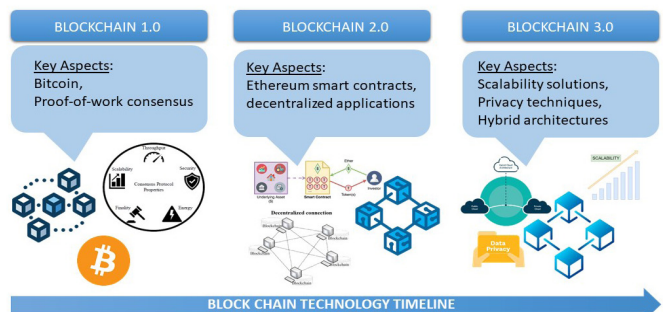


Figure 2: Evolution of blockchain technology

adoption is on the horizon as foundations strengthen around standards, scalability, interoperability, data security, and governance for next-generation pharmaceutical supply networks powered by blockchain.

CONCLUSION

Blockchain technology holds tremendous potential to transform pharmaceutical supply chains by enhancing transparency, security, efficiency, and collaboration across the healthcare ecosystem. However, there are still notable challenges surrounding integration, interoperability, scalability, privacy, regulations, and standardization that need concerted efforts to address. However, recent advances in consortium building, IoT integrations, new architectures, and regulatory guidance indicate the technology is maturing rapidly to meet the industry's complex needs. With sustained collaboration, skills development, innovation, and supportive policies, blockchain is poised to move beyond pilots into widespread production systems. This could profoundly improve patient outcomes, safety, trust, and access across pharmaceutical value chains. The possibilities are exciting as long as stakeholders collectively shape pragmatic adoption pathways.

