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DSCSA Glossary

Term	Definition
Affiliate	A business entity related to another where one controls (or can control) the other, or a third party controls (or can control) both.
Authorized Trading Partner (ATP)	A trading partner that meets DSCSA's "authorized" standard: manufacturers and repackagers hold a valid FDA registration; wholesale distributors and 3PLs hold a valid state or federal license and comply with FDA licensure reporting; dispensers hold a valid state license.
Dispenser	A retail pharmacy, hospital pharmacy, chain pharmacy group under common ownership, or anyone else legally authorized to dispense or administer prescription drugs, including their affiliated warehouses or distribution centers that don't act as wholesale distributors. Excludes those who dispense only animal drugs.
Drug Supply Chain Security Act (DSCSA)	Title II of the Drug Quality and Security Act, signed into law November 27, 2013. It establishes steps to build an electronic, interoperable system to identify and trace certain prescription drugs at the package level as they move through the US supply chain.
Electronic Product Code Information Services (EPCIS)	A GS1 data standard that trading partners use to exchange DSCSA tracing data electronically. Each EPCIS event records what product was involved, when and where the event happened, and why.

Global Location Number (GLN)	A 13-digit GS1 number that identifies a physical location or legal entity. In EPCIS data, it shows who handled the product and where.
Global Trade Item Number (GTIN)	A unique GS1 number that identifies a product. For DSCSA, it's a 14-digit format that includes the NDC and defines what the product is.
Interoperability	Under DSCSA's enhanced requirements, the secure, electronic exchange of transaction information and transaction statements between trading partners. It includes package-level product identifiers, package-level verification, the ability to gather tracing data back to the manufacturer for recalls or investigations, and accepting saleable returns only when they can be matched to their TI and TS.
Manufacturer	The holder of an FDA-approved drug application or biologics license for a product (or, if none, whoever made it). Also includes a co-licensed partner or affiliate that receives the product directly from that party.
National Drug Code (NDC)	FDA's standard for uniquely identifying drugs marketed in the US. It has three segments: labeler, product, and package code. Currently 10 digits; effective March 7, 2033, all NDCs move to a uniform 12-digit (6-4-2) format.
Product Identifier	A standardized graphic, in human-readable form and a machine-readable 2D data matrix barcode, containing the product's standardized numerical identifier (NDC plus a unique serial number of up to 20 characters), lot number, and expiration date.
Repackager	A person who owns or operates an establishment that repacks and relabels a product or package for further sale or for distribution without a further transaction.

Suspect Product	A product with reason to believe it is potentially counterfeit, diverted, stolen, intentionally adulterated, the subject of a fraudulent transaction, or otherwise unfit for distribution such that it could cause serious harm or death. It must be quarantined and investigated.
Third Party Logistics (3PL)	An entity that provides or coordinates warehousing or other logistics services for a manufacturer, wholesale distributor, or dispenser, without taking ownership of the product or directing its sale or disposition.
Transaction Information (TI)	The data provided with each transaction: product name, strength and dosage form, NDC, container size, number of containers, lot number, transaction date, shipment date (if more than 24 hours after the transaction), and the business name and address of the seller and buyer.
Transaction History (TH)	A paper or electronic statement with the TI for each prior transaction going back to the manufacturer. The requirement to provide and receive TH ended on November 27, 2023.
Transaction Statement (TS)	A paper or electronic statement in which the seller attests that it is authorized, received the product from an authorized party, received TI and TS from the prior owner, did not knowingly ship a suspect or illegitimate product, had verification systems in place, did not knowingly provide false TI, and did not knowingly alter the TH.
Wholesaler	A person engaged in wholesale distribution, other than a manufacturer, co-licensed partner, 3PL, or repackager.