



Pharmaceutical Compliance Case Study

NDC Distributors

Prepared by Blue Link ERP



Situation

NDC Distributors, an independently owned pharmaceutical wholesale distributor based in Cranbury, NJ, has been serving the industry since 2013. As one of the fastest-growing pharmaceutical distributors in the United States, NDC Distributors is licensed in all 50 states and proudly holds NABP accreditation. The company specializes in supplying generic pharmaceuticals to a diverse range of customers, including long-term care pharmacies, mental health facilities, retail chains, and GPOs. The business prides itself on the effective partnerships they have garnered with manufacturers to offer their customers the best price, convenient ordering and amazing customer service.

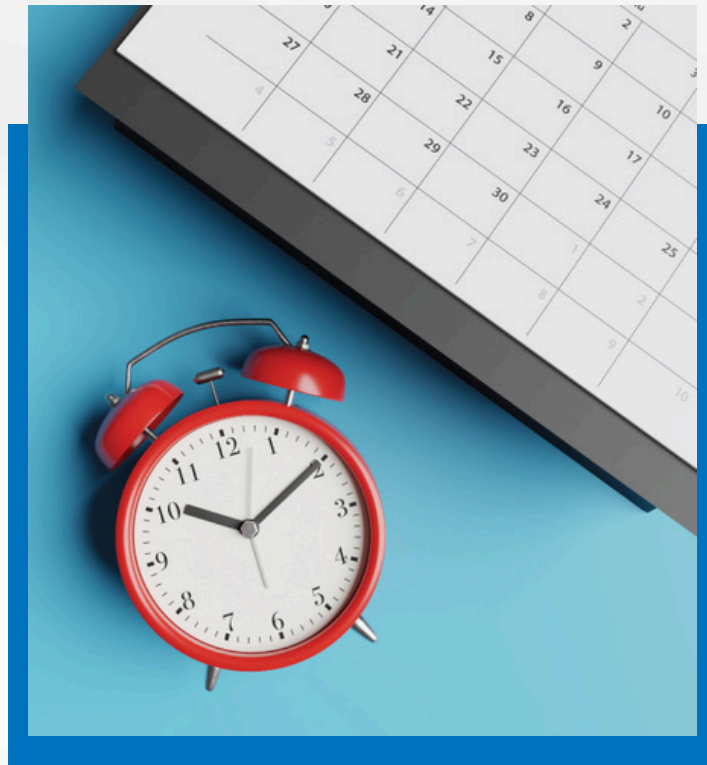
In the pharmaceutical industry, the DSCSA (Drug Supply Chain Security Act) mandates that pharmaceutical distributors implement electronic systems to trace prescription drugs through the supply chain. The act was introduced in 2013 and non-compliance risks significant penalties and operational disruptions, making adherence to these regulations a top priority for NDC Distributors.



Challenge

NDC Distributors had been working over the years to get their systems and processes compliant, but the existing system was requiring substantial time and effort to handle inventory scans and data transfers. These manual processes not only increased the workload but also introduced a higher risk of errors.

In 2023, the FDA announced a stabilization period, allowing those with unsuitable systems to fix and update what they needed to. The stabilization period extended the original November 2023 deadline by exactly one year, giving NDC an opportunity to perfect their processes and systems before the FDA started enforcing the regulations.



They needed to ensure that the new system had functionality to manage a pharmaceutical wholesale distribution business including inventory management, sales, order management and accounting plus the ability to manage and comply with the DSCSA requirements. Having already spoken briefly in the past, Blue Link ERP seemed the obvious choice for NDC Distributors. They knew that Blue Link ERP could handle the distribution criteria and trusted the SaaS vendor when they promised that NDC would be compliant with the DSCSA before the (new) November 2024 deadline. Blue Link already had an existing relationship with Gateway Checker to handle DSCSA document parsing and storage and was confident that they could fulfill this promise.

During the early stages of implementing the Blue Link ERP and Gateway Checker Integration, the NDC team encountered a few technical limitations, including issues with file size capacities and inconsistent data transfer processes.

Solution

Blue Link ERP quickly addressed the hurdles and worked closely with NDC and Gateway Checker to refine the integration including expanded file size capabilities – Gateway Checker updated its system to accommodate larger data files, which was essential for NDC to handle their high-volume orders effectively.

Simplified Onboarding and Day-to-Day Operations

What once required multiple manual steps has been reduced to a single scan within Blue Link ERP. NDC now has greater visibility into their files and inventory, with key data available in both Blue Link ERP and Gateway Checker.

During a discussion about the integration, Mark Grant, Systems Analyst at NDC, mentioned that while learning to use Blue Link's scanning feature was straightforward, the team benefited from instructional videos and a call with Blue Link's CTO, Darren Myher, who provided valuable guidance to help the NDC team get up to speed.

