RESOURCES

Traceability from Lot-Level to Unit-Level: How to Assess Your Receiving Options



DSCSA 2023 lays out several requirements that health systems and retail pharmacies must comply with as they receive products from manufacturers and other members of the medicine supply chain.

In our recent DSCSA 2023 webinar, "Transitioning from Lot-Level to Item-Level Traceability Under DSCSA and the Need for an Experienced Partner," we explained that in less than a year, health systems and retail pharmacies must be able to:

- Store serialized Transaction Information (TI) and Transaction Statements (T2) in an electronic database
- Ensure secure, interoperable, electronic unit-level traceability of all the drugs and medicines they distribute
- Retrieve product identifier verification data for the investigation of suspicious or contaminated products
- Assemble individual transaction statements for products into a product history for tracing purposes
- Verify Authorized Trading Partners are currently licensed to ensure DSCSA-compliant interactions

These new regulatory requirements for traceability iInformation exchange under DSCSA 2023 represent a major step change from the current standard introduced

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in 2015.

As health systems and retail pharmacies make this challenging transition, they'll need to be able to receive EPCIS transactions and be able to produce that information as part of an investigation or audit, and therefore one must carefully consider how they'll approach reconciling physical product with their compliance data.

During the webinar, we looked at some of the different receiving and reconciliation approaches dispensers can take. These approaches vary from simply receiving EPCIS data from trading partners to receiving, reconciling, and enriching this data to drive significant business value. Here are the top three takeaways from the session:

- **Each approach has tradeoffs.** While being able to receive EPCIS from your trading partners and retrieve it during an audit will make you compliant by law, it could leave some compliance blindspots. On the other end of the spectrum, receiving, reconciling, and enriching data can significantly improve your processes, but also has a monetary and operational cost.
- **There is no "recommended" approach.** Most dispensers need to weigh your specific business requirements when choosing the best way to manage their compliance obligations.It ultimately depends on a variety of factors, ranging from the makeup of your supply chain network to the operating conditions of your specific business.
- **An experienced partner is an invaluable asset.** Regardless of which approach you choose, it helps to have an experienced track-and-trace partner by your side. They can leverage the experience they have working with other dispensers to help you navigate the risks and fasttrack the opportunities.

Since 2020, TraceLink has supported a variety of dispenser reconciliation approaches to ease the transition from lot-level to item-level traceability. We can help address new required data elements, identifying whether you have a GLN

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(and providing resources if you need to obtain one) and pre-loading nearly 50,000 GTINs. Our track-and-trace solutions are also battle-tested and proven—more than 41.2 billion serialized units are currently tracked on our network, with 47,000 in-network GTINs and 135 companies exchanging EPCIS-compliant transactions.

The TraceLink Healthcare Operations Services Team (HOST) can help you prepare for audits, regardless of whether they're instigated by the FDA, state boards, or internal stakeholders. HOST has supported more than 50 audits across our health system and pharmacy customers, ensuring they have the information they need, plus dedicated resources over the phone and advisory support after the fact to improve compliance.

If you're interested in learning more about DSCSA 2023 from a panel of subject matter experts and your industry peers, sign up for the next session in our DSCSA webinar series today. We've got a special track dedicated specifically for dispensers.

REGISTER TODAY

And if you'd like to learn more about the transition to item-level traceability, watch the on-demand recording. You'll get more on DSCSA requirements, as well as the necessary capabilities for meeting them and how TraceLink can help.

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