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DSCSA 2023 Compliance: A Step-By-Step Guide to November 2023





Your pharmacy's **FDA DSCSA 2023 compliance deadline** is November 27, 2023! **Health systems and retail pharmacies** will be required to receive electronic transactions that include serialization and item-level traceability data that must match the physical receipt. When electronic data does not match the drugs received, the receipt must be quarantined and the exception resolved before the product can be stocked. That's why you need to get ready now.

Watch our on-demand webinar, "**DSCSA 2023 Compliance: A Step-By-Step Guide to November 2023**" and you'll get a step-by-step guide to achieving compliance before the deadline while improving operational efficiency and patient care. Watch the webinar to:

- See how the **TraceLink network platform** simplifies fully interoperable and seamless EPCIS data exchange with your suppliers, and get an overview of our fast and easy supplier onboarding process. Most of your drug suppliers are already on the TraceLink network!

- Meet the **TraceLink Healthcare Operations Services Team** (HOST), which

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provides support services and shoulders your compliance workload by managing product, partner, and company master data; paper-to-digital processing; continuous quality control checks; exception handling; and document preparation for audits.

- Learn how the TraceLink Customer Success Team continues to support health systems and retail pharmacies after they implement the TraceLink platform by sharing monthly statistics and holding quarterly business reviews.

You'll also learn how our compliance solution yields additional benefits by leveraging serialized receiving and scanning tools to improve inventory accuracy and speed up recalls. Fill out the form on this page to watch the webinar now!

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Transcript

Dan Walles: Thank you, Melanie, and good morning everyone. Thank you for joining us for our webinar series today, focusing on dispensers. I'm joined by a number of my colleagues that have various roles within our healthcare organization.

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Kate Fitzpatrick, who is our Director of Customer Success for Health Care.

Caitlin Czulada, who's our Director of Center of Excellence and focuses on all of our traceability products.

Jeff Agersea, who's a manager within our customer service organization and responsible for our post service out to our dispenser customers.

My name's Dan Wallace. I'm the General Manager of the track and trace and compliance business here at TraceLink.

We want to talk to you about an important topic related to DSCSA, and that's how do we get started and meet this timeline that's coming at us fairly quickly in November.

We want to lay out the journey of steps and activities that we're recommending that our customers take, as well as prospects that we're working within the dispenser community, whether they're health systems or retail pharmacies.

Before we get started, just a presentation disclaimer in terms of the information that we're presenting here today. We're presenting this information for discussion purposes. As I mentioned, this has been a series of webinars that we've conducted going back to November of last year.

We're starting to wind down on the series, but we will be restarting at the end of February, beginning of March, with some additional topics where we expect to bring in a number of our customers, where they can talk to you about their experiences directly in terms of preparing for and deploying DSCSA.

Today's topic will be available as a recording, and we hope that you get a chance

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to join us on the 16th where we talk about some of the business value associated with your DSCSA investments.

Let's jump into today's webinar. The focus of today is to outline the steps that we believe dispensers' health systems and retail pharmacies should be taking as part of their journey to compliance in November of 2023.

One of the things that we do want to include in this is really looking at the activities that a customer would perform. As well some of the differentiating value that TraceLink adds in terms of the activities that we're performing on your behalf as your compliance partner.

Then we also want to talk about some of the corresponding benefits that TraceLink provides post-implementation, largely through our host services.

In terms of a recap, as many of you are familiar with, TraceLink has been pursuing traceability and serialization in compliance since 2009 and many in the organization, myself included, have really built a career on helping customers in the area of traceability specifically around pharmaceuticals.

We're approaching 1,300 customers globally, over 900 of them are actively serializing. Within that, although it may not be on this screen, we have about 300 of our customers in that dispenser segment, whether they're a health system or retail pharmacy.

I think a couple of items to really hone in on in terms of this is with November requiring item-level traceability for dispensers. It's important that as you're evaluating solutions, looking at partners, looking at your processes, that you really take into account the experience that companies have. Not just from a technology perspective but also from a services and support perspective around managing

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item-level traceability. Most notably serialization and the DSCSA compliance information.

If you look over at the right-hand side here, our experience in this area is quite deep—44 billion serialized units track through the TraceLink network and approaching almost a billion transaction histories. That's a billion transaction histories tracking the chain of custody of medicines as they flow through the U.S. supply chain.

That's a U.S.-specific metric there. Then in terms of the number of GTINs that we're actively managing within the TraceLink network, we're approaching almost 50,000. When you look at that in terms of the total number of GTINs that are in the market, we represent well over half of the products flowing through the U.S. supply chain today, almost approaching two-thirds of those products.

