



DSCSA 2023 for Manufacturers: Critical 2022 Partner Requirements

Presented by TraceLink and Henry Schein

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DSCSA 2023 for Manufacturers

- DSCSA 2023 requirements: What is different?
- GTIN, Master Data, and aggregation requirements
- Preparing for EPCIS data exchange with your partners
- Timelines for partner onboarding, solution testing, and rollout
- The business risks of non-compliance
- How TraceLink streamlines your DSCSA journey
- Q&A/Next steps

DSCSA 2023 for Manufacturers



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DSCSA 2023 Requirements: What is different?

DSCSA 2023 Requirements: Manufacturer View of “What”

One Hundred Thirteenth Congress
of the
United States of America
AT THE FIRST SESSION
Began and held at the City of Washington on Thursday,
the third day of January, two thousand and thirteen

An Act
To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug
outpounding and drug supply chain security, and for other purposes.
Enacted by the Senate and House of Representatives of
the United States of America in Congress assembled.

SECTION 1. SHORT TITLE.
This Act may be cited as the “Drug Quality and Security
Act”.

SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.

(a) REFERENCES IN ACT.—Except as otherwise specified, amend-
ments made by this Act to a section or other provision of law
are amendments to such section or other provision of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) TABLE OF CONTENTS.—The table of contents of this Act
is as follows:

2015

- Lot-level traceability (T3)
- Product and transaction verification
- Tracing and verification archival

