Research and Inspiration of Drug Traceability System in the USA

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Abstract

Objective To draw on the experience of the construction and development of drug traceability system in the USA and to provide reference for improving China's drug traceability system. **Methods** Literature research and comparative study were used to sort out the background and development of drug traceability system in the USA, including drug traceability code, drug traceability model, drug traceability platform and the application of blockchain technology. On this basis, some suggestions on the construction of drug traceability system in China were put forward. **Results and Conclusion** The United States has a perfect system of laws and regulations on drug traceability, which encourages the construction of third-party traceability platforms to avoid the formation of monopolies. Besides, the application of blockchain technology in the construction of drug traceability system is also relatively mature. It is suggested that China strengthen the construction of drug traceability system, give play to the advantages of third-party traceability platforms, and improve the application of blockchain technology in drug traceability.

Keywords: drug traceability; drug traceability code; blockchain

Medication safety is closely related to people's daily lives because medication errors can happen in all aspects of the production, distribution and use of medicines. If information about medicines cannot be traced, then the flow of medicines cannot be effectively tracked, which can lead to risks when there are quality problems. The establishment of a drug traceability system is conducive to the accurate recall of problematic products, as well as the prevention of counterfeit and substandard drugs from entering the drug distribution and sales channels. The new version of the "Drug Administration Law of the People's Republic of China" also clearly proposes that the government should establish a sound drug tracing system to promote the sharing of drug tracing information. However, China has not yet introduced the relevant system today. Therefore, to establish a sound drug tracing system and strengthen the whole process of drug supply chain supervision can ensure drug quality and safety, which will achieve the goal of "traceable source, traceable destination and traceable responsibility" for drugs. In addition, it can effectively combat counterfeit and substandard drugs. This paper compares the current situation of the drug traceability system in China and the USA, drawing on the advanced experience of the U.S.A to provide reference for improving the drug traceability system in China.

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1 Drug traceability system in the USA

The drug traceability system in the USA is a process in which all stakeholders, including drug manufacturers, specialist packers, distributors, sellers, regulators and consumers, can trace information throughout the life cycle of a drug using information technology. The US Food and Drug Administration (FDA), the regulatory authority, is responsible for overseeing the implementation of the responsibilities of all participants and controlling the quality of medicines in the supply chain and holding them accountable through suspicious product investigations and recalls. The rest of the parties involved cooperate with each other through a "whole process traceability" model to prevent counterfeit and illegal drugs from entering the drug supply chain, thereby ensuring the quality and safety of medicines for consumers.

1.1 Background and development history

In 1987, the USA enacted the "Prescription Drug Marketing Act (PDMA)" to prevent counterfeit and substandard drugs from entering the market, requiring drug manufacturers to keep records of where drugs come from and where they are sold [1]. In 2007, the USA began to build a prescription drug traceability system, attempting to identify, verify, validate, track and trace information related to prescription drugs [2]. On 27 November 2013, the US Congress enacted the "Drug Supply Chain Security Act (DSCSA)", which clearly defines the responsibilities and obligations of various stakeholders in the drug supply chain and sets out a 10-year-long plan to strengthen drug supply chain security in the USA. Its goal is to establish an electronic drug information traceability system by November 27, 2023 [3]. Since the enactment of the DSCSA in 2013, the FDA has issued regulations and policies to strengthen the construction of drug traceability system, as shown in Table 1.

Table 1 Drug traceability system construction-related regulations and policies in the USA

Release date	Regulations and policies	Main content
2014.12	DSCSA Implementation: Product Traceability Requirements – Guidance for Industry Compliance Policies	Announced the FDA's plans to implement certain product tracking requirements under the "Federal Food, Drug, and Cosmetic Act (FD&CA Act)"
2016.12	DSCSA Implementation: Guidance on the Identification of Suspicious Products and Industry Notification	Designed to help stakeholders in the pharmaceutical supply chain identify suspect products
2018.09	Product Identification Code Requirements under the DSCSA – Guidance for Industry Compliance Policies	Extension of 1 year for manufacturers' product identification code compliance, adjusted to 27 November 2018
2019.09	Distributor Validation Requirements – Industry Compliance Policy Guide	Require distributors to validate product identification codes from 27 November 2019
2020.04	Certain Requirements for Exemption and Exclusion from DSCSA during COVID-19 Public Health Emergencies	Ensure adequate distribution of prescription drugs throughout the supply chain to address COVID-19
2020.10	Requirements for Distributor Verification and Pharmacy Verification in the Investigation of Suspected or Illegal Products	Pharmacies required to validate product identification codes for suspect or illegal products from 27 November 2020
2021.06	DSCSA Implementation: Identification and Notification of Suspicious Products	Designed to help stakeholders in the pharmaceutical supply chain identify suspect products

