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4 Must-Have Capabilities for DSCSA 2023 Compliance for Manufacturers





The **compliance deadline for the U.S. Drug Supply Chain Security Act** is less than ten months away—and your organization needs to get ready now! The good news is that the investments you make can provide significant business and operational benefits beyond compliance with the law.

Watch our on-demand webinar, "**4 Must-Have Capabilities for DSCSA 2023 Compliance**," to see how DSCSA compliance on a **digital supply chain network platform** enables quick and complete compliance with the four critical requirements laid out by the FDA:

- Product tracing
- Unit-level product identification
- Product verification

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- Authorized Trading Partner credentialing

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The final phase of the DSCSA mandate goes into effect on November 27, 2023. Arm yourself with the expert insights you need to get ready now and turn DSCSA compliance into a competitive advantage. 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. Welcome to the last of our current series on DSCSA 2023.

Today we thought we would spend the time to do a bit of a recap, but somewhat of a summary around DSCSA 2023 and bubbling this up into a couple of key capabilities that are required for DSCSA compliance as the November date rapidly approaches.

Although this is the last in our current series, we will be kicking off another set of

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webinars in the March timeframe where we're going to be hearing from our customers as well as stakeholders in the industry about. Their thoughts around DSCSA, the current status of implementation, what some of their expectations might be from their suppliers and customers. Certainly, more to come throughout the rest of the year.

Today's presentation, TraceLink makes no warranty regarding the information, this is a standard disclaimer here.

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The intent of this information is for discussion purposes and to help educate the market in the area of DSCSA.

Today, I want to talk about a few different things. We will review, at a high level, the requirements for 2023. One of the things I hope that you take away from this is that it's a step change over what manufacturers, wholesalers, and dispensers do today to meet the current lot-level traceability requirements.

As we look at this set of requirements, consolidating the capabilities into four themes essentially, one is this concept of “network”. The DSCSA requirement for traceability is a network challenge. It's different and unique from other markets around the globe, which are more of a central reporting requirement. With DSCSA, it's that requirement to exchange that information securely and electronically between trade partners.

We'll also talk a little bit about scalability and a recognition that item-level

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traceability will introduce substantially more transactional process requirements. Being able to not just store this information, but retrieve information, process the EPCIS transactions at scale so that it does not impact or delay your operations.

The third category is in the area of compliance and a recognition that compliance requirements are something that will continue to evolve up to and after the deadline. We learned this in 2015 with the first milestone for lot-level traceability. We've learned this as we started to roll out serialization as well as some of the ancillary milestones along the way. We have to take that as a given that will continue to evolve as companies become more comfortable with serialization and traceability, they'll introduce more requirements.

Then the fourth category is a recognition that compliance is now a mission-critical application. What I mean by that is, if an organization is not able to either ship or receive the required DSCSA information, they're not able to legally sell or distribute that product if that information is not available. That not only has a direct impact on your operations and the performance of your operations but clearly impacts the patient, which we're all here to jointly serve.

Then we'll wrap it up with some of our experience through some case studies, as well as the investment that we're making throughout various industry organizations to continue to drive a standardized adoption across the industry.

A lot to cover in the next 40-45 minutes or so, but we think that you'll find this particular content valid as we recap what we've been going through since November across a variety of topics.

One of the first things I want to introduce you to is TraceLink as an organization. We were founded in 2009 with a focus to build out a life science and healthcare network to help companies exchange information, particularly around various

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supply chain business processes.

[TraceLink] has been built on the backs of the compliance regulations in the US as well as in other markets around the globe. We have about 1,300 customers today, spread across 50 different countries.

A couple of key things to call out are the number of our customers that are actively serializing product or managing serialized products. A large percentage of our customers are well underway in either creating serial numbers, or as wholesalers receiving serial numbers, or as health systems and retail pharmacies, receiving serialized shipments and receiving in serialized data about those shipments.

