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DSCSA 2023: Requirements, Necessary Capabilities, and Preventing Drug Shortages for Dispensers





Watch this on-demand webinar to learn the fastest and most effective ways for health systems and retail pharmacies to meet complex DSCSA 2023 compliance mandates. Plus, you'll see how to leverage compliance technology investments to boost operational efficiency, ensure drug supply, and improve patient care.

Here are four reasons to watch the on-demand session:

1. Get a complete overview of item-level traceability and other critical **DSCSA 2023 requirements** for hospital and retail pharmacies. This includes a close look at the technical capabilities needed for achieving fully interoperable EPCIS data exchange with direct trading partners, electronic verification to support investigations, and electronic tracing of pharmaceutical products at the package level.

2. Learn how a digital network platform-based approach to **DSCSA 2023 compliance** enables pharmacies to collaborate seamlessly with all supply

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chain partners while taking advantage of data-driven solutions to manage exceptions, respond more quickly to drug recalls, and **predict drug shortages up to 90 days in advance with high accuracy**.

3. Gain a better understanding of DSCSA timelines and hear step-by-step strategies for achieving DSCSA 2023 compliance before the FDA deadline on November 27, 2023.

4. Discover why existing TraceLink customers are much closer to achieving DSCSA 2023 compliance than you may think.

This webinar is part of the TraceLink DSCSA 2023 Webinar Series. Watch the whole series to learn how TraceLink can help you turn compliance efforts into real business value—just fill out the form on this page to get started.

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Transcript

Dan Walles: Good morning, everyone. Welcome to our first webinar in our DSCSA 2023 webinar series specifically focused on the dispenser segment.

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Today, we'll be taking on a topic where we'll review the requirements, the necessary capabilities associated with DSCSA, and also how you can leverage the tools in DSCSA to address some pretty compelling industry challenges, most notably drug shortage predictions.

Today, I'm joined by my colleague, Allan Bowyer. Many of you probably recognize Allan. Allan is a senior director for our industry and community organizations, Bharath Sundararaman, who is the general manager of our intelligent supply network, and my name's Dan Walles. I'm the general manager of TraceLink's track and trace and compliance business here at TraceLink.

As I had mentioned, this is the first in a webinar series. Once a week, we will be getting together to cover a variety of topics related to the Drug Supply Chain and Security Act.

Every three weeks, we'll meet specifically on some of the dispenser challenges associated with the Drug Supply Chain and Security Act. We'll take some deep dives into various topics, such as transitioning from lot-level to item-level, balancing risk and operational impact when complying with DSCSA, preparing for the exchange of EPCIS information and verification.

We'll also talk about what your journey to DSCSA compliance should look like. Then we'll go much more deeply into how you can improve your business, essentially, through the investment that you're making in DSCSA.

First, today, let's focus on requirements and required capability around the Drug Supply Chain and Security Act. As we get into that, there's a few things that I'd like to call your attention to as you listen to the material today.

First and foremost, I think we have to look at the Drug Supply Chain and Security

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Act as a step in digitizing our supply chains. This has become a business imperative in a number of industries, and the medicine supply chain is no exception.

The other key point that we want you to walk away with today is that the requirements in 2023 are a step change over what you are doing today to meet the 2015 requirements.

That equates to pharmacies must be prepared to exchange information electronically with your suppliers, whether you're receiving EPCIS information for each shipment coming into your facility, verification requirements to support investigations, managing the inevitable exceptions that will come up as we start to track product at an item level and no longer just a lot level, and then requirements around tracing a product's chain of custody.

It's certainly a lot for us to do and a lot for us to accomplish as an industry as we move to 2023.

The last piece I'll leave you with is thinking about how your investment in a solution for the Drug Supply Chain and Security Act can start to build capability for your organization in the area around drug shortage detection. My colleague Bharath will talk about some of the advancements and exciting things we have about to hit the market in that area.

Also, opportunities around the recall management process and digitizing that process to streamline our effectiveness in identifying and retrieving recalled product out of our inventory.

With that, I'll just jump in and talk a little bit about TraceLink, introduce you to TraceLink, for those that may not be familiar with us. TraceLink was founded in

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2009. We have offices around the globe. Our key tenet of our value proposition is our network.

Our network represents the pharmaceutical supply chain around the globe and has over 290,000 members.

