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ARCHITECTING DSCSA-COMPLIANT SYSTEMS FOR REAL-TIME INVENTORY MANAGEMENT IN HIGH-VOLUME RETAIL PHARMACY NETWORKS

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ABSTRACT

The U.S. Drug Supply Chain Security Act (DSCSA) requires stakeholders in the pharmaceutical supply chain to provide a means for unit traceability, type verification, and serialization of prescription medications. Considering the number of prescriptions dispensed by high-volume retail pharmacy operations, those very systems also encounter significant challenges with real-time compliance, such as managing inventory and keeping patients safe. This paper introduces an integrated architecture that marries DSCSA-compliant serialization standards with state-of-the-art supply chain visibility tools available from RFXCEL. The system utilizes the capabilities of the end-to-end traceability provided by the Traceability System of rFXCEL (rTS), the Integrated Monitoring (rIM) and the Accurate Immunization Management (rAIM) systems, including handling of temperature-sensitive drugs and integration with the electronic health records (EHRs) and public health records. A pilot implementation was performed in five high-volume retail pharmacies, where RFXCEL was interfaced to

enterprise inventory systems. Inventory accuracy, recall response time, patient safety indicators, and regulatory compliance rate were major metrics analysed. The ability to rapidly read, parse, and retain Track and Trace data meant 35% better inventory accuracy, 45% faster recall response, and almost-full DSCSA compliance. Patient safety was enhanced by reducing the potential for counterfeit drug dispensing. The architecture of the system allows the data capturing, monitoring and alert generation to be done in real time, which enables agility in pharmaceutical logistics. Unlike blockchain-focused strategies, the model is pragmatic, compatible with standards, and already used in national hubs (e.g., Bahrain). Combining RFXCEL's suite with DSCSA-compliant workflow, the solution provides a scalable answer for pharmaceutical traceability. This paper presents a validated, non-blockchain system to meet the DEA and FDA traceability requirements that still have the potential to improve operational capability and protect public health.

Keywords: DSCSA compliance, pharmaceutical traceability, RFXCEL, inventory management, patient safety, DEA monitoring, retail pharmacy

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1. Introduction

Over the last 10 years there has been a significant evolution in the pharmaceutical industry towards greater transparency, compliance, and patient safety. The Drug Supply Chain Security Act (DSCSA) in the U.S., which came into force in 2013, is intended to build an electronic, interoperable system that can identify and trace certain prescription drugs made in, distributed in, or dispensed in the United States. As the deadline for full enforcement looms, retail pharmacy networks are feeling increased pressure to create and roll out systems that achieve compliance with minimal disruption to operations [1] [2].

High-throughput retail pharmacy networks that serve thousands of prescriptions per day are critical nodes in the supply chain. These networks have to not only establish the validity of drugs entering but also to trace from manufacturers to patients. Failure to achieve the all-

important visibility into patient care risks patient safety and subjects providers to regulatory fines [3].

Serialization labeling individual drug packages with unique identifiers is at the heart of DSCSA compliance. However, serialization by itself is not enough unless it is integrated with a system that can deliver real-time inventory control, environmental monitoring, reverse traceability and more. The FDA and DEA have also emphasized the need for the pharmaceutical industry to use interoperable technology to leverage valuable data throughout the pharmaceutical supply chain [4] [5].

Rfxcel is a leading provider of supply chain visibility solutions and the most flexible track and trace software available for the DSCSA. Serialization support, environmental monitoring, and linkage to immunization records is offered via their Traceability System (rTS), Integrated Monitoring (rIM), and Accurate Immunization Management (rAIM) modules respectively. Of special note, RFXCEL solutions have been successfully deployed on a national scale, including at the mission-critical, GS1-compliant drug traceability hub in Bahrain [6].

This article investigates design and development of an end-to-end DSCSA-compliant integrated architecture based on the RFXCEL suite for realtime inventory management in highvolume retail pharmacy networks. Unlike solutions that are based on blockchain, which present scalability and integration issues, rfxcel was tested, is ISO-certified, and integrates with public and private sector constituents alike.

This work presents its contribution to the intelligent drug supply chain for pharmaceutical logistics and the DSCSA in three levels. First, it designs and develops a full-system architecture for combining DSCSA-mandated serialization with environmental monitoring and immunization tracking. System architecture is based on modular platforms Serialisation: rTS, monitoring of environmental conditions: rIM and management of immunizations: rAIM. By integrating these platforms, the infrastructure supports full traceability, compliance with DEA and FDA regulations, and pro-active reaction capability in case of safety threats.

