Körber Supply Chain

Why you need to prepare for 2023's pharmaceutical DSCSA today

The Drug Supply Chain Security Act (DSCSA) will take full effect in 2023, with far-reaching implications for the pharmaceutical industry. While it's years away, it's critical to prepare well in advance.

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With a total value tipping $1.12 trillion dollars,[1] the global pharmaceutical industry is a massive, complex machine. Due to the size of the market, it can be difficult for industry leaders to keep a close eye on quality standards. As a result, as much as ten percent of the world's medications are counterfeit.

To combat this problem, the United States Congress passed the Drug Supply Chain Security Act (DSCSA) in 2013.[2] The act is inspired in part by prior California and Florida crackdowns on drug inventory tracking systems in 2004 and 2005. The objectives of the DSCSA are to secure the pharmaceutical supply chain, streamline traceability, and prevent counterfeit medications from entering the market. To facilitate this, manufacturers, repackagers, wholesale distributors, dispensers, and third party logistics (3PL) providers will receive a new framework of compliance regulations as set by the Food and Drug Administration (FDA).

By the time all pharmaceutical supply chains become DSCSA-compliant and enter the "Enhanced Drug Distribution Security (EDDS)" phase by November 27, 2023, there will be a fully electronic and interoperable data system in place to identify and track drugs as they make their way across the United States. Because of the 10-year grace period to become DSCSA compliant and a rising need for these new standards, the FDA will not delay this law. Companies that don't comply risk federal fines and lost business to competitors.

The deadline might not feel pressing, but there are a few reasons to act quickly. Transforming your operations for this new regulation won't happen overnight, so it's critical to plan and move on DSCSA well ahead of the 2023 enactment. Here we break down DSCSA requirements, discuss compliance challenges, and explain why it's critically important for supply chain leaders and 3PL management businesses to become DSCSA-compliant as soon as possible.

[1] https://www.pharmalogisticsiq.com/supply-chain-security/news/a-serialized-guide-to-serialization-4

[2] https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

This rise of serialization in supply chain management

Changes to supply chain management and WMS integration under the DSCSA can be broken down into two broad categories: serialization[3] and procedure. There's no DSCSA requirement for drug registration beyond the original National Drug Code (NDC) requirements, but that may change in the name of standardization and synchronization. Since the DSCSA requires the development of a standardized system for drug identification, the three largest wholesale pharmaceutical distributors are initiating a shift toward serialization according to Global Trade Item Number (GTIN).

This approach is likely to have a profound impact on the pharmaceutical supply chain. By identifying products in high volume groupings like pallets, in addition to those at the individual saleable level, serialization according to GTIN will enhance DSCSA compliance.

For instance, if a company ships Serial 1 to CVS and Serial 1 appears in Walgreens as a returned product, it's relatively simple to find out how it got to Walgreens. Following the supply chain back to its source reveals that CVS returned Serial 1 to the wholesaler and the wholesaler then shipped it to Walgreens. Serialization allows for easy traceability at this level, but it can also be used to track complex, high volume shipments. The advanced serialization protocols proposed under the DSCSA reduce product loss, eliminate fines for losing said products, and reduce the risk that customers will find themselves with a counterfeit drug.

[3] https://www.datexcorp.com/the-dscsa-pharmaceutical-serialization-deadline-looms/

Changes for supply chain leaders and 3PLs

In terms of procedure, drug manufacturers must change the ways they interact with their trading partners and 3PL providers. In addition to knowing the letter of the law and making sure that trading partners are also in compliance with the DSCSA, manufacturers must:

- Provide product tracking information in accordance with new guidelines[4]
- Know the protocols for handling suspicious or illegitimate packages
- Check the FDA database to confirm the authenticity of all trading partners
- Confirm and report licensures

Almost half of pharmaceutical manufacturers failed to comply[5] with the DSCSA's initial deadline in 2018. So what caused the delay? The most common reason companies failed to update their inventory tracking systems is that they were confused about what exactly the DSCSA's requirements were and whose job it was to meet them.

[4] https://www.fda.gov/media/90548/download

[5] https://www.contractpharma.com/issues/2019-06-01/view_features/serialization-and-the-rest-of-us/

The time to build a solution is now

There are numerous businesses with serialization solutions and DSCSA-ready procedures already in place. These businesses are already refining their processes and learning how to manage DSCSA. This will be a major differentiator for them moving forward. As DSCSA compliance becomes more important to the industry, those with more best practices, experience, and data behind their operations will be in position to lead the industry, make valuable partnerships, and win business more easily than those playing catchup.

Beyond the business benefit of working ahead of the deadline, consider that launching an initiative of this magnitude impacts every link of your supply chain. It will take time to find the right partners, systems, and processes to get it right. By not working ahead of the clock, you are risking compliance, which incurs fines on top of reputation damages from failing to meet compliance.
The key to complying with DSCSA regulations is to start redefining serial numbers and making the necessary changes to warehouse management systems and delivery tracking software as soon as possible. Changing serialization protocols is the most challenging part of preparing for DSCSA because serialization impacts every leg of an organization, from manufacturing to IT. To manage this, you can pilot a serialization program with a few serials to test and troubleshoot your systems and operations.

Data interoperability will also play a significant role in 2023, so it's best to spend some time revamping and reevaluating software systems now. Supply chain managers should implement and practice new scanning, tracking, and tracing processes ahead of time, as they will be more complex under DSCSA regulations. It's also important to choose systems that can scale with a growing business, as well as effectively integrate robotics and automated warehouse management systems.

This new requirement will put many drug supply chains through their paces, but the ultimate goal of less counterfeit inventory and full serial visibility is worthwhile. Lost product is risky from both profitability and safety viewpoints. Fortunately, we have the technology available to solve this problem.

It may be worthwhile engaging with vendors and partners equipped for DSCSA. Getting the perspectives and best practices from these resources can help you build the right business requirements. With the proper planning, all pharmaceutical companies and supply chain leaders can become DSCSA-compliant by November 27, 2023.

Discover more

For more information on how Körber's serialization solutions can transform your supply chain please visit:

https://www.koerber-supplychain.com/supply-chain-solutions/supply-chain-software/dscsa-serialization