2023 Traceability Webinar Series

GS1 GLN Management and DataHub Overview: How to Acquire and Maintain GLN Data

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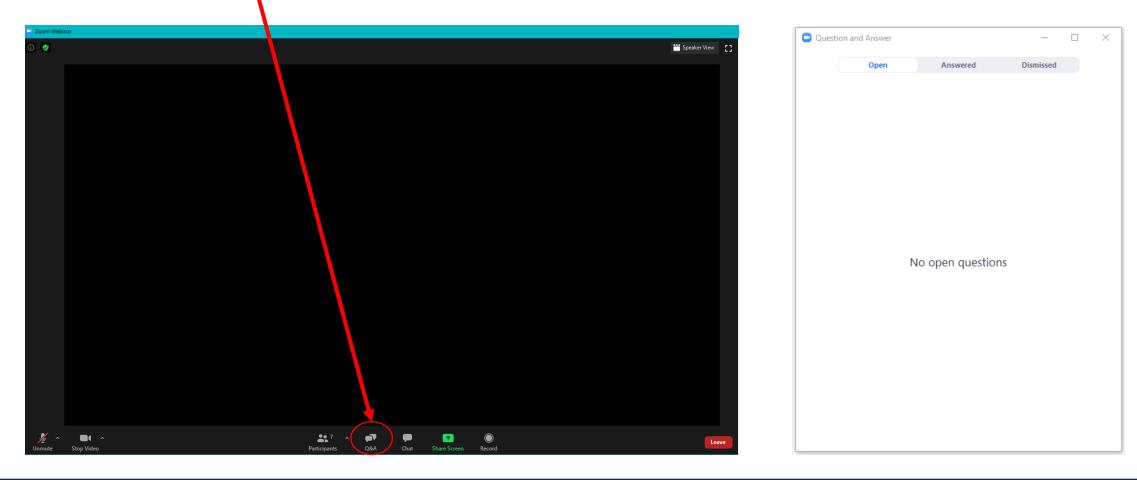






Questions & Answers

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The Global Language of Business

Healthcare

GS1 GLN Management and Data Hub Overview

July 6, 2023





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Agenda



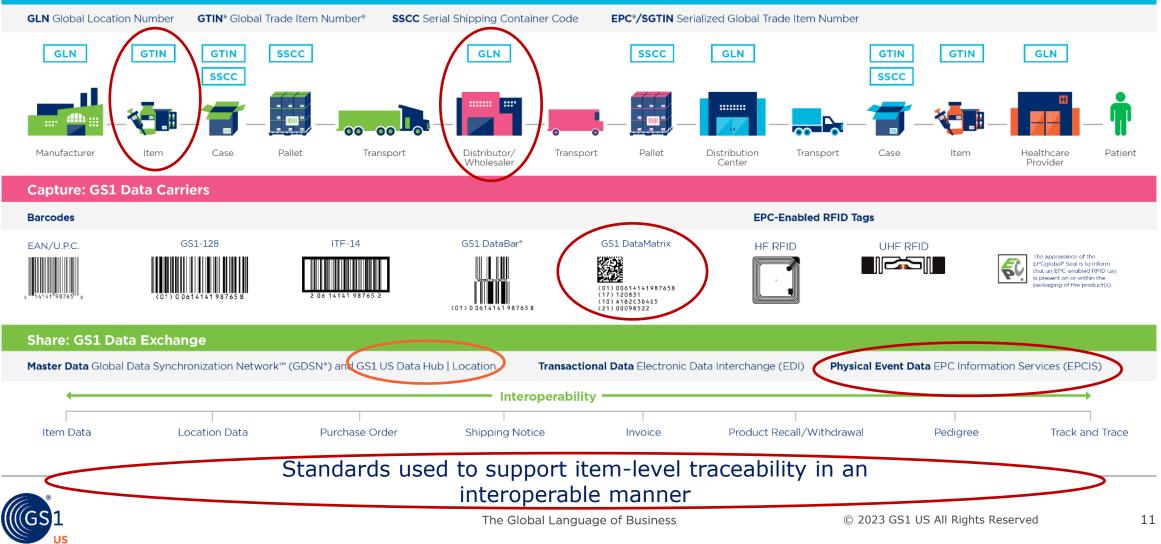
- GLN "101"
 - What, Why, and How
- How to check if you need one or if one exists already
- 340B
- SGLN Translation
- Data Hub Location
- Resources



GS1 Standards: Identify, Capture, and Share



Identify: GS1 Identification Numbers



Location Identification: Global Location Number (GLN)



The "WHO & WHERE"