Through our network model, called "Integrate once, Interoperate with Everyone," we've created a set of what we call active network service links. This is the connectivity that was previously performed in a point-to-point manner.

TraceLink has now transitioned all of that away from point-to-point integrations into this "Integrate once, Interoperate with Everyone" model to about 340,000 different service links between manufacturers, wholesalers, dispensers, CMOs, and 3PLs.

Over the past 10-12 years or so, [TraceLink] focused on connecting the life sciences supply chain. We're about 800 employees, and the vast majority of our employees spend their time in the R&D space as well as servicing our clients.

We talked in the key takeaway section about how compliance continues to evolve. This is what's led to our investment in both R&D and on the services side to make sure that we're able to keep our customers compliant with various regulations.

Then, in the last column, specifically as it relates to DSCSA and traceability, is just

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the number of serialized units that we're managing within the TraceLink life sciences cloud. In excess of 40 billion and growing on a daily basis, close to a billion transaction histories processed, 885 million transaction histories, and that's at the lot-level.

If you now fast forward to where we have to be in 2023, you can see the amount of transactional scale that a system will need to take that 885 million transaction histories and be tracking it at an item level as opposed to a lot level.

We represent about 50,000 product GTINs, which is more than half of the number of GTINs that are out in the market, whether it be identifying an individual item or a particular case being managed throughout the network. I think access through integration with other lookup directories and other systems to about 85,000 GTINs around the globe with the majority of them representing products being distributed in the U.S. A fair amount of capability, fair amount of investment, very healthy organization that's really focused almost exclusively on helping our customers maintain their compliance.

What our customers are telling us is that, although compliance is often an area that they're focused on and has a certain level of urgency, they talk a lot about the challenges that they face as organizations in just managing their supply chains, and why digitalization of the supply chain has become a business imperative for them.

Whether it be traceability and compliance requirements that we see in the U.S. or in other markets such as Europe, Russia, China, or India, they're focused on how do we just get better visibility, better transparency in our supply chains.

This is being combined also with some of the sustainability efforts happening in other markets, most notably in Europe, as well as Brazil with some work around

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digital leaflets, and then just being able to collaborate better with suppliers around different supply chain issues.

We learned a lot about the resiliency of our supply chains during the pandemic, and we continue to learn about that on a daily basis. It's led to this need of, "How can I deploy platforms that can help me manage my supply chains better, get better visibility into my supply chains?" Compliance and traceability is just one business process related to that.

When we look at that problem, in that challenge in the aggregate, it's led to this concept of being able to link people, processes, enterprise systems, and information together. Not just for information and reporting, but to execute our businesses, to execute our use cases that we have with various suppliers, or with our customers, with direct material suppliers, whatever it might be.

When we think about that in the aggregate in solving that challenge, it breaks down into a set of core capabilities that are needed to integrate across what is really a complex supply chain. That is really being able to create these digital networks across different processes.

Today, we're digitizing the compliance process, the item identification process, but then being able to share those processes and applications across the network, compliance, and DSCSA is inherently a network problem.

I'm not just worried about my operations inside my four walls, I have to be able to collaborate and orchestrate processes with a wholesaler, with my 3PL, or with a CMO, depending on where I sit in the supply chain.

What is unique and differentiated about TraceLink is focusing on making sure that we can exchange the information, but really driving a common data model across

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the network.

If you can think of this in the analogy of driving to some standardization in how we communicate and how we express certain things in our supply chain, that will really help us create a dataset that is very clean, very actionable, and very timely. By creating that common data model like we have within the TraceLink network, it positions TraceLink to do some interesting things.

One of the things we're bringing to market now is in the area of collective intelligence, particularly in the area of drug shortage detection.

In some of the previous webinars, you've heard from my colleague, Bharath Sundararaman. Bharath is heading up our product availability intelligence solution area that is taking advantage of this actionable dataset that is flowing across the network to try to solve some pretty complex and challenging problems.

