Review Article
Food Science and Technology

ISSN 0101-2061 (Print)
ISSN 1678-457X (Online)

DOI: https://doi.org/10.5327/fst.122022

TCMQMS system: a digital twin and blockchain-based platform for tracing the whole process of Chinese medicine quality information

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Abstract

Traditional Chinese medicine is an important medicine and health food in China. In the process of making Chinese medicines, the main active ingredients of the medicines are highly dependent on the production environment due to the special physical characteristics of the medicines themselves. Any slight change in the environment can lead to changes in the active ingredients as well as the final efficacy, even affecting the patient treatment cycle, and this characteristic is not conducive to quality control by national drug quality regulators. In order to enhance the quality management of TCM, a blockchain and digital twin based whole process monitoring system for TCM quality is proposed: Traditional Chinese Medicine Quality Monitoring System (TCMQMS), in order to achieve a whole process, full scope and highly transparent TCM quality monitoring model for TCM production from the source of cultivation to the final patient. And. A blockchain platform based on Fabric blockchain data development platform as well as Sia distributed data storage was designed. With the help of Sia distributed storage technology, the amount of data storage is significantly compressed, which achieves the purpose of unifying the huge information data flow into the TCMQMS system and quickly building the system platform using the Fabric platform. In addition, in order to ensure that data is read and written in real time during the manufacturing and transportation of Chinese medicine, environmental sensors, such as temperature and humidity sensors, are placed in the Chinese medicine processing plant and in the transport sector. The environmental sensors, such as temperature and humidity sensors, are placed inside the Chinese medicine processing plants and transport vehicles. The environmental data is combined with the production data recorded by the TCMQMS system and sent to the digital twin TCM manufacturing simulation environment in real time, and through the simulation of the TCM manufacturing environment, the TCM quality environment parameters are continuously iteratively updated to be more suitable for production. This is coupled with real-time linkage with environmental sensors to achieve real-time adjustment of environmental parameters. In addition, the TCMQMS system records the entire process data, giving each data block a unique and tamper-proof hash value and CA certificate, so that when there is a possible quality problem, the hash value and CA certificate will be used to quickly trace the person responsible and the details of the environment in which the TCM was produced in real time. Finally, we present a real-life example of the use of the TCMQMS system to validate our proposed approach.

Keywords: traditional Chinese medicine; pharmacy; digital twin; block chain; internet of things; Chinese medicine supply chain; tracking and tracing.

Practical Application: The research presented in this paper addresses critical challenges within the traditional Chinese medicine industry and proposes an innovative solution that leverages blockchain and digital twin technologies. The proposed Chinese Medicine Quality Traceability Platform, TCMQMS, aims to revolutionize how traditional Chinese medicine companies manage their processes, enhance product quality, and ensure supply chain transparency.

The practical application of the TCMQMS platform holds significant promise for various stakeholders within the Chinese medicine industry, including manufacturers, suppliers, regulators, and consumers. By adopting this solution, tangible benefits can be realized:

Enhanced Quality Control and Traceability: TCMQMS provides an advanced and decentralized framework for tracking the entire lifecycle of Chinese medicine products, from raw material sourcing to manufacturing and distribution. This allows for real-time monitoring, quality assurance, and timely identification of any quality-related issues, ensuring that the products meet rigorous standards.

Improved Transparency and Information Exchange: The platform facilitates seamless and efficient information exchange across the supply chain. Manufacturers, suppliers, and other stakeholders can access accurate and up-to-date information regarding product origins, processing, and distribution, fostering a transparent and collaborative ecosystem. Mitigation of Quality Risks: By leveraging blockchain and digital twin technologies, TCMQMS minimizes the risk of counterfeit or substandard products entering the market. The immutable and tamper-proof nature of blockchain ensures the integrity of product data. At the same time, digital twin technology allows for the creation of virtual representations of physical products, aiding in quality assessments.

Cost Savings and Efficiency Gains: Traditional Chinese medicine companies can optimize their supply chain management processes through the TCMQMS platform. Companies can realize cost savings and enhance overall operational efficiency by reducing inefficiencies, streamlining processes, and minimizing the impact of quality-related issues. Consumer Confidence and Safety: The TCMQMS platform instills greater consumer confidence by providing precise and accessible information about the quality and authenticity of Chinese medicine products. This fosters trust among consumers, leading to increased demand and a positive impact on market growth.

Regulatory Compliance and Accountability: TCMQMS assists manufacturers and suppliers in adhering to regulatory requirements by maintaining accurate records and documentation. This promotes accountability and facilitates smoother interactions with regulatory bodies.

In summary, the TCMQMS platform offers a practical and transformative solution to the challenges faced by the traditional Chinese medicine industry. By integrating cutting-edge technologies and establishing a decentralized quality traceability ecosystem, TCMQMS empowers stakeholders to enhance product quality, optimize supply chain management, and ensure the safety and efficacy of Chinese medicine products. Its potential to revolutionize the industry's operations, improve transparency, and bolster consumer confidence makes TCMQMS a valuable and essential tool for advancing the traditional Chinese medicine sector.

Received 01 Nov., 2022
Accepted 12 Jan., 2023
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1 Introduction

In the traditional Chinese medical concept, the excellent therapeutic effects of herbal treatments and the mysterious impression of herbs as magical plants have become an inseparable part of Chinese culture. And the medical approach centred on Chinese medicine has had a profound impact on neighbouring Asian countries for thousands of years and still has a great influence today. However, with the development of the times and the improvement of management technology, the Chinese medicine industry is facing an industrial transformation. Rising manufacturing costs, increasing quality control costs and asymmetrical information exchange in the supply chain have led to a gradual hindrance in the development of the Chinese medicine industry. The management model and mindset of proprietary Chinese medicines is generally similar to that of Western medicines, with quality control achieved through strict control of the pharmaceutical process and standardised raw materials. However, the use of dried Chinese medicines is just as much a part of the patient's daily treatment process as proprietary Chinese medicines, but the quality control and traceability of these products is much more difficult than that of proprietary Chinese medicines, which can be standardised.

For thousands of years, Chinese medicine and herbalism has been a mysterious healing art known as coming from the East. The mystery of Chinese medicine lies in the fact that it is made by decocting and boiling a variety of herbs, mostly in water, and adding other types of herbs during the production process, depending on the changes in the physical properties of the herbs at hand, which results in a variety of rather complex and mutually catalytic reactions, the order of which is the result of thousands of years of experience in the development of Chinese medicine, to obtain the herbs that can cure diseases. At the same time, the complexity of the herbal medicine combinations and the experience in judging the quality of the herbal medicine required are quite demanding on the professionalism of traditional Chinese medicine practitioners. It is worth noting that many long-running herbal clinics have been handed down from one family to another for hundreds of years over several or even a dozen generations.

After thousands of years of development, traditional Chinese medicine has permeated the daily life of the Chinese people in all aspects. Chinese medicine has also gradually evolved in other directions, including pharmaceutical proprietary Chinese medicine, traditional Chinese medicine, and traditional Chinese medicine health food. Chinese medicine health food is based on the theory of traditional Chinese medicine, in the natural food to join the Ministry of Health promulgated both food and medicine edible medicinal materials, which is a combination of drugs and food special food. Due to the special nature of TCM, whose active ingredients are easily affected by environmental and processing factors, the food safety of TCM has been a concern for the Chinese public.