What I mean by members, the 290,000 business entities that are responsible for some part of the medicine supply chain, whether it be API suppliers or contract manufacturers, pharmaceutical manufacturers, drug wholesalers, and of course, you, the drug dispensers, whether you're a health system, a retail pharmacy, or an independent pharmacy.

Those members are operating on our network. Not all of them are direct TraceLink customers, but the commitment that we make to our almost 1,300 customers is that we will onboard and integrate to your partners, whether they be suppliers or customers, to receive the required compliance and serialization information.

Our network is quite active in terms of the number of participants. When we talk about serialization, we have close to 900 companies that are serializing product today using the TraceLink network and TraceLink solutions. The amount that we've saved the industry through our integrate once, interoperate with everyone model is well in excess of $4.4 billion.

We're a sizable organization. One thing I'll call out here is the number of employees that we have dedicated to bringing solutions to market and then supporting you in the deployment and operation of those services.

Specifically related to DSCSA, close to 40 billion serial units being tracked today, almost a billion transaction histories, that's the current DSCSA requirement managed through the network, and almost 50,000 GTINs in network that we're

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managing to support things like serialization and verification.

One thing to walk away with, we are a digital supply network, but as we think about DSCSA and we think about the requirements associated with DSCSA, this is something that we're doing today. We're managing this today for a number of our customers across all segments -- manufacturers, wholesalers, and dispensers.

One of the first points that we made was that our supply chains are global in nature, and we really have a requirement in the industry to start to digitalize our supply chains. DSCSA is tightly rooted in traceability, being able to trace where a product has been, what the chain of custody of that product has been before it gets dispensed to a patient.

The reason that's so important is not just because of the compliance requirements, but it really starts to drive our ability to get better transparency in the supply chain to start to address other challenges around sustainability.

There's a lot of work that's being done, particularly in the US as well as EMEA, around how do we make our supply chains more sustainable activities such as moving to digital leaflets and then just better visibility in our supply chains, the better ability to collaborate with our suppliers.

If we learned one thing from the pandemic is that we have to be much more responsive to changing supply chain conditions. Digitalizing our supply chains is really going to allow us to do that.

Now, in order for us to be able to digitalize supply chains and create this Internet of supply chains, to be able to integrate systems, processes, and people, we have to start to deploy and create some very key artifacts and capabilities.

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That really starts with being able to digitalize processes across the supply chain. To be able to share and collaborate across processes and applications on a network.

The reason that we want to be operating on a network is so that we can establish a common data model, not just inside my four walls as a company but really across the supply chain, because when we have a common data model that we're operating on, we can be much more responsive because we're dealing with incredibly clean data...

With incredibly clean data, and that allows us to now start to derive intelligence from the information, from the data that's moving through that network.

When we think about DSCSA, it's not just this compliance requirement to exchange some information, it's an opportunity to make that first step into digitalizing our supply chain, which is going to provide full transparency, real-time adaptability, and overall faster response times.

As we look to where we want to be as an industry in the next 5 years, in the next 10 years, digitalization is a foundational element that we have to achieve. Over the years, traceability in the initial underpinnings of DSCSA has really built out the foundation for this first Internet of supply chains.

If you look at what we've done to date on the backs of regulations like DSCSA, like what's happened in Europe, Russia, and other markets, we've built this active in thriving network around drug supply.

Whether it be with folks like yourself on the customer side in terms of dispensers, whether they be health systems, or retail pharmacies, your suppliers like wholesalers and distributors, manufacturers, who you may not have a direct

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commercial relationship within, but your ability to collaborate with them and gain visibility into product supply becomes very important.

Then obviously, moving back upstream into contract manufacturers, direct materials suppliers. Imagine starting to be able to link together and glean insights into a shutdown of an API manufacturer in China, and the impact that that is going to have on your ability to dispense medicines to patients.

We've started with this, and have started to put together the building blocks of this Internet of supply chains around drug supply. That's really at the foundation in the heart of TraceLink Solution Suite.

Today we're going to talk about regulatory and compliance, but that starts to incorporate this digital supply network that we've built out, these capabilities and tools that are primary requirements around being able to manage a network, being able to integrate with my suppliers, having data and application catalogues, low code development environments, as we want to start to do more with the information that we're capturing.

