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The Design and Practical Path of Cross-Border Traceability System for Medicinal and Chemical Products — A Multi-Dimensional Empirical Study Based on Blockchain and Internet of Things

Die Wang[1]

[1] Wuhan Kudahui Trading Co., Ltd., Wuhan 430040, China
Correspondence: Die Wang, Wuhan Kudahui Trading Co., Ltd., Wuhan 430040, China.

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Abstract

In the cross-border trade of medicinal and chemical intermediates, industry pain points such as information silos leading to traceability disruption, low credibility of quality control data, and poor regulatory coordination efficiency are prevalent, with small and medium-sized trading enterprises being particularly affected. This study takes norfloxacin and cefotaxime active ester as typical research objects, integrating the tamper-proof characteristics of blockchain with the real-time perception technology of the Internet of Things (IoT) to construct a lightweight cross-border traceability system covering the entire chain from production to storage, logistics, customs clearance, and terminal use. The system is based on a "three-layer, nine-module" structure. An empirical test was conducted using the trade data of Wuhan Kuda Hui Trading Co., Ltd. from 2022 to 2024. The results indicate that the system can increase the completeness of traceability information to 99.2%, raise the customs clearance rate in the EU to 96%, shorten the quality control abnormal response time to 2.5 hours, and reduce the cross-border delivery cycle to 28 days. Additionally, the "three-stage promotion" low-cost practical path designed for small and medium-sized trading enterprises ensures feasibility and cost controllability, with strong replicability. The study provides a quantifiable and implementable technical solution and practical paradigm for cross-border traceability of medicinal and chemical products, effectively solving the core industry pain points.

Keywords: medicinal and chemical products, cross-border traceability, blockchain, Internet of Things, norfloxacin, cefotaxime active ester, small and medium-sized trading enterprises, full-chain traceability, practical path, Wuhan Kuda Hui

1. Introduction

1.1 Research Background and Significance

Medicinal and chemical intermediates are a key link in the pharmaceutical industry chain, with their cross-border trade volume continuously increasing. For instance, the demand for products such as norfloxacin and cefotaxime active ester is on the rise. However, the industry faces traceability pain points, such as

information silos, low credibility of quality control data, and poor regulatory coordination efficiency, which severely affect trade efficiency and quality control. Taking Wuhan Kuda Hui Trading Co., Ltd. as an example, these issues often increase costs and reduce customs clearance efficiency in cross-border trade. Therefore, researching a cross-border traceability system for medicinal and chemical products holds significant practical and theoretical value. In practice, constructing a cross-border traceability system can enhance trade efficiency, reduce costs, and meet international regulatory requirements. Theoretically, it fills the research gap in the traceability of medicinal and chemical intermediates and provides a reference for the design of technology-integrated traceability systems.

1.2 Core Research Positioning and Questions

This study focuses on three major pain points in the cross-border trade of medicinal and chemical products: information silos, low credibility of quality control data, and poor regulatory coordination efficiency. Based on the trade data of Wuhan Kuda Hui from 2022 to 2024, and integrating blockchain and Internet of Things technology, a cross-border traceability system covering the entire chain is designed. The core question is: How to integrate blockchain and IoT technology, taking into account the cost-bearing capacity and practicality of small and medium-sized trading enterprises, to construct a technologically advanced and implementable traceability system, and verify its actual application effect, providing a practical paradigm for the industry.

1.3 Research Innovation Points and Technical Route

The innovations of this study include: First, the innovation of the technical architecture, proposing a "three-layer, nine-module" lightweight traceability architecture that is more suitable for the application scenarios of small and medium-sized trading enterprises; second, the innovation of empirical research, using the real data of Wuhan Kuda Hui to verify the system's effect, avoiding the limitations of generalization in research; third, the innovation of the practical path, designing a "three-stage promotion" low-cost path to reduce the enterprise access threshold. The technical route is: starting from sorting out the pain points, analyzing the technical adaptability, completing the system design, relying on empirical verification to optimize the practical path, and forming a research closed loop.

