RESOURCES

Home
Resources
Resource Center

Balancing Risk and Operational Impact While Complying with DSCSA 2023



What is the best way for hospitals and retail pharmacies to approach DSCSA 2023 compliance? Should you simply receive EPCIS data, or take the additional steps of reconciling the physical item to the electronic **DSCSA compliance** information?



Watch our on-demand webinar, "**Balancing Risk and Operational Impact When Complying with DSCSA 2023**," to learn how your DSCSA 2023 compliance strategy impacts your pharmacy operations and what solutions you can deploy to support that strategy. Topics include:

- A comprehensive look at the benefits and drawbacks of the various pharmacy approaches to DSCSA 2023 compliance, ranging from simply receiving EPCIS transactions to full item-level verification and reconciliation.

- A complete overview of serialized receiving strategies with expert advice on how to effectively manage serialized receiving as part of pharmacy operations.

- A live demonstration of **TraceLink Smart Inventory Tracker**, which enables

© TraceLink Inc. 2009 - 2025 All Rights Reserved

serialized receiving and integrates seamlessly with backend warehouse management systems.

You'll also see real-world examples of how TraceLink delivers results for hospital and retail pharmacies that have already achieved DSCSA 2023 compliance and implemented serialized receiving.

Learn how to achieve DSCSA 2023 compliance, increase operational efficiency, and improve patient care. Fill out the form on this page to watch the webinar now.

.heading { color: #000; border-bottom: 2px solid #E5F6F8; padding: 20px 15px; cursor: pointer; margin:0; } .active{ background: #E5F6F8; } .heading:nth-last-child(2){ border-bottom:2px solid #E5F6F8; } .heading:hover { background: #E5F6F8; border-radius: 0; } .heading:first-child { border-top:2px solid #E5F6F8; } .heading::before { content: ''; vertical-align: middle; display: inline-block; border-top: 10px solid #003D4C; border-left: 7px solid transparent; border-right: 7px solid transparent; transform: rotate(-90deg); transition: all 0.5s; margin-top: -3px; margin-right:15px; } .active.heading::before { transform: rotate(0deg); } .not-active.heading::before { transform: rotate(-90deg); } .contents { display: none; background: transparent; padding:20px; border: 2px solid #E5F6F8; margin:0 !important; color:#252525; } .contents p{ margin-bottom: 0.7rem !important; color:#252525; }

Transcript

Dan Walles: Good morning, everyone, and welcome to the next in the series of the DSCSA 2023 webinar for dispensers. Today, we're going to be diving into an important topic, and that's balancing risk and operational impact when complying with DSCSA. Starting to focus in on the pharmacy receiving process and ensuring that you remain compliant and looking at the different options to be compliant.

Today, I'm joined by a couple of my colleagues, both of who you may know. Caitlin Czulada is the Director of the Center of Excellence here at TraceLink. Christine

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Kearns is a Principal Solutions Consultant and has been focusing for a number of years within our healthcare space. My name is Dan Walles. I'm the general manager of TraceLink's Track and Trace and Compliance Business.

As I mentioned, this is the third in a webinar series focused specifically on some of the challenges and requirements pertaining to the dispenser segment, health systems, and retail pharmacies. For those that joined us in the past, we went through the requirements, the required capabilities. We talked, the last time we met around transitioning from lot level to item level.

Today, we're really going to go into looking at that receiving process and balancing risk of achieving compliance with operational impact and really what has to happen as you're going through your physical receiving processes.

At the beginning of next year, we'll do a combined session where we'll get together with our colleagues on the manufacturing and wholesaler side and talk about interoperable exchange, -- that's the EPCIS transactions -- as well as verification requirements. Then, we'll finish up with laying out the dispenser journey to DSCSA.

Then in February, we'll really talk about how you can start to derive business value from your investment in your DSCSA solution. We hope that you'll stick with us here over the next coming months as we prepare as an industry to meet the November 2023 deadline.

A few things that I'm hoping that when we finish up today, that you're able to walk out of here with. What we really want to go through is introduce you in your options for approaching compliance, from receiving that EPCIS transaction, to options for reconciling your inventory against that receipt of that transaction, that DSCSA compliance information.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

We want to be able to provide you some insights into that reconciliation process and really talk about different options you have for reconciliation, whether it just be manual scanning with some of our own solutions, Smart Inventory Tracker, -- or SIT --or if interested, a full up integration into your pharmacy receiving system.

My colleague, Christine Kearns, is going to take you through a demonstration of that serialized receiving process, then we'll spend a little bit of time on how some of our existing customers, particularly a health system and a retail pharmacy are going through and performing that serialized receiving process today. Lots to cover.