We'll go deep into this regulatory compliance box here today with DSCSA. We want to be able to set the foundation of what is available to you as you start to look at not just checking the box with DSCSA, but how do I now start to drive some pretty substantial value and transformation through my organization.

Let's dive deeper into DSCSA and what the specific challenges are. Capabilities that it requires, and ultimately the value in addition to achieving compliance and maintaining compliance that DSCSA can introduce.

What I'd like to do now is pass it over to my colleague, Allan Bowyer, who's going to walk us through some of the high-level requirements from an FDA perspective

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around DSCSA. Allan?

Allan Bowyer: Thank you, Dan. As Dan mentioned, I host TraceLink community groups where we endeavor to create a place and a space for our members to help one another out because it's not just about complying with the law, but also talking about how operations can be streamlined once these legal requirements go into place.

In fact, we have a dedicated dispenser community, and we have an advice column discussing what members can do today so that you don't reach November 2023 and have to do all of this preparation.

Let's talk about the DSCSA. That's the Drug Supply Chain Security Act that was signed into law by President Obama in 2013, the Wednesday before Thanksgiving to be very specific.

The ambition was to make the prescription medicine supply chain more secure. There had been some incidents in the US that quite shocked the industry and served as a wake-up call.

The DSCSA laid out a 10-year industry roadmap. We'll go into that detail a little in shortly, but the idea is that when the DSCSA is fully implemented, a prescription drug can be traced securely from the manufacturer through the wholesale distributor and to the dispenser.

One key term for everyone to understand is a product tracing. This refers to requirements for each trade partner to either provide or probably in the dispenser case to receive information on a product transaction.

The information on this slide comes from a 2021 webinar that the FDA put on. The

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FDA continues to hold periodic meetings around DSCSA, in general, as well as meetings on specific topics.

There are some pending guidance documents, for example. The latest announcement is there'll be a two-day meeting, five hours a piece, on December 7th and 8th, that will be an online meeting that you can register for.

Let's get back to the FDAs goals with DSCSA. They've laid out two high-level goals. The first is to implement this secure, interoperable electronic exchange of product-tracing information at the package level.

Let's see what that means. I'll go block by block in those white squares. Today, trade partners exchange transaction information at the lot level. In 2023, this changes, this information exchange will be fully electronic and at the package level for everyone.

That means essentially sending each and every serial number that's on the package that you will receive physically. In the second box, we have this package-level information which is encoded on the pack via an identifier that most of you will have seen. This identifier serves to allow verification through electronic means.

The FDA has put forth in accordance with DSCSA a number of additional scenarios under which you can apply those verification tools, so dispensers will see much more verification in their toolbox, let's say in 2023.

In the third block, if through a series of processes and verifications you find a suspect or illegitimate product, then the pack level tracing information would be used to locate that packed, quarantine, dispose of it. You might be in possession of that pack and would be required to carry out providing that tracing information or quarantining that pack, for example.

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Now, in the fourth box, the applications of DSCSA don't just stop with suspect or illegitimate product, but in scope is also for a trade partner to let the FDA know of a recall and that that state regulatory authority could ask for tracing information on a product subject to a recall.

You might receive a formal request by these authorities, and you would need to respond to that with the tracing information in a short time. Essentially, for dispensers there's an electronic retention requirement. There's a provision of such tracing information. There's a tight timeline for doing so, and there's verification obligations along the way.

What dispensers and all other trade partners will be responsible for in 2023 is matching the physical supply chain with what is sometimes called the virtual or electronic supply chain, and that's the information that's transmitted to you.

The second goal at the bottom, we won't spend too much time today. It's about nationalizing standards for licensure on wholesale distributors and for 3PLs. This may impact some dispensers who also carry out distribution operations, but we won't talk about that so much in this webinar.

We will go on to get your opinion. We'd like to launch a poll and hear from our audience. On the aspects of DSCSA, which, you believe, will be the most challenging? You'll see a poll pop up on your screen. If we could advance the slide, I'll take you through the options.

This is fully anonymous. We want to take the temperature in the room, if you will. We'd like to see which of these requirements you personally, your organization finds the most challenging.

The first is about exchanging information electronically and securely. In 2023, all

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exchanges will be electronic, even between wholesale distributors and dispensers.

Perhaps it's this expanded verification. Perhaps you will have received a suspicious-looking package and you need to pull out your verifier to make sure, to see whether that identifier was the one intended by the manufacturer, so performing a verification operation.