Improved Troubleshooting and Flexibility

Since everything can be accessed in Blue Link ERP, Mark noted that Gateway Checker serves as more of a troubleshooting tool now, its availability providing peace of mind. If a data discrepancy arises, the team can quickly cross-check between systems to identify and resolve the issue.

For example, the visibility provided by the EPCIS inbound review screen in Blue Link ERP minimizes the need to log into Gateway Checker regularly, but the tool remains valuable when troubleshooting specific issues.

Seamless Collaboration with Vendors and Customers

NDC has successfully established connections with around 70 vendors and is steadily rolling out the system for their remaining customers. Gateway Checker has been instrumental in ensuring smooth communication and data transfer with partners.

"It's easy with Gateway Checker... just have them take the reins." Mark suggested when working with suppliers/customers and getting connections set up. This hands-off approach has freed up NDC's internal resources to focus on other critical tasks.

"We don't really need to go into Gateway Checker because we're able to see it over here [in Elite]"

- Mark, NDC

Results

The integration has positioned NDC Distributors as a forward-thinking company that takes DSCSA compliance seriously – the system is already yielding significant operational efficiencies.

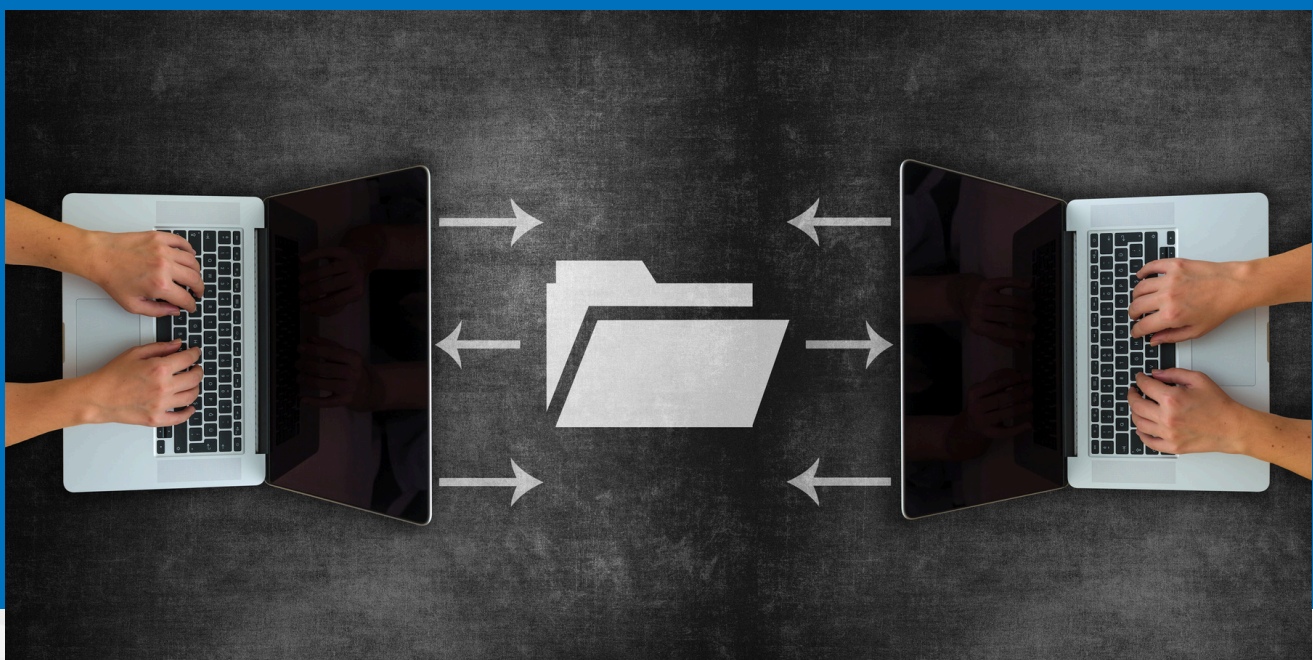
For NDC Distributors, the integration between Blue Link ERP and Gateway Checker has been a game-changer. It provides a strong foundation for long-term success, and with the support of Blue Link ERP and Gateway Checker, NDC is confident in its ability to navigate the complexities of DSCSA compliance and maintain its reputation as a trusted pharmaceutical distributor. By automating DSCSA compliance processes and improving operational efficiency, NDC has not only enhanced their workflows but also ensured they remain ahead of industry regulations.

Lessons Learnt and Recommendations

Mark emphasized the importance of adopting a proactive approach to compliance. “We got lucky that it did get pushed this year, but considering where the industry stands right now... I don’t see it happening again.” he cautioned.

When asked for advice for other pharmaceutical distributors, Mark stressed the importance of finding the right compliance solution and acting quickly.

“Gateway Checker is probably a good option... only because it's easy with Gateway Checker to get the information you need.” he said. He also encouraged distributors to prioritize compliance now, rather than waiting until the last minute.





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Marnie Hughes, Intlvac