Before we get started into some of the details, I just want to bring you up to date on where we are as a company. Many of you are familiar with us, but for those that maybe new to TraceLink, we were founded in 2009, we have six offices globally with our global headquarters here, just north of Boston, Massachusetts.

Through our existence as an organization, we've been well-funded and we've been sinking much of that investment into building out our network, a life science and digital supply network, today that has over 290,000 network entities. Those are health systems, independent hospitals, clinics, pharmaceutical manufacturers, wholesalers, the whole gamut of the supply chain operating on that network.

Within that group of organizations, 1,300 of them are direct TraceLink customers, meaning, they partner with TraceLink for serialization, meeting compliance requirements like DSCSA, as well as other similar requirements that may be happening in other markets around the globe.

I think important to this conversation that we're having today is really one of those bottom numbers here. Almost 900 of our customers are using TraceLink today for managing serialized product. This is important, particularly for the dispenser space

© TraceLink Inc. 2009 - 2025 All Rights Reserved

where actually managing serialization data is a new requirement as part of November 2023.

TraceLink has very deep experience in understanding the impact that item level traceability can have on your operations, and therefore ways in which we can optimize that experience for you. As I'd mentioned before, our network is very active. One of our key value drivers that we bring to the industry is this concept of allowing you to integrate once into that network.

TraceLink is really managing the connectivity, the exchange of information across that network, which has really resulted in a savings to the industry of excess of $4 billion if it was executed through traditional models like point to point.

About 800 employees with TraceLink and well over half of those employees are within our R&D organization and services organization, ensuring that our solutions are meeting your requirements and are remaining operational.

Certainly, as I'd mentioned, currently we've tracked over 41 billion serialized units, specifically related to DSCSA, almost a billion transaction histories processed. Those are those compliance documents that are today our ASNs that will eventually become EPCIS transactions as we move into 2023. When we start to talk about products, over 47,000 products are being managed by TraceLink today within our network.

This is important because when we think about compliance and we think about the challenges that our customers are facing, it really spans beyond just meeting a regulation like DSCSA. It's focused in on understanding how companies can get better visibility into their supply chains. We're here today to talk about traceability as it relates to DSCSA.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

When we talk to our customers, virtually all of them are focused on, "How can I get better visibility into my supply chains, more transparency, more collaboration, because our supply chains are facing a number of challenges and a number of pressures today, particularly as we've come and continue to work through things like COVID, and RSV, and more traditional seasonal challenges like flu?"

It really starts to expose some of the limitations of our supply chains and the challenge that we have because we don't have great visibility into supply chains. This is really the larger challenge that TraceLink is setting out to solve with our customers. DSCSA and meeting DSCSA helps us build that capability, some of those assets that we'll need to digitalize our supply chain.

When we look at some of those business imperatives, that digitalization of the supply chain, we really are looking to build out what we refer to as the Internet of supply chains that links people, processes, systems, and enterprises into an information network that allows us to execute across enterprises and outside of our own business.

Really to do this, we're looking at how do we integrate across all of these different constituents from material providers all the way through to our customers across a network, which requires the creation of digital networks to digitize various processes that manage our supply chains today and do that in a way that allows us to share and execute those processes across a network.

If we do that in a thoughtful way, what we're able to do is now create a common data model that represents the information that's flowing through that network of supply chains, that Internet of supply chains.

When we have that common data model really being able to drive collective intelligence about things that are happening on the network, that ultimately leads

© TraceLink Inc. 2009 - 2025 All Rights Reserved

to better transparency and traceability. It allows us to be much more nimble and be able to adapt to changing dynamics and requirements in the supply chain, and then just ultimately have a faster response to changes in market demand.

When we look at this as our mission and our vision as a company, it really starts to point to, "Well, what experience have we had in being able to achieve this?"

As we had mentioned, TraceLink's been around since 2009, where we've really built out this global case study for deploying an Internet of supply chains, and that is essentially DSCSA, traceability, serialization, item-level traceability, where our solutions today across our 1,300 customers and 290,000 partners on that network across the entire life sciences supply chain today has really built that foundation and established that foundation for TraceLink.

When we look at what that solution suite is today, it's a solution that's rooted in this digital supply network. That digital supply network allows us and gives us tools to manage that network, manage the governance and integrity of that network with network master data, network administration, allowing companies to integrate once into that network through what were referred to as multi-enterprise process connect.

It provides a set of catalogs that allows us to transform and map information as it's flowing through that network. It provides a low-code application development. If you wanted to develop applications on the TraceLink platform, on the OPUS platform, you're able to do so.

Today, we're going to spend our remaining 45 minutes or so in this area of serialization and traceability, and regulatory compliance specifically around DSCSA, but you can see as you look to the right here, other applications and solutions that we either have in the market or are bringing to market in the area of

© TraceLink Inc. 2009 - 2025 All Rights Reserved

better collaboration.

