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Industry Perspective: Drug Manufacturers Need to Get Ready for DSCSA 2023 Now!

The final phase of the U.S. Drug Supply Chain Security Act (DSCSA) goes into effect later this year on November 27, 2023. Before that deadline, pharmaceutical manufacturers and their supply chain trading partners are required to implement a 100% electronic and interoperable system for the secure exchange of item-level product traceability information. Failure to achieve compliance in time could lead to FDA fines, unhappy customers, and medicine shortages that impact patients. But many organizations across the end-to-end pharmaceutical supply chain are lagging behind on DSCSA compliance initiatives, according to TraceLink customer Robin Dunchack, Senior Manager of Customer Solutions at Merz Therapeutics.

In this interview, Dunchack, who is spearheading the DSCSA compliance initiative at Merz and held a similar DSCSA leadership position in her previous role at a pharmaceutical company, offers practical advice on how to get a DSCSA project up and running. She also discusses the value of working with a trusted DSCSA compliance partner and explains why pharmaceutical companies need to act with urgency and take steps to ***ensure DSCSA compliance now.***

Do

Robin Dunchack

you get the sense that there is a lack of urgency in the life sciences and pharmaceutical industry when it comes to complying with new DSCSA regulations?

Robin Dunchack: Yes, absolutely. The reason for this is the lack of familiarity with the law. This lack of clarity means that implementation hesitancy persists; which now means that everyone is attempting to sprint to the finish line.

What advice do you have for pharmaceutical companies that are lagging on DSCSA 2023 preparations?

Dunchack: My advice would be to evaluate and cleanse your master data. Effective management of master data is critical to mitigating business risk. Secondly, assessing your systems and identifying any disruptions that could occur in data transfer due to lack of validation. Lastly, if you are really lagging behind, quickly find a trusted solution provider that can automate and streamline your data to keep manual tasks to a minimum.

You have managed DSCSA projects at multiple pharma companies. What is the best way to get executive buy-in for a DSCSA compliance project?

Dunchack: This is a tough one, and I am sure that many organizations have dealt with this. From my experience, I first educated myself on DSCSA and then took what I learned and presented it to my leadership team. Helping them understand that this isn't

just a project, but it is a law that is intended to help protect patients from exposure to drugs that may be counterfeit, stolen, or harmful. Also, if we do not comply with these requirements, we will no longer be able to sell our products in the supply chain. I know that at **Merz Therapeutics**, the well-being of our patients is our top priority.

Who are the stakeholders across the organization that should ultimately own responsibility for a DSCSA compliance initiative?

Dunchack: Ultimately, the internal stakeholders should be a cross-functional team consisting of IT, Regulatory, Quality, Warehouse, and Commercial Teams. Once implemented in our organization, the exception reports will be monitored by Commercial and Warehouse functions.

What practical advice do you have for someone at a pharma company who is spearheading a DSCSA compliance initiative?

Dunchack: Collaborate closely with your trading partners and stay up to date with industry standards by participating in calls and seminars hosted by the HDA, FDA, GS1, and experts in the field. Working closely with your trading partners will help facilitate efficient distribution. Understanding the expectations of your trading partners will eliminate roadblocks in the future.

[**Editor's Note:** For those that do not have the time to attend HDA, FDA, and GS1 meetings, consider joining the TraceLink **US DSCSA 2023 Innovation Forum - Manufacturers & Wholesale Distributors Forum** to stay abreast of evolving standards discussed at HDA, FDA, PDG, and GS1 in a single monthly meeting.]

TraceLink takes an "Integrate Once, Interoperate with Everyone™" network approach to delivering DSCSA compliance for customers, which eliminates the need for individual point-to-point integrations with supply chain partners. Do you see value in this approach for your organization?

Dunchack: Absolutely! The timelines for compliance are tight, and with TraceLink working behind the scenes to eliminate customer integrations, Merz can concentrate solely on preparing and validating our systems to minimize any disruptions in our product distribution.

What has your experience been like working with the TraceLink team?

Dunchack: The TraceLink team is certainly committed to providing knowledgeable and resourceful information to their customers. I am always impressed with the host of employees that travel to events such as the HDA Distribution Conference. The team is well balanced, and they provide insightful information about upcoming regulations. Over the years, my contacts at TraceLink have shown authenticity and they have proven that they are invested in the success of Merz and our DSCSA journey.

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