In the context of increasingly complex supply, how to scientifically and effectively promote the development of a virtuous cycle in the Chinese medicine manufacturing industry has become a matter of concern to the academic as well as the business community. According to the relevant requirements of the National Health Care Administration of the People's Republic of China, it is stipulated that the loss of Chinese medicine products as well as raw material drugs during storage in pharmacies should generally be less than 1%, but as most pharmacies manufacturing and selling Chinese medicine products are unable to effectively monitor the real-time environment of the drugs, they are unable to accurately track the quality of the drugs and generally lose more than 1%. Moreover, Chinese medicine faces a lack of quality supervision of the whole process from source collection to processing, and remains in a more traditional point-to-point quality screening, with a high degree of information asymmetry. Most of them use their own experience to carry out rough inspections of raw drugs, and are unable to grasp the quality accurately and in real time, which can easily lead to a decline in the quality of Chinese medicine, and the result of the residual efficacy of drugs. With the development of Industry 4.0, various emerging technologies have been introduced, and the application of blockchain, digital twin and the Internet of Things in various industries has become a mainstream research topic in academia, among which the application about emerging technologies in the pharmaceutical field is also gradually strengthened (Reyna et al., 2018).

Innovative production methods based on the combination of digital twin technology and pharmaceutical engineering have been proposed (Lopes et al., 2020). In the last decade or so, academia has made significant breakthroughs in the application of new technologies to western pharmaceuticals, with outstanding progress in traceable quality control of drugs (Schöner et al., 2017). the gradual integration of RFID technology with IoT has also led to a more tangible assurance of the integrity of supply chain information in the pharmaceutical sector (Safkhani et al., 2020). The application of digital twin technology in pharmaceutical companies and laboratories has also led to new research directions and application scenarios for quality control (Coito et al., 2022). In contrast, herbal medicines are usually harvested directly from nature, and their quality and active ingredients are highly dependent on the external environment, which makes them susceptible to changes in efficacy. Due to the specific physical characteristics of TCM and its complex manufacturing process, there is still a gap in the application of emerging technologies related to TCM. The following problems are prevalent in the field of Chinese medicine manufacturing.

Quality problems cannot be traced back to their source. Due to the intertwined and complex supply network involved in the Chinese medicine industry, it is impossible to quickly trace the source of problems and related details when quality problems occur in the final product, which indirectly leads to the fact that the quality of Chinese medicine is not easily controlled and the cost of environmental control and transportation is higher than the cost of raw materials.

Traditional and outdated information transfer methods. SMEs lack the knowledge and ability of digitization (Khlystova et al., 2022). Continuing to use the old drug management mode and traditional peer-to-peer, non-instantaneous information transfer methods, which can make information transfer lag behind the actual drug situation. Moreover, there is no information control platform developed for the whole process of Chinese medicine in the market, and the information flow of drugs is scattered and unintegrated among the relevant companies in the supply

chain, making the information transfer extremely inefficient and unable to effectively map the real quality to the transmitted information.

Drug supply sources are complex and medicines are difficult to trace (Zhang et al., 2020). The source supply of Chinese medicine production is in a complex and confusing state. Most are grown and sold independently by farmers, although China has promulgated relevant national standards for the quality of Chinese medicine production in the last decade. In 2020, the Shanghai Municipal Drug Administration organised a quality sampling inspection of drug production, management and use units in Shanghai. Among the drugs that failed the sampling test, 4 batches were Chinese medicine tablets and 4 batches were proprietary Chinese medicines. 2014 to date, a pharmaceutical company in Shandong was found to have failed 16 batches of drugs, 12 of which were of the same species, and the quality of the raw material supply chain as well as the Chinese medicine manufacturing chain was a concern.

Therefore, based on the above issues we have identified the following three research questions. Firstly, how to optimise the current level and efficiency of information exchange in the whole process of Chinese medicine production. Secondly, how to leverage blockchain federated chain technology and digital twin technology to solve the problem of difficult quality control at the source of Chinese medicine. Thirdly, how to enhance the overall supply chain transparency level of TCM and enhance its traceability and reliability.

In order to solve these problems, this paper proposes a blockchain and digital twin technology based Chinese medicine quality traceability platform called TCMQMS. In response to the pain points of the traditional Chinese medicine industry with varying levels of raw material drug quality, difficulties in supervising the whole process and the whole link, and the low level of information technology targeted to provide a Chinese medicine quality monitoring platform that combines blockchain alliance chain and digital twin. Compared to traditional pharmaceutical industry systems, is the first to provide a decentralised framework that combines blockchain and digital twin technologies.

Based on these development issues and the current state of the industry, this paper will be based on the following four areas.

1. A quality tracing platform supported by blockchain and digital twin technology is proposed to facilitate the transformation of traditional Chinese medicine companies.
2. A new digital twin model for the traditional Chinese medicine industry was developed, transforming its physical entities into virtual resources.
3. A trustworthy decentralised platform is built in the context of blockchain and federated chain based to achieve quality traceability of Chinese medicine.
4. Optimise the supply chain management model of the traditional Chinese medicine pharmaceutical industry, enabling it to save costs while improving product quality.

The rest of the paper is structured as follows. Section 2 (section is used in paper to indicate chapters and chapter is used in thesis to indicate chapters) Chapter 2 is a Literature review of the Chinese medicine supply chain, the application of blockchain technology in the supply chain and the application of digital twin technology in the supply chain**.** chapter 3 introduces our designed Chapter 3 introduces the operational model and the principle of the blockchain and digital twin technology based Chinese medicine quality monitoring platform (TCMQMS) we designed. Chapter 4 describes how our innovation core technology is applied and how it works. Case studies will be presented in Section 5. Conclusions and future perspectives are discussed in Section 6.

2 Literature review

The related research conducted a literature review from scientific databases (Web of Science and Google Scholar) in three areas: Chinese medicine supply chain context, blockchain technology in the supply chain and implementation of digital twin technology in the supply chain. The literature search for the TCM supply chain context ranged from 2007 to 2022 with the following keywords: TCM logistics, TCM supply chain, quality improvement and food traceability. For the application of blockchain technology in the supply chain, the search ranged from 2008 to 2020, using the keywords blockchain technology and cloud manufacturing, and federated chain applications, respectively. 2017 to 2022, the keywords for the implementation of digital twin technology in the supply chain: simulation, early warning, quality monitoring. Therefore, some of the most representative literature has been selected and summarised.

2.1 Chinese medicine supply chain

With the continuous development of the TCM industry, the manufacturing and management of TCM has shifted from the original crude management to refined and scientific management, and the concept of TCM supply chain has gradually been brought to the attention of academia. The proposed supply chain of TCM can systematically control the whole process of TCM production, improve the quality control level of TCM, optimize the production process of TCM, and achieve the maximum retention of active ingredients of drugs with the help of scientific supply chain design, so that its quality can be significantly improved.

