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# REGULATORY REQUIREMENTS FOR BLOCKCHAIN TECHNOLOGY FOR ENSURING DRUG TRACEABILITY AND COMPLIANCE IN THE INDIAN PHARMACEUTICAL SUPPLY CHAIN IN COMPARISON WITH USA

**Dr. Ashok Kumar P.*, Harshitha Y. G., Godavari C. S., Bhavana, Ankita Malatesh Madivalar, Aishwarya**

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road, Batwadi, Tumkur-572103, Karnataka, India.

***Corresponding Author: Dr. Ashok Kumar P.**

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road, Batwadi, Tumkur-572103, Karnataka, India.

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## ABSTRACT

The pharmaceutical industry faces unprecedented challenges in ensuring drug authenticity, maintaining supply chain integrity, and achieving regulatory compliance across global markets. This research examines the transformative potential of blockchain technology in addressing these critical issues within the Indian and USA pharmaceutical supply chains. Through a comprehensive analysis of current implementations, regulatory frameworks, and case studies, this study demonstrates how blockchain's core principles of immutability, transparency, and decentralization create an unbreakable chain of trust throughout pharmaceutical distribution networks. The research reveals that counterfeit drugs represent a $4.4 billion global market[1], with approximately 10.5% of drugs in low- and middle-income countries being fake or substandard[2]. In response, both India and the USA have implemented significant regulatory amendments and blockchain pilot programs. The study analyses major initiatives including MediLedger, BRUINchain, and India's Drug Authentication and Verification Application (DAVA), demonstrating how blockchain technology can achieve up to 99.9% recall efficiency and generate substantial economic benefits including $1 billion in increased revenue through improved patient outcomes.[3] The findings indicate that blockchain implementation can reduce counterfeit drug incidents by up to 30%[4], streamline regulatory compliance, and enhance stakeholder collaboration. This research provides critical insights for policymakers, pharmaceutical companies, and technology developers seeking to implement blockchain solutions for drug traceability and compliance in complex global supply chains.

**KEYWORDS:** Blockchain, Mediledger, DAVA, BRUNchain, India.

### The Global Scourge of Counterfeit Drugs: A Public Health Crisis

The global pharmaceutical supply chain is a cornerstone of healthcare, yet it faces constant threats from the lucrative trade in counterfeit medicines. The World Health Organization (WHO) defines these as products deliberately and fraudulently mislabelled regarding their identity or source. Counterfeit drugs often mimic legitimate medications but may contain incorrect ingredients, the wrong quantity of active pharmaceutical ingredients (APIs), or, in some cases, toxic substances such as mercury, arsenic, rat poison, or cement.

The scale of the problem is staggering, with the counterfeit drug market valued between $200 billion and $431 billion annually. In low- and middle-income countries, one in ten medicines is estimated to be substandard or falsified. The consequences are devastating: up to 169,000 children die from pneumonia each year after receiving counterfeit antibiotics, and fake or sub-potent antimicrobials contribute directly to antimicrobial resistance by exposing pathogens to inadequate dosages. Beyond therapeutic failure and adverse reactions, counterfeit drugs erode trust in healthcare systems worldwide.

The rise of online pharmacies has amplified risks, as nearly 96% of the 35,000 sites selling prescription drugs to U.S. consumers fail to comply with legal standards, while a quarter of adults admit to purchasing medicines online. Traditional drug tracking methods—often reliant on manual records or siloed digital systems—cannot guarantee full transparency, creating "dark matter gaps" that counterfeiters exploit.[1]

Regulators have responded with stricter frameworks. In the United States, the Drug Supply Chain Security Act (DSCSA) mandates an interoperable electronic system to track and trace prescription drugs at the package level. India, the "pharmacy of the world," has introduced serialization for exports and is developing good distribution practices to secure its vast domestic market. The COVID-19 pandemic further exposed vulnerabilities in pharmaceutical supply chains, underscoring the urgent need for transparency, technological integration, and improved data-sharing among stakeholders.

Against this backdrop, blockchain technology offers transformative potential. As a decentralized and immutable digital ledger, blockchain provides end-to-end traceability, tamper-proof audit trails, and a single source of truth accessible to all supply chain participants. By eliminating data silos and ensuring consensus-driven verification, it not only secures pharmaceutical logistics but also rebuilds trust in a system undermined by counterfeiters. Unlike centralized systems, blockchain removes single points of failure and creates a permanent, transparent history of every product.