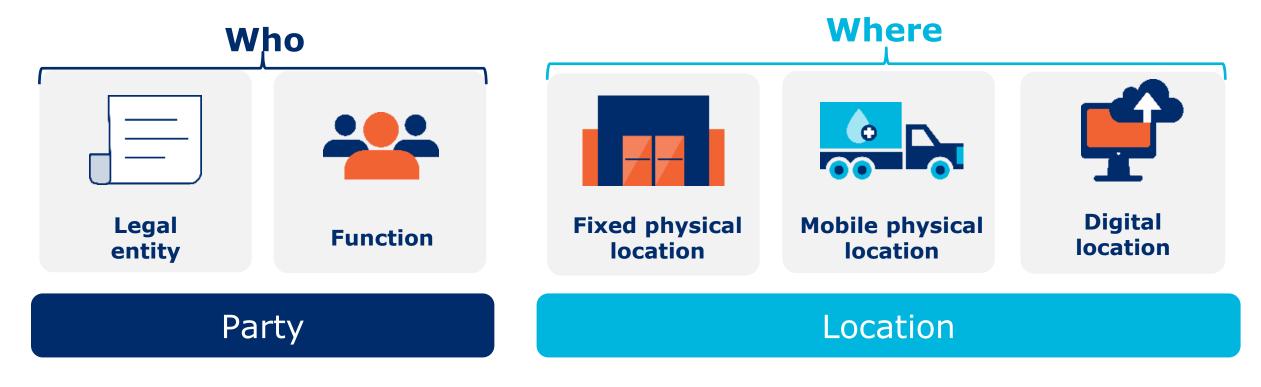
A 13-digit number that provides businesses the ability to know who is involved in transactions and where things are located throughout the supply chain. By uniquely identifying parties and locations, GLN helps with tracking products, optimizing processes, and providing greater visibility to transactions taking place in the supply chain.







GLN provides answers to "who" and "where" by identifying parties and locations.







A GLN can be used to identify a **single** legal entity, function, physical location, or digital location. These different options are known as **GLN types**.



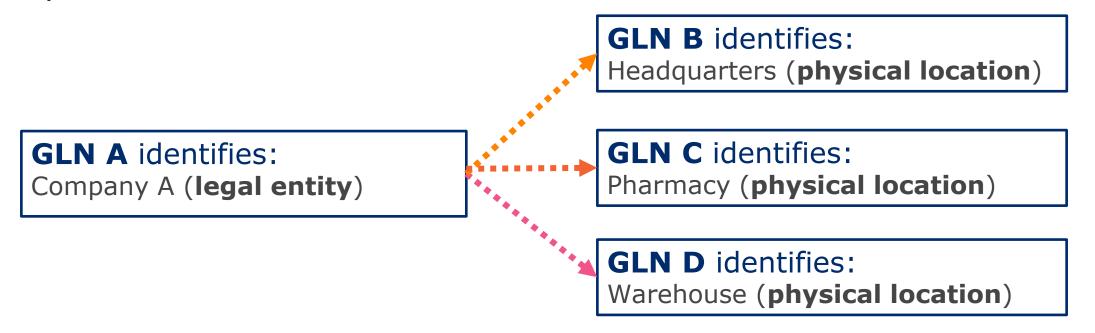
GLN may also be used to identify a **combination** of **GLN types**.



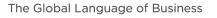




When a GLN identifies a **single** party or location, multiple GLNs can be used in any combination required by specific use cases without duplication.





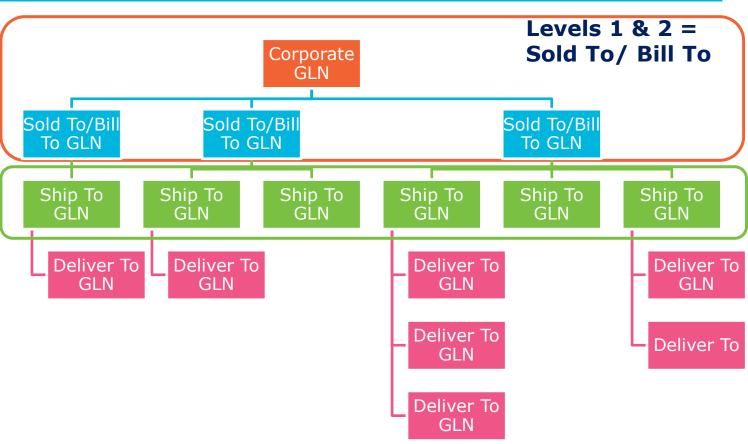


GLN Hierarchy

- A GLN hierarchy is a classification structure presenting organizational locations arranged in levels of detail from the broadest to the most detailed.
- The purpose is to define a relational structure of supply chain locations that supports supply chain operations.
- The **Bill-To** or also known as • **Sold-To** is critical for DSCSA as it is a change of ownership law. As the **Ship-To** is important for the traceability of the product.