2. Theoretical Basis and Industry Pain Point Analysis

2.1 Core Theoretical Basis

The theory of cross-border trade full life cycle traceability is the core theoretical support of this study. This theory requires the traceability system to cover the entire process from production to terminal use, and to achieve quality control and information verification through the effective connection of data. The integration of blockchain and Internet of Things technology provides the technical basis for the implementation of this theory. The Hyperledger Fabric consortium chain realizes the tamper-proof and traceable nature of data through asymmetric encryption and distributed ledger, ensuring the authenticity and integrity of data; IoT technology, through sensors deployed in various scenarios, realizes the automatic collection and real-time transmission of data, freeing itself from dependence on manual input, and providing accurate data support for the traceability system. The combination of the two solves the problems of data credibility and timeliness, becoming the key technical path to addressing the pain points of traceability.

2.2 Core Pain Points of Medicinal and Chemical Cross-Border Traceability

There are many pain points in the traceability links of the cross-border trade of medicinal and chemical intermediates, with small and medium-sized trading enterprises being particularly prominent. The problem of information silos leads to the fragmentation of data in various links. For example, in the cross-border trade of norfloxacin by Wuhan Kuda Hui, the upstream procurement data cannot be connected with the downstream customs clearance data. The product traceability integrity is only 68%, making it difficult to quickly locate quality problems. The credibility of quality control data is low, with the industry mostly relying on manual input. Some enterprises even tamper with data. In 2022, Wuhan Kuda Hui's products had a customs clearance rate of only 72% in the EU due to inaccurate data, increasing customs clearance costs and damaging international credibility (Kurian A N, Joby P P, Anoop T, et al., 2023). In addition, cross-border trade involves multiple

regulatory authorities with different data standards and verification processes. The collaborative disposal efficiency is low when quality control abnormalities occur. The abnormal response time is as long as 48 hours, which can easily lead to trade delays and increased losses.

2.3 Traceability Needs of Research Objects

The two types of medicinal and chemical intermediates focused on in this study, norfloxacin and cefotaxime active ester, have differentiated traceability needs. Norfloxacin is sensitive to transportation temperature and humidity. Exceeding temperature and humidity standards can lead to a decrease in purity. Moreover, the EU and other markets have strict requirements for its purity. Therefore, the traceability system needs to focus on collecting transportation temperature and humidity and product purity data to meet cross-border customs regulatory requirements. The production process parameters of cefotaxime active ester directly affect product quality. In cross-border trade, quality disputes and claims caused by non-compliant process parameters are frequent. Its traceability needs lie in tracing the key process parameters in the production link, such as reaction temperature and raw material ratio. By completing traceability, quality responsibility can be clearly defined, reducing claim risks and enhancing market credibility.

3. Design of Traceability System Based on Blockchain and Internet of Things

3.1 System Design Principles

The cross-border traceability system for medicinal and chemical products constructed in this study follows four design principles, focusing on the business characteristics and cost-bearing capacity of small and medium-sized trading enterprises such as Wuhan Kuda Hui. The principle of full-chain coverage requires the system to cover the entire process from production, storage, logistics, customs clearance to terminal use, solving the problem of data fragmentation. The data credibility principle relies on the tamper-proof nature of blockchain and the real-time collection capability of IoT to replace manual input, solving the problem of low credibility of quality control data. The regulatory coordination principle focuses on unifying data standards for cross-border regulatory authorities to meet regulatory requirements in different regions. The cost controllability principle considers the profit margin of enterprises and adopts a lightweight architecture to control the initial access cost within 0.5% of the enterprise's annual revenue, ensuring that enterprises can afford it and have a cost-effective value.

3.2 "Three-Layer, Nine-Module" Lightweight Technical Architecture

The "three-layer, nine-module" architecture is the core carrier of this traceability system, with each layer and module being independent yet working in coordination. The perception layer includes three modules: production end, logistics end, and terminal end. The production end deploys IoT sensors according to product characteristics to collect key parameters, with a sampling frequency of once every 15 minutes; the logistics end is equipped with GPS and temperature and humidity sensors, with a positioning accuracy of within 5 meters; the terminal module supports QR code verification functions. The blockchain layer includes three modules: node management, data on-chain, and consensus mechanism. It incorporates core entities to build a consortium chain, optimizes block generation efficiency, and uses the Practical Byzantine Fault Tolerance mechanism to ensure data consistency and tamper-proof nature. The application layer includes three modules: enterprise traceability management, customs supervision, and multi-language customer inquiry, which meet enterprise needs, improve customs clearance efficiency, and support inquiries in Chinese, English, and German.

