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How Emerging Technologies Improving Pharmaceutical Drug Traceability

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***Abstract*— Pharmaceutical drug counterfeiting is a global challenge for governments and regulatory agencies. Generally, Counterfeit medicines are manufactured in compromised environments with incorrect active pharmaceutical ingredients (API) and low potency. Today, it is crucial for the entire world to find solutions to the challenges of drug counterfeiting by determining the most effective and cutting-edge technology for safeguarding people's health. From the perspective of preventing pharmaceutical drug counterfeiting, the pharmaceutical industry can adopt sustainable emerging technologies to perform in social, economic, and environmental dimensions through digital transformation. This study uses empirical analysis to examine the impact of digital transformation on the pharmaceutical industry by adopting cutting-edge technologies to secure medicines in the supply chain. Blockchain, IoT, ML, and Big Data are potent technologies that satisfy crucial requirements for drug traceability, including privacy, trust, transparency, security, authorization and authentication, and scalability. These are the most recent and strictest technologies that increase the security of drug delivery and traceability in the supply chain. Innovative technologies for digital transformation improve drug lifecycle management and increase businesses' capacity for transparent developments. In the healthcare sector, it is also creating a paradigm shift for digital drug traceability.**

***Index Terms*—Blockchain, IoT, Machine Learning, Big Data, Drug Counterfeiting, Pharmaceutical Supply Chain, Serialization, Digital Drug traceability.**

I. INTRODUCTION

In today's world, pharmaceutical businesses are concentrating on how to achieve significant success during the medical market's rapid expansion. The growth of the whole supply chain and attaining sustainable supply performance through effective supply chain management are the main areas of attention for large pharmaceutical firms, ensuring the company's long-term competitive advantage [1]. Future demand for healthcare services will increase, and effective supply chain management will be a crucial factor in fostering market expansion and company innovation [2]. Pharmaceutical drug traceability has a significant impact on drug packaging, including label design and serialization properties, graphic components, and barcodes. Using cutting-edge technology to attach the proper barcodes to pharmaceutical packages is essential drug traceability has a significant impact on drug packaging, including label design and serialization properties, graphic components, and barcodes. Using cutting-edge technology to attach the proper barcodes to pharmaceutical packages is essential for the pharmaceutical sector if it wants to prevent adverse events from suspected drugs due to mislabelled or wrong barcodes [3]. Sharing and collaboration among supply chain clusters provide for complementary knowledge and resources, enabling quick responses to outside developments and flexible strategic choices, strengthening the cluster's capacity for sustaining innovation [4]. Consequently, it has been proposed that information sharing, aided by digital transformation, is a catalyst for enhancing supply efficiency and continues to fuel corporate growth [5]. In order to ensure that data is generated, gathered, transformed, and distributed securely and effectively, the flow of pharmaceutical drugs through the supply chain is precisely recorded when blockchain technology is applied to pharmaceutical business processes [6, 7]. The Internet of Things (IoT), blockchain, big data analytics, cloud computing, augmented reality, 3D printing, artificial intelligence, robotics, and electronic data interchange (EDI) are just a few examples of the digital technologies that are powering "smart manufacturing." [8]. In the future, with the rapid development of patient-centered emerging medical services, on-time dispensing of medicines and their traceability will not be possible without the support of emerging technologies. Innovative technologies for pharmaceutical drug traceability will help the pharmaceutical supply chain achieve sustainable supply performance and digital transformation. It will also spur innovation in the pharmaceutical supply sector in terms of business models, product processes, and organizational structures [9]. The current efforts in the field of pharmaceutical drug traceability and preventing counterfeiting tend to innovate the supply chain through digital technology [10]. To reduce the risk of illegal and counterfeit pharmaceutical drugs entering the market, digital traceability technologies such as blockchain, ML, AL, and Big data have been proven to be very effective [11]. Pharmaceutical industries are improving the ability of