In the 20th century, many researchers have realized that a well-developed supply network plays a decisive role in pharmaceutical manufacturing management and product quality control (Shah, 2004), was the first to systematically describe the positive effects of an optimized supply chain on pharmaceutical supply chain management from the perspective of supply chain optimization. Rossetti et al. (2011) suggest the main drivers of change that will influence the future of biopharmaceutical supply chains, where redesign of the pharmaceutical supply chain structure and quality supply chain people management will have positive feedback on pharmaceutical management. Yu et al. (2010) pointed out that the Chinese pharmaceutical supply chain and the Chinese pharmaceutical market suffer from poor market regulation, confusion in product supply and inadequate pricing

mechanisms, and concluded that combining pricing reform with supply chain reform promotes the positive development of Chinese pharmaceuticals. Abdallah (2013), from the perspective of the global supply chain, points out that drug quality problems can have a devastating impact on a company's reputation and that continuous optimisation of the supply chain to reduce drug quality problems is a growing concern for pharmaceutical companies. Tat & Heydari (2021) mentions that by introducing sustainable drug management practices and new optimization models into the pharmaceutical supply chain, it is possible to optimize drug supply while reducing drug waste. Papert et al. (2016) suggests that the introduction of Auto-ID technology into the pharmaceutical supply chain can effectively enhance supply chain visibility (SCV) and provide a technical support for sustainable development of the pharmaceutical supply chain. Laurie (2017) describes the performance of a new technology for tracing food in the supply chain using DNA barcodes that can be applied directly to the food.

2.2 Blockchain technology in the supply chain

Blockchain technology, the core technology of virtual currencies, is a distributed ledger to establish a secure and reliable source of cryptographically secured timestamped transaction records (Nofer et al., 2017), which has the advantages of being tamper-proof, traceable and reliable information. The core applications of blockchain technology include virtual currency, information traceability, and decentralization.

At this stage, blockchain technology is already showing its powerful application scenarios and possibilities in the supply chain. The focus is on drug traceability, decentralised establishment and quality control (Mettler, 2016). In order to enable accurate monitoring of drugs in the "last mile", William Chien proposed the BRUINchain system as a way to improve quality control in the drug delivery chain (Chien et al., 2020). Blockchain technology is proposed to be used for inspection and pre-market evaluation of new drugs as well as to combat counterfeit drugs in less developed regions and ultimately to protect consumer rights.

Drug ledger, a blockchain system for drug traceability regulation, was proposed to effectively track drugs while ensuring information security and privacy (Huang et al., 2018; Hollands et al., 2018) explores the advantages and pitfalls of blockchain under the premise that existing ERP systems can achieve traceability. At the same time, with the development of globalization, supply chain management has become increasingly difficult, and the use of blockchain can enable supply chain management to overcome existing problems and achieve sustainable development (Saberi et al., 2019; Hollands et al., 2021) proposed a nascent theoretical framework to grant different access levels and permissions to enterprises and final consumers in the supply chain. It not only ensures the information security of enterprises, but also enables consumers to trace the food information they want. The integration of IoT technology with blockchain technology to achieve increased effectiveness and significantly improved operational efficiency in modern supply chains is presented (Rejeb et al., 2019).

2.3 Application of digital twin technology in the supply chain

Digital twin is a cutting-edge technology that combines physical entities with virtual simulations, and he builds a bridge for information exchange between real entities and virtual models (Kritzinger et al., 2018). Tao, Fei presented detailed guidelines for the application of digital twin technology and thoughts on the future application scenarios of digital twin, and analysed the differences between digital twin technology (DT) and information physical systems (CPS) (Tao et al., 2018, 2019), and the application and development of DT in intelligent manufacturing (Tao et al., 2019). Kritzinger, Werner, describes the difference between Digital twin, Digital Model and Digital Shadow in manufacturing (Kritzinger et al., 2018). Barykin discusses the place of digital twin in supply chain management and its positive role (Barykin et al., 2021). M. Raza proposes digital twin technology as a breakthrough technology support for Industry 4.0 (Raza et al., 2020). DTaaS has powerful advantages in equipment maintenance, real-time monitoring, remote management, and predictive alerting (Aheleroff et al., 2021).

From the above three aspects, (1) The general academic community has focused on the research and exploration of the supply chain of western medicines at the level of drug supply chain, while there is a lack of research on the supply chain of traditional Chinese medicine. (2) Existing blockchain technology, while some scholars have chosen to study it in Western medicine traceability, is still in a gap in Chinese medicine traceability research. (3) The application of digital twin technology in general manufacturing plants is still in its infancy, although many scholars have put forward insightful proposals, and no scholars have yet studied the application of digital twin technology in the manufacturing process of Chinese medicine. To fill these gaps, this study aims to establish a multi-dimensional and multi-level Chinese medicine quality monitoring system based on digital twin technology and blockchain technology to address the current confusing situation of Chinese medicine management and provide an academic support for Chinese medicine reform. To the best of our knowledge, this study is one of the first implementations and applications of digital twin technology and blockchain technology for TCM quality monitoring in the TCM field.

3 TCMQMS: blockchain technology and digital twin technology based whole process monitoring platform for Chinese medicine quality

This section will introduce TCMQMS from two main aspects: the architecture of TCMQMS, the application scenarios of the digital twin and blockchain technology model, and the hardware configuration.

3.1 The architecture of TCMQMS

As shown in Figure 1, the entire process of Chinese herbal medicine, from cultivation, harvesting, processing, transportation, and all the way to the hands of consumers, is under the quality control of the TCMQMS system.In the initial phase of the system's operation for growing herbs and supplying raw herbs to downstream pharmaceutical companies' phase, the role of cultivation consists of combination of cultivation bases and

