IJIRCCE

e-ISSN: 2320-9801 | p-ISSN: 2320-9798

INTERNATIONAL JOURNAL OF INNOVATIVE RESEARCH

IN COMPUTER & COMMUNICATION ENGINEERING

Volume 12, Issue 12, December 2024

INTERNATIONAL STANDARD SERIAL NUMBER INDIA

Impact Factor: 8.625

© 2024 IJIRCCE | Volume 12, Issue 12, December 2024| DOI: 10.15680/IJIRCCE.2024.1212108

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

Ensuring Patient Safety and Regulatory Compliance with Advanced Pharmaceutical Supply Chain Systems

Rajesh Karvannan

Senior Specialist Engineer, Global Logic Worldwide Holdings Inc–A Hitachi Group Company, USA

ABSTRACT: The Drug Supply Chain Security Act (DSCSA) aims to enhance the integrity of the pharmaceutical supply chain within the United States by incorporating serialization, traceability, and electronic data exchange for prescription drugs. The capacity to securely and efficiently provide real-time monitoring and tracking of a product throughout the supply chain using edge IoT devices, data pipelines, serialization technologies, and cloud-based compliance methods are a unified, component-focused method. Compliance with the GS1 EPCIS standards, exception/recall management, and unique identification of a product using 2D Data Matrix barcodes are important components of adherence to the DSCSA. The ecosystem we have described is built on RFXCEL's technology (for example: Traceability System, Integrated Monitoring, Accurate Immunization Management), which provides a response to complex needs, such as the tracking of temperature-sensitive medications, whilst also enabling direct connectivity to electronic health records. A pilot study conducted at five high-volume retail pharmacies exhibited a large reduction in the response time to a recall, improved inventory accuracy, and adherence to compliance with DSCSA standards, while supporting patient safety. This technology is a compelling alternative to blockchain solutions in the pharmaceutical industry as it supports real-time data capture and alerts while improving the operational capabilities and security of the pharmaceutical supply chain in compliance with FDA and DEA traceability standards.

KEYWORDS: Drug Serialization, Traceability, 2D Data Matrix, Drug Supply Chain Security Act, Blockchain, Pharmaceutical Supply Chain

I. INTRODUCTION

The purpose of the Drug Supply Chain Security Act (DSCSA) is to improve the security of the pharmaceutical supply chain within the United States by requiring secure tracking and tracing of prescription drugs as they are passed from the manufacturer, through wholesalers and distributors, to pharmacies and ultimately, patientsThe DSCSA was enacted in 2013 and has been phased in over time as a means to prevent unsafe medications from entering the drug delivery system and to improve patient safety. The general premise of the DSCSA will be to require participants in the drug supply chain–manufacturers, repackagers, distributors, and pharmacies–to maintain records that may be comprehensive and verifiable for counterfeit or questionable drugs, in an expedient manner. Pharmacies will have operational responsibilities, including the use of electronic tools to track these requirements at the package level. Pharmacies will be expected to receive and hold relevant information - such as National Drug Code (NDC), lot number, serial number, expiration date, etc. – through a mechanized means, rather than by hand on a paper log. In addition, each package of prescription medication will have a unique product identifier for verification purposes in the form of a 2D barcode; this requirement will minimize compliance challenges when conducting any of the pharmacy operations of receiving, dispensing, or inventorying drugs. Pharmacies will also be required to maintain transaction records (Transaction Information, Transaction History, and Transaction Statement) for six years to provide verification of product or chain of custody [1].

Pharmacists must be prepared to develop processes concerning the management of suspicious or illegitimate items including what the reporting processes will need to be to the appropriate authorities in a timely manner. The operation also extends to requiring that all suppliers and distributors are DSCSA-compliant. This is a jointly held responsibility that supports supply chain integrity. To achieve the objectives required under DSCSA compliance, large retail pharmacy networks must implement sophisticated inventory management systems that facilitate real-time verification of product and reconciliation of product via standardized communications protocols.Such event-driven architectures

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

should allow for the synchronicity of product movement and transactional data, as well as integrating liability, inspection, and regulatory functions related to improved data storage and audit trails. In summary, DSCSA has shifted the pharmacy inventory management process from a manual method for inventories and a batch process for transaction data, to a continuous-method inventory process that now relies on data. Pharmacists have had to change their behaviors when managing inventory with a commitment to detailed recording of all transactions, modifying inventory practices accordingly with supplier level commitments to compliance, and training staff members in the processes. The act not only affects the ability to improve safety within the pharmaceutical supply chain and imposes significant responsibilities for compliance verification and maintenance on pharmacy systems. Real-time inventory systems could be particularly essential utility features in high-volume retail pharmacy practices due to the complexities surrounding pharmacy operations and pharmacy practice settings, and the new regulatory obligations included in the DSCSA. Real-time inventory systems mean pharmacy teams and pharmacists have continuous visibility of stock counts in various pharmacy locations filled with inventory and maintain ideal stock balances, which can directly impact patient care and operational efficiency. Having a real-time approach to inventory means better data integrity and stock movement can be synchronized to represent real time counts and efficiencies in stock balances to alleviate stockouts and overstocks that can be damaging to service delivery and profit. Additionally, they provide access to real-time sales and inventory patterns to better inform demand forecasting, determine consumption trends, and timely restocking, even when there are rapid demand fluctuations or seasonal patterns.

