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DSCSA 2023 Deep Dive: The Importance of Standards to DSCSA Success





The U.S. Drug Supply Chain Security Act (DSCSA) requires all **pharma manufacturers**, **wholesalers**, and **dispensers** to implement a fully interoperable, industry-wide system for item-level traceability and the secure, interoperable exchange of transaction information and transaction statements by November 27, 2023. Your organization's ability to implement industry standards will be critical to success. Is your organization ready?

Watch our on-demand webinar, "**DSCSA 2023 Deep Dive: The Importance of Standards to DSCSA Success**" to get the information you need to navigate the various standards, blueprints, and industry activities that can help you gain a better understanding of DSCSA models and implementation recommendations. Three reasons to watch now:

1. Get a complete overview of the key standards, industry blueprints, and critical initiatives associated with DSCSA, including GS1, EPCIS, PDG, OCI, and much more.

2. Learn why adhering to industry standards is critical to achieving interoperable

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exchange, interoperable verification, and interoperable tracing across the **end-to-end pharma supply chain**.

3. See how TraceLink acts on behalf of its customers by leading industry organizations and serving as a major contributor to the standards community.

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Transcript

Dan Walles: [0:01] Good morning everyone. Thank you for joining us, again for many of you, as we're in the midst of our DSCSA 2023 Webinar Series. Today in the series we'll be walking through an important topic as it relates to DSCSA. That is the role of standards in contributing to the success of an individual's DSCSA program and really the success for the industry.

[0:30] I'm fortunate to be joined today by two people who have really been leaders within the industry around a number of initiatives in and around standards. First and foremost, Elizabeth Waldorf, formerly of AMGEN, heads up our global

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traceability and standards organization, and Lucy Deus. Lucy is a co-founder of TraceLink and is a Senior Vice President of our product management group.

[1:04] Between these two subject matter experts, it's getting a good understanding of what's the current landscape of standards and then how that translates into our products and our solutions.

[1:21] As I had mentioned, this is a webinar that is part of a larger series, targeted at manufacturers, wholesalers, and dispensers. In this particular track, we refer to this as a deep dive session, where we take a particular topic and we dive deeply into that topic area. Today, it revolves around standards.

[1:47] There's upcoming deep dives over the coming weeks, where we'll be able to show you some of our solutions that we're working on for DSCSA, some new capabilities that we'll be delivering through the OPUS Platform as well. Then in January, where we're excited about showing you some end-to-end capability through our DSCSA platform.

[2:15] Specifically to this webinar, what I'd like to set as the backdrop of some key takeaways that you can be thinking about as we go through the material.

[2:27] The first one is something that we've been communicating, I think, a number of times through our previous sessions together. That is the role of digitizing or digitalizing our supply chains and the fact that this is a business imperative for all organizations across the healthcare supply chains.

[2:51] What we also want you to recognize is how DSCSA starts to create a series of fundamental elements as it relates to supply chain digitalization. Capabilities such as putting unique identification on products, integrating to partners, operating within a network, and having a platform to now start to orchestrate

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business processes is crucial.

[3:20] DSCSA, like any other supply chain process, is starting to deliver those foundational elements. Specifically, because this is a network challenge, digitalizing the supply chain requires interoperability. Interoperability requires that we all operate and speak a common language, if you will. That is the role of standards within the supply chain, and specifically around DSCSA.

[3:51] We'll show you how TraceLink is embracing industry standards, and not only incorporating support for those standards but really investing heavily in leading the discussion within industry around the adoption of standards.

[4:11] That will all be combined as we start to educate on what is the current status of the standards process within the industry, as it relates to the overall DSCSA landscape. Certainly, a lot to cover today.

[4:29] Before we get in, we just want to continue to reinforce our role in the industry as the world's largest digital supply network. We're approaching 1300 total customers globally, over 50 different countries represented.

[4:49] More importantly, as you look across our customer base, the number of companies or customers that are engaged and partnered with TraceLink around serialization is close to 900.

[5:02] The reason that's important is, as DSCSA starts to require not just the creation of serialization and serial numbers in the commissioning of them but orchestrating and managing serialized events across our distribution and logistics processes.

[5:25] In terms of the connectivity across the network, we have 340,000 active

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links or connections, where companies are collaborating or exchanging compliance information, interoperate with everyone has eliminated well over four billion dollars in what would have been point-to-point integrations. Close to 800 employees, over half of them are dedicated to developing products and supporting you through services.

[6:03] Again, as we reinforce TraceLink's position in the market, in terms of the number of serialized products that we are managing, the number of transaction histories, this is the 2015 requirement that we're processing and managing is approaching a billion. Almost 50,000 GTINs that are currently managed within the TraceLink Network ready for verification.

[6:36] You can see some of our investment and growth over the years, and again, this organization is dedicated to helping companies be compliant with DSCSA, other global regulations, and supporting them in their digital supply chain initiatives.