1.2 Drug traceability codes

Drug traceability codes establish a link between a drug and its traceability data, ensuring that information related to drug traceability can be correctly transmitted, and are a necessary prerequisite

and an important foundation for achieving drug traceability. A third-party drug traceability platform codes medicines and serializes them through product identification codes in the USA. The minimum sales unit is displayed as a machine-readable 2D code and a human-readable text part, of which the human-readable text part includes three valid pieces of information: Standardized numerical identification (SNI), batch number and expiry date, see Fig. 1 for an example of product identification code composition [4].

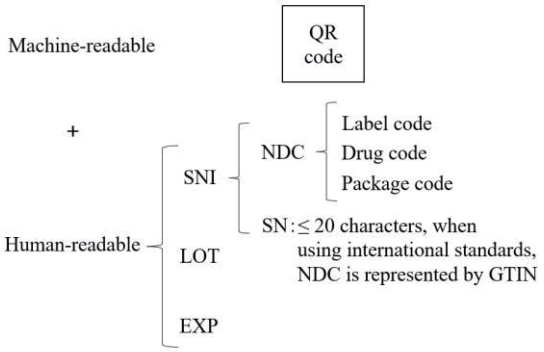

Fig. 1 Example of product identification code composition

The SNI is a barcode consisting of the national drug code (NDC) plus a serial number of no more than 20 characters, while the NDC consists of a label code, a drug code and a packaging code of 10 characters [5]. In order to meet the needs of the globalized drug trade, the U.S.A has established a global trade item number (GTIN) to identify imported and exported drugs. When the DSCSA is implemented using the globe standard 1 (GS1), the NDC is represented by the GTIN. The two main types of encoding vehicles for U.S. product identification codes are 2D codes and radio frequency identification tags, as shown in the examples in Fig. 2 and Fig. 3.

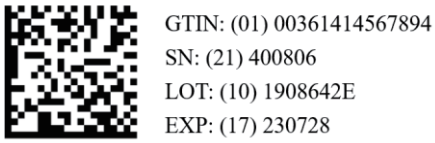

Fig. 2 Example of QR code

Fig. 3 RF identification tag example

1.3 Drug traceability models

1.3.1 Stakeholders in the drug traceability system

Raw material suppliers are responsible for delivering raw materials that are used to manufacture pharmaceutical products that have been approved for production by the regulatory agency, the FDA. The manufacturer transfers the manufactured drugs to a primary distributor or transfers them to a repackager for repackaging. The primary distributor receives the drugs and either transfers them to pharmacies and healthcare facilities, depending on the demand for the drugs, or is responsible for transferring these drugs to secondary distributors. Finally, pharmacies sell the medicines to patients based on a doctor's prescription. Throughout pharmaceutical supply chain, the transfer of medicines is usually facilitated by third party logistics service providers, and in some cases, distributors operate their own vehicles to transport the products [6]. The various stakeholders in the drug traceability system and their relationships are shown in Fig. 4.

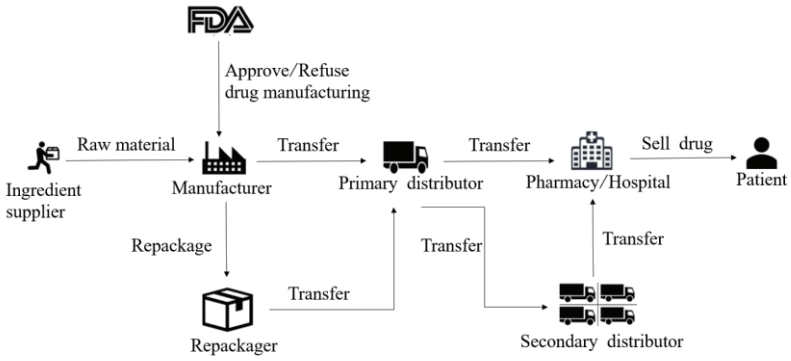

Fig. 4 Stakeholders of drug traceability system and their relationships

1.3.2 Specific traceability models

In order to ensure the safety of the drug supply chain, the USA adopts the model of "whole process traceability", in which the transaction information is verified at every link of the drug supply chain. Drug manufacturers bear the main responsibility in the process of drug traceability [7]. Drug manufacturers choose legitimate third-party traceability service platforms to realize drug serialization, encode and label drugs, and transmit transaction information to sub-distributors, who verify the authenticity and integrity of information, and transmit transaction information to sub-distributors for further verification [8]. FDA is responsible for providing guidance and assistance to pharmaceutical supply chain industry, but it does not participate in the establishment of third-party platforms. The feature of this model is to realize drug traceability through layer-by-layer code scanning, thus improving the transparency of the supply chain, making the responsibility of each link more clear, which fundamentally prevents counterfeit and substandard drugs from entering circulation and use channels. When quality problems or other safety risks of drugs are found, it is necessary to start the drug recall procedures. The drug traceability system can accurately identify the source and destination of drugs, greatly simplifying the work flow of drug recall [9].