Real-time systems also improve traceability and regulation compliance with respect to records of product identities, lot identifiers and expiration dates for legal reporting. They will improve operational efficiency by allowing staff to manage dispensing and stock levels in pharmacies without delays for presentation of inaccurate data and ultimately data will be saved on labor and warehousing. These systems also help limit waste and lost revenue for the pharmacy through balancing inventories and alerting about low stock levels or expired products, and can inform other supply chain decisions. In addition, these systems can provide insight into the supply chain so pharmacy can address bottlenecks and improve relationships with suppliers. With respect to multi-location networks, real-time inventory management allows for coordinated adaptive data syncing, adapting, transferring, and reporting in methodologies that represents a similar level of standardization.

Overall, advanced, integrated inventory solutions that leverage analytics and automation are becoming more and more necessary for pharmacy operations at high-volume levels to navigate the complexities of the pharmaceutical supply chain to maintain compliance, operational efficiency, patient access, and cost continue to decrease. For the past decade, the pharmaceutical industry has ramped up efforts in the interest of patient safety, transparency in the supply chain and regulatory compliance with the Drug Supply Chain Security Act (DSCSA) [2] passed in 2013. The DSCSA aims to establish an electronic interoperable system to facilitate the identification of prescription medications as they are distributed along the supply chain from the point of manufacture to the point of dispensing in an effort to maintain the safety of the supply against counterfeit drugs.. As enforcement deadlines in 2025 draw near, retail pharmacy networks, which handle high volumes of prescriptions, will be pressured to adopt dispensing systems that not only ensure compliance with DSCSA regulations, but are also able to carry forward the pharmacy's operational processes with little disruption. Serialization, the ability to label packages of medicine with unique identifiers, is necessary to be compliant with the regulations; however, to provide traceability from the manufacturer through pharmacy inventory, systems will need to be adjacency and interact with comprehensive systems and reflect that in the pharmacy's inventory management.

Rfxcel, as a leading provider of supply chain visibility systems, provides a modular platform which includes tools to support immunization management, environmental monitoring, and serialization based on GS1 standards.This paper investigates the methodology and case study for the design and deployment of a DSCSA-compliant architecture to support real-time inventory management in large pharmacy networks using Rfxcel's technology suite. In contrast to blockchain solutions, Rfxcel's ISO-certified platform integrates very well with others public and private sector organizations and networks. The three overarching contributions include: a modular system architecture that supports environmental monitoring, vaccination management, and serialization for total traceability; operational efficacy of the architecture is evaluated by way of pilot implementation tests installed in five pharmacy networks; compliance and improved recall response times and accuracy of inventory are measured and compared. Collectively, these improvements represent enhancements to operational efficiencies and regulatory compliance that ultimately support patient safety in retail pharmacies while demonstrating the conceptual scalability and utility of the technology platform

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

for more comprehensive implementation by us government pharmacy networks or public health systems to support their vaccination and inventory management programs [4].

This article discusses the creation of an integrated architecture for real-time inventory management in high-volume retail pharmacy networks that will provide compliance with Drug Supply Chain Security Act (DSCSA) regulations. As mentioned previously, the article describes a modular system architecture consisting of the use of Rfxcel technologies for environmental monitoring for temperature excursions, immunization management, and serialization for total traceability to comply with FDA and DEA regulations. The article highlights the importance of tracking inventory accuracy rates, compliance, recall response time, vaccination management, and user acceptability through research projects and pilot studies conducted with a variety of large pharmacy networks to demonstrate operational effectiveness. Ultimately, this paper will quantify improvements in inventory management, counterfeit threat, and biologic integrity utilizing Rfxcel technologies with the associated enhancements in patient safety and compliance with regulatory mandates. The architecture is defined by being interoperable and scalable, utilizing ISO certified software to address gaps encountered with current workarounds, similar to blockchain and other technologies.

The impact of Rfxcel technologies has been applied to public and private sector organizations, and corporate based systems in the area of inventory management and compliance, to mitigate the timely access to pharmaceuticals and complicated regulatory framework facing pharmaceutical manufacturing and distribution. This article also recognizes the increasing encroachment of regulatory demands and scrutiny on the safe distribution of pharmaceuticals. Lastly, we conclude that we have demonstrated a framework for value-added technical implementation, evaluation of pilot and case studies in collaborative community efforts, principles of a architectural framework utilizing a DSCSA compliant value-added architecture offering a technical reference for system architects, compliance officers and pharma/logistics practitioners facing disruptions to their supply chains created by the regulatory context offered by the DSCSA regulatory context which also creates an opening for evaluating emerging technologies, data integration methods, and opportunities for verifying the efficacy of pharmacy logistics, operations and ultimately patient safety.

II. BACKGROUND WORK

The evaluation of the array of standards for compliance with DSCSA related to system standards means that the system must be a complete and secure system that enables the serialization and tracing of prescription drugs with the use of unique product identifiers (UPIs) and 2D Data Matrix barcodes. The system must also be able to support electronic interoperability and data exchange between authorized trading partners in compliance with GS1 so that transaction data can be shared between authorized partners in a timely manner. There must be data exchange requirements that include strong verification capabilities and investigations that will provide authorities with a means to verify legitimacy of the product and to assist in managing risks associated with suspicious product detection. The system architecture must allow transactions to be conducted only by authorized trading partners and be compliant with applicable license regulations for pharmaceuticals. Recordkeeping of transaction data is significant, and the audit trail must be kept for at least 6 years securely, which is insightful for regulatory audits. The system architecture must also support integration to provide scalability, enabling processing transaction volume across the pharmaceutical supply chain and interaction with corporate systems. In conclusion, the system must provide tracing from end to end with the support of patient safety while being compliant with regulatory requirements throughout the supply chain.

