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Transitioning from Lot-Level to Item-Level Traceability Under DSCSA and the Need for an Experienced Partner



DSCSA will require **hospitals and retail pharmacies** to receive EPCIS data from suppliers electronically by November 27, 2023. That means “paper” is going away and storing information that was sent on a packing slip will no longer be a viable solution. Is your pharmacy prepared?



Watch our on-demand webinar, "**Transitioning from Lot-Level to Item-Level Traceability Under DSCSA and the Need for an Experienced Partner**," to learn the most effective ways for health systems and retail pharmacies to meet complex **DSCSA 2023 compliance** mandates like item-level traceability and electronic, interoperable EPCIS data sharing. Topics include:

- A complete overview of the pros and cons of different approaches to DSCSA 2023 compliance, and a look at the benefits of deploying your own solution as opposed to relying on wholesaler portals.

- The impact that the transition from lot-level traceability to item-level traceability will have on pharmacy operations—along with a deep dive into

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what it will take to respond to audits under DSCSA 2023.

- Real-world examples of how the TraceLink Healthcare Operations Services Team (HOST) helps hospital and retail pharmacies significantly reduce the operational burden associated with DSCSA compliance.

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Transcript

Dan Walles: Good morning, everyone. Thank you for joining us on a holiday week here in the US. Today is the second of our webinar series installment for the dispenser community, and we're really focusing on transitioning from lot-level compliance to item-level traceability under the drug supply chain and security act.

I'm joined today by a couple of my colleagues, Brian Daleiden, who's the vice president of our corporate marketing organization, and Jeff Agersea, who is a manager in our customer service organization. My name's Dan Wallace, I'm the general manager of TraceLink's track and trace and compliance business.

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As I had mentioned, today is the second installment in our webinar series. We covered, about three weeks ago, a session where we took a deeper dive into the requirements of DSCSA, the required capability, and we touched a bit on how our solution can be used to improve drug shortages.

Today, we're going to be focusing on the transition from lot-level to item-level traceability, some of the key things that you should be aware of as long as some of the additional benefits that TraceLink can provide.

[sniffles] Excuse me. We will also provide some insights into some of our services offerings, one particularly our health care operational services team focus that Jeff will walk us through in terms of how that helps you manage your compliance program.

These webinars continue to roll out through February. In February we'll likely to add some more topics based on what the current thinking and status of the industry is at that point.

One other note that I'd like to call out, many of you are likely preparing for the ASHP mid-year show in December in Las Vegas. We are pleased to be able to partner with one of our customers, Sentara, for a poster session that they will be delivering on Tuesday, December 6th, at 2:00 PM.

The reason we bring this up is it would be a great opportunity for you to stop by, look at how Sentara is meeting DSCSA compliance, particularly for the 2023 requirements that are coming up, and get an opportunity to understand how they rolled out their solution and some of the challenges that they ran into and how they addressed them.

If you're heading out to ASHP, we hope to see you there. Again, this session is on

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December 6th at 2:00 PM, and it's with Sentara. Specifically, to this webinar, there's a few key takeaways that we hope that you walk out of here today with.

One is, when you look at being compliant in 2023, you really have multiple options that are available to you. These all are related to essentially how much operational effort you want to put into your compliance program. It also looks at what your risk profile is in terms of compliance.

Today, we'll walk through the different options that you have available to you based on how you want to operate your business and how you want to achieve for compliance.

What we'll also go deeply into is the need for interoperability, and we covered this in a couple of previous webinars, but more specifically, as it relates to interoperability, how TraceLink can help your organization in managing DSCSA through our healthcare operations and services team.

My colleague, Jeff, will walk through what audits might look like as part of DSCSA 2023, and give you some insights into how TraceLink has supported our customers through regulatory audits in the past. Then we'll talk about our solution, our customer base, and some of our experience in delivering serialization, traceability, and DSCSA solutions into the market.

What I'd like to do now is pass it over to my colleague, Brian Daleiden, who will walk you through the next portion of the presentation. Brian.

Brian Daleiden: Thank you, Dan, and hello, everybody. Very nice to talk with you today.

What we wanted to do, for those that aren't familiar with TraceLink and are not

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familiar with our company, with the work we've been doing over the past decade-plus, is introduce you a little bit to TraceLink.

Why we care so much about these topics that we're talking about and some of the background fundamental things that we've been investing in to support your companies as pharmacies, hospitals, healthcare organizations, as well as supporting your organizations when you're gearing up to meet DSCSA requirements.

Without spending a lot of time talking about a bunch of the numbers that we constantly think about as TraceLink, more importantly, TraceLink's been focused for over a decade in helping organizations like yours, pharmacies, hospitals, healthcare organizations, and other key members of the global pharma and healthcare supply chain to help you meet your most pressing business challenges, such as DSCSA compliance.