That's really been the vision. You're probably asking yourself, "How does TraceLink feel that it's positioned to be able to deliver on this network value proposition?" It's really rooted in what we've been focused on over the past 10 years with many of you, and that's this area of global compliance.

This ability to apply unique item identification to individual units, integrate across my trade partners, both direct and indirect, and then to be able to have applications in a platform that helps you govern and execute different business processes that I execute with my partners.

Whether you're on the healthcare side or the distribution side, a manufacturer, CMO, direct material supplier, we've been able to now start to digitize this business process of traceability and compliance.

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When you're making your own investments in your compliance solution, we want to be able to think about, "How can I benefit from this investment that I'm making to solve other supply chain challenges?"

It's really rooted in this digital supply network, in the OPUS platform that we're building out that provides the capability around network administration, this ability to rapidly integrate and exchange information with my trade partners, various software catalogs that provide different applications.

We've talked to many of you about our low-code application development environment and plug-in framework, which using through our solution designer capability enables you to start to build out your own applications, or maybe your system integrator partner that you're using to build out applications on the TraceLink network in building out this solution partner ecosystem.

Today, we're very much focused on serialization and traceability, and regulatory compliance, but that leads into things like better supply chain collaboration. One of the things that we've talked about in the webinar series is this concept of exception management, and knowing that exceptions will occur as we start to track things at the item level.

Just being able to collaborate between companies on a DSCSA exception and resolve that quickly using the tools of the network. Network applications like verification, which is part and parcel to DSCSA, or being able to share GTIN information and master data information across different stakeholders within the supply chain.

Then, of course, digital recalls. Being able to broadcast digital recall messages out across the network to quickly identify where product is in the supply chain, and be able to retrieve it back.

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Collective intelligence to use information that is available on the network to understand the ebbs and flows of the supply chain and how product is moving through the supply chain to determine, are there patterns that we can learn from and make decisions from?

Then ultimately leading up to just being able to fully orchestrate a critical business process, which many of you are focused on today. That is in the area of cell and gene therapy.

Cell and gene therapy really increases the requirements set, the speed required to be able to integrate a number of different stakeholders, where the medicine essentially has a one-to-one relationship with the patient. Those are areas that we're starting to explore with a number of you in terms of how a network platform can enable better capability.

Although we're here to talk today about DSCSA compliance and item-level traceability, you can start to see how this platform that we're building out becomes this Internet of Supply Chains and your way to create these digital networks across different business processes with your partners.

What I'd like to do now is now jump a little bit deeper into DSCSA and again, take a step back as we're about nine months away from the deadline that's rapidly approaching to start to summarize what we've learned over the past couple of months.

I want to go back to a slide from an FDA presentation to ground us in what the FDA is trying to do with the DSCSA regulation. First and foremost, the statement of being able to implement interoperable electronic tracing of products at the package level.

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Moving away from exchanging paper, tracking things that may be the product or the lot-level, and try to use the tools available to us in industry, to drive interoperable electronic tracing.

The reasons for this is to be able to trace product at the package level, to use the product identifiers in various business processes like verification and help the industry respond quickly to suspect and illegitimate product in investigations when they occur.

Then something that's maybe not talked about enough, but a goal with DSCSA is to improve the efficiency of recalls. We know that recalls is part of our industry and starting to focus on how we get better at executing recalls and pulling recalled product and product that may not be safe to distribute and dispense to patients, getting that out of the supply chain and being handled appropriately.

Then of course, the other part of DSCSA was to start to provide some more nationally organized standards for wholesaler and 3PL licensing, which was somewhat scattered and fragmented across the individual states trying to create a national standard in that particular area.

It's important to recognize how the FDA is viewing this particular regulation and what they're trying to do. It's not necessarily a final set of requirements, but building out a toolset that the industry and the FDA can use as part of its toolbox when helping to govern the overall industry.