[6:56] What I'd like to do now is pass it to my colleague, Lucy Deus, to take us and start the presentation. Lucy.

Lucy Deus: [7:07] All right. Well, thank you, Dan, and welcome everyone. We'll spend the next few minutes talking about how the court elements that enabled DSCSA. The unique identification plus the supply chain partner integration on an interoperable network and provide the foundational elements not only for DSCSA compliance, but also for supply chain digitalization.

[7:30] We hear supply chain issues making the news every day and many of these impact our businesses. These include things like what we're discussing today. The need for product traceability to deter counterfeiting and diversion. Poor transparency into product supply against demand and inter-product quality which

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leads ultimately to uncertainty and product availability or in-product recalls.

[7:54] Limited supply chain visibility across partner relationships and transactions that then lead to material shortages of production, which then, result in delays of product shipments in global supply channels.

[8:06] This list is long and underlying these challenges are some fundamental systemic issues. These include things like lack of timely visibility into the activities and the events that are occurring in the supply chain relationships, or information sharing with partners because of differences in their systems and challenges in integrating across the diverse partner networks.

[8:31] The inability to identify products and manage their information at the individual serialized unit level, and then manage and trace those product movements and status.

[8:43] Finally, simply work between companies and partners on shared processes is disjointed. It's not always well-coordinated because the systems that companies are using are built around traditional enterprise needs rather than what's emerging as the supply network requirements.

[9:02] At the core, we see that the systems, the processes, the people, and the enterprises are disconnected, and they're not well aligned to meet today's supply chain needs. What this leads us to is the Internet of supply chains. Next, Dan.

[9:23] The Internet of supply chains is an interoperable network of networks built on Industry 4. principles. This helps us address the challenges we were discussing.

[9:35] How does it do this? It does it by linking the people, the processes, the systems, and the business enterprises into a collective information network. That

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network conducts the shared business processes that enable that intelligent business execution.

[9:50] This may sound pretty fancy and it may look pretty fancy on what you're seeing on the screen, but let's decompose it a bit and look at the foundational elements.

[9:58] First, we have the ability to create these business context-driven digital networks across the supply chain for all of the processes. Some examples are things like supply networks, CMO networks, your track and trace networks for distribution on things like that.

[10:15] Second, the ability to share processes and applications across the networks between supply chain partners. Third, providing the environment to work cross-functionally and cross-company to execute on our shared business processes together. Then fourth, a common data model for information sharing on the network.

[10:38] That provides the shared understanding of the information between the supply chain partners, and then it also drives how companies can connect to the information in a consistent way and have that same meaning from company to company.

[10:50] When we combine all these different elements, what we have now is actionable collective intelligence from the network, the participants, and the activities that they're conducting with each other, so that we can improve supply chain outcomes.

[11:05] What this means is that, the data on the products in the supply chain events can now be used to do things like predicted drug shortage in the supply

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chain. That's pretty powerful. With this Internet of Supply Chains, we now have the digital networks around our supply chain ecosystems, we have the data, and we have the business process tools.

[11:24] What this lets us do, is now finally realize full supply chain transparency and traceability of our products across the supply chain as they're moving forward to gain real-time visibility and adaptability and to changing market dynamics.

[11:40] This allows us to now start to create new business opportunities. It allows us to leverage faster response time for a changing market signals that we can now pick up on, and allows us to capture real-time market demand and then be able to solve them.

[11:58] Next. The Internet of Supply Chains is a fairly new concept, but in fact, it's been a fundamental factor in helping companies to meet track and trace requirements already.

[12:12] For over a decade, TraceLink has worked to build the world's largest track and trace network, because we consider the network to be such a critical foundation in meeting the serialization and track and trace requirements, like what we have in DSCSA.

[12:27] We embarked on building out those network capabilities and those interoperable network capabilities from day one and a lot of the elements that you just heard me talk about. As Dan mentioned, today, as a result of that, we now have over 290,000 entities on the TraceLink network.

[12:46] All of these companies have been working together using these Internet of Supply Chain capabilities that are on the TraceLink platform, like that digital network creation, the shared processes, the common data models, the data

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transformation, all built into the core of TraceLink, serializations and DSCSA solutions.

[13:04] That's one of the key differences on that. That what we embarked on in our approach in creating our serialization and DSCSA solutions.

[13:13] That's why today, that we have over 37 billion serial number units created in track globally, over 13,000 serialization connections created and being managed, over 339,000 networks and links actively connecting supply chain network partners exchanging a variety of data, and over 885 million DSCSA transaction histories processed to date for our T3 requirements that we've been working on over the last several years as an industry.

[13:44] The Internet of Supply Chains is a critical foundation for track and trace success under DSCSA. It's also laid this important foundation for the next evolution of digitalizing our supply chain activities.