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information sharing through digital transparency and traceability in the supply chain by introducing emerging technologies such as blockchain, IoT, Cloud databases, and ML to effectively improve supply chain security [12]. By coordinating strategic direction, marketing, customer behavior, and supply chain management, new digital technologies fundamentally improve company continuity [13, 14, 15]. Basically, to enhance business operations, customer interactions, and operational effectiveness, digital technologies are integrated throughout the entire organization [16]. For instance, in the pharmaceutical sector, big data analytics skills speed up the creation of new drugs, while AI simplifies the clinical trial procedure, robots' lower production costs, and blockchain technology improves drug safety and traceability in the supply chain. By utilizing digital technology in the pharmaceutical supply chain, businesses are better able to develop freely and provide more sustainable products [17, 18]. Traditional pharmaceutical supply procedures are evolving as a result of digital technologies, increasing profit margins for businesses and offering them an advantage in a fiercely competitive industry. The sharing of data pertaining to information between stakeholders in the pharmaceutical industry is made accessible by stringent, secure technologies throughout the supply chain. The digital technology dimension enables the supply chain stakeholder to exchange pharmaceutical critical data in an interoperable manner among the supply chain stakeholder [19]. With current emerging technologies, traceability solutions enhance the visibility of pharmaceutical products along the whole supply chain, from the acquisition of raw materials through manufacturing, processing, storage, and distribution [20]. Pharmaceutical supply chain adaptability and rapidity can be increased by utilizing pharmaceutical medication traceability systems in conjunction with blockchain and IoT to deploy medicinal supplies in response to unanticipated adverse occurrences in the pharmaceutical and healthcare industries. [21]. The majority of the time, the pharmaceutical sector deals with delicate concerns, and the use of traceability solutions is still minimal. As a result, additional investigation is still needed to determine the importance of traceability in supply chain management. Digital interoperable network design can assist supply chain participants in achieving data transparency, which enables them to gain quick insight into market trends, make quick decisions, adopt adaptable measures, and ensure secure supply. They can also use the collaborative capabilities of inter-organizational networks to respond to consumer demand and modify the supply chain's framework, acceleration, ability, and delivery in order to meet that demand. On the basis of adopting emerging technologies that match the organization's need for pharmaceutical drug traceability, it develops new processes and stringent policies and adds momentum to obtain a secure supply chain for drug distribution [22]. Strict network control also guarantees the safety and integrity of the drug supply chain, assuring drug safety and efficacy, preventing the risk of counterfeit drugs, preserving medical confidentiality, and, finally, ensuring the socially sound and steady growth of the pharmaceutical supply chain. Pharmaceutical supply chain management is aided by digital transformation, which converts port-to-port operations into more effective systems that enable on-demand purchase, flexible manufacturing, and quick delivery. Suppliers can foresee future client demands, reduce waste, and improve economics for on-demand allocation with the aid of big data research. Digital transformation permeates the production, packaging, medicine recall, and scrapping processes to achieve sustainable supply performance by consuming less energy and resources. New online health techniques using blockchain and IoT are making it easier for consumers to get health services, and the social healthcare industry is still being driven by the digital change in the pharmaceutical sector. The foundation for large-scale information identification, gathering, and processing is provided by new digital technologies, which are also necessary for system-wide information interaction with different systems for pharmaceutical drug traceability.

II. DIGITAL INTEROPERABLE NETWORK FOR PHARMACEUTICAL DRUG TRACEABILITY

Healthcare is an important sector for both the developed and under developing countries. They have their own challenges to implement emerging technologies in their pharmaceutical supply chain [23, 24]. Drug traceability issues can be resolved by utilizing blockchain-enabled interoperable networks in healthcare big data management systems. In the core of the digital data interoperability solution, a shared and secure network allows supply chain participants to see the status of digital drug transactions in real time for further traceability. It can provide advanced levels of interoperable data exchange between supply chain participants. By obtaining consensus from all participants, blockchain technology in the pharmaceutical supply chain ensures data quality, data reliance, and stakeholder opinion on the same platform [25]. All digital drug transaction data stored on the framework of the blockchain network conforms to standardized data interoperability, making these data easy to access and use by authorized supply chain partners. Interoperability itself is a complex data transmission process as it requires two digital data systems to be interoperable by exchanging data with each other without any transactional data interpretation issues. To make this happen, the message must be transfer with uniformed coded data that the receiving system can easily decode. Interoperability for pharmaceutical drug traceability in the supply chain network requires the collaboration of various participants, including manufacturers, wholesalers, distributors, dispensers, and hospitals. The semantic interoperability between digitally connected systems is a