When we take that and we break that down into "What does this mean from a timeline perspective?" You can look at what this represents from a manufacturer and distributor set of requirements. We'll talk about the dispensers on the next slide.

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The two key milestones that we've been through were really 2015 and then in the 2018 timeframe where we started with lot-level traceability. That's what's in place today. Many of you are using ASNs to communicate that information. Some are still using paper packing slips. Then we moved into the area of serialization.

Then in the 2020 time frame, there was a set of requirements around verification, around salable returns, other verification use cases that, with the pandemic coming at us in 2020, there was some enforcement discretion provided in that area.

That really increased the work that we have to do here by November of 2023. The requirement is around exchanging serialized transaction information, product-identifier verification for not just salable returns but suspect product investigations, product tracing requirements, and then this concept of supporting Authorized Trade Partner credentialing.

On the dispenser side, the spirit of the requirements are quite the same. Although your timelines may be a bit different, I'll focus primarily here on what we have to do in 2023, which is being able to receive that serialized TI and Transaction Statements (TS).

Remember. The transaction history is sunset in 2023, in the spirit of providing that secure interoperable electronic unit-level traceability system. Again, requirements for verification around suspect products, product tracing, and Authorized Trade Partner credentialing. The requirements across the industry are somewhat standardized.

Of course, you all have different operations in which those requirements need to be met. An organization that has done a really good job at taking those requirements and starting to translate them into more functionally oriented

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requirements.

I would encourage you, if you are not already, to engage with an organization known as the Partnership for DSCSA Governance, otherwise known as PDG. It's an industry group that's represented by manufacturers, repackagers, wholesalers, distributors, 3PLs, dispensers. There's a number of industry associations that participate.

The association that represents your business is typically involved in this, whatever segment that you might be operating in. Then companies like TraceLink—whether technical experts, solution providers—that are really trying to drive the industry in helping them create a standardized approach in DSCSA compliance.

PDG has done a really good job at summarizing the requirements. They break it down into three, what they refer to as specific but highly interrelated components. The first is interoperable exchange, in which trade partners must exchange the TI, the TS, in a secure electronic interoperable manner. This comes right from their website.

Interoperable verification trading partners must be able to verify a product identifier on a package in a secure, electronic, interoperable manner. Tracing, which is about trade partners, must maintain this information, the TI and the TS and in response to a request for it, be able to serve that up whether it be to a government official or to a trade partner that is requesting it.

This really does a great job of succinctly stating the requirements that we have to bring to bear by November of 2023 in order to meet the requirements for DSCSA. You can look at these and think about, "OK, well what does this mean for me as a manufacturer? What does this mean for me as a wholesaler? What does this mean for me as a dispenser?"

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When we think about this, and again, I'd encourage you to reach out to PDG, they have a lot of great information on their website. One of their resources is an industry blueprint that they've developed, which creates a deep set of functional requirements.

When we look at those requirements and we try to provide a visual around, where were we in 2015? Where were we in 2018? What do we have to do in 2023? You can start to see there's this whole host of capabilities that we maybe weren't thinking about previously, that now become a requirement as part of meeting the 2023 deadline.

There's all sorts of integration, whether it be our warehouse management systems, pharmacy management systems, 3PLs, to be able to understand what's being shipped into the supply chain.

Being able to do mobile scanning, whether it be for shipping or receiving the sharing of master data, getting access from the system of records, or from the source of truth on what is the definition of the GTIN? What is the PAC-level master data? Is this GTIN identifying an item? Is it identifying a case?

Being able to just manage and administer the serialized TI and TS, capability and processes around not just saleable return verification, but suspect product verification.

We also know that as we start to track things at the item level that exceptions will occur. What the electronic information represents may be different from the physical receipt that's being received at that pharmacy or at the wholesaler.

