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Home
Resources
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Wholesale Distributor Summit SD Relies on TraceLink for DSCSA Compliance



Ryan O'Neill, Director of Operations at Summit SD, a wholesale pharmaceutical distributor, discusses why his company chose TraceLink to ensure compliance with the U.S. Drug Supply Chain Security Act (DSCSA).

O'Neill explains that TraceLink was more than just a solution provider, serving as a trusted implementation advisor as the DSCSA regulations rolled out. He also discusses how Summit SD is leveraging **TraceLink Smart Inventory Tracker** for product scanning, investigations, and more. Finally, O'Neill explains the business value of leveraging the TraceLink network to continue receiving Advance Ship Notices (ASNs) after the DSCSA stabilization period ends. Watch the video to learn more.

Video Highlights:

00:44 - What challenges is Summit SD facing as the DSCSA stabilization period ends?
01:34 - How is Summit SD leveraging TraceLink Smart Inventory Tracker?
02:21 - Why will Summit SD continue receiving ASNs after the DSCSA stabilization period?

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02:48 - Why did Summit SD choose TraceLink for DSCSA compliance?

TRANSCRIPT

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My name is Ryan O'Neill. I am the Director of Operations at Summit SD. We are the exclusive distributor of products for an overseas manufacturer called Pharmaand. And so we import those drugs, bring them into the U.S., and then we distribute them out downstream to customers.

We are in this stage where DSCSA has been implemented. We're still in the stabilization period. But then, I like to see, now that TraceLink is going beyond just the DSCSA requirements and actually providing different tools and using the dataset that we do have already existing to create brand new visibility into the supply chain, to get new solutions for partners, and ultimately become that one-stop shop.

In preparing for DSCSA, right now we're around, I would say, 95% of the way there. I think the biggest challenges right now are the lack of standardization in how different partners are using their data.

And so, while we are, quote, fully connected, we still have challenges, and so there still are a lot of things we're doing with our partners to be able to send and receive the data, to make sure it's accurate, to make sure it's timely, and to make sure that they are able to accept the drug. I think if we did not have this stabilization period, that would have resulted in a lot of back orders, and would have definitely impacted patient care.

So, I think going from now until November 27th, we really have a challenge in front of us in making sure that we can, you know, get everything we need in order, and having that ample time at the end to make sure that things are in place prior to

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the deadline is going to be very important.

We're leveraging SIT a little bit differently than other people, I think. Part of that is like, let's say a customer calls and they have a reported discrepancy, one of the first things we do is actually go into the SIT program, and we go look at the data files that we sent them, making sure everything matches, to use that data outside of just the compliance aspect of it.

We use Smart Inventory Tracker for a lot of things. Obviously, we're gonna use that for the scanning function. But on top of that, we're gonna use Smart Inventory Tracker for doing investigative procedures.

If there are any reported discrepancies or anything from any of our downstream customers, it's very helpful to identify exactly what was in the box and we can verify what was in there. And so outside of just the compliance application, it's really helpful to have that for a business application.

We're still going to be leveraging ASNs. I think there is still a lot of value in having those documents. I mean, just like any shipment you get in, you're not just getting one document in. So, it's a good additional verification tool for the product you're receiving. It'll also tell you when you can expect to receive the product. It can have other helpful identifiers in there that you can use and leverage to be able to plan out your receiving processes.

So, when the FDA came out with DSCSA, we knew we had to have some sort of solution. And what's hard is that they're gonna come out with regulations, and they're not really going to tell you how they need to be enacted, what it's gonna look like in a practical application. So, what TraceLink has done a very good job of is bridging that gap between compliance, and then the real-life application of it for your use case.

And we're actually going to be implementing TraceLink into our ERP system now, because we're running into a lot of issues where the data is very siloed and we

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want to get rid of those challenges that we have from the data being siloed. And so, our next step is to integrate to have a full, all-in-one network.

I think the catalyst for us partnering with TraceLink was because TraceLink was really on the cutting edge of this, and we needed a solution, and we needed subject matter experts that knew what they were doing, essentially, and that knew the industry, that knew the challenges, and could help us with that.

And that's one thing that TraceLink has been very good at is understanding the compliance portion of it, the application portion of it, and then understanding how it can fit our business use case.

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