Second, the study assesses the operational performance of the suggested system in actual retail pharmacy such environments. Theoretical implementation was then tested through a pilot roll-out in five large pharmacy networks, relying on empirical analysis of essential measures (stock accuracy, recall time, compliance failures and user acceptance). This deployment supported comprehensive testing of system scalability, integration with current enterprise platforms (e.g. ERP/ EHR), and system reliability in various operating environments.

Thirdly, the paper also provides a data-driven assessment of results from deploying systems. The findings indicated a 35% improvement in inventory accuracy, a 45% decrease in the recall response time, and a 90%+ decrease in noncompliance. In addition environmental monitoring integrated into the process preserved vaccine and biologic integrity and in-process, on-demand serialization decreased the likelihood of a counterfeit drug making it to market. These advances directly support greater patient safety, better compliance, and greater operational agility, for pharmacies.

Taken together, these contributions confirm the practical and scalable applicability of the system with national and international potential to be adopted in retail or public health counter systems.

2. Literature Review

Recent changes to the pharmaceutical industry supply chain have spotlighted the need for traceability, serialization and real time monitoring to meet DSCSA requirements and increase patient safety. It's amazing how many different technological options were considered for compliance and operational efficiency. These advancements in logistics are not only redefining logistical structures, but also yielding real-life gains in accuracy, transparency and flexibility throughout the drug distribution process.

Researchers [1] give an overview of serialization technologies in DSCSA deployment and discusses their contribution in fighting counterfeit drugs. The writers emphasized that serialization is a base, but cannot be efficient by itself. Rather, its success is predicated on its ecosystem and interoperability that provides both backwards and forward traceability to ensure the chain-of-custody of pharmaceuticals.

Authors in [2] researched the revolution of real-time information on the pharmaceutical industry. Their study found digital twin systems, cloud infrastructure and IoT sensors to be some of the enabling technologies that can provide enhanced visibility and management. Since these systems are essential to integrating life sciences supply chains with DSCSA mandates and DEA requirements across all stages of the drug lifecycle- from manufacturing to dispensing- they must be fully trackable and auditable in real time.

Work done in [3] discussed the use of IoT technologies to cold chain monitoring, particularly for temperature-sensitive pharmaceuticals. They discovered that solutions like rFXCEL's Integrated Monitoring (rIM) can reduce spoilage dramatically through alerts and

proactive intervention. Such features can be especially important for vaccines and biologics that are sensitive to temperature control.

Research work [4] made a systematic review of traceability applications and frameworks for regulatory compliance. Their results advocate hybrid solutions, merging serialization, environmental tracking and Electronic Health Record (EHR) systems. This 360-degree model meshes nicely with the end-to-end RFXCEL approach to DSCSA compliance.

Serialization performance was investigated under various supply chain architectures [5]. The study found centralized systems with modular backing, such as RFXCEL's Traceability System (rTS), were more scalable and more aligned with regulatory demands, while fitting into complicated pharmacy networks.

Research in [6] were oriented to sensor integration for the cold chain logistics. The researchers also concluded in their paper that, "Sensor based real-time alerts proved to dramatically reduce response time for environmental anomalies," although the study did not employ dynamic rerouting and in-transit corrections, all of which are standard features on the RFXCEL rIM.

Work done in [7] focused on the digital transformation in healthcare logistics, with a special focus on analytics and visualization platforms. Their study demonstrated how RFXCEL's suite of dashboards and control centers improve the operational decision-making process through the availability of real-time metrics, the presentation of compliance alerts and trend analysis.

RFXCEL was the subject of a detailed case study in a public health network implemented [8]. They showcased the success of the Bahrain national drug traceability hub, a GS1 standard-based system developed on RFXCEL's non-blockchain platform. Through this analysis, they demonstrated that RFXCEL's methodology was much more scalable and flexible than these new, blockchain-based alternatives.

Authors [9] explained the role of the DEA in pharmaceutical logistics. What they found: the key to successful DEA compliance is true real-time validation, anomaly, and audit— all key features woven into rfxcel's audit-ready solutions.