Drug traceability has evolved from paper pedigrees to barcodes and RFID tags, but centralized databases remain vulnerable. Blockchain advances this evolution by ensuring authenticity verification, rapid recall management, and compliance with global standards. Its promise lies not only in technical security but also in restoring confidence among patients, providers, and regulators.

This report examines the adoption of blockchain in two major pharmaceutical markets—the United States and India. While the U.S. pursues a unified federal mandate through the DSCSA, India must secure its fragmented domestic system while meeting export demands. The study compares regulatory requirements, implementation strategies, and socio-economic drivers in both contexts. It also explores real-world platforms such as MediLedger and Hyperledger, and considers future perspectives and policy recommendations.

Ultimately, the integration of blockchain into pharmaceutical supply chains represents more than a technological upgrade; it is a public health imperative. By enhancing drug traceability and closing supply chain vulnerabilities, blockchain can significantly reduce the risks posed by counterfeit medicines and safeguard global healthcare.[2]

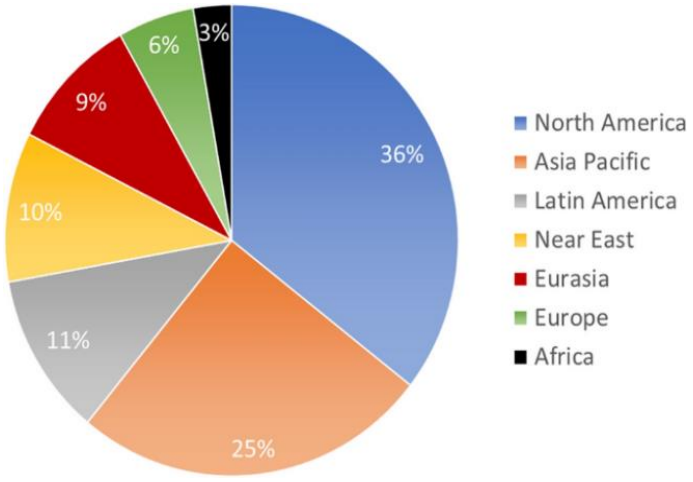


**Figure 1: Global Counterfiet Drug Market Overvier.**

## BASICS AND BACKGROUND OF BLOCKCHAIN

The spread of counterfeit medicines has become one of the most alarming threats to global public health. These fake drugs, deliberately mislabelled to appear genuine, often mimic the packaging and appearance of trusted brands, making them difficult to identify. Unlike legitimate medicines, they may contain the wrong ingredients, harmful substances, or no active ingredient at all, putting millions of lives at risk. The World Health Organization warns that such falsified medicines circulate widely across borders, especially in regions with weak regulatory systems, limited supply chain oversight, and high demand for affordable treatment. Beyond the immediate danger to patients, counterfeit drugs erode trust in healthcare systems and legitimate pharmaceutical companies. Tackling this crisis requires international cooperation, stronger regulations, improved supply chain security, and public awareness, as the trade in counterfeit medicines remains not only lucrative but devastating to global health.

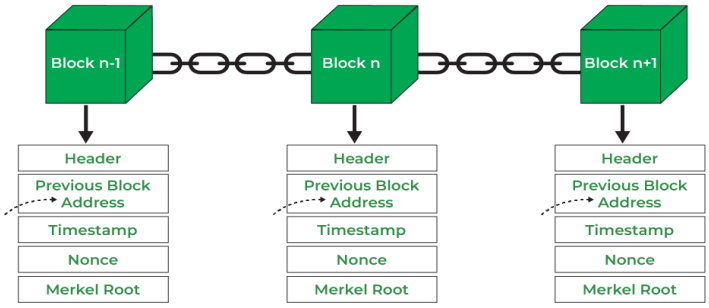


**Figure 2: Blockchain structure(linked blocks illustration).**

## REGULATORY FRAMEWORKS

### The U.S. Regulatory Framework: The Drug Supply Chain Security Act (DSCSA)

The United States has one of the world's safest drug supply chains, yet it has never been entirely free from counterfeiting, theft, or diversion. Before 2013, oversight was fragmented by state-level pedigree laws, creating confusion for manufacturers and distributors. To close these gaps, Congress passed the Drug Supply Chain Security Act (DSCSA) in November 2013, aiming to establish a single national system to trace prescription drugs electronically. Its purpose is to prevent harmful products from entering the market, detect them quickly if they do, and enable their removal to protect patients.

