Frequently Asked Questions (FAQs) on Preparing for DSCSA with Fresenius Kabi

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What is DSCSA?

The Drug Supply Chain Security Act (DSCSA) is a law enacted by Congress on November 27, 2013. It outlines steps to achieve interoperable, electronic tracing of products at the unit level to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. This law applies to most prescription medicine to ensure safety for patients. More information can be found in the additional resources section.

What is EPCIS?

Track and Trace will be accomplished with GS1 Electronic Product Code Information Services (EPCIS) as recommended by the FDA. The EPCIS standard defines a data model and a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. The standard will be applied to serialized product in scope for the DSCSA regulation.

What is a serialized product?

A serialized product is one that contains a 14-digit GTIN in conjunction with a unique serial number. It is often signified by a 2D barcode (Figure 1.1)

Figure 1.1

What information is needed by Fresenius Kabi for your company to purchase serialized product from Fresenius Kabi?

To sell serialized product, Fresenius Kabi must have the following information from a customer:

- Global Location Number (GLN) – one from the corporate location and each shipping location
- Global Company Prefix (GCP), if available
- DEA and HIN Numbers may be requested for cross reference as available

What is a GLN?

A GLN (Global Location Number) is a 13-digit globally unique GS1 Identification Number used to identify parties and locations. It can be used to identify a legal entity (like a health system), a functional entity (like a pharmacy dispenser or accounting department), or a physical location

(like a distribution center, hospital wing, loading dock door, storage location or nursing station). The GLN assures trading partners can share information related to the transaction.

How do I find my GLN?

There are a few ways a company can find their GLN for DSCSA. If the company is a pharmaceutical manufacturer or wholesale distributor that is currently assigning Global Trade Item Numbers (GTINs) or Serialized Shipping Container Codes (SSCCs), the company should already have registered for a GLN. If they need more than one GLN, they can access their GS1 Company Prefix (GCP) to enumerate additional locations or parties.

For dispensers such as hospitals, retail pharmacies, home health agencies and long-term care facilities, a GLN might already be assigned by their Wholesale Distributor or Group Purchasing Organization. You can contact them to see if they already have an assigned GLN for your location(s).

If none of the above applies to your company, you will need to reach out to GS1 to determine membership and obtain a GLN.

What is a GCP?

A **Global Company Prefix (GCP)** is a way for GS1 Member Companies to uniquely identify things like trade items, logistic units, locations, parties, and assets. The GCP is used to construct GS1 identification keys and is issued by GS1. It can contain anywhere from 6 to 11 digits depending on how the company was set up in GS1.

It is possible for a company to not have a GCP if they do not label products.

Where can I find my GCP?

First ask within your company to determine if there is a GCP assigned. If the GCP is unknown, you can reach out to GS1 for more guidance.

What is a SGLN?

The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. It can be thought of as another way to display the GLN. The SGLN is the format used in the data exchange. An example is given below on how to read and form an SGLN, but it is suggested to consult GS1 for accuracy.

Example: If a company has a GCP of 112233 and a GLN of 1122334455667, the SGLN will be displayed as 112233.445566.0. The first segment indicates the GCP.

For instances where the GLN is not derived from a GCP, the first 12 digits of the GLN will be used to denote the first segment of the SGLN.

Example: if a company has a GLN of 1122334455667 but no registered GCP, the SGLN will be displayed as 112233445566..0.

How is information shared between Fresenius Kabi and the customer?

Serialized product information needs to flow through the supply chain from manufacturer to distributor or to final customer. Fresenius Kabi utilizes a third-party service provider, called TraceLink, for EPCIS transmittal to comply with the DSCSA regulation.

What is TraceLink?

TraceLink is a company that creates a broad range of solutions for supply chain management. It helps companies manage and transmit data for regulatory compliance and traceability mandates.

Using TraceLink as your provider is not required because the program is able to communicate with other service providers if necessary. However, onboarding with TraceLink is needed to be able to access the compliance data provided by Fresenius Kabi. There should not be any cost associated to onboard with our service provider.

How to onboard with Fresenius Kabi and TraceLink to receive compliance data:

Please look at the three groups below to determine your next steps.

Group #1 - Trade partners that have not worked with TraceLink before, are unsure of who their NSM is or are unsure of which group you fall into:

STEP 1
Send an email to verification@tracelink.com and cc EPCISSetup@fresenius-kabi.com with the below items:
- Your Company Name
- Your Company Address
- Your Company GLN
- Your Company Prefix GCP
- Your Company SGLN
- Your Company's Serialization Point of Contact
- Email address for your Company's Serialization Point of Contact

STEP 2
TraceLink will assign a point-of-contact to assist with the onboarding called an NSM (Network Success Manager)

STEP 3

Your TraceLink NSM will reach out to you or your technical contact to discuss some topics including the following:

1. B2B electronic connection capabilities
2. File format – TraceLink uses GS1 US Healthcare EPCIS
3. Serialization readiness and testing schedule

Group #2 - Trade partners that are not TraceLink customers, but already have a TraceLink Network Success Manager (NSM):

Email **your TraceLink NSM** and EPCISSetup@fresenius-kabi.com letting them know that you would like to initiate your connection to Fresenius Kabi.

- Please include the information requested on the attached Customer Master Data Input form.

Group #3 - Paying TraceLink customers:

Reply to this email, EPCISSetup@fresenius-kabi.com, and cc any of your relevant TraceLink contacts to initiate our serialization discussions. Please include the information requested on the attached Customer Master Data Input form.

How would a customer access serialized information in TraceLink?

- Integration: Work with your solution provider to integrate with Fresenius Kabi and receive the data.
- Portal access: All shipments from Fresenius Kabi will include a packing slip containing the portal credentials that can be used to access product information online.

Additional Resources

The following links may be helpful and contain more detailed information regarding DSCSA and GS1 requirements

- Drug Supply Chain Security Act (DSCSA) | FDA

- o The FDA website contains more information on DSCSA including the law itself in original writing.

- https://www.gs1us.org/industries-and-insights/by-industry/healthcare/standards-in-use/pharmaceutical/dscsa-frequently-asked-questions
    - o GS1 Website contains a detailed outline of DSCSA and requirements to be compliant.