Is it product tracing? Maybe a state board pharmacy has asked you to supply electronic information that you've received alongside the product. How quickly will you be able to retrieve that from your archives and transmit it to that authority?

Is it the fourth? Exceptions happen. Perhaps there's a mismatch between the electronic record that you're getting from your distributor, say, and the actual shipment you receive. How do you resolve that so you don't block supply to patients?

The fifth and final is about authorized trade partner credentialing. In the 2023 world, there will be a third-party service that will do checks on different trading partners to make sure they are who they say they are and that they have the right to perform certain actions.

This will be done electronically. It won't just be about knowing who you do business with. There'll be more IT formality on there.

Please do indicate where you find the requirements most challenging. Hopefully, we can spend more time on this or in a future webinar to go over those. Let's take maybe five more seconds, four, three, two, and one.

We're going to display the results in aggregate, so get an idea. We have quite a spread. It looks as though DSCSA exceptions nudged the other ones by some

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margin, but closely behind managing exceptions is the tracing and the verification.

I see most of you are somewhat comfortable with the serialized transaction information exchange and the credentialing. Indeed, it's not particularly surprising about these three middle ones because they do require some active processes.

You have a trigger point, and you may need to verify, or you may need to provide that product tracing information on a request, or there's an exception. You need to do something. The other ones are percolating in the background. It's great information. We will definitely loop back with this group on exceptions.

Let's move to at least my final slide. That will be about how the 2023 requirements have evolved over time. This is just to give you a perspective on the step changes that Dan referred to earlier. We do see that for dispensers at all. It very much culminates in November 2023.

There were some notifications by the FDA of enforcement discretion. Early about in 2019, etc., but all of that ends in 2023. Dispensers are on the hook for quite a lot, and that's why we're enacting this series of webinars to get you started. Let's start earlier in the 2015, 2017 timeframe. This is where the law dictated that entities could only do business with another authorized trade partner.

Know who you're doing business with. You saw from credentialing in 2023 that there'll be electronic means to do that in a third-party verifier. In the early days, you began to receive that T3. It was lot level information. It might've been paper or electronic. You needed to keep that for six years, 2023, all electronic.

Also, the TH will be going away. I'll get to that in a second. On that third bullet point, you needed the systems and capabilities to say quarantine a suspect product that you possessed or controlled. DSCSA also covers borrowing and

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loaning operations. There's another point to look at carefully, particularly if you are transacting with a pharmacy that's not in your affiliate group.

Let's move to 2020. Those requirements included dispensers being able to transact only in serialized product. That's where we see, for example, the encoding on the product of the...We call the product identifier. That basically means a combination of the product code and the serial numbers. Those two together are the product identifier.

That's where we, as TraceLink, saw some of our dispensers begin to scan some or all of the received product to see are they effectively transacting in product with those identifiers.

Then, as far as suspect and illegitimate product are concerned, we saw that even as dispensers were not required to report a suspect product, they're required to investigate one if requested. If that investigation turns out to be an illegitimate product, they are required to report that, so another tool in the toolbox is verifying that identifier.

Now in 2023, the FDA enters what's called the enhanced drug distribution security, or EDDS, phase. That will come into play the Monday after Thanksgiving weekend next year. There'll be a four-day weekend. Then all of these requirements will go into effect.

The tracing information is TI and TS, but TH has been removed from the equation basically because it would have been too much data. That means that you, as a dispenser, may need to retrieve from your systems TI information related to a certain set of transactions and to transmit that to a requester.

That needs to be you no longer have a TH to rely on that specific TI will need to be

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retrieved. The second point is on electronic unit-level traceability. The industry has opted to use what is called EPCIS. That stands for electronic product code information services. That's essentially the lingua franca of DSCSA paper is out. EPCIS is in.

Then, when you investigate suspect products, the law does set out some minimum requirements for dispensers. They need to verify the lot number and the product identifier of at least three packages or 10 percent, whichever is more.

Dispensers will see a lot more responsibility for suspect product investigations. Then I mentioned that the TH, or transaction history, will be gone. That transaction history will now need to be reconstructed if necessary, upon request, say by the FDA.

The TIs will basically be glued together in a one-up-one-down manner to find out the entire history of a product. That's where speed of retrieval and provision is critical for dispensers.