The Food and Drug Administration (FDA) was tasked with implementing the DSCSA. It issues guidance, maintains a public database of licensed distributors and logistics providers, manages exemptions, engages with stakeholders, and has run pilot projects to test technologies that could support traceability. Central to the law are requirements for serialization of drug packages with unique identifiers, the exchange of transaction information at every transfer of ownership, and verification systems to confirm authenticity. Only licensed and registered partners can participate in the supply chain, ensuring accountability.

Implementation was phased over a decade, with the final deadline set for November 2023, when an interoperable package-level system was expected to go live. Recognizing industry challenges, the FDA introduced a one-year stabilization period and later granted phased exemptions: manufacturers and repackagers until May 2025, wholesalers until August, larger dispensers until November, and small pharmacies until 2026.

Technology has played a major role in this transition. The U.S. pharmaceutical sector has pioneered blockchain adoption through projects such as MediLedger, IBM–KPMG–Merck–Walmart, UCLA's BRUINchain, and other FDA pilot programs. These demonstrated blockchain's potential to provide tamper-proof records, secure data sharing, and rapid counterfeit detection, while addressing interoperability and privacy concerns.

Despite progress, challenges remain, particularly for small and independent pharmacies that face high costs, limited IT infrastructure, and reliance on distributors or vendors. Many fear that compliance pressures could accelerate market consolidation. Still, the FDA's flexible, collaborative approach—focusing on outcomes rather than mandating specific technologies—has allowed innovation to guide solutions while ensuring patients continue to have access to safe medicines. This adaptive model of regulation highlights how large-scale health security challenges can be addressed without compromising care.[3]

### The Indian Regulatory Framework: A Dual-Pronged Approach

India's pharmaceutical regulation is built on the Drugs and Cosmetics Act of 1940 and its rules of 1945, which govern the entire lifecycle of medicines. While the central government sets standards, enforcement lies with the states, often leading to uneven oversight. To modernize this system, amendments such as QR code mandates have been introduced. At the apex sits the Central Drugs Standard Control Organisation (CDSCO), headed by the Drugs Controller General of India (DCGI), which approves new drugs, monitors imports, coordinates with state regulators, and manages recalls to ensure safety and traceability.

India's position as the "pharmacy of the world" has made export security a priority. To meet global standards, the government first created the DAVA portal, later replaced in 2020 by the more efficient iVEDA system. Using GS1 standards, exporters must serialize drugs at carton and case levels, maintain packaging hierarchies, and upload data to the central portal, allowing customs and regulators abroad to verify authenticity. This system has successfully safeguarded India's pharmaceutical exports to nearly 200 countries.

Domestically, however, challenges persist. Widespread circulation of spurious drugs led to a 2023 mandate requiring QR codes on the top 300 selling drug brands, carrying details like product ID, batch number, and expiry date. But the system suffers from flaws: static or batch-level QR codes are easily copied, enforcement is weak, and no large-scale public awareness campaign has been run, leaving consumers largely disengaged.

High implementation costs, especially for small and medium enterprises, along with a shortage of inspectors, underfunded labs, and lenient penalties, further weaken domestic safeguards. Still, India is experimenting with blockchain, nano-tags, and digital authentication systems to strengthen supply chains. The draft National Pharmaceutical Policy even highlights blockchain, AI, and machine learning as future tools for drug safety.

This dual-track approach reflects India's split priorities: a stringent export system enforced by global trade demands, and a weaker domestic system designed as a low-cost public health measure. While exports remain secure, the domestic framework continues to struggle in protecting citizens from counterfeit medicines.[4]

## AMENDMENTS

### Recent Pharmaceutical Regulatory Amendments in the U.S. and India

In the United States, recent amendments reflect a strong push to secure the pharmaceutical supply chain. In 2022, the FDA proposed national standards for licensing wholesale distributors and third-party logistics providers to ensure only qualified participants handle prescription drugs. These standards are supported by enhanced inspection requirements, with mandatory audits at least every three years and detailed SOPs for equipment, personnel, and transportation. To ease implementation challenges, the FDA extended compliance deadlines under the Drug Supply Chain Security Act (DSCSA) to 2025—May for manufacturers and repackagers, August for wholesale distributors, and November for large dispensers.

