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DSCSA 2023 Compliance Readiness a Hot Topic at HDA DMC Conference as Preparation Accelerates



Mar 22, 2023

TraceLink ramps up deployment of its end-to-end Drug Supply Chain Security Act (DSCSA) compliance solutions for over 1,200 companies and their 290,000+ trade partners as November 27, 2023 DSCSA deadlines approach.

TraceLink Inc., the leading digital network platform company connecting more than 290,000 entities across the Healthcare and Life Sciences industry, attended the Healthcare Distribution Alliance's Distribution Management Conference (HDA DMC) this past week to share learnings and discuss critical preparation steps for DSCSA readiness. With the deadline fast approaching, the industry still faces significant work to do in meeting the internal operational process, network connectivity, and multienterprise data exchange requirements stemming from the final phase of DSCSA regulations. Many of the prepared sessions, roundtable discussions, and networking conversation at HDA DMC were focused on DSCSA, including panel discussions which included both

TraceLink experts and TraceLink customer leaders.

TraceLink's team has assembled a few key takeaways from the hundreds of conversations we had at HDA DMC. These include:

- **EPCIS Exchange of DSCSA Data.** Testing and deployment of platforms for the exchange of serialized Transaction Information (TI) and Transaction Statement (TS) data using the standard GS1 EPCIS format continue to ramp up. TraceLink has processed over 880,000 DSCSA EPCIS transactions on the TraceLink Network in support of these efforts. Questions were raised as to the awareness and readiness of the healthcare provider and retail pharmacy segments for these requirements, an area that TraceLink continues to target through our extensive **DSCSA education programs** with these segments.
- **Exception Management.** Awareness and concern is growing about the broad range of deviations and compliance exceptions expected by the industry as DSCSA 2023's expanded serialized product traceability requirements go into effect. Discussions at HDA DMC focused not only on why exceptions may occur, but how a company and its trading partners should effectively analyze and resolve such exceptions to minimize product supply impacts. TraceLink held a recent **webinar** on this topic, and at HDA DMC led over 20 demonstrations of our Supply Chain Work Management for Compliance Exceptions solution, which is purpose-built for this need.

- **Network Interoperability.** DSCSA doesn't specifically document "how" companies and their trading partners should implement data exchanges, verification inquiries, and other multienterprise shared processes, prompting intense conversations on how to ensure end-to-end network interoperability across the supply chain. These included numerous attendee discussions on the publication of recent foundational blueprints for DSCSA 2023 interoperability by the Partnership for DSCSA Governance (PDG) to help facilitate sTI/TS data exchange, verification, product tracing, and other key DSCSA requirements.
- **Aggregation.** Configuring serialized product identifiers across packaging hierarchies in shipments to include aggregation relationships remains a hot topic. Requirements for aggregation and exchange of aggregation data, including penalties such as product quarantines and returns, are now being included in supplier letters.

In summary, many that we talked to felt a growing sense of concern at the progress being made towards November 2023 readiness. Much of this had to do with who wasn't in the room. There was considerable conversation about the large segment of the industry that hasn't been attending conferences like these or webinars like TraceLink's DSCSA webinar series. TraceLink has seen a week-by-week growth of companies contacting us who are either just now hearing about the new DSCSA 2023 requirements, or are now coming to realize that their diligent efforts towards preparing for the lot-level traceability and product serialization phases does not mean that they are ready for

November. In fact, far from it. To them we say: TraceLink is ready to help.

For companies concerned about their DSCSA 2023 readiness plan, we invite them to join over 200 industry leaders and TraceLink experts at our **FutureLink** conference, May 22-24, in Boston, Mass. With over 25 sessions and workshops dedicated to DSCSA 2023 preparedness, FutureLink is an unsurpassed opportunity for manufacturers, distributors, healthcare providers, and retail pharmacies to build a confident plan for November compliance. Register by April 1 and save \$200. Visit the **FutureLink site** to learn more now!

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