SERIALIZATION TRACEABILITY: WHERE THE PIECES HAVE TO CONNECT

Traceability requires more than a barcode. This infographic shows how the product, data, trading partners, and investigation process need to work together, and what to watch as the small dispenser exemption winds down.



SMALL DISPENSER EXEMPTION

Dispensers with **25 or fewer** full-time pharmacists or pharmacy technicians generally qualify under the FDA exemption, which now runs through **Nov. 27, 2027**.

Confirm your eligibility, then use the extra time to prepare, not pause. Foundational DSCSA obligations still apply.



12-24 MONTHS

Strengthen data quality and investigation workflows now as enforcement and operational expectations increase.



DISPENSER PARTICIPATION
More active verification at the final checkpoint.

ENFORCEMENT
Greater scrutiny of real-world compliance.

INTEGRATION
Better-connected systems, data, and workflows.

COUNTERFEIT THREATS
More sophisticated product and data imitation.





1-UP, 1-DOWN

DISTRIBUTED TRACING

Reliable tracing depends on connected trading partners, not a central database.

6 FACTORS

TO VERIFY LEGITIMACY

- PRODUCT
- DATA
- SOURCE
- OWNERSHIP HISTORY
- TRADING-PARTNER AUTHORIZATION
- SURROUNDING CIRCUMSTANCES

No single scan or data point proves that a product is legitimate.



SERIALIZED PACKAGE + 2D DATAMATRIX BARCODE + EPCIS TRANSACTION DATA

3 FOUNDATIONAL TECHNOLOGIES

Technology is not enough; accurate data and effective processes make traceability work.

Prepare your systems for NDC-12

NDC-12 will put pressure on master data, labeling, barcode accuracy, and the connection between the physical product and its digital record.

MARCH 7, 2033 — The 12-digit NDC format takes effect

THROUGH MARCH 6, 2036 — Systems must support the transition period

NEXT STEP

Turn serialization into something you can prove.

Two Labs helps manufacturers strengthen DSCSA strategy, data exchange, trading-partner onboarding, SOPs, exception handling, and NDC-12 readiness.

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