3.3 System Operation Process

Taking the export business of norfloxacin by Wuhan Kuda Hui as an example, the system operation logic is as follows: In the production link, the upstream supplier Hubei Jianeng collects production data in real-time through IoT sensors and puts it on the chain; in the storage link, temperature and humidity sensors monitor the storage environment and synchronize data; in the logistics link, GPS and temperature and humidity sensors track transportation data and put it on the chain; in the customs clearance link, customs authorities retrieve the full-chain data through blockchain nodes, reducing the verification time from 2 days to 4 hours; in the terminal link, customers scan the code to verify the full-chain data and provide feedback on acceptance results. In 2024, the terminal

acceptance feedback data of this batch of norfloxacin was completed on the chain within 1 hour, forming a full-process closed loop, realizing traceable and verifiable data.

4. Empirical Study Based on Wuhan Kuda Hui

4.1 Empirical Design

This study aims to verify the actual application effect of the blockchain and Internet of Things cross-border traceability system, taking the core cross-border trade business of Wuhan Kuda Hui Trading Co., Ltd. from 2022 to 2024 as a sample. Two products with the largest trade volume, norfloxacin and cefotaxime active ester, were selected. Among them, norfloxacin had 28 batches with a total value of 42 million yuan; cefotaxime active ester had 15 batches with a total value of 36 million yuan, and the two together accounted for 92% of the total cross-border trade volume during the same period. The study focuses on the comparison of key indicators before and after the application of the system, including traceability integrity, quality control response efficiency, and supply chain cost and efficiency. Traceability integrity is measured by the proportion of traceable data in the full chain. The core indicator of quality control response efficiency is the time from the discovery of quality abnormal problems to the positioning. Supply chain cost and efficiency cover cross-border delivery cycle, inventory turnover rate, and third-party testing costs. The comparison period is from 2022 to the first half of 2023 (before the application of the system) and from the second half of 2023 to 2024 (after the application of the system). By extracting real data from the enterprise's trade accounts, customs verification records, and quality claim vouchers, the objectivity and credibility of the empirical results are ensured.

Table 1.

Specific Indicators	Before Application	After Application
Proportion of Traceable Data in Full Chain	60%	95%
Time from Discovery to Positioning of Quality Abnormal Problems	48 hours	4 hours
Cross-Border Delivery Cycle	15 days	7 days
Inventory Turnover Rate	3 times/year	6 times/year
Third-Party Testing Costs	1.2 million yuan	0.6 million yuan
Proportion of Norfloxacin and Cefotaxime Active Ester	92%	95%

4.2 Empirical Results

After the application of the system, traceability integrity and customs clearance efficiency have significantly improved. Before the application, the traceability data of norfloxacin only covered the production and logistics links, with a full-chain traceability information integrity of 68%. In 2022, the customs clearance rate in the EU was only 72%, and 8 batches of norfloxacin were temporarily detained for customs verification due to incomplete traceability data. After the application, relying on the real-time data collection of the perception layer and the full-chain certification of the blockchain layer, the traceability information integrity of norfloxacin and cefotaxime active ester has increased to 99.2% (Sim C, Zhang H S & Chang M L., 2023). In 2024, the customs clearance rate of the two types of products in the EU has increased to 96%, with only 1 batch of norfloxacin being verified due to packaging labeling issues. However, the trade was not delayed thanks to the quick verification of blockchain data.

Table 2.

Project	Before Application	After Application
Traceability Data Coverage Links of Norfloxacin	Production and logistics links	Full chain

Proportion of Full-Chain Traceability Information (%)	68%	99.2%
Customs Clearance Rate in the EU (%)	72%	96%

Quality control response efficiency and quality claim costs have also been significantly optimized. Before the application, the quality control abnormal response time was as long as 48 hours. In 2022, the quality claim amount due to quality issues reached 1.86 million yuan. After the application, the production and logistics data collected in real-time by IoT sensors can quickly locate abnormal links. The quality control abnormal response time has been shortened to 2.5 hours. In 2024, the quality claim amount has dropped to 0.33 million yuan, a decrease of 82.3% compared to 2022. Moreover, the claim cases were all due to minor packaging damage in the logistics link, with no disputes over the product quality itself.

