**GS1 Standards for DSCSA Compliance**

**1. Overview**

The US Drug Supply Chain Security Act (DSCSA) mandates that all prescription drug products be tracked and traced throughout the supply chain to improve patient safety and reduce counterfeit medicines. The GS1 standards provide the technical framework for serialization and data exchange. In particular, the GS1 Electronic Product Code Information Services (EPCIS) model is used to capture events (such as product commissioning, aggregation, shipping, and receiving) and ensure an unbroken chain of custody.

**Key Objectives of DSCSA:**

• **Serialization:** Every package is uniquely identified using a Serialized GTIN (SGTIN).

• **Aggregation:** Individual serialized items are grouped into logistic units (cases or pallets) using an SSCC.

• **Event Capture:** All supply chain transactions (commissioning, packing, shipping, receiving, dispensing, etc.) are recorded electronically.

• **Verification:** Trading partners verify that products have been properly serialized, aggregated, and transferred.

• **Interoperability:** Data exchanged between manufacturers, wholesalers, and pharmacies must follow a standard format (typically EPCIS XML/JSON) based on GS1 standards.

**2. Key GS1 Identifiers and Their Formats**

**2.1 SGTIN (Serialized Global Trade Item Number)**

• **Purpose:** Uniquely identifies individual saleable units.

• **Format:** Expressed as an EPC URI:

urn:epc:id:sgtin:<CompanyPrefix>.<ItemReference>.<SerialNumber>

• **CompanyPrefix + ItemReference:** Together, these form the GTIN base (typically 13 digits for DSCSA). The full GTIN is 14 digits (including a packaging indicator and a check digit, which is not transmitted in the EPC URI).

• **SerialNumber:** Up to 20 alphanumeric characters; must be unique for each product.

**2.2 SSCC (Serial Shipping Container Code)**

• **Purpose:** Identifies logistic units (e.g., cases, pallets).

• **Format:** Expressed as an EPC URI:

urn:epc:id:sscc:<CompanyPrefix>.<SerialReference>

• **CompanyPrefix + SerialReference:** Together, these form a 17-digit base. A check digit is calculated by the GS1 algorithm to form the 18-digit SSCC (the check digit is implicit in the EPC URI).

**2.3 SGLN (Global Location Number)**

• **Purpose:** Identifies physical locations (manufacturing sites, warehouses, pharmacies) or parties.

• **Format:** Expressed as an EPC URI:

urn:epc:id:sgln:<CompanyPrefix>.<LocationReference>.<Extension>

• **CompanyPrefix + LocationReference:** Typically 12 digits.

• **Extension:** A subsidiary identifier (for a specific department or sub-location), often “0” if not used.

**3. EPCIS Event Flow for DSCSA Compliance**

The DSCSA chain-of-custody is maintained through a series of EPCIS events. Each event must be validated for data quality and sequence. The following diagram and descriptions provide a complete picture of the process.

**3.1 DSCSA Event Sequence**

The key steps in the DSCSA supply chain include:

1. **Commissioning (Serialization)**

• **What Happens:** The manufacturer creates the product and assigns a unique SGTIN to each saleable unit. This event is recorded as an Object Event.

• **Required Data:**

• **Identifiers:** SGTIN for each item.

• **ILMD:** Lot number, item expiration date, production date.

• **BizStep:** urn:epcglobal:cbv:bizstep:commissioning

• **Disposition:** Typically active (or in\_progress until fully validated).

2. **Aggregation (Packing)**

• **What Happens:** Individual SGTIN items are aggregated into a case or pallet. The aggregation event links child SGTINs to a parent SSCC.

• **Required Data:**

• **Parent ID:** SSCC for the case/pallet.

• **Child EPCs:** SGTINs that are being aggregated.

• **BizStep:** urn:epcglobal:cbv:bizstep:packing

• **Disposition:** in\_progress (as items are being prepared for shipment).

3. **Shipping**

• **What Happens:** The logistic unit (case or pallet) is shipped from the manufacturer/distributor.

• **Required Data:**

• **Identifiers:** Typically, the parent SSCC (or individual SGTINs if not aggregated).

• **Business Transactions:** Must include at least a Purchase Order (urn:epcglobal:cbv:btt:po) and Despatch Advice/ASN (urn:epcglobal:cbv:btt:desadv).

• **Source/Destination:** Source and destination GLNs (via SGLN) provided in the sourceList/destinationList.

• **BizStep:** urn:epcglobal:cbv:bizstep:shipping

• **Disposition:** in\_transit

4. **Receiving**

• **What Happens:** The receiving party (wholesaler, pharmacy, etc.) records the receipt of the logistic unit.

