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Troubleshooting and Managing Exceptions Under DSCSA



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In this quick video clip from our DSCSA Webinar Series, Amanda Bettman, GM of Supply Network Orchestration at TraceLink, explains how TraceLink helps you resolve DSCSA-driven exceptions faster, better, and more cost-effectively than ever before. Watch the clip now and then fill out the form to see the entire webinar.

Your company's **FDA DSCSA 2023 compliance deadline** is November 27, 2023. As **DSCSA 2023** adds an interoperable data exchange step to the shipping process, **pharma manufacturers** and wholesale distributors can expect a sharp increase in exceptions due to missing data, product holds, packaging issues, and more, according to the Healthcare Distribution Alliance (HDA). Slow response to exceptions will negatively impact customer service. That's why you need to get ready now.

Watch the full on-demand DSCSA webinar, "Troubleshooting and Managing

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Exceptions Under DSCSA," and you'll learn how to rapidly troubleshoot and identify DSCSA exceptions. You'll also learn how to work with your customers in real time to resolve exceptions fast—before they lead to disruptions, delays, and unhappy customers. Why should you watch now?

- Get a complete overview of the exceptions you can expect when operating under DSCSA, according to the HDA—and get guidance from TraceLink on how to resolve them fast.

- Learn how manufacturers, **wholesale distributors**, and pharmacies can collaborate in real time on a digital network platform to get exceptions resolved quickly and ensure shipments are received on time, in full.

- Discover the latest tools and best practices for troubleshooting and collaborating with customers to resolve exceptions quickly.

Fill out the form on this page to watch the webinar now.

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Transcript

Dan Walles: Good morning, everyone. Thank you for joining us today. Today we're

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continuing our webinar series with a focus on the manufacturer and distributor segment on a topic that is growing in popularity, I would say, in various industry discussions. That is "Troubleshooting and Managing Exceptions Under DSCSA."

Today what we're really hoping to do is start to unpack this challenge that the industry will be facing once we move to true item-level traceability as a result of the upcoming milestones for the Drug Supply Chain and Security Act in November.

This is the fifth webinar in this series where we've covered a variety of topics related to the U.S. Drug Supply Chain Security Act with a specific focus on the 2023 milestones. Each of these are available to you as recordings that you can navigate to.

In addition to that, our next webinar focusing on manufacturers and wholesalers will be February 9, at 11:00 AM, where we'll be focusing on product tracing, another topic that is increasing in terms of discussions on how the industry will meet that part of the regulation.

For today's topic specifically, what we really want to do is start to dive into the November 2023 regulation and start to look at why we believe exceptions will increase. There's discussion that's going on in the industry around exception management in a variety of different forums.

We'll introduce you to what those forums are, the topics that are happening within those forums, and how you can start to get involved yourself in some of those industry discussions.

In addition to that, we'll focus on the Supply Chain Work Management solution that TraceLink is bringing to market that is really focused on helping companies collaborate both internally as well as externally around DSCSA exceptions.

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Today, I'm joined by my colleague, Amanda Bettman, who's the general manager of TraceLink's supply network orchestration area, where Supply Chain Work Management solutions really resides within TraceLink. Amanda will be leading a big part of the presentation today.

Before we do that, I'd like to just spend a few moments talking a little bit about TraceLink and our experience specifically around DSCSA and the relevance of our company and our position in the market as it relates to exceptions.

We've been in this space since 2009. Over that time, we've accumulated over 1,300 customers. Those customers are global, whether they're pharmaceutical manufacturers, wholesale distributors in the U.S., retail pharmacies, health systems primarily in the U.S.

Our network spans about 290,000 different members and it's fairly routine when we do a network analysis of our customers, whether they are pharmaceutical manufacturer or wholesale distributor or health system or retail pharmacy, that typically over 90 percent of their suppliers or customers are represented on our network.

What that means for you, as a TraceLink customer is, much of the heavy lifting around integrating to and creating B2B connections to these different customers is largely in place. That's evident in this particular number here, this 339,000, which are active network ServiceLinks.

What we mean by ServiceLinks, or you can think of these as collaboration pipes or relationships between two companies, in which we're managing a business process. Now due to our business and our focus on compliance, typically, that may be that process that we're collaborating on, maybe the exchange of a lot level ASN document or the exchange of serialization information between a pharmaceutical

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manufacturer and a CMO.