It is critical to ensure data accuracy and integrity. There are several inconsistencies in transaction data that obstruct product verification for the purposes of using transaction data in a reconciliation process. The management of inventory discrepancies is quite complex, featuring a large number of units in a state of exception which creates compliance issues and operational burdens (CS) issues. As part of the complexity associated with DSCSA regulatory compliance, the requirement to be audit ready and verifying your trade partners with transaction history has consequences on regulatory compliance. In a retail setting characterized by high volumes of transactions, having systems that are scalable and performant are key to efficiently managing and processing large numbers of serialized products. As it pertains to pharmaceuticals, being able to track environmental conditions while utilizing systems that have environmental control capabilities will be essential. Achieving these goals will require collaboration across multiple teams and agencies to address the complexities of regulatory compliance along with operational challenges. Finally, there will be part of this task that will include the adoption of technology and change management to completely refresh or supplement existing systems, including staff training. It will take predictive software that is reliably effective

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

in automation and analytical functionality, while being interoperable aside from developing a reliable and compliant pharmacy supply chain. [6] Moreover, it will be necessary to operationalize the warehouse processes to conform at all levels to the regulated directives around the DSCSA.

It is especially important for all prescription medication to contain distinct serialized identification labels, and for a barcode scanner and verification system to be in place that integrates into the system. Software programs must also be employed to record the different serialized product identification numbers through the various warehouse processes. It will also be important for the system to maintain the EPCIS events in order for serial number tracking of transactions to be fully functional within the inventory management system. Additionally, a set of procedures to create and manage parent-child packaging relationships will need to exist so that tracking products can occur without scanning every product. The serialized product identification numbers will need to cross-verify with the transaction history data reports provided by trading partners to validate products. All differences will require a quarantine process. When third party trading partners share transaction data, it will not matter due to using GS1 standards, but it will be secure to help decrease error and decrease manual data transaction entry. Exception and recall management procedures shall also need to be created to provide the ability to track products inventory condition and location to fulfill an emergency product recall response to an audit request with speed. Environmental monitoring systems will need to be designed to meet compliance to provide the conditions for temperature-sensitive products. Compliance reporting and auditing may need to be created by keeping good records of all product movements to fulfill government inspection requests. Procedures may need to be created andAdditionally, it is critical for organizations to verify and monitor the license(s) of their trading partners to minimize the risks of doing business with entities that are not authorized to transact. Verifying trading partner licenses, in turn, will result in better accuracy related to inventory, throughput, and supply chain integrity, as well as better adherence to regulatory requirements and ultimately impact patient safety [7].

In summary, significant changes have occurred in the pharmaceutical supply chain to promote patient safety and for DSCSA compliance, focused on end-to-end traceability, unit-level serialization and real-time monitoring. Serialization, via the use of 2D Data Matrix coding, uses metrics to define product useful attributes that are helpful for use for unit-level verification, traceability, and data exchange with trading partners. The FDA encourages trading partners to leverage GS1 EPCIS for the communication of necessary data to support the tracking of events in the supply chain. Technologies such as IoT sensors, cloud systems or digital twin enables "real-time" visibility and a full lifecycle view from production to dispensing, allowing for informed inventory management and regulatory compliance. Automated tracking of the cold chain such as an integrated monitoring system, such as rfxcel Integrated Monitoring allows you to quickly react, manage your risk, and reduce spoilage if a temperature breach occurs [8].

Providing integrated framework in alignment with the product data sharing intent of the DSCSA, enhance patient safety and provide a compliance framework. Rfxcel solutions, for example, are an model integrated approach that unify system tools to monitor and manage monitoring or serialization or immunizing process within a collaborative framework . The Bahrain national traceability hub is an example of an interoperability solution utilizing GS1's standards for compliance, end-to-end visibility, scalability for information sharing, along with successful implementation of a non-blockchain system. The system will be developed with interoperability as a focus during system design and with an increased electronic transaction, record retention and investigation protocols, eventually EPCIS provides the backbone for tracking transaction event data. A holistic model is one option for providing compliance with the DSCSA while providing evidence based enhancements to quality, safety, and efficiency will potential benefit outputs at the enterprise and corporation level [9].

III. SYSTEM ARCHITECTURE

A pharmaceutical supply chain system that follows the guidelines of the DSCSA is built on key architectural components. The centralized hubs are the main sources of data for decision making, visibility, and analytics as they aggregate data from many locations and partners. The edge systems, at the warehouses and pharmacies, have the responsibility for local data gathering and processing, even if the central hubs are not accessible. Integration APIs and middleware provide seamless data flow between different systems and schemas, meeting GS1 EPCIS standards. Serialization and traceability platforms manage product identifiers and transactional data, and environmental monitoring modules with IoT sensors manage the environmental conditions that matter to medication. Dashboards provide real-time visibility and analytics associated with compliance to assist with decision making and to be audit-

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

ready. A full suite of security measures protects data, while backup systems protect continuity and data integrity. Collectively, these components comprise the architecture of the system, balancing centralized control with operational autonomy, and assists with both patient safety and compliance in high-volume, multi-chain retail pharmacy networks [11].