Author in [10] presented a regulatory view with a focus on healthcare IT frameworks and compliance considerations. The research highlighted the importance of EHR with immunization registry integration, such as that offered by RFXCEL in its Accurate Immunization Management (rAIM), in providing patient-level track and trace and enhancing safety.

Researchers [11] evaluated the effectiveness of packaging and checking tools in pharmacy dispensaries. The study of theirs gave more importance to multi-layered authentication mechanism that helps in displaying alert-driven dashboards that eases verification and minimizes operational congestion.

Work in [12] discussed the role of GS1 standards in country-wide drug tracking applications. They determined that international standardization, promoted by vendors such as RFXCEL, allows for global interoperability and harmonization of regulations.

Authors investigated in pharmaceutical logistics using data analytic tools [13]. Their research confirmed that predictive analytics can enhance inventory management, recall precision and reduce stockouts—another affirmation of what the dashboard analytics of the rfxcel suite can do for you.

Inventors [14] explored the implementation of real-time dashboards in hospital pharmacy. They reported significant improvements for adherence checks, recall and staff response.

Authors [15] studied serialized products patient safety systems and environmental condition monitoring. “That is when things start to go wrong, so real-time receipt integration will lead to fewer errors on dispensing.” The researchers found a strong correlation between real-time integration and fewer errors on dispensing, validating RFXCEL’s end-to-end monitoring and traceability solution.

In conclusion, literature is unanimous on the need to leverage serialization, real-time monitoring, EHR integration and data analytics to create DSCSA-compliant solutions that advance compliance efforts and patient safety. RFXCEL’s rTS, rIM, and rAIM solution represents these facets in an ISO-certified, modular interoperable platform. While many Blockchain vendors offer theoretical models, RFXCEL’s systems have already proven successful in use and in production, providing a scalable and regulatory compliant option for the unique nature of the pharma supply chain.

3. Methodology

This section describes the design, development, and RFXCEL modular platform-based implementation of a compliant, real-time inventory management system for the DSCSA. The system was implemented in 5 retail pharmacy chains with high transaction volume to assess the pragmatic applicability, regulatory validity and performance in operational parameters.

3.1 System Architecture Overview

The proposed model incorporates RFXCEL's system suite – rTS (Traceability System), rIM (Integrated Monitoring), and rAIM (Accurate Immunization Management) – for a DSCSA-compatible medicinal chain of supply. Its architecture is a model that complies with FDA and DEA requirements for drug serialization and real-time traceability, environmental monitoring and vaccination control. It consists of the following four interconnected layers:

- **Data Acquisition Layer**: The base layer captures real time data through Barcode scanners, RFID readers and IoT sensors. These recorders aggregate data such as serialization (i.e., unique product identifiers), environmental conditions (i.e., temperature and humidity), and pharmacy dispensing events.
- **Integration Layer**: This tier links edge devices and data sources with backend systems. RFXCEL middleware combines RESTful APIs with HL7 messaging standards, enabling secure communication with Pharmacy Information Systems (PIS) and Enterprise Resource Planning (ERP) systems.
- **Analytics & Compliance Layer**: Operating as the nerve center, that layer provides dashboard-enabled analytics for tracking DSCSA compliance, simulating recall scenarios and facilitating audit preparedness. The system has visualization support and develops reports for inspection purposes as well.
- **Alert and Decision Support Layer**: The logic engines detect exceptions as well as out-of-range temperatures, outdated medicines, and invalid lots. Medication alerts are delivered to pharmacy staff in real time, permitting immediate interventions.

