DSCSA & Cloud ERP

How Cloud-Native ERP Simplifies DSCSA,
EPCIS, and Serialization at Scale

For Pharmacy, Pharmaceutical, and Medical Distributors

A White Paper by Ximple Solutions

1. Executive Overview

The Drug Supply Chain Security Act (DSCSA) has fundamentally transformed how pharmaceutical and medical products move through the U.S. healthcare supply chain. What began as aspirational legislation in 2013 has evolved into a comprehensive regulatory framework mandating unit-level serialization, electronic traceability, and verified trading partners throughout the distribution network.

The regulatory landscape continues to evolve with increasing complexity. Unit-level serialization requirements mandate unique identifiers for every saleable unit. Electronic Product Code Information Services (EPCIS) establishes standardized data exchange protocols. Product verification systems ensure authenticity. Authorized Trading Partner validation confirms licensing integrity.

Traditional ERP systems, built before DSCSA requirements emerged, struggle with these demands. Legacy platforms lack native serialization support, real-time EPCIS data exchange, and integrated verification routing. Many distributors supplement inadequate core systems with disconnected point solutions—creating data silos, manual workflows, and compliance gaps.

Cloud-native ERP represents a paradigm shift. Purpose-built for pharmaceutical compliance, these platforms provide the operational backbone needed to manage serialization at scale, automate EPCIS event capture, integrate verification services, and enforce trading partner controls—all while maintaining the speed, accuracy, and audit trails regulatory agencies demand.

2. DSCSA Requirements Driving Modernization

DSCSA establishes a comprehensive framework for pharmaceutical supply chain integrity. Understanding these requirements is critical for selecting technology solutions.

Unit-Level Serialization Requirements

Every prescription drug package must carry a unique product identifier containing the National Drug Code (NDC), serial number, lot number, and expiration date in machine-readable format (typically 2D DataMatrix barcodes). Distributors must capture and maintain this serialization data throughout the product lifecycle—from receiving through final dispensing.

EPCIS-Based Traceability and Data Exchange

DSCSA mandates Electronic Product Code Information Services (EPCIS) as the standard for serialization data exchange. Every change in product ownership or location must be documented through standardized EPCIS events—Commission, Pack, Ship, Receive, Decommission—that create an unbroken chain of custody from manufacturer to patient.

Product Verification and Investigation

Distributors must verify product authenticity when suspect or illegitimate products are identified. This requires real-time integration with verification routing services that query manufacturer databases to confirm that serialization data matches authentic products. Investigation capabilities must trace products forward through the supply chain and backward to their origin within hours.

Authorized Trading Partners

All transactions must occur only with authorized trading partners—entities properly licensed and registered with appropriate regulatory authorities. Distributors must maintain current licensing documentation, monitor license expiration dates, and prevent transactions with unlicensed parties.

3. Serialization at Scale for Pharma & Medical Distribution

Operating a DSCSA-compliant distribution center requires capturing serialization data at multiple levels and integrating that data into every warehouse workflow.

Multi-Level Serialization Hierarchy

Pharmaceutical products arrive with serialization data at three levels: unit (individual saleable packages), case (shipping cases containing multiple units), and pallet (pallets containing multiple cases). Cloud ERP systems maintain these hierarchical relationships, enabling efficient receiving and order fulfillment without scanning every individual unit.

Serialized Receiving and Putaway

Receiving workflows validate serialization data against advance ship notices and manufacturer EPCIS data. Barcode scanners or RFID readers capture serial numbers, automatically verify data integrity, flag discrepancies, and update inventory records in real-time. Products with invalid serialization are immediately quarantined for investigation.

Serialized Picking, Packing, and Shipping

Order fulfillment becomes serialization-aware. When pharmacies order products, the system generates pick lists identifying specific serialized units based on FEFO logic. Packing validates that correct serialized units are included in each shipment. The system automatically generates EPCIS Ship events and transmits serialization data to customers electronically.

