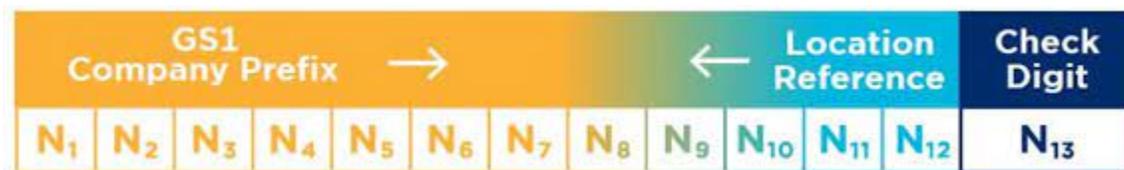


How to Identify your Location for DSCSA Requirements

When the U.S. Food and Drug Administration (U.S. FDA) enacted the Drug Supply Chain Security Act (DSCSA) in 2013, it aimed to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. To enable this level of traceability, product movement must be captured and shared along the supply chain. The GS1 Global Location Number (GLN) identifies the “Who” and “Where” of these product movement transactions.

A GLN is the globally unique GS1 Identification Number used to identify parties and locations. The GLN can be used to identify a legal entity (like a manufacturer corporate office), a functional entity (like the accounting department), or a physical location (like a distribution center, loading dock door, or storage location).



The goal of GLN implementation in the U.S. pharmaceutical industry is to use standardized location identification to uniquely identify any location, party, or legal entity to accurately track and trace pharmaceutical products across their supply chains in support of the following use cases:

- Track and trace with Electronic Product Code Information Services (EPCIS)¹ as recommended by the U.S. FDA for DSCSA Interoperable traceability.
- Management of saleable returns with Verification Router Services (VRS).
- Communicating master data with the Global Data Synchronization Network™ (GDSN®).

How do I get a GLN?

There are multiple ways to get a GLN. To help select the best option for you and your organization, please follow the appropriate Quick Start Guide, which includes a decision tree, to assist in your choice.

Quick Start Guide for Suppliers

Select one of the two options below based on your organization’s member status with GS1 US®. If you already have a GS1 Company Prefix to create Global Trade Item Numbers (GTIN) or Serial Shipping Container Codes (SSCC), you are a member of GS1 US and already have access to an entity GLN. If you do not have a GS1 Company Prefix, then review Option 2 for non-GS1 US members to learn how to license a GS1 Company Prefix and create your company’s uniquely identified Global Location Number(s). If you are not sure which option is right for you, check out our supplier decision tree.

¹ DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry, DRAFT GUIDANCE, July 2022 <https://www.fda.gov/media/90548/download>

Option 1: GS1 US Member with a GS1 Company Prefix

If your company already licenses a GS1 Company Prefix, these steps outline how to get, create, assign, and use your GLNs:

1. Determine if there is an individual within your company who assigns GLNs

Identify the person who manages your GS1 Company Prefix or subject matter expert (SME) on GLNs within the organization. This SME may be from your serialization, supply chain, regulatory, or other department within your organization.

2. Assign GLNs

As a member of GS1 US with a licensed GS1 Company Prefix, your company has access to the [GS1 US Data Hub | Location](#)[®] tool, which enables you to create and manage GLNs for your own locations, at no charge for a single user.

- Your company's Legal Entity GLN is preloaded in GS1 US Data Hub | Location and will serve as the top level of your GLN hierarchy.

Helpful Hint: A legal entity is any business, government body, department, individual, or other institution that has standing in the eyes of the law and has the capacity to enter into agreements or contracts. A legal entity must be allocated its own GLN when its legal name and/or legal address and/or legal registration number is different from other legal entities and there is a business need to identify the legal entity across organizations.

- If you have already assigned GLNs to your business locations and they are not in GS1 US Data Hub | Location, it is recommended you upload these locations before assigning new locations to avoid duplication. Uploading and managing your company locations in Data Hub allows industry supply chain partners access to view and use your location data.
- Assign additional GLNs as business needs dictate using GS1 US Data Hub | Location.
- Check the "Validate Location" box in GS1 US Data Hub | Location to show that you are regularly reviewing your GLNs.
- Access the [GS1 US Data Hub Location User Guide for Managed GLN Subscribers](#) to help with creating, managing, and sharing location data.

3. View and use your trading partners' GLNs

If you wish to view and use GLNs from your trading partners, you should subscribe to the GS1 US Data Hub | Location View/Use option. Annual fees apply, based on the options you choose and the number of users. Users with access to GS1 US Data Hub can log in [here](#).

Helpful Hint: A View/Use [subscription](#) is required to view other companies' location information, including Global Location Numbers and location organizational structure provided by location owners.

Option 2: Not a member of GS1 US.

1. Your company has the option to license a GS1 Company Prefix or license an individual GLN to identify locations to meet trading partner needs

If you have more than 9 locations to identify with a GLN, consider licensing a GS1 Company Prefix. [Fees](#) are based on the number of locations you need to identify. If you have less than 9 locations to identify with a GLN, you may license a single GLN for a small one-time fee.

You can apply for a GS1 US Company Prefix or license an individual GLN online at myGS1US.org.

Establish your password to the GS1 US User Portal (our online member center) as soon as you receive your welcome email. This login credential also support access to GS1 US Data Hub.

2. Create your GLN hierarchy in the GS1 US Data Hub | Location tool and check the “Validated” box

When your company licenses a GLN, you will receive a free subscription for one user to GS1 US Data Hub® | Location, an online tool you can use to identify, manage, and share your location data.

3. Designate responsible party within your organization for GLN assignment (e.g., IT, Marketing, Supply Chain)

4. View and use your trading partners’ GLNs in business transactions

If you wish to view and use GLNs from your trading partners, please subscribe to the GS1 US Data Hub | Location View/Use with the Export option. Annual fees apply, based on the options you choose and the number of users. Users with access to GS1 US Data Hub | Location can log in at <https://www.gs1us.org/tools/gs1-us-data-hub/location>.

Helpful Hint: A View/Use [subscription](#) is required to view other companies’ location information, including GLNs and location organizational structure provided by location owners.

5. Share Data

Use the GS1 US Data Hub | Location tool to share your location data before you transact with your trading partners using GLNs.

Need Additional Help?

If your company has no need to generate GLNs to identify locations, but still need access to location data, you can still sign up for GS1 US Data Hub | Location as a View/Use subscriber. This allows you to search for and export GLN information for your business partners, who also use the tool. Annual fees apply, based on your subscription options and the number of users accessing the tool.

See below for some additional resources to help:

- [Frequently Asked Questions in Preparing for the U.S. DSCSA](#)
- [Implementation Guide for GLNs in Healthcare](#)
- [Data Hub | Location User Guide](#)
- Attend GS1 US Data Hub | Location User Group meetings
 - Meeting the third Thursday of every month, the GS1 US Data Hub | Location User Group gives you the opportunity to ask questions and learn best practices from other industry members which the facilitator provides updates about the tool. Apply for membership through the GS1 US Community Room: community.gs1us.org/join or community.gs1us.org/apps/org/workgroup/dhlocusers.

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