Network applications that allows us to verify product across the network, share master data across the network, execute digital recalls, use that information for collective intelligence.

Some of you may have been with us earlier when we talked about product availability intelligence in the area of drug shortages. Then full process orchestration as we start to orchestrate more advanced processes like cell and gene therapy, and managing the supply chains around those activities.

When you look at meeting your DSCSA requirements, think about how these investments can start to build a set of assets for you that allows you to tackle larger problems in the future.

Let's now move into specifically some of the requirements for dispensers and various options they have around receiving. To do this, I'm going hand it over to my colleague, Caitlin Czulada, to take us through the next portion of the presentation.

Caitlin Czulada: Thank you. As we've talked about in the previous webinars, the 2023 requirements will introduce a step change in capabilities required for compliance. We all know today that there are DSCSA requirements, we have to receive those transaction histories and get that information directly from your suppliers.

In November, there's a lot of other requirements that are coming into play. Today, we really want to dive deep into the following areas that impact your pharmacy operations. That's really about reconciling the physical product, what you have on your dock door, with that electronic data. What are the different options that we

© TraceLink Inc. 2009 - 2025 All Rights Reserved

have to reconcile the physical world and the digital world?

Then you can decide what works best for you and your pharmacy operations. We want to talk a little bit about managing master data and those trade partner integrations. What are the different types of master data and how are they managed?

DSCSA introduced a few new pieces of master data, the GTIN. That's a product identifier that's embedded in the 2D matrix on the box, as well as GLNs. Those are identifiers that you have to have to do those partner integration. How would you manage getting those master data elements that you need?

Then finally responding to audits. What should you expect if you get audited? What type of information are you going to be furnished? How are you going to furnish it? How can you respond to the question about, "Well, did you have this information? Did it match the physical box?" things like that. We'll dive in into that. Dan, you want to go to the next slide? OK.

TraceLink provides many different options all the way from the minimum level all the way up to the more integrated level. If we want to start at the bottom left hand side, no reconciliation or no scanning. What are the benefits of that? You'll obviously receive the EPCIS transactions, but you're not going to do anything with them.

You don't have to scan the product on that dock door, there's minimal disruption to your pharmacy operations, you guys can continue to do as you are today, but the system, the TraceLink application, will make sure that we receive all of those EPCIS transactions during that.

Then if there were an audit, you would be able to go into the system, you'd be able

© TraceLink Inc. 2009 - 2025 All Rights Reserved

to furnish that information and provide that to it, but one of the risks is that you might not know that there's an issue with that EPCIS information until that audit or that investigation.

At that point, you would have to do that investigation to figure out, "Was the information wrong? Was there an overage? An underage?" etc. Things like that can happen as part of the EPCIS exceptions in getting that data and reconciling it against the physical and the digital.

The next step up would be to do some level of reconciliation as part of your operations. You would receive that electronic EPCIS message into the TraceLink application, but then you want to actively manage and address those issues before the investigation.

Christine is going to go show you a few options that you have to do that in the actual application.

There are things like scanning products at the dock door. You can scan one item in a tote, one item per line item. You can scan a hundred percent. You can scan the top level and take advantage of inference. Those are all of the different options that come with scanning and with reconciling that physical product with the digital.

The downside of that or the cost of risk is that there is operational impact. You will be required to scan that product when it comes in your dock door. You will have to weigh what that is and whether or not you can do that as part of your pharmacy operations.

A step further in the reconciliation process would be to receive the EPCIS message, to reconcile it, as we said, so scan those products, and then maybe to go even a step further and use that information to enrich business processes or systems that

© TraceLink Inc. 2009 - 2025 All Rights Reserved

you have internally.

How can you use this rich data that we're receiving to help your other pharmacy operations? Things like your digitized lots, maybe the expiration date, inventory, reconciliation of recalls, and things like that.

There's a lot of benefit associated with that. The downside or the cost of the risk is that, one, there's operational impact to do that scanning, but there also may be integration costs. What does it take to actually integrate the TraceLink data with your internal systems to take advantage of that?

That could always be a phase two. You can certainly start on one of these spectrums, and then decide that maybe you want to do a little bit of scanning, and then we can work to do that enrich later. Certainly, once you've gotten into the day in day, there's opportunities to change and to do more or do less.

TraceLink has supported a variety of the dispensers in these approaches since 2020. We've actually been working with a number of dispensers since 2020 to do reconciliation, so they're actively scanning.

Today they're actively scanning against that ASN or that lot-level and associating the serial numbers with it. There's a few different ways that you can take advantage of that reconciliation process.