It's these same links that will govern the process of sending EPCIS transactions for item-level traceability to meet the DSCSA requirements. If you're an existing customer today and you license our product track solution, you are really halfway there to meeting your 2023 requirements.

This is important because as we look at what we have to do in really less than a year before November is helping the industry and supporting the industry and meeting those item-level traceability requirements. Today, we have close to 900 customers that are actively serializing product, largely pharmaceutical manufacturers. We've tracked close to 40 billion serialized units.

We've processed almost 1,885,000,000 transaction histories. We're currently directly managing through our customers almost 50,000 GTINs, so close to close to 50,000 individual product SKUs that are being managed through the TraceLink network.

What this has really started to build out is this platform that is helping companies address not just compliance, but some of the other business challenges that are our priority discussions within the boardrooms of many of our customers.

We talk a lot about supply chain visibility. One of the things the pandemic has really shown us is that we need better tools to get better traceability within our supply chains, better transparency across our supply chains to support us and sustainability efforts that are happening within our supply chains, and just better collaboration with our suppliers and with our customers.

The way to view this is that supply chain digitalization and bringing digitalization to the supply chain has now become not just a nice to have but a business imperative

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in virtually every customer, whether it be a pharmaceutical company, a wholesale distributor, or retail pharmacy or a health system. It's becoming a top-level business imperative in all of these different organizations.

What that has led to is this concept of how we create through the TraceLink network, this Internet of Supply Chains that is focused on linking people, processes, systems, and enterprises across a network.

In order to do this, there's some enabling capabilities that are required. Starting to the left here, it's this need to be able to create these digital networks. Digital networks between a pharmaceutical manufacturer and their wholesaler customers, being able to share processes and applications across that network.

Now, an example of a process may be item-level traceability. Being able to track and manage product, the traceability of product as it's moving through the supply chain. That is at the heart of what is in the DSCSA regulation.

Being able to execute cross functionally, not just against that business process, not just internally with my peers within my own organization, but with my counterparts at, say a wholesaler. If I'm a pharmaceutical manufacturer and I'm in the commercial operations group, being able to work with my counterpart at a wholesale distributor.

If we do this in a thoughtful way, and we execute this across a network using a common data model, then there's innovative things that we can start to do with that information. Most notably, we can start to drive collective intelligence from what's happening across the network.

Examples of collective intelligence may be better predictions into drug shortages that may be pending within the global supply chain. This is where we start to look

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at what are some of the building blocks by which we can start to address these supply chain challenges that companies are facing.

Why do we feel that we're well positioned to do this? We've been building out this digital supply network and starting to look at what are the core capabilities and applications that organizations need in order to build out this Internet of Supply Chains. It's all rooted in this digital supply network.

Part of that digital supply network is providing capabilities to manage the networks that you're building on TraceLink with customer master data, company master data, and different network administration tools.

Driving this “Integrate Once, Interoperate with Everyone” process, so that once you are integrated into the TraceLink network for a business process, say a shipping business process, you don't then have to worry about point-to-point integrations with each of your different customers, whether they be direct customers or indirect customers.

Catalogs, data translation maps, plugins, application catalogs, moving to a low-code app development environment so that you, within the business organizations, can start to build applications within the TraceLink environment to solve challenges that might be specific to your organization. Then be able to tailor your user experience to the specific needs of your company.

Today, we're really talking about serialization and traceability and compliance in the context of DSCSA, but you can see how this really starts to lay the groundwork and start to build assets for you that will help you address better supply chain collaboration, network applications in terms of how do I distribute information across the network?

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Collective intelligence, like better visibility into the availability of products. Then finally, which is really the Nirvana of where we want to be to full end-to-end process orchestration. You take something like cell and gene therapy where being able to orchestrate the process on that supply chain on an individual basis with the efficiencies that we need.

When we look at how we're going about building this vision and this platform within TraceLink, we really have a great foundation of work to build from. That's what we've been doing in the area of serialization and compliance, where we are essentially building these business processes and building these links between members of the healthcare segment, members of the distribution segment, pharmaceutical manufacturers, contract manufacturers, and direct material suppliers, whether they're providing you API or other critical components that are required for the manufacturing of a particular product.

This gives us a great background and has been a great case study, if you will, on not only the need for this Internet of supply chains, but why a network approach is so critical in meeting that.

What I'd like to do now is jump into another business process and that business process is the managing of exceptions related to serialization and compliance. To walk us through that is my colleague, Amanda Bettman. Amanda.