[13:58] This is where we can start to leverage this now to start doing more for our business value. Whether it's a pharmaceutical company, or a contract partner, wholesale distributor, all the way down to hospital in retail pharmacy.

[14:11] Next. What kinds of things are we enabling with our digital supply network approach? First, our serialization and traceability solutions from connecting manufacturers, CMOs, 3PLs, and the downstream supply chain partners.

[14:28] We also have a regulatory compliance solutions, which connect customers and suppliers for DSCSA, for ASNs, and also, for the TITS serialization exchange. Also, we use leverages for government system integration for our country compliance in other markets.

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[14:46] Our supply chain work management, to manage and execute shared processes with supply chain partners on digital networks, to collaborate on shared tasks across supply chain partners, and to manage incidents, including DSCSA exceptions and suspect product investigations with supply chain partners.

[15:02] Our network applications that reach across direct and indirect supply chain partners for our product in saleable return verification, master data sharing, digital recalls execution across the entire day of the supply chain network.

[15:16] Then finally, collective intelligence leveraging traceability data, so that we can improve supply chain visibility and identify product shortages. For the heart of this presentation, I'm going to turn you over to the very capable hands of Elizabeth Waldorf to focus on track and trace, and specifically DSCSA and its related industry standards.

Elizabeth Waldorf: [15:36] Thank Lucy. DSCSA has been signed into law in 2013. We have been in this journey for now nine years or about a year and 17 days into achieving our 10-year plan in 2023. What you see here is the first milestone kicking in in 2015.

[16:08] What it is, is the federal licensure standard for wholesalers as well as the beginning of the exchange of lot traceability exchange for product ownership changes. What that lot traceability is usually referred to is a T3.

[16:27] There's transaction information, transaction history, and transaction statement. Beginning 2017 is when manufacturers have the responsibility to start serializing product with a 2D barcode. That 2D barcode has the four product identifier elements, that's the global trade item number, serial number, lot number, and expiration date.

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[16:55] Now, beginning 2019 is when wholesalers have the responsibility to only accept and sell products that are serialized. Also, the manufacturers much respond to product identifier verification. You see here there is a verification requirement for wholesalers. There is been some enforcement discretion such that in 2023 when we have the 10-year plan.

[17:30] Not only will the verification for sellable return start kicking in, but other verifications for the reasons of suspect product investigation. Moreover, and more importantly, in 2023, it is not just sufficient for trading partners to be able to receive the physical product. What's needed in 2023 is the interoperable electronic tracing of product at package level and what that means is that product need to be exchanged using serialized transaction information and statements.

[18:08] We are transitioning from a T3 to what we're calling T2. Again, that serialized level of information needs to be exchanged between authorized trading partners. What's available in 2023 is that there is some capability to ensure the trading partner status is verified through electronic means.

[18:33] Next slide, Dan. This particular slide puts DSCSA requirements into the various business areas affecting each of the trading partners. There's three big areas, and one is serialization. That corresponds to the products for identifying and assigning, for example, the Global Trade Item Number for the product, as well as the product marking requirements.

[19:05] We talked about the 2D, which is basically the data matrix that has the GTIN, lot number, serial number, and expiration date. Also, the next big thing is the exchange of TI, TS, and TH information whenever there's an ownership change.

[19:25] As I mentioned, lot traceability includes the TH, but as soon as item traceability kicks in, we basically have the T2 data, which is the transaction

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information and transaction statement.

[19:38] Next is product investigation. DSCSA in terms of ensuring security is wanting to make sure that trading partners can support product investigation, and that could be for tracing purposes or for verification.

[19:54] Underpinning all these DSCSA requirements is the requirement for the various supply chain partners to be authorized, and only dealing with authorized trading partners. That is making sure that they have the authority. That they're properly licensed, for example.

[20:13] As a manufacturer, they need to have the valid registration. Wholesalers and dispensers need to have the valid state licenses. Among all these DSCSA requirements, in order to make sure that in 10 years we have the electronic interoperable exchange, we are relying on standards. As they mentioned, this is the common business language by which trading partners can exchange information needed. Next slide.

[20:41] What we've done here is superimpose the key standards from various industry groups and standard organizations that are related and relevant for the various business areas of DSCSA.

[21:00] Under product identification, you see the two key ones that we've highlighted, which is the G10 and SSCC for the logistic unit. For product marking, I talked about the 2D matrix, but there's also a GS1-128, which is for the logistics unit.

[21:20] In terms of the exchanging of information for ownership changes in lot traceability, the industry has been using the ASN.

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[21:31] In the item traceability, which is beginning November 27th, 2023, we are going to be exchanging the T2 information using EPCIS. That's the GS1 standard that's available to ensure that we are able to communicate real-life product ownership changes, and key in this EPCIS message exchange, are the use of the G10 and GLN.