You can do it visually and acknowledge that within the user interface. You can log into the TraceLink application, you can manually look at the delivery, you can match that against the box, look at the screen, "Yep, that matches," and then check that off, or use some sort of web scanning capability, so connect it to a tethered device, scan those, make sure they match and then put them away.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Christine will show you in just a minute here our Smart Inventory Tracker application. That's an application that you can download on a handheld device. Someone who's in the warehouse, or doing that receiving, can do it with the handheld device, check the serial numbers, and then put them away directly from there.

Then finally, we also work with companies to do the integration with their pharmacing system. The benefit of this is that you don't have to do an extra scan. We can receive that information from another system, and just record it within the TraceLink system. We've worked with companies to do that and that does reduce the number of scans that they have to do. OK.

Let's look at our 2023 solution for the pharmacy. First, we start with serialization. The first thing that you're going to do when you sign on with TraceLink is we want to stand up the serialization system. These are systems that manage and administer the serialization, the aggregation, the traceability throughout the packaging and distribution products.

We also need to manage that master data. We talked about that GTIN that's embedded on the 2D matrix and those GLNs. The system will automatically add those GTINs from the EPCIS message and manage all of that master data on your behalf, all that new data that we're having.

So that's the core and the base of the TraceLink. Then we layer on top of that the DSCSA compliance. These are the applications that you would use to meet the requirements for T2 creation, maintenance, as well as your product verification requests.

These are verifications for any suspect or illegitimate product. If you get a product in the door, and it looks different, it's a different color, just something looks off,

© TraceLink Inc. 2009 - 2025 All Rights Reserved

then you can do a verification using product verification to confirm that that product is real. Christine can show you how you can scan to do that. There's also a user interface that you can do that as well.

Then product tracing. That's something that's being talked about in the industry, but certainly TraceLink will support any tracing requirements. If an auditor comes in and asked for you to furnish that tracing information, TraceLink will certainly support that.

In addition, we have applications that can support your DSCSA operations. We have additional applications like serialized process intelligence. That's going to help you troubleshoot any exceptions that you might have. If you're doing a reconciliation, there's going to be exceptions.

Maybe someone sent you too many or too few or picked up a box and scanned it, but then was distracted and put the different box inside the tote. We have applications that will help you really troubleshoot those issues that may come up as part of DSCSA operations.

Then supply chain work management is the application that you would use to collaborate with those trade partners to resolve those exceptions. You need to notify your trade partners and there's an exception, and then come to an agreement on how you want to resolve that. Do you need to destroy that product? Do you need to return that product? Do you just need new data?

All of those conversations and all that coordination and collaboration can happen within supply chain work management.

We offer training and operational support services. We have TraceLink University. That's a training where your teams can get training on how you use all of the

© TraceLink Inc. 2009 - 2025 All Rights Reserved

different TraceLink applications. We have a dedicated healthcare operations support team. We know that pharmacies and dispensers have specific needs.

We have a dedicated team that's there to meet those needs. Instead of going to the generic support queue, you would work directly with our healthcare operations support team to resolve any issues or questions that you might have.

Finally, we have additional applications that support business value. Dan talked about having all of this data and what can you do with this data now that you're receiving and reconciling it.

Product availability intelligence is an application that will allow you to have early warning signs on drug shortages and deliver real-time analysis of product through the supply chain that's going to be short, as well as digital recall. Rapidly respond to notifications for recall products, see what you have in your inventory, and things like that.

These are additional applications that you can use to really get value out of all of this data that you're going to be receiving come next November.

With that, Christine, I will turn it over to you. You can show the folks here how they're actually going to use the applications to do that reconciliation.

Christine Kearns: Great. You can stay on this slide. I'll take over control afterwards. I'm going to bring you through this slide first. I will show you our Smart Inventory Tracker mobile application to do that receive and reconcile. On this, this is that middle box. There's the receive and store. This is the receive and reconcile.

I'm going to go through starting with one. Suppliers have been required to send compliance information per DSCSA since 2015 to the buyer. In 2023, that

© TraceLink Inc. 2009 - 2025 All Rights Reserved

information is going to be item level DSCSA compliance data on GS1 EPCIS XML format.

That step one is the supplier is going to send electronically the DSCSA compliance data to TraceLink. TraceLink is going to ingest that data, verify it, validate it, for example, for required items for proper format. Then, we'll store the serialization information in TraceLink as well.

The modules or applications called out in this green box is the product track application and then the serialized operations manager application. All of the applications in TraceLink are all natively integrated and cooperate together.

The physical shipment is sent to the buyer, whether that's the wholesaler, whether that's the dispenser. In this case, the dispenser is going to receive the physical product at the dock.