What our experience has led to when we talk to companies like yourself in the health system and retail pharmacy space, it's led to a discussion around the challenges that they're having in managing their supply chain.

I think we're all familiar with some of the challenges we've had based on the COVID pandemic with not having great visibility into where products are. Although the health systems and retail pharmacies are located here in the U.S., your supply chains are obviously global. Having visibility into an API material shortage or a shipment delay becomes quite valuable to you as you look to meet the demand of your customers and your patients.

When we talk at the executive level within health systems and retail pharmacies, they're certainly concerned about traceability from a compliance perspective. But areas such as visibility, better collaboration with their suppliers, ensuring that suppliers are meeting requirements around sustainability become quite important.

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What this leads to is a number of efforts happening within our customer base around supply chain digitalization. Digitalizing the supply chain is becoming a business imperative, not just the processes inside our four walls as a company, but digitalizing the processes that we have with our suppliers and our supplier's suppliers across the supply chain.

That's led to this need of what we refer to as the Internet of Supply Chains, a platform that's able to link people, processes, systems, and enterprises together into a collective information network, which allows us to be able to execute those business processes in a more intelligent way and provide information to us to be able to optimize our execution.

What that spoke to is what we need as an industry in order to be able to create that Internet of Supply Chains, to be able to digitalize the supply chain. It comes down to having a network platform, being able to create a set of networks around different processes. Today, we're going to talk to you a lot about the compliance process.

Think about how you digitalize other processes between yourself and your suppliers and being able to share those processes across a network through applications, whether they be things like Product Track or exchanging purchase orders or invoices, and being able to execute across those processes. Not just inside our four walls, but with companies outside with my suppliers as well.

What's unique to TraceLink in terms of how we go through and we execute this is not just in the ability to create those networks, but to be able to establish a common data model for the industry by which that information flows through.

When you execute a network in that fashion, and you have that network data model it results in an incredibly clean and actionable dataset for the industry, for

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health systems, for retail pharmacies, the wholesalers, and the manufacturers.

With that clean dataset, representing the movement of products in our supply chain, we can now start to solve some challenging problems. Things like the optimization of recalls, or being able to detect drug shortages far in advance of what we're able to do today.

We certainly have a lot of work to do as an industry to meet the compliance requirements, but being thoughtful about how we address those requirements sets us up for some pretty substantial value down the road as we look at managing our supply chains in general.

Why does TraceLink feel that it's positioned to be able to do this? When you look at our history as an organization and what we've been doing since 2009, we've really been executing a global case study for what an Internet of Supply Chains platform really is.

If you look at what's been happening around the globe with serialization requirements in markets, not just in the U.S., but in Europe, Russia, China, India, and many of these large markets, these BRIC countries, we've been able to establish this network that is managing the exchange of serialization and traceability information from suppliers, contract manufacturers, packagers, through pharmaceutical manufacturers, distributors, and ultimately out to you, healthcare and retail pharmacies.

We have this foundation in which the industry has had to execute on a network across global processes that we've had tremendous amounts of success with. That's really led to the formulation of our platform, which is this digital supply network.

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We call it the OPUS platform. That at its foundation is the digital supply network, which provides the tools and capabilities for managing that network, to be able to quickly integrate with your suppliers to be able to exchange information with them.

The use of catalogs, and low-code application development environments, and plug-in frameworks allow us to rapidly deploy applications that make use of that information flowing through the supply chain. Today, we're going to be talking largely about serialization, traceability, and DSCSA in the journey to get you from where you are now to compliance in November.

But think about the investment that you're making in a platform that will really pay dividends in the area of supply chain collaboration, verification, master data sharing, recalls, product availability intelligence, and ultimately where we're heading is in the area of cell and gene therapy orchestration as that becomes a very important evolution in terms of where our industry is heading.

Keep that in mind as we go through this particular presentation as a backdrop. What I'd like to do now is transition just into a quick review of the DSCSA requirements for a dispenser. What we want to do here is paint this in the picture of what you're doing today against what you'll be required to do in 2023.

This is a view of the capabilities that are required by a health system. On the left-hand side, what you're doing today is you may be receiving advanced ship notices, which is currently the carrier of the DSCSA information, the transaction history information, and transaction statement.

As we move to 2023 and your requirement is to ensure that you have this compliance information available to you for each item in your inventory, it starts to introduce new capabilities. It may be mobile scanning as you start to incorporate compliance into your receiving process, integrations with your pharmacy systems.

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Serialization has introduced new master data elements, things like GTIN and new pack-level master data elements. The exchange of that compliance information is moving from the ASN, which is a EDI technology that goes back almost 50 years, to this new XML-based EPCIS format that is better suited to handling the massive amounts of data that we'll have with serialization.