[21:59] From a tracing perspective, we see that there are various industry and standards that apply. Here we are guided by the PDG tracing data model and blueprint, as well as the OCI credential. I mentioned that we have the capability to digitally confirm that the partners that are engaged in the tracing information are authorized, and that is being supported by the OCI specifications.

[22:36] With tracing, we are heavily utilizing the transaction information that's coming in from the TITS exchange and that is again relying on EPCIS, G10, and GLN.

[22:50] From a product investigation perspective, we also have verification. That's ensuring that the product identifier is indeed something that has been marked by the manufacturer. With that, we have the G10, GLN, of course, required from being able to utilize the verification of what we're calling lightweight verification messaging standard which is from GS1. That is how trading partners are able to issue a verification request and respond.

[23:26] That is also backed by the Lookup directory, and because it is a network of solution providers, the 8discs that are supporting the various verification responders, the Lookup directory is a structure that allows us to be able to route to the specific manufacturer or responder for a particular GTIN.

[23:52] Again, from a credential perspective, we are ensuring that the party who is making the verification request is indeed an authorized trading partner, and the

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party responding to the verification is also an authorized trading partner. With that, Dan, can you move to the next slide?

[24:15] Core to the standards that I have highlighted, that's needed for DSCSA, are the standards provided to us by GS1. Here, we are showing you that for GS1 they have provided us many standards in the areas of identify, capture, and share.

[24:38] Highlighted here in the red boxes are the ones that we have noted as playing a key role in DSCSA, but as we could see, GS1 offers many other standard identifiers that can be used. Many different bar codes that are also applicable for your supply chain processes. Next slide.

[25:03] Highlighting the particular identify standards, I mentioned a global location number and that's the GLN. That is the primary identifier that you need to be able to indicate your location as a corporate or as a shipping distribution location.

[25:28] For your product, as I mentioned, is needed for marking your products in the 2D barcode is the global trade item number. This is an identifier that is uniquely assigned to your product, but note, that in this global trade item number, there is a provision for the US to embed the National Drug Code.

[25:53] Now the difference in the National Drug Code and the GTIN is that the GTIN allows you to be able to specify and differentiate between the various packaging levels. For the same NDC, you may have a GTIN for your pack level and you may have a different GTIN for your case.

[26:12] In terms of the capture, this is where you have the barcodes. For DSCSA, the 2D matrix is what's required. As I mentioned, there are those four data elements what's called the product identifier in the form of a GTIN exploration batch and serial number. For your logistics units, you could see that for an SSCC,

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you will be using the linear GS1-128 barcode.

[26:41] Sharing your T2 Data. This is transaction information and transaction statement. EPCIS is the GS1 standard that's most relevant. I have also mentioned that in order to do verification of your product identifier, we are leveraging the lightweight verification messaging standard that GS1 created. This allows the verification requests and responses to be common among the various trading partners. Next slide.

[27:16] Now, we are able to embrace the GS1 standards because of the work that many industry groups have come together to collaborate to figure out how we can do this in an interoperable standard manner. Next slide, Dan.

[27:37] Foremost, for the standards that we highly leveraged is the global standards one, that is GS1 organization. It is a global organization that is federated with many country organizations. This is the main body that provides us the standard for the "identify, capture, and share" that I talked about. As you can see, it also supports other sectors, not just the healthcare.

[28:12] GS1 standard is used in the retail, transport logistics with service, and technical industries. What we've shown, captured there on the top, is a snippet of what an EPCIS is th at message looks like. Again, this is the common business language in the form of EPCIS, indicating the key information that's needed for transaction information. Next slide.

[28:42] The other organizations that are critical to enabling us with interoperable standards of exchange are HDA, PDG, and OTI. HDA, founded in 1876, was formerly known as HDMA. It is an organization that consists of wholesalers but also includes manufacturers. They are very much focused on DSCSA, but they are also engaged in helping the industry with other supply-chain business processes.

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[29:25] We have been working with them, for example, in the exception management. PDG, which is the partnership for DSCSA governance, was formed in 2019. This particular organization formed specifically to help prepare for DSCSA 2023's deadline.

[29:45] With PDG is helping the industry create a blueprint for how the various business aspects, as I've discussed, can be done by the industry in a coordinated way. The OCI, as I mentioned, was formed in 2021. It's basically an industry organization that utilizes W3C standards for enabling the digital verification of authorized trading partners. Next slide.

[30:28] As you can see, in the various industry groups, TreeSync is very committed in order to engage, not just in participating in the various organizations, but we are also actively involved in driving the development of standards. Next slide, Dan.

[30:54] In the various industry groups that I've mentioned, we hold in GS1, we're a member of the executive leadership committee. We are involved in both the global and the country organization from a global perspective. We co-chair the EPCIS 2.. We also have been member of the GS1 Architecture Group and been a liaison to various working groups within GS1.

