

DSCSA FAQ -

Q: What is DSCSA? Drug Supply Chain Security Act. Enacted in 2013 to protect our supply chain against counterfeit and illegitimate drugs. The law was created to prevent, detect and respond to suspect and illegitimate product.

Q: What DSCSA regulations does a dispenser need to comply with? Dispensers are required to work with an Authorized Training Partner (ATP), have processes to receive and maintain product tracing data, identify and investigate suspect product, and verify product is legitimate. As of November 27, 2023, dispensers will need a Global location number (GLN), their own standard operating procedures for identifying, quarantining, and investigating suspect product.

Q: What is an Authorized Trading Partner and how can I verify an ATP is authorized to trade with? ATP –Authorized Trading Partner is a properly licensed distributor of pharmaceutical products. An ATP must have current State and DEA licenses and FDA registration. The verification of licenses can be found on many government websites for example, FDA, State Boards of Pharmacy, the NABP website are just a few.

Q: What is a Product Identifier? A product identifier must be on every container label and include serial number, NDC, lot number and expiration date. This information can be found in the format of a 2D bar code.

Q: What is on a current traceability statement? T3 Data –Drug tracing history (pedigree), tracing information, and tracing statement. This information is included in an advanced shipping notice (ASN)

Q: What is an ASN? –Advance Ship Notice is an electronic data interchange (EDI) message sent from the shipper to the receiver prior to the departure of the shipment from the shipper’s facility. The message includes complete information about the shipment and its contents. Information contained within the ASN includes a description of the medication being shipped: serial number, NDC, lot number and expiration date.

Q: What is EPCIS and how does it relate to traceability statements? –Electronic Product Code Information Services will be the standard for tracing medications

electronically after November 27, 2023. The data will include product identifiers (serial numbers, name, strength, container size) and GLN information that will follow the medications and track the physical location of the medication throughout the supply chain.

Q: What is a global location number (GLN) and why is a dispenser required to have one? A Global Location Number is assigned to a pharmacy based on the United States postal address. The GLN is necessary for track and trace statement requirements as of November 27, 2023.

Q: How does a pharmacy obtain a GLN? A global location number is assigned by GS1. Go to [GS1us.org](https://gs1us.org) store to purchase a GLN for \$30. [HOME - GS1US Ecommerce](#)

Q: How can I look up a GLN? A global location number can be looked up for a specific customer by going to [GEPIR.gs1.org](https://gepir.gs1.org) then search by party name. If the dispenser has a common name, you can expand the search function to include a specific address by clicking on show option fields. [Search by Party Name | GEPIR \(gs1.org\)](#)

Q: What is interoperability tracing? Tracing data must follow the medications throughout the supply chain. Starting with medications shipping from the manufacturers to an Authorized Trading Partner (ATP) to a dispenser or another ATP. The ability to track the medications up and down stream is the interoperability required to meet the DSCSA regulations.

Q: Third Party solution providers: what are they? Third party DSCSA solution providers are companies that will help dispensers manage the DSCSA compliance regulations by monitoring traceability documents. There are a variety of these companies contacting dispensers to sell their solution (scanners, software systems, repositories, etc.).