Finally, the authorized trade partner credentialing I mentioned, there'll be third-party issuers that will vet trade partners and provide those technical credentials. That's something that TraceLink will be implementing, we actually have been implementing as well, so that you don't need to...

You may be dealing with trade partners you've never heard of before because of all these new requirements. This will be an assurance that you are dealing with an authorized trade partner.

That, in a very quick nutshell, is DSCSA over the years and in 2023. Accomplishing that is quite a different story. I'm going to pass the ball back to Dan, who's going to tell you exactly how it can be done. Hey, Dan.

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Dan: Great. Thanks, Allan. Appreciate the level of expertise in terms of understanding the requirement and putting it into terms that we can understand. What we see here is we certainly have accomplished a lot, but there's a lot to do in a short amount of time. We're in November of 2022, so 12 months away.

If you start to unpack the requirements that Allan has walked us through, you can see what we accomplished in 2015 and what we still have to accomplish in 2023.

It is this concept of a step change, a step change in capabilities where you are now receiving serialized product, and the requirements to make sure that the items that are in your inventory have the required compliance information associated with them.

That may involve changes to your receiving process, integrations into your pharmacy systems. We've now introduced new types of master data. We all recognize the challenges with master data, item master, and partner master data. Now, we're introducing additional elements around this concept of a GTIN and pack-level master data.

Allan introduced the term EPCIS. As he had mentioned, no longer are we operating in paper, or is the ASN, the vehicle for communicating compliance information, we're now as an industry moving to this transaction type of EPCIS. The reason for that is because it is a much better vehicle to communicate this item-level traceability.

Verification, the use cases around verification to support investigations, saleable returns, be able to do that efficiently in an automated or an electronic way. Then, as some of you called out in the survey, exception management. You can now think about, we're now tracking things no longer at the lot level but at the item level.

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If there is a disconnect between the physical item and the digital representation of that item, the digital compliance information, those are exceptions that we need to manage and will require collaborating with our wholesale suppliers in terms of understanding what happened and how we reconcile those exceptions, credentialing, tracing.

Then understanding how DSCSA impacts recalls in the execution of recalls. We have a significant amount of work to do as an industry. It now starts to speak to, how can we get started? What capabilities do I need to start to deploy above and beyond what I may have deployed already?

If you start to think about this in chunks, first and foremost, this concept of serialization now, this is something that your colleagues in the industry, your manufacturing partners, and some of your wholesale partners have started to deploy their requirements for serialization, at least the manufacturers were back in 2018.

In order to be able to operate in a serialized world to meet the requirements around item-level traceability, it's really being able to deploy capability in your organization around serialized operations. How do I receive serialized products? How do I reconcile those items to the physical items in my inventory?

That now starts to enable what we need to do around compliance, the ability to be able to receive and manage, maybe in some cases create the transaction information and transaction statements. For products, being able to verify products as part of an investigation, being able to on-demand trace the chain of custody of that product to support an investigation of a particular product.

That's the table stakes of becoming compliant. You start to layer on, I have to now incorporate this into my normal operations. This is now the new world that we're

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operating in. We need to get to business as usual with item-level traceability and DSCSA.

I need tools available to me to understand what exceptions are happening, how I identify and troubleshoot those exceptions that may be operational in nature. They may be compliance-related in nature and may require collaboration with my suppliers, with my trade partners.

That's moving to this business-as-usual state, and then getting to that, making sure that my staff has the appropriate training. We recognize in this segment, in particular, the demands on your staff and the workers within the pharmacies are high.

TraceLink has its host services where we're able to take on some of that operational and administrative tasks on your behalf to make sure that your pharmacy operations personnel, can stay focused on their day job and serving patients.

Then looking to the future of, how do we now start to use this information to better detect drug shortages that are happening, to more efficiently handle recalls. Thinking about the TraceLink solution, it is from the ground up here rooted in serialization and compliance. Then thinking about, how do I incorporate this into my operations?

Then, how do I drive business value from this investment that I'm making? Not just in IT, but this operational investment I'm making, to incorporate item-level traceability into my day-to-day operations.

Now, the good thing is, in terms of TraceLink, as a company, this is something that we have been doing for a number of years. In addition to lot level compliance,

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which these metrics here, the 762, these are the number of companies across manufacturers, and wholesalers, and dispensers that rely on TraceLink as their partner for DSCSA.