India, too, has moved to tighten its regulatory framework. The Drugs Controller General of India (DCGI) introduced new guidelines mandating detailed documentation of batch numbers, expiry dates, and distribution channels to strengthen traceability and facilitate recalls. Senior management is now explicitly held accountable for maintaining quality systems, creating clearer responsibility for supply chain integrity. These draft guidelines are aligned with World Health Organization standards, bringing India closer to global best practices. A 30-day consultation period has also been built in, ensuring stakeholder input before final implementation.[5]

### Comparative Summary

The analysis reveals that both India and the USA are actively pursuing blockchain solutions for pharmaceutical supply chain challenges, but with different approaches and emphases:

**Market Scale**: India leads in volume with 10% of global pharmaceutical production, while the US leads in value with sophisticated regulatory frameworks.

**Regulatory Approach:** The US emphasizes comprehensive electronic traceability through DSCSA, while India focuses on good distribution practices and export-oriented serialization.

**Technology Implementation:** The US has more mature blockchain pilot programs and commercial deployments, while India is rapidly advancing government-led digital initiatives.

**Global Impact:** Both countries serve as models for other nations implementing pharmaceutical traceability systems, with their approaches influencing international best practices.[6]

**Table 1: Detailed Comparison of US DSCSA and Indian Traceability Regulations.**

| Feature | United States (DSCSA) | India (Dual Framework) |
|---|---|---|
| **Primary Legislation** | Drug Supply Chain Security Act (2013) | Drugs and Cosmetics Act, 1940 & subsequent amendments (e.g., Drugs Rules, 2022) |
| **Regulatory Body** | Food and Drug Administration (FDA) | Central Drugs Standard Control Organisation (CDSCO) & State Regulators |
| **Scope** | All prescription drugs for the domestic market | **Export:** All drug formulations. **Domestic:** Top 300 brands. |
| **Core Philosophy** | Unified, single interoperable system | Bifurcated: High-standard for export, lower-standard for domestic |
| **Technology Mandate** | Electronic, interoperable system (Technology-agnostic, but EPCIS is de facto standard) | **Export:** GS1 serialization. **Domestic:** QR Code (technical specs are loose) |
| **Data Repository** | Decentralized, point-to-point data exchange between trading partners | **Export:** Centralized government portal (iVEDA). **Domestic:** No central repository; authentication via manufacturer's data. |
| **Verification Point** | On receipt, for saleable returns, and for suspect product investigations | **Export:** At customs/by importer. **Domestic:** At point-of-sale by consumer/pharmacist (in theory). |
| **Implementation Status (2025)** | Phased enforcement active after stabilization period | **Export:** Largely implemented. **Domestic:** Mandate active, but facing significant security and adoption challenges. |
| **Key Challenge** | Interoperability and data quality across a complex, decentralized network; SME readiness. | Security flaws in domestic QR system; lack of public awareness; inconsistent enforcement. |

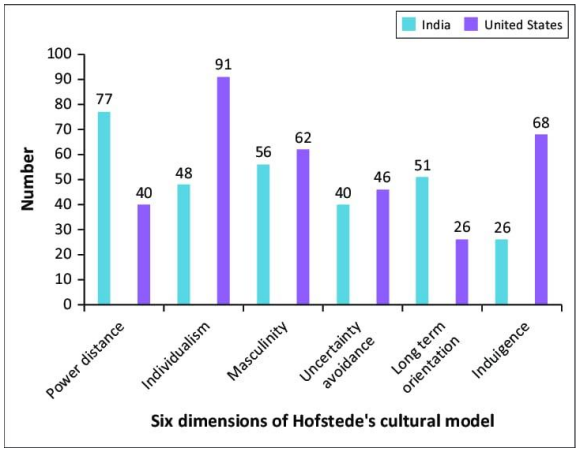


**Figure 3: Comparative framework(India vs USA).**

**Real-World Use Cases**

Hyperledger Fabric has emerged as a preferred framework for pharmaceutical pilots and proofs-of-concept, with studies highlighting its effectiveness in creating secure drug distribution systems that enhance transaction speed, strengthen data integrity, and allow real-time tracking from manufacturer to dispenser. The IBM/KPMG/Merck/Walmart DSCSA pilot also demonstrated how permissioned blockchain can connect fragmented systems and improve patient safety through faster alerts.