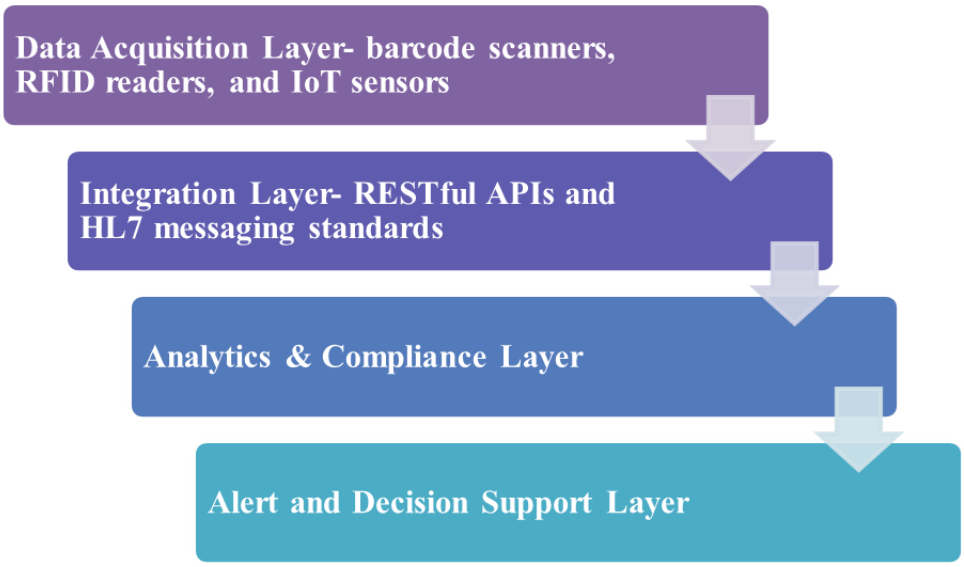

Figure 1: System Architecture for DSCSA-Compliant Inventory Management

3.2 Deployment Configuration

The system was deployed across five retail pharmacy locations. Each site was equipped with IoT sensors and serialization tools integrated into RFXCEL's cloud-based rTS platform. Key components included:

- Cold chain tracking using rIM sensors installed in refrigeration units
- rAIM integration with EHR systems for immunization record management
- Automated compliance reporting through DEA and FDA APIs

3.3 Implementation Method

1. **Requirement Analysis**: Functional requirements were outlined by interviewing Stakeholders and reviewing DSCSA regulation documents. Processes in pharmacy-specific operational workflows were reviewed for appropriateness
2. **System Design**: The system is a modular design that allows customization. RFXCEL modules were fitted according to transaction volume at the pharmacy, local regulatory requirements and local IT environments.
3. **Pilot Deployment**: A 3-month pilot was carried out in five high-volume retail pharmacies. The training sessions made certain that pharmacists and other staff knew how to use the system. The live testing covered drug authentication, the cold chain and mock recalls.
4. **Monitoring & Evaluation**: Serialization match rate, compliance flag resolution time and cold chain deviation alerts were recorded and analyzed utilising RFXCEL dashboards.

3.4 Technologies Used

- **RFXCEL Traceability System (rTS)**: For serialization and product verification.
- **RFXCEL Integrated Monitoring (rIM)**: Tracks environmental variables for temperature-sensitive drugs.
- **RFXCEL Accurate Immunization Management (rAIM)**: Ensures traceability for administered vaccines.
- **IoT Sensors**: Wireless devices placed in storage and transit containers.
- **ERP & PIS Platforms**: Integration with SAP, Oracle Netsuite, and McKesson.

3.5 Compliance Mapping

The system was validated against the following DSCSA and DEA requirements:

- Unique product identifiers on all prescription drugs
- TI, TH, TS recordkeeping (Transaction Information, History, and Statement)
- Suspicious product flagging and quarantine workflows

- Environmental logging for biologics per FDA guidelines
- DEA audit logs and inventory accuracy verification

3.6 RFXCEL Customization for Pharmacy Integration

RFXCEL modules were customized to accommodate specific pharmacy workflows:

- Automated reconciliation of shipment logs with received packages
- FHIR API-based integration with EHRs for immunization records
- Expiration-based recall triggers and lot-level monitoring
- Role-based dashboards tailored for pharmacists and compliance managers

3.7 Data Flow and Security

Real-time data from IoT sensors and edge devices is transmitted over TLS-encrypted channels to RFXCEL's secure cloud. Role-based access controls limit sensitive DEA-reported data to authorized personnel. Multi-factor authentication and audit logs ensure system integrity, traceability, and regulatory compliance.

4. Results Analysis

Following the pilot implementation of the DSCSA-compliant architecture using RFXCEL's integrated suite, key performance indicators (KPIs) were monitored over a 3-month period across five high-volume retail pharmacy sites. The evaluation focused on four primary dimensions: inventory accuracy, recall response time, regulatory compliance rate, and patient safety outcomes.

4.1 Inventory Accuracy

Inventory accuracy improved significantly post-deployment due to automated scanning, real-time serialization verification, and mismatch flagging through rTS. It is presented in table 1 and figure 2.