The hierarchy above is only be used for demonstrative purposes and is not representative of all allowable hierarchies.









Companies with **limited identification requirements** can successfully utilize a single GLN to identify a combination of party and location.

Companies using this allocation method may experience issues when scaling due to business needs or trying to meet more complex use case requirements.

GLN A identifies **both**:

- 1. Company A (legal entity)
- 2. Headquarters (**physical location**)

GLN B identifies:

HR department (**function**)



Allocation option comparison



1 GLN = **1** GLN Type

- Always clear on what is being referred to
- Simplified application of management rules, attributes, validation rules
- Noted as being less confusing for users when creating/managing GLNs
- May support consistency and quality of data

1 GLN = >1 GLN Type

- All GS1 standards permit this
- Existing GLNs in use may already be used to identify more than one GLN type
- It may be deemed cost prohibitive to take this route
- Systems will require logic to consume
 GLNs with more than one GLN type



Rule 1: New Party/Location Introduction



A new party or location is considered an addition to what already exists and has been allocated a GLN.

When a new party and/or location is added that will engage in business transactions, it must be allocated a new GLN.





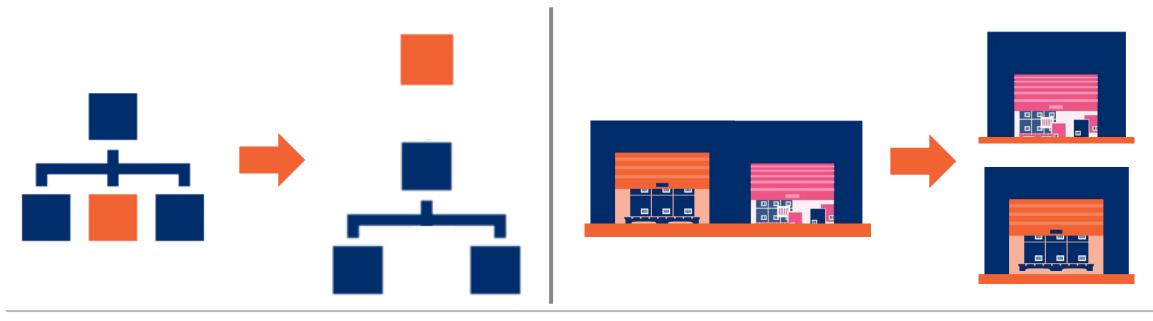


Rule 2: Party/Location Split



A split occurs when the party/location being identified by a single GLN is divided into two or more parties/locations.

When a party or location is divided into multiple parties/locations, one may keep the existing GLN, provided that the company keeps control over the GS1 Company Prefix or individually licensed GLN.





Rule 3: Party/Location Merger



A merger occurs when a two or more parties/locations are combined into a single party/location.

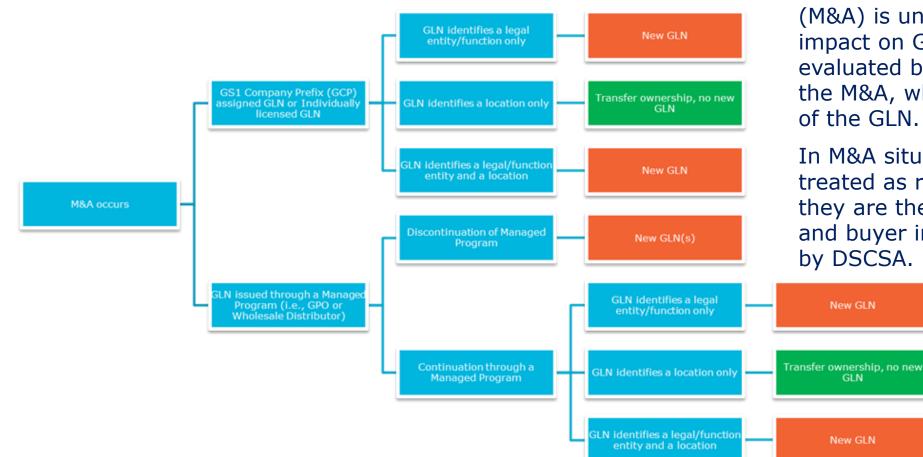
When a party or location is merged with another so that they will no longer function independently, one of the existing GLNs may remain in use. All other GLNs merged SHALL be removed from active use once their transition is completed.





Mergers and Acquisitions (M&A) Impact on GLNs





As each merger and acquisition (M&A) is unique and different, the impact on GLN(s) needs to be evaluated based on the end state of the M&A, who is the definitive owner of the GLN.