4. EPCIS 1.2 Data Exchange & Interoperability

EPCIS (Electronic Product Code Information Services) provides the standardized language for pharmaceutical supply chain communication. Cloud ERP systems must serve as the single source of truth for EPCIS event generation and data exchange.

How EPCIS Works

EPCIS defines five core event types: Commission (when manufacturers create serialized products), Pack (when units are aggregated into cases or pallets), Ship (when products leave a facility), Receive (when products arrive at a facility), and Decommission (when products are destroyed or consumed). Each event includes the what (serialization data), when (timestamp), where (facility identifier), why (business context), and how (business transaction references).

Cloud ERP as Single Point of Truth

Fragmented systems create data inconsistencies. Cloud ERP consolidates all serialization and transaction data in a single database, ensuring that inventory transactions, order fulfillment, and EPCIS event generation stay perfectly synchronized. When a shipment leaves the facility, the ERP system simultaneously updates inventory, generates invoices, and creates EPCIS Ship events—atomically, ensuring data integrity.

Real-Time Data Exchange

API-first architectures enable real-time EPCIS data exchange. When a shipment leaves a distributor's facility, the system immediately transmits EPCIS Ship events to the receiving pharmacy or hospital. Real-time exchange eliminates data latency, enables faster investigation responses, and ensures compliance with regulatory timelines.

Ready to implement DSCSA-compliant cloud ERP?

Schedule Your Consultation

5. Verifying Products Under DSCSA

Product verification is the critical control that protects patients from counterfeit, adulterated, or diverted pharmaceuticals. Cloud ERP systems integrate verification workflows directly into daily operations.

Real-Time Product Verification

When verification is required, warehouse staff scan the product's serialization data. The cloud ERP system extracts the NDC, serial number, lot, and expiration date, then routes a verification request to the appropriate verification service. The service queries manufacturer databases and returns a verification response within seconds. The ERP system logs the complete transaction for audit purposes.

Automated Quarantine and Investigation

When verification fails or products are flagged as suspect, cloud ERP systems automatically trigger documented workflows. Products are immediately moved to quarantine inventory. Investigation cases are created with complete chain-of-custody documentation. Quality assurance teams receive alerts. The system prevents any further transactions involving suspect serialization until investigations conclude.

6. Managing Authorized Trading Partners

DSCSA requires that pharmaceutical transactions occur only between authorized trading partners. Cloud ERP systems automate trading partner verification and compliance monitoring.

Automated ATP Verification

Before accepting an order from a pharmacy, clinic, hospital, or wholesale partner, distributors must verify that the entity holds valid licenses and registrations. Cloud ERP systems integrate with state licensing databases and FDA registration systems to automatically validate credentials. New customer onboarding includes automated license verification as a prerequisite for account activation.

License Monitoring and Alerts

Trading partner credentials are stored in customer master data, linked to every order and shipment. When an order is entered, the system validates that all required licenses remain current. Automated monitoring checks license expiration dates daily, generating alerts 30, 60, and 90 days before expiration. Orders to customers with expired licenses are automatically blocked until documentation is updated.

7. DSCSA-Compliant Warehouse Operations

Every warehouse workflow must support DSCSA serialization and traceability requirements. Cloud ERP systems embed compliance into daily operations.

Serialized Inbound Validation

Receiving teams validate incoming shipments against advance ship notices containing serialization data. Products with invalid serial numbers, mismatched lot numbers, or expired dates are flagged immediately. The system creates exception reports for investigation and prevents defective inventory from entering available stock.

FEFO Picking with Expiry Control

First-Expired, First-Out (FEFO) logic is essential for pharmaceutical distribution. Cloud ERP systems enforce FEFO rules automatically. When orders are picked, the system directs warehouse staff to units with the shortest remaining shelf life. Configurable expiry thresholds prevent shipment of products nearing expiration, protecting customers from unusable inventory.