Being able to quickly define and record those exceptions and reconcile those expectations with partners, credentialing, product tracing, and then we can't forget

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about recalls and the FDA's intention on using these tools to more efficiently execute recalls.

Certainly, a very lengthy and complex set of requirements that we have to be ready for by November of this year.

When we think about that as a solution provider, we think about at its core, what do companies need in order to meet the requirements. They really break down into these four core capabilities.

Network, and we talk about network. This is all about the information exchange. Being able to exchange the EPCIS information with my customers or receive it from my suppliers. If we have to go through and integrate each of those companies one by one by one by one, we won't make it.

We'll go through a case study in a few slides of one of our customers that has 1,500 customers that they ship product to, that they need to provide this DCSA EPCIS information to. If you can imagine just going through and trying to do that one by one and the time it would take, it's almost nonsensical in terms of a point-to-point approach.

Then from a scalability perspective, you think about now we're tracking things at an item level. Previously, we were tracking things at a lot level, where a lot may have 100,000 units in it or 500,000 units in it, but you didn't have to necessarily track each one of those units.

Scalability becomes incredibly important in terms of I have to make sure I receive this information and process this information, ensure its accuracy, and do all of that at operational scale because I can't slow down the receipt of the product or I can't slow down shipping the product out to my customer.

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If any of you have spent any time in a warehouse you can recognize, or in the receiving area of a pharmacy, speed is important. Our systems have to be able to process and retrieve this information and update this information in a timely manner, which is often sub-seconds.

Then compliance. We talk about compliance, or continuous compliance, is to rapidly comply with the regulatory requirements and standards that are still evolving. We're still learning about what the product tracing requirements might need to be, but partner requirements. If you're on the manufacturer side, you may be getting individual requirements from the different wholesalers about what their expectations are.

If you're on the health system side, you may be getting some details from the wholesalers about what they're planning to send you or you may have your own requirements in terms of how you want to receive the information, or what data that you might want decorated in that EPCIS transaction, in addition to the required compliance data, the TI and TS.

Then finally, ensuring supply and this comes down to a couple different areas. One is this notion of the system being mission-critical within our organizations, but also being able to use this capability to be able to detect drug shortages, to be able to optimize various recalls.

Let's look at some of these and when we network. Let's look at what we really mean by that and break down some of these individual processes. If you look at the primary requirement of EPCIS transaction exchange, it's fairly straightforward. It's sending an EPCIS transaction from the manufacturer to the wholesaler, and then from the wholesaler out to the dispenser.

Now let's look at something like verification whereas a manufacturer, you may be

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receiving verification requests from companies that you have a direct relationship with such as a wholesaler, but you may also be receiving verification requests from a retail pharmacy or from a health system.

If you're on the dispensary side, you may have to submit that verification to the manufacturer. It speaks to being able to quickly and programmatically identify, where do I submit this verification request so that I get a response back and do that in software.

We're not in a position where manual processes are going to scale in any reasonable way. Similarly, with master data, I know a number of manufacturers are getting inundated with requests to provide your GTIN information. Those requests are coming in from wholesalers, they're coming in from the dispensers.

Being able to programmatically and in an automated way push not only the initial information but updates to that information out to different stakeholders, whether they be direct partners or indirect partners, the customers of your customers.

Product tracing, which is essentially being able to build the transaction history on the fly. To be able to identify where I have to make this request from to retrieve the serialized TI in transaction statement.

Then recalls. Being able to push information about a recall. Then if you're the receiver of that information, being able to respond to that. We have all of these different threads of information that are all interrelated to DSCSA. You can see, it's not just a matter of "I need to send information to who I sell the product to" although that's certainly a key part of it. That's just one use case.

You start to see not only do I have to interact and collaborate with my direct partners, companies that I know, there's also this requirement to interact and

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exchange information electronically, with companies that I may not have a direct relationship with. What are those kinds of controls and governance around that particular process?