Amanda Bettman: Thank you so much, Dan.

All right. If you look back on the last decade or so of the DSCSA regulations, many of us on this call have been involved in really a tremendous digitalization effort across the industry to meet these requirements. I think everyone would agree that there's tremendous complexity in what we're all trying to achieve before November 2023.

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It's not necessary to be alarmist on this session today thinking about exceptions. If you consider the combination of processes and data and people that are all going to be involved in the DSCSA requirements, it's inevitable that there are things that are going to happen along the way outside of what we would consider a happy path scenario.

Exceptions are inevitable. Here to kick us off, I pulled four top-of-mind examples that came up from current TraceLink customers over the past few weeks. This is four of a much longer list when we start to talk about exception management with customers as they plan for their 2023 processes.

There's almost an unlimited number of places that there are concerns, but just to pull out a few to get the conversation started. The first one here would be when you scan a pallet, and there's no EPCIS file. There's a product, and there's no data associated with that product.

The second one, let's say you scan, and it turns out there's an overage. You're sitting there with product overage, not enough data.

The third one is the other way around. There's some bottles that have maybe been removed randomly. Of course, if an enforcement agency is doing this, they don't tell you what's removed, and the EPCIS file doesn't have enough data.

The final one is one that is nothing new. This has been in existence throughout the DSCSA requirements. Just something wrong with a barcode, some visual inspection, and it's not readable. It can't even be scanned.

Just wanted to get everybody starting to think about the variety of exceptions that could occur at any step in the process. What's most important here is that the FDA has said that product cannot be sold ahead, downstream, until these types of

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exceptions have been addressed.

That's really what we're here to discuss today and more broadly in the industry. We're hearing about exception management, something I'm very excited to see is picking up within the industry over the next couple of months.

This is fundamentally the challenge here. How to deal with what we expect to be a sharp increase in exceptions as we move from lot level to serialized product, and how can these be addressed to allow product to be sold downstream.

There's a wide variety of places we imagine these exceptions will occur. I will, in a few minutes, start to talk about some of the things that are already being done in the industry, mostly the HDA guidelines, which are top of mind for everyone. Before we get there, I wanted to set the stage and think through all of the areas where exceptions will occur.

On the previous slide, I mostly had serialized transaction information exceptions. Those are top of mind for the industry right now, the second on this list on this slide. It's important to think about exceptions holistically. Even within your internal processes, before the first change of ownership takes place just within serialized product management, there will be exceptions that go on.

They could be internal. They could be between a manufacturer and a CMO, and they'll need to be addressed. Like I said, the second here is where we will delve more deeply on the upcoming slides but it has to do with serialized transaction information exchange. That's where some of the industry work is already underway.

It's not the only place. Of course, with product tracing, the subject of an upcoming webinar, if you imagine the tracing requirements outlined by the FDA under certain

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situations, if that trace fails or if there's an issue there, how do you operationalize the troubleshooting of that?

The same with verification. VRS has been in the industry for a few years already and I know many people are already operationalizing the troubleshooting there, but as those requirements evolve in 2023, there will be, again, an increase in the volume of those errors.

Finally, I just wanted to jog everybody's thinking and point out that with all of the ongoing industry discussions around identity and credentialing, there's likely to be exceptions there as well. What's an efficient way to resolve this with supply chain partners when, let's say, credentialing fails, for example?

For most of the rest of today's session, practically speaking, we'll be sticking with serialized transaction information, but when you're thinking internally about exception management, and as we move as an industry through this throughout the year, it's important to consider how you will cope and handle exceptions arising from all of these areas.

As mentioned, when I say exceptions, these days most people think immediately of the HDA guidelines. HDA took a crucial first step for the entire industry in putting this out there for everyone early on. It's an excellent document. I highly recommend you Google it and download it if you haven't already.

What they've done is, they've focused on the serialized transaction information exchange, and started to categorize and lay out the types of exceptions that people expect to occur.

On the left-hand side of the slide, they've categorized these exceptions into six major categories. Data issues, damaged product issues, both product without data,

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data without product, packaging and then product holds status issues.

If you think back to my introductory slide on exceptions, those were very focused down to the type where they would arise. Something coming off a dock. You scan a pallet, it doesn't have enough serial numbers for the amount of product you've received.

Each of those exceptions would fall under one of these categories, so the HDA guidelines have generalized them so they can be applied to any serialized transaction information exception. On the right-hand side, there's a few examples.