REFERENCES

- Mackey TK, Nayyar G. A review of existing and emerging digital technologies to combat the global trade in fake medicines. *Expert Opin Drug Saf.* 2017;16(5):587-602.
- Ton AT, De Meulenaer B. Critical reviews in food science and nutrition impact of modern retail on food safety in Vietnam: the case of fresh produce. *Crit Rev Food Sci Nutr.* 2015;57(17):3112-9.
- Norton S, Suh J, Chow A. Pharmaceutical counterfeiting and blockchain technology. *Pharmaceutics.* 2020;12(8):1-17.
- Tseng JH, Liao YC, Chong BF, Liao WS. Governance on the drug supply chain via Gcoin blockchain. *Int J Environ Res Public Health.* 2018;15(6):1055.
- Bocek T, Rodrigues BB, Strasser T, Stiller B. Blockchains everywhere - a use-case of blockchains in the pharma supply-chain. 2017 IFIP/IEEE Symposium on Integrated Network and Service Management (IM); 2017.
- Feng T, Wang X, Duan Y, Zhang Y, Zhang X. Applying blockchain technology to improve agri-food traceability: A review of development methods, benefits and challenges. *J Clean Prod.* 2020;260:121031.
- Korpisaari P, Latvala O. Leaning on ledger: Peer-to-peer lending on blockchain. *Res Technol Manag.* 2020 Jul 3;63(4):46-54.
- Benchoufi M, Ravaud P. Blockchain technology for improving clinical research quality. *Trials.* 2017;18(1):335.
- Zhang J, Schmidt DC, White J, Lenz G. Blockchain technology use cases in healthcare. *Adv Comput.* 2018:1-41.
- Kuo T, Kim H, Ohno-Machado L. Blockchain distributed ledger technologies for biomedical and health care applications. *J Am Med Inform Assoc.* 2017;24(6):1211-20.
- Margulis S. Conceptualizing the blockchain: Socio-technical knowledge claims about the Bitcoin digital currency socio-technical system. *Proc Am Soc Info Sci Tech.* 2017;53(1):1-1.
- Benchoufi M, Porcher R, Ravaud P. Blockchain protocols in clinical trials: Transparency and traceability of consent. *F1000Research.* 2017;6:66.
- Yue X, Wang H, Jin D, Li M, Jiang W. Healthcare data gateways: found healthcare intelligence on blockchain with novel privacy risk control. *J Med Syst.* 2016;40(10):218.
- Gordon WJ, Catalini C. Blockchain technology for healthcare: Facilitating the transition to patient-driven interoperability. *Comput Struct Biotechnol J.* 2018;16:224-30.
- McFarlane C, Beer M, Brown J, Prendergast N. Patientory: A healthcare peer-to-peer EMR storage network v1.0. 2017.
- Azaria A, Ekblaw A, Vieira T, Lippman A. Medrec: Using blockchain for medical data access and permission management. 2016 2nd International Conference on Open and Big Data (OBD); 2016.
- Peterson K, Deeduvanu R, Kanjamala P, Boles K. A blockchain-based approach to health information exchange networks. *Proc 2016 ACM Workshop Blockchain, Cryptocurrencies Contracts - BCC 16.* 2016.
- Xia Q, Sifah EB, Smahi A, Amofa S, Zhang X. BBDS: Blockchain-based data sharing for electronic medical records in cloud environments. *Information.* 2017;8(2):44.
- Zhang P, White J, Schmidt DC, Lenz G, Rosenbloom ST. FHIRChain: Applying blockchain to securely and scalably share clinical data. *Comput Struct Biotechnol J.* 2018;16:267-78.
- Zhang P, Schmidt DC, White J, Lenz G. Blockchain technology use cases in healthcare. *Adv Comput.* 2018:1-41.
- Kuo TT, Kim HE, Ohno-Machado L. Blockchain distributed ledger technologies for biomedical and health care applications. *J Am Med Inform Assoc.* 2017 Nov 1;24(6):1211-20.
- Ølnes S, Ubacht J, Janssen M. Blockchain in government: Benefits and implications of distributed ledger technology for information sharing. *Government Information Quarterly.* 2017;34(3):355-64.
- Mamoshina P, Ojomoko L, Yanovich Y, Ostrovski A, Botezatu A, Prikhodko P, Izumchenko E. Converging blockchain and next-generation artificial intelligence technologies to decentralize and accelerate biomedical research and healthcare. *Oncotarget.* 2018;9(5):5665.
- Hylock RH, Zeng X. A blockchain framework for patient-centered health records and exchange (HealthChain): Evaluation and proof-of-concept study. *J Med Internet Res.* 2019;21(8):e13592.
- Dubovitskaya A, Xu Z, Ryu S, Schumacher M, Wang F. Secure and trustable electronic medical records sharing using blockchain. *AMIA Annu Symp Proc.* 2017;2017:650.
- Peterson K, Deeduvanu R, Kanjamala P, Boles K. A blockchain-based approach to health information exchange networks. *Proc 2016 ACM Workshop Blockchain, Cryptocurrencies Contracts - BCC 16.* 2016.
- Xia Q, Sifah EB, Smahi A, Amofa S, Zhang X. BBDS: Blockchain-based data sharing for electronic medical records in cloud environments. *Information.* 2017;8(2):44.
- Tian F. An agri-food supply chain traceability system for China based on RFID & blockchain technology. 2016 13th International Conference on Service Systems and Service Management (ICSSSM). 2016.
- Caro MP, Ali MS, Vecchio M, Giaffreda R. Blockchain-based traceability in Agri-Food supply chain management: A practical implementation. 2018 IoT Vertical and Topical Summit on Agriculture-Tuscany (IOT Tuscany). 2018.
- Ramachandran B, Krishnamachari S. Blockchain For ensuring data veracity in food supply chains. 2018 IEEE International Conference on Data Mining Workshops (ICDMW). 2018.
- Lin H, Wang J, Pei J, Wang S. Food safety traceability system based on blockchain and EPCIS. 2018 IEEE Int Conf Big Data