If you look at that 762, almost half of them are in the dispenser segment. Certainly, a large part of our customer base are your colleagues in the industry, health systems, and retail pharmacies. In terms of what we're doing with ASN and exchanging the T3 information, close to a billion transactions are being managed in production in TraceLink, specifically related to DSCSA.

I want to call your attention to these bottom two metrics here. As we move to EPCIS, this is certainly new for the dispenser segment, but TraceLink is sending and receiving EPCIS transactions today with our manufacturing customers and wholesaler customers and partners.

Some of your colleagues in the industry we're working with today that are receiving EPCIS transactions and have gotten a head start in that. We have processed already over 680,000 of these EPCIS transactions for DSCSA already.

We've already gone through the growing pains in the learning's of what it means to exchange this information, the challenges around why it's different than an ASN, and understanding those complexities. We are ready to support you. Our solutions have been battle tested if you will, in terms of transacting in EPCIS information.

If we drill down on this more specifically, this is an example of one of our health system customers preparing for DSCSA. We've been their partner for the 2015 solution, their partner for what they need to do in 2023. You can see we've already reconciled over 180,000 serialized products as we get started deploying this solution.

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15 of their locations are currently receiving and reconciling serialized product. You can see the progress that we made in the bottom row or the green box there as it relates to ASN. This is all rooted on the fundamental challenge as this company equated it to was, they want to comply with DSCSA, use that to enhance patient safety.

Get better visibility into inventory across their health systems, and start to look at how they can use serialization and item traceability to optimize the recall process. The decision to partner with TraceLink was not just in our capability, but partnering with an organization that understands the complex challenges that are coming at us.

Their system vice president saw the value in partnering with a subject-matter expert, a trusted advisor, in addition to the leading solution provider. We have a lot to do, but I would say you're not on the bleeding edge if you partner with TraceLink around DSCSA and item-level traceability.

What this has taught us is that, you can think about DSCSA in these three areas, and then this fourth area at the bottom here around achieving business value.

Breaking DSCSA down into number one, it is a network challenge. This ability to be able to integrate with 5, 10, maybe hundreds of suppliers that you receive product from.

Recognizing the operational scalability requirements around moving from tracking something at a lot level, where we track things in batches to tracking things at an item level and the processing scalability that that requires in order to be able to manage that.

Then to be able to rapidly maintain compliance as we go through this evolution as

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an industry, we know that come 2023, this isn't over. As we start to live with DSCSA and item-level traceability, that will introduce new requirements, evolution in standards.

Our partners will start to define new business requirements that we have to maintain and incorporate into our solutions and into our processes.

If we take this approach and we think about it thoughtfully, there is substantial opportunity for our industry, for the dispenser segment particularly, to start to drive advancements in how we manage the supply chain and how we make sure our patients have the products that they need when they need it.

That comes down to where we're focusing today is in that area of something that you've told us is a top-of-mind challenge for you. That's the prediction of drug shortages and recall execution. We'll look at the network challenges here and why do we say that DSCSA is a network challenge?

If you start to think about what's happening and the information flows as a dispenser represented in this right-hand side here, the information flows not just with the wholesalers that I operate with, but in situations where I have to ask questions of or exchange information with the manufacturer represented on the left-hand side here.

These indirect suppliers, when I need to perform a verification, when I need to be communicated new G10s, new products that are entering the supply chain. Requirements around product tracing, requirements around getting recall notices distributed to me.

When we think about what we have to accomplish, it's not just about receiving some new information from my wholesaler, it's being able to collaborate with the

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supply chain collectively, not just my direct suppliers, but my indirect suppliers, wholesalers, and manufacturers.

When we talk about scalability, the point here is that in the past, I received an ASN. I got to go through and receive the physical items and then reconcile those items to the information that was in the ASN. This is a fairly straightforward challenge. It's a simple number of transactions. ASNs are pretty well understood.

Now when we look at moving to item-level traceability, a batch of 10,000 units that previously was fairly straightforward because we were tracking things at the lot level, now explodes into marking those individual items as pending receipt. We have to deal with aggregation, understanding which items are in which tote.

Being able to record the receipt of those items, each individual items that they've physically been received and that they've been reconciled against the DSCSA information, and then going through and marking them as completely reconciled and received.