Then new use case requirements, requirements for verifying product, whether it be part of a suspect or illegitimate product investigation. For those of you that also have wholesaler operations, you have a saleable return verification requirement as well.

As we track things at the item-level, we'll have new exceptions that are introduced that we'll need to collaborate with our suppliers on to be able to reconcile those exceptions. Requirements around Authorized Trading Partners, product tracing, and then new recall status.

The FDA has made it clear that they want to be able to use the tools introduced by DSCSA to better execute recalls and retrieve products off the shelves and out of inventory much faster than we're capable of doing today.

When we look at our solution for pharmacies specifically, it's clearly this serialization aspect, being able to manage serial numbers, incorporate serialization data into your operations, manage that master data, and receive master data from the manufacturers.

Also be able to meet your compliance requirements, verification, through our VRS solution, and then product tracing, which is really being able to assemble that chain of custody for products essentially in real-time or on-demand as part of an investigation.

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With that, there's capabilities to now direct analytics tools, things like Serialized Process Intelligence or Supply Chain Work Management to be able to facilitate understanding where exceptions are happening, how do I collaborate on those exceptions, troubleshooting those exceptions within my operations, then ultimately being able to support the training of your staff through TraceLink University.

Then HOST, a service that many of you are familiar with where TraceLink takes on a lot of the overall administration and care and feeding of the system in terms of adding users, getting users trained, managing exceptions, and providing audit support. Jeff will walk us through some of those capabilities here in a few moments.

Then finally, as we spoke earlier, looking at that investment in DSCSA. How do I now start to address other critical business processes and our Product Availability Intelligence solution, which we're in the process of deploying to the market today, that now detects drug shortages in the market 90 days in advance—a substantial improvement over what the industry average is today at about 10 days.

Then our digital recall solution, which is really focused on optimizing the distribution of recall notifications and being able to quickly identify the impact of a recall against product that I've received at my health system or at my pharmacy.

You're starting to see here through DSCSA, this tightly integrated approach of not just providing a point solution but setting you up to start to manage your supply chain in a much more optimized way.

Finally, what I'd like to do is call out here, some guidance from ASHP and want to be clear, this is excerpts from a document from ASHP. You can see the URL there, and I've embedded it in a QR code for those that want to take a snapshot of that.

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They've done a nice job here of laying out the high-level new responsibilities for dispensers in 2023, talking about that exchange of the TI and the TS. Making sure that the products you receive are serialized with that product identifier. Requirements for verifying the identifier, Authorized Trading Partners, interoperable electronic systems for exchanging that information, and then saleable returns verification.

A couple of things to call out here is many of you are relying on things like physical paper and packing slips. As you can see here, particularly through a number of these, that the requirements require us to move to an interoperable, secure, electronic system to exchange this information.

In addition to that, key considerations for compliance, and I won't go through each of these, but I think what was well stated here was three things you should be doing now to prepare for DSCSA compliance. We'll talk about these. These fit very much into our journey.

Being able to identify your team, you should have a team in place now. If you don't, I would strongly recommend that you start assembling your team with representation from obviously your pharmacy organization, if you have a pharmacy operations team, your IT organization. Then, of course, compliance and legal to start to study and understand the regulation, understand the impact to you, understand what your risk profile is in terms of complying with that regulation.

Assess your technology needs and your solution needs, and then start to look at the current standards for determining where you are positioned for 2023. Are you ready?

We know many of you are in the process of getting ready while some of you

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haven't started just yet, but are starting to put your projects in place. With it being February now, and the requirement going into effect in November, it's rapidly approaching.

What I'd like to do now is hand it over to my colleague Kate Fitzpatrick, who's going to walk you through what we refer to as the dispenser journey.

It takes those steps that you would execute in a project and start to map them into phases, not just dealing with the implementation aspect but also dealing with the larger project and program management. Kate?

Kate Fitzpatrick: Great. Thank you very much, Dan. Thanks also for bringing up the ASHP information that we shared. They play a tremendous role in informing pharmacies about regulatory changes and providing great high-level information like that.

One of TraceLink's customers, Sentara Health, actually was selected and presented a poster session at ASHP's most recent mid-year session about their journey on DSCSA and with TraceLink.

With that, this is geared to folks whether you're managing your DSCSA in-house now or potentially with some sort of hybrid approach.

As Dan went over, the scope and change required for November ushers in a new set of capabilities that pharmacies and dispensers must have in order to comply with the regulation, while also balancing and mitigating the impact on their supply chain and pharmacy operations.