Early on, one of the things that we realized is that some of the biggest challenges companies faced were network-based, not within the four walls of your organization. Challenges that depended on a company getting the data you needed from suppliers or effectively working together with suppliers on multi-enterprise-shared business processes as you procure, receive, or manage medicines.

Because of that, we've focused very heavily on building a digital supply network and the necessary underlying platform capabilities and solutions that will help organizations like yours to effectively work in such an interdependent environment.

Today, we're very pleased that we have over 1,300 customers that have put their trust in TraceLink to help them achieve these goals. Together, with those

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customers, we work with over 290,000 network partner entities on the TraceLink network.

Not only are these companies successfully meeting numerous compliance and business challenges, they're working daily together to serialize medicines, to track those medicines as they move through the supply chain.

To create and exchange the required compliance documentation as well, such as DSCSA transaction histories today is this deep collaboration over the years with companies and organizations like yours that really has given us the deep insight.

We think the understanding to be your true business partner in meeting DSCSA compliance and other supply chain business requirements.

Next, let's take a look and talk a little bit about supply chain digitalization. Supply chain issues, they're making the news every day, and they impact you as an individual, they impact your business.

Some of these, just to touch on a few, are poor product traceability that opens the doors for counterfeiting of products or diversion of products from their intended channels and markets. We see every day-limited supply chain visibility across partner relationships and transactions, which leads to material shortages in production and also delays of product shipments across the global supply channels.

Sustainability initiatives and the financial pressures that organizations who do not implement those initiatives have caused companies to start looking at replacing the movement of paper with digital alternatives in the supply chain.

Finally, poor transparency into current product and supply against product demand

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or product quality leading to uncertainty in product availability and product recalls.

The list is long and we could spend hours talking about these issues that you see, but underlying these challenges are some fundamental systemic issues. There's data that's constantly being locked in different enterprise systems. It's being siloed and these systems oftentimes are containing out-of-date or inaccurate information.

Lack of timely visibility into the activities and events that are occurring across supply chain relationships and with your upstream suppliers. Poor information sharing with partners due to differences in systems used, or challenges in integrating different partner networks, and different types of information.

Really, an inability to identify products and to manage that product information at the individual serialized level, something that's a key foundation of DSCSA, and to manage and trace product movements and status where you need to.

Finally, work between companies and partners on these shared processes is really too disjointed. It's uncoordinated, particularly as I mentioned because systems are built around traditional enterprise needs, not to serve the emerging supply network requirements.

In some at its core, we see that the systems and the processes, the people, the enterprises are disconnected, and they're really poorly aligned to meet today's supply chain needs. Next, let's talk about a different mindset for how to tackle some of these issues.

The Internet of supply chains. The Internet of supply chains, you can think of it as a network of interoperable networks that's built on what's known as industry 4.0 principles, can help to strategically address many of these critical supply chain challenges.

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The Internet of supply chains, it links these people, these processes, these systems, and these business enterprises into a collective information network. A network of shared contextual business processes that will enable you and your network partners better business process execution. What are some of the foundations of IOSC?

First off, digital networks. The ability to create these contextual digital networks across the supply chains for all the processes that you rely upon, networks for supply and procurement. Networks working with upstream pharmaceutical manufacturers, track and trace networks, maybe participation in specialty distribution networks.

Second, shared processes and applications. The ability to share processes and applications at scale across the network with all of your network partners.

Third, cross-functional and cross-company execution. Creating an environment where each solution and its processes becomes a point around which team members from you and your partner can jointly work and collaborate.

Fourth, a common data model and a semantic understanding of that data. A common data model for all of the objects on the network and a shared semantic understanding of the information flowing between partners coupled with a simplified way for companies and their teams to connect and utilize this information.

Then finally, collective intelligence. Combining all of this. Now, we start to gain an actionable collective intelligence from the network, its participants, and its activities. For example, we could now leverage data on products, inventory levels, supply chain events, demand forecasts, supply plans, all to be used to predict a potential drug shortage in the network.

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With the advent of the Internet of supply chains, now we start to have the critical network and data, and business process tools to finally realize the full supply chain transparency and traceability of products across these supply chain transactions, enabling you to reduce risk in supply planning and execution to gain better real-time adaptivity and agility to changing market dynamics and requirements.

Allowing companies like yours to keep up with changing regulations while seizing the opportunity to grab new business capabilities that may improve your organization. Then finally, to leverage faster response to changing market signals, allowing you to capture real-time market demand, real-time market supply information and serve and react to it more effectively.

Next, let's look at how IOSC has been put into practice. The Internet of supply chains is a fairly new concept to the marketplace, but it's been a fundamental factor in helping companies meet, track, and trace requirements today and for the past several years.

