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Interoperability Standards Expert: DSCSA Compliance Requires a Re-Examination of Business Processes

Under the U.S. Drug Supply Chain Security Act (DSCSA), pharmaceutical manufacturers and their supply chain trading partners have until November 27, 2023 to implement a 100% electronic and interoperable system for exchanging item-level compliance data. But industry efforts to achieve DSCSA compliance are lagging behind expected readiness timeframe, according to Elizabeth Waldorf, Director of Global Traceability and Standards at TraceLink, and winner of the ***GS1 Ken Traub Standards Award****.*

Waldorf, who previously led the Global Traceability Team at Amgen, is a key contributor to the GS1 standards organization's work in EPCIS, verification, serialization, barcoding, traceability, data management, operational processes, and technical standards for DSCSA. Waldorf currently spearheads TraceLink efforts to support the creation and development of global interoperability standards from concept to implementation and interoperability testing.

In this interview, Waldorf discusses industry readiness for DSCSA and the need to update business processes to reduce compliance errors after DSCSA 2023 goes into effect. She also covers TraceLink's participation in the creation of global interoperability standards and offers some expert advice for organizations getting

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ready for the upcoming DSCSA deadline.

How close is the pharmaceutical industry to being ready for the November 27th DSCSA deadline?

Elizabeth Waldorf: One of the biggest challenges is onboarding. People in the industry are articulating that the rate of trading partners getting onboarded has fallen behind the schedules set by wholesale distributors and retail pharmacy chains. There is a great sense of worry that companies won't be onboarded in time. That's part of the reason why it's important to ramp up community education in all areas. Whether it's through TraceLink or other organizations, it's critical to raise awareness of what's required. For example, TraceLink has **offered several presentations and webinars** that talk about **DSCSA readiness** and what to do. But it's really about reaching out to everybody. The industry workgroups consist of active participants that are aware of what is coming. The concern has always been for industry stakeholders who may not always be actively participating. For example, do they know what they need to do? Do they know that they are not ready? TraceLink and I have worked with the GS1 standards organization to provide playbooks **describing what manufacturers, wholesalers, and dispensers need to do to ensure DSCSA compliance**. We have also led the development of standards and implementation guidelines.

How does TraceLink support the creation of industry standards that support interoperable data exchange between trading partners and overall DSCSA compliance?

Waldorf: We try the best we can to be part of the leadership group—to be a thought leader. We do that by leading workgroups and by being a key contributor to the material through active discussion and participation and even by authoring and editing standard implementation guidelines and industry specifications. And then we champion the use of industry standards throughout the industry, either by

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presenting at conferences and webinars or facilitating round table discussions for education and outreach. TraceLink takes an active role in the creation and development of standards, and then we actually internalize the standards and take those learnings in and integrate it into the design of our products to enable customers to achieve continuous compliance.

TraceLink Standards and Interoperability Leadership

GS1	Healthcare Distribution Alliance (HDA)	Partnership for DSCSA Governance (PDG)	Open Credentialing Initiative (OCI)
• Executive Leadership Committee for Healthcare in the US • GS1 Architecture • Co-chair for EPCIS 2.0 dev'l • Member of EPCIS 1.2 team • Co-chair of Secure Supply Chain Group • Winner of the Ken Traub Industry Standards Award • Noted contributor to GS1 Global Public Policy group • Co-chair and editor of GS1 Lightweight Messaging Standard for DSCSA Verification of Product Identifiers • Co-editor of GS1 Implementation Guideline for Applying GS1 Standards for DSCSA and Traceability	• Active participant in the design and implementation of the Request, Response, and Lookup Directory protocols • Leading VRS taskforce and Interoperability testing • Industry expert presenter during conferences and quarterly business reviews	• Founding solution provider member • Key technical leader in Serialized TI/TS Exchange, Tracing Architecture, Verification Architecture, and Credentialing and User Authentication workgroups to inform blueprint discussions • Active member interoperability committee to help inform discussions on industry adoption and education	• Steering committee member • Co-chair of policy and architecture committee

Pharma supply chain stakeholders can expect a significant rise in compliance errors, also known as exceptions, when the final phase of DSCSA takes effect. Exceptions can lead to product holds and shortages. You recently participated in a TraceLink Community forum on exception handling. What were some key takeaways?

Waldorf: When it comes to exception handling, there is no "one-size-fits-all" approach. Exceptions can occur at any point in the supply chain and any part of the process, and the earlier you detect them, the better. Ideally, each stakeholder company establishes processes and measures in place to proactively prevent exceptions from occurring. The process of identifying, understanding, and resolving exceptions really depends on where you find them, what the situation is, and what the errors are. Flexibility is going to be key. Exception handling requires a flexible solution.

How can the industry work together to reduce the impact of compliance data errors and exceptions on patient access to medicine?

Waldorf: While there's acknowledgement among the participants that making

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sure that the data aligns with the product is important, it is encouraging to know that there is also recognition that the patient comes first. So, in situations where there is a high risk and a high need for the patient to have critical products, there are discussions about how to make sure that the patients get what they need, while making sure to manage their risks.

What is TraceLink doing to help pharmaceutical supply chain stakeholders manage and resolve exceptions?

Waldorf: Part of what we do at TraceLink is bring the discussion to the community. We also take that input from the community and then, as we partake in the different industry discussions, we use that information to represent our customers' needs. For example, we recently held a TraceLink Community forum on the topic of exception management that attracted more than 110 participants. From a product perspective, part of TraceLink's role is to identify what solutions are needed and to provide a systematic way for customers to be able to detect and correct the issues. We accomplish this with our **Supply Chain Work Management (now POET)** solution. But it's more than just the technical piece—it's also important to enable clear communication between trading partners. We are looking at exception management holistically from communication down to resolution to help customers avoid disruptions and ensure supply.

What advice do you have for organizations still getting ready for the November 27th deadline?

Waldorf: It's critical to ensure that the onboarding is done and an ongoing maintenance of master data collection and exchange is in-place. Moreover, it is imperative that organizations have the business processes in place to support all of the various aspects of DSCSA compliance because it's not just about the manufacturing. There is also a lot to do in receiving and in the warehouse, for example. It's important to make sure that all involved parties have all of the right processes, tools, and training. Companies that are unsure or that have not started

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their DSCSA update project should contact their TraceLink account executive immediately to set up a readiness assessment.

You mentioned the importance of looking at business processes. How are manufacturers addressing business process changes to support DSCSA compliance?

Waldorf: One of the learnings that manufacturers have communicated is that operationally, in terms of their processes, it's important to take a defensive or quality-focused approach. That means looking at what they can do in terms of their business processes to detect and prevent exceptions. A lot of the manufacturers who have shared their experiences have said that they have built some internal checks to ensure, for example, that if there is something missing in the data, they don't ship out the product. One of the benefits of using TraceLink's Supply Chain Work Management (now POET) solution to track and resolve exceptions is the history that it collects on exceptions which can be used for analysis to prevent them from happening again—data which can be securely shared with trading partners based on workflows and permissions established by the data owner in order to eliminate root causes of the exceptions.

What should wholesale distributors and dispensers think about when it comes to updating warehouse and pharmacy receiving business processes to support DSCSA compliance and reduce exceptions?

Waldorf: When item level traceability (the final phase of DSCSA compliance) kicks in, organizations will need to receive both physical product and digital DSCSA transaction data. The increase in granularity adds a layer of complexity in business process and system solutions. From a general warehousing perspective, it's important to think about receiving processes. It's designing quality checks into their end-to-end process to make sure they have safety checks and balances so that exceptions don't go unnoticed—because when exceptions go unnoticed, it's much more difficult.

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