HOW TECH PLAYS A CRITICAL ROLE IN MEETING UPCOMING DSCSA DEADLINES

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As pharmaceutical wholesalers and distributors alter their supply chain protocols ahead of upcoming Drug Supply Chain Security Act (DSCSA) deadlines, they face an uphill battle against operational challenges. And with less than a month to go until these new regulations take effect, even the most prepared companies will encounter stark realities.

By now, wholesalers and distributors are familiar with the demands these new regulations have on returned drugs. Hopefully, they have pursued new technology and process changes that will keep them from falling out of compliance and spending significant time and resources in the verification process.

At its core, the new regulation makes two demands. First, wholesalers must prove returned drugs were sold to a given customer. Second, if a returned product has a serial number, it must be verified against the barcode assigned by the manufacturer.

While drugs can be returned for any number of reasons, the burden in the process lies with wholesalers and distributors — if the product comes back, they must comply with the new rules. Failure to do so doesn't just risk fines and penalties, but could also leave a sizable dent in the $11 billion annual market for salable returned pharmaceuticals.

What's more, it appears there are cracks in some purportedly DSCSA compliant methods already in use. In a recent test of 2D barcodes by serialization software engineers, nearly a third failed to scan. If the test holds true to scale, an already time-consuming verification process will require manual work to verify and trace the origin of nearly one in three returned drugs.

Not only is this a threat to the industry, but also to the true intent of the regulation. The DSCSA's noble goal of keeping recalled, suspect, counterfeit and expired drugs off shelves is severely impacted by this high rate of negative verifications. Fortunately for wholesalers and distributors, there are solutions that can help ease the pressures created by the looming DSCSA deadlines.

Enterprise resource planning (ERP) tech saves time and makes the resale market safer

The DSCSA aims to make the entire pharmaceutical supply chain safer by demanding better reporting and accountability at every step. In the end, consumers are confident the drugs they take are safe, retailers have faith

that what they are selling can be tracked and the possibility of fraud is greatly reduced.

However, the DSCSA's specific rules surrounding serialization is causing specific challenges in the industry. As it stands, many wholesale and pharmaceutical distribution companies are multiple steps away from achieving the level of serialization required to achieve compliance, including unique identifiers and expiration dates that can be traced back to each products place of origin.

On the problem of negative verifications via 2D barcodes, companies still face the challenge of manual verification. In many cases, a viable solution is to look to ERP software to close the gap. These systems — commonly used outside the pharma industry to track and trace products in warehouses and supply chains — can reduce the labor hours spent verifying the origin of returned drugs in a piecemeal fashion. Instead, these systems automatically update the information of a particular product or shipment and help automate the verification process when a barcode scan fails.

Even more, the best ERP solutions on the market have begun partnering with VRS (verification routing service) vendors, which have real-time access to manufacturer information in the pharmaceutical supply chain, making the job of compliance much simpler. If a wholesaler or distributor has yet to complete their compliance plan, the right ERP and VRS vendor combination can help companies get their systems in line even with the rapidly approaching deadline.

Beyond simply reducing the time to complete verifications and eliminating manual processes, these systems solve for a host of other challenges in the new regulatory framework. The Drug Enforcement Administration, for example, requires proof that transactions are in accordance with the law and prevent drugs from landing in the wrong hands. Additionally, the agency requires the verification of specific licenses and other documents. Without ERP systems, the increased possibility of errors in this process can lead to fines, lost time and even the risk of losing necessary licenses.

But compliance isn't only about avoiding fines. Upgrading technology is also an investment in the future, and done correctly, it can position a business ahead of competitors. Most distributors and wholesalers have at least heard of technology like Internet of Things (IoT). With a system like ERP in place, future IoT implementations that can significantly accelerate business are easier.

An IoT enabled system, for example, can use small sensors to track and trace products as they are returned, automating an entire sequence of events based on the reason for the return. If the drug was recalled, it can be grouped and quarantined with other drugs as they come in, making a formerly manual process much simpler and more effective.

The looming DSCSA deadline shouldn't produce a scramble for bare-minimum compliance. Instead, wholesalers and distributors that treat the new regulations as an opportunity to invest in technology improvements are setting themselves up for long-term success. And by doing so, they assure any drug they help return to the supply chain is safe and fulfills its intended purpose.