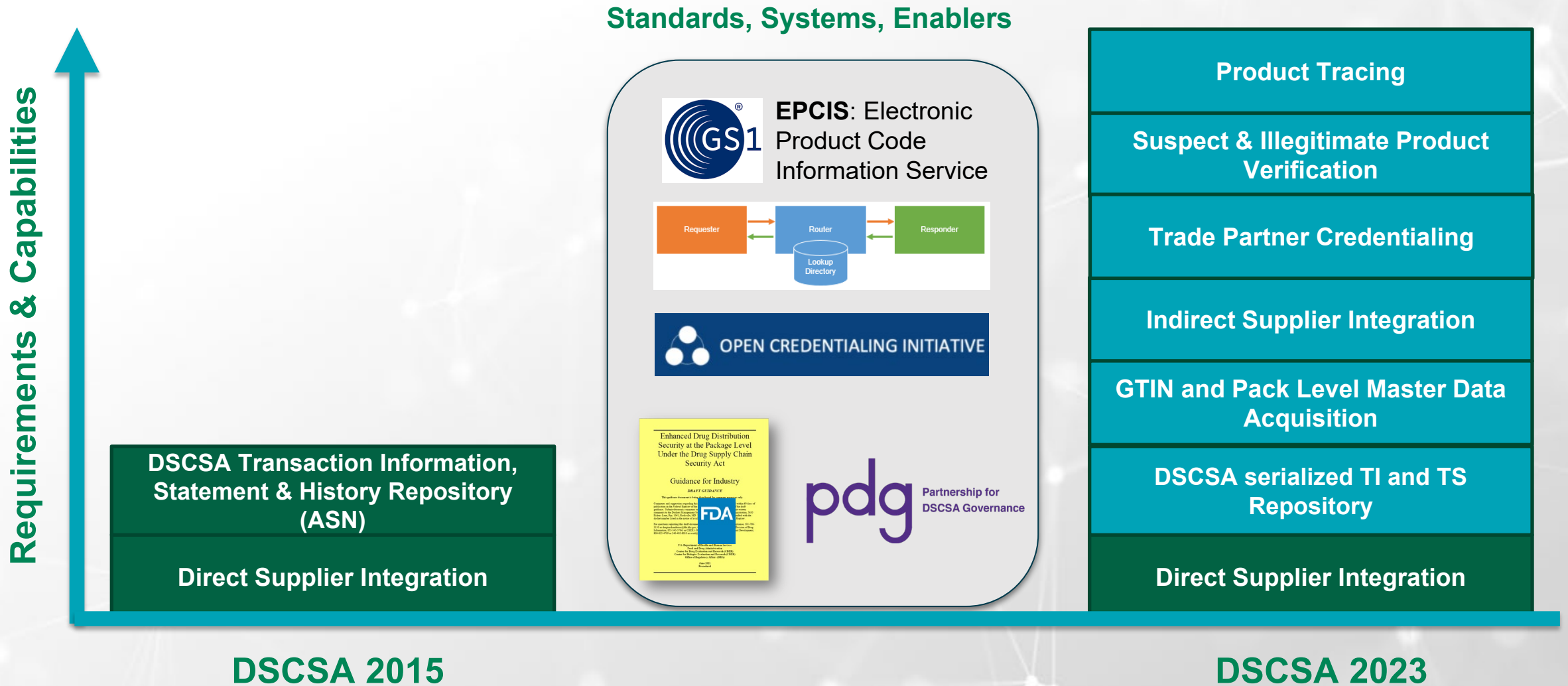
2017-2020

- Serialized product identifiers
- Electronic transfer of T3
- Respond to requests for verification (saleable returns)

2023: Interoperable, electronic tracing at the package level

- Serialized TI
- Processes and systems to:
 - Verify product at package level
 - Respond to requests for TI and TS
 - Facilitate gathering of TI back to manufacturer
 - Associate saleable returns with TI and TS

DSCSA 2023 Requirements: Manufacturer View of “How”



EPCIS: An Industry-Wide Data Standard

- *Electronic Product Code Information Services*
- 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.
- EPCIS breaks down supply chain business processes into individual steps such as commissioning, packing, shipping, or receiving, so trading partners know the what, when, where, and why of each step.
- Each such step is called an “event”, and the term “EPCIS event” refers to the data record that describes an event using the standard EPCIS language.



GTIN, Master Data, and Aggregation

GTINs and Master Data

A Global Trade Item Number (GTIN) identifies any item for which there is predefined information (master data) and that may be priced, or ordered, or invoiced at any point in any supply chain.

- Product master data includes:
 - GTIN, NTIN, country drug codes, internal material codes
 - Target, export markets
 - Serialization packaging codes
 - Product attributes (strength, dosage, package size, etc.)
- Company and trade partner master data includes:
 - Global company identifiers (GCP, GLN, DUNS, CN, CNPJ, CIT, DEA, HIN, etc.)
 - Business types
 - Location codes (corporate, facility, store level) and address information
 - License information (wholesale distribution licenses, DEA, etc.)

Hierarchy levels and GTIN assignment

- A unique GTIN is assigned at every existing level of the hierarchy. An “each” is typically the smallest saleable unit (and where EPCIS tracking begins).
- Business cases where a unique GTIN at the higher-level packaging (e.g., pack, case, pallet) are required:
 - A case configuration changes from 8 trade items to 12 trade items. The case needs to be uniquely identified.
 - A pallet configuration changes from 12 cases to 16 cases. The pallet needs to be uniquely identified.





Preparing for EPCIS data exchange with your partners

Poll

When do you expect to be ready to send production EPCIS messages?

A. We are already sending production EPCIS messages

B. Planning to send Q1-Q2 2022


C. Planning to send Q3-Q4 2022

D. Planning to send Q1-Q2 2023

E. We have not set a target date yet

EPCIS data exchange: Best Practices

- Provide Henry Schein your complete list of saleable unit GTINs, company and location GLN and SGLNs. Load all Henry Schein GLN and SGLNs in your master data.
- Ensure your Sales Shipment messages contain a Commissioning event and Vocabulary list for each GTIN
- Work with your TraceLink Network Services Manager, NSM, to establish SFTP or AS2 connectivity. Test the connectivity prior to sending a first test file.
- Work with your Solutions Provider regarding the creation time of your Commissioning and vs Aggregation events. If you are Commissioning a large number of Product Identifiers, be sure the Aggregation events for these products occurs **after** the Commissioning events are complete.
- Be sure to send the correct NDC-11 XML tag and 5-4-2 NDC format in your data.
- Whenever possible test using an item and GTIN that Henry Schein purchases from you in Production.
- Always send the Henry Schein purchase order number, or ASN reference number, (for multi PO shipments), in your Shipping event.