As I mentioned, TraceLink for over a decade has been working to build the world's largest track and trace network, because we consider the network to be a critical foundation in meeting serialization and track and trace requirements like DSCSA.

As we mentioned, today we have over 290,000 entities on the TraceLink network, from hospital and pharmacy all the way back to material suppliers. Beyond that, though, all of these companies can and have been working together using IOSC capabilities. Like digital network creation, shared processes, common data models, data transformation between disparate data types.

That's why today, if we look at some of the numbers on the network, we have over 37 and a half billion serialized units of medicine that have been created and tracked in the supply chain. We have over 13,000 sterilization connections that

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have been created and are being managed on a daily basis.

There's over 339,000 network service links that have been developed and are connecting these active network partners. Almost a billion DSCSA transaction histories have been processed today on the TraceLink network. The Internet of supply chains, it is a critical foundation for track and trace success under DSCSA.

It's also laid an important foundation for the next evolution of digitalizing the supply chain activities from the pharmaceutical company and the contract partner to the hospital and retail pharmacy and healthcare system. I'd ask you, what can the Internet of supply chains on the OPUS platform do for you?

Finally, let's look at why we make the statement next that OPUS is the operating platform for the Internet of supply chains.

Before we dive into DSCSA 2023 Dispenser requirements in our discussion today and receiving processes and other related services, let's finally take a look at how TraceLink provides a comprehensive platform and solution suite, and related capabilities that you can take advantage of today.

That can ensure that your pharmacy or hospital or health system is able to achieve, secure DSCSA compliance while building a platform for future supply chain success.

Underpinning all of this is the OPUS platform, their services, and capabilities. On the digital supply network that we just talked about, first, OPUS enables companies to create these unique business process networks for specific business contents contexts.

For example, supply networks that you work with to acquire the medicines that you

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dispensed and use. In addition, OPUS supports the management of those networks through an extensive set of administration capabilities to administer networks, administer companies on the network.

Administer users on the network through what we call our integrate once interoperate with everyone platform, OPUS simplifies the access to critical data and it enhances your ability to connect with all of your supply and trade partners. We use what's called a canonical data model and message mapping that allows us to transform data between different data types.

You receive the data types you need, your supplier can send the data types they need, those don't have to be the same. Then we connect all the dots through our flexible interfacing tools, open APIs, plugins, etc.

We also leverage what's called low-code application development. Through that, we can rapidly design and iterate upon applications in a metadata-driven way. What this does is, it helps us to speed application development, and we think it provides critical agility to help companies like yours meet new and evolving business needs.

For example, in the last year of the sprint to DSCSA 2023, as the industry is organizing how to meet all of the various nuanced requirements, technical and business requirements, process requirements will change, and we want to keep ahead of the curve in how we develop things.

Last two points, creating baseline applications is important, but so is the ability to configure and customize applications together into tailored solutions for your business needs.

With Solution Designer, people can customize the solution based on company and

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network ecosystem needs. The user experiences the workflow, the data, the roles. The permissions can all be customized in Solution Designer studios.

Then finally and lastly, all of these things have enabled TraceLink to build a wide range of solution suites to meet the needs of companies like yours across the supply chain.

Ranging from serialization, traceability solutions, regulatory compliance solutions for DSCSA, to supply chain collaboration solutions to improve your ability to manage supply chain and business performance. Finally, to collective intelligence solutions, to combat drug shortages and improve product availability for you.

Our network, our platform, and our solutions are all combined together to give you the business operating system and the capabilities you need to meet your most pressing business challenges, like DSCSA compliance.

[pause]

Jeff Agersea: Great. Thank you, Brian. Fantastic work on walking through what is an important opportunity that we believe we as an industry have to look at something like DSCSA and be able to not only meet the requirements in a cost-effective way, and in an efficient way with minimal impact to your operations.

But really start to invest in this Internet of a supply chains platform that can now start to drive meaningful change throughout other parts of your organization, and meaningful change in terms of how you manage your supply chains. Thank you for walking through that, Brian.

Dan: What we'd like to do now is transition a bit into the specific requirements of November 2023. Focusing on the dispensers, and then from that drill a bit deeper

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into the receiving process.

We wanted to focus on this because this is really where I'd say the rubber meets the road in terms of how companies can be compliant with DSCSA and the decisions that they'll be making around how they want to be compliant and then the impact that that may have on their overall operations.

Before we get into that, let's recap a bit about the drug supply chain requirements for dispensers, health systems, and retail pharmacies, and compare and contrast where we are today based on the requirements that went into effect in 2015 and where we need to be by November of 2023, almost exactly a year away from today's date.

I think as many of you know, where we are today is we are in this model of lot-level traceability where companies are receiving in transaction information, transaction history, and transaction statements. There are requirements that this information be sent to you electronically. We do however recognize that in many cases, paper is still being used throughout the industry.