significant challenge to improving drug counterfeiting problems and patient safety. To enhance medicine traceability, safety, and effectiveness, semantic interoperability enables pharmaceutical stakeholders to exchange drug summary information with other authorized parties utilizing a variety of secure technologies. Drug authentication data interoperable network allows participants to seamlessly share information to reduce duplicative validation, enable better-informed drug authentication results, and avoid adverse health events from counterfeited medicines.

III. BLOCKCHAIN ENABLED SUPPLY CHAIN FOR DRUG TRACEABILITY

Any innovation in technology, such as blockchain, that may safely address the issue of drug fraud has the potential to revolutionize the pharmaceutical industry. Blockchain is an emerging technology that is being used to create a successful drug tracing and anti-counterfeiting system. Blockchain technology offers benefits in terms of organization, legitimacy, and transparency [32]. The pharmaceutical supply chain system could employ blockchain to increase traceability and transparency. The platform's network is where the system uploads and stores the full history and summary of each medication transaction. By building a platform for the secure exchange of data, blockchain technology offers an appealing way to address the problems associated with medicine counterfeiting. Due to their inherent design characteristics, such as secure encryption and a robust peer-to-peer network, blockchain technologies are emerging as attractive and affordable ways to satisfy some of these needs. Blockchain provides a high-level framework for how a pharmaceutical stakeholder network could securely interact with multiple systems, identify themselves across each entity, and aggregate their drug data in a persistent form for traceability [33]. Blockchain-based technologies have capabilities for asset sharing and drug tracing audit trails, which can be useful in the healthcare industry. The decentralized and distributed blockchain database that contains drug information allows for an auditable and distributed ledger to see every transaction in the pharmaceutical supply chain [26]. There are some innovative blockchain-based traceability systems in use in the pharmaceutical sector. For instance, the pharmaceutical supply chain's distributed and transparent ledger system can investigate counterfeit drugs and unauthorized sources. The blockchain-enabled system permanently saves all drug transaction history in a global database, forming a secure network that can be traced back to the source of products in the pharmaceutical supply chain [27, 28]. By recording every electronic record of every transaction, blockchain can reduce inaccuracies brought on by traditional manual drug authentication between stakeholders. Blockchain also refers to a network of interconnected nodes that serves as a public, decentralized, and distributed database that is operated by a number of individuals. Blockchain functions as a distributed ledger technology (DLT) that enables users to electronically confirm issued transactions without the assistance of reputable, authorized supply chain partners. Blockchain typically offers a safe, independent, and consentaneous method of extending the DLT over time while maintaining the data's immutability and veracity. Using blockchain in healthcare and medical areas and focusing on the unique issues and problems of drug counterfeiting and authentication in the supply chain can mitigate the risk of adverse events. To address problems with drug traceability, a number of decentralized blockchain approaches have been suggested. A blockchain system called Drugledger has been frequently suggested for the privacy and veracity of tracing data. To make it simple to trace such pharmaceuticals, Drugledger often combines the Blockchain with the whole drug supply chain [29]. Drugledger specifically contains two different pharmaceutical flows: the data flow regarding the drug ledge and the physical distribution of the actual drug, both of which travel to the drug ledge network in the form of a chain network of pharmaceuticals. The authors (Ratta and Kaur; 2021) proposed a mechanism for preventing drug fraud that would keep track of each drug along the supply chain [36].