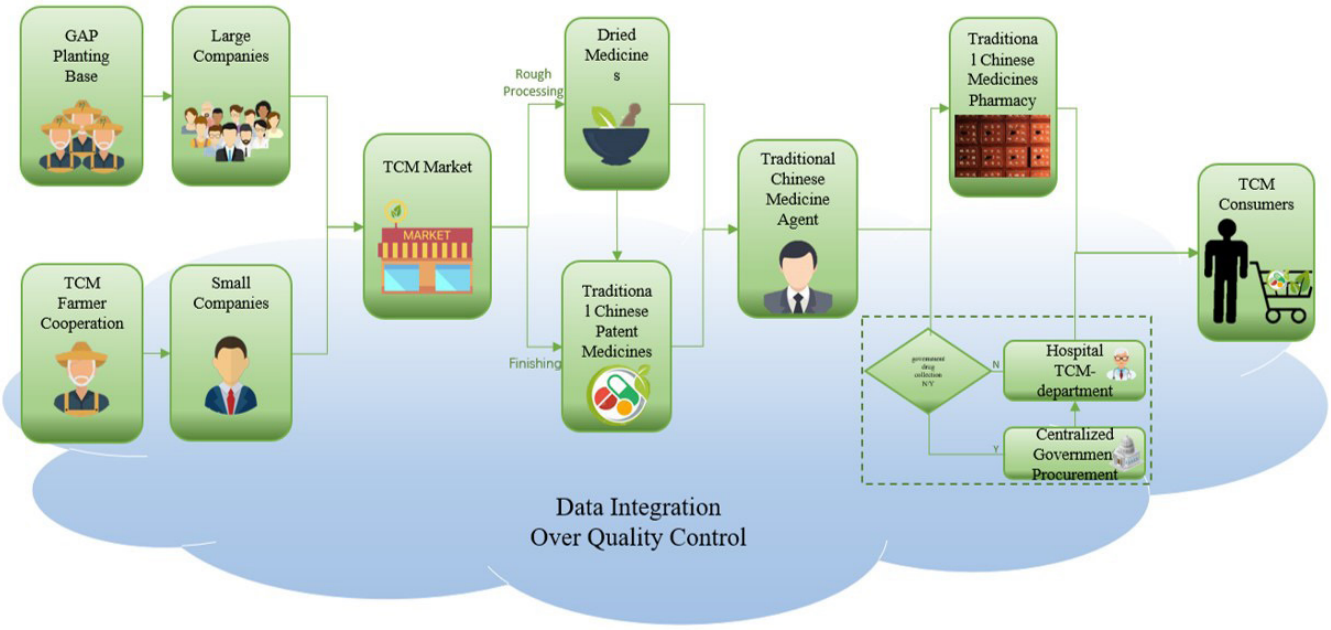

Figure 1. Depicts the entire process of Chinese herbal medicine under the quality control of the TCMQMS system, from planting, harvesting, processing and transportation to the consumer.

herbal rural cooperatives. As a result of the centralised planting, it belongs directly to the large herbal medicine suppliers and has more financial support. Therefore, the centralised planting is on a larger scale, the methods used, etc. are more advanced and the final output will all be distributed to the herbal medicine supplier to which it belongs. Under this model, most of the herbs produced are grown in large quantities and include some herbs that have special requirements for the growing environment. Rural Chinese medicine co-operatives generally work with small companies where farmers grow herbs according to Chinese herbal medicine standards. When mature, the herbs are distributed to these smaller herbal procurement companies. This cooperative model is usually a specialty herb of a particular region, or some wild herbs picked by farmers. Ultimately, the herbs transported upstream to the TCM sourcing company are first screened in accordance with the relevant regulations of China's TCM quality requirements, and then RIFD labels are placed on each herb, recording information such as origin, production time, growing conditions, and the person in charge of the growing company, before they are all sold to the centralised TCM sales marketplace under national control.

The second stage is the process by which the herbs from the centralised Chinese medicine sales market enter the Chinese medicine pharmaceutical factory, where they are processed and then passed on to the Chinese medicine distributors. Most of the medicines entering the central market are relatively fresh herbs and need to enter the herbal processing plant for processing. The processing is carried out under simulated high-quality conditions based on the characteristics of the herbs. The processing methods can be divided into the following two types, the first being rough processing into dried herbs which are then delivered directly to the herbal agent. The second is to become dried herbs after air-drying, drying, cutting, slicing and sorting, and then processed into refined Chinese medicine products such as capsules, tablets and oral liquids through steps such as powdering, purification and extraction to become proprietary Chinese medicines. Eventually, the finished products processed by the Chinese medicine factory will be labeled with RFID tags on the surface of the packaging, and the tags will add all the information about the manufacturing process of the Chinese medicine factory, including pharmaceutical humidity, temperature, information about the pharmaceutical factory, information about the person in charge of quality, the internal temperature and humidity of the carrier vehicle, GPS route information, etc., and then delivered to the Chinese medicine agent.

The final stage is the delivery of RFID-tagged TCM products to patients by TCM agents through small TCM clinics at or TCM treatment departments within large general hospitals at. It is important to note that the Chinese government will use a centralised procurement model for some of the most in-demand Chinese medicines to significantly reduce the price of Chinese medicines in order to reduce the burden on patients, by having the Chinese medicine agents determine whether the Chinese medicines are designated for centralised procurement based on the Chinese medicine purchase orders. If it is designated for centralised government procurement, it will be delivered to the centralised government procurement department, which will then wholesale it to the Chinese medicine departments of large general hospitals. If the herbs are not designated for centralised government procurement, they will be delivered directly to small Chinese medicine clinics.

At the final TCM distribution stage, if TCM pharmacists and doctors in small TCM clinics find quality problems with TCM, they can provide real-time feedback to the person in charge of the TCM manufacturer and the person in charge of the source of TCM cultivation through the TCMQMS system.

The information of the whole process is generated through blockchain technology to generate unique and unmodifiable hash values and correspondingly generated CA certificates to achieve quality traceability of TCM. Moreover, with the application of the digital twin in the Chinese medicine factory, the real-time feedback of the Chinese medicine production information can be used to continuously simulate and iterate the quality problems that the Chinese medicine may face, as well as to automatically optimize the Chinese medicine production process.

The most common source of Chinese herbal medicine for those who need it is a small herbal clinic. Most of the herbs sold in small herbal clinics are dried herbs. By scanning the RFID tag attached to the small package of raw herbal medicine using a handheld terminal embedded in the TCMQMS system, the pharmacist can obtain information on the entire process of the medicine from cultivation and collection to final manufacturing and distribution, as well as all the data on where the medicine was processed. In small herbal clinics, there are traditional pharmaceutical practices on site such as decoction and boiling, as well as dried and mixed herbs that are delivered to the patient according to a fully formulated prescription from the pharmacy.

The study uses a set of RFID tags to record the entire process and writes a unique code generated by blockchain technology into the RFID tags, recording all the details of the herbs from the time they are picked all the way to the patient. Not only does this reduce the costs associated with redundant information recording, but it also increases the transparency of the information transmission chain. In the manufacturer's pharmaceutical process, the digital twin technology is used to construct a virtual manufacturing environment through the design of the Chinese medicine manufacturing process, pharmaceutical process modelling and management of the site's humidity, temperature and other conditions, and the environment itself is constantly iteratively optimised and continuously improved, and then fed back to the sensors at the production site in real time to achieve real-time control of the manufacturing environment, with the best manufacturing production state for Chinese medicine Manufacturing.

The quality of the entire pharmaceutical process is closely monitored by the TCMQMS system. Whether it is the initial planting and harvesting of the herbs or the manufacturing in the herbal medicine factory, including the transport information, environmental information and logistics information of each delivery, the transparency of the process is so high that any deviation at any step can be sensed and dealt with in real time, effectively solving the practical problem of uncontrolled quality of herbal products and dried herbal medicines.

3.2 Digital twin technology and blockchain technology-oriented quality traceability

Digital twin technology is used to create virtual spaces and provide a quality environment for manufacturing. Digital twin technology and blockchain technology monitor quality throughout the process, improving transparency throughout the supply chain as well as controlling logistics for accurate distribution. The following are four extensions: digital twin and blockchain scenarios, operational applications, operational configuration and execution.

Digital twin and blockchain scenario definition

In the scenario of a manufacturer making herbal medicines, the characteristics of the various drugs vary. In order that better medicinal effects can be achieved, it is necessary to provide a production environment that is better suited to each according to their differences. Such environmental factors include temperature, humidity, air, etc. For example, to find the best environment for processing an herbal medicine, one can use digital twin technology to create a virtual space in which constant testing is carried out to eventually find the best environment.

Combining digital twin technology and blockchain in quality control and precision distribution, RFID tags are used to record the entire flow of information. This allows users to view and review information, and can also be used to improve quality control efficiency and tracking accuracy.

