RESOURCES

Norwegian American Hospital Cuts Through DSCSA Complexity



Norwegian American Hospital is a 200-bed, acute care facility that is, literally, a lifeline to the Humboldt Park community that it serves. When Director of Pharmacy Jigar Thakkar came onboard at the Chicago, Illinois-based hospital in October 2015, with FDA enforcement of the Drug Supply Chain Security Act (DSCSA) looming, he made DSCSA compliance a top priority. Even with “hundreds of other things going on at the hospital,” Thakkar says, “I put DSCSA compliance as number two on my list.”

Read on and find out what played into Norwegian American Hospital’s decision to outsource their compliance solution and ensure their readiness.

The reality of regulatory inspection

Some smaller hospitals may decide to put off putting processes in place that ensure compliance, believing their chances of being inspected are slim. Norwegian American Hospital is not one of them. “Did I ever consider doing nothing, hoping the FDA won’t come around and enforce the law?” Thakkar says. “Definitely not. The FDA has been at this hospital.”

When it comes to complying with government regulations, Tina Spriggs, Pharmacy Buyer at Norwegian American Hospital, is no proponent of a “wait and see”

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approach either. She understands that regulatory inspections can occur at random and without notice. Other hospitals may not feel pressured about DSCSA compliance but, she notes, “We respect that the FDA comes in and does inspect.”

With federal involvement in DSCSA, not doing due diligence just wasn’t an option for Norwegian American. “To not be thorough about compliance would be too risky,” Thakkar says.

A search to streamline

Norwegian American Hospital regularly orders product from 15 wholesale distributors. From time to time, the hospital buys from additional suppliers, and in some cases, directly from the manufacturer. “With this level of complication, it’s hard to do record keeping and traceability on our own,” Thakkar says.

The hospital at first considered tackling traceability in-house. But after recognizing the complexity of the work that would be involved with each supply partner sending its own forms of paper and electronic documentation, “we were afraid we would get behind with compliance,” Spriggs says. “We have a lot of other priorities,” she notes, “so it would have been difficult to handle ourselves.”

Being aware that the scope and complexity of DSCSA requirements could place untold demands on hospital staff and pull resources away from other urgencies, “We knew we needed a streamlined process,” Thakkar says. “TraceLink’s solution makes it easy.”

Appreciation for data ownership

Of Norwegian American’s 15-plus suppliers, several did offer the hospital portal access to compliance data. But Thakkar understood that having to manage various logins, interfaces, and processes is not the most efficient way for the hospital to have easy, reliable access to required information.

“Data ownership definitely played into our decision to outsource to TraceLink,” he

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says. “You want to have your data in your hands. You want to know that it’s in your shared drive and backed up. You never know what will happen with someone else’s system.”

With a reliable third-party solution, Norwegian American Hospital could avoid the pitfalls of suppliers’ website portals going down at inopportune moments. “We want to be sure that for any inquiries or inspections, we can pull out the data we need in a timely manner,” Thakkar says.

A trusted advisor

For hospitals and pharmacies, it’s no easy task to fully comprehend DSCSA and all the implications. Requirements for staying in compliance with government regulations are constantly evolving. Norwegian American Hospital understands that in a DSCSA-regulated world, partnering with a DSCSA solution provider lays the groundwork for future success. “We’re confident TraceLink will continue to guide us,” Spriggs says.

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