IV. BENEFIT OF IMPLEMENTING IOT IN PHARMACEUTICAL INDUSTRY

The majority of the younger population uses the internet for social media, chatting, and online shopping, including buying prescription drugs. The majority of social networking networks, search engines, and other websites use algorithmic tools to track all activity and access browsing histories [37]. The pharmaceutical industry needs to adopt strong technology that can search for potential fake sites and prevent fraudulent marketing. The IoT is typically used to gather healthcare data from numerous linked network devices. A significant amount of drug authentication and traceability data is generated by the businesses involved in the manufacture and distribution processes. Descriptive, predictive, and prescriptive analytics, which are AI-enabled tools for data analysis, can assist pharmaceutical industries in analyzing current events, comparing them to records, and providing information on how they can better prepare themselves for any upcoming health emergencies. Analytics will show the results of the semantic interoperability of healthcare data that has been gathered from different sources. The entire production, processing, storage, and transportation processes, transactions, and other tracking records are all recorded by reliable IoT devices [30]. Pharmaceutical systems can control drug identity and traceability in the supply chain using smart contracts and IoT-related technologies. IoT makes it possible

to incorporate sensors into real-world objects that can gather health information like vital signs [31]. IoT has emerged as a crucial source of medical data in the evolving healthcare sector. Many IoT medical device-based applications for healthcare, like drug traceability systems, already exist [34, 35]. Blockchain technology has been presented in numerous recent publications as a way to safeguard data that is altered by IoT medical devices in healthcare systems. Blockchain is worth investigating for complete end-to-end pharmaceutical drug tracking in the supply chain using IoT security to watch remotely. Blockchain technology and the Internet of Things (IoT) have made it possible for pharmaceutical supply chains to prevent drug counterfeiting by using more scalable and consistent technology on a decentralized platform [38]. Ourad et al. [39] suggested a blockchain-based framework for securely authenticating stakeholders to access IoT devices. The author also proposed an architecture to fix the problems of drug traceability with current methods of authentication and enable credibility, transparency, and reliability through secure, unmodifiable records. IoT sensors can be used in the pharmaceutical cold chain to trace the location of drugs and keep an eye on their transit circumstances, such as temperature, moisture, unforeseen disintegration, and broken tamper-evident seals. The IoT-based transportation model in the pharmaceutical supply chain has revolutionized drug delivery systems by connecting smart sensors for drug authentication and traceability. Interoperable networks can have strict security by restricting unauthorized access to IoT devices. After successful authentication of the user, security can be achieved by applying encryption and decryption techniques during secure SSL sessions [40, 41, 42]. IoT-based systems implemented in the pharmaceutical supply chain offer a stringent process that allows partners or IoT-enabled devices to be assigned a unique 20-byte EA instantaneously with no collisions, so seamless data exchange in an interoperable network can be achieved without any interruption [43]. Some authorized trading partners have full access to the smart contract's functions in IoT-based systems that determine that drug summary records should only be accessed through proper authentication. For instance, all changed statuses of the drug summary will be restored if any unauthorized access is found, resulting in an error. To guarantee the validity of the data source, the identities of IoT devices in the traceability system are authorized and authenticated. There are a few methods by which the blockchain-enabled applications of the secure devices can collect drug traceability transactions. One is to upload the collected transactional data upfront to the blockchain network via a secure IoT device. The second technique entails using the device's drug traceability program to connect to the interface of the pharmaceutical network, upload the original event data, and then store it in the off-chain EPCIS. There are some dark sides in the pharmaceutical industry, where small manufacturers generally do not have the capabilities to invest in emerging technology or improve the manufacturing infrastructure [44]. Major pharmaceutical corporations do not make investments or establish production facilities in developing countries due to geopolitics, challenges with market accessibility, and political uncertainty [45].

