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DSCSA Inspection Readiness Scorecard

Small Dispensers

Test your current Drug Supply Chain Security Act (DSCSA) process and prepare for electronic package-level tracing. Pick one recent shipment and one older record. Run the checks with staff who handle receiving and records.

Pharmacy or location | **Completed by** | **Date**

Score what your team can show

Select one score per check. Use a record or run a drill.

0 Could not show or unsure **1 Partly demonstrated** **2 Demonstrated**

	Readiness check	0	1	2
01	**Authorized trading partners** Show a dated authorization check for one supplier you buy from.	○	○	○
02	**Transaction data at receiving** Show the transaction information and transaction statement for a recent covered shipment.	○	○	○
03	**Receiving and reconciliation** Use your receiving procedure to compare the product you received with the supplier's transaction record.	○	○	○
04	**Missing or mismatched data** Show an exception record or run a drill. Explain who decides to hold product and how the issue is closed.	○	○	○
05	**Six-year access to records** Pull an older record and show how required transaction records stay accessible for six years after the transaction.	○	○	○
06	**Record retrieval drill** Ask your backup to pull the transaction information and statement for a recent shipment.	○	○	○
07	**Suspect product quarantine** Show where staff quarantine suspect product, how they keep it out of use, and who they contact.	○	○	○
08	**Suspect product investigation** Show how your lead investigates with trading partners as applicable and documents how the case was resolved.	○	○	○
09	**Illegitimate product response** Run a drill. Identify who sends both required notices and who keeps the product quarantined through disposition.	○	○	○
10	**Procedures and training** Show your current DSCSA procedure, staff training records, and the name of your lead and backup.	○	○	○

Priority checks A 0 on any of checks 7 to 9 goes at the top of your action plan.

Add your scores and assign follow-up on page 2.

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Your Results and Next Steps

Total score

_____ / 20

Add all ten scores. Use this self-assessment to plan follow-up.
Fix any 0 on checks 7 to 9 first, whatever the total.

17 to 20	10 to 16	0 to 9
Close open gaps and repeat the drill with another shift.	Assign owners to the lowest-scoring checks and retest.	Practice receiving and record retrieval with your DSCSA lead.

Your three priority fixes

	Fix	Owner	Due date
1			
2			
3			

Prepare for electronic tracing

FDA extended specified DSCSA exemptions until November 27, 2027. To qualify, the owning company must have 25 or fewer full-time employees who are licensed pharmacists or qualified pharmacy technicians across its locations as of November 27, 2026.

Keep required records accessible. List untested supplier connections and set a date to test electronic data receipt, package-level matching, and how staff handle missing data.

Next supplier connection to test _____ **Test date** _____

Records requests and notifications

For a covered federal or state request about a recall or a suspect or illegitimate product investigation, provide records within two business days of receipt or within another timeframe FDA sets.

Within 24 hours of an illegitimate product determination, notify FDA through the 3911 platform in CDER NextGen (preferred) or email Form FDA 3911. Separately notify immediate trading partners you have reason to believe may have received the product within the same 24 hours.

Keep suspect product investigation and illegitimate product disposition records for at least six years after each concludes.

How Advasur 360 can help

Advasur 360 helps you compare received product with supplier data, document discrepancies, and retrieve transaction records. Bring one check your team struggled to demonstrate.

Schedule a 30-minute DSCSA Readiness Review calendly.com/j-shaver/360-demo

Federal sources DSCSA Section 582 FDA exemption letter FDA 3911 instructions

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