

## 2024 Traceability Webinar Series: Master Data – GTINs & GLN Overview & Update

### Questions and Answers

1. J&J - Please repeat the % of error you are currently encountering related to GTINs.

1.5 % of issues reported by customers since January 2024 - this of course should consider the fact that <1% of our cusotmers (80-90% of shipments) are actively providing feedback on data quality.

2. How Pack Profiles Quantities changes should be managed? For example, if Inner Qty is changing, do we need to create a new GTIN? How do we manage the packaging level for the GTIN change?

Any inner-pack quantity change to a case requires a new GTIN be created with a new package indicator, specify on the HDA short-form the inner-pack quantity of the new GTIN, leave the old GTIN in effect until at least all that sealed case product is consumed.

3. we are being asked for AS2 information from the DSCSA Support team from one of our suppliers, does anyone know what this is?

AS2 is a type of connection that is established to exchange data files (EDI or EPCIS). I recommend that you check with your IT team or your EPCIS Solution Provider if you have one.

4. Hello! Any challanges with being a distrubitor providing a SSCC file to another distrubitor?

Distributors should be capable of providing EPCIS files to their customers including other distributors. EPCIS files includes data aggregated to the SSCCs. The SSCC should be based on the sender's Global Company Prefix (GCP).

5. Thanks Scott. What would you do if the vendor has a no return policy. Can this product be resold commerically?

DSCSA sattes that any sale of product by someone other than the manufacturer or dispensing to a patient by a dispenser requires a wholesale distribution license and you must meet the DSCSA requirements for wholesale distributors such as FDA reporting.

6. Data Hub...how is that accessed?

GS1 Global Location Number Lookup - Search by GLN ([gs1us.org](https://gs1us.org)) - free public access

7. Who is cleaning up the GLNs?

GS1 US and the Managed GLN Program Subscribers meet every other week and have a Data Quality Improvement Plan. We meet in-person based on need and did earlier this month. We have milestones to the clean up, we discuss issues to get resolution, and are implementing program/process improvements to mitigate repeat issues.

8. Is there source for a sample SSCC that can be used to test connectivity? Or sample for a Pallet Level Gtin?

GS1 US can provide test identifiers. Our published implementation guidelines have XML examples with identifiers that can be used for testing.

9. For Tracy: Not sure if a GCP/GLN identifies an ATP status. I can still have a contract with a Dispenser, which makes them an ATP, but the dispenser may use a WH assigned GLN as their own. The lack of a GS1 assigned GLN does not make the Dispenser Un-atho

I agree that there can be other aspects to determine whether a trading partner is a ATP. It depends on the organization as to what their policy is. We have received inquiries as to incorrect/invalid GCPs as it is an aspect of some organizations as supporting their determination that the trading partner is Authorized.

10. For Scott, Is it true, or is there an expectation that the address associated to a GLN in the GS1 datahub would be exactly the same in all different EPCIS systems used by every trading partner within the supply chain.

I am going to postulate that they should be directionally similar but may not be exact. Different systems have different field lengths so often there need to be abbreviations made to fit an address into a system. Also, many sellers have rules that regardless of the address as it is presented in the DataHub tool, they may load the address exactly as it appears on the customers license when dealing with Ship To addresses.

11. If SKU is having 2 Saleable packs with different NDC in product hierarchy then which NDC to be used for GTIN formation for Bundle and Case

If the product has an NDC the NDC is the basis for the GTIN that is assigned to that product in the US US based GTINs for DSCSA must embed the NDC in the GTIN. This is due to the FDA requirement that the NDC appear in the bar code and it was chosen to do that by embedding it in the GTIN. So if you have two NDCs, then you will have two GTINs. You can pack one GTIN as a child of a different GTIN if you wish if you have a NDC for a vial and a different NDC for a pack of ten vials.

12. If I am a dispenser who repackages bulk products and sells products to another external dispenser. I have a GLN that I got from my GPO it starts with 1100 - do I need a GCP? What if I want to create a SSCC?

If you need a SSCC then you would need to license a GCP. The GLN is a separate identifier.

Separate from GS1 Standards but want to mention that if you are selling to other trading partners - you may have other requirements based on the law as you are acting beyond a Dispenser.