When we look at this journey, it's really based on TraceLink with over hundreds of dispenser customers having worked with them for 10 years from lot-level all the

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way through to some doing serialization and scanning now. That's what this journey is based on, those many years of experience with many, many customers.

When you think about change management and with November quickly approaching, one of the big keys is going to be getting your organization aware and ready of the changes.

If you go to different forums or you've listened to different seminars, it's important to make sure that you, on this call or in any of the associations, bring back to your organization the need to be ready and create that awareness. I'll go into a little bit more of that in some of the next slides.

Then the next step is going through discovery requirements and analysis. That's at a point where does your organization want or need from your solution provider? What's the functionality? What's the support level? Where you're, as a dispenser, developing what you need so that you can go to the market and select the best solution provider for you.

Next phase is deploying the solution. That's getting it live, all of that interoperability, your suppliers connected, and getting users engaged. Then you settle into business as usual. That's where TraceLink really features a lot of support with our HOST team, a lot of account engagement with account managers, showing you report cards, benefits, and tracking some key metrics for you.

Stage five, as Dan said, is building upon your implementation for DSCSA to create that additional business value. You can think of your implementation, if done thoughtfully of DSCSA to meet the November requirements, has already built that foundation for you.

You would have that interoperability, the network, your business processes to be

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able to leverage the additional business value that TraceLink provides. That's the high level of the journey. If we proceed to the next slide, I'm going to go into that first step, which is organizational awareness and support. Creating awareness in a sense of urgency will help secure a business sponsor.

Identifying somebody that can sponsor your project in your organization, prioritize a project, align resources—that really will drive your ultimate success in November. It also allows you, when you're working with that sponsor, to let the sponsor know that there's the implementation of the compliance requirements, but then there's this huge upside of value creation if it's done thoughtfully.

We'll go into that a bit more on the value creation. I want to go over some of the teams that you'll want to get involved, at a minimum.

Pharmacy at its core, DSCSA is designed to protect patients through the supply chain. Your pharmacy teams need to be aware of these changes and to what extent these regulations will impact their workflows and SOPs.

Your regulatory and compliance teams. They can provide guidance and direction on the best strategy for your organization. They manage risk at a corporate level. They need to be aware of the risks associated with non-compliance and how it could impact any audits that come along. When we get down to business as usual, you'll see that audits do happen. We have a tremendous experience at TraceLink supporting our customers with audits. It's key that your regulatory and compliance teams are aware of the FDA requirement, and then also that there is enforcements and audits around it, where they're coming in and looking specifically for DSCSA information.

Your information technology teams and departments are going to be really important. You want to make sure as you're thinking about what you want your

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solution and your workflows to be. Are you looking to integrate with other systems? TraceLink has APIs and we integrate with many other systems that do require some IT folks to be involved. To help you understand the scope of change and to support that change.

Dan mentioned that one of the requirements or features and capabilities is the ability to understand at receipt if you've got your compliance data.

You could potentially be rolling out support of hardware that, again, would need IT support to get that up and running. Getting those key team members together, creating a core team, and making sure that you have a project sponsor's essential at this stage.

One of the things that you'll want to do at this stage as well, and I want to take a little bit of a deeper dive on this, is really look at pharmacy and compliance. As you develop your requirements, think about what are you doing now? What's your procurement process like from an SOP?

Compare that to some of the FDA guidance. They had some tremendous guidance back in 2021 on hints and signs about what could significantly increase the risk of suspect product entering the supply chain.

The other SOPs that you'll want to pull out and make sure that you have handy to see if they're going to meet the needs are TI and TS, serialized information, transaction stored in a secure environment, verification of packages on receipts, the labeling, etc., managing any suspect or illegitimate product, which is your quarantine policy. What triggers something like that to go into quarantine?

All of those are some of the SOPs that we've worked with our customers on. Ultimately, the customers, you own your SOPs, they help you enforce and codify

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your compliance strategy.

With our experience and our expertise in the field, we bring a lot of value to our customers as they go through this process. That's the awareness and support. If we can skip down to some requirements analysis and discovery. Great.

At this point, ideally, your team is put together. You've got a sponsor, you've got a sense of urgency that you need to do something and do it pretty quickly because November's coming. You should have your framework and your objectives for where you want to end up by November defined.

Hopefully, you've identified some gaps in where you want to be between what you're doing now and what you'll be doing in November. You can, with this team and as part of the analysis and discovery by working with vendors and looking at solution providers, refine what is going to be the best approach for your organization.

As you look at different organizations, some of the key areas that you'll want to consider and activities are, what is their experience to date? What's the depth of their experience to date with healthcare systems and retailers? How long have they been working with them? What have the results been? How successful have they been at network coverage?