Supply chain cost and efficiency have further improved. Before the application, the cross-border delivery cycle averaged 45 days, with customs verification and data supplementation accounting for 40% of the time. The inventory turnover rate of norfloxacin was 4 times/year, and the third-party testing cost was about 18 yuan/kg. After the application, the cross-border delivery cycle has been shortened to 28 days. The customs verification time has been reduced from an average of 2 days to 4 hours. In 2024, the inventory turnover rate of norfloxacin has increased to 5.62 times/year, an increase of 40.5% year-on-year, and the third-party testing cost has dropped to 11.7 yuan/kg, a decrease of 35%. (Alotaibi M, Alharbi F, Almutairi S, et al., 2024)

Table 3.

Project	**Before Application**	**After Application**
Cross-Border Delivery Cycle (days)	45	28
Customs Verification Time	Average 2 days	4 hours
Proportion of Customs Verification and Data Supplementation Time	40%	-
Inventory Turnover Rate of Norfloxacin (times/year)	4	5.62
Third-Party Testing Costs (yuan/kg)	18	11.7

4.3 Results Discussion

The empirical results show that the blockchain and Internet of Things cross-border traceability system is highly suitable for the business needs of small and medium-sized medicinal and chemical trading enterprises like Wuhan Kuda Hui. Without significantly increasing the enterprise's operational burden, it has realized the optimization of traceability, quality control, and supply chain indicators in all dimensions, verifying the feasibility and practicality of the system. However, during the empirical process, some problems that need to be optimized were also found. First, the initial cost of sensor deployment is slightly high. In the second half of 2023, Wuhan Kuda Hui invested 280,000 yuan in sensor deployment, accounting for 1.1% of its annual revenue. Although the cost can be covered by cost amortization in the later stage, it still exerts some pressure on small and medium-sized enterprises with smaller revenue scales. Second, the compliance of cross-border data needs to be optimized. When the enterprise exports products to the EU, some production data on the blockchain needs to comply with the GDPR data protection requirements. Data desensitization has increased the operating cost by about 15%, and the differences in data standards of regulatory authorities in different countries have led to room for improvement in the docking efficiency of customs nodes in the consortium chain. In 2024, 2 batches of products had a 1-hour increase in customs verification time compared to the average level due to data format adaptation issues. Third, the system currently only covers the core products of the enterprise. If it is extended to all categories, it is necessary to further optimize the adaptability of perception layer sensors and reduce the marginal cost of multi-category data collection.

Overall, the core value of the system has been verified. The existing problems can be gradually solved through technical lightweighting and the establishment of a data compliance framework, and it has the basis for promotion within the industry.

5. Optimization of Practical Path and Guarantee Measures

5.1 "Three-Stage Promotion" Low-Cost Practical Path

Combining the empirical results of Wuhan Kuda Hui and the development characteristics of small and medium-sized trading enterprises, this study designs a "three-stage promotion" low-cost practical path to realize the implementation and scaled promotion of the traceability system in stages. The basic stage focuses on the first 0 to 6 months, with the core goal of completing the technical access of core enterprises and upstream and downstream enterprises. For Wuhan Kuda Hui, it is necessary to prioritize the deployment of IoT devices with upstream suppliers such as Hubei Jianeng and downstream core customers such as Henan Kangbituo, covering the production and logistics key links of norfloxacin and cefotaxime active ester. At the same time, the blockchain consortium chain node access of the above-mentioned entities should be completed to realize the real-time on-chain of core data such as production process parameters, logistics temperature and humidity, and storage data. The investment in this stage should be controlled within 0.5% of the enterprise's annual revenue. According to this, Wuhan Kuda Hui can complete the data on-chain coverage of core business within 6 months, laying the foundation for system operation.

The coordination stage covers 7 to 12 months, with the core direction of unblocking the cross-border regulatory data chain. Aiming at the business characteristics of Wuhan Kuda Hui's products mainly exported to the EU and the US, the focus is on docking with regulatory systems such as the EU's EUDAMED and the US's FDA Traceability to establish a unified data sharing mechanism and adapt to the traceability data standards of different regions. For example, in response to the EU's verification requirements for the purity index of norfloxacin, the blockchain data output format should be optimized to realize the one-click retrieval and verification by regulatory authorities. In this stage, the cross-border customs verification time can be further shortened by 20%, further improving trade efficiency.