• **Required Data:**

• **Identifiers:** Same as in shipping (SSCCs/SGTINs).

• **Business Transactions:** Typically a Receiving Advice (urn:epcglobal:cbv:btt:recadv) along with PO/ASN details.

• **Location:** Read point (the receiving dock) identified by a valid SGLN.

• **BizStep:** urn:epcglobal:cbv:bizstep:receiving

• **Disposition:** active (or in\_progress if not fully reconciled)

5. **Dispensing / Decommissioning**

• **What Happens:** At the point of sale (pharmacy) or in the case of returns, the product is dispensed (or decommissioned if destroyed, recalled, etc.).

• **Required Data:**

• **Identifiers:** SGTINs of the individual saleable units.

• **BizStep:** urn:epcglobal:cbv:bizstep:dispensing (or decommissioning for recalls/damage)

• **Disposition:** dispensed, partially\_dispensed, or destroyed/recalled as appropriate.

**4. Detailed Flow Chart for DSCSA EPCIS Validation**

Below is a complete flowchart that describes the EPCIS DSCSA event sequence and the key validations at each step.

A diagram of a flowchart

AI-generated content may be incorrect.

**Explanation of Flow Chart Steps and Validations**

1. **Commissioning Event**

• **Data Captured:** Each product is serialized using SGTIN, along with ILMD attributes such as lot number and expiration date.

• **Validations:**

• Ensure SGTIN conforms to the format (using regex and check digit calculation).

• Verify ILMD fields (e.g., lotNumber exists; itemExpirationDate is in YYYY-MM-DD format and is later than productionDate).

2. **Aggregation (Packing) Event**

• **Data Captured:** Items are grouped into a logistic unit (case or pallet).

• **Validations:**

• Validate parent SSCC format.

• Check that all child SGTINs have been previously commissioned.

• Ensure no child EPC is aggregated into multiple parents.

• Verify packaging rules (e.g., number of child items does not exceed maximum allowed).

3. **Shipping Event**

• **Data Captured:** The logistic unit is shipped.

• **Validations:**

• Check that the event contains required business transactions (Purchase Order and Despatch Advice/ASN).

• Validate that source and destination are provided as valid SGLNs.

• Ensure the disposition is set to “in\_transit” and that the event timestamp follows proper sequence.

4. **Receiving Event**

• **Data Captured:** The receiving party logs receipt of the shipment.

• **Validations:**

• Ensure the received EPCs match those from shipping.

• Validate the readPoint (must be a valid SGLN).

• Check for necessary business transactions (including Receiving Advice).

5. **Dispensing/Decommissioning Event**

• **Data Captured:** When a product is dispensed or decommissioned, the event records this final state.

• **Validations:**

• Verify that the SGTINs are still valid.

• Ensure the business step and disposition correctly indicate a product that is dispensed, destroyed, or recalled.

6. **Overall Sequence and Timing Checks:**

• Across all events, the validator must ensure that the sequence follows the DSCSA rules (e.g., an item must be commissioned before it is packed, and packed before it is shipped).

• Timestamps are checked to enforce chronological order, and any out-of-sequence occurrence is flagged with detailed error messages (including the EPC and the conflicting event times).

7. **Scorecard Calculation (Optional):**

• Based on the number and severity of validation errors, a score is calculated. Fewer errors mean a higher score, reflecting better compliance with DSCSA requirements.

**5. Summary**

This guide explains how the GS1 standard is applied within DSCSA for tracking and tracing pharmaceuticals. The key points include:

• **Identifier Formats:**

• **SGTIN** for individual saleable units (13-digit company prefix+item reference plus serial).

• **SSCC** for logistic units (17-digit base plus check digit).

• **SGLN** for locations (12-digit company prefix+location reference).

• **EPCIS Event Flow:**

• **Commissioning:** Product serialization with ILMD.

• **Aggregation:** Packing items into cases or pallets.

• **Shipping:** Outbound shipment with transaction data and source/destination GLNs.

• **Receiving:** Confirmation of receipt.

• **Dispensing/Decommissioning:** Final state update.

• **Validation Rules:**

• Each event must include all required fields, adhere to the proper GS1 identifier formats, and follow the chronological sequence.

• Specific DSCSA checks include validating ILMD (lot, expiration, production dates), ensuring business transaction data is present in shipping and receiving events, and enforcing that an item cannot be aggregated, shipped, or received without having been commissioned first.

• Detailed error messages, including EPC details and event times, are critical for troubleshooting and for maintaining a complete audit trail.