In M&A situations, GLNs should be treated as regulatory information as they are the identifiers of the seller and buyer in transactions governed by DSCSA.

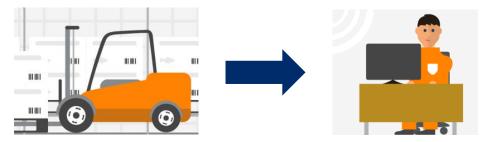


Rule 4: Change of Party/Location Use or Purpose



A change of use or purpose occurs when the activities, purpose, or functionality of a party/location is modified resulting in persistent differences in how that party/location can be interacted with.

Changes to the activities or purpose of a party or location which impact the guiding principles require a GLN change



Example likely to require a new GLN: A distribution center is converted into office space.



Example **not** likely to require a new GLN: Equipment upgrades made





Physical and Digital Location Address Change

Changes to the access point, coordinates, or other representation of location which impact the guiding principles require the allocation of a new GLN.

- This includes the following changes:
 - Change of the physical location
 - Change to digital location





Legal Entity and Function Relocation

Changes to the location(s) associated to a legal entity or function do not require the allocation of a new GLN.

This includes:

- Relocation of a legal entity
- Changing operating location(s) of a function









Changes to the..



..do not require the allocation of a new GLN.





It is used to identify locations, legal entities, and functions in electronic business transactions in:

- Electronic Product Code Information Service (EPCIS) In FDA's <u>DSCSA Standards for the</u> <u>Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription</u> <u>Drugs, Revised Draft Guidance</u>, it recommends that trading partners use GS1's Electronic Product Code Information Services (EPCIS) standard to provide and maintain the electronic data associated with transaction information and transaction statements.
 - GLNs are required for transactions as it identifies the ship from/to and sold from/to.
- Verification Router Service (VRS) solutions verification router service refers to using a thirdparty routing system to send product information back and forth between Trading Partners.



The ways a GLN is used in EPCIS data for DSCSA:

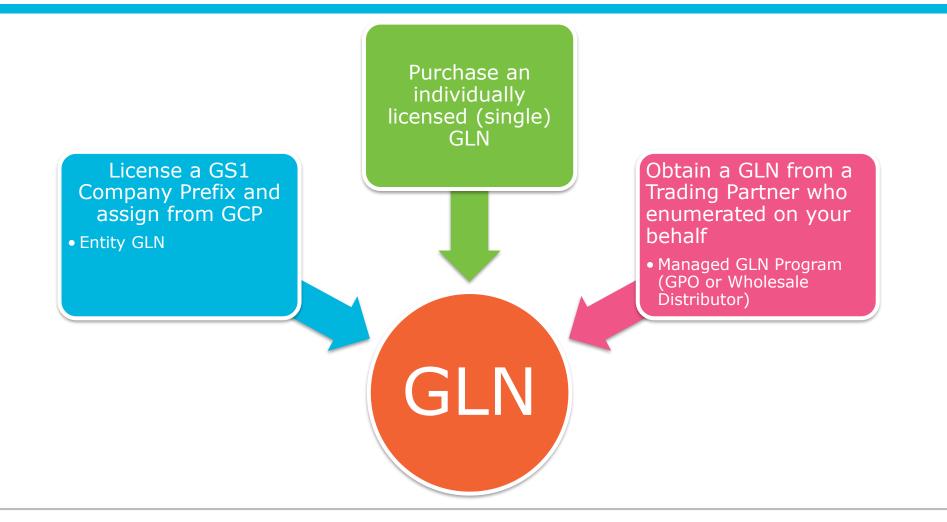


- <u>Read Point of an EPCIS event</u> identifies the **physical location where a business process step** took place
- Business location of an EPCIS event identifies the physical location where physical objects are
- <u>Source and destination lists</u> of an EPCIS shipping or receiving event identify the "sold by" and "sold to" parties to the transaction and the identify the "ship from" and "ship to" parties to the transaction
- <u>Business transaction lists</u> of an EPCIS event uniquely qualify a **business transaction identifier** such as a purchase order number or invoice number
- <u>Master data</u> contained within the EPCIS header of an EPCIS document link party and location master data to the GLNs contained within the EPCIS events
- <u>Standard business document header (SBDH)</u> in the EPCIS header of an EPCIS document identify the **party sending the message and the receiving party**



GLN Assignment Options







How Do I get a GLN?