1.4 Drug traceability platform

The United States FDA does not plan to build an official drug traceability platform, and most drug manufacturers and distributors choose to provide services such as information storage, exchange, and response to FDA verification through third-party traceability platforms [10]. The FDA only provides guidance related to the system construction and data security of third-party platforms, and supervises the daily operation of the platforms. At present, there now three major commercial traceability platforms in the US market, mainly including TraceLink, Rxfcel and SAP-ATTP.

TraceLink focuses solely on tracking and tracing in the pharmaceutical sector to connect the life sciences supply chain and prevent counterfeit medicines from the global marketplace. TraceLink enables the secure exchange of large amounts of information and product data between various stakeholders in the pharmaceutical supply chain, providing customers with automated reporting and end-to-end visibility of serialized products [11].

The Rfxcel platform is used in the pharmaceutical and medical device, food and consumer goods sectors. In the pharmaceutical sector, it focuses on pharmaceutical supply chain security and providing advanced tracking technology for various stakeholders. Rfxcel's serialization software dynamically identifies relevant data and extracts it into the system, which assigns serial and batch numbers to products and provides extensive data validation checks to ensure data quality.

The SAP-ATTP platform is targeted at the pharmaceutical industry for serialization and tracking of pharmaceutical products. Its specific functions include managing serial number ranges and random

serial number lists, tracking and aggregating serialization data, storing large volumes of data and transaction information and generating reports as required based on the data, meeting relevant US regulatory requirements and responding to FDA regulatory verification.

1.5 The application of blockchain technology in the drug traceability system in the USA

1.5.1 Definition and characteristics

Blockchain technology is a chained data structure that uses cryptographic methods to associate blocks of data in chronological order, recording and synchronizing information about transactions between different subjects [12]. Features of blockchain technology are as follows: (1) Data is difficult to tamper with; (2) It is decentralized. Blockchain data is stored in a distributed manner as there is no central server or organization, and each node exchanges data resources directly, making it easier to share between nodes [13]; (3) It increases security; (4) It has greater transparency.

1.5.2 The application status of blockchain technology in the USA

In September 2017, Chronicled and LinkLab announced the Medi Ledger project, which aims to help pharmaceutical companies achieve DSCSA compliance and explore and develop blockchain solutions for pharmaceutical industry. It is the first major project to use blockchain technology in the pharmaceutical supply chain in the USA [14]. In September 2018, the US National Institutes of Health explored the development of a distributed application (DApp), running on blockchain that simulates the drug supply chain process in a network governed by a regulatory agency [15]. In June 2019, Walmart joined the blockchain project MediLedger, which already included pharmaceutical companies such as Pfizer and three largest drug wholesalers McKesson, AmerisourceBergen and Cardinal Health, with the aim of providing broader tracking of all pharmaceuticals involving interoperable data and packaging serialization [16]. Blockchain technology can oversee the entire drug manufacturing, distribution and use process to ensure the quality and safety of medicines for consumers.

The drug traceability process based on blockchain technology is shown in Fig. 5. First, the drug manufacturer uploads the drug production information to the blockchain network and provides the traceability information to wholesalers. When the wholesaler receives the drug, it shall verify the drug information, release the drug transportation information to the blockchain network if the verification is correct, and provide the traceability information to the distributor. Then, the seller verifies the traceability information provided by the upstream agency, and uploads the sales information to the blockchain. When purchasing or using drugs, consumers can query the information of each stage of production, circulation and sales through the drug traceability system, which is obtained through the blockchain network [17].