That's why DSCSA is inherently a network challenge. Then on the scalability side, this is really just an example of where we are today, and how we process information at the system level and at the database level, to where we will need to be come November 2023.

You just take a very simple use case of a manufacturer creating a batch and shipping product from that batch. It's pretty straightforward when you think about it in terms of executing various database actions. It's a transaction to create the batch, a transaction to pick the pallet, ship the pallet, and send the ASN.

All right, so pretty straightforward and something that was easily handled by some of the current systems, whether they be ERP systems or WMS systems in place today. When you multiply that to what will happen in the item-level traceability world, you start to introduce this concept of serialization and the events associated with serialization.

This is an example of a manufacturer but think about on the receiving side, if you're a wholesaler or you're a dispenser and when you receive this information, that time it takes to receive the file and process it. We know today that there are a number of systems out there that receive an ASN, and they don't do any inspection of that ASN.

It takes the payload and stuffs it into a digital file cabinet and doesn't do any verification of the data that is in there. When we get to the EPCIS world, number one, the file sizes and the amount of data increases substantially.

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Number two, you want to be able to make sure the information in that file is correct, that it's well-structured because you're going to be called upon to use that information during an investigation as part of an audit. It's important that we have the systems in place that are not just receiving the information but are actively managing it for you in a very scalable way.

To do this, it's going to result in a different model, say a relational database model, or if you try to build this capability into your warehouse management system or pharmacy management system, you're going to bring it to its knees because they're not architected to deal with this type of information.

Continuous compliance. What we've learned over the years is that compliance will continue to evolve, whether it'd be interpretation, continued FDA guidelines, and guidance activity that's happening through standards organizations or organizations with PDG.

Then, on the bottom here, your environments change. As a health system, you're adding new suppliers or you're decommissioning other suppliers. You're going through acquisitions of new sites or divestitures, whatever it might be.

On the right-hand side of this infinity loop, they're some of the more regulatory-related aspects directly related to compliance. Then we have the normal change that occurs when you're dealing with any enterprise system. Whether it'd be changes to your business environment, the normal product enhancements that are released, or infrastructure and security patches.

You very quickly get to a point where your compliance solution and your ability to maintain compliance is tightly related to your ability and your solution provider's ability to adapt to these changes quickly and not roll them out into your own organization, but ensure that your integrations with the tens, hundreds, thousands

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of suppliers or customers that you might have remain intact.

A really important concept here. I'll add to this area where we're maybe not completely focused on yet and the industry's starting to spend some time on this, is in the area of exceptions. The reason I bring this up is, it's not like we're going to get to the November date and we deploy and we're done with it.

We wash our hands and we're done with compliance. Compliance and maintaining compliance lives on. I know this may not translate to all segments, but there's this concept of large IT deployments and change management of getting to business as usual.

Compliance is going to be getting to a normal operating state of managing compliance. Part of that is going to be able to manage exceptions and be able to reconcile exceptions across my supplier base or with my customers depending on what side of the supply chain that you're operating in.

This becomes one of those operational tools that will become a requirement in order to keep our supply chains operating in the most optimized way.

Then finally ensuring supply. This gets back to that always on 24/7. Being able to do this and as we're receiving this information into the network, being able to make decisions about that information that are solving critical problems.

Being able to detect patterns, for a number of you have seen some of the work we've done in the area of product availability, intelligence, and for certain therapeutic categories and under certain conditions, being able to move the detection time from 10 days, which is the industry standard now of a potential shortage, to in some cases, up to 90 days.

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Therefore, giving the industry much more advanced warning of a potential detection, so that you can now prepare for that shortage that may be occurring. Again, being able to do that, because we're operating on this network, we're using a common data model across the network.

We're able to start to study different patterns in this very clean and actionable data set that we've built out. What that leads into is kind of how we think about the DSCSA solution. It's really rooted in serialization, and being able to not just manage serialized data, but being able to integrate the process of serialization and traceability within your operations.