[31:33] From the U.S. perspective, we co-chair the Secure Supply Chain Workgroup, as well as the UMBC Format Workgroup. From a development and driving the standards, we also are co-editors of the Implementation Guideline for DSCSA, as well as the Lightweight Messaging Standard.

[31:57] As you can see, we are working collaboratively with the industry and the standards organization to ensure that we have the standards that we need to meet DSCSA requirements. From an HDA perspective, we actively participate in the development of, for example, the look-up directories, synchronization specification,

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as well as bleed the various solution provider groups in the interoperability testing of the verification tools and solutions.

[32:34] From the PDG, as we develop the blueprint, we are actively engaged in the various working groups. There are four. There's the Serialized TI/TS Exchange, Credentialing, Tracing and Verifcation, and, ultimately, the Interoperability Committee Workgroup.

[32:52] We are actively engaged in technical discussions, as well as in the review of the blueprints, to ensure that, together as an industry, we are leveraging our experience and contributing back to the industry workgroup.

[33:08] From an OCI perspective, we are a Steering Committee member, as well as co-chair of the Policy and Architecture Committee. As you can see, from a commitment to industry and standards, we are there, working on the ground, and helping the industry and our customers meet the requirements. Now, I'd like to turn it over to Lucy.

Lucy: [33:37] All right, thanks Elizabeth. As you can see, TraceLink's not only engaged in driving and forming the standards, but as you expect, the standards and interoperability are part and parcel of our DSCSA 2023 solution.

[33:59] Our serialization and our serialized operations capability that manage serialization, aggregation, traceability of products from packaging through distribution with manufacturing plants, contract manufacturers, 3PLs, re-packagers, wholesale distributors, pharmacies, and hospitals...

[34:16] All of this is done with the full set of standards for SG10 and SSEC configuration and coding, and EPCIS event capture and exchange for item traceability. Our master data supports not just all the G10 and its attributes but,

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importantly, association back to the NDC so that we can do that reconciliation and resolution back to the product identifier.

[34:41] Master data also supports GLNs for the trade partners, along with a number of other identifiers.

[34:45] TraceLink also supports master data sharing of the G10 and the pack level product master data that's necessary for serialization, so that the manufacturers can share this information with any direct or indirect downstream supply-chain partner, to enable them to prepare for their serialization requirements and be able to reconcile the product information.

[35:07] Our DSCSA compliance meets the compliance requirements for the TI/TS creation and the exchange and receipt of that data, and also managing the product verification request and response, doing this leveraging as G10, GLN, the EPCIS, look-up directory, OCI credentials, authorized trade partner verification, and the Lightweight Verification Messaging Standard for product verification.

[35:32] Of course, TraceLink will continue to be engaged in, and support, the industry and product-tracing requirements as they continue to evolve from PDG and GS1 in support of the 2023 tracing requirements.

[35:46] As we start to wrap up, there's one last note on the next slide, Dan, about the standards that's important to be aware of. GS1 EPCIS standards, like many other established industry standards, are designed with flexibility in mind.

[36:06] This flexibility is provided to enable the ability to add extensions for exchanging additional information that may not have been included in the standard from the onset but might be important to allow supply-chain partners to meet some specific business needs that they may have. This data might be things

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like additional supply-chain partners to meet some specific business needs that they may have.

[36:24] This data might be things like additional supply chain partner identifiers that they need to reconcile with their internal business systems or internal business operations to connect that message that they're receiving to that business operation that they're conducting.

[36:39] Product attributes, for same reason, or other types of business data that might be associated with the event or in this case, the shipment that's occurring. EPCIS has a defined set of rules for how a company can include these extensions to be able to provide that data while exchanging EPCIS still in a conformant manner.

[37:01] With this in mind, one of the questions that we need to ask is, can it be guaranteed that the standard, as it's being put forth for you, so DSCSA and the implementation guideline, that that's going to be adhered to 100 percent as is, verbatim, by all supply chain parties?

[37:18] Will they treat it 100 percent like a pure compliance document exchange and leave it at that, or might some supply chain partners start to request additional business data from their suppliers to support specific business needs they might have like we saw happening with the EDI ASN?

[37:38] There was a guideline put forth for the EDI ASN for this is how it will be used for DSCSA purposes, but then we also saw companies asking for, if you will, above and beyond information because they were trying to connect it to their internal business operations when they were going to receive and reconcile that product.

[37:57] I think that's an open question. How do you prepare? What are some of the

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things we need to think about when we prepare for that? When you're looking at solution providers, it's important to ask how they support EPCIS.

[38:09] If they can support, can they support the variability in sending or receiving EPCIS messages with different supply chain partners that might require or might include different extensions for the industry-mandated business purposes by those supply chain partners?

[38:30] Like what we had with ASN when we saw certain companies asking for, you must include your DUNS+4 number for this ship-to location. Or you must include the DEA number under this scenario, or you must include the catalog item number or the UPC number, and sometimes carrier information.