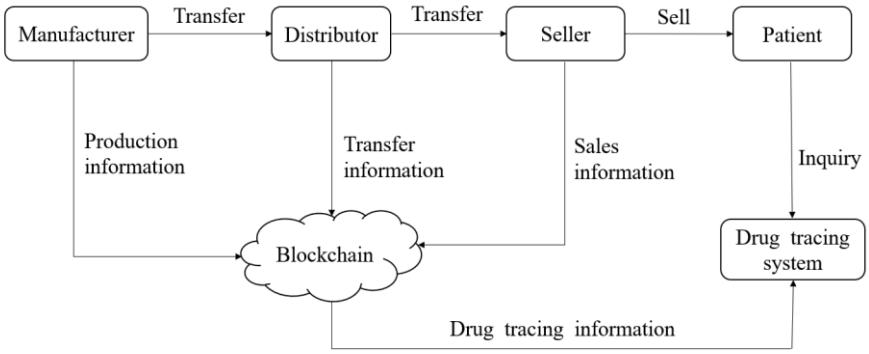

Fig. 5 Blockchain technology-based drug traceability process in the USA

1.6 Experience of drug traceability system construction in the USA

The USA has been working on drug traceability since the 1980s and possess a sound legal and regulatory system, with legislation to implement the main responsibilities of relevant stakeholders for traceability. In 2013, the DSCSA was enacted, and it set out the core tasks and implementation points for drug traceability in the United States for up to 10 years, which would flexibly adjust the enforcement time according to the actual situation of enterprises. In addition, a number of guidance documents have been issued to ensure the smooth implementation of the act and to address any problems encountered during implementation.

The government in the USA encourages the construction of third-party drug traceability platforms, and relevant enterprises can choose their legal platforms for serializing medicines and transmitting transaction information. This prevents third-party platforms from monopolizing the market, while reducing the operating costs of all stakeholders in the drug traceability system. By encouraging market competition, the service quality of third-party platforms will be continuously improved. Besides, some third-party platforms with excellent expertise and operation will be cultivated, thereby enhancing the overall operation of the drug traceability system.

The application of blockchain technology in drug traceability in the USA is relatively mature, particularly the MediLedger project, which first applied blockchain technology and was selected by the FDA as a DSCSA pilot project in June 2019 due to its increasing adoption within the drug traceability industry in recent years, and the final report of the pilot project was released in February 2020. It demonstrates that the blockchain platform can successfully meet the requirements of the DSCSA interoperable system in 2023, further proving the viability of blockchain solutions in the pharmaceutical traceability space [18].

2 Overview of China's drug traceability system

From 2006 to 2016, the State Food and Drug Administration (SFDA) had been actively promoting the work of electronic regulation of medicines, and it achieved the full range and process of regulation of medicines in phases and steps. Due to some problems in the implementation process, in February 2016, the former China Food and Drug Administration (CFDA) announced the suspension of drug electronic supervision and it began to explore a new regulatory model. in July 2016, in the "Decision on Amending the Drug Quality Management Code", the relevant expressions of drug electronic supervision code were all taken into the drug traceability system, marking the legal status of China's drug traceability system was formally established [19]. After that, in order to accelerate the construction of China's drug traceability system, the government has issued a number of regulations and policies to support it. In particular, the new version of the "Drug Administration Law" clearly proposes that the government should establish a sound drug traceability system.

Different manufacturers will choose different drug codes to uniquely identify drug sales packaging units, and assign codes to drug packaging through carriers, mainly including the code on the assured traceability code, international item code and enterprise custom code [20], the specific classification is shown in Table 2. The carrier of the drug traceability code can choose 1D barcode, 2D barcode or RFID tag according to the need, as shown in Fig. 6 and Fig. 7 with 1D barcode and 2D code identification schematic.

Table 2 Classification of drug traceability codes

Company	Drug traceability codes	Coding carrier
Drug manufacturer	Overwhelmingly: Code on assurance traceability code (formerly China drug electronic supervision code) Few: Aichance traceability code, Ziyun Stock traceability code	1D barcode
Drug import and export company	GS1-compliant international item codes	QR code
Individual company	Enterprise custom codes (e.g., HARM traceability codes)	RFID tags

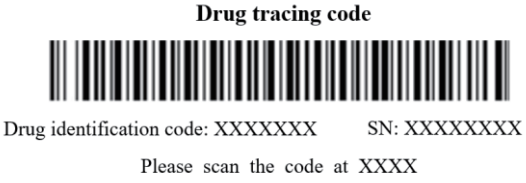

Fig. 6 Schematic diagram of marking with 1D barcode

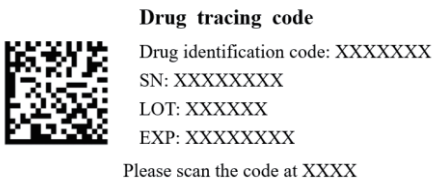

Fig. 7 Schematic diagram of the logo using QR code

China's drug traceability system mainly adopts the "whole process traceability" model, in which the transaction information is verified during the production, circulation and use of drugs. First of all, the drug licensee and the manufacturer are responsible for assigning codes to the drugs they produce and passing the transaction information to the downstream enterprises or users. When purchasing medicines, pharmaceutical enterprises and users should obtain relevant transaction information from upstream enterprises and verify and provide feedback on the information. When selling medicines, sales records should be kept and the status of medicines sold should be updated in a timely manner. When consumers purchase medicines, they can check the information related to medicines by scanning the medicine traceability code on the medicine packaging [21].