License a GS1 Company Prefix and assign from GCP

- Common for Manufacturers and Wholesale Distributors as the same GCP can be used to enumerate GTINs and SSCCs
- Create/Manage access to DHL
- Capacity is based on GCP length
- SGLN is derived from the GCP length

Individually license a GLN

GS1 Company Prefix →

- This is ideal if no other identification keys are necessary and only a few GLNs are necessary
- Create/Manage access to DHL
- Need to make GLN active
- SGLN is derived as the full GLN minus the check digit as the *CompanyPrefix* component

Obtain a GLN from a Trading Partner who enumerated on your behalf

Check

Digit

N13

Location

Reference

N₉ N₁₀ N₁₁ N₁₂

- Specific parameters and Trading Partners
 - Certain Group Purchasing Organizations
 - Select Wholesale Distributors
- SGLN is derived the same way as an individually licensed GLN



GS1 Company Prefix Fun Facts



GTIN for Pharmaceutical Products – 7 Digit GCP is used

- 7 Digit GCP which embeds the Labeler Code = 100,000 Capacity
- NDC can be embedded into the GTIN

Can license a combination

- GCP + Single GLN
- The entity GLN is based on the first license

Can license multiple GCPs	GS1 COMPANY PREFIX LENGTH	GLN CAPACITY	GTIN CAPACITY	SSCC CAPACITY
	7	100,000	100,000	10,000,000,000
	8	10,000	10,000	1,000,000,000
	9	1,000	1,000	100,000,000
	10	100	100	10,000,000
	11	10	10	1,000,000
	12	1	1	100,000





Managed GLN Program



Reserved for the Healthcare Industry – supporting a regulatory requirement

- Healthcare Stakeholder:
 - Healthcare Wholesale Distributors
- **Current Participants:** ۲
 - AmerisourceBergen
 - **McKesson**
 - Smith Drug Company
 - Cardinal Health

- Healthcare Stakeholder:
 - Group Purchasing Organizations

- **Current Participants:**
 - HealthTrust
 - Premier
 - Vizient
 - The Resource Group (New)



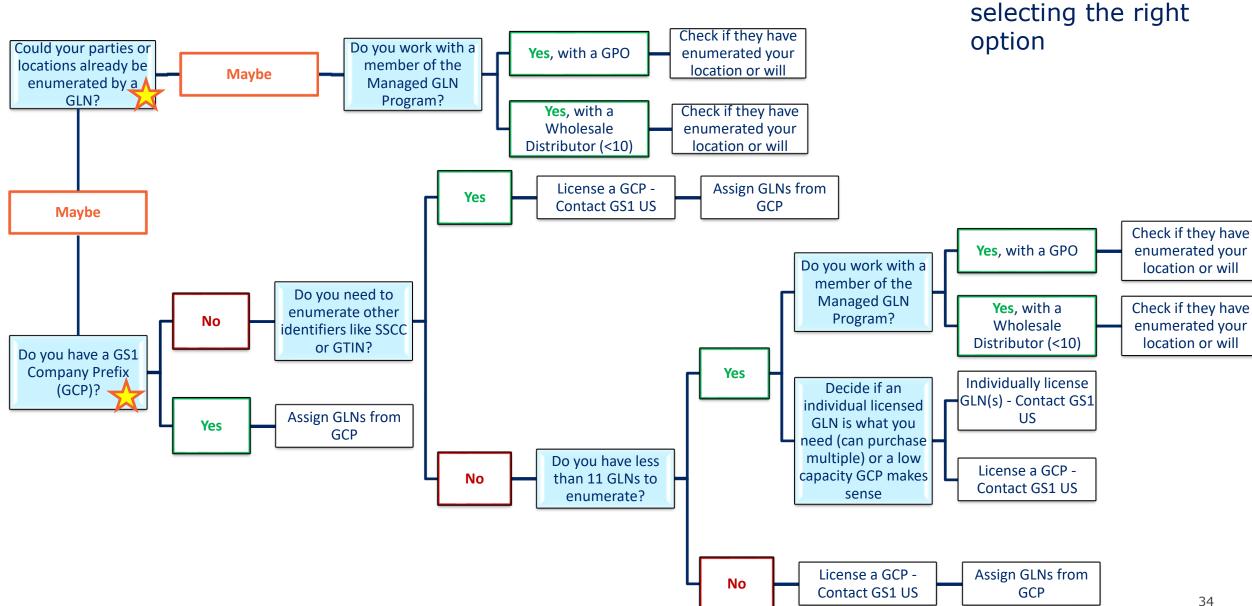
Managed GLN Program



- Who can join and whom can they enumerate?
 - Wholesalers can enumerate:
 - Independent dispensers, individual practitioners, and other businesses (with less than 10 locations) subject to the Drug Supply Chain Security Act (DSCSA).
 - GPOs, in providing purchasing opportunities to individuals or groups of entities (the "GPO Members") designated by the GPO to purchase under its contracts
- Impact to GLNs if change GPO or Wholesale Distributor
 - Can transfer GLNs between GPOs that are participating in the program
 - GLNs enumerated by Wholesale Distributors are not exclusive to the Wholesale Distributor and therefore do not need to be transferred, will remain active