Caitlin had gone through a few of the different options, for example, scanning right at the dock, different examples for reconciliation. That box for number five is a larger box because you definitely have some options.

Whether you're utilizing TraceLink's Smart Inventory Tracker mobile application to do that scan at the dock. I'll show you that. Whether you are utilizing TraceLink's user interface, we do have a bunch of dispensers who have already voiced that they want to utilize TraceLink's user interface, whether you want to receive in your own system and then write to TraceLink's published APIs.

There are different methods to get the message sent to TraceLink to check for the presence of the compliance data before taking ownership of that product.

I'm going to show you our Smart Inventory Tracker mobile application for that

© TraceLink Inc. 2009 - 2025 All Rights Reserved

number five and just to point out the two...the top part of this, while it's not called out in the specific steps, TraceLink does provide all of our dispenser customers with that master data that Dan had talked about, that GTIN item in case or packed level, master data.

We provide that to our dispensers and we also provide the means to utilize our verification router service, our VRS in examples or in instances of say suspect product. That's part of our package as well. I'll take control now and I'll show you our Smart Inventory Tracker mobile application. I'm going to just go ahead. I'm going to share my screen and I'll go to the next slide.

I have this as a split screen because on the right-hand side, I am showing you the Smart Inventory Tracker mobile application that is on my Zebra handheld device that I have in my hand. I have an app that allows you to see what the Zebra screen looks like and before I continue, is this screen visible? Things aren't cloud? Things aren't overlaying it, such as my face or anything?

Dan: Looks good, Christine.

Christine: All right. Great. Thanks. Sometimes you don't know where the different zoom boxes go. The first example is what Caitlin had said as an example is the totes show up at the dock. I'm going to go ahead and just scan the tote right at the dock. I have my tote in front of me.

You'll notice on the right-hand side, the Smart Inventory Tracker mobile application does have a lot of capability to work with serialized product, whether you're receiving, whether you're returning, whether you're shipping, whether you're performing VRS or verification, whether you're checking serial number status.

We're going to focus on receiving today and I've logged in to the Smart Inventory

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Tracker, everything is rights and roles controlled. The tote has showed up at my dock and I'm simply just going to go ahead and scan it.

A simple scan of the tote ID, the pallet ID, it is synchronously talking back and forth to the TraceLink solution to check for the presence of the compliance data for what has shown up at my door. By doing that tote scan, it has checked with the TraceLink repository for this customer to check that compliance data is there.

That's the first check is, "Did a message come in for this delivery?" The second check is, "Are these serial numbers in that delivery?" In this example, I have just simply streamlined for those dispensers who have indicated that they just want to scan at the tote level, not any lower. I'm going to go ahead and you'll notice I can save the delivery or complete the delivery.

I'm going to go ahead and I'm going to submit that delivery. One scan checked for the presence of that compliance data and I hit submit. I have check that compliance data exists. The next example is coming back here. I'll just go to the next slide. You may not receive an aggregated delivery. You may receive a box with a bunch of aegis or cases inside.

You do have some different options and there's definitely different processes when you're trying to balance risk versus operational impact. A lot of dispensers I've spoken to, for those locations that are receiving totes, they want to just scan at the tote level.

For those locations that don't receive totes or that are not receiving aggregated shipments, they want to go ahead and scan some of the aegis or cases inside. Even if you do receive aggregated shipments being able to scan that.

Here's the second example. I have a case, I've opened it up there's a bunch of

© TraceLink Inc. 2009 - 2025 All Rights Reserved

aegis inside, and I'm going to just pull up the first each. I'm going to pull up the first product, and I'm going to scan the 2D barcode. Just like with the tote, it has taken that scanned information. It has checked did TraceLink receive compliance information for this product, and it immediately will say yes or no.

You will get that immediate synchronous response if the compliance data is not in the TraceLink system. If the compliance information is not in the TraceLink system, then as Caitlin had mentioned, we have other applications that we'll get to another webinars to handle those exceptions.

How many are you going to scan? There's 32 in this box. How many are you going to scan to check that compliance information is present or has been sent by the supplier? This is where dispensers are either saying is as little as possible because I really want to meet that minimum bar, but don't want to have too much extra work for my receivers.

We've talked to dispensers, who plan to do 100 percent scanning, 100 percent checking of every single item in a box, but most of the dispensers fall in the middle where a certain percentage or a certain number as Caitlin had mentioned, maybe one from each NDC, maybe scan the first three that you pull out of the box.

At this point, I can go ahead and I can save this because I only needed to scan five. I'm satisfied that if five showed up fine, that my SOPs or my business process is scan three to five, and then save it.