Digital twins & blockchain operational applications

The use of digital twin technology is mainly applied in the processing phase of Chinese medicine pharmaceutical factories. Blockchain technology is then used in combination with digital twin technology in the direction of quality monitoring of the production and production of Chinese medicine.

Pharmaceutical factory processing stage

A virtual TCM manufacturing scenario is established using digital twin technology to simulate the running TCM processing environment and to exchange data and information with the real TCM processing plant sensor information. Using technologies such as TCM manufacturing process simulation verification, TCM pharmaceutical state analysis and TCM pharmaceutical process problem prediction to make changes to the TCM manufacturing process and real-time data distribution by associating sensors and temperature and humidity controllers within the processing plant with each other, and by associating hardware such as smart gateways, Wi-Fi and Bluetooth with profiles such as wireless transmission protocols and network transmission protocols to realise the physical equipment of TCM manufacturing Real-time regulation and control of the physical equipment used in the manufacture of Chinese medicine, iterative optimisation and continuous improvement of the Chinese medicine manufacturing process, and ultimately the optimal Chinese medicine manufacturing parameters.

Quality control of Chinese medicine production and manufacturing

Using the digital twin in combination with the blockchain to form the Physical Layer, Digital Infrastructure, Digital Layer and Service Layer. Figure 2 shows the architecture of a Chinese medicine quality traceability platform primarily based on blockchain and digital twin technologies.

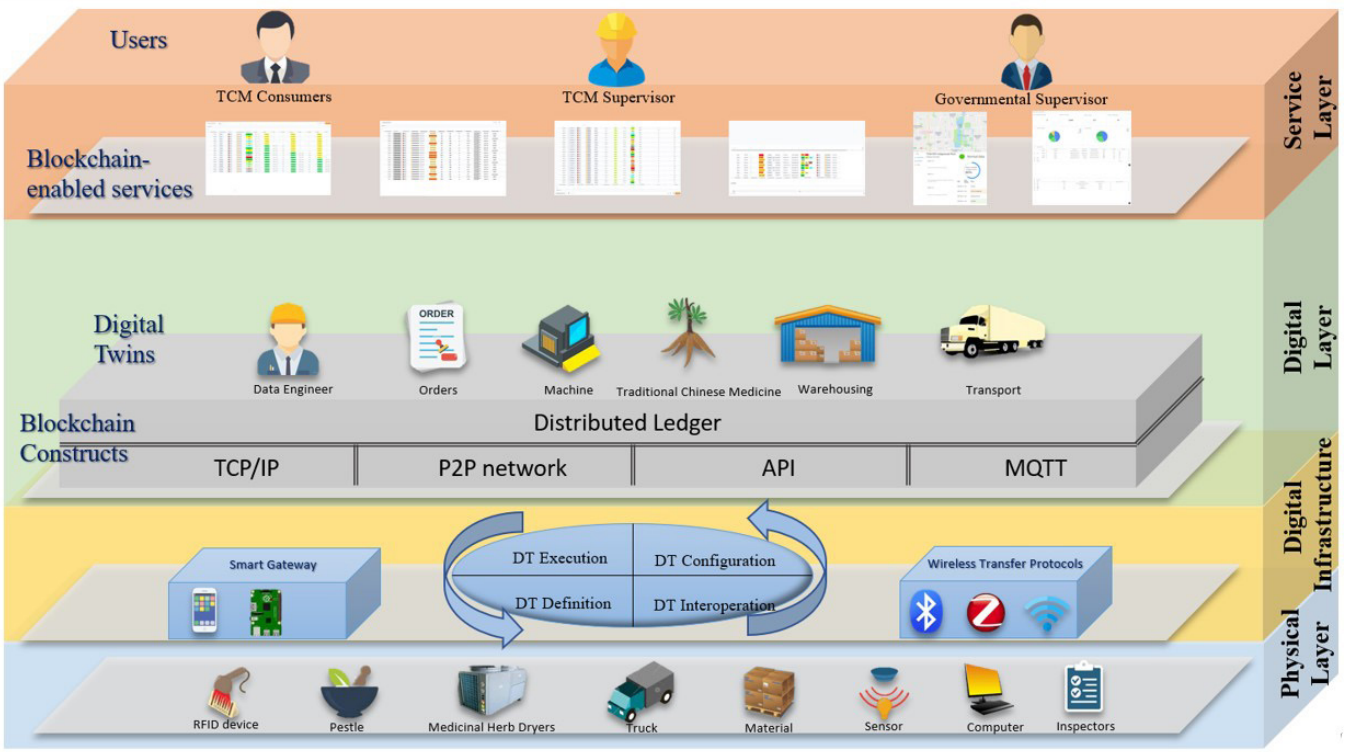

Figure 2. Blockchain and digital twin technology-based Chinese medicine quality tracing platform architecture, there are four layers: Physical Layer, Digital Infrastructure, Digital Layer, Service Layer.

The Physical Layer captures information from RFID readers, sensors and so on. The Digital Layer processes the information and passes it on to the Service Layer, which presents the data in a comprehensive manner and provides the user with a graphical representation of the environment in which the Chinese medicine is processed and its quality level, making it more intuitive and convenient. The Service Layer provides a comprehensive presentation of the data and a graphical representation of the environment in which the Chinese medicine is processed and its quality level.

Operational configuration of the digital twin & blockchain

The digital twin configuration is embodied in a variety of operations such as input, modification, update, iteration and simulation. Developers can use the digital twin to carry out simulations of raw materials in the state of the environment and combine it with blockchain to accomplish quality production, intelligent distribution, etc. This research focuses on automated operations and intelligent traceability.

Automatic operation and intelligent traceability rely on the combination of real state and virtual environment, with the simultaneous operation of hardware and software, to create an interlinked, real-time information transfer, intelligent manufacturing and information analysis system with full process traceability.

Manual operation allows the creator to set the initial data manually or to correct some incorrect data according to the real state.

The study can better control the entire quality information of TCM by acquiring, defining and compiling the data of each variable (Supplementary Material Table S1), ensuring that the quality information of TCM is in a unique and non-tamper able form by recording the hash value, as well as recording the TCM species, origin, cold chain transport vehicle code, temperature, relevant handover staff identity information, and TCM quality electronic certificate CA information. For example, once an order is received from a pharmaceutical company, the system will quickly call the data chain of the whole process with the relevant hash value and CA certificate information to repeatedly verify the source and flow of the medicine, so as to achieve "multiple codes for one thing" and "multiple data traceability" and ensure the high quality of the medicine from production to delivery. This ensures high quality from production to delivery.

As shown in Supplementary Material Table S2, the blockchain and digital twin-based traceability mechanism for Chinese medicine is developed on the basis of a combination of basic hardware configuration rules and full-flow inter-ordination rules. Pseudo-code is used to demonstrate the processing flow of the Chinese medicine information flow in the quality monitoring system. The input is a customer order with different requirements. The output is a data flow to provide downstream suppliers with blockchain information corroboration and an API interface. In Supplementary Material Table S2, "i" is the order of the customer order and k is the number of the Chinese medicine details.

Digital twin and blockchain implementation

The operation of the digital twin module is reflected in the simulation of the manufacturer's processing environment as realistic TCM manufacturing scenarios are mapped onto each other with digital TCM manufacturing scenarios.

