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MUST-KNOW QUESTIONS ON **SERIALIZATION & DSCSA COMPLIANCE**

Unlock
expert insights
to navigate
serialization
with confidence.

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Q1

What exactly needs to be serialized under DSCSA?

Under the Drug Supply Chain Security Act (DSCSA), manufacturers and repackagers must serialize prescription drug packages at the smallest saleable unit level. Each unit must carry a unique product identifier encoded in a 2D Data Matrix barcode, containing the following elements:

- National Drug Code (NDC) – typically embedded in a Global Trade Item Number (GTIN)
- Serial Number
- Lot Number
- Expiration Date

Q2

What's the difference between serialization and aggregation? Do I need both?

Serialization assigns a unique identifier to each saleable unit. Aggregation links those serialized units to their parent packaging levels (e.g., bundles, cases, or pallets).

While aggregation is not mandated under DSCSA, it significantly improves traceability and logistics efficiency. Though not legally required yet, it is widely expected by trading partners and is considered an industry best practice.

Q3

How should we handle returns under DSCSA?

As of November 27, 2023, wholesale distributors must verify the serialized product identifier of returned saleable products before resale. This is typically done using the Verification Router Service (VRS), which facilitates real-time verification with the manufacturer's EPCIS data.

Returned products lacking proper serialization or VRS integration may be rejected from reentry into the supply chain.

Q4

If we outsource packaging, who is responsible for compliance?

The ultimate responsibility for DSCSA compliance lies with the manufacturer or labeler, not the contract packaging organization (CPO). You must ensure that:

- The CPO complies with serialization requirements.
- Serialized data is securely exchanged and captured in your systems.
- Data is properly uploaded to your EPCIS repository.

Q5

What is EPCIS, and why does it matter?

Electronic Product Code Information Services (EPCIS) is a GS1 standard for capturing and sharing serialization and event data across the supply chain. Under DSCSA, EPCIS enables interoperable electronic tracing of product movements and is the preferred method for sharing T3 data (Transaction Information, History, and Statement).

Q6

As a small pharmacy, do we need to serialize each prescription?

Pharmacies are not required to serialize products. Serialization is the responsibility of manufacturers and repackagers. However, as dispensers, you must:

- Receive and scan serialized products.
- Store and retrieve T3 data.
- Verify products when handling suspect/illegitimate items.
- Transact only with Authorized Trading Partners (ATPs).

Your systems must be capable of handling serialized data and supporting compliance requirements.

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Q7

What must be encoded in the 2D Data Matrix barcode?

The barcode must include:

- GTIN (incorporating the NDC)
- Serial Number
- Lot Number
- Expiration Date
- These are encoded per GS1 standards and are typically accompanied by human-readable text.

Q8

Our WMS isn't serialization-ready. What upgrades should we consider?

Look for a WMS or serialization solution with:

- Serialized inventory tracking
- 2D barcode scanning capabilities
- EPCIS data exchange functionality
- T3 data capture and management
- Integration with trading partners
- Product identifier verification tools
- Evaluate vendors with proven DSCSA experience, scalable infrastructure, and strong support services.

Q9

Why is EPCIS so frequently mentioned in DSCSA discussions?

EPCIS is critical because it supports:

- Interoperability between different trading partner systems
- Scalability for growing volumes of serialized data
- Efficiency through electronic, standardized data exchange
- It's the industry standard for meeting the 2027 DSCSA milestone for full electronic, interoperable tracing.

Q10

Do repackagers need to generate new serial numbers?

Yes—if a repackager alters the product packaging, they must assign a new serial number. If the original manufacturer's packaging remains intact, the existing serial number can be retained.

Regardless, full traceability must be maintained between original and repackaged items.

Q11

How should we manage serialization for exempt products?

Some products (e.g., medical gases, compounded drugs) are exempt from serialization. If a product is exempt but still covered by DSCSA, you must track it at the lot level. Best practices:

- Document exemption status
- Flag exempt SKUs in your system
- Prevent errors in compliance workflows

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Q12

What are the risks of DSCSA non-compliance?

- FDA enforcement actions (e.g., warning letters, fines)
- Product seizures
- Trading partner refusals
- Disrupted supply chain operations

Q13

How do we verify serialized products?

- Scanning product identifiers
- Confirming against the manufacturer's EPCIS records or VRS
- Maintaining verification records for at least 6 years

Q14

Can we use paper records for serialization data?

No. While T3 data may initially be exchanged in paper or PDF format, serialization data must be stored electronically to support real-time verification and interoperability.

By 2027, all stakeholders must support fully electronic, interoperable tracing.

Q15

How do we ensure serialization data accuracy?

- Automated data validation rules
- Periodic internal audits
- Format compliance checks
- Ensure all systems comply with FDA formatting, transmission, and retention standards.

Q16

What's the role of the FDA's DSCSA database?

The FDA's Product Tracing System will support the nationwide exchange of T3 data. Your serialization and traceability systems must be designed to communicate with and support this infrastructure by 2027.

Q17

How do we future-proof our serialization system?

- Modular design
- Standards-based architecture (e.g., GS1, EPCIS)
- Easy software updates
- Stay agile in response to changing regulatory requirements and global serialization needs.

Q18

How do we integrate serialization with ERP or WMS?

- Conduct system gap analysis
- Define clear data exchange formats (preferably GS1/EPCIS)
- Ensure bi-directional synchronization of serialized data
- Test and validate integrations thoroughly
- Work with vendors who understand pharmaceutical serialization requirements.

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Q19

How do we serialize complex packaging (e.g., kits)?

- Serialize individual components
- Assign a parent serial number for the kit
- Maintain a traceable relationship across levels
- Ensure your system can support aggregation and disaggregation as needed.

Q20

How does serialization impact logistics and operations?

- Updated packaging and labeling lines
- New scanners and infrastructure
- Staff training
- Conduct a comprehensive impact assessment to identify cost, time, and workflow implications across your supply chain.

Q21

How do we protect serialization data from cyber threats?

- Encrypted data transmission and storage
- Strict access controls and audit trails
- Firewalls and network segmentation
- Employee cybersecurity training
- Serialization data is sensitive and must be protected against tampering and breaches.

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Don’t let serialization challenges put your business at risk.

At VariTec Consulting, we help you build a future-ready serialization strategy that keeps you compliant, connected, and in control.

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