In India, blockchain adoption is not yet mandated by regulation but is being explored as a response to the weaknesses of the current traceability system, which relies on static QR codes tied to centralized databases that are vulnerable to replication. A proposed approach is to integrate these QR codes with a decentralized blockchain ledger, where unique serial numbers would be registered and verified on an immutable system. This would enable real-time detection of duplicates, ensure a tamper-proof product history, and shift trust from individual companies to a shared, decentralized infrastructure, thereby increasing transparency and accountability across the pharmaceutical supply chain.[7]

**Case Studies or Examples**

The **MediLedger Project**, launched by Chronicled Inc. in collaboration with LinkLab LLC, is one of the most prominent blockchain initiatives in the pharmaceutical sector, involving major players such as Genentech, Pfizer, Roche, AmerisourceBergen, and McKesson. Its primary goal is to build an open, blockchain-based network to strengthen compliance with the Drug Supply Chain Security Act (DSCSA), improve patient safety, and enhance interoperability across supply chains. By leveraging blockchain for verification, MediLedger accelerates authentication processes that traditionally take up to 48 hours, particularly in product returns, using networks and barcode scanners to ensure faster and more reliable verification. The project has already demonstrated blockchain's capacity to securely link diverse systems and organizations to meet DSCSA 2023 requirements, establishing a prototype for wider adoption and developing operational frameworks for future deployment.

The **IBM-KPMG-Merck-Walmart pilot**, approved by the FDA, further showcased blockchain's potential in addressing DSCSA obligations while boosting patient safety. Designed to enable rapid alerts during recalls, the system provided precise identification of affected lots and resolved inefficiencies caused by fragmented, manual notification processes. By integrating enterprise systems on a permissioned blockchain, the pilot created a unified view of product movement across manufacturers, distributors, and dispensers. The results confirmed blockchain's ability to enhance transparency, reduce unnecessary communication, and prevent legitimate products from being wrongly quarantined, thereby minimizing pharmaceutical waste.[8]

At the last mile of distribution, the **BRUINchain Project**—a collaboration between UCLA Health and LedgerDomain—focused on tracking drug custody within dispenser organizations. Using FDA-mandated barcodes, the system incorporated multiple safeguards, such as label verification, expiration checks, manufacturer authentication, and visual inspections, to prevent suspect products from reaching patients. Tested in one of the busiest U.S. pharmacies, BRUINchain achieved 100% accuracy in scanning, expiration detection, and counterfeit identification, while automating product-tracing notifications for stakeholders. With near real-time performance and just 50 milliseconds of latency, the project not only strengthened patient safety but also reduced paperwork and improved operational efficiency.

**Indian DAVA System Implementation**

India's **Drug Authentication and Verification Application (DAVA)**, developed by the National Informatics Centre (NIC) using GS1 standards, is a government-led system to enhance pharmaceutical traceability and transparency. Covering nearly 2,000 manufacturers, it allows regulators and patients worldwide to verify product details, including the specific Indian facility where a drug was produced. By enabling unique identification and secure sharing of pharmaceutical data, DAVA not only strengthens oversight of India's drug exports but also reinforces the country's reputation as a reliable producer of safe, high-quality medicines.

**Economic and Market Factors**

The global pharmaceutical supply chain management market is expanding rapidly, valued at USD 2.86 billion in 2025 and projected to reach USD 3.93 billion by 2029 at a CAGR of 8.3%, fueled by rising demand for medicines, stricter compliance needs, and the growing importance of supply chain visibility. The broader pharmaceutical logistics market reflects even greater scale, expected to grow from USD 91.4 billion in 2024 to USD 154.0 billion by 2033 at a CAGR of 5.96%, while

the digital supply chain management segment alone is forecasted to rise from USD 1.16 billion in 2024 to USD 2.53 billion by 2034 at a CAGR of 8.2%. However, counterfeit drugs continue to pose a severe economic and health threat, with the global fake drug trade estimated at USD 200 to 432 billion annually, accounting for 3.3% of the global market. In low- and middle-income countries, counterfeit medicines amount to a $30 billion problem, contributing to as many as 158,000 deaths annually from fake malaria treatments in sub-Saharan Africa, alongside significant economic losses from reduced productivity, higher healthcare costs, and weakened consumer trust. In this context, blockchain technology is emerging as a transformative solution, with its role in pharmaceutical supply chain management projected to reach USD 5.15 billion by 2032 at a CAGR of 19.9%, marking it as one of the fastest-growing areas within the pharmaceutical technology sector.[9]

