AEROZ

US PHARMA · DSCSA · READINESS CHECKLIST

DSCSA Enhanced Requirements Readiness Checklist

Section 582(g) enhanced drug distribution security — what to have in place now.

WHO MUST COMPLY

Pharmaceutical manufacturers, repackagers, wholesale distributors, dispensers (pharmacies) and 3PLs handling prescription human drugs in the US supply chain.

THE DEADLINE

The one-year stabilization period ended **27 Nov 2024**. FDA's tiered exemptions have since expired for wholesale distributors (27 Aug 2025) and larger dispensers (27 Nov 2025); the small-dispenser exemption (25 or fewer full-time pharmacists and technicians) was extended by FDA in Aug 2026 and now ends **27 Nov 2027**. Treat the enhanced requirements as live.

1 · Know your obligations & timeline

- [ ] Confirm each trading-partner role you hold (manufacturer, repackager, wholesaler, dispenser, 3PL) and the enhanced §582(g) duties that attach to each.
- [ ] Confirm whether any FDA exemption or waiver still applies to you — the small-dispenser exemption is the last one open, and FDA moved its close to 27 Nov 2027 (August 2026 extension).
- [ ] Map every product to DSCSA scope: prescription human drugs in finished form, and document any lawful exclusions.

2 · Interoperable, package-level data (EPCIS)

- [ ] Exchange Transaction Information (TI) and Transaction Statements (TS) electronically at the package level for every change of ownership.
- [ ] Adopt EPCIS (1.2 or 2.0) as the interoperable format for tracing data with trading partners.
- [ ] Capture serialized GTIN (sGTIN): GTIN + serial number + lot + expiry on every saleable package.
- [ ] Validate aggregation (case-to-pallet parent-child) and decide inference vs. scan-based verification with each partner.
- [ ] Run connectivity + error-handling tests with each trading partner before go-live.

3 · Authorized Trading Partners (ATP)

- [ ] Verify every trading partner holds a valid state license or FDA registration before transacting.
- [ ] Maintain an ATP monitoring cadence so a lapsed license is caught before the next transaction.

4 · Verification & suspect product

- [ ] Stand up saleable-returns verification: respond to a product-identifier request within 24 hours.
- [ ] Verify the product identifier at the package level whenever product is flagged as suspect.
- [ ] Document the suspect / illegitimate product workflow: quarantine, investigate, and notify FDA on Form 3911 when confirmed.

5 · Records, systems & audit

- [ ] Retain TI/TS records for 6 years and be able to produce them on request.
- [ ] Ensure systems can respond promptly to an FDA or trading-partner tracing request.
- [ ] Govern serialization + aggregation master data (one source of truth, versioned).

WHERE AEROZ FITS

Serialization proves the data about a unit moved correctly — it does not prove the physical unit in hand is genuine. Aeroz adds a tamper-evident physical anchor bonded to the package, so a copied serial or 2D code fails verification, plus an EPCIS 2.0 custody record and a verification page for returns and suspect-product checks.

Book a fixed-fee, 14-day Aeroz Readiness Audit — a written gap analysis, no commitment to proceed. **aeroz.io/contact**

Sources: FDA DSCSA guidance & exemptions (2024–2025); 21 U.S.C. §360eee-1 (Section 582).

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