Because you do need a network with all of your suppliers and it needs to be interoperable. You're going to want to probe those questions and you're going to want to see demonstrations.

Dan had also mentioned on an earlier slide, the operational component. You're going to want to understand what kit type of dedicated support there is for dispensers. We have a HOST team that is dedicated to dispensers because you

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want a team with any solution provider that knows your business, knows the importance of efficient workflows in minimizing operational impacts. I think that's another area that you should really look at, so that in the long run you're not surprised come November or December when you're not getting the support you need for an audit or there's lack of available training to onboard new staff members.

Those are really some key areas to look out for. As you go through your discovery process, you'll want a partner that can sit with you and help you look thoroughly at your current state and then help you develop based on their expertise through a design or an assessment session of what you want your future to look like.

That you don't have a vendor coming in and saying this is what you must do, A, B, C, and D. That you have a partner that can sit and listen to your current state, understand where you want to go, identify those gaps with you, and then create the solution to bridge those gaps.

That's what this entire phase is about. If we skip onto the next slide, we've got a handy summary for folks on the key requirements to be successful. This is driven by those step changes that we saw.

One of the things that you'll want to think about is those multi-enterprise capabilities. They're under here. Do folks have electronic interoperable systems in place with all of your suppliers? Do they only have a few? What's their recall like a network analysis? What's the network coverage that they can give to you right out of the box that takes away any work that your teams would need to do?

It allows your organization to also be ready for EPCIS transactions. If you're looking at a solution partner, you want to make sure you know where that partner is as far as onboarding the upstream suppliers and making sure that they're ready and

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sending the serialized data in the new format of EPCIS. Because you don't want to find out after you've made a decision or sometime in July or August or in September, that a vast majority of your suppliers are not going to be sending EPCIS because it hasn't been tested by your solution provider. That's a big one I'd be looking for.

Another one that is new and pretty outstanding, and we did another webinar for it earlier this year, is looking at the key requirements for a solution provider. TraceLink, it's secure, it's interoperable, it allows you to search, create reports, anything you would need for audit purposes or tracking and tracing purposes.

When you look at the functionality required for November, where would a potential vendor be on something to support you with any verification? We had one of our sessions that went through our verification functionality. You're going to want to see a demo of that, make sure that it works and you've seen it and it's not vaporware.

The other part that we talked about a little bit is making sure that if your compliance strategy for your organization wants you to reconcile your product with the electronic compliance data, which is what the law requires, what tools and support would a solution provider have for you to do that?

TraceLink has many options. We've gone over a few in our other presentations. We've got a scanning application that can do it right at receipt. Then there's other ways to do it within the app.

You're going to want flexibility there because it may not be a one-size-fits-all for your entire organization, but you are going to want a solution provider that does offer you that.

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In closing, I think we'll get on to HOST a little bit more, but I can't emphasize enough how important a dedicated support team is so that your pharmacists aren't weighed down with extra administrative work.

You'll want to get a clear definition on how they can support you, what they will support you for, and what are those hours of support. This is a pretty handy reference you may want to go back to as you're looking at different solution providers.

With that summary, I will hand it off to the solution implementation and deployment part with my colleague Caitlin Czulada.

Caitlin Czulada: Thank you, Kate. OK, so once you have completed the first two stages and you've selected a solution provider, the next stage is to implement that solution provider's system.

You'll want to make sure that you deploy your TraceLink DSCSA solution for your various different pharmacies. If you have multiple locations, rolling that out to all of the operations and ensuring that your operations are ready to meet compliance. As part of this, we'll work with you to define what your strategy is for meeting the DSCSA compliance.

We'll work with you to discuss the scanning strategy. Are you going to scan at all of your pharmacies? Do you want to scan at just the top level? Do you want to spot-check some of the other boxes that are coming in? What really makes sense for you and your operation?

We'll work with you to define all of that strategy and make sure that we put that in place in terms of a system.

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We'll work with your operations team. We'll work with your regulatory and compliance team, your IT team. If we need to install new devices or new software on-site, we'll make sure that the IT team is involved to do that work.

Then on our side, you'll work with a dedicated project team to make sure that they understand your needs and are working with you to set up your system.

One of the things that's really unique to TraceLink is that we also have a dedicated team for all of your suppliers and all of the partners who are not TraceLink customers.

As you are well aware, DSCSA is really about connecting data and connecting companies to exchange that data. It's not just about you. It's really about all of your suppliers.

We've learned over the years that those suppliers also need dedicated contacts at TraceLink, so we have a whole team of people who are dedicated, who understand those partners' business, those partners' IT connections, and will work to make sure that they're connected to you.