Ways to check for a GCP or GLN(s) for location(s):

- <u>GS1 US GEPIR</u> or <u>GS1 GEPIR</u> allows you to have 30 searches per day for free. You can search by Company, GTIN, GLN, or other identifiers. <u>This will show your</u> <u>GCP and the address of the license information</u>.
- For dispensers, we advise first to consult with their Group Purchasing Organization (GPO) and/or Wholesale Distributor (if part of the <u>Managed GLN</u> <u>Program</u>) to verify if locations are already enumerated with a GLN as part of the Managed GLN Program.
- Data Hub Location GLNs are searchable including ones enumerated through the Managed GLN Program and included in export and API. (Can request access if not shared).



GLN FAQs



- Who "owns" the GLN maintenance?
 - Whether you were enumerated directly or through the Managed GLN Program, the location/party owner will know if the data is correct or needs to be updated.
 - The maintenance is really needed by the "owner of the data" as it is the best way to ensure the data is correct. This can be done directly into the Data Hub tool or through the administrator of the Managed GLN Program if you are not a part of the Self-Managed model.
- How do GLNs get "validated" by Data Hub?
 - Data Hub checks 2 things if there is a duplicate address and does the address adhere to the U.S. Postal system.
 - You can enumerate your GLN in Data Hub by using your licensing which is automatically populated when licensed.



GLN FAQs

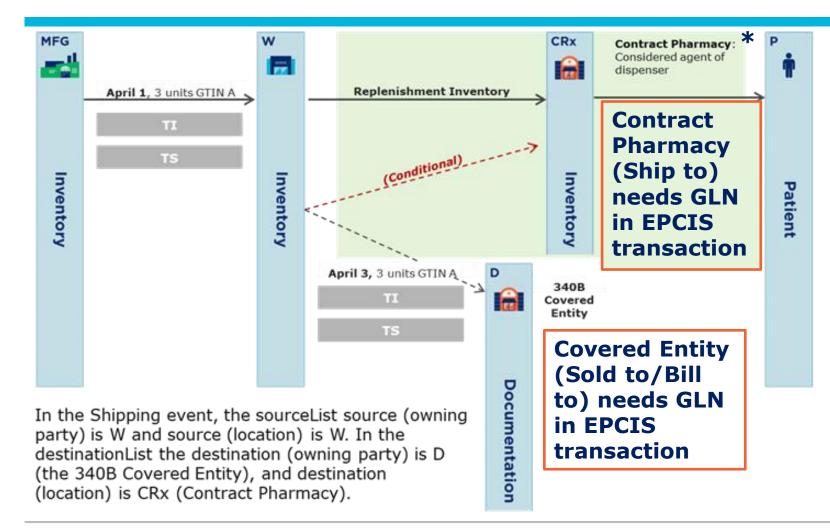


- Have GLNs that are being created on behalf, but also have a GCP. What to do?
 - If the decision is to use the GCP to enumerate independently. Let your GPO or Wholesaler know that decision and share your GLN information. The GLNs that have been enumerated on your behalf can be inactivated to eliminate duplications.
- How many GLNs do I need?
 - At a minimum, a separate GLN is needed for each physical street address that a Trading Partner ships product to. Within the EPCIS message, both a "Ship-to" GLN and a "Sold-to" GLN must be identified. These GLNs can be the same or different numbers. Many companies set up one GLN to identify the corporate entity as the "Sold-to" and then set up additional "Ship-to" GLNs to identify multiple shipping locations. There is also the option to identify location information in EPCIS with greater granularity (i.e., Floor or Suite #), but this is not required.



340B Program Scenario





*Caution: From a DSCSA transaction perspective, having duplicate Ship-to locations can hinder the ability to transact a combined shipment of 340B products and non-340B products in an aggregated SSCC and therefore would require separate shipments.