Timelines for partner onboarding, solution testing, and rollout

Partner onboarding, solution testing, and rollout

- Henry Schein continues to work with Trading Partners on both VRS and EPCIS.
- We need to focus on the EPCIS connectivity in 2022 with all Trading Partners in order to allocate sufficient IT resources
- Onboarding takes a few weeks to complete
- We won't be able to onboard all Trading Partners at the same time. If you're ready to start today, we want to start today!

Partner onboarding, solution testing, and rollout

- Lessons learned transitioning into sending electronic TI/TH/TS via EDI ASN 856
 - Some Trading Partners didn't have this capability
 - IT: Initial data exchange information was messy
 - Missing details required new ASNs
 - Operations: Practical use took time to understand
 - Matching up physical shipment to ASN was new, training rushed

Partner onboarding, solution testing, and rollout

- Henry Schein to begin serialized operations in Q1 2023. We anticipate complex logistics to be uncovered and returned as feedback to the Trading Partner for solution collaboration.
- Ramp up of serialized operation activities throughout year, smooth out “bugs”, recover lost efficiencies
- Business requirement for Trading Partners to complete EPCIS connectivity by November 2022. Those who aren't ready ultimately risk supply chain impacting patient care.

The business risks of non-compliance

- Supply chain disruption
- Business revenue disruption
- Impact on patient care



Choosing a DSCSA solution provider

Capabilities Required For DSCSA Compliance

Enterprise Capability

Master Data Integration

Serial Number Generation & Management

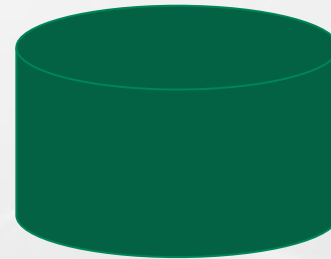
Aggregation Event Capture

Packaging Line Management

Warehouse Management System Integration

ERP Integration

Exception Management



Serialization & EPCIS Repository

Multi-Enterprise Network Capability (direct & indirect partner integration)

GTIN & Pack Level Master Data Sharing

Authorized Trade Partner Check

Wholesaler Integration

Dispenser Integration

EPCIS Data Exchange

Suspect Product Verification

Product Tracing

Recalled Product Tracing

Partnering with Tracelink

- **Experience:** Partner with a solution provider with the largest serialization and DSCSA customer base
- **Compliance:** Continuous compliance with evolving DSCSA rules, industry standards and partner requirements
- **Network:** Reduce supply chain partner integration costs with wholesalers and dispensers - from 100s of connections to 1 connection
- **Scalability:** Manage large complex serialization choreographies at operational scale without disrupting operations and product delivery
- **Opus Platform:** Network construction toolkit to connect people, processes, systems, and information across the end-to-end supply chain.



2022 Checklist

Preparing for EPCIS data exchange: Checklist

- ✓ Contact Henry Schein at Serialization@HenrySchein.com with your:
 - Technical contact name and email address
 - Regulatory contact name and email address
 - Solutions Provider contact name and email address (if not TraceLink)
 - Complete list of product GTINs for all saleable units
 - Your company and shipping location GLN and SGLNs
- ✓ Load Henry Schein's company GLN and SGLNs into your master data
- ✓ Provide your TraceLink NSM information to Henry Schein. If you do not have an NSM let us know and we will contact TraceLink on your behalf.
- ✓ Establish and test connectivity with TraceLink
- ✓ Send a Product Track ServiceLink, (TraceLink partners), or put in a request to your TraceLink NSM for a ServiceLink to be created and sent to Henry Schein
- ✓ Configure the PT ServiceLink using your company GLN as the sender and Henry Schein's company GLN of 0304040000007 as the receiver
- ✓ Send a test Sales Shipment EPCIS message with Aggregated data to Henry Schein's TraceLink iTest environment
- ✓ Confirm successful receipt and processing by Henry Schein
- ✓ Schedule go-live date



Q&A



• Thank You