Cold-Chain & Controlled Substances

Cloud ERP platforms integrate with cold-chain monitoring systems, capturing temperature data throughout distribution. Temperature excursions automatically trigger alerts and quarantine workflows. Controlled substance security requires dual verification, access controls, and complete audit trails—capabilities cloud ERP systems enforce programmatically.

8. Medical Device & UDI Traceability

Medical device distributors face unique traceability requirements centered on the FDA's Unique Device Identifier (UDI) system.

UDI Integration

The UDI consists of a device identifier and production identifier, encoding information about the device, manufacturer, lot number, serial number, and expiration date. Cloud ERP systems capture UDI data during receiving, maintain traceability throughout distribution, and include UDI information in customer shipment documentation. Integration with FDA's Global UDI Database (GUDID) enables automatic product master data enrichment.

Recalls and Field Safety Corrective Actions

When manufacturers issue device recalls or field safety corrective actions (FSCA), distributors must identify affected inventory and notify customers. Cloud ERP systems query serialization data to identify affected units, automatically generate customer notification lists, and track customer acknowledgments. Complete audit trails document recall execution for regulatory reporting.

9. Cloud ERP Architecture for DSCSA Compliance

The architectural foundation of cloud-native ERP platforms provides essential capabilities for managing the scale, complexity, and regulatory requirements of DSCSA compliance.

Why Cloud-Native is Essential

Cloud-native architecture delivers critical advantages:

- Scalability: Systems automatically scale to handle peak transaction volumes
- Reliability: Multi-region redundancy and automated failover ensure continuous operations
- Real-time processing: Subsecond query response times across billions of serialization records
- Continuous updates: Automatic platform updates deliver new features without costly upgrade projects

Event Capture and Immutable Audit Trails

Every transaction, scan, verification, and data change is recorded in tamper-proof audit logs. Cloud ERP platforms capture detailed event logs for all DSCSA-relevant activities—serialization captures, verification requests, trading partner validations, inventory adjustments—with user identification, timestamps, and complete context. Immutable audit trails satisfy regulatory requirements and support investigations.

API-First Design

Cloud ERP platforms expose comprehensive REST and GraphQL APIs for EPCIS data exchange, verification routing, trading partner data sharing, and third-party integrations. API-first architecture enables real-time connectivity with manufacturer repositories, verification services, pharmacy systems, and industry traceability networks.

10. Role-Based Security & 21 CFR Part 11 Support

Pharmaceutical distribution requires robust security controls and electronic record integrity that satisfy FDA 21 CFR Part 11 requirements.

Tamper-Proof Audit Trails

21 CFR Part 11 requires secure, time-stamped audit trails documenting the creation, modification, and deletion of records. Cloud ERP systems automatically capture user identity, timestamps, previous values, and new values for all database changes. Audit logs are stored in append-only tables that prevent tampering and support long-term retention requirements.

Electronic Signatures and Access Control

Electronic signatures provide legally binding approval for critical decisions. Cloud ERP platforms support 21 CFR Part 11 compliant electronic signatures for product disposition, investigation conclusions, and batch release decisions. Role-based access control enforces separation of duties, ensuring that only authorized personnel can access sensitive functions.

11. Integrations Required for DSCSA Compliance

DSCSA compliance requires integration across a complex ecosystem:

- EPCIS Repositories: Bidirectional data flows with manufacturer repositories and industry-wide traceability networks
- Verification Services: Real-time verification requests and responses with automated documentation
- Pharmacy/Hospital Systems: Electronic ordering, automated replenishment, and real-time inventory visibility
- 3PL Partners: Unified visibility across distributed operations for complete DSCSA compliance

12. Data Quality & Governance

DSCSA compliance depends on data accuracy. Cloud ERP platforms provide data quality controls that prevent errors before they propagate through the supply chain.

Product master data—NDC codes, UDI identifiers, lot numbers, expiration dates—is validated against authoritative sources such as the FDA National Drug Code Directory and Global UDI Database. Automated validation rules prevent invalid entries. Data stewardship workflows ensure that master data remains current as regulatory requirements evolve.