Through that information, the actual compliance layer, where the capability for exchanging the T2 information, being able to support verification, whatever the product tracing requirements and model end up being, being able to provide capability in that area.

Then, adding some of these tools to what I would call business as usual or DSCSA operations to inspect the data to troubleshoot exceptions, to collaborate on exceptions in order to reconcile them.

Then, surrounding that with, for those of you that are in the GMP space that have validation requirements, supporting your needs around validation, across all segments, driving training through our TraceLink University, capability and offering, and then adding on that the business value of the investment that you're making.

Whether it be product availability intelligence or recalls. Really thinking about this is how do I invest in a platform that gets me to compliance, but then being able to derive some value from that, to help me solve some other challenging use cases.

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In order for us to do this, we have to take a leadership position. My apologies on that graphic, but take a leadership position in a number of these different organizations. I won't go through each of these.

The point here is that, as your solution provider, we feel it's our responsibility to be representing you in these different organizations and representing your interests in these organizations where we're not just your solution provider, but we're your compliance partner.

Although we sit with many of you in these organizations side by side, there are a number of you that may not have the resources or the bandwidth to participate in all of these organizations.

This is why we invest quite heavily in not just participating in these organizations, but as you can see, taking various leadership positions, whether it'd be through as an editor or a co-chair in terms of how we participate.

That's something that we just believe is part of our responsibility to be a good partner to our customers, and something we will continue to invest in strongly. With that, let's talk a little bit about some examples.

This is an example of a health system that has been working with TraceLink for a number of years now and their perspective was not just being able to comply with DSCSA, which they felt would enhance their ability to protect patients, but just gain better visibility into what product they were receiving across the entire health system. This is something that we hear a lot from health systems, just getting visibility into all different locations that might be receiving product and getting that into a single pane of glass. Then, working with them on their recall processes as well.

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This is where we deployed the DSCSA solution within this organization, collaborating on the use cases around product availability intelligence and digital recalls.

We are in this transition period where we're managing over a million transaction histories for them, although we have 15 sites that are now up and running, where they're receiving and reconciling serialized product against the receipt.

We have 16 of their partners, suppliers that are currently integrated. Same kind of story when they look at, why TraceLink and why they partnered with TraceLink certainly for the capability. This is an organization that saw a lot of value in our expertise in this particular area.

Retail pharmacy example, this is a large retail pharmacy, incredibly complex in that they have a number of different business units that, in their words, were quite siloed. Looking for again that enterprise-wide visibility that we could provide across all of their different business units.

This particular organization is receiving serialized products today. They're doing some scanning of those products. They take an approach where they're sampling a percentage of their receipts and scanning those items and reconciling against the physical product.

This is a bit dated, but this is growing almost exponentially in terms of the amount of serialized product that we're currently working with them on in the area of scanning.

Again, the value that this organization saw was our industry expertise in our ability to help them achieve compliance. Because of the size of this organization, it was important that they start early.

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We've been working with the organization for a couple of years, and just peeling back the different organizations and the different operational processes that they have, and then systematically going in, in deploying out at each one. It's been an incredibly complex product, but also an incredibly rewarding one as well as we look at everything that we've been able to accomplish.

The last case study that I'll provide here speaks to the fundamental challenge that many of you had, whether it be integrating with customers or integrating with suppliers.

This is a global pharmaceutical company, and in full disclosure, is using another solution for their level-four capability and some sort of network capability. After doing some due diligence with their provider at the time, they became concerned about the ability of that provider to onboard and integrate all of their customers in the U.S., which measured in about 1,500.

Now, they have a lot of investment and integration in their current level-four system in terms of its integration into packaging lines, warehouse management systems, and those types of things. We arrived at a solution that worked for them where we integrate with that other solution, but TraceLink is managing the network aspect.

It's not a rip-and-replace. It's where we're pairing with the existing solution provider where we're taking on the challenge of integrating to their 1,500 customers in the U.S.