These parallel the examples I started out with, but they've now been generalized to apply more broadly any incorrectly formatted EPCIS file, a damaged case, a serial number not found, etc.

To get started, think about the types of exceptions that your downstream partners will uncover. It could also be something where a manufacturer has shipped out a product and then they find that some things were not included.

These exceptions may be uncovered anywhere in the supply chain, although we do imagine a majority of them will be turned up by downstream trade partners. Just to think about the operational impact of all of this exception management is the product cannot be sold until these are addressed.

The final thing I want to point out here is that, frequently when we talk to people about exception management and their SOPs, and their planning for this fall and winter, people are thinking about exceptions that will arise from a scan of a product. Many of these will arise from the scan of a product.

Either there's an error upon scanning, or again, there's some mismatch between

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the EPCIS and the actual product received. If you think back to that non-human readable barcode in my first slide, or one of the packaging exceptions that the HDA guidelines have addressed, some of these are going to be visual.

I wanted to set the stage in everyone's memory as we move forward. Yes, some of these will come from a digital system, in many cases they'll come from multiple digital systems. They may come from your serialization system. They may come from your WMS. They could come from a variety of places. They may arise visually. There may be a need to enter these manually in some way. Just really want to expand the thinking here.

The HDA guidelines have laid out the scope for us. If you read into it, you start to realize these are going to arise from a wide variety of places in a wide variety of forms. All right, so there was a question in the chat about the upcoming DSCSA exception handling workshop. TraceLink is not alone on this subject.

This is an industry discussion that is ongoing. As I said, it's really heating up this quarter and next quarter. As always, we're committed to working with the industry standards and the industry organizational guidelines to prepare for this.

If you think back again to the past 10 years of DSCSA compliance, the industry has never yet aligned on a single solution. What I'm going to talk to you today around Supply Chain Work Management will be one tool in a broader ecosystem here. We're following the GS1 guidelines, the HDA guidelines, the PDG work that's been being done.

I highly recommend if anybody's interested in this subject to sign up to attend the upcoming DSCSA exception handling workshop that's being hosted by PDG, HDA, and GS1. That is February 6th and 7th in DC. There is an option to attend virtually as it's proving to be very popular so space will definitely be limited.

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Just to finish up this first portion of the conversation, thinking about the problem really that the industry is facing. It's that exceptions can happen anywhere. The volume will increase. You can't have a discussion on the DSCSA regulations without throwing up the word promptly.

They arise again in this situation. These must be resolved quickly. Of course, they block the movement of product across the supply chain. There's an operational risk to these exceptions. It's not just a compliance risk. It really is operational as well.

Of course, nobody wants to be in an environment with lingering open exceptions building up unresolved. There’s not only uncertainty there, but if you think about all the work being done for 2023 compliance, it is the exceptions that get the most attention because that is a sign that something has gone wrong in the process that needs to be addressed.

Moving on from this discussion of the challenge, it can also be viewed as quite an opportunity. We believe that there's a huge opportunity here for network solution to play a role in operationalizing and addressing exception resolution.

Similar to all of the discussion Dan led in with around a network to handle compliance, you're using the TraceLink network to transact and serialize product. The same network can be used for exception management. The volume of partners already on the network means that you can begin to think about how to interoperate with those stakeholders to collaborate on exception resolution.

I want to point out more broadly that the thought that point-to-point connections, even if you were trying to digitalize this process, would not be an efficient approach. That really when you're thinking about exception management, the same scalability concerns that arise with serialization will arise when you're thinking about serialized exceptions.

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There could be a very large volume of data associated with a serialized exception if you're thinking about trying to reconcile all the serial numbers in a batch or an order and trying to figure out what went wrong. There's more data volume requirements here than in pretty much any other business requirement that we have to deal with.

It's important to think about a network that can scale and a network where you're not managing all these point-to-point connections. Then in the lower right, the last point I want to make, as we're just thinking more broadly about the challenge here, and the opportunity is that of continuous compliance.

It's been stressful, when starting to talk about exceptions in the industry, that we don't really know what we're going to be faced with in advance of the deadline. Once everything falls into place, that's really when we're going to get a much clearer picture of the volume of exceptions, the types of exceptions, and yet we have to be prepared ahead of time.

TraceLink's committed to a solution that follows all current guidelines but also that can evolve over time with the industry.