Simultaneous simulation of Chinese medicine production in real time in the virtual scene, the optimal data is passed to the real manufacturing plant, and after the real plant executes it, the feedback data is then provided to the virtual scene in real time for continuous data analysis and processing and optimisation.

The combination of digital twin and blockchain operation is reflected in the quality traceability of Chinese medicine.

Firstly, physical devices have the ability to recognize and communicate. Then the processing of real-time information from the physical world is upgraded to the processing of twin data predicted by the simulation of the information world. Finally, the idle TCM manufacturing devices actively and automatically apply for tasks, are self-organising and self-adapting. This not only ensures the efficiency of TCM manufacturing, but also uses blockchain technology to encode the entire information flow with a unique identification code and CA certificate information, ensuring a high degree of information fidelity and making the whole process of TCM manufacturing more transparent.

4 Application mechanisms and operating principles of core technologies

The prototype TCMQMS system was developed through laboratory simulation. Service oriented development based on blockchain with digital twins and its deployment and configuration are discussed below.

4.1 Development for quality control and information management

The TCMQMS system has been designed as a web-based digital platform developed in line with the SOA design methodology and the blockchain traceability module is developed based on the Fabric blockchain framework. As shown in Figure 3, the TCMQMS system will be divided into three parts: the blockchain usage UI, the Fabric blockchain-federation chain platform and the SIA distributed storage system. As the system design is based on the SOA platform design approach, the three main parts are relatively independent and interconnected, which is a great improvement for development convenience. The three systems are interconnected and combined through APIs, and Figure 3 shows a scenario based on the blockchain module, illustrating the information flow and relationship between the three modules.

Blockchain Usage UI

The Blockchain Usage UI was designed based on a survey of the requirements of herbal growers and herbal processing factories as well as hospitals. Three blockchain usage UI's were developed to meet customer requirements, including a hospital client UI, a supplier client UI and a Fabric blockchain-federated chain development platform. The Hospital Client UI is designed for use with Traditional Chinese Medicine products to verify the quality of medicines and trace the flow of drug information. Fabric Blockchain - Alliance Chain Development Platform is a development system designed for blockchain engineers to assist developers in the maintenance and construction of blockchain platforms. HTML, React.js, CSS will be used to provide rapid development of the web architecture, featuring efficient development, stable architecture and simple code.

Fabric Blockchain - Alliance Chain Platform

The Fabric Blockchain-Federation Chain Platform module is placed in the middle of Figure 3 and acts as the core data module connecting the front and back system services, connecting, managing and maintaining other user nodes through the blockchain. the Fabric Blockchain-Federation Chain Platform is used to implement the basic blockchain functions, including the establishment of subnet Channels, EOA wallets, CA user authentication, and RAFT node sequencing (Supplementary Material Table S3).

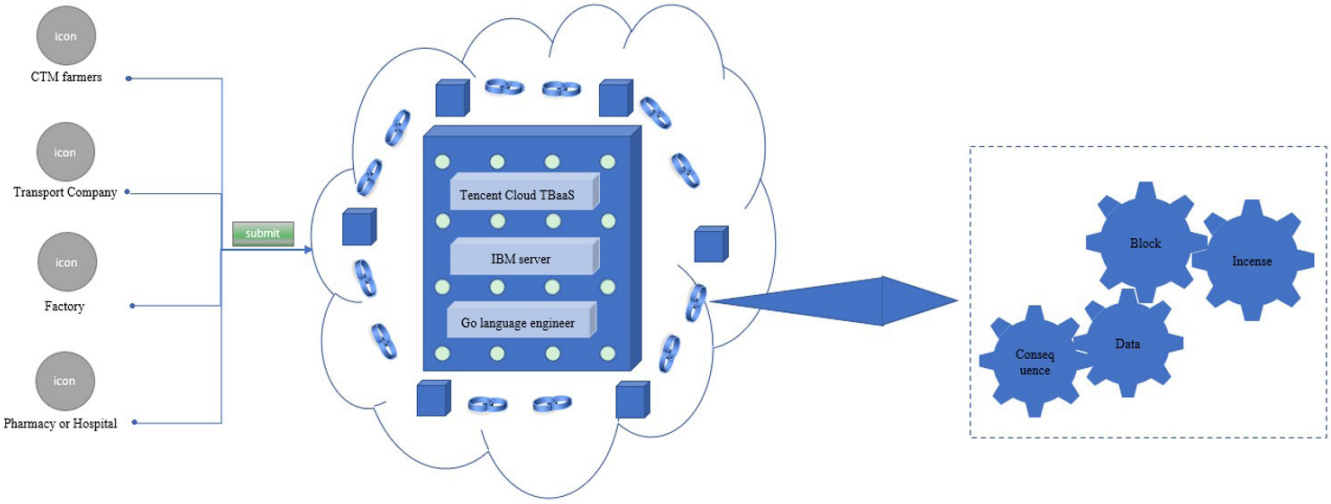

Figure 3. Blockchain module-based scenarios.

In the Fabric Blockchain - Alliance Chain Platform module, Fabric divides the entire blockchain process into three parts:

Information endorsement phase: The client sends the request information to the endorsement node, completes the business calculation through the smart contract system, completes the endorsement at the same time, and sends the result back to the client.

Data sorting phase: The client sends the endorsement results to the sorting node (orderer) via the channel, where the task information is sorted and packed into blocks, and finally distributed to all nodes connected to the channel.

Data validation and writing to the ledger phase: The system will receive the new block information to all Channel nodes through the Gossip network and will validate the block details to ensure they are complete and valid, invalid information will be marked as "invalid".

Sia distributed storage system

Sia is a distributed and decentralised storage system. Sia is used to store large files and images, etc. It is used to improve the efficiency of data transfer within the blockchain and to increase the storage limit, and with the blockchain transfer of relevant item information and traceability information, it can significantly save blockchain storage space and optimise the platform performance can also be optimised.

5 CASE STUDIES

5.1 Scene description

The TCMQMS system is a complete supply chain system for Chinese medicine. The main objective of the system is to shape a complete, transparent, accurate and traceable TCM supply chain. As shown in Figure 4, the entire supply chain can be divided into four stages: origin, processing, transportation and retail. In the origin stage, harvesting is carried out by the herbal growers, and after harvesting, a special RFID tag is attached to the product packaging. In the processing stage, the raw materials are first read and written to, and the incoming Chinese medicine information can be quickly identified and compared with the RFID reader set up on the roof of the Chinese medicine processing plant, and then the rough processing and finishing of the Chinese medicine is carried out in batches, and after processing in the Chinese medicine factory, in-depth information on each step of the processing process is added to the RFID tag, including information on the production process, production environment While processing, the digital twin system module will match all the blockchain data streams in the factory with the production line's pharmaceutical machines, and by continuously inputting new processing data into the digital twin module, the system will simulate the entire digital process of the pharmaceutical factory and rely on the constantly updated processing data of the Chinese medicine The information flow allows for better iterative upgrading of the current digital twin module, making it more capable of predicting possible problems in the production line, with higher prediction accuracy, and reaching a level where the environmental parameters of the production line are adaptively improved with the predicted values of the digital twin module at the same pace as the information from the environmental sensors (temperature, humidity, oxygen content) in the factory, resulting in fully automated production parameter adjustment.

