PREPARING FOR THE 2023 DSCSA DEADLINE

Pharma can do better than 50% compliance

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With the FDA's November 2023 deadline to comply with the Drug Supply Chain Security Act (DSCSA) looming it's critical for pharma manufacturers who should have already started to prepare — especially since nearly half of pharma manufacturers missed the last deadline.

Signed into law in 2013, the DSCSA combats the spread of counterfeit prescription drugs. As part of the legislation, the FDA outlined a long list of traceability and security requirements that pharma stakeholders must abide by. However, many organizations previously struggled to meet deadlines due to poor internal communication and what some perceived as unclear instructions from the FDA.

To avoid a similar outcome in 2023, manufacturers need to ensure their technology, hardware, and internal processes are ready to accommodate an expanded list of requirements.

The ins and outs of the DSCSA

Illegitimate online pharmacies are contributing to the global rise in counterfeit drugs. While these pharmacies appeal to consumers looking to buy medications at a low cost, more than half of all medications purchased through these outlets are counterfeit and therefore very dangerous to consumers. In some cases, counterfeit pharmaceuticals are laced with addictive drugs, which has led to increases in drug-related deaths and overdoses.

Introduced nearly a decade ago, the first phase of DSCSA required all products to be traceable at the lot level. The goal of this policy was to help pharma companies identify counterfeits.

Phase two takes the FDA's requirements a step further. By Nov. 7, 2023, pharma manufacturers, distributors, wholesalers and dispensers are required to incorporate the following:

Interoperable exchange: Trading partners must have the ability to securely exchange transaction information (TI) and transaction statements (TS). In addition, TI must include a product identifier for individual packages.

Interoperable verification: After receiving data, trading partners must be able to verify the product identifier on a package. For example, a pharmacist who receives a shipment of drugs should be able to scan a barcode to confirm its authenticity.

Interoperable tracing: Pharmaceutical stakeholders

must be able to trace a product's journey throughout the supply chain. That means that every detail of a product's TI and TS must be available upon request.

While the FDA has delayed the implementation of DSCSA regulations multiple times, the upcoming phase two deadline is final. Companies that fail to comply with these new regulations risk fines, loss of licenses, and a loss of business to competitors.

3 tips for DSCSA compliance

Phase one of the DSCSA proved difficult for some pharma stakeholders. Many failed to meet the 2018 deadline due to confusion about the FDA's instructions and who was responsible for meeting the requirements.

The problem of counterfeit drugs won't go away unless interoperability standards are consistent across the country. To prevent counterfeit drugs from slipping through the cracks, every company in a drug's supply chain needs to be on the same page.

As your organization looks ahead to this next phase, here are three tips to keep in mind:

1. Communicate and plan effectively: Many companies struggled to adjust to phase one requirements due to poor planning. This time around, your organization needs to thoroughly understand the FDA's guidelines and should have already developed a company-wide plan. You should view this plan as a process of trial and error rather than as a series of boxes to be checked off. In practice, this means creating a buffer period before the November deadline to work out any issues. Additionally, your preparation shouldn't take place in a vacuum. Constantly communicate with the manufacturers, distributors, and dispensers along the supply chain that you work with to ensure everyone remains on the same page.

2. Update your software and protocols: Phase two requirements are more comprehensive than the initial requirements, so you'll need to re-evaluate your systems to determine whether they're capable of complying. For example, instead of simply tracing packages at the lot level, you'll now need to track each sellable unit you receive and ship. To accomplish this, your organization will require the ability to handle complex product information in real-time. One option is to enlist the help of enterprise resource planning (ERP) software, which handles these moving parts for you and keeps your organization compliant.

3. Invest in new hardware: In addition to software updates, you may need to upgrade your hardware. For example, when it comes to tracking individual packages, the bar codes you'll have to scan will be different from the linear barcodes you're used to and that means you'll need new barcode scanners and RFID readers. Since purchasing and implementing new hardware can require a lengthy process, it's important to identify required hardware upgrades sooner rather than later.

If you need assistance, a third-party auditor can play an important role in helping you fully comply with phase two requirements. At a minimum, you should plan to perform an internal audit and leave no stone unturned when it comes to evaluating your progress.

Pharma can do better than 50% compliance in 2023

As long as the problem of counterfeit drugs persists, pharma companies will need to improve their practices to increase visibility into the pharmaceutical supply chain. Revamping operations twice in one decade is no small task, but the benefits are massive for both your organization and for public health. By committing to meet the phase two requirements, you can lay the blueprint for continuous improvement in 2023 and beyond.