Starting with next month's workshop, we imagine a lot of good conversation and maybe starting to approach some additional clarity around processes but that's going to be an ongoing conversation between now and November and certainly beyond November as well.

It's important to be thinking about systems and processes that can evolve to meet compliance needs as best practices evolve as well.

I wanted to spend the first half of the session talking about the problem in general. Like I said, exception conversations are getting started in the industry.

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I also wanted to point out the way TraceLink is thinking of exceptions and exception management. The TraceLink solution Supply Chain Work Management has actually been out in the industry for multiple years now. It's being used with customers for use cases outside of DSCSA.

We have customers using this to manage their quality complaints, process artwork changes, any sort of collaboration between you and your partners is what Work Management is designed to address.

Very early on last year, we started to get inquiries about using Work Management to address DSCSA exceptions as well as global compliance exceptions, although that's not necessarily the focus of today's conversation.

Just like with compliance, we onboard all of our customers' partners. That would allow distributors, retail pharmacies, health systems as they're receiving product, as they're uncovering all of those DSCSA exception types either visually or via scan, to record those exceptions. They can triage them internally if they need to, and then they can share them upstream to resolve.

The manufacturer can also do some internal collaborating, let's say between teams, depending who needs to be involved in the investigation, and then report back downstream. Because again, those products need to be sold forward, and it requires the exception to be resolved before they can do so.

On the right-hand side of the slide, I've outlined what we believe are some essential components of any robust exception management process. These exceptions need to be created quickly. They're likely to be coming from distribution sites. It's unlikely that your downstream partners will be creating these at headquarters.

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It may be somebody on a loading dock, so it needs to be a quick and flexible way of creating an issue or an exception via an API into their operational systems—that would be a quick way to do it. They may be tracking damaged product already for their operational processes, and they don't want to edit or enter data in multiple places.

They don't want to be taking time away from their operational processes. Quick exception creation, flexible exception creation. The ability then for maybe internal teams at that distributor or that retail pharmacy to triage and include additional information before it's shared with a supply chain partner.

From your perspective, many of those exceptions will flow in from downstream trade partners. There are situations that we can envision where they would be created by you as well, and you may need to go back and forth. You may say, "Can you attach a picture? Can you add additional detail here?"

Going back and forth with that, as well as internally, may require some communication with a CMO to resolve. A flexible solution to handle all of that collaboration and then to read out the resolution back downstream.

Somewhere there's a loading dock where somebody is waiting to release that product. That information needs to flow both ways through the system. It almost goes without saying, but the benefit here of digitalizing this process gives you dashboarding, reporting, historical data, visibility.

A lot of discussion has gone on in the industry on how on earth do we manage this via email? If you think about the ways you collaborate currently with partners, outside of a digital solution, it's frequently email, it's phone, and it's going to be hard to show historical compliance, that you're following your exception management SOPs if this is all being handled in email. Not to mention the difficulty

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then of managing all of these in one place given the volume.

This is to say we envision a network solution playing an important role in making these exceptions manageable, so they're not impacting day-to-day processes, not only for manufacturers, but for the downstream having to deal with quarantine, etc.

We've talked to distributors and dispensers who have said if this is too difficult, I'm going to throw it in the bin for return. That's obviously not something as an industry that we want to be the default for any of this.

Let's get in a little more detail. How does this work? Conceptually a network, great idea, but how might that operate? Let's start at the top of this very detailed slide, in the green with all of the different stakeholders representing a TraceLink network, because exceptions could arise at any point here. The dispenser, the distributor, manufacturer.

Also 3PLs and CPOs. This is probably a good point to answer a question here. One of the things that was so important with compliance. With compliance, you are transacting serialized data with other TraceLink customers, but you're also transacting in serialized information with non-TraceLink customers.

They may be using an alternative solution or they may not have a solution at all. One of the things that was important as an industry in order for us to meet DSCSA 2023 as a whole was, to onboard all partners.

As a customer of TraceLink, we have onboarded all of your downstream partners so you can send them serialized transaction information. They may be TraceLink customers. It's always nice if they are. Many of them are not.

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Regardless of whether they're using TraceLink, they're using a competitive solution or if they don't have their own solution at all, we onboard them and they have access to the same, the multi-enterprise solution that you have access to and that's when we talk about the TraceLink network.

It's not a number of TraceLink customers, it's TraceLink customers and all of their partners who have access to the solution in order to collaborate. To answer the question in the chat around, what happens if they're not a customer?