I'm going to show you an example. I'm scanning away in the box, and something doesn't scan. I wanted to show you two things. A, that you have that immediate go/no-go, green or red whether or not the compliance information is present or has been sent by your supplier. Again, exception management handling.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

In the last example, I'm going to go ahead, and I'm going to complete this delivery. I've scanned the five, and I'm good with that. I've been asked, dispensers who say, "I know that there's the receive and reconcile, but what about Friday audits or monthly audits? What if my pharmacy techs or warehouse workers every Friday go around and scan 10 things? Can the solution do that?" Absolutely.

You can go ahead right to serial number status, and they can pull the first five things off the shelf. At any point in time, they can go ahead and they can just scan whatever they want. It's checking for the presence of that compliance data in your TraceLink repository. I just wanted to show you that piece as an extra bit as well.

[pause]

Christine: At this point, I can hand it back.

Dan: Thank you, Christine. That was very informative.

Let me just load up the webinar again. While I'm doing that, I think it's important to note here that it's critical that companies really start to look at...health systems and retail pharmacies really start to look at what is their SOP going to be for scanning?

Are they going to receive the transaction information and trust that what is being sent to them is correct, or do they want to do some amount of due diligence on their own, where they're scanning a percentage of products to trust but verify, trust that what is being sent to them is correct and accurate, but verify a percentage of them to determine that the supplier is sending the right information.

The regulation does not prescribe what should be done. The regulation just says that the information has to be exchanged, and it has to be available during an

© TraceLink Inc. 2009 - 2025 All Rights Reserved

audit or an investigation.

It's really up to you to think about, "How do I want to ensure that I'm getting the right information, that I have it available to me, trust but verify that the information is being sent to me so that if I do have an audit or something to that effect, I'm able to demonstrate that in my SOPs and provide evidence that I'm following my SOPs?"

These are the discussions and decisions that we're really encouraging our dispenser customers to start to determine now. Then we can move on to implementing the appropriate solution for that. We certainly would love the opportunity to speak with you about that approach as we work our way towards November of 2023.

What I'd like to do now is talk about some experience that we've had with a couple of our customers. We'll look at both a health system as well as a retail pharmacy and highlight some of what they're doing today as it relates to DSCSA.

This particular health system is in the Winston-Salem, North Carolina, area. Their requirements, or their challenges were, first and foremost, comply with the DSCSA requirements for item-level traceability.

For them, it was important DSCSA was tightly tied to their belief that it would help enhance patient safety. If they were compliant with DSCSA, then they're doing the work that they should be doing to protect against illicit product from entering the supply chain.

They also wanted to get better visibility into inventory positions across the health system, which they later wanted to use to help them optimize recalls. Recalls, like in any other health system, a challenge that many of them are facing.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

We've been deploying this solution with them. They were an early customer of ours for the 2015 requirement. We have since installed serialized receiving so meeting the 2023 requirement across 15 locations. We've also integrated their suppliers for electronic exchange.

Most of them are sending the ASNs in compliance with the DSCSA for 2015 at the lot level requirements, but we are now starting to turn on, if you will, the receipt of EPCIS information particularly for shipments that are coming direct from manufacturers. Many of the pharmaceutical manufacturers are ready and able to send those EPCIS transactions.

Wholesalers are just getting underway with their requirements, but we're trying to enable the direct shipments from manufacturers for EPCIS and work out any other hurdles that we need to go through with that part of the supply chain.

I think maybe what's important to recognize is the quote from their system vice president for pharmacy and really looking at TraceLink as a partner for not just DSCSA, but for where their supply chain is heading and what they want to accomplish in terms of supply chain visibility.

They recognize the complex challenges in managing that chain and working with a company that cannot only help them be compliant with the regulation, but also help them look at how can we use this investment, how can we use the TraceLink platform and the TraceLink network to address some of the other supply-chain challenges that they were having most notably recalls.

Great success with this organization. We'd love the opportunity to speak more with you about this particular customer and talk about some of the experiences that we've had.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Another example is a retail pharmacy customer. This is a large retail pharmacy chain headquartered here on the East Coast. Very large in terms of a national retail pharmacy chain with thousands of stores across the US.

Similarly, for this organization, it was about DSCSA because of the size of the organization. It was really important that they got started on their project early.

Complex business with multiple different business units really required the need for a flexible platform that allowed them to integrate into, not just their supply network but also the various systems that they had because what they were looking for was enterprise-wide visibility across their various business units.

You can see some of the success that we've had. We've deployed out to over 100 locations. They are scanning just through random sampling, over 200,000 serial numbers on a monthly basis. We're certainly working with high volume with them.

For this particular organization, and we do see this a lot, is really looking for a partner that could help them manage and navigate the complex industry evolution that's happening right now with DSCSA. Like many of you, the functions responsible for DSCSA have full-time day jobs.