And all these data will be packaged into information blocks on the blockchain, endowed with unique hash values and CA

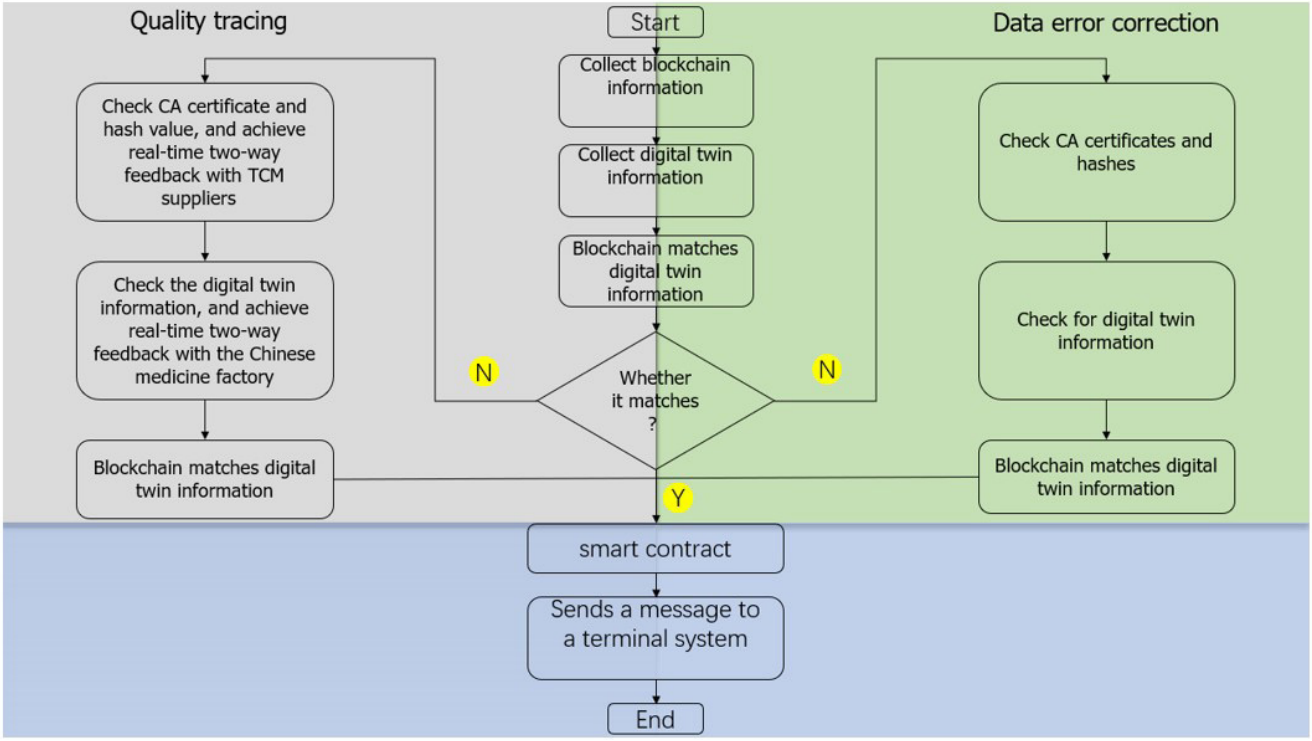

Figure 4. TCMQMS system flow chart.

certificates, and automatically entered into the TCMQMS Chinese medicine quality traceability system. Next, in the transport chain, the handheld RFID terminal embedded in the TCMQMS system will carry out the identification of the transport outgoing information, which will allow the carrier information, carrier vehicle number and the environmental sensor data inside the vehicle to be updated to the RFID tag and the TCMQMS system in real time, while simulating the transport situation inside the vehicle in real time with the help of the digital twin module, and reaching two-way transmission with the environmental sensor data inside the transport vehicle.

Based on the digital twin module, the best suitable environmental parameters are predicted in real time. Finally, during the sales phase of Chinese medicine, Chinese medicine pharmacies and hospitals can scan RFID tags to obtain all information about the Chinese medicine, including the entire and untameable Chinese medicine production data stream, so that if a patient gives feedback on the possible quality of the medicine, doctors and pharmacy staff can quickly pull out the entire information stream to assist in quality tracing, and information on quality issues will be synchronised in real time to the relevant The information on quality issues is synchronised in real time to the relevant system users and managers, providing real-time solutions.

The main scope of this paper is to propose a complete Chinese medicine quality traceability scheme from scratch to ensure quantitative control of the Chinese medicine production environment as well as efficient information transfer and quality monitoring.

The TCMQMS system is designed to provide a complete overview of the whole process of quality tracing of Chinese herbs, but in terms of implementation, there are two problems. Firstly, as most herbs have a short processing period after harvesting, it is a key issue to reduce transport losses quickly, in real time and to a large extent. The digital twin is a very effective way to simulate the transport environment. So how can digital twins be used to find the most suitable environment? How can RFID technology be used to accurately record all information about a medicine?

Step1:Adding RFID tags to medicines. The herbal medicines produced by the plantation and the herbal rural cooperative are tagged with RFID tags before moving on to the next stage. The RFID tag will be used throughout the supply chain to record all information about the medicine at that stage, such as origin, planting time, picking time, maturity level, soil environment, etc. All information will be uploaded to the TCMQMS Chinese Medicine Quality Tracking System in real time, helping to improve data accuracy and traceability of the medicines. As most medicines are produced in bulk, the RFID tags are packaged to record the information as a unit.

Step2:During the transport process, the sensor data in the vehicle will be combined with the digital twin module to simulate the temperature, humidity and other conditions in the vehicle according to the suitable storage environment of the medicine, adjusting the optimum environment in real time for application and transporting herbs with similar suitable environment in the same batch. Real-time information about the transport will also be transmitted in real time to the TCMQMS Chinese medicine quality monitoring system via tags, facilitating storage preparation and quality management.

Step3:In a Chinese medicine factory, raw materials are received and roughly processed and refined according to their use and formulation. In order to ensure that the efficacy of the herbs can be monitored in real time and that the quality can be traced, we have embedded a digital twin module in the TCMQMS system to explore the optimum environment in real time by simulating a series of production conditions such as temperature and humidity to optimise the processing of the medicine.

Step4:Adding information to the RFID tag. In Step1, details such as the origin and picking time of the medicine and the subsequent transport environment are added to the RFID tag. In Step3, information on the environment of the drug production line and the name of the drug after processing and the person in charge of the pharmaceutical are added to the RFID tag. The information is highly transparent, tamper-evident and updated in real time throughout the entire process of the drug. For example, if a Chinese medicine pharmacy or hospital receives a drug and finds that there may be a quality problem with it, the information on the RFID tag can be read to trace the quality and the information is synchronised in real time to the person responsible for the drug and the person responsible for providing a solution in real time.

Step5:Reading the data packets carried in RFID tags. During the flow of Chinese medicine, the RFID tags are scanned by staff as the medicine flows into pharmacies and hospitals to capture the full flow of information and timelines about the planting, harvesting and transport of the medicine. The information is used to further process the Chinese medicine. From a TCM perspective, the most significant impact on the quality of TCM is the growing and transport environment. The TCMQMS system can be used to provide real-time feedback on the whole process of Chinese medicine, and can be used to guide pharmaceutical companies in Chinese medicine by relying on blockchain technology and digital twin technology.