In a pharmaceutical supply chain, data flow integration and event-driven pipelines allow real-time synchronization and communication to be attained through the interconnectedness of individual parties. Events are generated at the edge, where equipment, such as barcode scanners and IoT sensors, generate new unique events each time serialized products are received, stored, moved, or otherwise monitored. Events include metadata associated with the event; for example, time stamps and product identifiers. Once the event is generated it is sent to the centralized data platform in real time utilizing messaging systems that guarantee reliable deliver and can envelope any breaking parts of the network; for example if the Internet goes down for an entire store location. Real-time processing engines authenticate and enhance ingested data by validating serialized IDs and ensuring compliance with hierarchy packaging. The validated event-data is then aggregated and stored in scalable databases that are purpose-built for time-series data while supporting historical analytics and traceability. Communication between trading partners is made through GS1 EPCIS standards which describe discrete event types related to handling product.

Integrating with systems, like ERP and WMS, is standardized through APIs. The real-time and historical data is part of automated processes and alerts. Event driven systems allow real-time alerts to be generated concerning either environmental or serialization issues which assist in taking necessary actions such as quarantine or recall. Then there are data visualization tools that allow teams to view dashboards that illustrate compliance status; KPIs, and trends that can be utilized for using quality control and across supply chain. To sum up, this architecture develops a seamless, automated pipeline that triggers action, increasing responsiveness, accuracy, and transparency of information, that is utilized as part of DSCSA compliance [11].

In DSCSA-compliant inventory management systems, the data validation and conflict resolution process concentrate on the integrity of the serialized medication data and the immediacy of its resolution to the inconsistency. Strong emphasis is placed on validating serialized events immediately as they are captured, utilizing vision verification systems to assist in eliminating scanning errors, and by comparing the reads against master product and locations for verification in consistency. The reconciliation validation process requires comparing the physical reads against the successful transaction information received as transaction data in the incoming transactions, and verifying the shipment of units aligned with the EPCIS event count with flags that indicated their discrepancies.

Alarms are raised for things like missing information, or flagged if the two serial numbers are the same; systems are in place to help the repair the issue, including sorting exceptions by threat level. Automated algorithms will respond to simple conflicts in the chain, or they may require a tracer team to manually review the more complex situations that arise. Aggregation verification will validate the relationship of different packaging levels related to tracking and tracing the product. Anti-counterfeiting or tamper-evident processes involve visual assurances to verify tamper evident characteristics, while all abnormalities are documented for regulatory purposes. Continuously validating compliance using documentation of testing and routine audits show that Good Manufacturing Practice (GMP) and regulatory compliance occurs. In addition, these systems ensure both inventory accuracy and patient safety while all of these monitoring mechanisms ensure reasonable protection against errors, fraudulent activities, and non-compliance that are crucial for a successful implementation of Drug Supply Chain Security Act (DSCSA) serialization [12].

At the highest-level objectives of security and privacy in the pharmaceutical supply chain, which implements the Drug Supply Chain Security Act (DSCSA), oversees the protection against counterfeit products, and continues to assure that procedures are confident in the data comprehended. Key methods of accomplishing this are implementing serialization to prescription medication packages where all packages being dispensed have a unique barcode to trace individual productsThe product's description provides evidence that the product or its contents has not changed by comparing serialized numbers. Data prospecting can be included as it is deemed as required because the FDA mandates secure exchange of electronic transactional information in an FDA approved manner using various methods of protection to validate the integrity of the data, including the encrypted and secure protocols the exchange of data requires. Verification of Authorized Trading Partners (ATP) is a necessary step in the supply chain to further reduce an organization's risk of illicit activity associated with counterfeit products. ATP verifies original licensing and the

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

continual audit of practice ongoing. Access to sensitive data is limited to select individuals including the use of role based permissions and multifactor authentication. All data even in error, must be held in accordance to regulations as much as practical to protect privacy. There are strict verification protocols in place to recognize potentially suspicious products. There are procedures that also remediate an identified product (quarantine) and recommendations for compliant reporting to regulatory agencies that ultimately resulted in the incident or believed anti-counterfeiting event. There are physical and digital security measures, for example tamper-evident packaging with, again, digital protections against counterfeiting. Lastly, DSCSA regulations also require secure storage procedures for transaction information and documentation in some fashion for at least six years in order to comply with audit regulations. Incident responses protocols and systems will be in place to quickly respond to recalls and breaches reduces risk to patients and for downstream, regulatory compliance. Overall, each stage of these security and privacy objectives will ultimately lead to patient safety and reflective standards that are legally enforced, acting as a solid premise of DSCSA solutions such as Rfxcel in part that may also include real-time visibility and other enhanced security features.