It doesn't matter. They can use the same platform because the value of using a network here is that everybody is able to enter the solution and have access. For TraceLink, having everybody on the network is valuable regardless of whether they're a customer or not. The TraceLink network is fundamental to making this solution work. Anyone along this list could create an exception.

Let's say it's a dispenser, who's not a TraceLink customer, they can create an exception, and it will come to the manufacturer if needed. Going counterclockwise around this process here, what that requires is for us to be very flexible with how we're getting those exceptions. As I mentioned before, they could come via scan. They could come from a WMS. They could come from an operational system at a distributor or a dispenser. They could come via user interface.

Someone may need to type in manually that the barcode looks funny. I think it's really important to point out that in the industry discussion around email, there will be some trade partners who will need to be using email, whether that's just what they've chosen to use or whether that's all that they have the capacity to implement.

This solution will intake those emails so that your partners can use email, if that's what works for them. You can receive that in an automated way and have it turned

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into a much more digitally rich user interface or integration experience to track, keeping all of that tracked in a single place, and auditable.

If they need to have the dispensation information read back out to them via email as well, that's fine, too.

Your partners may be interacting with you on the TraceLink user interface, they may be interacting with you via an integration into their ERP or their WMS, or they may be interacting via email. It's really fundamental to the success of an industry solution here that all of that is incorporated and all of that is supported.

In the lower left, you've seen these types of exceptions before, the six exception types that the HDA has laid out. Those will become very familiar if you follow this conversation through the workshop next month.

In the lower right the solution I introduced on the previous slide, one place to manage and collaborate on all of those exceptions, providing visibility into historical exceptions, the ability to show that all of your exceptions, for example, are being resolved in a timely manner, and one place for all teams to collaborate there.

That shows how that solution works within the broader industry ecosystem.

The last thing that is really important to point out here, the first thing that was really important here is that network concept, that this works with customers, and this works with partners in a variety of ways.

The second thing that's really important to point out that frequently comes up when we start to get into the solution is questions around, "OK, so I can have a solution and my partners can interact with me, but I have unique processes."

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Everyone has their own unique processes and so, is this solution flexible enough to handle how I want to handle my exceptions?

I think it's important to point out that the solution is set up to be very flexible. No code customization is available. If there are fields that you call certain things in your quality management system and you want to have the same naming conventions in this system to make it easier for your teams, you can change field names. You can add fields. You can remove fields.

Again, if you're thinking about using this via an integration, the ability to add or remove fields is of primary importance, and of course, the ability to change workflows as well. Because I pointed out that it is a multi-enterprise solution, and you may be on it interacting with a partner, permissions are very important.

You don't want to invite them in to see all of the data that you have on their exception. There may be data that you want to keep to yourself, internal-only, and other data that may be shared. That can all be handled via the permissioning component as well.

I will say, as a good example of this, we're currently implementing this at a major retailer for the November deadline. One of the requests there was to integrate into their internal site-level operational system. Again, that solves the problem of entering duplicate exceptions.

The other thing they've asked for are around custom fields. For example, being able to show the value at risk for an exception, what is the dollar value of the product that's at risk? Being able to just add in a field like that to handle their unique processes is one of the ways we make sure that the burden here operationally is as minimal as possible.

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All right. That concludes what I really wanted to say about the network component of managing these exceptions. The last thing I wanted to point out, I've really been focusing on the network component. I keep saying collaboration with trade partners, how are you communicating back and forth. I didn't want to avoid the topic.

Of course, there's going to be a lot of internal troubleshooting associated with serialized exceptions. I did want to point out that TraceLink has an additional solution called Serialized Product Intelligence, another solution that's been on the market for multiple years right now, that really is more focused on internal troubleshooting.

As you're thinking about your processes between now and November, of course, encouraging you to think about how you're working with your trade partners, but also be thinking about how you're going to manage this internally, in a way that disrupts your operational processes as little as humanly possible. SPI is an additional tool to be thinking about. It allows you to monitor serialization activities.

Obviously, that feasibility allows you to resolve them more quickly. When you're thinking about exception resolution and minimizing operational impact, it's all about freeing up your resources. Your teams can be doing something besides reading through a huge number of emails a day about exception in different formats, and then poking through a system trying to figure out what went wrong.

That's not what we want our teams to be doing come November. To close out this discussion on serialized product intelligence, there's a variety of levels this can be used for. Event level of visibility.