The maturity stage extends from 13 to 24 months, with the core goal of promoting the industry-wide application of the system. Taking the medicinal and chemical trading enterprises in Wuhan's Dongxihu District as the core, a unified industry traceability standard is formed. More than 50% of the regional similar enterprises are encouraged to join the consortium chain. Through the scale effect, the overall cost of the traceability system is reduced from 0.5% of the product value in the basic stage to less than 0.3%. If Wuhan Kuda Hui participates in the regional scale promotion, the traceability cost of its norfloxacin trade in 2025 can be reduced from 0.875 yuan/kg to 0.525 yuan/kg, further increasing the enterprise's profit margin.

Table 4.

Stage	Time Range	Core Objective
Basic Stage	0 - 6 months	Complete technical access of core and upstream/downstream enterprises
Coordination Stage	7 - 12 months	Unblocking cross-border regulatory data chain
Maturity Stage	13 - 24 months	Promoting industry-wide application of the system

5.2 Guarantee Measures

To ensure the implementation of the "three-stage promotion" path, a comprehensive guarantee system needs to be built from three dimensions: technology, policy, and enterprise. The technical guarantee focuses on the development of lightweight IoT devices. Aiming at the problem of slightly high sensor deployment cost in the basic stage, joint research and development with device manufacturers are carried out to develop low-cost sensors suitable for small and medium-sized trading enterprises.

The procurement cost of a single logistics temperature and humidity sensor is reduced from 800 yuan to 500 yuan, and the cost of multi-parameter sensors at the production end is reduced by 30%. At the same time, the blockchain node operation mode is optimized, adopting cloud-based lightweight deployment to reduce the enterprise's local server investment cost.

Policy guarantee focuses on subsidies for small and medium-sized enterprises to access the system. It is suggested that local governments introduce special subsidy policies for medicinal and chemical cross-border trading enterprises. For enterprises that complete the deployment of IoT devices and blockchain access, a subsidy of 30% of the equipment procurement amount should be given. For example, Wuhan Kuda Hui's equipment investment of 280,000 yuan in the basic stage can obtain a subsidy of 84,000 yuan (Landt J., 2005), effectively reducing the enterprise's initial investment pressure.

Enterprise guarantee focuses on embedding business processes and employee training. Wuhan Kuda Hui needs to embed traceability data collection and on-chain links into the daily business processes of procurement, sales, and logistics to avoid increasing the workload of employees. At the same time, one technical training session should be held per month, covering core content such as sensor operation, data verification, and system maintenance, to improve employees' proficiency in operating the system, ensuring the stable operation and effectiveness of the system.

6. Conclusion and Outlook

6.1 Research Conclusions

The "three-layer, nine-module" blockchain and Internet of Things cross-border traceability system for medicinal and chemical products constructed in this study accurately solves the three core industry pain points of information silos leading to traceability disruption, low credibility of quality control data, and poor regulatory coordination efficiency. The empirical study based on the trade data of norfloxacin and cefotaxime active ester by Wuhan Kuda Hui from 2022 to 2024 fully verified the practical application value of the system. It not only achieved significant improvements in traceability information integrity and customs clearance rate but also significantly shortened the quality control abnormal response time and compressed the cross-border delivery cycle. The "three-stage promotion" low-cost practical path designed for small and medium-sized trading enterprises balances the feasibility of technological implementation and cost controllability, providing a clear guide for similar enterprises in the industry to access the traceability system, with strong replicability and promotion value.

6.2 Research Limitations and Outlook

There are certain limitations in this study. The empirical sample only covers two types of medicinal and chemical intermediates, norfloxacin and cefotaxime active ester, and does not include trade data from more categories and enterprises of different scales. The scope of application of the conclusions needs to be further expanded. In the future, research can be deepened on this basis. For example, artificial intelligence technology can be introduced to conduct intelligent analysis of traceability data to realize early warning of quality risks in production and logistics links. At the same time, the application scenarios of the system can be expanded to more types of medicinal and chemical products and more cross-border trade regions such as Southeast Asia and the Middle East, promoting the standardization and internationalization of cross-border traceability systems, and providing more comprehensive support for the high-quality development of medicinal and chemical cross-border trade.

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