We've now gone through something that is a pretty standard business process of receiving an ASN and reconciling that receipt to something that now introduces a substantial amount of transactional processing in order to truly reconcile and maintain compliance.

If you're not looking at this from an architectural perspective that is dedicated to this type of scale, then you're now going to start to create some pretty substantial delays in your overall operations.

Maintaining compliance, this gets back to compliance continuing to evolve, whether it'd be through updated guidance, interpretation, new standards, new trade partner requirements. Being able to deploy new capability into the market

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rapidly, that does not disrupt your operations or the integrations that you have with your different suppliers.

That extends into managing exceptions. Being able to manage exceptions, whether it'd be through creating those exceptions through user interface and an API, and then being able to collaborate on those exceptions with a wholesaler, potentially with the manufacturer.

Then having the dashboards available to you to understand, are you trending in the right direction or not with particular suppliers that you're operating with. We'll go more deeply into this topic and TraceLink solution in this area as part of the December 22nd webinar.

Then finally ensuring supply and making sure that, if we're operating on this network, that we have the ability to and glean information to improve things like drug shortage detection, and recall execution.

With that as a backdrop, let's ask you as part of the survey question here. When you're considering your organization's objectives for DSCSA, what is most important for you? How are you starting to think about this? Is it the most cost-effective integrations with your suppliers? Not your customers, but your suppliers.

Is it challenges around scalability being able to process DSCSA transactions that are going to introduce the substantial amount of data inside your business systems? Being able to comply with the various evolution of the regulations.

Or are you looking to be able to exercise the investments that you've made in DSCSA to look at challenges around drug shortages? Or is it optimizing recalls, and being able to drive better performance of how you identify recalled products that are in your possession, and being able to extract them out of inventory?

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It looks like we have a good group of respondents already. We'll give it a few more seconds here. Three, two, one. We'll take a quick look at the results. This is maybe not surprising. For this particular segment, the dispenser segment, many of you recognize what we went through in 2015 and '16 as things were continuing to evolve around ASNs.

You recognized that evolution that we're continuing to go through as we've moved to item-level traceability. Really starting to focus, how do I ensure that I maintain compliance all of the time?

Then some of you, also looking at and recognizing there's a lot of data here, there's a lot of transactions here. I'm moving to an electronic world where I'm exchanging information electronically, maybe not relying on paper anymore. How do I ensure that I can incorporate this into my operations, and do that without significantly disrupting those operations?

We'll share these results with you as part of an upcoming readout when we share the materials with you.

What I'd like to do now is pass it over to my colleague Bharath, who can talk a little bit more about product availability intelligence and what we're doing in that area. Bharath.

Bharath Sundararaman: Thank you, Dan. Product availability intelligence is our solution, TraceLink solution to provide an early warning of drug shortages, which Dan has referred to several times already in this presentation. Let's get into it.

How did this come about? Back in 2020, at the peak of COVID, we pulled together TraceLink, an executive forum that we called the Collective Intelligence Executive Forum.

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We invited industry leaders and decision-makers from these leading companies to talk together on what is it that TraceLink could be doing with all the valuable data on our network to drive value beyond DSCSA.

Dan's referred to this several times also in this presentation. One of the biggest differentiators for TraceLink is a network. That's what allows us to help customers communicate and collaborate and interoperate with each other to exchange serialized data. That's what allows us also to go beyond serialization compliance, to work on things like predicting drug shortages.

This compelling forum and you can see the brands on the screen here came together and prioritized a whole list of use cases on what we could do with the data on our network. The number one use case, the most pressing need across the board.

Unanimous vote was, please give us an early warning of drug shortages, because every one of us in the chain suffer when there is unforeseen shortages. Most importantly, it's the patients that suffer the most.

We all feel helpless in just reacting to shortages when they happen as opposed to having any means to get proactive and get ahead of potential supply crisis.

Some of you might be seeing in the news. There's been a lot of coverage on Lidocaine shortage issues and more recently, Amoxicillin. This has been happening as you all know, well before COVID, but especially after COVID, it has exacerbated the issue of shortages.

We at TraceLink strongly believe with guidance from industry leaders that there's no better time to go after this critical industry problem, and the enabler to go after the problem is DSCSA and all the data from DSCSA. Maybe Dan, if you can go to

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the next slide, I'll say a few more words.