When we looked at their customers, we found that 93 percent of them were already onboarded to the TraceLink network. And many of them, particularly the larger wholesalers, health systems, and retail pharmacies, we had already had B2B integrations on that network.

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When you look at the implementation from a TraceLink services perspective, it's a 37-day implementation because we're not going point to point, we're not going through and doing this one by one by one. That was the fundamental driver for this particular pharmaceutical company.

With that, I know we're coming up against the clock here, just a couple of comments. Before I get into the wrap-up, I just...Melanie, I was hoping we could maybe pop up the poll question.

[pause]

Dan: If we can just take a few moments here and just let us know if the information that we provided to you was valuable. I recognize it was a bit of a recap from information that we covered previously, but hoping that the summary of the information was useful to you, and to be able to more succinctly state some of the challenges around it.

A couple of questions here. Some of these are fairly technical in nature that I might need to take offline. One question around, this is a great question. What does interoperable mean?

Really interoperable means that we have agreed, and two companies can exchange information so that what I'm sending to that other organization can be consumed and it can be understood, it can be processed. We're speaking the same language, if you will.

A big part of achieving interoperability was the industry coming together around a standard. That standard is EPCIS and there's, I think we're heading to version 1.3 of EPCIS, at this point. Now, there's a couple of things to note about that EPCIS as a standard has been fantastic to help us align on a common way to share

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information, but it's not a silver bullet, right?

EPCIS allows you the ability to, through the use of field extensions to customize that transaction in a certain way. When that happens, TraceLink's able to work with you, work with your customers or your suppliers, where we can accommodate those customizations very similar to what we did with ASNs. I think there's probably 40 different versions of ASNs that we're currently supporting today.

From a key takeaway perspective, I know I'm just about a minute here, couple of things I hope you walked away with.

First and foremost, we have a lot to do as an industry, 2023 requirements are a step change. I really encourage you, if you're not already, to get your project started, to start to ramp up your project. Think about your project in these four dimensions.

Do you have the ability to integrate all of the suppliers and customers and do that in an expeditious way in the nine months that we have remaining? Remember, if you're a manufacturer, the deadlines of your wholesalers are not November. Many of them want to be receiving information from you already today. In some of the communications that they've published because, they need to consume that into their systems and get it out to their customers, the health systems, and retail pharmacies.

I hope you recognize the network challenge around that. I hope we gave some color to scalability and why trying to embed this into a pharmacy management system is probably not a good technical choice in the impact that may have to your operations. Compliance as a service, or continuous compliance, this ability to be able to keep up with the evolution of compliance that will happen.

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Then this is a mission-critical application. This isn't necessarily “check the box and be done with it”—this has to be running 24/7, 365 days a year, in terms of making sure that it's not impeding your ability to ship, receive, and serve the patient.

Then I hope you recognize through this webinar as well as the investment we make in certain areas that this is what we do. This is what we focus on. We take pride in being the market leader. We take pride in the expertise that we can provide to our customers as part of that.

If you're an existing customer, join our innovation forum. You can reach out to community [at] tracelink.com if you're not currently registered in these areas. This is where we're talking about the detailed use case work around achieving compliance. We're bringing to you the latest and greatest from the FDA and PDG.

Certainly, the last thing I'll call out here is FutureLink in May, which we'll all be quite busy with getting to compliance. Hopefully, you can join us for a break from that implementation to meet with us here in Boston, where we'll really be taking some deep dives into DSCSA as well as some of the other areas that we're moving towards in the area of just supply chain digitalization.

Certainly, join us for that in May. I hope to see you here in Boston. With that, that's the last of our webinar in this particular series. I thank you for spending the time with us over the past four months or so. I hope to see you on our future webinars that will be kicking off in the March timeframe.

Be well, be safe, and thank you for your time. Have a great day, everyone.

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