- (Big Data). 2018.
32. Casino F, Kanakaris V, Dasaklis TK, Moschuris S, Rachaniotis NP. Modeling food supply chain traceability based on blockchain technology. *IFAC-PapersOnLine*. 2019;52(13):2728-33.
 33. Tian F. A supply chain traceability system for food safety based on HACCP, blockchain & Internet of things. 2017 International Conference on Service Systems and Service Management. 2017.
 34. Caro MP, Ali MS, Vecchio M, Giaffreda R. Blockchain-based traceability in Agri-Food supply chain management: A practical implementation. 2018 IoT Vertical and Topical Summit on Agriculture-Tuscany (IOT Tuscany). 2018.
 35. Ramachandran B, Krishnamachari S. Blockchain For ensuring data veracity in food supply chains. 2018 IEEE International Conference on Data Mining Workshops (ICDMW). 2018.
 36. Casino F, Kanakaris V, Dasaklis TK, Moschuris S, Rachaniotis NP. Modeling food supply chain traceability based on blockchain technology. *IFAC-PapersOnLine*. 2019;52(13):2728-33.
 37. Tian F. An agri-food supply chain traceability system for China based on RFID & blockchain technology. 2016 13th International Conference on Service Systems and Service Management (ICSSSM). 2016.
 38. Caro MP, Ali MS, Vecchio M, Giaffreda R. Blockchain-based traceability in Agri-Food supply chain management: A practical implementation. 2018 IoT Vertical and Topical Summit on Agriculture-Tuscany (IOT Tuscany). 2018.
 39. Shahid M, Arain F, Farooq O, Arif M. Blockchain securing sustainable supply chain. *IJDDT*. 2019;9:987-90.
 40. Chowdary TK, Sreedevi V. A critical evaluation on applications of block chain technology in pharmaceutical industry. *Int J Pharm Sci Drug Res*. 2019;11(3):115-20.
 41. Shah M, Farooq O, Ahmad A. Unchained! Blockchain technology and its impact on supply chain. *Int J Eng Appl Sci Technol*. 2019;4(2):289-95.
 42. Sukumar A, Vijayakumar A, Belgamwar S. Pharmaceutical supply chain security enhanced by blockchain. *Int J Pharm Pharm Sci*. 2019;11(9):57-61.
 43. Patil SU, Rao RS. A comprehensive review on usage of blockchain in pharmaceutical industry. *Int J Pharm Drug Anal*. 2019;7(8):246-51.
 44. Nath V, Jadhav R, Haq EQ, Bandari S, Singh V. Applications of blockchain technology in the pharmaceutical industry. *Int J Drug Deliv Tech*. 2021;11(3):699-706.
 45. Thomas SV, Nair A. Blockchain technology: A panacea for pharmaceutical supply chains transparency. *Int J Drug Deliv Tech*. 2021;11(3):707-10.
 46. Shah S, Chircu A. IoT and blockchain enabled supply chain transformation for pharmaceutical track and trace. *Int J Drug Deliv Tech*. 2020;10(3):476-81.
 47. Rajagopal K, Gunasekaran A, Gaur SS. Towards creating a blockchain enabled logistics and supply chain environment. *Int J Drug Deliv Tech*. 2020;10(4):831-8.
 48. Raj PP, Sriram V. Piloting blockchain technology for enhancing supply chain visibility within pharmaceutical manufacturing. *Int J Drug Deliv Tech*. 2019;9(2):177-82.
 49. Bocek T, Rodrigues BB, Strasser T, Stiller B. Blockchains everywhere - a use-case of blockchains in the pharma supply-chain. 2017 IFIP/IEEE Symposium on Integrated Network and Service Management (IM). 2017.
 50. Benchoufi M, Porcher R, Ravaud P. Blockchain protocols in clinical trials: Transparency and traceability of consent. *F1000Research*. 2017; 6:66.
 51. Peterson K, Deeduvanu R, Kanjamala P, Boles K. A blockchain-based approach to health information exchange networks. *Proc 2016 ACM Workshop Blockchain, Cryptocurrencies Contracts - BCC 16*. 2016.
 52. Xia Q, Sifah EB, Smahi A, Amofa S, Zhang X. BBDS: Blockchain-based data sharing for electronic medical records in cloud environments. *Information*. 2017;8(2):44.
 53. Dubovitskaya A, Xu Z, Ryu S, Schumacher M, Wang F. Secure and trustable electronic medical records sharing using blockchain. *AMIA Annu Symp Proc*. 2017;2017:650.
 54. Zhang P, White J, Schmidt DC, Lenz G, Rosenbloom ST. FHIRChain: Applying blockchain to securely and scalably share clinical data. *Comput Struct Biotechnol J*. 2018;16:267-78.