[38:47] There was a number of different requirements that we saw coming from different parties in the supply chain because they were connecting it to what they were doing internally in their receiving operations.

[38:57] In addition to this, there's another consideration as EPCIS versions are updated. We, for example, move from version 1.2 to 1.3 or other versions in the future. You should be informed and ask how the solution provider will keep you interoperable. The reality is the entire supply chain is not going to update to a new version simultaneously. That's just not possible to do.

[39:26] What happens when there are differences, whether they are extensions, whether their version updates, etc.? What happens when some of the parties of the supply chain are doing something a little bit different and yet you still need to maintain interoperability? How will you deal with that? How will your solution providers support you in that?

[39:48] These are some considerations we wanted to leave with you because there

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are important things to ask when you are working with and embarking on selecting a solution provider. Of course, for TraceLink, we can tell you and confidently tell you that for both of these scenarios, we have you covered.

[40:05] How we have you covered is, with our Integrate Once, Interoperate with Everyone approach. What we'll do is just give you a quick look at what that looks like. Our Integrate Once, Interoperate with Everyone model supports maintaining that interoperability while supporting the real-world business requirements and changes that might occur with supply chain partners.

[40:27] What this means, is when you integrate with TraceLink to provide your event data, you do that one way. One standard way with all the information that you need to provide.

[40:39] Then what TraceLink does is it can send the data to the different supply chain partners in the standard EPCIS format, if that's what supply chain partner A is expecting, and I think hopefully most well, but also we can send EPCIS message in supply chain partner's B extended EPCIS format that includes their specific extensions that they may have mandated for their particular business requirements.

[41:07] Same thing when there's different versions, because we can translate with the different versions, but for you, it means we leverage that singular integration you made, so you don't have to worry about, "If I have 100 trade partners, do I have 20 different models I have to worry about across those 100 supply chain partners?"

[41:26] The same is true on the flip when you're receiving EPCIS information from a supply chain partner, and if they're sending you something that may be slightly different or augmented for whatever business purposes that may have driven that.

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[41:41] At the heart of this, is the common canonicalized data model for information sharing on the network that we talked about at the very beginning.

[41:49] That, coupled with our simultaneous support for multiple EPCIS versions and the data translation mechanisms to that canonical data model, that future proofs you for real-world requirements that ultimately will emerge.

[42:06] I just wanted to leave you with that last little bit. I think we're kind of at time so that we can get to our questions. I thank you all for your time and I'll hand it back to Dan so he can take us home.

Dan: [42:20] Great. Thank you, Lucy and Elizabeth. Very informative. I think what was important to recognize is that there is certainly a lot of activity that's happening in the industry beyond just implementing and beyond just sending an EPCIS transaction from point A to point B.

[42:45] We'll talk about this a little bit at the end, but I think it really speaks to the need. As Lucy mentioned, when you're evaluating solution providers and evaluating your approach, there's certainly the technical capabilities and the functional capabilities that have to be understood in terms of your solution providers ability to meet those.

[43:09] One thing that we want to impress upon you is that DSCSA, and really any compliance is not one and done. What I mean by that is, when we get to November of 2023, and after the deadline goes into effect, we will continue to see the industry evolve. We will see the standards evolve.

[43:35] As companies start to consume serialization data and incorporate serialization into their overall operations, they will look to use that information to improve their business processes and get more efficient beyond what they need to

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do from just the letter of the law from compliance.

[43:59] As Lucy noted earlier, what we learned in 2015 is many of the additional requests for data in the ASN were less about helping companies meet the regulatory requirement and more about, "Hey, we can start to get some business value through additional information in the ASN."

[44:25] Or, "This will make us more efficient if we can get this additional data element sent to us electronically so we don't have to manually key it in." We'll just start to see these use cases and these improvements happen up to November of 2023 and well beyond.

[44:47] Really requires that your solution partner is with you for the long haul and is making investments in following these developments within the industry, following these discussions within the industry. It's certainly not something that comes for free as a solution provider.

[45:09] We're investing heavily in this, but we believe it's important as a solution provider to be your trusted partner in this area and to really be not just providing a solution to you, but guiding you in providing counsel on best implementation practices and best approaches.

[45:35] With that, and in the spirit of being a good trusted partner, our next webinar is on Thursday of next week, where we'll be taking on the topic of preparing for electronic and interoperable exchange of DSCSA compliance information.

[45:54] This is all about, how do we get to interoperability and exchanging EPCIS transactions? Really understanding these new concepts of what is serialized transaction information, what are authorized trade partners, what is the process

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for onboarding partners and driving integration so that we are interoperable when we're exchanging that serialized TI through the EPCIS.

[46:25] We'll also talk about, what is the current conversation or current discussion in the industry around drop shipments. This is a use case that is certainly an important one that the industry align on. There's been a number of discussions and approaches that have been introduced.