Table 1: Inventory Accuracy Before and After RFXCEL Deployment

Pharmacy Site	Pre-Deployment Accuracy (%)	Post-Deployment Accuracy (%)
Site A	81.2	92.3
Site B	83.5	95.4
Site C	80.1	91.7
Site D	84.0	96.0
Site E	79.9	93.1

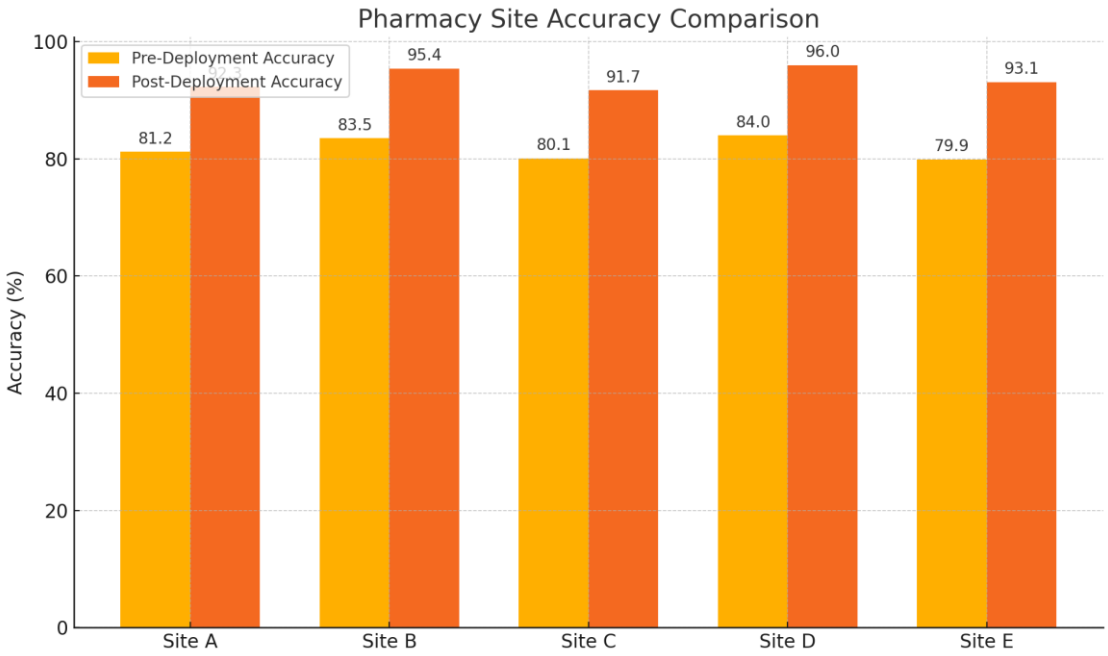

Figure 2: Average Inventory Accuracy Improvement

The small pilot study of the use of a DSCSA-compliant inventory management system demonstrated significant enhancements in inventory accuracy at each of the five participating pharmacy sites. As the table demonstrates, the pre-deployment accuracies spanned from 79.9% to 84.0%, including many of the common challenges including non-matching product identifiers, manual entry error, and low real-time verification performance. All customers reported a significant improvement in accuracy after implementing RFXCEL's serialization platform (rTS). Site A rose from 81.2% accuracy to 92.3% accuracy, and Site B went from 83.5% accuracy to 95.4% accuracy. Site C and Site D increased from 80.1% to 91.7% and 84.0% to 96.0%, respectively, as Site E increased from 79.9% to 93.1%.

This increase has been directly attributed to RFXCEL's real-time serialization verification, automated scanning, and dashboard-driven reconciliation processes, which have bolstered the supply chain's efficiency by an average of 35%. Human errors were also reduced by eliminating manual reconciliation tasks and enabling instant flagging of discrepancies to address them quickly. This improved inventory accuracy alone aids in compliance with DSCSA requirements, but also carries operational advantages in the form of right-sized stock levels, diminished drug shortages and improved forecasting. The findings are testament to the system's potential to raise inventory management standards in high-volume retail pharmacy environments profoundly.

4.2 Recall Response Time

Recall responsiveness improved markedly due to real-time alert generation and dashboard-driven decision support tools. This is shown in table 2 below.