This is an important topic that we want to drill in on is because as we move to item-level traceability in 2023, the requirements, the data requirements that need to be communicated, individual serialization or product identifier information increases pretty dramatically.

In 2023, our requirements presented in a somewhat a simple model are, we have to be able to store what is now the serialized TI. The transaction information that describes the products that we're receiving, the lot number, the expiration date, the individual serial numbers associated with those products, and a transaction statement and be maintaining that in an electronic form.

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One thing to call out is this concept of the transaction history sunsets. It goes away in November of 2023. That starts to introduce the need for industry-wide or segment-wide traceability because to support an investigation, we will have to be able to assemble essentially that transaction history on the fly, to understand what the chain of custody was for that product as part of responding to an investigation.

Clearly, the exchange of information, what used to be an ASN, an advanced ship notice, that was the carrier of this lot-level traceability information included the TI, the TH, and TS is now moving to this new format of what is called EPCIS. Within that EPCIS transaction is that unit-level information, the item-level information, aggregation information.

There's requirements around verification, being able to verify that product identifier, that product code, that GTIN, the serial number, the lot number, and the expiration date as part of an investigation.

Product tracing is assembling those individual transaction history statements in order to build a full chain of custody. Then new requirements around credentialing authorized trade partner credentialing, which we'll go into in much more detail as part of an upcoming webinar.

What you'll see here is that the capabilities that are required as part of moving from lot-level to item-level increase pretty substantially. We've gone through this particular list before of the impact on your receiving systems.

The need to be able to receive and maintain this Electronic Product Code Information System, this EPCIS transaction, new requirements for verification, requirements around exception management. Exceptions will happen on a daily basis in terms of the type of information that is sent to us and how do we efficiently and effectively collaborate.

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What we're going to focus on today, as part of today's webinar, is going into that receiving process and understanding the options around reconciliation under DSCSA, reconciling physical products to the compliance information.

There's three options that are available to you. This is where as a dispenser, it's having discussions internally within your own organizations to understand how you want to be compliant with the law. The law basically says that you need to be able to receive this EPCIS transaction and be able to produce that information as part of an investigation or an audit.

At its completely simplest form, one approach to compliance would be to simply receive that EPCIS transaction, keep it in a system where it's available to you in an investigation or as part of an audit, and you can retrieve that information when you need it.

Now, what this infers is that you are entrusting your supplier that is sending you the information, to make sure the information that is being sent is accurate, timely, and it is being sent 100 percent of the time. That then puts the onus on you as the dispenser to make sure that the information is being sent and is it accurate to what my physical inventory represents.

That's one option. It's this very minimal bar. There's risk associated with that. If there is an audit or if there is an investigation and you go to retrieve that EPCIS transaction. You find out at that point in time that the supplier never sent it or what the supplier sent was incorrect in some way, or it was missing some data in some way.

Then that's the compliance and business risk that's introduced at that point in time. If you move to the right, the next option is to do what we refer to as receive and reconcile. Under this model, you make decisions where you are saying, when I

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receive a shipment in from my suppliers, I am going to scan a certain amount. I could scan 100 percent of my receipts.

I could scan some percentage, some sample to check to make sure is my supplier sending what they should be sending to me, and is it correct?

In this model, you're entrusting that your supplier is doing the right thing most of the time, but you are protecting your own interest to essentially do some sampling to ensure that the information being sent to you is accurate, it's correct, it's not missing.

Now, with this, there is some operational impact. There is the additional steps that may be involved in scanning those individual items, scanning those serial numbers, and going through the reconciliation process where you're reconciling that physical item to the compliance information.

You can do this for five percent of your receipts, 10 percent of your receipts, 100 percent of your receipts, and that's really for you to decide. Now, TraceLink has solutions to make this a much more efficient process for you, but we shouldn't underestimate and gloss over the operational impact.

Then if you move further to the right, this is where we start to think about what are some of the business opportunities that can now be introduced if I am making this investment in scanning and going through this operational process.

What you're doing at this point is you are essentially building up this repository of information that can now be used to enrich other systems and other business processes within your organization. Is this something that needs to be done by November 2023?

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No, but it is that option where you start to look at what is my long-term plan for not just meeting the DSCSA requirements, but how do I drive optimization in terms of improving other business processes, making information available to other systems.

Things like lot number, things like expiration so that I don't have to manually key that information in as part of a subsequent step. These are the things that you want to start to consider, and TraceLink is happy to walk through the pros and cons with you. Now, TraceLink is not advocating any specific approach. We support all three of these obviously.

We do find that the vast majority of our customers are in this middle bucket where they're saying, "By and large, I trust what my suppliers are sending me in terms of compliance information, but I want to do some checking. I want to do some sampling to make sure that they're doing that."