There are some general building blocks that are inherent in a pharmaceutical supply chain system's deployment of production architecture to follow the Drug Supply Chain Security Acts (DSCSA.) These are important in regard to accomplishing core objectives of serialization that streamlines a single identifying number of each actual drug product; traceability that can track the drugs through various points in the supply chain; a real-time monitoring concept in order to provide accurate information regarding the status and place of products; and regulatory compliance that is met means by law the system has met the expectations of the codes of practice and legal acts to ensure qualification of safety and worker safety to stop faulty drugs from being introduced into the supply chain. Each of these components helps improve integrity and security of the pharmaceutical supply chain. Ultimately, protecting health and safety by combating counterfeit drugs to country may easily assist in satisfying, see below Figure 1:

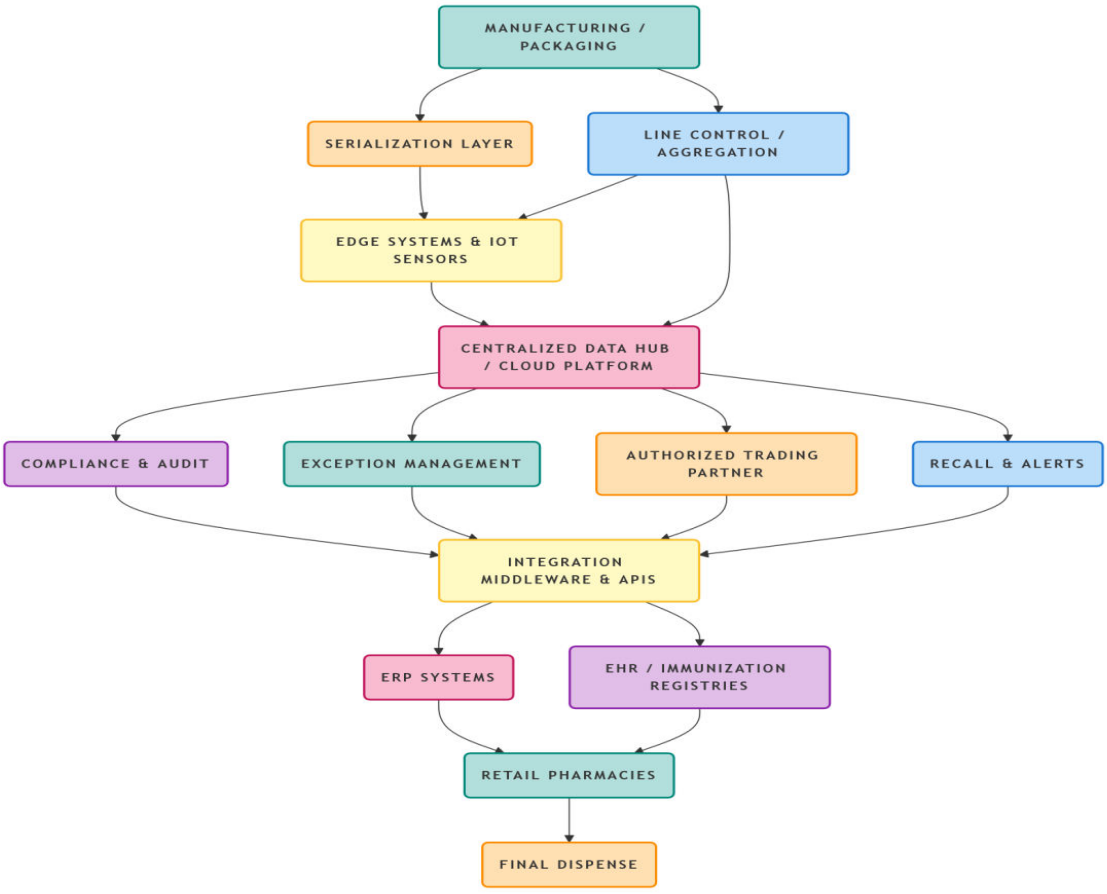

Figure 1: DSCSA-Compliant Pharmaceutical Supply Chain System

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

- Serialization Layer: Uses 2D Data Matrix barcodes and unique identifiers on various medication packages; Manufacturers serialize the data (NDC, serial, lot, expiration) and manage the serialization using software to manage the serialization.
- IoT Integration and Edge Systems: Uses edge devices on-site during manufacturing, distribution, in warehouses, and at dispensaries to record events locally, track environmental conditions, and scan items in real time. Monitoring cold chain temperature the IoT sensors continuously collect temperature points during shipping.
- Event-driven Data Pipelines: Uses message brokers for low latency, secure transfer of events generated by edge technologies such as transaction data, and environmental conditions.
- Centralized Data Hub and Compliance Platform: This is a cloud-based platform that collects and tracks serialized product data, and has compliance process tools (product verification, product recall).
- Integration Middleware and APIs: Integration middleware layers and APIs offer simple standardized data exchange between centralized systems and designated/approved external systems. Additionally, there are security applications that allow for access, encryption, etc.
- Monitoring, Analytics, and Visualization: There are packaged modules and dashboards that allow for business intelligence, monitoring trends, and confirming compliance, and reports can be part of role access for users.
- Framework for Security and Privacy: The technology component comes with extensive security and privacy frameworks and controls consistent with DSCSA terms and requirements (encryption, role access, incident response).
- Redundancy, Backup, and Disaster Recovery: A combination of redundancy and backup procedures for ongoing availability and resiliency of the data (replication, failover structures).