What have we done with product availability intelligence in response to this number one ask on drug shortages? We took the feedback from the forum, which as I said, started back in 2020.

One year later, we put our money where our mouth is, so to speak, in coming out with an actual solution, not just brainstorming and discussions, but here's a product that gets out of shortages.

The first output was predicting shortages 10 days in advance at 90 percent accuracy in the US. As you would expect, the feedback was, "Hey that's great, but there's not much I can do in 10 days. You know, it doesn't even give me enough time to communicate to patients that there might be a supply risk, I need a better head's up. Can you please go back to the drawing board and give me a little bit more of an early warning."

That's what we did this year is we came back with the next reiteration of that solution to now be able to predict shortages up to 90 days in advance, still with high accuracy.

Every health system or pharmacy that is picked though is drawn to that because what I hear is that every single week there is at least a handful of unforeseen shortages that cause a lot of chaos and takes the focus away from taking care of the patients. There is a lot of value in being able to provide that feasibility.

In the future, the goal is to go even further up, up to 180 days in advance, so it truly gives enough time to respond and get ahead of the shortage. The goal here is not only to predict and provide a warning.

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Even help drug shortages to improve the patient experience, to improve their access to health, to lower drug sourcing costs for you -- folks on the call -- because we all know that when you have to switch to an alternate drug, it costs you a lot more when you go off contract and the big problem of excessive labor overhead when shortages hit, multiple functions get pulled in, and it distracts you from things that matter the most.

That's another important goal we have. It's all about the patients, but we also want to help you manage your budget, save your labor to work on important projects, and help the industry get over this problem of drug shortages.

That's our mission, passion, obsession, so I look forward to more opportunities to speak about this with you.

Dan: Great. Thank you, Bharath. I just want to reinforce the work that's being done here and something that was not really possible previously when we weren't operating in a digital world. Of course, as we move to item-level traceability, it certainly gives us much more information that we're able to make decisions on and start to drive our particular algorithms.

This is a great example of making a strategic decision within your organizations. Do I want to address DSCSA with a point solution or do I want to take a more of a platform approach that is a solution that's part of an overall infrastructure and platform that helps me manage my supply chain better?

Product availability intelligence is the first example of an application there, but you can see the use cases are multiple, as you start to look at supply chain visibility and recalls and expiry management, some of the things that we can do by operating on a network. With that, I know we're running right up against the clock here.

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What I would like to do is just call your attention to the next webinar, which will be...This is the week of Thanksgiving. We've moved it to Tuesday, November 22nd. This is where we'll dive much deeper into how a dispenser transitions from lot-level traceability to item-level traceability and really things that you should look out for, recommendations on your deployment.

I encourage you, if you look at the webinar series, we're taking a step-by-step approach as you start to go down this journey of achieving compliance.

We'll be joined again by Allan, another gentleman who many of you know, Jeff Agersea, who heads up our customer support area and more specifically our host operations, to really talk about what to be prepared for as we move from lot level to item level.

The final point that I'll make is, really I hope you recognized here that, digitalization is no longer a nice to have, but really a business imperative for our supply chains. DSCSA, as we think about it is really a, an opportunity to advance, your capability in that area of digitalization.

We have a lot to do, it is a step change over what you're doing today. We must be prepared to receive information electronically, manage item level traceability exceptions, verify product, trace that product, but thinking about that thoughtful approach if you take a strategic approach to your solution, what opportunities that creates and Bharath has given us some examples around that.

I know we are one minute past our time, there's a whole host of questions that have come in. What I will say because I know we've kept you longer than we expected. We will get back to each of you individually. I will address one of the questions where we will make this material available to you, the slides as well as the recording.

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We certainly appreciate you joining us today. If you're an existing customer, we really appreciate your business and partnership. Please contact your account executive, to get started on your 2023 projects. If you require a solution or you're considering a solution, certainly reach out to us at marketing at tracelink.com.

We can do a DSCSA assessment. If you're just stepping into this, if you have a solution that maybe you want to see, a comparison, we'd be happy to conduct that comparison against your current approach or your current solution.

I thank you for your time today. I look forward to meeting with you on a regular basis to help you on your DSCSA journey. Thank you, Alan. Thank you, Bharath for joining us, and enjoy the rest of your day. Thank you, everyone.

Allan: Bye everybody.

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