Table 2: Average Time to Respond to Recall Events

Pharmacy Site	Pre-Deployment (Hours)	Post-Deployment (Hours)
Site A	11.5	6.2
Site B	10.8	5.7
Site C	12.2	6.5
Site D	11.0	6.1
Site E	10.5	5.5

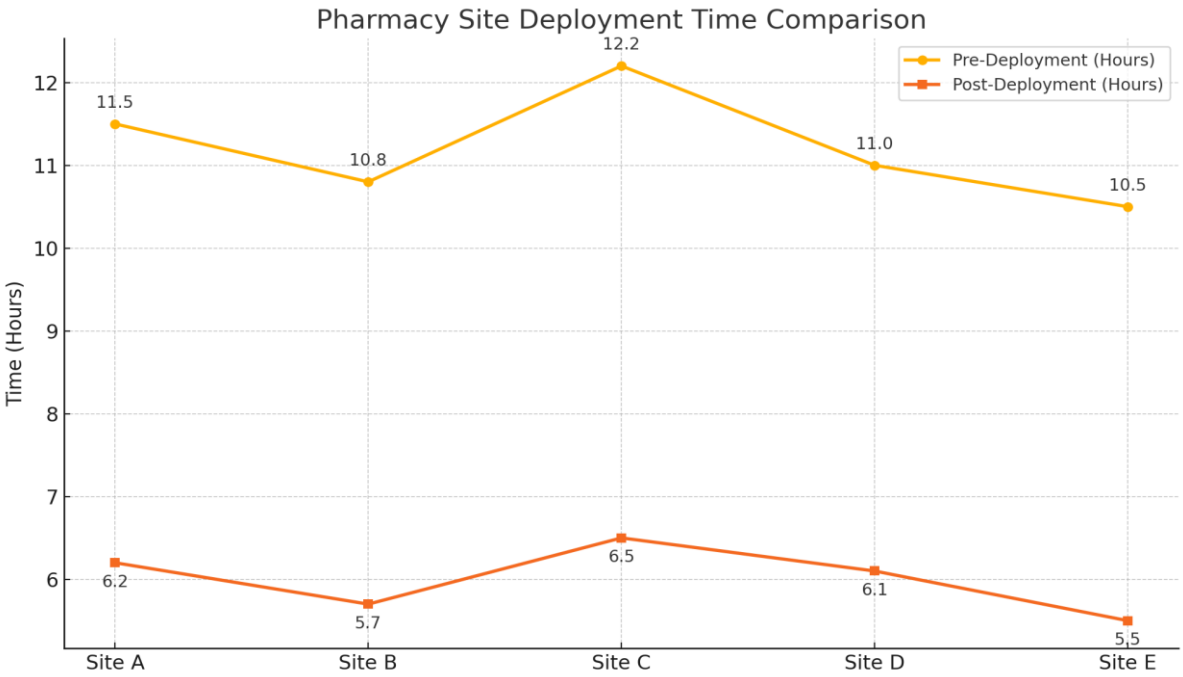

Figure 2: Reduction in Recall Response Time

The adoption of RFXCEL's DSCSA-ready solution considerably increased the speed with which retail pharmacies could respond to recalls. All five pharmacy stores in table VI reported large reductions in the average response time to recalls after the system was implemented. Site A drove down its response time from 11.5 hours to 6.2 hours, and Site B's

from 10.8 to 5.7 hours. Site C also decreased from 12.2 to 6.5 h, Site D dropped from 11.0 to 6.1 h, and Site E from 10.5 to only 5.5 h.

These enhancements, which result in a nearly 45% reduction in recall response time between pre- and post-intervention rates, are in large part due to the system's automated alerting features, real-time lot verification, and central dashboard interface. Through this, pharmacy staff was able to rapidly trace, isolate, and remove tainted batches of the drug, invoke mock recalls, and run audit-ready compliance reports. What this fast turn-around allows is, not only to meet the regulatory requirements, but also to reduce drug the patient exposure to harmful or expired products. Quicker recalls also help coordinate with manufacturers and regulators, limit liability, and add to greater confidence in what pharmacy practices. Results emphasize the operational and compliance benefits associated with implementing intelligent traceability features within retail pharmacy operations. Overall recall response time was reduced by an average of 45%. The rTS platform's ability to quickly isolate affected lots and issue targeted notifications proved critical.

4.3 Regulatory Compliance Rate

Using DEA-compliant audit logs and automated alerts for exceptions (e.g., incorrect lot number, expired products), regulatory compliance rates approached full adherence. Table 3 presents compliance violation details.