13. Implementation Roadmap

Implementing DSCSA-compliant cloud ERP requires careful planning, phased execution, and comprehensive change management.

Migration from Non-Serialized to Serialized Inventory

The approach depends on inventory volumes and business requirements. Some distributors choose a cutover approach, transitioning all products on a single date. Others implement phased transitions, prioritizing high-value or high-risk products first. Cloud ERP systems support both strategies, maintaining separate serialized and non-serialized inventory pools during transition periods.

Trading Partner Onboarding and Training

EPCIS implementation requires coordination with trading partners. Implementation roadmaps include partner onboarding programs that provide technical specifications, test environments, and validation procedures. Training ensures that customers understand new data exchange protocols and can consume EPCIS events effectively.

14. Measurable ROI of DSCSA-Enabled Cloud ERP

Cloud ERP investments deliver quantifiable returns that extend beyond regulatory compliance.

- Lower Compliance Risk: 60-80% reduction in audit preparation time. The cost of a single serious DSCSA violation often exceeds the entire cost of cloud ERP implementation
- Faster Investigations: Investigation queries complete in minutes versus days. Recall execution reduced from 15-20 days to 3-5 days
- Reduced Operational Errors: 50-70% reduction in picking errors, 30-50% decrease in expired inventory write-offs. For mid-sized distributors, this often represents $200,000-$500,000 in annual savings
- Labor Savings: 40-60% reduction in compliance-related labor, allowing staff redeployment to value-added activities
- Customer Trust: Demonstrated product integrity builds relationships and creates competitive differentiation

15. DSCSA Readiness Checklist

Use this checklist to assess DSCSA compliance readiness:

Serialization Coverage

- ■ All pharmaceutical inventory includes complete serialization data
- ■ Receiving validates serialization against advance ship notices
- ■ Picking, packing, shipping capture unit-level serialization
- ■ Returns validate serialization against original shipment records

EPCIS Event Capture

- ■ Automatic Ship event generation for all outbound shipments
- ■ Automatic Receive event generation for all inbound receipts
- ■ EPCIS events include all required data elements
- ■ Real-time transmission to trading partners

Verification & Trading Partners

- ■ Operational integration with verification routing services
- ■ Failed verification triggers automatic quarantine workflows
- ■ All customers have validated state pharmacy licenses on file
- ■ Automated license expiration monitoring with proactive alerts

Audit & Compliance

- ■ Complete, tamper-proof audit trails for all critical transactions
- ■ 21 CFR Part 11 compliant electronic signatures
- ■ Six-year audit log retention with access protection
- ■ FEFO logic ensures shortest-dated inventory is picked first

- Temperature monitoring with automated alerts for excursions
- Controlled substance security controls and dual verification enforced

Ready to achieve DSCSA compliance?

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Conclusion

DSCSA compliance represents a fundamental transformation of pharmaceutical distribution operations. The regulatory requirements—unit-level serialization, EPCIS traceability, product verification, and authorized trading partner controls—demand technology capabilities that legacy ERP systems simply cannot provide.

Cloud-native ERP platforms deliver the capabilities pharmaceutical distributors need: serialization at scale, automated EPCIS data exchange, integrated verification workflows, and comprehensive audit trails. Beyond compliance, these platforms drive operational excellence through improved inventory accuracy, faster investigations, reduced errors, and enhanced customer trust.

The question for pharmaceutical and medical distributors is not whether to implement DSCSA-compliant cloud ERP, but how quickly they can complete the transition. Organizations that modernize now position themselves for long-term competitive advantage while those that delay face increasing compliance risk and operational inefficiency.

Contact Us Today

Let's discuss how Ximple Solutions can help your pharmaceutical distribution business achieve DSCSA compliance and operational excellence through cloud ERP transformation.

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Learn More About Ximple Solutions