Pharmaceutical distribution systems that meet Drug Supply Chain Security Act (DSCSA) standards will employ different systems and technology. Featured elements include unit-level serialization using 2D Data Matrix barcodes to store critical identifiers such as a National Drug Codes (NDC), serial numbers, lot numbers, and expiration dates. Safety and environment monitoring will utilize wireless sensors to monitor all conditions throughout cold chain transport. These will then be contextualized and enhanced with data collection portals, in real-time, and alerts. Event data will be exchanged under the GS1 EPCIS model, while reliable messaging will be in support of the messaging will multiple APIs standardized under REST or simpler APIs, or MQTT. Additionally, scalable cloud infrastructure will support centralized storage and processing of transaction and serialization data, consuming compliant displays through an operational dashboard. Integration layers promote interoperability with multiple systems, and secure API gateways ensure appropriate access and encryption.

Security frameworks use TLS/SSL encryption, multi-factor authentication, and also address data privacy through frameworks such as HIPAA. Some use cases investigate blockchain technologies as a means of automating and publishing immutable event data. Overall, these analytics and visualization tools promote ad hoc decision making around trend analysis through real-time key performance indicators (KPIs). DevOps frameworks ensure high quality of software, and regulatory compliance, through the iterative process of validation and application to version control and continuous integration. Combined, these technologies promote compliance with the DSCSA by facilitating secure serialization management, real-time tracking and monitoring of environmental oversights, and providing visibility into compliance audits, across a larger pharmaceutical supply chain.

In a pharmaceutical supply chain operating under the Drug Supply Chain Security Act, (DSCSA) the strategies around visibility network-wide focus on secure collaboration, interoperability, and seamless electronic data exchange between all trading partners. Some of the core strategies include utilizing cloud-based solution for real-time electronic communications of serialization data, continuing to utilize standardized data formats such as GS1 EPCIS to create consistency in event based data exchange while using middleware and secure API gateways to create communication between disparate corporate systems. Role-based access control is crucial to protect sensitive information of entity stakeholders, and exception management frameworks will enable the timely identification and resolution of exception events.

Collaborative governance and data-sharing agreements will ensure the party relationships are strengthened through trust. Considering interoperability, some networks focus blockchain as an enabler to improve visibility and transparency in share transactions, while blockchain has it own challenges regarding scalability. Comprehensive

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

training and change management is essential to assure security processes have been followed, and data standards addressed. This allows for an secure, scalable, and interoperable ecosystem to be created within the DSCSA, while increasing visibility to required information and fulfilling required compliance to operate within the pharmaceutical supply chain. [13] depicts this ecosystem through Table 1:

Table 1: Technologies used in Pharmaceutical Traceability Pilots

Pilot / Project Name	Technologies Used	Key Outcomes and Impact
FDA Track-and-Trace Pilot (USA)	Blockchain, GS1 EPCIS, Serialization with 2D barcodes, Secure Cloud Data Platforms	Improved drug traceability and verification; validated interoperability protocols and data exchange standards; enhanced counterfeit drug detection
DrugXafe (Turkey, Saudi, Qatar)	Unique identifiers on packages, Real-time data transmission, Centralized databases for tracking	Significant reduction in counterfeit drugs; faster recall responses; elevated public health safety; honored as global best practice
European Falsified Medicines Directive (EU)	Serialization, QR codes, Aggregation, Secure national databases	Enhanced cross-border interoperability; reduced falsified medicine incidents; compliance with EU regulations
PharmaChain (Blockchain pilot)	Hyperledger Fabric blockchain for immutable traceability records	Increased transparency; resistance to data tampering; pilot demonstrated feasibility of distributed ledgers
RFID Tag Pilots (Germany, Taiwan, Pakistan)	RFID technology for package identification and tracking	Mixed results; in Germany showed promise for centralized data sharing; less success in Pakistan and Taiwan due to integration and adoption challenges

There are various approaches to provide scalability and/or performance improvement of high-volume pharmaceutical supply chain processes that require monitoring in compliance with the Drug Supply Chain Security Act (DSCSA). One option is distributed edge processing, which allows for serialization scanning and Internet of Things (IoT) sensor data to be processed locally, without incurring the latency and/or load on a network. Second, event-driven architecture can help organizations with efficiencies realized from scalable messaging systems to process event streams in real time. Issue from this phenomenon, is it can provide greater throughput in processing messages that traverse multiple components of the system, facilitating decoupled interactions when multiple services interact with events. Third, a cloud infrastructure can provide horizontal scalability through automatic provisioning of additional resources in response to increased load, particularly relevant during a recall or a new batch release to sale. Additionally, microservice design allows the different services for monitoring the environment and compliance reporting to be deployed and scaled independently, which promotes efficiency of resource.

Caches and data partitioning provide for speed of common queries, while new models and improved indexes can facilitate a more timely process of transaction events and inventory counts. Additionally, automated prioritization or rating of exception management with AI/ML analytical tools helps decision makers respond to exceptions with urgency to reduce the possibility of slowing operations down. Fourth, asynchronous processing of non-time sensitive processing

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

aids improved responsiveness and throughput. Finally, having strong monitoring and capacity planning is critical to/or ensures the performance system can be proactively managed. All of this enables the pharmaceutical networks to efficiently facilitate tracking and comply with millions of serialized packages every day to ensure patient safety and operational flexibility, especially at peak load or emergency moments. Finally, as the discussion about scaling to support performance improvements occurs, there are some performance metrics to consider in evaluating both the efficacy of the performance system and evaluating in compliance systems in pharmaceutical serialization system.