In addition, one of the unique things about TraceLink is part of this implementation. Because we have a network, what that means is that your supplier isn't having to create a unique connection for you and your company.

As long as they're already exchanging data with the TraceLink system, it's a simple process of us outreaching on your behalf to get them to start sending data to you. Since the connection is already there, it's a much easier process than with other solution providers that are having to build unique connections for every vendor.

You get to take advantage of all of those connections that Dan mentioned at the

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beginning, all those companies exchanging data. You get to take advantage of the work that was already done.

All we'll do on your behalf is reach out to get that company to start sending on your behalf. It cuts the time down that you need to connect significantly from other vendors that are doing traditional point-to-point.

Some of the key activities as part of the implementation that you'll do, as I mentioned, is we'll work with you to develop those SOPs for compliance. What makes sense for you and your business to meet DSCSA requirements? We'll work with you, we'll try to understand your operations and help you create those SOPs.

The project team here will configure your DSCSA solution. We'll go into the system. We'll make sure it's set up based on the design that we have agreed on. We'll do all of that for you.

As I mentioned earlier, we'll do all of the onboarding and the configuration of your suppliers for you. We'll work with you to get a list of those suppliers, and then we'll do the outreach on your behalf. We'll make sure that you're getting that data, that everything's flowing in the system, and make sure that you're getting regular updates as to where those integrations are.

Any testing that you might want to do so we can support you, and we have a test environment that is dedicated for testing so we can support any testing that may or may not be required.

Then finally, once the system is up and running, we'll want to make sure that your users have access to the system and are fully trained. We do have a dedicated training department as well as on-demand training.

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If you have new employees that are coming in or changing jobs, you always have access to all that material on demand so that it's available should you need it. Then finally, going live with the application and the system.

If we go to the next slide for a second, what does that look like in terms of the timeline? Obviously, you need to sign the contract, that will be done with your procurement department, and then it gets handed over to your project teams.

You'll get a dedicated project team here at TraceLink that will work with you in the second phase to do all of that system setup. What we need from you is your GLNs, that's a global location number issued by GS1. If you're not familiar with that information now, it'll be provided to you as part of the project process.

It's really that key identifier that's used in that data message that gets sent between suppliers. It's the key thing that will work with you to gather. If you don't have it, we can work with you to create them with GS1.

Then TraceLink will go and will configure the system to the main applications that we're going to configure. Dan went through them, but it's all around that serialized data exchange. Configuring the system, doing that onboarding, making sure that we're getting the data, making sure that your VRS system for a suspect investigations (if you happen to be doing so) returns as a wholesaler, we can set that up as well. Then any additional credentialing that you might need to add to meet the Authorized Trading Partner credential requirement.

We'll set that up and then we'll really work with you to do all that onboarding. We need to know who your suppliers are. Then we'll send outreach to them to onboard, to send EPCIS.

As I mentioned a minute ago, if they're already on the network and already

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exchanging data, we don't have to set up a new connection. We just have to tell them to send data to you. It makes things significantly quicker than where their traditional solution provider that's building point-to-point connections. Then we'll notify you the partners are going to have onboarded. We'll provide you with regular updates on the things that are happening.

That can vary in time depending on how quickly your vendors are, how many vendors you do have. The more vendors you have, the longer it'll take. We'll work with you to provide you regular updates between now and the time that all of your vendors are onboarded.

Once the system is up and running then we'll provide user access and training. As I mentioned, I will make sure you have access to the system and then have those materials available to you on demand, as well as any in-person training that you might want to do.

From there, we have the existing clients. Ongoing, what does that look like? How are you accessing the system, and how are you being compliant with DSCSA? Kate, I will turn it back to you.

Kate: If we could hand it over to Jeff Agersea to go over business as usual and how we support our customers there, that would be great.

Jeff Agersea: Thank you, Kate. Basically, once you get through implementation, the question is where do you go from there? You're trying to get what your day-to-day business is going to be and what's going to be going on after that.

We are here to help you manage your compliance as a standard process. We do this through a whole bunch of different systems, proactive exception management. We have a number of systems in place to deal with exceptions.

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These could be workflow exceptions or data exceptions. We have a staff who's been trained in working on these for years, and we try to deal with a lot of these proactively. Our goal is to deal with them so you never even see them, they're done and fixed before they even become a problem.

We have Supply Chain Work Management to help you manage all of these or anything that we can't manage proactively. We have additional services to help out with that.

Over time, your business is going to change. We have to onboard new vendors. We do this every single day. Anytime you have a new vendor, we help you onboard them. Make sure they're sending a day view or sometimes you have a new account you set up with the same vendor and we help you get that configured as well.