13. What due diligence is expected on a seller, especially when there is a known misuse of a GLN (Ex. Company prefix belongs to someone else other than the buyer, is marked Inactive in GS1, or is Invalid per GS1 etc.)

It depends on the organizations' policies but the requirement is to trade with Authorized Trading Partners. The concern is if the identifier of the product and/or party is derived from an incorrect licensed Prefix or an invalid GCP then how are they defined as an ATP? How do you ensure you are documenting the correct change of ownership and providing the correct data elements required by the law in the Transaction Information?

14. Are GTIN's/GLNs required for OTC products?

Most OTC products have a linear bar code which is a UPC or a GS1-128 bar code. This contains a 12 or 14 digit GTIN. I am assuming here you are asking about a 2D data matrix bar code which is the DSCSA requirement. The DSCSA applies to finished, human Rx drugs and does not include OTCs. There are also a couple pages of exemptions in the DSCSA such as nuclear medicine, blood derivatives, etc.

15. I work at a hospital that lends or sells products to neighboring pharmacies - to send the data along do I need anything besides my GLN? Sometimes I take products that contain vials or pre-filled syringes and repackage them, do I need to re-label them?

On the subject of sending product to another hospital that is allowed under the DSCSA without sending Transaction Information when there is a identifiable specific patient need. It is prohibited in anticipation of a future patient according to the FDA guidance. Watch out for the hospital sending you product back to compensate for the specific patient need as that could be construed under the DSCSA to be "distribution" and requires licensing and other actions.

16. Are these required for OTC product?

OTC products are not in scope of DSCSA. Just FYI, OTC products with NDC follow the same format with its GTIN embeds their NDC. GLNs are used the same and EPCIS can be used as well.

17. Thanks April. I am involved in a ERP rollout and data migration and need to capture GTIN's for thousands of products. I will look for another method to obtain this information.

Sure - the only reason I say to reach out to the Manufacturers which would be the source - GTINs as we have mentioned can change. Each manufacturer can lookup what products you procure from them and provide a bulk list of GTINs since each product can have up to four levels of GTINs.

18. Is there an easy way to look up a GTIN by product name? GS1 allows you to search but you can only search on GTIN.

The best way is to reach out to the manufacturer for the GTIN since product name would be tied to a few different strengths and presentations of that product.

19. For Tracy, when I try to confirm a GLN on the GS1 website, I get "location Reserved" that doesn't confirm the location, what can I do?

The GS1 Database (replace GEPiR) is a license database. GS1 US Location reserved indicates it is a Managed GLN Program GLN as it is not directly licensed by a party and an issuance based on reserved Prefix pools by GS1 US.

We just published a free public access to the Data Hub Location that can be used to confirm a GLN issued through the program. I will provide the link to HDA so they can send out.

20. There is no clear guidance for companies that purchase commercial product for use in clinical. There is no formal decommission process in the US like there is with FMD. How would a drug packager handle tracking if a product was purchased for a clinical

There is a FDA guidance on investigational drugs being used in clinical trials as being exempt from DSCSA marking and tracing. However, you are right that there is no language about any special for commercial comparator products so one should assume they are subject to DSCSA like all other products. Without any specific guidance you should apply the expectation to have transaction information, transaction statement and transaction history as applicable when purchased. As to returns, presuming the return is to the immediate trading partner it was purchased from and subjected to the DSCSA return requirements and the returning party has properly stored the product when returning unopened containers, there appears to be no restriction from the DSCSA on returns

21. For Scott - are the SGLN/GLN numbers that were printed on our McKesson invoices the numbers we provide to our other trader partners?

Yes, the GLNs we believe belong to you which we display can be used with other suppliers you purchase from. If you believe that the GLN we print is incorrect, please advise us what you prefer to use so we can change it.

22. Is it possible for a single entity/address to have more than one GLN associated with it?

Yes. Grocery stores, Medical Buildings, and Hospitals are good examples as they could need/want to identify specific locations within a location. Grocery store - receiving versus Pharmacy. Medical Buildings usually have suites and floors to differentiate. Hospitals may identify Outpatient versus Pharmacy versus Receiving dock.

23. Since exemptions are not public knowledge can this information be shared broadly via an 832?

Your downstream customer needs to have an understanding as to whether you will or will not be sending DSCSA transaction data or not. The 832 will address that expectation.