When you take that as a backdrop, this middle bucket, what are the options that you have available? Well, one is a brute force of manual reconciliation, where you receive in the physical items and then you go through and you figure out, do I have that compliance information available to me? You're searching through systems.

The second approach which most of our customers are doing is, they're doing some automated reconciliation where they have determined that they want to scan a percentage or all of their product as part of the receiving or put-away process.

This is deployed using our solution smart inventory tracker, which is a mobile scanning solution that's natively integrated into the overall compliance solution. To date, we've been working with our Dispenser customers that have been reconciling serialized product that is being sent to them. Over five million individual units have

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been reconciled through the TraceLink solution since 2020.

The point here is that, if you are putting yourself in this camp, this middle category here, where you want to do some trust but verify model, where you're receiving in those EPCIS transactions as a baseline and then going through and doing some reconciliation as part of that, then there is a commercially hardened and battle-tested solution that's available to you.

Now, another consideration as you move from lot-level to item-level traceability is some new data elements that are now required. These are not unique to TraceLink, these are unique to the industry moving to this new standard, this GS1 standard of communicating information through an EPCIS format.

What this implies is that there's a new data element called a GLN, which is a Global Location Number. This identifies companies and their locations. TraceLink can work with you to help you acquire a GLN.

We can work with you to determine does your organization already have a GLN in many cases based on the med-surge side of your business who may already have adopted GS1 standards. You may have GLN information already and then a GTIN and more specifically as we move into serialized GTINs.

A GTIN is a Global Trade Identification number. This is essentially a product code that is defining the physical item that you're now receiving. The GTIN stands for Global Trade Identification Number. It provides a way in which we can uniquely identify not only products but what is their packaging level.

For many of you, you receive items and totes, but some of you may also have warehouses, particularly on the retail pharmacy side, warehouses and distribution centers where you may be receiving full pallets or certainly full cases, that GTIN is

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defining not only the product but what is the packaging level.

When you scan that package, that case, you want to make sure that your system knows that that's a case that may have 24 individual items in it, and not an individual item. We manage that through master data. Today, TraceLink will support you in getting that master data around GTIN's preloaded into your system and providing regular updates to you.

This is another consideration that, if we're fortunate enough to partner with you for your 2023 solution, we'll be walking you through these requirements and how you acquire and prepare your organization through the TraceLink solution to be able to handle and manage these.

Now, I won't go through this in tremendous detail. We'll certainly make these slides available to you, but I did want to call out the difference from a regulatory perspective of what is required from lot-level traceability, which is the 2015 requirement to what will be required in 2023.

Today through that ASN, we're communicating lot-level information. It's that transaction information, that transaction history, transaction statement.

We're operating in both a paper and electronic form. We're communicating information at the lot-level, meaning, the information is, I'm sending you this product code, this NDC at this lot, this batch number, and this is the quantity.

In 2023, that information set that you are required to use and maintain is what is now the serialized version of that transaction history, which is the addition of package level information, the GTIN, the serial number, the lot number, the expiration date. Having a system that is secure, interoperable, and electronic.

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That is a requirement in the 2023 regulatory requirements around communicating this information in an electronic way.

Then there are requirements around having systems and processes in place for verification as well as systems and processes in place for verification, as well as systems and processes in place to respond with the request for a TI or a TS upon a recall or some sort of a suspect or illegitimate product investigation.

Now, as many of you know, the FDA does not necessarily endorse specific approaches to how an individual organization or a company meets their requirements. However, they are strongly recommending that we use technological approaches based on standards and the industry has aligned on the EPCIS standard managed by GS1 as the way we will communicate that information.

To try to visualize this for you today, your current state is many of you are probably receiving paper. You could be working with us where we're taking that paper on your behalf and we're scanning it in and storing it in a repository for you.

You may be relying on various portals from your suppliers where you're logging into multiple portals in order to retrieve that information, and you're hoping that it is available. As we move to 2023, really that future state is having systems in place to receive things electronically and being able to initiate verifications or tracing requests in support of investigations.

Your world starts to expand in terms of all of the different ways that, as a dispenser, you may need to interact with not only your suppliers but potentially your indirect suppliers. What I mean by that for many of you, an indirect supplier may be a manufacturer.

That manufacturer may be sending you product directly, as is the case in a drop

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shipment, or maybe they're just sending to you directly because it's the type of relationship that you have with them. You may need to interact with that manufacturer to perform a verification.

You may need to interact with that manufacturer to retrieve their latest GTIN information for new products that they're introducing into the market, then product tracing and recalls. This is where your requirements now move from something that was maybe more straightforward to something that becomes much more complex.

Now, fortunately, [laughs] one of the reasons why we're here is TraceLink has a solution that can manage this integration and exchange of information and communication with those manufacturers.