V. EMBRACING BIG DATA, MACHINE LEARNING IN THE SUPPLY CHAIN

In recent years, the pharmaceutical industry has constantly demanded an innovative solution to manage bulk data processing rapidly and efficiently. This desire can also be seen in the study of big data, or massive amounts of data. Pharmaceutical industries are thought to benefit from using big data, although the results of doing so in actual practice across various organizational types are still mostly unknown as some more research needs to be done [53]. The healthcare industry has always generated huge amounts of data through medical records and drug transactions. Nowadays, the introduction of pharmaceutical serialization for drug traceability as well as the huge amount of data exchanged by various types of systems generated by sales transactions seem to be growing constantly. The power of big data is being used by businesses to enhance decision-making, competitive advantage, and operational effectiveness [54, 55]. We found that blockchain technology can be integrated with AI-based customizable index technology to create a more complete and effective system. It can enable statistical and aggregate searches, among other things. Additionally, by creating an effective index for on-chain data, the performance of the data transaction inquiries might be increased while taking into account the features of the IoT object IDs and the event data. The combination and use of emerging technologies such as machine learning (ML) and artificial intelligence (AI) can guarantee the capture, transparency in the supply chain, digital drug traceability, immutability, high availability of transactional data, real-time drug authentications, and secure and reliable information related to drugs, which will improve the quality and safety of drugs in the pharmaceutical interoperable network [46, 47]. The main goal and novelty scheme of implementing a blockchain and machine learning-enabled system is to predict the flaws of illegal drug counterfeiting networks. These new technological systems use machine learning (ML) algorithms and blockchain technology in health care to prevent adverse events caused by drug counterfeiting. A number of cutting-edge applications, including the Internet of Things, machine learning, and deep learning, allow building an interoperable network for effective tracking and traceability of drugs. These technologies not only improve supply chain inefficiencies and prevent the potential risk of drug counterfeiting but also minimize the negative impact on patients' health due to fraudulent drugs [48]. Big Data technologies clean up and disperse medication data storage issues, as well as enhance data exchange and traceability capabilities in the supply chain

network. Ensuring the secure storage of traceability data and enhancing the traceability procedure are both necessary to enhance the drug traceability function [49]. Big Data are large-scale digital datasets that are frequently created as a result of interactions with web technologies [50]. Big Data is defined as collections of information that are so enormous that they pose difficulties for conventional methods of analysis and storage [51]. Big Data is a strong digital data repository that is unorganized, acquired from a variety of sources, and difficult or even impossible to examine using the traditional methods employed up until now to study relational databases. Big Data demands new technologies because it is too vast for existing data-processing systems as well as software tools to acquire, store, manage, and analyze [52]. The concept of big data makes it possible to access insightful analyses and findings as well as the ability to make more informed decisions because it is inextricably linked to the enormous growth in data that is now available to different companies or individuals. The notion of big data is continually changing, and at the moment it is more concerned with the process of extracting value from this data than with the sheer volume of data. A big data chain is created when big data is gathered from numerous sources with different data attributes and handled by various organizational units. Analytics of large datasets must bring together the organizations associated with data analytics. healthcare information technology to fully utilize the potential enormous volume of data in healthcare transactions to ensure that the appropriate action for the right patient is properly timed, customized, and possibly advantageous to all stakeholders involved in the healthcare system. Big Data Analytics can simplify the drug transactional data and help pharmaceutical stakeholders make well-informed choices on drug counterfeit results, adverse events in the supply chain, and other issues. By exploiting the data's potential, big data analytics can also increase the efficiency of healthcare companies. There are some basic challenges to implementing these emerging technologies in the healthcare supply chain. The cost of implementing a blockchain-enabled interoperable network is borne by the drug manufacturer, which must make significant investments in IT and equipment. In the end, the producer must include this additional cost in the price of the drug [56]. In developing countries, regulatory agencies or the government should fund a pilot project to invent a cost-effective, interoperable network where all supply chain partners should integrate with each other.

VI. CONCLUSION

It is necessary for every country to have a stringent and secure system to prevent drug counterfeiting in the pharmaceutical supply chain. It is necessary for every country to have a stringent and secure system to prevent drug counterfeiting in the pharmaceutical supply chain. In this article, we have explained how emerging technologies such as blockchain, machine learning, artificial intelligence, and big data can be useful in the pharmaceutical industry to mitigate the risk of drug counterfeiting. These technologies offer an integrated, trusted, secured, and distributed platform for storage and data transactions between various supply chain partners in the pharmaceutical supply chain in a way that can satisfy essential needs and features like safety, confidentiality, availability, transparency, and scalability.

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