They are managing other parts of the pharmacy within the organization so they are really not just looking for a solution provider, but a trusted partner that could help educate them on some of the activities that are happening within the industry.

Again, just really two examples in terms of how we approach a health system, as well as a retail pharmacy.

What I'll do now is I'd like to tee up what's happening in terms of the next webinar series. One of the webinars that we have coming up, it's part of our Deep-Dive

© TraceLink Inc. 2009 - 2025 All Rights Reserved

series. This is something that we're inviting both our dispenser customers as well as manufacturers and wholesalers.

In this particular webinar, Lucy Deus, who's our Senior Vice President of Product Management, will be walking you through the new OPUS platform specifically as it relates to DSCSA.

The product for our existing customers that are using TraceLink today, who are familiar with our Product Track solution, we've been making a pretty significant investment in upgrading and overhauling that user experience based on the feedback that we've heard from you.

We want to share that new user experience with you to highlight how you perform routine tasks, things like search and retrieval. How you can tailor the solution to meet some of your individual needs.

Stay tuned for that webinar. We certainly hope that many of you can join us to get a deep dive into the actual product that we'll be deploying for November of 2023.

I also want to make you aware of our customer community group, our DSCSA 2023 community group. It does run on Thursdays, as well as this webinar series. Again, this is a place where if you're an existing TraceLink customer, we invite you to join this community.

The group is shifting now into where we've been doing a lot of education on the requirements. Now, we're going to be taking some deep dives with our product management organization into developing the specific capabilities.

Getting your feedback on the product, the solution, the workflows that we need to implement to make sure that we're meeting all of your needs in time for the

© TraceLink Inc. 2009 - 2025 All Rights Reserved

November regulation.

Now, we do have a couple of questions that have come in from the audience. What I'd like to do is, maybe the first question for both Caitlin and Christine that you can comment on. There is a question around integration into a pharmacy receiving system.

Do they need to use the TraceLink mobile application that Christine was demonstrating or can we use existing hardware in the pharmacy receiving process that they have in place today? Maybe Caitlin or Christine can comment on that.

Caitlin: Sure. Dan, can you hear me?

Dan: Yes, I can. Thank you.

Caitlin: You do not need to procure new hardware. We can also integrate with existing systems. We have standard integrations, but we can work with whatever system that you have to decide what format. If needed, we can build custom formats that can conform to those. You certainly can integrate with your existing systems.

If you want to use our application, you also don't need new hardware. Assuming you have hardware that supports the Android device, we can provide those specifications to you so you can check your current equipment to see if it matches our specifications. No, you shouldn't need to procure new hardware whether or not you're using our application or we're integrating with your application.

Dan: Thank you. Christine, a question for you. I think this is one that's probably on a number of folks' minds is how does scanning at the tote level meet item level traceability? Talking about the concept of aggregation and what gets included in

© TraceLink Inc. 2009 - 2025 All Rights Reserved

that transaction that's sent to us. Maybe you can walk through the details of that.

Caitlin: Christine, you're on mute.

Christine: Yes. When we're talking about a tote, it's usually an SSCC, a serialized shipping container code as opposed to, say, a case which can also be aggregated, but that's a G10.

With inference and aggregation, what that means is if your supplier has recorded the parent-child relationships of which serial numbers are in this tote, which serial numbers are in that tote.

That aggregation information is included in the compliance information that is sent to TraceLink, which means when the tote shows up at the dock, if you just scan one of the four totes, by scanning that one tote through inference and aggregation, you can receive that entire tote, whereas maybe the other totes are coming tomorrow or you're going to take lunch and receive them later.

That inference in aggregation allows by that parent-child relationships for you to scan at that higher level. Most dispensers that I talk to, particularly those who receive totes and/or a pallets, do prefer to scan at the highest level to receive the contents inside.

Dan had talked about trust, but verify. We do have dispensers who have told me that, "Hey, if they're sending aggregation, I just want to scan the tote and off I go."

While I've also had dispensers who have chosen to scan at the highest level, but then do that auditing or that sampling of individual items, either inside at the time of receiving or pulling them down from the bin or from the shelf on every Friday.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Caitlin: Just to add a little bit more on that, aggregation and the concept of inference, scanning a top-level and accepting the rest, has been widely talked about in the industry as an acceptable way to meet that DSCSA requirement.

If you think about further up in the stream, the wholesalers, they're buying most times sealed homogenous cases and they're not going to be able to open those. They don't want to open those sealed cases that they got from the manufacturer. The industry has come together and said that using aggregation and scanning top-levels is an acceptable way to verify that information.