Again, if you think back to my very first slide now that we're at the very last slide, every single one of these can be tied back to one of those issues that we thought

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about from the operational perspective. Something shows up on a dock and it's missing the EPCIS file, follow that all the way back through that supply chain work management solution.

The distributor creates an exception, you receive that exception, it has some serialized information. SPI gives you the ability to look into your own internal serialization systems and figure out what the cause was more efficiently and effectively. Either at the event level or at the serial number level. Maybe it's a lot-level problem. Lot-level issues are not going to go away now that we have to deal with serialized issues as well and being able to reconcile everything.

It's just to think about. As you plan for November, as you plan for exception management, there's this one component which is the collaborative component. That's what the HDA guidelines are focused on. I imagine a lot of the industry discussion will be focused on that as well.

It's also good to be thinking about the tools and tricks that you can have internally to try and minimize the amount of time spent on this as well.

Dan, do you want to jump in and add anything on SPI?

Dan: Yeah. I think you teed it up very well. If I take a step back and we think about what's happening, not just in the U.S. but globally, in whether it be the U.S. market through DSCSA for many of the manufacturers on the phone, you have been through the EU FMD journey.

The Middle East, as a region, is moving to serialization and item-level traceability and government reporting. Russia and Eastern Europe. As we've talked about in other forums, this move towards tracking and recording on the movement of pharmaceuticals is really becoming our normal operating procedure.

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Today, we got here through a discussion on managing exceptions in the U.S. supply chain that will be generated through item-level traceability in DSCSA, but we just have to think about item level traceability as a process we need to manage from a business-as-usual perspective.

This is where things like Supply Chain Work Management for Compliance Exceptions, Serialized Product Intelligence become these tools by which we manage this as an industry. There are other alternative solutions in the market to address some of these.

We have to work with all of them, and we will. I think the message here is, as you're thinking about not just what I need to do by November, which is certainly important, but how do I manage my item-level traceability processes more efficiently and more effectively, or what new SOPs does this create for me.

These are things when Serialized Product Intelligence and the analytics around that become really important. I think the DSCSA use case around exceptions is really going to drive us to a need for just maneuvering through this massive amount of data more efficiently.

I appreciate Amanda obviously has a great overview of where we are with exceptions. I do have a couple of questions that have come up that I'd like to maybe address now.

Amanda: Yeah. Dan, I did want to say there's a couple of questions about specific companies that maybe I'll reach out to the asker and we'll handle those offline. Don't want to call out anybody online specifically, but I will reach out and follow up on all of those. Those aren't going unread or ignored.

Dan: Great, thank you. I guess one question I have is maybe a bit of a follow-up to

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a material you presented earlier, which is, if I'm on the call, how can I get more information directly from the source?

You mentioned some industry groups, there's a public work group that's happening on February 6. Maybe you can just talk about how folks can get more connected to the conversations that are happening in the industry.

Amanda: Really good question because I really hope, if anybody takes one thing away from this, it's that the industry is really starting to discuss exceptions in great detail. One of the ways to best position ourselves between now and November is to really tune in to the industry discussions.

The first one is the PDG, HDA, and GS1. That's a triple threat workshop going on at the beginning of February. I would definitely recommend attending that virtually, or just checking up on what comes out of it. What's published or discussed arising from that.

In the meantime, I'd highly encourage you to download the HDA guidelines. Like I said, those were a hugely valuable first step for the industry on serialized exceptions. Read and familiarize yourselves with those.

GS1 also has some standards, and I would just say if you're following in an ongoing fashion, the HDA publications, the PDG publications, and the GS1 publications around 2023 as a whole, as exceptions come up, you'll be really tuned into whatever you might want.

Then, TraceLink's always happy to talk about what's going on in the industry. We attend all of this. You'll see our coworker, Elizabeth Waldorf, in person at the PDG workshop, if anybody else is attending in person.

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We'll be at any and all of the above and always happy to either point out the next upcoming thing or share our thoughts on what's happening. Some things to download as a starting point and then a workshop to attend next month, if anybody is interested.

Dan: OK, great. We do have one question that's more of a series. Somebody's preparing a series of questions, and they're wondering the best way to engage TraceLink around that.

I would encourage you to send that information to marketing [at] tracelink.com. I've taken a note of your name, and we'll be on the lookout for those particular questions as well.

I guess just as we wrap up because we're running up against the clock here, we do just have a quick poll. If we can just pop up the poll. I think, one, how was the information that was presented today, was this helpful? Was it not helpful? Was the overall pace OK?