Note: The Covered Entity and Contract Pharmacy could be the same physical address



340B Program Scenario



Contract Pharmacy is a Separate Location from the Covered Entity





Examples of Translation per GCP length, per Scenario



GS1 COMPANY PREFIX LENGTH	GLN CAPACITY	COMMENT
7	100,000	Typical for GCP with Labeler Code embedded (usually used for GTINs and SSCCs as well)
8	10,000	
9	1,000	
10	100	Lower capacity needed – may just be for GLNs
11	10	Lower capacity needed – may just be for GLNs
12*	1	Single GLN or enumerated through Managed GLN Program

SGLN Translation examples:

- SGLN is derived from the GCP with a length of 7 (Labeler Code is embedded)
 - Example: GCP=1234567, GLN = 1234567890128
 - Translated into an SGLN = urn:epc:id:sgln:1234567.89012.0
- SGLN is derived from the GCP with a length of 10 (licensed only to enumerate GLNs)
 - Example: GCP=1234567890, GLN = 1234567890128
 - Translated into an SGLN = urn:epc:id:sgln:1234567890.12.0
- *Single GLN, or GLN enumerated through the Managed GLN Program: SGLN is derived from the first 12-digits (the GLN minus the check digit)
 - Example: GLN = 1234567890128, GCP = N/A
 - Translated into an SGLN urn:epc:id:sgln:123456789012.0



GLN Comparison and SGLN Translation



License a GS1 Company Prefix and assign from GCP

- Capacity is based on GCP length
 - Capacity for an embedded GCP with Labeler Code = 100,000 GLNs
- sGLN is derived from the GCP length
 - Example: GCP=1234567
 GLN = 1234567890128
 Translated into an SGLN
 urn:epc:id:sgln:1234567.89012.0

Individually licensed (single) GLN or GLN enumerated through the Managed GLN Program

- In both cases, 1 GLN issued represents 1 Location identified
- SGLN is derived from the first 12-digits (the GLN minus the check digit) as the *CompanyPrefix* component
 - Example: GLN = 1234567890128

GCP = None

Translated into an SGLN urn:epc:id:sgln:123456789012..0

The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS.



Whether you are a manufacturer, healthcare provider, distributor, or

dispenser, you can use **GS1 US Data Hub | Location** to view and use accurate location information that is created and maintained by your trading partners in addition to creating and managing your own GLNs.

Subscription Types:

- Create/Manage
- View/Use
- Export
- API

Learn more: <u>https://www.gs1us.org/tools/gs1-</u> <u>us-data-hub/location</u>

The Global Language of Business





GS1 US Data Hub | Product

Taking the guesswork out of creating barcodes and managing and sharing product information



INNOVATION LAB

GS1 US Data Hub | Location

Driving reliable location identification and information to improve business efficiencies

GS1 US Data Hub | Company

Accessing validated U.P.C. and company information for better business processes







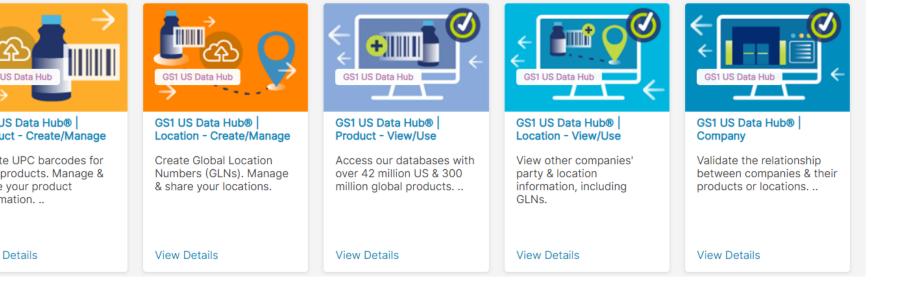
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companies tied to identification numbers Please note, a free "Create/Manage" subscription comes with your license of a GS1 Company Sort: Best Match Prefix, GS1 US GTIN, or Global Location Number. Sign in to see your active subscriptions. **GS1 US Data Hub** GS1 US Data Hub GS1 US Data Hub **GS1 US Data Hub GS1 US Data Hub** GS1 US Data Hub® Location - View/Use Product - Create/Manage Location - Create/Manage Product - View/Use Company Create UPC barcodes for Create Global Location Access our databases with View other companies' Validate the relationship your products. Manage & Numbers (GLNs). Manage over 42 million US & 300 party & location between companies & their share your product & share your locations. million global products... information, including products or locations. .. information. .. GLNs. View Details View Details View Details View Details View Details

GS1 US Data Hub

We offer multiple subscriptions to our online tool GS1 US Data Hub.