[46:52] We want to provide an update into what's the industry's position on this or multiple positions and then how TraceLink can support you in that area and what TraceLink is doing in that area.

[47:04] In reviewing just what we covered today, so a couple of things, I think we have to paint DSCSA in the backdrop of the larger supply chain challenges and supply chain initiatives that all of our organizations are going through.

[47:22] As Lucy mentioned, from, not just those that work in supply chain, but talking about supply chain has become the hot topic and is really driving transformation in a number of your organizations.

[47:40] It's important that you view DSCSA as not just this point-in-time compliance requirement, but have really approached in a thoughtful way, in a more strategic way, really starts to help you drive towards supply chain interoperability and supply chain digitalization and transformation that will pay dividends for you, not just in compliance, but throughout your business.

[48:10] We also hope that you recognize, not just the role of standards, but TraceLink's approach to standards, how we're investing in driving discussions within the standards organizations and understanding the role of the different standard organizations.

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[48:34] Also, I'm pressing upon you that we recognize that you have full-time jobs and that you are trying to manage your business and make sure our product is moving through the supply chain.

[48:48] We recognize and understand that a big part of our value to you is not just within the solution, but our ability to be representing your interests and representing your use cases in your business challenges so that they are accounted for appropriately within the industry discussions, within the industry standards.

[49:16] Before we get to the questions, we have a number of questions that have come in, you just want to help guide in terms of, how do you get started today?

[49:30] A couple of things for, if you're an existing TraceLink customer, your TraceLink account executive will be following up with you to be preparing you for EPCIS exchange as well as requirements around verification.

[49:46] If you are not already, our account executives will be providing guidance on how you can get connected into our Cloud community, specifically our DSCSA special interest group.

[50:02] Many of you do participate in this today, but it's a benefit that we offer to our customers where on a biweekly basis, we are discussing the current topics that are going on within the industry. Elizabeth participates in this group fairly regularly.

[50:24] She's providing readouts of what's happening within these standards organizations, how these translate into business requirements, how these translate into solutions. It's a great opportunity for our existing customers to stay up to date on what is happening in the industry and how we're preparing you for your

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compliance requirements in November.

[50:53] For those that are, maybe not currently partnered with TraceLink, certainly reach out to us. We'd love to spend some time with you.

[51:03] Whether you don't have a solution today, maybe you're launching your product into the market for the first time, or maybe you're using an existing solution, maybe it's something that you built internally for the 2015 requirement.

[51:17] We'd love to spend some time with you and take you through what we call a "DSCSA impact assessment," where we can really look at your current capabilities and recommend approaches that you can be taking to meet the November requirement.

[51:38] Certainly, reach out to us through marketing [at] tracelink.com. First, what I'd like to do is we have a number of questions here. One is fairly straightforward. This came in a couple of times. My apologies because we were remiss in mentioning this. Yes, the slides will be available to you.

[51:59] This recording of this webinar will be available. The slides will be available plus a recording. You can view it on demand. You can share it with your colleagues. We'll certainly make that available to you.

[52:19] One question that did come in, and I did address a part of this is, where can companies go to get more information? We presented some of these, but maybe Elizabeth and maybe Lucy, I did mention the DSCSA SIG group for our existing customers.

[52:40] I do want to impress upon you the value of the information exchange that's happening in there. I guess Elizabeth or Lucy, what are some of the ways that

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companies can get involved in these industry discussions if they're not already part of it?

Elizabeth: [52:57] Dan, the GS 1 US, our secure supply chain work group is a very good mix of various industry trading partners. We have manufacturers, wholesalers, and dispensers participating in that. It is basically the practical application of GS 1 standards for what DSCSA means. I would encourage reaching out to GS1 US.

[53:30] Tracy Nasarenko is the facilitator, of that work group to join. Another one would be the PEG work group. We are close to finishing up the blueprint, but it's never too late to get engaged. But that is another forum where specific DSCSA topics and again the practical implementations, discussions of various supply chain choreographies and even the nuances and the complexities.

[54:06] These are where those complexities are discussed among the various trading partners. There's agreements and discussions as to what can be done electronically through the standards, and what needs to be handled by the company through SOPs and so forth.

[54:30] Again, those two are what I recommend. Perhaps also, the HDA organization. It is more than just DSCSA. You could join in various discussion points and topics to prepare for DSCSA, but also to manage your other business processes.

Dan: [54:52] Great, thank you. Another question that's come in, Lucy, maybe I'll direct this to you. The question came in as it relates to the TraceLink network. This is something that I think we've heard before, it's been asked before, and maybe you can address this. It's in the question of, does the TraceLink OPUS network communicate with other competitive DSCSA solution providers?

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[55:25] They drew the example to maybe highlight an EDI VAN works. Maybe you can first talk about the integration and compatibility with competitive solution providers. Then maybe briefly touch upon the difference between a network and a VAN, essentially.