Audit support is one of our biggest services we offer. Most companies can go years without seeing an audit, then all of a sudden you have 48 hours to comply with an audit request. This is panic-inducing to companies, but we have a lot of experience. We helped with an audit just last week and we are always ready to help out. We can turn these around in hours, sometimes even faster if you can let us know ahead of time. So you can rest assured that we know what we're doing and we're prepared for this.

Through the course of business, you'll also have new users come on board. We have all the training options. We have regular monthly training that's available online. We have a landing page with all resources, including recorded trainings as well as some specialized individual trainings documentation that we can give to you to cover any individual topics you may have.

Finally, we have the executive business review meetings. These help you go through and make sure you're meeting all your goals with TraceLink. Make sure

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you're compliant where you need to be. View your company at a high-level and make sure you're doing what you need to do. We can also share any industry updates or information that may be relevant to you.

I also saw a question come through talking about switching from ASNs to EPCIS. One of the things that's very important is, if we have our customers set up right now receiving ASNs, if one of the vendors wanted to switch to EPCIS today, we're ready to receive that data. They can make that switch over.

It's virtually zero effort to change over. You see them both at the same time and we are ready to do that. All right. Kate, I'll hand it back to you.

Kate: Great. Thanks. Let me start the wrap-up. Now you know if you think about the phases, your business is usual. You're ready before November. You worked out any tweaks. You've got this foundation and we keep emphasizing the network, the scalability, the integration.

With the TraceLink solution for DSCSA, you have all of that. From there, it's very easy for organizations and dispensers in particular to work with TraceLink and learn more about and understand “how can I leverage all of this serialized data to improve my supply chain visibility? Improve my ability to handle specific exceptions?” Because it's already built-in.

In this value realization phase, you want to keep that team together. You want to see where you are in your steady-state and see within your broader supply chain and with leadership that since you've already created this network in the entire foundation, what other business problems can you tackle?

We've mentioned so far improving the recall process, so alerts for recalls, finding out what you received to recall, because remember it's all serialized data now, and

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then helping understand what's been pulled or sent back for recalls.

There's the product availability. Again, making sure that you leverage DSCSA data and the TraceLink platform to help you ensure that your patients have the medications and products that they need when they need it, all built upon your foundation of DSCSA.

Then as Jeff mentioned for more enhanced exception management, we have Supply Chain Work Management specifically designed for DSCSA but Supply Chain Work Management at TraceLink has other offerings too with other suppliers for other incidents.

We also as I said have one specifically for the exceptions handling for DSCSA. With the foundation of DSCSA, you've basically created that network. You've onboarded your partners, you've got your workflows together.

You've got your user access. You're using the system. You've got the data in the system. It's the perfect opportunity to take it to the next level, which is to get that value realization in addition to the compliance benefits. That is stage five and we would like to see everybody end up.

Going forward on the timeline. I wanted to be careful with our time speaking of timelines and looking at the key activity. These are those milestones in that journey. November isn't very far off and having worked at health systems primarily for over 20 years of my career, getting that organizational awareness and support can take a bit of time.

If you don't have it now, you're going to want to go back and emphasize and create the understanding and that need for change and the urgency because November's coming and it's not going to change. It's a law.

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That's one that you'll want to make sure that you have your awareness. You have the folks in your organization aware. You've got a team and a sponsor so that within the next six weeks, by the end of March, early April, you're out looking at vendors.

We went through what you should look for when you're looking for a solution provider. You should give yourself six to eight weeks to do that because again, you want a solution provider that's not going to give you a cookie-cutter solution. You want a solution provider that's going to understand what you're currently doing, what you want to be doing, and not one-size-fits-all. You want a solution provider that's going to help you get to where you want to go. Then you're going to need to leave time for the implementation in the solution deployment. Ms. Caitlin went over.

There's some key steps with onboarding your partners and then ultimately getting all of your users trained, and then transitioning to business as usual before November.

My goal, having done probably more EMR implementations and I'd like to admit, you want to be done before the due date so you can work out any workflow issues, you can refine anything, you can start tracking your key metrics.

How many active users are looking at the system? How many transaction histories am I getting? Who am I getting these transaction histories from? Validating that and also validating any of your reconciliation processes and making sure that those are optimized for you before November.

That's the timeline to get yourself ready by November based on our journey. We hope that it's provided you with a lot of value and help you realize that starting now is very important because these steps do take time, particularly in the

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dispenser world getting that alignment buy-in, getting purchases made.

We wanted to supply you with everything that you'd need so that you can hit the ground running and be ready by November.

I think the next one is, I wanted to go over with you folks. A quick checklist again. Another handy reminder to help you get ready a little cheat sheet for serialized data exchange.