## PENALTIES

In India, violations of drug traceability and pharmaceutical regulations carry serious consequences, creating a high-stakes environment for the industry. Companies risk suspension or cancellation of manufacturing licenses, heavy fines of up to ₹5 lakhs per offense, and even criminal liability with prison terms of up to 10 years in cases involving spurious or adulterated drugs. International trade bans and blacklisting by global regulators like the US FDA or EMA can further threaten revenues and market access, while reputational damage may cause lasting loss of consumer trust. Beyond traceability, Indian pharmaceutical firms also face broader compliance challenges such as navigating diverse labor laws, meeting environmental and workplace safety standards, renewing licenses and statutory filings, ensuring ethical and ESG compliance, managing contract labor and vendors, and adhering to new data privacy requirements under the Digital Personal Data Protection Act. These complex obligations, combined with the severe penalties for lapses, drive companies to prioritize compliance, often balancing it against the pressures of operating in a highly cost-sensitive market.

## Future Perspectives and Recommendations

The global pharmaceutical industry is in a crucial phase of digital transformation, as regulations in the U.S. and E.U. combined with the rapid development of blockchain and AI are reshaping supply chain security. These technologies offer enormous potential, but their adoption is hindered by challenges of interoperability, scalability, and cost. The existence of multiple blockchain platforms risks creating new silos, making universal standards essential for seamless data exchange. At the same time, the massive scale of pharmaceutical transactions demands highly efficient solutions, while high implementation costs remain a barrier for smaller players, highlighting the need for shared platforms and financial support to enable broader participation.

Regional differences further emphasize the importance of global harmonization. The U.S. Drug Supply Chain Security Act (DSCSA) focuses on tracing ownership through transaction records, while the EU's Falsified Medicines Directive (FMD) enforces end-to-end verification at the point of dispense. These contrasting approaches underline the necessity of global standards, such as those advanced by the World Health Organization and GS1, to build interoperable systems that simplify compliance and strengthen defenses against counterfeit medicines worldwide.

The integration of blockchain with IoT and AI represents the next stage in this transformation, enabling a shift from reactive to predictive supply chains. IoT sensors embedded in packaging or containers can continuously capture data on temperature, humidity, and location, recording it immutably on the blockchain. AI can then analyze this data to predict spoilage, forecast disruptions, and optimize inventory, transforming the supply chain into a transparent, resilient, and intelligent system.

In India, advancing traceability requires reforming the QR code mandate to include secure serialized identifiers in line with global standards, launching awareness campaigns to educate consumers and healthcare providers, providing financial and technical support to SMEs, and ensuring stronger regulatory enforcement through better-equipped inspectors, modernized laboratories, and consistent penalties. In the U.S., where DSCSA systems are already in place, the focus now lies on optimization through collaborative platforms, improved data governance, and the integration of AI and IoT to unlock strategic business value beyond compliance.

The long-term future of pharmaceutical traceability depends on moving past fragmented national systems toward a globally interconnected framework. As pharmaceutical production and consumption are inherently international, a federated blockchain network built on universal standards such as GS1 offers the most logical solution. Such a system would enable medicines serialized in one country to be verified seamlessly across borders, creating a unified foundation of trust to safeguard patient safety and strengthen the integrity of the global supply chain.[10]

## CONCLUSION

Blockchain is emerging as a transformative solution for pharmaceutical supply chains, addressing key challenges like counterfeiting, limited visibility, and regulatory complexity. Implementations such as MediLedger, BRUINchain, and India's DAVA demonstrate near-perfect verification, recall efficiency, and significant economic benefits. The U.S. emphasizes electronic traceability through DSCSA, while India leverages government-led digital initiatives and serialization standards, offering complementary models for global best practices. With the blockchain market projected to

reach USD 5.15 billion by 2032, success relies on stakeholder collaboration, phased deployment, and integration with AI and IoT for real-time monitoring and predictive analytics. Overall, blockchain promises enhanced patient safety, regulatory compliance, and supply chain transparency, marking a shift toward more accountable and patient-centric pharmaceutical systems.[11]

**Compliance with ethical standards**

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No conflict pf interest to be disclosed.

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