The serialization rate is the percentage of scanned serialized units that were accurately scanned throughout the various aspects of the supply chain. The accuracy of transaction data assesses whether the record transcriptions were fundamentally correct for movements of all the participating goods in the system to enable data integrity. The exception rate reveals issues about the quality of data, while the first time correct rate assesses operational quality by measuring the percentage of goods that passed quality testing on the first attempt, Response time to recalls considers the system in the managing of questionable items, and the validation rate considers how authorized trading partners validate authorized specifications. Environmental compliance tracks products to measure the time and conditions that goods are stored and transported, dated maturity of audit trails are available for compliance audit reporting. System resilience and latency dual performance measures assess performance of the system under load. The performance of CAPA, Corrective and Preventative Actions, measure data quality effectiveness considerations tracking as directed. Cycle time or lot release measures efficiency of the supply chain. Data interoperability assesses the success of the datasets standardization and sharing. All the performance metrics presented contribute to an overall performance assessment of the DSCSA traceability systems all of which favor operational excellence, regulatory compliance and transparency in the supply chain and product safety.

The pharmaceutical supply chain systems require integrity in their inventory, rapid reconciliation and audit readiness as part of the compliance systems for the Drug Supply Chain Security Act (DSCSA). Traditions of KPIs, Key Performance Indicators, will serve these purposes well. The serialization rate will ensure the degree of the goods that were successfully scanned in at shipment reflect the number of goods actually kept in inventory for purposes of traceability. The match rate of physical transactions will together confirm any transactional reconciling of the physical data of the movement data and the systems transactions records. Accurate aggregation of the relationships of packaged goods will ensure less space for mistakes in the recall queue and preparation closures and shipping confirmations. Cycle time for reconciliation measures the speed of reconciling discrepancies between serialized data and the physical data representing events concludes about the serialized events. This performance dimension will improve responsiveness in the supply chain. The time to complete serialized product listings for recalls is useful in establishing the system's 'readiness' in these emergencies in the well-being chain.

Completeness of the audit trail is a measure of enforcement in regulatory compliance by assessing what is documented in terms of transaction events. The average time it took to resolve any data inconsistencies is to help capture operational effectiveness in the organization. Monitoring any unauthorized attempt to change the data in the system is to safeguard security of data. The label reprint rate helps with awareness of quality in the serialization process and whether it is adding to or detracting from operating costs. Inventory turnover accuracy - which can be offsets from serialized data - is a way of optimizing stock levels. The latency of the data is about timeliness of being able to have visibility and acting on a decision. Regular exercises for recall practice help maintain stakeholders, readiness in compliance. Overall, these KPIs will minimize risk, optimize to operationally effective, and re-extend audit readiness to compliance with DSCSA are illustrated in below Figure 2.

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

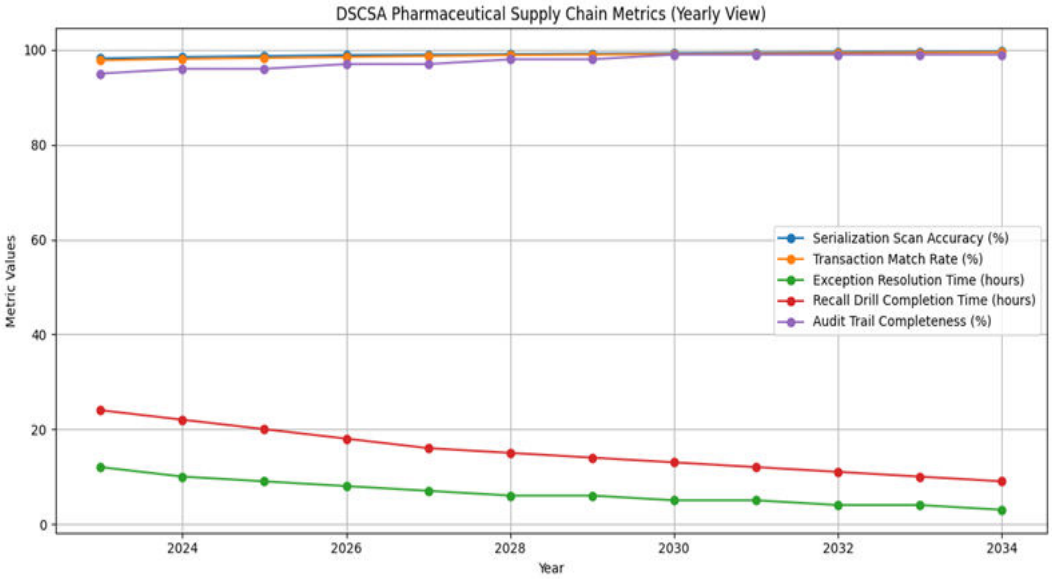

Figure 2: DSCSA Pharmaceutical Supply Chain Metrics

Assessing system pros and cons has created several pros, such as enhanced safety with counterfeit medications, enhanced supply chain visibility through rapid recall capabilities, and improved operational efficiencies through cloud platforms and standardizing data sharing. The scalability features support predictable management of high-volume transactions, and strong audit trails maintain data privacy and compliance with regulatory expectations. Despite pros, some challenges remain, including the complexity of implementation and costs for small companies, integrating legacy systems and disparate adoption of technology, and the need for sustained compliance efforts. New developments in artificial intelligence and machine learning, blockchain technologies, and the improvement of IoT sensors may develop in order to create improved transparency and operational effectiveness. New policies are also expected to develop in order to manage new risks of publicly-facing digital management measures and create more flexible frameworks for sustainability and compliance.