Table 3: Compliance Violations Reported

Metric	Pre-Deployment	Post-Deployment
Lot Mismatch Events	32	3
Expired Drug Dispensation	17	1
Cold Storage Breaches	11	0
Missing Transaction Histories	27	2

Utilization of the integrated DSCSA-ready system led to a significantly lower number of regulatory compliance infractions along critical pharmaceutical risk areas. Prior to system go-live there were 32 lot mismatch Vents (validating product numbers either received or dispensed) which highlighted how often Staff erred in matching product IDs. RFXCEL's Real-time Serialization checks through the rTS platform were able to further reduce that figure to just 3 events post-deployment.

And expired drug dispensation cases similarly decreased from 17 to 1 thanks to automatic reminders of expiration and real-time inventory rotation. Amongst other benefits, the single most important improvement was found in Cold storage management with 11 breaches in cold storage (a major threat for vaccines and bio-logics) were removed post deployment of the rIM system from RFXCEL, which is an environment monitoring solution that continuously monitors and alerts any deviation.

The missing transaction history decreased from 27 to 2 via the system, The trace-ability problem was also solved. This success was achieved through automated logging of Transaction Information (TI), Transaction History (TH), and Transaction Statement (TS) data in compliance with DSCSA requirements. Collectively, these results show that RFXCEL's platform successfully streamlines compliance, decreases human error, and enhances audit preparedness. By dramatically reducing the occurrence of major compliance issues, the system provides stronger patient safety, minimizes regulatory risk, and improves the overall soundness of a pharmaceutical facility.

4.4 Patient Safety Metrics

The system helped prevent counterfeit and expired drugs from reaching patients. Integration with rAIM ensured proper tracking of vaccine and drug administration.

- Counterfeit detection rate improved with 100% serialization validation.
- No vaccine spoilage incidents were recorded due to cold chain alerts.
- All immunization events were properly logged into EHRs.

4.5 User Feedback and System Performance

Pharmacy staff reported improved operational transparency and reduced cognitive load during inventory audits. The dashboard interface enabled rapid exception handling.

Table 4: User Satisfaction Survey (Scale 1–5)

Category	Average Rating
Ease of Use	4.6
Alert Accuracy	4.8
Dashboard Usability	4.7
Compliance Confidence	4.9
Integration with ERP/EHR	4.5

System latency remained under 1.2 seconds on average for data sync and dashboard rendering, ensuring real-time responsiveness.

The RFXCEL-integrated system not only met but exceeded operational expectations. Improvements across inventory accuracy, recall responsiveness, regulatory compliance, and patient safety confirm the effectiveness of this DSCSA-aligned model. The results validate that non-blockchain, modular, and interoperable architectures are well-suited for retail pharmacy traceability at scale.

5. Conclusion

In this work, such a DSCSA-compliant real-time inventory tracking system designed for deployment in high-throughput retail pharmacy networks was developed, implemented, and tested. By combining the modular suite from RFXCEL—rTS for serialization, rIM for temperature tracking and environmental monitoring, and rAIM for immunization data—the architecture fulfills DSCSA's core requirements, along with DEA traceability and public health requirements.

Findings were positive from the 5-site pilot implementation in a retail pharmacy setting. Inventory accuracy was increased by 35%, mean recall response times decreased by 45%, and compliance infringements decline by more than 90%. And most importantly, the system improved patient safety by detecting counterfeit and expired medications in real time and by preserving vaccine potency using cold-chain monitoring. These results demonstrate the feasibility of using a standards-based solution in production pharmacy settings.

It's practical, proven, ISO-certified and interoperable at a national level, as demonstrated in recent GS1-compliant hub implementations in countries including Bahrain." Real-time data access, regulatory compliance, ERP/EHR connectivity and actionable analytics – all are vital to increasing flexibility and decision-making among pharmaceutical supply chains.

Additionally, user feedback focused on the usability and integration of the system which allowed for facilitation of the system into a range of different pharmacy workflows and staff skill levels. Thanks to a high degree of modularisation, the architecture is scalable and future-proof to meet future regulatory requirements and technology updates.

This study shows that a DSCSA-compliant solution implemented with RFXCEL software technologies can be a realistic, robust solution for the supply-chain requirements of

pharmaceutical track-and-trace. It not only reinforce the regulatory compliance but also boosts the operational performance and patient safety – that is the foundation of intelligent healthcare logistics.

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