Caitlin talked about creating and sharing a GLN. If you don't have it with TraceLink as your partner, we can help you find it or help you get one. Onboarding those suppliers that they're sending the transaction information that is serialized which is very different than the ASN transactions.

You're receiving, in reconciliation strategy, SOPs for checking that you receive T2 data and that it matches the product identifiers, what you've received.

Suspect and illegitimate product verification, you want to enable the VRS system, perform those verification requests, and then create those SOPs. I talked about those early on for suspect and illegitimate product investigations. Credentialing and trade partner authentication, determine your approach to verifying trade partners and create credentials for verified trade partners if you need to.

Those are some of the key things and milestones that I'd be looking at if I were a leader within a health system and I'm working with my project team. This is a guide and a quick reference for really what you need to get done.

With that, I will hand it over to Dan for a quick wrap-up.

Dan: One thing I'd like to touch upon is I hope what we've got from this part of the

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presentation is an appreciation for the amount of work that has to happen.

Some of the initial mindset might be we're just moving from one version of a file in ASN to another version of a file. As you peel that onion back, there's more that is involved in that particular process.

We have a number of questions that have come in. What I'd like to do is maybe go to a quick poll. I'll try to answer a couple of the questions that have come in, and then we'll be able to wrap up.

If we can take a couple of moments here, did you find the information presented today helpful for you, and would you like somebody to follow up with you for more information on this particular topic or perhaps other DSCSA-related topics?

You can just take a few moments there. It looks like some people are just catching up with that.

What I'd like to do now is there's a couple of questions. If we don't get to your questions, I want to be respectful of folks' time. If we don't get to your questions, we'll certainly reach out to you directly to provide that information and some insights to you.

One of these I thought was an important topic. The question was, what does the FDA require in terms of which item-level to scan at when products are being received? There's a lot to unpack there. First and foremost, the FDA does not dictate what level of scanning, or even if any scanning is done at all.

What the FDA and the law states is that the dispenser or anyone on the supply chain must be able to prove that they have the required compliance information available to them for items that they receive. This comes down to what is the

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decision that a health system or retail pharmacy wants to make in complying with that?

Now, if we didn't have day jobs if you will, then we would go through and we would check each individual item and retrieve the compliance information related to that item. That's certainly a strategy that some of our customers are taking. They're scanning each item and ensuring that the required compliance documentation is there.

We have other clients that are taking, I'd say more a risk-adjusted approach around that, where they are assuming that the information has been sent to them for all of the products being received to them and that their suppliers are doing what they're required under the law if you will. Then they're doing some sampling and sampling on a variety of criteria.

It may be quantities, it may be a certain part of a shipment, it may be at specific locations. We've seen a wide variety of uses, but then doing some sampling and saying, I'm going to scan these items and ensure that I have the compliance information and it's correct, in a sense of auditing their processes and that the information has been received.

I think that's really a key part of ramping up your project, is establishing where you want to be on that continuum of reconciling the physical item to the compliance materials.

Now, TraceLink solution supports both of those use cases and I would love to have the opportunity to discuss that with you but that's probably one of the key points that companies need to review with their project teams because it does have a tremendous impact on your operations.

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This particular person who submitted the question talked about their pharmacy technicians. All of the pharmacies are clearly overloaded with work. Staffing is a challenge. Training is a challenge. We really want to think about how do we balance the risk around this process, and we'd love to have the opportunity to chat with you about that.

I know we are up against the clock here, so one thing that I would like to call out, I'm going to just go quickly to...For those that are able, we have our FutureLink conference in Boston, coming up in May of this year. We will certainly talk about DSCSA compliance, it will be a big focus of the conference.

This is also an opportunity where we really try to provide more thought leadership topics to the industry in which we bring together senior supply chain members from not just the healthcare side of our business, but also the pharmaceutical manufacturer's as well as distributors.

To talk about how we can help solve some of these large supply chain challenge problems. This year's theme is around orchestrating the end-to-end supply chain. Then the final thing I'll bring up is our community group. If you are an existing TraceLink customer, first off, we appreciate being able to partner with you.

If you are not already, please join our DSCSA community group where we're going through and we're talking about getting ready for compliance. This is your place to ask all the questions you want to ask. We think this is an incredibly valuable forum, this is one of the reasons why we restrict it to our customers that have made a commitment to partner with TraceLink.

I'd really encourage you to take advantage of this community forum, where we go into much more detail, bring in our subject matter experts from the company, bring in customers to have some dialogue and collaboration. This group meets

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every two weeks.

With that, I know I am a few minutes over my time. I wish you a good day, and I appreciate your time for spending it with us. Thank you. Have a great day.

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