Drug traceability system in China takes the form of "enterprise self-establishment + third party". Most enterprises realize drug traceability through the use of third-party platforms. The third-party platforms in the market mainly include Ali Health's "secure traceability platform on code", Aichance's "Link-Link traceability cloud platform" and Ziyun Stock's "drug traceability cloud service platform" based on blockchain technology. Among them, Ali Health's "code assured traceability platform" has the largest market share, while other third-party traceability platforms have a very small market share.

As for the application of blockchain technology in drug traceability, China is also actively carrying out relevant projects. In June 2017, China's first blockchain technology-based drug traceability platform went online [22]. In November 2019, Jingdong Digital Science launched a blockchain-based traceability platform. Based on the platform, it offers an intelligent solution for vaccines to ensure the transparent circulation of information related to the whole life cycle of vaccines [23]. In May 2022, the National Development and Reform Commission released the "14th Five-Year Plan for the Development of Bioeconomy", which mentions the use of blockchain and other technologies to realize the full lifecycle management of drugs and vaccines in the drug traceability system [24].

3 Inspiration of the US drug traceability system to China

3.1 Strengths and weaknesses of China's drug traceability system

At present, China's drug traceability code has a variety of carrier forms. For example, the most common forms include 1D barcode, 2D code and radio frequency identification tag. Because the cost of codes varies, drug listing licensees and manufacturers can combine their own needs to choose the carrier form suitable for them. Third-party traceability platforms are developing well, with each platform building a drug traceability system based on cloud computing, Internet of Things and big data technologies, thus realizing the whole process of traceability and supervision of products from production to circulation to use. Therefore, it breaks the information barrier among the government, enterprises and consumers, thus realizing the closed loop of the pharmaceutical supply chain. Some of these platforms are also able to meet international traceability requirements and provide services for global pharmaceutical companies. Others apply advanced blockchain technology.

However, the construction of China's drug traceability system still faces many difficulties and challenges. (1) The top-level design is not specific

and in-depth enough, and there is a lack of laws and regulations targeted at drug traceability. At present, only some traceability-related policy documents, national standards and industry standards have been introduced. In addition, although the new version of the "Drug Administration Law" proposed to establish a sound drug traceability system, China has not yet issued a relevant system, nor does it have supporting guidance documents. (2) China's drug traceability system takes the mode of "enterprise self-built + third-party traceability platform". Because the enterprise self-built system requires the enterprise to purchase some hardware facilities, such as scanners and encryption equipment, and to employ relevant technical personnel, it will increase the operating costs of the enterprise. Therefore, most enterprises are not willing to building their drug traceability system. Their enthusiasm and initiative are not high. (3) The application of blockchain technology in drug traceability is not quite mature because there is a lack of relevant laws and regulations and professional technical personnel. For enterprises, blockchain technology is also costly to invest in. For instance, they have to purchase relevant hardware facilities and pay for the development, maintenance and personnel.

3.2 Suggestions for improving China's drug traceability system

To strengthen the construction of China's drug traceability system, the national drug regulatory authorities should formulate laws and regulations for the promotion of the drug traceability system. For example, it should clarify when the drug traceability collaborative service platform and drug traceability supervision system should be completed. Industry associations and research institutes related to drug traceability can also assist the national drug regulatory authorities in issuing relevant standards and specifications, thus ensuring that all parties involved in drug traceability can work smoothly.

In terms of drug traceability system construction, China's government should encourage third-party platforms to build drug traceability systems. At the same time, to prevent data leakage, the government should introduce relevant credit policies and establish credit mechanisms to guide and regulate third-party platforms to provide services to various related parties. Enterprises and third-party platforms can also sign a data security management contract to guarantee data security.

For the application of blockchain technology in the drug traceability system, the government should formulate corresponding laws and regulations, increase the training of technical talents, which can promote the construction of the drug traceability system based on blockchain technology. To alleviate the financial pressure on enterprises and third-party platforms, government departments can consider broadening funding channels and introducing diversified funding policies. For example, government departments can invest special funds in the construction of blockchain-based drug traceability systems for small and medium-sized enterprises. They can consider giving enterprises some subsidies, tax concessions and extra points for bidding. In addition, they can encourage some social forces and financial institutions to provide financial support to enterprises and third-party platforms.

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