The point of this today's presentation and message is that your requirements are increasing pretty substantially. This is much more than just receiving a new type of transaction.

I think as I've talked to many in the dispenser space, the current thinking is, I'm moving from this one transaction called an ASN to this new transaction called an EPCIS document. That's probably an incorrect oversimplification of the requirements you have in front of you.

Finally, exceptions. We know that exceptions are going to happen, and they're part of the normal operational processes that we go through. The Healthcare Distribution Alliance, HDA, which is an industry organization representing some dispensers, but primarily the wholesalers and manufacturers, have gone through.

They've produced a report, we can make it available to you. It's also available on their website, that has started to define exception categories. Data issued,

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damaged products, no data arrived, or maybe you have data, but you don't have the product.

This introduces a way in which you're now going to have to collaborate with your suppliers in order to rectify these exceptions and to get those exceptions corrected in your systems. As we move to item-level, the exceptions around the item are now going to increase pretty dramatically.

What I'd like to do now is, hand it over to my colleague, Jeff Agersea, who's going to walk you through how TraceLink supports you, not just with our product. We certainly have talked about our specific solutions, but we also recognize your needs as organizations for more hands essentially, more services.

You have incredibly busy day-to-day jobs. These are some additional services that we offer to our dispenser customers. Jeff, can I hand it over to you?

Jeff: Sure. I manage the host team here at TraceLink. We're the healthcare operations services team. Our job is to try and make your jobs easier. We try to assist with day-to-day activities, compliance activities, because at the end of the day, what we care about is that you're able to take care of your main job, which is caring for patients.

One of the biggest things we do to assist with this is helping with audits. We have a fairly long history of helping with audits. We've helped 50 audits across several customers. Many of our customers have had multiple audits.

That's why it's not 50 audits for 50 customers, it's 50 audits across less customers than that because an audit can be at a company level, it can be at a location level. Especially with some of the hospital chains, you can see multiple audits at the same time and different locations.

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Some of the things we've learned about these audits, is they can come from all different sources. The FDA and state boards are unquestionably the most common ones, but we've seen internal audits, we've seen governing company audits, we've seen even practice audits to make sure you're ready to go.

The amount of these audits has changed a lot throughout the years. We used to receive a few per year, and then they slowly started increasing. Then the pandemic happened, and all of a sudden, they stopped. We went a year and a half with no audits, and then all of a sudden now we're starting to see a huge resurgence of these audits.

In the past six months, I've seen more audits than the last two years. We're now at a point where audits are becoming very, very common, and being prepared for them is extremely important.

Most audits that we get are very, very straightforward. When you think of an audit, you think of them digging through all your data, but realistically, especially with an FDA audit, they're usually looking for a specific product and say, "You receive this product, what can you tell us about it?"

"Did you receive your compliance information? Have you been following the proper procedures? Are you all ready to present that to the FDA should one of these arrive?" Anecdotally speaking, like I said, these are usually very specific.

They don't say, "Oh, we want all your products for a certain month." We say, "We have this one NDC. This is what we want information on." Sometimes they're more comprehensive in that. It really depends what the FDA or what that state board is looking for.

Next we can talk about some of the ways we prepare for these audits. The most

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important thing is always being prepared ahead of time, making sure you have procedures and processes in place to say, "If an audit comes along, here's what we do. Here are the things we are using to be prepared for it."

Such as making sure you have documentation of this, making sure you'll have a system in place to track all your information. Then it always comes down to the most common question we get is, "Well, I now have an audit. What do I do? What is my next step?"

The first thing we always say is, "Don't panic. We have a lot of experience with this and we really want to make sure that you know we are here to help you and we've done this many, many times." Always contact TraceLink and we'll walk you through the steps of what you need to do and what we're here to help you with.

Typically, when an audit comes along, they'll say, "Oh, we're going to either come in on this date, or you need to send us this information by this date of what we're looking for." It can be as little as 24 hours in advance but most of the time, it's usually 48 hours, 72 hours in advance.

A day or two, they'll let you know, "We're going to be coming in, and here's exactly what we're looking for." You have, according to the law, 24 hours to produce this data, but usually, they give you a little bit more time than that.

When it comes to the time of the audit, if you know ahead of time that someone's going to be on-site and you need support, we can assign a dedicated person to be available during that time period and provide you with any assistance you need, either phone or electronic email, chat.

Just someone that can be like, "Oh, I have these questions about the audit," or the auditor has these questions and we can have someone there ready and waiting for

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you.

Then to provide the information back to the auditor, we can provide an either a PDF or CSV format. These are just two standard data formats and we are prepared to provide you either or both depending on what you're looking for and provide all the data necessary for your audit.