IV. CONCLUSION

The Drug Supply Chain Security Act (DSCSA) mandates that a unique identifier associated with transaction data is used for electronic serialization and traceability of pharmaceuticals. To maintain compliance, interoperable systems must be established that will allow for real time data sharing, authenticate trading partners, and preserve secure transaction history. Coupling serialization with IoT monitoring with data pipelines, and leveraging cloud platforms to augment the supply chain begins to promote more visibility into it, and helps diminish counterfeit products in the marketplace. Entering the pharmaceutical operating space requires management to have the ability to scale and optimize with cloud technology, edge processing, micro-services and AI used in exception managing. Metrics of success in a pharmaceutical operation are critical in ongoing compliance monitoring, specific to audit trail, recall readines, and serialized data accuracy, Metrics of success are also appropriate for pharmacy operations when considering update initiatives of technology. Recent pilot programming, an example were utilized both blockchain and cloud platforms, improved traceability and posibility of counterfeits being detected, solely based on logistical collaborations amongst all other trading partners. A retail pharmacy must be prepared to modernize its systems to serialize and share data, while still providing an accurate inventory daily and readiness for the necessary audit trails to be compliant to regulatory regulations.

Collaborative and securely exchange with approved partners is important for generating and moving forward with interoperable systems. Possessing real-time analytics data provides actionable insight for operational efficency and recall management. Ongoing training and education of pharmacy staff for current and altering DSCSA standards will further ability and promote accuracy reporting and the needed adjustments to maintain aclculated reporting accuracy

www.ijircce.com | e-ISSN: 2320-9801, p-ISSN: 2320-9798| Impact Factor: 8.625| ESTD Year: 2013|

International Journal of Innovative Research in Computer and Communication Engineering (IJIRCCE)

(A Monthly, Peer Reviewed, Refereed, Scholarly Indexed, Open Access Journal)

within the rapidly changing systemic flow in pharmacy operations. Their investment on scalable secure IT infrastructure for a assured time for success may be the approach that generates competitive advantage in retail pharmacy operation and if continue to support facilitating the drug was tracked for authenticity to further increase safety and security for the patient.

REFERENCES

1. "DRUG SUPPLY CHAIN AND SECURITY ACT REQUIREMENTS", Nov. 27, 2023, https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/drug-supply-chain/docs/ASHP-Drug-Supply-Chain-and-Security-Act-Requirements.pdf.
2. "Understanding DSCSA Compliance: A Guide for Pharma Supply Chain Managers", https://supplychainwizard.com/dscsa-compliance-for-pharma-supply-chain/.
3. "Pharmacy Inventory Management System: 10 Best Inventory Management Software for Pharmacy", Thierry Tremblay, September 12, 2024, https://www.kohezion.com/blog/pharmacy-inventory-management-system.
4. "DSCSA compliance and 2024 implementation timeline", Marcus Chang, October 10, 2024, https://blog.axway.com/industry-insights/healthcare-life-sciences/ready-serialization-dscsa-compliance.
5. Sarkar, S. (2022). *Digital Traceability of pharmaceutical drugs in supply chain.* International Journal of Advance Research in Computer Science and Management Studies, 10(2), 39-44. https://doi.org/10.32628/CSEIT228428
6. "How to Manage DSCSA Requirements with Pharmaceutical Software", Michael Benedick, https://www.bluelinkerp.com/blog/how-to-manage-dscsa-requirements-with-pharmaceutical-software/.
7. "Rfxcel, part of antares vision group, and mvc launch the traceability hub for the kingdom of bahrain to track end-to-end pharma supply chain", ANTARES VISION S.P.A., June, 2021, https://solution-providers.gs1.org/news/rfxcel-part-antares-vision-group-and-mvc-launch-traceability-hub-kingdom-bahrain-track-end-end.
8. "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry", September 2023, https://www.fda.gov/media/171796/download.
9. "A Proposed Architecture for Pharmaceutical Supply Chain Based Semantic Blockchain", Shimaa Ouf, September 30, 2020, https://inass.org/wp-content/uploads/2021/06/2021063004.pdf.
10. Yousefi N, Alibabaei A., "Information flow in the pharmaceutical supply chain", Iran J Pharm Res. 2015 Fall;14(4):1299-303. PMID: 26664401; PMCID: PMC4673962.
11. "DSCSA Serialization End-to-End Proof of Concept Pilot", MICHELLE RICH, https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/ xavier-dscsa-end-to-end-poc-pilot.pdf.
12. "DSCSA and Compliance", Nicole Berryman, Jul 8, 2024, https://verisys.com/blog/dscsa-compliance/.

INTERNATIONAL STANDARD SERIAL NUMBER INDIA

INNO SPACE SJIF Scientific Journal Impact Factor

doi crossref

निस्केयर NISCAIR

INTERNATIONAL JOURNAL OF INNOVATIVE RESEARCH

IN COMPUTER & COMMUNICATION ENGINEERING

9940 572 462 6381 907 438 ijircce@gmail.com

www.ijircce.com

Scan to save the contact details