Lucy: [55:56] The punch line part of the answer is, yes. TraceLink can connect to both. We have the ability to connect directly to another supply chain partner.

[56:05] How we go about that is for all the different, if you will, TraceLink customers, you become, think of it as a node on the network. We set you up, and we establish your unique identity on the network so that you can authenticate to that, or your systems can, to securely send and exchange information through the network.

[56:29] We do the same thing with supply chain partners even if they're not TraceLink customers. We establish those nodes on the network and then they're able to connect, and then exchange the information. That's how we manage, I'll call it the direct connection because each company is configured with what is their B2B endpoint, how are they technically exchanging the information?

[56:50] When that supply chain partner, if they don't have a direct B2B connection that they're managing themselves, that comes into their company, but they might be leveraging a third party like a VAN or some other network to do that, we still set them up and configure them.

[57:13] We still set up that company. We configure their unique identity so that we know who they are, and making sure that messages that are sent and received are really sent and received to that company.

[57:21] When we set up their B2B configuration for what's their B2B endpoint, we

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simply just configure it to be their information that they provide for that VAN or that other third-party provider that they're leveraging for that.

[57:39] That makes it very seamless and it makes everyone look the same in terms of your connectivity on the TraceLink network because our TraceLink network operations team does all of that setup and configuration. Then, it's available for any TraceLink customer to connect with any other party on the network.

[57:57] We do that proactively for our customers to ensure that all of the different supply chain parties, it's a win-win thing. We invest in that to make sure that all of those parties are available on the network. We also do some testing with them to make sure that they're capable of sending and receiving that.

[58:15] That whether it's their own B2B connection or one in the third-party network, is it up and running? Is it active? Is it configured properly? The exchange of that particular type of information, whether it's ASN or EPCIS, or what have you, making sure that exchange can happen successfully.

[58:33] Once that happens, and that's the "integrate once and interoperate with everyone", that's part of that element, not just the data translation, but the communication, because once that happens, then anybody can connect to that party on the network and start to freely exchange information.

[58:46] That's a big difference from when you're trying to manage point-to-point connections with every trade partner. Everybody's got to connect to party A, party B, party C, point-to-point, whereas here, you connect, you make that connection, you can leverage that connection across the board with anything that you're operating on.

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Dan: [59:03] That's great. I'll add to that and make this point. For existing TraceLink customers, going back to 2015, we worked with many of you in a model where you would provide, if you're a manufacturer, essentially, your customer list, if you are a wholesaler or, your suppliers, as well as your customers, if you're a dispenser, your supplier list.

[59:31] We went off and, through our network services team, we onboarded those partners, and for those that were capable, set up and configured B2B connectivity with them. That's how we're sending the ASN. The good thing is that the B2B connectivity for many of your customers or suppliers, if you are a TraceLink customer, is already in place today.

[1:00:01] The payload or the transaction that we will send through that B2B connection, obviously, will be different in EPCIS transaction. Even with that, we have been sending EPCIS transactions, particularly to the big three, going on probably about five, six, seven years. I think we've exchanged about 650,000 EPCIS transactions, largely with the big three today.

[1:00:31] The message here is, if you're an existing TraceLink customer, a lot of the heavy lifting has already been done. It's configuring your existing implementation to turn on, if you will, the exchange of the EPCIS transactions. That's positive, and we should be engaging in those discussions with you today.

[1:00:55] If you're now looking for a solution to exchange that information-maybe you built something homegrown with your EDI system, maybe you're just focused on the serialization capability for 2017 and 2018-we can now layer our network across, so that you're just informing TraceLink of that shipment notification, as Lucy said, integrate once, interoperate with everyone.

[1:01:27] We will manage the delivery of that EPCIS transaction to your customer.

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If you're on the dispenser side, we'll manage onboarding the receipt of that EPCIS transaction from your supplier. Much of the capability around EPCIS exchange is already in place with TraceLink. It's been in the market for some time. It's been commercially hardened.

[1:01:55] We'd love to get started with you and get moving on getting you production-ready well in advance of the deadline. I know we're a bit overtime. Last thing I'll call out is there was a question about how we get signed up into the DSCSA sig that's available for our existing customers.

[1:02:23] Your account executive will be reaching out to you, or you can contact your account executive. They'll manage getting you registered for that biweekly meeting, if you're not already. That way you'll get the automated emails and calendar invites so that you're aware of when those meetings are happening. They're on a regular schedule. I believe they're on Thursdays, as well.

[1:02:49] If we didn't get to your question, I know we didn't. We have a number of questions that came in. We'll be reaching out to you directly. Some of these questions around interoperability, we'll be going into some detail next week. I thank you for your time.

[1:03:04] Elizabeth, Lucy, thank you for your participation. Have a great rest of your week and we look forward to speaking with you next Thursday. Thank you, everyone.See Notes Below

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