Would you like more information on this particular topic, whether it'd be where the industry is at or TraceLink's individual solutions? Certainly respond yes to that.

That will give us a note to reach back out to you directly. Then, in terms of a wrap up, a couple of things that I'd like to cover. One, we're meeting again on the 2nd, which is the next part of the webinar series.

This is going to be more targeted towards pharmacies and health systems, but I would encourage you from the manufacturer and dispenser side that there's some really interesting pieces of information about how your customers are managing DSCSA and preparing for DSCSA.

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This is a collaborative effort across the supply chain. There are things that dispensers need from wholesalers, and need from manufacturers in order to drive their compliance. I'd encourage you to certainly attend that if you're able to.

We are also kicking off our FutureLink event again after being on a brief hiatus for a couple of years due to the pandemic. Block your calendars for May 22-24, where the theme of the FutureLink conferences is orchestrating your end-to-end supply chain.

This is where we really go through not just compliance-related topics. That will certainly be a major theme, but just how compliance serialization starts to drive just better supply chain orchestration and product orchestration across the supply chain.

I hope that we see you there. We've talked about this in the past. For those of you that are TraceLink customers, as Amanda had mentioned, we attend all of the forums, we're not only attending but participating and leading a number of these discussions on behalf of our customers.

Where we go through those is through the Innovation Forum. This is open to TraceLink customers of our solution. If you're a subscriber of our Product Track solutions, we certainly encourage you to be participating in this forum.

You can get more information through community [at] tracelink.com. Maybe Amanda, you can just walk us through the key takeaways here.

Amanda: Sure. I think with all the uncertainty in the industry around November exceptions, it's hard to have a crystal ball and know what it's going to look like before we get there. Everybody seems to agree that moving to serialized product will cause a sharp increase in exceptions in parallel with the increased operational

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complexity.

Of course, the burning platform we are on that makes all of this so relevant is you have to resolve this before product can be sold. Nobody wants DSCSA compliance to be preventing product from being sold in the market. One of our foremost guiding ideas as a company is that our goal is to ensure supply to customers of product. The goal is not to implement compliance solutions which prevent the supply of life-saving products to the market.

The entire conversation is around how do we manage these exceptions so they do not hold up product in the market. As I've said so many times, the industry discussion is absolutely underway. That's a bit of a change from even a quarter ago. It's starting to be picked up in multiple forums. The TraceLink perspective is that there's a role here for a network solution.

As Dan said, it's never the only solution, we're committed to making it interoperable and fitting in with both manual and other digital processes. Just in terms of managing exceptions efficiently, the idea of not impacting operational processes more than we need to. Network solution is a crucial tool there.

The last bullet here is, we have a work management solution that's in the market today to enable trade partner collaboration. Crucially, both with TradeLink customers and with non-TradeLink customers, with all of your trade partners.

That is built on the same network as our compliance solution. The ways that you're sending serialized information to downstream trade partners right now leverage that same network, those same connections, for the exception management on top of that, instead of thinking about how to build out a new network or new processes.

Dan: Great, thanks Amanda. I know there's certainly a lot more to discuss

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regarding this topic. We're going to learn a lot, not just in February's part of the workshop, but going forward as an industry, as this becomes more top of mind.

As the industry gets sending EPCIS transactions under their belt, they'll quickly be switching their attention to how do we manage the exceptions that are just going to be inevitable as we move to item-level traceability. Stay tuned for more on this topic.

You'll be seeing a lot more of Amanda, which I think is great for everyone in the industry as she's a leading expert on this particular topic.

As I had mentioned, if you're a TraceLink customer, reach out to us. We're also putting together some programs around having your account executive reach out to you to make sure we can get your system configured and ready, and sending EPCIS transactions if you're not already. We have a number of you that are all ready which is fantastic.

If you need a solution, if you're looking at potentially replacing your existing solution, or perhaps you built something internally on your EDI capability for a lot-level, certainly reach out to us at marketing [at] tracelink.com and we'll be sure to be in touch with you.

If you're looking to maybe switch from your current provider or introduce a new provider into your current architecture or footprint, reach out to us.

With that, I thank you for your time and attention today on an important topic. I hope that we see some of you at the workshop and others on our next webinar on February 2. In the meantime, be safe, be healthy, be well. We look forward to speaking with you again. Thanks, everyone.

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