Once your audit is finished, we can go a little bit further in depth. Especially if it's an internal audit or trial audit, a lot of companies want to talk about what their findings were, things we can do better.

For an actual official audit, [laughs] I don't think we've ever received any follow-up questions but if you ever want one, we can do that as well and go over everything we learned during that audit and how we can be more prepared for next time.

Beyond though just audits, the HOST team does offer a lot of different services. Obviously, audits are the ones everyone's worried about, and we do that but we do a lot of things day to day to keep you prepared for these so you don't have to worry about it when it comes up. Some of the main things we handle are...As Dan was just talking about, managing errors.

This is something we've spent a lot of time on. We used to see tons of errors per customers. Now, we have many customers that go months without seeing any exceptions. We put a lot of effort into that and it makes a very big difference. We have significantly less customers worrying about missing anything because they're confident that their data is going to be there.

We also offer live training sessions every month as part of our service. You can join in those. We also have those pre-recorded. On top of that, we have a lot of documentation and short videos that if you need help on a specific topic, such as

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how to search for a TH, we can put all that information out there.

There's the video documentation as well as [inaudible 49:58] documentation with screenshots that walk you through everything you could need to know.

We also assist with day-to-day operations. These could be simple things such as adding or removing users, changing access, managing master data such as what NDCs you have, what locations you have, or even connecting with new trade partners.

We do this every single day and we have...I don't remember the number offhand, but it was 200,000 connections we manage. It's quite a bit. [laughs] Finally, I said the audit support...I said this is one we get the most questions on. We really are always making sure we're there to support with that.

Brian: Dan, you're on mute.

Dan: Thank you. Thank you, Jeff. I think this is a critical part of the overall TraceLink solution. If you look at our offering as an organization, there's clearly the software and applications that we provide.

Many of you are familiar with our network service capability where in addition to that software, we are taking on the responsibility of onboarding and integrating to your suppliers.

What Jeff just described is this host service that is really looking at where are the areas that are requiring effort from your staff, which we know is oversubscribed to manage their overall DSCSA system. These are the services that we surround the software with to help you remain compliant and keep your system operational.

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This is a mission-critical system to ensure that you maintain compliance. It's something that we believe is a strong differentiator for TraceLink as we look at alternative approaches in the marketplace. I'm not going to go through each one of these in detail, but I will touch upon as you're looking at various approaches to meeting DSCSA.

There's essentially three buckets. Does the provider have the application and solutions and approach to meet the DSCSA requirements? This is a network challenge. We have to integrate all the suppliers -- some direct suppliers, some indirect suppliers. We need to be able to support verifications, the ability to respond to investigations that may involve recalls.

Doing this across a network creates opportunities, as Brian mentioned, to be able to address other challenges that we're facing specifically in this segment around managing drug shortages and getting visibility into drug shortages.

I'll also call your attention to the last two categories here of services and support and just experience. As you look at our experience, the decade of working within deploying serialized solutions into high volume, high-speed operations, this is where we excel.

Then we've learned from you to surround our solution with these specific offerings like our network success team, like our host team, in order to be able to support you.

That's a stark contrast to other solution approaches those that may primarily be a returns processor or somebody that's providing a pharmacy management system or a wholesaler portal or just a serialization toolkit. Think about how these various approaches are architected, not just from a capability perspective but how that organization can support you beyond November 2023.

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Just a bit more if we drill down into TraceLink's scorecard, we have almost 800 customers that partner with TraceLink specifically for DSCSA across manufactures, wholesalers, and many of your colleagues in the dispenser community.

We are well on the way of deploying serialization. We have 135 companies that are exchanging serialization data today in that EPCIS transaction format.

That includes multiple dispensers, large retail organizations, large health systems, mid-size health systems, small health systems that we're working with on DSCSA 2023 requirements. Our solution's available. It's been battle tested and ready for you to start to deploy.

An example of that is, this is a health system headquartered in Winston-Salem. They got started with us early. They wanted to comply with DSCSA requirements, get better visibility into inventory positions through serialization, and really looking at how they can use serialization to improve recall processes. We deployed our solution, and you see some of the numbers here. They're well on their way.

They've received over 180,000 serialized products across 15 locations, where they're receiving those products and doing some amounts of scanning. This is an example of where they're not scanning everything. They're scanning a percentage where eventually we'll roll out to about all of those 293 locations and we've integrated across all of their suppliers.

If you look at their assistant vice president, the criteria was not from the solution perspective, but looking at who could be a trusted partner for this mission-critical application. That cannot only address the compliance challenges but grow into solving other more complicated supply chain challenges.

We'd love to talk to you more about this particular client and some of our other

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clients as part of a next step. On December first, my colleague Broth will be leading us through looking at DSCSA as a way to reduce some of our operational cost. Looking at how do we use DSCSA as a network business model. We'll show some of our product in terms of exchanging EPCIS transactions.