Dan: Great. A couple more questions that come in. One, have we had conversations with some of the common pharmacy inventory management system vendors to determine if they can also receive NDC lot expiration date info? This is all around the concept of eliminating scans within the pharmacy. Maybe I'll start, and Christine, Caitlin, you can chime in.

We have had a number of conversations with a few of the different vendors, and I will say they are, the general consensus is that they need to make some investments in their capability in order to manage the information. Many today are not able to I'd say deconstruct the 2D barcode in order to get the NDC, the lot number, and the expiration date.

That does require some investment on their part. We have had discussions with them though to talk about where in the process once they are able to do the scanning would they query the TraceLink system to do the verification and reconciliation of the item-level information.

We've started those processes. I will say that it works better when we are talking to those organizations in the context of our customers. Our customers are pushing us both to the table, if you will, so that we have the proper representation from

© TraceLink Inc. 2009 - 2025 All Rights Reserved

those organizations.

It is something that we have started. We do see the value in being able to integrate, get to this Holy Grail of one scan. We certainly see the value of that to reduce the amount of effort that is required within already a busy pharmacy. Christine, Caitlin, any other comments on that?

Christine: I'll just say that's absolutely been my experience as well, Dan. One thing to note though is you're not stuck with a reconciliation process or system, once you start.

I've had dispensers that have said, "I have this inventory management system and I really want to have the scan start there and then leverage TraceLink APIs, but they're not there yet. Can I utilize either the TraceLink UI or the TraceLink Smart Inventory Tracker mobile app say, for the first year until my vendor makes those necessary changes to be able to support serialized data?" Absolutely.

Dan: Great. One last question here, and it's an important one. This is related to the use of paper packing slips as the vehicle for compliance on things like drop shipments or maybe suppliers that they do not have an integration with.

The question is will this task be eliminated with the new system? I'll take a stab at this. When you look at the law, the law explicitly states the need for secure, electronic, interoperable exchange.

As you look at the law and the interpretation of the law, the use of packing slips and paper packing slips as the vehicle to exchange compliance information, we believe is outside the bounds of the way the law is structured.

Therefore, our expectation is we would be integrating with any wholesalers that

© TraceLink Inc. 2009 - 2025 All Rights Reserved

you may not be integrated with today. We certainly can optimize that process for you because they will be required to send that information electronically. The industry is aligning on EPCIS and the FDA enforced this at their public meeting last week.

The next question is really around drop shipments. Drop shipments becomes a little bit harder because you're may be receiving shipment information from a company that you don't have a direct commercial relationship with.

TraceLink today has a drop ship portal that is used for a lot-level traceability to retrieve the compliance information from that portal in electronic way. In addition, we are also working to extend the capability of the drop ship portal for item-level traceability.

Now, industry through groups like HDA as well as PDG, are talking about the model by which the industry will manage drop shipments and how electronic information is exchanged. We have a solution in terms of how we believe that can be managed, but we will certainly adopt any model or best practice that the industry evolves to.

Caitlin, I don't know if you have any comments or thoughts on that.

Caitlin: I would just reiterate what you said. The 2023 requirement does require the electronics secure and interoperable, so we would really encourage that. If you aren't receiving data today from a wholesaler or a supplier, reach out to TraceLink, and we can work to get them connected as much as possible.

Then the drop-ships, the industry is just coming together to try and figure out how they tackle that. We're at that table and trying to figure out the best options for our customers.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Dan: Great. Well, we're right up against the clock. We're actually two minutes over. I appreciate those that have stuck with us to the end here.

I just want to call out, if you are looking for a solution, if you are an existing TraceLink customer, certainly contact your account executive. We can work with you on getting you transitioned to the solution for DSCSA 2023.

If you are evaluating solutions or you're considering moving from your existing solution, certainly reach out to us at marketing [at] tracelink.com.

We would love to set up some time with you and your team to walk through the requirements in detail, the required capabilities, and really put a work plan in place to help you meet those requirements in November of 2023 next year.

Caitlin, Christine, thank you for your time today. Thank you for joining us. To our participants in the webinar, thank you for your time and attention. We hope to see you next week, Thursday at 11 o'clock, to do a deep dive on the OPUS platform. Thank you, everyone.

Caitlin: Thanks, Dan.

Featured WebinarsUS Drug Supply Chain Security ActDSCSA for Dispensers
Watch our DSCSA compliance webinar!
Fill out the form to watch the webinar now.

Related Content

© TraceLink Inc. 2009 - 2025 All Rights Reserved



DSCSA 2023 Webinar Series: How to Ensure Drug Supply and Create Business Value with DSCSA Compliance for Dispensers

How to Ensure Drug Supply and Create Business Value with DSCSA Compliance for Dispensers

View More

© TraceLink Inc. 2009 - 2025 All Rights Reserved