5.2 System applications

In order to demonstrate the effectiveness of the TCMQMS system, the key services, workflows and supporting technologies of the system are discussed in this sub-section.

UI interface

Image X shows the operation of the TCMQMS system to provide information technology services to a Chinese medicine manufacturer. The system is designed specifically for Chinese medicine manufacturers, Chinese medicine suppliers and Chinese medicine pharmacies to create their own orders, update material information, manage the status of their medicines, view their environment, track their movements and monitor their overall information. TCMQMS system specifically has the following 6 steps.

Step 1: Create a new order message. There are two ways to create new order information. The first way is for the supplier to

synchronise the sales order to the cloud in real time and the information will be synchronised back to the TCM company. The second method is for the TCM company to manually enter the order information. The main difference is that using a real-time synchronised cloud computing platform to transfer the data will improve the accuracy of the data and save the company time in filling it.

Step 2: Update corporate material information. When the product information is transmitted to the pharmaceutical company through the platform, the pharmaceutical company will be able to see the implementation status of their purchased medicines and their location in real time in the system platform. The blockchain technology is used to control the accuracy of the information transmission, ensuring that the information is highly transparent, tamper-proof and updated in real time throughout the whole process of transporting the goods from the supplier to the manufacturer.

Step 3: Manage the status of the medication. When the drug arrives at the pharmaceutical company's warehouse, the system matches the RFID tags in the warehouse and completes the information transfer process. For example, the system will capture the raw materials, basic drug information, transit time, transit location, transit environment and arrival time via RFID tags. When the product arrives, this information will be read directly from the RFID reader at a fixed location in the warehouse.

Step 4: View the drug environment. Once the drug information is synchronised to the system platform in real time, company managers can use the system's pre-defined dashboard to conduct comprehensive analysis and observation of the drug's environment and make targeted adjustments to the drug production line to meet quality control needs.

Step 5: Track the drug's path. Once the raw drug has been produced at the Chinese medicine manufacturer, information from the assembly line will be synchronised to the system in real time. The system will prompt the purchaser in the next stage to prepare the drug for receipt and hand over the relevant information.

Step 6 Overall information monitoring. At the end of each order, the system will automatically analyse the information quality of the whole process to determine whether there is any tampering with every detail of the information and the information on the blockchain. This ensures that the information in the system is reliable and tamper-proof at all times.

Analysis of results

In the solution, the digital twin and blockchain technology embody several resultant features.

Traceability: Blockchain combined with IoT technology, each package of stored and transported Chinese medicine has an RFID Tag on top, by writing information such as time, location, temperature, humidity and handover personnel into the RIFD tag in real time. The smart gateway can ensure the integrity of the sensor data of the cargo medicine with the help of the data blocks of the blockchain. This information can reflect the quality traceability of the Chinese medicine during the transportation process. TCMQMS users can access this information to achieve quality traceability and quality control of the Chinese medicine.

Immutability of information: Immutability is where blockchain technology excels and is at the heart of building trust relationships. Blockchain's immutability of information can avoid a crisis of trust while ensuring reliable and valid information in the whole process of Chinese medicine. Each block is associated with the hash value and CA certificate of the previous block. Once any Chinese medicine information data is changed, it may lead to the invalidation of all the data that follows due to the waterfall effect, ensuring that any forgery can be reacted to in real time.

High transparency: All stakeholders using the TCMQMS system and possessing the public key can freely view the recorded TCM information and quality information. Each stakeholder has access to quality information details from TCMQMS. This equal access mechanism establishes a quality information system that is jointly monitored upstream and downstream in the supply chain.

Non-repudiation: Spatio-temporal tokens are added to the sensor data to verify the data blocks generated by the blockchain data. The private key is used to endorse each operation. Neither of these actions can be denied by any third party.

Accurate mapping, intelligent intervention: TCMQMS can use digital twin technology to achieve accurate mapping in terms of pharmaceuticals and herbal transport, simulating the entire digital process of a pharmaceutical factory and making adaptive adjustments to the Chinese medicine processing machines and sensor linkages while continuously optimising iterations in the simulation process.

6 Conclusion and future work

From the practical case studies, key findings and results have been summarised which will help to provide a new Chinese medicine quality traceability solution for Chinese medicine manufacturing plants. Due to the special physical nature of TCM, it is highly susceptible to the external environment of cultivation and transportation, which in turn affects the drug activity, thus leading to the inability to accurately quantify the treatment of TCM-based therapeutic modalities and affecting the development of the Chinese TCM industry. From different perspectives, stakeholders want a reliable whole process system for monitoring the quality of TCM. To address these issues, we propose a platform (called TCMQMS) for addressing the whole process information monitoring of TCM quality. The main contributions of this paper include, firstly, providing a common quality monitoring platform for the whole process of the TCM supply chain stakeholders, taking into account the complexity of TCM cultivation as well as distribution. The main technologies involved are a blend of blockchain technology, digital twin technology, and IoT technology. Secondly, through the in-depth integration of digital twin technology and blockchain technology, we have achieved a quality control method for the

whole process of Chinese medicine from cultivation to final delivery to patients, especially for the possible environmental factors in the processing and transportation of Chinese medicine. The information is fully transparent. It solves the fundamental problem that raw materials of Chinese medicine cannot be traced back to their source. Through this system, stakeholders in the entire Chinese medicine supply chain can precisely control the current status of Chinese medicine. The introduction of digital twin technology also makes a positive contribution to the overall level of TCM manufacturing and the reduction of TCM manufacturing losses, by simulating the TCM production line in real time without interruption, predicting possible quality problems and transmitting the simulation data back to the production line in real time in both directions to achieve autonomous control of the production line and real-time quality warning.

Moreover, as the system introduces a quality traceability system fused with blockchain and digital twin, it can provide real-time feedback to the person in charge of Chinese medicine manufacturing and other stakeholders in the first instance when they discover possible quality problems, and jointly assist in solving possible problems with the quality of Chinese medicine. Thirdly, by introducing the Fabric blockchain construction model and the Sia distributed storage system, we have successfully solved the problem of implementing the traceability function of the whole process of Chinese medicine quality and the storage and management of the whole process and large flow of Chinese medicine information data. The introduction of the Fabric blockchain construction platform and Sia distributed storage system can significantly reduce the investment cost of the system users, and at the same time, the platform can be built quickly and customized by enterprises, which lays a cost basis for the future promotion of the system. We have also proven the effectiveness of the TCMQMS system at a practical level by introducing real-life cases.

In future research, we will focus on the following areas: (1) Exploring how to motivate more TCM supply chain stakeholders to join the platform and improve the relevant joining incentive mechanism to achieve a breakthrough in the number of platform users. (2) To investigate more advanced data storage compression algorithms, as the storage capacity of RFID tags and the bandwidth of data that TCMQMS systems can handle simultaneously are limited.

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Supplementary Material

Supplementary material accompanies this paper.

Table S1. The notation in Chinese medicine quality monitoring system

Table S2. System data flow code

Table S3. TCMQMS System development and deployment environment

This material is available as part of the online article from https://doi.org/10.1590/fst.122022