Talk a bit about how our solution can enable you to get more value, not just within your operations, but by looking across the network, and understanding the velocity of product moving through that particular network.

Brian, maybe you can talk a little bit about another service or offering that TraceLink makes available to its customers.

Brian: Yeah, thanks, Dan. Real quickly, Dan touched upon education expertise, bringing people together on the network. For us, it's also bringing people together to share information, to learn from each other.

Back in 2014, we created the TraceLink community, because we knew that as much as we would always know and as much education as we could provide, working with the FDA, working with the partnership for DSCSA governance, working with HDA.

On understanding the regulations, understanding the business requirements, a lot of the secret sauce is connecting people like you together with your peers to share your questions, your concerns, your experiences, etc.

We launched the TraceLink community back then. We have several groups that are very focused, specifically on DSCSA. We have one particular community group that is very micro-focused on the DSCSA healthcare systems and pharmacies and hospitals. We meet regularly.

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Really, think of it as your place. It's your place to ask us questions. It's your place to learn as we do a debrief on the latest FDA meeting or the latest guidance that comes out.

It's also your place to ask each other questions and to share information. We would love to talk with you more about and love to get you involved with our community. Thanks, Dan.

Dan: Great, thank you, Brian. Finally, key takeaways, we hope through the hour that you've spent with us here that we've been able to provide some education and perspective on the different ways you can meet your DSCSA compliance, with the consideration of how that may impact your overall operations.

We hope that you recognize the additional services that TraceLink offers in the value of our hosting, our ability to support you through audits, and that audits will continue even though we had a bit of a pause. Audits will continue and are ramping up.

We hope that we've been able to give you some perspective of our experience here in this space compared to alternative approaches in the market, and how we are leveraging that experience to, first and foremost, help educate you on your requirements and the impact of those requirements, but also how you may need to deploy your solutions in the future.

Finally, I'd ask that if you're an existing TraceLink customer, please reach out to your account executive. Your account executive will be in touch with you as well to discuss how we transition you from your existing product track solution to our 2023 solution. We have some really exciting commercial models that we are making available to dispensers.

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If you require a solution, perhaps you have another provider or maybe you were manually addressing the 2015 requirements, certainly reach out to us at marketing [at] tracelink.com. We'd love to come in and meet with you, and if you're new to DSCSA, provide some more education and guidance and walk you through the requirements.

If you're familiar with DSCSA, and you're really looking for an alternative approach, we'd love to be able to compare and contrast TraceLink's network approach against what you're doing today. Account executives will be reaching out to you. If you're new to TraceLink, certainly reach out to us at marketing [at] tracelink.com.

I know we are over our time here by a few minutes. We have a number of questions that have come in, I did want to address one question because I think it's important and it's a recognition of what the implications are of moving from lot-level to item-level, and that's around capacity and processing.

The question is really related to, today, there's some backlog with gathering information and maybe scanning in lot-level traceability information, essentially paper documents into a repository. The question is really related, "How is TraceLink being able to deal with more information?"

I'll answer in two parts. A couple of things, TraceLink continues to invest in not only staff but also technologies to accelerate our ability to get information into the system. That being said, in 2023, as more and more of the industry moves to electronic transactions, moves to this EPCIS format, the amount of paper that we're dealing with should go down.

This is an artifact by moving to...This isn't a TraceLink requirement, but as the FDA states, a secure, interoperable electronic system. That leads to the second point of the question, if you're receiving these transactions that have all of this item-level

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information in it, are your systems prepared to be able to handle it?

Quite candidly, this is where TraceLink excels, and we'd love to have an opportunity to come in and talk to you about our ability to receive and process transactions that are in the hundreds of thousands of items.

Now, most of you in the dispenser community are not receiving shipments that are in that volume, but the same solution that we're deploying into our dispenser space is being used today to receive shipments into wholesalers which have much higher quantities of items.

We'd love to walk through how we do that and demonstrate our ability to process information in seconds so that once that transaction is received in electronically, it is immediately available to you in the repository.

Great question. I think in summary, it touches upon two things. Is TraceLink ready from just an organizational point of view? The answer is, yes, and we continue to ramp up our staff of 800 employees today, most of which are in our R&D and services organization. Then our ability to handle just the move to electronic information exchange. This is really something that we excel at.

We'd love to talk to you more about that. Unfortunately, we're well over our time, and I appreciate many of you who've stuck here with us. We'll get back to those that sent in other questions, we'll get back to you directly.

Jeff, Brian, thank you for your time today and your insights, and I thank everybody else that was able to join us. For those in the US, have a great holiday week. I look forward to speaking with you again. Thanks, everyone.

Jeff: Thank you.

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Brian: Thank you, everybody.

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