Our "Create/Manage" subscriptions allow you to create product and barcodes, or party and location data to share with trading partners. Our "View/Use" subscriptions offer access to validated Product or Location data for trusted data sharing. "Company" provides access to our database of



GS1 US Data Hub Subscriptions





<u>GS1 US Data Hub | Location</u> - Subscription Details



Subscription	Tiers	Cost	Functionality	Edit/Add	View Others
Туре		(as of July 2023)		GLNs	GLNs
Create/Manage	Single User	\$500* Free with licensing	Use to create and manage GLNs and organizational relationships for your locations. Choose to share your location information with trading partners.	Yes	No
	1-5 Users	\$1,000		Yes	No
	1-10 Users	\$1,500		Yes	No
	Unlimited	\$2,500		Yes	No
<u>View/Use</u>	Single User	\$500	View other companies' location information, including GLNs (Global Location Numbers) and location organizational structure provided by location owners.	No	Yes
	1-5 Users	\$1,000		No	Yes
	1-10 Users	\$1,500		No	Yes
	Unlimited	\$2,500		No	Yes
Export Add-On		\$4,500	These add-on	N/A	N/A
API Add-On		\$6,500	subscriptions only need to be purchased once per company.	N/A	N/A 44

GLN Metrics – 200K GLN increase in 3 months



Stakeholder	Number of GLNs in Data Hub (as of July 3, 2023)
Manufacturer	1,625
Wholesale Distributor	490
Repackager/3PL	23
Hospital Provider	633,427
Dispenser	<mark>282,042*</mark>
Undefined (HPs predominantly)	13,611
Total	931,218
	637 Unique GCPs

*Enumeration has been increasing on average 5-10K GLNs per week



Data Hub Location Updates



• Current State:

- GCP available via Export-Healthcare Download report (no customization)
- GCP has a null value in the API
- SGLN provided to all View/Use subscribers through SharePoint site in the interim

• July 14th Release:

- API overhaul, new version, v4
- GCP is available via API

• October (mid) Release:

- Calculated SGLN available
- GCP in User Interface
 - GCP, Single GLN, or Managed GLN
- GCP as a searchable field
- Healthcare export file with customization







- <u>GS1 US DSCSA (Drug Supply Chain Security Act)</u> Overview
- How to Identify your Location for DSCSA Requirements
 - Overview
 - Quick start guides for how to identify your locations for DSCSA
- <u>30-minute webinar on how dispensers can prepare for an interoperable</u> <u>pharmaceutical supply chain</u>
- GS1 US DSCSA Implementation Guideline R1.3
 - Sections 5.10-5.18 (GLNs related)
- <u>GS1 US DSCSA FAQs</u>
 - Section 2.4 Questions about the Global Location Number (GLN)





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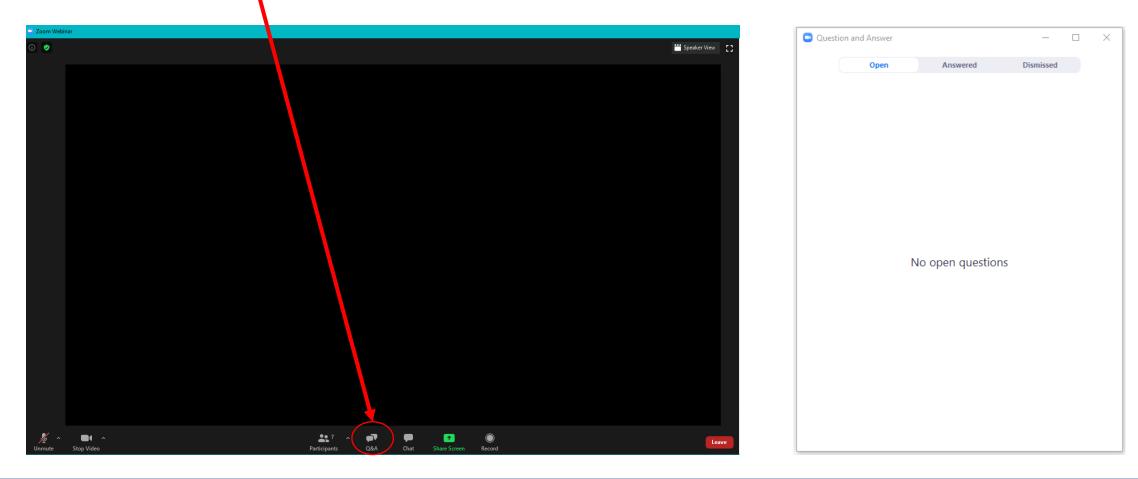






Questions & Answers

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Upcoming Events

Traceability Webinar Series | Thursday, July 27, 2023, 1:00 PM - 2:00 PM ET | DSCSA Implementation: A Phased Approach and Other Industry Recommendations

Traceability Webinar Series | Thursday, August 17, 2023, 1:00 PM - 2:15 PM ET | DSCSA Solutions Panel: Innovative Systems for Solving Compliance Requirements

2023 Traceability Seminar | August 29—31, 2023 | Marriott Marquis, Washington, D.C.

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